



## Current Status of Hybrid Repair of Aortic Arch and Thoracic Aortic Aneurysms Using Thoraflex (Hybrid) and Relay Devices for Frozen Elephant Trunk (FET) and TEVAR: Indications and Results




Tuesday - Saturday, November 19-23, 2024


### Joseph S. Coselli, MD

Executive Vice Chair, Department of Surgery  
Professor, and Cullen Foundation Endowed Chair  
Division of Cardiothoracic Surgery  
Baylor College of Medicine  
51<sup>st</sup> VEITH Symposium 2024  
New York, NY • November 19-23, 2024



@JCoselli\_MD







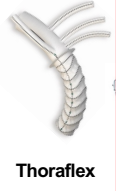
Tuesday - Saturday, November 19-23, 2024




## Disclosures

Medtronic, Inc	PI Clinical Trials Consultant
Terumo Aortic	Consultant, PI Clinical Trials, Royalties Coselli branched graft
WL Gore & Associates	PI Clinical Trials Consultant
Edwards Lifesciences	PI Clinical Trials Consultant
Artivion	PI Clinical Trials Consultant
AstraZeneca	Co-Investigator


## Frozen Elephant Trunk: Devices



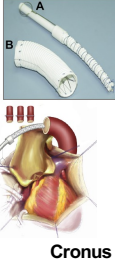
**Thoraflex**




**E-vita Neo**



**Chavan Haverich**



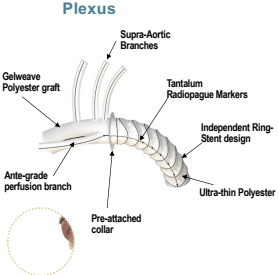
**Cronus**



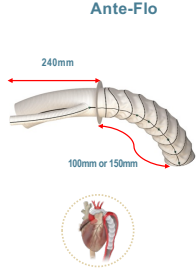
**Frozenix J Graft**

## Design Features

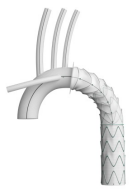
### Plexus



### Ante-Flo

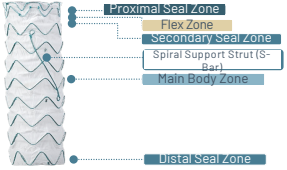


### Thoraflex Hybrid



Thoraflex Hybrid Approval:  
April 19, 2022

### RelayPro NBS Extension Device


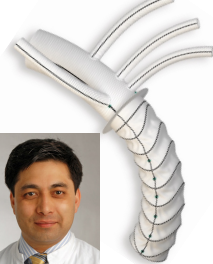


RelayPro NBS  
Expanded Indications Approval:  
March 7, 2023

**100 cases FET**

<b>Preoperative</b>	
Acute dissection	37
Chronic dissection	31
Aneurysm	32
<b>Postoperative</b>	
Early death	7%
Stroke	9%
Paraparesis	7%
Dialysis	14%

**Shrestha et al**  
The Journal of Thoracic and Cardiovascular Surgery • July 2016

**FET : 15-year Outcomes**  
2007 – 2022 (n= 186)

**Early Outcomes**

Outcome	Thoraflex (n=186)
Permanent dialysis	16 (8.6%)
Paraparesis	5 (2.7%)
Paraplegia	3 (1.6%)
Stroke	14 (7.5%)
30-day mortality	28 (15.1%)

Murana EACTS 2023

**Aortic reinterventions after the frozen elephant trunk procedure**

Marcusson Korhola, MD, Tim Bergs, MD, Ravish Kishor, MD, Zhiqing Chen, BA, Fredricka Rosenblatt, MD, Matthew Taylor, MD, and Mattia Corneo, MD, PhD

**Abstract**

**Objective:** The frozen elephant trunk (FET) procedure has emerged as a potential single step treatment for pathologies of the thoracic aorta, but the procedure has generally been a single stage procedure. We aimed to evaluate the need and outcomes of aortic reinterventions after frozen FET implantation.

**Methods:** Retrospective analysis and follow-up data of 177 patients following the FET procedure were analyzed. A secondary endpoint was to assess the need for aortic reinterventions. Re-interventions were analyzed according to the type of reintervention and the need for reintervention.

**Results:** In total, 177 patients underwent FET procedures. A total of 47 patients (26.5%) underwent aortic reintervention. The reintervention was performed in 24 patients (13.5%), open surgery in 18 patients (10.2%), and hybrid approach in 10 patients (5.6%). No reintervention was observed in 130 patients. In total, 177 reinterventions were performed. The need for aortic reintervention was 11% (19%) and 13% (23%) after 12, 24, and 36 months, respectively.

