



Multicenter trans-Atlantic experience with fenestrated-branched endovascular aortic repair of chronic post-dissection thoracoabdominal aortic aneurysms

Mohamed A. Abdelhalim, MBChB, MRCS,^a Emanuel R. Tenorio, MD, PhD,^b Gustavo S. Oderich, MD, FACS,^b Stephan Haulon, MD, PhD,^c Gasper Warren, MD,^d Donald Adam, MBChB, MD, FRCS,^e Martin Claridge, MBBS, MD, FRCS,^e Talha Butt, MD, PhD,^{f,g} Said Abisi, MD, FRCS,^h Nuno V. Dias, MD, PhD,^{f,g} Tilo Kölbel, MD, PhD,ⁱ Enrico Gallitto, MD, PhD,^j Mauro Gargiulo, MD, PhD,^j Panos Gkoutzios, MD, FRCR,^k Giuseppe Panuccio, MD, PhD,ⁱ Marek Kuzniar, MD,^l Kevin Mani, MD, PhD, FEBVS,^l Barend M. Mees, MD, PhD, FEBVS,^m Geert W. Schurink, MD, PhD,^m Björn Sonesson, MD, PhD,^{f,g} Paolo Spath, MD,^j Anders Wanhainen, MD, PhD,^l Andres Schanzer, MD, FACS,ⁿ Adam W. Beck, MD, FACS,^o Darren B. Schneider, MD,^p Carlos H. Timaran, MD,^q Matthew Eagleton, MD,^r Mark A. Farber, MD, FACS,^s and Bijan Modarai, PhD, MBBS, FRCS,^a on behalf of the Multicenter International Aortic Research Group, *London, United Kingdom; Houston and Dallas, TX; Paris, France; San Francisco, CA; Birmingham, United Kingdom; Malmö, Sweden; Hamburg, Germany; Bologna, Italy; Uppsala, Sweden; Maastricht, The Netherlands; Worcester and Boston, MA; Birmingham, AL; Philadelphia, PA; and Chapel Hill, NC*

ABSTRACT

Objective: This multicenter international study aimed to describe outcomes of fenestrated-branched endovascular aortic repairs (FB-EVAR) in a cohort of patients treated for chronic post-dissection thoracoabdominal aortic aneurysms (PD-TAAAs).

From the Academic Department of Vascular Surgery, School of Cardiovascular and Metabolic Medicine and Sciences, King's College London, British Heart Foundation Centre of Research Excellence, London^a; the Department of Cardiothoracic and Vascular Surgery, Advanced Aortic Research Program, McGovern Medical School at The University of Texas Health Science Center at Houston (UTHealth), Houston^b; the Department of Cardiac and Vascular Surgery, Hôpital Marie Lannelongue, GHPSJ, Université Paris Saclay, Paris^c; the Department of Surgery, University of California, San Francisco, San Francisco^d; the Birmingham Vascular Centre, University Hospitals Birmingham NHS Foundation Trust, Birmingham^e; the Vascular Center, Department of Thoracic and Vascular Surgery, Skåne University Hospital,^f and the Department of Clinical Sciences Malmö, Lund University,^g Malmö; the Department of Vascular Surgery, Guy's and St. Thomas' National Health Service Foundation Trust, London^h; the German Aortic Center, Department of Vascular Medicine, University Heart and Vascular Center Hamburg, University Medical Center Eppendorf, Hamburgⁱ; the Metropolitan Unit of Vascular Surgery, IRCCS S. Orsola Hospital, Bologna^j; the Department of Interventional Radiology, Guy's and St. Thomas' National Health Service Foundation Trust, London^k; the Section of Vascular Surgery, Department of Surgical Sciences, Uppsala University, Uppsala^l; the Department of Vascular Surgery, Maastricht University Medical Center, Maastricht^m; the Division of Vascular Surgery, University of Massachusetts, Worcesterⁿ; the Division of Vascular Surgery and Endovascular Therapy, University of Alabama at Birmingham, Birmingham^o; the Division of Vascular Surgery and Endovascular Therapy, Perelman School of Medicine, University of Pennsylvania, Philadelphia^p; the Clinical Heart and Vascular Center, University of Texas Southwestern, Dallas^q; the Division of Vascular and Endovascular Surgery, Massachusetts General Hospital, Boston^r; and the Division of Vascular Surgery, Department of Surgery, University of North Carolina, Chapel Hill.^s

Author conflict of interest: G.O. reports consulting agreements with Cook Medical Inc, WL Gore, Centerline Biomedical, and GE Healthcare; and research grants from WL Gore and GE Healthcare. S.H. reports consulting agreements and intellectual property (IP) with Cook Medical Inc, GE Healthcare, and Bentley. D.A. reports consulting agreements with Cook Medical Inc. N.D. reports consulting agreement and IP with Cook Medical Inc. T.K. reports

consulting agreements, IP, royalties, and research and travel grants with Cook Medical Inc; consulting agreements with Getinge and Philips; and IP and royalties with Terumo Aortic. G.P. reports consulting agreements with Cook Medical Inc, BD, and Philips. K.M. reports consulting agreements and research grants from Cook Medical Inc. B.M.M. reports consulting agreements with Philips, Cook, Bentley, Terumo, and Gore. G.S. reports consulting agreements and research grants from Cook Medical Inc. and Philips Medical Systems. A.S. reports consulting agreements and research grants from Cook Medical, Artivion, and Phillips Imaging. All compensation goes to the UMass Memorial Foundation. A.B. reports research support from Cook Medical, Medtronic, Philips, Terumo, and WL Gore & Associates; and consulting agreements for Artivion, Cook Medical, Medtronic, Philips, and Terumo. D.S. reports consulting agreements with Cook Medical Inc, Medtronic, Penumbra, and W.L. Gore; and research grants from Cook Medical and Philips Medical Systems. M.F. reports consulting agreements and clinical trial and research support from Cook Medical; consulting agreements and clinical trial support from WL Gore and VITAA; and consulting agreements for Getinge. B.M. reports consulting agreements with Cook Medical Inc, Cydar Medical, and Philips.

