Technical feasibility and device stability of the Gore Excluder iliac branch endoprosthesis as abdominal aortic bifurcated device

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ABSTRACT

The aim is to describe the technical feasibility, early outcomes, and graft stability of the Excluder iliac branch endoprosthesis (W.L. Gore & Associates) used as an infrarenal abdominal bifurcated endograft in cases unsuitable for standard endovascular aortic repair. The technique was used in 13 cases with abdominal and/or iliac aneurysms (n = 6), occlusive disease (n = 3), or complex aneurysms in association with a proximal fenestrated/branched endograft (n = 4). Technical success was 100%, and there were no adverse events, with 100% graft stability at 3 months. This case series demonstrates, in extremely selected cases, the feasibility and safety of Excluder iliac branch endoprosthesis used as an infrarenal aortic bifurcated device. (J Vasc Surg Cases Innov Tech 2024;10:101517.)

Keywords: Endovascular aneurysm repair; Abdominal aortic aneurysm; Peripheral artery disease; Iliac branch device

Iliac branch devices (IBDs) have been introduced to allow for the endovascular treatment of common iliac aneurysms, maintaining the patency of the hypogastric artery through a directional branch. IBDs have been widely investigated, showing a remarkable technical success rate, sustained patency, and a minimal need for subsequent interventions during short- and midterm follow-up.[1-3]

Aside from their use to treat aortoiliac aneurysms, off-label applications of IBD devices have been described in highly selected cases.[4-6] In particular, the Excluder iliac branch endoprosthesis (IBE; W.L. Gore & Associates) is characterized by a 23-mm proximal diameter and a 5.5-cm contralateral gate length with a 13-mm diameter. These characteristics could provide particular versatility in other settings, such as in the case of a short distance between the lowest renal artery and aortic bifurcation in the context of an aneurysm of the distal aortic bifurcation with a narrow aorta or to overcome the presence of a short available length in the case of a bilateral iliac branch or proximal fenestrated/branched thoracoabdominal endovascular aortic repair (F/BEVAR) endograft. Also, it might be helpful in selected cases of obstructive disease as an alternative to the covered endovascular reconstruction of the aortic bifurcation (CERAB) technique. However, its use in these specific anatomical situations is not standardized, and no data are available regarding the safety and efficacy of the procedure.

Our aim is to describe the technique and report the safety and efficacy of the Gore IBE in the treatment of this extremely selected subset of patients.

TECHNIQUE

All patients were treated in a hybrid operating room (Artis Pheno; Siemens AG) in a tertiary vascular surgery center. From January 2023 to December 2023, 13 patients were treated with the IBE as an infrarenal aortic bifurcated device for aortic and/or iliac aneurysms (n = 6), endovascular reconstruction of aortoiliac obstructive disease (n = 3), or as a distal device after F/BEVAR (n = 4). The anatomical and procedural characteristics of the patients and 30-day stability (ie, absence of any variation in the aneurysmal sac dimensions after the procedure, absence of endoleak, absence of device migration) are reported in Table I.[7]

The technique is based on the removal of the IBE preloaded catheter. The device is then inserted and deployed until opening the contralateral gate, as a standard EVAR procedure. The contralateral gate is cannulated and extended with a standard Excluder contralateral iliac limb with an appropriate size and length. The ipsilateral limb of the IBE is then completely deployed and extended with an appropriate iliac limb, as needed. Postdilatation of the proximal neck and iliac limbs (in kissing technique) is routinely performed. This technique can be adopted for both aneurysmal and obstructive disease. In the case of aortoiliac obstructive disease, adequate vessel preparation is necessary to

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Table. Patient characteristics

