Endovascular repair of thoracoabdominal aortic aneurysms using fenestrated and branched endografts

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ABSTRACT

Purpose: The study purpose was to review the outcomes of patients treated for thoracoabdominal aortic aneurysms using endovascular repair with fenestrated and branched stent-grafts in a single center.

Methods: We reviewed the clinical data of the first 185 consecutive patients (134 male; mean age, 75 ± 7 years) treated for thoracoabdominal aortic aneurysms using fenestrated and branched stent-grafts. Graft design evolved from physician-modified endografts (2007-2013) to off-the-shelf or patient-specific manufactured devices in patients enrolled in a prospective physician-sponsored investigational device exemption protocol (NCT 1937949 and 2089607). Outcomes were reported for extent IV and extent I to III thoracoabdominal aortic aneurysms, including 30-day mortality, major adverse events, patient survival, primary target vessel patency, and reintervention.

Results: A total of 112 patients (60%) were treated for extent IV thoracoabdominal aortic aneurysms, and 73 patients (40%) were treated for extent I to III thoracoabdominal aortic aneurysms. Demographics and cardiovascular risk factors were similar in both groups. A total of 687 renal-mesenteric arteries (3.7 vessels/patient) were targeted by 540 fenestrations and 147 directional branches. Technical success was 94%. Thirty-day mortality was 4.3%, including a mortality of 1.8% for extent IV and 8.2% for extent I to III thoracoabdominal aortic aneurysms ($P = .03$). Mortality decreased in the second half of clinical experience from 7.5% to 1.2%, including a decrease of 3.3% to 0% for extent IV thoracoabdominal aortic aneurysms ($P = .12$) and 15.6% to 2.4% for extent I to III thoracoabdominal aortic aneurysms ($P = .04$). Early major adverse events occurred in 36 patients (32%) with extent IV thoracoabdominal aortic aneurysms and 26 patients (36%) with extent I to III thoracoabdominal aortic aneurysms, including spinal cord injury in 2 patients (1.8%) and 4 patients (3.2%), respectively. Mean follow-up was 21 ± 20 months. At 5 years, patient survival (56% and 59%, $P = .37$) and freedom from any reintervention (50% and 53%, $P = .26$) were similar in those with extent IV and extent I to III thoracoabdominal aortic aneurysms. Primary patency was 93% at 5 years.

Conclusions: Endovascular repair of thoracoabdominal aortic aneurysms can be performed with high technical success and low mortality and morbidity. However, the need for secondary reinterventions and continued graft surveillance represents major limitations compared with results of conventional open surgical repair. Long-term follow-up is needed before the widespread use of these techniques in younger or lower-risk patients. (J Thorac Cardiovasc Surg 2017;153:S32-41)

Branch incorporation can be done with reinforced fenestrations or branches.

Central Message

This article reviews the outcomes of novel fenestrated and branched endografts to treat TAAAs in a single center.

Perspective

Fenestrated and branched endografts have been used to treat TAAAs in elderly and higher-risk patients. This study shows low mortality (4%), SCI (3%), and dialysis rate (1%), which compares favorably to historical results of conventional open repair in large centers. Rate of reinterventions was high because of endoleak of branch vessel stenosis.

See Editorial Commentary page S42.

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Abbreviations and Acronyms

F-BEVAR	= fenestrated and branched endovascular aortic repair
IDE	= investigational device exemption
MAE	= major adverse event
PMEG	= physician-modified endovascular graft
SCI	= spinal cord injury
TAAA	= thoracoabdominal aortic aneurysm
TASP	= temporary aneurysm sac perfusion

Scanning this QR code will take you to supplemental figures, tables, and video for this article.

Fenestrated and branched stent-grafts have been increasingly used to extend the indications of endovascular aortic aneurysm repair to patients with complex aortic aneurysms involving the supra-aortic trunks, renal-mesenteric arteries, and iliac bifurcation. Since the first report of an endovascular repair of a thoracoabdominal aortic aneurysm (TAAA) by Chuter and colleagues¹ in 2001, the technique has evolved from physician-modified endovascular grafts (PMEGs) to manufactured off-the-shelf or patient-specific endografts.¹ Several refinements in device design, including reinforced fenestrations; straight, helical, internal, and external branches; preloaded catheters and guidewire systems; and lower profile fabric, have facilitated or simplified these procedures, accounting for the high technical success (>95%) in most reports.²⁻⁶ The mortality rate has varied in the literature depending on clinical experience, learning curve, and adoption of specific protocols to reduce spinal cord injury (SCI), including staging, early limb reperfusion, and neuromonitoring.⁵⁻⁹ It is evident from these reports that development of dedicated teams and improvements in preoperative planning, patient selection, techniques of implantation, and perioperative intensive care have lowered perioperative mortality and paraplegia. The purpose of this study was to review the outcomes of endovascular repair using fenestrated and branched endovascular aortic repair (F-BEVAR) in consecutive patients treated at a single center.

MATERIALS AND METHODS

The study was approved by the Institutional Review Board of the Mayo Clinic. All patients consented for participation in clinical research studies. We identified all consecutive patients treated for TAAAs by F-BEVAR. All patients included in the study had at least more than 2 sealing stents above the celiac axis. Selection of fenestrated and branched endograft design evolved from PMEGs (2007-2013) to manufactured devices (2012-

2016), which were performed using Cook Zenith (Cook Medical Inc, Bloomington, Ind) off-the-shelf or patient-specific thoracoabdominal stent-grafts. Patients treated since 2013 were enrolled in a prospective physician-sponsored investigational device exemption (IDE) protocol (www.ClinicalTrials.gov, NCT 1937949 and 2089607).

