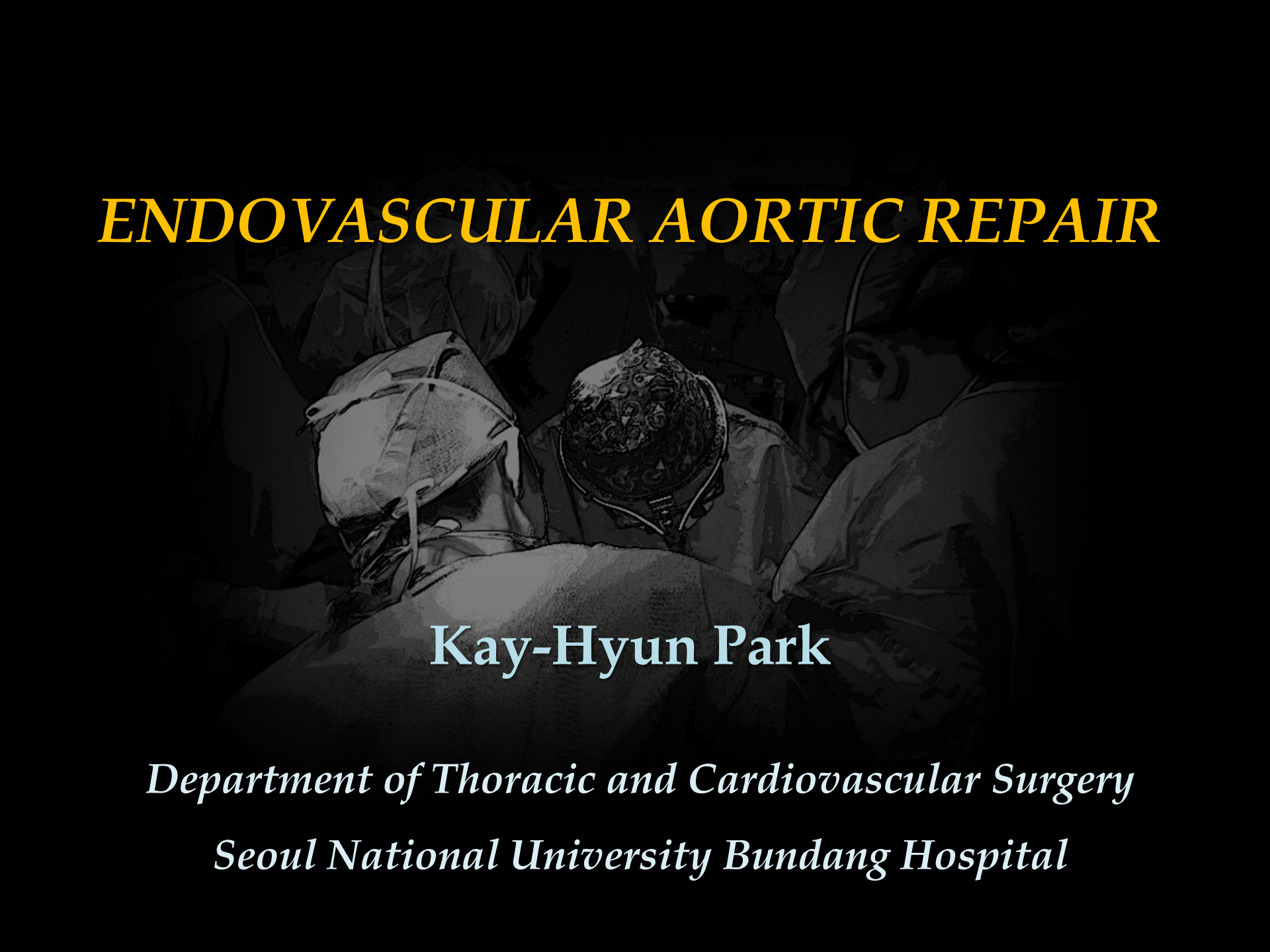
ENDOVASCULAR AORTIC REPAIR



Kay-Hyun Park

Department of Thoracic and Cardiovascular Surgery

Seoul National University Bundang Hospital

"Many cardiovascular surgeons are looking at the achievement of TEVAR with a bitter-jealous admiration. Some pessimists tend to think that shrewd cardiologists and radiologists will overtake surgeons in treating aortic aneurysms."

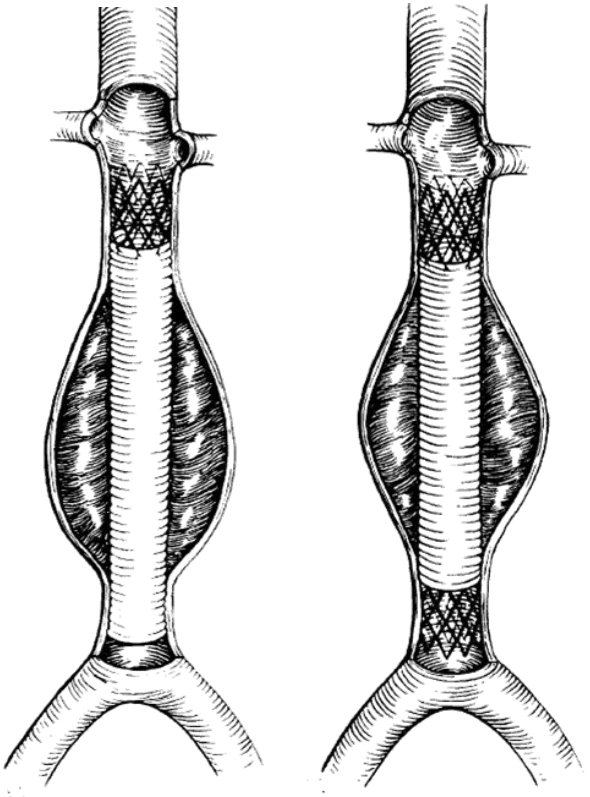
- Yutaka Okita, 2007 -

Endangered Species ??

Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms

J.C. Parodi, MD*, J.C. Palmaz, MD†, H.D. Barone, PhD, *Buenos Aires, Argentina, and San Antonio, Texas*

(Ann Vasc Surg 1991;5:491-499)



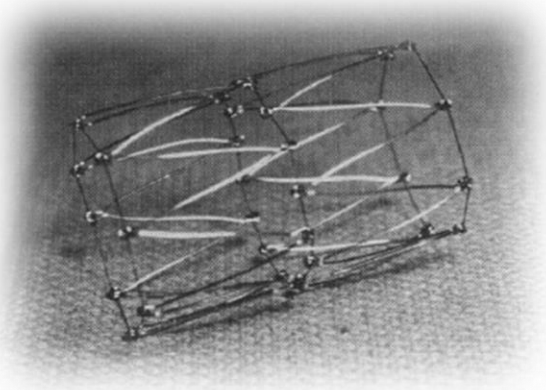
- Experiments since 1976
- First clinical application in 1990
- Report of 5 cases
  - 3 success
  - 1 endoleak
  - 1 conversion to open surgery

The New England
Journal of Medicine

Volume 331 DECEMBER 29, 1994 Number 26

TRANSLUMINAL PLACEMENT OF ENDOVASCULAR STENT–GRAFTS FOR THE TREATMENT OF DESCENDING THORACIC AORTIC ANEURYSMS

MICHAEL D. DAKE, M.D., D. CRAIG MILLER, M.D., CHARLES P. SEMBA, M.D., R. SCOTT MITCHELL, M.D., PHILIP J. WALKER, M.B., B.S., AND ROBERT P. LIDDELL, B.A.



- First clinical application in 1992
- 13 patients

Nikolai L. Volodos

- Animal study since 1984
- Clinical use since 1985

B

СОЮЗ СОВЕТСКИХ СОЦИАЛИСТИЧЕСКИХ РЕСПУБЛИК

(19) SU (11) 1217402 A

(51) 4 A 61 F 2/06

ГОСУДАРСТВЕННЫЙ КОМИТЕТ СССР ПО ДЕЛАМ ИЗОБРЕТЕНИЙ И ОТКРЫТИЙ

ОПИСАНИЕ ИЗОБРЕТЕНИЯ

К АВТОРСКОМУ СВИДЕТЕЛЬСТВУ

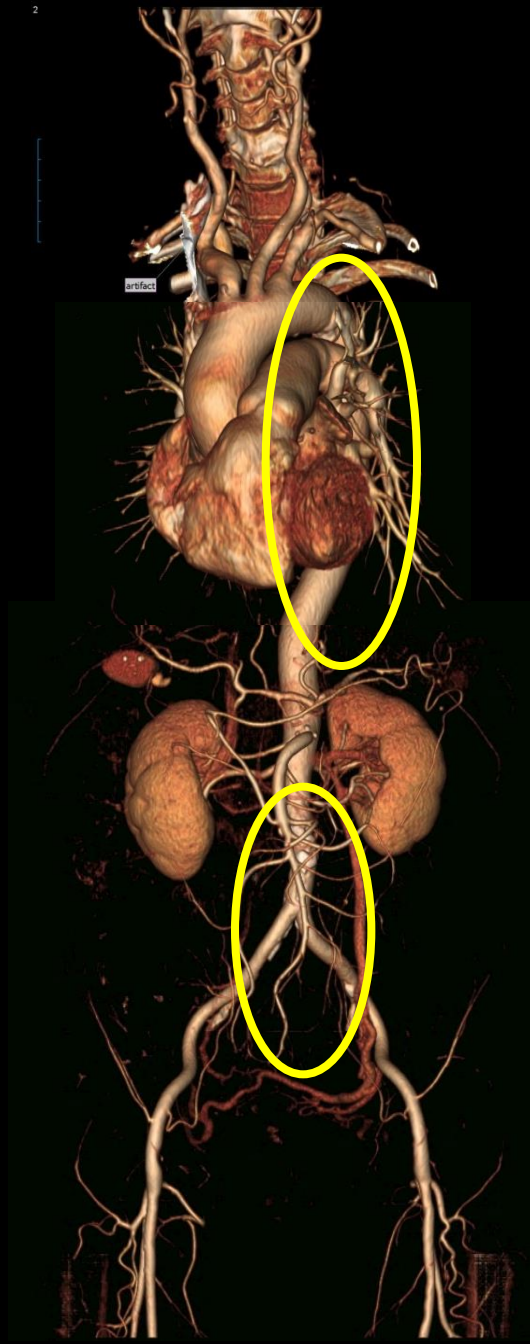
(21) 3744158/28-14
(22) 22.05.84
(46) 15.03.86. Бюл. № 10
(71) Харьковский научно-исследовательский институт общей и неотложной хирургии и Харьковский ордена Ленина, ордена Октябрьской Революции и ордена Трудового Красного Знамени моторостроительный завод «Серп и Молот»
(72) Н. Л. Володось, В. Е. Шеханин и И. П. Карпович
(53) 615.475(088.8)
(56) Авторское свидетельство СССР № 660689, кл. А 61 М 29/00, 1977.

(54) (57) ПРОТЕЗ КРОВЕНОСНОГО СОСУДА, состоящий из эластичной оболочки с фиксирующим элементом, *отличающийся* тем, что, с целью упрощения установки протеза и увеличения надежности фиксации, фиксирующий элемент выполнен в виде плоской изогнутой пружины, вершины изгибов которой имеют петлеобразную форму и закреплены на внутренней стенке протеза.

Фиг.1

(19) SU (11) 1217402 A

Endovascular zone

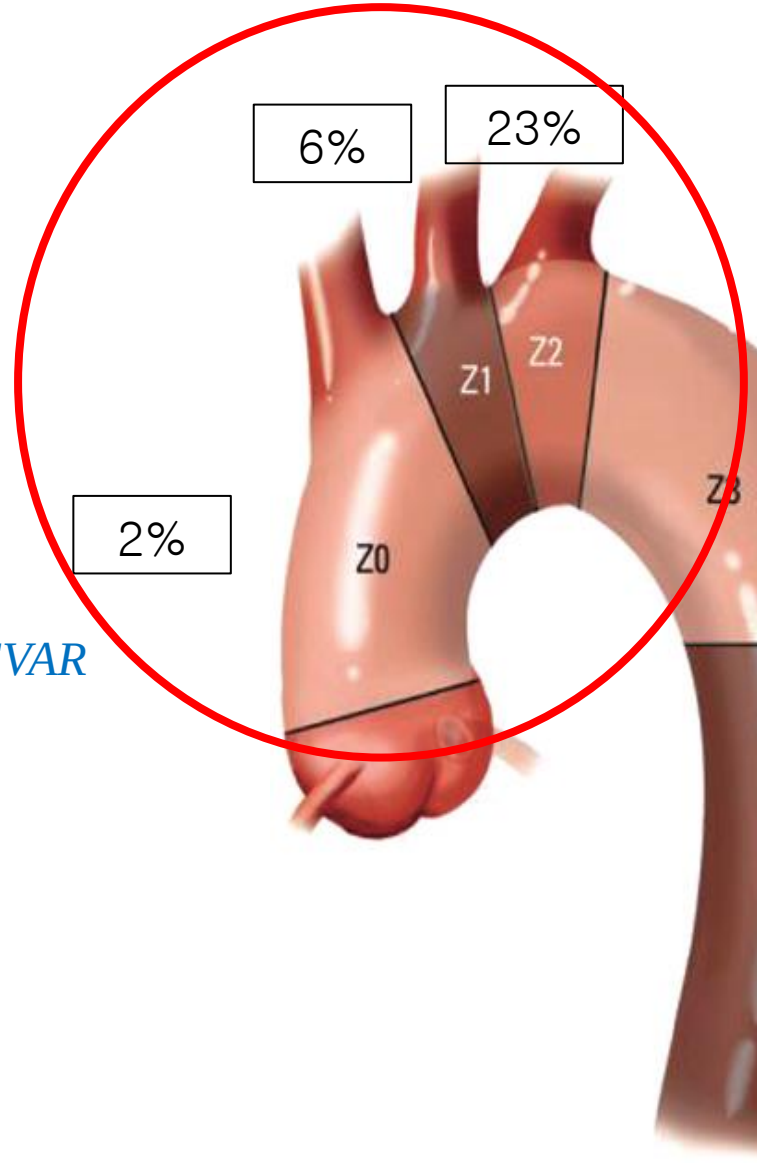


Case selection - feasibility

- *고정할 곳이 있는가?*
- *적당한 크기의 stent graft가 있는가?*
- *Stent graft를 target까지 집어 넣을 수 있는가?*
- *Contrast agent를 사용할 수 있는가?*

- **Landing zones – proximal & distal**
  - Length **: ≥ 2cm**, *the longer the better*
  - Diameter
- Access vessel size & tortuosity
- Renal function
- Contrast allergy