Sex	Age, years	Indication	Previous/concomitant aortic intervention	Reason for IBE	Technical success	90-Day stability
Male	71	AAA	—	Short distance between renal artery and aortic bifurcation	Yes	Yes
Male	44	Iliac aneurysms	—	Short renal—iliac bifurcation length in bilateral iliac branch repair	Yes	Yes
Female	77	Pseudoaneurysm in previous aorto-bifemoral bypass	—	Short distance between renal artery and aortic bifurcation	Yes	Yes
Male	81	AAA	—	Short distance between renal artery and aortic bifurcation	Yes	Yes
Male	69	AAA	—	Narrow aorta	Yes	Yes
Female	71	Distal aortic bifurcation AAA	—	Short distance between renal artery and aortic bifurcation	Yes	Yes
Male	86	Occlusive disease involving the aortic bifurcation	Bilateral iliac stenting (kissing stents technique)	Short distance between renal artery and kissing stents	Yes	Yes
Female	77	Occlusive disease involving the aortic bifurcation	—	Short distance between renal artery and aortic bifurcation	Yes	Yes
Female	79	Occlusive disease involving the aortic bifurcation	—	Narrow aorta	Yes	Yes
Male	83	Proximal F/BEVAR	Single fenestration PMEG	Short distance between fenestrated main body and aortic bifurcation	Yes	Yes
Male	81	Proximal F/BEVAR	4 Fenestration BEVAR off-the-shelf	Short distance between fenestrated main body and aortic bifurcation	Yes	Yes
Female	75	Proximal F/BEVAR	4 Fenestration patient specific FEVAR	Short distance between fenestrated main body and aortic bifurcation	Yes	Yes
Male	87	Proximal F/BEVAR	4 Fenestration BEVAR off-the-shelf	Short distance between fenestrated main body and aortic bifurcation	Yes	Yes

AAA, Abdominal aortic aneurysm; *BEVAR*, branched endovascular aortic repair; *F/BEVAR*, fenestrated/branched endovascular aortic repair; *IBE*, iliac branch endoprosthesis; *PMEG*, physician-modified endograft.

insert a 16F DrySeal sheath (W.L. Gore & Associates), usually from the side with less severe obstructive disease. All the steps of the procedure are presented in Supplementary Video 1.

In contrast to the standard EVAR device, the IBE does not rely on a proximal active fixation system. Although this should not represent an issue in the treatment of obstructive disease, all the patients with an abdominal aortic aneurysm were highly selected, and a standard EVAR was not feasible. All of these aneurysms were in the distal infrarenal aorta, with a long proximal neck and adequate oversizing to reduce the eventuality of graft migration or endoleak development. Nevertheless, strict follow-up is also indicated, and we obtained follow-up computed tomography angiography (CTA) for all the patients. All the patients provided written informed consent. After the procedure, dual antiplatelet therapy (100 mg aspirin and 75 mg clopidogrel daily) was prescribed for 6 months for patients receiving an IBE for aortoiliac obstructive disease. Single antiplatelet therapy was prescribed to patients treated for an aortoiliac aneurysm. CTA was obtained for all patients 3 months after the index procedure.

EVAR with a short renal-to-aortic bifurcation distance. The IBE was used as an EVAR device in two patients with an infrarenal aortic aneurysm with <7.5 cm distance between the lowest renal artery and aortic bifurcation. This anatomical condition excludes the use of any commercially available standard EVAR device, because the shortest available contralateral gate length is 7 cm. In both treated cases, there was a saccular

