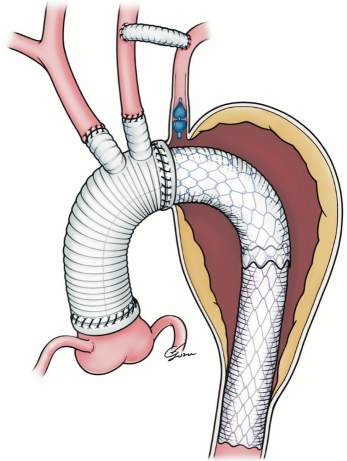
Surgical outcomes of total arch replacement with frozen elephant trunk deployment: a comparison of the Thoraflex device with traditional techniques

Markian Bojko MD MPH[1], William Oslund MD[1], Emma Longo BS[1], Kamso Okonkwo BS[1], Herbert James III MD[1], Jessica Clothier MD[1], Nithya Rajeev BS[1], Serge Kobsa MD PhD[1], Fernando Fleischman MD[1]

[1]Division of Cardiac Surgery, Department of Surgery, University of Southern California, Los Angeles, CA

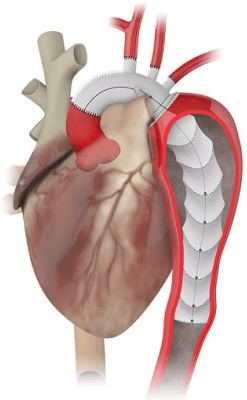
Background

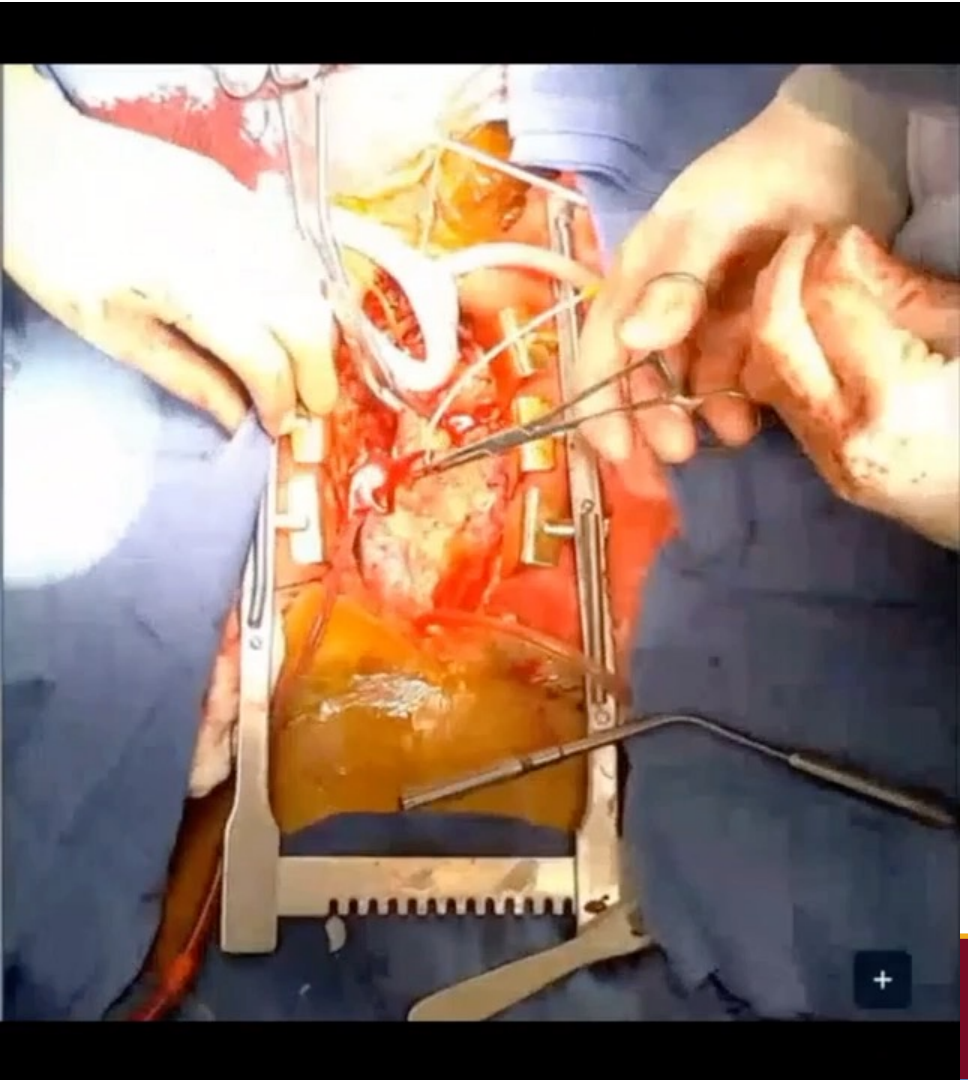
Traditional total arch replacement (TAR) with frozen elephant trunk (FET) requires a graft-to-graft anastomosis in the distal aortic arch