Presented at the 2022 Vascular Annual Meeting of the Society for Vascular Surgery, Boston, Massachusetts, June 15-18, 2022.

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

Correspondence: Bijan Modarai, PhD, MBBS, FRCS, Academic Department of Vascular Surgery, School of Cardiovascular and Metabolic Medicine and Sciences, King's College London, St Thomas' Hospital, London, SE1 7EH United Kingdom (e-mail: bijan.modarai@kcl.ac.uk).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

Copyright © 2023 The Authors. Published by Elsevier Inc. on behalf of the Society for Vascular Surgery. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

<https://doi.org/10.1016/j.jvs.2023.05.053>

Methods: We reviewed the clinical data of all consecutive patients treated by FB-EVAR for repair of extent I to III PD-TAAAs in 16 centers from the United States and Europe (2008-2021). Data were extracted from institutional prospectively maintained databases and electronic patient records. All patients received off-the-shelf or patient-specific manufactured fenestrated-branched stent grafts. Endpoints were any cause mortality and major adverse events at 30 days, technical success, target artery (TA) patency, freedom from TA instability, minor (endovascular with <12 Fr sheath) and major (open or \geq 12 Fr sheath) secondary interventions, patient survival, and freedom from aortic-related mortality (ARM).

Results: A total of 246 patients (76% male; median age, 67 years [interquartile range, 61-73 years]) were treated for extent I (7%), extent II (55%), and extent III (35%) PD-TAAAs by FB-EVAR. The median aneurysm diameter was 65 mm (interquartile range, 59-73 mm). Eighteen patients (7%) were octogenarians, 212 (86%) were American Society of Anesthesiologists class \geq 3, and 21 (9%) presented with contained ruptured or symptomatic aneurysms. There were 917 renal-mesenteric vessels targeted by 581 fenestrations (63%) and 336 directional branches (37%), with a mean of 3.7 vessels per patient. Technical success was 96%. Mortality and rate of major adverse events at 30 days was 3% and 28%, including disabling complications such as new onset dialysis in 1%, major stroke in 1%, and permanent paraplegia in 2%. Mean follow-up was 24 months. Kaplan-Meier (KM) estimated patient survival at 3 and 5 years was $79\% \pm 6\%$ and $65\% \pm 10\%$. KM estimated freedom from ARM was $95\% \pm 3\%$ and $93\% \pm 5\%$ at the same intervals. Unplanned secondary interventions were needed in 94 patients (38%), including minor procedures in 64 (25%) and major procedures in 30 (12%). There was one conversion to open surgical repair (<1%). KM estimated freedom from any secondary intervention was $44\% \pm 9\%$ at 5 years. KM estimated primary and secondary TA patency were $93\% \pm 2\%$ and $96\% \pm 1\%$ at 5 years, respectively.

Conclusions: FB-EVAR for chronic PD-TAAAs was associated with high technical success and a low rate of mortality (3%) and disabling complications at 30 days. Although the procedure is effective in the prevention of ARM, patient survival was low at 5 years (65%), likely due to the significant comorbidities in this cohort of patients. Freedom from secondary interventions at 5 years was 44%, although most procedures were minor. The significant rate of reinterventions highlights the need for continued patient surveillance. (*J Vasc Surg* 2023;78:854-62.)

Keywords: Aortic dissection; BEVAR; Branched; Fenestrated; FEVAR; Thoracoabdominal aortic aneurysm

A large proportion of patients who present with acute aortic dissections develop chronic post-dissection thoracoabdominal aortic aneurysms (PD-TAAAs). It is estimated that within 5 years, over 60% of patients have progressive aneurysm enlargement with risk of rupture or need for definitive treatment.¹ Whereas open surgical repair is still considered the first line of treatment in young and fit patients with heritable thoracic aortic disease, fenestrated and branched endovascular aortic repair (FB-EVAR) offers an alternative option to intermediate- and higher-risk patients with PD-TAAAs and suitable anatomy. Clinical data from selected single-center experiences suggests that mortality and risk of disabling complications with FB-EVAR is similar to the historical results of open surgical repair, despite its use in older and higher-risk patients.²⁻⁸

The presence of suitable aortic and target vessel sealing zones and adequate iliofemoral access are basic requirements of candidacy for FB-EVAR in patients with PD-TAAAs. Unique anatomic challenges inherent to PD-TAAAs include a true lumen that is frequently compressed, dissection extending into TAs, or vessel origin arising from the false lumen, which all present technical challenges requiring careful operative planning. Moreover, a large proportion of these patients have already had previous endovascular or open surgical procedures. Catheterization of mesenteric and renal TAs can be

more difficult due to space restriction, often requiring modification of the endovascular approach or the device delivery system.⁹ Given the relatively small clinical experience from large aortic centers with FB-EVAR for PD-TAAAs as compared with the larger experience achieved with degenerative TAAAs, analysis of a collective experience provides additional insight into best FB-EVAR strategies in this patient cohort. The aim of this study is to describe the clinical outcomes of FB-EVAR for PD-TAAAs in a multicenter international trans-Atlantic experience.

METHODS

The study was approved by the Institutional Review Boards of all 16 participating centers in the United States and Europe. Details of these contributing centers are supplied in the [Supplementary Table](#) (online only). We included all consecutive patients treated by FB-EVAR for extent I to III chronic PD-TAAAs between 2008 and 2021. All patients were treated using a multi-branch off-the-shelf or custom-made fenestrated-branched stent graft manufactured by Cook Medical Inc. Clinical outcomes were extracted from prospectively maintained institutional databases and electronic patient records. All data were anonymized and collated into a standardized database.

