Physician modification of the Gore conformable endovascular aortic device using inner branches

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ABSTRACT

Endovascular aortic repair has become the preferred treatment modality for patients with abdominal aortic aneurysms. However, there are no commercially available endovascular options in patients with infrarenal necks measuring <4 mm. To address the limitations of commercially available options, physician-modified endografts became a technique used by vascular surgeons. In this report, we describe a case of a patient treated with a physician-modified Gore conformable endograft using inner branches along with how to perform the procedure. (J Vasc Surg Cases Innov Tech 2025;11:101710.)

Keywords: Aorta; Aneurysm; Endovascular; Physician modified; Inner branches

Endovascular aortic repair (EVAR) has become the preferred treatment modality in patients with abdominal aortic aneurysms (AAAs).[1,2] However, to treat AAAs with an EVAR, certain anatomical criteria should be met. For most devices on the market, these criteria include a healthy infrarenal neck length of 15 mm. This makes treatment of pararenal and juxtarenal aneurysms with an EVAR device challenging and exposes patients to significant complications. Currently, the Zenith fenestrated device from Cook Medical (Bloomington, IN) is the only commercially available device on the market for treatment of juxtarenal aneurysms, which requires at least a 4-mm healthy infrarenal aortic neck for proper placement.[3] To address the limitations of commercially available endovascular options on the market, physician-modified endografts became a technique used by vascular surgeons to artificially expand the instructions for use of various devices.[4,5]

The Gore Excluder conformable AAA endoprosthesis (W. L. Gore & Associates, Flagstaff, AZ) was introduced in the United States in 2020. The device has an active control system that allows orthogonal placement within the aortic lumen.[6] The features of this device make it ideal for modification in complex AAAs. In this article, we describe how to modify the Gore Excluder Conformable endoprosthesis with the use of inner branches for complex AAAs. The patient provided consent of the accurate case details and imaging studies.

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Additional material for this article may be found online at www.jvscit.org.

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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

https://doi.org/10.1016/j.jvscit.2024.101710

CASE REPORT AND PROCEDURE DETAILS

A 75-year-old man presented with a 7.4-cm juxtarenal aneurysm. The patient has a past medical history of hypertension along with a prior smoking history. The patient did not have an infrarenal neck (Fig 1) and, therefore, was not a good candidate for the Food and Drug Administration-approved Zenith fenestrated (Cook Medical) endovascular device. The risks and benefits of different treatment options, including open aneurysm repair, continued surveillance, and endovascular repair using physician-modified stent grafts were discussed with and offered to the patient. We discussed that modifications to endovascular devices are off-label. The patient elected to proceed with and consented for a physician-modified endografts of the Gore conformable device. The case was compassionate use without investigational device exemptions.

Inner branches were used for the renal vessels for multiple reasons. First, the downward trajectory of the renal vessels makes it more suitable for branches vs a fenestration. We prefer inner over outer branches in aortic diameters of <28 mm, this patient's intravascular diameter in healthy aorta was approximately 25 mm. We do not use branches for aortas ≤18 mm in intravascular diameter. In addition, the orifice of the left renal artery came off the proximal portion of the aneurysm sac. If a fenestration was used for the left renal artery, there would have been a fenestration gap of approximately 5 mm. Last, we prefer inner branches when there is an angulated aortic neck because it is uncertain how the graft will exactly lie onto the aortic wall. The Gore conformable graft was chosen owing to its active fixation, which makes it easier to rotate the device.

The case was performed without complications and the patient was discharged home on post-operative day 2 (Fig 2). A 1-month computed tomography angiography scan demonstrated patent visceral targets and no endoleaks (Fig 3).

Device modification and implantation. Arc length and distance from the proximal portion of the endograft for the placement of the renal inner branches and superior mesenteric artery (SMA) fenestration were calculated via centerline analysis on computed tomography angiography scan (TeraRecon, Inc, Durham, NC). A

