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A Multicenter Experience With a New Fenestrated-Branched Device for Endovascular Repair of Thoracoabdominal Aortic Aneurysms

Marwan Youssef, MD[1], Sebastien Deglise, MD[2], Piotr Szopinski, PhD[3], Schäfer Jost-Philipp, PhD[4], Amer Jomha, MD[5], Christian F. Vahl, MD, PhD[1], and Ahmed Koshty, MD[6]

Abstract

Purpose: To investigate the outcomes of patients who were treated for thoracoabdominal aortic aneurysms (TAAAs) using custom-made fenestrated-branched stent-grafts. **Methods:** A consecutive series of 108 patients (mean age 73.5 years; 73 men) with TAAA were treated with E-xtra Design Engineering customized fenestrated-branched stent-grafts between November 2011 and January 2017. Data on baseline characteristics, procedures, and clinical follow-up were collected from 6 regional European surgical centers for retrospective analysis of endoleaks, reinterventions, and target vessel patency. The median aneurysm diameter was 6.75 cm (range 5.5–13). The distribution of the TAAA according to the modified Crawford classification of extent was 25 (24%) type I, 19 (17%) type II, 20 (18%) type III, 29 (27%) type IV, and 15 (14%) type V. **Results:** Technical success was achieved in 95% (103/108) of cases. Major early perioperative complications occurred in 40 (37%) patients. The 30-day mortality was 9.2% (10/108), and perioperative spinal cord ischemia was observed in 6 (5.5%) patients [2 (1.8%) permanent]. During the mean follow-up of 17.6 months (range 3–52), 28 (26%) patients required late reintervention. Two patients died due to aneurysm- or procedure-related causes. The estimated survival rates at 1, 2, and 4 years were 87%, 84%, and 51%, respectively. The estimated target vessel patency rates at the same time points were 95%, 91%, and 90%, respectively. The freedom from reintervention estimates were 84% and 73% at 1 and 4 years, respectively. **Conclusion:** Endovascular repair of TAAA using Jotec customized fenestrated-branched stent-grafts appears to be safe and effective in the early to midterm. The considerable rate of secondary interventions indicates that further improvements, graft surveillance, and follow-up are required.

Keywords

branched stent-graft, complications, endoleak, endovascular repair, fenestrated stent-graft, morbidity, mortality, reinterventions, spinal cord ischemia, thoracoabdominal aortic aneurysm

Introduction

Thoracoabdominal aortic aneurysm (TAAA) repair is the most challenging procedure for vascular physicians to perform. The excellent outcomes of open repair that were reported by Coselli et al[1,2] may not reflect the worldwide reality and the widespread experiences of open TAAA surgery.[3] Even in centers with large experience, an early perioperative mortality of 15.9% has been reported.[4] The invasive nature and considerable mortality and morbidity of open surgical repair has led to a shift toward endovascular aortic repair using fenestrated and branched endografts. Since Chuter et al[5] implanted the first customized branched endograft in 2001, the technology has been increasingly

[1]Department of Cardiothoracic and Vascular Surgery, Medical Center of the Johannes Gutenberg-University Mainz, Germany
[2]Department of Vascular Surgery, University Hospital of Lausanne, Switzerland
[3]Department of Vascular Surgery, Institution of Hematology and Transfusion Medicine, Warsaw, Poland
[4]Department of Radiology, University of Kiel, Germany
[5]Department of Vascular Surgery, Hospital of Bad-Hersfeld, Germany
[6]Department of Vascular Surgery, Hospital of Diakonie-Jung-Stilling, Siegen, Germany

Corresponding Author:
Marwan Youssef, Department of Cardiothoracic and Vascular Surgery, Medical Center of Johannes Gutenberg-University Mainz, Langenbeckstraße 1, 55131 Mainz, Germany.
Email: marwanjousef@yahoo.com

evolving to treat patients with varied anatomies and complex pathologies. Furthermore, total endovascular repair of TAAAs is well established at high-volume aortic centers, and it is the first-line therapy for elderly and high-risk patients.[6,7] Furthermore, this technique has been demonstrated to have favorable results that are based on robust outcome data. However, currently only 2 branched systems are readily available in Europe.

The aim of the present study was to evaluate the feasibility, efficacy, and outcomes of a novel E-extra Design Engineering stent-graft (Jotec GmbH, Hechingen, Germany) to treat patients with TAAAs.

Methods

Study Design and Patient Population

A retrospective review was conducted of 108 consecutive patients (mean age 73.5 years; 73 men) with TAAA treated using E-xtra Design Engineering fenestrated-branched stent-grafts at 6 European tertiary care centers between November 2011 and January 2017. Only pathologies with thoracoabdominal extent were investigated; patients with postdissection TAAA were also included. Patients with supra- and juxtarenal aortic aneurysms were not eligible for this analysis.

Each center had experience with fenestrated and branched endovascular repairs and had performed at least 20 procedures using the study device to treat TAAA and pararenal aortic aneurysms. Ethics board approval to participate in this study was obtained at all institutions. Patients provided written informed consent prior to undergoing aneurysm repair at each institution, though individual patient consent was waived for this retrospective analysis of anonymized data.

All patients were considered unfit to undergo open surgical aortic repair due to advanced age or severe comorbidities [American Society of Anesthesiologists (ASA) III/IV]. The median TAAA diameter was 6.75 cm (range 5.5–13). The distribution of the TAAA according to the modified Crawford classification of extent was 25 (24%) type I, 19 (17%) type II, 20 (18%) type III, 29 (27%) type IV, and 15 (14%) type V. The patient demographics and aneurysm characteristics are shown in Table 1.

