Vascutek Ltd. (dba Terumo Aortic)
Thoraflex Hybrid (P210006)
PMA Annual Clinical Update 2023 - 2024

I. Overview:

This annual clinical update provides a review of the ongoing experience with Thoraflex Hybrid (P210006) used for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta with or without involvement of the ascending aorta in cases of aneurysm and/or dissection, covering the time period from April 01, 2023 – March 31, 2024. Thoraflex Hybrid originally received CE Mark in November 2012 and has since been commercially distributed globally in the EU, ASPAC, Latin America and Canada; it has been commercially available in the United States since April 2022. In this update, Post-Approval Study (PAS) data and over 10 years of worldwide commercial experience is presented. The IDE clinical study supporting the PMA approval is complete with the last subject follow-up through 3 years completed July 30, 2021.

FDA approval of Thoraflex Hybrid was granted on April 19, 2022.

PMA Approval Order	https://www.accessdata.fda.gov/cdrh_docs/pdf21/P210006A.pdf
Instructions for Use (IFU)*	https://www.accessdata.fda.gov/cdrh_docs/pdf21/P210006C.pdf
Summary of Safety and Effectiveness (SSED)	https://www.accessdata.fda.gov/cdrh_docs/pdf21/P210006B.pdf
Post Approval Study (PAS) Webpage	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=729036&c_id=6977

*Latest version available at https://eifu.terumoaortic.com/TAG/US/THOR

II. Worldwide Device Distribution:

Approximately 5245 Thoraflex Hybrids have been shipped worldwide between April 01, 2023 and March 31, 2024. During this time, there have been 702 devices implanted in the US.

III. Clinical Evaluations:

US Pivotal Study:

The Thoraflex Hybrid Pivotal study was a prospective, multicenter, open-label study initiated in the US in 2015 and included 65 patients in the main study arm and 9 patients in the aortic rupture arm. Patients were treated between August 22, 2016 and May 29, 2018 and were scheduled for postoperative follow-up examinations at 30 days, 3 months, 12 months and annually through 3 years. The last subject follow-up visit data was complete on July 30, 2021. The main study arm included subjects presenting with disease of the aortic arch and the descending thoracic aorta, with or without involvement of the ascending aorta, and aortic rupture arm included subjects with a ruptured aorta (true rupture or high risk of imminent rupture). The primary objective was to assess the effectiveness, safety and clinical outcomes of the Thoraflex Hybrid device in the treatment of patients in the main study arm. Assessing the safety and clinical outcomes of the device in the aortic rupture arm was a secondary objective of the study, therefore both groups were analyzed separately. Assessing the safety and early clinical outcomes in patients who receive an extension procedure within 1 year of device implantation was an additional secondary objective of the study. Safety and effectiveness of the main study arm were evaluated with a hypothesis-driven 1-year endpoint. The aortic rupture arm was not a hypothesis-driven arm. The study design took into

consideration that the Thoraflex Hybrid device is implanted in an open surgical procedure. As such, the composite primary endpoint included those components that are important for an open aortic arch repair, including permanent stroke, permanent paraplegia/paraparesis, and all-cause mortality, as well as unanticipated aortic-related re-operation occurring ≤1 year post-procedure. This primary endpoint was compared to a performance goal of 57.4% (established from a historical conventional open surgical cohort). The performance goal was met with 76.9% of subjects (50/65, 95% CI 66.7% to 87.2%) free from major adverse events (MAE) at one year. Additional secondary endpoints reported also demonstrated the benefits of the Thoraflex Hybrid in the intended patient population. At conclusion of the study, 56 of 65 treated subjects in the main study arm had one-year follow-up data available; 7 (10.8% all-cause mortality) had died (3 were aortic-related, 4.6%) and 2 (3.1%) had no visit. At three-year follow-up, 46 subjects were assessed: 6 (9.2%) further mortalities, and 6 (9.2%) were lost to follow-up or withdrew. This data was used to support PMA approval and complete details are found in the SSED (see link above).

