

Long-term performance of endovascular repair of abdominal aortic aneurysms with the TREO graft:

Jörg Teßarek MD

Vascular Surgery

Bonifatius Hospital Lingen

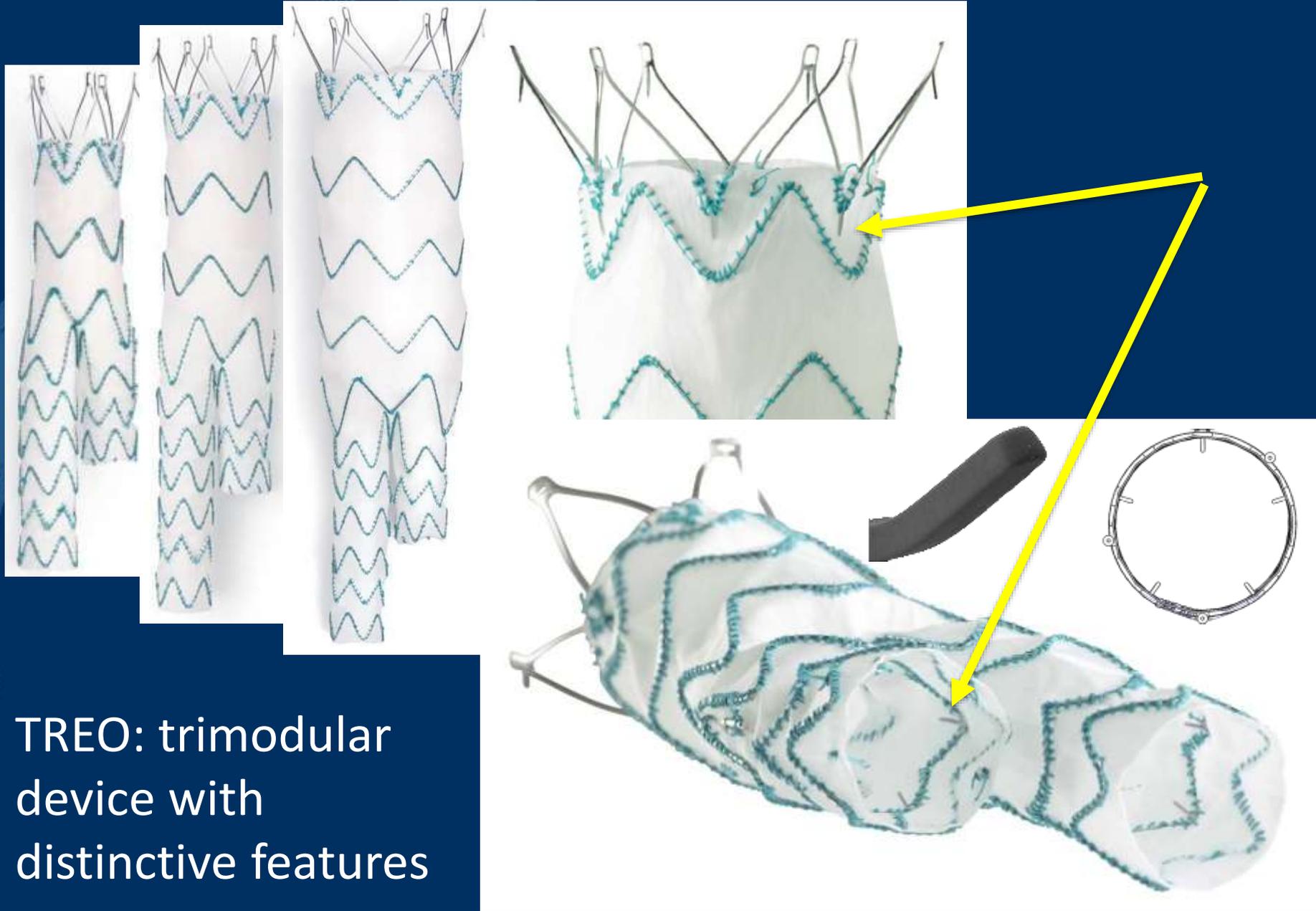
Disclosure

Speaker name:

.....Jörg Teßarek.....