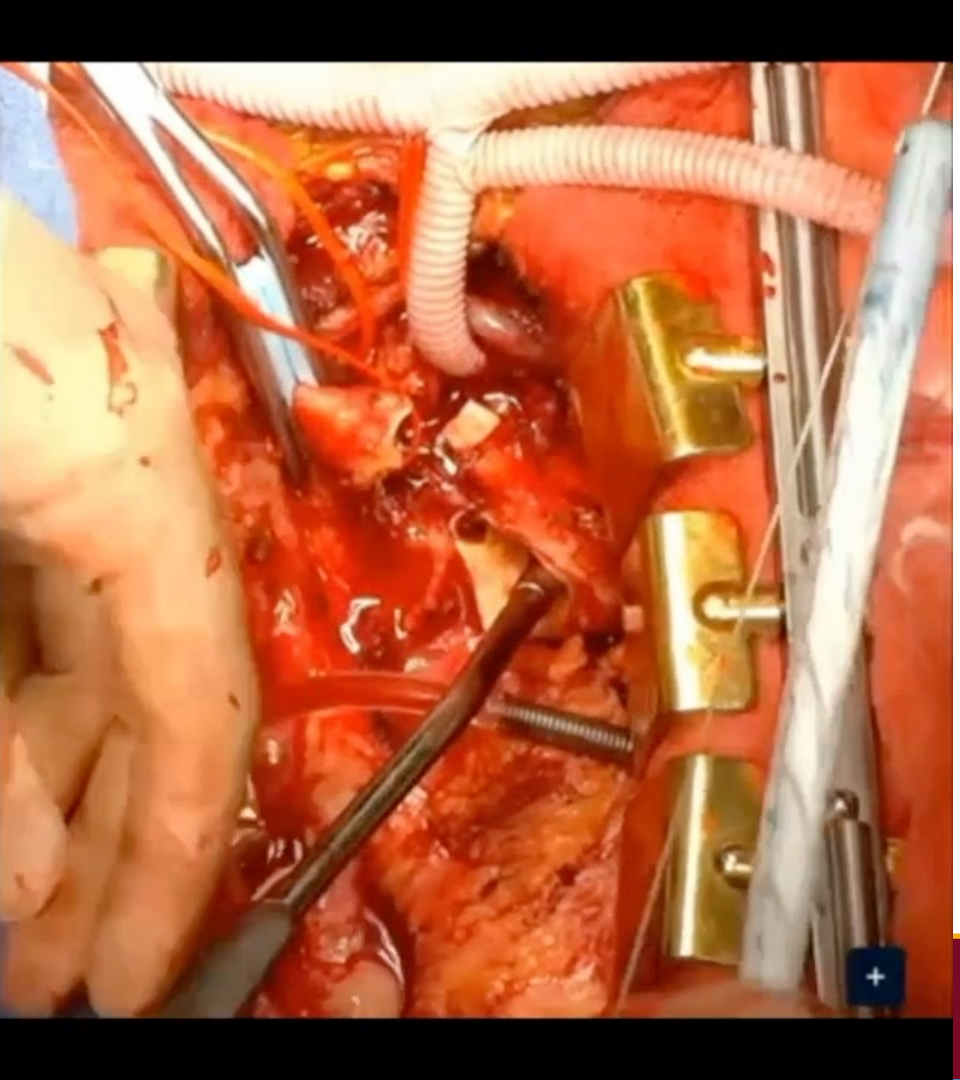
Thoraflex™ Hybrid is an endoprosthesis that treats the arch and thoracic aorta in a single device