Thoraflex Hybrid and RelayPro NBS Post Approval Study:

The Thoraflex Hybrid and RelayPro NBS Extension PAS (EXTEND-001) is a multi-center, prospective study to evaluate the Thoraflex Hybrid device alone and in combination with the RelayPro NBS stent-graft in the treatment of aortic disease affecting the aortic arch and descending aorta with or without involvement of the ascending aorta. All subjects will be treated for aortic disease with any commercially available Thoraflex Hybrid device and, if required, the RelayPro NBS Thoracic Stent-Graft System. The devices may be placed during a single procedure or two separate procedures (note: there is no stipulated minimum or maximum time between the two procedures). This study will include 200 subjects, with a minimum 65 subjects with RelayPro NBS distal extension at up to 55 sites in Europe and North America. Each site is permitted to enroll a maximum of 15 patients, and at least 50% of the overall subject number must be from the USA. The study will have a 10-year follow-up period (from the index Thoraflex Hybrid procedure). Data will be collected at the following timepoints: Pre-operative, Intra-operative (Implant, index and first extension, when applicable), and Post-operative (Discharge/30 Days, 1 year and annually to 10 years). The primary safety endpoint is a composite of the following: Permanent disabling stroke, Grade 3 Spinal cord Ischemia (per SVS reporting standards), All-Cause Mortality within one year of either procedure. The primary safety endpoint will be measured at one-year after the index procedure and again at least 8 months after the (first) extension procedure. The primary effectiveness endpoint is Treatment Success, defined as device technical success (of either procedure) with absence of the following at one year; Lesion-related mortality, Aortic rupture in the treated segment, lesion expansion ≥5mm from measurement at discharge or within 30-days of procedure and secondary interventions to address; Stent graft-induced aortic wall injury (SAWI); Fistula; Type I or III endoleak; Migration; Loss of Patency; Thromboembolic events or Failure of integrity. The primary effectiveness endpoint will be measured at one-year after the index procedure and again at least 8 months after the (first) extension procedure. Note: The exact point of primary endpoint evaluation after extension will vary in relation to the index procedure with the Thoraflex Hybrid, but it will be at a minimum of 8 months if the extension happens within 4 months of the index procedure (i.e., the evaluation will take place at 1 year post-index procedure). If the extension takes place later than 4 months after the index procedure, then the evaluation will take place at one of the later follow up timepoints.

As of February 16, 2024, 26 subjects have been enrolled in EXTEND. Sixteen (16) investigational sites are actively enrolling (14 US and 2 OUS) with 26/200 subjects enrolled (2/26 are reported and have data with a RelayPro NBS extension device implanted). Thirteen (13) subjects have imaging available for the 30-day/discharge visit. One subject was withdrawn early after the 30-day/discharge visit; no 12-month data is available.

In the EXTEND study, 38.5% (10/26) of subjects that have a primary indication of Aneurysm of which the majority are fusiform (70.0%, 7/10). Fourteen (14/26, 53.8%) subjects had a primary indication of dissection. Regarding chronicity, the following were reported: Hyperacute (3), Acute (4), Sub-acute (4), and Chronic (3). Regarding classification, the majority of subjects were classified as DeBakey Type I (66.7%, 8/12); however, subjects with DeBakey Type II (16.7%, 2/12), DeBakey Type IIIa (8.3%, 1/12), and DeBakey Type IIIb (8.3%, 1/12) were also reported. Malperfusion was reported in three dissection subjects, including coronary (33.3%, 1/3) and spinal/visceral or iliac (66.7%, 2/3). Additional indications for treatment included aortic rupture (3.8%, 1/26), post-dissection aneurysm (11.5%, 3/26), penetrating atherosclerotic ulcer (PAU) (3.8%, 1/26), and other (3.8%, 1/26).

The Core Laboratory have reviewed pre-operative imaging for 16 subjects; the majority of subjects had the proximal end of the disease reported at Zone 0 (56.3%, 9/16) and distal end of the disease at Zone 11 (50.0%, 8/16). The mean maximum thoracic aortic diameter was 65.5 ± 10.7 mm on pre-operative imaging. For those subjects presenting with dissection, the primary intimal tear was primarily located in Zone 0 (72.7%, 8/11).

There have been seven (28.0%, 7/25) all-cause mortality events reported to date; all deaths occurred within 90 days of the Thoraflex Hybrid procedure. Six (6) of the deaths have been determined by the site to not be related to the device; one is pending relatedness information from the site. Five (5) deaths have been site-reported to be related to the procedure. As of the data cut, Clinical Events Committee (CEC) adjudication for these events is pending. No aortic ruptures have occurred.