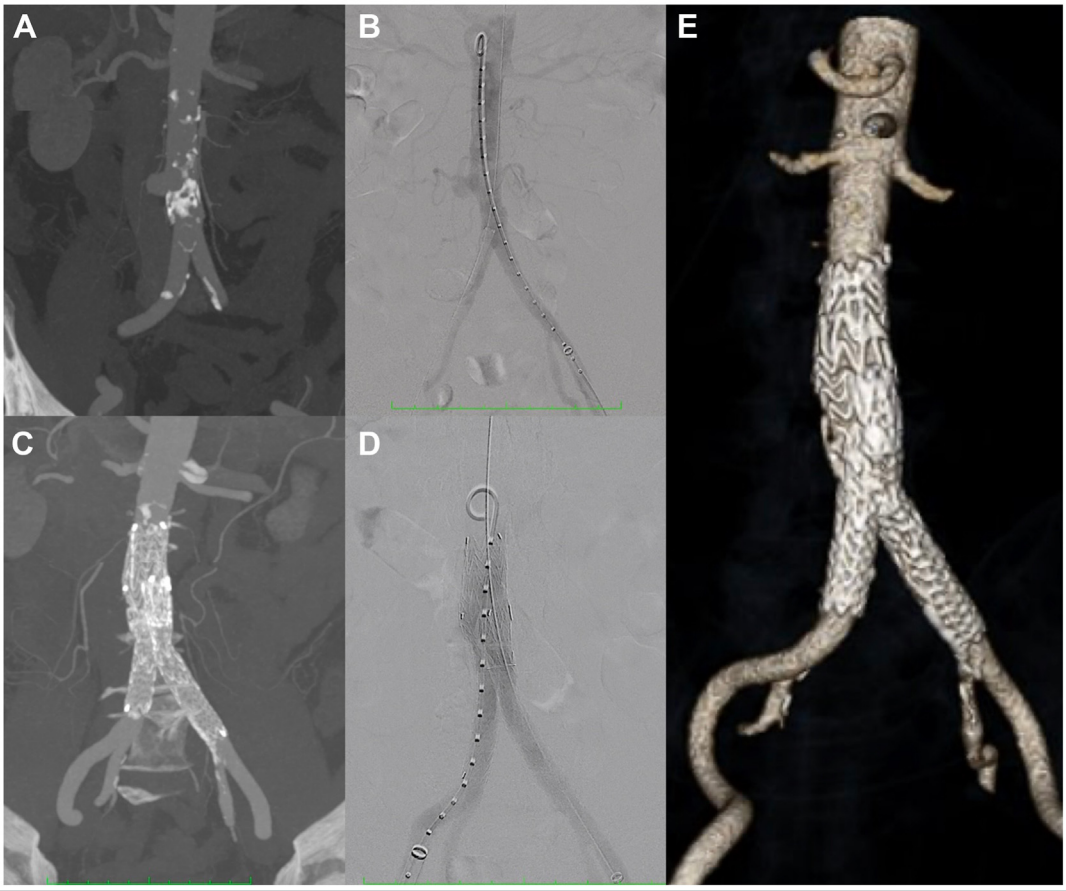

Fig 1. Use of the Excluder iliac branch endoprosthesis (IBE; W.L. Gore & Associates) in a standard endovascular aortic repair (EVAR). Preoperative computed tomography angiography (CTA; **A**) and preoperative angiography (**B)** showing the presence of a saccular aneurysm of the distal aorta. **C,** Postoperative CTA. **D,** Postoperative angiography. **E,** Three-dimensional reconstruction of the postoperative CTA.

aneurysm at the level of the aortic bifurcation, with a proximal long infrarenal aortic segment <21 mm in diameter and a narrow aortic bifurcation (Fig 1). A standard EVAR device was not considered appropriate because of the risk of contralateral gate opening in the narrow aorta, with consequent compression and difficult cannulation. Also, the standard EVAR requires coverage of the entire infrarenal aortic length, and the shorter device length of the IBE allows for partial coverage if needed. Anatomical suitability for the IBE in standard infrarenal EVAR requires the presence of a proximal aortic neck of 16 to 21 mm in diameter and a sufficient length >15 mm.

EVAR with bilateral iliac branch repair. One of the limiting factors of bilateral iliac branch repair is the distance between the lowest renal artery and the iliac bifurcation. In the case of standard EVAR associated with bilateral IBEs, the minimum required length is 165 mm on one side and 190 mm on the other side. This issue can be overcome with the use of a shorter abdominal graft. The case of a patient with bilateral common iliac aneurysms (35 mm on the left; 39 mm on the right), a mean infrarenal aorta diameter of 19 mm, a 70-mm distance between the lowest renal artery and the aortic bifurcation, and a short distance between the renal artery and iliac bifurcation (150 mm on the right; 140 on the left) is shown in Fig 2. Two IBEs (23-14-100 mm on the left; 23-12-100 mm on the right) were deployed in sequence at the level of the iliac bifurcation in standard fashion. The internal iliac gates were extended with an internal iliac component (16-12-70 mm on the right; 16-10-70 mm on the left). Finally, the aortic IBE (23-14-100 mm) was released just below the left renal artery and connected with the iliac IBEs using two contralateral leg components (23-120 mm on the right; 23-120 mm on the left). A 3-month postoperative CTA scan confirmed the correct position and patency of all endovascular components with no signs of endoleak.

