Treatment Strategies for Endoleaks from Prevention to Treatment

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Presenter Disclosure Information

Name: ***RICHARD R. HEUSER M.D.***

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Patents *-- RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure*

EVAR

Endovascular Aneurysm Repair

- 1990 implanted the first Aortic Stent Graft in a high-risk pt with a symptomatic AAA
- Pt survived and died of pancreatic cancer nine years later
- 1991 Reported initial clinical results

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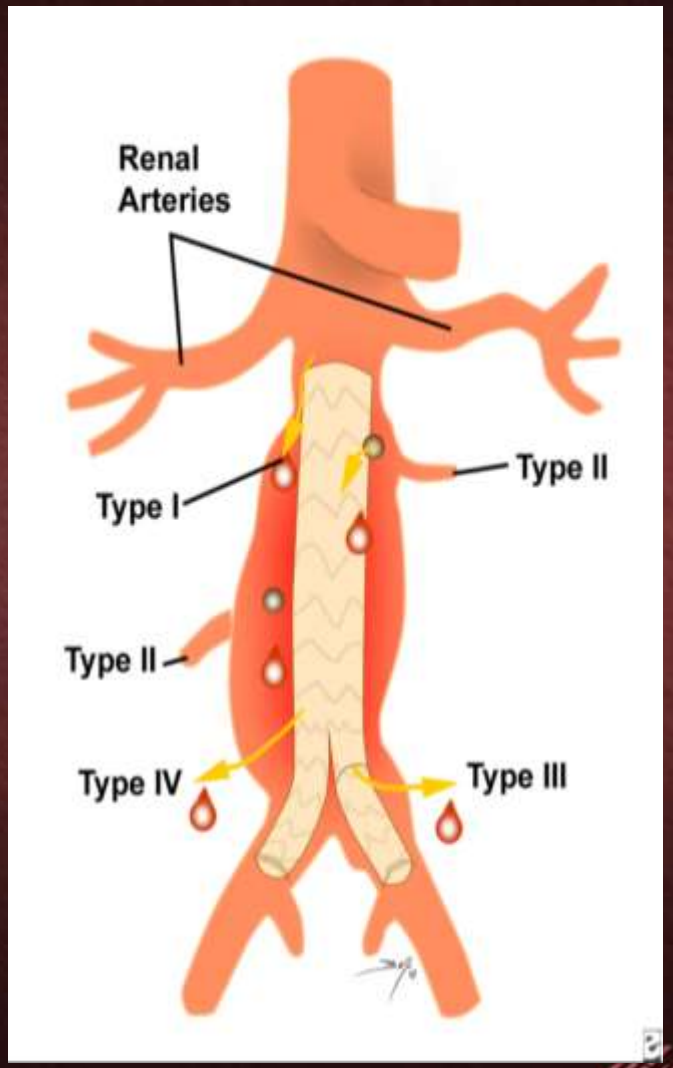
EVAR of AAA

- Goal of EVAR (stent-graft) – Exclusion of aneurysm sac
  Procedural success is defined by the "total exclusion" of the aneurysm.

- **Endoleak**
  - Failure to totally excluded blood flow to the aneurysm sac
  - Major cause of complications → "failure" of EVAR
  - Continued pressurization of the sac leaving the patient at risk for rupture of AAA

EVAR *and* Endoleaks

- Endoleak - continued perfusion of the aneurysm sac post-endograft/EVAR
  The aneurysm sac is **not excluded** from the systemic circulation

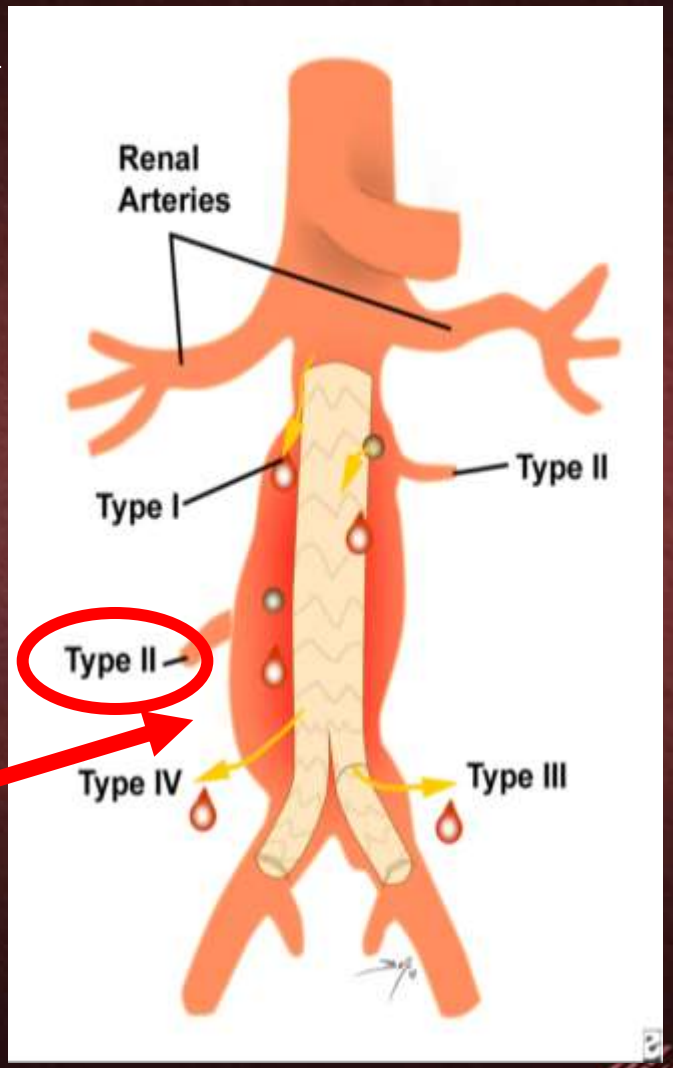


EVAR *and* Endoleaks

- Endoleak - continued perfusion of the aneurysm sac post-endograft/EVAR

  The aneurysm sac is **not excluded** from the systemic circulation

- **Type II endoleaks**
  - Most common after EVAR
  - Backflow of collateral arteries into the aneurysm sac



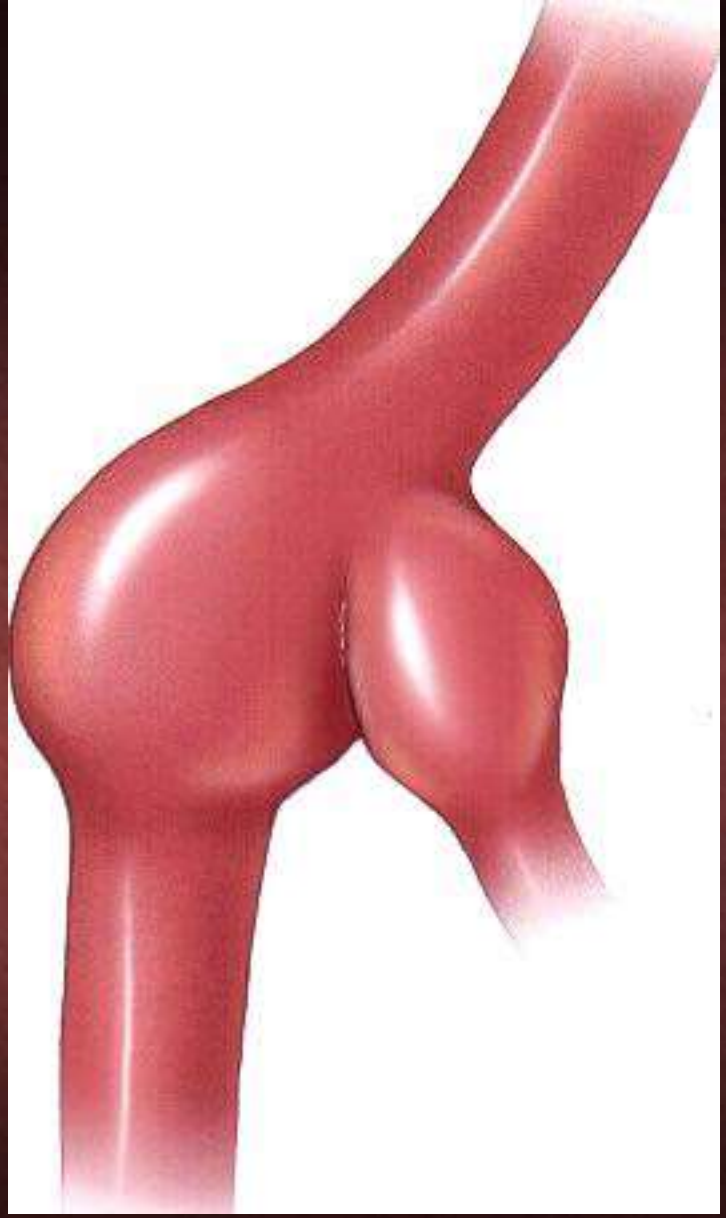
- When patients undergo EVAR of AAA, there are increased rates of graft related complications and reinterventions (by a factor of 3-4) and EVAR is more costly

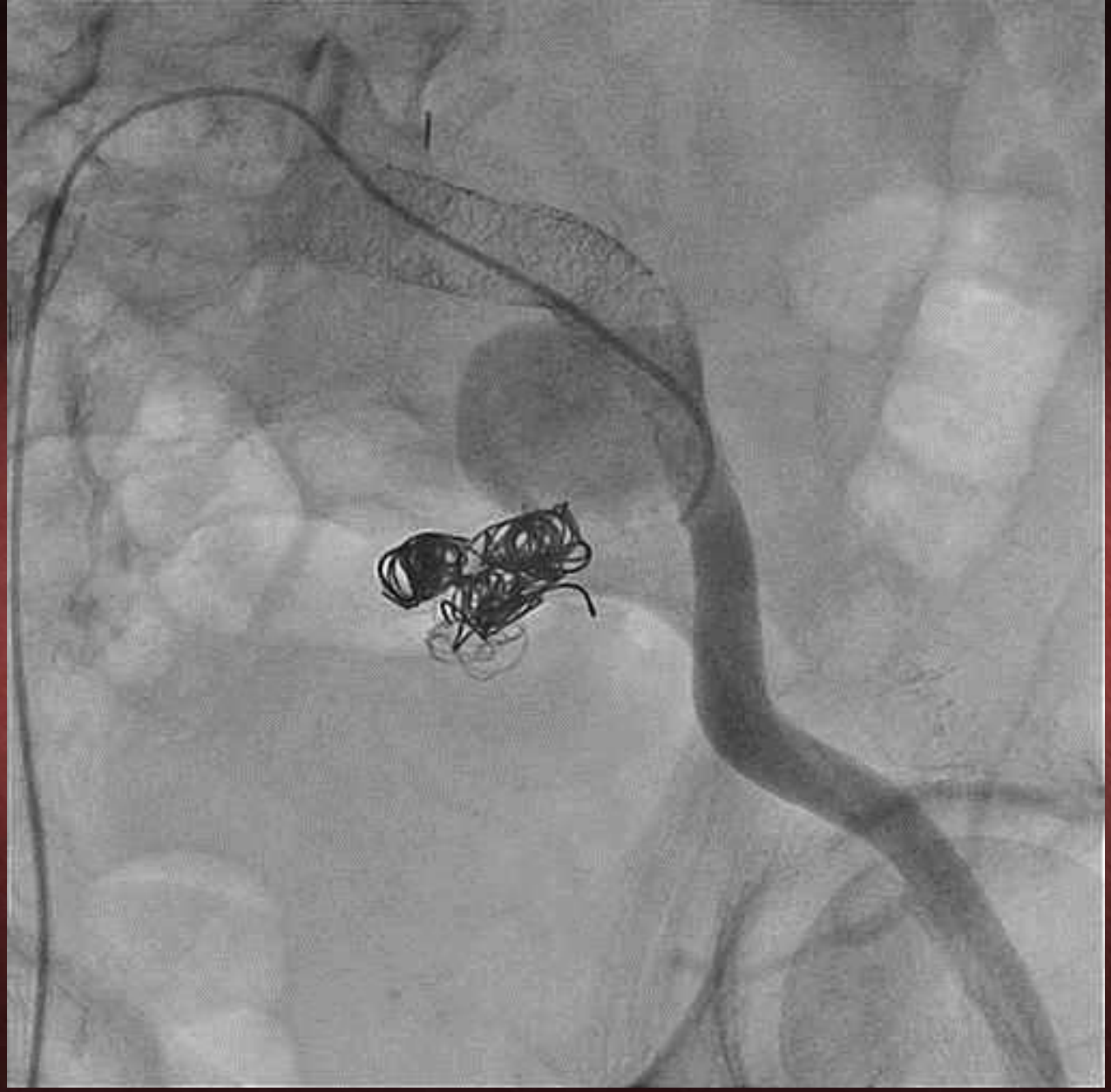
N. Engl J Med 2010; 362:1863-1871. The United Kingdom. EVAR Trial Investigators.

EVAR Failure

- Progression of aortic disease results in a loss of proximal seal and late failure from poor proximal attachment
- Type I endoleak
- Pressurization of the aneurysm sac

Johnstone JK, Oderich GS. Mechanisms of EVAR failure and new surveillance strategies. Cover Story. *EuroIntervention Today*. February 2014; 63-68.





