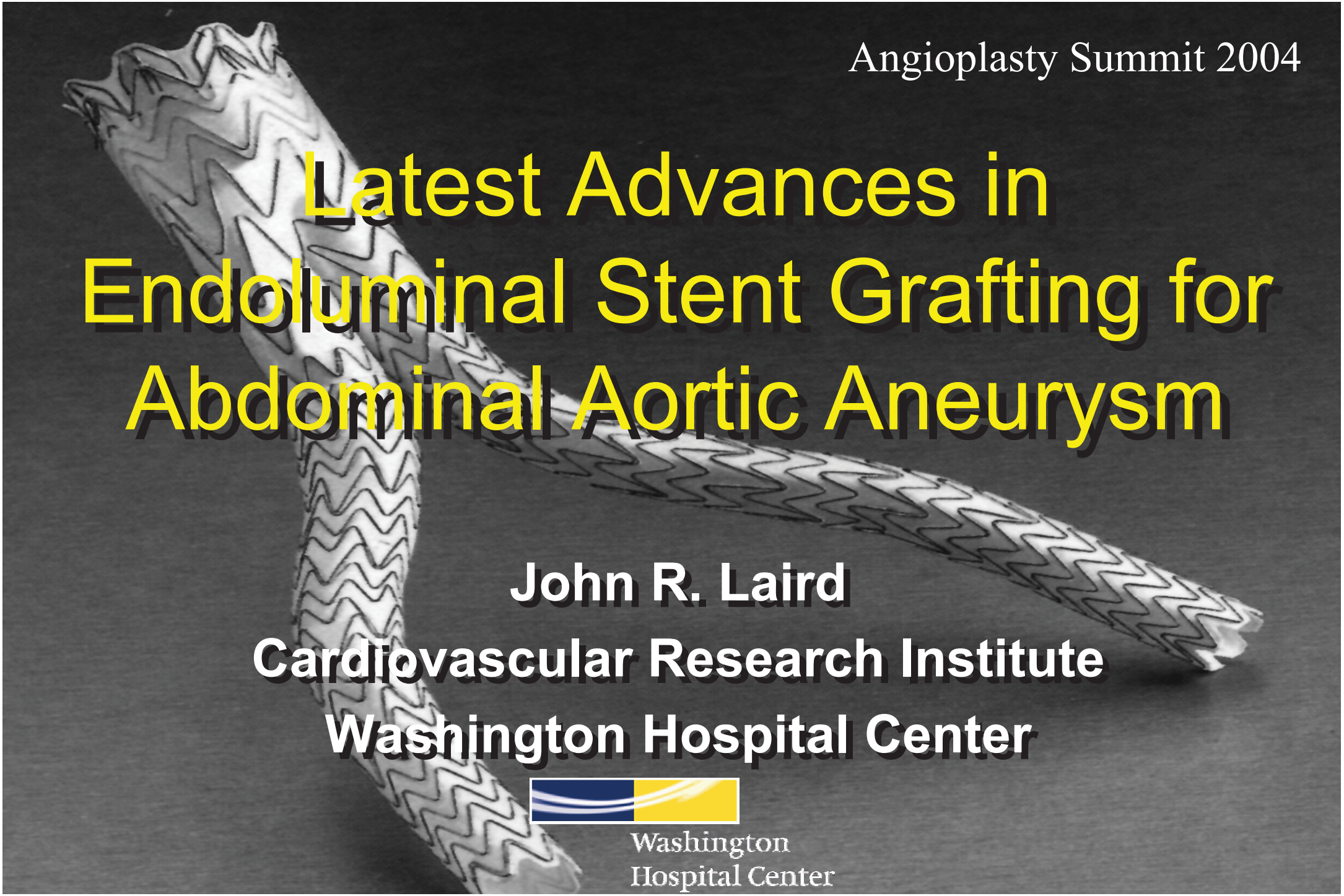


Angioplasty Summit 2004

Latest Advances in Endoluminal Stent Grafting for Abdominal Aortic Aneurysm

John R. Laird

Cardiovascular Research Institute

Washington Hospital Center

Washington Hospital Center

Endoluminal Stent-Graft
Demonstrated Advantages

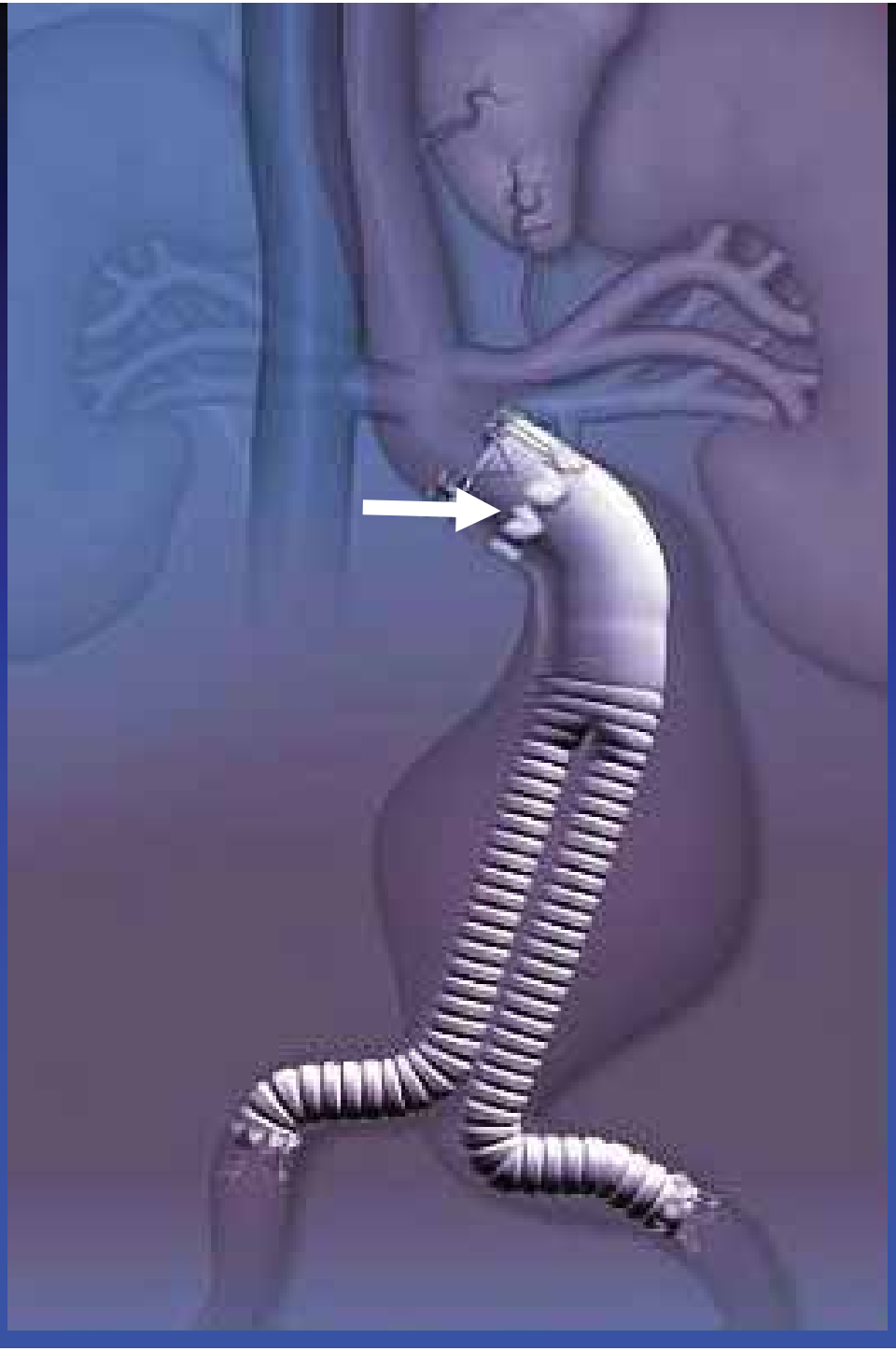
- Minimally invasive surgery
- Reduced morbidity and ?mortality
- Less blood loss/need for transfusion
- Shorter hospital stay
- Quicker recovery time

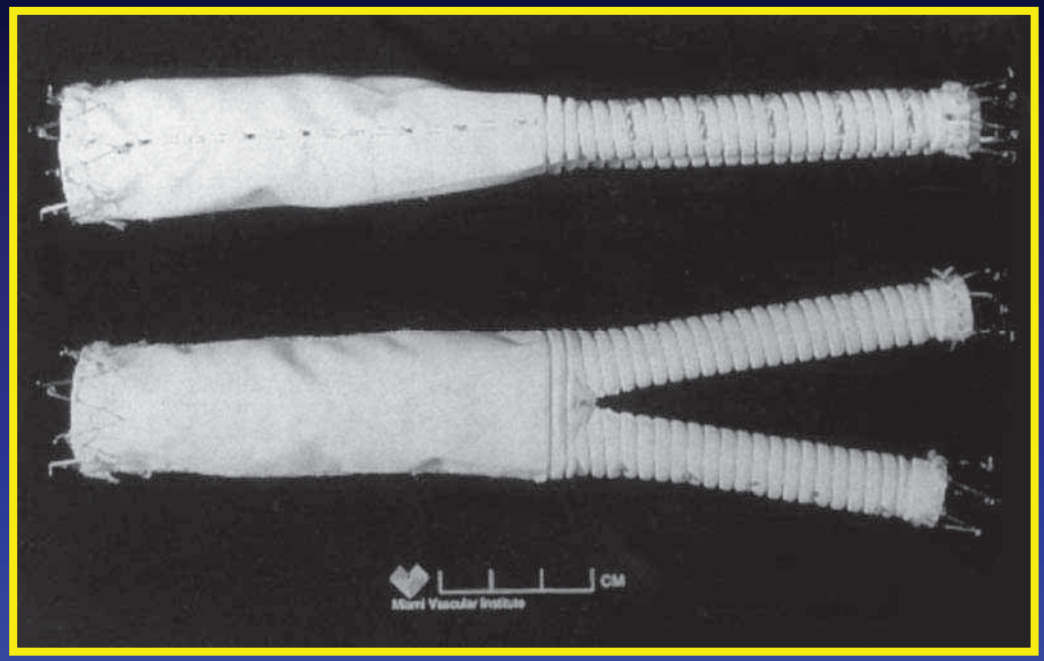
Patient Preferred Treatment

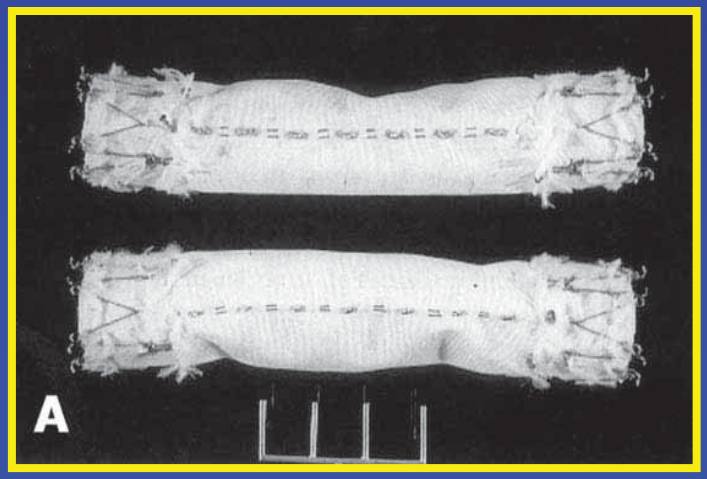
Endoluminal Stent-Grafts
Devices for AAA

- Ancure (Endovascular Technologies/Guidant)
- AneuRx (Medtronic)
- Excluder (WL Gore)
- Zenith (Cook)
- Talent (World Medical/AVE/Medtronic)
- Lifepath (Edwards)
- Teramed, Quantum LP (Cordis)
- Endologix
- TriVascular

