Long-term outcomes of the Physician-Modified Fenestrated and Branched Endovascular Grafts for Complex Aortic Disease

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Conflict of Interest Disclosures

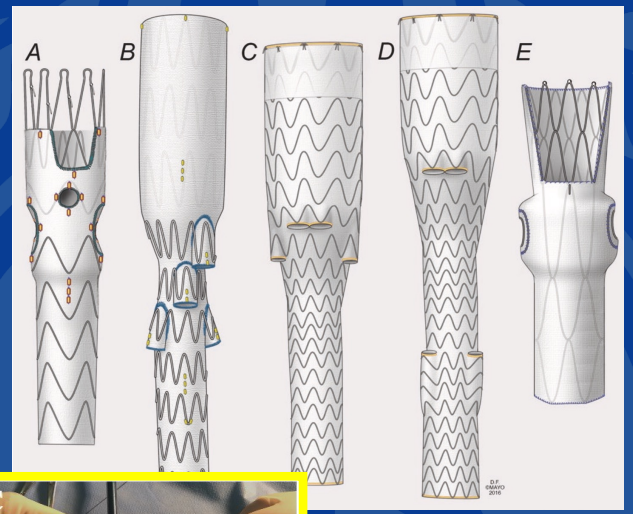
I have no relevant financial relationships to disclose at this time.

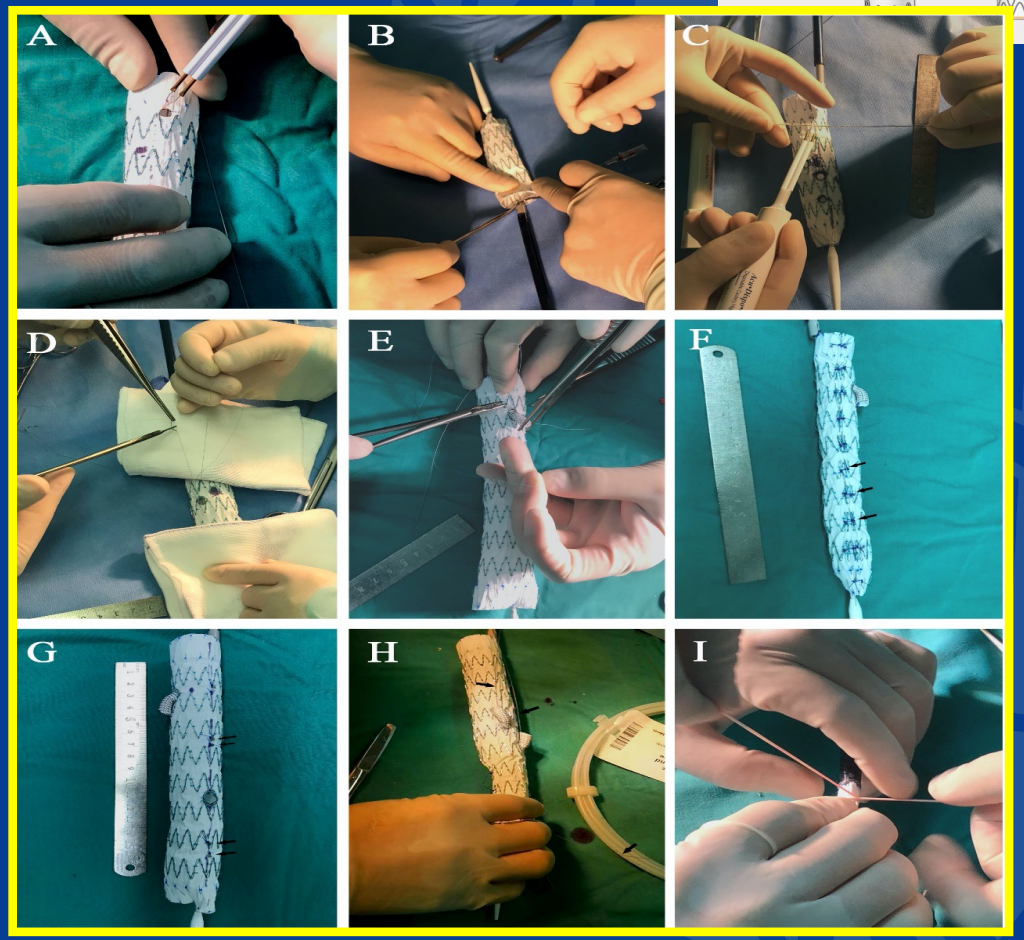
Background

- Current Endo Solutions Either Approved or Under Industry Sponsored Study

  - T-Branch
    Approved in Europe and undergoing clinical trail in the U.S
  - Z-Fem
    4 fenestrations currently undergoing clinical trail in the U.S
  - Tambe
    Completed Pivotal Enrollment
  - Jotec E-nside

- Can One System Work Everywhere?
- Not universally accessible, including China;
- PMEG/ or other parallel graft.





