E-vita Open Experience

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Disclosure

Speaker name:

Heinz Jakob.....

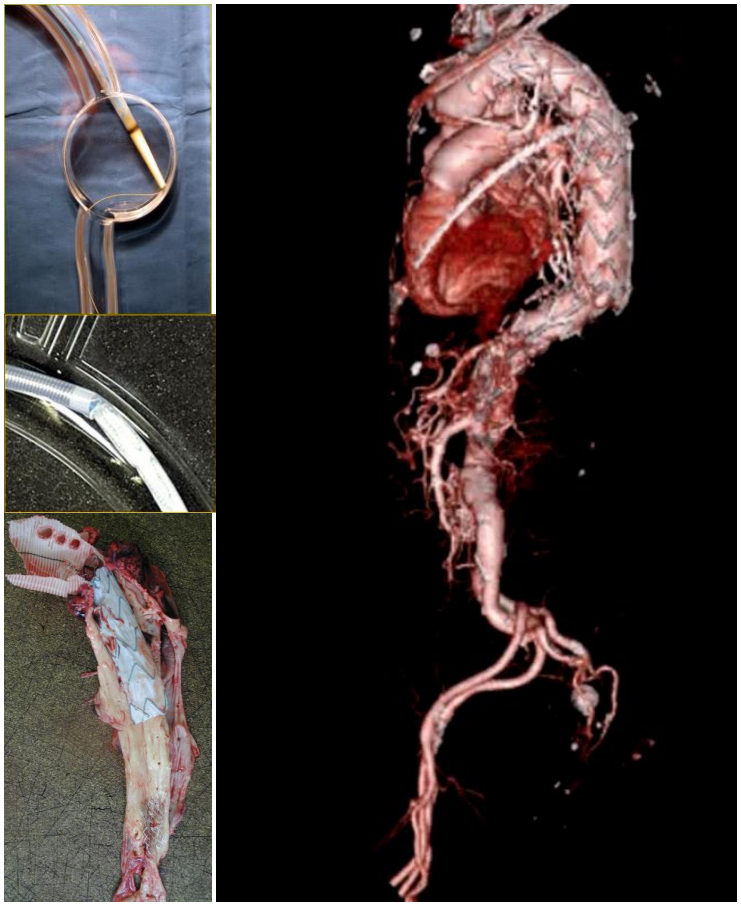
I have the following potential conflicts of interest to report:

- [x] Consulting to Jotec GmbH
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

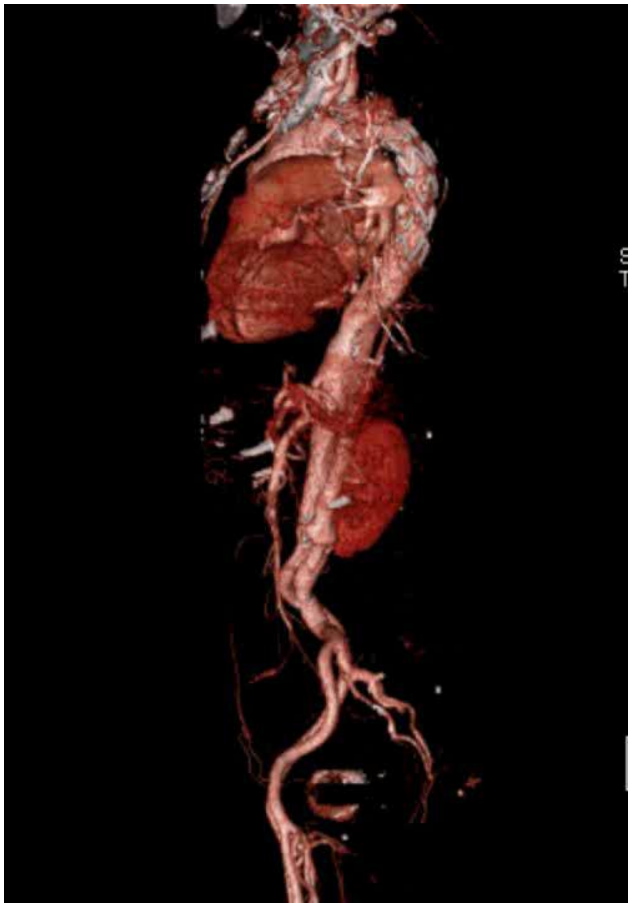
History of FET in Essen 2001-2016

1st Experience 06.2001-10.2004 (Talent N=14)



15 years FU

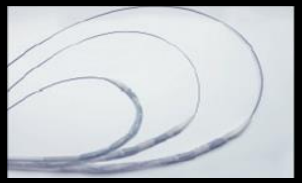
E-vita open concept 02.2005-10.2016, N=225)



11 years FU

E-vita open : Evolution of FET Technique in 2005

Soft introducer



No bare springs

Integrated arch prosthesis

E-vita Open 1st Generation

Herz © Urban & Vogel 2005 Hot Topic

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Department of Cardiology, West German Heart Center Essen, University Hospital Essen, Germany.

Development of an Integrated Stent Graft-Dacron Prosthesis for Intended One-Stage Repair in Complex Thoracic Aortic Disease

Heinz Jakob, Konstantinos Tsagakis, Rainer Leyh, Thomas Buck, Ulf Herold

Herz 2005;30:766–8
DOI 10.1007/s00059-005-2765-7

Complex thoracic aortic disease involving the ascending aorta, the aortic arch and the descending aorta still represents a challenge for the cardiothoracic surgeon. The classic approach for this pathology consists of a two-stage strategy, summing up to a mortality up to 40%, with a 5% mortality for the waiting period between both surgical stages [1–3].

One-stage repair can be performed, if required, via a clamshell thoracotomy, but is associated with major surgical trauma and perioperative morbidity as pulmonary or renal dysfunction, indicating that elderly patients probably are poor candidates for this strategy [4].

