Featured Article

Total aortic arch replacement using the Thoraflex Hybrid device: evolution from investigational to federally approved use in the United States

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Background: After the US Food and Drug Administration (FDA) approved the Thoraflex Hybrid device in April 2022, hybrid devices to facilitate total arch replacement (TAR) became commercially available in the United States. However, little is known about how the Thoraflex device has been used since then. We present our experience (2016–2025) with this device.

Methods: At our practice, 62 patients [median age, 65 (54–73) years] underwent frozen elephant trunk (FET) TAR with the Thoraflex device: 14 under an investigational device exemption (IDE) (2016–2018) and 48 after FDA approval (2022–2025). Both Ante-Flo (straight) and Plexus (branched) models were used.

Results: Patients with aortic dissection were common (n=38; 61%). Many patients had prior open or endovascular aortic repair (n=28; 45%). Initial cannulation was commonly done via the innominate artery (n=30; 48%) or the right axillary artery (n=22; 36%). Both branched and island strategies were used to reattach the brachiocephalic arteries. Selectively, left subclavian artery (LSCA) bypass was performed before TAR in 18 patients (29%). The distal anastomosis was performed proximal to the LSCA in 27 repairs (43%). A short (10-cm) endograft extension was used in most cases (n=49; 79%). Eight (13%) patients underwent concomitant aortic root replacement. Overall, four patients (7%) had operative deaths, and three (5%) were discharged with stroke or persistent need for renal dialysis. Two patients had spinal cord deficits that resolved before discharge. Twenty-five downstream extensions (12 open, 13 endovascular) were needed in 22 patients; two patients underwent more than one repair. After discharge, seven additional patients died within one year of surgery.

Conclusions: TAR is a complex procedure. Patients requiring such repair tend to have substantial disease that often eventually necessitates subsequent downstream aortic repair, especially when dissection is present. Using the Thoraflex Hybrid device in TAR results in good early outcomes and provides a reliable base for extension.

Keywords: Aortic aneurysm; aortic dissection; total arch replacement (TAR); frozen elephant trunk (FET); transverse aortic arch

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Introduction

The frozen elephant trunk (FET) technique represents a significant advancement in addressing complex thoracic aortic disease by simultaneously treating the transverse aortic arch and the proximal segment of the descending thoracic aorta, as well as providing a stable landing zone for future downstream extension. Initially, FET prostheses were manually crafted by combining polyester grafts with endovascular stent-grafts (1,2). The FET procedure evolved with the introduction of prefabricated hybrid devices; notably, these included the Thoraflex Hybrid device (Terumo Aortic, Sunrise, FL, USA), which has been available in Europe and elsewhere since 2012 (1,3).

In the United States, FET procedures were historically performed with off-label combinations of open and endovascular repair (4,5). Most commonly, this involved using a collared elephant trunk graft as part of a total arch replacement (TAR) with open antegrade deployment of the endograft into the polyester trunk (5-8). Several sites in the United States participated in the investigational device exemption (IDE) trial, the pivotal *Thoraflex™ Hybrid IDE Study*, with Joseph S. Coselli serving as the trial's principal investigator; patient enrollment was completed in 2018 (9). The US Food and Drug Administration (FDA) gave the Thoraflex Breakthrough Device Designation in April 2020 and formally approved it for the treatment of patients with complex aortic disease in April 2022, allowing more widespread use in the United States. However, little of this emerging experience has been published.

We describe our experience with TAR using the Thoraflex device, from our experience leading the US IDE trial (9) to our contemporary use of the device after FDA approval, including how any remaining diseased segments of the downstream aorta were subsequently addressed.

Methods

Study protocol and patient cohort

Baylor College of Medicine's Institutional Review Board (IRB) granted approval for our clinical research protocol (#18095) in 2006. For patients operated on after protocol approval, clinical data were collected prospectively, with informed consent obtained whenever clinically and logistically feasible. When patients were unable to provide consent due to their medical condition and had no available family members or legally authorized representatives to provide consent on their behalf, a waiver of informed consent was granted. For those who underwent surgery before protocol approval, data were collected retrospectively from medical records under an approved waiver of consent. When needed, medical records were reviewed to verify and clarify previously abstracted data.

From 2016 to 2025, 62 patients underwent TAR using the Thoraflex Hybrid device at our practice. Fourteen of these repairs were part of the US IDE trial (2016–2018); the other 48 were performed after FDA approval (2022–2025).

Study definitions and follow-up

All data were collected using standard definitions reported in recent publications. Operative death was defined as death within 30 days of surgery or before final discharge from the hospital, including transfers to another hospital or a long-term acute care facility. Adverse event—a composite endpoint—was defined as operative death or persistent (present at hospital discharge) stroke, spinal cord deficit, or renal failure necessitating dialysis. Operative survivors were generally contacted for clinical follow-up 30 days postoperatively and then annually; patients participating in the IDE trial were contacted more frequently. We reviewed medical records (including those in Care Everywhere), made follow-up calls, and performed internet searches to enhance the completeness of our data. Although no patients were lost to follow-up at the time of hospital discharge, internet obituary searches were used to determine vital status for some patients. All surviving patients had follow-up in 2024 or 2025.

