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CLINICAL INVESTIGATION

Custom-Made Endograft for Endovascular Repair of Thoraco-Abdominal Aneurysm and Type B Dissection: Single-Centre Experience

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Abstract

Aims To report a series of patients treated with the Jotec custom-made endograft for thoraco-abdominal aneurysms and dissections and identify predictive factors for re-intervention.

Methods We retrospectively analysed 49 patients unsuitable for surgery, treated between 2011 and 2017 (71.3 ± 9.5 years; 15 females). Indications included Crawford type 4 aneurysm in 25 patients, type 3 in 13, type 2 in 4, type 1 in 2 and chronic aneurysmal dilatation of the false lumen following dissection in 5 cases. Mean aneurysm diameter was 58.7 ± 8.4 mm. The study aims were to assess procedural success, complications rate, mortality and long-term follow-up. We also analysed factors that predicted the need for re-intervention.

Results The endograft was successfully deployed in all patients, catheterization of the fenestration and/or branches was achieved in 152/156 (97.4%) vessels. Early complications occurred in 10 patients (3 paraplegia, 3 haemorrhages, pancreatitis, aortic rupture, iliac artery rupture, 2 strokes). Thirty-day mortality was 10.2% and 180-day mortality 14.3%; two non procedure related deaths occurred. Mean follow-up was 23.6 ± 29.9 months [range 1–80]. No patients needed surgical explantation or developed significant renal impairment. Endoleak rate was 34.6% and re-intervention rate 9.7%. The aneurysm sac reduced or was stable in 36/49, and enlarged in 9/49

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patients prompting re-intervention. Primary, primary-assisted and secondary patency of fenestrations/branches at 80 months was 90, 96 and 100%. Re-intervention was required more frequently in braches than in fenestrations, most commonly the external type branches.
Conclusions The results of the Jotec endograft are comparable to other devices, with acceptable complication and re-intervention rates. Fenestration and inner-branch should be preferred due to lower re-intervention rates.

Keywords b-EVAR · f-EVAR · TEVAR · EVAR · Thoraco-abdominal aneurysm · Type B dissection · Endovascular repair

Introduction

The management of thoraco-abdominal aneurysms and false lumen aneurysmal dilatation in type B chronic dissection patients still represents a major challenge, due to their high risk of spontaneous rupture and death [1].

During the last decade there has been a shift in treatment modality moving from open surgical reconstruction in favour of the less invasive endovascular repair. Fenestrated or multi-branch devices have been reported to potentially reduce both morbidity and mortality [2]. Two different types of endovascular devices are currently available: "off-the-shelf" and custom-made devices. Off-the-shelf devices consist of a standard multi-branch (4 branches) endograft. These have been demonstrated to be anatomically suitable for use in 88% of patients with aneurysmal disease [3]. Excellent clinical results have been reported in elective [4] and emergency [5] settings. On the other hand, different manufacturers have developed a customization programme to overcome the known limits of the "off-the-shelf" devices, for example anatomy unfit for standard devices, patients that require additional branches or those in the retrograde direction, and patients whose aortic diameter is outside of the standard sizes [6]. Jotec GmbH (Hechingen, Germany EU) E-xtra design programme was launched back in 2011, but to date, only a few studies on the utility of fenestrated or multi-branch devices [7–9] have been reported and no long-term results are available. For these reasons the aim of this study is to report the long-term follow-up of a large cohort of patients treated with a Jotec custom-made endograft for thoraco-abdominal aneurysms and type B dissection and to identify technical and clinical factors that predict the need for re-intervention.

Materials and Methods

A retrospective analysis of our electronic database and clinical records of all patients treated with an E-xtra design engineering endograft from Jotec GmbH (Hechingen, Germany EU) was performed. From the time the device became available in January 2011 till January 2017, we treated 49 patients (71.3 ± 9.5 years old; 15 females). Demographic and clinical characteristics of the study are summarised in Table 1.

