VEITH SYMPOSIUM

A Novel Low Profile Stent-Graft For The Treatment Of All Thoracic Aortic Segments: What Makes It Unique And Clinical Status

Francesco Setacci, MD
Kore University of Enna, Italy
Vascular Surgery and Transplant Unit University of Catania, Italy
Chief P. Veroux, MD

Faculty Disclosure

Disclosure

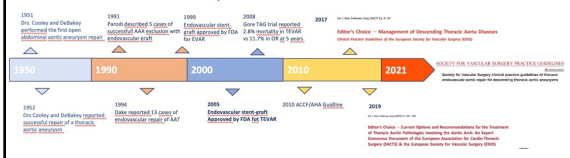
Speaker name: Francesco Setacci, MD

I have the following potential conflicts of interest to report:

- ❑ Consulting
- ❑ Employment in industry
- ❑ Shareholder in a healthcare company
- ❑ Owner of a healthcare company
- ❑ Other(s)
- ✓ I do not have any potential conflict of interest

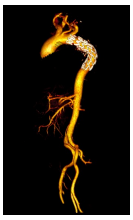
Thoracic Aortic Pathologies

Innovations in endograft engineering design and clinical results make TEVAR to the treatment of choice in elective thoracic aortic repair.



Thoracic Aortic Pathologies

ELECTIVE SETTING.
IN PATIENTS WITH FAVOURABLE ANATOMY,
TEVAR SHOULD BE CONSIDERED FOR DTAA >
60 MM DIAMETER



Recommendation 46a	Class	Level of evidence	References
In fit and unfit patients with favourable anatomy, endovascular repair may be considered for descending thoracic aorta aneurysms between 56 and 59 mm diameter	IIb	B	88,211–215
Recommendation 46b			
In fit and unfit patients with favourable anatomy, endovascular repair should be considered for descending thoracic aorta aneurysms >60 mm diameter	IIa	B	88,211–215

Thoracic Aortic Pathologies


Editor's Choice – Management of Descending Thoracic Aorta Diseases
Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS)

7. TEN POINTS DESCRIBING WHEN TO CHOOSE WHAT KIND OF APPROACH

Table 3. Factors favouring one or the other approach

Factors favouring one or the other approach	Endovascular repair	Open repair
Previous coronary artery bypass grafting with patent IMA graft at risk at resternotomy	+	–
Poor left ventricular or right ventricular function	+	–
Poor pulmonary function	+	–
Poor liver function	+	–
Connective tissue disorder in patients with landing zones in native tissue	–	+
Access vessels (femoral and iliac) diameter <7 mm	–	+
Native ascending aorta diameter >38 mm	–	+
Valvular heart disease necessitating concomitant repair	–	+
Previous mechanical aortic valve replacement	–	+
Prosthetic ascending aorta short or kinked	–	+

+: favours; –: discourages.

URGENT SETTING

IN CASES OF COMPLICATED ACUTE TYPE B AD, ANEURYSM RUPTURE OR TRAUMATIC AORTIC INJURY TEVAR SHOULD BE PERFORMED AS THE FIRST LINE TREATMENT

Recommendation 16	Class	Level of evidence	References
In patients with complicated acute type B aortic dissection, endovascular repair with thoracic endografting should be the first line intervention	I	C	6,85–89,92–94,96–99, 103,109

Recommendation 23	Class	Level of evidence	References
In patients with ruptured descending thoracic aortic aneurysm, endovascular repair should be the first treatment option when the anatomy is appropriate	I	B	127

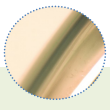
Recommendation 29	Class	Level of evidence	References
In patients with traumatic thoracic aorta injury and suitable anatomy, endovascular repair should be performed as the first option	I	C	157,159,160

Terumo Relay Pro

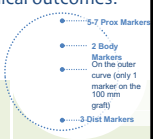
RelayPro is the latest generation low profile thoracic Stent-Graft system, designed to treat thoracic aorta diseases, showing a high level of **performance and safety** in the clinical outcomes.