The clinical data were retrospectively reviewed for demographics, clinical characteristics, cardiovascular risk factors, comorbidity scores, radiologic imaging, operative data, and outcomes. The early postoperative period was defined as within the first 30 days or within the hospital stay if more than 30 days. Follow-up consisted of clinical examination and diagnostic imaging before discharge and at 2, 6, and 12 months and annually thereafter. Imaging evaluation included computed tomography angiography or computed tomography without contrast and duplex ultrasound of the renal-mesenteric arteries. All imaging studies were independently evaluated by a group of vascular radiologists. Clinical and imaging follow-up was obtained prospectively in all patients treated under the IDE protocols. Among patients included in the prospective arm, adverse events were reviewed and adjudicated by an independent clinical event committee and Data Safety Monitoring Board.

Statistical Analysis

Data were managed and stored in a MEDIDATA Rave (New York, NY) database and analyzed using SAS 9.1 software (SAS Institute, Inc, Cary, NC). Outcomes were analyzed separately for extent IV and extent I to III TAAAs using Crawford and colleagues' classification.¹⁰ The reporting standards of the Society for Vascular Surgery for endovascular repair of thoracic aneurysms were used to define technical success, aneurysm sac changes, endoleak, migration, and device integrity.¹¹ Major adverse events (MAEs) were defined using a composite end point, which included any cause mortality, severe acute kidney injury (>50% decrease in estimated glomerular filtration rate), new-onset dialysis, myocardial infarction, respiratory failure requiring prolonged mechanical ventilation or reintubation, paraplegia (nonambulatory, grade 3a-3c Spinal Cord Injury Scale),¹¹ stroke, bowel ischemia requiring surgical resection or intensification of medical therapy, and estimated blood loss more than 1 liter. Primary and secondary patency were defined by uninterrupted patency from index procedure until occlusion or any stent reintervention for stenosis and by an occlusion treated by surgical bypass or not suitable to endovascular salvage, respectively. Time-dependent outcomes were reported using Kaplan-Meier estimates. Differences were determined by the log-rank test. Results were reported as percent for categorical variables and mean $\pm$ standard deviation for continuous variables. The Pearson's chi-square or Fisher exact test was used for analysis of categorical variables. Differences between means were tested with the 2-sided Student *t* test, Wilcoxon rank-sum test, or Mann-Whitney test. Data are presented as median values or mean $\pm$ standard deviation, as appropriate.

Device Design

Aneurysm morphology was determined by high-resolution computed tomography angiography datasets. Device design was planned using the centerline of flow measurements with a minimum proximal landing zone of 20 mm based on healthy aortic segments with a parallel aortic wall with no thrombus or calcium. The technique of device design, modification, and implantation of PMEGs has been described in detail¹²⁻¹⁴ and is summarized in the [Video 1](#). Physician-modified fenestrated stent-grafts were customized onsite under a strict sterile technique using the Cook Zenith or TX2 platform (Cook Medical Inc) with 1 to 5 reinforced fenestrations or directional branches. A diameter-reducing wire was used to facilitate target vessel catheterization. For manufactured devices, the design consisted of an off-the-shelf multibranch stent-graft (t-Branch, Cook Medical Inc, Brisbane, Australia) or a patient-specific design with any combination of 1 to 5 fenestrations or branches ([Figure 1](#)). In general, directional branches were preferentially selected for longitudinally oriented vessels that originated from a large luminal aortic diameter

VIDEO 1. The technique of endovascular repair of a TAAA using fenestrated-branched stent-grafts is shown. Preoperative imaging is reviewed using centerline of flow analysis for measurements of lengths, angle, and clock position of the mesenteric and renal target vessels. A patient-specific stent-graft is designed with 2 directional branches for the celiac and superior mesenteric arteries and 2 renal fenestrations. The procedure is performed using transfemoral and brachial access. Once the target vessels are located, the device is oriented and introduced via the femoral approach. Preloaded catheters allow guidewires to be snared via the brachial approach. The device is partially deployed to the level of the mesenteric arteries. By using the brachial approach, the celiac and superior mesenteric arteries are accessed and the hydrophilic sheaths are advanced over stiff guidewires. The rest of the device is deployed below the renal arteries. The renal fenestrations and renal arteries are accessed via the femoral approach. The device is completely deployed, followed by sequential stenting of the renal and mesenteric arteries using covered stent-grafts. The repair is extended distally using a bifurcated stent-graft and iliac limbs. A completion angiography is performed to document patency of the side branches and absence of endoleak. Video available at: [http://www.jtcvsonline.org/article/S0022-5223\(16\)31379-4/addons](http://www.jtcvsonline.org/article/S0022-5223(16)31379-4/addons).

(>30 mm) (Figure E1), whereas fenestrations were selected for transversely originating vessels with an origin in narrow aortic segments (Figure E2).

Alignment Stents

Alignment stents were used in all vessels accommodated by fenestrations or directional branches. For fenestrations, iCAST balloon-expandable covered stents (Atrium Maquet, Hudson, NH) were used with or without selective placement of self-expandable bare metal stents at the distal edge to prevent kinks. Directional branches were bridged to the target vessels using a Viabahn stent-graft (WL Gore & Associates, Flagstaff, Ariz) for the renal arteries or a Fluency stent-graft (Bard, Covington, Ga) for the celiac axis and superior mesenteric artery.

Prevention of Spinal Cord Injury

Our protocol of SCI prevention has been reported.⁹ Staged endovascular repair was indicated for extent I to II TAAAs (Figure E3). Subclavian and hypogastric artery revascularization was performed if needed to extend a landing zone. Perioperative measures included discontinuation of calcium channel blockers and angiotensin inhibitors 1 week before and up to 4 to 6 weeks after the procedure. Permissive hypertension with mean arterial pressure targeted at 80 mm Hg or more was used in the first 72 hours after the operation. Transfusion of blood products was indicated in the first 48 hours after the procedure to keep a target hemoglobin 10 mg/dL or more and normal coagulation profile. Cerebrospinal fluid drainage was indicated routinely in all extent I to III TAAAs and has been used for extent IV TAAAs since 2013. Total intravenous anesthesia was used to allow

FIGURE 1. Advantages of patient-specific fenestrated and off-the-shelf multibranched stent-grafts.

intraoperative neurophysiologic monitoring of motor-evoked potential and somatosensory-evoked potentials. A 75% or greater reduction from baseline evoked potential amplitude was considered to be significant and triggered standardized maneuvers (Figure E4) to increase spinal cord perfusion and restore flow to the pelvis and lower extremities.