Ancure Stent Graft



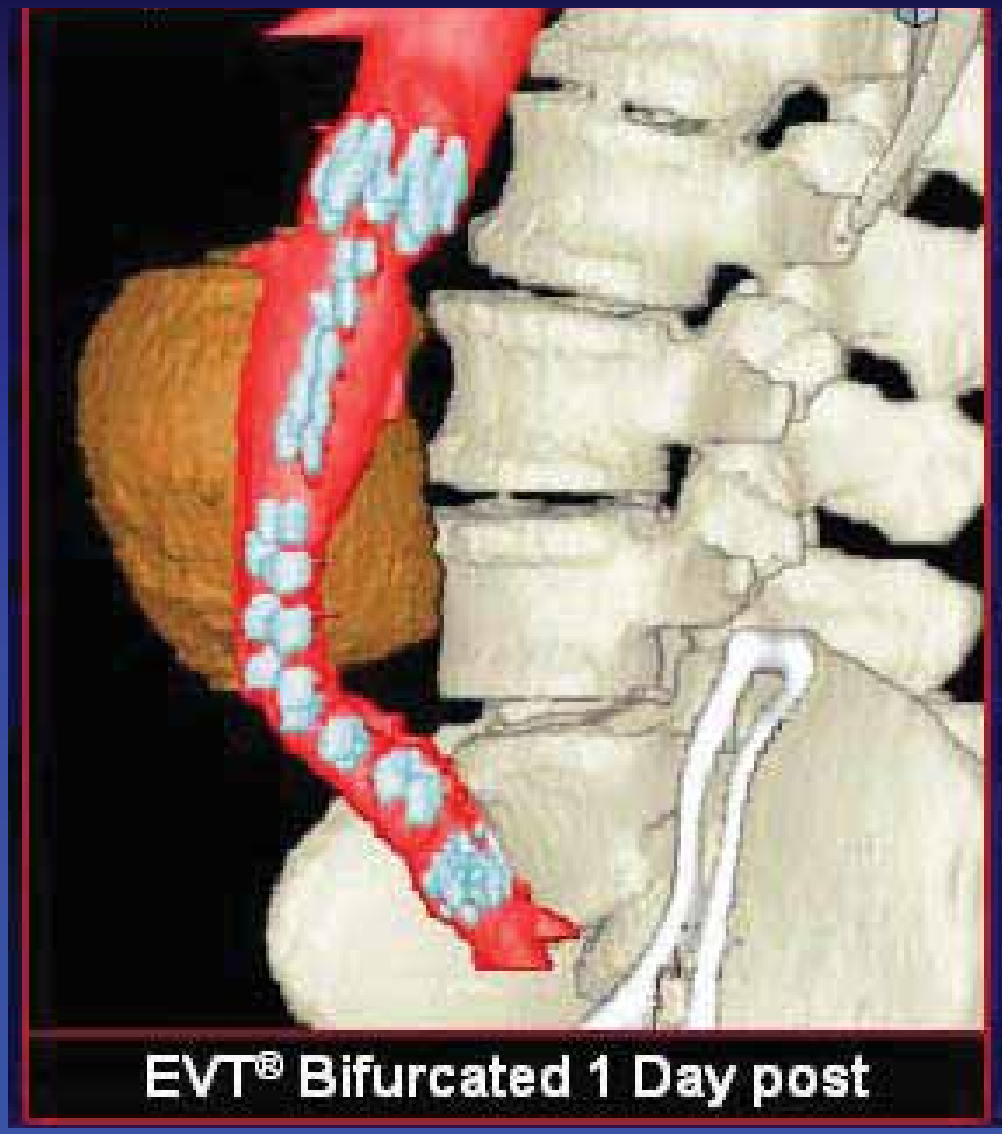




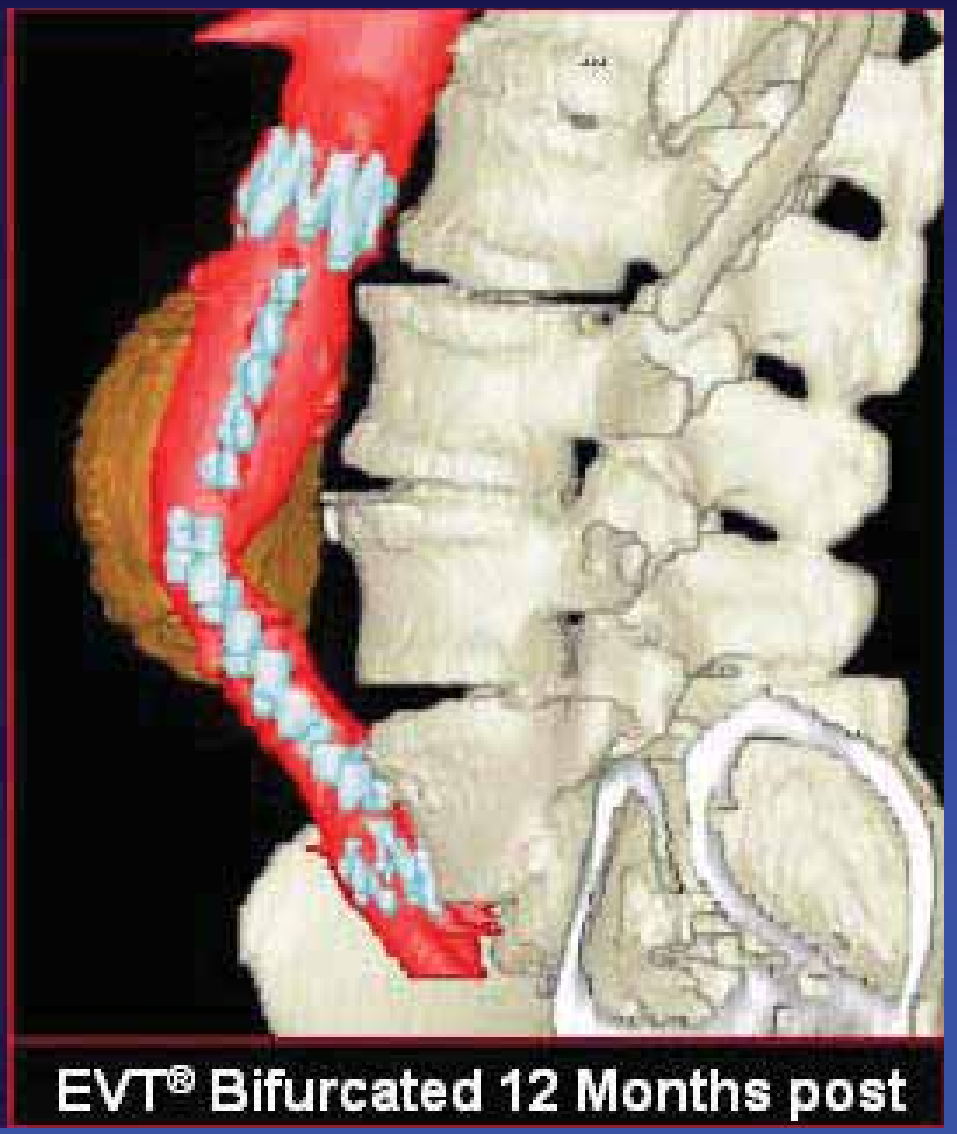
Ancure Results

- No ruptures in long-term follow-up cohort
- 97.4% free from aneurysm related death at 5 years
- 97.6% decreasing or stable AAA size at 5 years
  - 78.6% with decreasing AAA size at 5 years
  - 19% with stable AAA size at 5 years
- 99% free from migration at 5 years

AAA Shrinkage



EVT® Bifurcated 1 Day post



EVT® Bifurcated 12 Months post

Troubles with Ancure

- Problems related with device deployment and limb closure
- March 2001 – Guidant admits failure to submit 2,628 Medical Device Reports out of a total of 7,632 devices sold
- Convicted by DOJ of 10 felonies
- Paid $92.4 million fine

None of allegations related to long-term performance of device

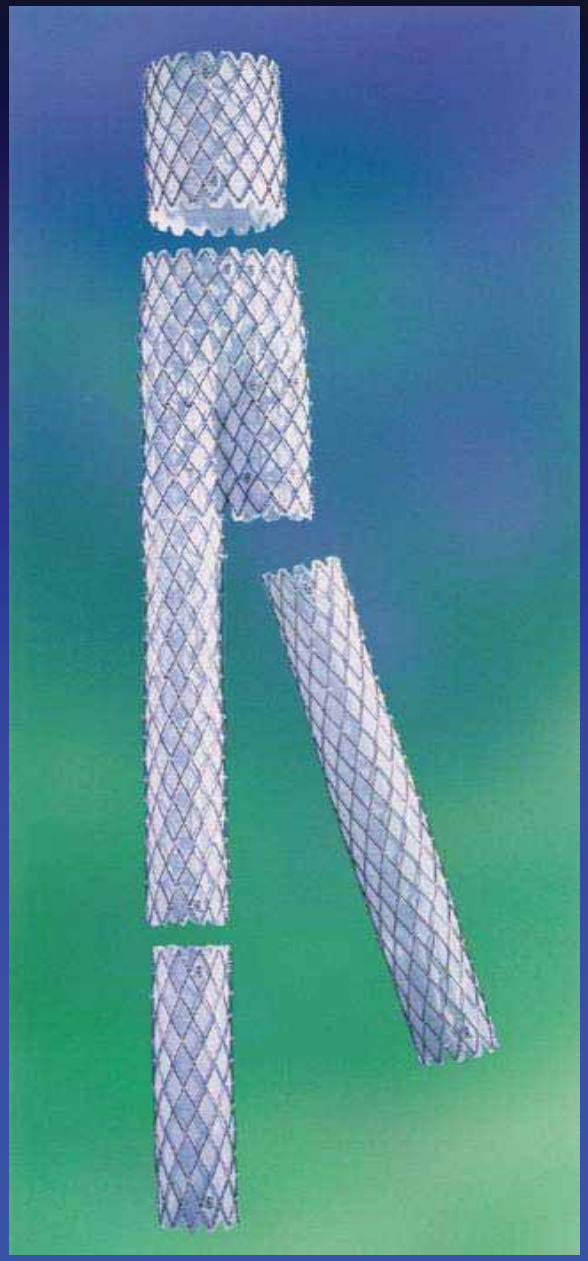
BUSINESS/FINANCIAL DESK | June 17, 2003, Tuesday

Medical Concern Will Halt Sales Of Artery Device Linked to Deaths

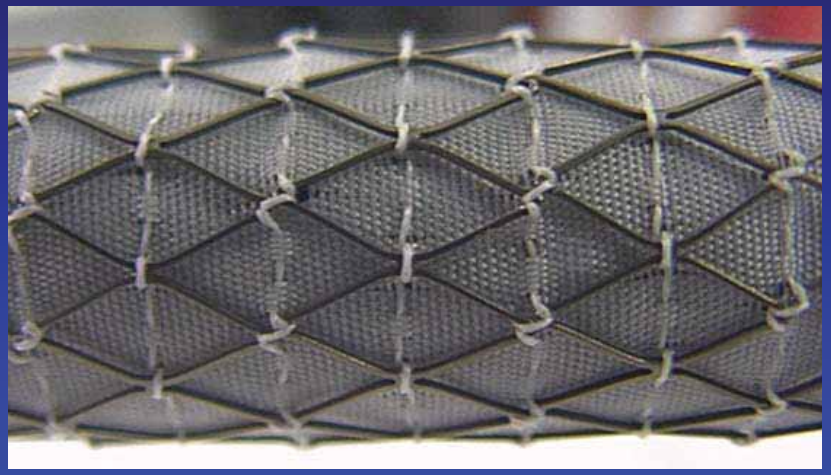
By MELODY PETERSEN (NYT) 746 words

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)



AneuRx Stent Graft



AneuRx Phase 2 Clinical Trial Early Outcomes

Decreased Events Compared to Open Surgical Repair

- Incidence of blood loss ($p < .001$)
- Transfusion ($p < .001$)
- Time to extubation ($p < .05$)
- ICU days ($p < .05$)
- Hospital stay ($p < .001$)
- Return to normal function ($p < .001$)

J Vasc Surg 1999;29:292-305

AneuRx Four-Year Results

The AneuRx stent graft: Four-year results and worldwide experience 2000

Christopher K. Zarins, MD,[a] Rodney A. White, MD,[c] Frans L. Moll, MD,[d] Tami Crabtree, MS,[e] Daniel A. Bloch, PhD,[b] Kim J. Hodgson, MD,[f] Mark F. Fillinger, MD,[g] and Thomas J. Fogarty, MD,[a] *Stanford, Torrance, and Santa Rosa, Calif, Nieuwegein, The Netherlands, Springfield, Ill, and Lebanon, NH*

Objective: The objective was to review the current results of endovascular abdominal aortic aneurysm repair with the AneuRx stent graft and to determine the effectiveness of the device in achieving the primary objective of preventing aneurysm rupture.

Methods: The outcome of all patients treated during the past 4 years in the U.S. AneuRx clinical trial was determined, and the worldwide clinical experience was reviewed.

Results: A total of 1192 patients were treated with the AneuRx stent graft during all phases of the U.S. Clinical Trial from June 1996 to November 1999, with follow-up extending to June 2000. Ten (0.8%) patients have had aneurysm rupture, with most ruptures (n = 6) occurring in 174 (3.4%) patients treated with an early stiff bifurcation stent graft design used in phase I and in the initial stages of phase II. Since the current, flexible, segmented bifurcation stent graft design was introduced, four (0.4%) ruptures have occurred among 1018 patients treated. Of these, one was during implantation, two were placed too far below the renal arteries, and one patient refused treatment of a type I endoleak. Kaplan-Meier analysis of all 1192 patients treated with the AneuRx stent graft including both stent graft designs revealed the patient survival rate to be 93% at 1 year, 88% at 2 years, and 86% at 3 years, freedom from conversion to open repair to be 98% at 1 year, 97% at 2 years, and 93% at 3 years, and freedom from secondary procedure to be 94% at 1 year, 92% at 2 years, and 88% at 3 years. Freedom from aneurysm rupture with the commercially available segmented bifurcation stent graft was 99.7% at 1 year, 99.5% at 2 years, and 99.5% at 3 years. The presence or absence of endoleak on contrast computed tomography scanning after stent graft placement was not found to be a significant predictor of long-term outcome measures. Worldwide experience with the AneuRx device now approaches 10,000 patients.

Conclusions: Endovascular management of abdominal aortic aneurysms with the AneuRx stent graft has markedly reduced the risk of aneurysm rupture while eliminating the need for open aneurysm surgery in 98% of patients at 1 year and 93% of patients at 3 years. The device was effective in preventing aneurysm rupture in 99.5% of patients over a 3-year period. The overall patient survival rate was 93% at 1 year and 86% at 3 years. (J Vasc Surg 2001;33:S135-45.)

J Vasc Surg 2001;33:S135-45c

AneuRx
Four Year Review

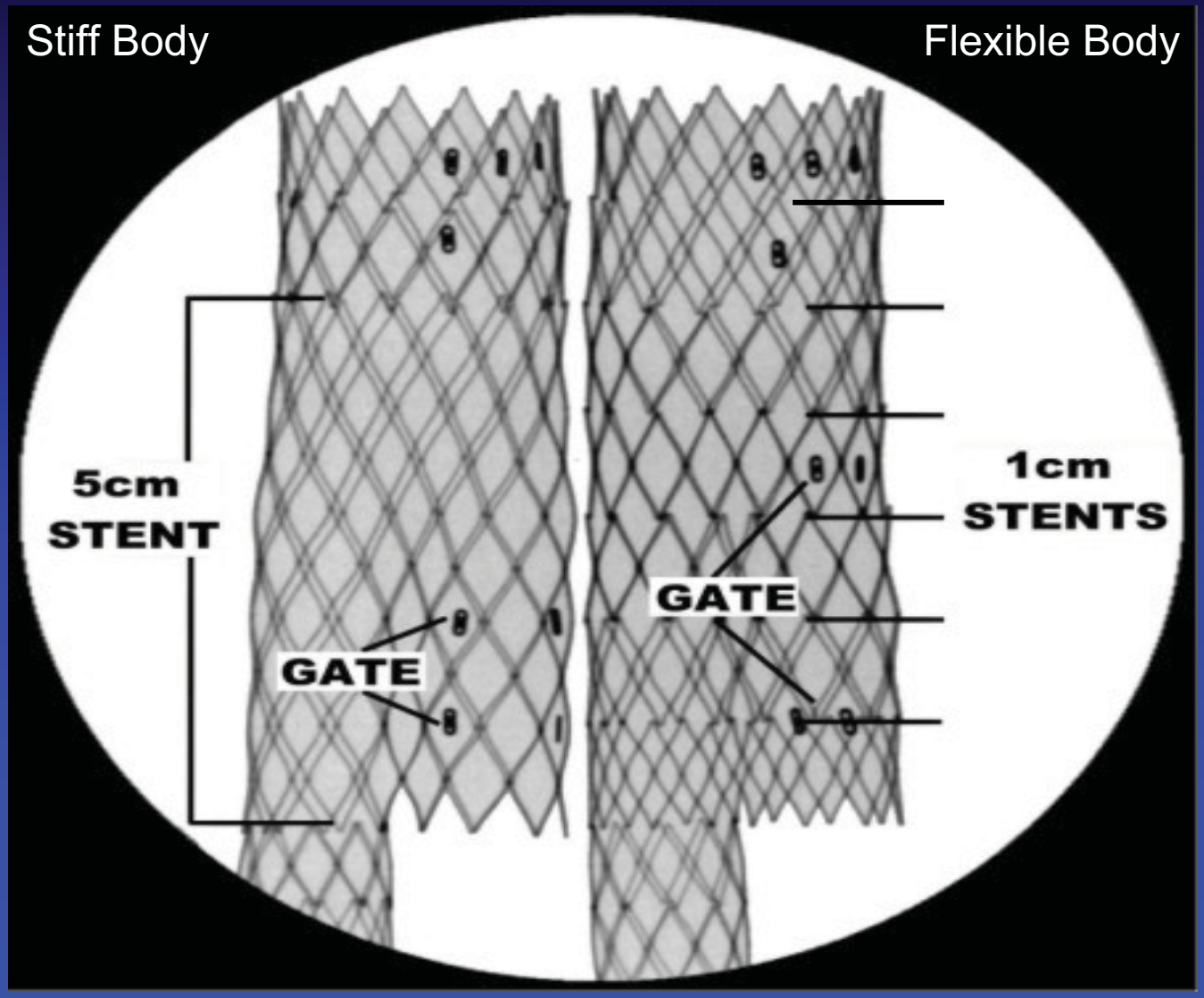
- Successful Implants: 98%
- Procedure Mortality (30 day): 1.8%
- Surgical Conversion: 2.8%
- Secondary Procedures: 8.0%
- Death from Any Cause: 10.3%
- Aneurysm Ruptures (early & late): 0.8%
- Death From Rupture: 0.3%