Distal bifurcated graft after F/BEVAR. In four patients, the IBE was used as a distal aortic bifurcated component after F/BEVAR. The proximal graft consisted of physician-modified FEVAR in one patient treated for a juxtarenal

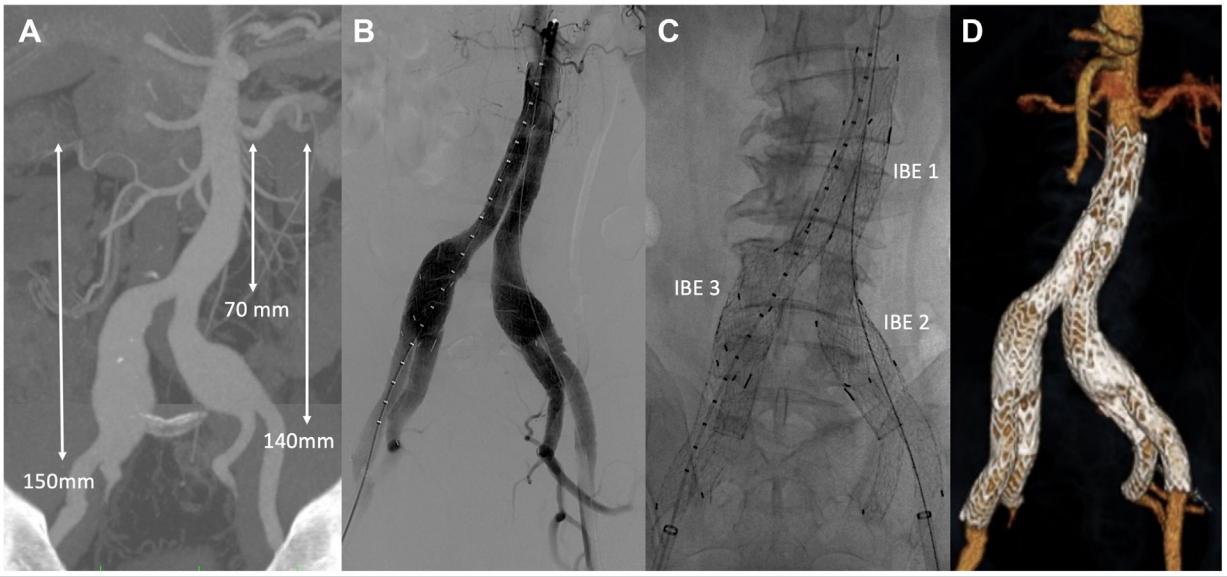

Fig 2. Use of the Excluder iliac branch endoprosthesis (IBE; W.L. Gore & Associates) in a standard endovascular aortic repair (EVAR) in association with bilateral iliac branches. **A,** Preoperative computed tomography angiography (CTA) and measurements. **B,** Postoperative angiography. **C,** Postoperative cone-beam computed tomography showing the three IBEs. **D,** Three-dimensional reconstruction of the postoperative CTA.

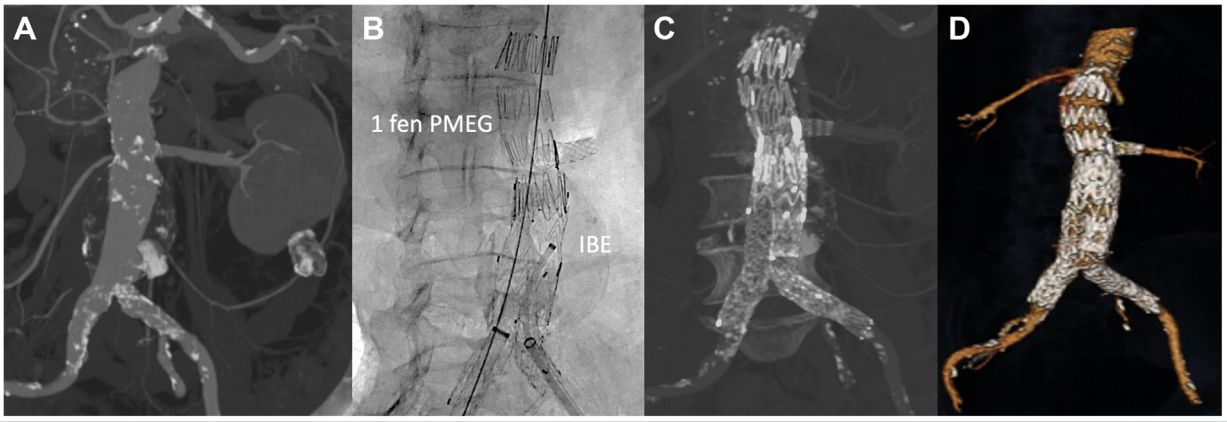

Fig 3. Use of the Excluder iliac branch endoprosthesis (IBE; W.L. Gore & Associates) as a distal bifurcated graft after single fenestration (*fen*) physician-modified endograft (*PMEG*) fenestrated endovascular aortic repair (FEVAR). Preoperative computed tomography angiography (CTA; **A**) and postoperative cone-beam computed tomography still image (**B**) showing the single fenestrated physician-modified endograft and distal IBE. **C,** Postoperative CTA. **D,** Three-dimensional reconstruction of the postoperative CTA.