- Sewing collar for distal arch anastomosis





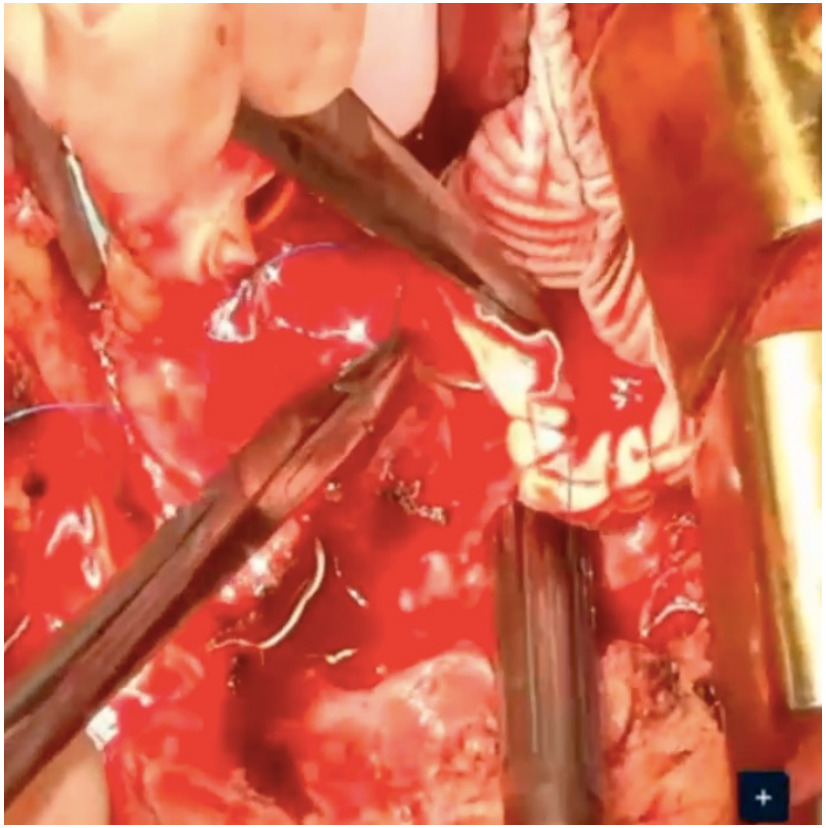
- Bypass has been initiated via right axillary artery
- Trifurcated Gleason graft sewn to left carotid
- Heart arrested
- Clamp applied to innominate, beginning circulatory arrest
- Crossclamp removed and aortotomy created for arch resection



- Thoraflex preloaded on Lunderquist wire
- Wire passed antegrade down thoracic aorta and device deployed

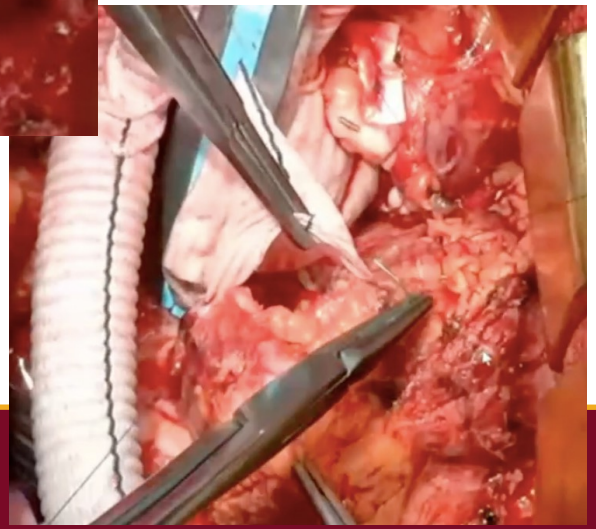
- Sewing collar facilitates distal anastomosis

