

MEET 2015

MULTIDISCIPLINARY EUROPEAN
ENDOVASCULAR THERAPY



11.20 Thoracic pathology

Moderators: *S. Ronchey, S. Haulon, F. Veith*

How I deal with the aortic arch: from planning to follow-up

- 11.20 My experience in ascending aorta TEVAR, *I. Loftus*
- 11.28 Open surgery conventional: discrepancy in results (lights and shadow), *D. Pacini*
- 11.36 Custom-made solution: how my planning evolved, *S. Haulon*
- 11.44 Off the shelf solution: selection based on planning, *N. Mangialardi*
- 11.52 My planning for arch Chimney, *J. Brunkwall*
- 12.00 Endoleak after arch Chimney, *R. Kolvenbach*
- 12.08 Hybrid repair: technique for total debranching, *P. Bergeron, A. Petrosyan*
- 12.16 Stroke rate and mortality in arch procedures, *M. Lachat, F. Pecoraro*
- 12.24 Endovascular arch repair following ascending aorta open surgery, *S. Haulon*
- 12.32 Complications of supraaortic debranching, *S. Ronchey*
- 12.40 Demonstration (crazy arch case), *T. Larzon*
- 12.48 Discussion

Disclosure

Speaker name:

Mario L. Lachat

I have the following potential conflicts of interest to report:

- Consulting (Jotec, Gore, Medtronic, Endospan, Philips,)

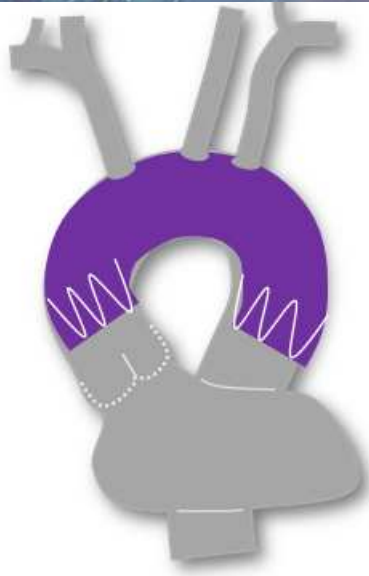
Great Times

- For patient and for physician
 - Plenty of treatment options
- On the way to “personalized aortic treatment”
- ...

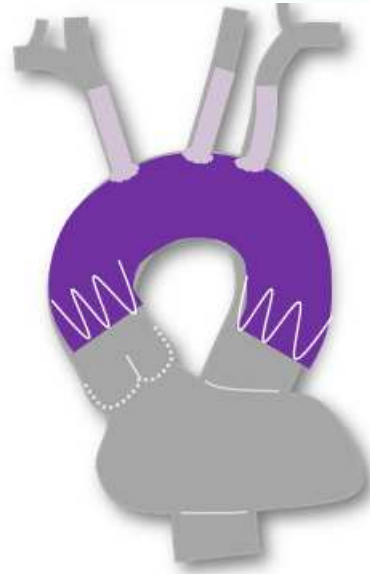
- Multiple repair techniques

Endovascular

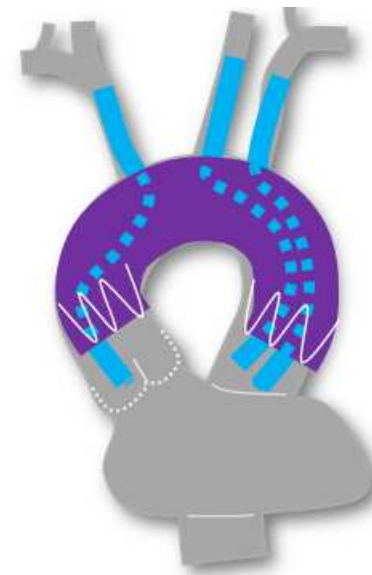
FEVAR



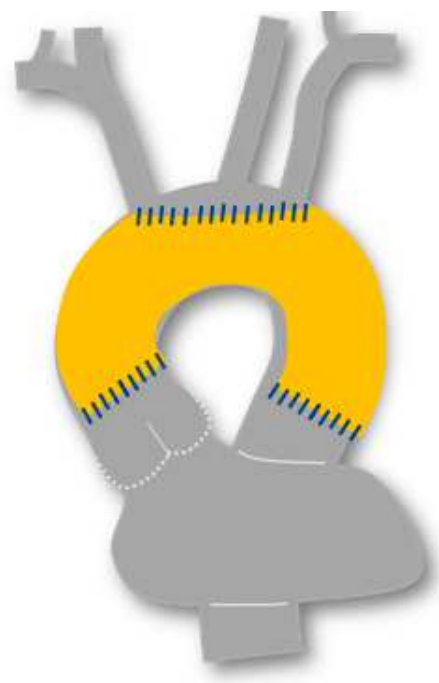
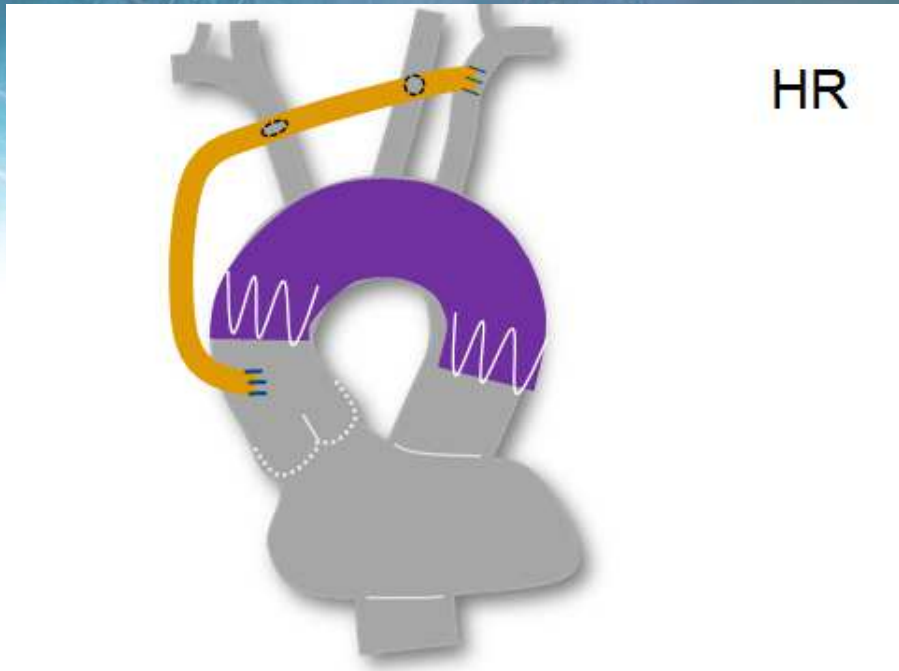
BEVAR



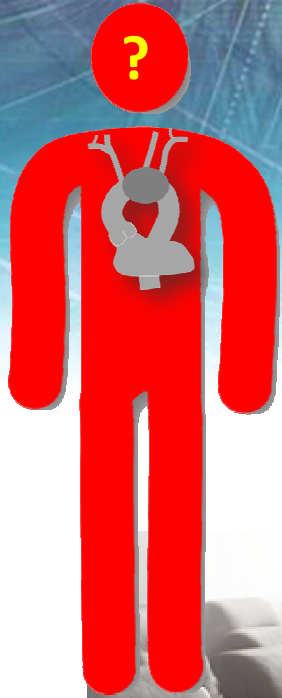
PG-EVAR



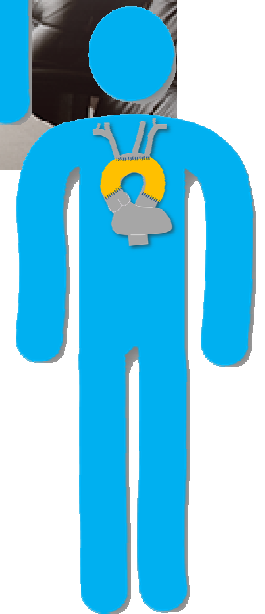
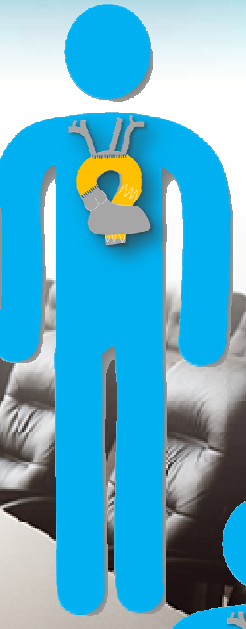
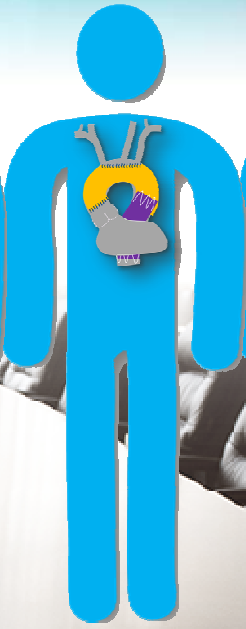
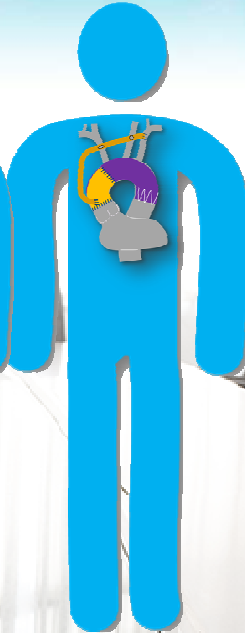
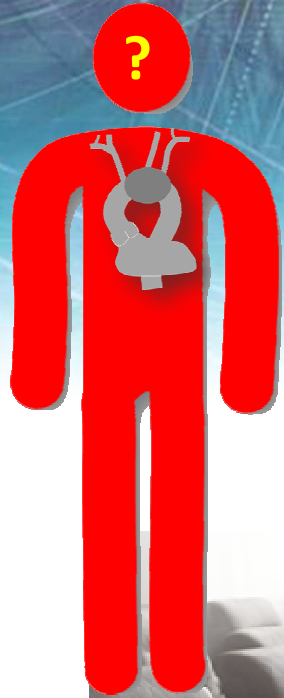
Surgery



Aorta board



Aorta board



- Multiple repair techniques
- **What are the results?**

Literature search

- Aortic arch
 - Open repair, F/BEVAR, PG-EVAR, Hybrid repair
- 30 day results
 - Stroke, mortality
- Follow-up

Author	Year	Patients	30d Results				FUP	
Conventional Open Repair			death	stroke and/or paraplegia	EL	reintervention	reintervention	survival
Andersen	2012	20	2	1	-	3	0	51@5y
Baraki	2007	39	5	5	-	0	3	87@1.9Y
Chen	2010	28	4	6	-	1	0	88%@5y
Di eusanio	2013	122	21	20	-	15	0	97%@1y
Flores	2006	25	3	8	-	-	-	-
Hofferberth	2012	19	1	3	-	0	4	-
Hoffmann	2012	32	1	1	-	4	0	-
Ius	2013	131	20	15	-	24	0	72%@5y
Jakob	2011	270	41	35	-	38	0	74%@5y
Jim	2011	10	1	1	2	0	1	50%@3Y
Kawaharada	2009	31	2	1	1	0	4	73%@5Y
Lee	2011	21	4	3	2	0	5	-
Leontyev	2013	46	4	11	-	6	0	68%@5y
Lima	2012	50	4	6	1	2	0	87%@2Y
Nishi	2011	61	2	6	-	0	3	-
Pochettino	2009	36	5	1	-	-	-	-
Roselli	2013	17	0	2	-	-	-	-
Shen	2012	38	3	2	-	-	-	91%@5y
Shi	2011	46	1	1	-	2	0	-
Shimamura	2008	126	4	11	-	3	0	63%@5y
Shimamura	2009	69	5	6	6	2	6	89%@3Y
Shrestha	2012	34	3	1	-	6	2	-
Sun	2013	398	31	20	-	28	0	-
Uchida	2011	80	3	7	-	2	0	-
Usui	2002	24	0	4	-	-	-	96%@1year
Xiao	2013	33	6	0	0	-	-	-
Zhao	2012	24	1	1	1	0	1	92%@5Y
Total		1830	176	180	13	135	29	
%			10	10	5,5	8	1,8	"79%"@4years"

A systematic review and meta-analysis on the safety and efficacy of the frozen elephant trunk technique in aortic arch surgery

David H. Tian¹, Benjamin Wan¹, Marco Di Eusanio^{1,2}, Deborah Black³, Tristan D. Yan^{1,4}