Aneurysm Rupture

10 of 1192 patients (0.8%)

- Procedure Related
  - < 24 hour 2
- Endoleak
  - Refused Treatment 2
- No Endoleak
  - Angulation, poor fixation 6

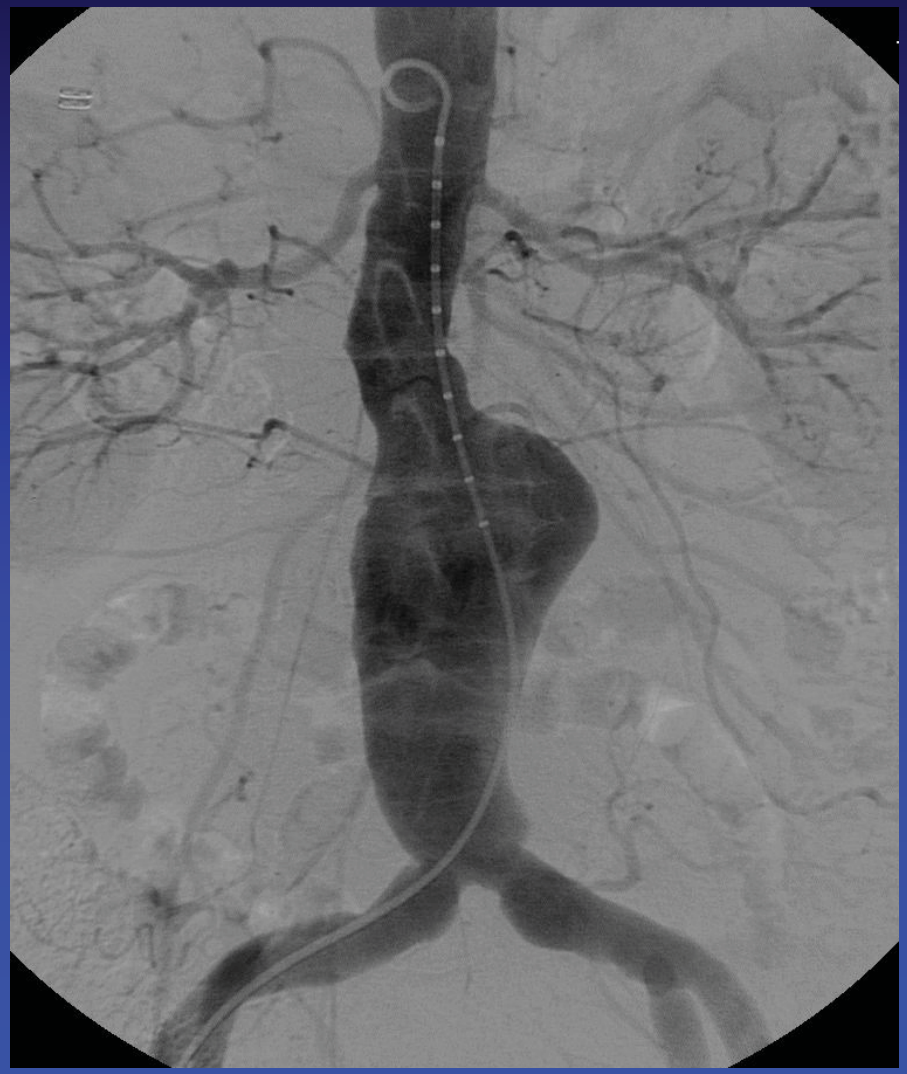
AneuRx Stent Graft Design

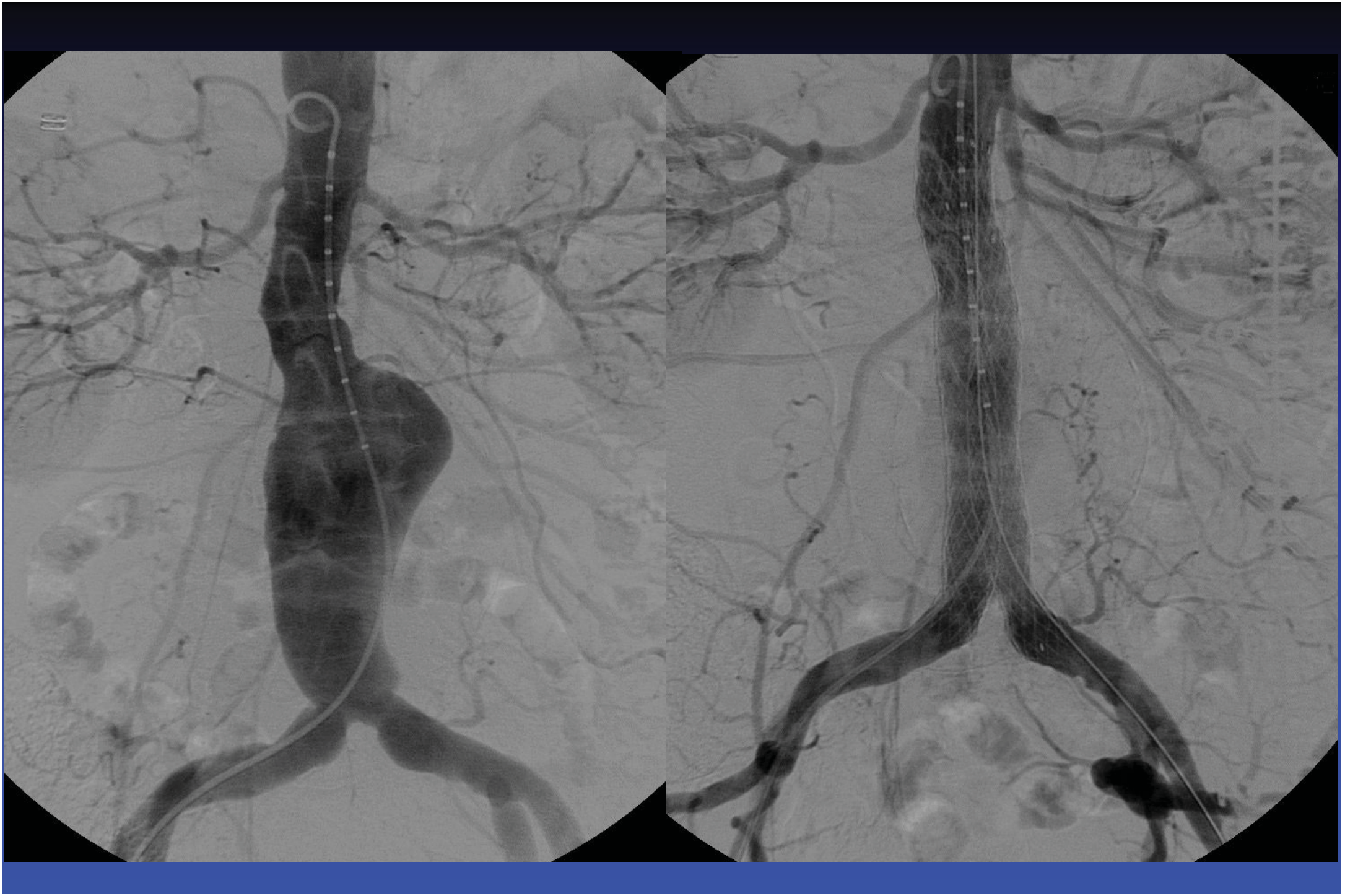


J Endovasc Ther 2001;8:583-591

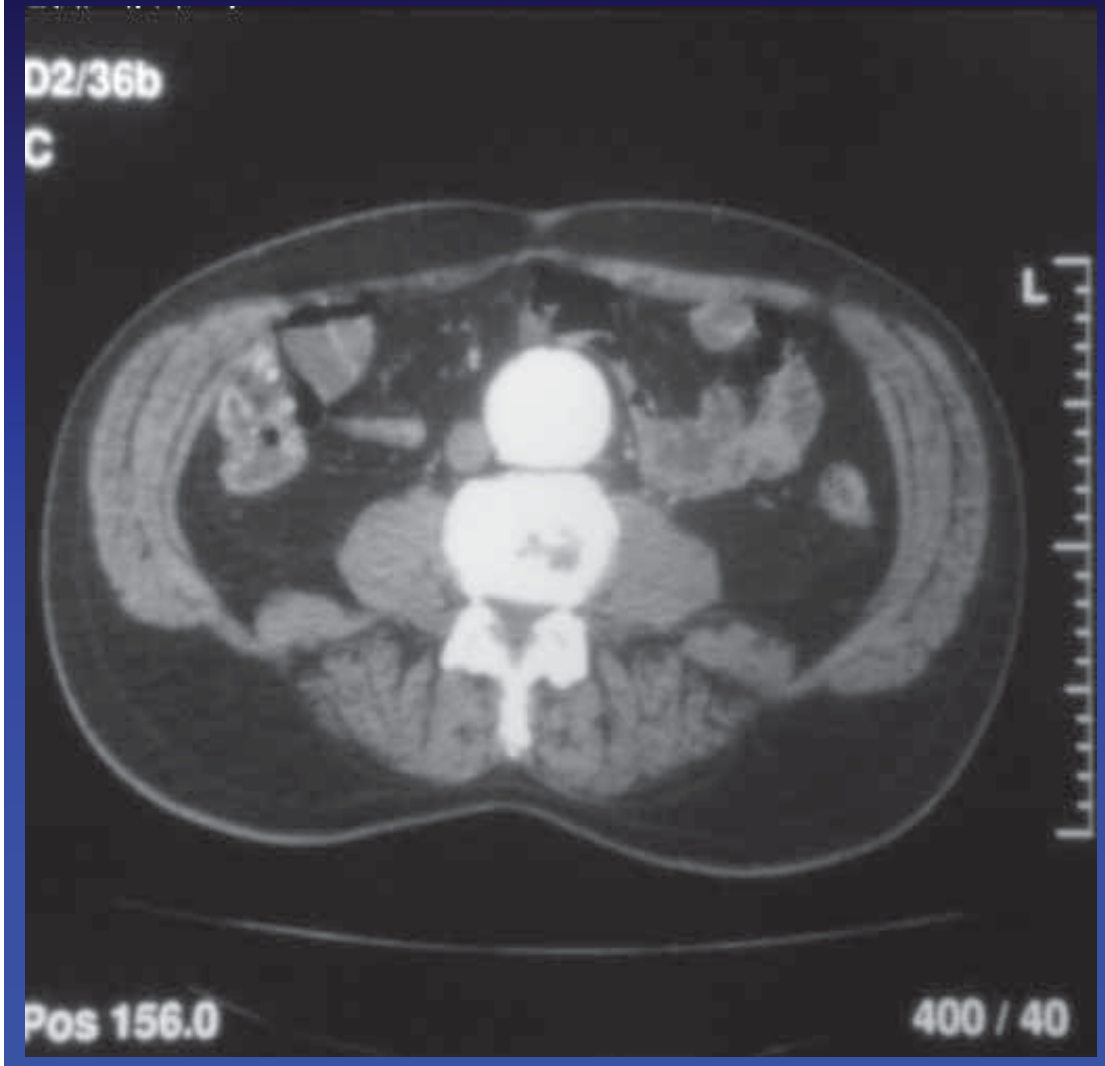
Endoluminal Stent-Grafts

- 88 year old male
- History of COPD and pacemaker
- High surgical risk
- 6.5 cm AAA