Patient demographics, clinical characteristics, and cardiovascular risk factors were collected. Anatomical findings were reviewed from preoperative computed tomography angiography (CTA). Aneurysm extent was categorized using the extent of the repair according to the Crawford classification.^{10,11} Preoperative planning, stent design, procedural details, and follow-up data were noted.

Endpoints. The Society for Vascular Surgery reporting standards for endovascular repair of aneurysms involving the renal and mesenteric arteries were used.¹² Endpoints at 30 days included all-cause mortality and major adverse events (MAEs). Secondary endpoints were technical success, TA patency, and freedom from TA instability. Technical success was defined as successful implantation of the fenestrated-branched aortic stent graft and all its modular components, including all intended TA stents on an intention-to-treat basis.^{7,12} Technical success also required the absence of type I or III endoleak, patency of TAs, absence of conversion to open surgical repair, and patient survival >24 hours. Patient survival at 5 years and freedom from aortic-related mortality (ARM), as well as freedom from minor and major secondary interventions were analyzed. Secondary interventions were categorized as minor if the procedure was performed using an endovascular approach with small (<12 Fr) profile sheath or major if the intervention required deployment of larger profile (≥ 12 Fr) aortic extensions, thrombectomy, thrombolysis, or any open surgical procedure.¹²

Major adverse events and spinal cord injury. MAEs were defined according to the recognized reporting standards as a composite of all-cause mortality, myocardial infarction, respiratory failure requiring prolonged mechanical ventilation or reintubation, acute kidney injury defined by estimated glomerular filtration rate decline of >50% or new onset dialysis, bowel ischemia, major stroke, or paraplegia (grade 3 spinal cord injury [SCI]).^{12,13} SCI was classified as grade 1 if the neurological deficit resulted in minimal sensory deficit but no loss of motor function, grade 2 if the motor deficit was partial and the patient was able to walk with assistance or independently (paraparesis), or grade 3 if the injury resulted in inability to walk (paraplegia).¹²

Statistical analysis. Clinical, anatomical, perioperative, and outcome data were described and analyzed. Comparisons were made between renal and mesenteric target vessel outcomes and method of incorporation (fenestrations vs directional branches). Categorical variables were presented as numbers and percentages. Continuous variables were expressed as mean \pm standard deviation if normally distributed, or median and interquartile range ([IQR] median, Q1-Q3) for non-normal distributions. The Pearson χ^2 or Fisher exact test was used for analysis of categorical variables. Continuous

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter, retrospective analysis of prospectively maintained databases
- **Key Findings:** Fenestrated-branched endovascular aortic repair used to treat 246 patients with chronic post-dissection thoracoabdominal aortic aneurysms in 16 centers was technically successful in 96% and resulted in 3% early mortality and 65% \pm 10% 5-year survival. Major disabling complications occurred in 4% of patients, and 38% required secondary interventions during follow-up.
- **Take Home Message:** Fenestrated-branched endovascular aortic repair has high technical success and low mortality in the treatment of chronic post-dissection thoracoabdominal aortic aneurysms.

variables were analyzed using the two-sided Student *t*-test or Wilcoxon rank-sum test as appropriate. Time dependent outcomes were reported using Kaplan-Meier estimates with standard error and life tables. Intergroup differences were determined by log-rank test. SAS 9.1 software (SAS Institute) was used for statistical analyses.

RESULTS

Study patients. There were 246 patients treated by FB-EVAR for PD-TAAAs at 16 participating centers in the United States and Europe. Clinical data from the United States was obtained from eight centers participating in the United States Aortic Research Consortium of ongoing prospective, non-randomized, physician-sponsored, investigational device exemption studies.

There were 187 men (76%) and 59 women (24%) with a median age of 67 years (IQR, 61-73 years) (Table 1). Eighteen patients (7%) were octogenarians. The vast majority of patients had significant comorbidities documented, and the rates of these are shown in Table 1. Of note, a diagnosis of a heritable thoracic aortic disease was present in 18 patients (7%). Prior aortic repairs were recorded in 221 patients (90%). These consisted of 151 prior open repairs in 134 patients and 195 prior endovascular repairs in 178 patients, with some patients having more than one prior aortic procedure. The open repairs were 48 open ascending aortic repairs, 48 aortic arch repairs, 27 thoracic aortic repairs, three juxtarenal aneurysm repairs, and 25 open infrarenal aneurysm repairs. The prior endovascular procedures consisted of 111 TEVARs performed as part of an intentional first stage, 67 TEVARs performed historically (not intentional first stage), as well as 13 infrarenal EVARs and four arch branch repairs.

Crawford classifications were based on anticipated endovascular aortic coverage and are provided in Table 1, along with anatomical characteristics and details of prior aortic repairs. Clinical presentation was asymptomatic in 225 patients (91%) who underwent elective

Table I. Demographics, clinical and anatomical characteristics of 246 patients treated by fenestrated-branched endovascular aortic repair (FB-EVAR) for treatment of post-dissection thoracoabdominal aortic aneurysms (PD-TAAAs)

Variable	Overall (n = 246)
Demographics	
Age, years	67 (61-73)
Age >80 years	18 (7)
Male gender	186 (76)
Cardiovascular risk factors	
Hypertension	232 (94)
Cigarette smoking	131 (53)
Chronic kidney disease stage III-V	86 (35)
Coronary artery disease	68 (28)
Chronic obstructive pulmonary disease	59 (24)
Stroke/TIA	30 (12)
Congestive heart failure	26 (11)
Heritable thoracic aortic disease	18 (7)
Preoperative evaluation	
Serum creatinine, mg/dL	1.0 (0.8-1.3)
eGFR, mL/min/1.73 m ²	67 (51-87)
ASA score ≥ 3	212 (86)
Prior aortic repair	221 (90)
Prior open aortic repair	134 (54)
Prior endovascular aortic repair	178 (72)
Intentional first stage	111 (45)
Anatomical characteristics	
Maximum aortic diameter, mm	65 (59-73)
Aneurysm type	
Crawford extent I	17 (7)
Crawford extent II	136 (55)
Crawford extent III	86 (35)
Unknown	7 (3)
Status of aneurysm	
Asymptomatic non-ruptured	225 (91)
Symptomatic non-ruptured	14 (6)
Contained ruptured	7 (3)
<small>ASA, American Society of Anesthesiologists; eGFR, estimated glomerular filtration rate; TAAA, thoracoabdominal aortic aneurysm; TIA, transient ischemic attack. Data are presented as number (%) or median (interquartile range).</small>	

repair. Fourteen patients (6%) presented with symptomatic, non-ruptured TAAAs, and seven (3%) had contained ruptured TAAAs requiring urgent or emergent repair.