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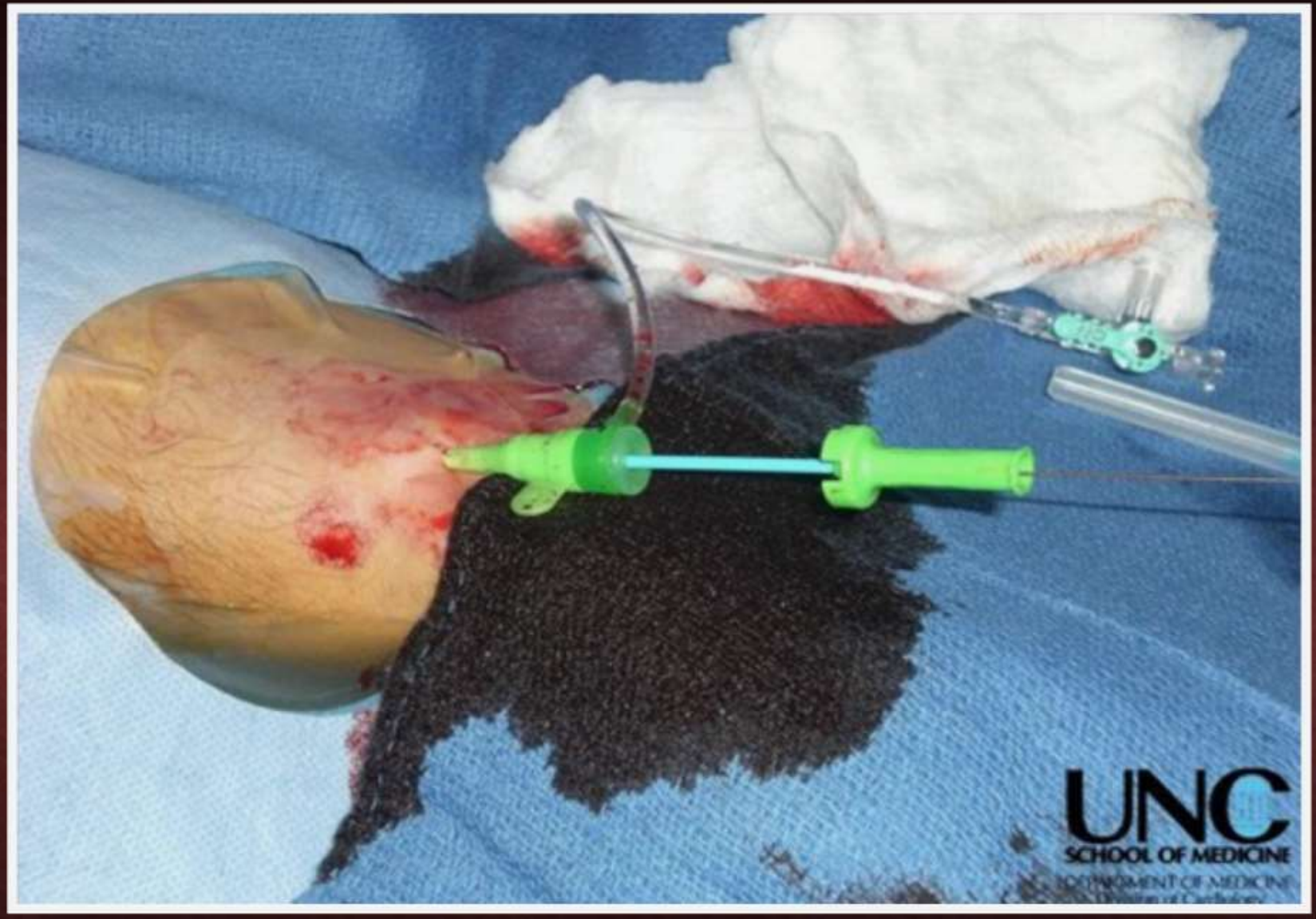

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A 47 year old white male presented with infra-renal abdominal aortic aneurysm that was symptomatic

- His CT angiogram revealed a very proximal left interior iliac artery and a dissection of the left common iliac artery.

Figure 1 -- Angiogram showing abdominal aneurysm with left common and external iliac dissection. Note the proximal takeoff of the left internal iliac artery.

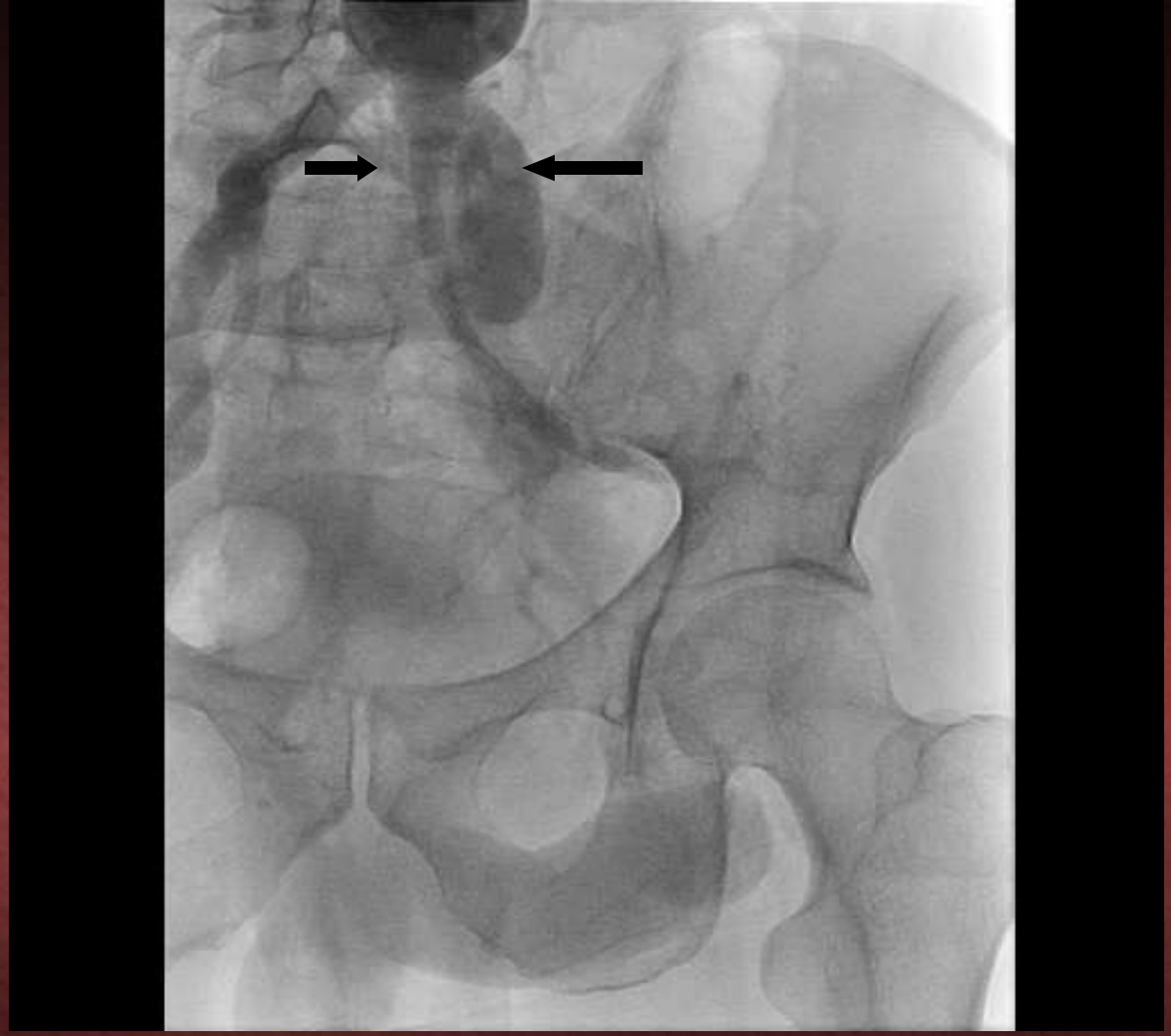

Figure 2 -- Large arrow showing chronic dissection of left common iliac artery.
Small arrow showing proximal take-off of left internal iliac artery.

Figure 3 -- Selective angiogram of the left internal iliac artery.

Figure 4 -- Angiogram of left internal iliac artery post coil placement.

Figure 5 -- Final result post endograft placement. Note there is no flow noted in the left internal iliac.

EVAR


OUCH!

Post Implant Syndrome

- Back pain
- Fever
- 50% of cases
- 2-3 days (up to 7)
- Negative cultures
- No increase in white blood count
- Usually benign

Endoleak

- Implies persistent blood flow outside of the lumen of the endograft and with the aneurysm sac…resulting in incomplete exclusion
- Main target of surveillance protocols
- Persistence of a Type II endoleak on follow-up imaging correlates with sac enlargement, reintervention, rupture and the need for open repair

Johnstone JK, Oderich GS. Mechanisms of EVAR failure and new surveillance strategies. Cover Story. *EuroIntervention Today*. February 2014; 63-68.

Endoleak

- Fix at the time of procedure
- Don’t convert to open repair

Primary Endoleaks

- Present at first imaging study
- Occur 20-25% of patients
- Majority are Type II (>95%)
- These are independent of device selection
- If there is no sac growth, there is a relatively benign course

Johnstone JK, Oderich GS. Mechanisms of EVAR failure and new surveillance strategies. Cover Story. *EuroIntervention Today*. February 2014; 63-68.

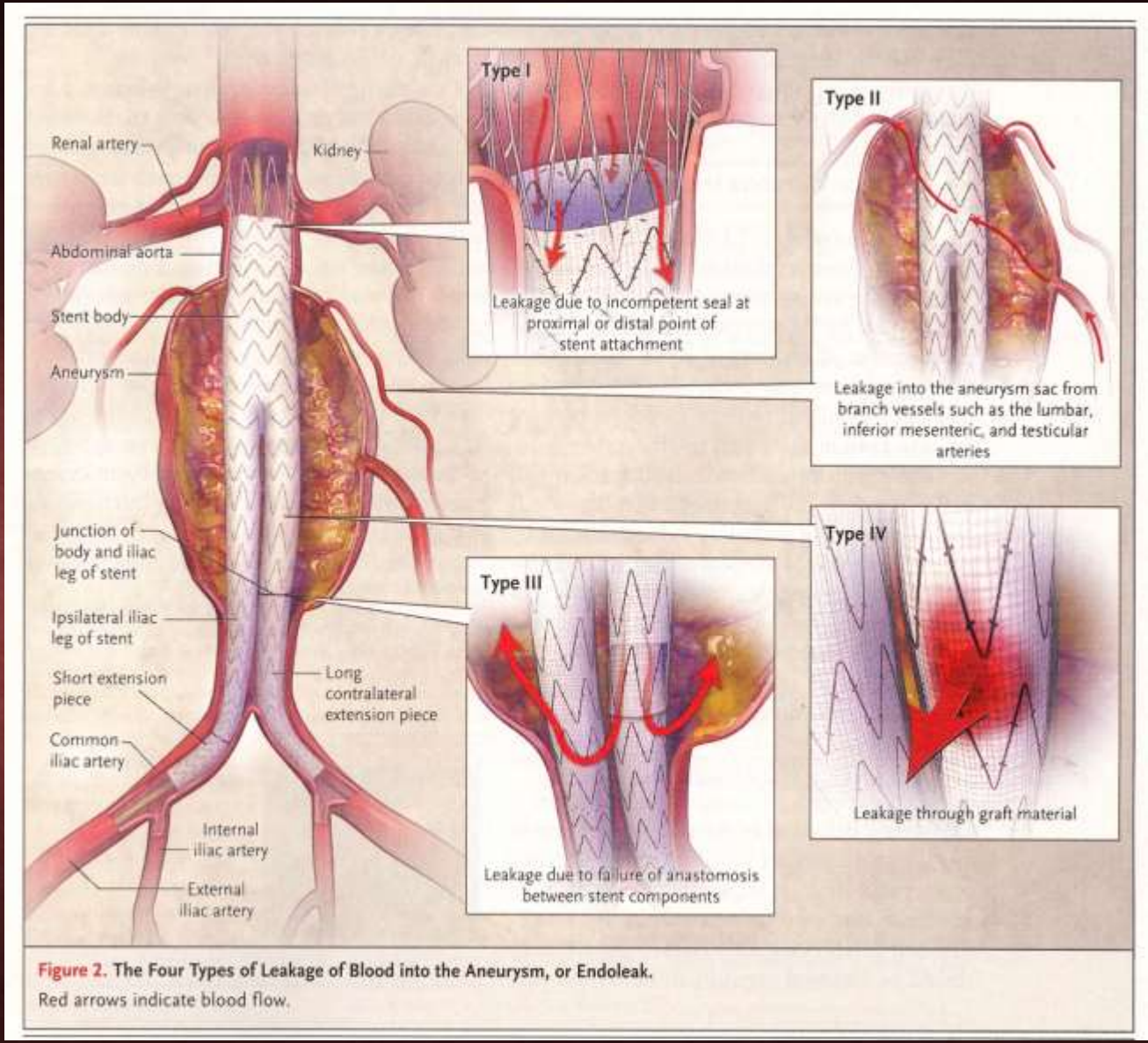

Figure 2. The Four Types of Leakage of Blood into the Aneurysm, or Endoleak.
Red arrows indicate blood flow.