Table 1. Clinical and Aneurysm Characteristics of the 108 Patients in the Study.[a]

Age, y	73.5±7.3 (51–87)
Men	73 (68)
Smoking	69 (64)
Hypertension	94 (87)
Hypercholesterolemia	90 (83)
Diabetes	15 (14)
Coronary artery disease	52 (48)
Congestive heart failure	13 (12)
Chronic obstructive pulmonary disease	41 (38)
Peripheral artery disease	36 (33)
Stroke / TIA	13 (12)
Baseline creatinine >1.2 mg/dL	12 (11)
ASA	
II	17 (16)
III	73 (67)
IV	18 (17)
History of malignancy	12 (11)
Connective tissue disorder	4 (4)
Previous aortic surgery	41 (38)
Previous endovascular aortic repair	14 (13)
TAAA diameter, cm	6.75 (5.5–13)
Postdissection aneurysms	14 (13)
Modified Crawford classification extent	
I	25 (24)
II	19 (17)
III	20 (18)
IV	29 (27)
V	15 (14)

Abbreviations: ASA, American Society of Anesthesiologists; TAAA, thoracoabdominal aortic aneurysm; TIA, transient ischemic attack.
[a]Continuous data are presented as the means ± standard deviation (range) or median (range); categorical data are given as the counts (percentage).

Device Design

The fenestrated and/or branched stent-grafts were custom made based on preoperative imaging. Electrocardiogram-gated, high-resolution, contrast-enhanced computed tomography angiography (CTA) scans were acquired with 1-mm sections of the entire aorta from the neck to groin to delineate aneurysm morphology and evaluate the supra-aortic and iliofemoral anatomy for access to the renovisceral target vessels.

The customized 24-F stent-graft is based on the Jotec delivery system. The most commonly used configuration has 3 proximal internal sealing stents, which are provided with 2 anterior radiopaque E-markers for anterior-posterior rotation. The grafts are tapered below these internal sealing stents to include fenestrations or branches. The ostia of the fenestrations and branches are indicated by 4 horizontal and vertical radiopaque markers. The branches are 15 to 18 mm long, and the outer ostium has an upper gold marker.

Depending on the diameter of the thrombus-free aortic lumen, the aortic stent-grafts were customized with fenestrations, branches, or combinations of both to accommodate the target renovisceral vessels, as follows:

1. Fenestrations were used for smaller diameter aortas (≥18 mm and ≤30 mm) provided the stent-grafts had direct circumferential contact with the aortic wall (Figure 1A).