RESULTS

Study Patients

There were 185 patients, 134 male (72%) and 51 female (28%), with a mean age of 75 ± 7 years (Table 1). Aneurysm classification was extent IV TAAA in 112 patients (60%) and extent I to III TAAA in 73 patients (40%). The maximum aneurysm diameter averaged 66 ± 13 mm. Patients in both groups had similar demographics and cardiovascular risk factors. Society for Vascular Surgery comorbidity scores were higher in patients with extent IV TAAAs (13 ± 4 vs 12 ± 4 , $P = .029$), but patients with extent I to III TAAAs had more prior aortic repairs (54% vs 27%, $P < .001$) and abdominal operations (57% vs 41%, $P = .035$). For the entire cohort, the most prevalent risk factors were hypertension in 164 patients (90%), cigarette smoking in 159 patients (87%), hyperlipidemia in 149 patients (81%), ischemic cardiomyopathy in 112 patients (61%), chronic obstructive pulmonary disease in 88 patients (48%), and stage III to V chronic kidney disease in 60 patients (32%).

Stent-Graft Design

Endovascular repair was performed using PMEGs in 78 patients (42%, 44 extent IV and 37 extent I-III)

TABLE 1. Demographics and clinical characteristics of 185 patients treated for thoracoabdominal aortic aneurysms with fenestrated-branched stent-grafts

Variable	Extent I-III			Extent IV			P value	Overall		
	(N = 73)	± SD or %	Median (Q1, Q3)	(N = 112)	± SD or %	Median (Q1, Q3)		(N = 185)	± SD or %	Median (Q1, Q3)
Age (y)	74	±7	74 (69, 79)	75	±7	76 (72.5, 79.5)	.12*	75	±7	75 (70, 79)
Male gender	48	66		86	77		.1	134	72	
Cardiovascular risk factors										
Hypertension	67	94		97	87		.09	164	90	
Smoker	63	89		96	86		.56	159	87	
Hypercholesterolemia	59	83		90	80		.64	149	81	
Coronary artery disease	43	61		69	62		.89	112	61	
Chronic obstructive pulmonary disease	37	52		51	46		.39	88	48	
MI	23	32		45	40		.29	68	37	
Arrhythmia	9	13		23	21		.17	32	17	
Diabetes mellitus	10	14		21	19		.41	31	17	
CHF	7	10		19	17		.18	26	14	
Stroke/TIA	7	10		13	12		.71	20	11	
Preoperative evaluation and comorbidity scores										
Positive cardiac stress test	9	14		28	29		.035	37	23	
Baseline creatinine (mg/dL)	1.4†	±1.4	1.0 (0.9, 1.3)	1.3	±0.5	1.1 (1.0, 1.4)	.32*	1.3	±1	1.1 (0.9, 1.4)
Baseline glomerular filtration rate (mL/min/1.73 m ²)	62†	±22	65 (48.5, 75)	60	±20	58.5 (45, 72)	.54*	60	±21	60.5 (45.5, 73)
Chronic kidney disease stage	23	32		37	33		.83	60	32	
III-V										
Stage III	19	83		30	81			49	82	
Stage IV	2	9		6	16			8	13	
Stage V	2	9		1	3			3	5	
BMI (kg/m ²)	27	±5		29	±6		.036	28	±6	
ASA clinical score							.13			
I	4	6		12	11			16	9	
II	34	47		57	51			91	49	
III	27	38		34	30			61	33	
IV	4	6		9	8			13	7	
V	3	4		0	0			3	2	
SVS total score (0-30)	12	±4		13	±4		.029	13	±4	
Connective tissue disorder	2	3		2	2		.91	4	2	
Peripheral arterial disease	22	31		38	34		.68	60	33	
Medical history										
Previous aortic surgery	39	54		30	27		<.001	69	38	
Previous abdominal surgery	41	57		46	41		.035	87	47	
Endovascular aortic intervention	18	25		17	15		.1	35	19	
History of malignancy	16	23		27	24		.81	43	23	
Family history of aortic aneurysm	10	15		10	12		.57	20	13	

Continuous data are presented as mean ± SD; categorical data are given in percentage. Q1 and Q3 refer to 25th and 75th percentiles, respectively. N, Number of patients; SD, standard deviation; MI, myocardial infarction; CHF, congestive heart failure; TIA, transient ischemic attack; BMI, body mass index; ASA, American Society of Anesthesiologists; SVS, Society for Vascular Surgery. *Equal variance *t* test. †One missing entry.

and manufactured devices in 107 patients (58%, 68 extent IV and 36 extent I-III). A total of 681 renal-mesenteric arteries (170 celiac, 183 superior mesenteric, 161 right renal, and 167 left renal arteries) were incorporated by 538 fenestrations and 143 directional branches, with a mean of 3.7 vessels per patient (Table E1).

Among patients treated for extent IV TAAAs, there were 421 vessels incorporated by 393 fenestrations (93%) and 28 directional branches (7%). For extent I to III TAAAs, there were 260 vessels incorporated by 145 fenestrations (56%) and 115 directional branches (44%).