With the introduction of endovascular stenting in combination with classic aortic arch surgery an attractive treatment alternative has emerged for facilitated repair of complex aneurysmal disease in the thoracic aorta [5, 6]. Modifying this new technique using self-expanding descending aortic stent grafts and the classic ascending and aortic arch replacement techniques seems to be the logical consequence for intended one-stage repair, which was started by our group 06/2001 [7, 8].

Standard thoracic aortic stent graft devices (e.g., Medtronic Talent®, Minneapolis, MN, USA) are designed for retrograde aortic delivery, which demonstrate shortcomings for the antegrade use: their stiffness limits steerability, causing problems to pass the angle between the distal aortic arch and proximal descending aorta, resulting in significant friction to the inner aortic wall. This is worsened by the stiff outer plastic sheath which frequently shows kinking when curved > 45°. The most rigid zone is identified to be at the proximal border between stent graft and tip of the introducer and at the distal site between stent graft and the wire-reinforced inner pusher, limiting continuous and precise stent graft opening. At that point the already opened distal bare springs only allow for minor correction in proximal direction in case of displacement.

A second significant problem is caused by the longitudinal wire (connecting bar), which is positioned along the outer curvature of the stent. This force provokes the stent to straighten up resulting in a significant protrusion of the proximal bare springs into the aortic wall.

To overcome those shortcomings, a new integrated stent graft-Dacron prosthesis for antegrade delivery through the open aortic arch into the descending aorta in an "elephant trunk"-like manner was created. This "Essen I prosthesis" (E-vita open; Jotec®, Hechingen, Germany [Figure 1]) consists of a polyester fabric with an extremely flexible Nitinol wire skeleton, fixed on the outer aspect of the fabric with polypropylene sutures. To increase flexibility, a longitudinal wire is abandoned, and no open bar ends or reinforced circular springs are incorporated distally or proximally. At the proximal end, a woven crimped vascular Dacron prosthesis of 7 cm length is incorporated continuously to the stent graft prosthesis, allowing for direct replacement of the aortic arch without an additional anastomosis like in classic elephant trunk operations, by simply pulling back the invaginated Dacron prosthesis at its sewn suture [illegible] position. Stent graft re-

Figure 1. Picture of Essen I prosthesis and application set.

Abbildung 1. Darstellung der entfalteten, integrierten Dacron-Stentgraft-Prothese und des Applikators mit abgezogener [illegible]

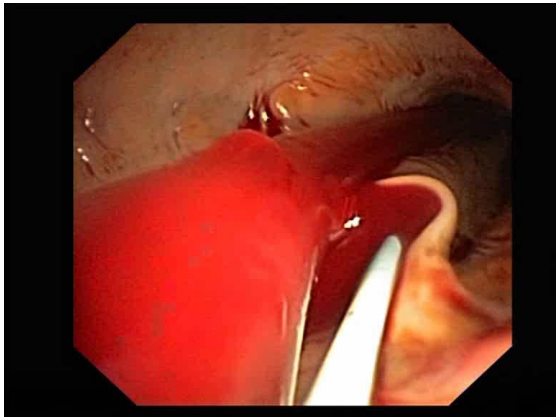
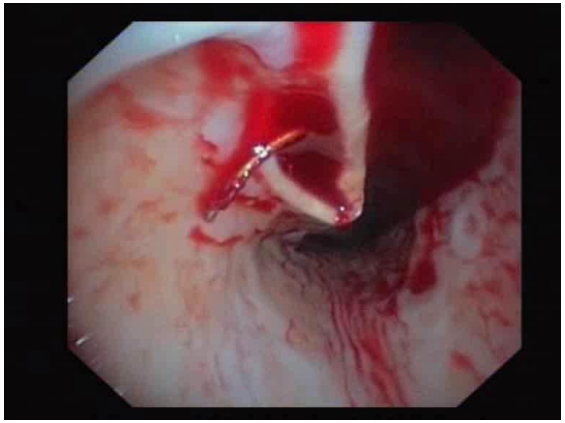
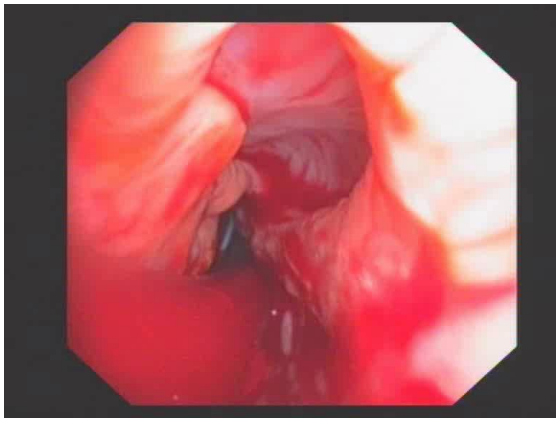
E-vita Open Plus
Fulfills Long-term Surgical and Endovascular Standards

E-vita Open Plus

- Blood tight polyester vascular grafts
- Collar for distal anastomosis
- Endovascular Z-shaped nitinol skeleton
- High SG and introducer flexibility
- Inflatable tip-balloon for atraumatic delivery