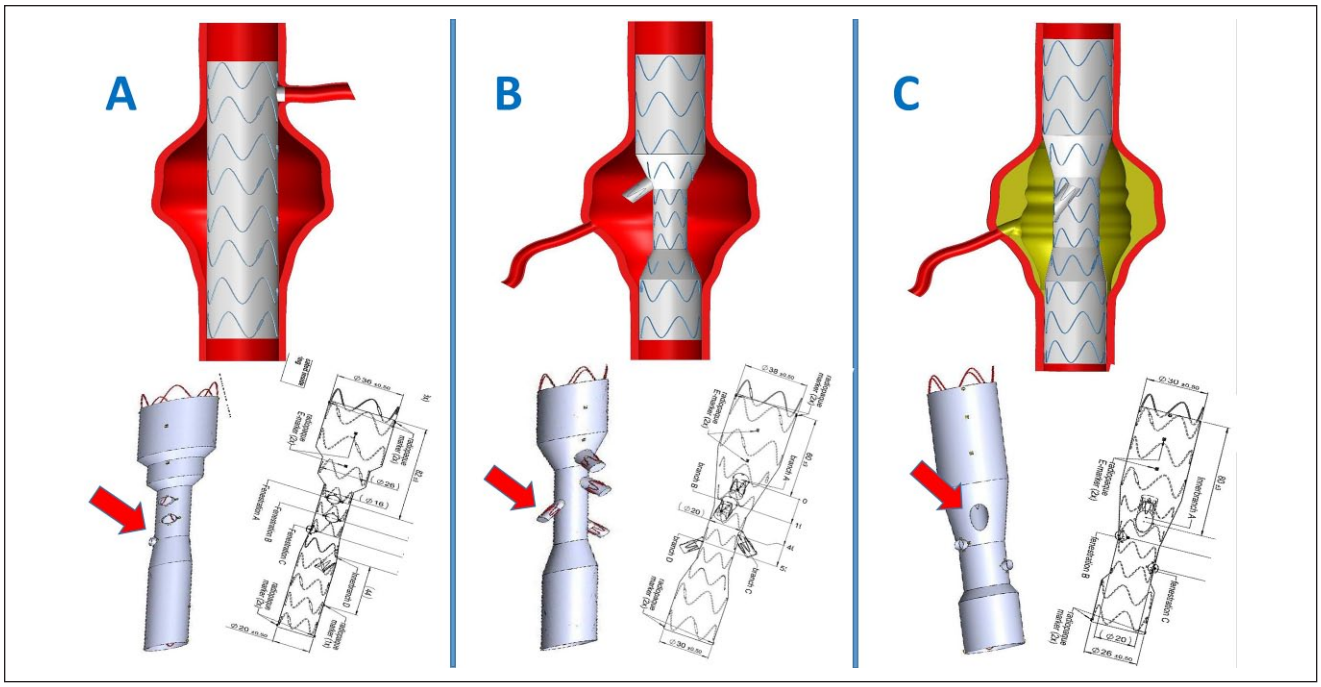


Figure 1. If the aortic diameter is ≥18 mm and ≤30 mm and the stent-grafts can create circumferential contact with the aortic wall, fenestrations are used. These are examples of fenestrated-branched stent-grafts in isometric views and manufacturing drafts. (A) The first is a customized stent-graft with 3 fenestrations (arrow) and 1 inner branch. (B) Example of a stent-graft with 4 outer branches (arrow) for aortic diameters >30 mm and enough space to accommodate the branches. (C) If the thrombus-free lumen is 24 to 28 mm in diameter and the stent-graft does not have circumferential contact with the aortic wall, a stent-graft with 2 fenestrations can be used and 1 inner branch (arrow) for the celiac and mesenteric arteries.

2. Outer branches were manufactured for larger aortas (>30 mm) with enough space to accommodate the branches (thrombus-free lumen >28 mm); this option was preferred whenever possible (Figure 1B).
3. The use of inner branches was considered if the diameter of the thrombus-free lumen was 24 to 28 mm, the stent-grafts did not have circumferential contact with the aortic wall, and/or there was not enough space for an outer branch (Figure 1C).

The direction of the branches depended on the orientation of the target vessels. Antegradely oriented branches were used mostly; however, retrogradely oriented branches were applied for upward-going target vessels (commonly the renal arteries) or if the approach from above was inaccessible, for example, after total debranching of the aortic arch (Figure 2).

Treatment Protocol

Each center used a similar treatment strategy to accomplish the repair of extensive TAAAs in a staged manner. In the first stage, a thoracic stent-graft was implanted into the proximal aneurysmal segment of the descending thoracic aorta. If needed, 2 endografts were deployed and the distal graft was tapered to be compatible with multibranched or fenestrated endografts that were planned for use in the later stage. After the first step, the patients underwent CTA control and were discharged. They were readmitted 6 to 8 weeks later for implantation of customized endografts into the renovisceral and abdominal aortic segments.

Implantation Technique

The endovascular procedures were performed electively under general anesthesia in operating rooms that were equipped with high-resolution imaging. Preoperative cerebrospinal fluid (CSF) drainage was routinely used to reduce the risk of spinal cord ischemia (SCI). An automated CSF pressure and drain monitoring system (LiquoGuard; Möller Medical GmbH & Co KG, Fulda, Germany) was applied with continuous and controlled drainage of no more than 10 mL/h. CSF pressure was maintained at 10 mm Hg for the first 3 to 4 days postoperatively. This CSF drainage protocol was considered initially for most of the patients, with some exceptions for those with type IV aneurysms.

Surgical access was obtained via cutdown at the groins bilaterally and exposure of the left axillary artery. An