Regarding effectiveness related observations, there have been no Core Laboratory reports of migration, endoleaks, aortic expansion, losses of patency, losses of device integrity, pseudoaneurysm, fistula formation, new dissection, or stent-graft induced aortic wall injury. Regarding the subjects with dissection (8 with discharge/30-day Core Laboratory data available), Type R endoleaks were noted in 3 subjects (2 at discharge/30-days and one at Discharge/30-days, as well as unscheduled visits through POD 238). No other false lumen perfusion was reported by the Core Laboratory. Regarding false lumen status, the majority of subjects had partially thrombosed false lumens at discharge/30-days (87.5%, 7/8).

Two subjects have been reported as of the data cut with any intervention (7 interventions); one subject underwent six (6) secondary interventions. Two (2/7) interventions were unplanned major reinterventions, one (1/7) was a planned minor reintervention and the remaining four (4/7) were non-vascular reinterventions.

IV. Worldwide Recalls, Safety Communications and Field Safety Notices:

There have been no US recalls, safety communications and/or Field Safety Notices issued for Thoraflex Hybrid during this reporting period.

V. Worldwide Commercial Experience:

Thoraflex Hybrid is distributed globally and receives feedback/learnings from this worldwide commercial use. The following table summarizes the associated complaints for this Annual Report timeframe. Most recently, a variant of the Thoraflex Hybrid was launched in Japan in 2023 featuring the same device design but using a different bovine-based gelatin sealant. It is also worth noting there was a substantial increase in device distribution volume for this reporting time period compared to last year's report.

Thoraflex Hybrid Complaints: 01 April 2023 – 31 March 2024		
Failure Mode Description	**# of complaints per failure mode**	**MDR Filed**
Clinical Observations		
Blood leakage	11	Yes
Occlusion/thrombosis (may include neurological symptoms) ‡*	6	Yes
Device kink (may include paraplegia) **	6	Yes
Type I Endoleak‡	4	Yes
Stroke‡	4	Yes (3)
Death‡ (may include Occlusion/Thrombosis)	4	Yes
Fever	2	Yes
Anemia‡	2	Yes
Unspecified Endoleak‡	1	Yes
Atrial Fibrillation‡	1	Yes
Type II Endoleak‡	1	No
Pleural effusion‡	1	No
Aortic dissection‡	1	No
Tachycardia‡	1	No
Metabolic Acidosis/lactate‡	1	No
Delivery / Deployment Observations		
Deployment Issues	4	Yes (1)

‡Reported incidents may include subject follow-up from Vascutek registries.

*Occlusion/Thrombosis Complaints:

- One patient was reported with occlusion of the branch for the left common carotid artery approximately 2 years post operative. The occlusion was noted at the origin of the LCC at level of the aortic arch portion of the device. The rest of the device was unremarkable. Patient presented with aphasic disorder and after confirmation of neurological symptoms underwent carotid-under left subclavian artery bypass.
- One patient had stenosis noted between the second and third stents of the Thoraflex Hybrid along the patient's aortic arch curvature, which was addressed with a TEVAR.
- One patient had lower extremity coolness, pain/tingling, and loss of left dorsalis pedalis/posterior tibialis pulses, secondary to embolus of the left common femoral artery & right common femoral artery pseudoaneurysm. Patient had embolectomy and repair of pseudoaneurysm.
- Investigation on the following is underway: 1) One patient had thrombosis of the hepatic artery with hepatic cytolysis treated with anticoagulation. 2) one patient with aortic thrombosis, and 3) one patient with thrombosis at the level of the visceral vessels which was addressed with recanalization of the renal artery and thrombus aspiration.

**Device Kink Complaints:

- One patient had deterioration of renal function post operative. The Thoraflex Hybrid lumen appeared compressed around the distal part of the aortic arch, which was addressed with a TEVAR emergently placed. The anastomosis (at the collar) was in Zone 2; there was retrograde blood flow from the left subclavian artery (LSA) into the aneurysm. A vascular plug was used to embolize the LSA. Patient is paraplegic and unable to move his/her legs. Complaint is under further investigation.
- One patient was treated with the Thoraflex Hybrid to address an additional Type A dissection with a compressed true lumen along inner curvature of the arch. Post-operative, the device was severely compressed in the true

lumen. Vascular was consulted regarding potential repair options; no clinical sequalae were communicated at time of complaint.