11 Yrs. E-vita Open Experience in Essen
Pioneering Work and Improvements for safe FET Treatment

1. Placement in Over the Wire Technique

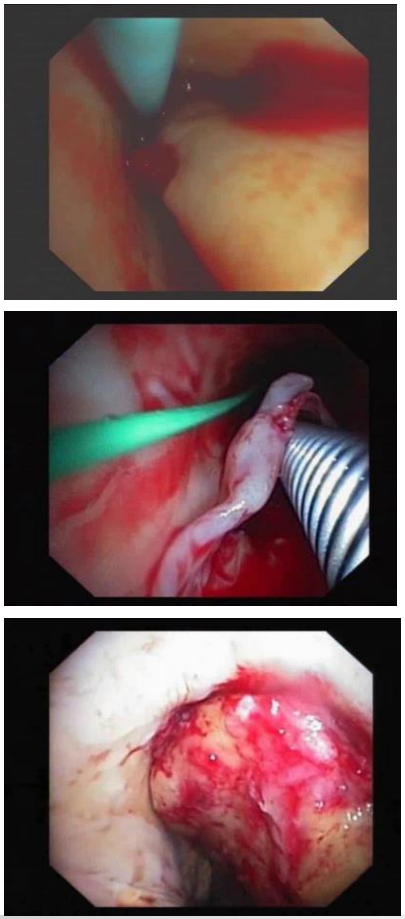
- To secure the FET placement and deployment into the TL
- No use of guide wire is risk factor for worse outcome *

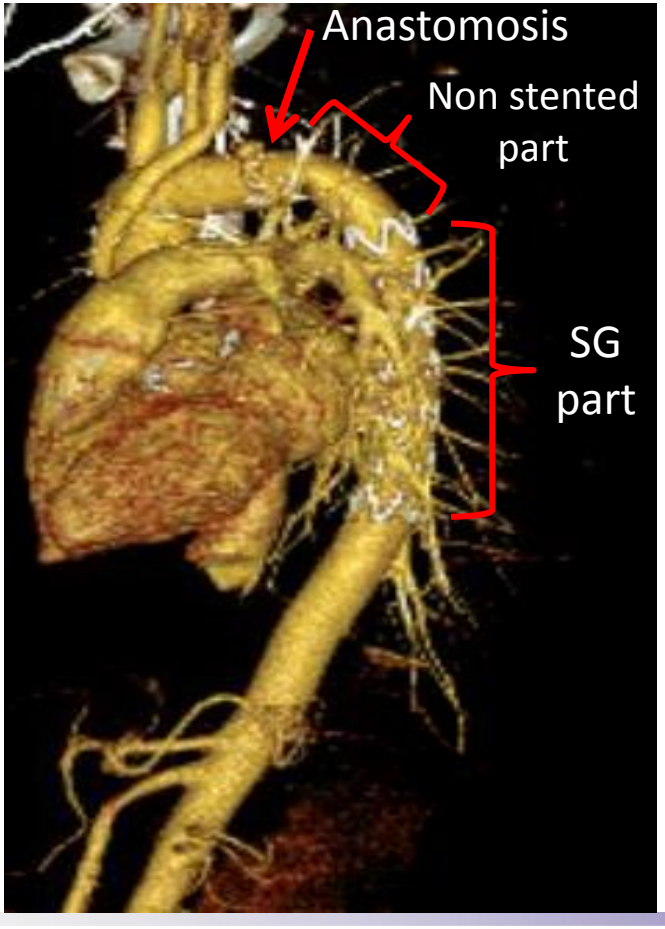
* International E-vita Open Registry

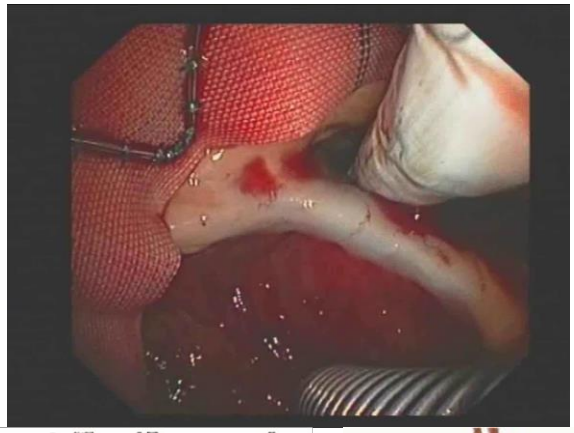
- Pacini et al, The frozen elephant trunk for the treatment of chronic dissection of the thoracic aorta: a multicenter experience. Ann Thorac Surg. 2011
- Leontyev et al, Impact of clinical factors and surgical techniques on early outcome of patients treated with frozen elephant trunk technique by using EVITA open stent-graft: results of a multicentre study. Eur J Cardiothorac Surg. 2016

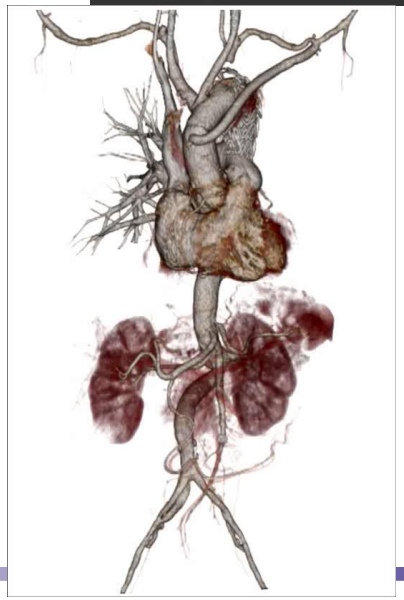
11 Yrs. E-vita Open Experience in Essen
Pioneering Work and Improvements for safe FET Treatment