Fabric
Woven Polyester with an optimized weave pattern:
- Low profile
- High strength
- Low permeability

Suture
5-0 braided polyester surgical suture impregnated with PTFE
- High wear resistance
- High tensile strength



Stents
Electropolished Nitinol
- Super-elastic properties
- Proven fatigue endurance



Radiopaque Marker
Platinum Iridium
- Radiopaque material for enhanced visibility

Terumo Relay Pro

The RelayPro is Terumo Aortic's next generation thoracic stent-graft system *"with a 3- to 4-Fr outer profile reduction employing the same stent design and fabric material."* [1]
Gennai et al., 2022

JOURNAL OF ENDOVASCULAR THERAPY

0% Type III/IV endoleak through 1 year[2,3]
2: 0/110
3: 0/58

0% Stent fractures through 1 year[2,3]
2: 0/110
3: 0/58

0% Stenosis/ thrombosis through 1 year[2,3]
2: 0/110
3: 0/58

0% Loss of patency through 1 year[2,3]
2: 0/110
3: 0/58

2: Thoracic Aortic Aneurysm and Penetrating Atherosclerotic Ulcer Cohort
3: Acute Complicated Type B Aortic Dissection Cohort

Terumo Relay Pro IFU

Indication For Use

*The RelayPro Thoracic Stent-Graft System is indicated for the treatment of **thoracic aortic pathologies** such as **aneurysms, pseudoaneurysms, dissections, penetrating ulcers, and intramural hematoma**, in adult patients with the following characteristics:*

Stent-Graft Diameter (mm)	Proximal Length Bare Stent Configuration (mm)	Proximal Length NBS Configuration (mm)	Distal Length Bare Stent & NBS Configuration (mm)
22-28	15	22	25
30-38	20	25	
40-46	25	30	30

48% of **REGENERATION**[4] patients treated in **Zo-Z3** of the thoracic aorta
4: 15/31

100% Technical Success[4]
Primary 90%
Assisted Primary 10%
4: 31/31

97% Freedom from secondary intervention at 1 year[4]
4: 30/31

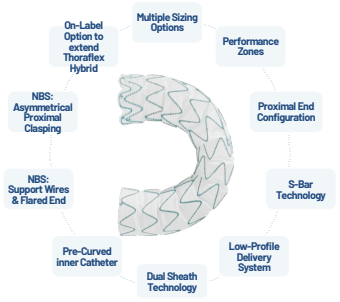
94% Freedom from device-related MAEs at 30 days[4]
4: 29/31

Terumo Relay Pro Key Features

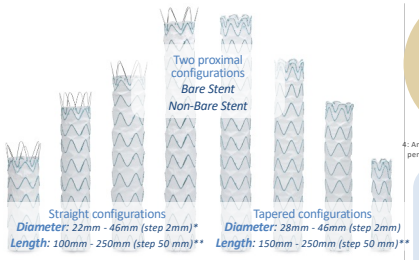
The RelayPro stent-graft builds on the proven RelayPlus design, described as:

"The Relay thoracic stent-graft system has been developed as a flexible stent-graft specifically designed for the thoracic aorta." [5]
Yunoki et al., 2014

Vascular Surgery Today



Terumo Relay Pro Multiple Size Options



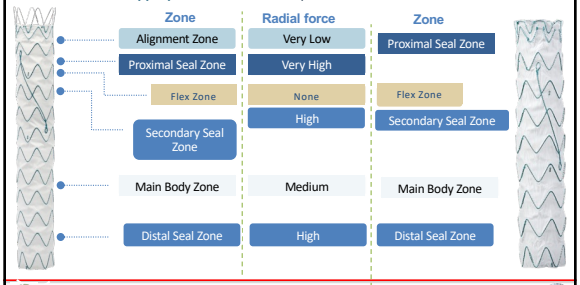
1.39 RelayPro mean number of units per procedure[4]
4: Aneurysm, pseudoaneurysm, dissection, penetrating atherosclerotic ulcer cohort