Indication for treatment was a Crawford type 4 aneurysm in 25 patients (51%), type 3 in 13 patients (26.5%), type 2 in 4 patients (8.1%), type 1 in 2 patients (4%) and a false lumen aneurysmal dilatation of a chronic dissection; in particular Stanford type B in 3 cases (6.1%) and a residual dissection, after a type A surgical repair in 2 cases (4%). All patients had been discussed at our multidisciplinary team meeting attended by interventional radiologists and cardiothoracic surgeons. The cases were all deemed unfit for open surgery due to either prior surgery precluding further repair or their co-morbidities making surgical risk unacceptably high. Mean aneurysm diameter was 58.7 ± 8.4 mm (range 50–78). Indication for the treatment of aneurysms < 6 cm was a rapid sac enlargement (> 5 mm at 6-month follow-up) or a morphology known to be at high risk of rupture (e.g. eccentric dilation).

All procedural details were recorded (procedural mean fluoroscopy time, mean contrast media volume administered during procedure and mean intervention duration).

Device Planning

All planning was performed by the same operator with more than 20 years of experience in advanced aortic procedures. Custom-made devices were planned on the basis of CT angiography (CTA) measurements taken within 3 months of the fenestrated-EVAR (f-EVAR) or branched-EVAR (b-EVAR) procedures [10]. Fenestration devices were used in all those cases in whom the endograft diameter could satisfactorily appose the aortic wall at the level of the visceral vessels. External branched devices were employed in cases where the aorta was aneurysmal at the level of the visceral vessels. If this segment was too dilated for a fenestrated device, but also not dilated enough to allow for the deployment of external branches, a device with internal branches was utilised. The orientation of the branch, either antegrade or retrograde, was chosen in order to conform to the native vessel anatomy. Retrograde branches were reserved for cases of complex aortic morphology or in patients in which technical constraints did not allow antegrade orientation, e.g. two closely positioned branches. A suitable proximal and distal landing zone,

Table 1 Study population demographic and clinical characteristics

Population characteristics	(*N* = 49)
Male/female	34/15
Age (years)	71.3 ± 9.5
Risk factors	
Hypertension	36 (73.4%)
Diabetes	7 (14.2%)
Dyslipidaemia	16 (32.6%)
Renal insufficiency	10 (20.4%)
Ex-smoker	22(44.9%);
Never smoker	12 (24.5%);
Current smoker	15 (30.6%)
At least one previous aortic intervention	21 (42.8%)
Elephant trunk	7
Great vessel transposition	1
Femoro-femoral bypass	1
Aortic-bifemoral bypass	4
Mechanical aortic valve	1
TEVAR	7
Descendant aortic surgery	1
EVAR	3
Ascendant aortic surgery	5
Coronary bypass	1
Heart transplant	1
Indication for treatment	
Crawford 4	25
Crawford 3	13
Crawford 2	4
Crawford 1	2
Dissection	5
Mean aneurysm diameter (mm)	58.7 ± 8.4 (50–78)

either surgical (e.g. proximal elephant trunk or distal aortic-bifemoral bypass) or native (> 2 cm), were employed in all cases. Completion of the fenestration was performed with balloon-expandable covered stents (Advanta V12, Maquet Holding, Germany), whereas branch completion was performed with self-expandable covered stents (Viabahn, Gore & Associates, Flagstaff, USA). Figures 1 and 2 show two challenging cases performed accordingly to our customization policy.

Procedure

All procedures were performed in a single session in a state-of-the-art angio-suite, under general anaesthesia. Custom-made devices were deployed via a surgical cut down of the femoral artery in all cases. Endovascular fenestration was performed, according to the previously published techniques [11], in all patients with dissection in whom the dissection membrane involved the juxtavisceral aorta. Catheterization of the visceral vessel fenestration or branch and consequent stenting was performed via a surgical left femoral access in all cases that needed an antegrade approach. Spinal cerebrospinal fluid (CSF) drainage was employed only in those cases in whom an associated thoracic endovascular aortic repair (TEVAR) procedure was planned or in patients with previous aortic procedures.

Follow-Up

Follow-up was performed with CTA at 30 days, 6 months, 1 year and annually thereafter [10]. In cases in which CTA depicted suspicious findings but did not require immediate re-intervention stricter imaging surveillance was performed. In all cases that required re-intervention, it was performed within 30 days. Moreover, all CTA datasets were studied in order to identify the presence of endoleaks. Complications were classified according to the CIRSE classification system [12].