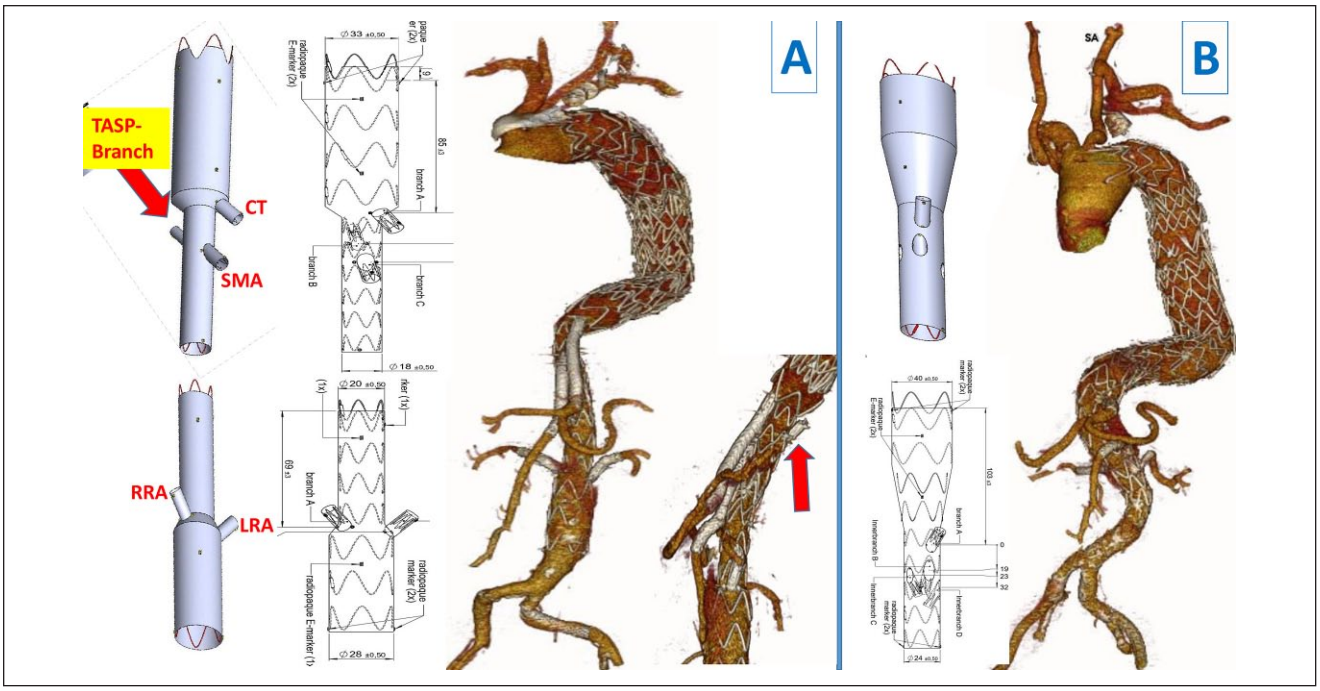


Figure 2. (A) Endovascular repair of a type II thoracoabdominal aneurysm after staged cervical debranching using 2 customized stent-grafts. The proximal graft has 2 downward-directed branches for the celiac trunk (CT) and superior mesenteric artery (SMA) and 1 dedicated perfusion branch for temporary aneurysm sac perfusion (TASP, arrow); the distal graft has 2 upward-directed branches for the right (RRA) and left (LRA) renal arteries. (B) Endovascular repair of a type II thoracoabdominal aneurysm after cervical debranching using a customized stent-graft with 3 upward-directed inner branches and 1 upward-directed outer branch.

angiographic pigtail catheter was inserted transfemorally and positioned at the supraceliac level. A continuous intravenous infusion of unfractionated heparin was begun and monitored using the activated partial thromboplastin time. The multibranched graft was subsequently inserted through the contralateral femoral artery. After angiography was performed, the E-shaped radiopaque markers were used for lateral and anterior-posterior orientation. The multibranched graft was released so that the distal renal branch was positioned about 15 mm above the lowest renal artery. The delivery system of the multibranched graft was retracted and replaced with short, large sheaths to restore perfusion of the hypogastric arteries and lower limbs. For kinked aortas, usually at the thoracoabdominal supraceliac or distal arch segments, the guidewire was snared initially from above and replaced with a stiff wire, and a through-and-through maneuver was needed to better control deployment of the branched grafts.

Seven- or 8-F sheaths with a length of 70 or 80 mm were introduced through the axillary artery access. After cannulation of the branches and target vessels, covered stents with 1-mm-diameter oversizing were implanted over stiff guidewires and placed at least 20 mm into the target vessel. The bridging branch devices were primarily balloon-expandable stent-grafts [E-ventus BX (Jotec) or Atrium Advanta V12 (Maquet Getinge Group, Mijdrecht, the Netherlands)]; however, self-expanding stent-grafts were also implanted [Viabahn (W.L. Gore & Associates, Flagstaff, AZ, USA) or Fluency (Bard Peripheral Vascular, Tempe, AZ, USA)]. Relining with self-expanding bare metal stents was not routinely performed and was used only in case of distal kinking. For fenestrations, only balloon-expandable stent-grafts were used and flared into the fenestration using larger angioplasty balloons.

A minimum 25-mm distal landing zone was required for adequate sealing, which was mostly achieved with tube configuration of the multibranched grafts in the infrarenal aorta. Otherwise, a bifurcated configuration or extension with bifurcated grafts was considered when implanting stent-grafts in the iliac arteries.

As soon as the CSF drain was removed, dual antiplatelet therapy (acetylsalicylic acid and clopidogrel) was initiated for 3 to 6 months postoperatively. This regimen was discontinued in favor of monotherapy with either acetylsalicylic acid or clopidogrel thereafter.

Follow-up Protocol

A similar follow-up protocol was applied at all 6 participating centers. The postoperative imaging protocol consisted of triple-phase CTA. After discharge, the patients participated in a follow-up program that consisted of laboratory,

clinical, and imaging (CTA) examinations at 3 and 6 months, with yearly repetition thereafter. Based on the postoperative and follow-up imaging data, 2 independent physicians who were experienced in CTA reconstructions performed a postprocessing analysis using the Aquarius workstation (TeraRecon, Frankfurt, Germany).

Definitions and Statistical Analyses

Technical success was defined as complete exclusion of the aneurysm, no type I or III endoleak, and patent target vessels on the final angiogram. Branch instability was defined according to Mastracci et al[8] as any occlusion, stenosis, endoleak, or death from a branch problem or resulting in branch reintervention. Renal function deterioration was defined as >30% drop in the estimated glomerular filtration rate.

Continuous data are presented as the means ± standard deviation or medians (range) if not normally distributed; categorical data are given as the counts (percentage). Survival, target vessel stent patency, freedom from reintervention, freedom from renal function deterioration, and freedom from branch instability[8] were estimated using Kaplan-Meier analysis. The threshold of statistical significance was $p<0.05$. The statistical analysis was performed with SPSS software (version 23.0; IBM Corporation, Armonk, NY, USA).

Results

Immediate Outcomes

Technical success was achieved in 103 (95%) patients using 131 customized branched or fenestrated devices. Twenty-three patients had 2 branched components (Figure 2). Sixty-six bifurcated aortoiliac endografts (2 monoiliac) and 9 tube endografts were used as distal extensions (Table 2).

An open access via surgical exposure of the left axillary artery was used in 95 (88%) patients, and exposure of the left and right subclavian arteries was performed in 1 and 2 patients, respectively. Left percutaneous transbrachial access was used in 10 patients. A retroperitoneal surgical approach was need in 2 patients to introduce the customized device. A through-and-through maneuver was employed to advance the branched grafts in 11 (10%) patients with tortuous anatomies. Preoperative CSF drainage was applied in 95 (88%) patients. One center used temporary aneurysm sac perfusion in 12 (11%) patients with extensive aneurysms (mostly type II), primarily using dedicated perfusion branches in 10.