Endovascular Repair

All procedures were performed in a hybrid endovascular room with a fixed imaging unit using general endotracheal anesthesia in 184 patients (99%) (Table 2). Cerebrospinal fluid drainage was used in 147 patients (79%), and neuro-monitoring was used in 110 patients (59%). Ninety-six patients (52%) had total percutaneous transfemoral approach with a preclosure technique, and 19 patients required an iliac conduit (10%). Total volume of contrast and fluoroscopy time averaged 183 ± 72 mL and 95 ± 44 minutes, respectively. Contrast use and fluoroscopy time were significantly higher in patients with extent I to III TAAAs ($P < .001$). Technical success, defined by placement of the aortic stent and all intended side branches, was achieved in 174 patients (94%) and was 96% for extent IV TAAAs (96%) and 90% for extent I to III TAAAs ($P = .09$). Estimated blood loss was 903 ± 1164 mL with no difference between groups. Eighty-one patients (44%) received transfusion of packed red blood cells during the procedure.

Mortality

There were 8 deaths (4.3%) within 30 days and 7 deaths (3.7%) within the hospital stay (Tables 3 and E2). There were 2 deaths among patients treated for extent IV TAAA repair (1.8%) and 6 deaths in those treated for extent I to III TAAA repair (8.2%, $P = .035$) in the first 30 days. All deaths occurred among patients treated by PMEGs, and there was no mortality in patients treated using manufactured devices under the prospective IDE study. Time to accumulate the first half of the experience was 78 months,

compared with 21 months for the second half of the experience (Figure 2). During this period, mortality decreased from 7.5% to 1.2% ($P = .03$), including a decrease of 3.3% to 0% for extent IV TAAAs ($P = .19$) and 15.6% to 2.4% for extent I to III TAAAs ($P = .04$). Causes of death were ischemic colitis with multisystem organ failure in 2 patients and myocardial infarction, cardiac arrest after rapid ventricular pacing, pulmonary aspiration, stroke, acute renal failure, and unknown cause in 1 patient each.

Major Adverse Events

There were 107 MAEs in 67 patients (36%) in the entire cohort (Table 3). In the early follow-up (<30 days), 62 patients had MAEs, including 36 patients (32%) treated for extent IV TAAAs and 26 patients (36%) treated for extent I to III TAAAs ($P = .91$). The most common MAE in the first 30 days was estimated blood loss of more than 1 liter in 41 patients (22%), followed by acute kidney injury in 23 patients (12%), respiratory failure requiring reintubation in 10 patients (5%), myocardial infarction in 9 patients (5%), paraplegia (grade 3a-c SCI) in 6 patients (4.3%), stroke in 5 patients (3%), and bowel ischemia requiring surgical resection or intensification of therapy in 4 patients (2%). Nine patients (4.8%) had spinal cord injuries, including 3 treated for extent IV TAAAs (2.7%) and 6 treated for extent I to III TAAAs (8.2%). Of these, 3 patients had grade I to II SCIs and were ambulatory. Six patients (3.6%) had grade IIIa to IIIc nonambulatory injuries, including 2 with extent IV TAAAs (1.8%) and 4 with extent I to III TAAAs

TABLE 2. Procedural details in 185 patients treated for thoracoabdominal aortic aneurysms with fenestrated-branched stent-grafts

Variable	Extent I-III		Extent IV		P value	Overall	
	(N = 73)		(N = 112)			(N = 185)	
General anesthesia	72	99%	112	100%		184	99%
Cerebrospinal fluid drainage	72	99%	75	67%	<.001	147	79%
SSP/motor-evoked potentials	50	68%	60	54%	.043	110	59%
Percutaneous	37	51%	59	54%	.7	96	52%
Amount of contrast used (mL)	206	±84	168	±58	<.001	183	±72
Total fluoroscopy time (min)	105	±54	89	±35	.015	95	±44
Estimated blood loss (mL)	1080	±1427	787	±945	.09	903	±1164
Transfusion of blood products							
PRBC	42	58%	39	35%	.002	81	44%
Volume (mL)	1094	±966	899	±883	.3	1000	±926
FFP	14	19%	11	10%	.07	25	14%
Volume (mL)	847	±354	773	±711	.7	814	±529
Platelets	16	22%	13	12%	.06	29	16%
Volume (mL)	426	±170	587	±337	.1	498	±266
Cryoprecipitate	8	11%	3	3%	.021	11	6%
Volume (mL)	187	±36	240	±42	.1	202	±43
Hypogastric branches (unilateral or bilateral)	1	1.4%	4	3.6%	.58	5	2.7%
No. of vessels stented per patient (mean)	3.6	±0.84	4	±0.72	.05	3.7	±0.77
Iliac conduit	5	6.8%	11	9.8%	.87	16	8.6%

N, Number of patients; SSP, somatosensory evoked potential; PRBC, packed red blood cells; FFP, Fresh-frozen plasma.

TABLE 3. Early mortality and major adverse events less than 30 days in 185 patients treated for thoracoabdominal aortic aneurysms with fenestrated-branched endovascular repair

Variable	Type I-III		Type IV		P value	Overall	
	(N = 73)		(N = 112)			(N = 185)	
Any cause of mortality	6	8%	2	2%	.83	8	4%
Any MAE	26	36%	36	32%	.62	62	34%
Estimate blood loss >1000 mL	20	27%	21	19%	.17	41	22%
Acute kidney injury (>50% decrease in GFR)	7	11%	14	13%	.62	21	11%
New-onset dialysis*	1	1.3%	1	0.8%	.74	2	1%
MI	1	1%	8	7%	.07	9	5%
Respiratory failure	7	10%	3	3%	.042	10	5%
Paraplegia (SCI grade 3a-3c)	4	5%	2	2%	.16	6	3%
Stroke	2	3%	3	3%	.98	5	3%
Bowel ischemia requiring intensification of medical therapy	1	1%	3	3%	.55	4	2%

N, Number of patients; MAE, major adverse event; GFR, glomerular filtration rate; MI, myocardial infarction; SCI, spinal cord injury. *One patient discontinued dialysis after 12 days.