- Two patients had device kink noted in the stented segment and TEVAR was performed to address the observation.
- Two patients had device kink noted and no intervention was planned.

Taking into consideration the increase in product distribution volume and new market introduction, the relative complaint rate remains stable. Blood leakage and device kink are newly reported during this time period where device kink was exclusively reported from Japan and blood leakage predominantly (>80%) reported from Japan.

In terms of the overall evaluation of reported complaints, the occurrence levels are still within the values estimated by Terumo Aortic and all complaints are assessed within the risk management system. Terumo Aortic continues its diligence in monitoring and investigating product complaints and takes necessary actions, as needed and concludes that the benefits of using Thoraflex Hybrid continue to outweigh the associated risks.

VI. Explant Analysis:

There have been no explants in the period April 01, 2023 through March 31, 2024.

VII. Literature Review:

There have been 14 publications with information on Thoraflex Hybrid in the period April 01, 2023 through March 31, 2024. A summary of these publications is provided below.

Article Citation	Brief Summary
Hostalrich A, Porterie J, Boisroux T, Marcheix B, Ricco JB, Chaufour X. Outcomes of Secondary Endovascular Aortic Repair After Frozen Elephant Trunk. J Endovasc Ther. Published online April 26, 2023. doi:10.1177/15266028231169172	The group from Toulouse, France reports a series of 30 (18.8%) post-FET TEVARs (RELAY but also ZTA, ZDEG, cTAG) from a total of 159 Thoraflex Hybrids (13 for TAAA aneurysm, 11 for a chronic aortic dissection, six emergency procedures for malperfusion or incomplete stent expansion). 93% of Thoraflex stented sections were 10 cm and the center standardly relines as far as the collar. There were two post-extension deaths (7%) and one case of paraplegia (3%). At a median follow-up of 21 months (IQR, 4.2–34.7), three patients had secondary interventions for Type III endoleak (disconnection between FET and TEVAR), all in patients who had FEVAR extension as well. Indications for TEVAR after FET were a Type I/II TAAA with a diameter of >6 cm, TAAD or TBAD with either organ malperfusion due to compression of the true lumen or aneurysmal evolution of the dissected aorta, and an incomplete expansion of the FET module.
Cuko B, Pernot M, Busuttil O, et al. Frozen elephant trunk technique for aortic arch surgery: the Bordeaux University Hospital experience with Thoraflex hybrid prosthesis. J Cardiovasc Surg (Torino). Published online June 19, 2023. doi:10.23736/S0021-9509.23.12706-6	The group from Bordeaux, France report on n=77 Thoraflex Hybrid procedures (56% elective; 44% emergency): 15.6% 30-day mortality (7% elective vs 26.5% urgent, P=0.043): 7.8% non-disabling strokes (1.9% bilateral selective antegrade cerebral perfusion vs 20% unilateral, P=0.021). One-year survival was 81.6±4.5%.
Adams B. Implantation of frozen elephant trunk (FET)—surgical technique—Thoraflex. Cardiovasc Diagn Ther. 2023;13(3):550-556. doi:10.21037/cdt-22-506	The FET technique has evolved as an elegant solution for a one staged aortic repair in a variety of aortic pathologies. Thoraflex Hybrid provides an ergonomic and neat delivery system with trusted gelatin coated surgical graft material making implantation and use as straightforward as possible. These features have meant that the device is a market leader in the field with outcome data and implant figures to support its efficacy globally. The argument between limited and extended repair of TAAD continues but the indications for a FET and the ability of the prosthesis to treat complex dissections of the arch and completely remodel the downstream aorta is very compelling. Of course, there are still developments and improvements to be made, particularly management