2. Angio- (Endo-) scopy









Tsagakis et al, EJTCS 2010

GoreTAG Extension

E-XL Extension

11 Yrs. E-vita Open Experience in Essen
Pioneering Work and Improvements for safe FET Treatment

3. Zone 2 FET Strategy (LSA Rerouting)

ao.-axillary

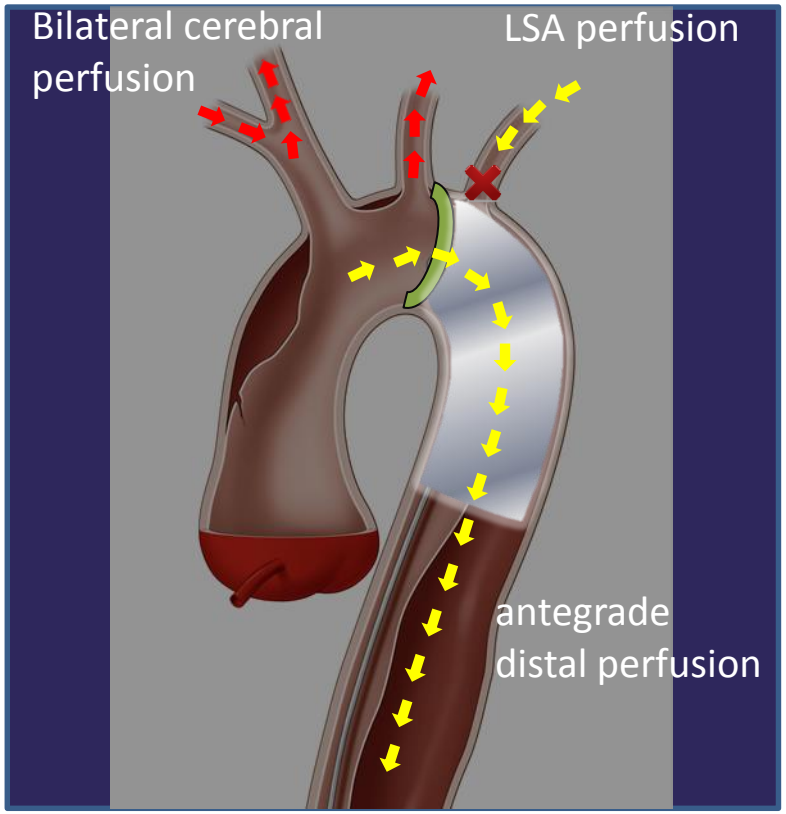
ao.-subclavian

carotid-subclavian

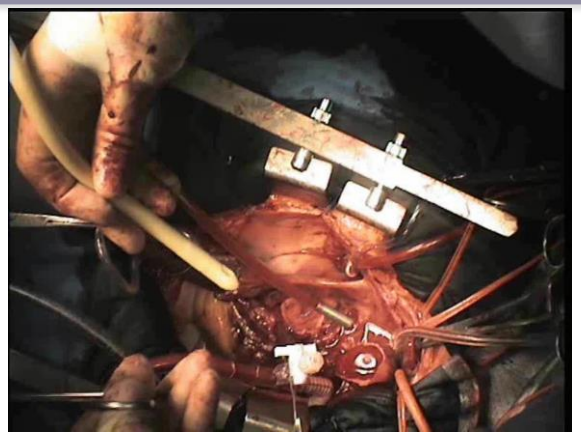
- **Significant reduction of SACP + distal hypothermic arrest time**
- **Zero recurrent nerve paresis**

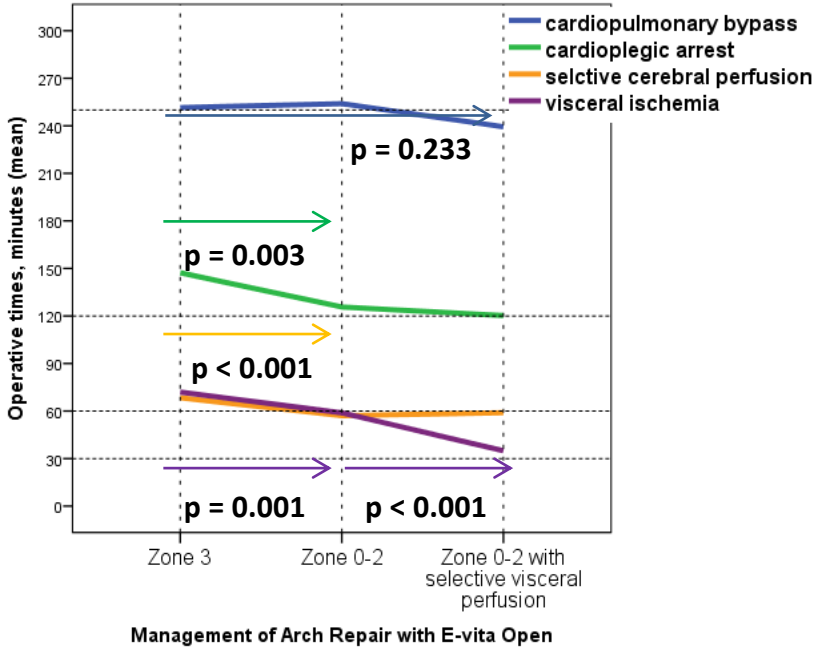
11 Yrs. E-vita Open Experience in Essen
Pioneering Work and Improvements for safe FET Treatment

