

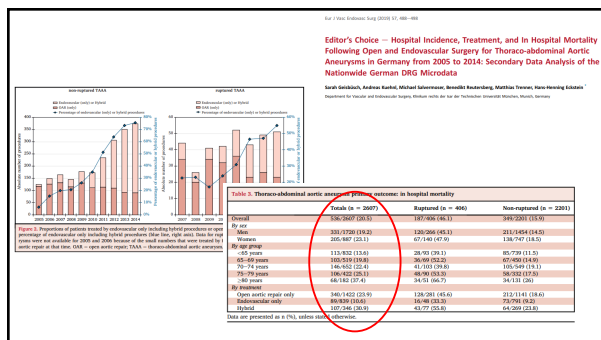
Universitäts Herz- und Gefäßzentrum
UKE Hamburg

Progress with a New Hybrid Device (Thoracoflo® from Terumo Aortic) for TAAA Repair: How It Works, Clinical Experience and Advantages

Sebastian Debus, Dept for Vascular Medicine, University Heart & Vascular Center Hamburg Eppendorf
with S Wipper, T Kölbl
and A Oo, B Rytski, F Thaveau, X Berard , J Touma, A Zimmermann,
B Dorweiler, A Oberhuber, E Mujagic, K Young

Universitätsklinikum Hamburg-Eppendorf

Conflicts of Interest:
Consultant for Terumo Aortic



Changes in treatment patterns of thoracoabdominal aortic aneurysms in the United States

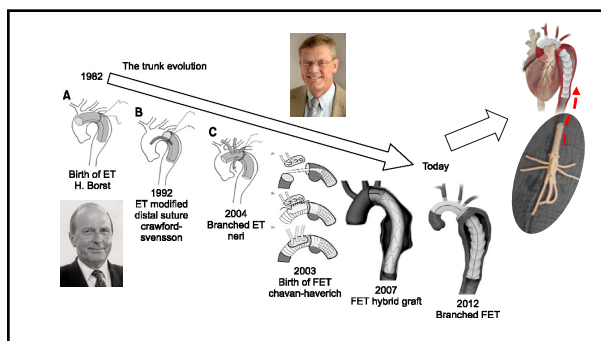
Joy Mohnot, BS,¹ Yunda (George) Wang, MS,² Kanhua Yin, MD, MPH,³ Mahmoud B. Malas, MD,² Nitoo M. Edwards, MD,⁴ Nikola Dobrilovic, MD,^{4,5} and Yong Zhan, MD⁶
(JTCVS Open 2023;6:48-65)