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	of the LSA, reduction in the risk of stent thrombosis as well as strategies to reduce the risk of circulatory arrest and duration of ACP. Finally, the inherent risk of SCI is for many the Achilles heel of the procedure, however, with the use of adjuncts such as spinal drain insertion when feasible and higher mean arterial pressure targets in addition to increased awareness of the risk and expedient management then this can be reduced.
Murana G, Costantino A, Campanini F, et al. Distal stent graft-induced new entry (dSINE) after frozen elephant trunk: a scoping review. Cardiovasc Diagn Ther. 2023;13(2):408-417. doi:10.21037/cdt-22-234	The Bologna, Italy group prefers Thoraflex Hybrid for ease of deployment but uses E-vita when longer stent coverage in descending aorta is needed meaning that their experience is evenly balanced: n=114, 50.7% vs n=111, 49.3% as is dSINE incidence of 54 dSINEs (24.0%; n=28, 51.9% Thoraflex; n=26, 48.1% E-vita).6 In addition, they reviewed the literature and found a dSINE incidence of 69/544 (12.7%), occurring between 12.6 to 30.6 months.
Di Marco L, Nocera C, Snaidero S, et al. Staging TEVAR after FET — an exception or the rule? Indian J Thorac Cardiovasc Surg. Published online October 28, 2023. doi:10.1007/s12055-023-01611-7	Of 371 FET procedures (54% Thoraflex; 46% E-Vita) in Bologna, Italy, 32.1% (n=119) had subsequent TEVAR extension (n=154 TEVARs in total, 13% urgent) at a mean 22.2±28.7 months.1 There was no statistically significant difference in the rates of TEVAR extension between Thoraflex and E-vita or between Z2 vs Z3 anastomosis or stent length. Intraoperative mortality was 1.7% (n=2 aortic ruptures). In 27 patients (23%), a complex and diffuse aortic pathology (typically dissection) required >1 TEVAR.
Shimamura J, Abazid R, Gelinas J, Valdis M, Duncan A, Power A, et al. Five-Year Outcomes of Hybrid Arch Frozen Elephant Trunk Repair With Novel Multibranched Hybrid Graft. Annals of Thoracic Surgery Short Reports [Internet]. 2023 Jul 14 [cited 2023 Nov 17]; Available from: https://www.sciencedirect.com/science/article/pii/S277299312300222X	Between 2014 and 2020, 50 consecutive patients (63±15 years; 34% women) underwent FET with Thoraflex Hybrid in London, Ontario for aneurysm (n=48, 96%), acute aortic dissection (n=10, 20%), and chronic dissection (n=20, 40%) and mean follow-up was 1455±664 days.2 30-day/in-hospital mortality was 2%; stroke, 2% and transient neurologic deficits, 6%; SCI, 6% (transient, 4%; permanent, 2%); thromboembolic complications, 2%. In follow-up, 6 patients died of aortic events, and there were 13 reinterventions in the downstream aorta, of which 46% (6/13) were planned second-stage operations. Reasons for the Canadian preference for Thoraflex Hybrid include: • Risk of type Ia endoleaks “abolished” due to surgically sewn arch anastomosis • Excellent hemostasis due to robust arch collar, FET seal, and gelatin-sealed Dacron • Easy-to-use short delivery system • Accommodate to aortic arch curvature due to ring stent • SINE risk may be reduced due to lower radial force
Murana G, Gliozzi G, Di Marco L, et al. Frozen Elephant Trunk technique using hybrid grafts: 15-years outcomes from a single center experience. Eur J Cardiothorac Surg. Published online October 31, 2023:ezad364. doi:10.1093/ejcts/ezad364	The group from Bologna, Italy compared outcomes of 367 FET procedures using either Thoraflex (51%) or E-vita (49%).3 In-hospital mortality was 13.1% with no difference between devices, but there was variability in mortality rates depending on underlying pathology; ranging from 9% in elective repair of residual aortic dissection to 25% in acute TAAD. Most recently, there has been a reduction in early mortality in patients with arch tear or rupture, as FET has been increasingly used in patients with only radiological—rather than clinical—signs of distal malperfusion. Thoraflex procedures were more likely to be in Z2 (68% vs 12%, p<0.001), with a shorter stent (103±11.3 mm vs 149±12.7 mm, p<0.001), shorter visceral ischemia time (42.5±14.2 min vs 61.0±20.2 min, p<0.001). There were no significant differences in overall survival but freedom from TEVAR at 1, 2, 5 years was significantly different (66.7%, 57.6% and 39.3% vs 79%, 69.7% and 66%, log-rank test=5.28, p=0.029). The group writes that bilateral cerebral perfusion is normal and trilateral ACP (additional cannulation of the LSA) is not uncommon; preoperative work-up includes a CTA of the SAT vessels and the Circle of Willis. Z2 is standard. In aneurysms, 10% oversizing: in dissections, 0%. Prophylactic CSF drainage is not standard. Post-operative anticoagulation comprises AAS 100 mg per day unless oral anticoagulation is otherwise indicated (no additional aspirin). More recently, prosthesis selection has been in favor of the Thoraflex Plexus because it facilitates an anatomical reconstruction of the epiaortic vessels allowing a fast distal reperfusion through the side branch after the circulatory arrest. E-vita was used in hostile arch lesions where a longer stent with a stronger radial force could be curative. [Thoraflex] is easier to maneuver and it also has a [shorter] stent-graft length and a dedicated side branch for distal reperfusion that allowed us to reduce operative times and risk of paraplegia. Following the improvements in our technique, the group of patients who received a trifurcated hybrid graft reported a lower ventilation time (61 versus 106 hours, p=0.025) and a lower rate of permanent new dialysis (8.6% versus 15.5%, p=0.045). However, the recent introduction of the new Evita-Open Neo from