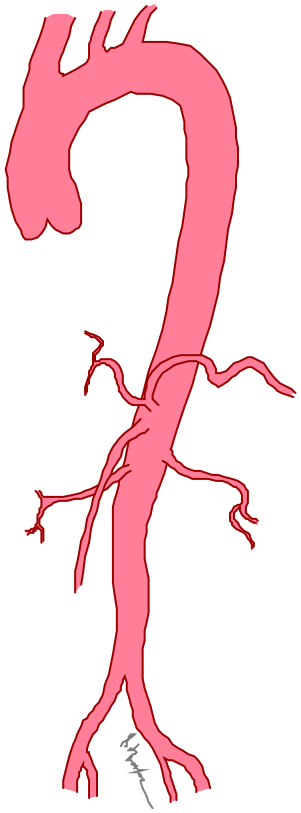
Proximal Landing Zone

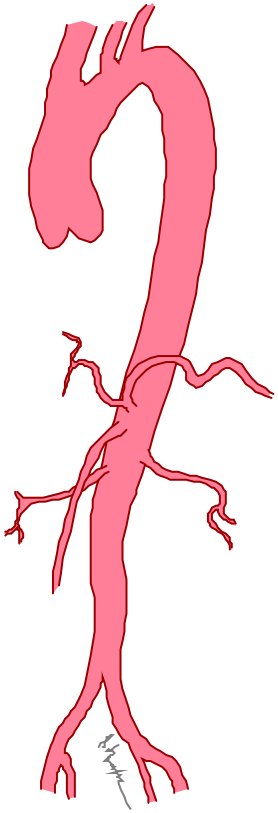


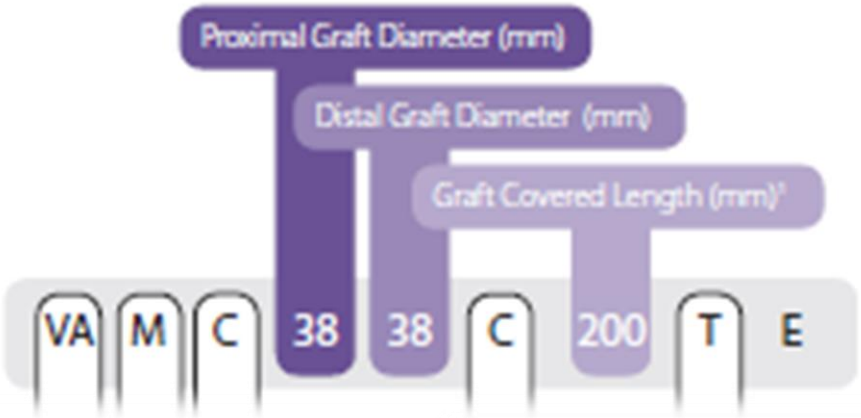
Hybrid *TEVAR*

Simple TEVAR

Good vs. poor proximal neck







Product Code

Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)				Graft Covered Length (mm)[1]	Total Stent Graft Length (mm)	Catheter Outer Diameter (F)
VAMF	22	22	C	100 TE	112	124	22
VAMF	24	24	C	100 TE	112	124	22
VAMF	26	26	C	100 TE	112	124	22
VAMF	34	34	C	200 TE	212	224	24
VAMF	36	36	C	200 TE	207	219	24
VAMF	38	38	C	200 TE	207	219	24
VAMF	40	40	C	200 TE	212	224	24
VAMF	42	42	C	200 TE	207	219	25
VAMF	44	44	C	200 TE	212	224	25
VAMF	46	46	C	200 TE	212	224	25

Difficult access

small vessel

tortuosity

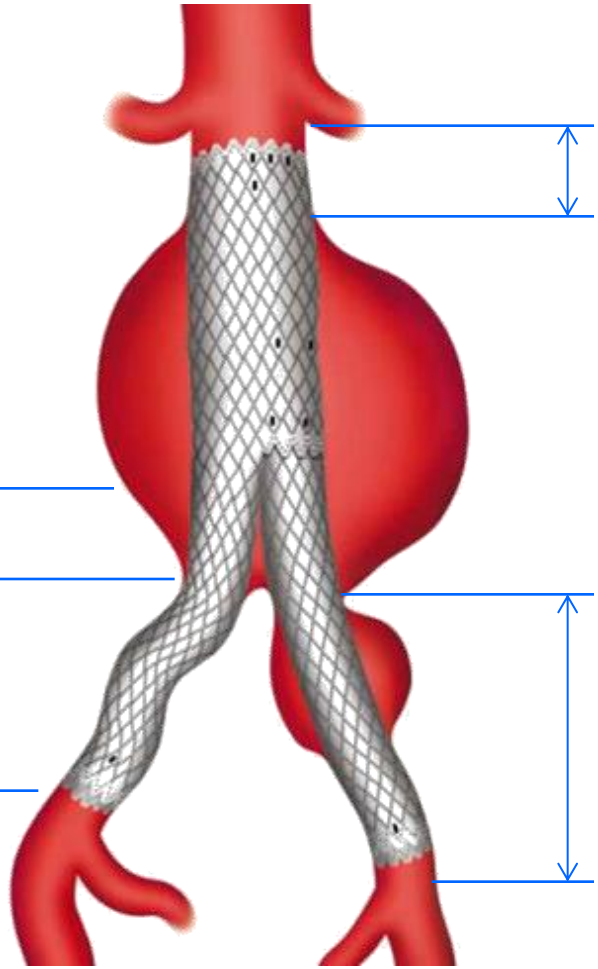
occlusive disease

Case selection - feasibility

- *고정할 곳이 있는가?*
- *적당한 크기의 stent graft가 있는가?*
- *Stent graft를 target까지 집어 넣을 수 있는가?*
- *Contrast agent를 사용할 수 있는가?*

- **Landing zones – proximal & distal**
  - Length
  - Diameter
  - Access vessel
  - Aortic tortuosity
  - Renal function
  - Contrast allergy

Suitability of EVAR



Neck

diameter < 26~28mm
length ≥ 1.5~2cm
angulation < 45~50°
no severe calcification
no diverging

Distal neck

diameter ≥ 20 mm
not much thrombus

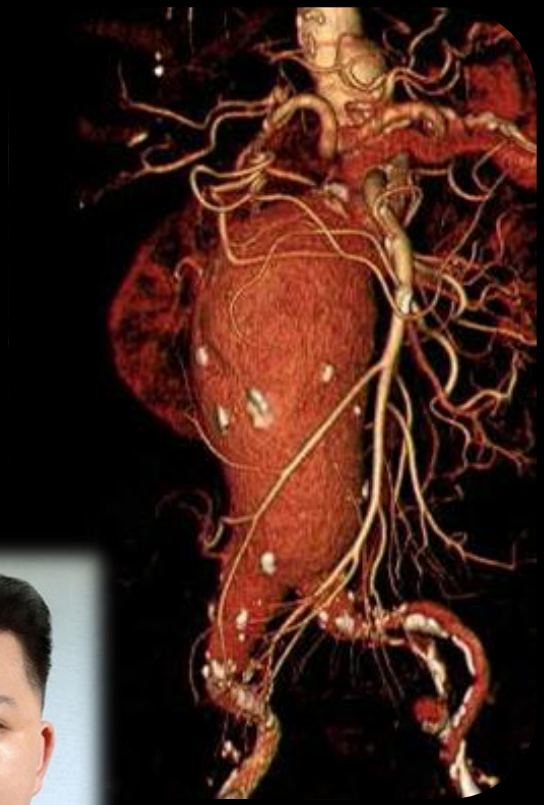
Common iliac artery

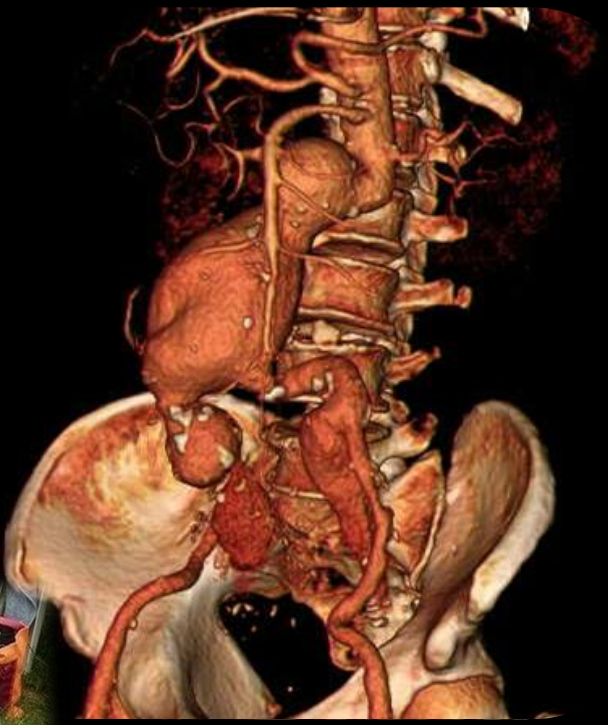
diameter < 18~20mm
length ≥ 2.0~2.5cm
no severe calcification
angulation < 45~60°

Arterial access

diameter ≥ 7 mm
no excessive tortuosity

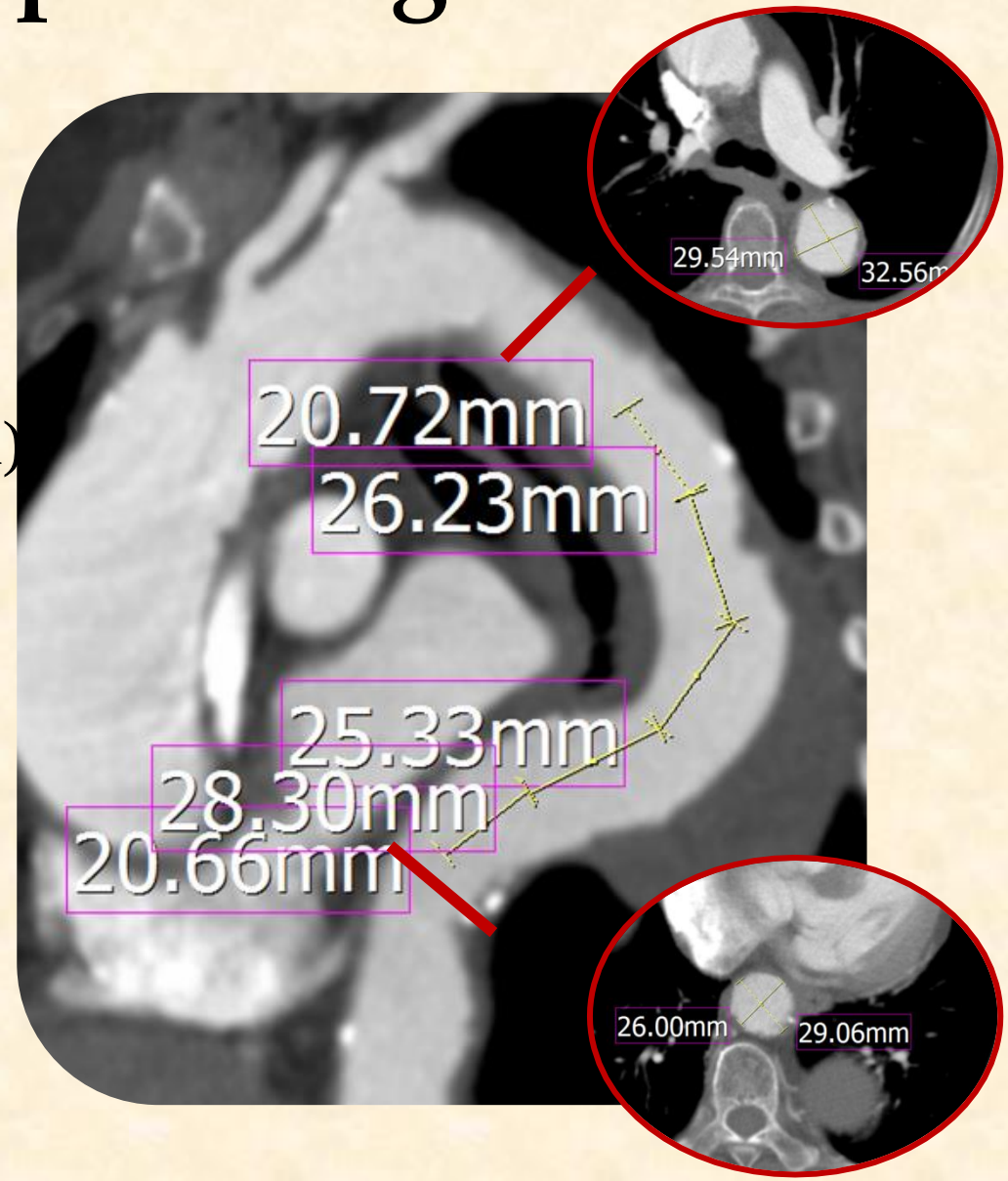
Hostile or marginal anatomy





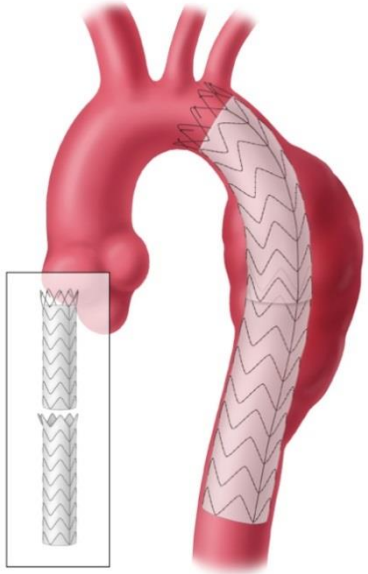
Case planning

- **Which device**?
- **Size (diameter)**
  --- oversizing 15~20%
  (around 10% for dissection)
- **Length**
  --- extent of coverage
- Number of device
  --- single or
  multiple with overlap
- Which route?



Thoracic EndoVascular Aortic Repair

Cook TX2



Gore TAG

S&G Seal

Medtronic
Captivia

Valiant® Thoracic Stent Graft System

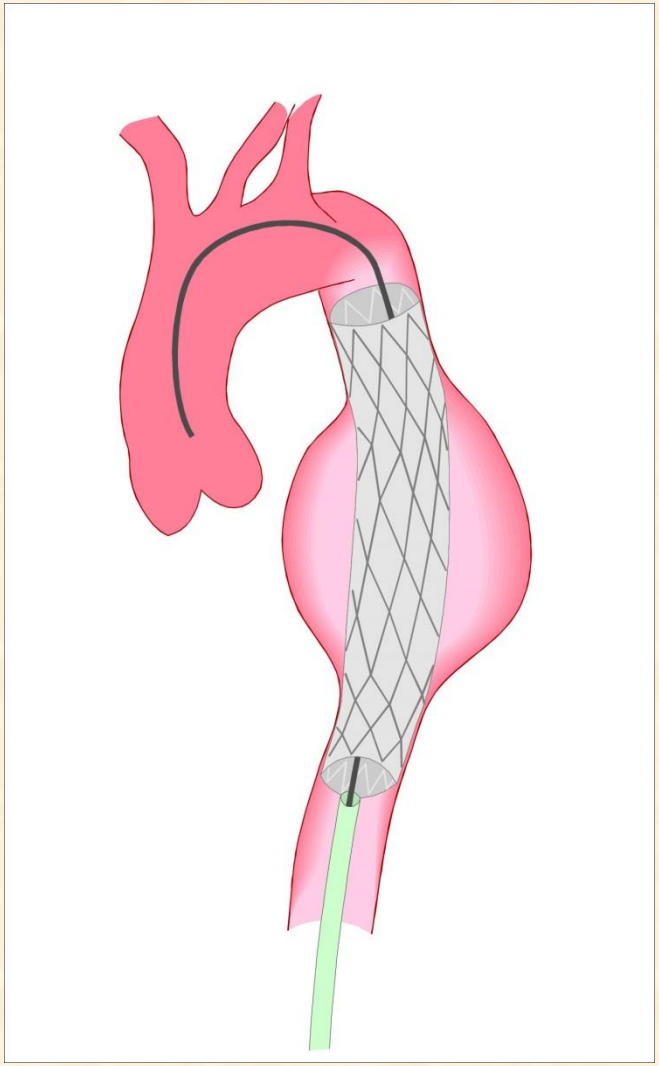
FREEFLO STRAIGHT
(PROXIMAL COMPONENT)
VAMF (22-46 mm)

CLOSED WEB STRAIGHT
(DISTAL COMPONENT)
VAMC (22-46 mm)