Aims

- Comprehensive analysis focusing on the long-term outcomes of physician-modified endografts (PMEGs) in the endovascular repair of complex aortic diseases, utilizing data from aortic centers in southeast China.

Methods

2017-2021

-Descriptive study

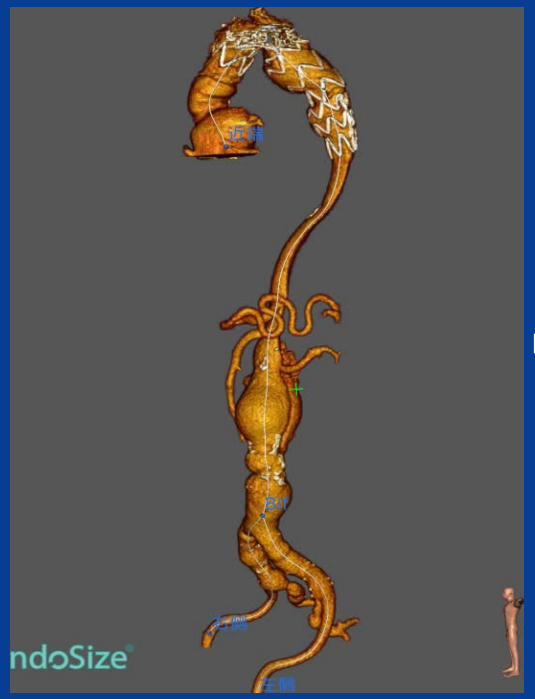
-Patient cohort

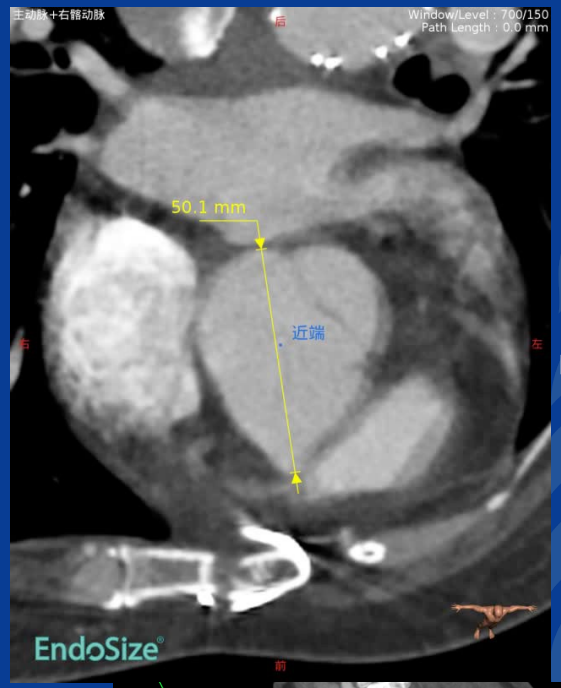
- aortic aneurysm size >55 mm or rapid growth (5 mm/year) and persistent back pain, a frank or impending rupture, organ/lower limb mal-perfusion or other aneurysm-related complications.
- Patient who had previous heart surgery or history of median sternotomy and unfitted for open surgery repair.
- Patients who reject open surgery repair.