Surgical techniques

Regarding the Thoraflex Hybrid device, we use both the Ante-Flo (straight tube) and Plexus (branched) models with both 10- and 15-cm endovascular segments (9). All procedures were performed through a median sternotomy under cardiopulmonary bypass, with moderate hypothermic circulatory arrest (which shifted from 22–24 to 26–28 ℃ in recent repairs), and antegrade cerebral perfusion (with or without retrograde cerebral perfusion). Perfusion was commonly initiated via right axillary or innominate artery cannulation, with additional support from a balloon perfusion catheter inserted into the left common carotid artery.

Although our precise approach to TAR varies depending on patient need, pathological anatomy, and surgeon

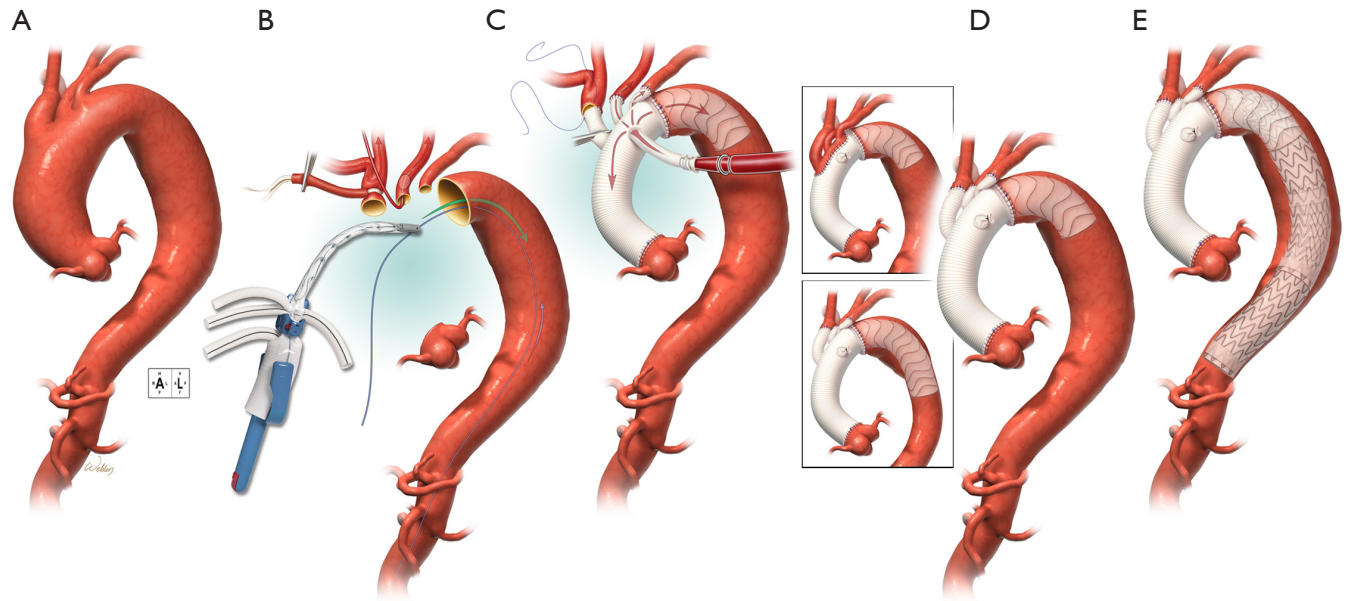

Figure 1 Illustration of total aortic arch replacement using the Thoraflex Hybrid Plexus (branched) device, manufactured by Terumo Aortic. (A) An extensive aneurysm spans the ascending aorta, aortic arch, and descending thoracic aorta. (B) The right axillary artery is cannulated, and antegrade cerebral perfusion is aided by inserting a balloon perfusion catheter into the left common carotid artery. The aorta is transected at the sinotubular junction and distal to the left subclavian artery. A guidewire is advanced retrograde via the femoral artery and manually retrieved through the transected descending thoracic aorta. The Thoraflex device is threaded onto the guidewire and advanced antegrade into the descending thoracic aorta. (C) After the endograft is deployed, the delivery system is removed. Incorporating the device collar and residual native aorta completes the distal anastomosis, which secures the endograft portion and prevents migration. The brachiocephalic arteries are incorporated into the non-stented graft portion of the device with graft bypass using the branched Plexus model or by island reattachment using the Ante-Flo model (inset). The proximal anastomosis is completed at the level of the sinotubular junction unless additional patient-specific repair is needed. Supplemental perfusion is provided through a side branch while the brachiocephalic arteries are incorporated into the repair. (D) Although the total arch replacement repair (stage 1) is complete, additional repair to address the descending thoracic aorta is needed. Inset: In some patients, definitive repair in a single stage is possible. (E) After a variable period of recovery, an endovascular completion (stage 2) repair is performed. Commonly, one or more stent-grafts are advanced retrograde via the femoral artery. Stent-grafts are recommended to overlap the Thoraflex by 4 cm whenever possible. Used with permission of Baylor College of Medicine.