- True lumen of arch graft continuous with descending thoracic stent graft

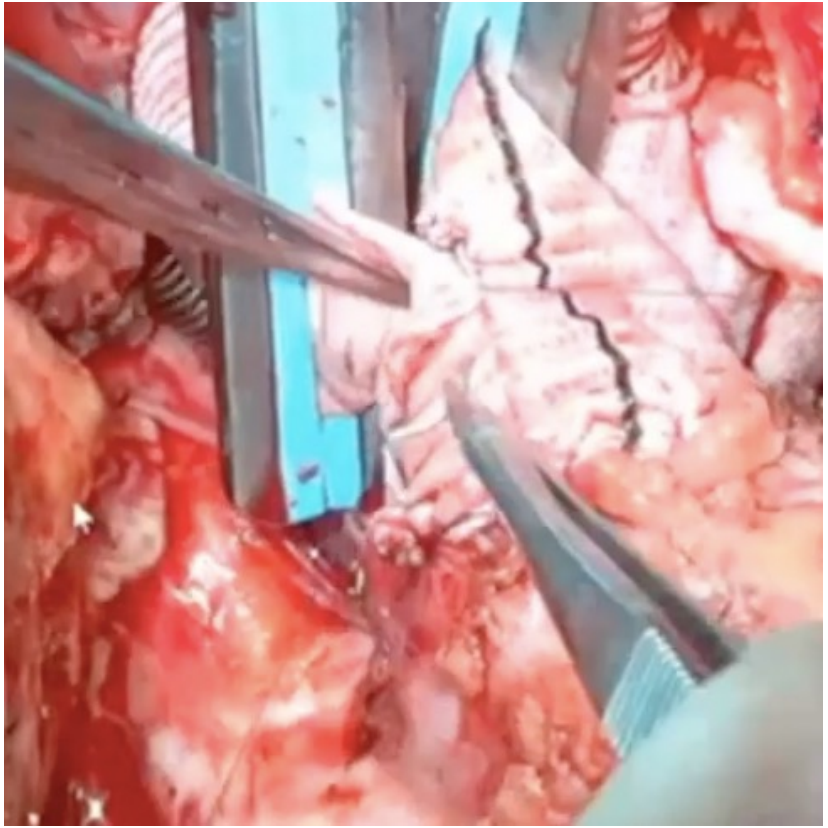


- Innominate artery prepared and anastomosed end-to-end to branch of the trifurcated graft

- Proximal Thoraflex anastomosed to ascending aorta



- Proximal graft-to-graft anastomosis



Methods

- Purpose: compare outcomes of traditional TAR/FET with thoraflex
- 225 patients identified who underwent TAR/FET between 2012 to 2023
  - 173 (77%) traditional TAR/FET
  - 52 (23%) Thoraflex implantation
- Propensity score matching performed to obtain comparable groups across preoperative risk factors in a 1:2 (Thoraflex:traditional) ratio
- Matched and unmatched patients compared across baseline characteristics, operative details, and postoperative outcomes
- Multivariable logistic regression identified risk factors for operative mortality

Preoperative Results

Unmatched	Total (N=225)	Traditional TAR/FET (N=173)	Thoraflex (N=52)	p-value	SMD
Age (years), med [IQR]	61 [52, 71]	60 [50, 71]	64 [57, 70]	0.117	0.317
Male gender, n (%)	**164 (72.9)**	**120 (69.4)**	**44 (84.6)**	**0.046**	**0.368**
Body mass index (kg/m2), med [IQR]	28.7 [24.6, 32.4]	28.7 [23.8, 32.4]	28.5 [26.4, 31.7]	0.342	0.036
Creatinine (mg/dL), med [IQR]	**1.06 [0.88, 1.48]**	**1.12 [0.90, 1.61]**	**0.95 [0.85, 1.14]**	**0.020**	**0.432**
Hypertension, n (%)	207 (92.0)	162 (93.6)	45 (86.5)	0.173	0.239
Peripheral vascular disease, n (%)	44 (19.6)	37 (21.4)	7 (13.5)	0.287	0.210
Cerebrovascular disease, n (%)	35 (15.6)	29 (16.8)	6 (11.5)	0.488	0.150
Matched		**N=104**	**N=52**	**p-value**	**SMD**
Age (years), med [IQR]		60 [52, 72]	64 [57, 70]	0.376	0.185
Male gender, n (%)		85 (81.7)	44 (84.6)	0.822	0.077
Body mass index (kg/m2), med [IQR]		28.1 [23.3, 31.4]	28.5 [26.4, 31.7]	0.182	0.056
Creatinine (mg/dL), med [IQR]		1.06 [0.88, 1.31]	0.95 [0.85, 1.14]	0.219	0.147
Hypertension, n (%)		95 (91.3)	45 (86.5)	0.514	0.154
Peripheral vascular disease, n (%)		18 (17.3)	7 (13.5)	0.700	0.107
Cerebrovascular disease, n (%)		13 (12.5)	6 (11.5)	1.000	0.030