Article Citation	Brief Summary
	Artivion with a new trifurcated configuration and an easy delivery system is expected to fill this gap.
Marné E, Guimbretière G, Mougin J, et al. Comparison of Short and Midterm Aortic Reinterventions in Acute Type A Aortic Dissection Treated by Frozen Elephant Trunk or Conventional Arch Repair. Ann Vasc Surg. 2023;95:3-13. doi:10.1016/j.avsg.2023.05.001	The SD-FET technique was associated with earlier aorta-related reintervention but less late reintervention when outcomes of acute TAAD patients who underwent conventional arch repair (n=22) and FET repair (n=17) were compared.4 Median maximum preoperative descending aortic diameter was larger in the FET group (33 mm [30; 37] vs 30 mm [28; 32] [P=0.0172]). At 30 days, the rate of negative remodeling on the descending thoracic aorta was significantly higher in the conventional group (50%) than in the FET group (8%, P=0.02). Within a year, freedom from reintervention was observed for 74.4% (95% CI 57.1–97%) in the conventional group and 75.5% (95% CI 57.1–99.7%) for FET group.
Fortin W, Gautier CH, Escande R, et al. Thoracic Endovascular Repair after Total Aortic Arch Replacement with Frozen Elephant Trunk for Type a Aortic Dissection. Ann Vasc Surg. Published online October 18, 2023. doi:10.1016/j.avsg.2023.08.026	Second-stage endovascular management of residual aortic dissection after index FET showed excellent perioperative and good midterm outcomes and induced significant remodeling of the entire aorta in most cases, particularly with the STABILISE technique. Of 49 Thoraflex Hybrid repairs for either acute or chronic TAAD, 34 patients (69%) had second stages (n=7 TEVAR extensions, n=1 STABILISE/PETTICOAT; n=26 STABILISE) during 23 months (range 2–66) median follow-up:7
Ravishankar R, Singh SA, Giordano V. The Thoraflex hybrid approach using a zone 0 proximal landing site for first-stage elective treatment of a thoracoabdominal aneurysm. J Surg Case Rep. 2023;2023(12):rjad692. doi:10.1093/jscr/rjad692	Utilizing Z0 FET with Thoraflex Hybrid can result in quicker organ perfusion and successful TEVAR if necessary: a woman with asymptomatic type II TAAA showed extensive disease in the distal arch and an acute bend prohibiting conventional ET
Berger T, Chikvatia S, Siepe M, Kondov S, Meissl D, Gottardi R, et al. Concomitant aortic root replacement during frozen elephant trunk implantation does not increase perioperative risk. European Journal of Cardio-Thoracic Surgery [Internet]. 2023 Apr 1 [cited 2023 May 1];63(4):ezad053. Available from: https://doi.org/10.1093/ejcts/ezad053	Our aim was to evaluate the risk of concomitant aortic root replacement during frozen elephant trunk (FET) total arch replacement.Between March 2013 and February 2021, 303 patients underwent aortic arch replacement using the FET technique. Patient characteristics, intra- and postoperative data were compared between patients with (n = 50) and without (n = 253) concomitant aortic root replacement (implantation of a valved conduit or using the reimplantation valve-sparing technique) after propensity score matching.After propensity score matching, there were no statistically significant differences in preoperative characteristics including the underlying pathology. There was no statistically significant difference regarding arterial inflow-cannulation or concomitant cardiac procedures, while cardiopulmonary bypass (P < 0.001) and aortic cross-clamp (P < 0.001) times were significantly longer in the root replacement group. Postoperative outcome was similar between the groups and there were no proximal reoperations in the root replacement group during follow-up. Root replacement was not predictive for mortality (P = 0.133, odds ratio: 0.291) in our Cox regression model. There was no statistically significant difference in overall survival (log rank: P = 0.062). Concomitant FET implantation and aortic root replacement prolongs operative times but does not influence postoperative outcomes or increase operative risk in an experienced high-volume centre. The FET procedure did not appear to be a contraindication for concomitant aortic root replacement even in patients with borderline indications for aortic root replacement. Zone 2 is the standard anastomosis site for FET implantation in this institution where the 100 mm Thoraflex is used exclusively.
Doonan RJ, Senanayake E, Claridge M, Juszczak M, Torella F, Mascaro J, et al. Distal Repair After Total Aortic Arch Replacement With Frozen Elephant Trunk in Patients With Chronic Multilevel Thoracic Aortic Disease. European Journal of Vascular and Endovascular Surgery [Internet]. 2024 Feb 23 [cited 2024 Feb 23]; Available from: https://www.sciencedirect.com/science/article/pii/S1078588424001928	Objective To examine the management of distal aortic disease after total arch replacement with the frozen elephant trunk (TAR + FET) in patients with chronic thoracic aortic disease. Methods Two centre retrospective study of consecutive patients treated between January 2010 and December 2019. Primary endpoint was 30 day/in hospital mortality. Secondary end point was mid-term survival. Data are presented as median (IQR). Chi squared or Fisher's exact test was used as appropriate. Estimated survival (standard error) was assessed by the calculating Kaplan–Meier product limit estimator with right censoring of survival data. A p value of < .050 was considered to be statistically significant. STROBE guidelines were followed. Results A total of 158 patients (72 men; median age 70, IQR 64, 75; median distal aortic diameter 58 mm (46, 68; 127 aneurysmal disease, 31 chronic dissection) underwent TAR + FET.