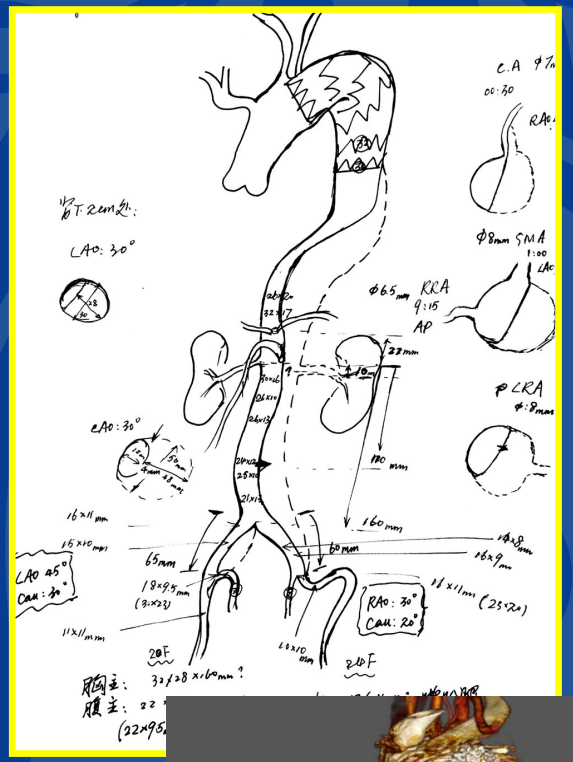
exclusion criteria for PMEGs

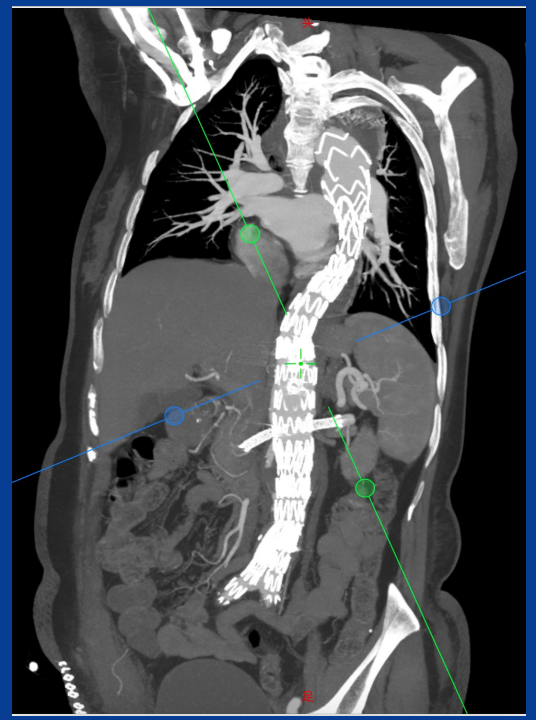
- small diameter (iliac artery <6 mm or target vessel <3 mm.
- excessive angulation or heavily calcified access.
- aberrant or early branching.
- Proximal landing zone >40 mm diameter.
- Connective tissue disease.

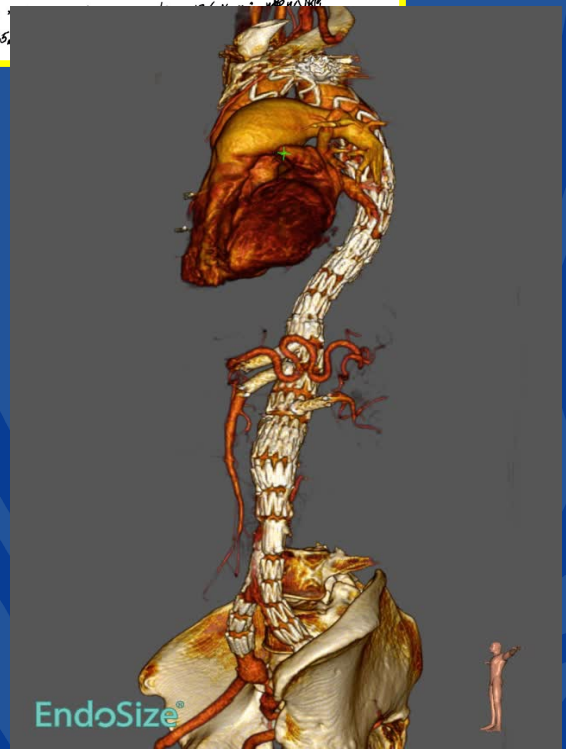
Post-dissection aneurysm following FET











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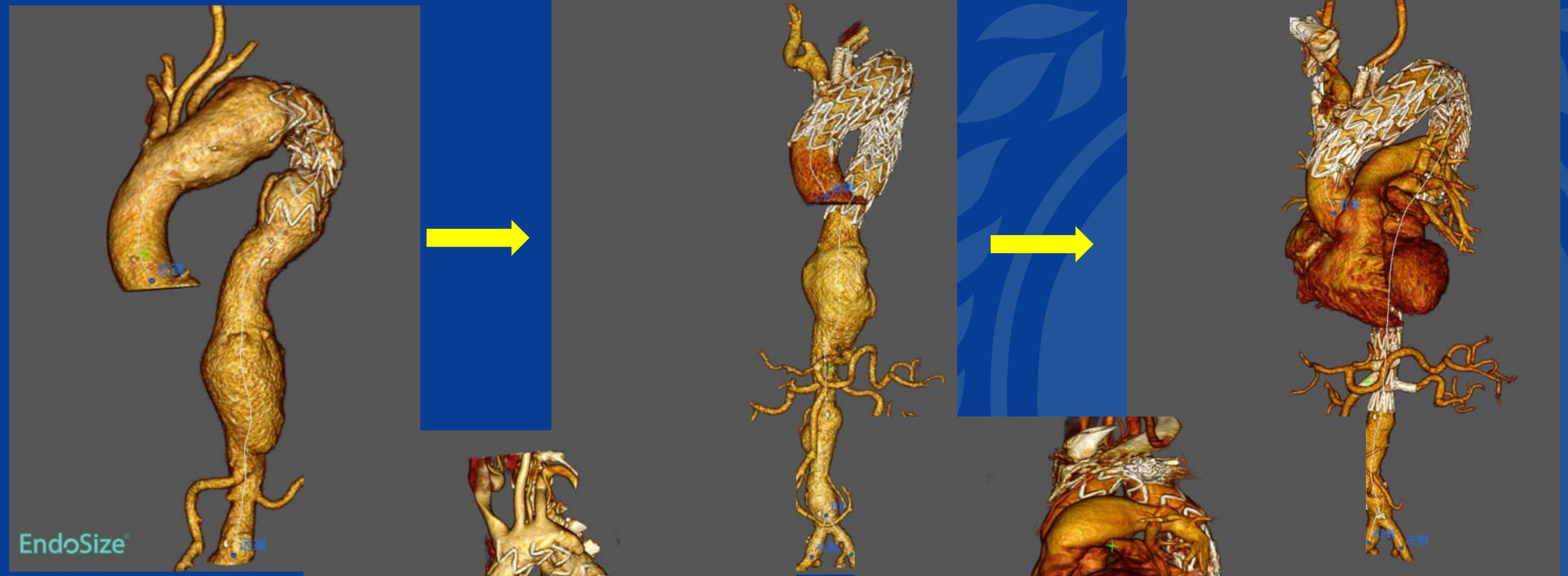