4. 3 Vessels Head Perfusion + Distal Early Perfusion

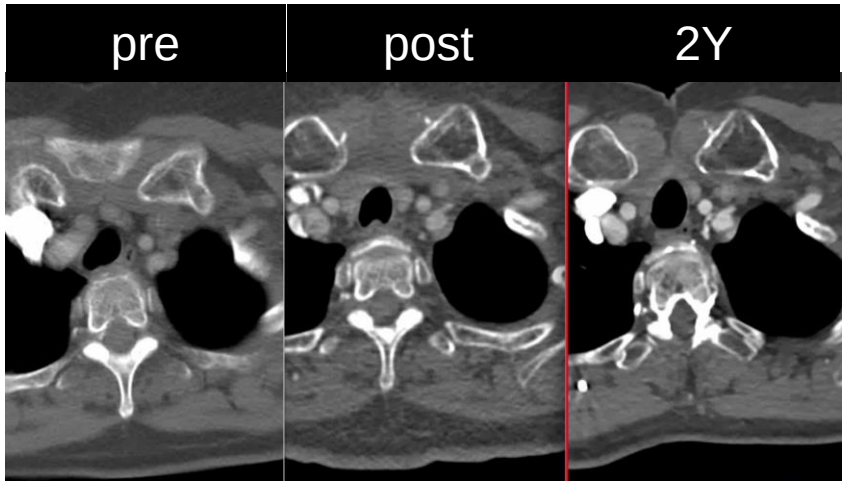


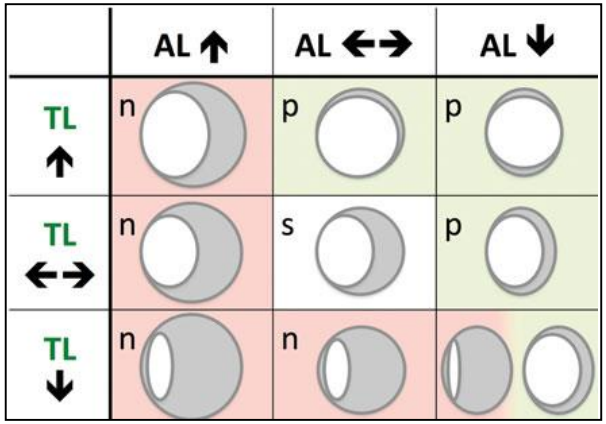
Cerebral + Spinal cord Protection



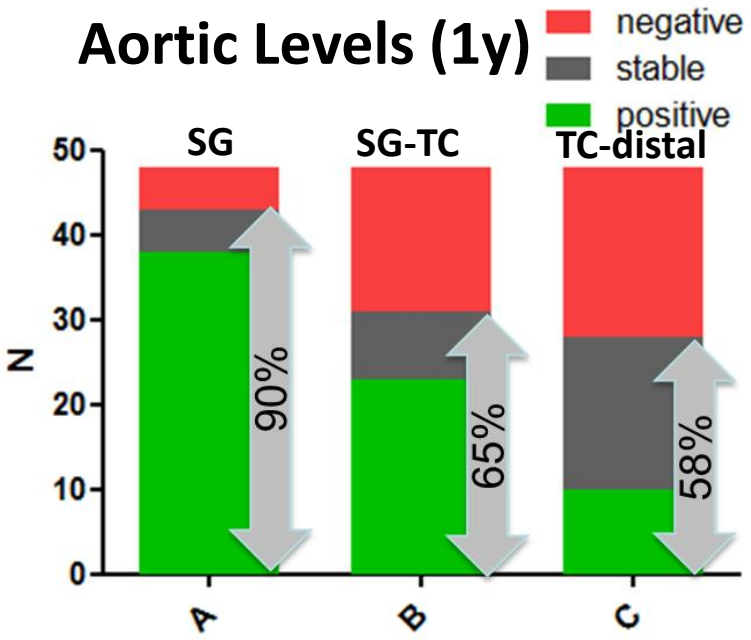


E-vita Open Concept – Change of Natural History of AD





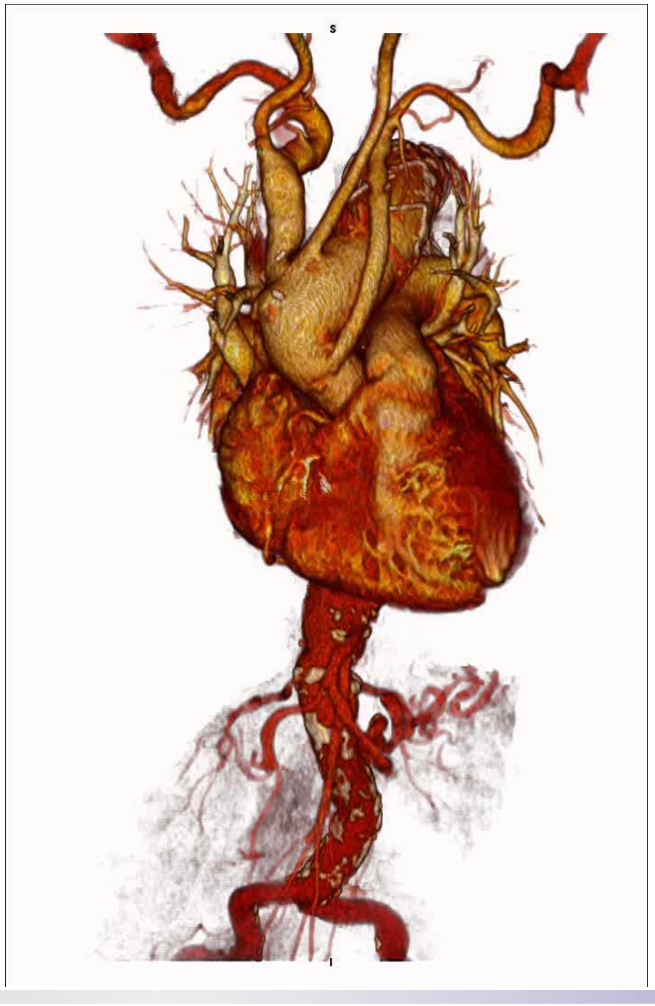
Dohle et al, EJTCS 2015



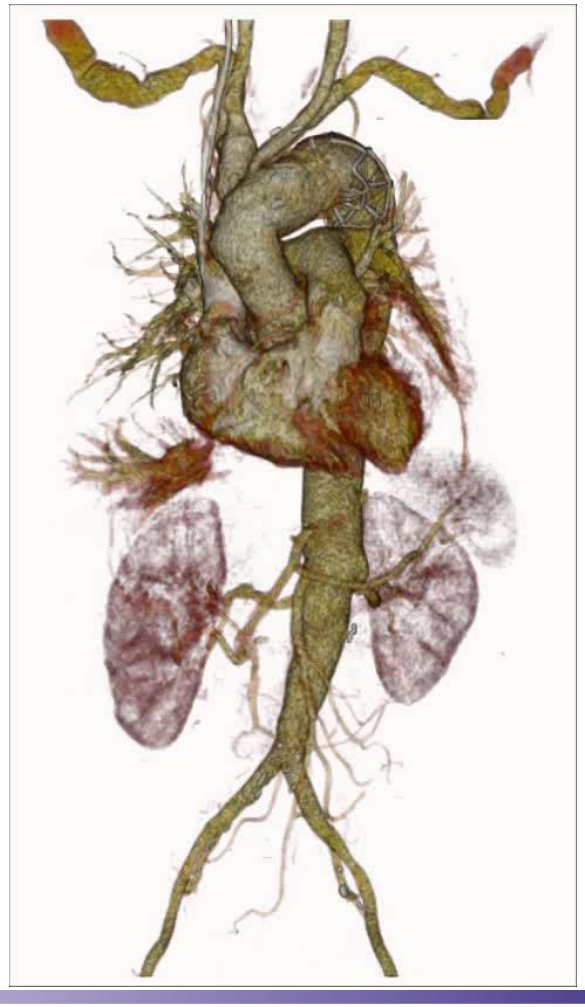
Remodeling based on <u>volume</u> changes

E-vita Open Concept – Docking Place in Safe Distance to the Arch