Procedure details. All patients underwent FB-EVAR in a hybrid endovascular suite with fixed imaging unit under general endotracheal anesthesia (Table II). Preoperative placement of a prophylactic cerebrospinal fluid drain (CSFD) was used in 174 patients (71%). In the first 6 years

of the study (2008-2013), all patients had a CSFD, whereas use became more selective thereafter, falling to 68% of patients between 2014 and 2021. In the final year of the study (2021), prophylactic CSFD was used in only three patients (17%). Device design choice was patient-specific in 209 patients (85%) and off-the-shelf multi-branch stent graft (t-Branch, Cook Medical Inc) in 37 patients (15%). These devices were purely fenestrated in 129 (52%) patients, purely branched in 72 (29%), and were of mixed fenestrated/branched design in 45 (18%) patients. A total of 917 mesenteric and renal arteries were incorporated with a mean of 3.7 ± 0.5 targeted arteries per patient. Of these, 581 TAs (63%) were incorporated using reinforced fenestrations and 336 (37%) using directional branches. There were 225 (25%) celiac arteries, 241 (26%) superior mesenteric arteries, and 450 (49%) renal arteries (RAs), of which seven were accessory RAs. There was also one hepatic artery. Iliac branch devices were used in 45 cases (18%), of which 11 (4%) were bilateral. Technical success was achieved in 235 patients (96%). Technically successful TA incorporation was achieved in 917 of the 927 intended TAs (99%). Technical failures were due to inability to complete catheterization and/or stent placement in six RAs, three celiac arteries, and one superior mesenteric artery. The median operating time, total fluoroscopy time, and median radiation dose area product are shown in Table II.

Early outcomes. There were eight deaths (3%) within the first 30 days (Table III). Of these, six were in elective asymptomatic patients, one had a symptomatic aneurysm, and one was a contained rupture. Therefore, in the subgroup of acute cases (n = 21), the 30-day mortality was 10%, compared with just under 3% in elective patients. MAEs were recorded in 68 patients (28%) and included acute kidney injury in 20 patients (8%), respiratory failure in 15 patients (6%), and estimated blood loss over 1 liter in 18 patients (7%). Eighteen patients (7%) developed spinal cord ischemia, which was graded as paraparesis (grade 1 or 2) in eight patients (3%) and paraplegia (grade 3) in 10 (4%). Among patients with paraplegia, four recovered to ambulatory status and six (2%) had permanent non-ambulatory deficits at the time of discharge. Major disabling complications at time of discharge occurred in 11 patients (4%), including major stroke in three (1%), new onset dialysis in two (1%), and permanent paraplegia in six (2%).

The median length of hospital stay was 8 days (IQR, 5-12 days), including admission to an intensive care unit for a median of 3 days (IQR, 3-4 days). Overall, 207 patients (84%) were discharged to their own home. Twenty-four patients (10%) required a period in a rehabilitation facility or swing bed before being discharged home. Nursing home care on discharge was required for seven patients (3%). Early mortality accounted for the remaining 3% of patients.

Table II. Procedural details and device design of 246 patients treated by fenestrated-branched endovascular aortic repair (FB-EVAR) for treatment of post-dissection thoracoabdominal aortic aneurysms (PD-TAAAs)

Variable	Overall (n = 246)
General anesthesia	246 (100)
Cerebrospinal fluid drainage	174 (71)
Brachial access	124 (53)
Left side	57 (24)
Right side	68 (29)
Device design	
Patient specific device	209 (85)
t-Branch	37 (15)
Iliac branch device	45 (18)
Bilateral percutaneous femoral access	153 (62)
Amount of contrast used, mL	142 ± 85 (125 [81-180])
Total operating time, minutes	363 ± 170 (325 [230-479])
Cumulative air kerma, Gy	3.0 ± 2.5 (2.2 [1.1-4.6])
Dose area product, Gy.cm ²	403 ± 601 (261 [178-403])
Total fluoroscopy time, minutes	91 ± 38 (84 [64-110])
Estimated blood loss, mL	492 ± 470 (362 [200-500])
Intensive care unit stay, days	3.7 ± 3.1 (3 [3-4])
Hospital stay, days	10 ± 8 (8 [5-12])
Discharge home	193 (78)
Target vessels incorporated per patient	3.7 ± 0.5 (4 [4-4])
Technical success per patient	235 (96)

Data are presented as number (%), mean ± standard deviation, or median [interquartile range].

In the subset of 10 patients in whom technical failures occurred, there were five MAEs including one mortality within 30 days secondary to major stroke. The other MAEs were two SCIs in which one patient made a complete recovery and the other made a partial recovery, as well as two acute kidney injuries not requiring dialysis. Of these 10 patients, seven were discharged to their own home, whereas two were discharged to a rehab facility.

Patient survival and aortic-related mortality. The mean patient follow-up was 24 ± 23 months. There were 45 deaths recorded during the study period, including eight deaths in the first 30 days and 37 deaths after the first 30 days. Cause of death was deemed aortic-related in 12 patients (27%) and non-aortic-related in 33 (73%). Estimated patient survival at 3 and 5 years was 79% ± 6% and 65% ± 10%, respectively. Freedom from ARM was 95% ± 3% and 93% ± 5% at the same intervals (Fig 1).