(5.5%). Four SCIs were immediate, and 5 SCIs were delayed. For the entire cohort, the rate of SCI decreased in the second half experience from 5.4% to 1.1% ($P = .09$). Two patients (1%) required new-onset dialysis, which was discontinued in 1 patient after 12 days and in the other patient after 4 months.

Late Outcomes

Mean follow-up averaged 22 ± 20 months (range, 1-97). Follow-up imaging studies were obtained in 179 patients with a mean of 3 studies per patient. Follow-up was

complete in all 105 patients treated with manufactured devices under a prospective IDE study. Patient survival at 5 years was similar for extent IV and extent I to III TAAAs (Figure 3), $56\% \pm 10\%$ and $59\% \pm 9\%$ ($P = .37$). There was 1 late aneurysm-related death due to rupture of the descending thoracic aortic dissection, which occurred proximal to a TAAA branched endograft used to treat an extent III TAAA. There were no conversions to open surgical repair or ruptures within the treated aortic segment.

Fifty-three patients (29%) required 68 secondary reinterventions, which were performed within the first 30 days in

FIGURE 2. Graph of number of consecutive patients treated for type IV and type I to III TAAAs between 2008 and March 2016. Note the decrease in mortality from 7.5% in the first half to 1.2% in the second half experience ($P = .04$). TAAA, Thoracoabdominal aortic aneurysm; F-BEVAR, fenestrated and branched endovascular aortic repair.

FIGURE 3. Kaplan–Meier estimates of overall patient survival in 185 consecutive patients treated for type IV and type I to III TAAAs between 2008 and March 2016.

26 patients (14%, 31 procedures) and after 30 days in 27 patients (15%, 37 procedures) (Tables 4 and E3). These included 48 aortic-related procedures (46 percutaneous, 2 open surgical) and 20 nonaortic-related procedures. The

most common indications for a reintervention were endoleak in 23 procedures (25%; 17 type III, 5 type II, 1 type I) or target vessel stenosis or kink in 13 procedures (19%). Freedom from any reintervention was 50% ± 9%

TABLE 4. Description of early and late reinterventions in patients treated by fenestrated and branched endovascular repair for thoracoabdominal aortic aneurysms

Types of reinterventions	<30 d		>30 d		Total	
	N = 185	%	N = 177	%	N = 185	%
Aortic						
Device or branch stenosis/kinking/occlusion	6	3	7	4	13	7
Device or branch migration	1	1	0	0	1	1
Aneurysm degeneration	0	0	2	1	2	1
Endoleak						
Type I	0	0	1	1	1	1
Type II	0	0	1	1	1	1
Type III	6	3	11	6	17	9
Combined	0	0	4	2	4	2
Endotension (V)	0	0	1	1	1	1
Type A dissection	1	1	0	0	1	1
Type B dissection	1	1	0	0	2	1
Planned reintervention (SCI prevention protocol)	6	3	0	0	6	3
Type of reintervention						
Percutaneous	19	10	27	15	46	25
Surgical	2	1	0	0	2	1
Total	21	11	27	15	48	26
Nonaortic						
Access site complications	5	3	8	5	13	7
Laparotomy	4	2	2	1	6	3
Lower-limb fasciotomy	1	1	0	0	1	1
Total	10	5	10	6	20	11

N, Number of patients; SCI, spinal cord injury.

for extent IV and $53\% \pm 10\%$ for extent I to III at 5 years ($P = .26$) (Figure 4).

Eighty-five patients had at least 1 endoleak identified by follow-up computed tomography angiography, including type I endoleak in 2 patients (type Ic), type II endoleak in 55 patients, type III endoleak in 29 patients, and indeterminate endoleak in 12 patients. Of these, 23 patients had reinterventions, including 17 (9%) who had treatment of type III endoleaks, in whom 12 (6%) were due to the attachment of the fenestration and alignment stent.

Thirteen patients (7%) had reinterventions to treat target vessel stenosis, kink, or occlusion. Primary target vessel patency at 1 and 5 years was $94\% \pm 0.9\%$ and $93\% \pm 2\%$, respectively (Figure E5).

DISCUSSION

Fenestrated and branched stent-grafts were introduced as an alternative to treat complex aneurysms in higher-risk patients who were not considered good candidates for open surgical repair. The indications of F-BEVAR have been broadened to patients with chronic dissection or failed aortic repair, and intermediate-risk patients.^{15,16} This report reflects the evolution of F-BEVAR techniques in our institution. Over nearly a decade of experience, the use of PMEGs was discontinued because of improved quality control, operating room efficiency, design versatility, and better reimbursement of manufactured devices, along with compliance with federal regulations and lack of long-term data for PMEGs. We also incorporated a number of adjunctive techniques, such as staging for extent I to II repairs and routine use of neuromonitoring,

cerebrospinal fluid drainage, and early limb reperfusion.⁹ Overall, our results demonstrate low morbidity and mortality (4.3%), which have declined significantly in the second half experience (7.5% to 1.2%). However, further technical refinements are needed to address the high rate of percutaneous aortic-related reinterventions to treat type III endoleaks or branch stenosis.