preference, the repair typically begins by opening the ascending aorta and transverse aortic arch, followed by manual retrieval of a guidewire that has been advanced retrograde from the femoral artery. Thereafter, the Thoraflex device is threaded onto the guidewire, the preloaded Thoraflex delivery system is inserted antegrade through the transected aorta, and the delivery system is positioned in the proximal segment of the descending thoracic aorta (*Figure 1*). In repairs involving acute aortic dissection and other such scenarios, alternate approaches to retrograde guidewire advancement include antegrade guidewire advancement—relying on transesophageal echocardiography to confirm device positioning in the true lumen—and direct placement (without using a guidewire) confirmed by echocardiography (as described above) or with a flexible endoscope.

The stent-graft portion is deployed by unsheathing, and the delivery system is carefully removed. With the sewing collar, the device is secured distally to the native aorta, preventing migration as the distal anastomosis is completed. The brachiocephalic arteries are incorporated into the non-stented graft portion of the device with a variety of techniques, including island reattachment using the Ante-Flo model, graft bypass with the Plexus model, and

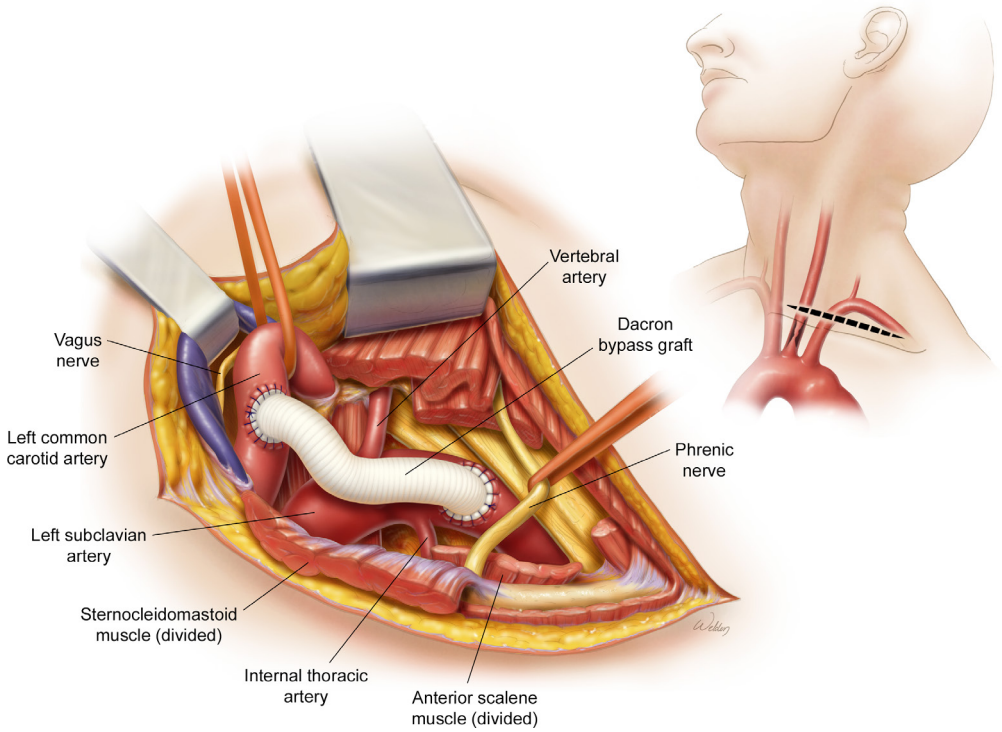

Figure 2 In advance of total aortic arch replacement, the left subclavian artery can be accessed through a minimal supraclavicular incision. The artery is exposed and bypassed to the left common carotid artery in a side-to-side fashion. An alternate approach (not shown) involves transposing native arteries rather than bypass grafting. Used with permission of Baylor College of Medicine.

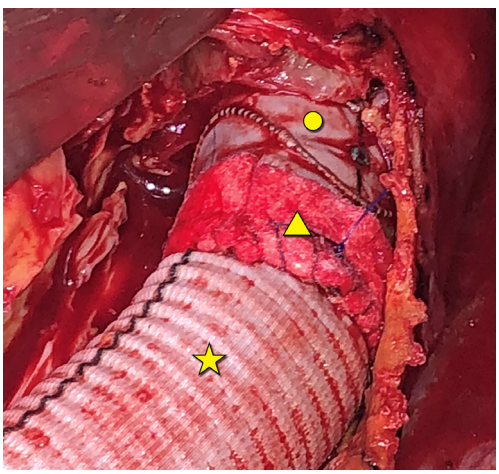

Figure 3 Surgical photograph of the proximal anastomosis during a completion Crawford extent II thoracoabdominal aortic aneurysm repair. Here, the distal edge of the Thoraflex device (circle) used in a prior frozen elephant trunk repair is directly incorporated into the open replacement graft (star). A band of felt (triangle) provides additional support. Used with permission of Baylor College of Medicine.

customization of the Ante-Flo model by using a Y-graft (10) or single-branch arch-vessel reconstruction (11). As needed, additional procedures (e.g., aortic root replacement, aortic valve replacement, coronary artery bypass grafting) are performed during rewarming.