Reinterventions. A total of 94 patients (38%) underwent 129 secondary interventions. Of these, 23 required

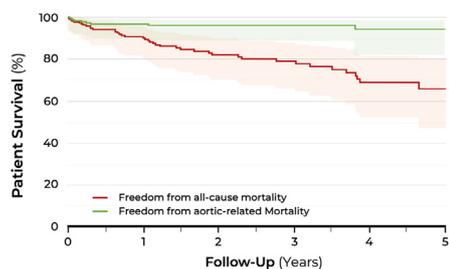
Table III. Mortality and major adverse events (MAEs) of 246 patients treated by fenestrated-branched endovascular aortic repair (FB-EVAR) for treatment of post-dissection thoracoabdominal aortic aneurysms (PD-TAAAs)

Variable	Overall (n = 246)
30-day mortality	8 (3)
Any MAE	68 (28)
Acute kidney injury	20 (8)
New onset dialysis	2 (1)
Any SCI ^a	18 (7)
Paraplegia	10 (4)
Grade 1-2	8 (3)
Permanent paraplegia	6 (2)
Estimated blood loss >1 liter	18 (7)
Respiratory failure	15 (6)
Stroke (minor or major)	3 (1)
Myocardial infarction	2 (1)
Bowel ischemia	1 (0.4)

SCI, Spinal cord injury.
Data are presented as number (%).
^aThree due to complication of spinal drain.

multiple reinterventions, and the highest number of reinterventions in a single patient was six. Secondary interventions included 99 minor procedures in 68 patients (28%), and major secondary interventions were required in 30 patients (12%) (Table IV). The most common indication for secondary interventions were TA-related problems in 59 patients. In 15 patients, secondary interventions were required for access site complications. Of these, 10 occurred in percutaneously accessed arteries, whereas five occurred after open access. Estimated freedom from any secondary intervention was 50% ± 8% and 44% ± 9% at 3 and 5 years, respectively. Freedom from major secondary interventions was 83% ± 6% and 80% ± 7% at 3 and 5 years, respectively (Fig 2). All secondary interventions are summarized in Table IV.

Target artery patency and instability. Stenoses or occlusions were recorded in 24 of the 917 TAs (3%) during follow-up, including 16 renal and 8 mesenteric vessels. Overall, TA stenosis/occlusion was more likely to affect a directional branch compared with a fenestration (14 [4%] vs 10 [2%]; $P = .025$). Overall primary and secondary patency at 5 years was 93% ± 2% and 96% ± 1% for all TAs, respectively. Target vessel-related endoleaks affected 55 vessels (6%), including type IC endoleak in 29 vessels (3%) and type IIIC endoleaks in 26 vessels (3%). There was no difference in the frequency of endoleaks affecting RAs as compared with mesenteric arteries, nor fenestrations as compared with directional branches. Freedom from secondary interventions to treat target-related problems was 87% ± 3% at 5 years.



—	Number at risk	246	146	94	67	42	18
	Kaplan–Meier estimate survival rates	1	.897	.817	.787	.685	.654
	Standard error	0	.022	.031	.034	.047	.054
—	Number at risk	246	146	94	67	42	18
	Kaplan–Meier estimate survival rates	1	.958	.951	.951	.931	.931
	Standard error	0	.014	.015	.015	.025	.025

Fig 1. Kaplan-Meier curves estimating freedom from all-cause mortality (red line) and freedom from aortic-related mortality (ARM) (green line) in 246 patients treated by fenestrated-branched endovascular aortic repair (FB-EVAR) for treatment of post-dissection thoracoabdominal aortic aneurysms (PD-TAAAs).

False lumen thrombosis and sac shrinkage. The median aneurysm diameter at the time of treatment was 65 mm (IQR, 59-73 mm). Comparative imaging data on aneurysm sac diameter during follow-up CTA surveillance was available for 219 patients. The median post-treatment aneurysm sac diameter on the most recent available CTA was 63 mm (IQR, 56-73 mm). Overall, 81 patients (37%) had aneurysm sac diameter reduction >5 mm, whereas 99 patients (45%) had no significant change noted. Expansion of the aneurysm sac by >5 mm was recorded in 39 patients (18%), of whom 20 patients had reinterventions to treat endoleaks and 16 patients had false lumen embolization. Data on false lumen patency was available for 118 patients. Preoperatively, 111 patients (94%) had a patent false lumen, whereas seven (6%) had a thrombosed or partially thrombosed false lumen. On the latest postoperative follow-up CTA, 67 patients (57%) had complete false lumen thrombosis, whereas in 39 patients (33%), there was partial false lumen thrombosis. In 12 patients (10%), the false lumen remained patent.

DISCUSSION

In this multicenter cohort study of 246 patients undergoing FB-EVAR for chronic PD-TAAA, technical success was high, and 30-day mortality was low, comparing favorably with open surgical results in younger patients. Despite the majority of patients having prior aortic interventions, the rate of SCI was 7%, with permanent paraplegia in 2%. The overall rate of permanent disabling complications (eg, major stroke, dialysis, or permanent paraplegia) was low given the extent of these aneurysms and the high-risk nature of the patient cohort.

Treatment of chronic post-dissection aneurysms has been traditionally approached by open surgical repair. This is a high-risk procedure with the potential

advantage of durability among those who survive the operation. A systematic review of studies reporting open repair of chronic post-dissection aneurysms showed an aggregate 30-day mortality of 11%.¹⁴ This included both thoracic aortic aneurysms and thoracoabdominal aortic aneurysms. In the same review, rates of stroke, SCI, and renal dysfunction were 6%, 5%, and 8%, respectively, whereas the reintervention rate was 13%, and the 5-year survival rate was 66%. Tanaka and colleagues reported a mortality rate and rate of disabling complications of 6% and 17%, respectively, for open surgical TAAA repair in patients younger than 50 years old, increasing to 17% and 40% for patients older than 50 years.¹⁵ A criticism to many open surgical series is that secondary interventions for early complications (eg, hemorrhage, bowel, and wound-related complications) are often omitted, with most studies focusing only on need for aortic reoperations.