CLOSED WEB TAPERED
(DISTAL COMPONENT)
VAMC (22-46 mm)
Tapered End (22-42 mm)

DISTAL BARE SPRING STRAIGHT
(DISTAL COMPONENT)
VAMC (22-46 mm)

Procedure



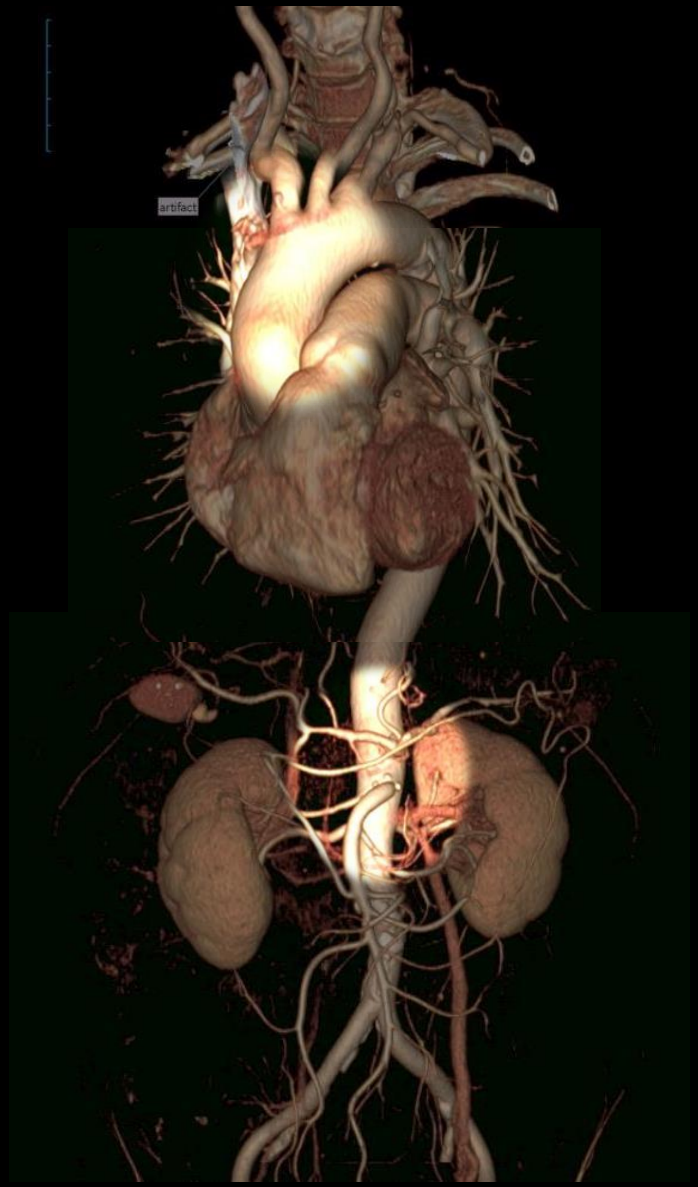
- Imaging
  --- fluoroscopy, screen, table
- Puncture kit
- Guidewire
- Catheter
- Sheath
- Dilator
- Balloon
- stent

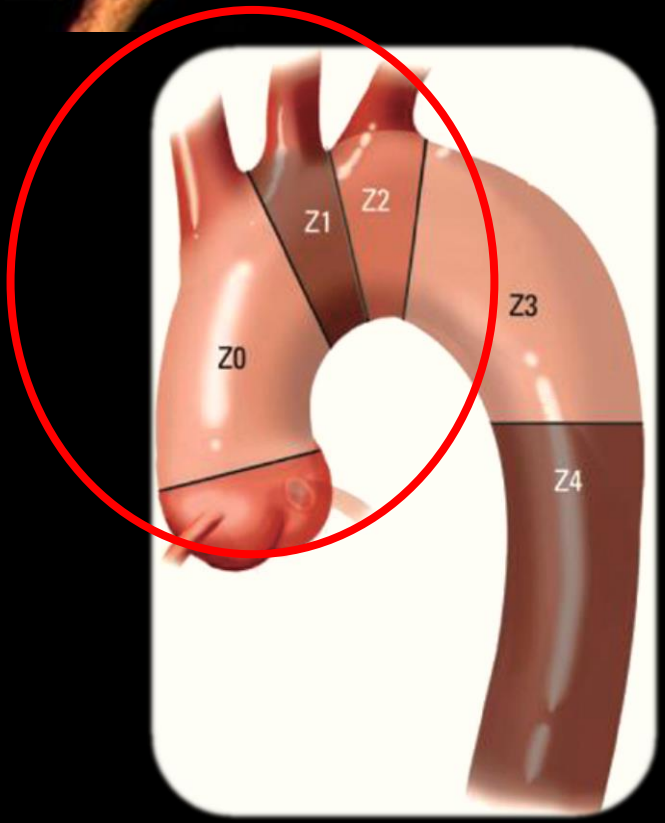
Qualifications for credentialing of cardiothoracic surgeons to perform endovascular stent-grafting of the thoracic aorta

- STS / AATS Position Statement, 2006 -

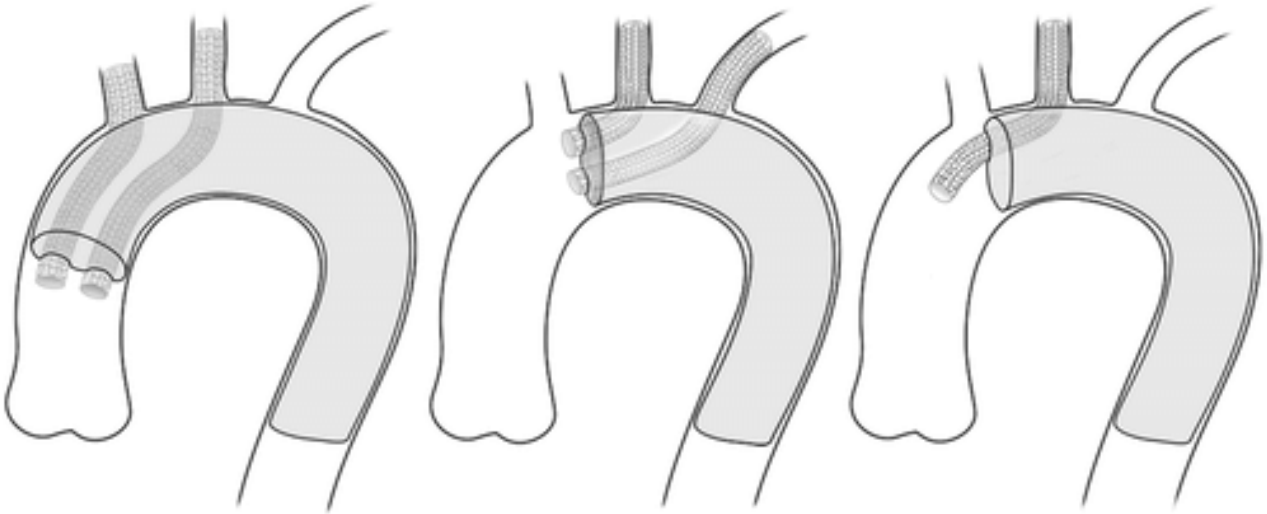
Knowledge	**Technical expertise**	**Training**
broad understanding of disease entity	*all therapeutic options (conventional & new)*	*specific to endo-vascular approach*

- Experience with 10 open surgical procedures
- Minimum of 25 wire/catheter placements
- Participation in 10 abdominal or 5 thoracic aortic EVSG
- Experience with large-bore femoral sheath cannulation
- Experience with retroperitoneal exposure of the iliac arteries