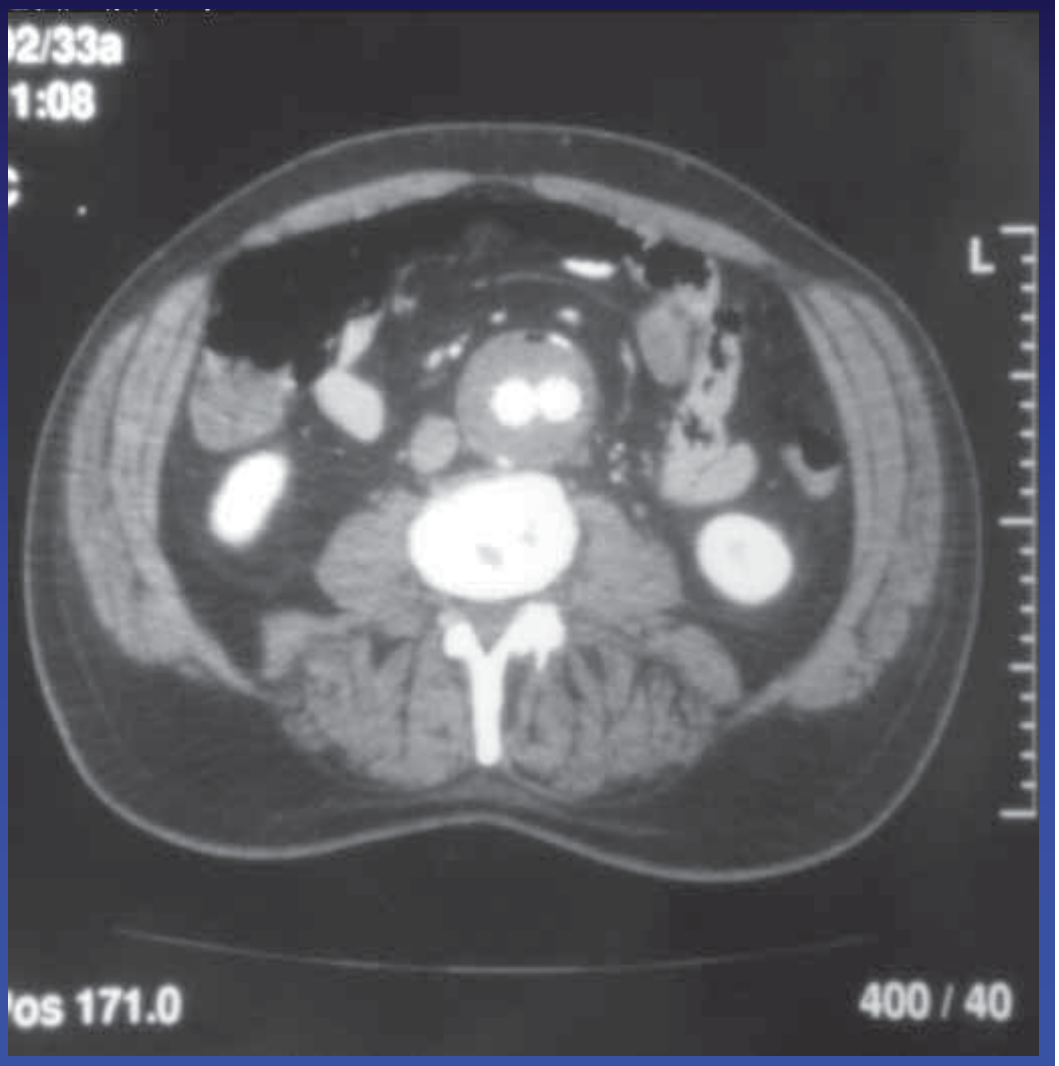




Endoluminal Stent-Grafts



Baseline CT Scan



Following Stent-Graft

Gore Excluder Stent-Graft

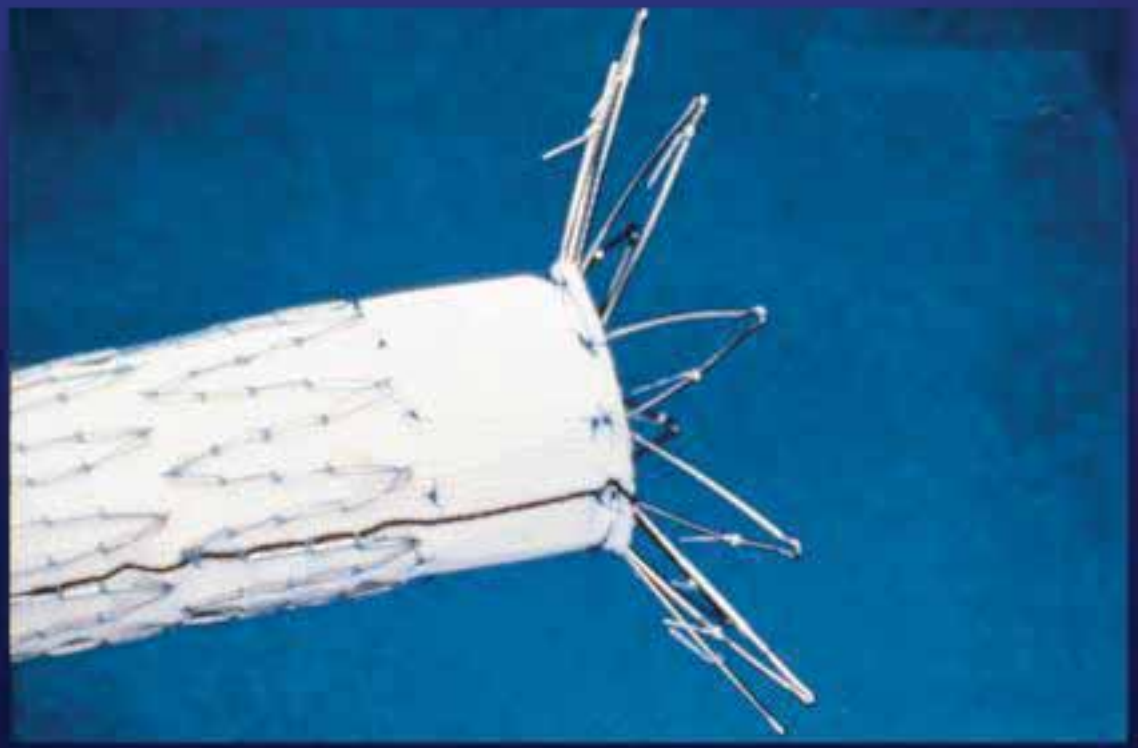
Gore Excluder Stent-Graft Advantages

- Relatively low profile (18 Fr main body, 12 Fr contralateral limb)
- Flexible
- Easy deployment mechanism
- Proximal fixation

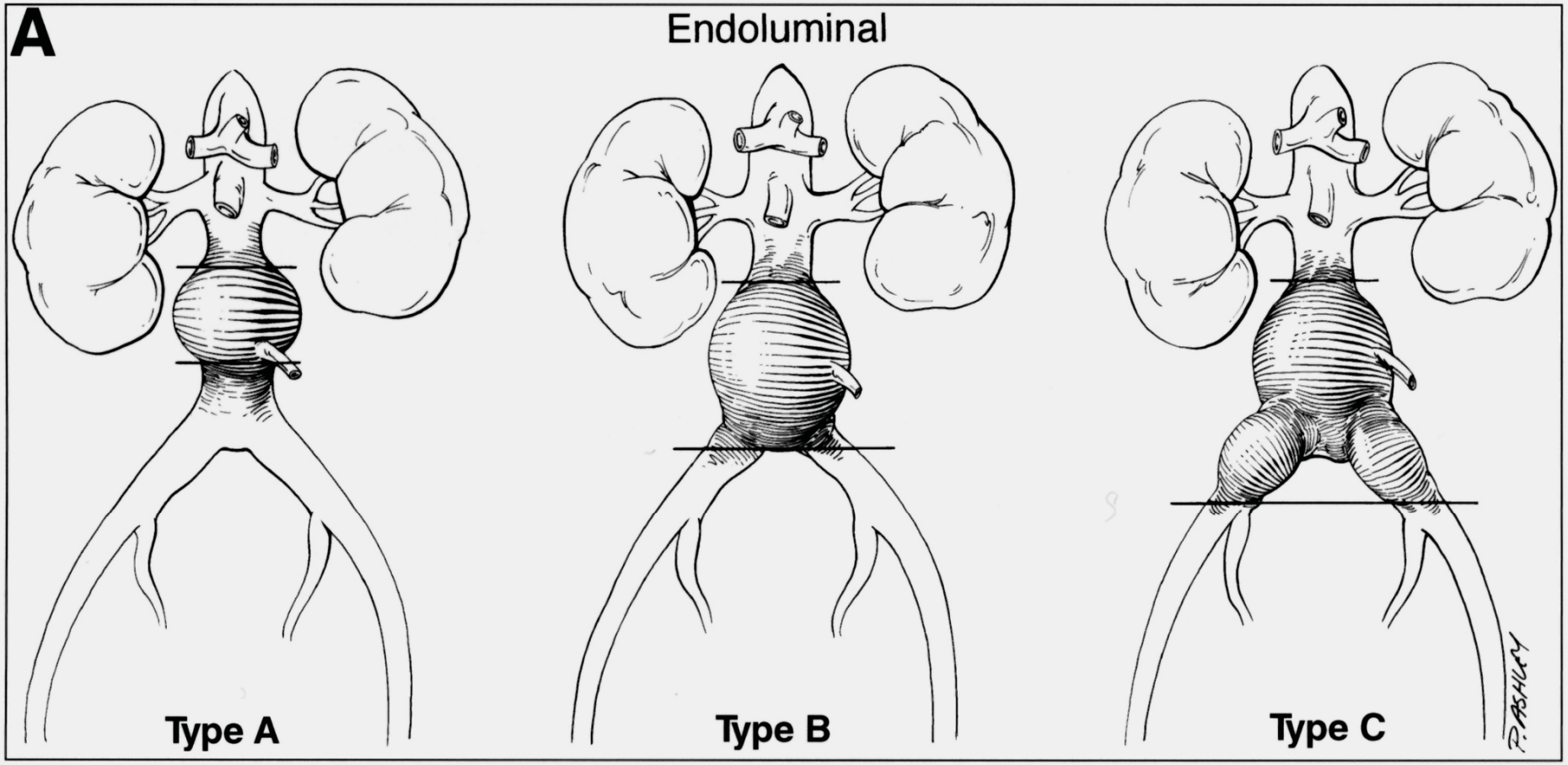
Cook Zenith Endograft

- Modular bifurcated design
- Long suprarenal attachment
- 16Fr and 18Fr delivery catheters
- Full thickness polyester graft material
- Proximal retention hooks

Zenith Stent Graft - retention hooks



Aneurysm Morphology

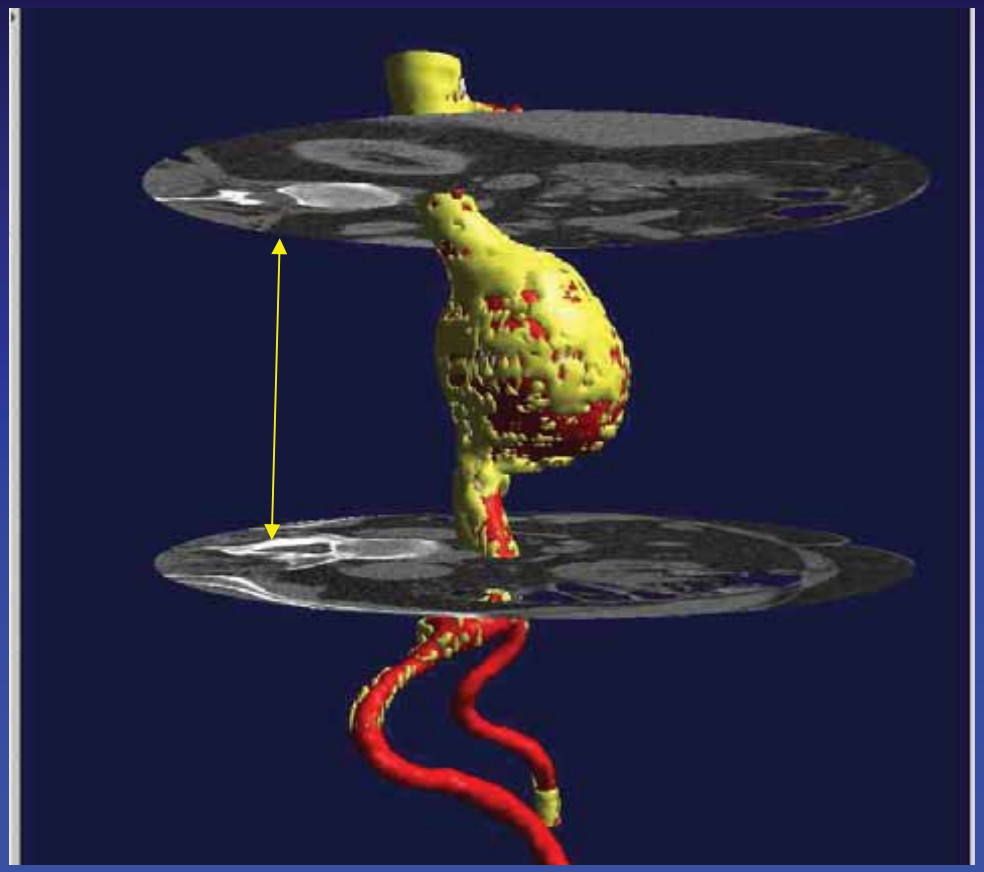


Endovascular Stent-Grafting
Technique

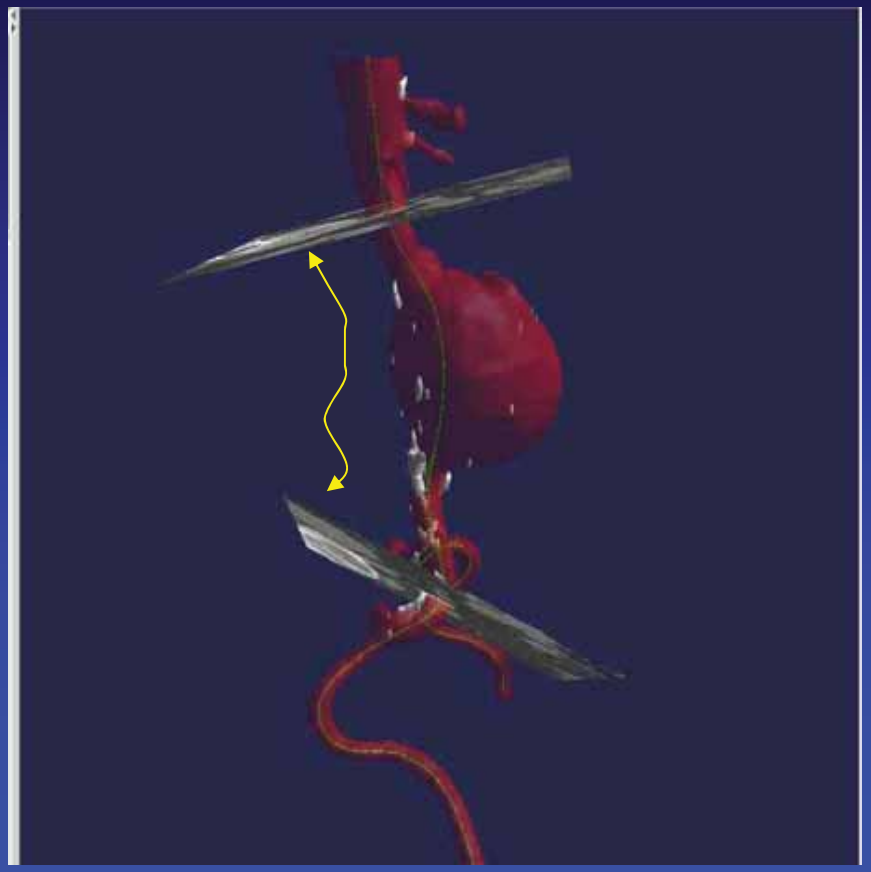
Critical Dimensions:

- Diameter and length of proximal neck
- Diameter and length of the common iliac arteries (attachment site)
- Diameter of external iliac and common femoral arteries (for device passage)
- Length from renal arteries to aortic bifurcation and iliac bifurcation (device selection)

Length Measurements



Standard length measurements from 2D axial slices do not account for vessel tortuosity



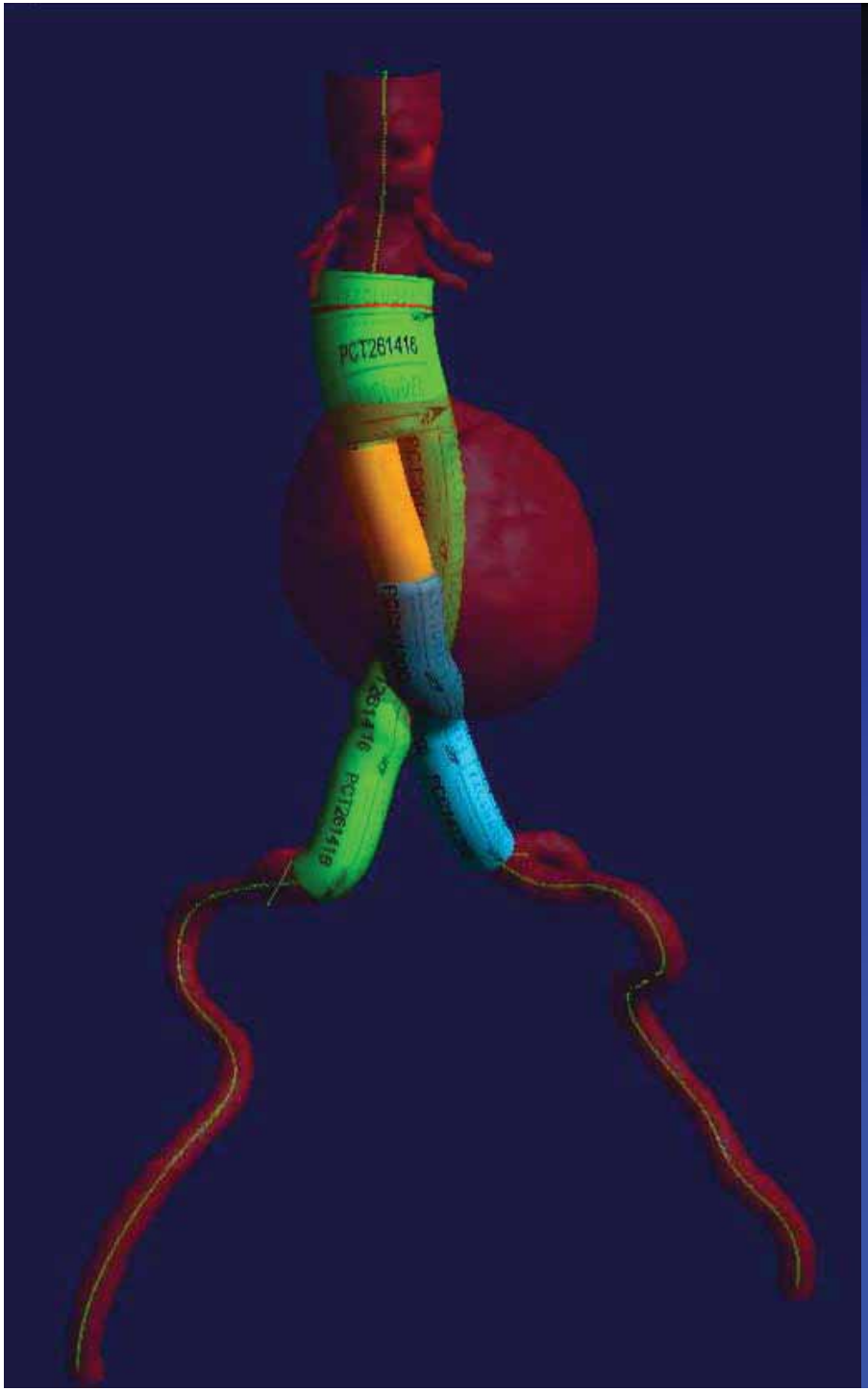
“Centerline” length measurements accurately define the vessel length