Because the left subclavian artery (LSCA) may be difficult to access during repair, one strategy for managing it relies on bypassing it two to three days before elective TAR via a supraclavicular incision (*Figure 2*). Benefits of this approach during TAR repair include proximalization of the distal anastomosis (which can aid in establishing hemostasis when the LSCA is deep in the chest and hard to secure) and a reduction in TAR operative time, because the LSCA has already been addressed (12).

Downstream extension can be performed by both open and endovascular approaches. Because the endograft portion of the Thoraflex device is sheathed in Dacron, it is readily anastomosed to an open replacement graft (*Figure 3*); this was a common approach in patients with aortic dissection. For patients better served by endovascular repair, a variety of stent-grafts can be landed proximally in the endograft

portion of the Thoraflex device. To secure the proximal landing zone, an overlapping seal of 4 cm is targeted. Stent-grafts are oversized on a case-by-case basis (typically by 15–25%), with an aim to avoid oversizing in patients with aortic dissection. One or more endografts can be used during the completion stage of the repair.

Statistical analysis

Statistical analyses were performed with IBM SPSS Statistics 29 (IBM Corp., Armonk, NY, USA). Continuous variables are presented as mean ± standard deviation (SD) or median [interquartile range (IQR), Q1–Q3], depending on their distribution. Categorical variables are presented as numbers and percentages. Data are presented for descriptive purposes; formal statistical comparison was hindered by the small sample size.

Results

Preoperative characteristics

The median patient age at repair was 65 years (IQR, 54–73 years); patients treated after FDA approval were younger than patients in the IDE trial (*Table 1*). Overall, patients were commonly diagnosed with aortic dissection (61%), with substantial portions of both DeBakey type I and III dissections. Compared with the IDE patients, the FDA patients had a lower rate of coronary artery disease but higher rates of diabetes, prior stroke, and chronic kidney disease. A substantial number of patients (n=28; 45%) had prior open or endovascular aortic repair (Table S1); most of these patients (n=21/28; 75%) underwent their initial repair to treat aortic dissection.

Operative details

More than a third of patients (36%) underwent urgent or emergency repair (*Table 2*). Redo sternotomy was common (40%). The initial cannulation site was most often the innominate artery (48%) or the right axillary artery (36%). Slightly more than half of the repairs involved graft replacement of one or more brachiocephalic arteries, including a substantial number of procedures (29%) in which LSCA bypass was performed before FET. We used the Ante-Flo model more frequently than the Plexus (57% *vs.* 42%). The location of the distal anastomosis was proximalized to the segment between the left common carotid artery and the LSCA in 40% of repairs. Most often, a short (10-cm) endograft extension was used (79%). Concomitant aortic root replacement was performed in eight patients, including three by a valve-sparing approach. Cerebrospinal fluid drainage was used sparingly.

Early outcomes

Overall, seven patients (11%) had adverse events: four (7%) operative deaths and three (5%) life-altering complications that persisted to discharge. All deaths occurred in patients treated after FDA approval (*Table 3*). Three patients experienced a stroke; two of these strokes resulted in death (*Table 4*), and one persisted at discharge. Two patients were discharged with persistent need for renal dialysis. Regarding other complications, two patients had immediate spinal cord deficits (paraparesis, n=1; paraplegia, n=1) that resolved before discharge; both patients received devices with 10-cm endograft segments, and cerebrospinal fluid drainage was used as a rescue measure in one patient.

Late events

Events after index hospital discharge included 10 late deaths among 58 operative survivors, including seven deaths (11%) that occurred within one year of surgery. Whenever possible, we determined the cause of late death (*Table 4*). Rupture of the descending thoracic aorta on postoperative day 41 resulted in death in a young patient with Marfan syndrome. A rare complication—spinal cord infarction—occurred in a patient who underwent three subsequent aortic repairs after index discharge; these included two endovascular extensions, followed by open endograft extraction and Crawford extent II aortic replacement for thoracoabdominal aortic aneurysm (TAAA) repair, during which the open replacement graft was directly sutured to the distal edge of the intact Thoraflex. The infarction (at T7–11) happened late in recovery—six weeks after TAAA repair and nearly four years after FET repair—and resulted in paraplegia and, ultimately, death.