Stent design for TAAA repair continues to evolve with the primary goals of facilitating technical implantation and optimizing branch outcomes. Although there is controversy with respect to the ideal configuration, most experts agree that directional branches are easier to implant, have longer attachment to the aortic component, and rarely lead to endoleaks.^{2,17-19} These devices are well suited for down-going vessels that have an origin from the large aortic lumen. Conversely, fenestrations require precise planning and implantation, and are ideal for vessels that have an origin from the narrow aortic lumen and that are oriented in a transverse or up-going angle, such as the renal arteries in patients with extent IV and extent I TAAAs.^{19,20} Because of some reports of higher rates of renal occlusion for directional branches (up to 10% in 5 years), several experts have advocated the preferential use of fenestrations, which have low occlusion rates (<2%).¹⁷⁻¹⁹ However, fenestrations may lead to type III endoleaks (12%) due to branch disconnection or short overlap.³ Our rate of type III endoleak (12%) from fenestrations was nearly identical to what has been reported by Eagleton and colleagues³ in a review of 354 patients treated for extent I to III TAAAs. To reduce rates of type III endoleaks, occlusions, and reinterventions, newer designs should focus on improvements in overlapping

FIGURE 4. Kaplan–Meier estimates of freedom from any aortic and nonaortic-related reintervention in 185 consecutive patients treated for type IV and type I to III TAAAs between 2008 and March 2016.

segments, bridging stent technology, and antiplatelet therapy.

The most feared complication of TAAA repair is paraplegia. Rates of SCI have varied from as low as 1.2% to as high as 31%.⁶⁻⁸ The risk is increased by extensive aortic coverage, occlusion of spinal collaterals, perioperative hypotension, lower-limb ischemia, and use of single-stage repair. Greenberg and colleagues²¹ reported a nonsignificant trend toward lower rates of SCI with endovascular repair (4.3%) compared with open surgical repair (7.8%) among 724 patients treated for TAAAs. For extent II TAAAs, both open (22%) and endovascular (19%) repair were associated with high rates of SCI. Subsequently, Eagleton and colleagues²² presented the results of 1251 patients with an overall rate of SCI of 2.9%. The authors found that subclavian or hypogastric artery occlusion predicted the immediate onset of paraplegia and lack of recovery.

The concept of adaptation of collateral spinal network has been studied in experimental models, with some early experience in humans.^{23,24} Strategies for staged segmental arterial coverage using endovascular techniques include proximal thoracic endovascular aortic repair (Figure E1), temporary aneurysm sac perfusion (TASP), or intentional coil embolization of intercostal arteries.^{4,7-9} O'Callaghan and colleagues⁷ reported on 87 patients treated for extent II TAAAs using a single or 2-stage approach. In that study, staged repair was associated with no early mortality (0% vs 19%) or permanent paraplegia (0% vs 16%). TASP requires specially designed perfusion branches to induce an endoleak, leaving the repair incomplete. Kasprzak and colleagues⁴ reported a decrease in paraplegia risk from 21% to 2.5% using TASP. Although we have used perfusion branches in 6 patients with good outcomes, we no longer apply the technique because of potential risk of disseminated intravascular coagulopathy from high-flow endoleaks and the need to place all stents within a single-stage procedure, which prolongs operating time. Etz and colleagues²⁵ recently reported on 2 patients who had intentional coil embolization of intercostal arteries before endovascular or open TAAA repair. Although this technique provides reliable segmental arterial occlusion, it adds a potential risk of embolization from catheter manipulations and requires that all stents be placed in a single operation. Maurel and associates⁸ reported lower rates of SCI (2% vs 25%) using early limb reperfusion. Our improved rates of SCI reflect better patient selection and techniques of implantation, as well as routine use of the preventive measures outlined earlier.

Branch stability continues to be a focus of research. The ideal branch should optimize flow and aneurysm seal, avoiding endoleak, migration, fracture, kinks, stenosis, or occlusions. Mastracci and colleagues¹⁸ reported a 10-year experience with 1679 target vessels using a composite end point to define branch stability, which included any endoleak, stenosis, occlusion, disconnection, or reintervention

in a branch. Freedom from branch-related events was 89% in 5 years and 70% in 10 years.¹⁸ O'Callaghan and associates²⁶ reported that most type I endoleaks after fenestrated endografts became evident after 2 to 5 years, and that patients with type I endoleaks had shortened survival. Fortunately, with proper planning, the risk of type I endoleak is low, as evidenced by our study (0.5%).

Endovascular aortic repair continues to be plagued by high reintervention rates, and it is logical that devices with multiple branches have more modules subjected to risk of failure. In our study, most reinterventions were done using percutaneous technique under local anesthesia, often as an outpatient. Coselli and colleagues²⁷ recently reported the largest worldwide experience in a seminal study of 3309 patients treated for TAAA by open surgical repair over 2 decades. Thirty-day mortality was 7.5% for the entire cohort and 6.5% for elective cases, including a mortality of 5.1% for extent IV and 8% for extent I to III TAAAs. The mean age of patients was 66 years, and one third of the patients had aortic dissections. Although mortality rates were remarkably low compared with other reports, there were significant complications, including SCI (9.6%), dialysis (7.6%), and tracheostomy (8.5%). The rate of any reintervention, which should factor all reoperations for bleeding, tracheostomy, wound problems, hernias, and other gastrointestinal complications, was not reported. However, freedom from aortic failure was remarkably low at 94% in 15 years, indicating that these procedures are incredibly durable and should be considered in young, fit patients with complex dissections and genetically triggered aortic diseases. For nondissected aneurysms, patient survival was 63% at 5 years, which compares favorably with our patient survival of 59% in a higher-risk group. In octogenarians, Aftab and colleagues²⁸ reported significantly higher morbidity and mortality.

Selection of open or endovascular repair should be tailored to patient age, clinical risk, presence of genetically triggered aortic diseases, and anatomy. For patients aged less than 65 years and who have genetically triggered aortic diseases, we continue to offer open surgical repair as the first treatment option. However, we have expanded the indications of endovascular repair to include not only higher-risk patients but also those who are low or intermediate risk and have favorable anatomy. The ideal patient has minimal atherosclerotic debris within healthy aortic segments, adequate iliofemoral and brachial access, and suitable renal and mesenteric target vessels with no early bifurcation or occlusive disease.