In total, 386 renovisceral vessels [85 celiac trunks, 106 superior mesenteric arteries (SMA), and 195 renal arteries] were targeted using 96 fenestrations and 290 branches (per patient mean 3.6). Of the 290 branches, 244 were outer branches and 46 were inner branches. A total of 229 branches had a downward direction and 61 had an upward direction.

Table 2. Operative and Technical Details.[a]

General anesthesia	108 (100)
Procedure time, min	280±140
Fluoroscopy time, min	90±48.7
Dose area product, Gy·cm^2	210,132±117
Contrast media, mL	220±187
Estimated blood loss, mL	950±450
Iliac conduits	8 (7)
Percutaneous femoral access	10 (9)
Through-and-through maneuver	11 (10)
Staged procedure	82 (76)
CSF drainage	95 (88)
Hospital stay, d	11 (5–61)
ICU stay, d	3 (1–19)
Target vessels (n=386) and stent-graft design	
Mean per patient	3.6
Fenestrations	96
Branches	290
Outer	244
Inner	46
Downward directed	229
Upward directed	61
Temporary sac perfusion	12 (11)
Dedicated perfusion branches	10 (9)
Unstented perfusion branches	2 (1.8)
Mean interval to perfusion branch occlusion, wk	8.2±2 (6–10)

Abbreviations: CSF, cerebrospinal fluid drainage; ICU, intensive care unit.
[a]Continuous data are presented as the means ± standard deviation or median (range); categorical data are given as the counts (percentage).

The causes of technical failure were types Ia and Ib endoleaks in 3 patients. The endoleaks were first detected on the postoperative CTA imaging and required early reintervention (within 10 days) with proximal and distal extensions. Catheterization of the renal arteries failed in 2 patients: the kidneys were preserved with the use of laparotomy with an iliorenal vein bypass in one and a reversed renal chimney graft in the other patient. The unstented renal branch was occluded using a vascular plug. The implanted chimney graft caused a gutter endoleak, which was embolized with coils 6 days later. Similarly, in another 2 patients, catheterization of the 2 renal arteries failed; they were revascularized with parallel grafts, and there were no endoleaks.

Perioperative Morbidity and Mortality

Major complications occurred in the perioperative period in 40 (37%) patients. The 30-day postoperative mortality was 9.3% (10/108). Details of the perioperative complications,

early revisions, reinterventions, and additional unplanned intraoperative procedures are listed in Table 3.

Access site complications were the most recorded causes of postoperative surgical revisions in 12 (11%) patients. Three (2.7%) patients required laparotomy; 1 patient was mentioned above and the other 2 needed a laparotomy due to bleeding (mesenteric injury and liver hematoma).

The neurological complications included stroke in 2 (1.8%) patients and SCI in 6 (5.5%). Complete paraplegia was encountered in 2 (1.8%) patients. One of these patients suffered from severe bilateral paraplegia and finally died after a prolonged hospital stay, whereas the other patient died 8 months postoperatively. Three patients had transient leg weakness, which was treated with CSF drainage for 5 days, maintenance of the mean arterial pressure at >85 mm Hg, and consequent elevation of the hemoglobin values to >12 g/dL. The symptoms completely receded, and these patients were discharged for further rehabilitation.

Follow-up Outcomes

During the mean follow-up of 17.6 months (range 3–52), 10 patients died. Two deaths were due to aneurysm- or procedure-related reasons. One patient with a type Ib endoleak refused to undergo reintervention and died due to aneurysm rupture 19 months after the procedure. The second patient presented with mesenteric infarction due to SMA branch occlusion and died after an extensive intestinal resection procedure. The estimated survival rates at 1, 2, and 4 years were 87%, 84%, and 51%, respectively (Figure 3A).

The overall reintervention rate was 25.9% (28 patients); of these, 16 required a branch-related reintervention and 12 had a reintervention due to endoleaks (Table 3). The freedom from reintervention estimates at 1 and 4 years were 84% and 73%, respectively (Figure 3B). During the follow-up period, 18 endoleaks were detected (9 type I and 9 type III) in 2 aortic and 7 target vessel grafts. Sixteen (15%) patients initially had a type II endoleak; 10 resolved over time, 5 remained unchanged, and 1 associated with sac expansion was successfully embolized with coils at 24 months postoperatively.

In total, 62% of the patients had aneurysm sac shrinkage, whereas no diameter changes were recorded in 31%; 7% had sac progression.

Branch-Related Outcomes

Of the 386 target vessels, 23 occlusions occurred during follow-up (2 SMA, 5 celiac, and 16 renal). The cumulative target vessel patency estimate was 94% at 4 years. The primary target vessel patency estimates at 1, 2, and 4 years were 95%, 91%, and 90%, respectively (Figure 3C). The 4-year patency estimates for each vessel were 94%, 98%, 93.6%, and 90% (p=0.11) for the celiac trunk, SMA, and left and right renal arteries, respectively. The cumulative secondary patency was 96%.

The overall freedom from branch instability was 92.2% (celiac 92.9%, SMA 98.1%, and renal 88.7%, p=0.18; Figure 3D). Of the 7 occluded visceral branches, only 1 occlusion (SMA) resulted in fatal intestinal infarction. On the other hand, 3 patients required permanent dialysis. In total, the freedom from renal function deterioration was 87% during the follow-up period (Figure 3E).