Safe LZ for SG Extension



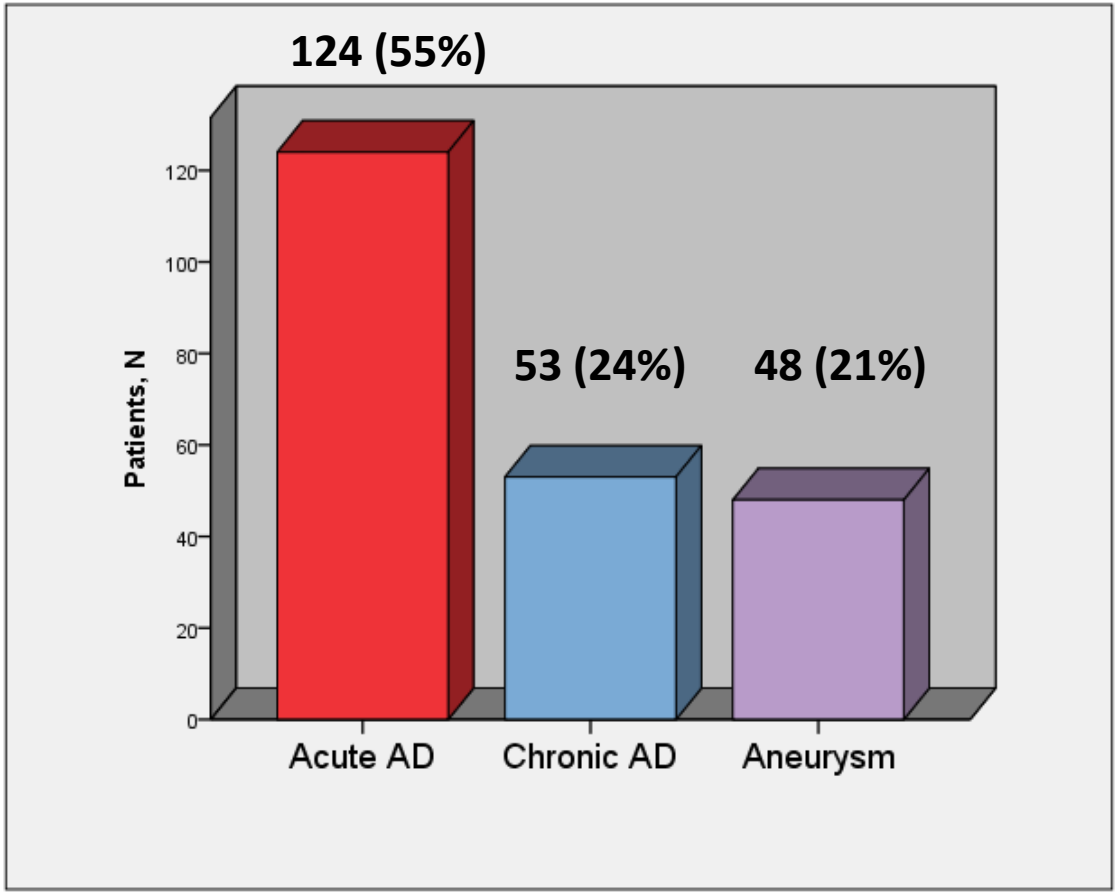
Safe Clamping Zone for Distal Replacement



E-vita Open Experience in Essen

02.2005 – 10.2016
N = 225

	N = 225
Age	59±11
Male	68%
Compromised HD	16%
S/p cardiac - vascular surg.	31%



E-vita Open in Essen – Intraoperative Data

Jakob et al, EJTCS 2016, ahead of print

Long-term experience with the E-vita Open hybrid graft in complex thoracic aortic disease

