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Upside-Down Gore Excluder as an Endoprosthesis for Aortoiliac Aneurysm Exclusion: A Retrospective Multicenter Study

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Abstract

Objective: The upside-down configuration of a Gore Excluder contralateral leg endoprosthesis has been used to overcome diameter differences in the endovascular treatment of aortoiliac aneurysms. Our goal was not to describe the technique but to study the applicability and safety.

Material and methods: Patients were retrospectively enrolled. The indication and details of the procedure were at the discretion of the treating physicians. A case report form was completed including baseline characteristics, indication for treatment, procedural data, and outcomes during follow-up.

Results: A total of 31 subjects were enrolled with a range of indications, including 3 patients treated in the emergency setting (9.7%). In 64.5% (n=20), it was a primary intervention for a common iliac aneurysm (n=10), internal iliac aneurysm (n=4), or abdominal aortic aneurysm (n=6). In 11 subjects (35.5%), treatment was performed after previous aortoiliac interventions, including anastomotic iliac artery aneurysm (n=5), type III endoleak (n=3), and endograft thrombus (n=3). Median follow-up was 13 months (range=1-142 months). During follow-up, 2 patients required an upside-down contralateral leg–related secondary intervention, one for an occlusion and another for a type Ia endoleak. There was no type Ib or III endoleak, and no migration, kinking/stenosis, or conversion to open repair was observed. The aneurysm-related mortality was 3.3% (n=1).

Conclusion: An upside-down contralateral leg is a valuable technique that can be used to achieve adequate aneurysm exclusion or resolve complications. It is associated with a limited number of complications.

Clinical impact

This article studies the use of an upside-down iliac endograft. We describe a wide range of indications in which this previously published technique has been applied. In elective and acute settings and as primary and revision intervention an upside-down iliac endograft was performed successfully. Furthermore, follow-up data is presented showing the effectiveness of the technique. Knowledge of this procedure is a valuable addition to the skillset of every interventionalist.

Keywords

endovascular aneurysm repair, common iliac artery, aorto-uni-iliac stent graft, off-label use, off-the-shelf device, complications

Introduction

Endovascular aneurysm repair (EVAR) has become the preferred treatment for most abdominal aortic aneurysms (AAA) and iliac artery aneurysms (IAA), provided a suitable anatomy. The EVAR has been proven to reduce early morbidity and mortality compared with open surgical repair.[1] However, the applicability of endografts is still hampered by morphological characteristics of the aortoiliac tract that are required to acquire adequate seal of the endograft. These characteristics are determined by the endograft manufacturer and stated in the instructions for use (IFU). Strict adherence to the IFU is estimated to exclude 40% of patients with AAA or IAA to be treated endovascularly.[2]

Techniques such as custom-made devices and the use of additional chimneys are developed to overcome morphological obstacles. In subjects where the diameter of the proximal sealing zone exceeds the diameter of the distal sealing zone, the off-label use of a reversed or upside-down tapered device promises to be a valuable addition to currently available techniques.[3] This is primarily the case in the common iliac artery but can also be part of revision surgery. Since the description of the technique of implanting an upside-down Gore Excluder contralateral leg endoprosthesis (W. L. Gore & Associates Inc, Flagstaff, Arizona) by Van der Steenhoven et al,[3–7] there have been few additional reports.[3–7] Because this application of the endoprosthesis is outside IFU, it raises questions about effectiveness and durability. However, the collection and analysis of relevant data is currently missing. In this study, we aimed to assess the long-term outcomes of the upside-down Gore Excluder contralateral leg endoprosthesis in the treatment of aortoiliac aneurysms.

Materials and Methods

Design of the Study

This is a retrospective study of patients treated across the Netherlands. All patients were treated for exclusion of an AAA and/or IAA with a Gore Excluder contralateral leg endoprosthesis in an upside-down configuration. There were no specific exclusion criteria. Thirty-one patients were identified who were treated between December 2009 and March 2021.

The Institutional Review Board approved the study (METc nr 2020/454). Research studies involving the retrospective review, collection, and analysis of patient records do not fall under the Dutch Medical Research Involving Human Subjects Act (WMO), and therefore individual patient informed consent was not required. The opt-out registry of the institutions was consulted to find out whether patients had objected to participating in scientific research. Storage and analysis of data was anonymized.