Check for updates

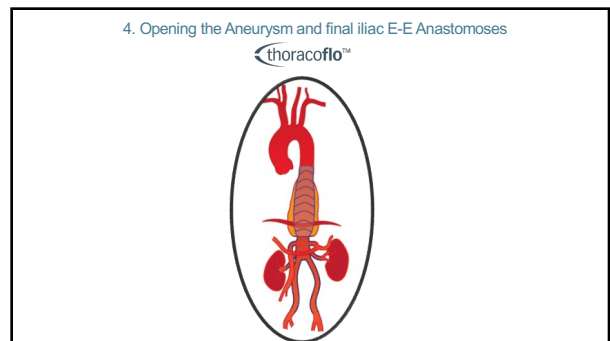
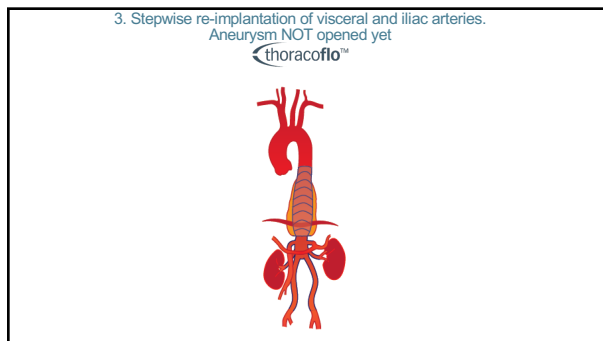
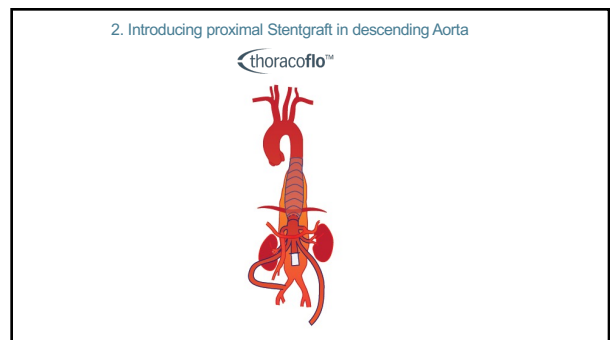
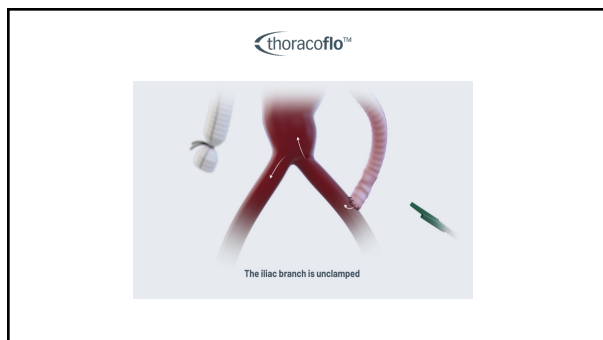
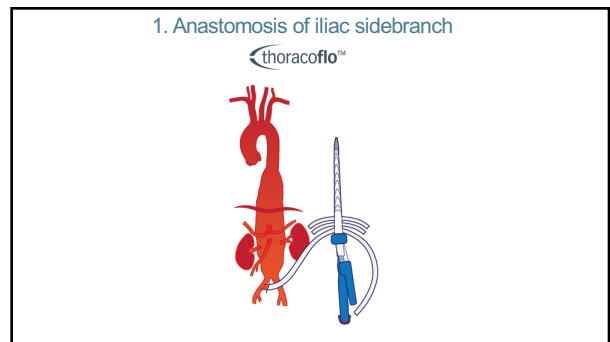
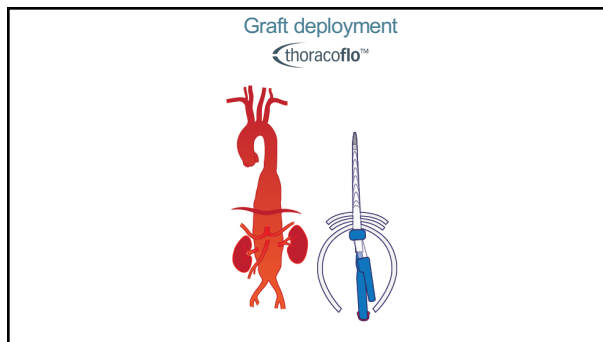
TABLE 2. In-hospital complications and outcomes in TAAA patients

Complication/outcome	Open repair (N = 15,228)	Endovascular repair (N = 12,341)	P value
Complications			
Cardiac, n (%)	2785 (18.3)	1034 (8.4)	<.001
Respiratory, n (%)	6911 (45.4)	2614 (21.2)	<.001
Renal, n (%)	5651 (37.1)	2671 (21.6)	<.001
Stroke, n (%)	683 (4.5)	423 (3.4)	.001
Paralysis, n (%)	762 (5.0)	463 (3.8)	.008
Spinal cord injury, n (%)	507 (3.3)	288 (2.3)	.007
Outcomes			
Mortality, n (%)	2395 (17.1)	1091 (8.9)	<.001
Length of stay, d, mean ± SD	17.1 ± 17.4	10.1 ± 12.2	<.001

TAAA, Thoracoabdominal aortic aneurysm.




- ### The thoracoflo™ Technique: Advantages
- ✓ Avoid aortic crossclamping by preliminary distal aortic Bypass
 - ✓ Avoid thoracotomy by endovascular treatment of the thoracic part
 - ✓ Avoid extracorporeal circulation by retrograde distal perfusion of the visceral branches via iliac sidebranch
 - ✓ Reduce risk of SCI by closed sac repair and reattachment of lumbar arteries
 - ✓ Avoid Radiation Exposure due to TEE - controlled Stent Placement



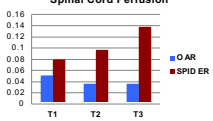
Feasibility Study of a Novel Thoraco-abdominal Aortic Hybrid Device (SPIDER-graft) in a Translational Pig Model