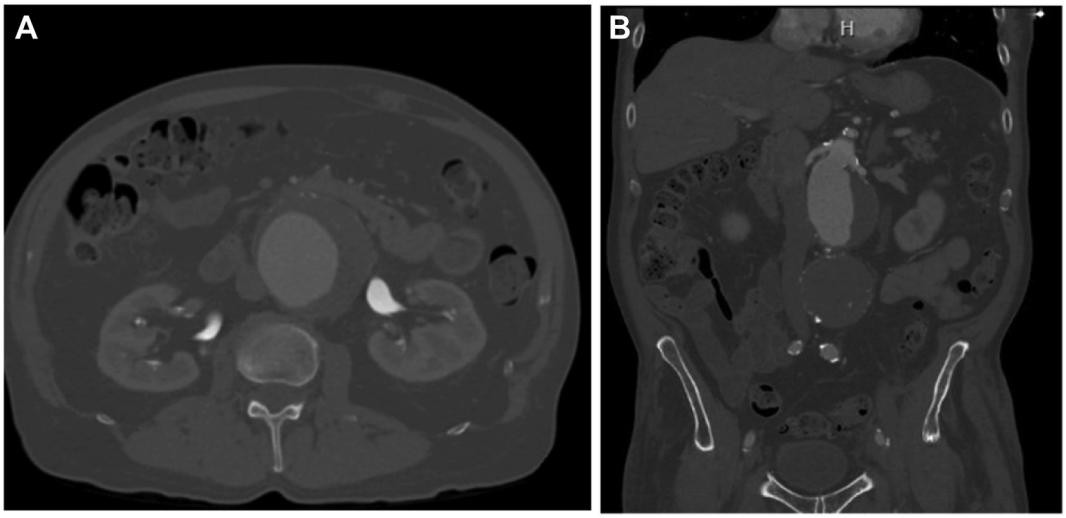

Fig 1. Representative **(A)** axial and **(B)** coronal images of a computed tomography angiography scan of a patient with a juxtarenal aneurysm.

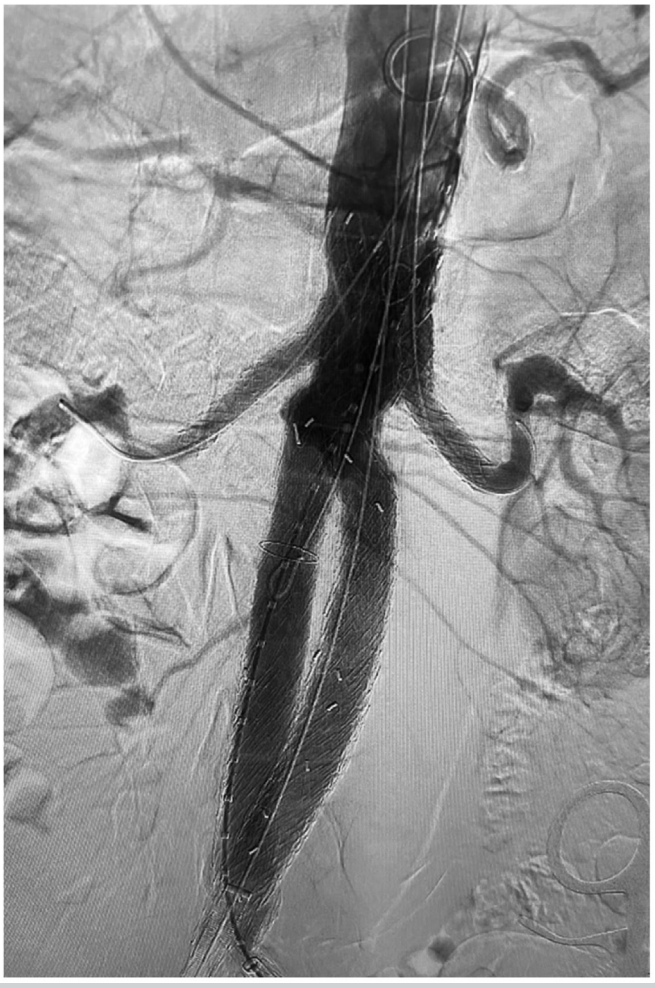

Fig 2. Completion angiogram of a patient treated with a modified Gore conformable device.

fenestration or scallop can be created for the celiac artery as needed. Intraoperative three-dimensional fusion is used to assist with vessel cannulation.