Patient and Procedural Characteristics

Medical records and imaging were reviewed to determine anatomic characteristics of the aneurysm, presurgical health status, intervention details, and follow-up data. Basic demographics including age, sex, and body mass index were collected, as well as data on comorbidities. These comorbidities, including diabetes mellitus, hypertension, smoking, dyslipidemia, and cardiac, pulmonary and renal status, were scored from 0 to 3 according to the Society of Vascular Surgery—American Association of Vascular Surgery medical comorbidity grading system.[8] Anatomic characteristics of the AAA/IAA, including aneurysm sac diameter, proximal neck diameter, and distal neck diameter, were measured from the computed tomographic scans by the vascular surgeon or interventional radiologist. Procedural details included the date of intervention, indication, procedure time, blood loss, access method, fluoroscopy time, date of discharge, duration of stay at intensive care unit (ICU), and the proximal and distal diameter of the Gore Excluder limb. Follow-up information included erectile dysfunction, buttock claudication, stent graft migration, endoleaks (type I–V), aneurysm diameter change, (>5 mm) aneurysm rupture, and any related secondary intervention.

Technique

The techniques of endograft preparation, introduction, and deployment have been described before and are illustrated in Figure 1.[3] Briefly summarized, to deploy a Gore Excluder contralateral leg endoprosthesis in the upside-down manner it has to be removed from the delivery device. First, the olive at the end of the device is removed by either breaking or cutting it with scissors. The knob used to deploy the device is unscrewed and the line is cut with scissors at this end. Then the devices can be removed while the sleeve is still attached. Now the leg can be introduced upside-down over a super-stiff wire mostly through an 18F sheath. The sheath with stent graft has to be positioned at the intended proximal sealing zone. The deployment wire is still outside the sheath. To ensure the position of the stent graft, the tip of the dilator is removed. Approximately 1 cm should be removed to prevent leaking. If too little is removed, the dilator can be introduced inside the stent graft. The endograft should be deployed using the deployment wire inside the sheath with the dilator to maintain position. With retracting the sheath while keeping the modified dilator in position, the endograft is properly placed in a push and pull fashion. This technique has also been used to reline a graft in case of a type III endoleak at the level of the bifurcation. Two upside-down

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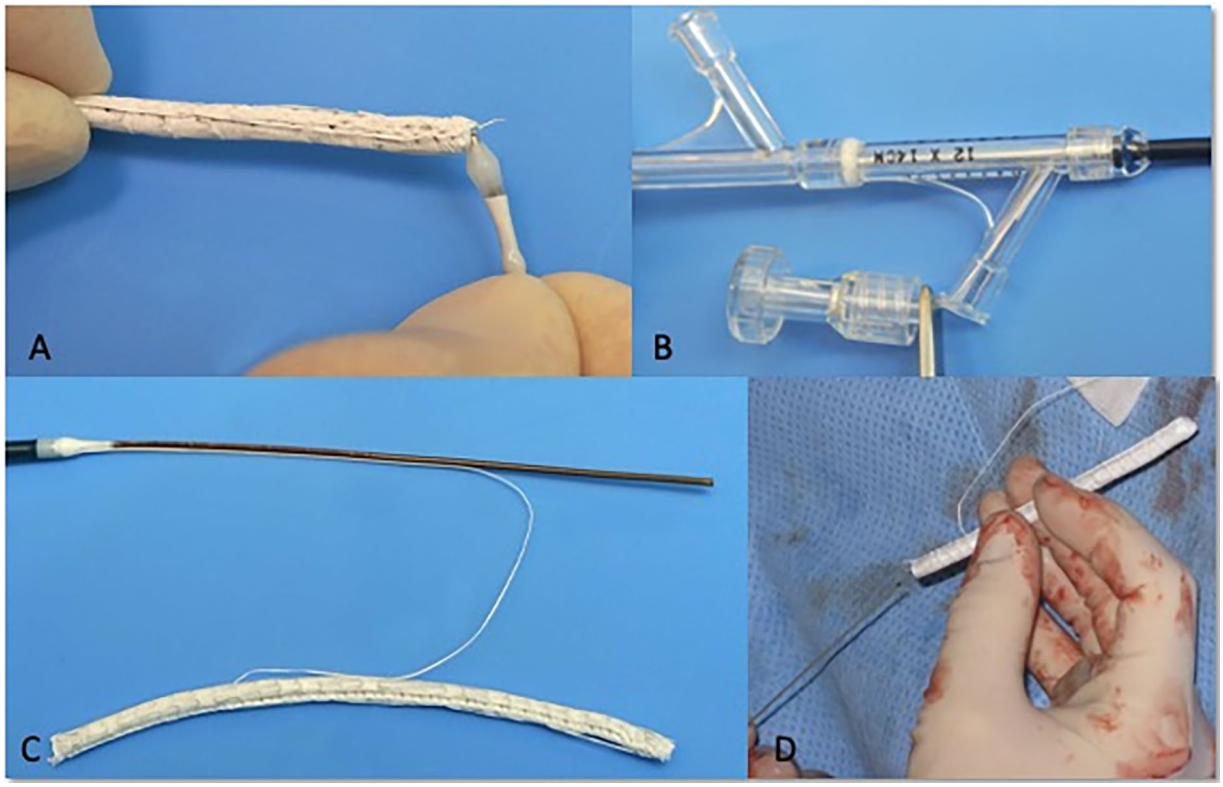