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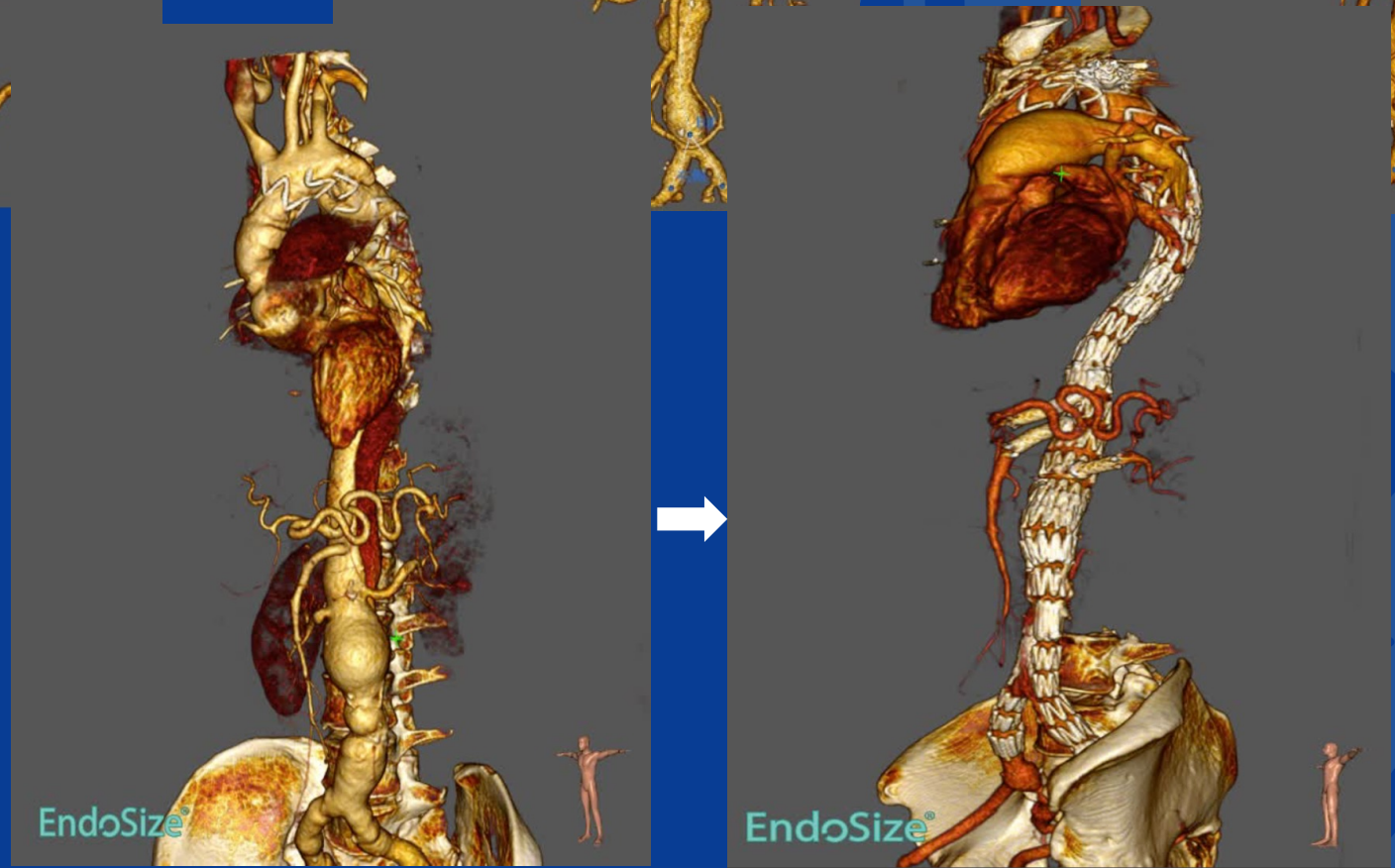