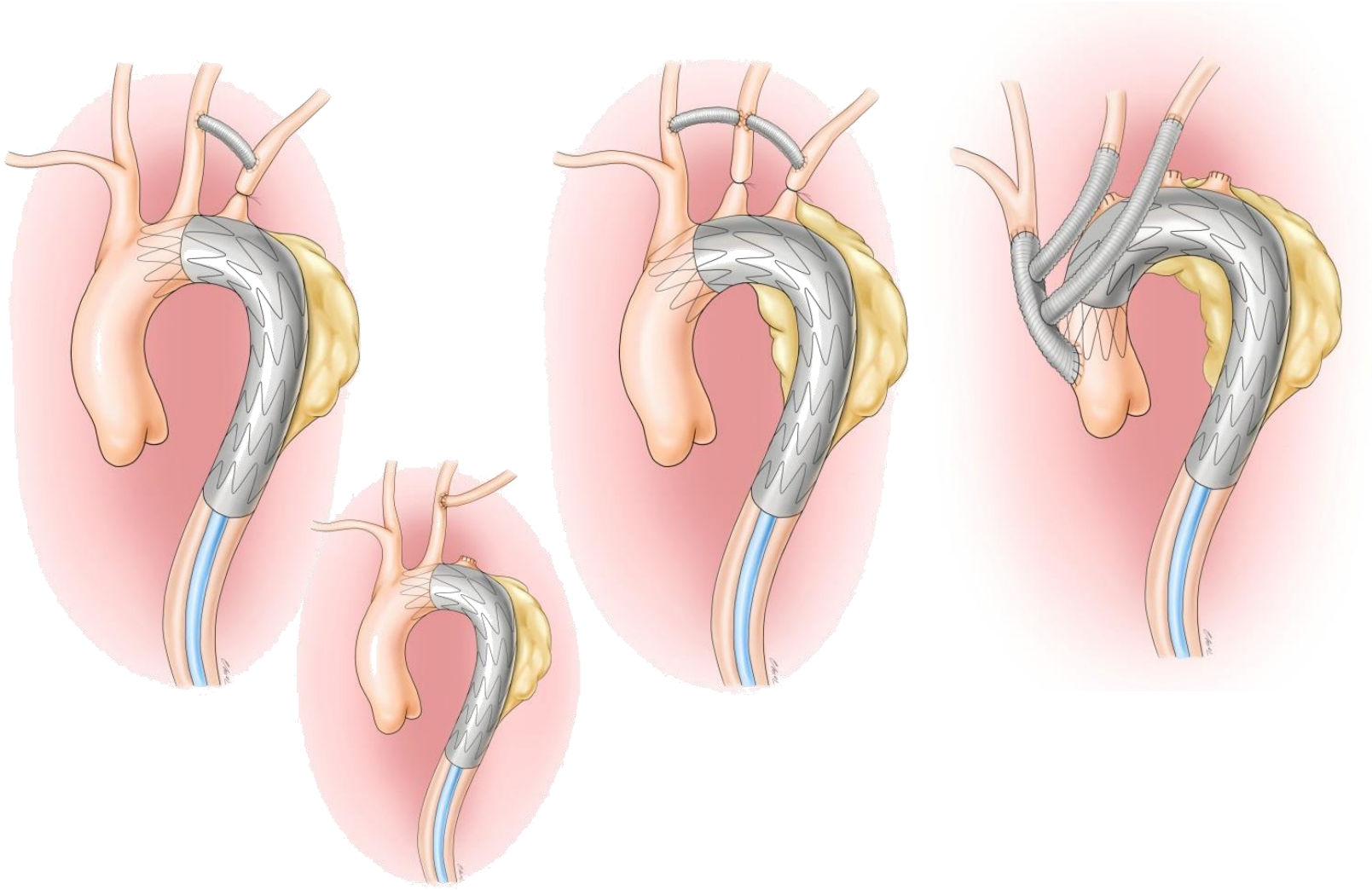

artifact


Z1
Z2
Z3
Z0
Z4

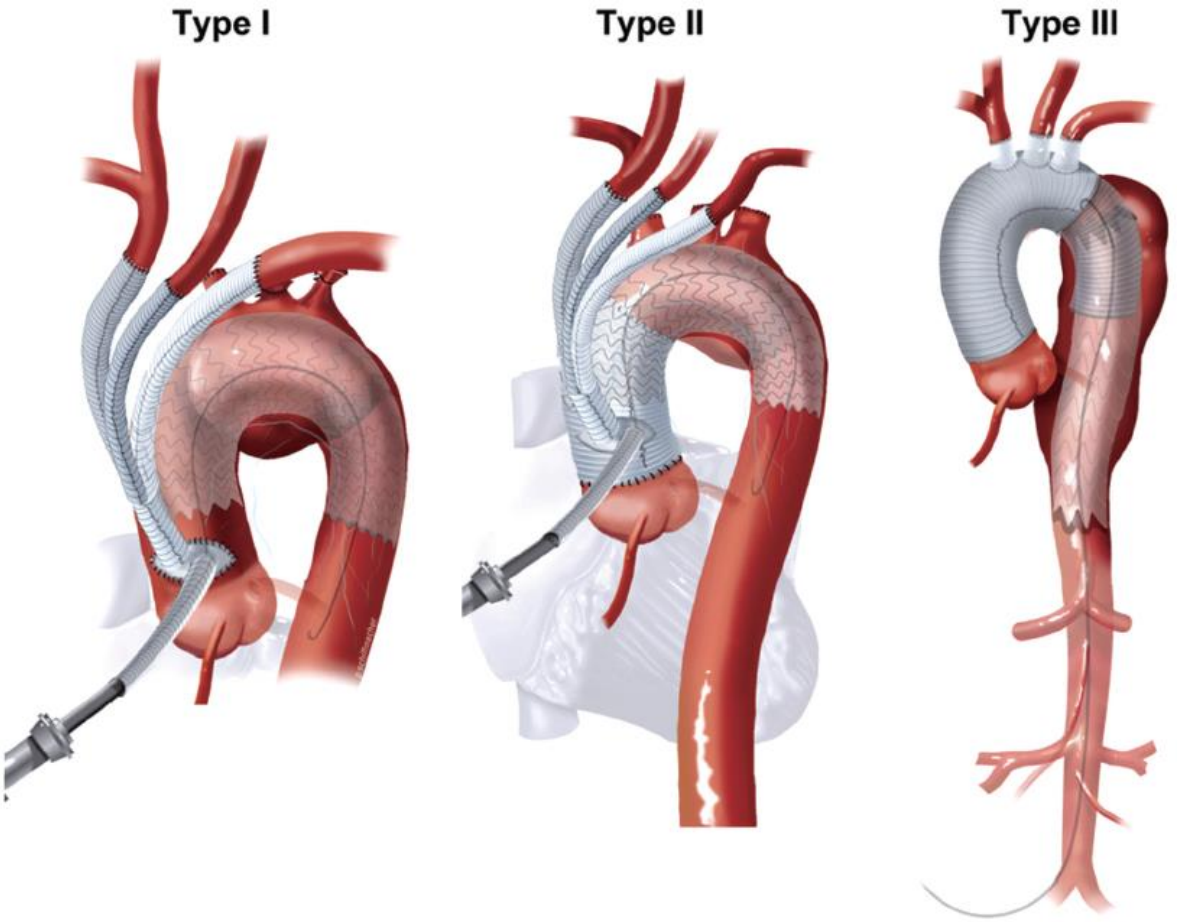
Chimney technique



Hybrid TEVAR *with arch debranching*

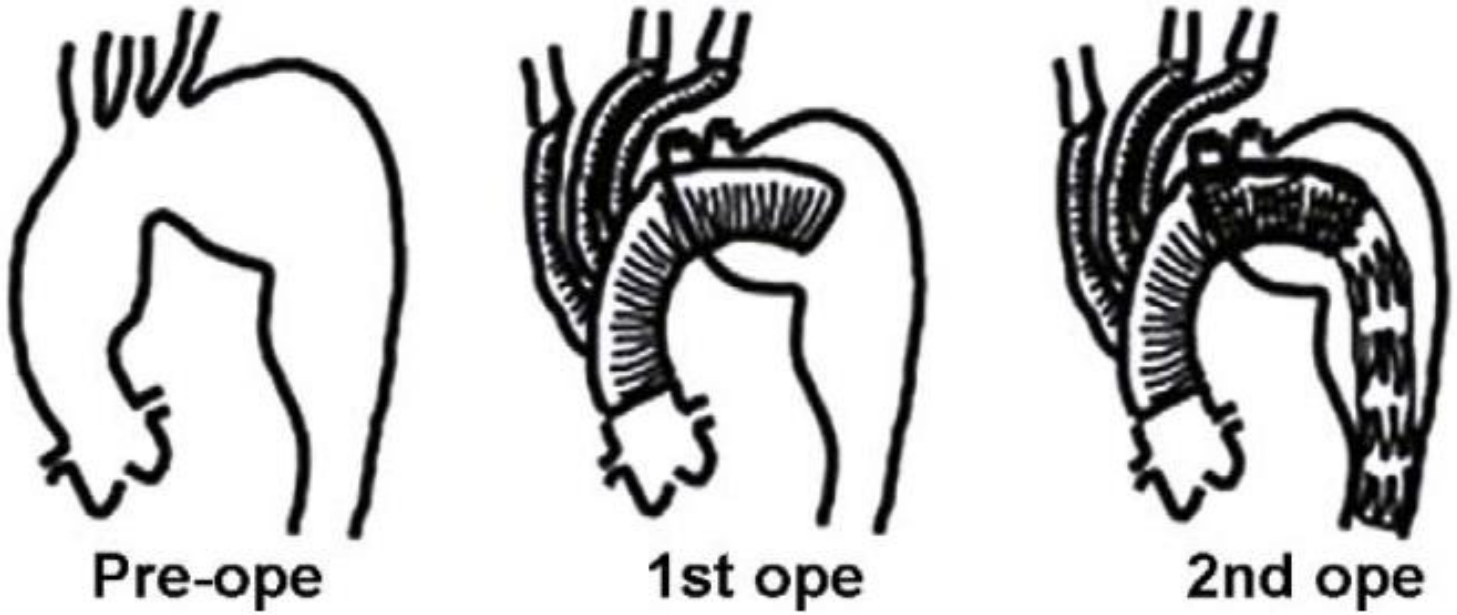


Zone 0 option

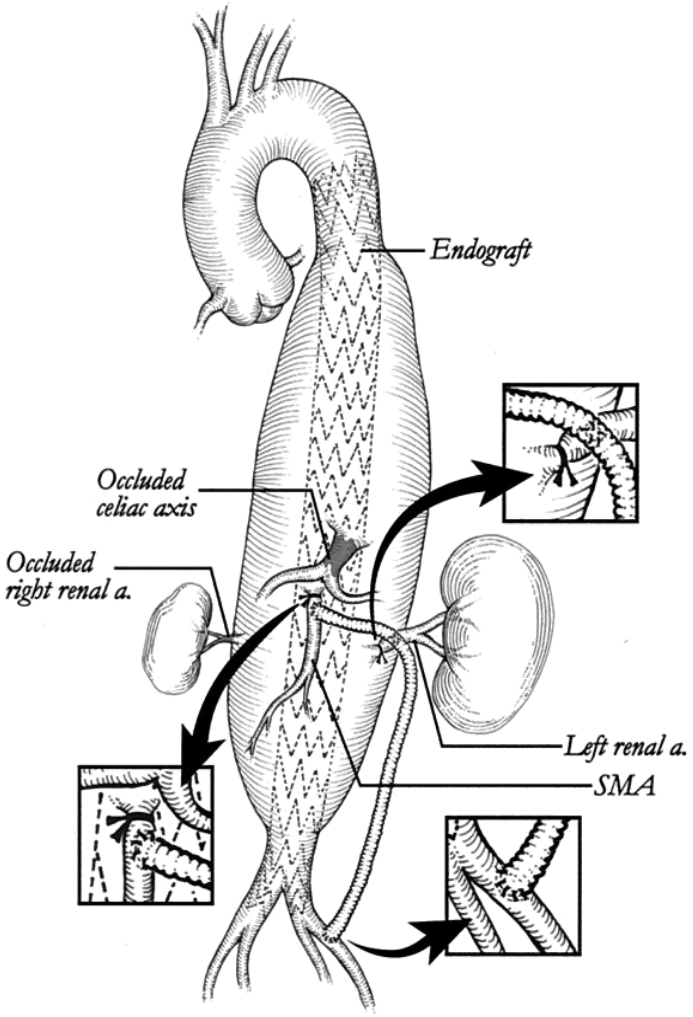


Elephant Trunk + TEVAR

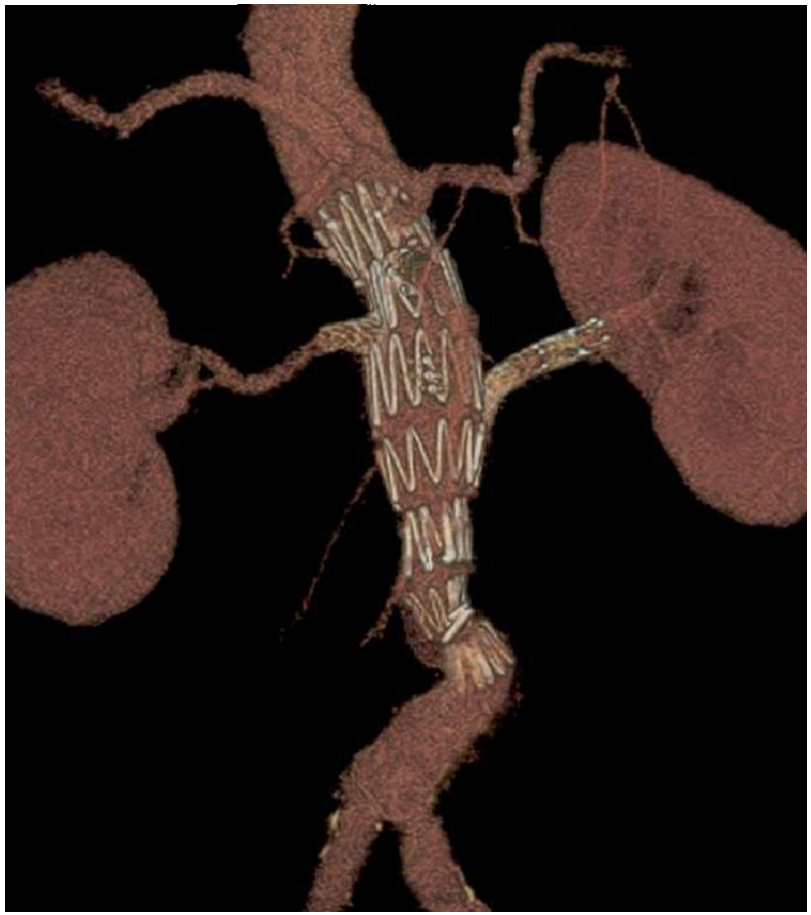
- Conventional total arch replacement with Elephant Trunk
- Second stage TEVAR instead of DTA replacement surgery



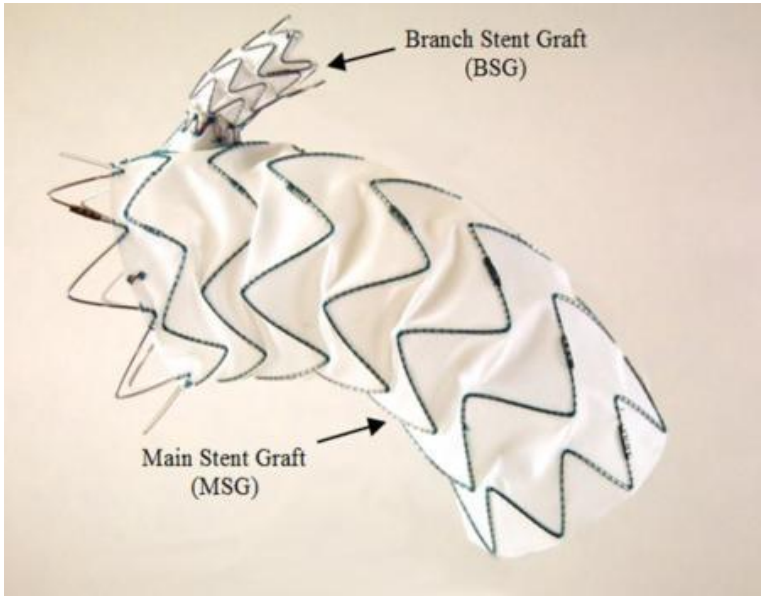
Hybrid repair of thoracoabdominal aneurysm

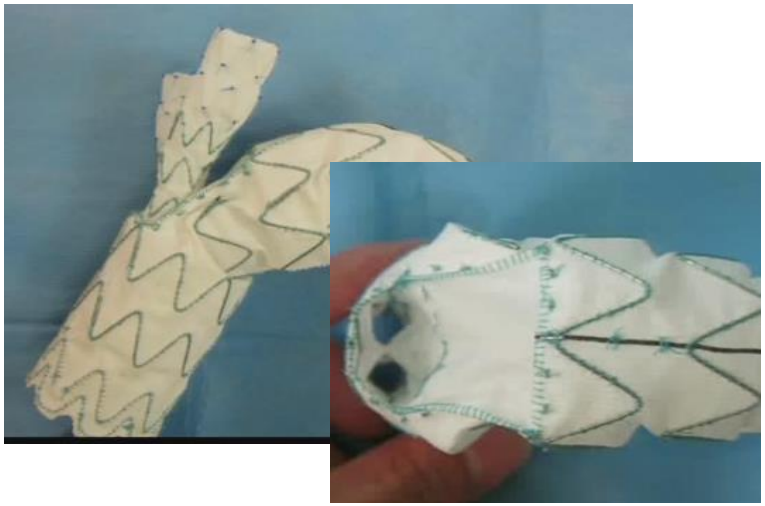


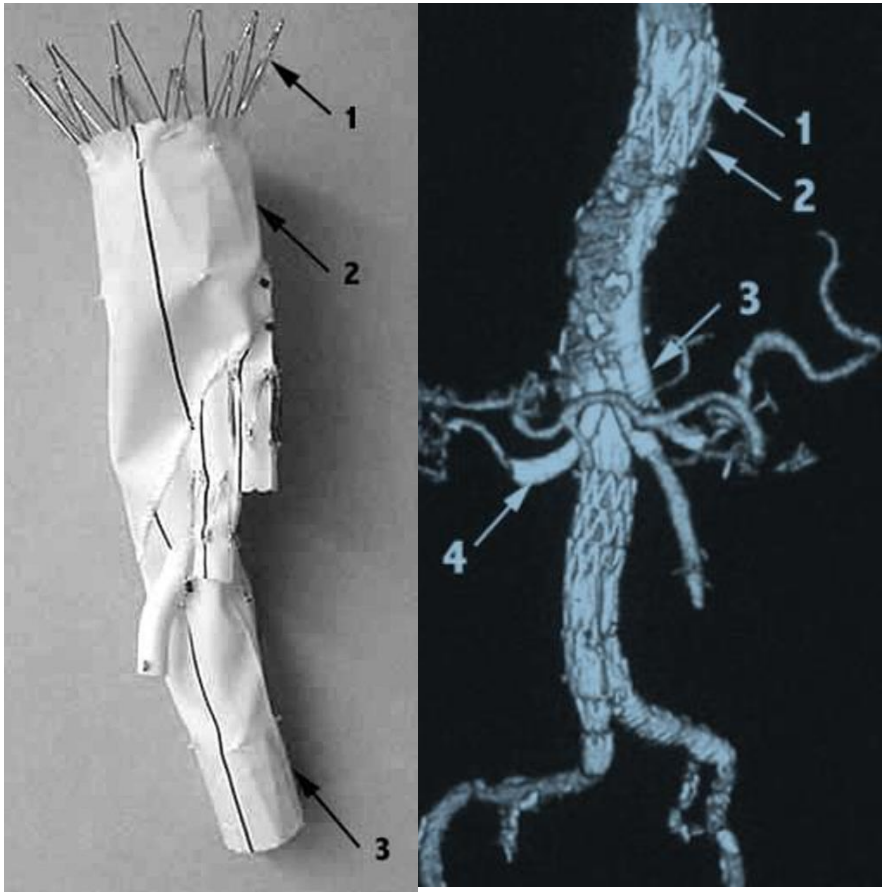
Fenestrated stent graft



Branch stent graft







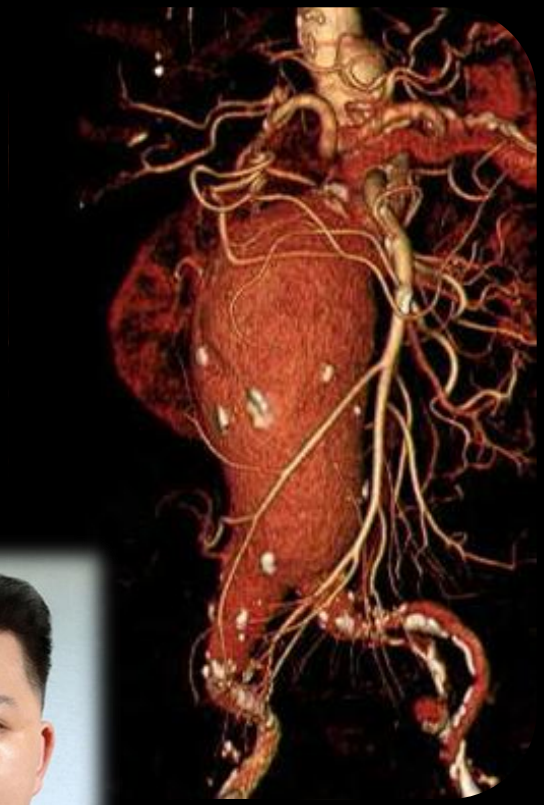
Questions to be answered

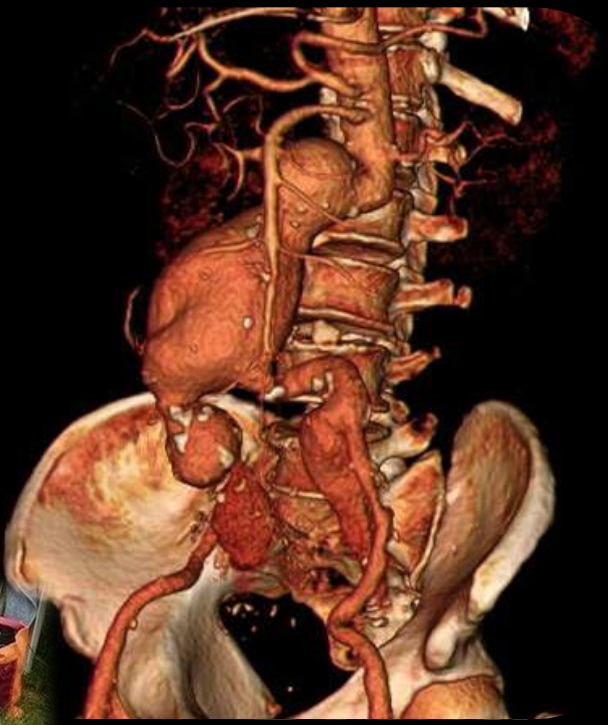
- **Is endovascular repair**
  - able to treat all lesions?
  - safer than open repair for all patients?
  - as durable as open repair?
  - equally available as open repair?
  - less costly than open repair?