Endograft modification was performed on the backtable under sterile conditions (Supplementary Video 1). The plastic cover surrounding the Gore Conformable device is peeled off toward the direction of the handle (Fig 4, *A*). A 3-0 silk is then placed around the second or third stent, which is determined based on where the modifications will be performed (Fig 4, *B*). The graft is partially deployed up to the silk tie. The deployment line loop is identified just distal to the silk tie and is pulled up using the back end of a needle. The gray constraining knob is then turned clockwise to keep the proximal portion of the graft constrained (the default for the graft is for it to be unconstrained). The deployment line loop is then tied to itself, which will prevent the graft from opening beyond the intended portion during modification (Fig 4, *C*). The deployment line distal to the loop is pulled towards the olive tip and the handle is re-engaged with the device. The 3-0 silk tie is then cut and the plastic sheath is trimmed to the level of the knot. The secondary sleeve is sutured circumferentially with a 5-0 Prolene, but left untied, to prevent it from moving during the modification process (optional step, Fig 4, *D*). The gray constraining knob is turned counterclockwise to fully expand the proximal extent of the graft. The location in which the inner branches for the renals and fenestration for the SMA is marked on the endograft. Of note, the inner branches should not be placed within 1 cm of the flow-divider as this will create a theoretical risk of limb occlusion. High-temperature handheld cautery is used to create the fenestrations which are reinforced with a Gooseneck snare (Fig 4, *E*).

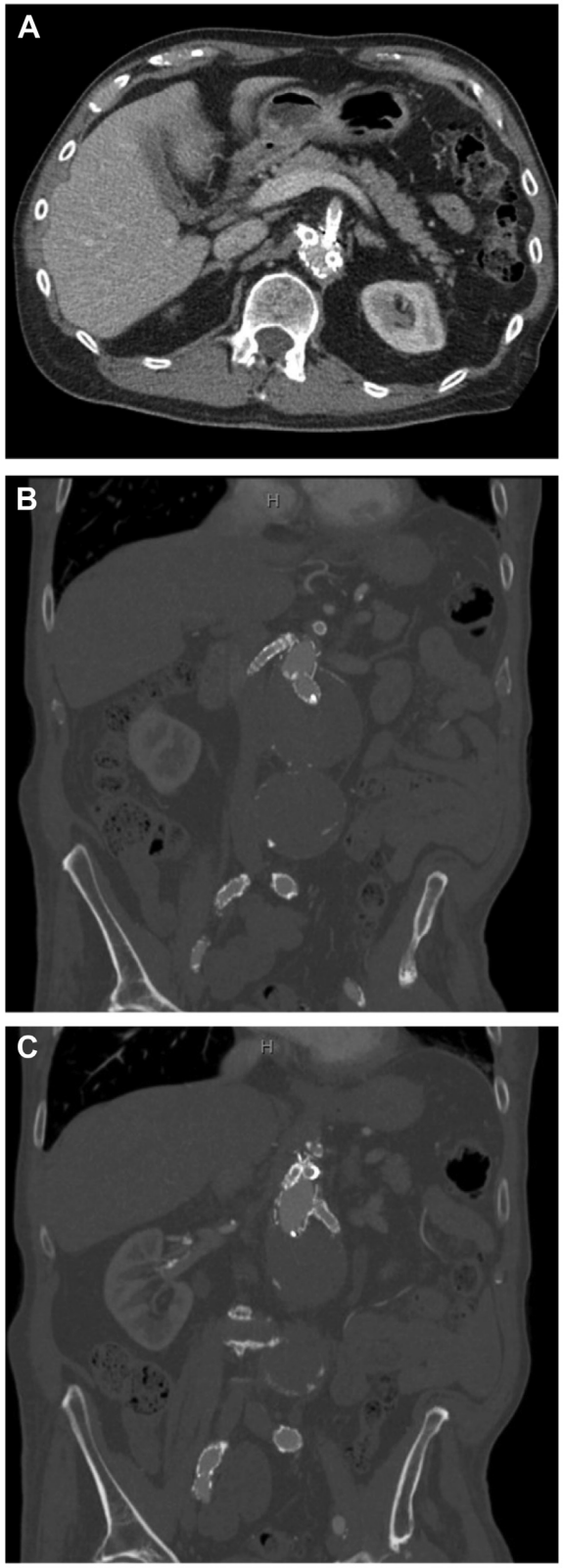

Fig 3. Representative **(A)** axial, **(B)**, coronal, and **(C)**, deeper coronal images of a one month computed tomography angiography scan following modification and implantation of Gore Conformable device.