N Eng J Med 338;5, January 31, 2008, p. 499

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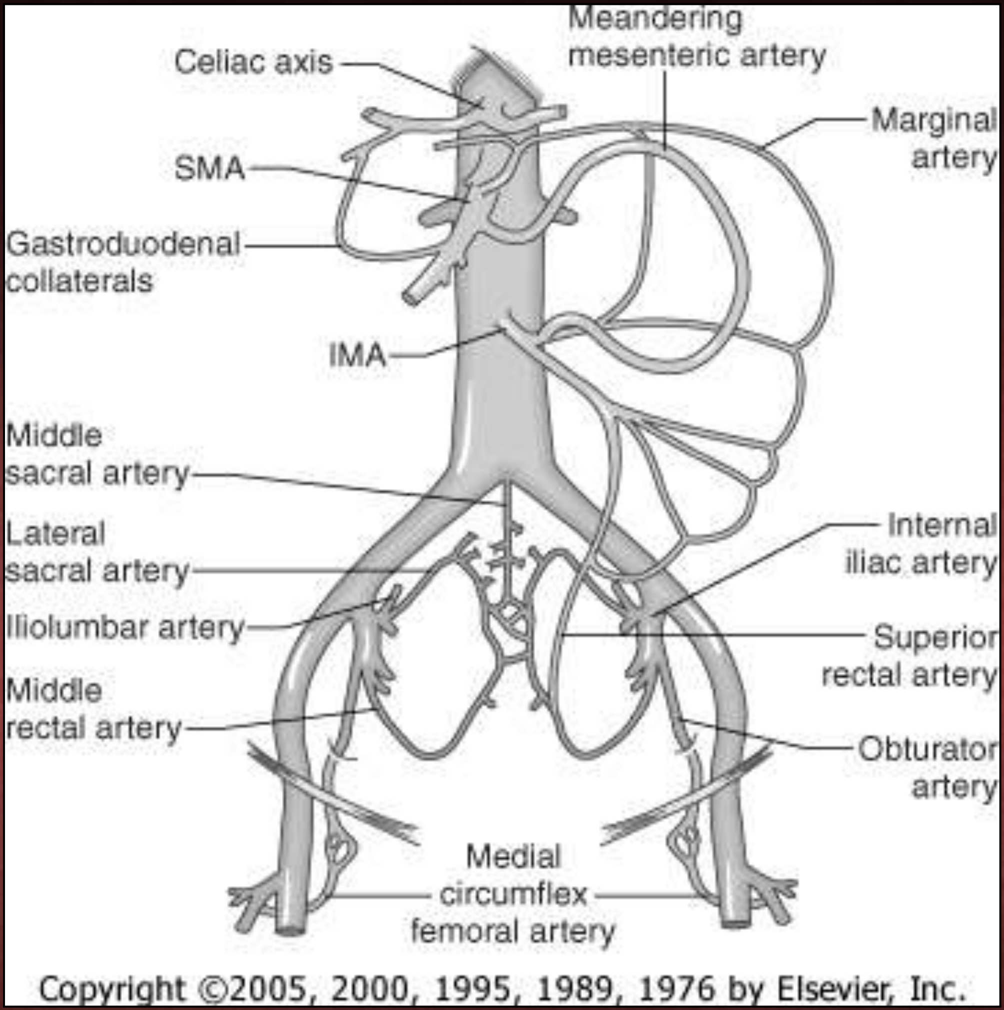
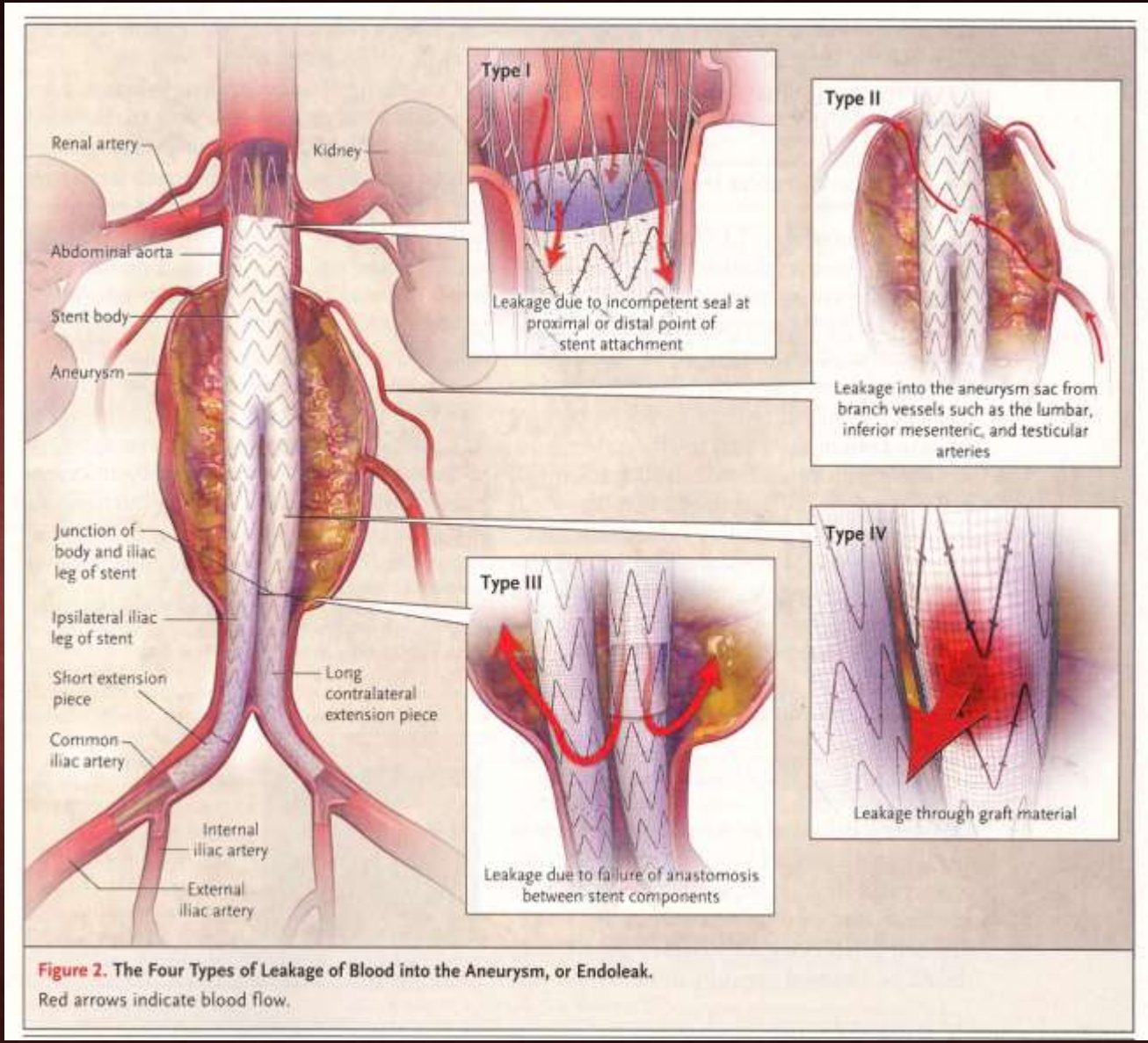


Figure 100-13 Important collateral pathways for the sigmoid colon and pelvis. IMA, inferior mesenteric artery; SMA, superior mesenteric artery. (From Bergman RT, Gloviczki P, Welch TJ, et al: The role of intravenous fluorescein in the detection of colon ischemia during aortic reconstruction. Ann Vasc Surg 6:74, 1992.)

AAA Endovascular Repair Follow Up

- 1 month CT
- 6 month CT
- 12 month CT
- 18 month CT
- Yearly CT

What about MRI or Abdominal Ultrasound?



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Type I Leak
All should be treated

- Extension cuff with noncompliant balloon
- When close to renal artery and persists a Palmaz stent
- Distal leaks can be repaired usually with extension limbs or cuffs (sometimes to the external iliac with coil embolization to the hypogastric)

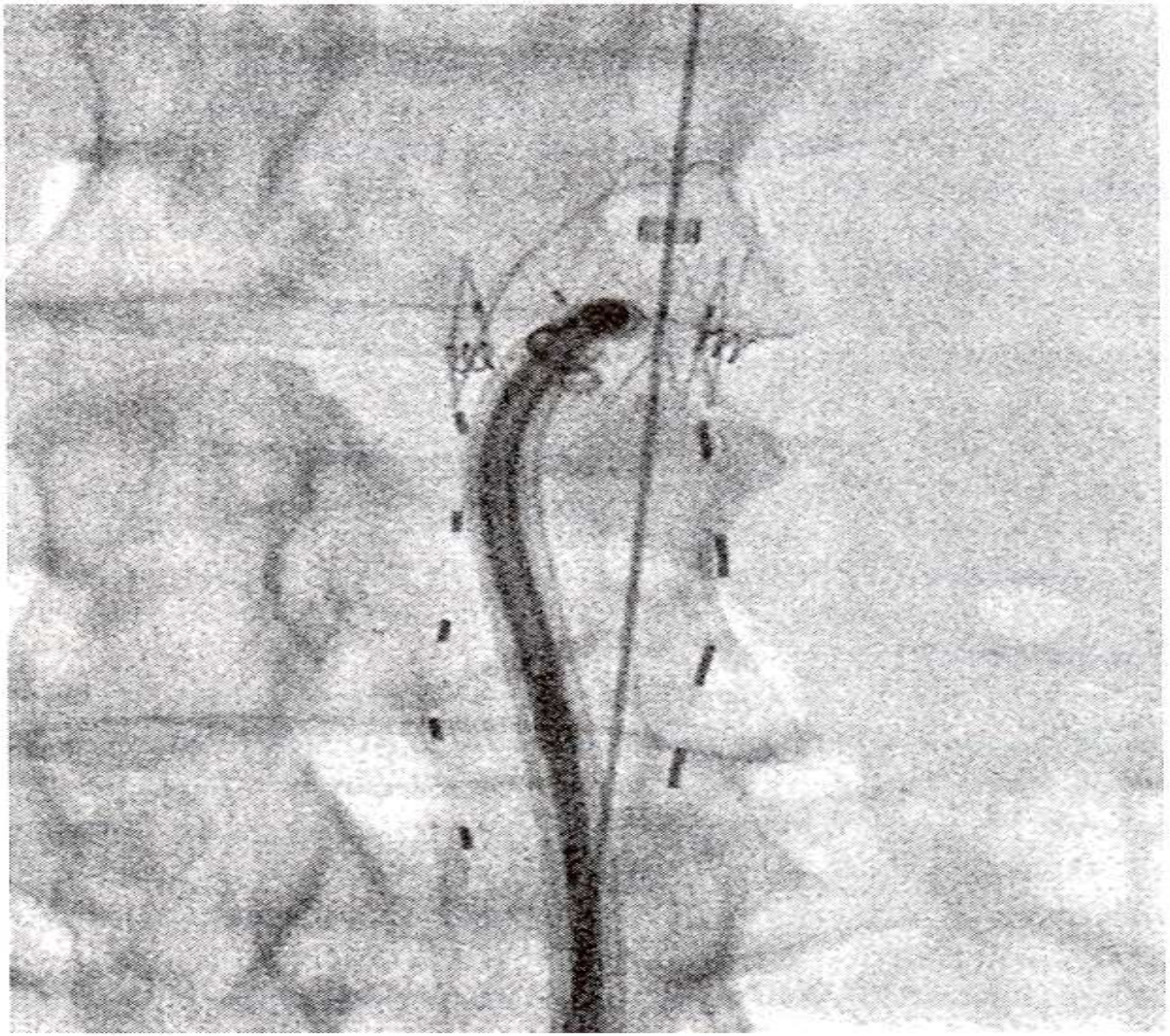
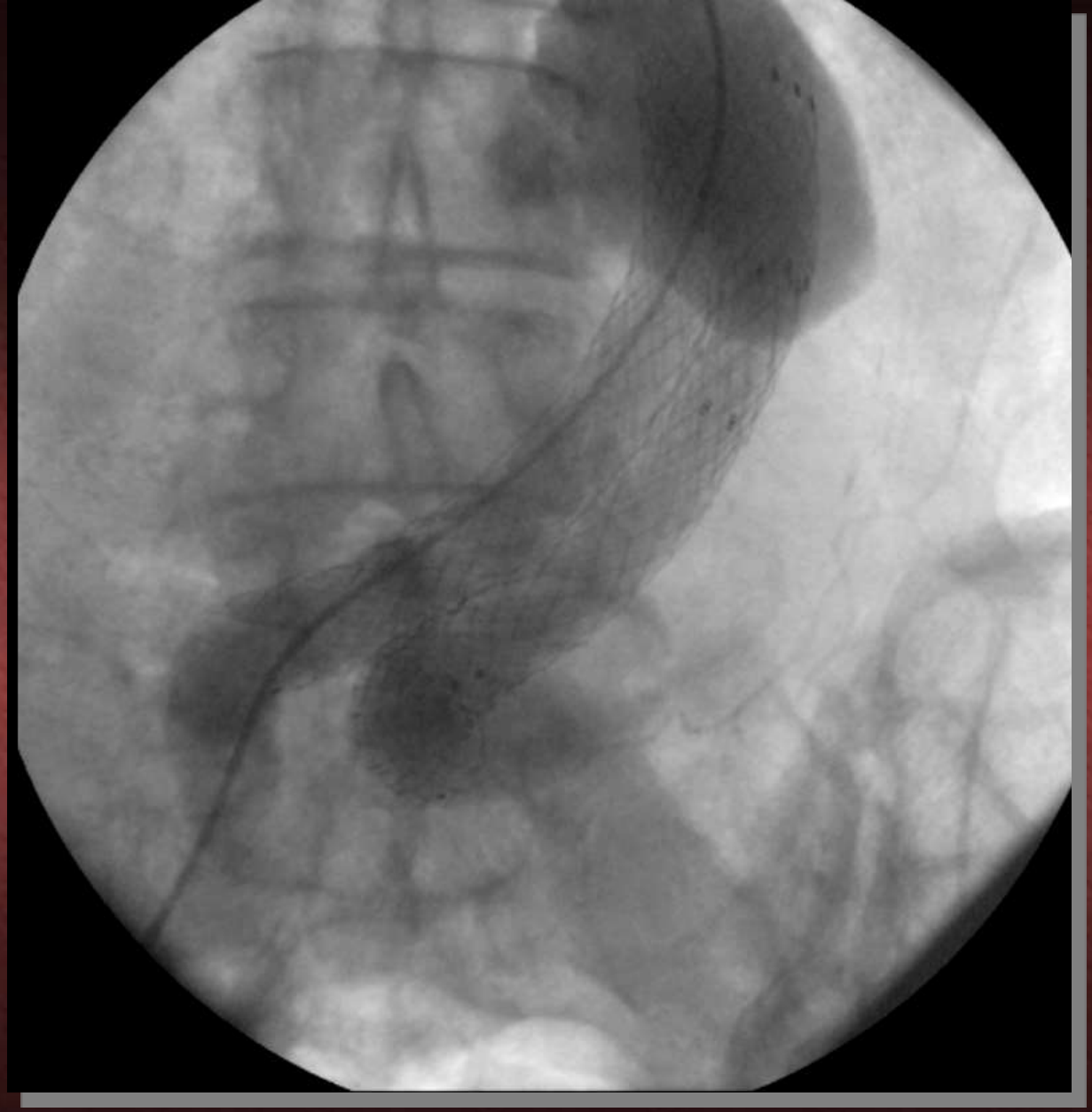


Fig. 9 *Nitinol stent frame of the Aptus device in the infrarenal aorta. Endostaples can be seen affixing the graft to the vessel wall.*