Indication of endovascular repair in thoracic aorta : established

- thoracic aneurysm with good landing zones
  - ‘neck’ length ≥ 2cm, ideally ≥ 4~5cm
  - +/- sacrifice of left subclavian/celiac a.
- traumatic (isthmic) rupture
- post-surgical anastomotic pseudoaneurysm
- penetrating atherosclerotic ulcer
  with IMH, false aneurysm, or pain
- complicated acute type B dissection

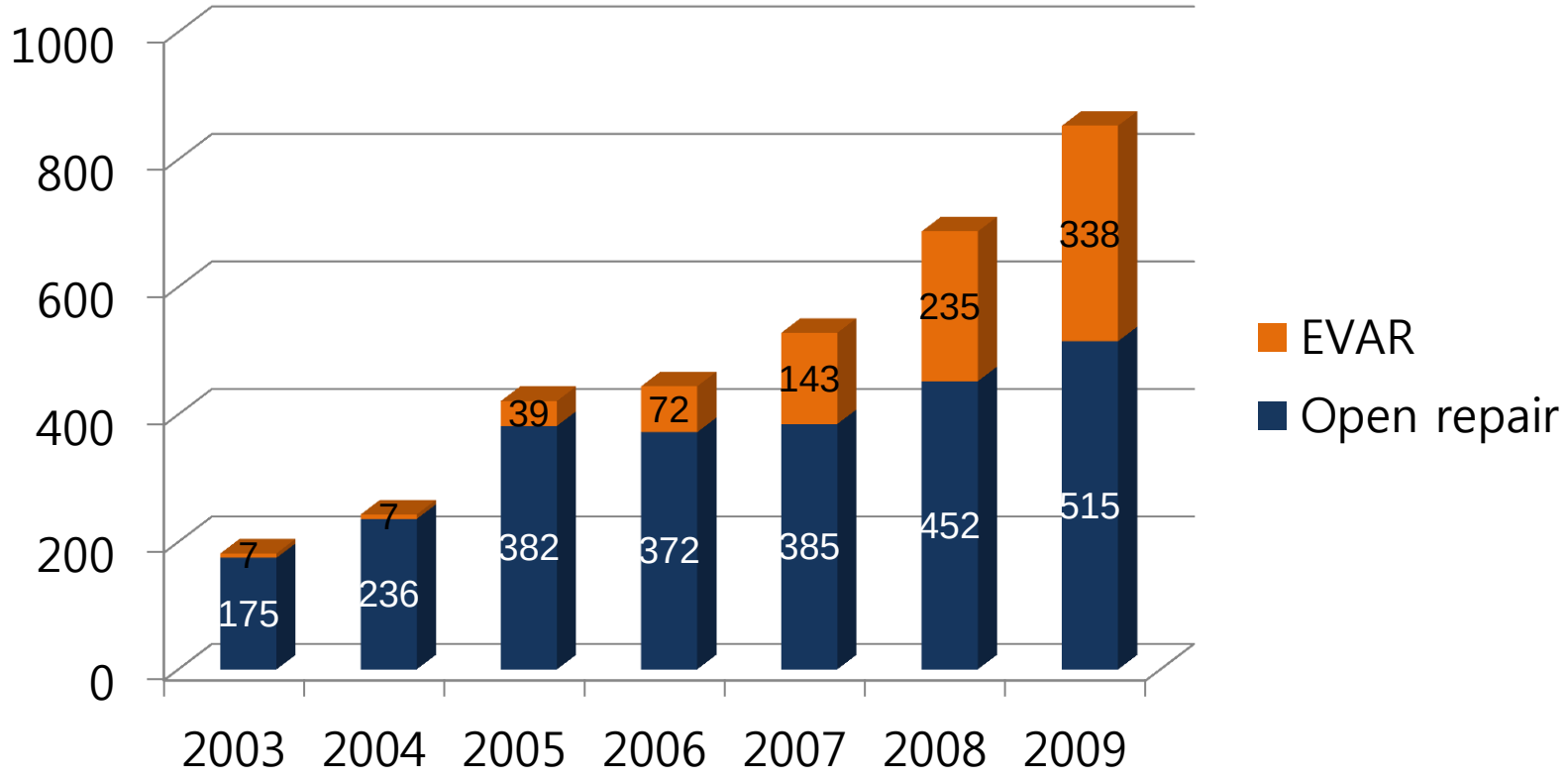
Hostile or marginal anatomy





Annual number of AAA treated in Korea

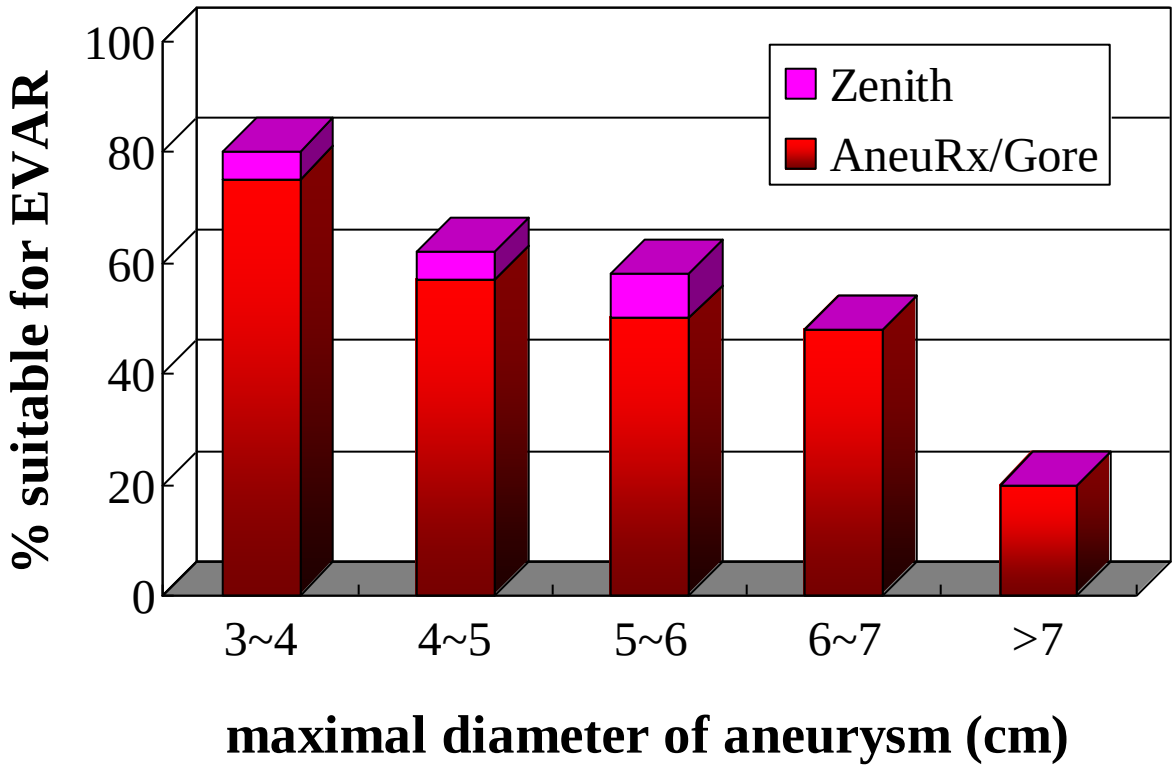
Data from HIRA



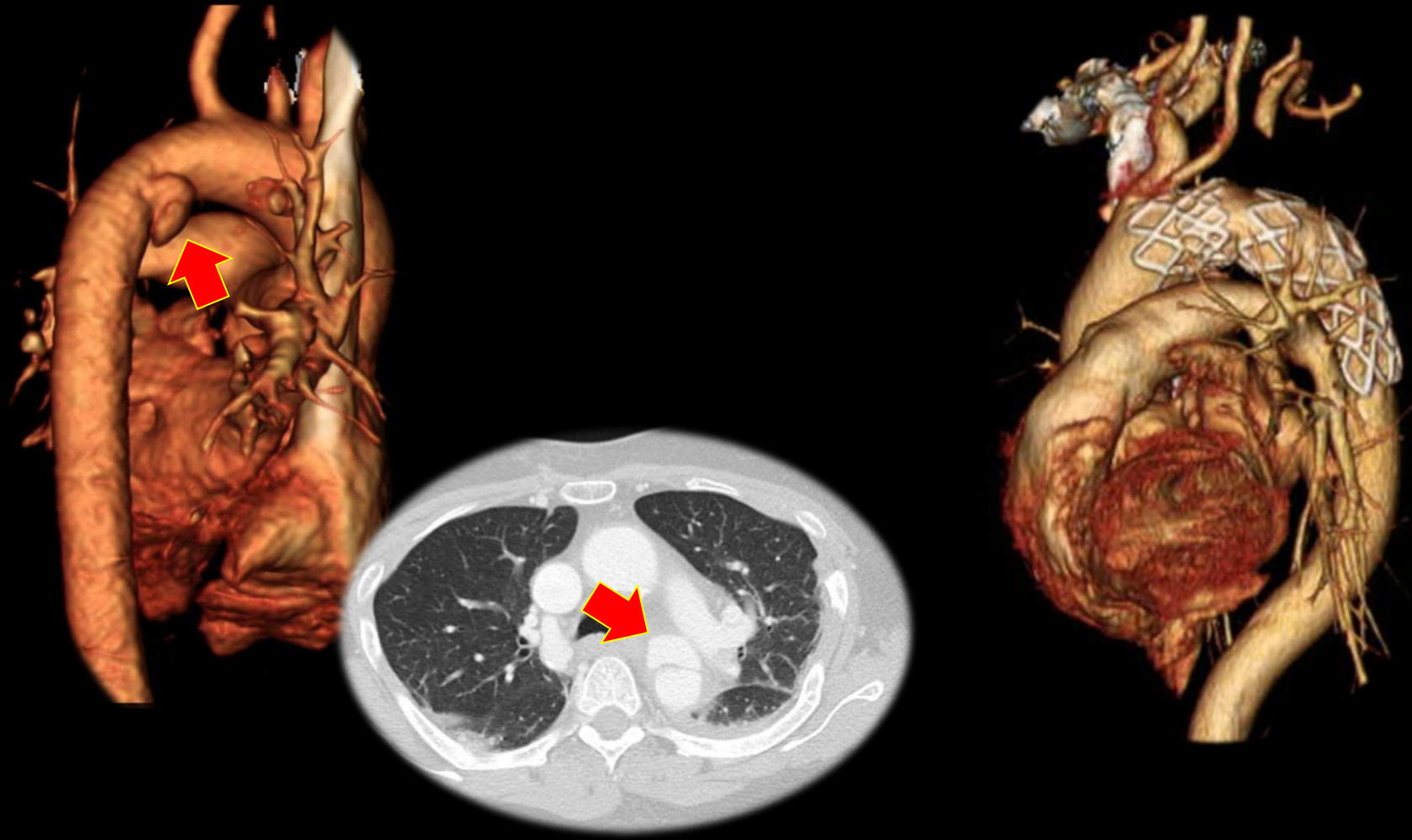
How many AAA can be treated with EVAR?

Endovascular Repair of Small Abdominal Aortic Aneurysms: A Paradigm Shift?

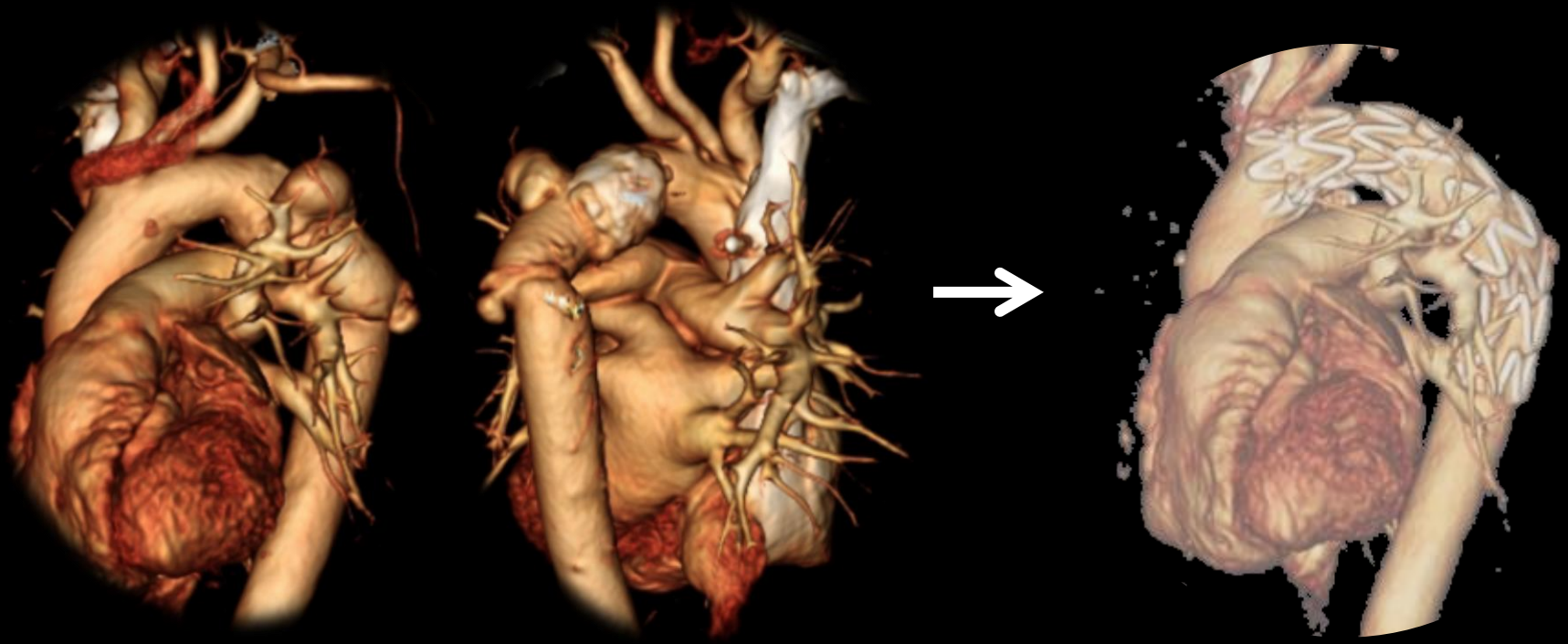
M. Burress Welborn III, MD,* Franklin S. Yau, MD,* J. Gregory Modrall, MD,* Jorge A. Lopez, MD,† Stephen Floyd, BSRT,† R. James Valentine, MD,* and G. Patrick Clagett, MD,* *Dallas, TX*