The inner branches are created by deploying a 6 × 25 mm Viabahan through the renal fenestrations, which is subsequently beveled and sutured to the fenestration. The final length of the Viabahn should be between 10 and 15 mm. Care should be taken not to cut the constraining loop of the proximal graft because this maneuver will damage the active control system. The inner branches are then tacked to the graft using an interrupted stitch (Fig 4, *F*). The inner branches and fenestrations are precannulated with an 0.014″ wire that enter from the top of the graft, into the inner branch, and outside the graft. If the circumferential 5-0 Prolene is opted to be placed, it is removed at this point. The device is then resheathed (Fig 4, *G*).

Bilateral femoral and axillary access is obtained. Left or right axillary access can be obtained depending on patient anatomy and surgeon preference. An appropriately sized Dryseal sheath is positioned proximal to where the landing zone will be. A 12F or 14F sheath is placed into the axillary artery and a through-and-through wire is obtained from the ipsilateral femoral and axillary access. A 5F catheter is introduced from the brachial access and exteriorized via the femoral sheath. The precannulated wires are then delivered through the catheter from the femoral into the axillary access. The prior through-and-through wire is removed and the graft is delivered through the ipsilateral femoral access over a Lunderquist wire. The graft is positioned and partially deployed by unsheathing the Dryseal over the graft. A 6F sheath is then advanced from the axillary access over each precannulated wire to sequentially cannulate the visceral vessels. The Gore conformable device can be angulated using the active control system to assist with alignment and cannulation of the visceral vessels. Once the viscerals have been cannulated, the precannulated 0.014″ wires are removed. The remainder of the Gore conformable device is deployed. The contralateral gate is cannulated and the contralateral limb is deployed. The delivery system is removed from the ipsilateral limb and an iliac limb extension is deployed. A 36-mm CODA balloon is used to angioplasty the main body of the endograft along with any overlapping segments of the iliac limbs. Next, the renals and SMA are then stented with a VBX (W. L. Gore & Associates). Bare metal stent extensions are used in cases where there are concerns for kinking at the distal aspect of the bridging stent.[7] The SMA bridging stent is flared. Completion angiography is performed.

DISCUSSION

There are a limited number of reports describing the modification of Gore EVAR devices for complex AAAs. In fact, the currently available reports describe modifying the C3 Excluder.[8,9] The greatest advantage to modifying the Gore conformable device over the C3 is the active

