

Surgical outcomes of the newly approved hybrid Thoraflex endoprosthesis in the United States: a multi-institutional experience

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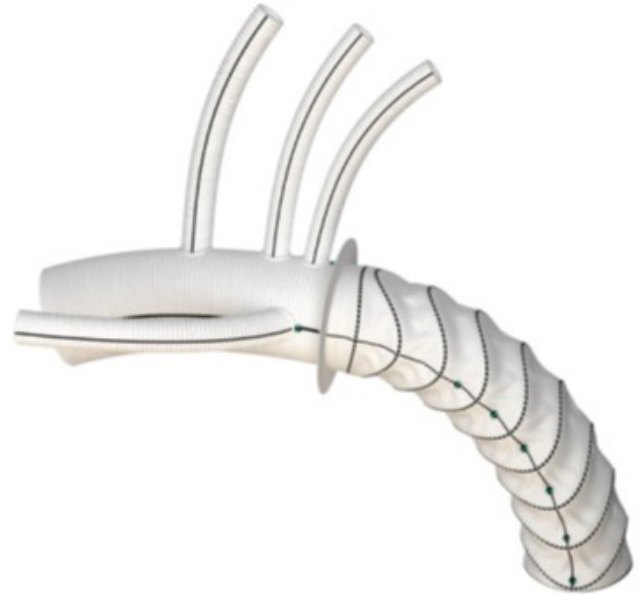
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Background

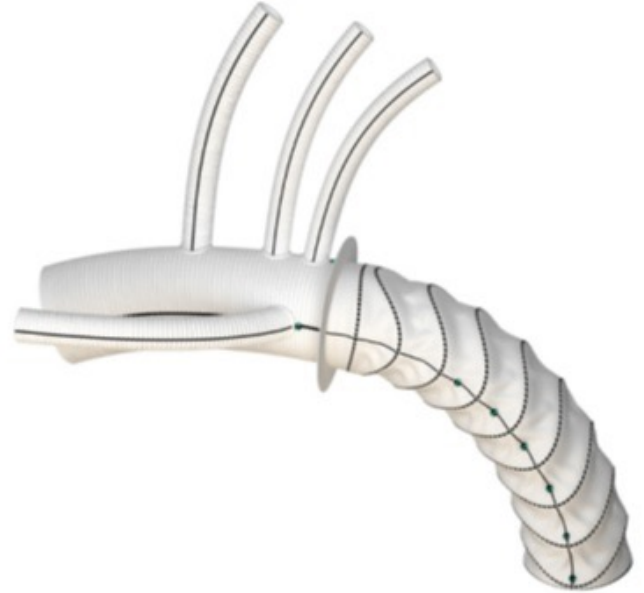
- Frozen elephant trunk (FET) repair of the aorta has traditionally relied upon distinct open and endovascular grafts, joined intraoperatively
- Thoraflex™ Hybrid was FDA approved in May 2022 as the first hybrid device for FET



<https://www.fda.gov/medical-devices/recently-approved-devices/thoraflex-hybrid-p210006>

Background

- Hybrid graft eliminates need for graft-to-graft anastomosis
 - Prone to bleeding
 - Extends circulatory arrest time



<https://www.fda.gov/medical-devices/recently-approved-devices/thoraflex-hybrid-p210006>

Aim

To combine data from multiple institutions to study early results of the Thoraflex Hybrid device

Methods

- Society of Thoracic Surgeons data were obtained for patients undergoing TAR/FET using the Thoraflex hybrid endoprosthesis
- Data were merged to assess baseline characteristics, operative details, and postoperative outcomes

Preoperative Results

Table 1. Summary of Patient Demographic Characteristics and Comorbidities

<i>Preoperative characteristics</i>	Total N=77	Acute type A aortic dissection N=23	Aneurysm N=17	Type B aortic dissection N=13	Previous type A with residual dissection N=24	p-value
Age (years), med [IQR]	64 [55, 70]	63 [57, 69]	72 [68, 76]	58 [52, 68]	60 [54, 64]	0.001
Body mass index (kg/m2), med[IQR]	29.1 [26.4, 33.1]	29.2 [26.6, 34.7]	28.7 [26.6, 30.7]	29.6 [27.2, 33.1]	28.2 [25.9, 31.3]	0.710
Male gender, n (%)	64 (83.1)	19 (82.6)	13 (76.5)	10 (76.9)	22 (91.7)	0.543
Renal disease, n (%)	9 (11.7)	2 (8.7)	4 (23.5)	1 (7.7)	2 (8.3)	0.396
Hypertension, n (%)	67 (87.0)	21 (91.3)	16 (94.1)	10 (76.9)	20 (83.3)	0.459
Chronic lung disease, n (%)	17 (22.1)	4 (17.4)	7 (41.2)	0 (0.0)	6 (25.0)	0.053
Peripheral vascular disease, n (%)	10 (13.0)	0 (0.0)	4 (23.5)	4 (30.8)	2 (8.3)	0.027
Cerebrovascular disease, n (%)	10 (13.0)	2 (8.7)	3 (17.6)	2 (15.4)	3 (12.5)	0.856
Heart failure, n (%)	11 (14.3)	1 (4.3)	4 (23.5)	1 (7.7)	5 (20.8)	0.227
Atrial fibrillation, n (%)	10 (13.0)	1 (4.3)	4 (23.5)	3 (23.1)	2 (8.3)	0.185
First time cardiac surgery, n (%)	38 (49.4)	18 (78.3)	12 (70.6)	8 (61.5)	0 (0.0)	<0.001
Status (%)						<0.001
Elective	34 (44.2)	4 (17.4)	9 (52.9)	7 (53.8)	14 (58.3)	
Urgent	26 (33.8)	4 (17.4)	7 (41.2)	6 (46.2)	9 (37.5)	
Emergent	17 (22.1)	15 (65.2)	1 (5.9)	0 (0.0)	1 (4.2)	