Figure 1. (A) Cutting or breaking of the olive. (B) Unscrewing the release wire and cutting the wire. (C) Removing the endograft from the device and turning it upside down. (D) Mounting the upside-limb on a super-stiff wire.

endografts are implanted to form a double-D configuration as displayed in Figure 2.[6]

Statistics

Data were collected through local investigators using a standardized case report form. Analyses were performed using SPSS 22 for Windows. Categorical variables are presented percentages with frequencies. Continuous variables are presented as means±standard deviation (SD). In case of skewed data, continuous variables are presented as median with range from minimum to maximum.

Results

A total of 31 subjects, from 15 different hospitals, were enrolled in this study. The first procedure was performed in 2009 and the last in 2021; 70.1% (N=22) of cases were treated between 2018 and 2021. Baseline characteristics are depicted in Table 1 and were as can be expected in an aneurysm population, the majority being male (80.6%), with a mean age of 76.0±7.6 years. Most subjects had hypertension requiring medication (74.2%) and impaired renal function (67.7%). Any cardiac disease was present in 35.5% of patients.

Indications for the use of the upside-down Gore Excluder contralateral leg endoprosthesis are specified in Table 2. In 3 (9.7%) subjects, the treatment was for either a ruptured or symptomatic nonruptured aneurysm. In 20 subjects (64.5%), this technique was applied as a primary intervention to exclude an aneurysm, and in the remaining 11 (35.5%), as part of revision intervention after previous open (n=5) or endovascular (n=6) repair.

Primary IAA was the most common indication (32.3%); median iliac aneurysm diameter was 56 mm ranging from 17 to 100 mm. The 17 mm case was a contained iliac artery rupture. In the treatment of AAAs in combination with atherosclerosis, the median diameter was 38 mm ranging from 32 to 53 mm. The upside-down contralateral leg was used in an aorto-uni-iliac (n=5) or a tube (n=1) configuration, of which 83.3% (n=5) were women. Four subjects were treated for an internal IAA without any previous surgery, median diameter of 44 mm ranging from 40 to 49 mm.

Upside-down contralateral legs were used as part of a revision intervention for a common IAA in 5 subjects with a median diameter of 40 mm ranging from 31 to 50 mm. In