We examined subsequent aortic repairs among all 58 operative survivors, stratified by dissection status (*Table 5*). Many patients underwent additional repair of the distal aorta (n=22; 38%), but none required additional proximal aortic repair. These distal aortic repairs were evenly split between open and endovascular completion procedures;

Table 1 Preoperative characteristics of 62 patients who underwent TAR with Thoraflex

Variable	All (N=62)	IDE (n=14)	FDA (n=48)
Age, years	65 [54–73]	71 [64–75]	62 [41–72]
≤50	11 (18%)	0	11 (23%)
≥75	8 (13%)	3 (21%)	5 (10%)
Male	38 (61%)	7 (50%)	31 (65%)
Genetic disorder (documented)	4 (7%)	0	4 (8%)
Marfan syndrome	2 (3%)	0	2 (4%)
Aortic aneurysm without dissection	24 (39%)	8 (57%)	16 (33%)
Aortic dissection (any segment of aorta)	38 (61%)	6 (43%)	32 (67%)
Acute	6 (10%)	0	6 (13%)
Chronic	32 (52%)	6 (43%)	26 (54%)
DeBakey type I	22 (36%)	6 (43%)	16 (33%)
DeBakey type II	4 (7%)	0	4 (8%)
DeBakey type III	12 (19%)	0	12 (25%)
More than one dissection	1 (2%)	1 (7%)	0
Maximum proximal aortic diameter, cm	5.6 [4.8–6.3]	5.7 [4.7–6.3]	5.6 [4.8–6.3]
Unknown, n	3	0	3
Hypertension	58 (94%)	12 (86%)	46 (96%)
Hyperlipidemia	31 (50%)	11 (79%)	20 (42%)
Diabetes	7 (11%)	0	7 (15%)
Coronary artery disease	12 (19%)	5 (36%)	7 (15%)
Cerebrovascular disease	9 (15%)	1 (7%)	8 (17%)
Prior stroke	6 (10%)	0	6 (13%)
Chronic kidney disease	16 (26%)	1 (7%)	15 (31%)
Active renal dialysis at time of repair	4 (7%)	0	4 (8%)
Body mass index, kg/m^2	27 [24–29]	27 [25–31]	27 [24–29]
Chronic obstructive pulmonary disease	5 (8%)	2 (14%)	3 (6%)
Current tobacco use	12 (19%)	3 (21%)	9 (19%)
Presentation			
Asymptomatic	23 (37%)	6 (43%)	17 (35%)
Symptomatic of aneurysm	39 (63%)	8 (57%)	31 (65%)
Acute (any)	17 (27%)	0	17 (35%)
Chronic (any)	22 (36%)	8 (57%)	14 (29%)
Rupture (indication)	2 (3%)	0	2 (4%)
Preoperative paraparesis	1 (2%)	1 (7%)	0
Prior aortic repair	28 (45%)	5 (36%)	23 (48%)

Values are presented as n (%) or median [quartile 1 – quartile 3]. FDA, Food and Drug Administration; IDE, investigational device exemption; TAR, total arch replacement.

Table 2 Operative details of 62 patients who underwent TAR with Thoraflex

Variable	All (N=62)	IDE (n=14)	FDA (n=48)
Urgency of operation			
Elective	40 (65%)	13 (93%)	27 (56%)
Urgent or emergency	22 (36%)	1 (7%)	21 (44%)
Type of incision			
Redo incision	25 (40%)	5 (36%)	20 (42%)
Arterial cannulation site (initial)			
Axillary	22 (36%)	3 (21%)	19 (40%)
Innominate	30 (48%)	11 (79%)	19 (40%)
Other	10 (16%)	0	10 (21%)
Brachiocephalic approach			
Innominate artery			
Graft	35 (57%)	7 (50%)	28 (58%)
Island	25 (40%)	7 (50%)	18 (38%)
Not manipulated (intact native)	2 (3%)	0	2 (4%)
Left common carotid artery			
Graft	33 (53%)	7 (50%)	26 (54%)
Island	27 (44%)	7 (50%)	20 (42%)
Not manipulated (prior bypass)	2 (3%)	0	2 (4%)
Left subclavian artery			
Graft	28 (45%)	8 (57%)	20 (42%)
Island	15 (24%)	6 (43%)	9 (19%)
Not manipulated (prior bypass)	18 (29%)	0	18 (38%)
Not manipulated (intact native)	1 (2%)	0	1 (2%)
Device			
Ante-Flo	35 (57%)	7 (50%)	28 (58%)
Plexus	26 (42%)	7 (50%)	19 (40%)
10-cm stent-graft component	49 (79%)	12 (86%)	37 (77%)
15-cm stent-graft component	13 (21%)	2 (14%)	11 (23%)
Location of distal anastomosis (collar)			
Between innominate and LCCA	2 (3%)	0	2 (4%)
Between LCCA and LSCA	25 (40%)	1 (7%)	24 (50%)
Distal to LSCA	35 (57%)	13 (93%)	22 (46%)