Statistical Analysis

Continuous data were described as the mean value ± SD, whereas non-Gaussian with median and percentiles. We took the clinical characteristics of the patients who had re-interventions on the aneurysmal sac. For re-intervention on fenestrations/branches all the technical features relating to the endovascular reconstruction like the number of stents employed, the length of the stented segment, fenestration versus branch, inner versus external branch, antegrade versus retrograde branch, the presence of interposed adjunctive stent (bridge stent) and vessel diameter were analysed. Multiple logistic regression analysis was performed to test the variables, and Kaplan–Meier analysis was performed to measure the fraction of subjects without complication for a certain amount of time after treatment. A p value < 0.05 was regarded to indicate a statistically significant association. All p values were calculated using a two-tailed significance level. Statistical analysis was performed with the SPSS 13.0 statistical package (SPSS Inc, Chicago, IL). Graphics were plotted with MedCalc 15.0 software (MedCalc, Mariakerke, Belgium).

Definition

Technical success was defined as endograft deployment and catheterization success of fenestrations and/or branches.

With regard to fenestration/branch patency, primary patency is defined as an uninterrupted patency without adjunctive interventions. Primary-assisted patency defines the patency of a fenestration/branch after re-intervention

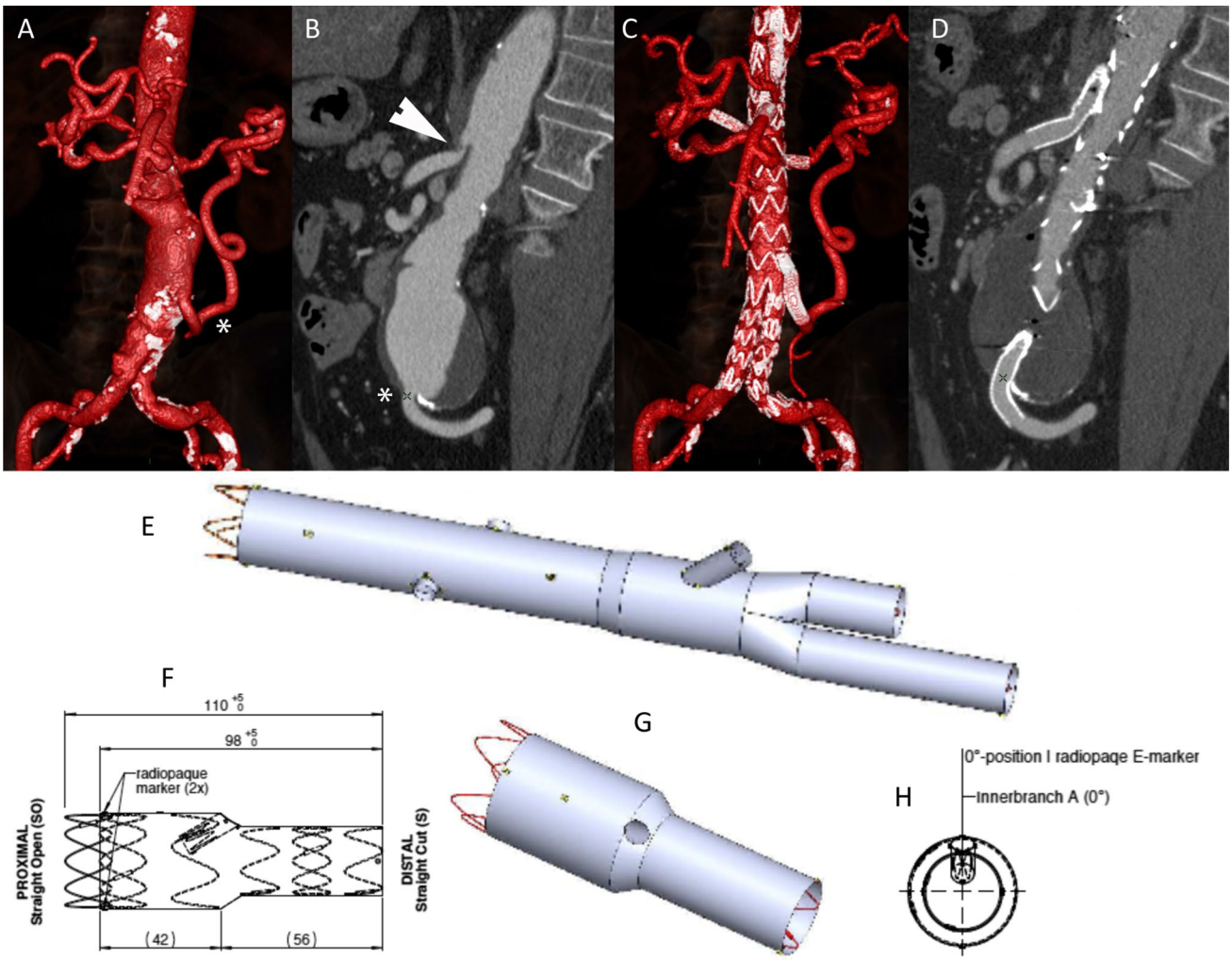

Fig. 1 Clinical case of a 67-year-old male patient with a 52-mm Crawford type 4 aneurysm. **A** Pre-procedural CT angiography (CTA) volume rendering (VR) reconstruction shows that the aneurysm involved the splanchnic vessels and depicts a hypertrophied inferior mesenteric artery (IMA; asterisk). **B** Oblique multi-planar