This study shows that FB-EVAR outcomes can be reproduced in multiple centers with low mortality and high technical success. Although open surgical repair can be performed with relatively low mortality (5%-10%) in patients with chronic dissections in select centers, the reality is that over two-thirds of patients with TAAAs are treated in low-volume centers with an average mortality of 20%.¹⁶ Conversely, the mortality of 3% in this study is a testament to the early advantage of endovascular approach and reproducibility among multiple high-volume centers.^{6,7,17-19} In addition, it is likely these outcomes will continue to improve as the global experience with fenestrated-branched devices is growing and the device technology is improving.

FB-EVAR in the context of chronic PD-TAAAs is considerably more technically challenging. Initially, there was concern that the chronic lamella would impede stent graft expansion and cause collapse, preventing incorporation of target vessels. In clinical practice, this concern has been shown to be unwarranted, as many patients with severe compression of the true lumen (<18 mm) have been successfully treated by FB-EVAR. Nonetheless, challenges including difficult target vessel catheterization can be created by true lumen morphology, extension of the dissection flap into target vessels, and the possibility of target vessels originating from either the true or false aortic lumen.^{9,20} Therefore, it is important to be facile with re-entry techniques and bail out maneuvers to overcome these difficulties. The ever-ongoing expansion of the endovascular toolbox, with modern devices such as steerable sheaths, re-entry devices, and laser technology for creation of new entries in the dissection membrane to reach target vessel ostium, when necessary, in combination with modern intraoperative imaging guidance with fusion technology and cone beam CT, has made it possible to overcome many of the initial challenges with endovascular treatment of PD-TAAAs. These difficulties are compounded by the

Table IV. Secondary interventions in 246 patients treated by fenestrated-branched endovascular aortic repair (FB-EVAR) for treatment of post-dissection thoracoabdominal aortic aneurysms (PD-TAAAs)

N=129 ^a	Reason	Description of secondary intervention
Access-related, n = 15	Femoral artery pseudoaneurysm, n = 8	Open pseudoaneurysm repair, n = 5 Thrombin injection, n = 3
	Thrombosis of access artery, n = 2	Thrombectomy, n = 2
	Groin hematoma, n = 4	Evacuation of hematoma, n = 4
	Access site occlusion, n = 1	Femoral endarterectomy, n = 1
Target artery related, n = 57	Type 1c endoleak, n = 28	CA stenting, n = 7 SMA stenting, n = 7 RRA stenting, n = 5 LRA stenting, n = 8
	Type 3c endoleak, n = 17	CA stent, n = 4 SMA stent, n = 6 LRA stent, n = 5 RRA stent, n = 2 RRA angioplasty, n = 1
	Target artery stenosis/occlusion, n = 12	CA stent, n = 1 SMA stent, n = 2 RRA stent, n = 3 LRA stent, n = 3 RRA angioplasty, n = 1 LRA angioplasty, n = 1 RRA thrombectomy, n = 1
Aorto-iliac related, n = 59	Type 1a endoleak, n = 7	TEVAR, n = 6 Carotid-subclavian bypass, n = 1 Arch debranching and proximal stent extension, n = 1
	Type 1b endoleak, n = 17	Iliac extension, n = 13 IBD, n = 2 IBE, n = 2 Open surgical banding of CIA, n = 1
	Type 2 endoleak, n = 17	Embolisation, n = 3 IMA embolization, n = 3 Polar renal embolization, n = 1 Splenic artery embolization, n = 3 Lumbar embolization, n = 5 Extension of IIA stent, n = 1 Open ligation for T2EL, n = 1
	Iliac limb stenosis/occlusion, n = 4	Relining of iliac limb, n = 2 EIA angioplasty, n = 1 CIA thrombolysis, n = 1
	Patent false lumen/expansion, n = 12	Aortic FL embolization, n = 7 Iliac FL embolization, n = 5
	Infected graft, n = 1	Percutaneous drainage of aneurysm sac, n = 1
	Contained rupture, n = 1	Emergency completion of BEVAR during staged repair, n = 1
Laparotomy, n = 1	Retroperitoneal hematoma, n = 1	Laparotomy for evacuation of hematoma, n = 1
Other, n = 3	Epidural hematoma, n = 2	Laminectomy, n = 2
	Failure to extubate, n = 1	Tracheostomy, n = 1

BEVAR, Branched endovascular aneurysm repair; CA, celiac artery; CIA, common iliac artery; EIA, external iliac artery; FL, false lumen; IBD, iliac branch device; IBE, iliac branch endoprosthesis; IIA, internal iliac artery; IMA, inferior mesenteric artery; LRA, left renal artery; RRA, right renal artery; SMA, superior mesenteric artery; T2EL, type II endoleak; TEVAR, thoracic endovascular aneurysm repair.

^aIn some cases, a single secondary intervention was composed of multiple procedures (eg stenting of both CA and SMA to treat type IIIc endoleaks, or treatment of both a type II endoleak and target artery stenosis during a single procedure).