I have the following potential conflicts of interest to report:

- Consulting
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - Other(s): PI for Rationale, Integrity, Tiger, honoraria for presentations
- I do not have any potential conflict of interest



TREO: trimodular device with distinctive features

Other features and pull out forces

18/19F mainbody
introducer *sheath*

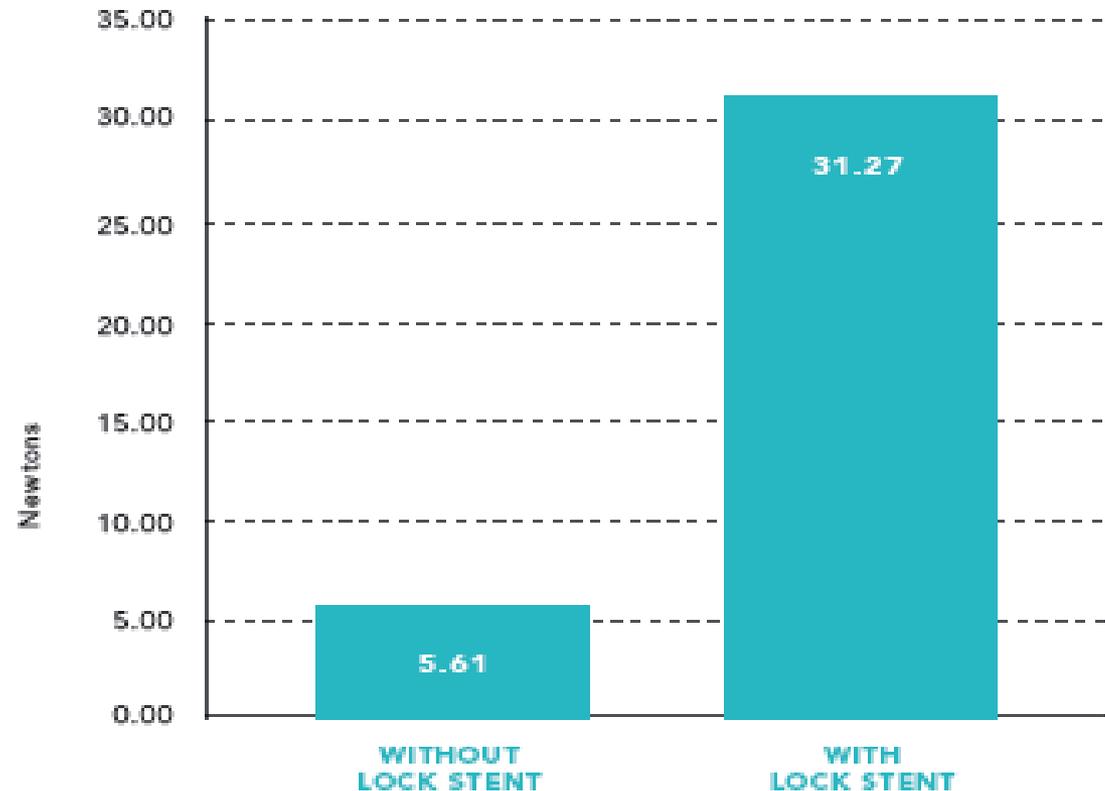
13F limb

Repositionable

-75° infrarenal neck
32mm diameter
15mm length

No limitations for
aortoiliac
angulation

PULLOUT FORCES OF BODY WITH
LIMB EXTENSIONS



Average pull out forces calculated during bench testing

trials with mid to long term FU

Global Post-Market Clinical Follow-up of the Treovance Stent-Graft for Endovascular Aneurysm Repair: One-Year Results From the RATIONALE Registry → 12 mo

US TREQ Clinical Evidence

Safety and efficacy of the TREQ stent-graft for the endovascular treatment of abdominal aortic aneurysms → 36 mo