reconstruction (MPR) confirms an occluded coeliac trunk, a pre-occlusive stenosis of the superior mesenteric artery (SMA; arrowhead) and a hypertrophied inferior mesenteric artery (IMA; asterisk) with an ostial stenosis. **C** Four-year CTA follow-up demonstrates patency of the endograft, all branches and fenestrations. **E**, **H** Endograft project was performed by selecting a proximal shorter segment with an inner branch for the SMA (**F**–**H**) and a second distal bifurcated custom device with two fenestrations for the renal arteries and an external branch for the IMA (**E**)

for a restenosis/disconnection, but no occlusion. Secondary patency defines as initially patent but then occluded side branch, which was reopened successfully.

Based on CTA measurements (maximum diameter) aneurysm sac behaviour was classified as follows: reduced (reduction greater than 5 mm), stable and enlarging (increase greater than 5 mm).

Results

Endograft deployment was achieved in all cases. The custom-made endografts comprised: fenestrated (n = 21; 42.8%), multi-branch (n = 24; 49%), and mixed (n = 4; 8.1%). In three patients with dissection endovascular fenestration of the dissecting membrane was performed prior to endograft deployment.

Catheterization of fenestration/branch was successful in 152/156 (97.4%) vessels. Details of the involved vessels and the types of reconstruction are summarized in Table 2.

In four patients a renal artery could not be catheterized. This was solved with chimney technique in one case; in two cases, the renal fenestrations were left unstented, but no late endoleak occurred. In the last case the left renal artery was impossible to catheterize. The corresponding branch was embolized with an Amplatzer vascular plug (St Jude Medical, Zaventem, Belgium). Of these four patients two experienced a significant renal infarction but did not