Study Limitations

Although the clinical data on patients treated by manufactured devices were collected prospectively, the experience with PMEGs was retrospective using off-label device modifications to treat a higher-risk group. There was a

significant impact of the learning curve, which is reflected by significant differences in patient selection (Table E4) and improvements in procedural variables (Table E5). As a result, we observed a significant decline in mortality from 7.5% to 1.2% in the second half experience. Our results should not be generalized, and outcomes such as type III endoleaks, branch stenosis, and reinterventions are likely to be affected by improvements in device design and side branch technology. Because our sample size is small, we were not able to analyze outcomes by specific groups among patients with more extensive TAAAs.

CONCLUSIONS

Endovascular repair of TAAAs continues to evolve with improvements in device design, implantation techniques, and adjunctive maneuvers to decrease mortality and paraplegia. Our study shows high technical success and low mortality and morbidity, which improved in the late experience after introduction of manufactured devices. There was a high rate of reinterventions to treat type III endoleaks and branch vessel stenosis, which should be the focus of future refinements in the technique. Although this technique has major benefits in the elderly and higher-risk patients, long-term data are still needed before widespread use in lower-risk groups.

Conflict of Interest Statement

G.S.O. has a consulting agreement with Cook Medical Inc, and WL Gore & Associates (all consulting fees paid to the Mayo Clinic) and receives research grants from Cook Medical Inc, and WL Gore & Associates (paid to the Mayo Clinic). All other authors have nothing to disclose with regard to commercial support.

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Key Words: fenestrated and branched stent-grafts, thoracoabdominal aortic aneurysms, endovascular repair, fenestrations, branches

FIGURE E1. Illustration of a patient who underwent prior elephant trunk repair for extensive thoracoabdominal dissection (A), followed by first-stage thoracic endovascular aortic repair with right iliac artery reconstruction (B and C). The patient had complete repair in 1 week using a multibranch off-the-shelf stent-graft (D and E).

FIGURE E2. Computed tomography angiography of a patient with extent III TAAA (A), treated by patient-specific design using directional branches for the celiac axis and superior mesenteric artery (B) and fenestrations for the renal arteries (C). Illustration and computed tomography angiography of the complete repair (D and E).

FIGURE E3. Staging of extensive TAAAs can be done using proximal thoracic endovascular repair or perfusion branches. Printed with permission from Banga and colleagues.⁹

FIGURE E4. Standardized maneuvers and protocol triggered by changes in motor and somatosensory evoked potentials. Printed with permission from Banga and colleagues.⁹ MEP, Motor evoked potential; SSEP, somatosensory evoked potential; CSF, cerebrospinal fluid; MAP, mean arterial pressure.

FIGURE E5. Kaplan–Meier estimates of primary target vessel patency in patients treated for TAAAs with 681 renal-mesenteric fenestrations and branches.

TABLE E1. Stent-graft design in 185 patients treated for thoracoabdominal aortic aneurysms with fenestrated-branched stent-grafts

Variable	Type I-III		Type IV		P value	Overall	
	(N = 73)	%	(N = 112)	%		(N = 185)	%
Manufactured grafts	39	53	68	61		107	58
Physician-modified grafts	34	47	44	39		78	42
Celiac axis					<.001		
No	9	12	5	5		14	8
Fenestration	27	37	96	86		123	67
Directional branch	37	51	10	9		47	26
SMA					<.001		
No*	2	3	0	0		2	1
Fenestration	34	47	103	92		137	74
Directional branch	37	51	9	8		46	25
Right renal artery					<.001		
No	12	16	11	10		23	13
Fenestration	38	52	96	86		134	73
Directional branch	23	32	4	4		27	15
Left renal artery					<.001		
No	9	12	8	7		17	9
Fenestration	46	63	98	88		144	78
Directional branch	18	25	5	5		23	13

N, Number of patients; SMA, superior mesenteric artery. *Two patients had celiomesenteric trunks incorporated by single fenestration.

TABLE E2. Causes of early and late death among patients treated for thoracoabdominal aortic aneurysms

Variable	Extent I-III		Extent IV		Total	
	N = 73	%	N = 112	%	N = 185	%
Early mortality	6	8	2	2	8	4
Acute MI	0	0	1	1	1	1
Multisystem failure due to sepsis (complications of ischemic colitis)	0	0	1	1	1	1
Type A dissection	1	1	0	0	1	1
Ischemic colitis	1	1	0	0	1	1
Cardiac arrest after rapid ventricular pace	1	1	0	0	1	1
Acute on chronic renal failure	1	1	0	0	1	1
Multifocal stroke/MI	1	1	0	0	1	1
Unknown	1	1	0	0	1	1
Late mortality	11	15	20	18	31	17
Metastatic advanced small cell	0	0	1	1	1	1
Respiratory failure/UTI/malnutrition	0	0	1	1	1	1
Complications of subdural hematoma	0	0	1	1	1	1
Esophageal cancer	0	0	1	1	1	1
Congestive heart failure	0	0	3	3	3	2
Consumptive syndrome/chronic	1	1	0	0	1	1
Mantle cell lymphoma	1	1	0	0	1	1
Proximal rupture of the descending thoracic aorta	1	1	0	0	1	1
Unknown	8	11	13	12	21	11
Total	17	23	22	20	39	21

N, Number of patients; MI, myocardial infarction; UTI, urinary tract infection.