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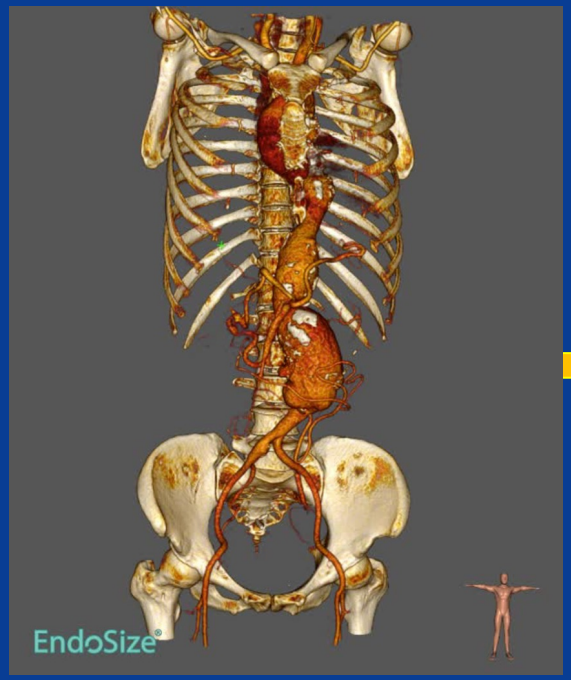

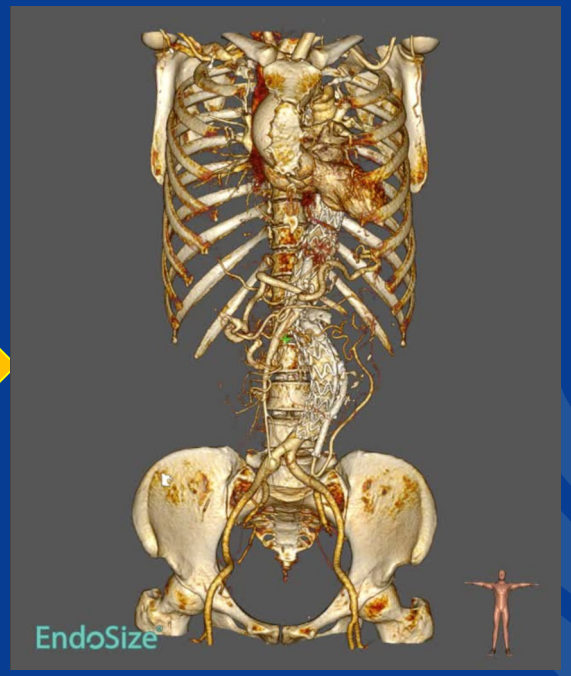

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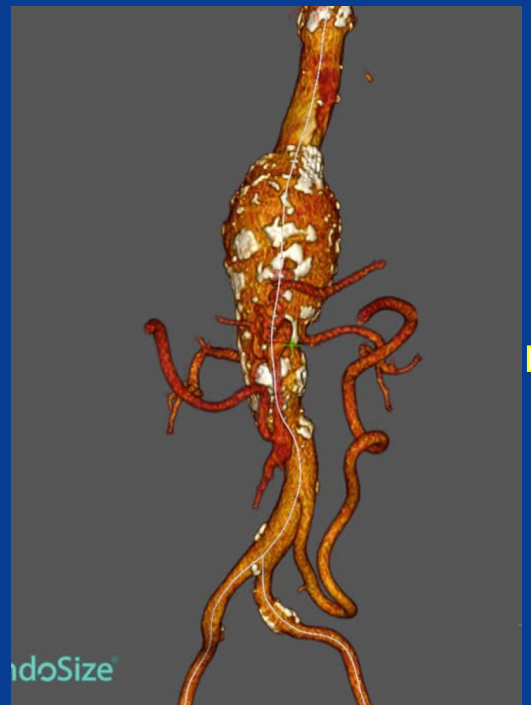