**Conclusions:** Aortic reintervention was common and likely after FET implantation. In this study, we clearly identified patients. Reintervention was performed in a predictable and timely manner. Close follow-up of all patients undergoing FET procedure is necessary. (J Thorac Cardiovasc Surg 2020;159:392)

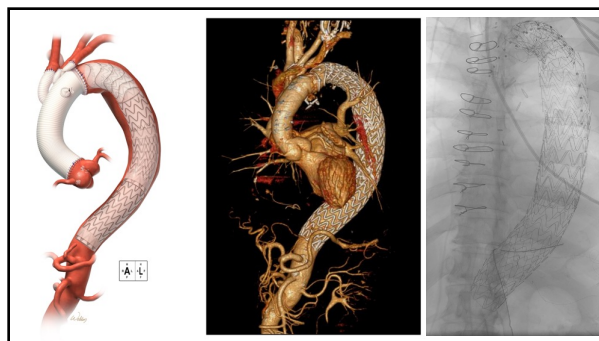
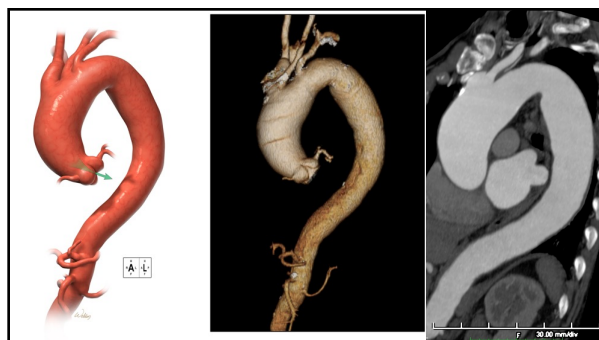
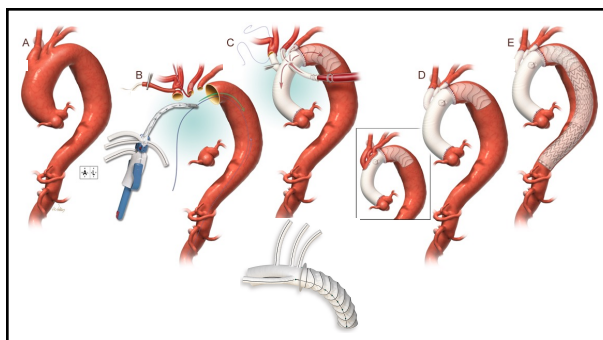
Competing Risks Regression for Reintervention

64% at 36 Months

Type of reintervention

Endovascular	n = 26 (88%)
Open surgical	n = 7 (20%)
Hybrid	n = 4 (11%)

JTCVS. 2020;159: 392

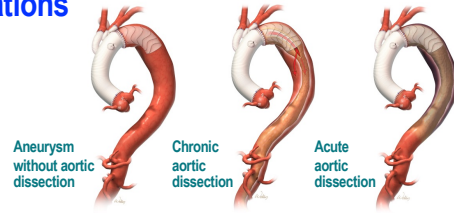


### Methods: Thoraflex FDA Trial

- Prospective, multi-center, open-label, single-arm study
- 12 sites across US; performance goal design
- 65 patients recruited to the primary study group
- 9 patients recruited to rupture study group
- Patients assessed and postoperatively at discharge/30 days, and at 3 m, 12 m, 24 m, and 36 months
- September 2016 to May 2018



### Indications



Group	Aneurysm without aortic dissection	Chronic aortic dissection	Acute aortic dissection
Primary (n=65)	27 (40%)	37 (57%)	1 (2%)
Rupture (n=9)	2 (22%)	1 (11%)	6 (67%)

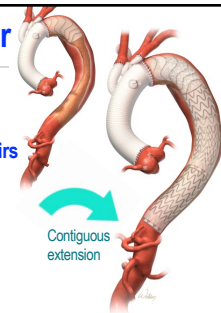
### Primary Endpoints: Primary Group (n=65)

	Early n (%)	1-Year n (%)
Major adverse event (MAE)	8 (12%)	13 (20%)
Patients with at least one MAE	8 (12%)	13 (20%)
All-cause mortality	2 (3%)	7 (11%)
Permanent stroke	4 (6%)	5 (8%)
Permanent paraplegia/paraparesis (n=64)*	2 (3%)	3 (5%)
Unanticipated aortic-related reoperation	1 (2%)	3 (5%)

Cumulative events  
\*Excludes one patient with preoperative paraplegia

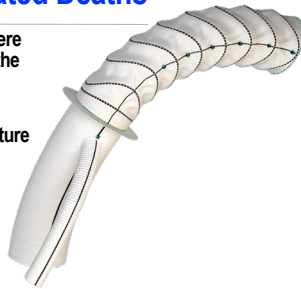
### Extension: Stage 2 Repair

- Within the first year, the planned extension (Stage-2) repair to treat the contiguous downstream distal aorta
- Primary Group: 26 (40%) planned repairs
  - Endovascular (n = 21, 32%)
  - Open (n = 5, 8%)
- 1 of 26 repairs underwent additional endovascular repair to treat acute dissection with rupture of distal aorta
- Rupture Group: no planned repairs



### Aortic-Disease Related Deaths

- Within the first year, there were two aortic-related deaths in the primary group
- Both deaths were due to rupture of the downstream aorta
- There were no aortic-related deaths in the rupture group



### Terumo Aortic announces launch of global Thoraflex Hybrid EXTEND study

13<sup>th</sup> June 2023

- Prospective, multicenter, nonrandomized, single arm
- Thoraflex graft
- Global study 55 centers
- Min 200 patients
- Follow-up 10 years
- 65 patients with RelayPro NBS distal extension