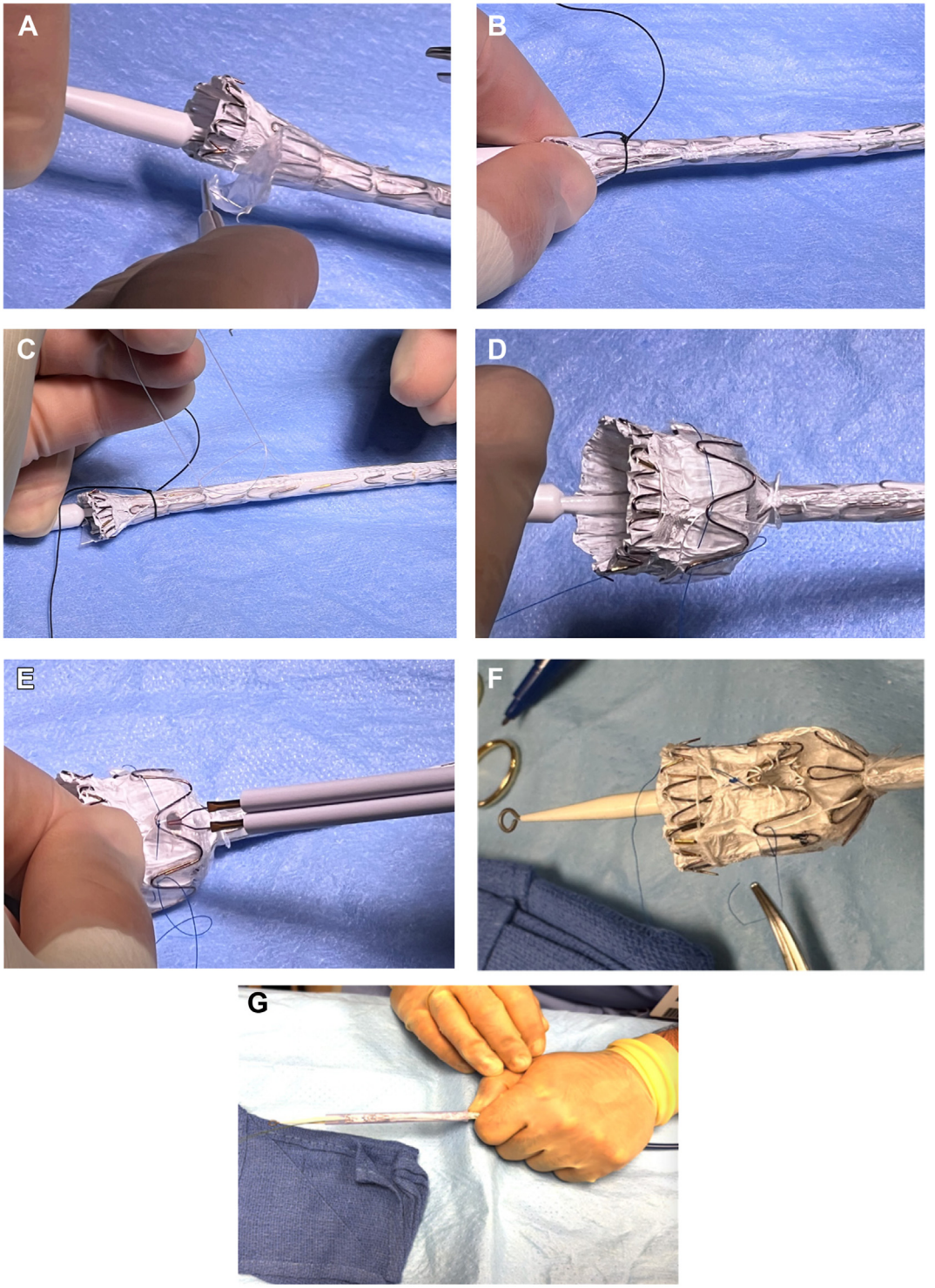

Fig 4. Step-by-step procedure of performing the modifications for the Gore conformable device. **(A)** The plastic cover surrounding the Gore conformable device is peeled off toward the direction of the handle. **(B)** A 3-0 silk is then placed around the second or third stent, which is determined based on where the modifications will be performed. **(C)** The graft is partially deployed up to the silk tie. The deployment line loop is identified just distal to the silk tie and is pulled up using the back end of a needle. This is then tied to itself, which will prevent the graft from opening beyond the intended portion during modification. **(D)** The secondary sleeve is sutured circumferentially with a 5-0 Prolene, but left untied, to prevent it from moving during the modification process. This step is optional. **(E)** High-temperature handheld cautery is used to create the fenestrations which are reinforced with a gooseneck snare. **(F)** The inner branches are created by deploying a 6-mm Viabahan through the renal fenestrations, which is subsequently sutured to the fenestration. The inner branches are then tacked to the graft using an interrupted stitch. **(G)** The inner branches and fenestrations are precannulated with an .014″ wire that enter from the top of the graft, into the inner branch, and outside the graft. The device is then resheathed.

control system. The active control system allows the surgeon to angulate the device and reconstrain the proximal portion of the endograft, which makes it easier to rotate the device and cannulate the visceral vessels. Also, the modification of the Gore conformable system allows one to exploit the principles of the sequential catheterization amid progressive endograft deployment technique described by Timaran et al.[10] The distal end of the graft remains sheathed, which promotes vertical and rotational repositioning of the endograft as needed during vessel cannulation. This, in combination with the use of precannulated inner branches and fenestrations, promotes facile cannulation of the visceral vessels.

Traditionally, fenestrations and directional outer branches were used in fenestrated/branched EVAR. Fenestrations have the benefit of being easily accessed through the femoral arteries, avoiding the need for upper arm access and its associated stroke risks. However, the use of fenestrations requires accurate alignment with the orifice of the vessel because failure to do so will make cannulation difficult or the bridging stent prone to target vessel instability.[11] Directional outer branches provide an overlap between the fenestrated/branched component and the bridging stent, which does not require as accurate alignment compared to fenestrations. Further, outer branches allow cannulation of caudally or cranially oriented vessels via the use of antegrade or retrograde branches, respectively. The greatest limitations of outer branches are that they can increase the length and overall diameter of the fenestrated/branched device. Increasing the length of the fenestrated/branch device increases the overall risk of spinal cord ischemia; whereas, increasing the diameter may make implantation difficult in smaller sized aortas. The inner branch use does not increase the overall diameter of the device, making them more optimal in small sized aortas, as is the case in most juxtarenal and pararenal AAAs.[12]

Another advantage to modifying the Gore conformable device is that the bifurcated piece is built into the fenestrated/branched component. This allows one piece to be delivered eliminating the possibility of a type III endoleak between the fenestrated/branched component and the bifurcated component. Further, by having one piece and performing the sequential catheterization amid progressive endograft deployment technique, the dreaded complication of the nose cone on the bifurcate piece damaging a bridging stent during delivery is also eliminated.