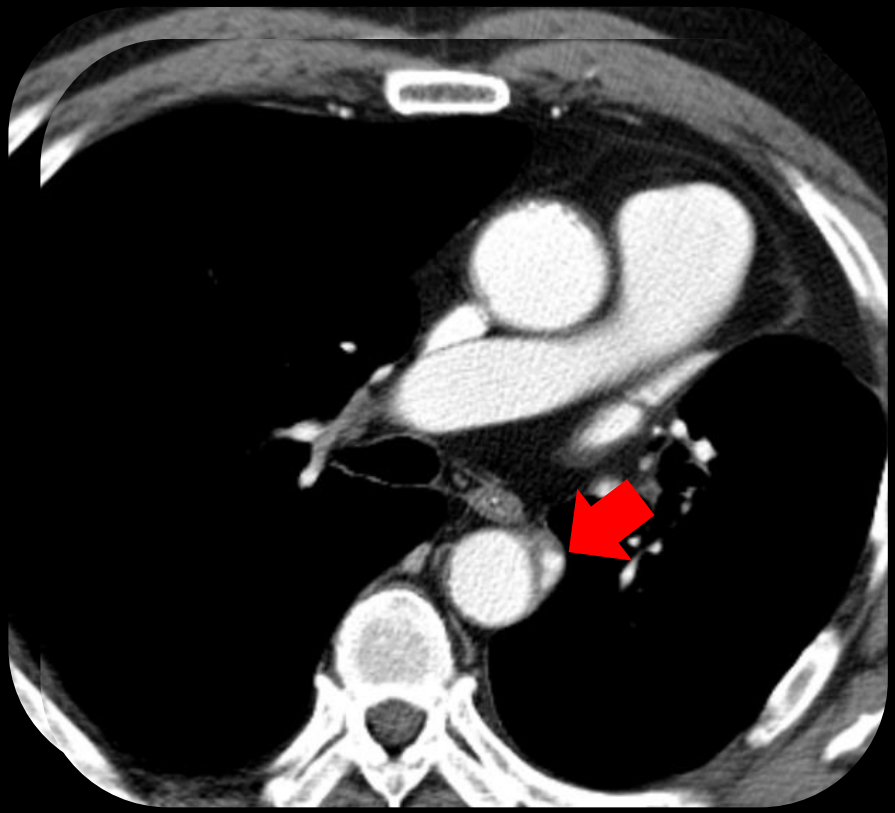
- 62-year-old female with fall-down injury → multiple fractures



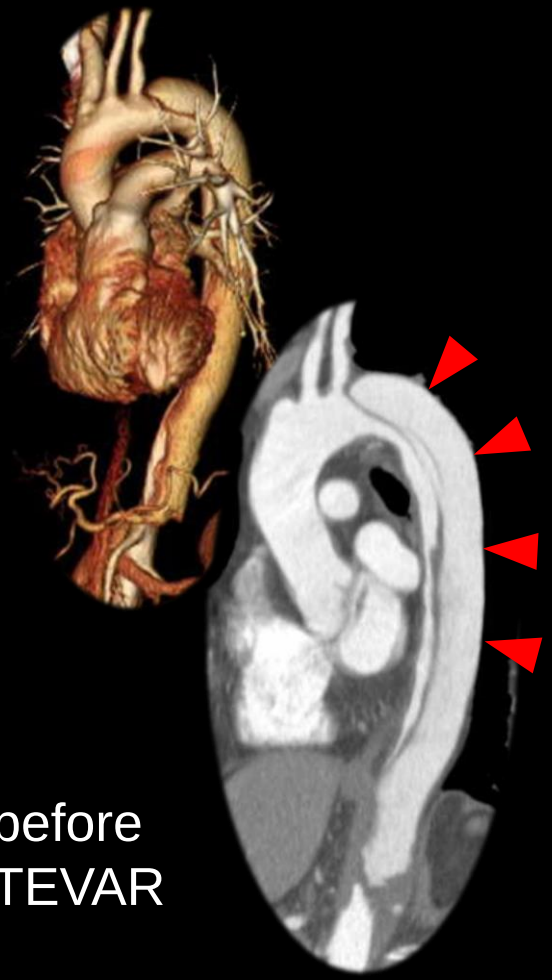
- 58-year-old female with previous DTA replacement 14 YA



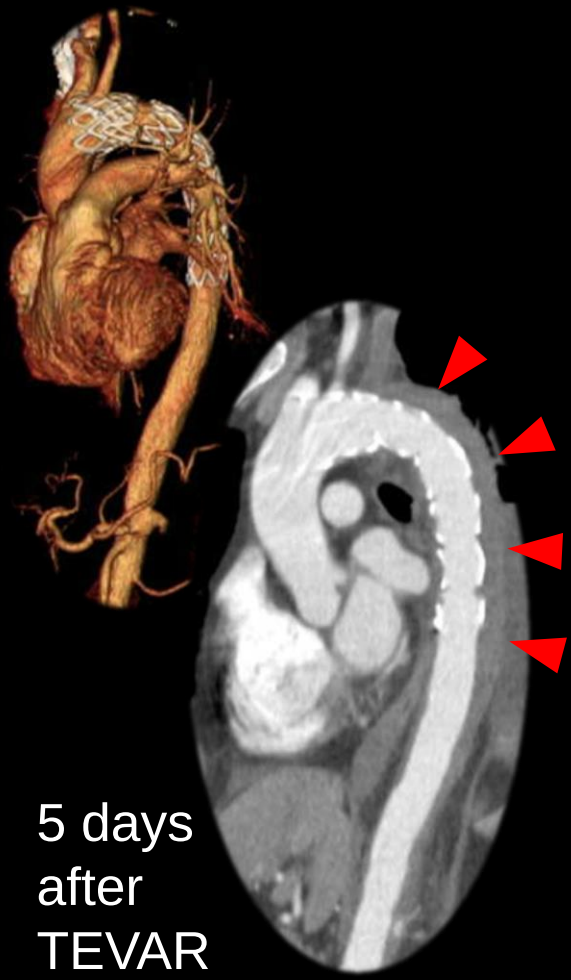
Penetrating atherosclerotic ulcer (PAU)



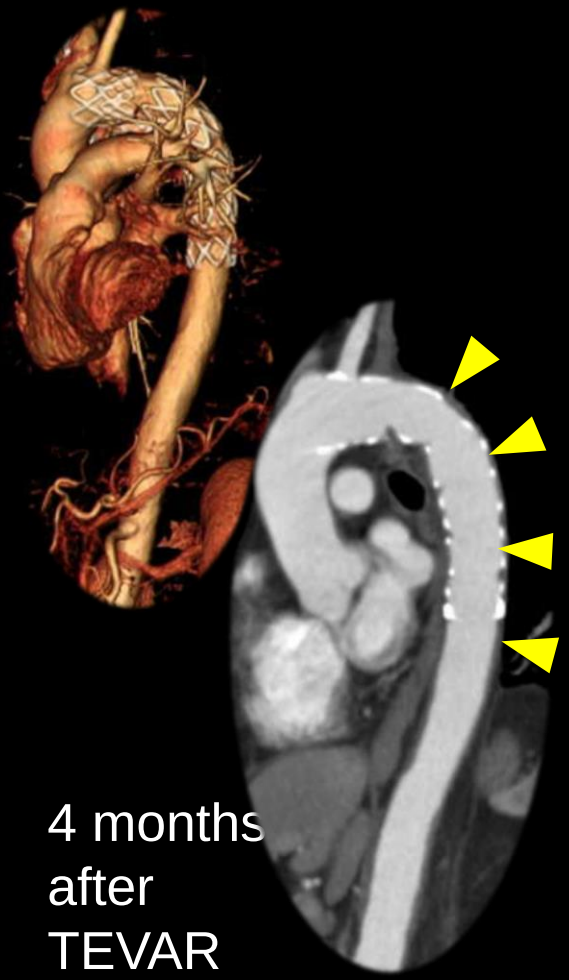
- 54-year-old male
- Acute type B dissection with intractable pain



before TEVAR

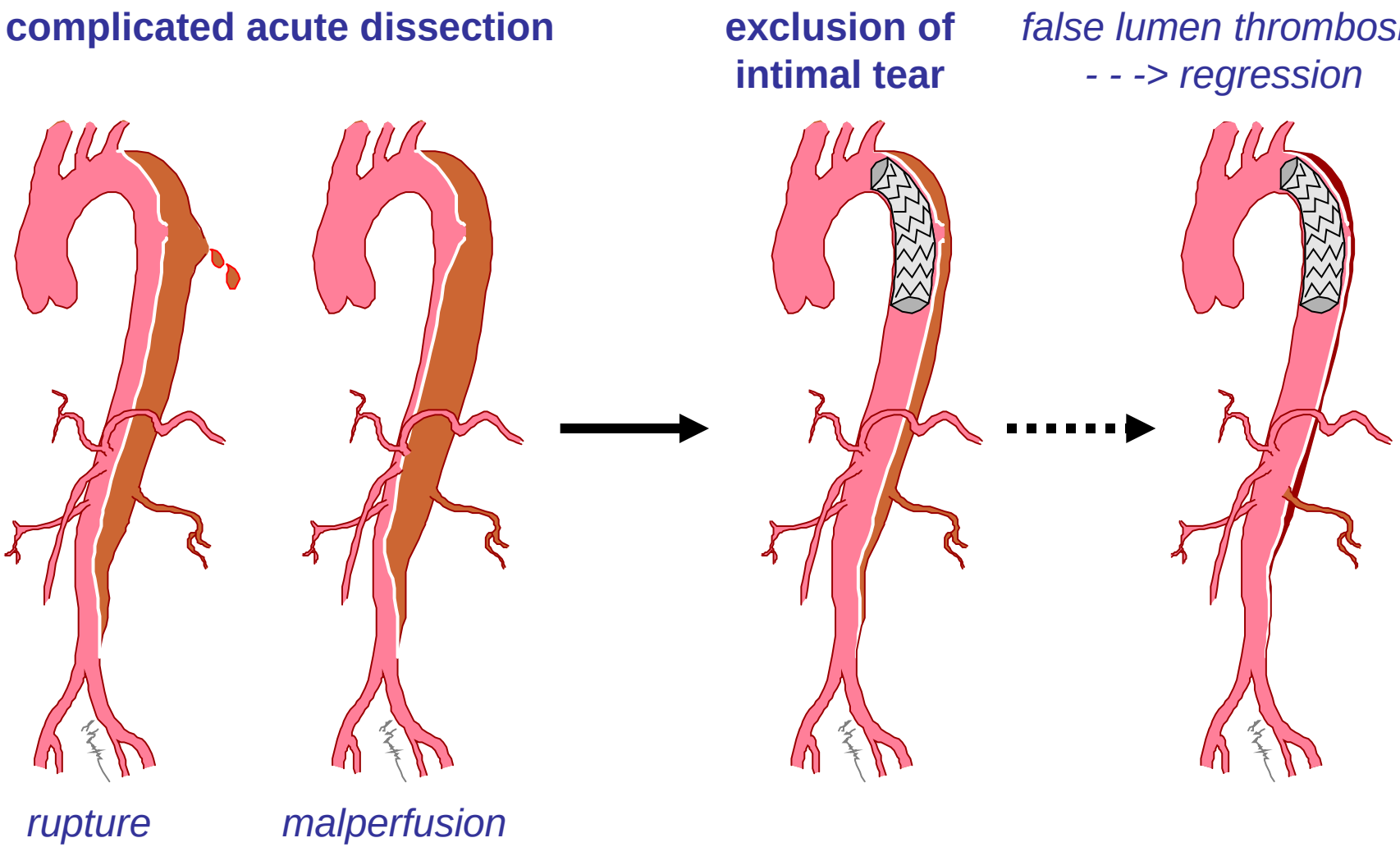


5 days after TEVAR



4 months after TEVAR

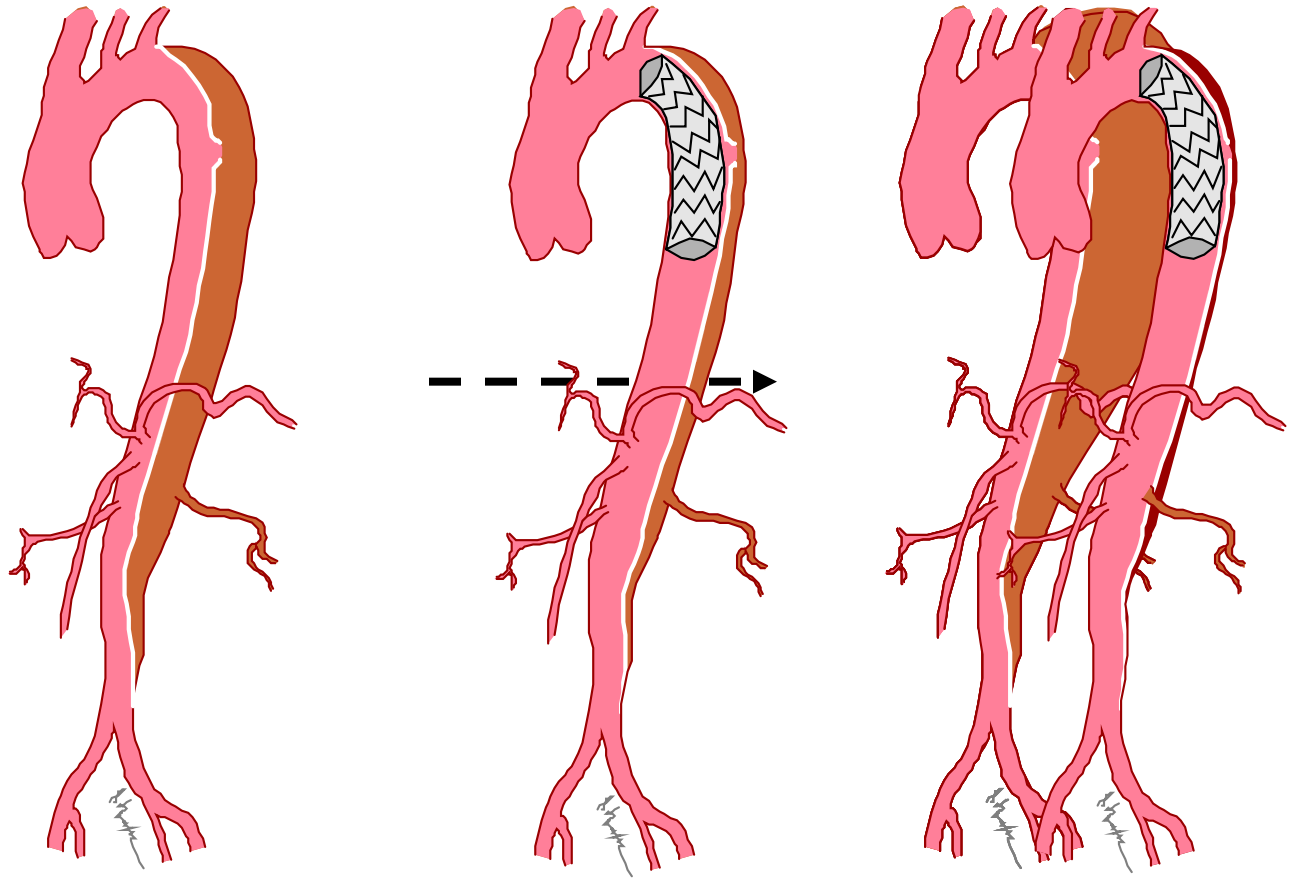
TEVAR in type B dissection



Indication of endovascular repair in thoracic aorta : controversial or undetermined

- retrograde type A dissection
  (primary tear in the descending aorta)
- infectious/mycotic aneurysm
- uncomplicated acute type B dissection
- chronic type B dissection
- inadequate landing zones necessitating
  - ‘debranching/rerouting’ procedures
  - adjunct procedures, e.g., chimney
  - new generation devices (fenestrated, branched)

Rationale of TEVAR in uncomplicated dissection

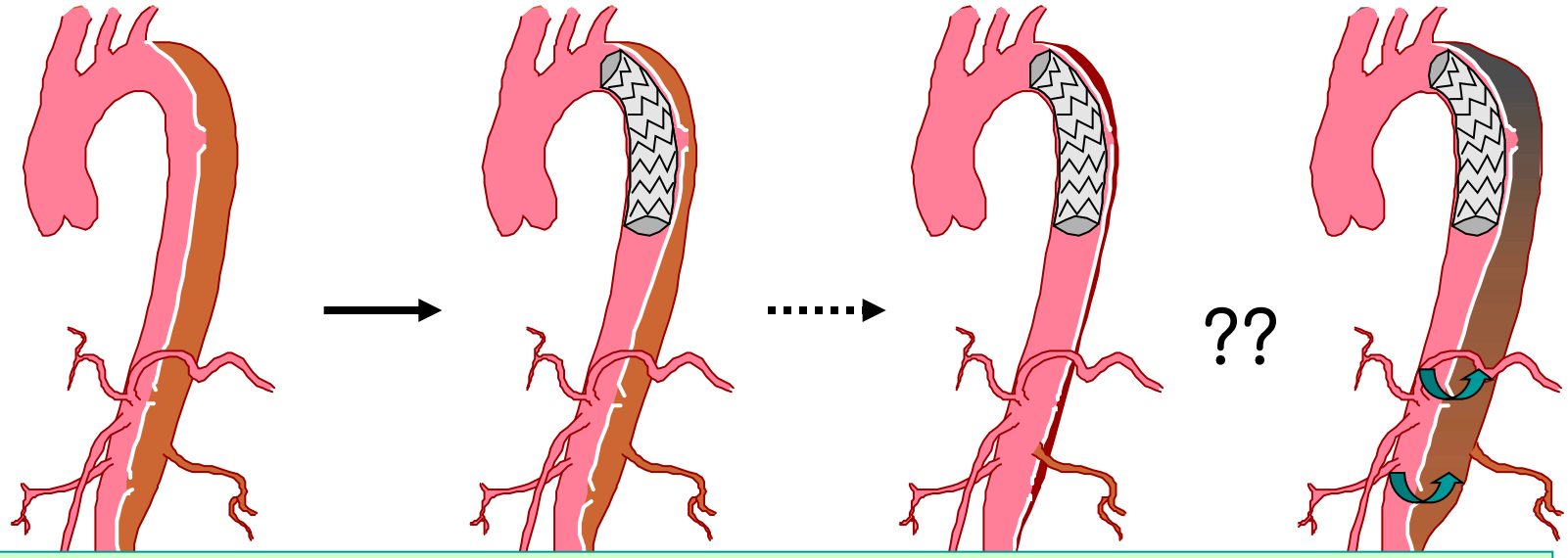


However, the reality is that

Most dissections have distal re-entry tears, especially in chronic stage.