Discussion

In Europe, there has been a recent significant decline in the numbers of open TAAA repairs and high-volume aortic centers performing open surgeries. With the exception of young Marfan patients, open TAAA surgery is no longer as widely accepted by vascular physicians or patients due to its invasiveness and the associated high mortality and morbidity. Based on this, total endovascular TAAA repair has increasingly been adopted to replace open surgery. Published studies have shown that this procedure has promising long-term outcomes, with high technical success and low mortality and morbidity.[8–11] Better outcomes are associated with passage of the learning curve and large volumes of surgeries that are performed in vascular centers. Based on close cooperation between vascular specialists and industrial engineering teams, improvement in the manufacture of devices has moved the technology forward. Development of dedicated endovascular teams and institutional standardization of perioperative protocols has resulted in reduced perioperative mortality and SCI.[12–14]

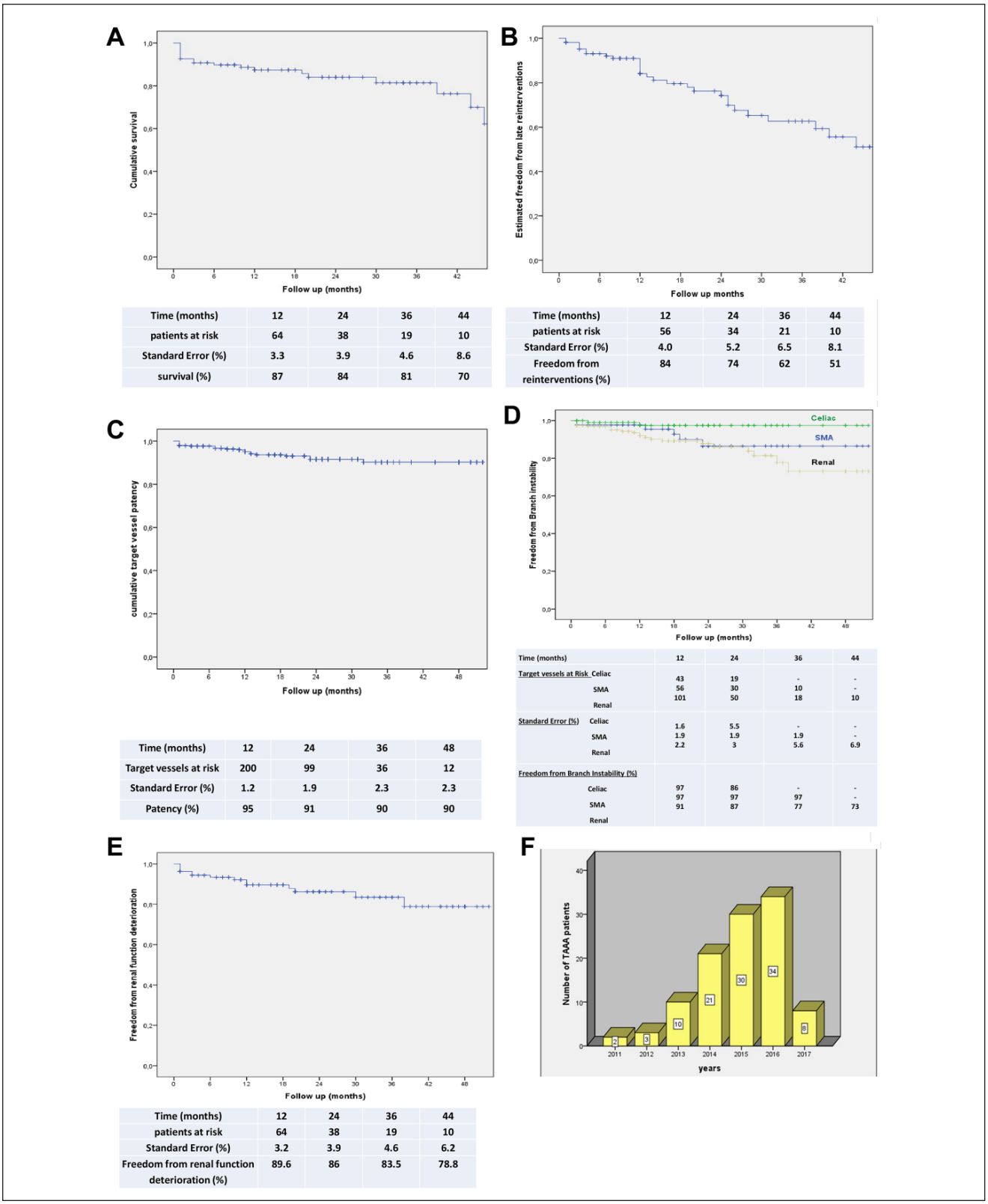
Currently, only 2 branched devices are commercially available in Europe for the endovascular treatment of TAAAs. The Cook Zenith (Cook Australia, Ltd, Brisbane, Australia) has been employed in most of the published literature on total endovascular TAAA repair. The Cook stent-grafts are often customized; however, to overcome delays in manufacturing of these grafts, Cook developed a new off-the-shelf multibranched device (t-branch; Cook Medical, Bloomington, IN, USA), which has proven suitable for use in at least 50% of patients with TAAA[15–17] and is now available in Europe. The present study investigated the safety and efficacy of Jotec's novel E-xtra Design Engineering customized stent-grafts, achieving a high technical success comparable with the reported rates in other large studies on total endovascular TAAA repair.[11,13,14]