Table 3 Summary of clinical outcomes

First author	30-day mortality (%)	Stroke (%)	Spinal cord injury (%)	Renal failure (%)	Reoperation for bleeding (%)	Hospital stay (days)	1-year survival (%)	5-year survival (%)
Usui (8)	0	4.2	12.5	NR	NR	36±15	96	NR
Flores (9)	12.0 [†]	16.0	24.0	NR	NR	NR	NR	NR
Shimamura (10)	3.2	5.6	6.3	4.8	2.4	29 ^M	81	63
Pochettino (11)	13.9 [†]	2.8	8.3	16.7	NR	NR	NR	NR
Uchida (12)	3.8	2.6	1.9	5.1	2.6	NR	NR	NR
Chen (13)	0	10.7	NR	7.1	3.6	NR	NR	88
Sun (14) [†]	1.4 [†]	2.1	2.8	1.4	7.0	NR	NR	NR
Jakob (15)	12	5.8	8.0	21.9	13.9	19 ^M	NR	74
Shi (16)	2.2	0	0	NR	4.3	19±6	NR	NR
Shen (17)	7.9 [†]	0	5.3	NR	0	21±13	91	NR
Hoffman (6)	0	0	0	NR	12.5	19±8	NR	NR
Leontyev (18)	8.7	13.0	21.7	23.9	13.0	NR	70	68
Xiao (23)	18.2 [†]	0	0	3.0	NR	26±11	NR	NR
Ius (19)	15.3	10.7	0.8	16.0	18.3	18±17	82	72
Sun (20)	7.8 [†]	2.5	2.5	4.3	2.5	NR	NR	NR
Di Eusanio (21)	17.2	7.4	9.0	24.6	12.3	15 ^M	97	NR
Roselli (22)	0	11.8	NR	5.9	NR	20±12	NR	NR
Minimum	0	0	0	0.7	0	15	70	63
Maximum	18.2	16.0	24.0	24.6	18.3	36	97	88
Weighted average	8.3	4.9	5.1	10.9	7.8	NA	84.7	71.5

†In-hospital mortality; †only chronic dissection cases; M, median; NA, not statistically available; NR, not reported

Author	Year	Patients	30d Results				FUP	
Hybrid Repair			death	stroke and/or paraplegia	EL	reintervention	reintervention	survival
Andersen	2012	48	10	7	11	3	11	51%@5y
Antoniou	2010	33	7	6	6	-	-	-
Bavaria	2010	23	3	5	-	-	-	-
Bergeron	2006	25	2	3	3	0	3	88%@1.3y
Canaud	2010	34	7	3	7	-	-	70%@2.4Y
Chan	2008	16	5	4	2	3	1	100%@1.2Y
Chiesa	2010	116	5	7	9	0	2	89%@2y
Czerny	2012	66	6	5	9	9	10	96%@5y
Donas	2010	20	2	3	0	0	1	-
Deriu	2012	48	7	2	-	-	-	-
Ferrero	2012	27	3	2	1	0	0	74@1.4Y
Geisbysch	2011	47	9	6	7	0	13	59@3y
Gelpi	2010	15	1	1	0	1	1	93%@5Y
Gottardi	2008	73	5	1	18	0	2	72%@5Y
Holt	2010	78	6	7	8	3	9	-
Hughes	2009	28	5	2	2	4	2	70%@3Y
Ingrund	2010	12	17	1	2	2	0	-
Ishilbashi	2012	12	1	1	0	-	-	-
Lee	2011	37	6	4	3	4	0	-
Lofti	2012	51	5	8	3	6	3	73%@2Y
Lu	2011	49	5	4	0	-	-	-
Ma	2011	24	1	1	-	-	-	-
Murashita	2012	27	1	4	-	-	-	86%@2Y
Saleh	2006	15	1	1	0	0	0	-
Vallejo	2012	38	9	6	5	5	2	50%@4Y
Weigang	2009	26	4	1	1	1	0	-
Total		988	133	95	97	41	60	
%			13	10	11	6	8	"76%"@3years"

Author	Year	Device	Patients	30d Results				FUP	
F/BEVAR				death	stroke and/or paraplegia	EL	reintervention	reintervention	survival
Inoue K	1999	BEVAR-Inoue	15	0	1	4	1	4	87%@1year
McWilliams	2004	FEVAR	1	0	0	0	0	0	100%@0.5Year
Saito N	2005	BEVAR-Inoue	17	0	1	3	0	2	88%@2.2years
Chuter T	2003	BEVAR	1	0	0	0	0	0	-
Brar R	2008	BEVAR	1	0	0	0	0	0	-
Kawaguchi	2008	FEVAR	288	-	16	-	-	-	62%@5years
Sonesson	2009	FEVAR	1	0	0	0	0	-	100%@0.1Year
Manning	2010	FEVAR	10	0	0	0	0	0	-
Yusa	2011	FEVAR	10	0	0	1	0	0	-
Lioupis	2012	BEVAR	6	0	2	2	1	0	-
Spear	2013	BEVAR	1	0	0	0	0	-	-
Azuma	2013	FEVAR	393	6	10	12	-	-	-
Haulon	2014	BEVAR	38	5	6		4	3	-
Anderson	2015	FEVAR	2	0	0	0	0	0	100%@0.5 years
Matsuyama	2015	FEVAR	37	1	2	1	0	11	65%@5years
Mangialardi	2015	FEAVR-Najuta	1	0	0	0	0	0	-
Tse	2015	FEVAR-insitu	6	0	1	0	0	0	-
Kurimoto	2015	FEVAR	37	0	5	12	0	4	86%@2years
Total			865	12	44	35	6	24	
%				1,5	5	4	0,7	3	«86%»@«2y»

Author	Year	Patients	30d Results				FUP	
Parallel grafts			death	stroke and/or paraplegia	EL	reintervention	reintervention	survival
Mangialardi	2014	26	1	2	6	3	-	80%@3years
Vicente	2014	1	0	0	0	0	0	100%@0.8years
Synoviecz	2013	1	0	0	0	0	0	-
Shahverdyan	2013	6	1	0	3	2	1	83%@0.2years
Samura	2013	2	0	0	2	0	0	100%@0.5years
Zhu	2013	34	0	0	2	4	4	94%@1year
Chang	2013	1	0	0	0	0	0	100%@1year
Zhou	2013	1	0	0	2	0	0	100%@1year
Vallejo	2012	8	1	1	0	3	5	-
Akchurin	2012	10	0	0	1	0	0	100%@0.5years
Cires	2011	9	1	1	0	1	3	100%@0.4years
Yoshida	2011	2	0	0	2	0	1	-
Shu	2011	8	0	0	0	0	0	100%@1year
Feng	2011	1	0	0	0	0	0	100%@1year
Gehringhoff	2011	9	1	0	1	0	1	79%@1year
Sugiura	2009	11	2	1	2	0	1	-
Baldwin	2008	7	0	1	1	0	0	-
Ohrlander	2008	4	0	0	2	1	2	-
Criado	2007	8	0	0	0	0	0	-
Hiramoto	2006	1	0	0	0	0	0	-
Larzon	2005	2	0	0	2	0	0	-
Total		152	7	6	26	14	18	
%			5	4	17	9	12	"94%"@1year"

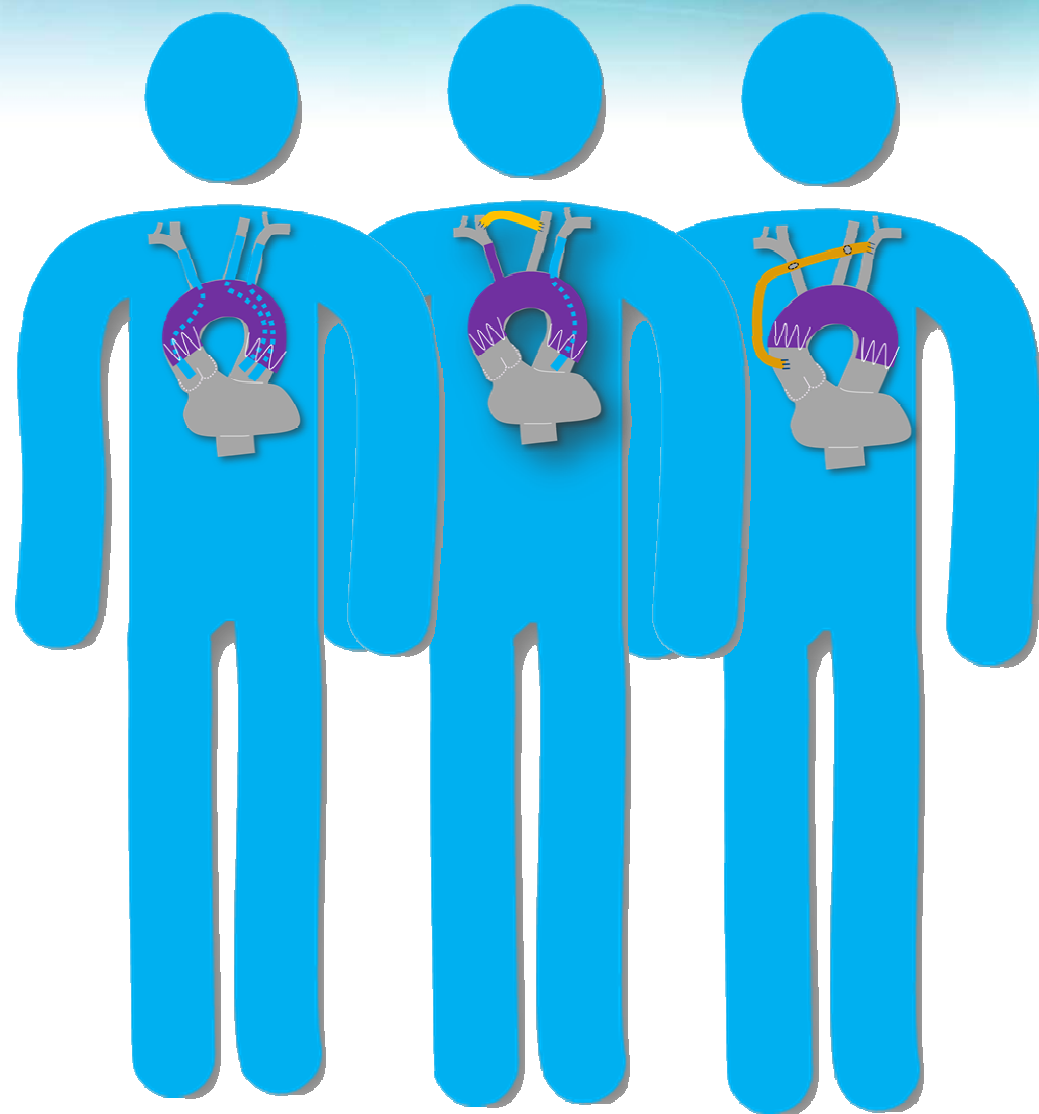
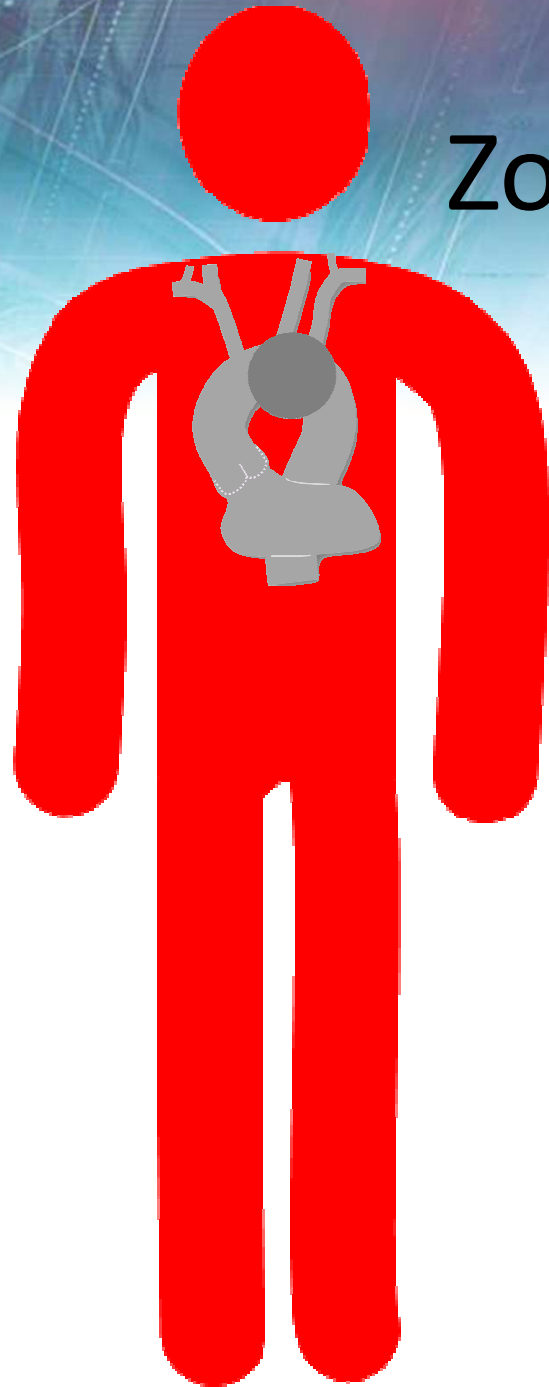
FACTS