Juxtarenal: Zenith® Fenestrated

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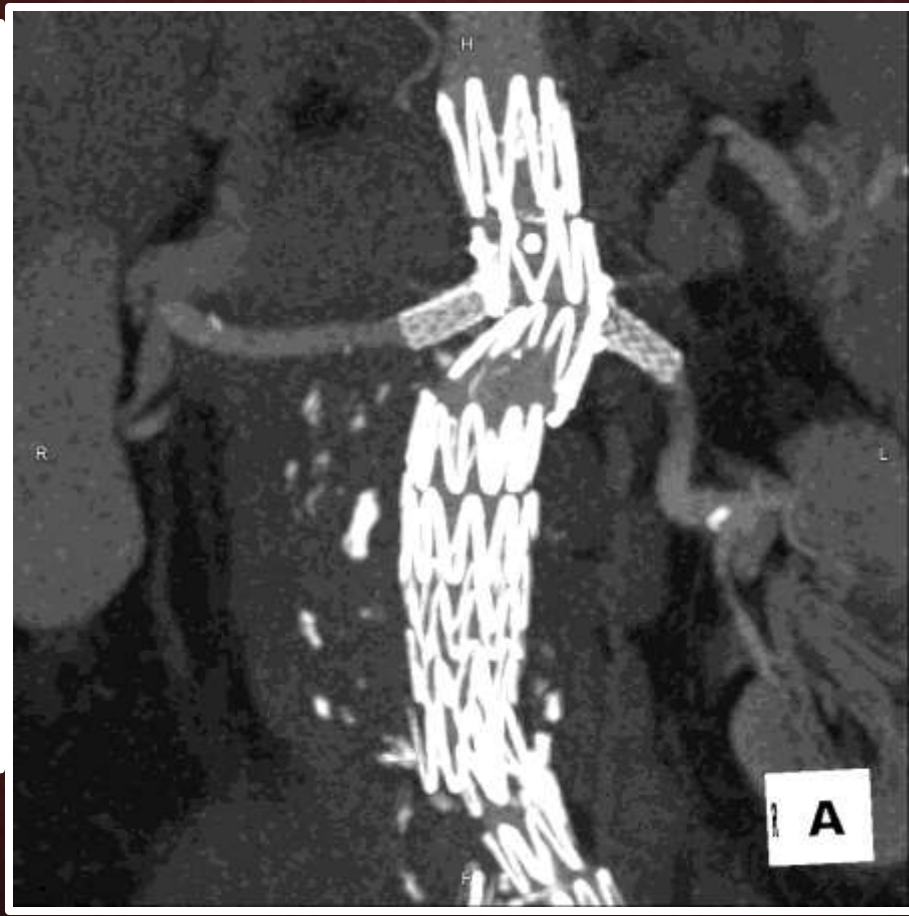

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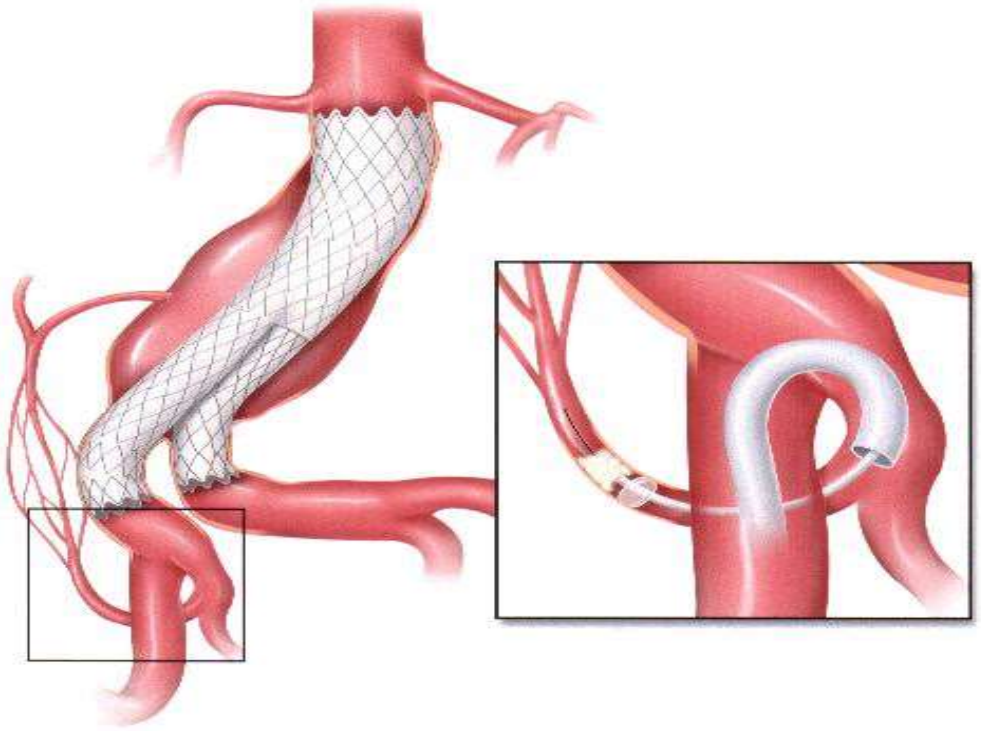
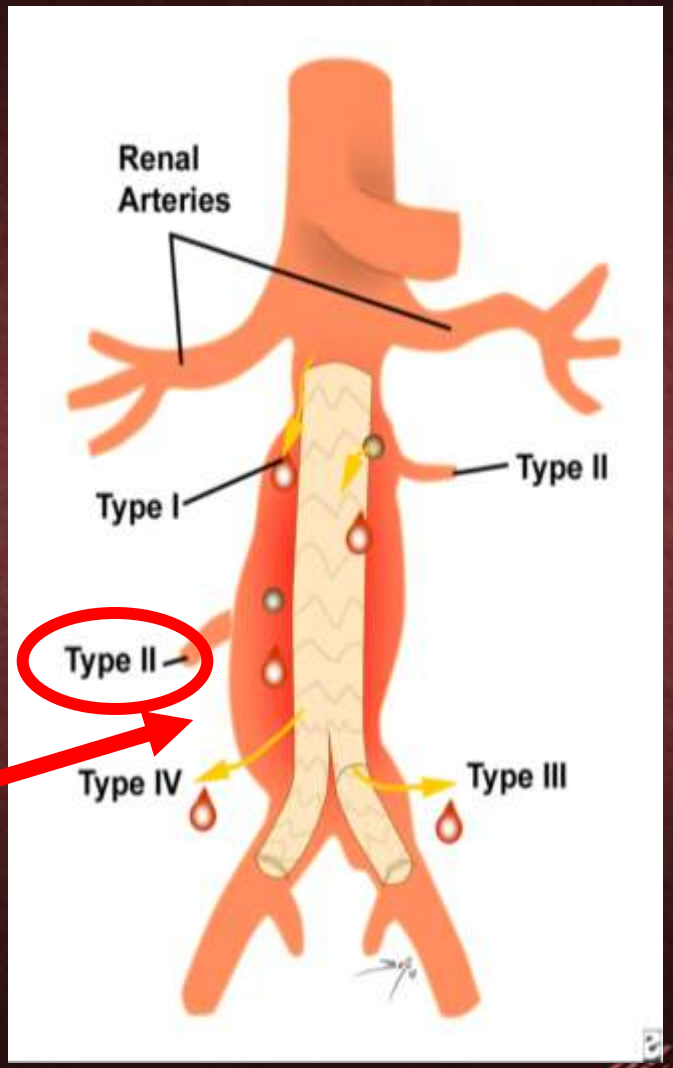
Type II Leak

- Extension cuff with noncompliant balloon
- If persistent and greater than 5mm growth after implant should be treated
- TLA needle cyanoacrylate glue



Type II Endoleak

- **Arterial branches** that give rise to type II endoleaks:
  - Inferior mesenteric artery
  - Lumbar arteries
  - Internal iliac arteries
- ??Natural history
  - Poorly understood
  - ??Management
  - **Benign *versus* late rupture**



Type II Endoleak

Sidloff, D.A. et. al.

British Journal of Surgery. 2013; 100:126-1270.

1. Incidence = **10.2%** (10-48 mos follow-up; n = 14,794 pxs)
2. Outcome:
    1. Spontaneous resolution = **35.4%** (3 mos to 4 years)
    2. Rupture = **0.9%**
        1. 8/14 = **57%** with (+) sac expansion
        2. 3/14 = **21%** NO sac expansion
    3. Open surgical repair = **1.4%** (21/1515 patients)
    4. Intervention (Embolization) ~ **26%**
    5. Success = **71.5%**

Type II Endoleak: What to do?

- Unlike other endoleaks, i.e. Type I & III, no urgency for immediate intervention

  Key: **Close surveillance imaging study** with continued monitoring of aneurysmal sac size

Type II Endoleak: What to do?

- Unlike other endoleaks, i.e. Type I & III, no urgency for immediate intervention

  Key: **Close surveillance imaging study** with continued monitoring of aneurysmal sac size

- **Rupture is rare <1%**
  - 1/3 with NO sac expansion
  - ??use of sac expansion as a surrogate marker for risk of rupture

Type II Endoleak: When to treat?

- **NO aneurysmal sac expansion**
  - Conservative ~ 'watchful waiting'
  - Majority resolve spontaneously during the 1st 6 months post-EVAR
- **WITH Aneurysmal sac expansion**
  - Growth of > 10 mm
  - Intervention – Endovascular 'repair'
- **'Open' surgical repair**
  - Failure of endovascular treatment

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Type II Endoleak: Treatment options

- **Embolization** – most common approach
  - Access – Transarterial or via direct sac puncture
- **Direct sac puncture**
  - Translumbar
  - Caval-aortic
- **Laparoscopic clipping**
- **'Open' surgical repair/conversion**

Transarterial Embolization

- Percutaneous arterial access
  - Transfemoral
  - Transbrachial
  - Radial approach
- Goal
  - Catheterize the nidus of the endoleak selectively via its collaterals – ideally at the ostium of the 'feeding' vessel
  - Treating type II endoleak arising from the IMA if there is a clear path from the SMA

Type II Endoleak

- Treatment options:
  - Embolization
    - **Transarterial embolization**

      Success = 62.5% (15-89%)
    - Translumbar embolization

      Success = 81% (67-100%)
  - Direct sac puncture
  - 'Open' surgical repair
  - Laparoscopic clipping

Type II Endoleak: Transarterial Embolization

- **"Failure"** of embolization:
  - **Persistent blood flow** through the coils of the treated endoleak
  - Development of **anastomoses** around the coiled vessel
  - **NOT able to embolize both** the vessel and the aneurysm sac

Sidloff, D.A. et. al. *Bristish Journal of Surgery.* 2013; 100:126-1270.

Type II Endoleak: Post-intervention

- ??large number of patients do not end with a 'stable' or decreasing aneurysm sac
  - Not associated with a significant increase in aneurysm rupture
    - Decreasing perfusion → reduce risk of rupture

      Inability to eradicate a type II endoleak does not equate to clinical failure

Translumbar Embolization

- Needle through the retroperitoneum at the level of the endoleak and advancing under imaging guidance, anterior to a vertebral body, to access the aneurysm sac
  - Performed from the left side of the patient to avoid the IVC
    can be performed also from the right side
  - Imaging guidance: Fluoroscopy, CT-scan
  - **'Higher' success rate** > transarterial technique

Type II Endoleak

- Treatment options:
  - Embolization
    - **Transarterial embolization**

      Success = 62.5% (15-89%)
    - **Translumbar embolization**

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  - 'Open' surgical repair
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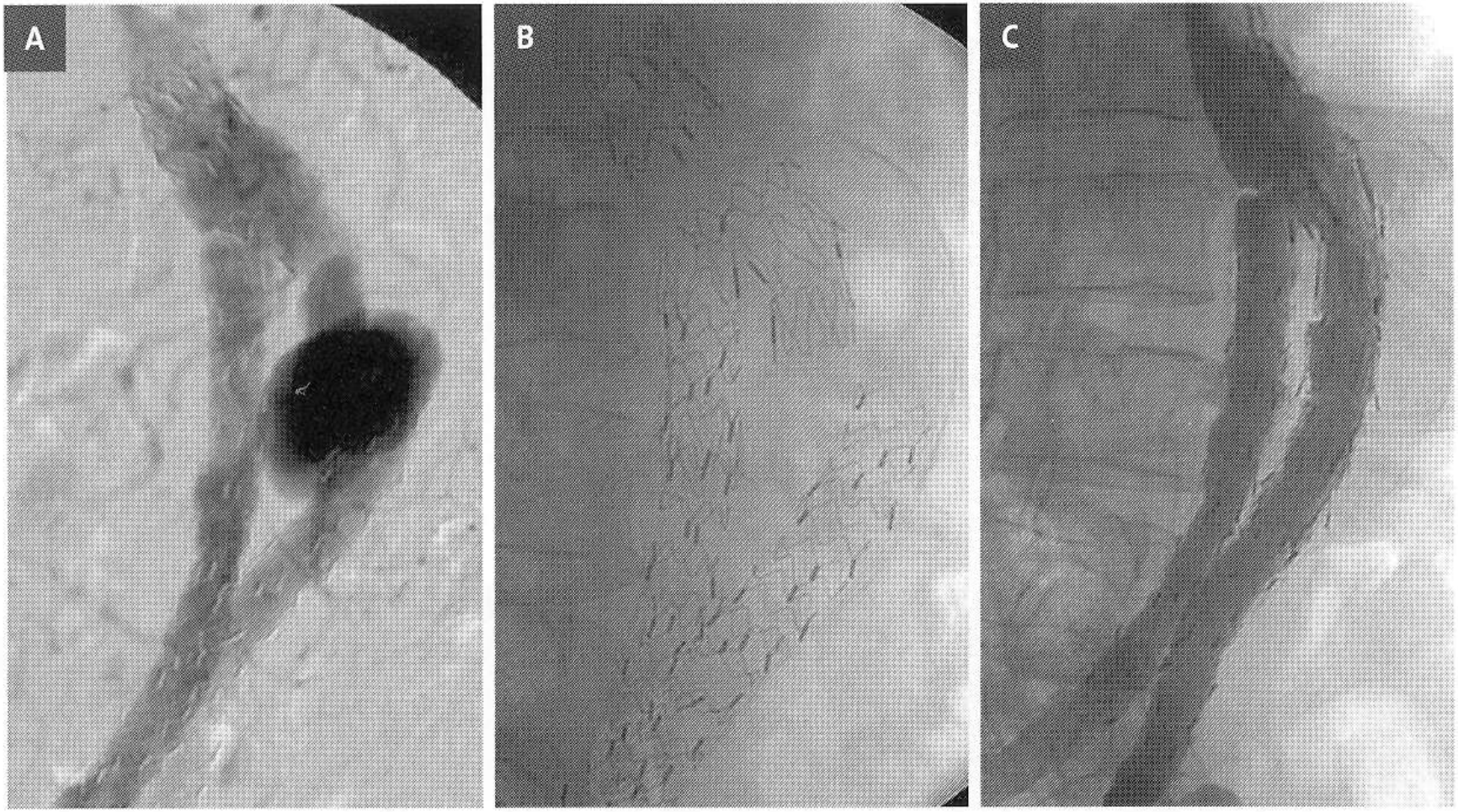
Type II endoleaks

- Things to ponder about?
  - **Occlude the 'source'**
    - Prophylactic' embolization/coiling of IMA, lumbar arteries
  - **Exclude the 'cavity'**
    - Nellix device

Summary: Type 2 endoleaks

- The most common 'complication' post-EVAR that usually spontaneously resolve with time. Rarely (<1%) can result in aneurysm rupture if with continued pressurization of the aneurysm sac.
- Long-term follow-up with close surveillance imaging study is mandatory to detect any endoleaks. Majority of which can be treated with endovascular techniques.
- Open surgical repair should be considered of the risk of aneurysm rupture is high.



