University Heart Center Hamburg

GERMAN AORTIC CENTER HAMBURG

Bridging Stents in Fenestrated Arch Repair

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Disclosures

- Research-grants, travelling, proctoring speaking-fees, IP, royalties with Cook Medical
- Consultant with Philips
- Speaking-fees, proctoring with Getinge
- Shareholder Mokita-Medical GmbH
- IP, Consultant with Terumo Aortic

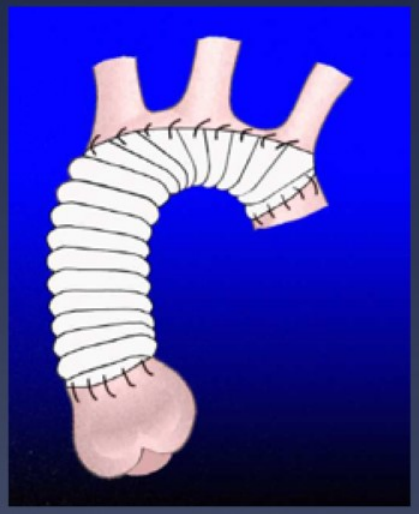
- ***Advanta V12 Covered Stent is indicated for restoring and improving the patency of the iliac and renal arteries. Renal approval includes 5, 6 and 7mm diameter Advanta V12.***

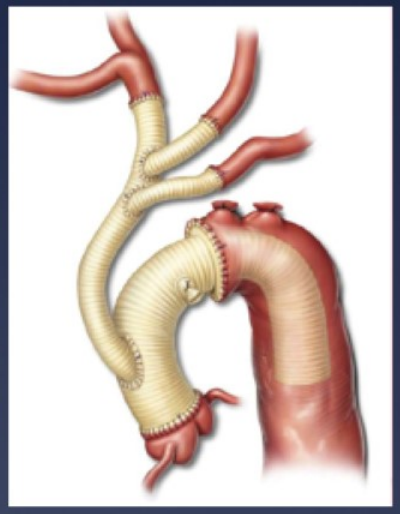
Gold Standard for the Arch

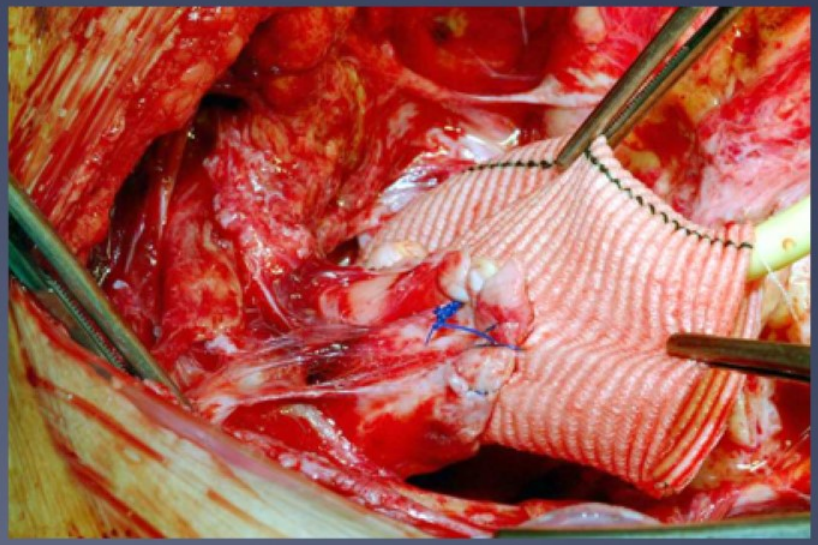
Surgery for the aortic arch:

- Open repair
- Elephant trunk

Age:	65-69y
Mortality rates:	5-15%
Stroke:	4-12%







Minakawa et al. 2010; Ann Thorac Surg 90:72-7
Sundt et al. 2008; Ann Thorac Surg 86:787-96

Risk Factors for Open Repair

Multicentre analysis of current strategies and outcomes in open aortic arch surgery: heterogeneity is still an issue

Paul P. Urbanski[a,*], Maximilian Luehr[b], Roberto Di Bartolomeo[c], Anno Diegeler[a], Ruggero De Paulis[d], Giampiero Esposito[e], Robert S. Bonser[f], Christian D. Etz[g], Klaus Kallenbach[h], Bartosz Rylski[i], Malakh Lal Shrestha[j], Konstantinos Tsagakis[k], Michael Zacher[a] and Andreas Zierer[l]

- 11 European centers
- 2004-2013, n=1232, age: 64y
- Mortality 12%
- Dialysis 13%
- Stroke 9%
- Risk factors:
  - Center
  - Age
  - Previous surgery
  - Concomittant surgery

Table 6: Multivariable analysis to identify risk factor for 30-day mortality

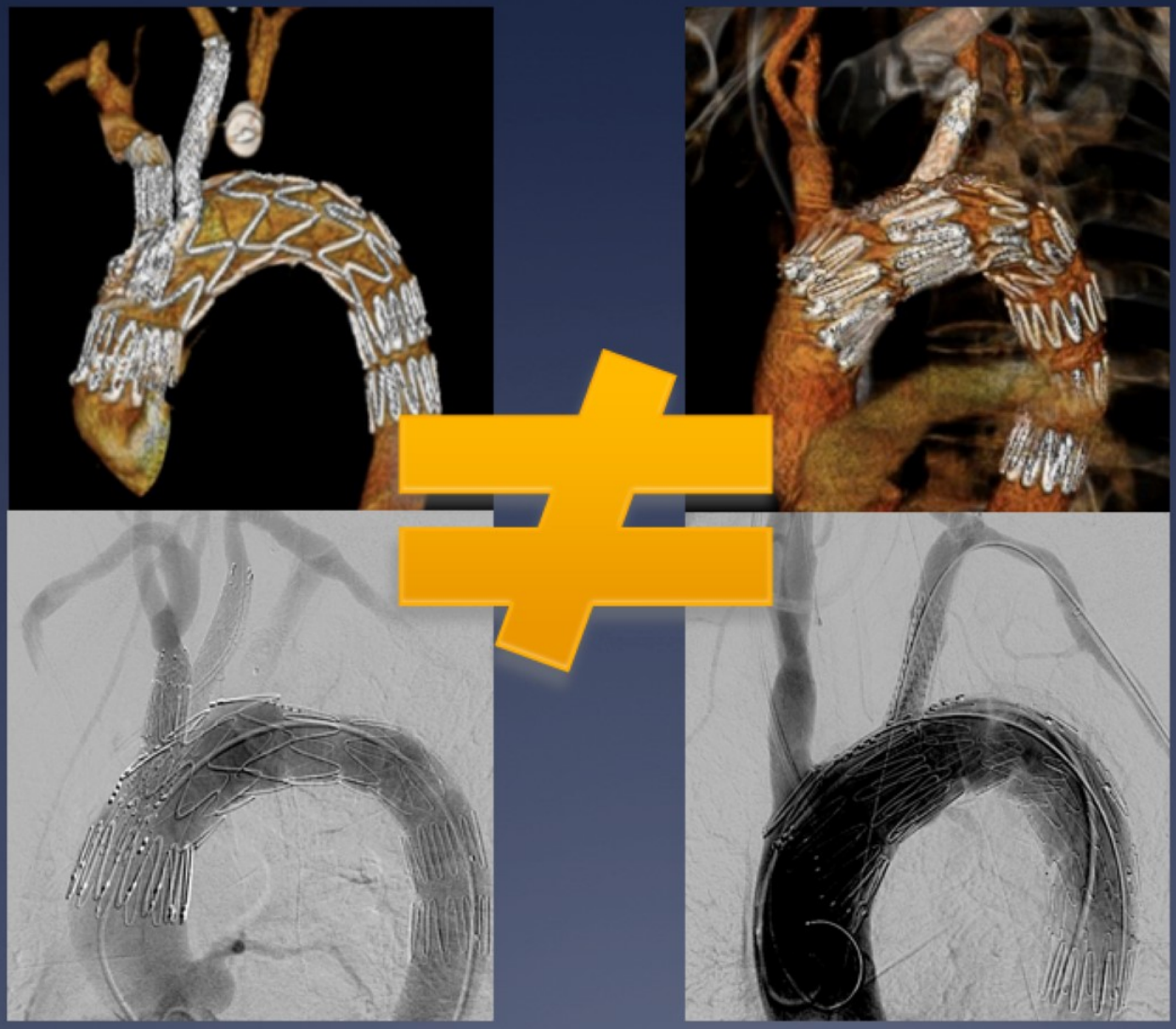
Variables	Odds Ratio	95% CI		*P*-value
		Low	High	
Centre B	2.83[a]	0.54	14.73	0.217
Centre C	6.82[a]	1.93	24.13	0.003
Centre D	7.28[a]	1.98	26.82	0.003
Centre E	2.51[a]	0.63	10.04	0.192
Centre F	14.30[a]	2.50	81.68	0.003
Centre G	8.30[a]	2.37	29.04	0.001
Centre H	6.20[a]	1.30	29.57	0.022
Centre I	6.35[a]	1.80	22.56	0.004
Centre K	12.57[a]	3.31	47.70	0.000
Centre L	4.02[a]	0.62	26.20	0.146
Age	1.05	1.02	1.07	0.000
No of previous surgeries[b]	1.21	1.04	1.42	0.016
Concomitant CABG	1.79	1.06	3.04	0.029
Concomitant MVR	2.35	0.75	4.61	0.143