- Mortality is significantly higher in surgery groups (COS & HR) when compared to endo repair (F/BEVAR & PG-EVAR)
- Neurological events are significantly less in group PG-EVAR when compared to other repair groups.
 - F/BEVAR had lower incidence of neurological events when compared to surgery groups

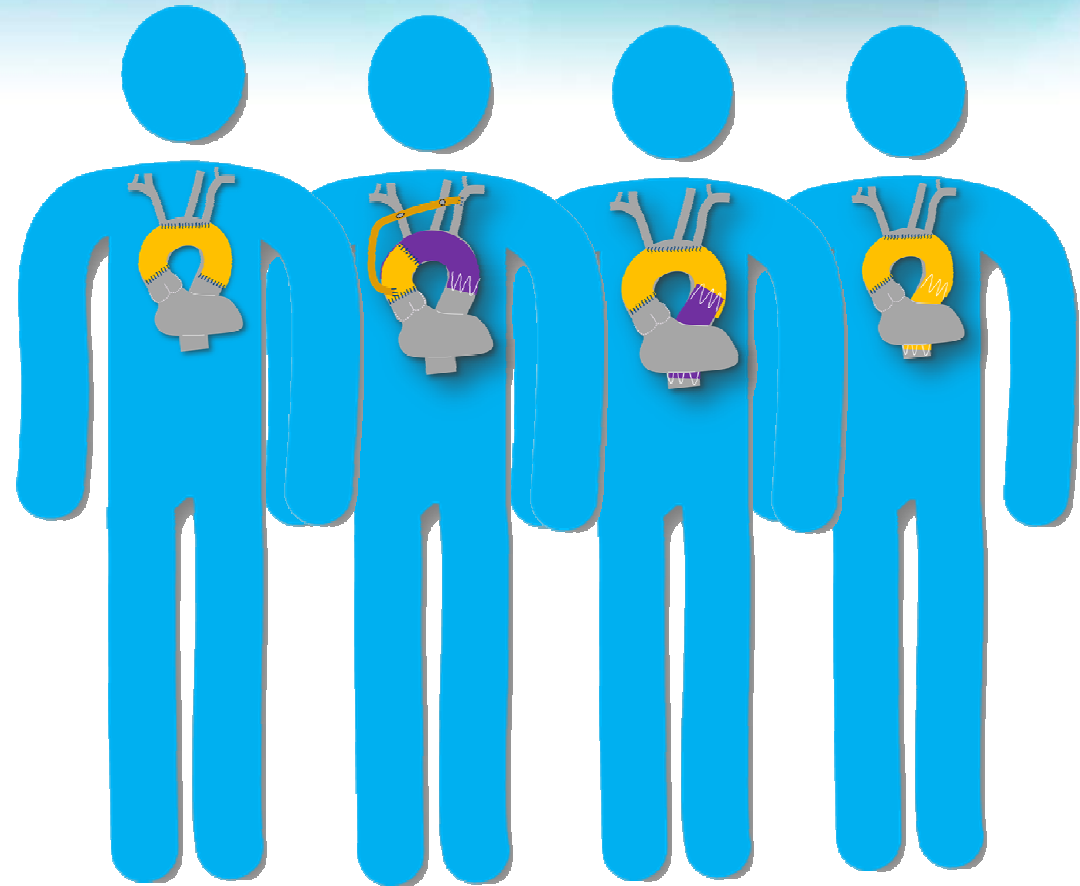
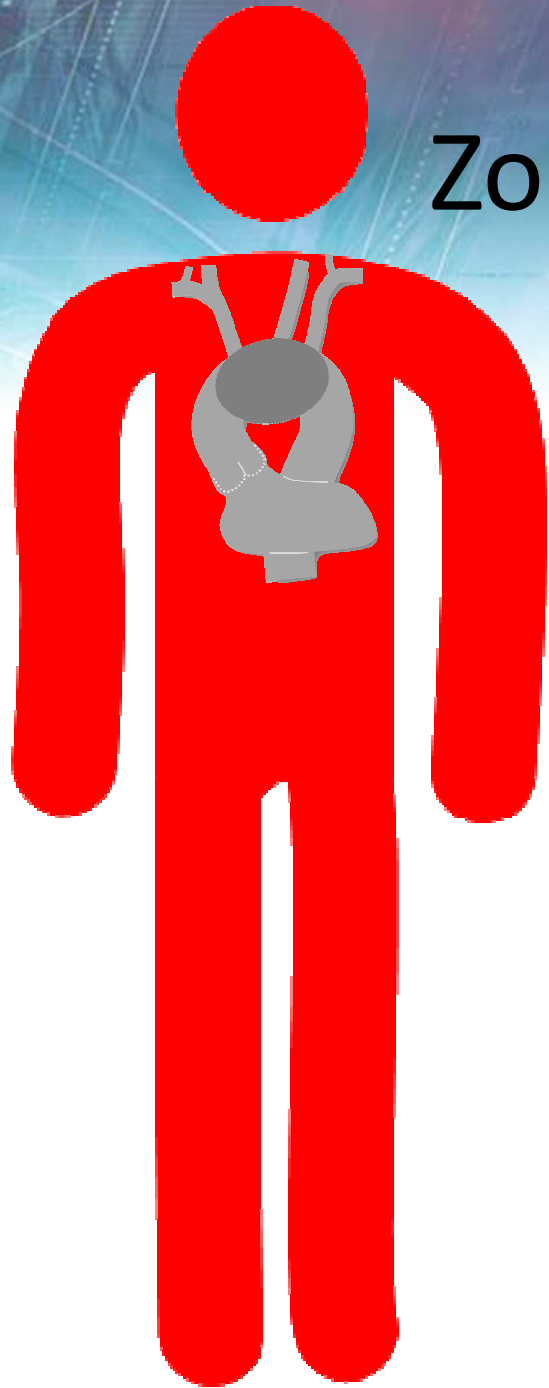
FACTS

- Endoleaks are significantly less in F/BEVAR when compared PG-EVAR and HR
- Reinterventions are significantly less in F/BEVAR and COS when compared to PG-EVAR and HR

Zone I pathology

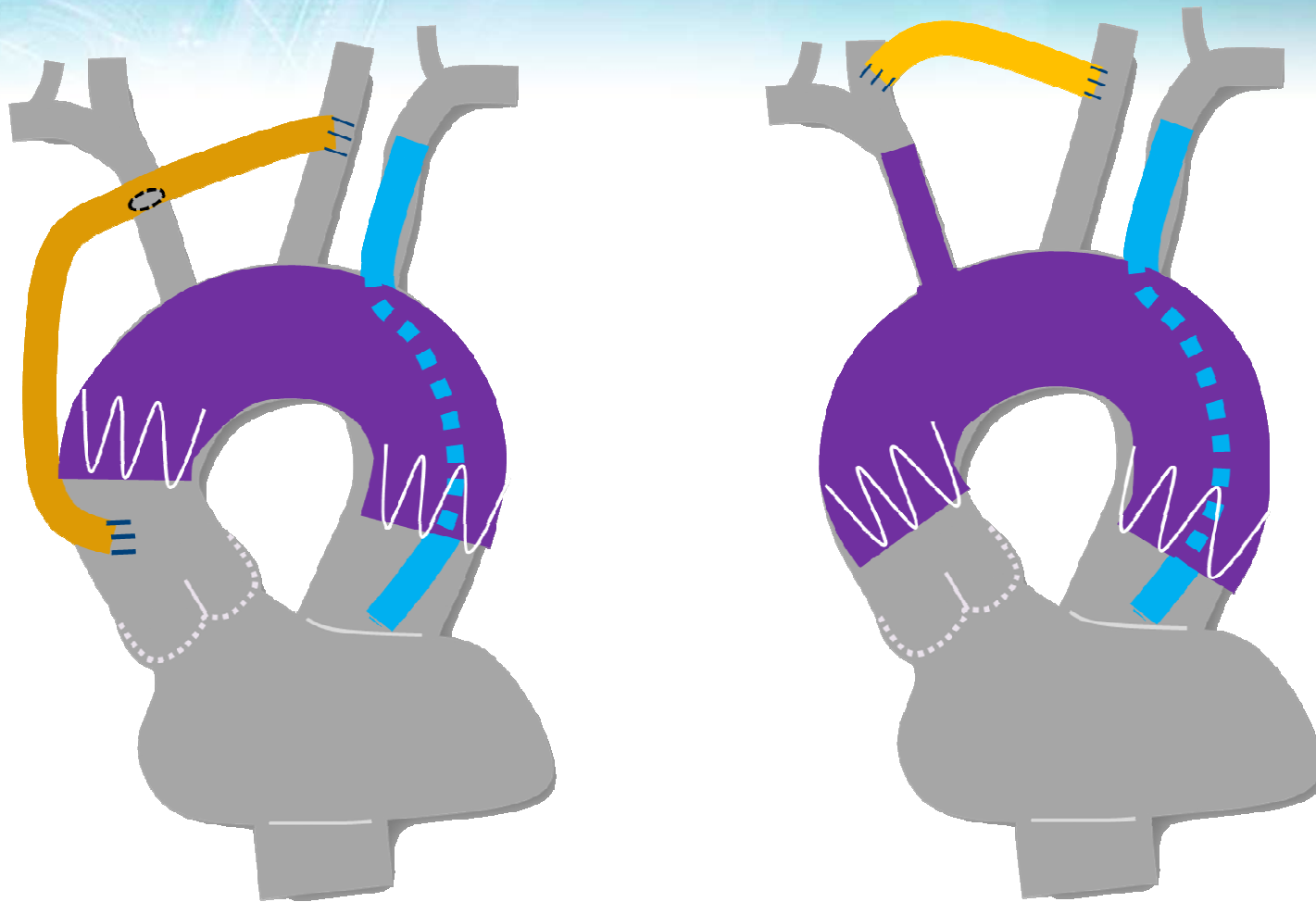


Zone 0 pathology



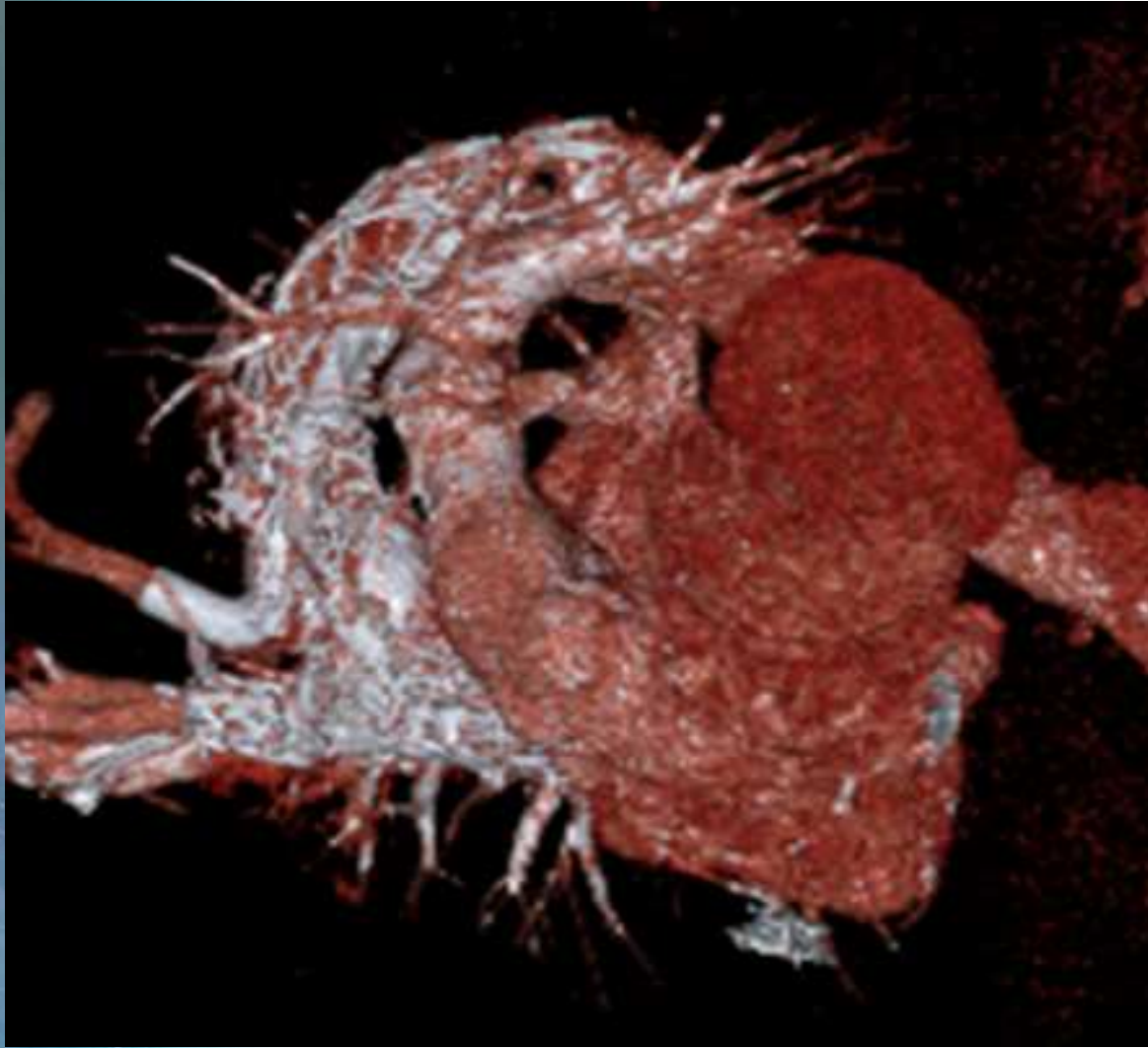
- Multiple repair techniques
- What are the results?
- **What do we not know?**