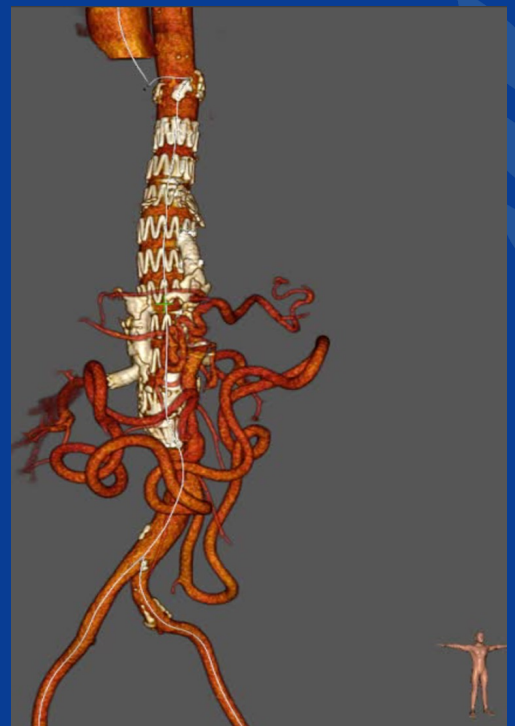

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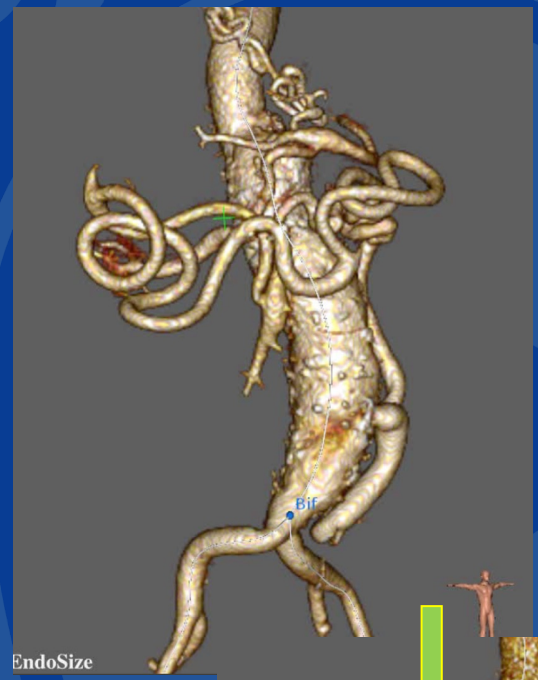
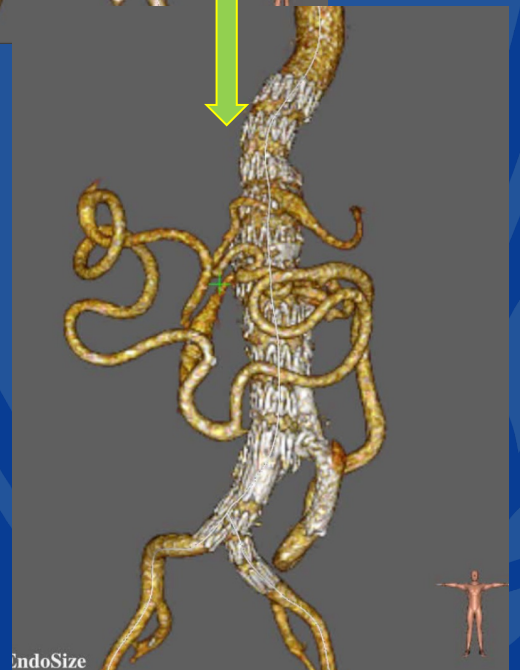




Results

Table. Patient Demographics

Variable	All patients(n=186)
Demographics	
Mean age, y	68.4 ± 13.4
Male (%)	156 (83.9)
Urgent procedure (%)	82 (44.1)
Cardiovascular risk factors	
Hypertension	165 (88.7)
Hypercholesterolemia	112 (60.2)
Coronary artery disease	43 (23.1)
CKD stage III-IV	27 (14.5)
COPD	24 (12.9)
Diabetes mellitus	47 (25.3)
Stroke	25 (13.4)
Congestive heart failure	21 (11.3)
ASA class ≥III	163 (87.6)
Prior aortic repair	
TEVAR	65 (34.9)
FET	15 (8.1)
FET+TEVAR	10 (5.4)
EVAR	6 (3.2)
Aneurysm type	
Extent I TAAAs	28 (15.5)
Extent II TAAAs	76 (42.0)
Extent III TAAAs	14 (7.7)
Extent IV TAAAs	33 (18.2)
CAAAs	
Pararenal AAAs	14 (7.7)
Juxtrenal AAAs	13 (7.1)
Short-neck AAAs	8 (4.4)
Anatomical characteristics	
Post-dissection AA	105 (56.5)
Degenerative AA	81 (43.5)
Aneurysm maximum Diameter, mm	56.5 ± 18.9