Patient data: US patients with higher comorbidity

		n=202
Medical History, n (%)	US data	
Peripheral vascular disease	25.3	29 (14.4%)
Coronary artery disease	56.0	74 (36.6%)
Chronic obstructive pulmonary disease		34 (16.9%)
Diabetes mellitus	28	41 (20.3%)
Hypertension	90.0	159 (78.7%)
Hypercholesterolemia	44.7	97 (48.0%)
Hyperlipidemia	73.3	74 (36.6%)
Smoking	85.3	126 (62.4%)
Ex-smoker	68.8	87 (43.1%)
Current smoker	31.3	35 (17.3%)
Renal insufficiency	13.3	33 (16.3%)
Current antiplatelet/anticoagulant therapy	78.7	119 (58.9%)
Limb ischemia		8 (4.0%)
Vascular intervention	18.0	18 (8.9%)
Impotence	16.0	7 (3.5%)
Other relevant medical conditions		43 (21.3%)

RATIONALE results @ 12 mo

Mean time to final follow-up (months) (SD)	13.7 (\pm 3.1)
Clinical success Defined as freedom from aneurysm growth or reintervention	194 (96.0%)
Secondary clinical success	1 (0.5%)
Clinical failure	8 (4.0%)
Graft infection or thrombosis	0
Aneurysm rupture	0
Surgical reintervention	1 (0.5%)
Endovascular reintervention	7 (3.5%)
Deaths	
Operative deaths (\leq 30 days after procedure)	0
Late deaths ($>$ 30 days after procedure)	15 (6.4%)
All-cause mortality 1–6 months	5 (2.5%)
All-cause mortality $>$ 6 months	8 (3.9%)
Aneurysm-related death	0

30day and 12 mo data from EU and US

	≤ 30 days n (%)	One year n (%)	US data
Type Ia	3 (1.6%)	1 (0.6%)	0.7%
Type Ib	2 (1.1%)	0	
Type II	28 (14.8%)	26 (15.3%)	23.3%
Type III	0	0	0
Type IV	0	0	0
Unknown	0	1 (0.6%)	0.7%
Stent-graft patency	199 (98.5%)		98.7%
Stent-graft migration	0		0
Wire form fractures	0		0

Long term results from US

	6M	12M	2Y	3Y
Type Ia	1.5% (2/134)	0.8% (1/133)	0.9% (1/113)	1.1% (1/94)
<i>New; persistent</i>	1;1	0;1	1;0	1;0
Type Ib	0.7% (1/134)	0% (0/133)	0% (0/113)	0% (0/94)
<i>New; persistent</i>	1;0	0;0	0;0	0;0
Type II	17.2% (23/134)	15.0% (20/133)	11.5% (13/113)	9.6% (9/94)
<i>New; persistent</i>	6;17	4;16	1;12	2;7
Type III	0	0	0	0
Type IV	0	0	0	0
Unknown	0% (0/134)	1.5% (2/133)	0.9% (1/113)	0% (0/94)
<i>New; persistent</i>	0;0	2;0	0;1	0;0

Long term results from US trial

	6M	12M	2Y	3Y
All-cause mortality	2	2	8	4
Aneurysm-related mortality	0	0	0	0
Migration >10 mm	0	0	0	0
Occlusion requiring intervention	0	0	0	0
Conversion	0	0	0	0
Any secondary intervention	2.0% (3/149)	0.7% (1/144)	2.3% (3/132)	1.7% (2/120)

In conclusion

TREO proved to be an easy to handle, easy to explain, safe and durable “work horse” graft

Reliable treatment @ 1 y with 99.4% and 99.3% freedom from IA/B EL and 98.9% @ 3y and 0% conversion up to 48mo

0 % type III EL @ 4 yrs (2018 FDA letter of concern addressing continuing risk of component separation)

No difference in outcome @ 1 y for neck angulation $<60^\circ$ and $\rightarrow 60^\circ$ (72.2° US)

No AAA or device related mortality up to 48mo (US) with a cumulative all cause mortality of 21.1% @ 4 yrs

3 trials run for 5y FU , TREO, US , Integrity (pending)



Thank you for your attention

joerg.tessarek@hospital-lingen.de

Long-term performance of endovascular repair of abdominal aortic aneurysms with the TREO graft:

Jörg Teßarek MD

Vascular Surgery

Bonifatius Hospital Lingen