

# Endovascular Debranched Aortic Repair Using the Unitary Stent Graft System for Treatment of Various Thoracoabdominal Aortopathies



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## BACKGROUND

- ❖ Physician-modified endografts (PMEG) now the prevailing treatment for complex aortic aneurysms and thoracoabdominal aortic aneurysms (TAAA)<sup>1</sup>
  - ❖ Increasingly used instead of custom manufactured grafts
  - ❖ Increasingly employed for juxta- and para-renal aortic pathologies
  - ❖ Increasing need for endovascular treatment of failed prior repairs
- ❖ Open surgical repair of TAAAs can be highly morbid<sup>2</sup>
- ❖ Operative mortality (30-day or in-hospital mortality) up to 7.5%; paraplegia and paraparesis up to 5.4%<sup>2</sup>
- ❖ This single center experience evaluates the investigational, physician-assembled unitary stent graft (USG) for endovascular debranched aortic repair (EDAR) of a diverse array of thoracoabdominal aortopathies.

## METHODS

- ❖ Between November 2021 and March 2023, 15 consecutive high-surgical risk patients underwent EDAR to treat dissecting and non-dissecting TAAA, including failed prior repairs.
- ❖ A physician-sponsored investigational device pre-submission database (Q222702) → prospectively maintained and retrospectively reviewed for:
  - ❖ Mortality and major adverse events (MAEs) at 30 days
  - ❖ **Technical success** (successful back-table assembly, delivery, and deployment of the USG; target vessel endoluminal bypasses; and infrarenal aortic interventions)
  - ❖ Treatment success as assessed via clinical follow-up with imaging

## RESULTS

- ❖ Technical success was achieved in all (100%), including endoluminal bypasses to all intended 57 visceral vessels.
- ❖ There was 1 episode of multiorgan failure and in-hospital mortality (6.7%) in a patient with disseminated intravascular coagulopathy.
- ❖ 30-day primary and secondary patency rates of 100%
- ❖ There were no type I or III endoleaks immediately or at 30-day follow up.