aortic aneurysm, an off-the-shelf branched device in two patients with an extent IV thoracoabdominal aneurysm, and a single patient-specific fenestrated endograft. The distal diameter of the thoracoabdominal device component was 20 mm for all FEVAR and BEVAR cases. The rationale for the use of the IBE was the short distance between the thoracoabdominal graft component and the aortic bifurcation that was unsuitable for a standard EVAR device, which typically requires about 7 to 8 cm in length for the opening of the contralateral limb (Figs 3 and 4). A narrow distal aorta diameter (<15 mm) was present in three patients. The IBE has a 3-cm-long main body, and a 5-cm length is sufficient for the contralateral limb opening. All four patients were successfully treated, without any related complications.

Extensive aortoiliac occlusive disease. The IBE was used for endovascular reconstruction of the aortic bifurcation in three patients treated for aortoiliac obstructive disease and presenting with rest pain (n = 2) or tissue loss

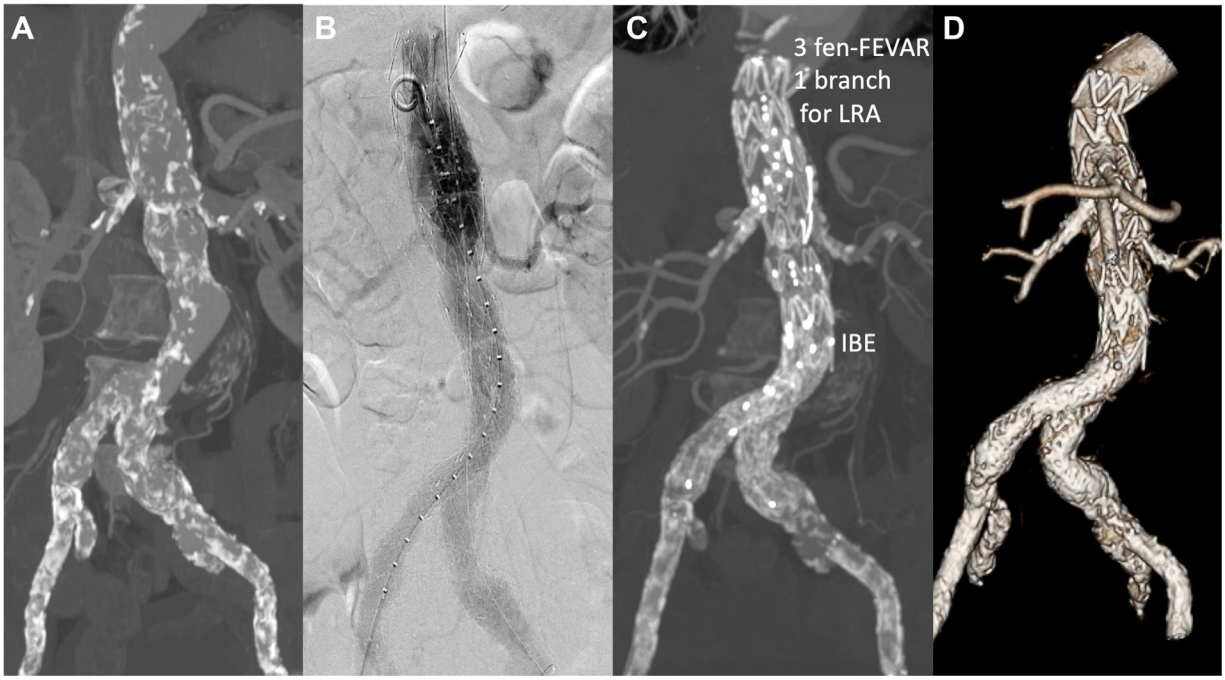

Fig 4. Use of the Excluder iliac branch endoprosthesis (IBE; W.L. Gore & Associates) as a distal bifurcated graft after three fenestrated (*fen*) endovascular aortic repair (FEVAR) with one branch for the left renal artery (*LRA*). **A,** Preoperative computed tomography angiography (CTA). **B,** Postoperative angiography. **C,** Postoperative CTA showing four fenestrated endovascular aortic repair (FEVAR) and distal IBE. **D,** Three-dimensional reconstruction of postoperative CTA.