Varied data have been reported in the literature regarding perioperative mortality due to endovascular TAAA repairs. Mortality is clearly related to patient selection and the volume and experience of each center. A recent meta-analysis stated that the 30-day mortality ranged from 3% to 19%,[18] and another literature review showed rates from 0 to 21%.[19] Not surprisingly, centers with large experience report lower mortality. Oderich et al[13] recently reported a low mortality

Table 3. Perioperative Complications, Unplanned Procedures, Reinterventions, and Late Mortality.[a]

Perioperative complications	
Respiratory failure	8 (7.4)
Myocardial infarction	4 (3.7)
Bleeding/hematoma complications required revision	
Access site	12 (11)
Mesenteric	1 (0.9)
Hepatic	1 (0.9)
Kidney hematoma (without revision)	1 (0.9)
Transient renal impairment >30% baseline	9 (9)
Temporary / permanent dialysis	6 / 3
Overall spinal cord ischemia	6 (5.5)
Temporary paraparesis / paresthesia	4 (3.7)
Permanent paraplegia	2 (1.8)
Intestinal/colon ischemia	1 (0.9)
Extremity ischemia (lower or upper)	2 (1.8)
Stroke	2 (1.8)
Retrograde type B dissection	1 (0.9)
Multiple organ failure	6 (5.5)
In-hospital and early mortality	10 (9.2)
Type II endoleak	16 (15)
Unplanned additional intraoperative procedures	
Stenting of the iliac arteries	11 (10)
Femoral artery reconstruction	6 (5.5)
Laparotomy	3 (2.7)
Renal chimney grafts	3 (2.7)
LSA chimney graft	1 (0.9)
Early revisions and reinterventions (<30 days)	
Access site complications (groin, brachial, and axillary)	12 (11)
Fasciotomy	1 (0.9)
Arm/leg thrombectomy	2 (1.8)
Proximal/distal aortic graft extension (type Ia/Ib endoleak)	3 (2.7)
Coil embolization (type Ib endoleak)	1 (0.9)
Late reinterventions (>30 days)	
Planned	
Completion of unstented perfusion branch	2 (1.8)
Occlusion of dedicated perfusion branch	10 (9)
Endoleak-related	
Type II: coil embolization	1 (0.9)
Type Ia/Ib: proximal/distal aortic tube graft extensions / IBD	9 (8.3)
Type III: bridging aortic grafts (disconnections/dislocations)	2 (1.8)
Branch-related	
Target vessel thrombolysis	4 (3.7)
Iliorenal bypass	2 (1.8)
Angioplasty and restenting (kinking, stenosis, or occlusions)	3 (2.7)
Relining, extensions, bridging grafts (endoleaks)	7 (6.4)
Causes of late mortality	
Aneurysm-/procedure-related (rupture/bowel ischemia)	2
Cardiac	2
Stroke	1
Cancer	2
Unknown	3

Abbreviations: IBD, iliac branch device; LSA, left subclavian artery.
[a]Data are presented as the counts (percentage).



Time (months)	12	24	36	44
patients at risk	64	38	19	10
Standard Error (%)	3.3	3.9	4.6	8.6
survival (%)	87	84	81	70

Time (months)	12	24	36	44
patients at risk	56	34	21	10
Standard Error (%)	4.0	5.2	6.5	8.1
Freedom from reinterventions (%)	84	74	62	51

Time (months)	12	24	36	48
Target vessels at risk	200	99	36	12
Standard Error (%)	1.2	1.9	2.3	2.3
Patency (%)	95	91	90	90

Time (months)		12	24	36	44
Target vessels at Risk	Celiac	43	19	-	-
	SMA	56	30	10	-
	Renal	101	50	18	10
Standard Error (%)	Celiac	1.6	5.5	-	-
	SMA	1.9	1.9	1.9	-
	Renal	2.2	3	5.6	6.9
Freedom from Branch Instability (%)					
	Celiac	97	86	-	-
	SMA	97	97	97	-
	Renal	91	87	77	73

Time (months)	12	24	36	44
patients at risk	64	38	19	10
Standard Error (%)	3.2	3.9	4.6	6.2
Freedom from renal function deterioration (%)	89.6	86	83.5	78.8

Figure 3. Kaplan-Meier estimates of (A) overall patient survival, (B) freedom from late reintervention, (C) primary target vessel patency, (D) freedom from branch instability for the target vessels, and (E) freedom from renal function deterioration. (F) Distribution of endovascular thoracoabdominal repairs over time among the 108 study patients. SMA, superior mesenteric artery.

of 4.3% among 184 patients treated for TAAA, while Eagleton et al[11] treated 354 high-risk patients with extensive types II and III aneurysms and reported perioperative mortality of 3.5% and 7%, respectively. In our multicenter study, the 9.2% perioperative mortality was largely due to the considerable number of older and sicker patients (mean age 73.5 years; 84% with ASA types III/IV). Our perioperative mortality was nearly identical to the 9% in-hospital rate reported by Verhoeven et al[14] in 166 patients.