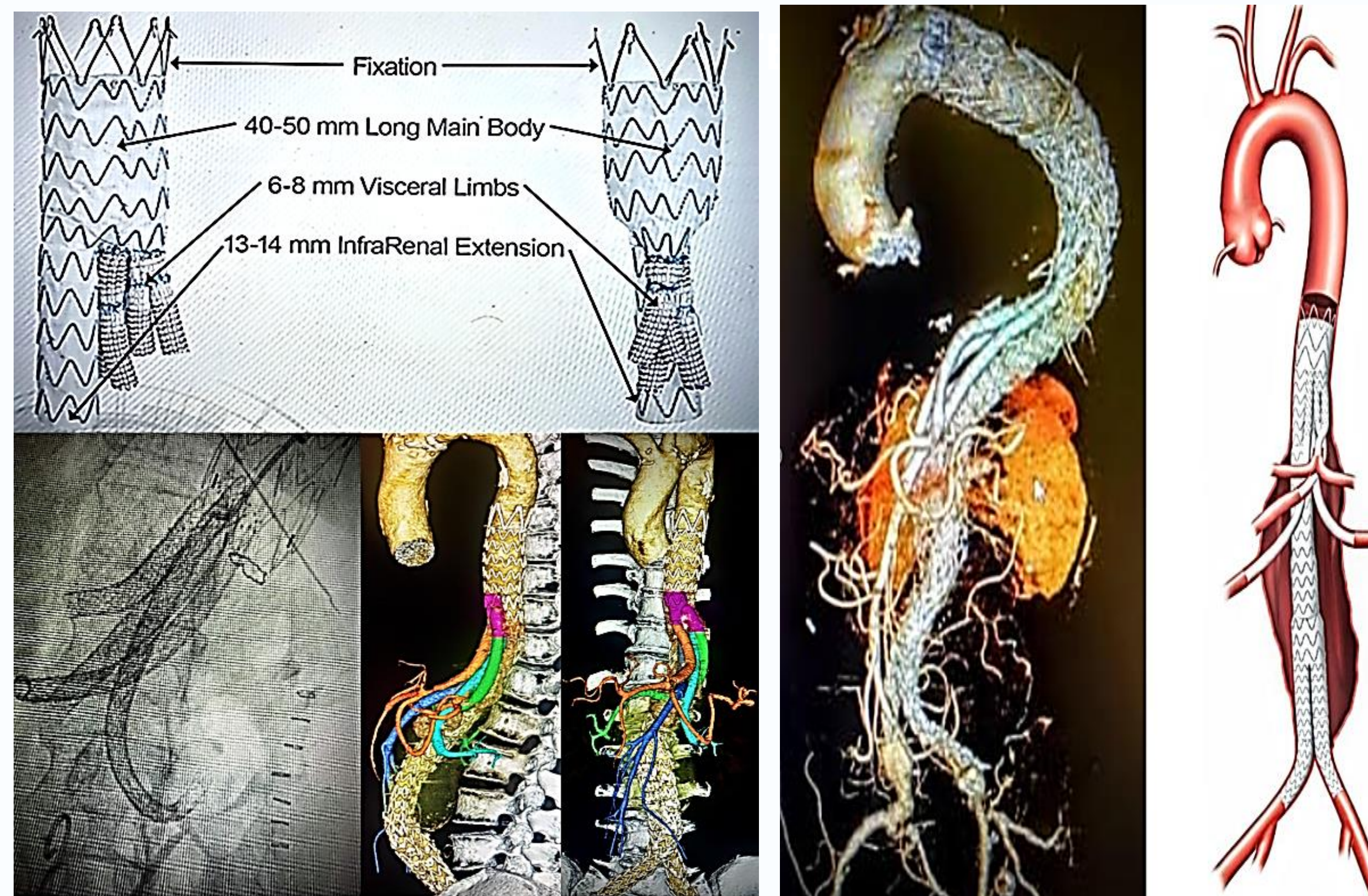


Figure 1. Endovascular debranched aortic repair utilizing the unitary stent graft system

Variables	Yale New Haven Hospital
<b>Number of Subjects</b>	<b>15</b>
Gender	
Female	7 (46.7)
Male	8 (53.3)
Cigarette smoking	
Current smoker	4 (26.7)
Previous smoker	9 (60.0)
Never	2 (13.3)
Renal failure (dialysis / creatinine ≥2)	1 (6.7)
Creatinine 1.4-1.9	3 (20.0)
Congestive heart failure	3 (20.0)
Chronic obstructive pulmonary disease	4 (26.7)
Prior vascular intervention [failed repair]	7 (46.7)
Type of aneurysm	
Type I	1 (6.7)
Type II	5 (33.3)
Type III	1 (6.7)
Type IV	5 (33.3)
Type V	1 (6.7)
Dissection	2 (13.3)

Table 1. Preoperative Patient Demographics

Variables	Yale New Haven Hospital
<b>Number of Subjects</b>	<b>15</b>
Time to Extubation	
12-24 Hours	0 (0.0)
<12 Hours	1 (6.7)
>24 Hours	0 (0.0)
In-OR	14 (93.3)
Length of Hospital Stay (day)	
Median	5
Interquartile range	2
Adverse Event	
All-Cause mortality (within 30 days or prior to discharge)	1 (6.7)
All-cause mortality at last follow up	1 (6.7)
Lesion-specific mortality at last follow up	1 (6.7)
Bowel ischemia	1 (6.7)
MI	0 (0.0)
Paraplegia	0 (0.0)
Renal failure	0 (0.0)
Respiratory failure	0 (0.0)
Stroke	0 (0.0)

## CONCLUSIONS

- ❖ The nonanatomic and modular-based design of the Unitary Stent Graft System affords:
  - ❖ Safe and effective, reproducible, “off-the-shelf” option for EDAR of various thoracoabdominal aortopathies
    - ❖ Including failed prior repairs
    - ❖ in patients at prohibitive risk for OSR and/or other endovascular branched and fenestrated therapies
- ❖ Staging option at every stage of implantation
- ❖ Applicable anatomically in 100% of patients in our experience
- ❖ Offers the advantages of ease of case planning, implantation, and reintervention

Disclosures: Naiem Nassiri MD is a consultant, speaker, proctor for Medtronic Aortic, Inc; Terumo Aortic, Inc.; WL Gore, Inc.; Penumbra, Inc.

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2. Coselli JS, LeMaire SA, Preventza O, de la Cruz KI, Cooley DA, Price MD, et al. Outcomes of 3309 thoracoabdominal aortic aneurysm repairs. J Thorac Cardiovasc Surg. 2015;151:1323-1338.