(n = 1). One patient had been treated with kissing stents of the aortic bifurcation and presented with occlusion of the two kissing stents (Fig 5).

Atherectomy with the Rotarex system (BD) was performed in one case. In all cases, the IBE was deployed after iliac recanalization and insertion of a 16F DrySeal (W.L. Gore & Associates) through the right femoral access. The iliac limbs were extended using contralateral iliac leg components in two cases and Viabahn balloon expandable stents (11 mm VBX; W.L. Gore & Associates) in one case. A 3-month postoperative CTA scan demonstrated the correct position and integrity of the entire implant.

DISCUSSION

This case series demonstrates the feasibility and efficacy of the use of the Gore IBE as an infrarenal endovascular graft for the treatment of aneurysmal and obstructive disease. IBEs have demonstrated excellent results in both bilateral and unilateral applications within and without the instructions for use.[2-8] However, its use as an aortic device has not been fully investigated. Because the endograft is currently approved for exclusive iliac aneurysm treatment with preservation of pelvic circulation, the treatment of all the patients in this series should be considered out of the instructions for use.

The IBE offers distinctive features that differentiate it from other commercially available iliac branch devices. The proximal diameter (23 mm) is significantly larger, allowing for deployment in the infrarenal aorta in the case of a suitable diameter. Compared with standard EVAR endografts, the IBE carries the advantage of a short body with a contralateral gate opening at 5.5 cm from the top of the graft, which can be used in the case of a short anatomy.

The IBE shares the same angulation in its hypogastric bifurcation as a standard Excluder endoprosthesis in its aortic bifurcation. An additional difference can be found in the conformation of the proximal stent of the main body.

For all the cases included in our series, the IBE was chosen because of the patients' unsuitable anatomy for other devices. The feasibility and safety of this approach was demonstrated by the 100% technical success, which was maintained for 100% of the patients after 3 months.

Proximal oversizing can vary depending on the type of treated disease. In the case of aneurysmal disease, typical 20% to 25% oversizing, such as for standard EVAR, is recommended to achieve adequate sealing and fixation. In our experience, this technique was adopted for cases of an aortic aneurysm concurrent with a narrow aorta or bilateral iliac aneurysms treated by bilateral IBEs, with a native infrarenal aortic size ranging from 16 to 20 mm. In the case of distal extension of a proximal F/BEVAR, an 18- to 20-mm distal endograft diameter might be ideal.