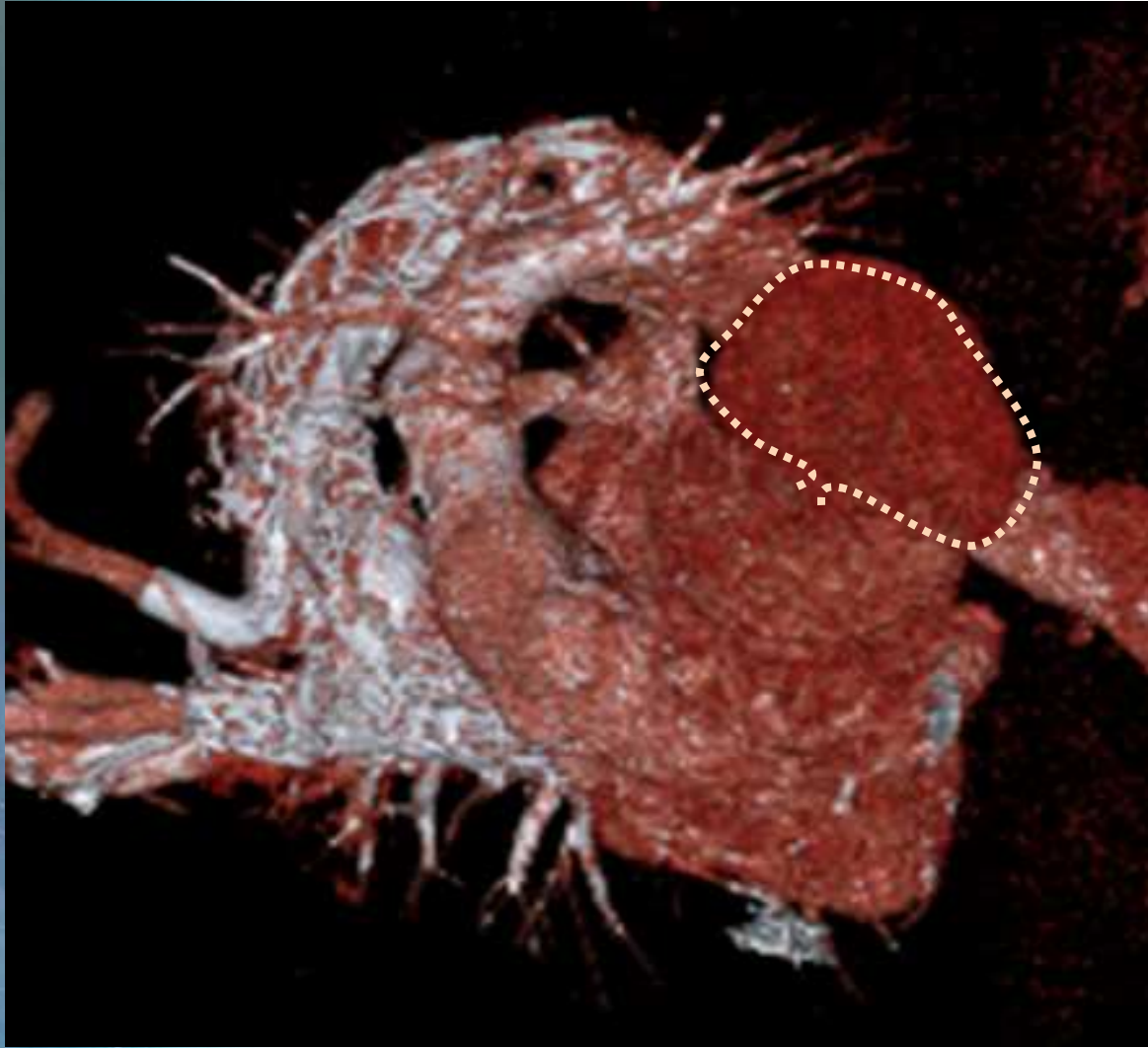
??MultiTech EVAR??

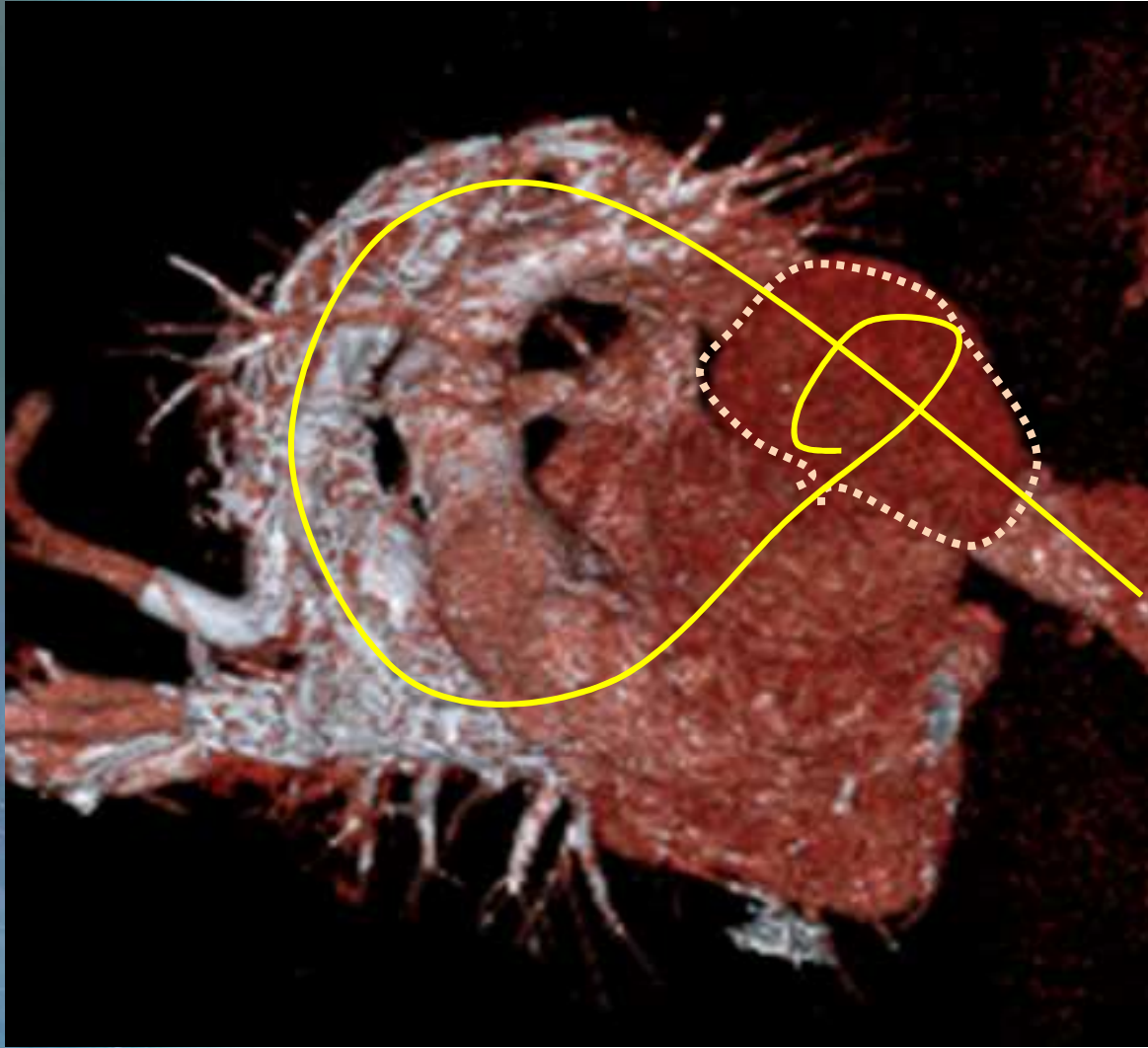


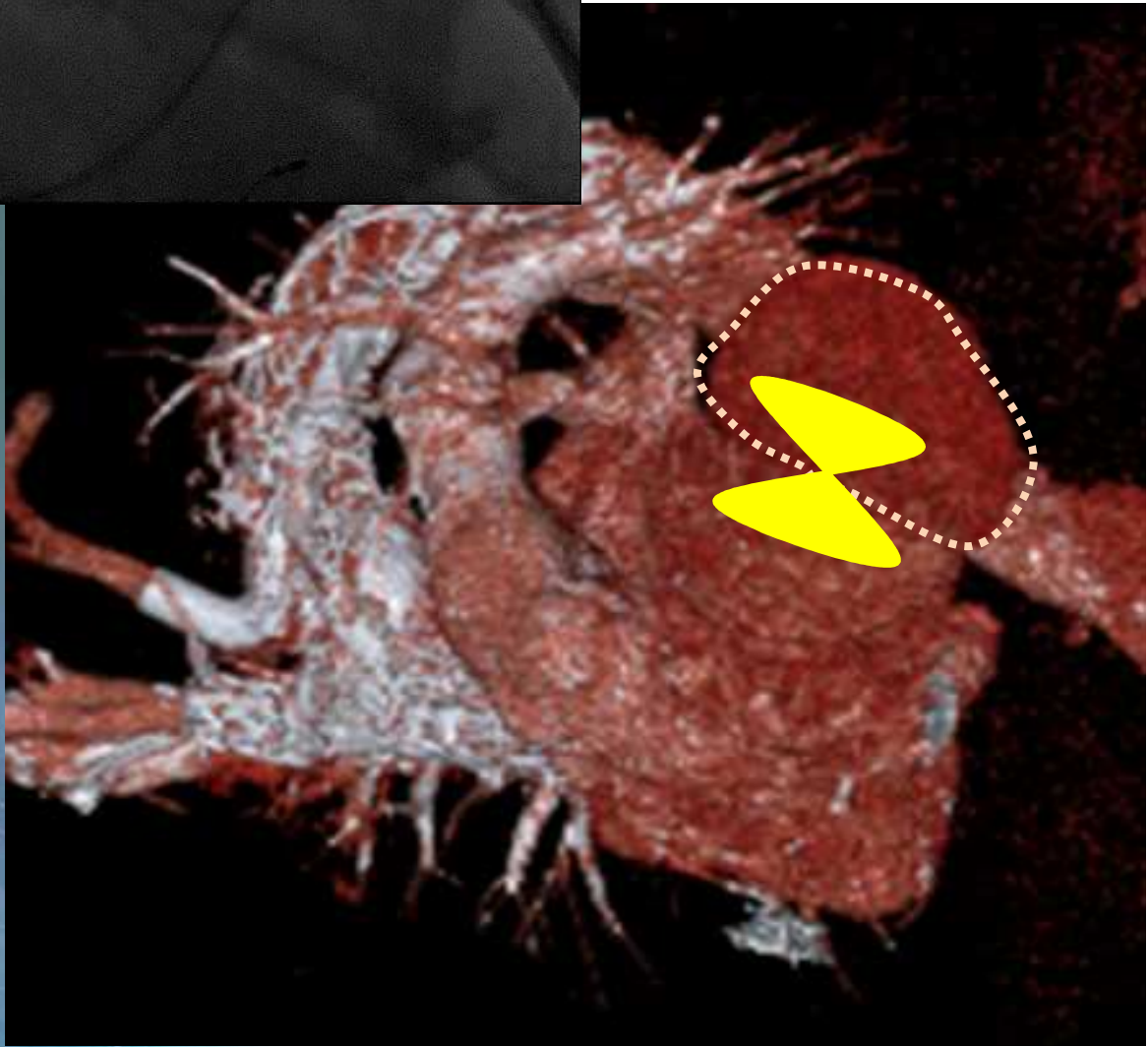
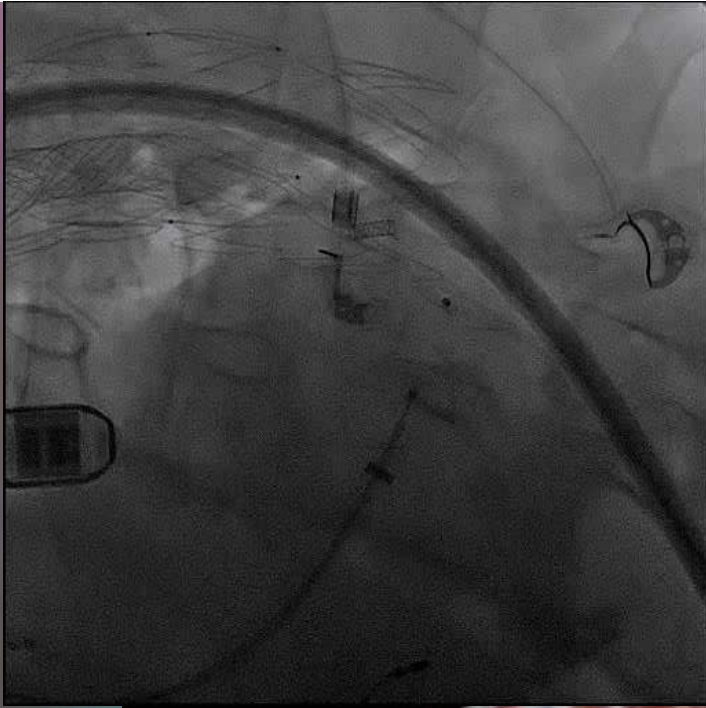
New complications!!