### Study Enrollment/Subject Disposition

	Institution Name	Principal Investigator	Subjects Enrolled
008	Universitätsklinik für Herzchirurgie	Andrea Votach	1
020	Hedinger Washington Hospital	Christian Shultz, MD	4
016	University of Pennsylvania	Wilson Szeto, MD	12
018	St. Luke's Medical Center/Baylor Houston (Common Spirit)	Dr. Joseph Coe III	6
019	Duke University Medical Center	Chad Hughes	1
022	University of Colorado	T. Brett Neece, MD	3
023	Keck hospital of USC	Fernando Fleischman, MD	7
021	Northwestern University	S. Chris Malalerie, MD	2
017	Cedars-Sinai Medical Center	Pedro Catarino, MD	8
025	UPMC Presbyterian ShadySide	Derek Serna-Gallaga, MD	8
028	Wall Cornell Medicine	Christopher Lau, MD	3
028	University of Alabama Birmingham	Kyle Eudaley	4
029	Massachusetts General Hospital	Arminder Jassar, MD	4
030	Washington University & Barnes Jewish Hospital	Puja Kachroo, MD	4

• 68 subjects enrolled  
• 9 subjects have discontinued  
• 11 subjects received a RelayPro NBS extension

Site Reported, Preliminary Data. Data may change. Data cut of 18 Jul 2024

### Indication for treatment 68 Patients

Aneurysm (Majority fusiform 75% [27/36])	53% (33/68)	Additional indications for treatment	
Dissection	47% (32/68)	Rupture	1.5% (1/68)
Hyperacute	10% (3/31)	Post-dissection aneurysm	13% (9/68)
Acute/Subacute	48% (15/31)	PAU	1.5% (1/68)
Chronic	42% (13/31)	Other	6% (4/68)
DeBakey Type I (Majority)	43% (12/28)		

Data reported on the number of subjects (n). Preliminary Data. Data may change. Data cut of 18 Jul 2024

### Baseline Comorbidities

Demographics			
% (n/N) or Mean ± SD (n)			
Age (years) at Treatment	62.5 ± 11.3 (63)	Coronary Artery Disease	32% (22/68)
Sex		Congestive Heart Failure	19% (13/68)
Male	82.5% (52/63)	Hypertension	74% (50/68)
Female	17.5% (11/63)	Hyperlipidemia	44% (30/68)
Age Group		COPD	12% (8/68)
18-64	47.6% (30/63)	Previous aortic surgery	50% (31/62)
65-74	38.1% (24/63)	Previous valve replacement	24% (15/62)
75+	14.3% (9/63)	History of Diabetes	13% (8/62)
Race		History of Smoking	
Caucasian	82.9% (59/62)	Former smoker	42% (26/62)
Black	22.6% (14/62)	Current smoker	13% (8/62)
Asian	12.9% (8/62)		
Other	1.6% (1/62)		

### Procedural Characteristics

- **Thoraflex Hybrid Configuration**
  - Ante-Flo configuration 39.3% (24/61)
  - Plexus configuration 60.7% (37/61)
- **Cut-down/collar attachment**
  - Between the IA and LSA (Zone 2): 63.2% (43/68)
- **2 (3.1%) endoleaks were reported by the site at the end of the procedure.**
- **No device deficiencies reported at the procedure.**
- **Anticoagulation and/or Antiplatelet Treatments Administered During Procedure, 80.3% (53/66)**

Procedural Characteristics	
General Anesthesia	100% (68/68)
Cerebral perfusion	
Antegrade	74% (48/65)
Retrograde	12% (8/65)
Both	14% (9/65)
Mean Cerebral Perfusion Time	48 ± 33 min
Mean CPB	200.4 ± 76.6 min
Mean total circulatory arrest	38.7 ± 22.9 min

### Mortality (All-Cause)

Mortality (All-Cause)	
All-cause mortality [n=68]	8 (11.8%)
Deaths (not related to the device)	7 (10.3%)
One pending relatedness	-
Deaths (related to the procedure)	5 (7.4%)
30-day Mortality (index procedure)	6 (8.8%)

### Major Adverse Events

	End of Procedure	30-Days	12 Months	2 Years
Number of Subjects Eligible	68	67	5	-
Myocardial Infarction (MI)	0	0	0	0
Stroke	0	0	0	0
Renal Failure	0	1.5% (1/67)	0	0
Respiratory Failure	1.5% (1/68)	1.5% (1/67)	0	0
Bowel Ischemia	0	0	0	0

Site Reported Data. Data reported on 6 (n/6). Preliminary Data. Data cut of 18 Jul 2024

## CONCLUSIONS

- The frozen elephant trunk (FET) procedure is an effective surgical treatment option for proximal thoracic aortic pathologies involving the distal arch and the descending aorta.
- Aortic reinterventions are common
- Reinterventions are associated with acceptable morbidity and mortality

# Thank you!



@JCoselli\_MD  
#NotRetiredYet