Urbanski et al. 2016; Eur J Cardiothor Surg 50:249-55

Endovascular Advantages:

- No Clamping of the Aorta
- No cardio-pulmonary Bypass
- No cardiac/circulatory arrest
- Reduced access trauma
- Repair while „engine running“

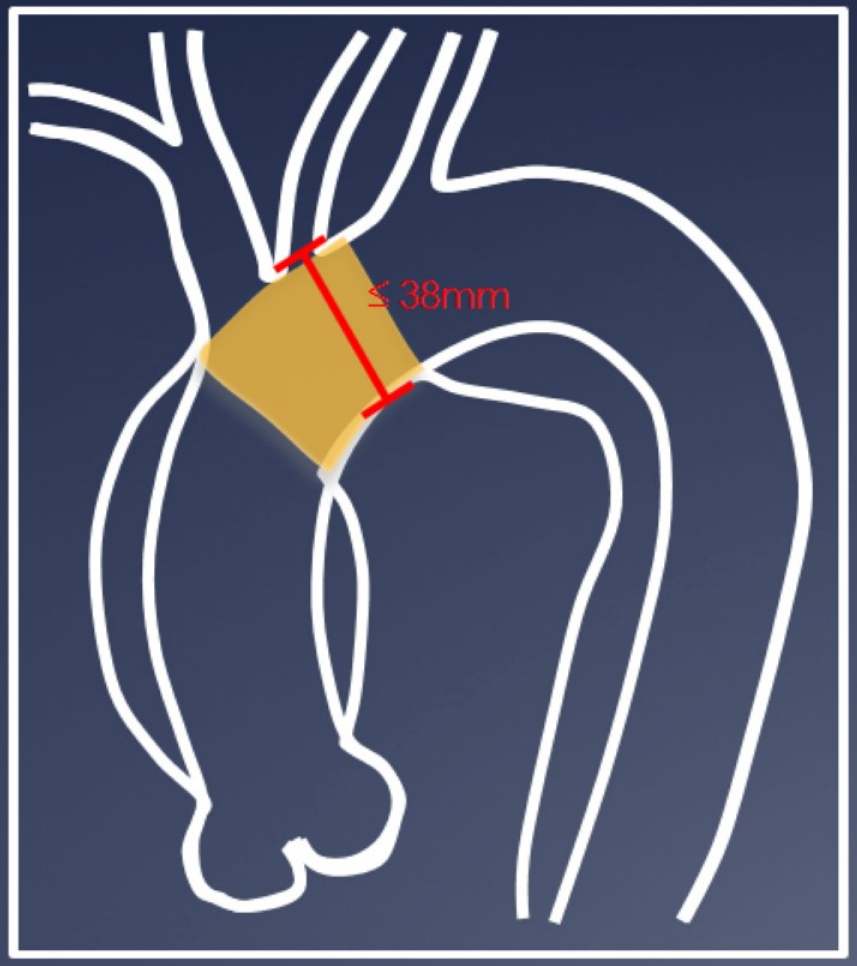
Complex Arch Endografts



Branched SG

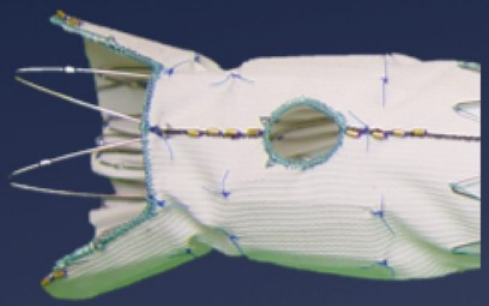
Fenestrated SG

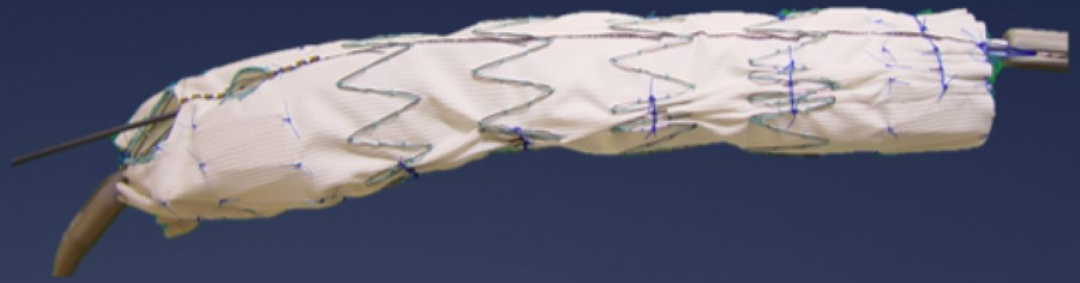
Fenestrated Arch Anatomical Suitability

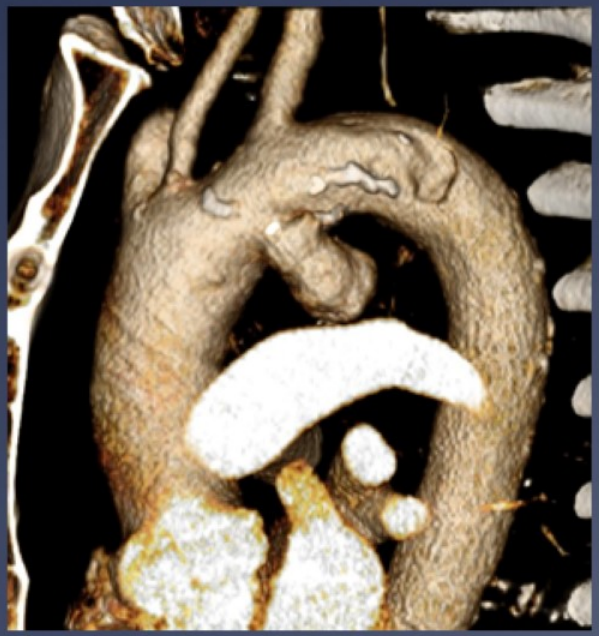


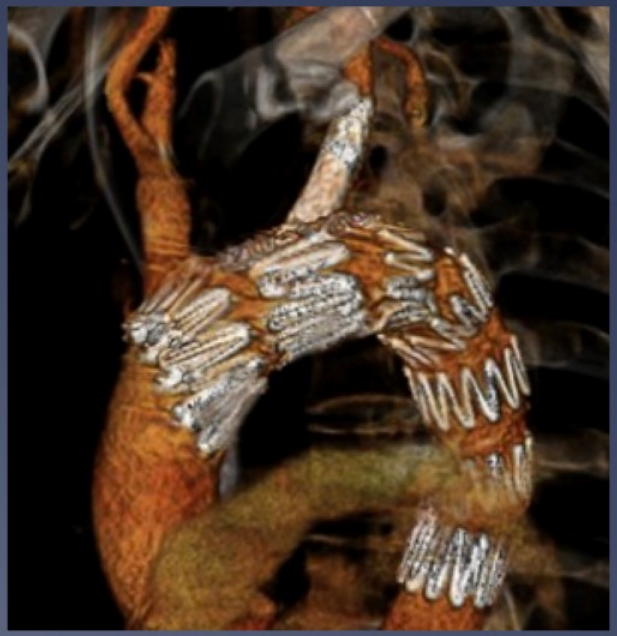
- Diameter ≤ 38mm
- Proximal landing zone ≥ 20mm