- **LV perforation**









Prevention

- Patient selection

ANATOMIC AND PHYSIOLOGIC CRITERIA FOR ENDOVASCULAR ARCH REPAIR

Anatomic Criteria:

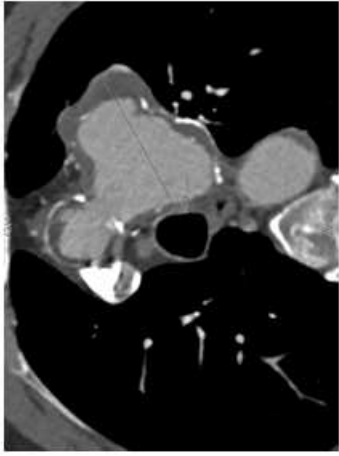
- Arch aneurysms and chronic dissections, no previous mechanical aortic valve replacement
- Ascending aortic length ≥ 50 mm (measured from sinotubular junction to origin of innominate artery)
- Sealing zone in the ascending aorta ≥ 40 mm in length and ≤ 38 mm diameter
- Sealing zone in the innominate artery ≥ 20 mm in length and ≤ 20 mm in diameter
- Access able to accommodate 22- or 24-F sheaths

Physiologic Criteria:

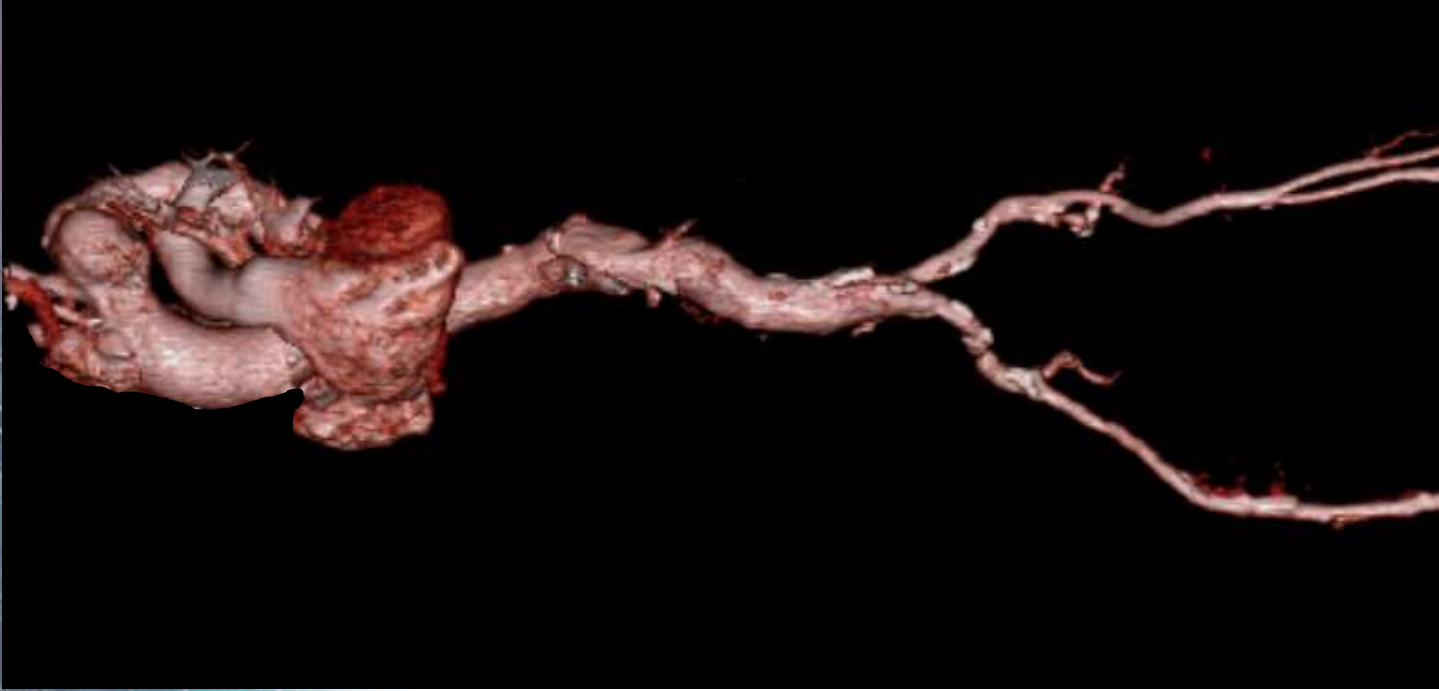
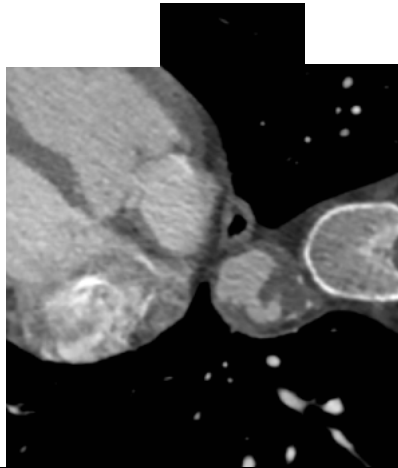
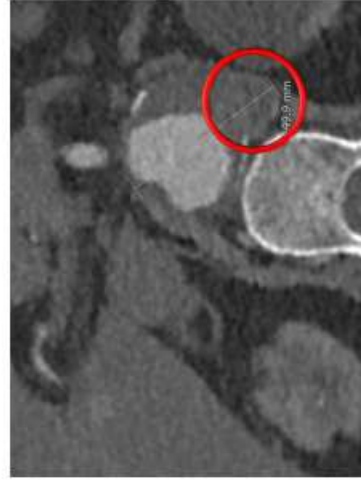
- Minimum of 2-year life expectancy
- Negative stress test (cardiology clearance required in the setting of positive stress test)
- No class III or IV congestive heart failure
- No stroke or myocardial infarction in the last year
- No significant carotid bifurcation disease ($\geq 75\%$ stenosis by North American Symptomatic Carotid Endarterectomy Trial criteria)
- Estimated glomerular filtration rate by modification of diet in renal disease method ≥ 45 mL/min/1.73 m²

No dissection of SAT
No endoluminal plaques

DB Aneurysm



lesion



Hybrid repair

- Aortic arch
- Visceral aorta
- Pelvine arteries



Prevention

- Assess supraaortic anatomy
- Protection devices

Prevention

- Assess supraaortic anatomy
- Protection devices
- High-dose heparinisation

Anticoagulation

	Intraoperative	Postoperative
F/BEVAR	Heparin	Aspirin and/or Plavix LMWH Coumadin
PG-EVAR	Heparin	Aspirin and/or Plavix LMWH Coumadin
HR	Heparin	Aspirin and/or Plavix LMWH Coumadin
COS	Heparin	Aspirin and/or Plavix Coumadin

ACT?

Prevention

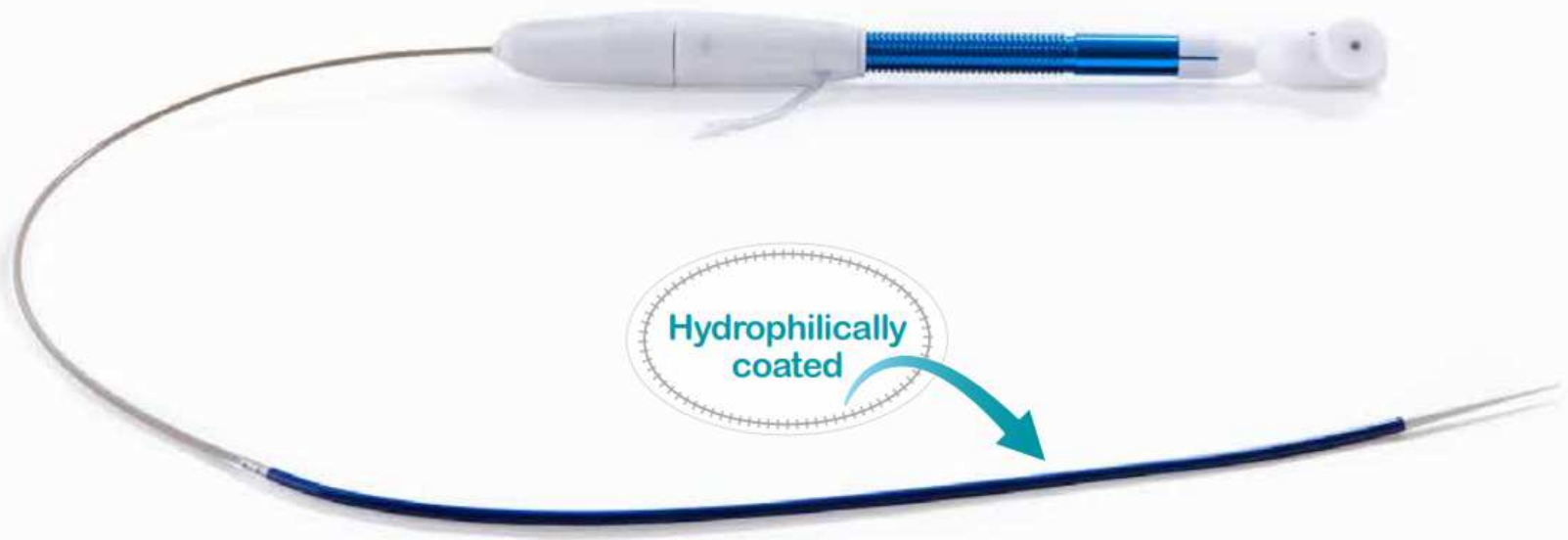
- Assess supraaortic anatomy
- Protection devices
- High-dose heparinisation
- Reduce manipulations in arch
- Avoid time consuming deployment devices

NEXUS (Endospan)