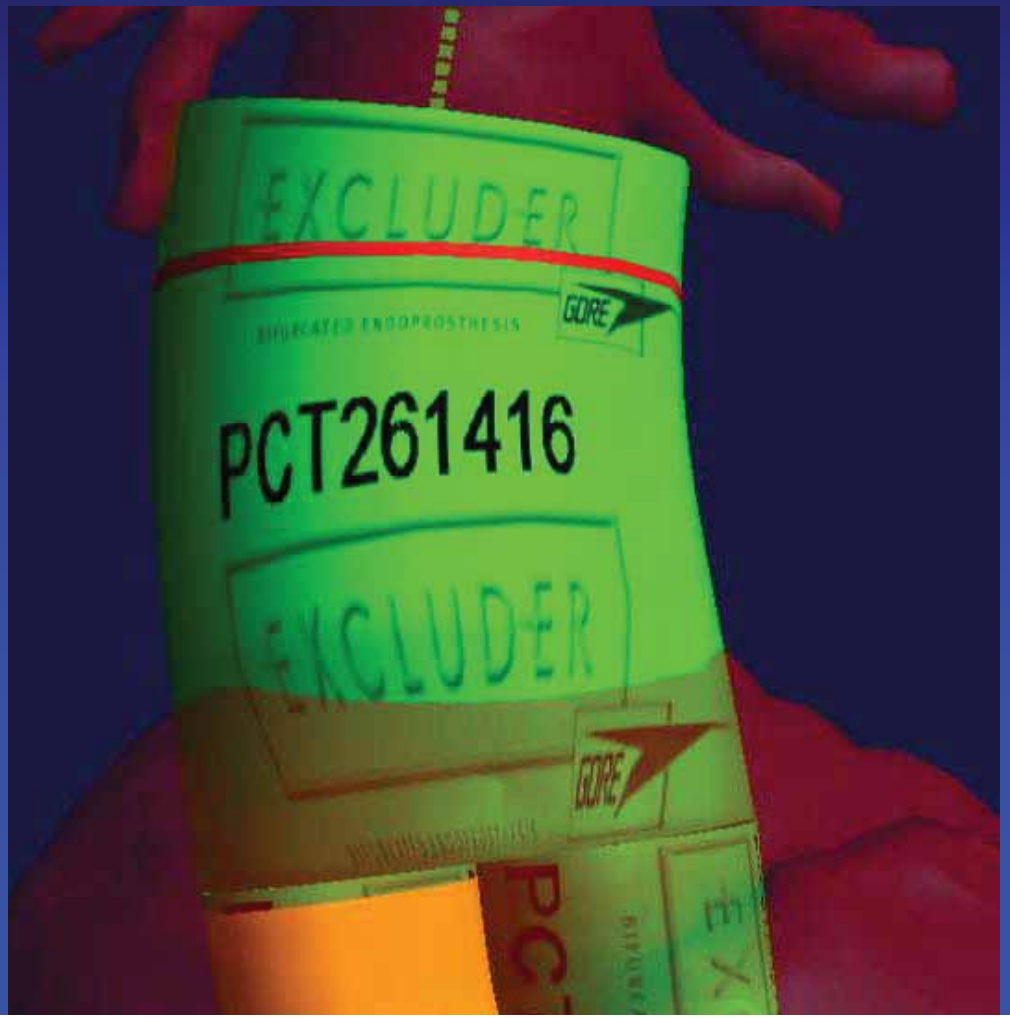
Angle Measurements

Vessel angulation is easily calculated

Manufacturer Specific Virtual Graft™

Computer Simulation of Graft Fit





Potential Endoluminal Graft Complications

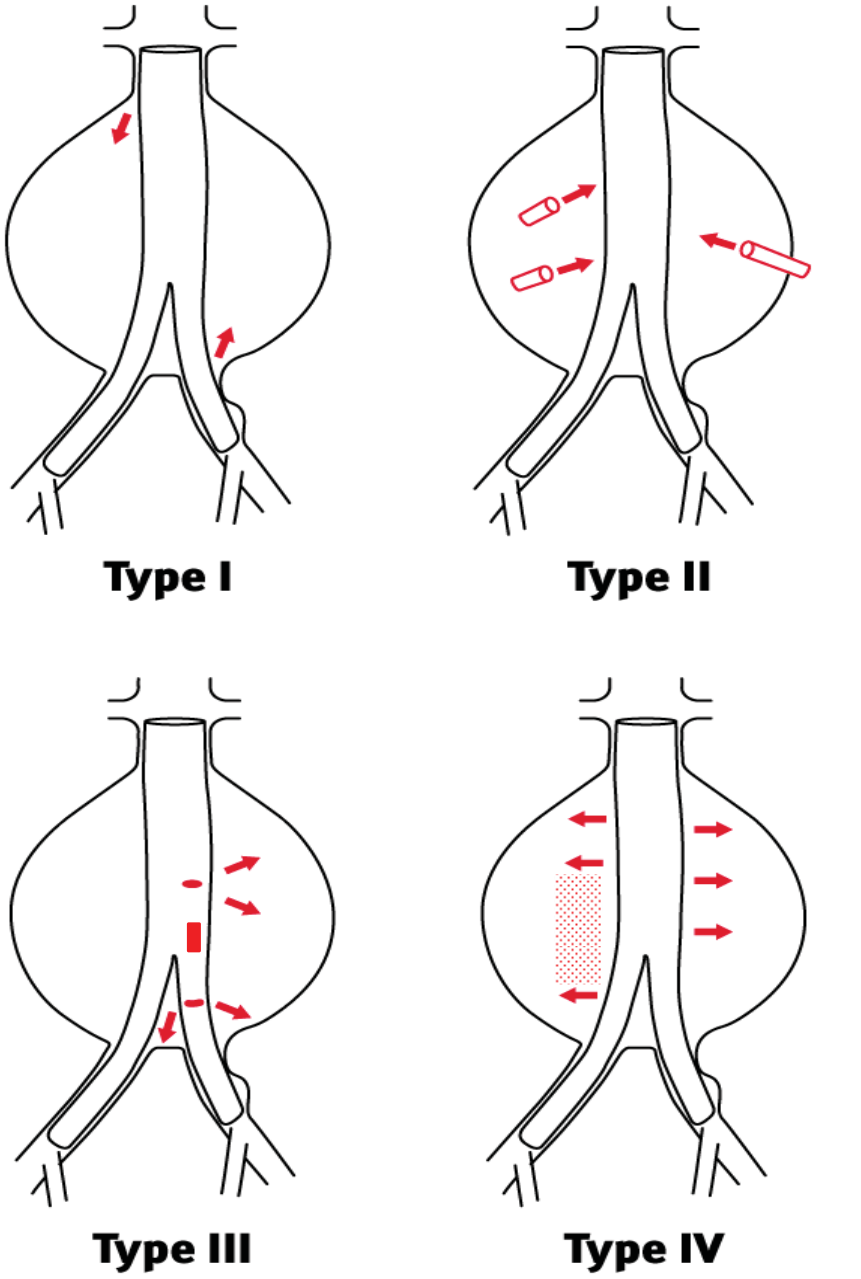
- Dissection/Perforation
- Device malfunction/failure
- Thromboembolic Event
- Prosthetic Occlusion
- Prosthetic Migration
- Prosthetic Leak
- Limb Ischemia
- Ischemic Bowel
- Renal Failure
- Wound Infection
- Coagulopathy
- MI
- Arrythmias

Endoleak

A condition associated with endoluminal vascular grafts defined by the persistence of blood flow outside the lumen of the endoluminal graft but within an aneurysm sac or adjacent vascular segment being treated by the graft

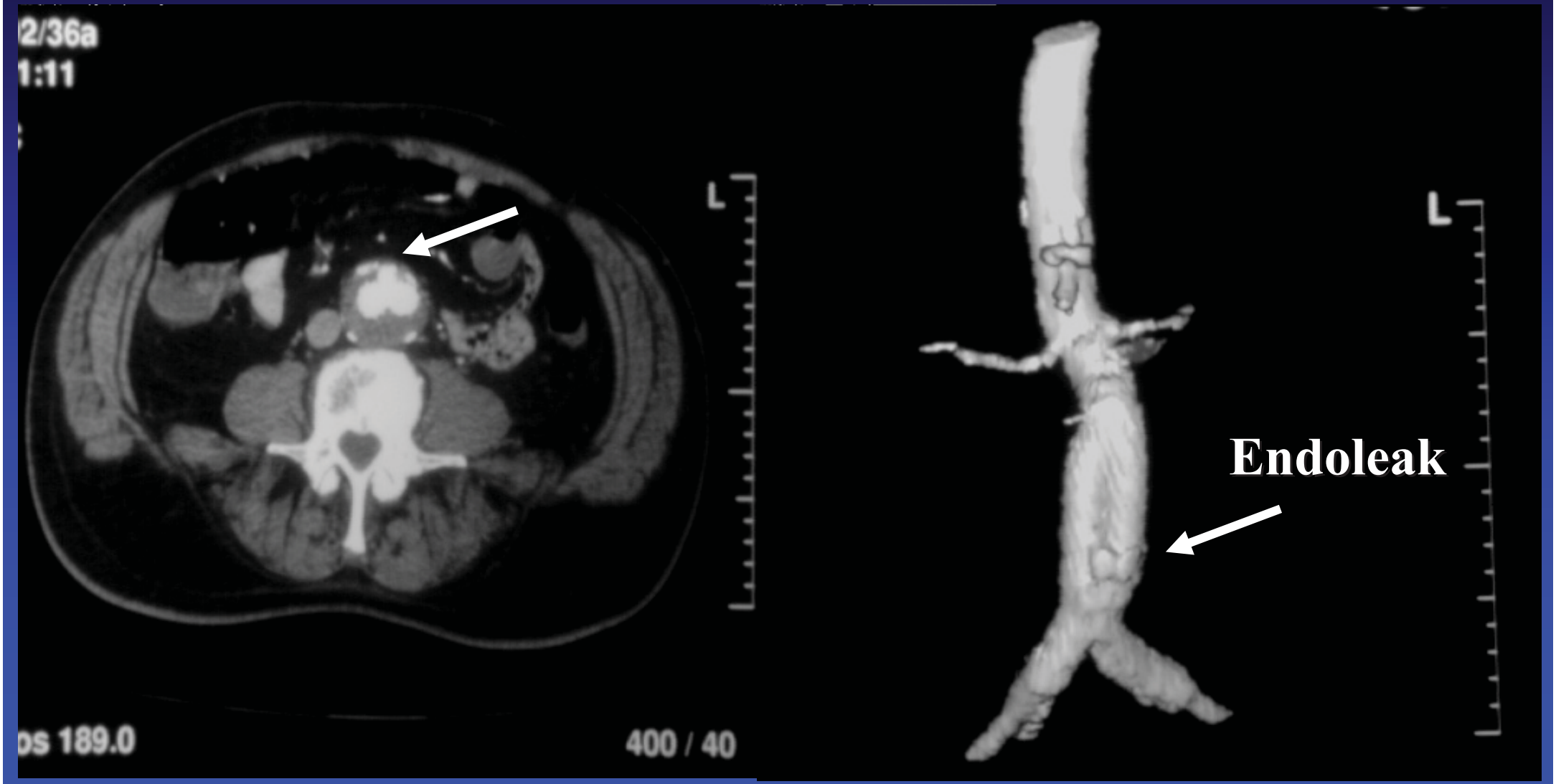
Endoleak

- Type I Endoleak
  - Proximal or distal attachment
- Type II Endoleak
  - Retrograde branch flow
- Type III Endoleak
  - Structural defect or junction
- Type IV Endoleak
  - Trans-graft “blush”