- Appropriate access vessels
- Landing zone in mid-arch

Fenestrated Arch Endograft





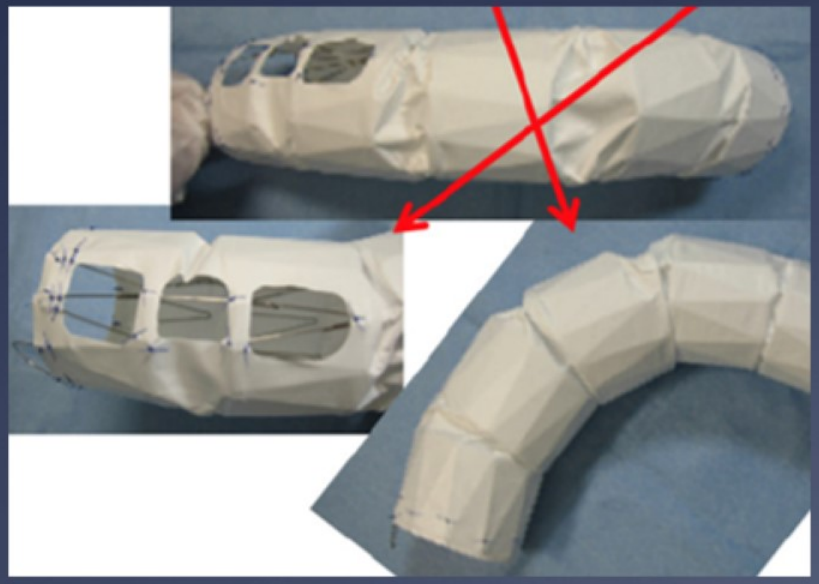




Large Fens: Crossing Struts

Advantage of a precurved fenestrated endograft for aortic arch disease: Simplified arch aneurysm treatment in Japan 2010 and 2011

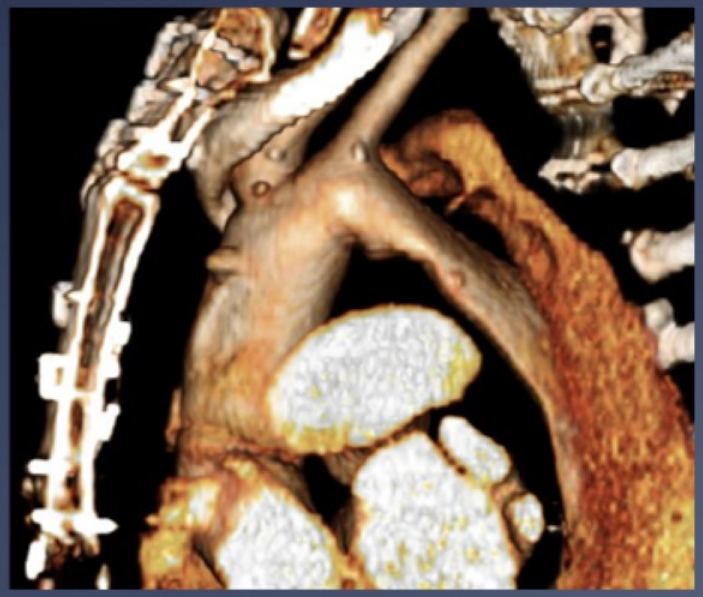
Yoshihiko Yokoi, MD, Takashi Azuma, MD, and Kenji Yamazaki, MD, PhD

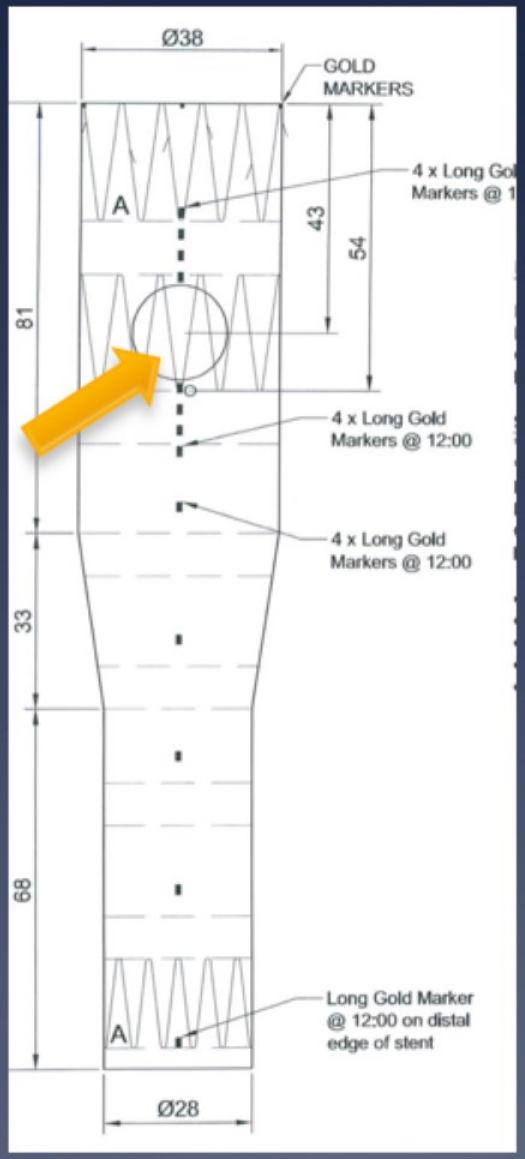


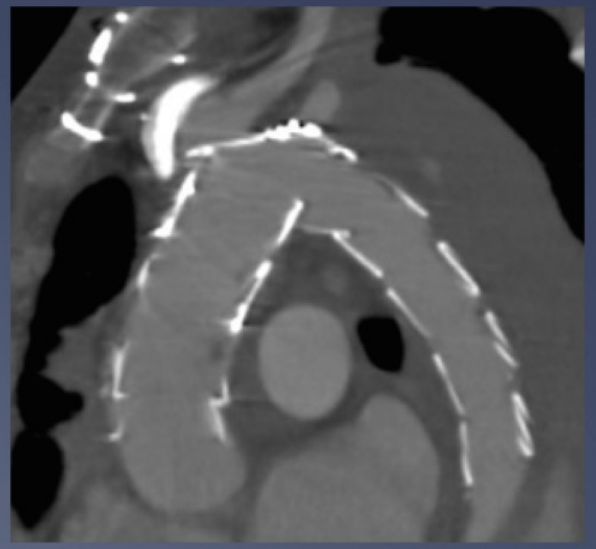
- Multicentre Japan; n=383
- Zone 0: n=363
- Technical success: 99%
- 30d mortality: 1.6%
- Stroke: 1.8%