Nexus™ Delivery System

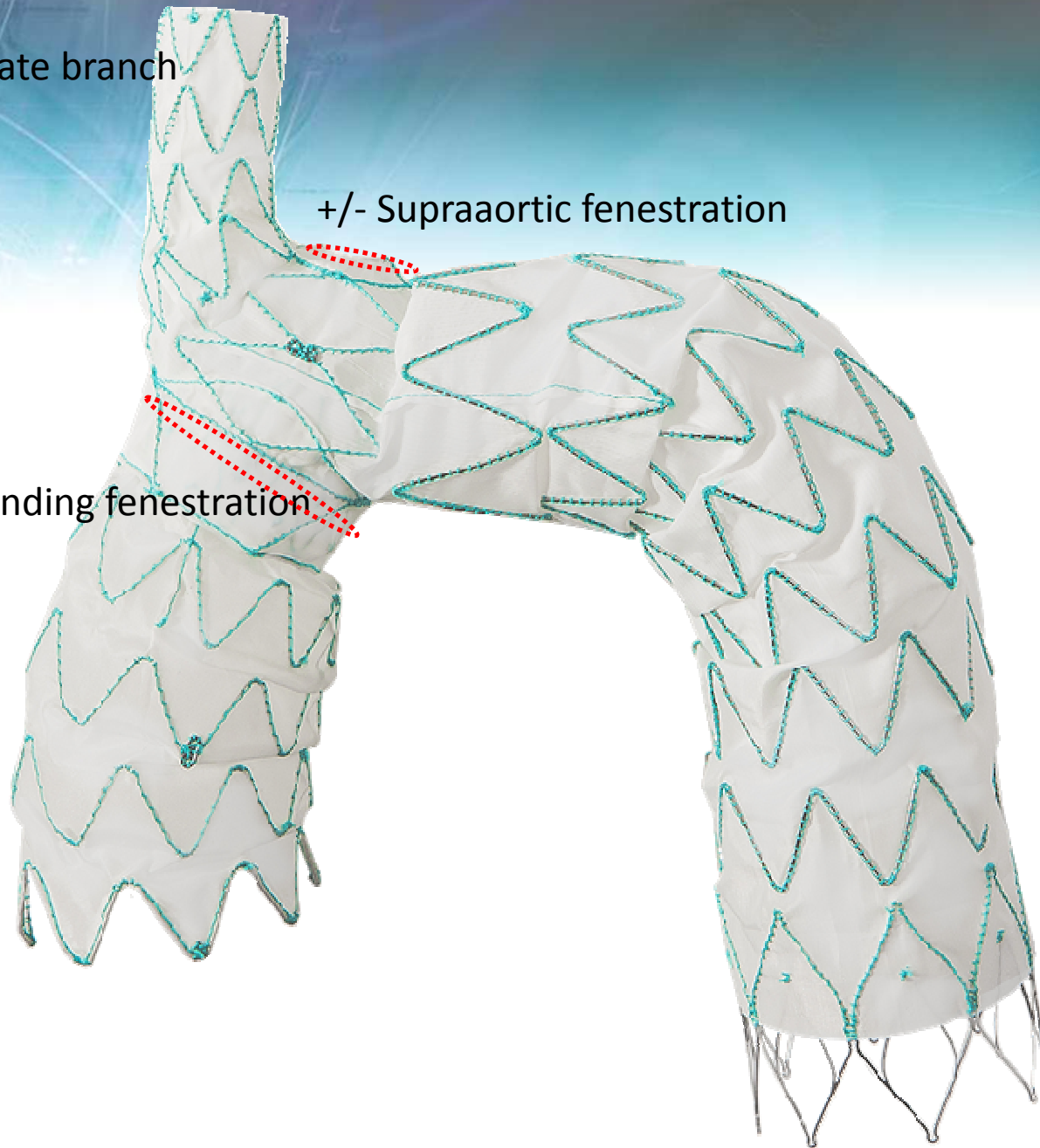
Nexus' low-profile, 20Fr delivery system makes this EVAR option available for a wide range of patients



Innominate branch

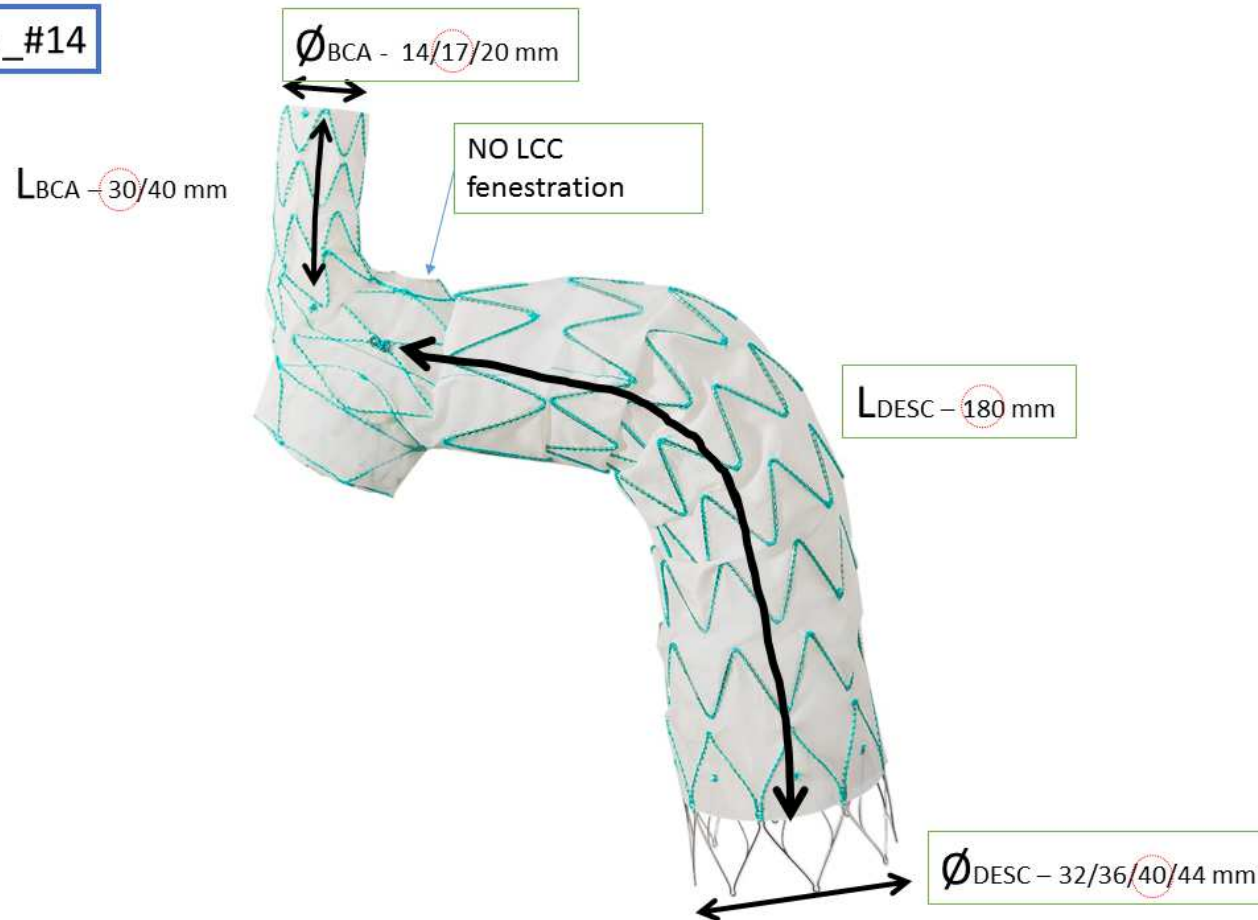
+/- Supraaortic fenestration

Ascending fenestration



Module 1 (OTS)

H.B.S – Nx_can_#14



Module 2 (OTS)



straight

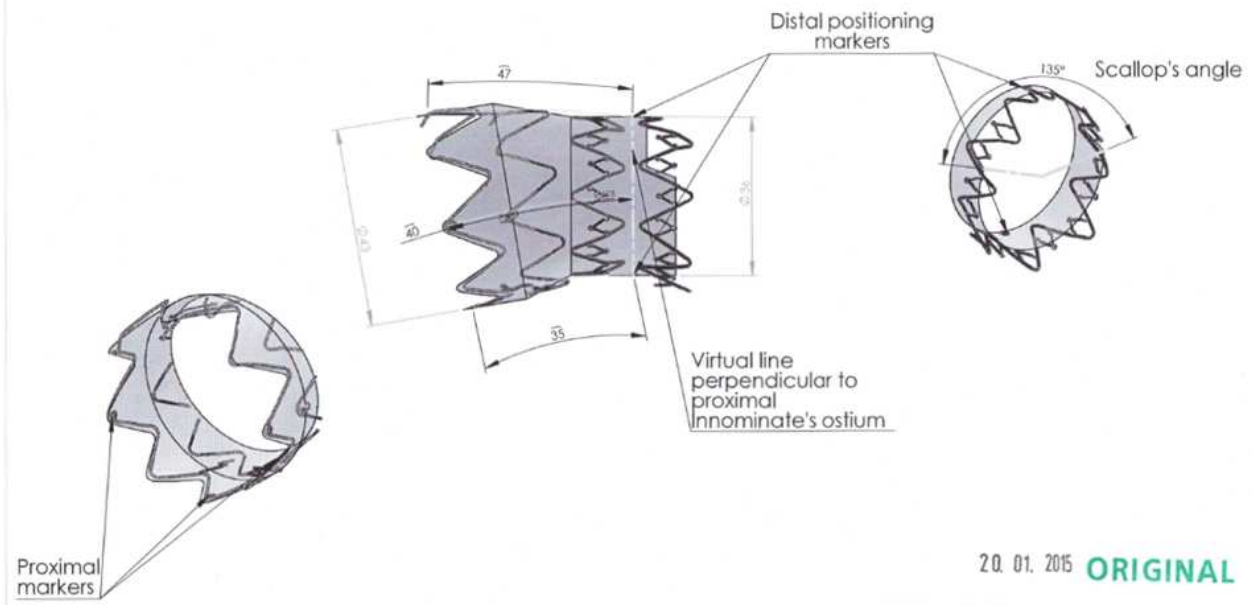


Pre-curved

CM Module 2

Final product

REVISIONS					
REV.	ECC No.	BY	DESCRIPTION	DATE	APPROVED
A	1401B	T.T.	Nexus ASC module curved design	29/09/14	K.M.