"This low mean number of units per procedure contributes to lower total TEVAR costs and is common across the studies using Relay" [6]
El Beyrouti et al., 2020

PLOS One

Performance Zone: Designed To Respect The Thoracic Anatomy

The RelayPro stent graft is divided into **performance zones**.
Each zone is designed to serve a **specific purpose** and therefore **distributes an appropriate radial load** independent of other zones



Performance Zone: Designed To Respect The Thoracic Anatomy

98.9% Freedom from aneurysm expansion at 1 year[2]
2: 109/110

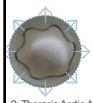
100% Absence of false lumen perfusion from 30 days to 1 year[3]
3: 56/56

2: Thoracic Aortic Aneurysm and Penetrating Atherosclerotic Ulcer Cohort
3: Acute Complicated Type B Aortic Dissection Cohort

Proximal End Configuration

Partial overlapping of the bare stent with the first covered stent to **maximise** the number of **sealing points**

A **crown-shaped** nitinol stent overlapping with the proximal sealing stent, both covered with fabric, designed to maximise conformability and **minimize infolding**



Both proximal configurations are designed to deliver **high radial load** for an effective apposition and fixation of the graft against the aortic wall

1.8% Type Ia endoleak at 12 months[2,3]
2: 2/110
3: 1/58

100% Technical Success through 24 hours[2,3]
2: 110/110
3: 58/58

0% Migration through 12 months[2]
2:0/110

2: Thoracic Aortic Aneurysm and Penetrating Atherosclerotic Ulcer Cohort
3: Acute Complicated Type B Aortic Dissection Cohort

S-Bare Technology Ahead of The Curve

S-Bar, a **curved nitinol wire** that starts 25 mm from the proximal edge of the graft, intended to provide **columnar strength** to the endograft and to enhance conformability by adapting to the natural curvature of the aorta

Shortened length to optimize the treatment in tortuous aortas, enabling the more distal portion of the graft to flex in any direction.

The **shorter** RelayPro S-Bar builds on the proven RelayPlus longer S-Bar design described as:

"[…] an outer curved Nitinol bar (S-bar) that allows for the gentle conformability of the device along the three-dimensional anatomy of the aortic arch."
Riambau, 2015 [7]

AORTA

Low-Profile Delivery System

RelayPro Profile OD	19 Fr	20Fr	21 Fr	22 Fr	
Proximal Stent Graft Diameter	22* - 30mm	32 - 36mm	38 - 40mm	42 - 46mm	
RelayPro NBS Profile OD	19 Fr	20Fr	21 Fr	22 Fr	23 Fr
Proximal Stent Graft Diameter	22* - 26mm	28 - 30mm	32 - 34mm	36 - 40mm	42 - 46mm

*22 mm diameter stent-grafts are only approved to treat traumatic aortic injuries (transactions)
** For tapered devices, Fr size based on largest diameter of the stent-graft

UP TO **85.5%** patients treated with a percutaneous femoral approach[2,3]
2: 50/68
3: 47/56

2: Thoracic Aortic Aneurysm and Penetrating Atherosclerotic Ulcer Cohort
3: Acute Complicated Type B Aortic Dissection Cohort

Low-Profile Delivery System

"The 3-4 French profile reduction of the new RelayPro is expected to offer operative advantages in terms of stent- graft introduction and deployment, particularly in patients with narrow or tortuous access vessels"
Riambau et al., 2019 [4]

Annals of Vascular Surgery

Dual Sheath Technology

An integrated **Dual Sheath system** designed to **minimise access vessel manipulation** and **provides atraumatic** thoracic aorta **navigation**

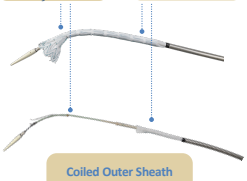
1.8% Disabling stroke rate at 30 days with no stroke during 1-year follow-up[3]
3: 1/56