Type III endoleak due to separation of the contralateral leg from the main body (a, b) treated by insertion of a stent graft (c).

Type III Leak

- Leak should be treated with a bridging endograft
- Relining if room between the renal arteries and bifurcation of the original endograft

Type IV Leak

- Heparin off
- Usually no Rx

TYPES, ETIOLOGY, AND TREATMENT OF ENDOLEAKS

Type	Etiology	Treatment
1	Attachment Site	PTA, Balloons, Stents
2	Collaterals	Embolization
3	Graft Failure	Graft Repair
4	Pourosity	No Treatment Needed

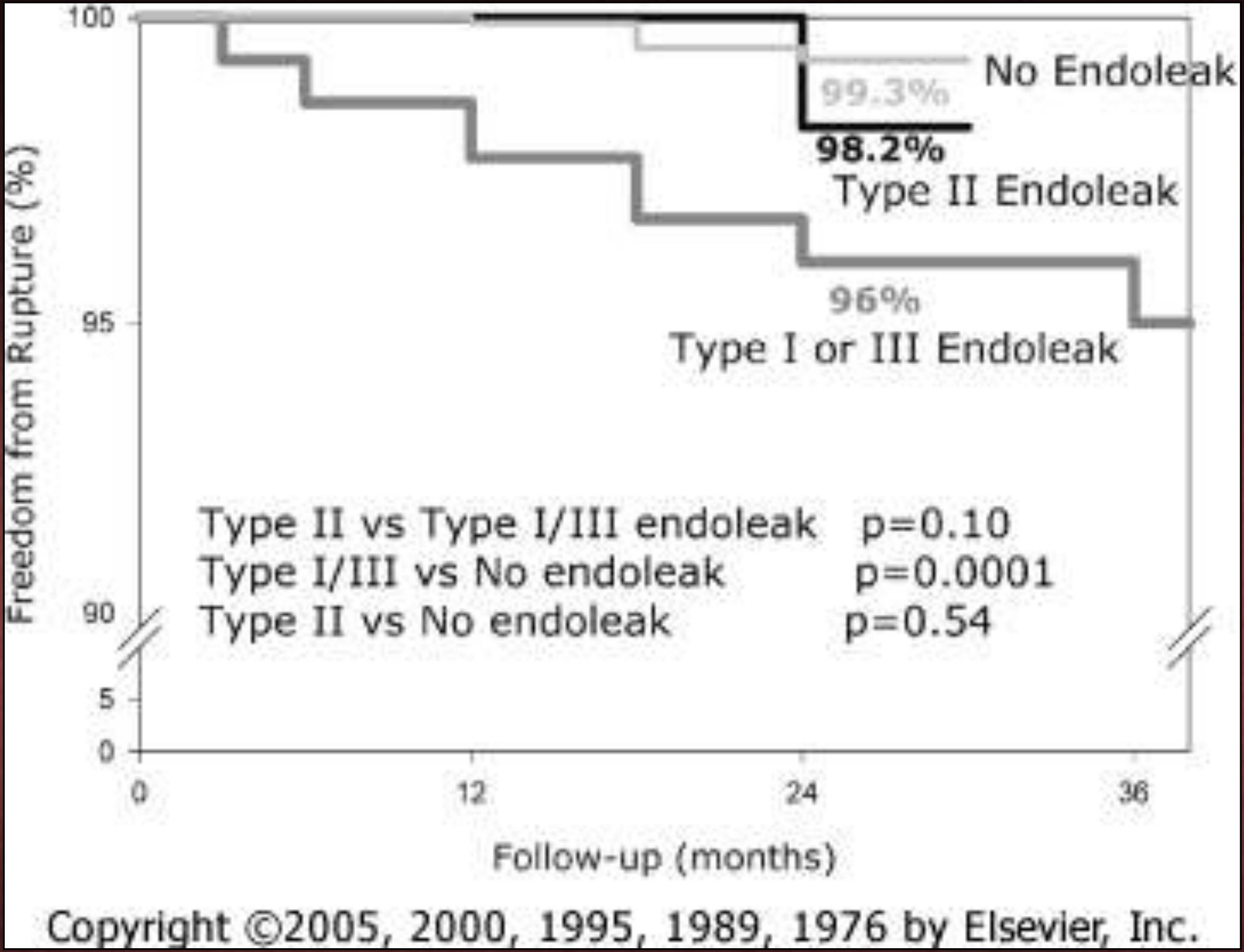
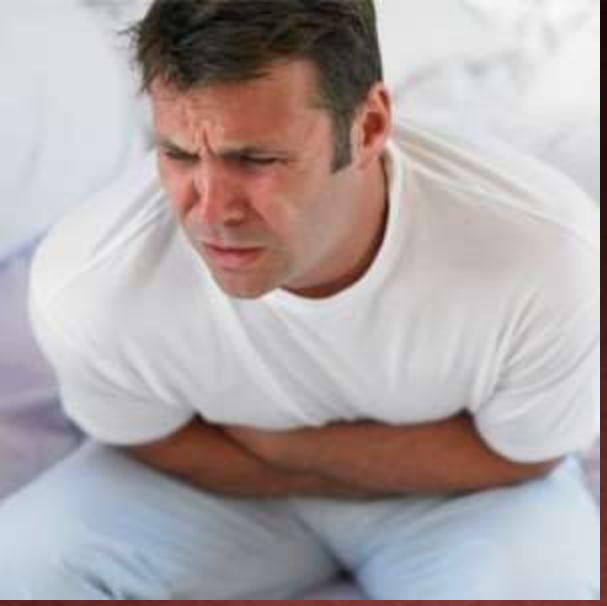


Figure 101-8 Freedom from aneurysm rupture after endovascular aneurysm repair in patients categorized according to endoleak: with isolated type II endoleak, with type I or type III endoleak, and without endoleak. (From Van Marrewijk C, Buth J, Harris PL, et al: Significance of endoleaks after endovascular repair of abdominal aortic aneurysms: The EUROSTAR experience. J Vasc Surg 35:461-473, 2002.)

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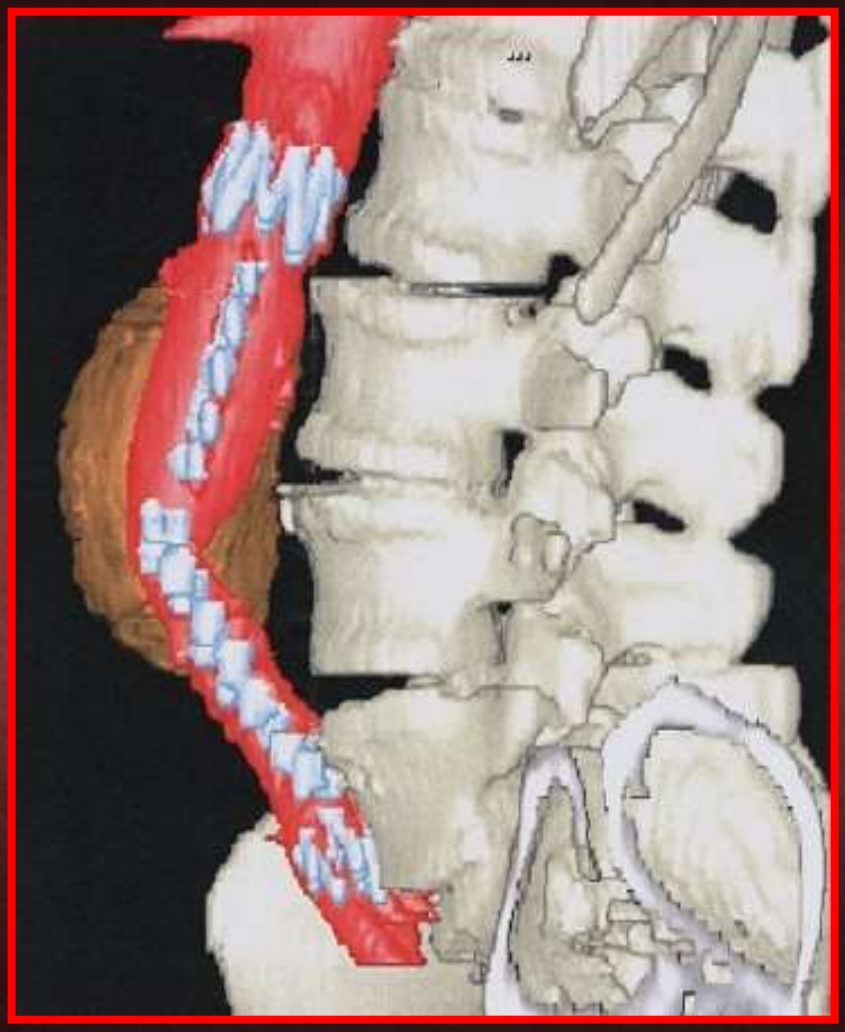


Abdominal Aortic Aneurysm Surveillance

- In patients with small aneurysms
- After endograft
- After open repair
- Many of these patients have renal insufficiency

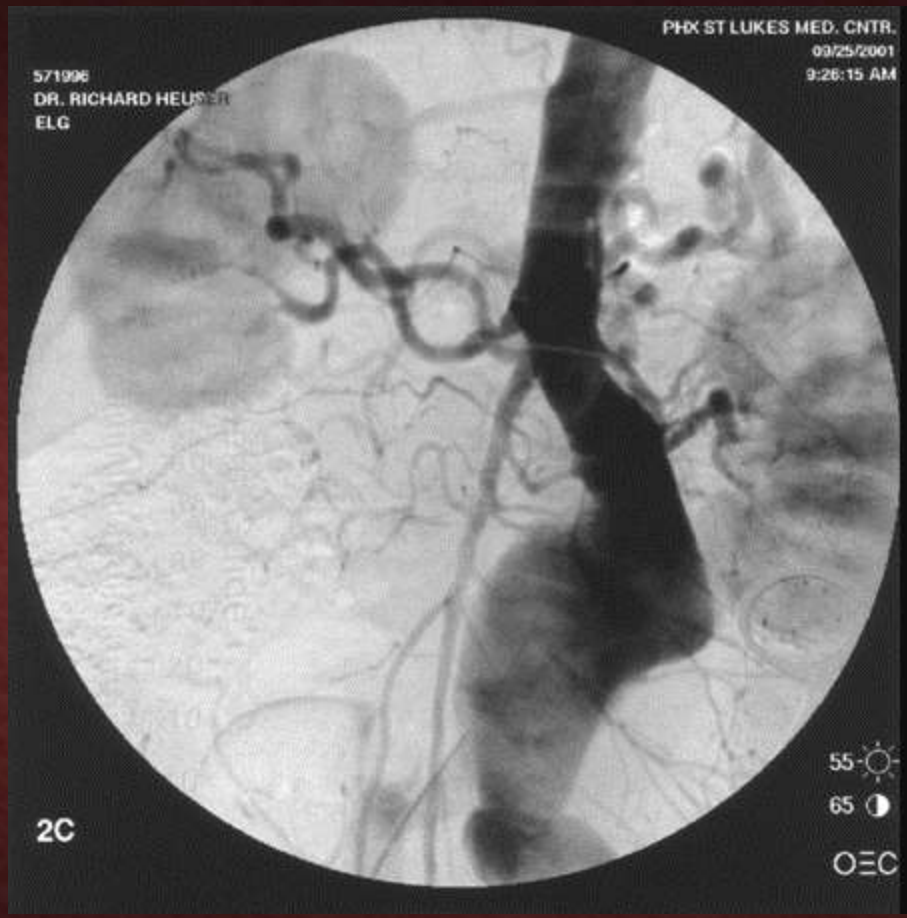
EVAR: Long term follow-up

- Post-EVAR – require long-term follow-up to evaluate for complications, i.e. endoleaks
- Follow-up surveillance imaging study
  - 1 month, 6 months, 1 year then q yearly
  - Endoleaks – Type I, II, III

  **** 20-40% of patients experience an endoleak at some point.**
  - Monitor aneurysmal sac size => Gradual diminution is to be expected