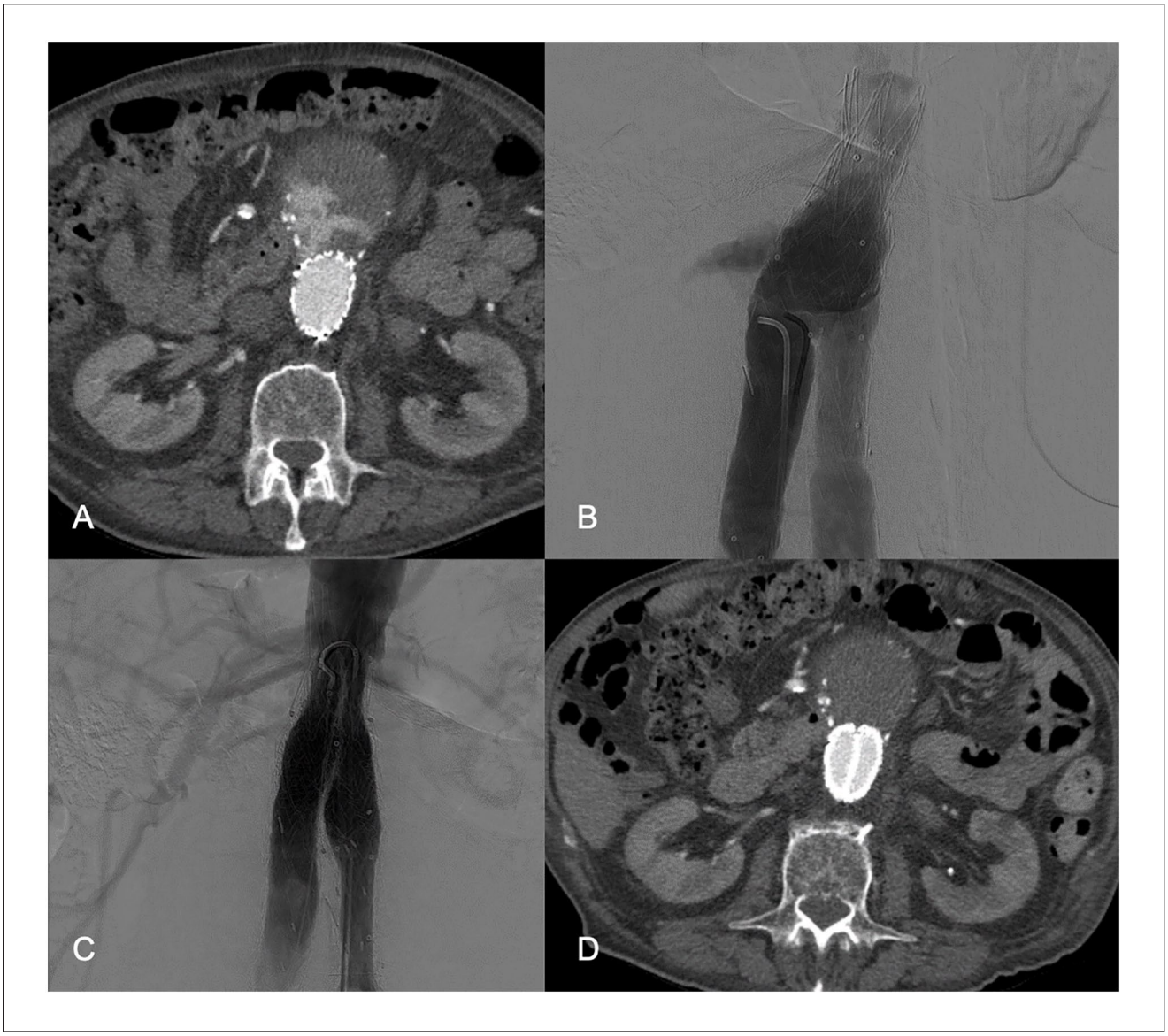

Figure 2. (A) Computed tomographic (CT) scan showing a type III endoleak at the level of the flow divider. (B) Angiography confirming a type III endoleak. (C) Completion angiography after implanting 2 upside-down Gore Excluder contralateral limbs. (D) Follow-up CT scan showing a double-D configuration and absence of any endoleak.

6 subjects, the upside-down contralateral legs were used for endovascular revision. In 3 subjects for a type III endoleak using 2 parallel-placed upside-down contralateral legs and[6] 3 others for limb thrombosis requiring relining after thrombectomy.

Procedurale characteristics are depicted in Table 3. The mean procedural time was 93±46 minutes. Procedural time varied with the shortest being 30 minutes. In 54.8% of procedures, an adjunctive intervention was performed ranging from IIA coiling to crossover bypass. Open femoral approach was used in 64.5%, but a percutaneous femoral approach was increasingly applied over time. In 87.1%, the technique was used in subjects with a greater proximal than distal diameter. In the remaining 12.9% (n=4), a bell-bottom configuration was applied with a 12 mm proximal diameter in the upside-down position. Three of these bell-bottom cases were relining of a previous EVAR and one secondary intervention after open aortic bifurcation procedure. Four subjects were admitted to ICU immediately after treatment. Median duration of hospital admission was 2 days ranging from 1 day to 45 days.

Follow-up

Follow-up date is presented in Table 3. One subject did not receive any follow-up in a participating center and was

Table 1. Baseline Characteristics.