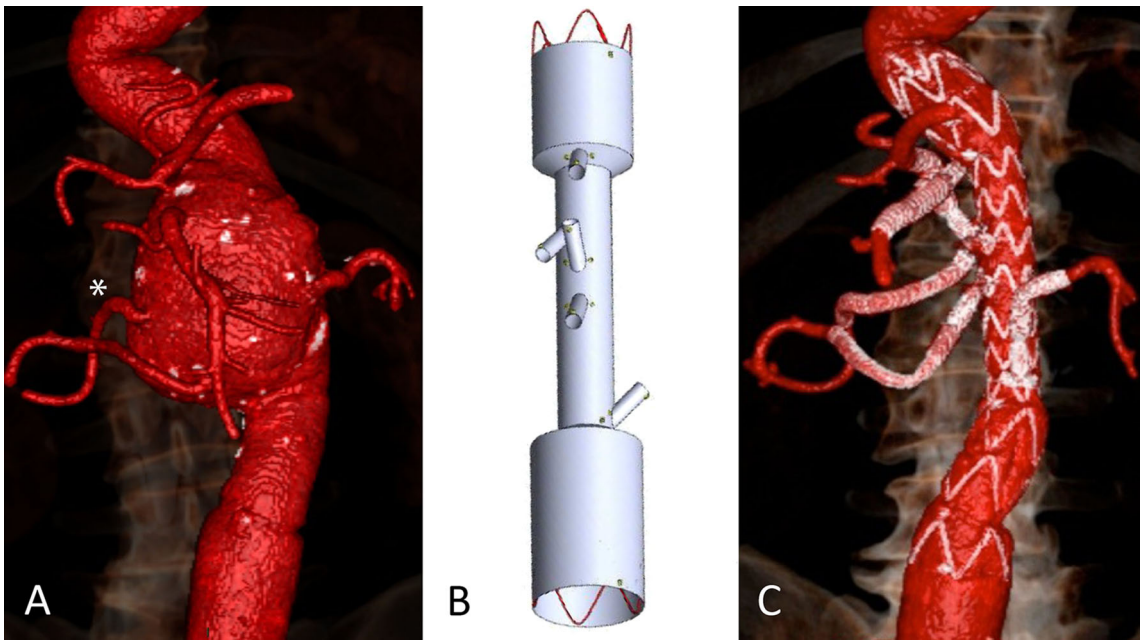

Fig. 2 Clinical case of a 70-year-old male patient with a 78-mm Crawford type 3 aneurysm after previous surgical repair of the descendent aorta and of the abdominal aorta. **A** Pre-procedural CT angiography (CTA) volume rendering (VR) reconstruction shows that the aneurysm involves all the splanchnic vessels origins and depicts a right accessory renal artery (asterisk). **B** Selected endograft project was a single segment with dog bone shape, utilized in order to facilitate external branch opening, with three antegrade external branches (coeliac trunk, SMA and right renal artery) and two retrograde external branches (right accessory renal artery and left renal artery) performed to facilitate catheterization due to the particular steep angles. Ceailing was performed over proximal and distal surgical neck. **C** Five-year CTA follow-up demonstrates the patency of the endograft and all antegrade and retrograde branches

require dialysis, but just a mild increase in creatinine level (1.4 mg/dL).

Procedural mean fluoroscopy time was 79 ± 34 min; mean contrast media volume administered during the procedures was 212 ± 93 ml; mean intervention duration was 330 ± 120 min. Associated surgical interventions were a carotid-subclavian bypass, one femoro-femoral bypass and three common femoral endarterectomies at the access site. Spinal CSF drainage was used in eleven cases.

Intra-procedural embolization of aortic side branches was performed prior to endograft deployment in 14 patients (28.5%). Different embolic materials were employed (plug/coils) according to the vessels dimension and morphology. 5 inferior mesenteric arteries, 4 hypogastric arteries, 3 accessory renal arteries, 1 left gastric artery arising directly from the aorta and 1 common iliac were embolized. In each case the vessel embolized potentially would have been responsible for an endoleak.

Table 2 Summary of typology and site of fenestrations and branches reconstruction

Technical success fenestrations/branches catheterization	97.4% (152/156)
Vessels	
Coeliac trunk	28
Superior mesenteric artery	36
Right renal artery	45*
Left renal artery	47*
Accessory renal artery	3
Inferior mesenteric artery	1
Fenestrations	*N* = 55
Branches	*N* = 97
Branches type: internal versus external	22 versus 75
Branches orientation: antegrade versus retrograde	77 versus 20

*Two right renal and two left renal vessels were not catheterized

Peri-procedural (30-day) complications were observed in ten patients (20.4%). Three patients experienced paraplegia: one permanent (grade 5) and two transient solved by spinal CSF drainage (grade 3). Three cases of haemorrhage, in particular 1 renal and 2 retroperitoneal, were all successfully treated with embolization; one mild pancreatitis (grade 3) was conservatively managed; 1 aortic perforation was treated with an adjunctive distal aortic cuff (grade 3).

One iliac artery rupture was surgically managed (grade 2); 2 cases with cerebrovascular accident occurred (CVA) (grade 5).

Thirty-day mortality was 10.2% ($n = 5$); the cause of death included two patients with multi-organ failure, two CVA and one myocardial infarction. 180-day mortality was 14.3% ($n = 7$); 2 additional deaths were not related to aortic pathology.

Mean follow-up was 23.6 ± 20.9 months (range 1–80). No patients needed surgical explant or experienced kidney function impairment related to contrast media administration. CTA follow-up showed sac shrinkage ($n = 12$) or a stable diameter ($n = 24$) in 36/49 (73.4%); in the remaining cases (9/49; 18.3%), sac enlargement was appreciable. All these nine patients underwent re-intervention.