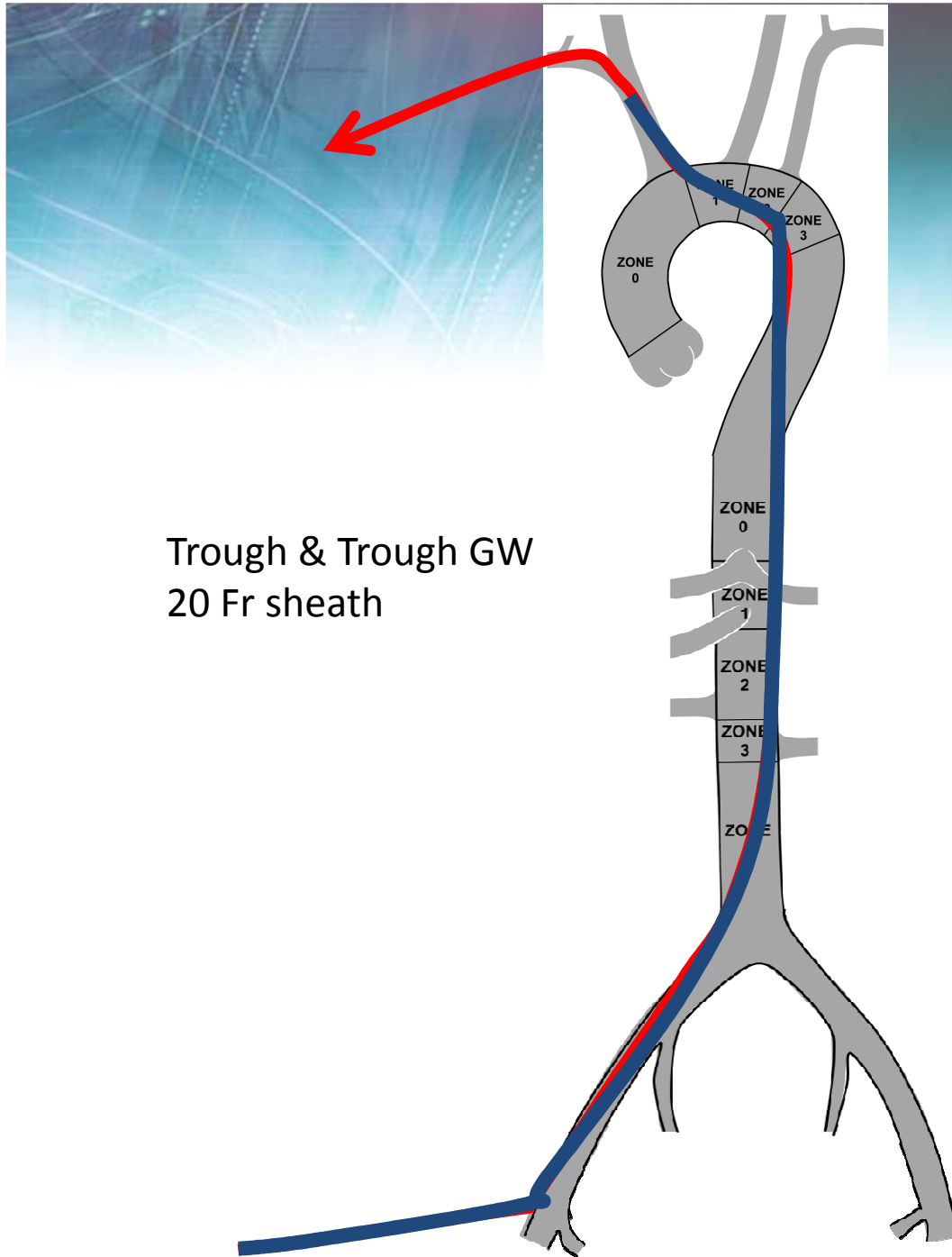


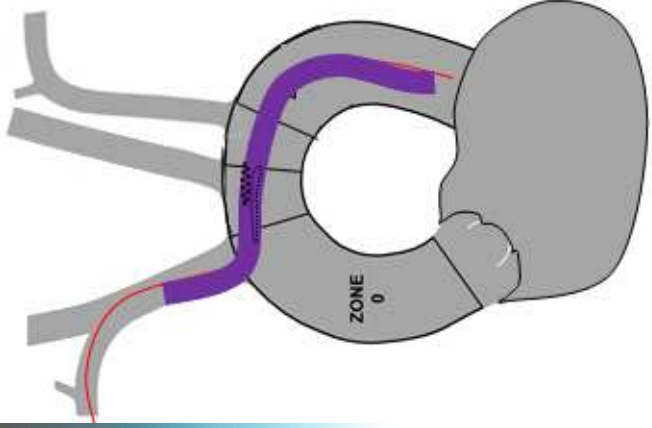
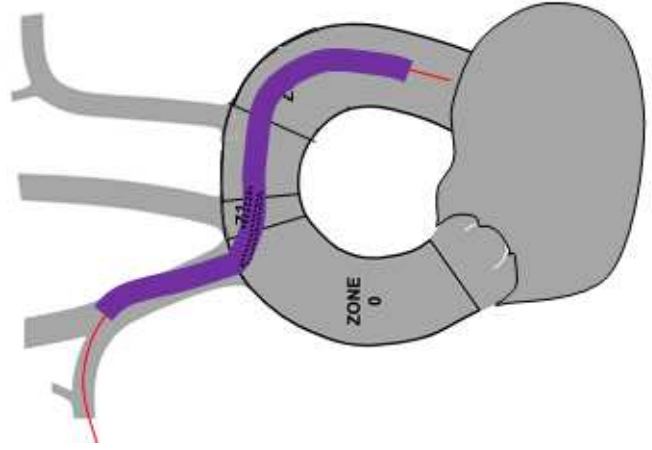
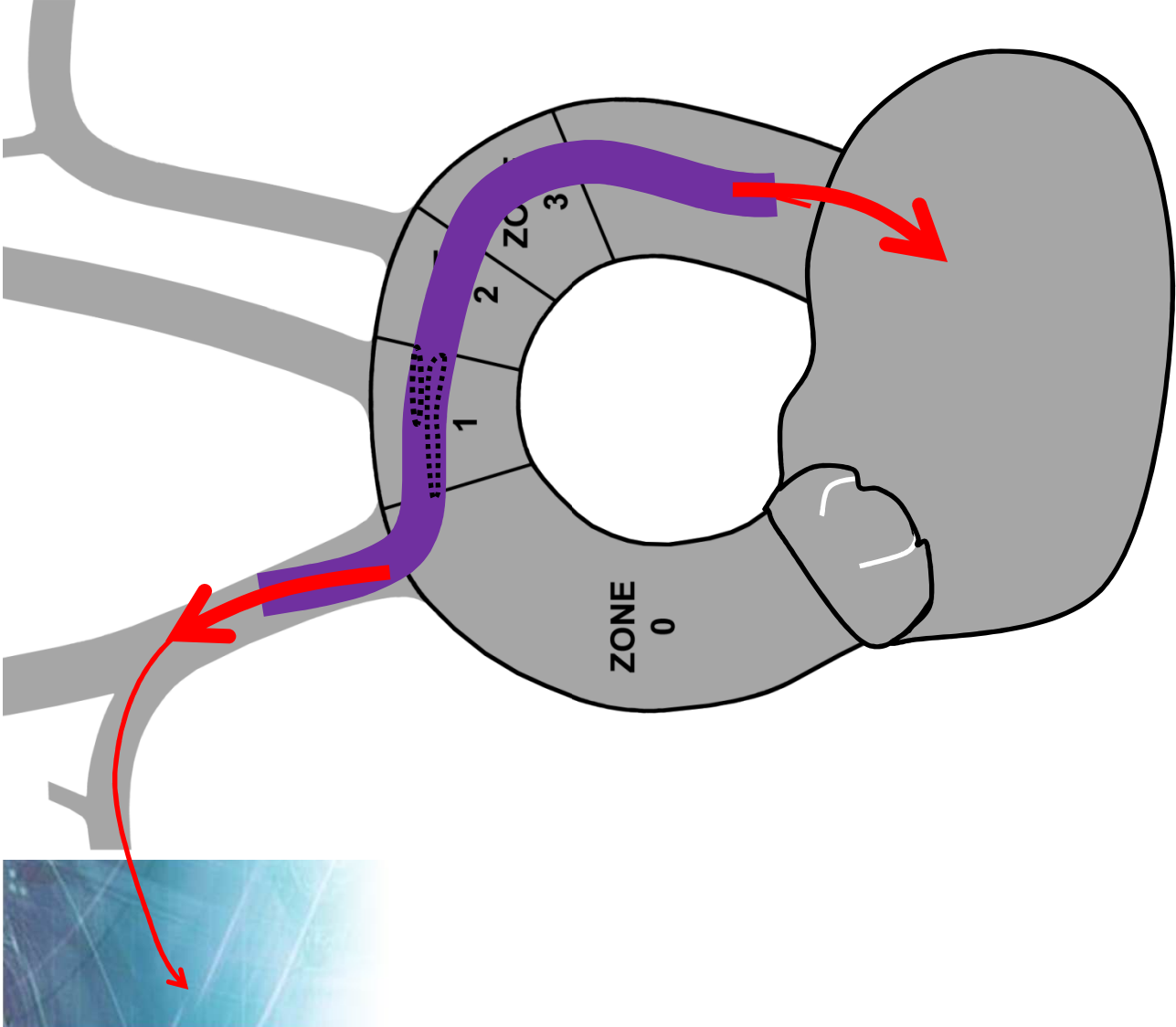
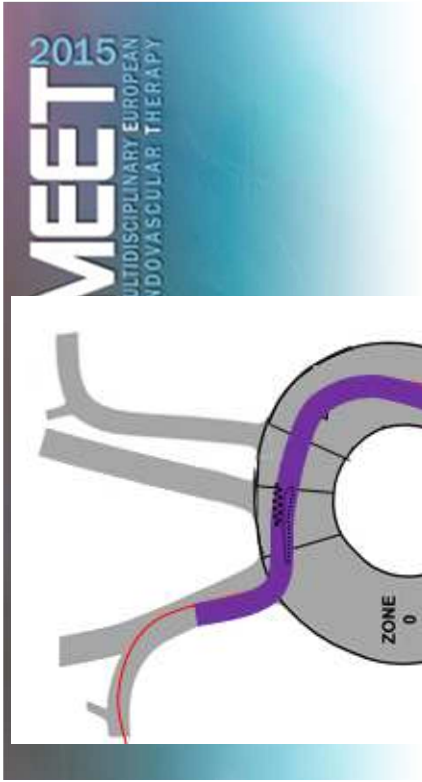
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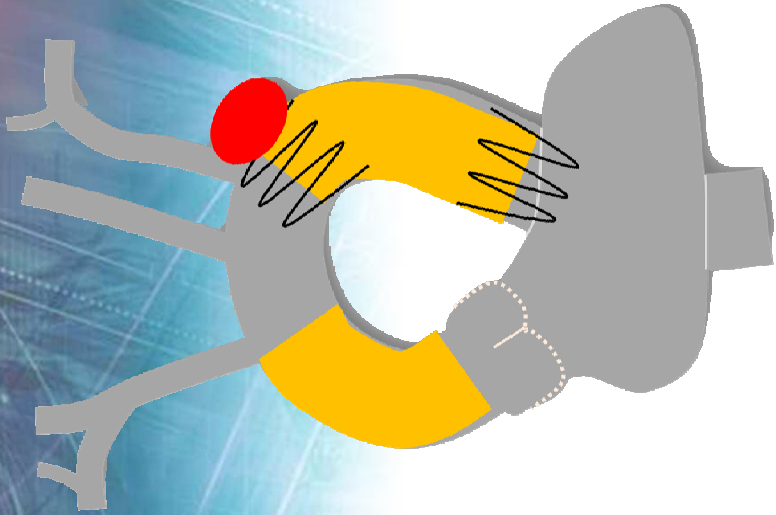
FINISH				SCALE		Endospin
As specified in part's drawings				1:1		
NAME	DESIGN	DATE	TOLERANCES	LINEAR DIM.	ANGULAR DIM.	DESCRIPTION Nexus crimped ASC module - 3x43mm, L=40
ENRICH	ENRICH	20/06/2014	LINEAR DIM.	±0.1		
ENRICH	ENRICH	20/06/2014	BORE	±0.1		
ENRICH	ENRICH	20/06/2014	ANGULAR DIM.	±0.5°		
A4						DRAWING No: A-ES-1664 Rev A SHEET 1 OF 3