1.8% Operative vascular access complications[3]
3:1/56

"RelayPro's ability to navigate smoothly over the arch as a result of the Dual Sheath system enables accurate deployment, and combined with the low profile of the device, this allows me to successfully treat complex anatomy with precision" [8]
W. Szeto

Pre-curved Nitinol Catheter designed for self-alignment

Soft Inner Sheath designed to provide **navigability**



Coiled Outer Sheath designed to provide **pushability**

3: Acute Complicated Type B Aortic Dissection Cohort

Support Wires, Asymmetrical Proximal Clasping, Flared End

Stop Birdbeaking and Retroflex

100% Accurate device deployment[6]

0% Bird-beak through 12 months[3]

* The support wires are only present in devices with 32 mmor greater proximal stent-graft diameters

RelayPro NBS delivery system implements **three features** to provide the ability to **reposition**, **prevent retroflex**, and **avoid birdbeaking**

Two clasping points, both located on the outer curve of the RelayPro NBS, for a precise and controlled deployment, preserving the **ability to reposition**

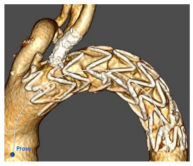
During deployment, two **support wires*** guide the inferior portion toward the inner aortic wall, keeping it aligned with the landing zone and **minimising the risk of retroflex**

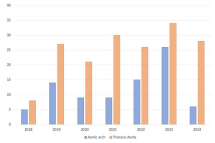
The **Flared End** configuration of the inner sheath enables partial expansion to improve the proximal alignment and precision for a correct apposition on the inner curve, **avoiding birdbeaking**

3:Acute, Complicated Type B Aortic Dissection Cohort.
6: Aortic dissection, aortic aneurysms, PAUs and IMH; N=1 aortic erosion and aortic rupture, each. The RelayPro is NOT indicated for erosion or rupture.

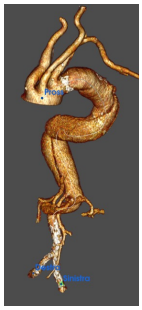
Catania Experience in Thoracic Aortic Pathologies

From 2019 to august 2024, ***a total of 311 patients with THORACIC AORTIC PATHOLOGIES underwent TEVAR.***





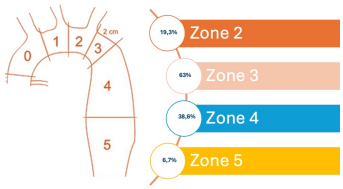
Terumo Relay ProCatania Experience



Between them, **165 consecutive patients** underwent TEVAR using a Relay Pro low profile stent graft.

Terumo Relay ProCatania Experience

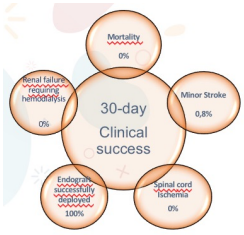
N=165	N	%
Age (mean, y)	68.9 ± 9	
Male	129	78.1
Preop. Comorbidities		
CAD	33	20
Smokers	89	53.9
Renal disease	21	12.7
COPD	23	13.9
Pathologies		
Aneurysms	68	41.2
Rupture	20	12.1
PAU	20	12.1
Post Dissect. An.	16	9.7
Pseudoaneurysms	3	1.8
Acute type B Dissection	16	9.7
Chronic Type B Dissection	22	13.3
Emergency	42	25.5
Hybrid Procedure	12	7.2
Local Anesthesia	119	72.1
Percutaneous access	161	97.5



Terumo Relay Results

N=165	N	%
Local anesthesia success	152/165	92.1
Access related success	159/165	96.3

N=165	N	%
Mortality	0/165	0
Stroke (minor stroke)	1/165	0.6
Paraplegia	0/165	0



Conclusions

- The minimally invasive approach and the low-profile RelayPro thoracic endograft showed an early high rate of feasibility and technical success
- No evidence of spinal cord ischemia, low rates of stroke and death also in emergency setting and a promising efficacy profile up to 3 year were reported.
- This method may contribute to extend the indications to a larger cohort of patients