SCI is the most catastrophic complication after TAAA repair. Although persistent paraplegia is rare (1.2%),[20] an estimated SCI incidence of almost 9.8% has been reported after endovascular TAAA procedures.[21] The institutional standardization of protective protocols and perioperative adjuvants is strongly recommended to improve the outcome of these procedures.[22] In our study, 6 (5.5%) patients developed SCI (2 permanent), which is similar to reports from other groups.[13,14,20] We also incorporated similar protocols using preventive measures, such as employing perioperative CSF drainage using automatic pressure-controlled monitoring,[23] avoiding perioperative hypotension and blood loss, elevating the hemoglobin level to >12 g/dL, paying attention to the patent subclavian and hypogastric arteries, and removing sheaths early during the procedures. Moreover, staged repair and gradual coverage of the aortic segments has been clearly advocated by other studies with a large series of patients. In this study, a staged approach was also routinely used for types I to III aneurysms.[24–26]

Clinical induction of arteriogenesis within the paraspinal collateral network has varied from staged endovascular aneurysm repair to preconditioning of the segmental collaterals using coil embolization of the intercostal arteries.[27] In this context, temporary aneurysm sac perfusion, which was first used by Ivancev et al[28] and advocated by Kazparzak et al,[29] focuses on intentional endoleaks from an unstented or dedicated perfusion branch. This concept has been controversial because of the potential risks of rupture in the interval to perfusion branch occlusion and complications of the reintervention. In our study, it was used successfully in 12 (11%) patients at 1 participating center.

Taking into consideration that this analysis includes both the initial and advanced experiences of the participating centers, a considerable rate of early perioperative major complications was encountered this series (37%); the most frequent were at the access site, followed by renal and respiratory insufficiency. Oderich et al[13] reported early major adverse events in between 32% and 36% of procedures. This significantly high rate of perioperative morbidity may reflect the high-risk nature of TAAA repair, even if an endovascular approach is used.

Throughout this study's observation period, the numbers of fenestrated-branched stent-graft implantations rose (Figure 3F), as has been reported with the Cook devices in the United States and Europe.[13,14] Since only 1 company manufactured these devices, significant delivery delays have been encountered due to the complex nature of these endovascular devices. A 1-month delay in repair of an aneurysm is assumed to increase the risk of mortality due to rupture by ~0.5% to 1.0%.[30] Our motivation in adopting the Jotec system was to avoid long waiting times and manufacturing delays. Shorter delivery times are an advantage in clinical practice, especially for anxious patients or those with large aneurysms.[31]

Similar to the other fenestrated or branched graft systems, the E-xtra Design Engineering stent-graft system has been improved over the years to facilitate implantation and reduce procedure times. For example, in 2015, the design was refined by adding a larger and funnel-shaped orifice to the outer branches to ease branch cannulation from inside the aortic grafts. Depending on the diameter of the thrombus-free renovisceral segment, fenestrations or branches are used to accommodate the target vessels. Because fenestrations are manufactured to suit vessels that originate from narrower aortic lumens, implantation of fenestrations requires greater accuracy to align with the vessel origins than implantation of branches. Furthermore, the fenestrations may be more difficult to cannulate and more subjected to dislocations and type III endoleaks than branches. Because of this, some endovascular experts may prefer the use of branches whenever possible.[13] In this study, directional branches predominated (290 vs 96 fenestrations).

Inner branches have been introduced to broaden the applicability of the branch technique. Depending on the orientation of the target vessels, the inner branch can also be manufactured with a downward or upward direction, allowing much easier cannulation and longer attachment to the aortic components. This technique is applied if the thrombus-free lumen is too narrow for the outer branches and too large to use fenestrations. Customization and a greater number of branch configurations (outer vs inner and downward vs upward branches) may enable repair of a large spectrum of morphologies and anatomies. Six of the patients who were included in our study were treated using multibranched grafts with 4 upward-directed branches because the supra-aortic vessels were not accessible from above.

In the literature, the estimated target vessel patency rates have varied between 93% and 98%.[32] In our study, 23 of the 386 target vessels occluded, resulting in a 4-year 94% cumulative patency rate, which is nearly identical to the 93% and 94% rates reported by Oderich et al[13] and Verhoeven et al,[14] respectively, at 5 years.

Mastracci et al[33] reviewed the data of 650 patients who underwent fenestrated and branched stent-grafting with a follow-up period of >9 years, focusing on secondary procedures that were performed in 11% of the target renal

arteries. Similarly, Premprabha et al[34] reported a significantly high incidence of renal occlusion after multibranched thoracoabdominal stent-grafting. In our series, 16 of 23 late target vessel occlusions involved the renal arteries (4% of all target vessels), though this was not significantly different from the other target vessels at 4 years. Interestingly, the inferiority of renal artery patency has been also reported after open thoracoabdominal repair.[35]

Reintervention, which is needed in up to 25% of patients who undergo endovascular TAAA repairs, is a cause for concern.[18,19] In our cohort, a quarter of the patients required a late secondary intervention, more than half of which were due to branch instability; the remainder were to treat endoleaks. There was a high rate (18%) of type I and III endoleaks in this study. The most common causes of type III endoleaks were branch related (7/9), whereas the other types I and III endoleaks due to inadequate oversizing, initial endograft selection, or progressive aneurysmal disease. Also, it should be remembered that this series included patients who were treated during the learning experience of the different participating centers. Rigorous graft surveillance and fundamental patient education are essential aspects of successful therapy and should be considered when deciding on whether or not to perform endovascular repair.

Limitations

Because of the retrospective design of this study and small subgroups, the impact of the aneurysm extent, learning curves of the different centers, and refinement of technical devices were not feasible. Therefore, the results cannot be generalized.

Conclusion

Endovascular TAAA repair using fenestrated and branched E-xtra Design Engineering stent-grafts appears to be safe and effective in the early to midterm. The considerable rate of secondary interventions is the main constraint to endovascular TAAA repair, and consequent stent-graft surveillance is required. Long-term data should be obtained to validate the outcomes and performance of this system.

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