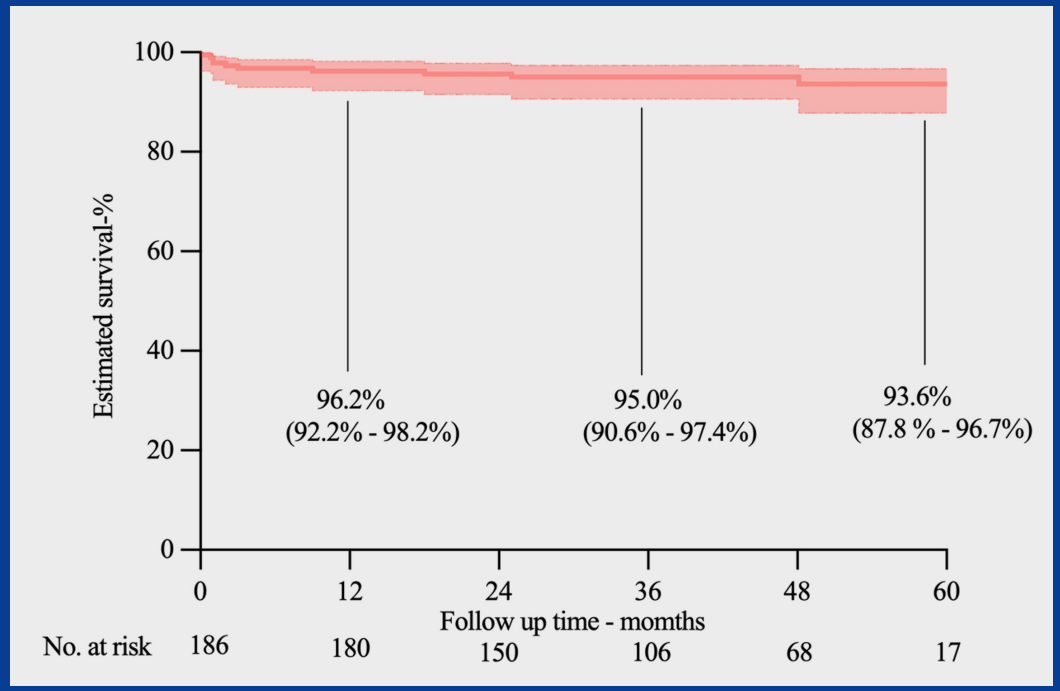
Table 2. Peri-operation characteristics

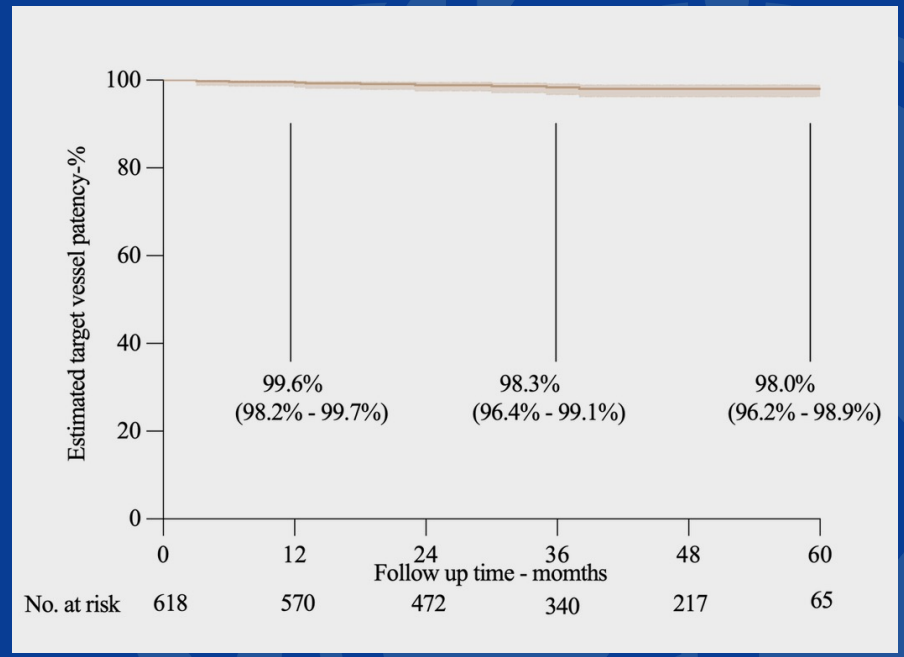
Variable	All patients n=186
Technical success per patient (%)	182 (97.8)
Temporary iliofemoral conduits (%)	25 (13.4)
Preloaded wire	44 (23.7)
Neuromonitoring	28 (15.1)
CFD	2 (1.1)
Contrast volume, ml	235 ± 45
Fluoroscopy time, min	68 ± 14
Total radiation dose, mGy	1685 ± 324
Percutaneous femoral access	77 (41.4)
Upper extremity access	177 (95.2)
Device platform	
Cook Zenith	62 (33.3)
Ankura	87 (46.8)
Hercules	37 (19.9)
Bifurcate body	74 (39.8)
Staged procedure	77 (41.4)
Vessels per patient	3.3 ± 0.9
Manufacturing time, min	40 ± 10
Type of incorporation	618
Fenestrations	530 (85.8)
Directional branches	86 (13.9)
Scallops	2 (0.3)
Total operative time, min	320 (130-720)
Estimated blood loss, ml	400 (100-2000)
Technical success per vessel (%)	614/618 (99.4)