Risk factors for mortality after FET

- *Duration of CPB*
- *Compromised hemodynamics*

Current status

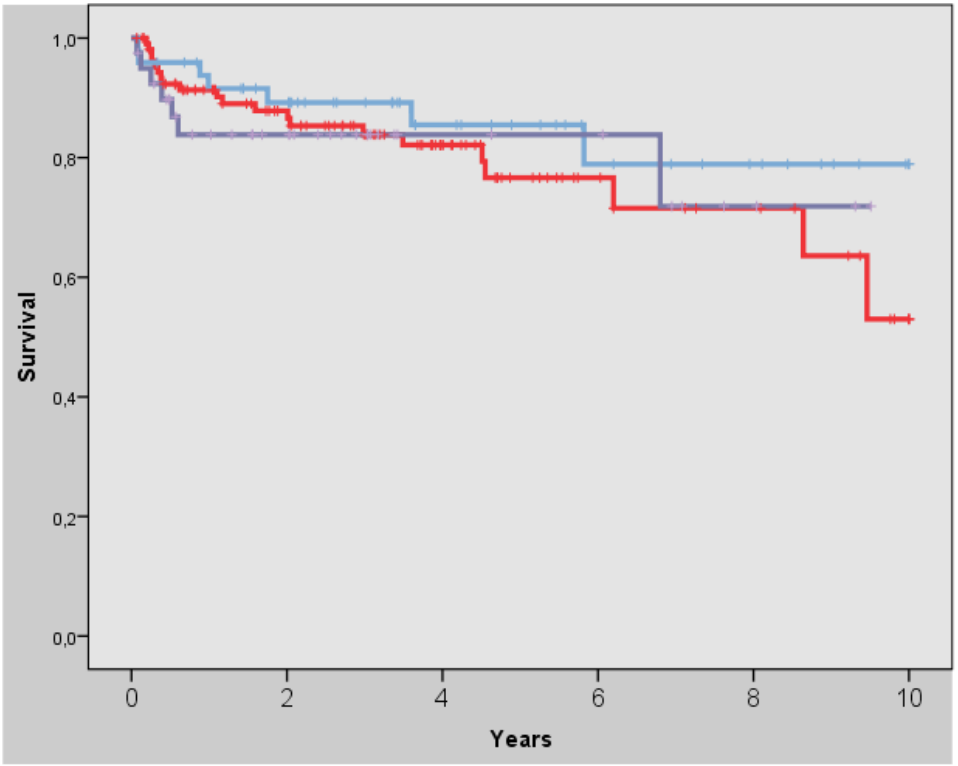
min.	Zone 3	Zone 2 + DP	p
CPB	252	226	<0.001
Cardioplegic arrest	141	119	<0.001
SACP	64	56	<0.001
Distal HCA	67	33	<0.001

CABG 21%, AV 47%, Root 37%, MV 5%, Island anastomosis 64%

E-vita Open Experience in Essen

	Overall N = 225	AAD N = 124	CAD N = 53	TAA N = 48
Hsp. Mortality	12%	13%	7%	17%
Stroke	8%	7%	7%	10%
Paraplegia	2%	1%	4%	4%