Yokoi et al. 2013; J Thorac Cardiovasc Surg 145:S103-9

Large Fens: Crossing Struts





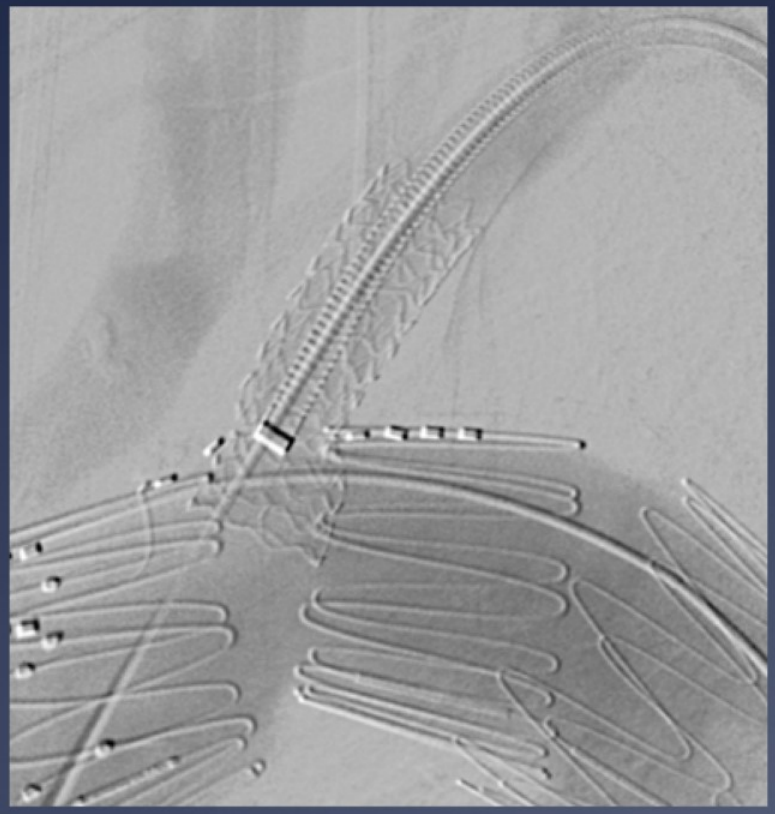


Advantages Fen-Arch

- Procedure is usually quick: 60-120min
- Treats other pathology than branched devices.
- Avoids landing in proximal native ascending aorta.

Snared Preloaded Wire

Bridging Covered Stent



Strategy:

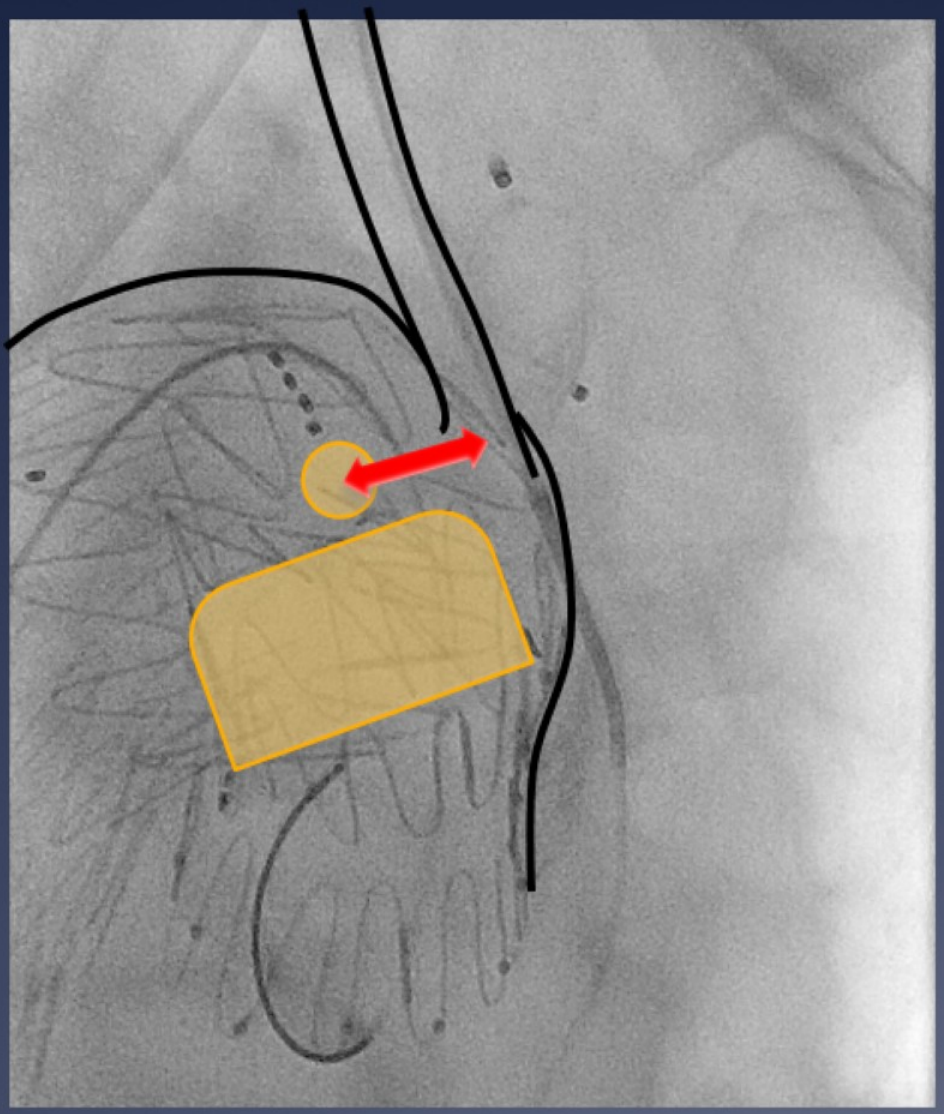
* Wire ascending aorta
* 5mm into main graft
* Flaring 12mm
* Relining if kinked by nitinol-stent

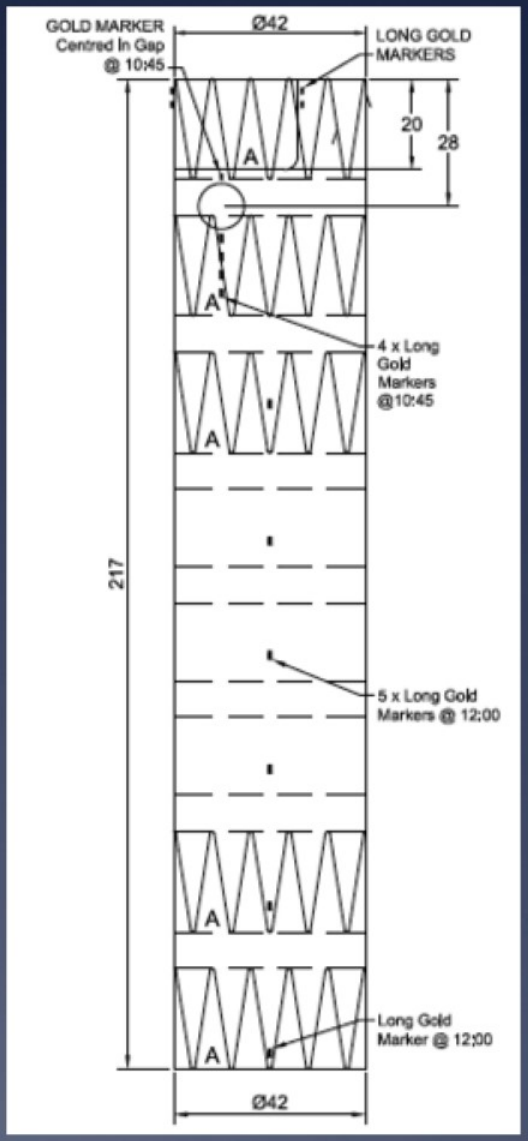
Bridging Covered Stent

Requirements:

* Profile: 7F
* Safe flaring
* Accessible for re-intervention
* Patency
* Long-term durability
* Tear-resistant

Risks Fen-Arch: Rotational Error





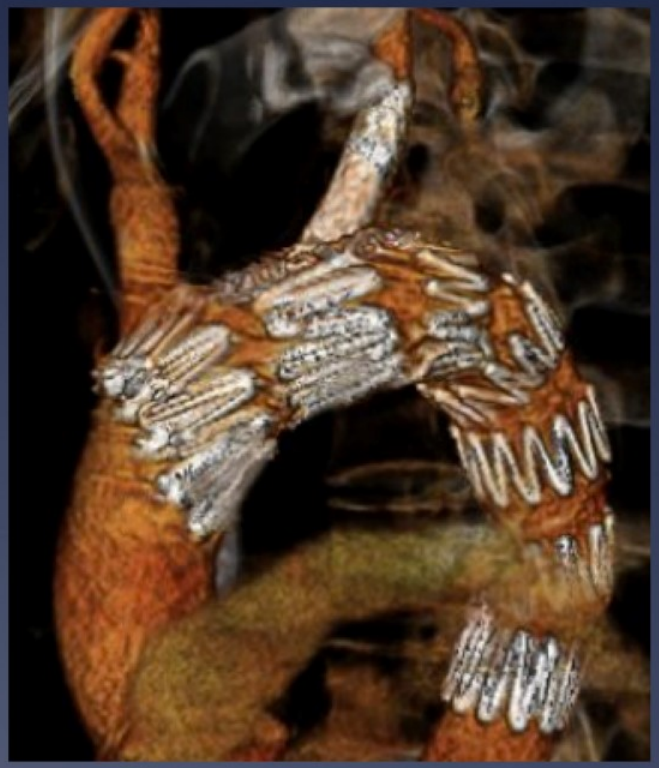
Fenestrated Arch Endograft

Hamburg Experience 2011-2017:

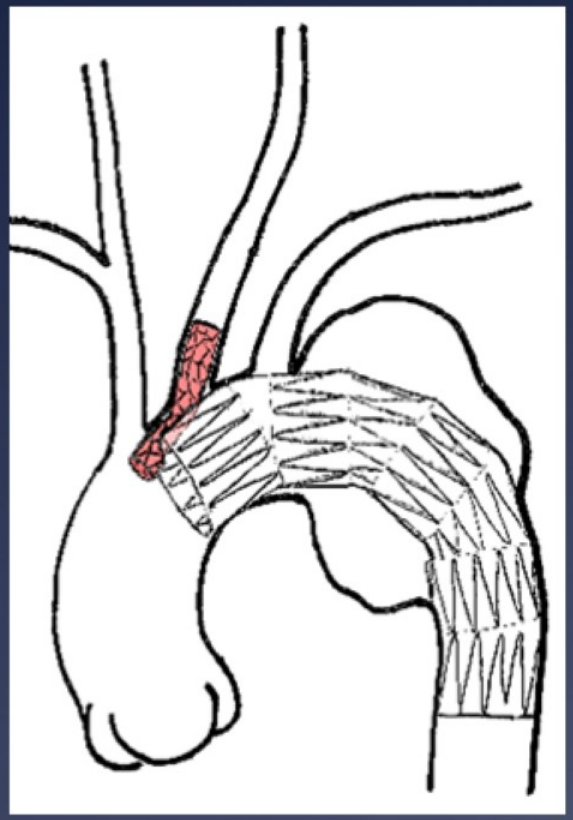
- Cases: 44
  - Aneuysm: 22
  - Chronic dissection: 13
  - PAU: 6
  - Komerell: 3
- Technical success 42 (95%)
- 30-day Mortality 4 (9%)
- Major Stroke 3 (7%)

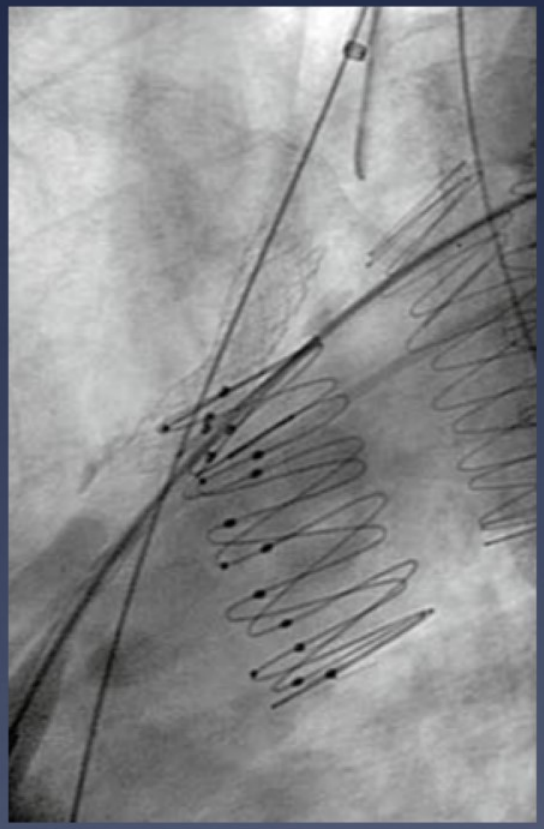
Fenestrated Arch Endograft

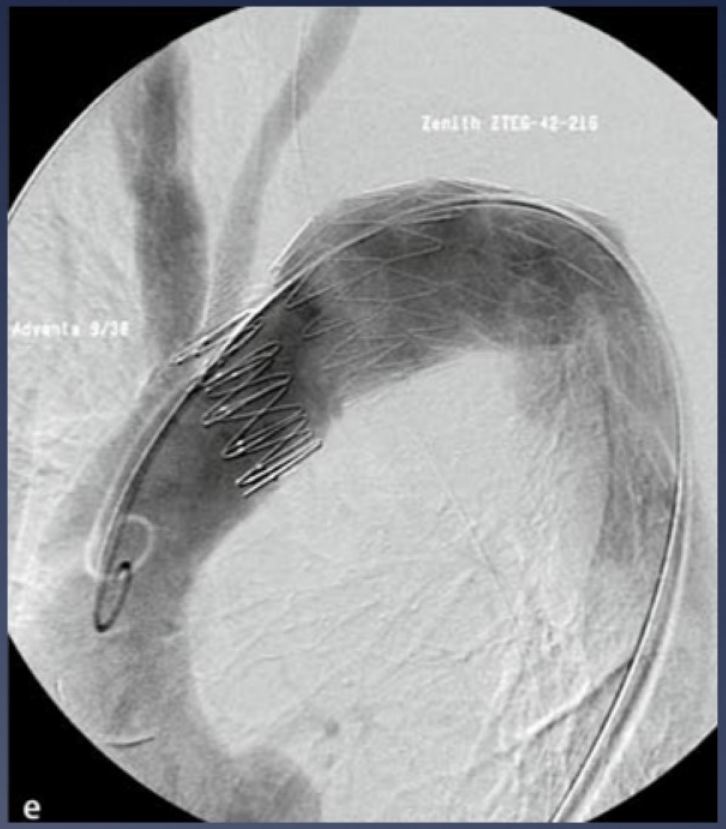
- Landing zone (Ishimaru):
  - Zone 0: 12 (27%)
  - Zone 1: 27 (62%)
  - Zone 2: 5 (11%)
- Target vessels: 74
  - Scallops: 35
  - Fenestrations: 39
    - Advanta V12: 36 (92%)
    - Relining: 16 (41%)
  - 1y Prim. patency 36 (92%)
  - 1y Prim. ass. patency: 38 (97%)