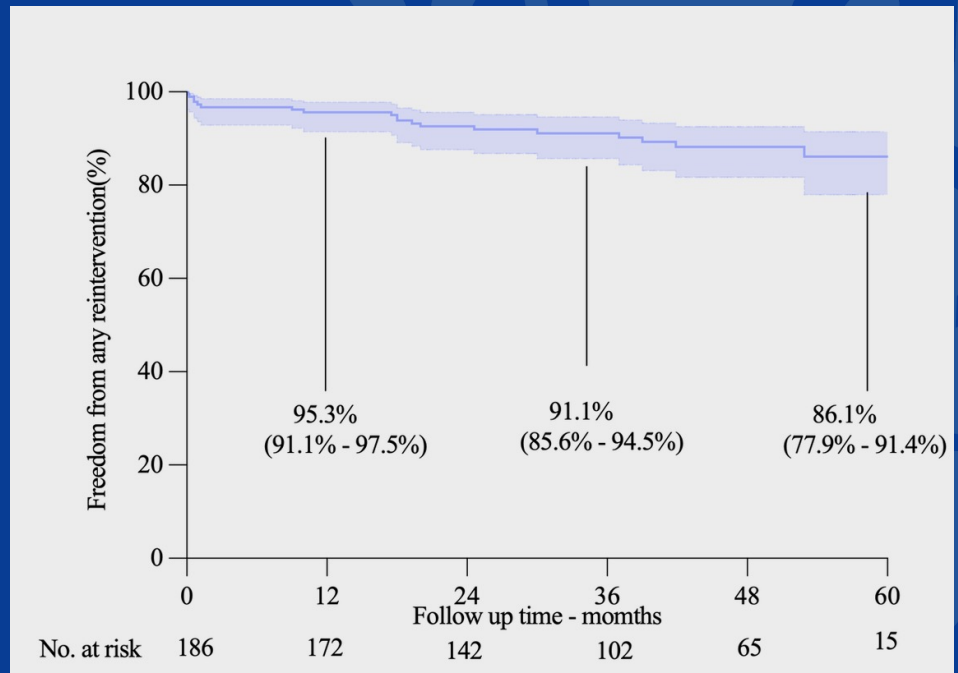
Table 3. late outcomes

Variable	All patients n=186
Any MAEs	42 (22.6)
Mortality	6 (3.2)
AKI by RIFLE criteria	11 (5.9)
New-onset dialysis	6 (3.2)
Any SCI	1 (0.54)
Myocardial infarction	5 (2.7)
Respiratory failure	7 (3.8)
Bowel ischemia requiring resection	3 (1.6)
Stroke	5 (2.7)
Limb ischemia	5 (2.7)
Hospital stay length, days	17.3 ± 8.5
ICU stay, days	1.6 ± 0.4
Any secondary intervention	4 (2.2)
Aortic secondary intervention	2 (1.1)
Follow-up (months)	40.5 ± 15.0
Mortality (%)	4 (2.2)
Type A dissection	1 (0.6)
Endoleaks (New onset)	17 (9.7)
Ia	1 (0.6)
Ib	2 (1.2)
Ic	10 (6.6)
II	2 (1.2)
Ia/III	1 (0.6)
Ic/III	1 (0.6)
Any secondary intervention	6 (3.4)
Aortic secondary intervention	7 (4.0)
Number of target vessels	602
Branch kinking, stenosis, occlusion, or dislodgment (%)	13 (2.2)

Results


Estimated survival-%
100
80
60
40
20
0
96.2%
(92.2% - 98.2%)
95.0%
(90.6% - 97.4%)
93.6%
(87.8 % - 96.7%)
0
12
24
36
48
60
Follow up time - momths
No. at risk
186
180
150
106
68
17


Estimated target vessel patency-%
100
80
60
40
20
0
99.6%
(98.2% - 99.7%)
98.3%
(96.4% - 99.1%)
98.0%
(96.2% - 98.9%)
0
12
24
36
48
60
Follow up time - momths
No. at risk
618
570
472
340
217
65


Freedom from any reintervention(%)
100
80
60
40
20
0
95.3%
(91.1% - 97.5%)
91.1%
(85.6% - 94.5%)
86.1%
(77.9% - 91.4%)
0
12
24
36
48
60
Follow up time - momths
No. at risk
186
172
142
102
65
15

Conclusion

- PMEGs serve as a crucial bridging tool in the toolkit of aortic surgeons, particularly when manufactured devices are not immediately accessible.
- Although initial outcomes are promising, pooled data and continued surveillance is a crucial component of endovascular repair.


THANK YOU!
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