Re-intervention was performed in sixteen patients (34.67%). Three patients had a branch/stent disconnection ($n = 3$) treated with endovascular relining (Fig. 3). In 3 patients a branch/stent occlusion was managed endovascularly, with no clinical sequelae. One iliac limb occlusion was treated with thrombolysis and stenting. There were ten interventions for endoleak. Endoleak rate was 34.6% ($n = 17$), in particular twelve type II, one type Ia, one type Ib and three type III endoleak; of these seventeen patients, only nine required further treatment. Table 3 summarizes indication and re-intervention type.

Kaplan–Meier curve results for primary, primary-assisted and secondary patency of fenestrations/branches are shown in Fig. 4. In particular at 80 months the reported patency percentage was 90, 96 and 100%, respectively.

Logistic regression results demonstrated that the need for re-intervention on the aneurysm sac was related to dissection, previous aortic surgery and intra-procedural embolization of aortic side branches, whereas the requirement for re-intervention on fenestrations/branches was increased in patients with branches especially external branches. Table 4 summarizes the results of the logistic regression analysis.

Discussion

The results of this study report the clinical outcome of a large series of patients treated for thoraco-abdominal aneurysm and false lumen aneurismal degeneration in type B chronic dissection with a Jotec custom-made endograft.

This series confirms how accurate pre-procedural planning could lead to technical success in all cases, thus increasing the number of patients that could benefit from such endovascular treatment as an alternative to open surgery. Catheterization of a renal fenestration or branch was unsuccessful in only four cases (2.6%). Despite failed catheterization, none of these patients required further re-intervention or dialysis. The reported high success rate for catheterization of fenestrations/branches is in line with that reported with other multi-branch [13–15] and fenestrated [16–18] devices. Our peri-procedural complication rate and 30-day mortality are broadly comparable with the available literature [14, 19], but it should be noted that most of our patients (42.8%) had previously undergone an aortic surgical/endovascular intervention. Additionally, nearly 40% of the patients were treated for a Crawford type I–III thoraco-abdominal aneurysm, which is associated with higher morbidity and mortality [20–22].

Long-term follow-up demonstrates that customized f-EVAR and b-EVAR procedures were able to avoid progression of aortic disease in nearly 75% of patients, as confirmed by sequential CTA diameter measurements that depicted a stable or shrinking aneurysm sac. Moreover, no patient throughout the entire follow-up required surgical explantation. This was possible thanks to strict surveillance applied to all patients treated with f-EVAR or b-EVAR in our centre. All patients shown to have sac reperfusion (endoleak) were shifted towards shorter imaging follow-up (6 months) in the case of stable aneurysmal sac diameter or towards re-intervention in cases of an enlarging aneurysm sac. Moreover, imaging surveillance follow-up was of paramount importance to identify the cause of sac reperfusion, aiding in the selection of the best treatment option to correct it. Classical type II endoleaks are easily identified and treated; however, the instability of fenestration/branch is more difficult to diagnose. The latter condition should be suspected in all sac reperfusions occurring around a fenestration/branch not in connection with an aortic side branches, even in the absence of frank stent disconnection. Relining of the fenestrations/branches resolved the problem in all cases. By employing this policy we were able to report an 80-month fenestration/branch secondary patency of 100%, results that are slightly superior compared to those reported in the literature for both f-EVAR [14, 23–27] and b-EVAR [14, 24] series.

Multivariate analysis identified that predictors for re-intervention on the aneurysmal sac were patients with dissection, previous aortic surgery and the need for intra-procedural embolization of an aortic side branch. Studying these results, it is not surprising that dissection and previous aortic surgery are statistically associated with re-intervention. In fact, these two clinical variables identify patients who are more fragile, since they are affected by a