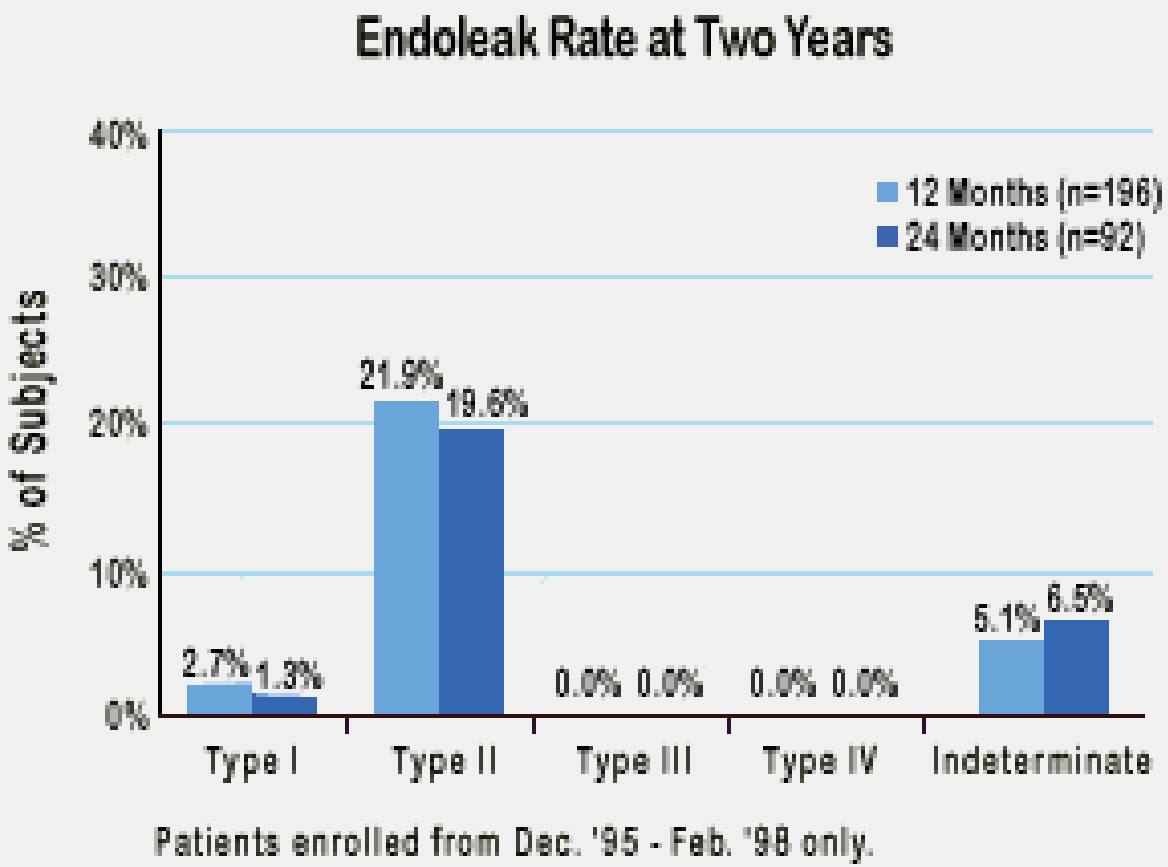


White, *et al*, JES, 1997;4:152-168

Endoluminal Stent-Grafts



Endoleak Rate
Ancure Device



AneuRx Phase II Clinical Trial
Endoleak on CT Scan

	CENTERS n = 398	CORE LAB n = 350	p
Discharge	38 %	50 %	<.001
6 months	16 %	27 %	<.001
12 months	13 %	20 %	<.001

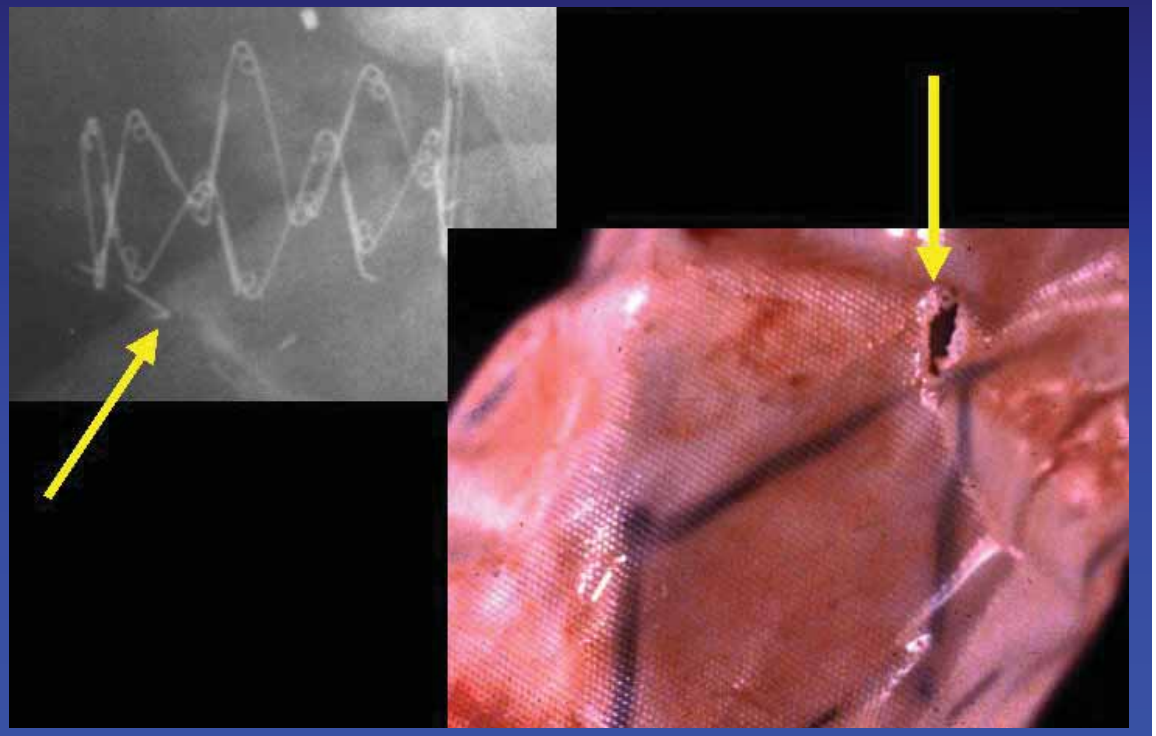
J Vasc Surg 2000;32:90-107

Management of Endoleak

- Type I or III: Correction by further endoluminal graft procedure or surgery
- Type II:
  - Conservative (observation, with monitoring by repeat imaging)
  - Embolization
  - Conversion to open repair of aneurysm
- Type IV: No therapy required

Late Graft Failure

- **Late endoleaks due to graft material failure seen with Vanguard device leading to withdrawal from investigation**
- **Stent fractures and graft material failure seen with AneuRx and other devices**



Endoluminal Stent Grafts
Areas of Development

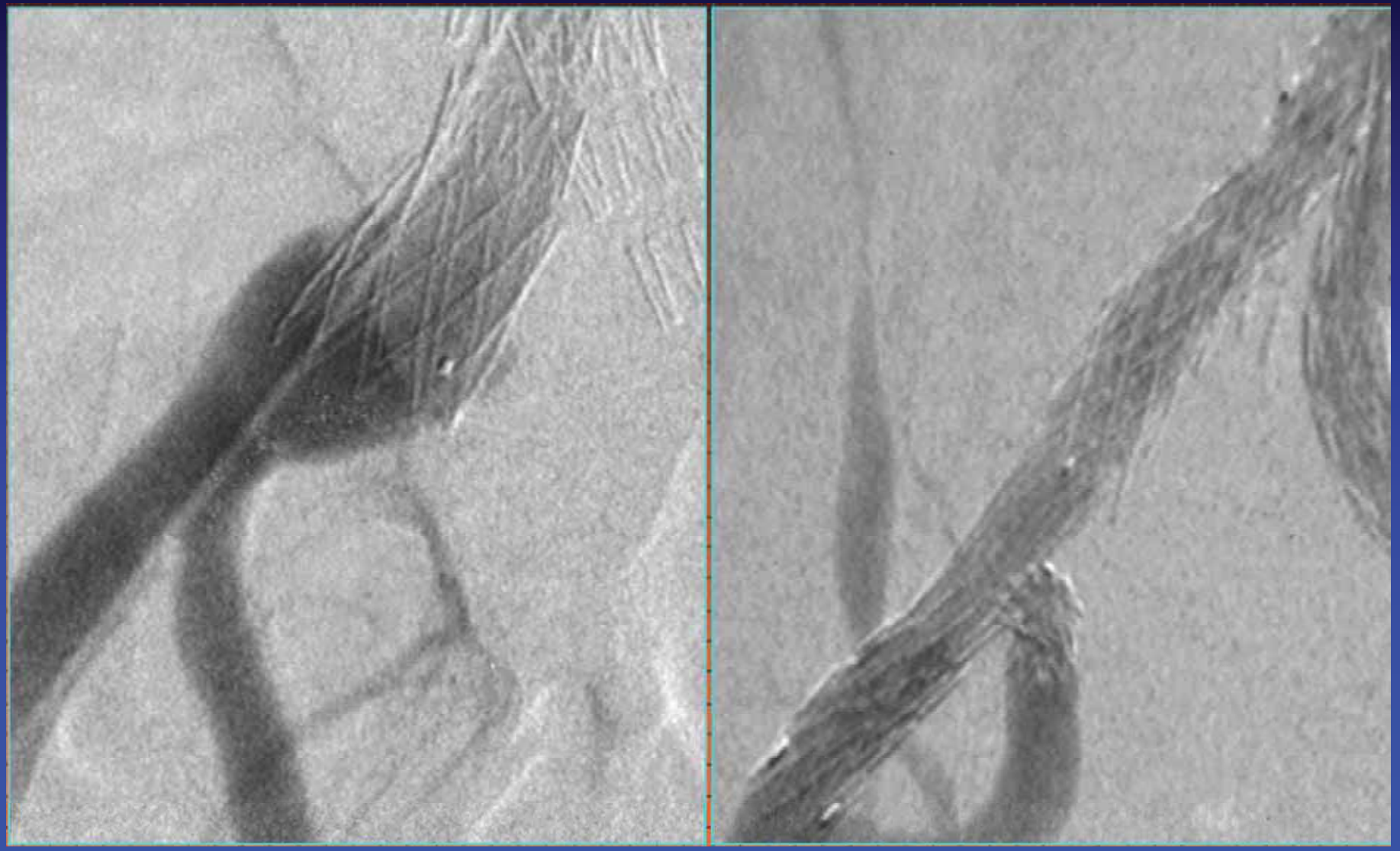
- Fenestrated grafts
- Lower profile systems (percutaneous deployment)
- Wireless pressure sensing of aneurysms (follow-up after EVAR)

Cordis/Teramed

Side branch device for co-existing common iliac aneurysms

B. Katzen

Side Branch Endograft



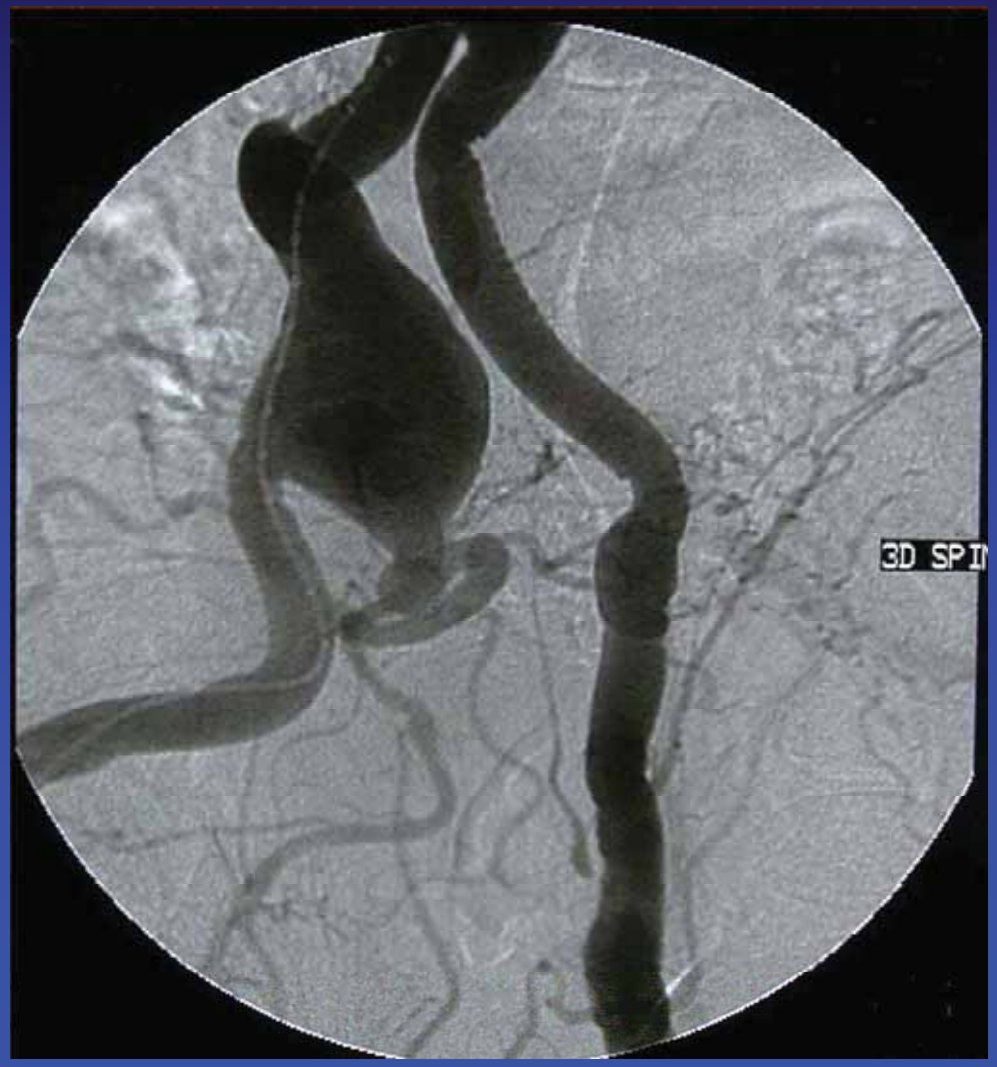
B. Katzen

Indication for Branched Grafts

- Unsuitable proximal neck
- Late or early failure of previous surgically implanted aortic graft
- Early or late failure of previous endoluminal aortic graft
- Preservation of hypogastric artery flow