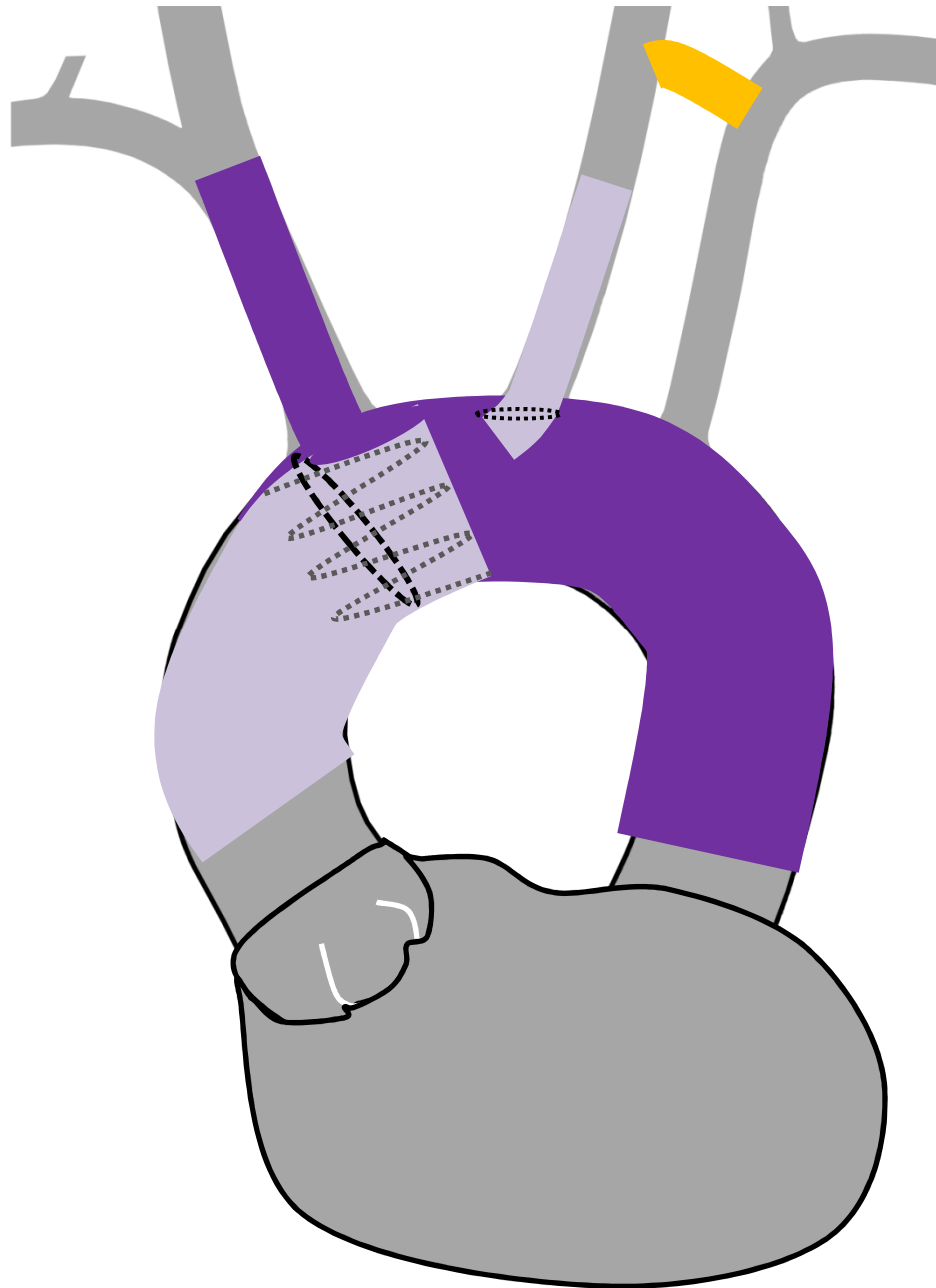
Implantation technique

Trough & Trough GW
20 Fr sheath



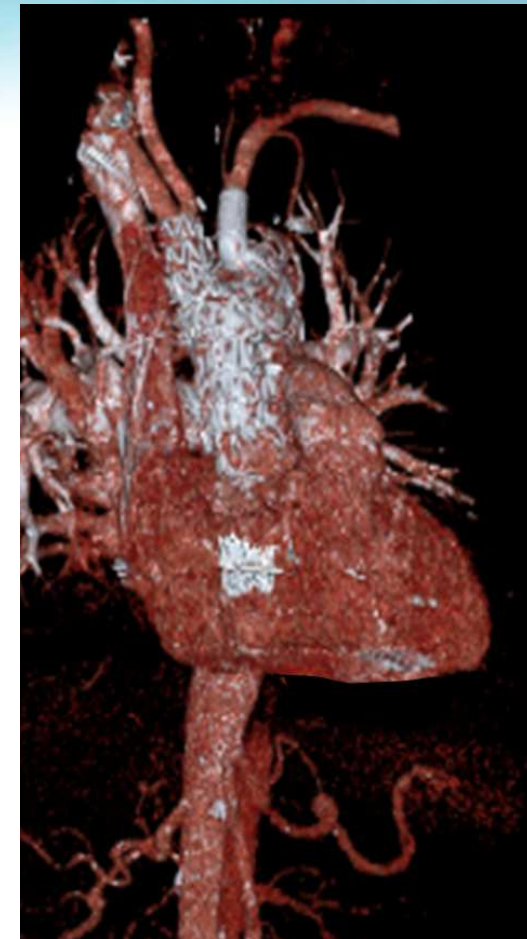
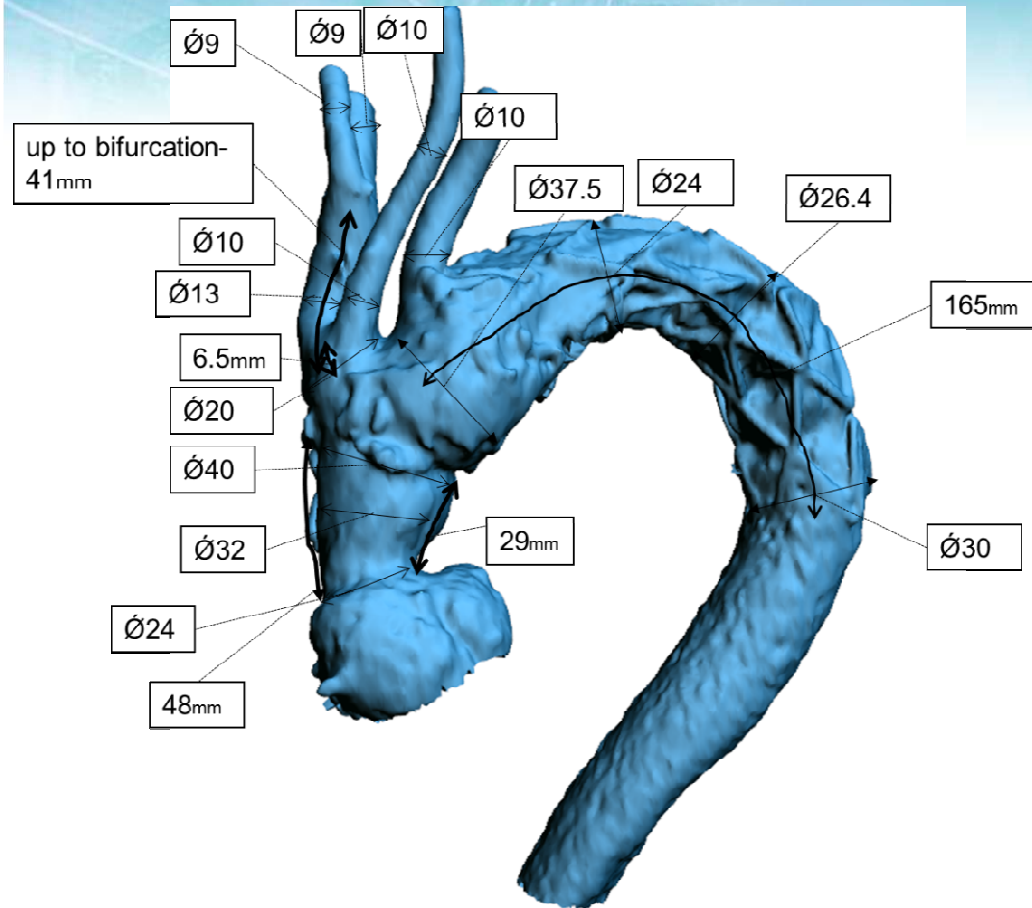






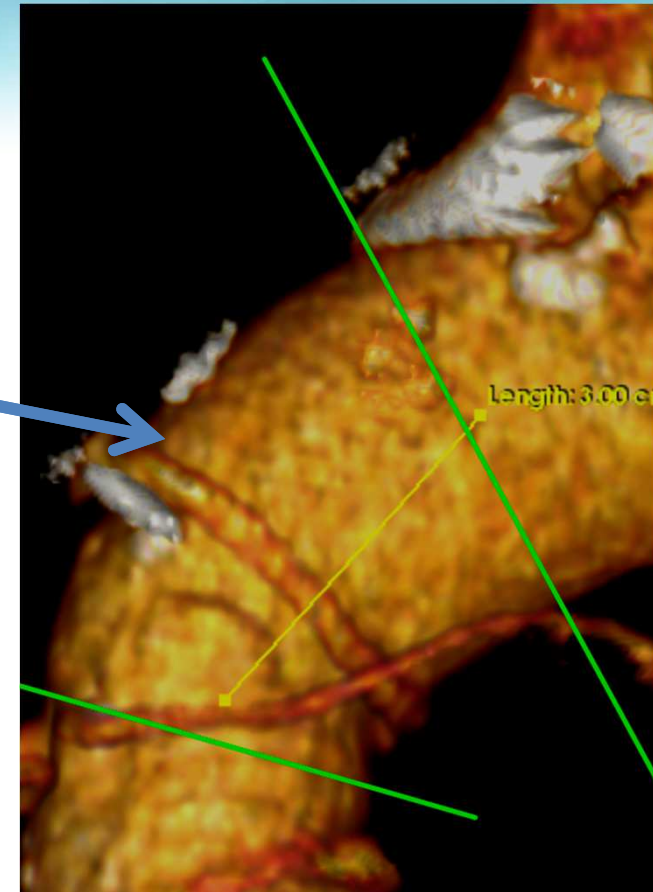
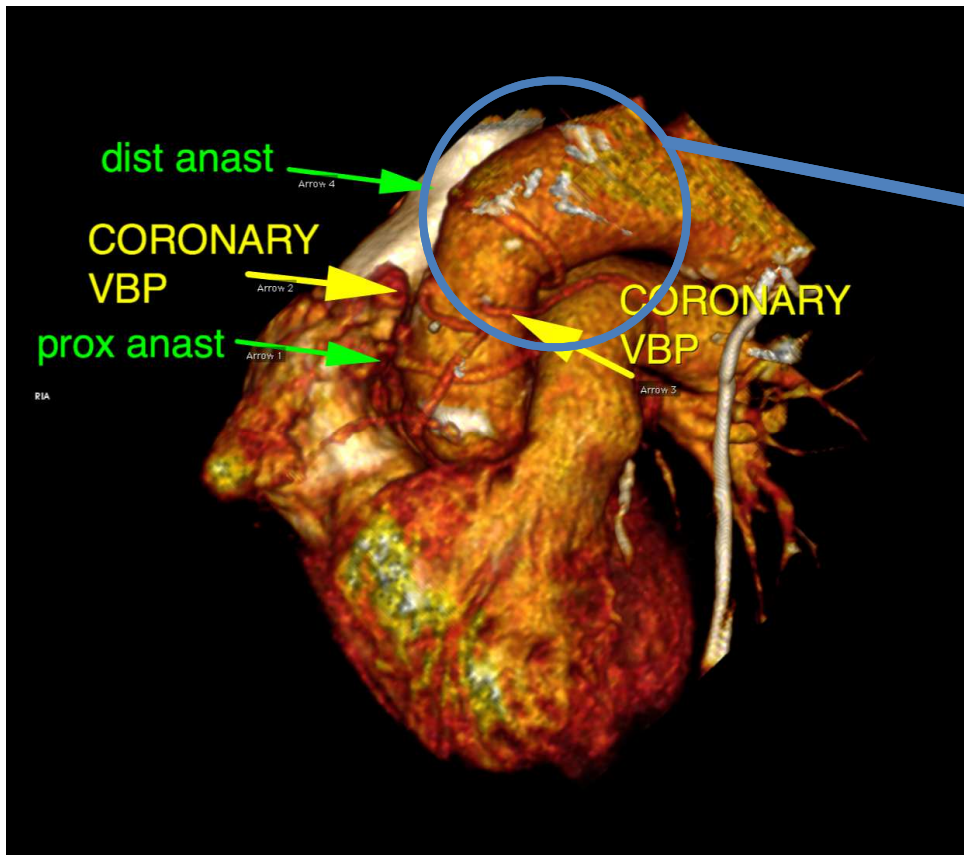
Carotid to LSA bypass optional

Challenging Zone 0

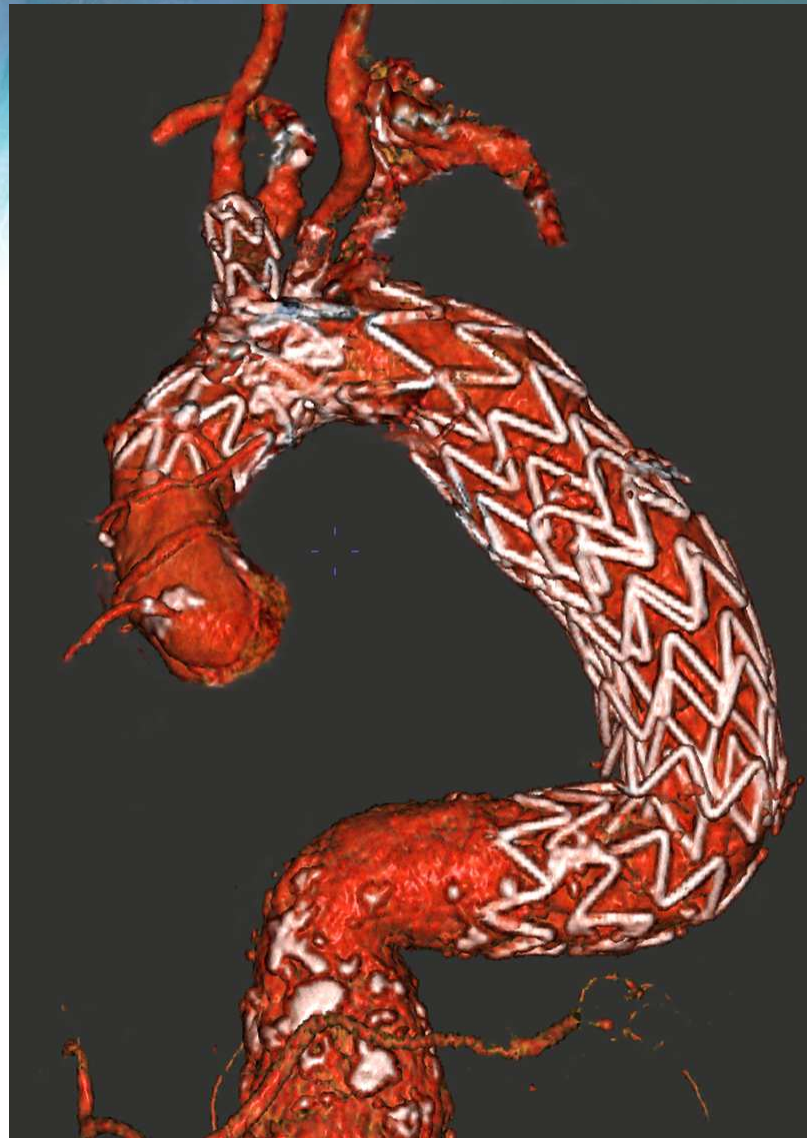


- Patient from Zurich

Challenging Zone 0



Patient from N. Mangialardi



Patient from N. Mangialardi

Clinical experience

- **8 patients (5m)**
- **76 +/- 7 years**
- **3 FIM, 5 CC**

Clinical experience

- 8 patients (5m)
- 76 +/- 7 years
- 3 FIM, 5 CC

30-day results

- 2 deaths (pneumonia, myocardial infarction)
- 3 strokes (one with paraplegia)
 - 1 stroke 4 weeks before Nexus (after debranching)
 - All recovered clinically
- 4 EL (1 EL I/III, 3 EL II)
 - Patients w. therapeutic heparinisation/anticoagulation
 - @ 6 +/-5 months mFUP: 1EL I/III or II??

Conclusions

- No randomized trial!
- Endovascular and open repair do not address same pathologies (and not same patients)
 - 100% Endo does not fit for aneurysm extending to Z0
- Stroke and mortality rates of endovascular repair techniques compare favorably to conventional open repair
 - Still in learning curve
 - Promising new devices



Thank You!