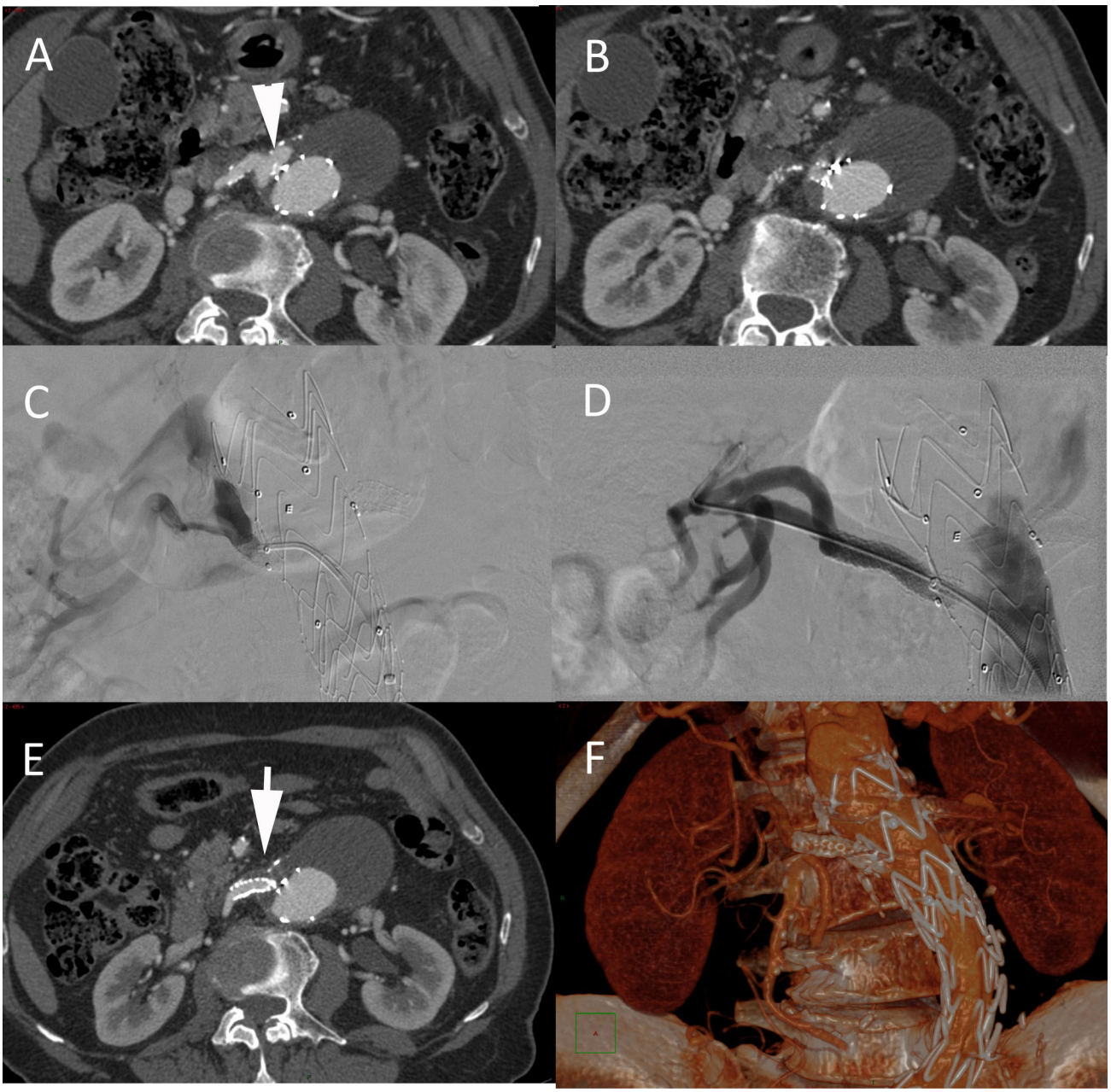

Fig. 3 Clinical case of a 69-year-old male patient with a 70-mm Crawford type 4 aneurysm, with the disconnection of the renal fenestration from the right renal artery. **A**, **B** Pre-procedural axial CT angiography (CTA) shows disconnection of the right renal stent from the renal artery with concomitant type III endoleak (arrowhead). **C** Selective digital subtraction angiography (DSA) confirms stent disconnection and type III endoleak. **D** Relining of the fenestration was then performed via the groin with a longer balloon-expandable covered stent in order to restore connection between the fenestration and the right renal artery. **E**, **F** Two-year axial CTA (E) and volume rendering (VR) reconstruction (F) follow-up demonstrate patency of the right renal fenestration with endoleak resolution (arrow)

rapidly evolving disease. Regarding the intra-procedural embolization of aortic side branches, no straightforward explanation is possible. In fact, none of the re-interventions was due to reperfusion of previously embolized vessels. Likely, the statistical association is due to the fact that the aneurysmal degeneration was more advanced including more aortic side branches. Finally, multivariate results demonstrated as predictors for re-intervention in fenestrations/branches: branch usage versus fenestration, external branch versus internal branch. Again, keeping in mind the policy of device customization that we used, branch usage and external branch were reserved for more advanced disease (e.g. Crawford type I–III aneurysm and dissection), those in which both fenestration and inner branch were not feasible. Moreover, multivariate analysis suggests that re-intervention on visceral vessels was not