	% (n/N)
Sex (male)	25 (80.6%) (25/31)
Age, y, mean±SD	76.0±7.6
BMI, mean±SD	27.0±3.9
History of smoking	35.5% (11/31)
Hypertension	74.2% (23/31)
Diabetes mellitus	19.4% (6/31)
Dyslipidemia	48.4% (15/31)
Cardiac disease[a]	35.5% (11/31)
Pulmonary disease[b]	32.2% (10/31)
Renal disease	67.7% (21/31)

Abbreviation: BMI, body mass index.
Continuous data are presented as the means±standard deviation; categorical data are given as the percentages (counts).
[a]Any cardiac history or signs of ischemia on electrocardiogram.
[b]Chronic pulmonary disease, dyspnea, or pulmonary function test <80% of expected value.

Table 2. Indications for Surgery.

Primary intervention	Median (min–max) or % (n/N)
Upside-down limb as primary treatment	64.5% (20/31)
Common iliac artery aneurysm	32.3% (10/31)
Diameter, mm	56 (17–100)
Proximal neck diameter, mm	16 (12–19)
Distal sealing diameter, mm	15 (12–19)
Internal iliac artery aneurysm	12.9% (4/31)
Diameter, mm	44 (40–49)
Abdominal aortic aneurysm[a]	19.3% (6/31)
Diameter, mm	38 (32–53)
Revision intervention	
Upside-down limb as revision	35.5% (11/31)
EVAR	N=6
Open aneurysm repair	N=5
Secondary common iliac artery aneurysm	16.1% (5/31)
Type III endoleak	9.7% (3/31)
Relining after thrombectomy	9.7% (3/31)

Abbreviation: EVAR, endovascular aneurysm repair.
Continuous data are presented as median with minimum and maximum; categorical data are given as percentages (counts).
[a]Five implantations in aorto-uni-iliac and one in an aortic tube configuration.

Table 3. Treatment Characteristics and Follow-up.

	% (n/N)
Procedure time (min)[a] Mean±SD	93±46
Adjunctive procedure	54.8% (17/31)
Admission, d Median [min–max]	2 [1–45]
Admissions to ICU	12.9% (4/31)
Proximal device diameter after upside-down deployment, mm	
12	12.9% (4/31)
18	3.2% (1/31)
20	54.8% (17/31)
23	19.4% (6/31)
27	9.7% (3/31)
Devices used upside-down	37
Follow-up	
Follow-up, mo Median [min–max]	13 [1–142]
Aneurysm diameter on follow-up,[b] mm Median [min–max]	47 [24–126]
Shrinkage	63.2% (12/19)
Stable	26.3% (5/19)
Growth	10.5% (2/19)
Endoleak	
Type I	3.3% (1/30)
Type II	13.3% (4/30)
Type III	0
Graft migration	0
Graft infection	0
Graft occlusion	3.3% (1/30)
Secondary intervention	10.0% (3/30)
1	Limb occlusion
2	Type 1A endoleak
3	Common iliac aneurysm contralateral side
Claudication (buttock, thigh, or calf)	20.0% (6/30)

Abbreviation: ICU, intensive care unit.
Continuous data are presented as the means±standard deviation if distributed normally; skewed data as median with minimum and maximum; categorical data are given as the percentages (counts).
[a]Procedural time missing for 3 subjects.
[b]N=19, missing 9 subjects and excluded relining for thrombosis.

excluded from any further analysis. Median follow-up was 13 months ranging from 1 month to 142 months. For 19 of the patients treated for an aneurysm or endoleak, a follow-up aneurysm diameter was available. In 63.2%, there was substantial sac shrinkage, growth was detected in 10.5% (n=2). Growth was seen in one coiled internal iliac aneurysm without flow and the second was a primary iliac aneurysm with 5 mm of growth without an endoleak. During follow-up, there were no reports of graft migration, kinking, infection, or conversion to open repair. After the intervention, there were 4 (13.3%) type II endoleaks, 1 of the endoleaks was already diagnosed prior to the intervention and none required a secondary intervention.

One (3.3%) type Ia endoleak was diagnosed in a patient treated for a ruptured common iliac aneurysm. The

diagnosis was made due to persistent blood loss during admission and treated 24 days after initial intervention with another upside-down contralateral leg. Thereafter, the endoleak resolved. During follow-up, 1 additional patient required a secondary intervention related to the upside-down contralateral leg, due to an occlusion of one the limbs 14 days after bilateral implantation for a type III endoleak. This patient died as a result of sepsis due to bowel perforation, while during laparotomy no signs of ischemia were seen. A third patient was treated 4 years after the index procedure with an endovascular bifurcation graft for a contralateral iliac aneurysm.