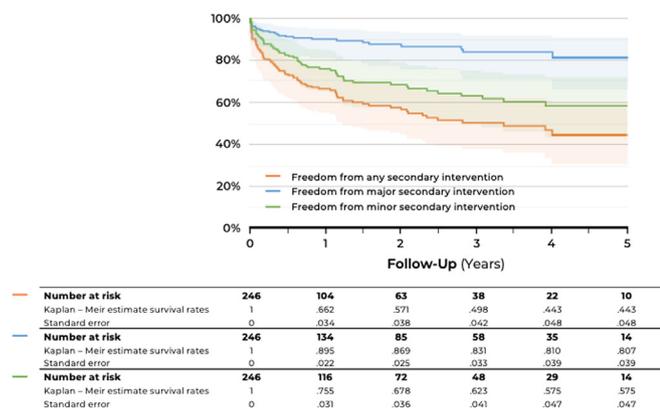


Fig 2. Kaplan-Meier curves estimating freedom from any secondary intervention (orange line), freedom from major secondary intervention (green line), and freedom from minor secondary intervention (blue line) in 246 patients treated by fenestrated-branched endovascular aortic repair (FB-EVAR) for treatment of post-dissection thoracoabdominal aortic aneurysms (PD-TAAAs).

need for more durable repairs as the cohort of patients presenting with PD-TAAAs is generally younger, with a longer life expectancy, compared with those presenting with degenerative aneurysms.²¹

A major limitation of FB-EVAR for chronic PD-TAAAs is the high rate of secondary interventions. This has been previously shown in a series of 71 consecutive patients.²² In that study, 32% of patients required secondary interventions, mostly to treat endoleaks. Overall, freedom from secondary interventions was 53% ± 8% at 3 years. This high rate of reintervention was also observed in a small series of 14 patients, in which 3-year freedom from reintervention was 48%.²³ In a report of the United States Aortic Research Consortium comparing FB-EVAR for chronic PD and degenerative TAAAs, freedom from reintervention at 2 years was 58% and 67% in the two groups, respectively.²¹ That study showed higher secondary patency for vessels targeted by fenestrations as compared with directional branches.²¹ In the present study, freedom from secondary intervention was 50% at 3 years and 44% at 5 years, which is comparable to prior reports.²¹⁻²³ However, this study provides a more detailed analysis of the nature of these reinterventions. The majority of reinterventions were minor procedures with low clinical magnitude, consisting of revision of target vessels or treatment of endoleaks using small profile sheaths. Major secondary interventions were less frequent. The study emphasizes the importance of maximizing seal zone in the target vessels to decrease risk of residual type IC or IIIC endoleaks and a tendency to be more aggressive with the sizing of mating stents relative to target vessel size. There may also be a role to pre-emptively embolize the aneurysm sac to minimize risk of type II endoleaks, although this has not been analyzed in conjunction with FB-EVAR for chronic PD-TAAAs.

This study has important limitations. There was not a standardized protocol dictating the selection of stent design, access sites, or perioperative care; these decisions were left to the discretion of individual operators and centers. Numbers are still relatively small to allow analysis of factors that may affect rate of secondary interventions, such as selection of method of incorporation, type of bridging stent, and center experience. Follow-up is still relatively short compared with other FB-EVAR series. The lack of a denominator does not allow us to make comparison with alternative repair techniques or devices.

CONCLUSIONS

This international multicenter study demonstrates a high technical success and low mortality and MAE rates associated with FB-EVAR in patients with chronic PD-TAAAs. Although the procedure is effective with respect to protection against ARM and aneurysm rupture, overall patient survival at 5 years was low, reflecting the extensive comorbid status of these patients and indicating a need for better addressing other cardiovascular risk factors. The high rate of secondary interventions during follow-up represents the most important limitation of this technique and creates a need for continued patient follow-up and surveillance.

AUTHOR CONTRIBUTIONS

Conception and design: MA, ET, GO, SH, GW, DA, MC, SA, ND, TK, EG, MG, PG, KM, BMM, GS, BS, AW, AS, AB, DS, CT, ME, MF, BM

Analysis and interpretation: MA, ET, GO, BM

Data collection: MA, ET, TB, GP, MK, PS

Writing the article: MA, ET, GO, BM

Critical revision of the article: MA, ET, GO, SH, GW, DA, MC, TB, SA, ND, TK, EG, MC, PG, GP, MK, KM, BMM, GS, BS, PS, AW, AS, AB, DS, CT, ME, MF, BM

Final approval of the article: MA, ET, GO, SH, GW, DA, MC, TB, SA, ND, TK, EG, MC, PG, GP, MK, KM, BMM, GS, BS, PS, AW, AS, AB, DS, CT, ME, MF, BM

Statistical analysis: MA

Obtained funding: Not applicable

Overall responsibility: BM

REFERENCES

- Fattori R, Montgomery D, Lovato L, et al. Survival after endovascular therapy in patients with type B aortic dissection: a report from the International Registry of Acute Aortic Dissection (IRAD). *JACC Cardiovasc Interv* 2013;6:876-82.
- Rocha RV, Lindsay TF, Friedrich JO, et al. Systematic review of contemporary outcomes of endovascular and open thoracoabdominal aortic aneurysm repair. *J Vasc Surg* 2020;71:1396-412.e12.
- Oderich GS, Farber MA, Schneider D, et al. Final 5-year results of the United States Zenith Fenestrated prospective multicenter study for juxtarenal abdominal aortic aneurysms. *J Vasc Surg* 2021;73:1128-38.e2.
- Antoniou GA, Antoniou SA, Torella F. Editor's choice – endovascular vs. Open repair for abdominal aortic aneurysm: systematic review and meta-analysis of updated peri-operative and long term data of randomised controlled trials. *Eur J Vasc Endovasc Surg* 2020;59:385-97.