Table 3 Summary of indication and re-interventions typology

Indication for re-intervention	Type of re-intervention	*N* =
Branch/stent disconnection	Relining	3
Branch/stent occlusion	Fibrinolysis	3
Iliac limb occlusion	Thrombolysis and stenting	1
Endoleak type Ia	TEVAR	1
Endoleak type IA	TEVAR	1
Endoleak type IB	Sac embolization and iliac extension	1
Endoleak type II	Collateral embolization	3
Endoleak type III	Relining	4
Endoleak type III	Relining	3

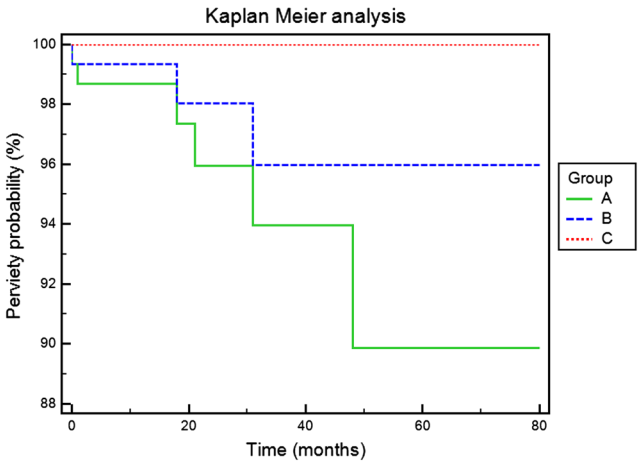

Fig. 4 Primary patency (green line), primary-assisted patency (blue dotted line) and secondary patency (red dotted line) Kaplan–Meier curves

related to the length of stented segment, the presence of a bridge, stent diameter, stent number and finally its orientation. This final consideration is of particular interest, especially because in all cases re-intervention was performed over a retrogradely orientated branch and no occlusions occurred. Our results substantially differ from the controversial literature evidence on snorkel parallel graft and on branched devices that, respectively, advocate how steep angulation [28, 29] and certain anatomy could be unfit for endovascular repair [30].

Study limitations include the retrospective nature of the study and the highly selected patients for this alternative

Table 4 Multiple logistic regression analysis for re-interventions on aneurismatic sac and fenestrations/branches

Variables	Coefficient	SE	$r_{partial}$	*t*	*p* value
Multiple logistic regression analysis for re-intervention on aneurismatic SAC					
Dissection	0.3969	0.1864	0.3289	2.284	0.039*
Previous aortic surgery	− 0.3744	0.1455	− 0.3652	− 2.573	0.0136*
Intra-procedural embolization of aortic collaterals	0.2895	0.1268	0.3289	2.284	0.0274*
Multiple logistic regression analysis for re-intervention on fenestrations/branches					
Branch	0.2859	0.123	0.1902	2.324	0.0215*
Bridge	− 0.09234	0.07017	− 0.109	− 1.316	0.1903
Diameter	− 0.005081	0.01309	− 0.03234	− 0.388	0.6984
Internal_external	− 0.1293	0.04792	− 0.2193	− 2.698	0.0078*
Length	− 0.0005692	0.0007643	− 0.06194	− 0.745	0.4577
Stent_number	0.08215	0.0601	0.1132	1.367	0.1738
Orientation	− 0.007093	0.05285	− 0.01118	− 0.134	0.8934

endovascular treatment. In fact, all enrolled patients suffered from multiple comorbidities and underwent multiple previous aortic interventions, thus limiting the strength of the identification of prognostic factors for re-intervention on the aneurysmal sac.

In conclusion, our study reports the first long-term result of the Jotec customization platform that is comparable to previously reported similar devices, with an acceptable complication and re-intervention rate. According to the customization policy we employed, fenestrations and inner branches should be preferred whenever possible because they were associated with a lower re-intervention rate. Retrograde branches should be considered as a safe alternative in all cases not fit for antegrade branches.

Compliance with Ethical Standards

Conflict of interest All authors declare that they have no conflict of interests.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Informed Consent Informed consent for the procedure for anonymized publication of this series of patients was obtained from all individual participants included in the study.

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