Table 2 (*continued*)

Table 2 (*continued*)

Variable	All (N=62)	IDE (n=14)	FDA (n=48)
Perfusion, ischemia, and temperature			
Cardiopulmonary bypass time, min	135 [103–170]	119 [91–141]	144 [109–178]
Aortic clamp time, min	49 [27–95]	45 [28–89]	52 [26–97]
Cardiac ischemic time, min	100 [70–126]	109 [76–132]	95 [67–120]
HCA time, min	52 [43–63]	59 [51–70]	51 [38–63]
Antegrade cerebral perfusion time, min	53 [44–61]	59 [51–70]	51 [38–61]
Lowest core temperature, ℃	22 [21–24]	24 [22–24]	22 [21–23]
Temperature <26 ℃	58 (94%)	14 (100%)	44 (92%)
Temperature ≥26 ℃	4 (6%)	0	4 (8%)
Cerebral perfusion			
None or retrograde only	0	0	0
Antegrade only	55 (89%)	14 (100%)	41 (85%)
Antegrade and retrograde	7 (11%)	0	7 (15%)
Adjuncts			
CSFD	2 (3%)	0	2 (4%)
CSFD rescue (postoperative use)	1 (2%)	0	1 (2%)
Concomitant repair			
Coronary artery bypass grafting	5 (8%)	2 (14%)	3 (6%)
Aortic valve replacement	7 (11%)	2 (14%)	5 (10%)
Aortic root replacement	8 (13%)	2 (14%)	6 (13%)
Valve-sparing	3 (5%)	1 (7%)	2 (4%)

Values are presented as n (%) or median [quartile 1 – quartile 3]. CSFD, cerebrospinal fluid drainage; FDA, Food and Drug Administration; HCA, hypothermic circulatory arrest; IDE, investigational device exemption; LCCA, left common carotid artery; LSCA, left subclavian artery; TAR, total arch replacement.

two patients underwent more than one repair. Patients with dissection at the time of index repair were more likely to undergo subsequent aortic repair than patients with non-dissecting aneurysms.

Discussion

Our experience with the Thoraflex hybrid device has shown good overall results in a complex patient cohort. Overall, there were four (7%) operative deaths, and three patients (5%) were discharged with a serious complication (stroke, n=1; renal failure, n=2). All deaths occurred in patients treated after FDA approval. Importantly, no patients developed persistent paraplegia after FET repair. Patients who undergo TAR tend to be complex, often having aortic dissection and prior aortic repair; many of these patients continue to have progressive aortic disease after repair and require careful postoperative management. We currently favor the short, 10-cm endograft extension in most cases in an attempt to reduce the risk of long-term spinal cord deficits whenever feasible. Use of the Thoraflex device appears to facilitate downstream aortic extension.

Regarding experience in the US, the results of our repairs after FDA approval were similar to those of the Thoraflex

Table 3 Early outcomes of Thoraflex repairs

Variable	All (N=62)	IDE (n=14)	FDA (n=48)
Adverse event[†]	7 (11%)	2 (14%)	5 (10%)
Operative death	4 (7%)	0	4 (8%)
30-day death	4 (7%)	0	4 (8%)
Stroke	3 (5%)	1 (7%)	2 (4%)
Persistent stroke[‡]	3 (5%)	1 (7%)	2 (4%)
Spinal cord deficit	2 (3%)	0	2 (4%)
Persistent paraplegia[‡]	0	0	0
Persistent paraparesis[‡]	0	0	0
Acute renal dysfunction	7 (11%)	1 (7%)	6 (13%)
Renal failure (need for dialysis)	2 (3%)	1 (7%)	1 (2%)
Persistent renal failure[‡]	2 (3%)	1 (7%)	1 (2%)
Cardiac complication	18 (29%)	10 (71%)	8 (17%)
Arrhythmia	12 (19%)	7 (50%)	5 (10%)
Cardiac failure	5 (8%)	3 (21%)	2 (4%)
Pulmonary complication	15 (24%)	5 (36%)	10 (21%)
Respiratory failure	12 (19%)	4 (29%)	8 (17%)
Necessitating tracheostomy	3 (5%)	1 (7%)	2 (4%)
Bleeding requiring reoperation	0	0	0
Early survivors	58 (94%)	14 (100%)	44 (92%)
Length of ICU stay, days	5 [3–7]	4 [3–7]	5 [3–7]
Length of hospital stay, days	11 [8–18]	11 [8–19]	11 [9–17]

Values are presented as n (%) or median [quartile 1 – quartile 3]. [†], defined as operative death or persistent (present at hospital discharge) stroke, spinal cord deficit, or renal failure necessitating dialysis. [‡], present at the time of hospital discharge or early death. ICU, intensive care unit; IDE, investigational device exemption; FDA, Food and Drug Administration.

pivotal trial (comprising 65 repairs in the nonemergency, primary group and nine repairs in the rupture group; n=74) in terms of operative mortality [4/48 (8%) *vs.* 3/74 (4%)], and stroke [2/48 (4%) *vs.* 6/74 (8%)]. However, none of our patients developed a persistent spinal cord deficit [*vs.* 4/74 (5%) in the pivotal trial] (9).