TEVAR

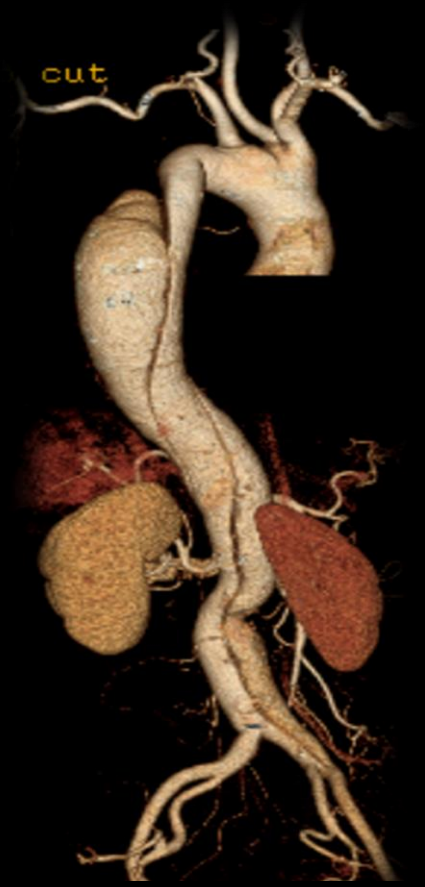
≤ 80% in acute
≤ 50% in chronic



Expert Consensus (report from STS task force) :
"*Neither open surgery nor stent-graft reverses the natural history of aortic dissection unless the entire extent of dissection is either resected or excluded, and that can be achieved only by surgical intervention*"

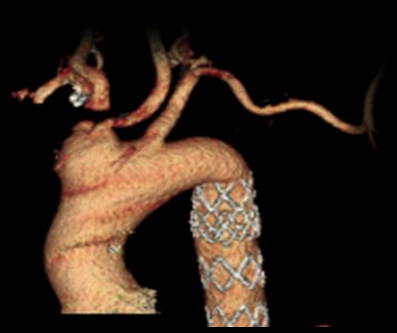
courtesy of Taek Yeon Lee, MD

- **F / 56, Marfan**
- **s/p TEVAR for type B dissection**



December 2009

June 2011



November 2011

EVAR trial

Lancet 2004;364:843-8

- Randomization of elective **AAA** patients fit for open surgery
  - endovascular stent-grafting (n=543) vs. open surgery (n=539)

	EVAR	open repair
• median length of operation :	180min	200min
• 30-day mortality :	1.7%	4.7%
• median length of admission :	7 days	12 days
• conversion to open repair	1.8%	-----
• correction of endoleak	3.3%	-----
• re-exploration	-----	2.8%

1st-generation stent-grafts in thoracic aorta

Demers P, Craig Miller D, et al. J Thorac Cardiovasc Surg 2004;127:664-73

- 103 patients between 1992~1997, mean follow-up for 4.5 years
  - 62 patients were '*unsuitable for conventional open repair*'.
- **mortality : 9%, paraplegia : 3%**
- **actuarial freedom from treatment failure : 67%/1-year, 56%/5-year**

Stent-grafting of thoracic aorta in France

Ricco JB, et al. J Thorac Cardiovasc Surg 2006;131:131-7

- Nationwide result of 166 patients in France between 1999 ~ 2001
- **in-hospital mortality : 10%**
- **49 complications in 34 patients (20.5%)**
  - *endoleak : 16.3%, other serious complications : **12.7%***

Secondary procedures after TEVAR

- **Talent registry** (*J Thorac Cardiovasc Surg 2006;132:332-9*)
  - 457 patients, 2nd procedure = 19% / 3 years, 30% / 5 years
- **Heidelberg** (*J Vasc Surg 2011*)
  - 47 patients of hybrid TEVAR (1997~2009)
  - 27.6% 2nd procedure, 6.3% open conversion
- **U Penn** (*J Thorac Cardiovasc Surg 2013;145:S165-70*)
  - 680 TEVAR (2000~2011) → 60 2nd TEVAR + 20 surgery
- **Kobe** (*Ann Thorac Surg 2013;95:1584-90*)
  - 147 TEVAR (2000~2011) → 10 2nd TEVAR + 9 surgery

Systematic review of clinical outcomes in hybrid procedures for aortic arch dissections and other arch diseases

Piergiorgio Cao, MD, FRCS,[a] Paola De Rango, MD, PhD,[b] Martin Czerny, MD,[c] Arturo Evangelista, MD,[d] Rossella Fattori, MD,[e] Christoph Nienaber, MD,[f] Hervè Rousseau, MD,[g] and Marc Schepens, MD[h]

J Thorac Cardiovasc Surg 2012;144:1286-1300

➢ Conclusion

- Hybrid arch repair present a persistent high risk of mortality and neurologic morbidity, comparable with open repair.
- Mortality was not affected by center volume or time of experience.
- Zone 0 deployment present 3 times higher mortality than zone 1 repair.
- No reliable long-term data exist to ascertain the durability.

Endovascular repair of thoracoabdominal aneurysms: design options, device construct, patient selection and complications

L. M. REILLY, T. A. M. CHUTER

J Cardiovasc Surg 2009;50:447-60

- Total number of pooled cases 287
- Follow-up < 18 months

- Early mortality **6.9%**
- Late mortality 13.6%
- Spinal cord ischemia
  - paraplegia **8.2%**
  - paraparesis 6.7%
  - permanent **6.7%**
  - temporary 10.0%

- Renal failure 9.8%
- Hemodialysis **5.1%**

- Early re-intervention 8.9%
- Late re-intervention **11.1%**

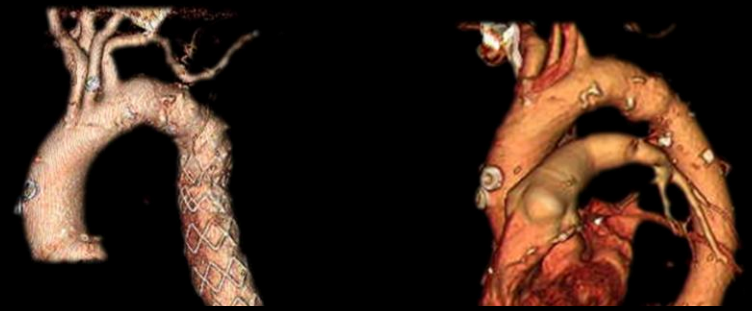
- Early endoleak 16.2%
- Late endoleak 14.3%
- Branch occlusion 3.5%

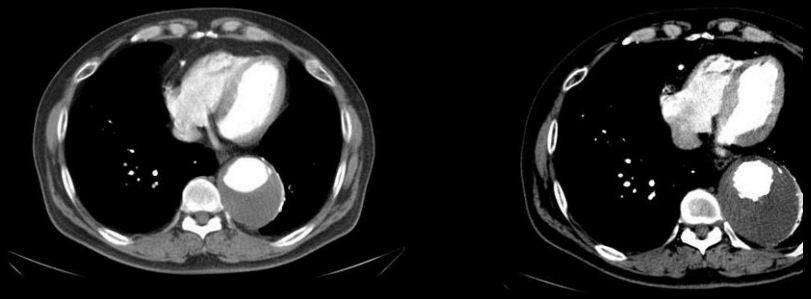
Problems/complications of TEVAR

◆ Mortality	1.5~6.5%
◆ Renal failure	5.2~13%
◆ Vascular access problems	
➢ need of iliac conduit	up to 40%
➢ serious injury to iliofemoral arteries	1.4~14%
◆ Neurological complications	
➢ stroke	2.9~11%
➢ paraplegia	2~5%
◆ Procedural failure	1~5%
◆ Retrograde type A dissection	2~6%
◆ Endoleak	0~45%
◆ Late mechanical failure (fracture/breakage/wear)	up to 9%
◆ Prosthesis infection	???

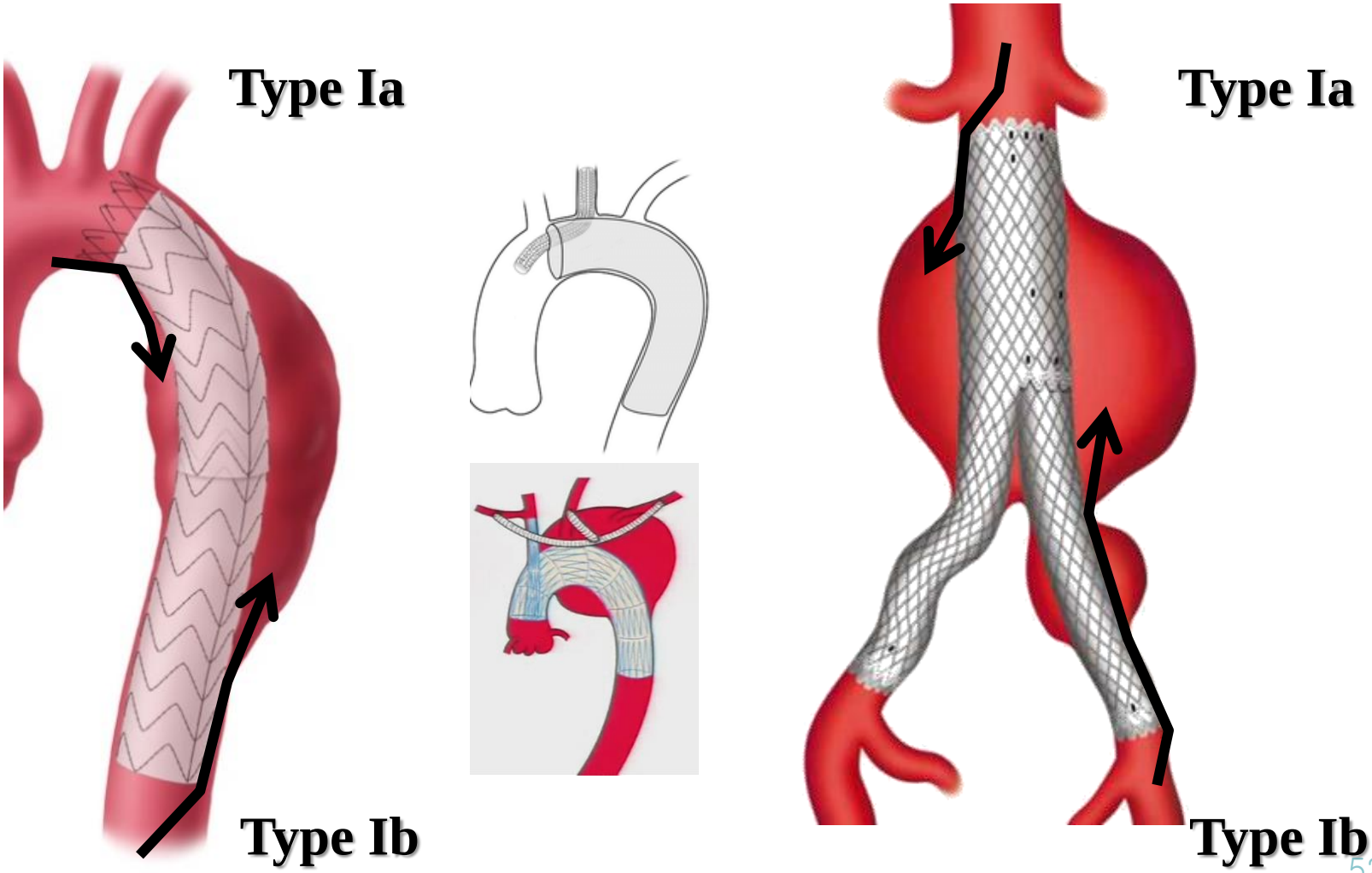
Shaggy aorta – *risk factor for both open repair and TEVAR*