5. Coselli JS, Lemaire SA, Preventza O, et al. Outcomes of 3309 thoracoabdominal aortic aneurysm repairs. *J Thorac Cardiovasc Surg* 2016;151:1323-38.
6. Verhoeven ELC, Katsargyris A, Bekkema F, et al. Editor's choice – ten-year experience with endovascular repair of thoracoabdominal aortic aneurysms: results from 166 consecutive patients. *Eur J Vasc Endovasc Surg* 2015;49:524-31.
7. Budtz-Lilly J, Wanhainen A, Eriksson J, Mani K. Adapting to a total endovascular approach for complex aortic aneurysm repair: outcomes after fenestrated and branched endovascular aortic repair. *J Vasc Surg* 2017;66:1349-56.
8. Adam D, Iafrancesco M, Juszcak M, et al. Open surgical replacement of the descending thoracic and thoracoabdominal aorta in patients with confirmed Marfan and Loeys-Dietz syndromes: a 20-year single-centre experience. *Eur J Cardio Thorac Surg* 2022;62:ezac137.
9. Oikonomou K, Katsargyris A, Ritter W, Spinelli D, Seto Y, Verhoeven EL. Endovascular management of chronic post-dissection aneurysms. *Ann Cardiothorac Surg* 2014;3:307-13.
10. Crawford ESC JL, Safi HJ, Coselli JS, et al. Thoracoabdominal aortic aneurysms: preoperative and intraoperative factors determining immediate and long-term results of operations in 605 patients. *J Vasc Surg* 1986;3:389-404.
11. Safi HJ, Miller CC. Spinal cord protection in descending thoracic and thoracoabdominal aortic repair. *Ann Thorac Surg* 1999;67:1937-9.
12. Oderich GS, Forbes TL, Chaer R, et al. Reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries. *J Vasc Surg* 2021;73:4S-52S.
13. Ouriel K, Fowl RJ, Davies MC, Forbes TL, Gambhir RPS, Ricci MA. Disease-specific guidelines for reporting adverse events for peripheral vascular medical devices. *J Vasc Surg* 2014;60:212-25.
14. Tian DHDS RP, Wang T, Yan TD. Open surgical repair for chronic type B aortic dissection: a systematic review. *Ann Cardiothorac Surg* 2014;3:340-50.
15. Tanaka A, Leonard SD, Sandhu HK, et al. Open descending and thoracoabdominal aortic repairs in patients younger than 50 Years old. *Ann Thorac Surg* 2019;108:693-9.
16. Polanco AR, D'Angelo AM, Shea NJ, Allen P, Takayama H, Patel VI. Increased hospital volume is associated with reduced mortality after thoracoabdominal aortic aneurysm repair. *J Vasc Surg* 2021;73:451-8.
17. Oderich GS, Ribeiro M, Hofer J, et al. Prospective, nonrandomized study to evaluate endovascular repair of pararenal and thoracoabdominal aortic aneurysms using fenestrated-branched endografts based on supraceliac sealing zones. *J Vasc Surg* 2017;65:1249-59.e10.
18. Shalan A, Tenorio ER, Mascaro JG, et al. Fenestrated-branched endovascular repair for distal thoracoabdominal aortic pathology after total aortic arch replacement with frozen elephant trunk. *J Vasc Surg* 2022;76:867-74.
19. Clough RE, Spear R, Mouglin J, et al. Midterm outcomes of BeGraft stent grafts used as bridging stents in fenestrated endovascular aortic aneurysm repair. *J Endovasc Ther* 2022;152660282210918.
20. Spear R, Sobocinski J, Settembre N, et al. Early experience of endovascular repair of post-dissection aneurysms involving the thoracoabdominal aorta and the arch. *Eur J Vasc Endovasc Surg* 2016;51:488-97.
21. Tenorio ER, Oderich GS, Farber MA, et al. Outcomes of endovascular repair of chronic postdissection compared with degenerative thoracoabdominal aortic aneurysms using fenestrated-branched stent grafts. *J Vasc Surg* 2020;72:822-36.e9.
22. Oikonomou K, Kasprzak P, Katsargyris A, Marques De Marino P, Pfister K, Verhoeven ELC. Mid-Term results of fenestrated/branched stent grafting to treat post-dissection thoraco-abdominal aneurysms. *Eur J Vasc Endovasc Surg* 2019;57:102-9.
23. Kuzniar MK, Wanhainen A, Tegler G, Mani K. Endovascular treatment of chronic aortic dissection with fenestrated and branched stent grafts. *J Vasc Surg* 2021;73:1573-1578.e1.

Submitted Mar 29, 2023; accepted May 23, 2023.

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

Supplementary Table (online only). Contributing centers and number of cases contributed

Contributing centers		
	Country	Cases contributed
Department of Cardiothoracic and Vascular Surgery, McGovern Medical School at The University of Texas Health Science Center, Houston, Texas	USA	38
Clinical Heart and Vascular Center, University of Texas Southwestern, Dallas, Texas	USA	17
Division of Vascular Surgery and Endovascular Therapy, University of Alabama at Birmingham, Birmingham, Alabama	USA	6
Division of Vascular Surgery, Department of Surgery, University of North Carolina, Chapel Hill, North Carolina	USA	15
Division of Vascular Surgery and Endovascular Therapy, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania	USA	5
Division of Vascular and Endovascular Surgery, Massachusetts General Hospital, Boston, Massachusetts	USA	6
Division of Vascular Surgery, University of Massachusetts, Worcester, Massachusetts	USA	12
Department of Surgery, University of California, San Francisco, San Francisco, California	USA	21
Academic Department of Vascular Surgery, St Thomas' Hospital, London	UK	12
University Hospitals Birmingham NHS Foundation Trust	UK	19
Department of Aortic and Vascular Surgery, Hôpital Marie Lannelongue, Paris	France	35
Section of Vascular Surgery, Department of Surgical Sciences, Uppsala University, Uppsala	Sweden	12
Department of Vascular Diseases, Malmö University Hospital, Malmö	Sweden	9
University Heart & Vascular Center, Hamburg	Germany	18
Metropolitan Unit of Vascular Surgery, IRCCS S. Orsola Hospital, Bologna	Italy	8
Department of Vascular Surgery, Maastricht University Medical Center, Maastricht	Netherlands	13

UK, United Kingdom; USA, United States.