To date, two additional reports have been published on the US experience with the Thoraflex (7,13). Shih and colleagues in Dallas described their use of the Thoraflex device in eight patients with acute aortic dissection (type A, n=6; type B, n=2) who were cooled to a target of 28 ℃. Although no patients died or needed renal dialysis, one patient developed permanent paraplegia after the only use of a 15-cm device in this series (13). Bojko and coauthors, examining the multicenter US experience of the Western Aortic Collaborative, described the use of the Thoraflex device in 83 patients (7). These complex patients were treated for aneurysm, acute dissection, and chronic dissection; nearly half of the patients underwent repair necessitating redo sternotomy, and target temperatures were 24–28 ℃ across the five centers. Operative mortality for their Thoraflex cohort was 13%, and the rates of stroke and paraplegia were 19% and 5%, respectively.

Limitations of this study include its small sample size,

Table 4 Causes of operative and late death after total aortic arch replacement with Thoraflex Hybrid device

No.	Age (years)	Sex	Indication for TAR	IDE/FDA	POD	Cause of death (comment)
Operative (early) deaths						
1	72	Female	Aneurysm	FDA	12	Stroke
2	82	Male	Acute retro DeBakey I	FDA	1	Bleeding, MSOF (failed retrieval of Amulet atrial device caused acute retrograde dissection and rupture, necessitating rescue TAR)
3	55	Male	Chronic DeBakey II	FDA	28	MSOF (critical after repair with failure to wean from pump, resulting in need for ECMO)
4	71	Male	Type 1 endoleak after TEVAR	FDA	2	Acute dissection of carotid artery resulting in fatal stroke
Late deaths						
5	72	Male	Chronic DeBakey I	IDE	1,263	COVID
6	61	Female	Aneurysm	IDE	1,433	Acute spinal cord infarction [during prolonged recovery from third subsequent aortic repair (open extent II TAAA repair to remove 2 distinct TEVAR repairs) with delayed paraplegia]
7	73	Female	Aneurysm	IDE	1,905	Malignant bladder cancer, pancreatitis, liver failure
8	74	Male	Chronic DeBakey I	FDA	222	Unknown
9	43	Male	Chronic DeBakey I	FDA	333	Unknown
10	77	Female	Aneurysm	FDA	203	Unknown
11	74	Male	Chronic DeBakey I	FDA	271	Unknown
12	78	Female	Aneurysm	FDA	88	Cardiac failure, ARDS, pneumonia, respiratory failure
13	48	Female	Acute retro DeBakey I	FDA	118	MSOF with sepsis, bleeding, hemorrhagic shock (complicated by bleeding from right radiocephalic arteriovenous fistula related to long-term dialysis)
14	45	Male	Chronic DeBakey I	FDA	41	Ruptured descending thoracic aneurysm (after readmission for hemoptysis due to excessive anticoagulation)

ARDS, acute respiratory distress syndrome; COVID, coronavirus disease; ECMO, extracorporeal membrane oxygenation; FDA, Food and Drug Administration; IDE, investigational device exemption; MSOF, multi-system organ failure; POD, postoperative day; TAAA, thoracoabdominal aortic aneurysm; TAR, total arch replacement; TEVAR, thoracic endovascular aortic repair.

which precluded formal comparative analysis. Although our experience may not be generalizable to other aortic centers because of selection bias related to our referral patterns, these data on our transition from IDE to FDA-approved use may be informative for similar practices in the United States and elsewhere. Additionally, we were unable to determine the cause of death in some of our patients.

Conclusions

Total aortic arch replacement is a complex procedure. Patients requiring such repair tend to have complex aortic disease; subsequent downstream aortic repair often becomes necessary over time. Using the Thoraflex Hybrid device as part of TAR results in good early outcomes and provides a reliable and efficient platform for subsequent aortic repair. After the shift from the IDE trial to clinical application following FDA approval, we observed that patients tended to be younger, with nearly a quarter being aged 50 or younger. Patients with dissection require careful postoperative management to assess the need for subsequent aortic repair.