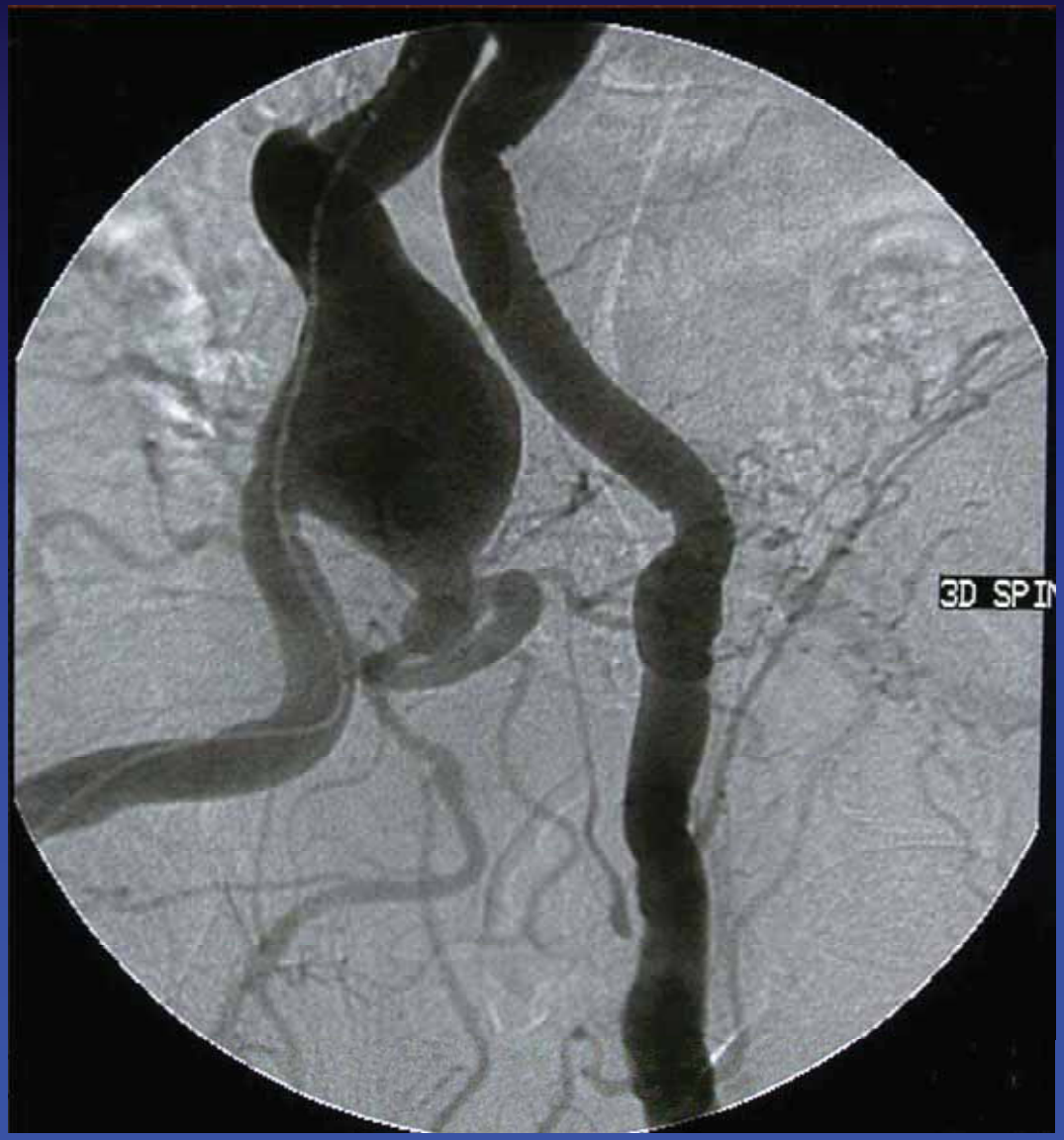
Cook Zenith

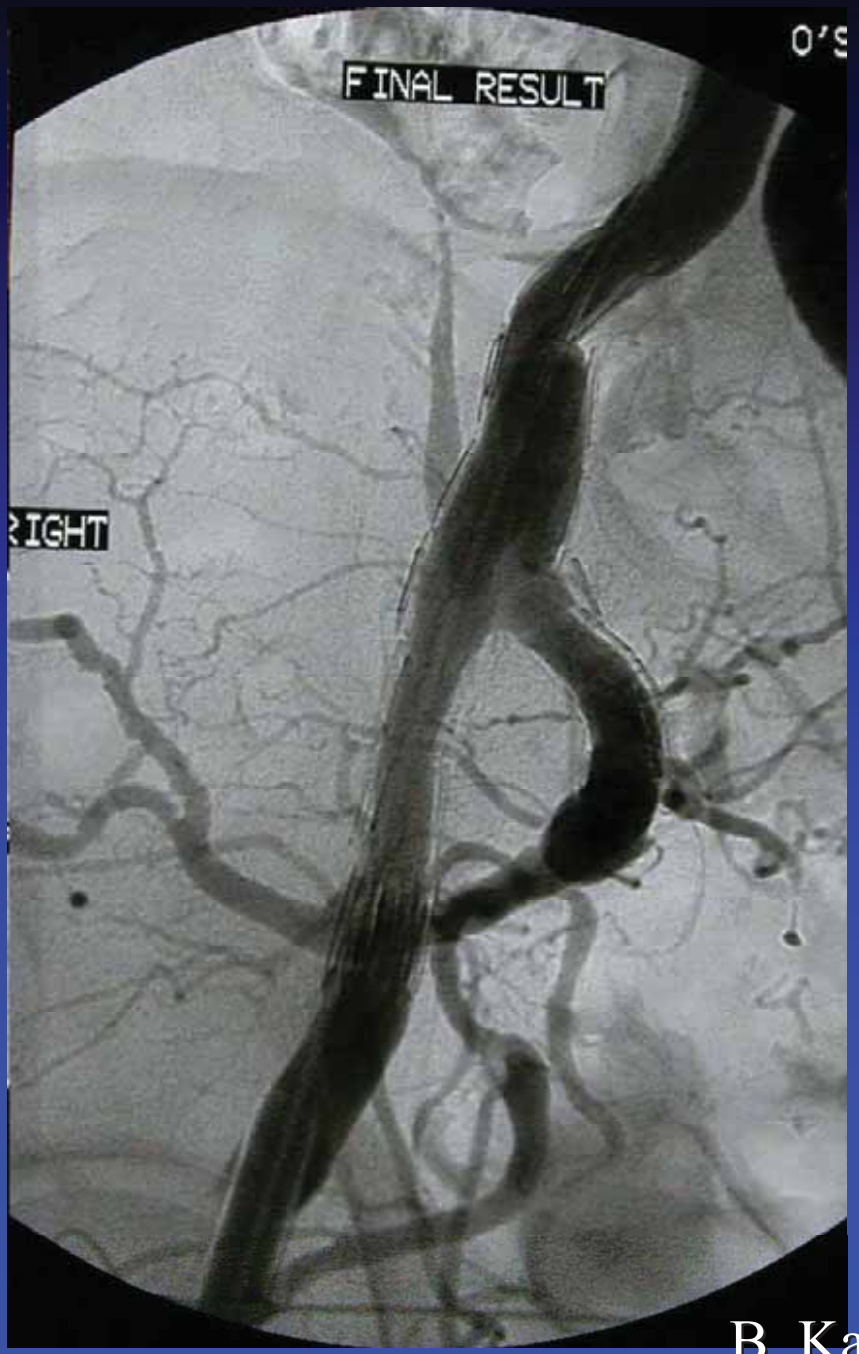
Long branch +/- extension



B. Katzen

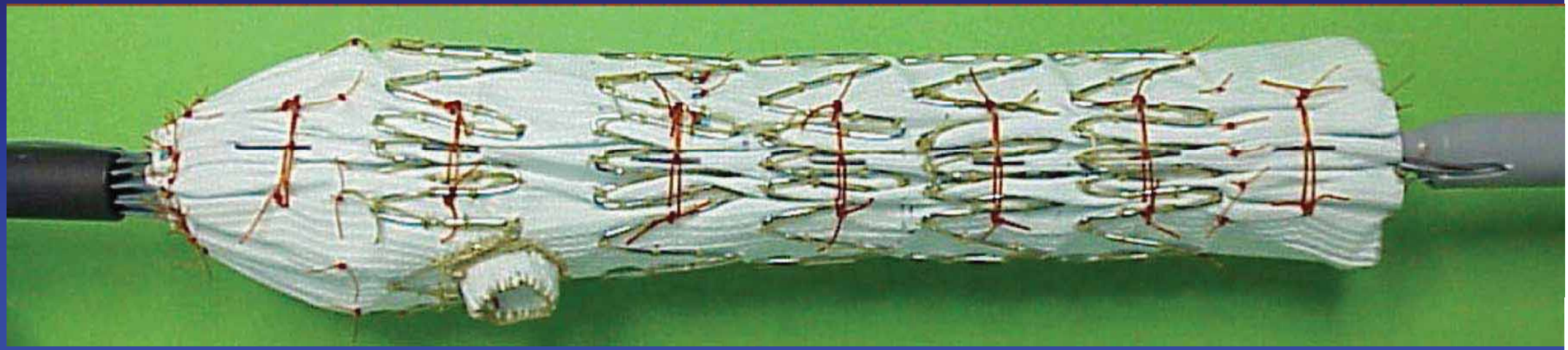
Cook Zenith





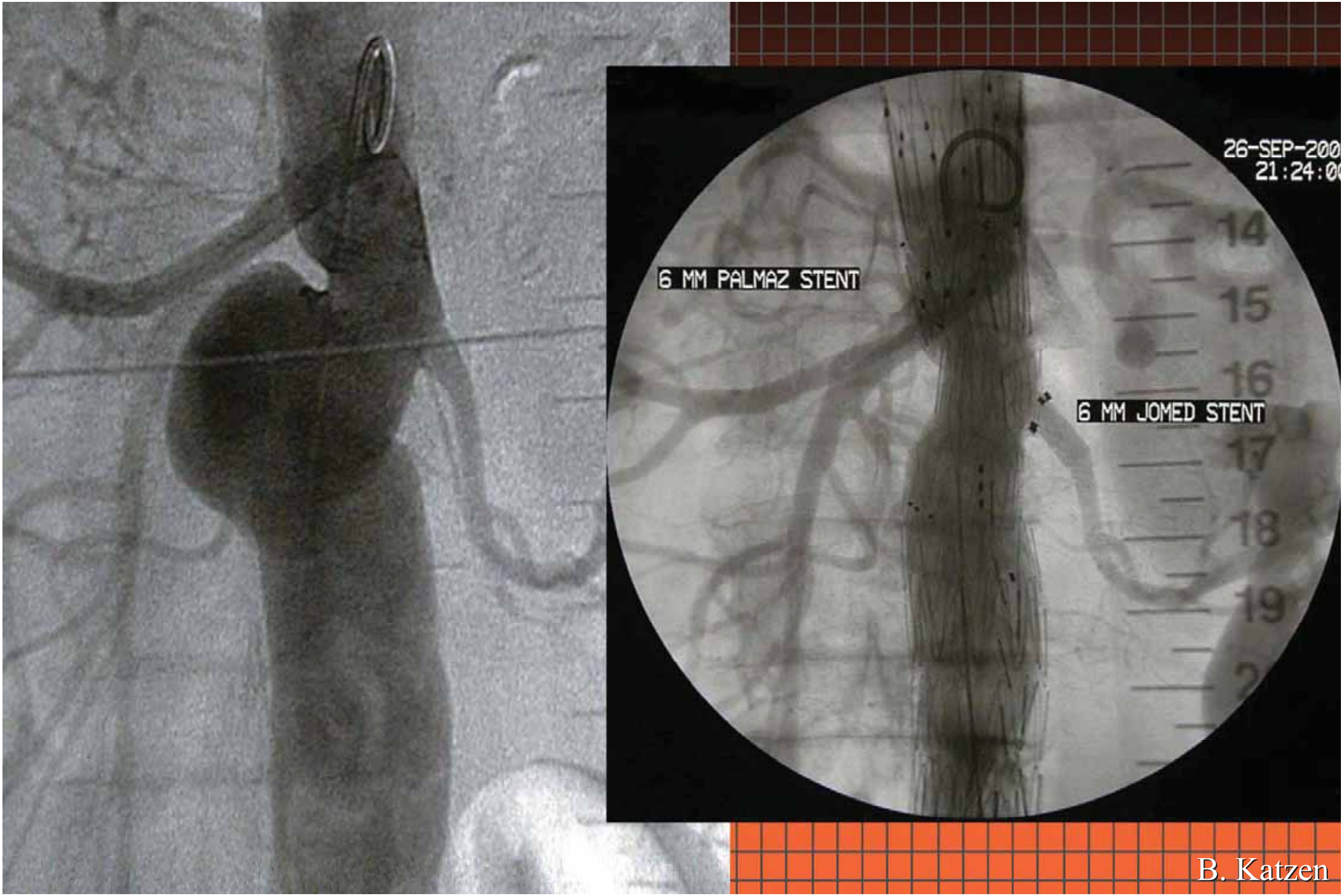
B. Katzen

Cook Zenith

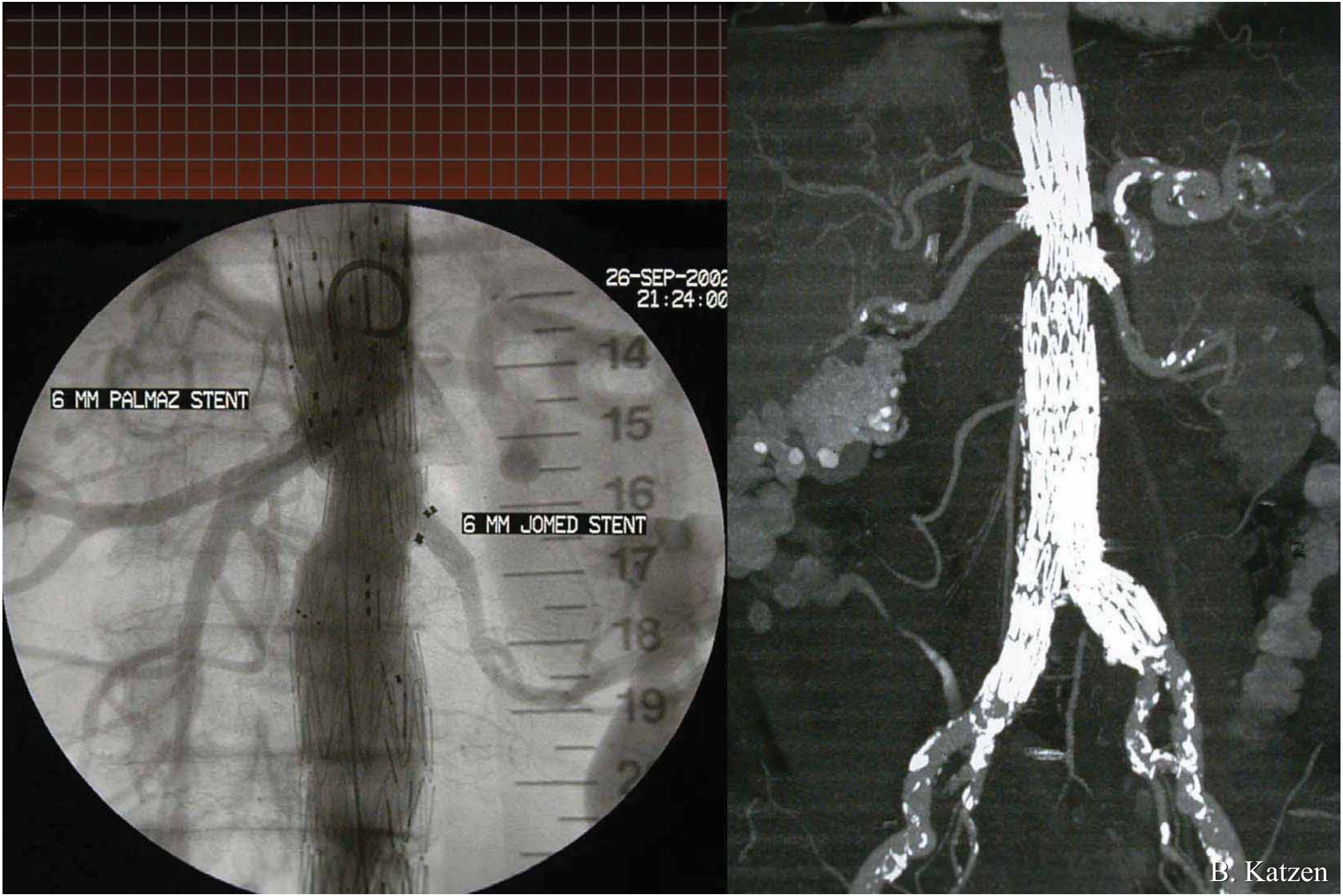


Short branch with stent extension

B. Katzen


6 MM PALMAZ STENT
6 MM JOMED STENT
26-SEP-200
21:24:0
14
15
16
17
18
19
2

B. Katzen


26-SEP-2002
21:24:00
6 MM PALMAZ STENT
6 MM JOMED STENT
14
15
16
17
18
19
B. Katzen

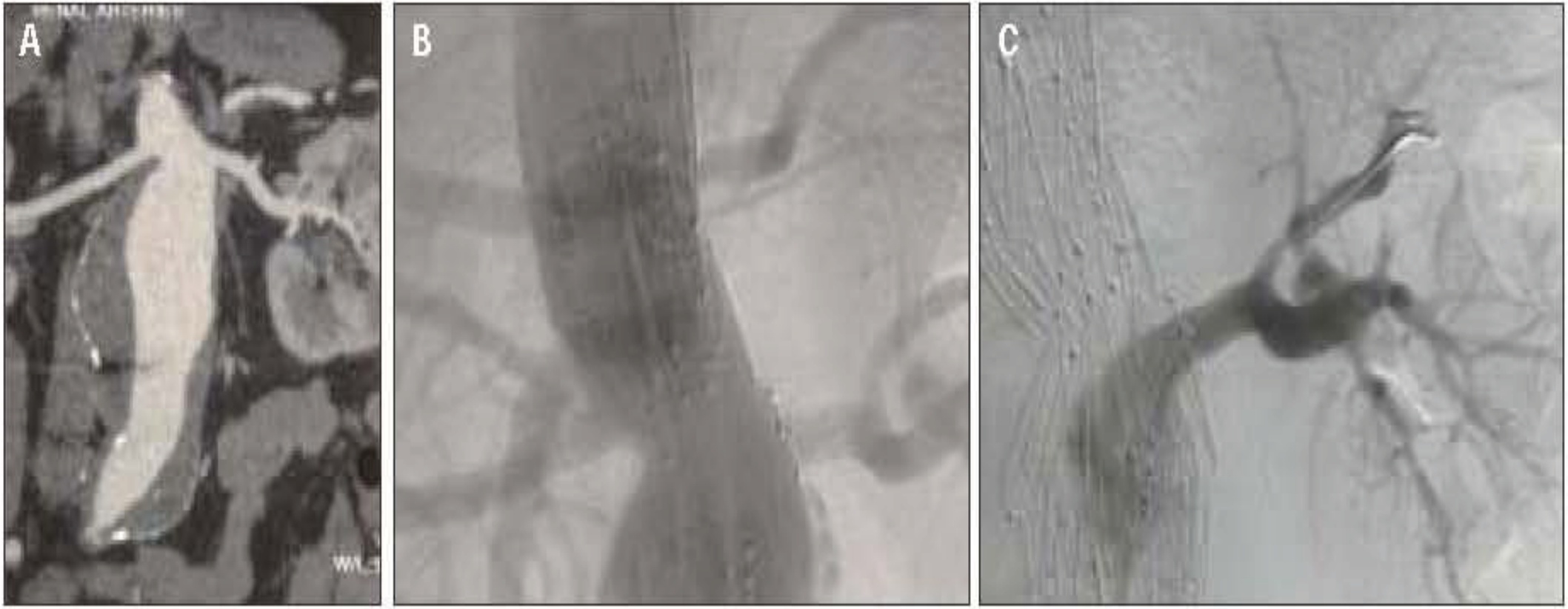


Figure 1. A 62-year-old man with ischemic heart disease, respiratory disease, and peripheral vascular disease presented with a large juxtarenal aortic aneurysm with an unfavorable neck due to length, shape, and angulation. Note that graft-to-wall contact is not possible in relation to the right renal artery (A). Treatment carried out with Zenith quadruple fenestrated graft. The vessels targeted for revascularization are the celiac, superior mesenteric artery, right renal, and left renal. Initial image after implantation shows an endoleak at the left renal (6 mm X 8 mm) fenestration (B). For the endoleak arising from the left renal artery, a Jomed (Beringen, Switzerland) stent graft was used (branched endograft) to achieve a satisfactory seal (C).

Fenestrated Graft

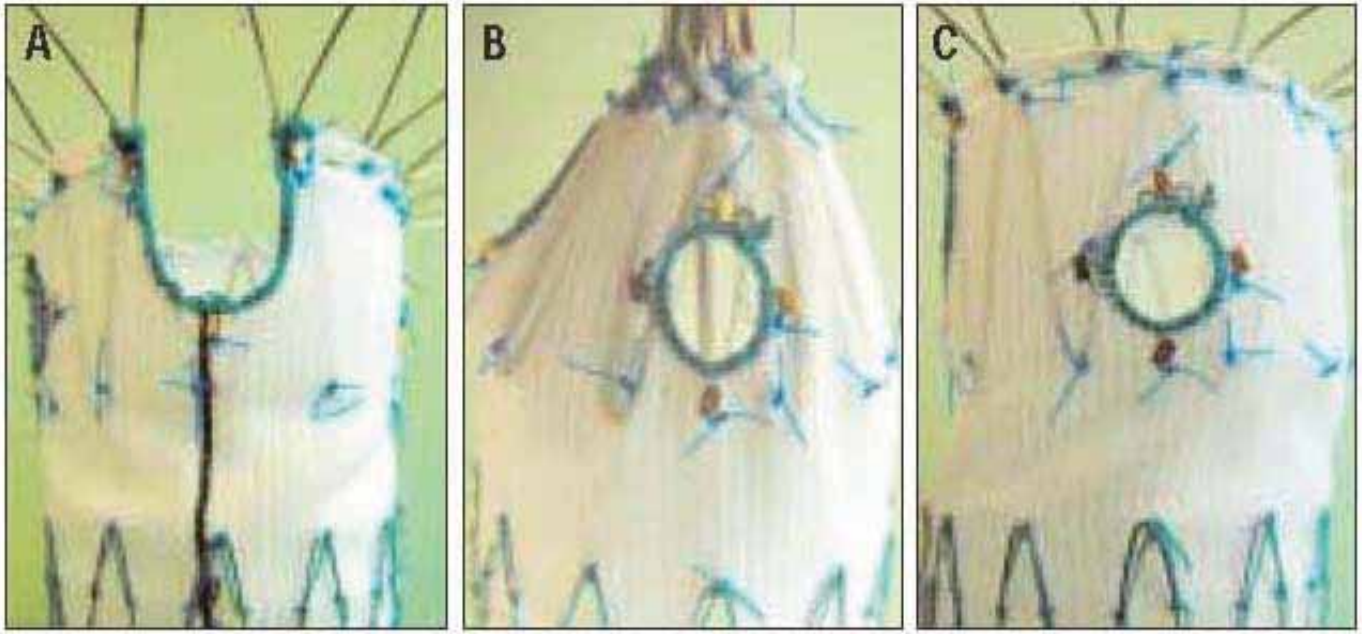