Article Citation	Brief Summary
	Peri-operative mortality was 10.1% (9/107 elective, 7/51 non-elective). Of 74 (46.8%) patients with a primary distal seal, seven (9.5%) died peri-operatively, distal seal was maintained during follow up in 51, nine underwent late distal repair (two planned, seven unplanned; one open, eight endovascular; one peri-operative death) with a median interval to unplanned repair of 777 days (462, 1480), and seven with loss of seal had no intervention. Distal seal failed in 2/28 (7%) patients with a distal seal length > 30 mm and device oversizing > 10%, compared with 12/39 (31%) patients who did not meet these criteria (p = .031). In 84 patients without primary distal seal, nine (10.7%) died peri-operatively, the distal aorta remained below the size threshold for repair during follow up in 12 patients, 44 had distal repair (median aortic diameter 64 mm, 60, 75; eight open, one hybrid, 35 endovascular repairs; no mortality) at a median of 256 days (135, 740), and 19 did not have distal repair at the end of the follow up period: six died before planned repair at a median interval of 115 days (85, 120); eight were considered unfit; one was assessed as fit but declined; and four patients were awaiting assessment). Median follow up was 46 months (26, 75): no patients were lost to follow up. Estimated ± standard error five year survival was 61.5 ± 4.1%: elective 70.6 ± 4.7%, non-elective 43.2 ± 7.2%. Conclusion TAR + FET achieved primary distal seal in 47% of patients, but late failure occurred in 21% of patients. Distal repair was ultimately indicated in 84% of survivors without primary distal seal and of these 70% underwent repair, almost 10% died before planned repair, and 13% were considered unfit. Earlier distal endovascular repair and better assessment of patient fitness may improve mid-term outcomes.
Misfeld M, Marin-Cuartas M, Ramirez P, Wehrmann K, Renatus K, Deo SV, et al. Early Intraluminal Frozen Elephant Trunk Stent-Graft Thrombosis Following Aortic Arch Surgery. The Annals of Thoracic Surgery [Internet]. 2023 Jan 4 [cited 2023 Jan 5]; Available from: https://www.sciencedirect.com/science/article/pii/S0003497523000048	The type of FET stent graft (ie, E-vita vs Thoraflex) did not influence the postoperative outcomes nor the occurrence of early postoperative FET thrombosis. Partial intraluminal thrombosis of the FET stent-graft is a poorly described but not infrequent complication after aortic arch surgery. This retrospective single-center analysis included patients who underwent aortic arch replacement with FET technique between 2006 and 2020. Stent-graft thrombosis was diagnosed through computed tomography scan. Several computed tomography scan parameters and clinical variables were analyzed as predictors of this event. A total of 125 patients were included for analysis. Amongst them, 21 (16.8%) patients developed early postoperative FET stent-graft thrombosis. Mean volumetric size of the aorta was 12.2cm3 ± 2.0 cm3 in patients with FET stent-graft thrombosis and 10.1cm3 ± 2.8cm3 in patients without thrombosis (P<0.01). Thrombosis occurred more frequently among patients requiring thoracic endovascular aortic repair (TEVAR) completion [15/21 (71.4%) patients] than in patients with completely excluded aneurysms [6/21 (28.6%) patients] (P=0.01). Mean stent-to-aneurysm diameter ratio was 0.8 ± 0.2 among patients with thrombosis and 1.0 ± 0.2 among patients without thrombosis (P<0.01). Thrombosis was more frequently observed among patients with conservative management of postoperative bleeding (P=0.04). Patients with early FET thrombosis had a non-significantly higher in-hospital all-cause mortality than patients without thrombosis (19.0% vs. 8.7%; P=0.3). Early postoperative intraluminal thrombosis is a frequent complication post-FET surgery. Smaller stent-graft sizes, larger or partially covered aneurysms, and major bleeding are associated with early thrombosis. Slight FET oversizing, prompt TEVAR completion and early reintervention for major bleeding may prevent early thrombosis.
Martens A, Beckmann E, Kaufeld T, Arar M, Natanov R, Fleissner F, et al. Features and risk factors of early intraluminal thrombus formation within the frozen elephant trunk stent graft. The Journal of Thoracic and Cardiovascular Surgery [Internet]. 2023 Jan 23 [cited 2023 Jan 24]; Available from: https://www.sciencedirect.com/science/article/pii/S002252232300082X	FET is a standard treatment method for aortic arch pathologies extending into the descending aorta. The phenomenon of early postoperative intraluminal thrombosis (ILT) within the FET was studied: 281 patients (66% male, mean age 60±12 years) underwent FET implantation between 05/10 and 11/19. In 268 patients (95%) early postoperative computed tomography angiography (CTA) was available to assess ILT. Incidence of ILT after FET implantation was 8.2%. ILT was diagnosed early after the procedure (4.6 ± 2.9 days) and could be successfully treated with anticoagulation in 55% of patients. 27% developed embolic complications. Mortality (27 vs. 11%, P=0.044) and morbidity were significantly higher in ILT patients. Our data showed a significant association of ILT with prothrombotic medical conditions and anatomical slow flow features. The incidence of heparin induced thrombopenia was higher in ILT patients (18