Intraoperative Results

Table 2. Summary of Intraoperative Outcomes

<i>Intraoperative details</i>	Total N=77	Acute type A aortic dissection N=23	Aneurysm N=17	Type B aortic dissection N=13	Previous type A with residual dissection N=24	p-value
Thoraflex deployment site, n (%)						0.069
Zone 1	12 (15.6)	4 (17.4)	0 (0.0)	4 (30.8)	4 (16.7)	
Zone 2	51 (66.2)	16 (69.6)	16 (94.1)	5 (38.5)	14 (58.3)	
Zone 3	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (8.3)	
Unclear	12 (15.6)	3 (13.0)	1 (5.9)	4 (30.8)	4 (16.7)	
Thoraflex stent diameter (mm), med [IQR]	32 [30, 36]	32 [30, 33]	34 [32, 38]	38 [34, 40]	32 [30, 34]	0.007
Thoraflex stent length (cm), med [IQR]	15 [10, 15]	10 [10, 15]	15 [15, 15]	15 [10, 15]	15 [14, 15]	0.122
Cardiopulmonary bypass time (min), med [IQR]	172 [148, 217]	191 [151, 244]	160 [145, 187]	162 [136, 185]	183 [156, 214]	0.439
Aortic cross clamp time (min), med [IQR]	66 [47, 99]	93 [57, 116]	56 [43, 82]	52 [45, 78]	70 [48, 99]	0.052
Circulatory arrest time (min), med [IQR]	19 [13, 28]	23 [16, 42]	20 [15, 25]	13 [12, 17]	16 [14, 27]	0.186
Lowest temperature (celsius), med [IQR]	28 [27, 28]	28 [26, 28]	28 [28, 28]	28 [27, 28]	28 [28, 29]	0.820
Red blood cell transfusions (units), med [IQR]	3 [1, 6]	2 [1, 7]	2 [1, 4]	5 [2, 7]	4 [2, 6]	0.418

Postoperative Results

Table 3. Summary of Postoperative Outcomes

<i>Postoperative outcomes</i>	Total N=77	Acute type A aortic dissection N=23	Aneurysm N=17	Type B aortic dissection N=13	Previous type A with residual dissection N=24	p-value
Open chest, n (%)	16 (20.8)	6 (26.1)	3 (17.6)	3 (23.1)	4 (16.7)	0.853
Reoperation for bleeding, n (%)	6 (7.8)	3 (13.0)	2 (11.8)	1 (7.7)	0 (0.0)	0.350
Stroke, n (%)	15 (19.5)	9 (39.1)	2 (11.8)	1 (7.7)	3 (12.5)	0.042
Renal failure, n (%)	9 (11.7)	3 (13.0)	1 (5.9)	3 (23.1)	2 (8.3)	0.477
Recurrent laryngeal nerve injury, n (%)	11 (14.3)	1 (4.3)	2 (11.8)	1 (7.7)	7 (29.2)	0.080
Ventilation time (hours), med [IQR]	17.8 [8.6, 90.2]	28.8 [12.1, 81.7]	16.0 [6.0, 62.6]	14.3 [7.6, 106.0]	20.7 [12.3, 95.7]	0.592
Length of stay (days), med [IQR]	11 [8, 18]	12 [9, 14]	10 [7, 16]	10 [8, 18]	11 [8, 18]	0.935
Operative mortality, n (%)	9 (11.7)	7 (30.4)	2 (11.8)	0 (0.0)	0 (0.0)	0.005

Conclusions

- Mortality was acceptable given acuity of patients
 - No deaths amongst patients presenting with Type B or previous Type A with residual dissection
 - Comparable to existing series outside the United States
- Outcomes will continue to improve with additional volume and experience
- Thoraflex is effective for TAR/FET across multiple aortic pathologies