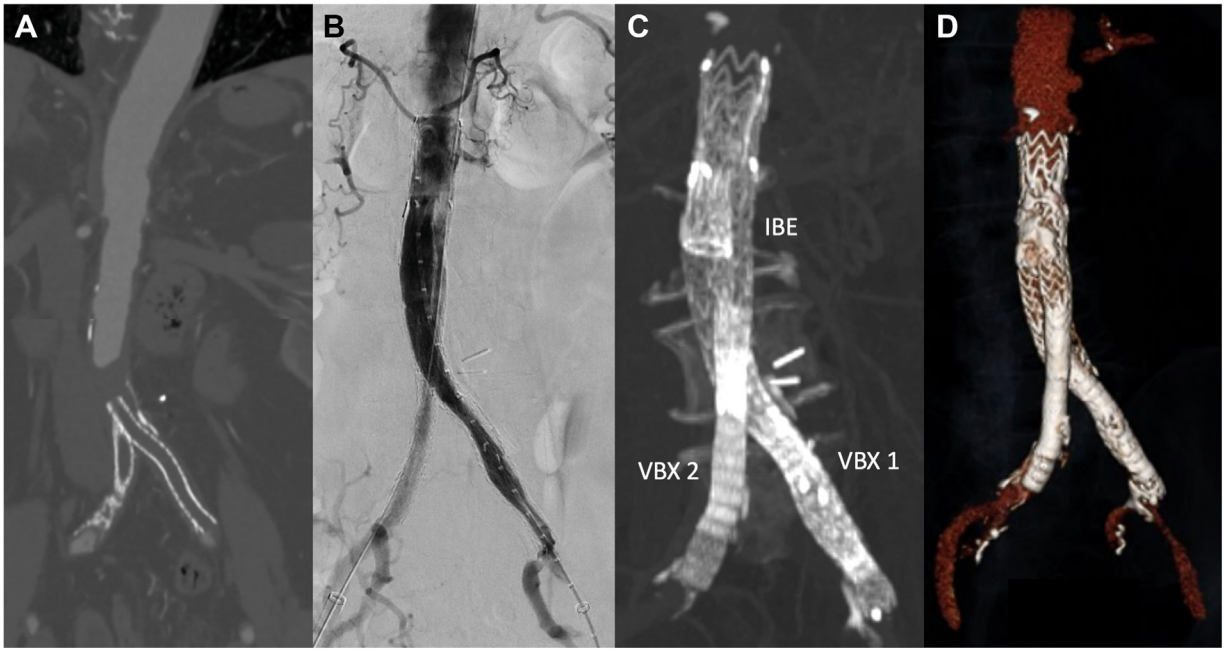

Fig 5. Use of the Excluder iliac branch endoprosthesis (IBE; W.L. Gore & Associates) in extensive aortoiliac occlusive disease. **A,** Preoperative computed tomography angiography (CTA) showing occluded kissing stents. **B,** Postoperative angiography. **C,** Postoperative CTA showing the IBE and the two VBX stents (W.L. Gore & Associates). **D,** Three-dimensional reconstruction of the postoperative CTA.

In the treatment of obstructive disease, smaller proximal oversizing can be adopted. The proximal end of the IBE in these cases is deployed in a region free of significant obstructive disease. The objective is to achieve good graft apposition to the aortic wall, ensuring an optimal hemodynamically stable conformation. In these cases, an aortic diameter of ≤22 mm can be treated. Similar to the CERAB technique, the use of the IBE allows for complete anatomical endovascular reconstruction of the aortic bifurcation, overcoming the limitations of the kissing stent technique regarding the resulting "gutter" between the two endovascular components at the aortic level.[9-11] Compared to the CERAB technique, the use of a bifurcated graft might have the advantage of better sealing between the endovascular components, avoiding possible complications when aggressive arterial dilatation is required (with risk of arterial rupture) and eliminates the risk of a radial and protrusion mismatch, which can undermine the efficacy of the CERAB technique. Also, the use of a proximal self-expanding endograft is useful in avoiding unnecessary ballooning of the aorta in those cases in which residual mural thrombus or calcifications are present at the proximal landing site. In the case of obstructive disease, the main limiting factor is the need for a 16F, 33-cm-long introducer sheath for its deployment. In particular, in cases with complete bilateral iliac axis occlusion, it can be difficult to advance a large profile sheath, and there could be an associated risk of arterial rupture, especially in heavily calcified vessels. Another theoretical risk in using the IBE for aortoiliac obstructive disease is represented by iliac limb occlusion or compression during follow-up, revealed by suboptimal iliac limb expansion in a narrow and/or calcified aortic bifurcation. Adequate predilatation, vessel preparation with eventual intravascular lithotripsy or atherectomy and routine postdilatation of the iliac limbs in a kissing fashion are mandatory to avoid this event.[12] With the use of this technique, in our experience, all three patients had an optimal immediate result, which was confirmed 3 months after treatment.

The use of the IBE as an aortic endograft has several limitations. It represents an outside of the instructions for use indication, with possible related issues. The device has not been investigated for use in the treatment of abdominal aneurysms, and the mid-term and long-term durability is unknown, especially in terms of proximal sealing.

CONCLUSIONS

The use of the IBE as an infrarenal aortic endograft has been adopted for the treatment of aneurysmal or obstructive disease, with 100% technical success that was maintained after 3 months. Possible advantages are offered by the short endograft length, which can overcome the issue of a short available aortic distance in the treatment of aneurysmal disease, eventually associated with a proximal F/BEVAR or a distal iliac branch device. In the treatment of obstructive disease, it might

represent an alternative to the CERAB technique. The use of the IBE can be considered for extremely selected cases; however, larger experience is still needed to evaluate the clinical applicability and long-term results of this approach.

DISCLOSURES

None.

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