Intraoperative Results

Unmatched	Total (N=225)	Traditional TAR/FET (N=173)	Thoraflex (N=52)	p-value
Perfusion time (min), med [IQR]	**187 [152, 239]**	**190 [153, 244]**	**172 [145, 208]**	**0.043**
Cross clamp time (min), med [IQR]	**96 [62, 131]**	**103 [64, 138]**	**77 [55, 101]**	**0.002**
Total circulatory arrest time (min), med [IQR]	**23 [16, 34]**	**27 [18, 36]**	**16 [13, 24]**	**<0.001**
Total operating room time (hours), med [IQR]	**8.8 [7.5, 10.4]**	**9.0 [7.8, 10.7]**	**8.0 [7.1, 9.2]**	**0.001**
Total procedure time (hours), med [IQR]	**6.9 [5.8, 8.5]**	**7.1 [6.0, 8.9]**	**6.1 [5.3, 7.4]**	**0.001**
Lowest temperature (celsius), med [IQR]	**27.6 [25.0, 28.3]**	**27.0 [25.0, 28.3]**	**28.0 [27.0, 28.4]**	**0.016**
Intraoperative Red Blood Cells (units), med [IQR]	**5 [3, 7]**	**5 [3, 7]**	**4 [2, 7]**	**0.033**
Matched		N=104	N=52	p-value
Perfusion time (min), med [IQR]		**194 [153, 245]**	**172 [145, 208]**	**0.049**
Cross clamp time (min), med [IQR]		**102 [63, 141]**	**77 [55, 101]**	**0.005**
Total circulatory arrest time (min), med [IQR]		**23 [17, 37]**	**16 [12, 23]**	**<0.001**
Total operating room time (hours), med [IQR]		**9.0 [7.8, 10.8]**	**8.0 [7.1, 9.2]**	**0.003**
Total procedure time (hours), med [IQR]		**7.0 [5.9, 8.9]**	**6.1 [5.3, 7.4]**	**0.002**
Lowest temperature (celsius), med [IQR]		27.7 [25.5, 28.5]	28.0 [27.0, 28.4]	0.177
Intraoperative Red Blood Cells (units), med [IQR]		5 [3, 7]	4 [2, 7]	0.122

Postoperative Results

Unmatched	Total (N=225)	Traditional TAR/FET (N=173)	Thoraflex (N=52)	p-value
Bleeding requiring reintervention, n (%)	13 (5.8)	11 (6.4)	2 (3.8)	0.732
Sepsis, n (%)	**28 (12.4)**	**27 (15.6)**	**1 (1.9)**	**0.017**
Stroke, n (%)	37 (16.4)	28 (16.2)	9 (17.3)	1.000
Renal failure, n (%)	47 (20.9)	41 (23.7)	6 (11.5)	0.090
Tracheostomy, n (%)	20 (8.9)	16 (9.2)	4 (7.7)	0.946
Highest creatinine (<48 hours), med [IQR	**1.63 [1.13, 2.54]**	**1.75 [1.18, 2.71]**	**1.31 [1.08, 1.91]**	**0.005**
Total ventilation time (hours), med [IQR]	**44 [16, 144]**	**51 [17, 177]**	**20 [11, 91]**	**0.014**
In hospital or 30 day mortality, n (%)	34 (15.1)	30 (17.3)	4 (7.7)	0.138
Matched		N=104	N=52	p-value
Bleeding requiring reintervention, n (%)		8 (7.7)	2 (3.8)	0.563
Sepsis, n (%)		**18 (17.3)**	**1 (1.9)**	**0.012**
Stroke, n (%)		15 (14.4)	9 (17.3)	0.814
Renal failure, n (%)		20 (19.2)	6 (11.5)	0.323
Tracheostomy, n (%)		11 (10.6)	4 (7.7)	0.773
Highest creatinine (<48 hours), med [IQR]		1.50 [1.16, 2.30]	1.31 [1.08, 1.91]	0.088
Total ventilation time (hours), med [IQR]		44 [15, 183]	20 [11, 91]	0.082
In hospital or 30 day mortality, n (%)		18 (17.3)	4 (7.7)	0.167

- Multivariable logistic regression: age (OR 1.04, p=0.032), cross clamp time (OR 1.01, p=0.004), and number of red blood cell transfusions (OR 1.22, p=0.002) were predictors of 30-day mortality

Conclusions

- Thoraflex simplifies the distal arch anastomosis in TAR/FET
  - Shorter cross clamp times
  - Lower transfusion requirement
  - Shorter procedure and OR time

- Thoraflex is effective for TAR/FET, showing meaningful improvements in operative and postoperative outcomes