E-vita Open in Essen – Survival in FU

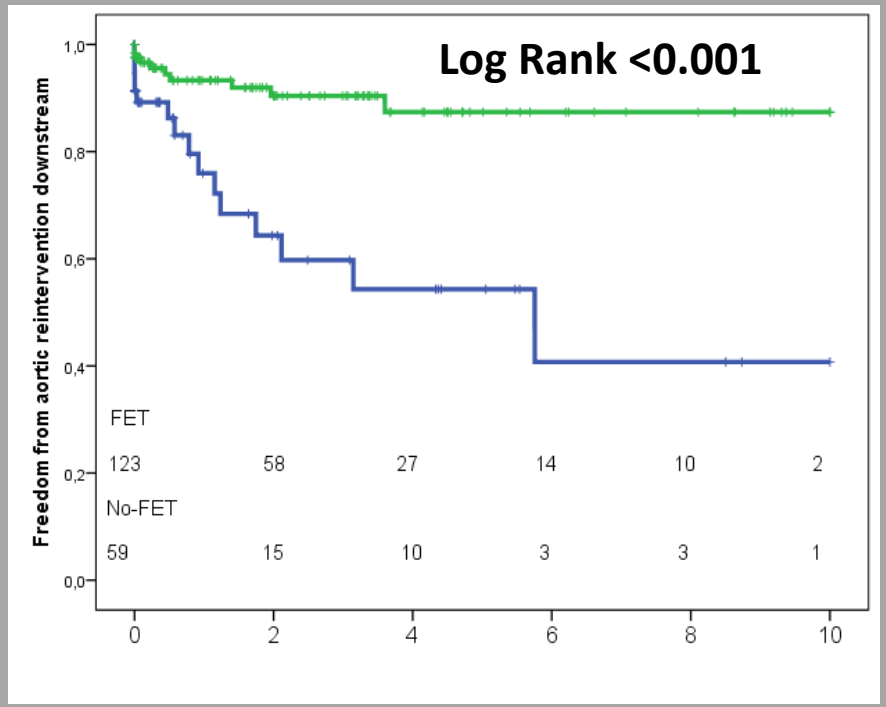


Years	0	2	5	7	10
N	196	130	48	28	5

Survival		
	5yrs	10yrs
AAD	77%	53%
CAD	86%	79%
TAA	84%	72%

E-vita Open in Essen – Acute Type I AD

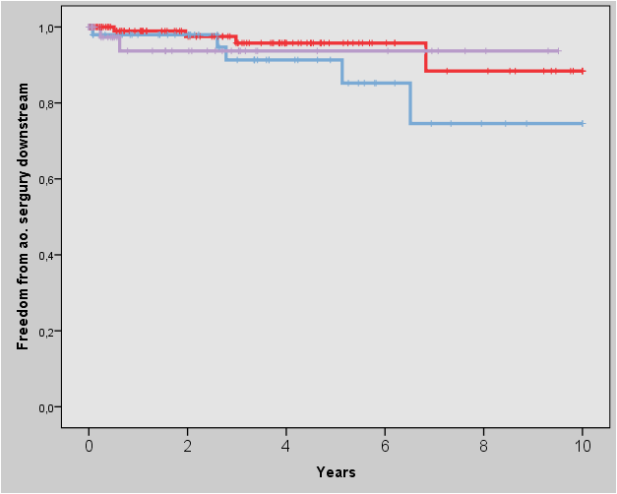
FET versus No-FET



Freedom Ao. Reintervention				
Years	2	5	8	10
FET	90	87	87	87
No-FET	64	54	41	41

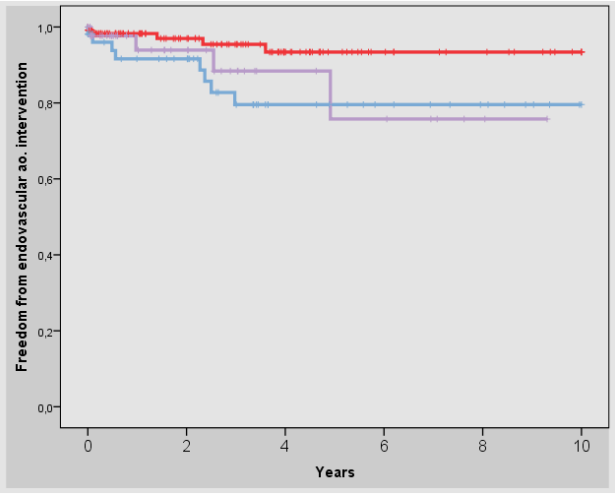
E-vita Open for FET– Long Term Results

Freedom from sec. Ao Surgery



	5yrs	10yrs
AAD	95%	88%
CAD	91%	75%
TAA	93%	93%

Freedom from sec. Endo Treatment



	5yrs	10yrs
AAD	93%	93%
CAD	80%	80%
TAA	76%	76%

FET with E-vita Open - Conclusion

E-vita Open

- Durable exclusion of thoracic aortic disease down to mid descending aorta
- Significant reduction of distal aortic problems in AD
- Zone 2 repair + early DP significantly reduces ischemic/ECC times
- Perfect docking target for surgical or endo redo, if required
- No Device related complications reported over 11 years f. up

International E-vita Open Registry

- Multicenter collaboration (appx. 1000 pat.) has resulted in 14 international peer reviewed publications and represents the basis for further FET research

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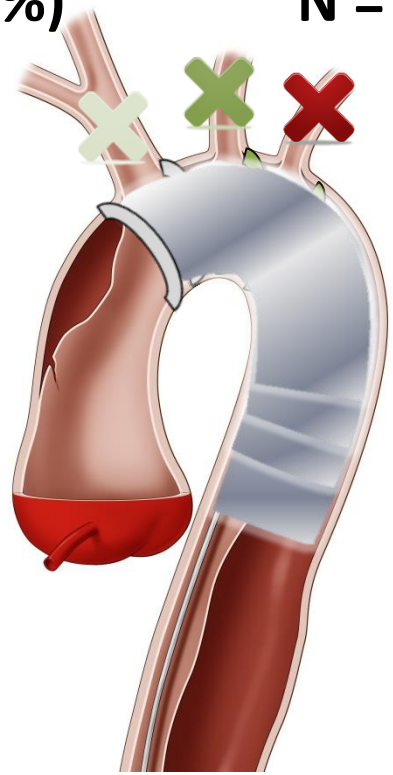
E-vita Open in Essen – Set Up

1. CSF Drainage in elective cases
   LiquoGuard (Müller Medical) for continuous pressure adjustment (8-10mmHg)
2. Heart Lung Mashine
   centrifugal pump (main), roll pump (LSA + distal body)
3. Guide wire
   8F Sheath right AFC (arterial line), Back-up Maier, 5F Pigtail catheter
4. Cannulation
   Right axillary artery (BCT, Open Vision Aortic Cannulation)
5. Angioscope
   autoclavable Olympus BF type Q180-AC bronchovideoscope
6. Selective Cerebral Perfusion (3 vessels perfusion, NIRS-SOMANETICS)
   28°C bladder temp., 22°C blood temp. , 50-60mmHg (Tip of LCCA cannula + LRA)
7. Distal Body Reperfusion
   28° blood temp, 30F Foley catheter
8. E-vita open Sizing
   AD norm- / undersizing , Aneurysm max. 10% oversizing

LSA Rerouting for Zone ≤2 Arch Replacement

Zone 1
N = 6 (3%)

Zone 2
N = 118 (52%)



Zone 0
N = 3 (1%)

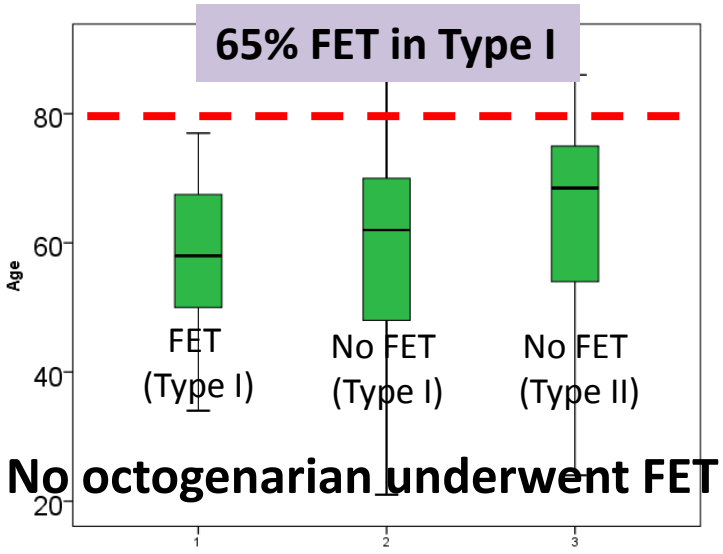
Zone 3
N = 98 (44%)

LSA-Rerouting	N = 127
Ao-axillary bypass	75 (59%)
Ao-subclavian bypass	48 (38%)
LSA-Transposition	1 (1%)
RCCA- LSA bypass	3 (2%)

Essen Concept in Acute Type I AD

FET in case of:

- **Reentry in distal arch /desc. aorta**
- **Severe TL collapse to avoid /resolve malperfusion**
- **Circumferential dissection in distal arch to stabilize the TL**
- **Hematothorax / imminent desc. aortic rupture**



No octogenarian underwent FET

Location of re-entry sites in Desc. Ao. Distance (cm) LSA to lesion