The primary patency of the upside-down contralateral limb was 96.7%. During follow-up, 6 subjects (20%) experienced any buttock, thigh, or calf claudication after the procedure; 1 patient after relining; 1 after internal IAA treatment; and in the remaining 4, treatment was for a primary common IAA. They all underwent IIA embolization during the procedure.

Aneurysm-related mortality was 3.3%. The overall mortality during follow-up was 23.3%.

Discussion

This study shows the results of an upside-down Gore Excluder contralateral leg endoprosthesis in 31 patients. Although the technique of a Gore Excluder contralateral leg endoprosthesis in an upside-down configuration has been described as single case reports, the extensive applicability was less highlighted.[3–7] The wide variety of indications in this study show that the technique is a valuable tool with good clinical outcomes.

First of all, data of our study confirmed the safety and applicability of the technique with a 6.7% (n=2) re-intervention rate related to the upside-down contralateral leg. Only 1 type Ia endoleak occurred that could be treated in a similar fashion. When taking into account this study also includes acute cases and secondary interventions, these outcomes could be considered good. The acceptable rate of complications and secondary interventions make it a valuable addition to the armamentarium for the vascular interventionalist to treat pathologies that cannot be treated with devices inside IFU, related to diameter mismatches.

In accord with previous publications on this technique, our data show that it is applied for a large variety of indications.[3–7] It can be used as a stand-alone for common IAAs with a larger diameter in the proximal seal zone, compared with the distal seal zone. With an upside-down bell-bottom limb, the sizing mismatch could be easily overcome with adequate oversizing. Also, the technique proved to be helpful in patients with a type IIIb endoleak with a tear near the endograft bifurcation. These are difficult to treat with regular endografts, but using 2 parallel-placed bell-bottom limbs in a double-D configuration, adequate seal can be achieved (Figure 2). By turning the endoprosthesis upside-down, it can also be used in combination with EVAR of different manufacturers if a device-specific solution is not immediately available. In 3 included cases, a 12 mm proximal limb diameter was required to accommodate the distal main body diameter. Obtaining this skill can extend the applicability of the endografts that are in stock.

Furthermore, it is a relatively simple process to turn the endoprosthesis upside-down. Because the endoprosthesis is not deployed but reversed while constrained in the sleeve, the risk of damaging the graft is low. Turning an endograft upside-down has been described for other endografts as well.[7,9–11] Due to the design turning some endografts upside-down require extracorporeal deployment and reloading. For reloading, the endograft must be constrained either manually or by using sutures. Reloading is time-consuming and manipulation increases the risk of damage to the endograft. The Excluder-based procedure can be performed swiftly in a minimum of 30 minutes from puncture to closure. In acute cases, this off-the-shelf solution can be applied successfully as was shown in 3 of our cases.

It should be noted that the use of an upside-down contralateral leg is outside the IFU and should therefore be considered with great care and only after informed consent with the patient. The indications and also location of the contralateral legs in this study differed, thus no strong conclusions can be drawn to advice this treatment in certain situations. Therefore, off-the-shelf or custom option indicated for certain pathologies, such as dedicated iliac branched technology, should always be considered first, staying inside the IFU for the devices, when appropriate. Unfortunately, custom-made or iliac branched options are not always directly available and have specific anatomical limitations, according to IFU requirements. In other cases, the use of these devices is not helpful, such as in cases with a type IIIb endoleak with a tear at the endograft bifurcation (Figure 2). However, based on our findings, the use of an upside-down contralateral leg is not associated with unacceptable risks.

Study Limitations

The study population is based on a retrospective database, hence the risk of selection bias. Furthermore, the authors have no information about why the decision was made to use an upside-down contralateral leg opposed to other, custom-made, options. However, the aim of this article is to evaluate applicability and outcomes as opposed to determine the best treatment. The variety of indications unfortunately make it difficult to perform extensive statistical analysis or compare with other techniques.

Conclusion

This article shows that with knowledge of a device and the way it is deployed it can be altered to suit the needs at that time. We report a number of different indications that were

successfully addressed with using an upside-down contralateral leg. Although it is off-label use, it can be a valuable addition to an endovascular toolbox.

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Declaration of Conflicting Interests

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