EVAR follow-up: Surveillance study

- Imaging Modality
  - **CT-scan** with contrast/CTA
    - ??standard-of-care
    - Most frequently used
    - Sensitivity & specificity superior
    - *Cons:* Radiation exposure, CIN
  - **Ultrasound-duplex scan**
    - Sensitivey = 77%, specificity = 94%
  - **MRI**
- Others: Direct/indirect sac measurements, nuclear scans → NOT stand-alone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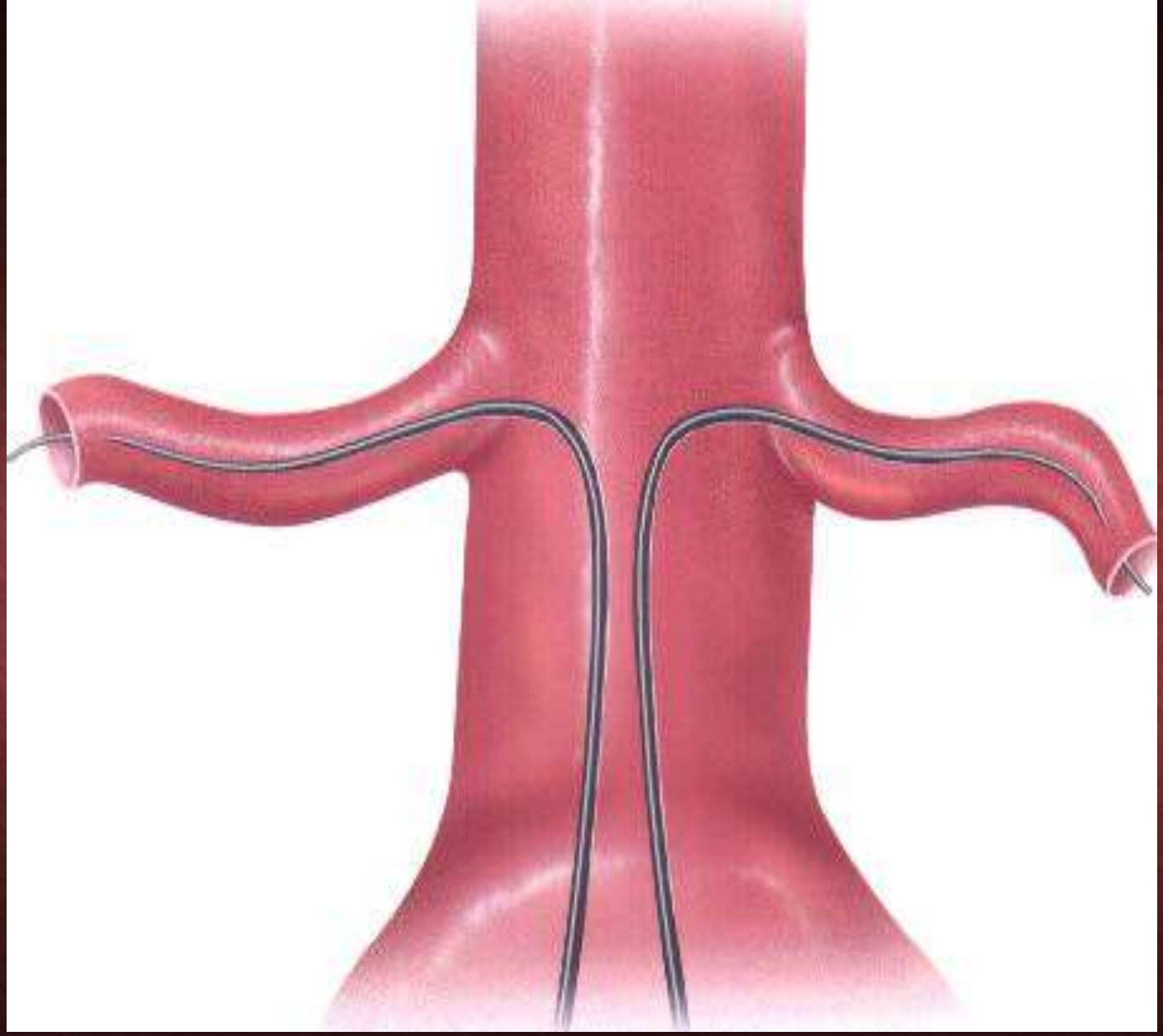
BUSINESS/FINANCIAL DESK | June 17, 2003, Tuesday

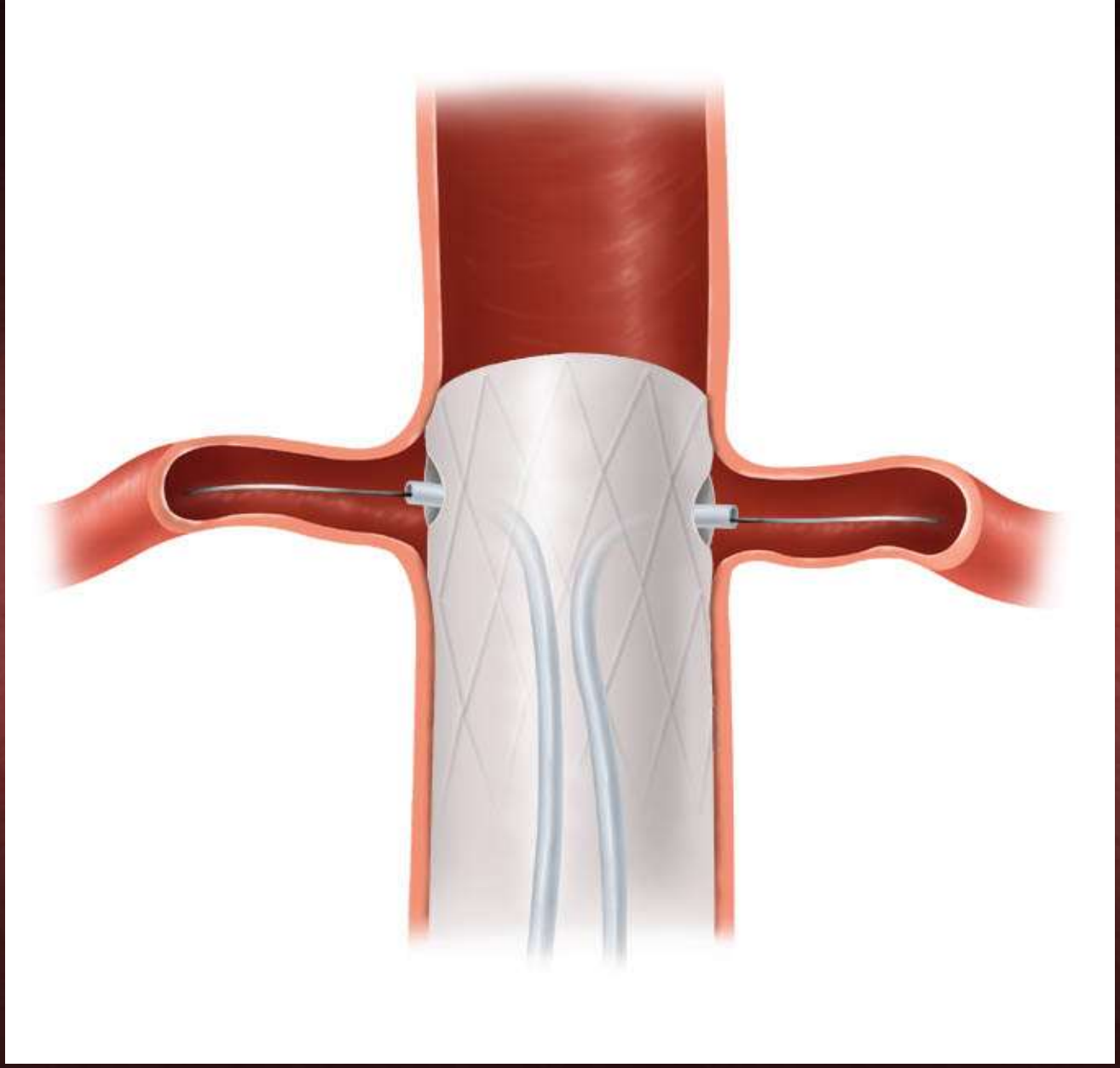
Medical Concern Will Halt Sales Of Artery Device Linked to Deaths

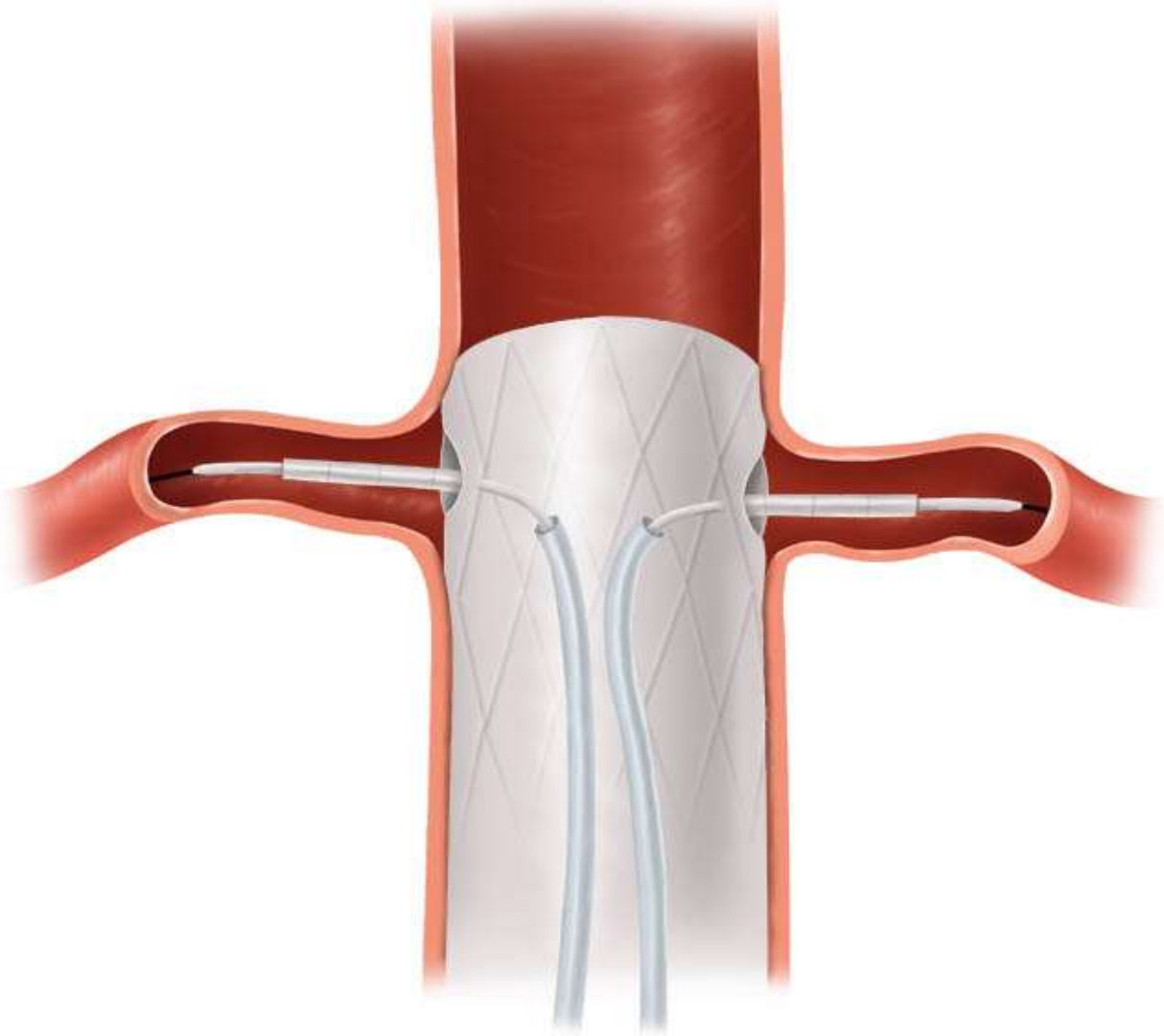
By MELODY PETERSEN (NYT) 746 words

Late Edition - Final , Section C , Page 1 , Column 5

ABSTRACT - Guidant Corp to stop selling device that helps treat weakened abdominal aorta after admitting it concealed thousands of problems linked to product; says 18,000 patients who already have device are safe because problems center on system used to insert it, not device itself; says it will continue to support those patients over years; group chairman Jay Graf says potential liability from dozen suits filed on behalf of patients who died or were injured by device is 'manageable' because product liability insurance will help pay costs (M)