Article Citation	Brief Summary
	vs. 3.3%, P=0.011). Stent graft diameter index, anticipated endoleak Ib, and degenerative aneurysm were significant independent predictors of ILT. Therapeutic anticoagulation was a protective factor. Glomerular filtration rate, extracorporeal circulation time, postoperative re-thoracotomy, and ILT (OR 3.19, P=0.047) were independent predictors of perioperative mortality. ILT is a underrecognized complication after FET implantation. In patients with risk factors of ILT indication for FET should be carefully evaluated and postoperative anticoagulation considered. Early TEVAR extension should be considered in patients with ILT to prevent embolic complications. Stent graft designs should be improved to prevent ILT after FET implantation.

VIII. Conclusion:

Based on available clinical study data and world-wide clinical experience to date, open surgical repair with Thoraflex Hybrid continues to be a viable treatment option for the repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta with or without involvement of the ascending aorta in cases of aneurysm and/or dissection.

Adverse Event Reporting:

As indicated in the Instructions for Use, adverse events or complaints should be reported to Vascutek using the email address complaintsUK@terumoaortic.com. Accurate and timely reporting of adverse events by the physician users to the device manufacturer and FDA (MedWatch Form 3500) is critical for monitoring device performance and detection of potential device-related safety issues.

Patient Follow-Up and Selection:

Regular follow-up of all patients treated with the Thoraflex Hybrid System is required. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient following device placement. Patients should be regularly monitored for endoleaks, lesion expansion or changes in the structure or position of the device. At a minimum, annual imaging is recommended.