3 months

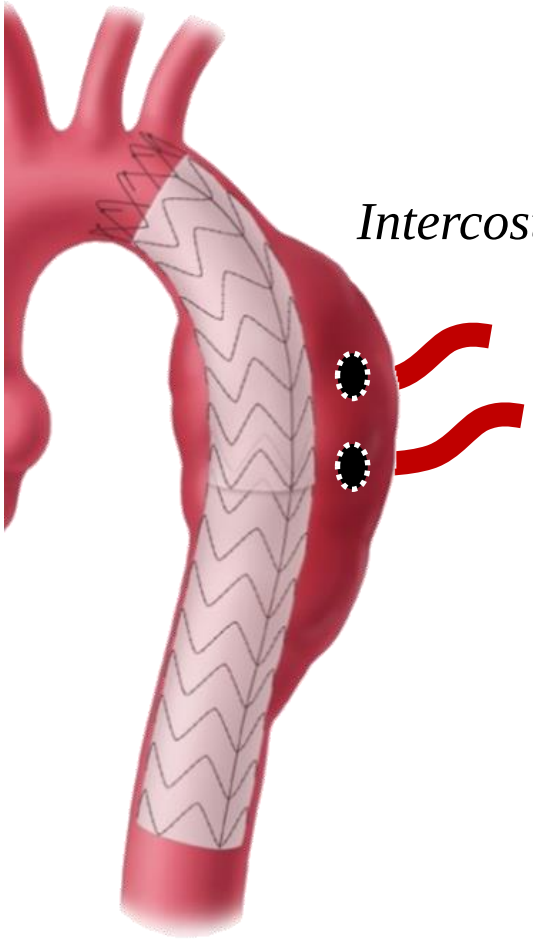




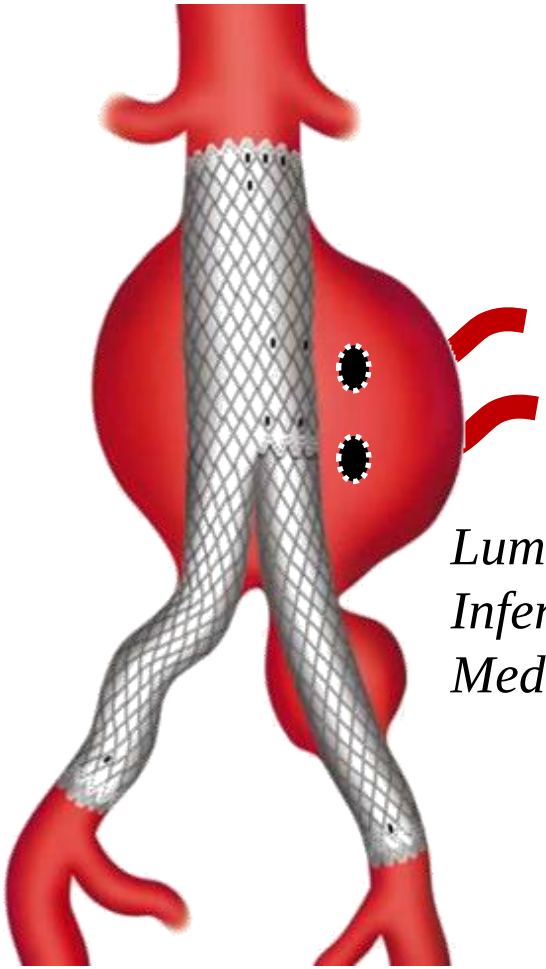
Endoleak – type I



Endoleak – type II

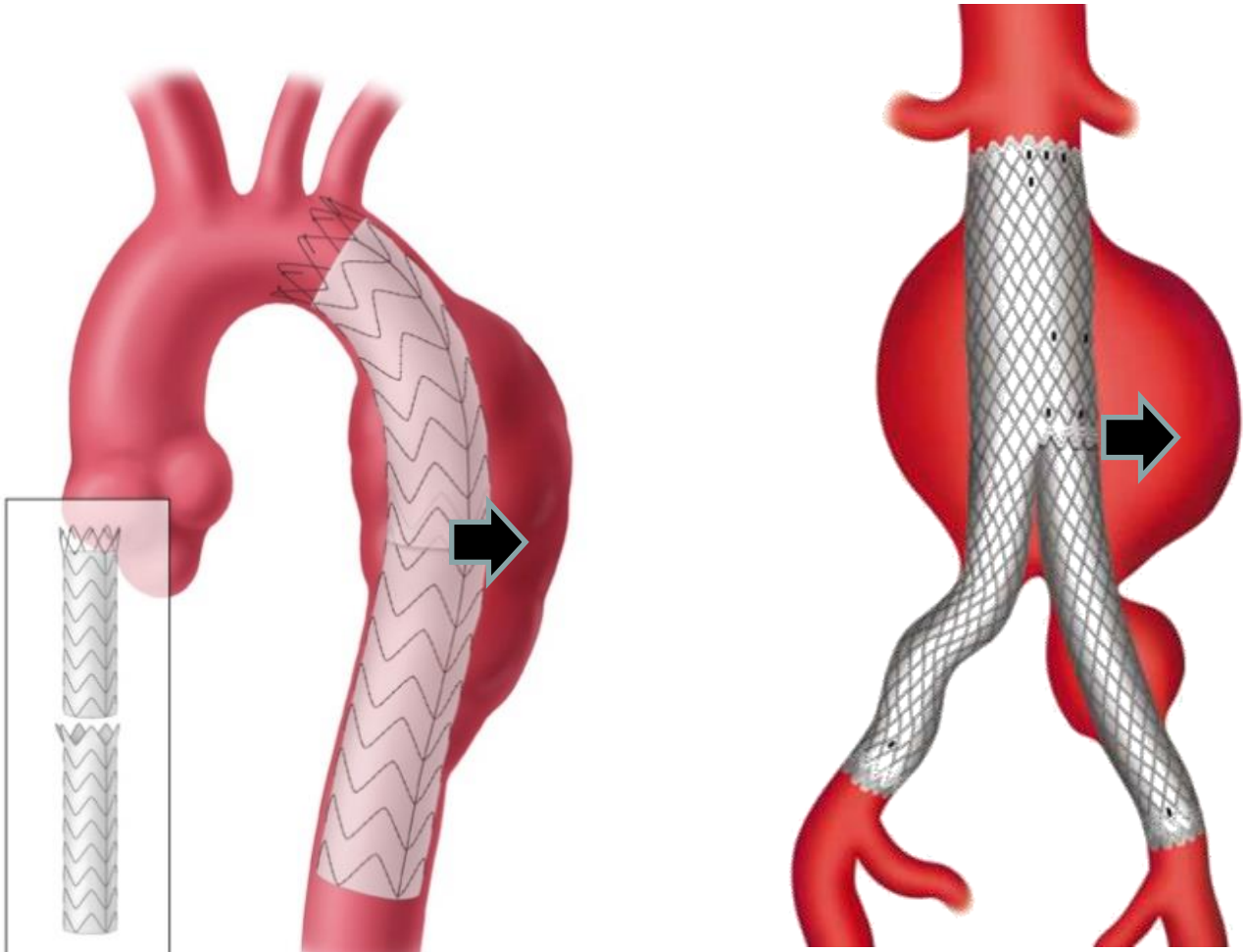


Intercostal artery

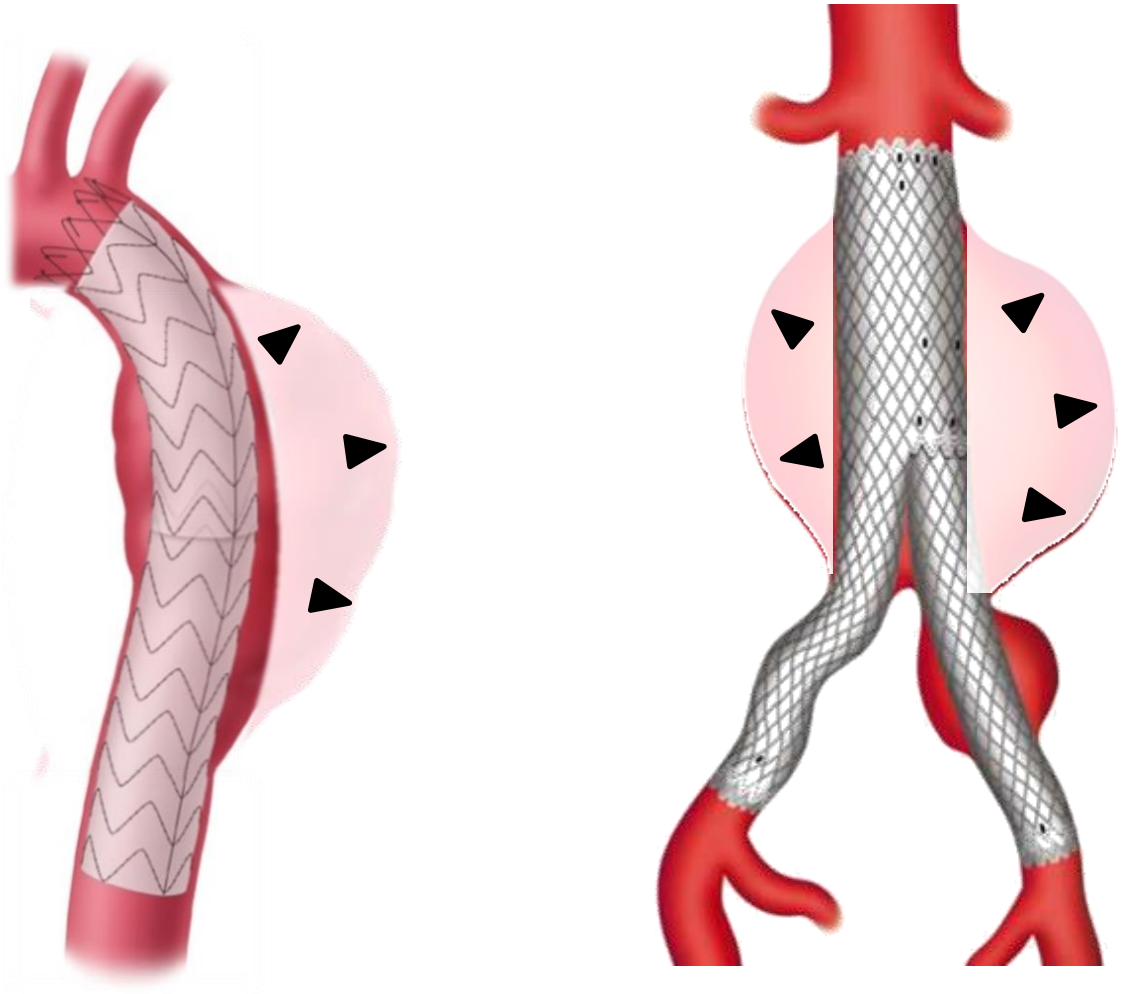


Lumbar artery
Inferior mesenteric arter
Median sacral artery

Endoleak – type III



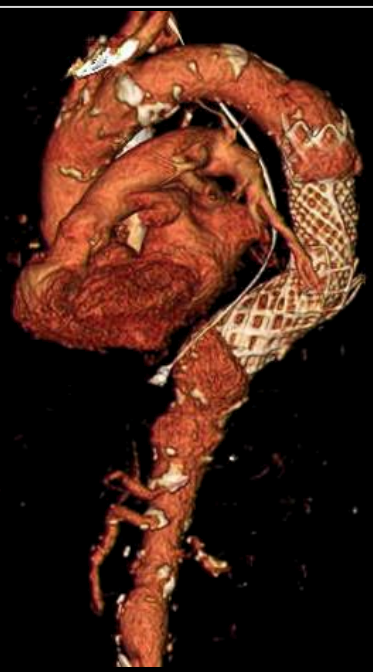
Endoleak – type IV (endotension)



Post-TEVAR complications

residual aneurysm

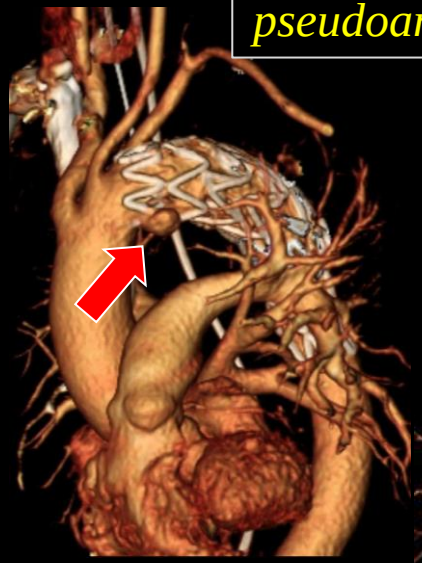
new adjacent aneurysm



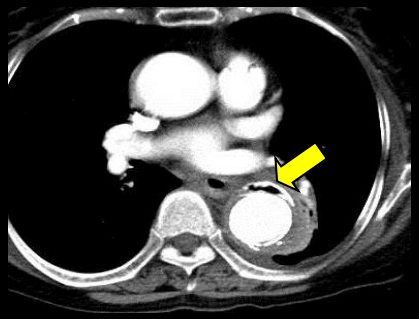
distal erosion -aneurysm

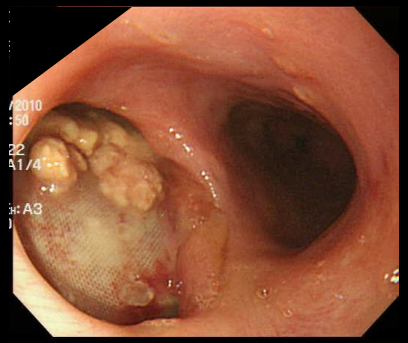
Post-TEVAR complications

pseudoaneurysm



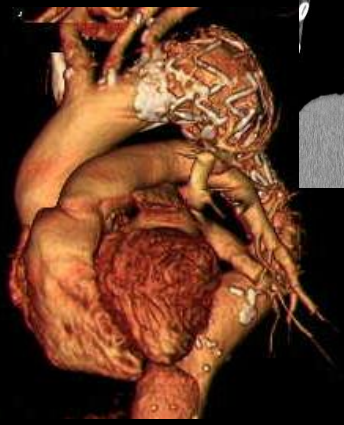
retrograde dissection

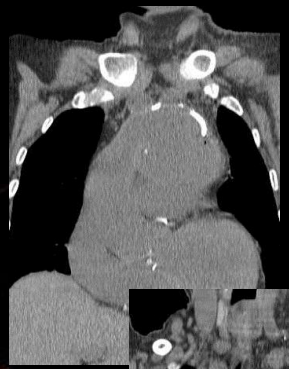




aortoesophageal fistula

stent-graft migration & false aneurysm





Mechanisms of Failure and Outcome of Secondary Surgical Interventions After Thoracic Endovascular Aortic Repair (TEVAR)

Julia Dumfarth, MD, Marc Michel, MD, Jürg Schmidli, MD, Gottfried Sodeck, MD, Marek Ehrlich, MD, Michael Grimm, MD, Thierry Carrel, MD, and Martin Czerny, MD

Departments of Cardiac Surgery, and Emergency Medicine, Medical University of Vienna, Vienna, Austria; Department of Cardiovascular Surgery, University Hospital Berne, Switzerland; and Department of Cardiac Surgery, Medical University of Innsbruck, Innsbruck, Austria

Background. We evaluated mechanisms of failure and outcome of secondary surgical interventions after tho-

formation as well as infection. Retrospectively, by analysing referral computed tomography scans and by current knowledge, failure could have been foreseen in 72% of patients. Median interval to secondary surgical inter-

vention was 24 months (IQR 8-40). Sixteen patients underwent thoracic or thoracoabdominal repair and five

formation, retrograde type A dissection, distal aneurysm formation as well as infection. Retrospectively, by analysing referral computed tomography scans and by current knowledge, failure could have been foreseen in 72% of patients. Median interval to secondary surgical inter-

further critical evaluation and respecting limitations of TEVAR will help to reduce the need for these operations.

(Ann Thorac Surg 2011;91:1141–6)

Lessons

- 2nd procedure is not rare after TEVAR, ≥20% of them should be open surgery.
  - *Causative factors for early failure*
    - *off-label use for unfavorable anatomy*
    - *wrong indication, e.g., Marfan, infection*
    - *inadequate landing zone*

- Procedural / early success

  ≠ clinical / long-lasting stabilization

  because of late endoleak, adjacent aneurysm, infection, erosion (fistula), etc.

- The best countermeasure to complication is prevention.
  Best outcome can be achieved by selecting appropriate procedures to appropriate patients.
  It is why we need a real '***bivascular***' team that is good at both open surgery and endovascular procedure.

Questions to be answered

- **Is endovascular repair**
  - safer than open repair for all patients?
    mostly but not always
  - as durable as open repair?
    questionable
  - able to treat all lesions?
    maybe in the future, not in my life
  - equally available as open repair?
    doubtful, probably not
  - less or more costly than open repair?
    Newer devices will be too expensive for wide use

"…… it is not prudent to offer endovascular stent graft repair to younger patients who do not have major contraindications to open surgical repair……careful selection is key with particular emphasis on favorable anatomic targets……"

- Demers P, Craig Miller D, et al. JTCS 2004;127:664-73 -

"The gold standard for treatment of the standard patient still is the conventional open procedure in the hands of excellence. Unfit for surgery is a term steeply increasing in the literature and sometimes seems to be occupied as license to stent in cases that could easily be handled in a specialized surgical centers" *– Sunder-Plassmann L. J Cardiovasc Surg 2005;46:121-30 -*

complement *rather than* **competition**