TABLE E3. Summary of types of branch related failures in patients with physician-modified endovascular grafts and manufactured devices

Variable	Vessel	Type of incorporation	Type of endograft
Reinterventions for endoleak			
Type Ic	LRA/SMA	Branches	MD
Type III	LRA	Fenestration	MD
Type III	SMA	Fenestration	MD
Type III	LRA	Fenestration	MD
Type III	CA/SMA/RRA/LRA	Fenestrations	MD
Type III	SMA	Fenestration	PMEG
Type III	SMA/LRA/RRA	Fenestrations	PMEG
Type III	SMA	Fenestration	PMEG
Type III	RRA	Fenestration	PMEG
Type III	CA/SMA/LRA/RRA	Fenestrations	PMEG
Type III	RRA	Fenestration	PMEG
Reinterventions for loss of patency			
Occlusion	RRA	Fenestration	PMEG
Stenosis	RRA/LRA	Fenestrations	MD
Stenosis	RRA	Branch	MD
Stenosis	RRA	Fenestration	MD
Stenosis	SMA	Fenestration	MD
Stenosis	LRA	Fenestration	MD
Stenosis	CA/LRA	Fenestrations	PMEG
Kinking	SMA	Fenestration	PMEG
Kinking	SMA	Fenestration	PMEG
Kinking	LRA	Fenestration	PMEG

LRA, Left renal artery; SMA, superior mesenteric artery; MD, manufactured device; CA, celiac artery; PMEG, physician-modified endovascular graft; RRA, right renal artery.

TABLE E4. Demographics and clinical characteristics in 185 patients treated for thoracoabdominal aortic aneurysms with fenestrated-branched stent-grafts, divided in the first and second halves of the surgeon experience

Variable	First half N = 93		Second half N = 92		P value	Overall (N = 185)	
	± SD or %		± SD or %				
Age (y)	75.01	±6.72	74.41	±7.29	.56	75	±7
Male gender	68	73	66	72	.83	134	72
Cardiovascular risk factors				0			
Hypertension	84	90	81	89	.77	164	90
Smoker	78	84	82	90	.21	159	87
Hypercholesterolemia	77	83	72	79	.53	149	81
Coronary artery disease	66	71	46	51	.005	112	61
Chronic obstructive pulmonary disease	57	61	32	35	<.001	88	48
MI	41	44	27	30	.043	68	37
Arrhythmia	25	27	7	8	<.001	32	17
Diabetes mellitus	13	14	18	20	.29	31	17
CHF	17	18	9	10	.1	26	14
Stroke/TIA	9	10	11	12	.6	20	11
Preoperative evaluation and comorbidity scores							
Positive cardiac stress test	24	30	13	15	.04	37	23
Baseline creatinine (mg/dL)	1.34	±1.08	1.28	±0.80	.7	1.3	±1
Baseline glomerular filtration rate (mL/min/1.73 m ²)	61.04	±21.80	59.85	±19.82	.7	60	±21
Chronic kidney disease stage III to V		0		0	.013	60	32
Stage III	35	83	14	74		49	82
Stage IV	3	7	5	26		8	13
Stage V	3	7	0	0		3	5
BMI (kg/m ²)	28.02	±6.33	28.16	±5.16	.87	28	±6
ASA clinical score					<.001		
I	7	8	9	10		16	9
II	32	34	60	65		91	49
III	43	46	18	20		61	33
IV	11	12	2	2		13	7
V	0	0	3	3		3	2
SVS total score (0-30)	1.35	±0.44	1.19	±0.40	.013	13	±4
Connective tissue disorder	3	3	1	1	.24	4	2
Peripheral arterial disease	36	39	24	26	.07	60	33
Medical history							
Previous aortic surgery	34	37	35	38	.83	69	38
Previous abdominal surgery	45	48	43	47	.82	87	47
Endovascular aortic intervention	13	14	22	24	.08	35	19
History of malignancy	26	28	18	20	.19	43	23
Family history of aortic aneurysm	4	100	12	80	.33	20	13
Hostile abdomen	39	42	18	20	<.001	57	31

Continuous data are presented as mean ± SD; categorical data are given in percentage. *N*, Number of patients; *SD*, standard deviation; *MI*, myocardial infarction; *CHF*, congestive heart failure; *TIA*, transient ischemic attack; *BMI*, body mass index; *ASA*, American Society of Anesthesiologists; *SVS*, Society for Vascular Surgery.

TABLE E5. Procedural variables and stent design in 185 patients treated for thoracoabdominal aortic aneurysms with fenestrated-branched stent-grafts, divided in the first and second halves of the surgeon experience

Variable	First half		Second half		P value
	N = 93	% or mean $\pm$ SD	N = 92	% or mean $\pm$ SD	
General anesthesia	93	100%	91	99%	.31
Cerebrospinal fluid drainage	69	74%	78	85%	.07
SSP/motor-evoked potentials	31	33%	79	86%	<.001
Percutaneous	27	29%	69	76%	<.001
Amount of contrast used (mL)	195	± 83.08	170.1	± 55.77	.016
Total fluoroscopy time (min)	109	± 49.99	80.14	± 30.00	<.001
Estimated blood loss (mL)	1268	± 1457.92	533.8	± 564.21	<.001
Transfusion of blood products					
PRBC	1208	± 1080.94	702.5	± 481.26	.015
FFP	863	± 604.39	726.9	± 375.83	.55
Platelets	539	± 278.38	371	± 183.44	.15
Cryoprecipitate	206	± 11.59	197	± 66.68	.76
Device					<.001
Manufactured grafts	19	20%	88	96%	
Physician modified	74	80%	4	4%	
Device type					<.001
IDE	18	19%	88	96%	
Z-fen	1	1%	0	0%	
Physician modified	74	80%	4	4%	
Total renal mesenteric vessels ≥ 4 target vessels	65	70%	76	83%	.042
Total renal-mesenteric vessels	3.58	± 0.78	3.8	± 0.77	.05
No. of fenestrations	3.39	± 1.09	2.43	± 1.71	<.001
No. of scallops	0.03	± 0.18	0	± 0.00	.09
No. of directional branches	0.16	± 0.66	1.45	± 1.63	<.001
No. of perfusion branches	0.03	± 0.18	0	± 0.00	.09
Conduit	24	27%	24	26%	.89

N, Number of patients; SD, standard deviation; SSP, somatosensory evoked potential; PRBC, packed red blood cells; FFP, Fresh-frozen plasma; IDE, investigational device exemption.