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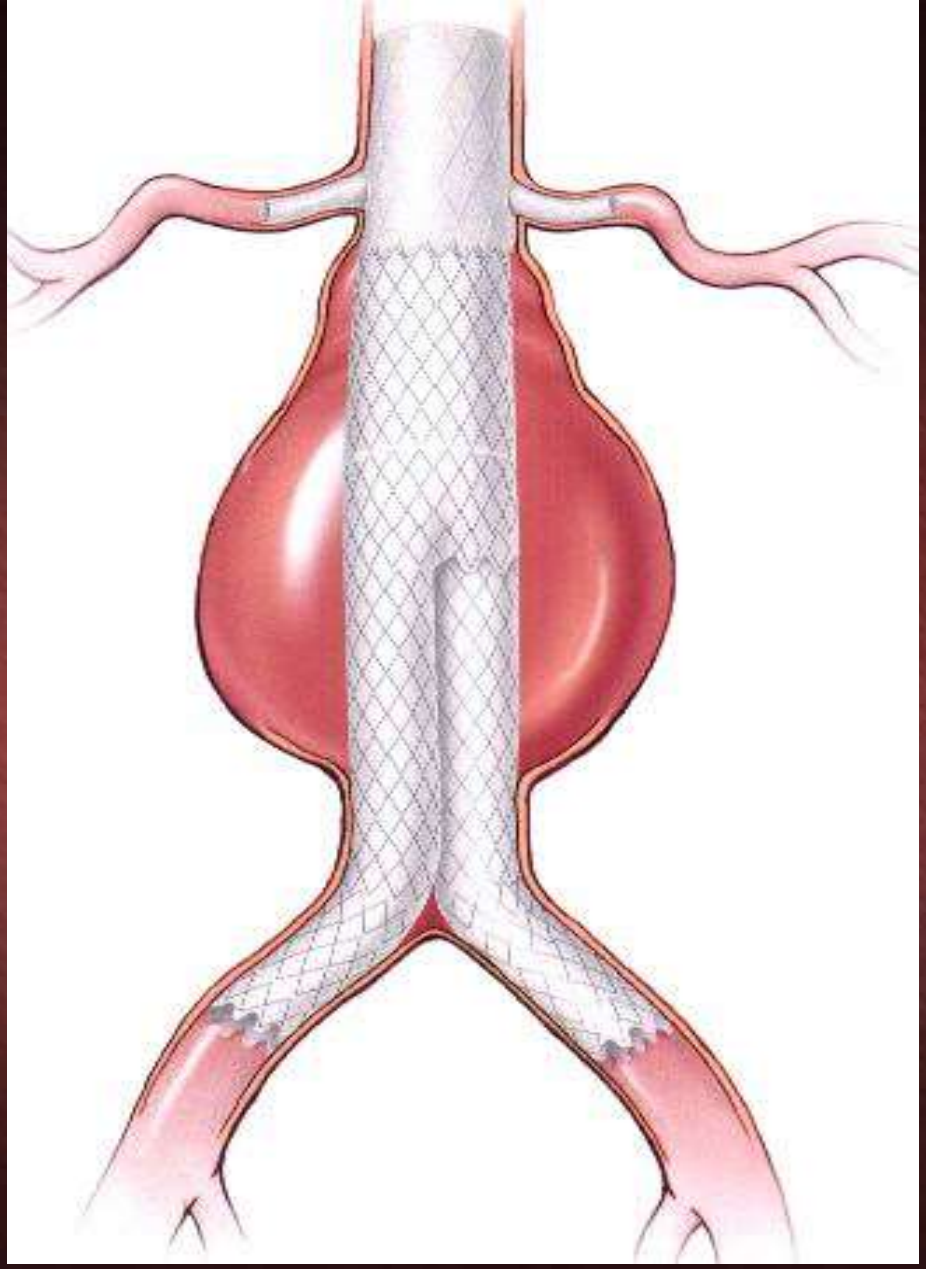
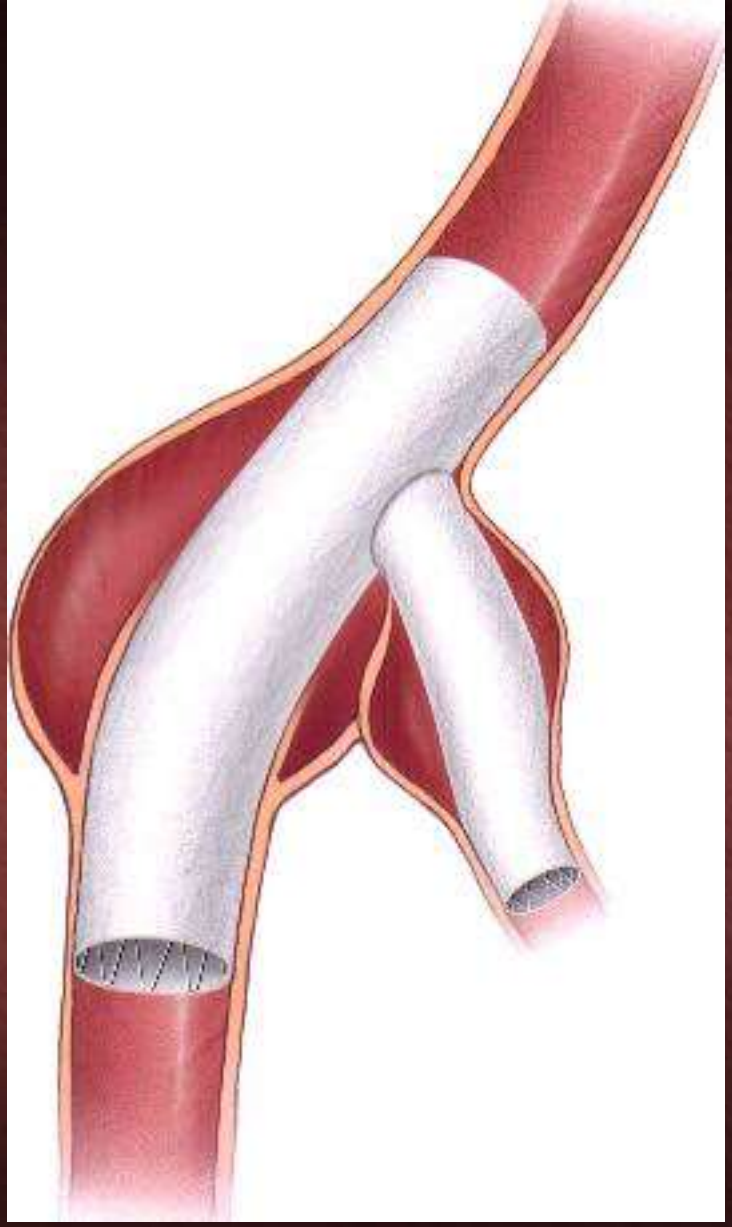
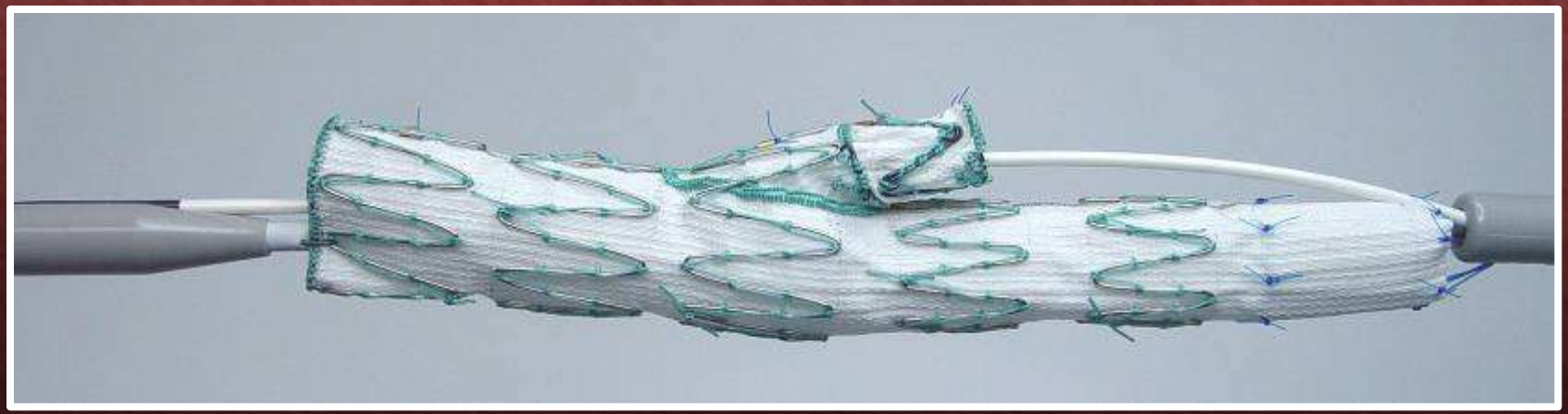




Common Iliac: Zenith® Branch Iliac Endovascular Graft

- Bifurcated Branch



Not available for sale in the U.S.

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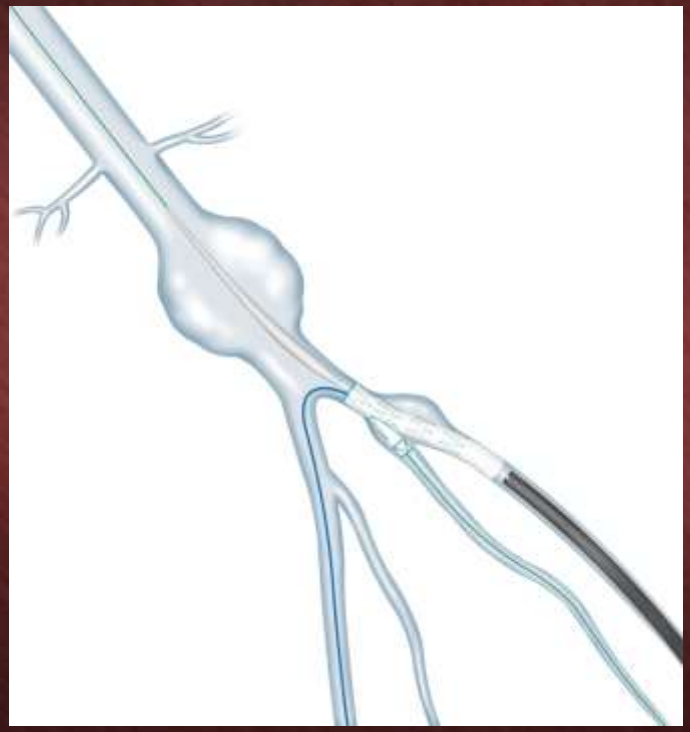
Common Iliac: Zenith® Branch Iliac Endovascular Graft



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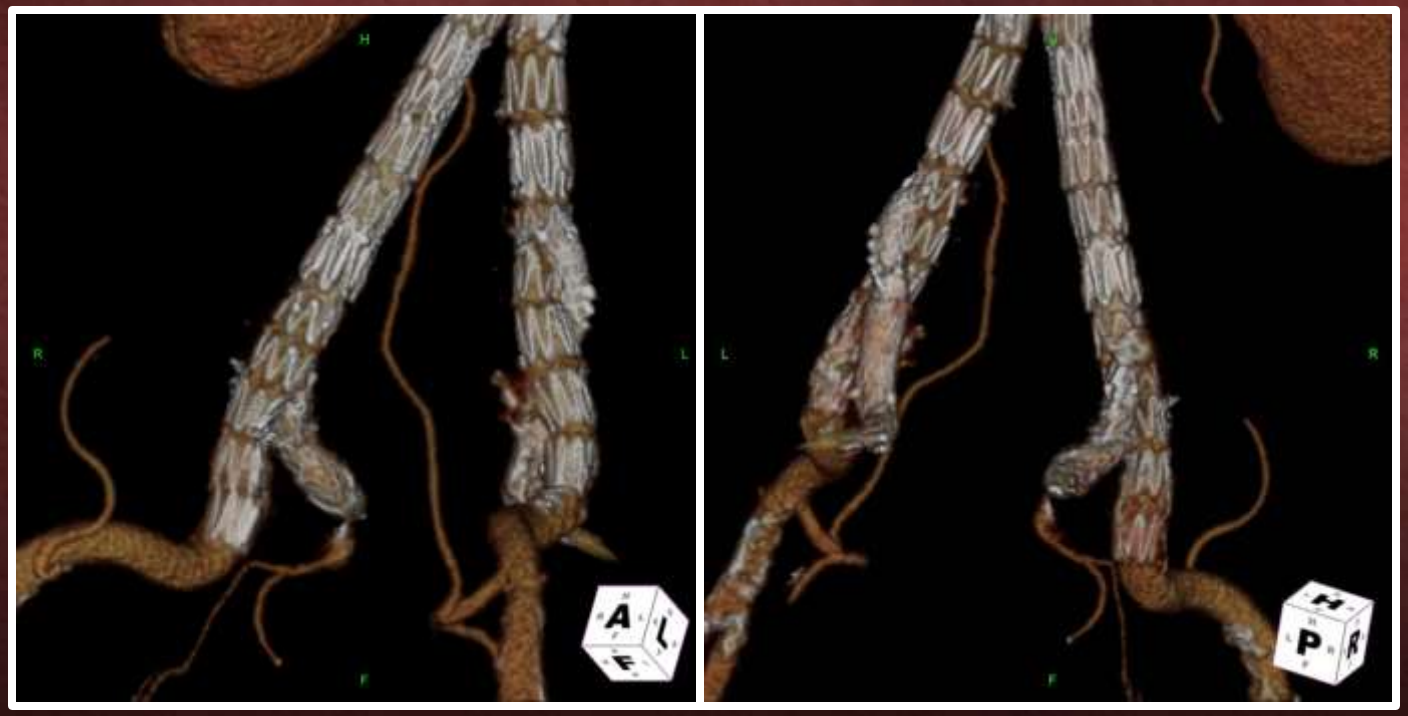
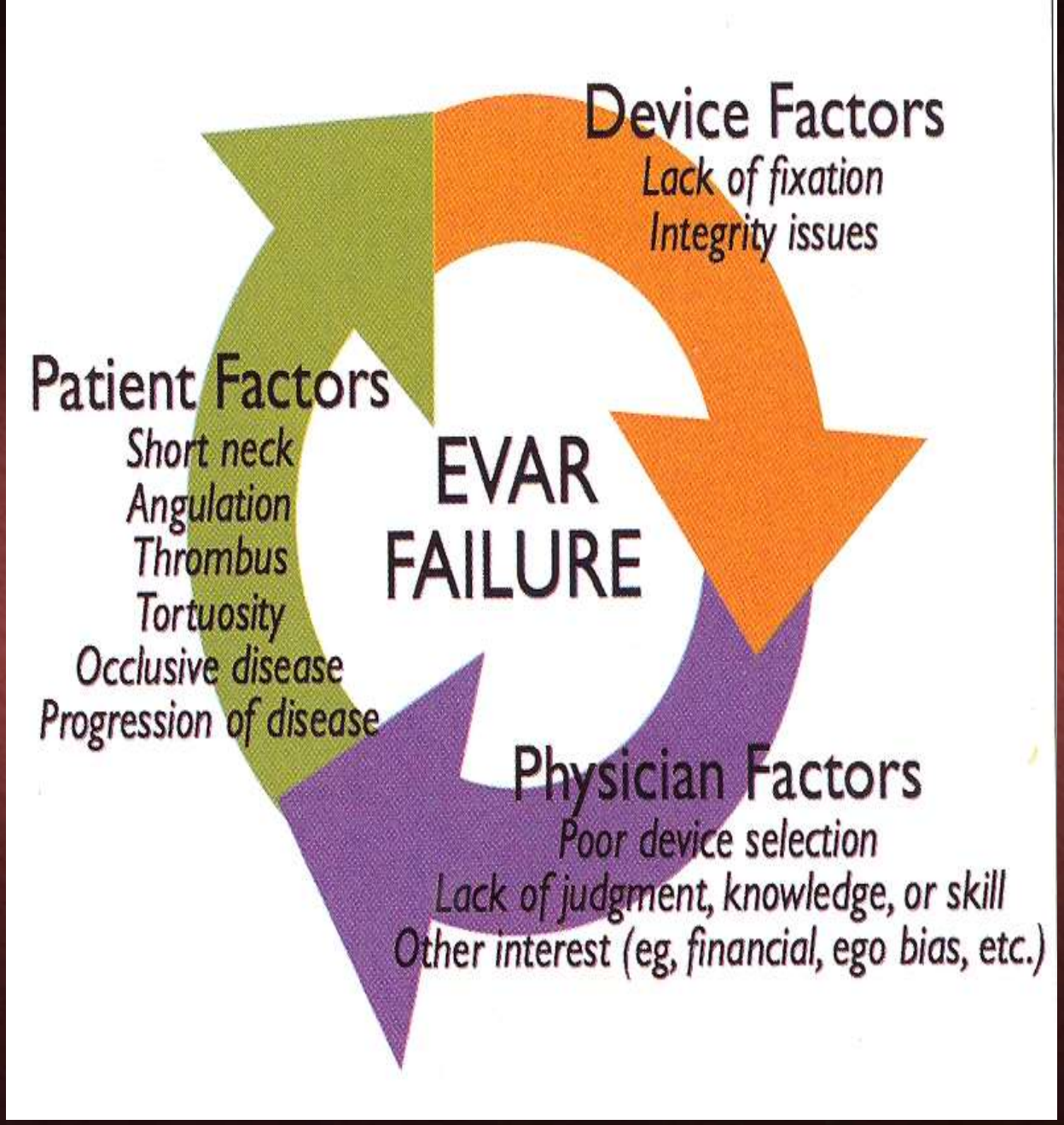
Common Iliac: Zenith® Branch Iliac Endovascular Graft