Chimney and In-Situ-Fen



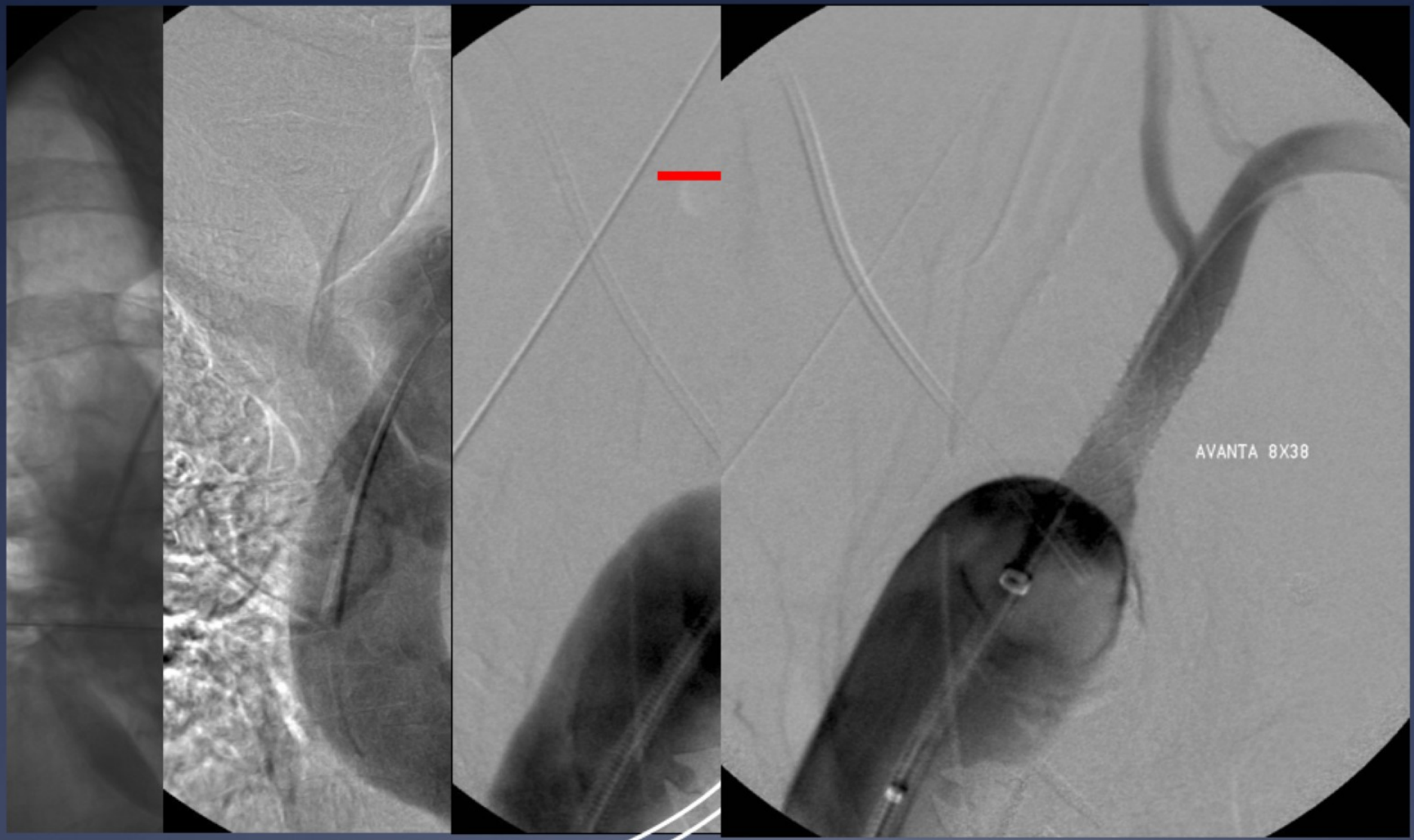




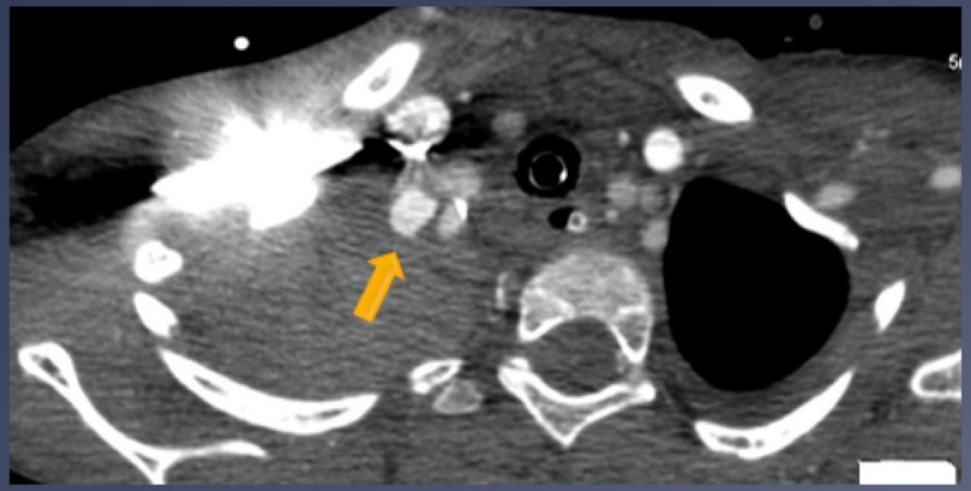
Kölbel 2009; Gefäßchirurgie 14:206-12

Cases:
Advanta V12 in Supraaortic Branches

Trauma LSA by CVL



Trauma RSA by CVL

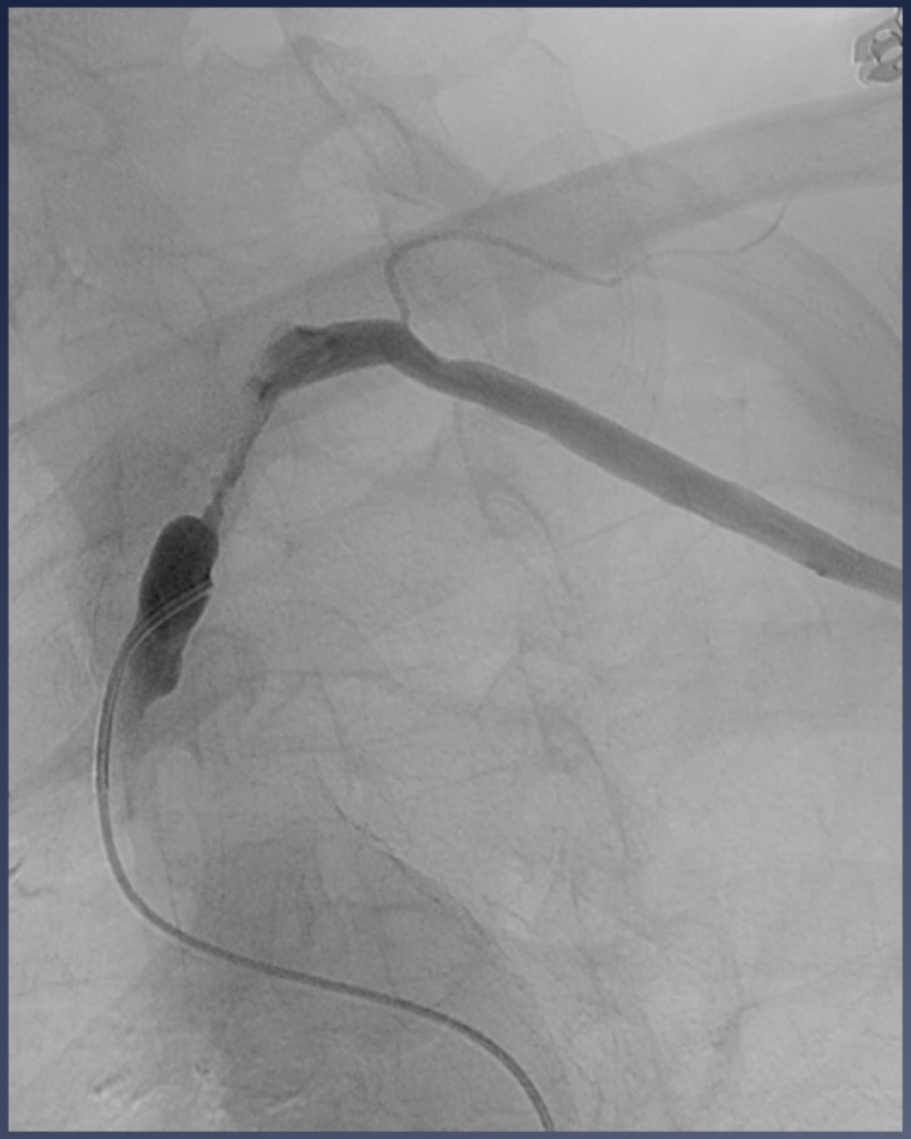


- 9y girl
- Planned scoliosis-surgery
- CVL-trauma to RSA
- Hemothorax
- Instable, intubated