There are limitations and technical considerations to consider before undertaking a physician modification of the Gore conformable device. First, the precannulated inner branches require high brachial or axillary access to perform the repair, which may increase the risk of stroke. One should carefully evaluate the aortic arch and access vessels to determine if the patient is a suitable candidate for axillary access. Also, the main body of the device is rather short, 5.5 cm or 6.5 cm depending on the diameter of the device, which limits the anatomical suitability this technique can be performed. Finally, it is vital that ≥15 mm of healthy parallel aortic wall is present for a landing zone since proximal bailout options in the event of a type Ia endoleak are limited given the proximity of the inner branches to the proximal portion of the device. In the event of proximal degeneration, outer branches will need to be used to seal into the inner branches. The Gore Excluder thoracoabdominal branch endoprosthesis would be a good off-the-shelf option in the event this does occur.

FUNDING

None.

DISCLOSURES

None.

REFERENCES

1. Lederle FA, Kyriakides TC, Stroupe KT, et al. Open versus endovascular repair of abdominal aortic aneurysm. *N Engl J Med*. 2019;380:2126–2135.
2. Patel R, Sweeting MJ, Powell JT, Greenhalgh RM. Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial. *Lancet*. 2016;388:2366–2374.
3. Oderich GS, Farber MA, Schneider D, et al. Final 5-year results of the United States Zenith Fenestrated prospective multicenter study for juxtarenal abdominal aortic aneurysms. *J Vasc Surg*. 2021;73:1128–1138.e2.
4. Georgiadis GS, van Herwaarden JA, Antoniou GA, et al. Systematic review of off-the-shelf or physician-modified fenestrated and branched endografts. *J Endovasc Ther*. 2016;23:98–109.
5. Gouveia EMR, Fernández Prendes C, Caldeira D, et al. Systematic review and meta-analysis of physician modified endografts for treatment of thoraco-abdominal and complex abdominal aortic aneurysms. *Eur J Vasc Endovasc Surg*. 2022;64:188–199.
6. Tsolakis IA, Kakkos SK, Papageorgopoulou CP, et al. Improved effectiveness of the repositionable GORE EXCLUDER AAA endoprosthesis featuring the C3 delivery system compared with the original GORE EXCLUDER AAA endoprosthesis for within the instructions for use treatment of aortoiliac aneurysms. *J Vasc Surg*. 2019;69:394–404.
7. Khoury MK, Timaran DE, Knowles M, Timaran CH. Visceral stent patency after fenestrated endovascular aneurysm repair using bare-metal stent extensions versus covered stents only. *J Vasc Surg*. 2020;71:23–29.
8. Lopez-Pena G, Garcia-Alva R, Laparra-Escareno H, Anaya-Ayala JE, Guerrero-Hernández M, Hinojosa CA. Physician-modified endovascular Gore excluder graft (Handmade modified) for complex abdominal aortic aneurysm: a step-by-step approach. *Vasc Endovascular Surg*. 2020;54:656–659.
9. Coulter AH, Tan TW, Zhang WW. Physician modification of Gore C3 excluder endograft for treatment of abdominal aortic aneurysms anatomically unsuitable for conventional endovascular repair. *J Vasc Surg*. 2014;59:1739–1743.
10. Timaran CH, Stanley GA, Baig MS, Timaran DE, Modrall JG, Knowles M. The sequential catheterization amid progressive endograft deployment technique for fenestrated endovascular aortic aneurysm repair. *J Vasc Surg*. 2017;66:311–315.
11. Squizzato F, Antonello M, Forcella E, et al. Geometrical determinants of target vessel instability in fenestrated endovascular aortic repair. *J Vasc Surg*. 2022;76:335–343.e2.
12. Katsargyris A, Marques de Marino P, Mufty H, Pedro LM, Fernandes R, Verhoeven ELG. Early experience with the use of inner branches in endovascular repair of complex abdominal and thoraco-abdominal aortic aneurysms. *Eur J Vasc Endovasc Surg*. 2018;55:640–646.

Submitted Jul 25, 2024; accepted Dec 5, 2024.