Table 5 Current follow-up and vital status for 58 early survivors stratified by aortic dissection

Variable	All (n=58)	With dissection (n=36)	Without dissection (n=22)
Part of IDE trial	14 (24%)	6 (17%)	8 (36%)
Follow-up within 1 year of repair	58 (100%)	58 (100%)	36 (100%)
Follow-up more than 1 year after repair	32 (55%)	16 (44%)	16 (73%)
Follow-up time from index repair, y	1.2 [0.3–2.5]	1.9 [0.9–6.9]	0.7 [0.3–1.8]
Events of interest			
Repair failure	0	0	0
Subsequent aortic rupture	1 (2%)	1 (3%)	0
Subsequent repair	22 (38%)	12 (33%)	10 (46%)
>1 subsequent repair	2 (3%)	0	2 (9%)
Subsequent repairs, by total	n=25	n=12	n=13
Distal (open) – TAAA	12 (48%)	9 (75%)	3 (23%)
Extent I	2 (8%)	1 (8%)	1 (8%)
Extent II	8 (32%)	7 (58%)	1 (8%)
Extent III	1 (4%)	1 (8%)	0
Extent IV	1 (4%)	0	1 (8%)
Endovascular – TEVAR	13 (52%)	3 (25%)	10 (77%)
Type of endograft used during repair			
Relay Pro[†]	n=3	n=2	n=1
Conformable Gore TAG[†]	n=6	n=1	n=5
Cook Zenith[†]	n=7	n=1	n=6
Medtronic Valient[†]	n=1	–	n=1
Late death	10 (17%)	6 (17%)	4 (18%)
Within 1 year	7 (12%)	5 (14%)	2 (9%)
By 5 years	2 (3%)	1 (3%)	1 (5%)
By 10 years	1 (2%)	0	1 (5%)

Values are presented as n (%) or median [quartile 1 – quartile 3]. [†], more than 1 endograft can be used during endovascular repair. IDE, investigational device exemption; TAAA, thoracoabdominal aortic aneurysm; TEVAR, thoracic endovascular aortic repair.

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Footnote

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Conflicts of Interest: Dr. Moon serves on an advisory board for Edwards Lifesciences. Dr. Coselli consults for and participates in clinical trials for Terumo Aortic; consults for and participates in clinical trials for Medtronic, Inc., and W.L. Gore & Associates; and participates in clinical trials for Abbott Laboratories, Artivion, AstraZenica, and Edwards Lifesciences. Dr. Barron serves as a speaker for Abiomed Inc. Dr. Orozco-Sevilla participates in clinical trials for Gore Medical, Cook Medical, and Terumo Aortic and consults for Cook Medical. Dr. Garnica participates in clinical trials for Terumo Aortic. The other authors have no conflicts of interest to declare.

References

1. Shrestha M, Bachet J, Bavaria J, et al. Current status and recommendations for use of the frozen elephant trunk technique: a position paper by the Vascular Domain of EACTS. Eur J Cardiothorac Surg 2015;47:759-69.
2. Karck M, Chavan A, Hagl C, et al. The frozen elephant trunk technique: a new treatment for thoracic aortic aneurysms. J Thorac Cardiovasc Surg 2003;125:1550-3.
3. Shrestha M, Martens A, Kaufeld T, et al. Single-centre experience with the frozen elephant trunk technique in 251 patients over 15 years. Eur J Cardiothorac Surg 2017;52:858-66.
4. Roselli EE, Tong MZ, Bakaeen FG. Frozen elephant trunk for DeBakey type 1 dissection: the Cleveland Clinic technique. Ann Cardiothorac Surg 2016;5:251-5.
5. Preventza O, Al-Najjar R, LeMaire SA, et al. Total arch replacement with frozen elephant trunk technique. Ann Cardiothorac Surg 2013;2:649-52.
6. Kemp C, Ghincea CV, Feng Z, et al. Evaluating the risk of spinal cord ischemia in zone 2 frozen elephant trunk replacement. Am J Surg 2022;224:1057-61.
7. Bojko MM, Oslund W, Kirsch MJ, et al. Commercial hybrid graft versus traditional arch replacement with frozen elephant trunk: A multi-institutional comparison. JTCVS Open 2025;23:19-33.
8. Lin PH, Dardik A, Coselli JS. A simple technique to facilitate antegrade thoracic endograft deployment using a hybrid elephant trunk procedure under hypothermic circulatory arrest. J Endovasc Ther 2007;14:669-71.
9. Coselli JS, Roselli EE, Preventza O, et al. Total aortic arch replacement using a frozen elephant trunk device: Results of a 1-year US multicenter trial. J Thorac Cardiovasc Surg 2024;167:1680-1692.e2.
10. LeMaire SA, Price MD, Parenti JL, et al. Early outcomes after aortic arch replacement by using the Y-graft technique. Ann Thorac Surg 2011;91:700-7; discussion 707-8.
11. Galla JD, McCullough JN, Ergin MA, et al. Surgical techniques. Aortic arch and deep hypothermic circulatory arrest: real-life suspended animation. Cardiol Clin 1999;17:767-78, ix.
12. Orozco-Sevilla V, Coselli JS. Management of the left subclavian artery during aortic arch replacement using a frozen elephant trunk approach: a review. Cardiovasc Diagn Ther 2023;13:736-42.
13. Shih E, Eisenga JB, McCullough KA, et al. An early experience using a hybrid graft for aortic arch dissection. Am J Cardiol 2024;233:96-100.

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