- Helical Branch





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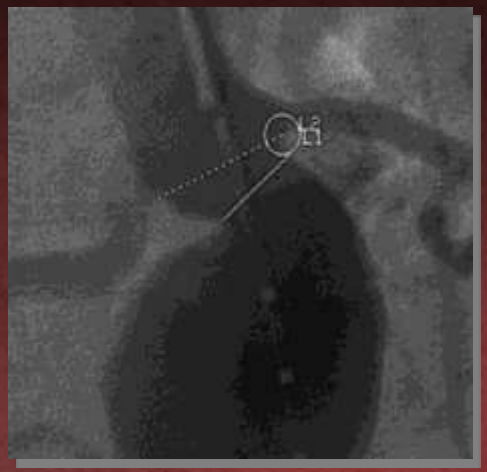
Challenging Infrarenal Aortic Neck Anatomy

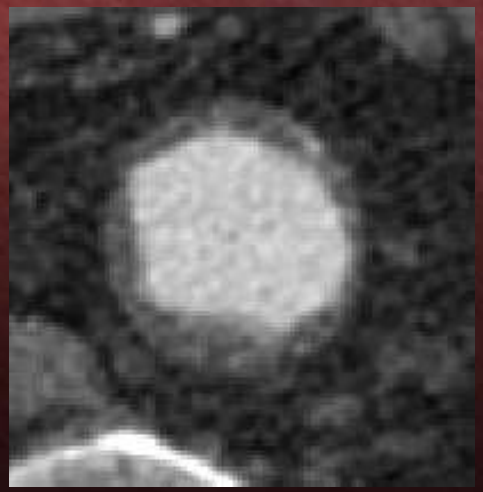
Short neck

Angulated neck



Tapered neck

Reverse Taper



Thrombus

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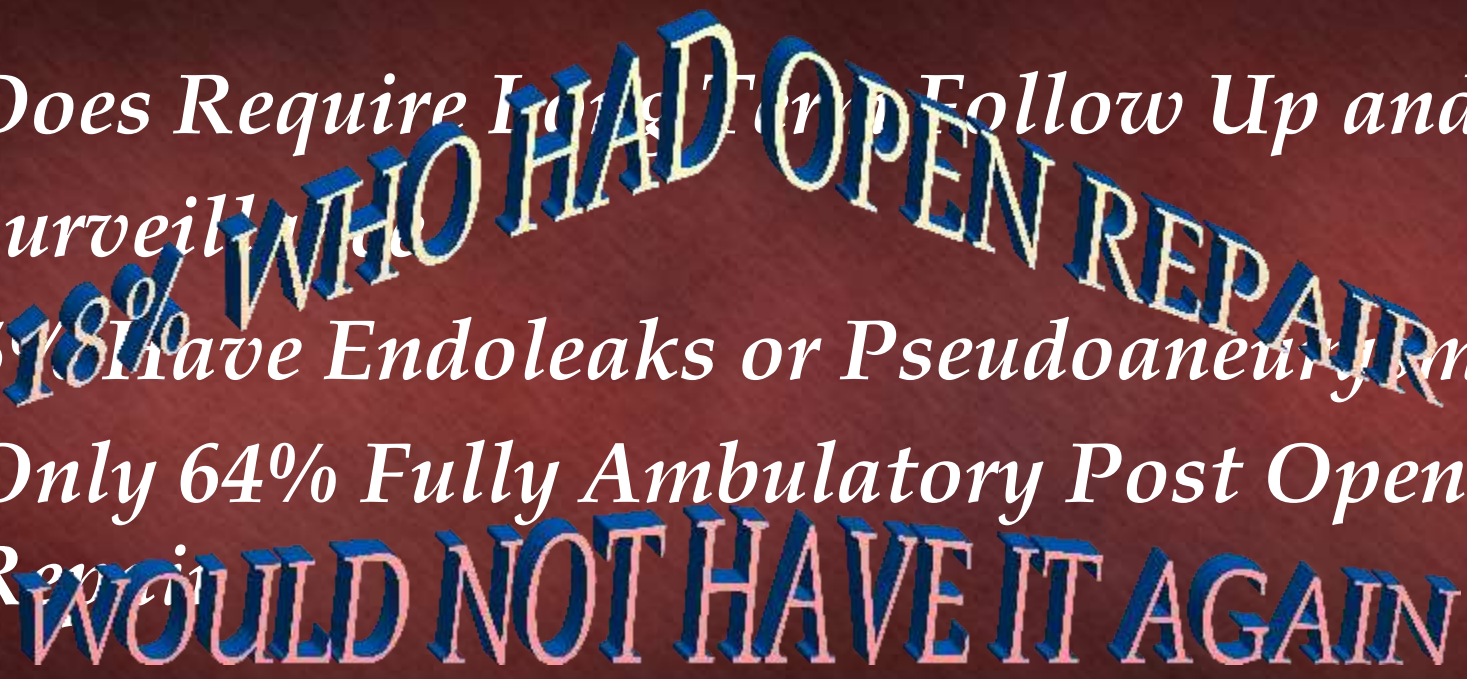
Aneurysms

- *1st successful [illegible] aneurysm repair was in 1951 by [illegible] Freeman using an autologous iliac vein graft*
  - *Charles Dubost used an aortic homograft to replace the aneurysm*
- *1st Complete Repair Occurred September 2, 1954 -- Michael DeBakey*

THESE THERAPIES HAVE NEVER BEEN SUBJECTED TO LEVEL 1 EVIDENCE

OPEN REPAIR

- *Does Require Long Term Follow Up and Surveillance*
- *5% Have Endoleaks or Pseudoaneurysms*
- *Only 64% Fully Ambulatory Post Open Repair*

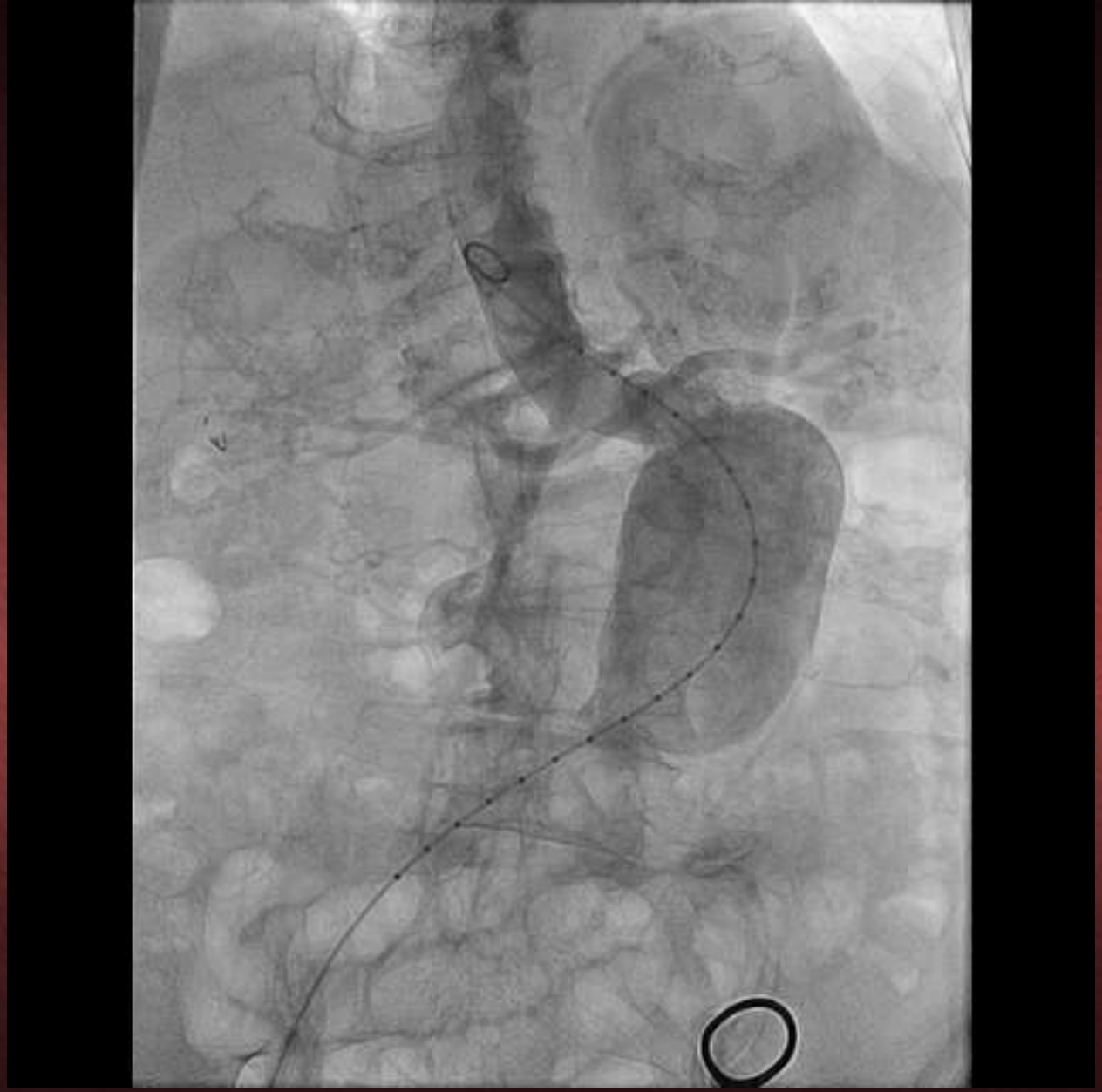


Endoluminal Stent-Graft Demonstrated Advantages

- *Minimally invasive surgery*
- *Reduced morbidity and ?mortality*
- *Less blood loss/need for transfusion*
- *Shorter hospital stay*
- *Quicker recovery time*

Patient Preferred Treatment

89 year old woman presents with a 6cm abdominal aortic aneurysm

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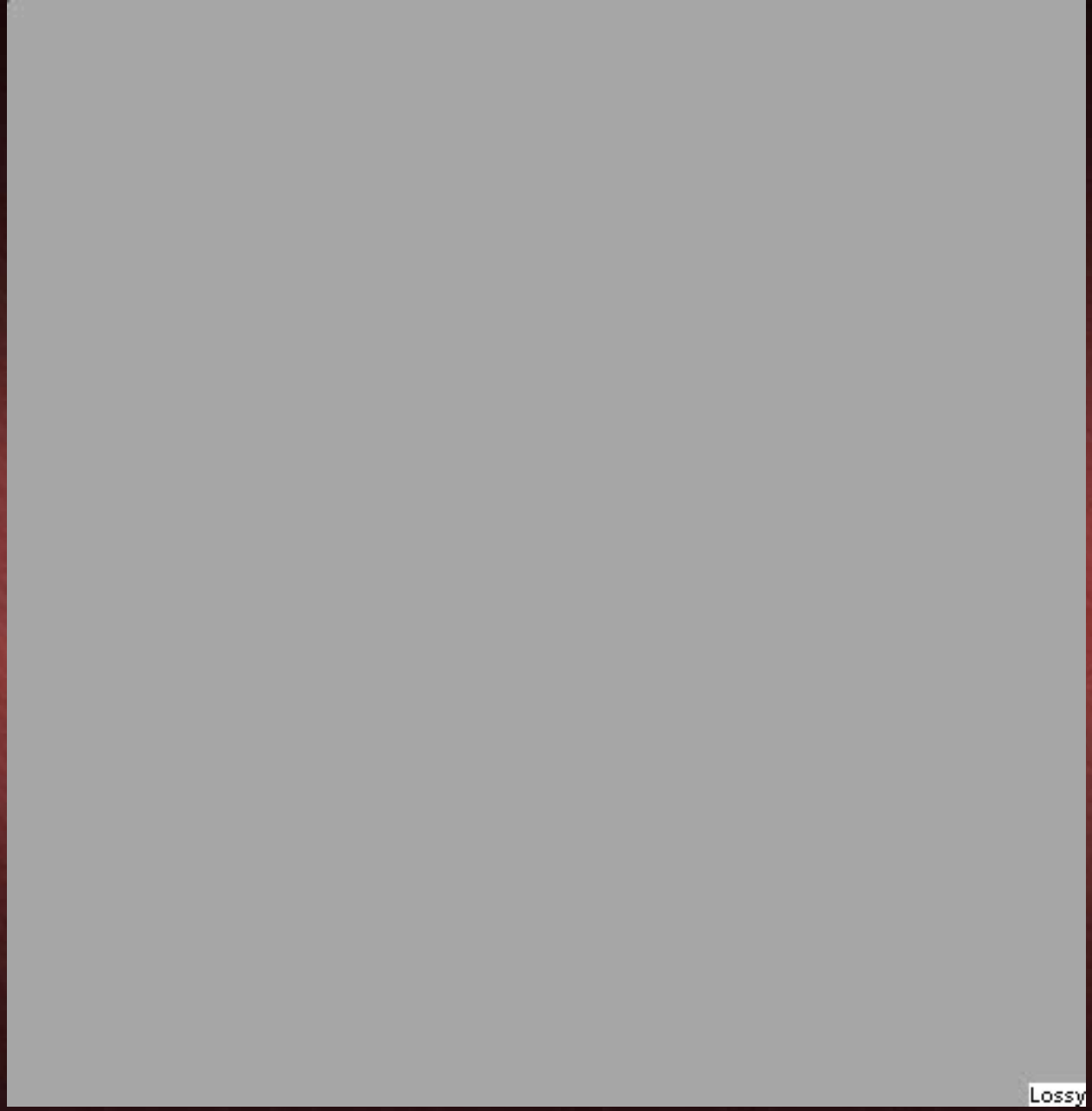
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RT POST

The endoluminal approach to AAA is a success story

- Vascular surgery has embraced
- Even rupture is fair game
- Thoracic aneurysms and dissection is becoming more often treated with ELGs

Endoleaks need to be treated according to type and rate of expansion. More importantly, they need to be prevented at the time of implant

Cardiovascular Disease Management:
A Case-Based Approach

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CONCLUSION

- **Endograft repair of abdominal aortic aneurysm should be considered in all patients who present with a significant AAA**
- **The results appear to be relatively safe**
- **Endoleaks and late complications can occur, but can usually be managed effectively non-surgically**