Trauma RSA by CVL

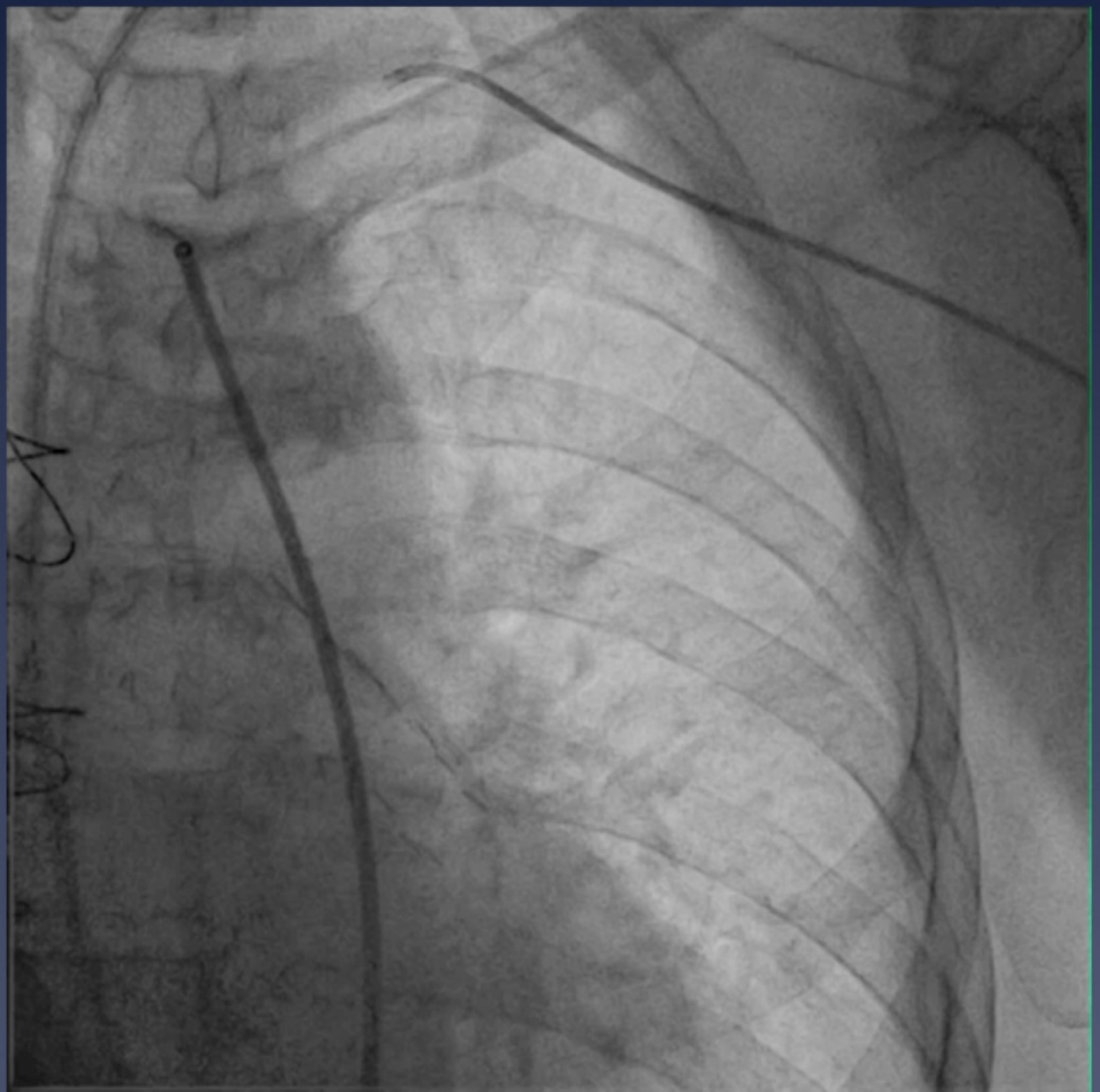
Trauma RSA by CVL

Coronary Steal Syndrome

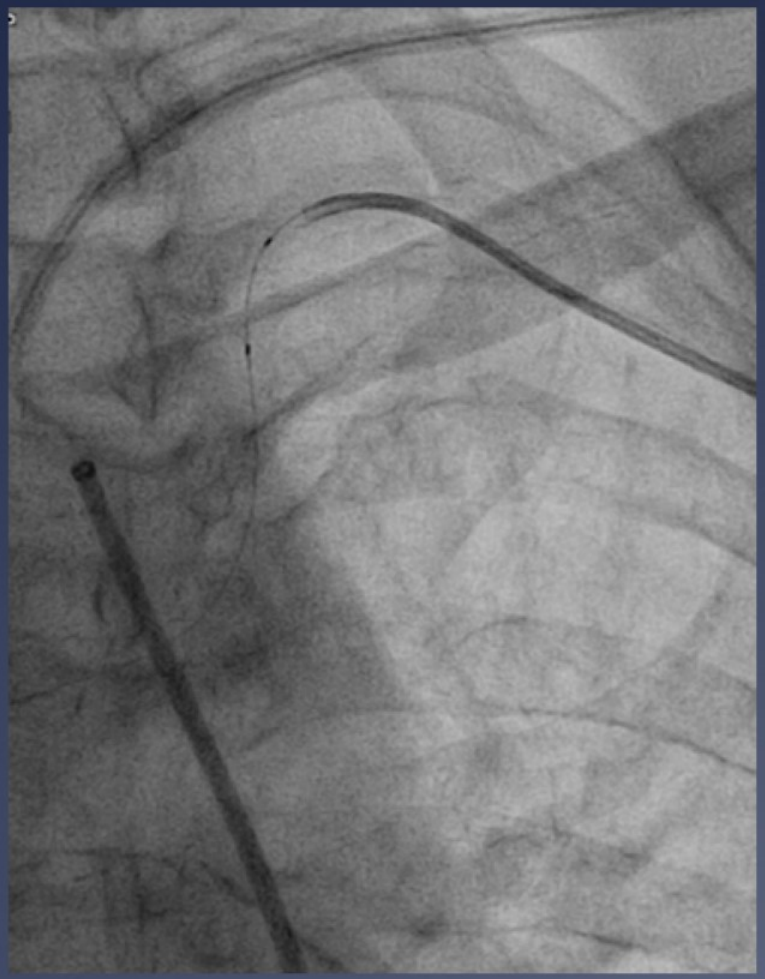


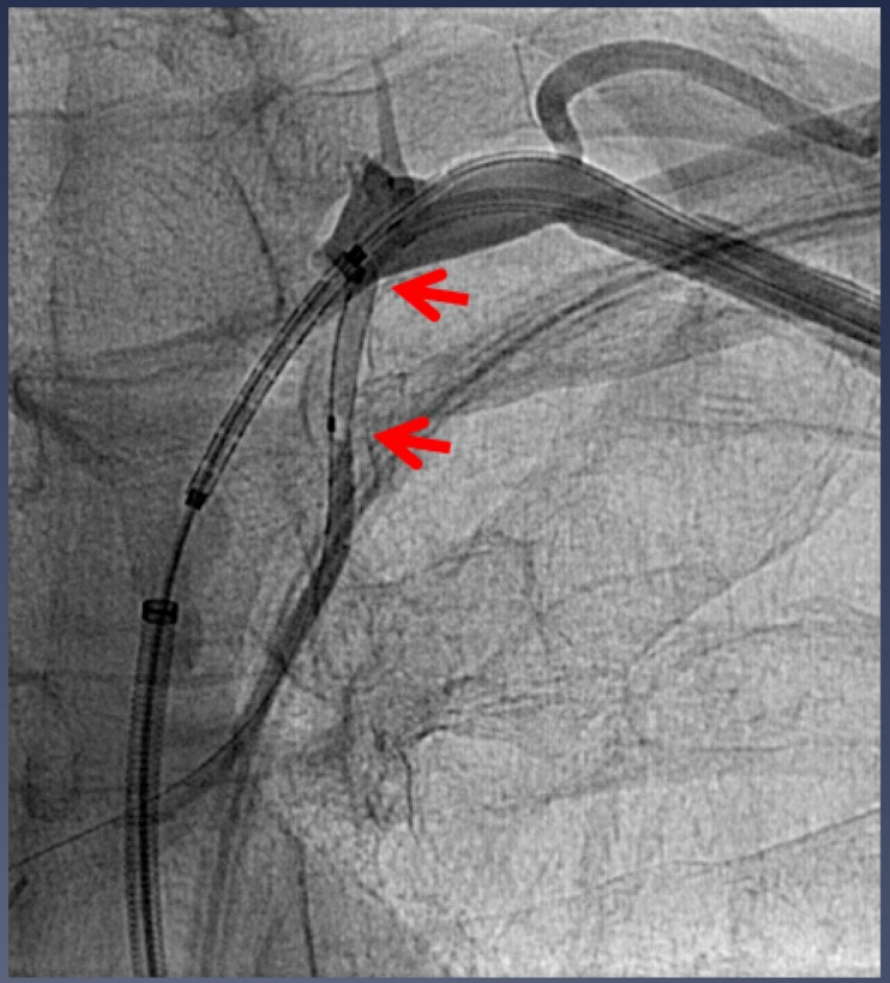
* Male, 57years
* MI and LIMA-LAD 3 years
* Angina under left-arm use

Coronary Steal Syndrome

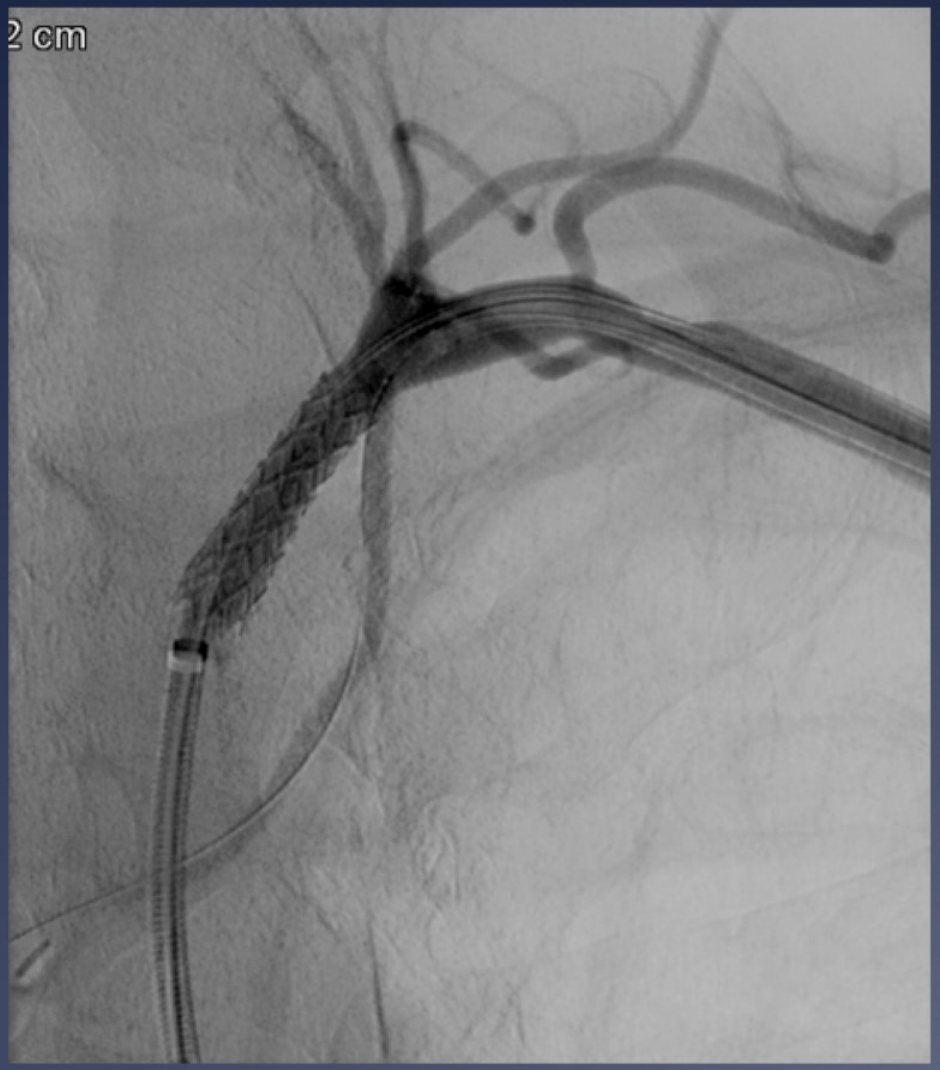


Coronary Steal Syndrome





Coronary Steal Syndrome



Conclusion

- Fenestrated aortic arch repair offers valid alternative to open surgery or hybrid-repair.
- Current devices under development and not approved.
- Covered balloon-expandable stents preferred for bridging to supraaortic branched with high patency rate of 97%.
- V12 Advanta preferred covered stent for supraaortic vessels offers high precision, reliability, proven long-term patency.