Elke S. Debus^{1,2}, Tilo Kübel¹, Anna Dupré¹, Günter Daum¹, Harfeen K. Sandhu¹, Daniel Manzoni¹, Sabine H. Wipper³

¹Department for Vascular Medicine, University Heart Centre, University Hospital Eppendorf Hamburg, Germany
²Department of General and Visceral Surgery, University Hospital Hamburg Eppendorf, Hamburg, Germany
³Department of Cardiothoracic and Vascular Surgery, Midwestern Medical School at UTHealth, Houston, TX, USA



Spinal Cord Perfusion



Level	OAR	SPIDER
T1	~0.04	~0.08
T2	~0.04	~0.10
T3	~0.04	~0.14

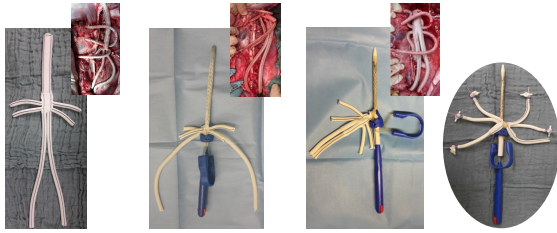
Evaluation in domestic pigs (75-85kg)

- ✓ Technical feasibility
- ✓ Hemodynamics: PICCo, Swan-Ganz
- ✓ Organ perfusion: Fluorescent Microspheres
- ✓ Blood flow: Transil-Time Flow Measurement
- ✓ Ischemic times
- ✓ Angiography
- ✓ Post Mortem CT Angiography

Timings: Baseline, 1h and 6h after implantation

Debus ES, et al. Eur J Vasc Endovasc Surg. 2018;55:196-205.

Hybrid Technology to Address High Risk Surgical Patients: thoracoflo™




SPIDER Generation 1

SPIDER Generation 2

First in woman implantation Hamburg september 2nd 2021 thoracoflo™

- EM (56 y, female), dissecting TAAA
- Loey's-Dietz Syndrome, anticoagulated for mechanic heart valve
- Dissecting TAAA aneurysm
- 1fen-TEVAR and Carotid- Subclavian Bypass left 05/2018
- Type 2 Endoleak with Coilembolization and Candy-Plug 07/2018



First in woman implantation Hamburg september 2nd 2021 thoracoflo™

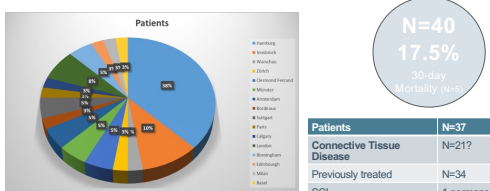
- Uneventful postop course
- Extubation 12h post procedure, no neurologic deficit
- 2 days ICU
- Stentangioplasty left RA (stenosis)
- 18. September: Demission (16 postop. Day)

Debus ES, et al. (2023). First in Human Implantation of the Thoracoflo Graft: A New Hybrid Device for Thoraco-Abdominal Aortic Repair. *EJVES Vascular Forum* (Vol. 58, pp. 28-31).

Glasgow: Terumo's Patients Day (Nov 2, 2022)



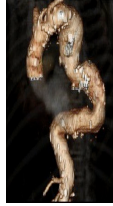
Thoracoflo™ Implant data



Patients	N=37
Connective Tissue Disease	N=217
Previously treated	N=34
SCI	1 permanent, 1 transient
30-day mortality	N=5 (16.2%)

Patient Selection

- ✓ Focus on patients with connective tissue disease
- ✓ Patients with prior open or endovascular aortic treatment
- ✓ Previous thoracotomy
- ✓ Anatomically difficult for solely endovascular repair
- ✓ Possible TEVAR as landing zone
- ✓ Staged repair for type II or native III TAAA but not for type IV



Requirements

- > Centers with experience in open and endo TAAA treatment
- > Expert team: vascular and cardiac surgeon, experienced anesthesiologist and cardiovascular intensive care, CPB backup, endovascular specialist, nurses...
- > Cases discussed with engineers and board including weekly online web-meeting before manufacturing of the graft
- > Manufacturing takes 6 weeks after approval
- > Special training and presence during one procedure required
- > Device implantation under supervision of proctor