Figure 4. A scallop in the open position. Typically, this is used to provide continued perfusion of the celiac or superior mesenteric artery (A). A small fenestration in the proximal covered stent. At this stage, the proximal noncovered stent is contained within the proximal cap of the delivery system. This is the state in which the fenestration is catheterized during implantation (B). A small fenestration in the open position. Typically, this type of fenestration is used for renal artery perfusion (C).

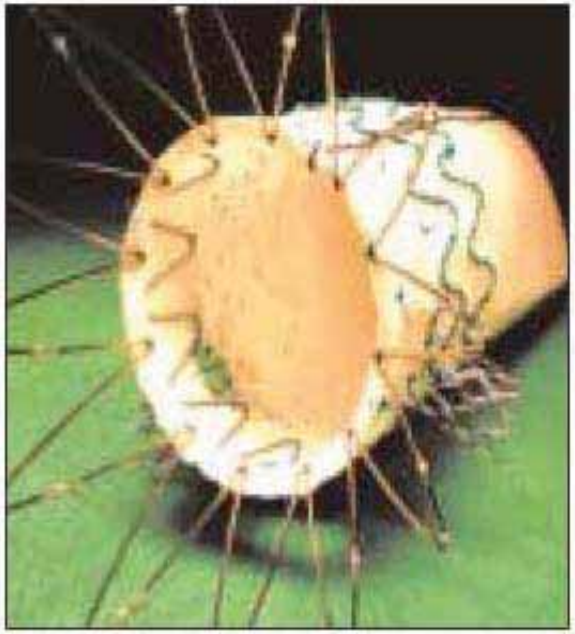


Figure 5. This image shows a bench model with the stents *in situ*. Note that the stents do not protrude into the lumen.

J. Anderson

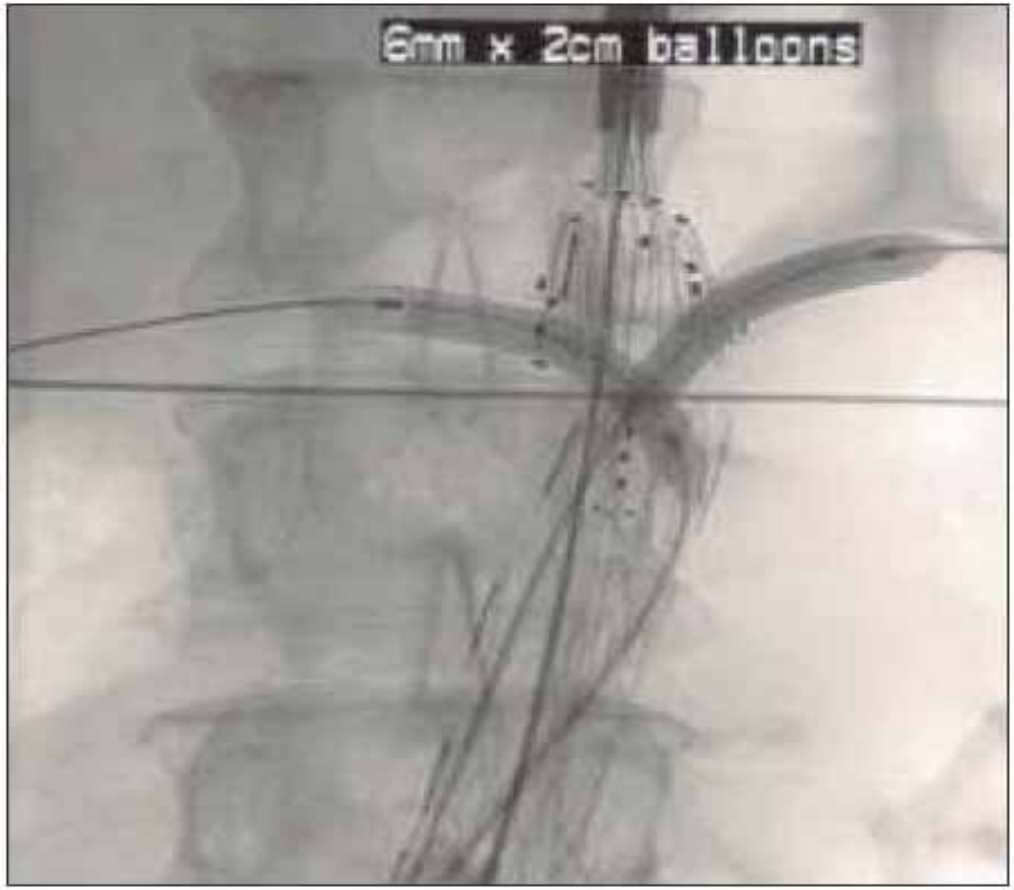


Figure 8. Balloons are placed in both renal vessels and inflated to a pressure of 2 to 4 atm prior to the release of the graft. With the balloons in place, the diameter-reducing tie and the proximal cap are released. With expansion of the graft the fenestrations can only travel along the balloon rail onto the targeted vessel ostia, thereby creating a good alignment between the targeted vessel ostia and the fenestration.

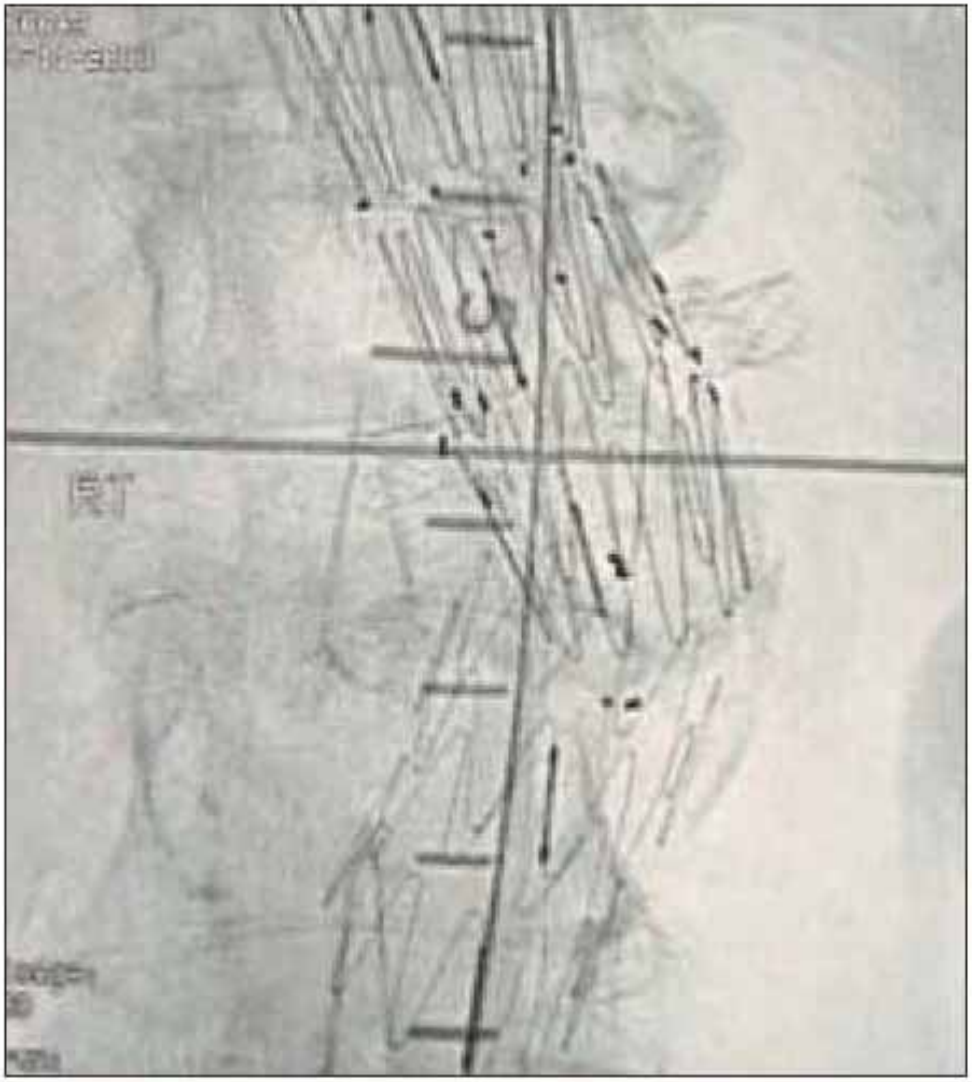


Figure 9. Graft-to-renal stenting using noncovered stents has been performed to maintain patency of the renal arteries.

J. Anderson

Wireless Pressure Sensing of Aneurysms

- Ultrasound based format (ImPressue, Remon Medical)
- RF energy (CardioMEMS)

Wireless Pressure Sensing

Figure 1. Example of a micromachine.

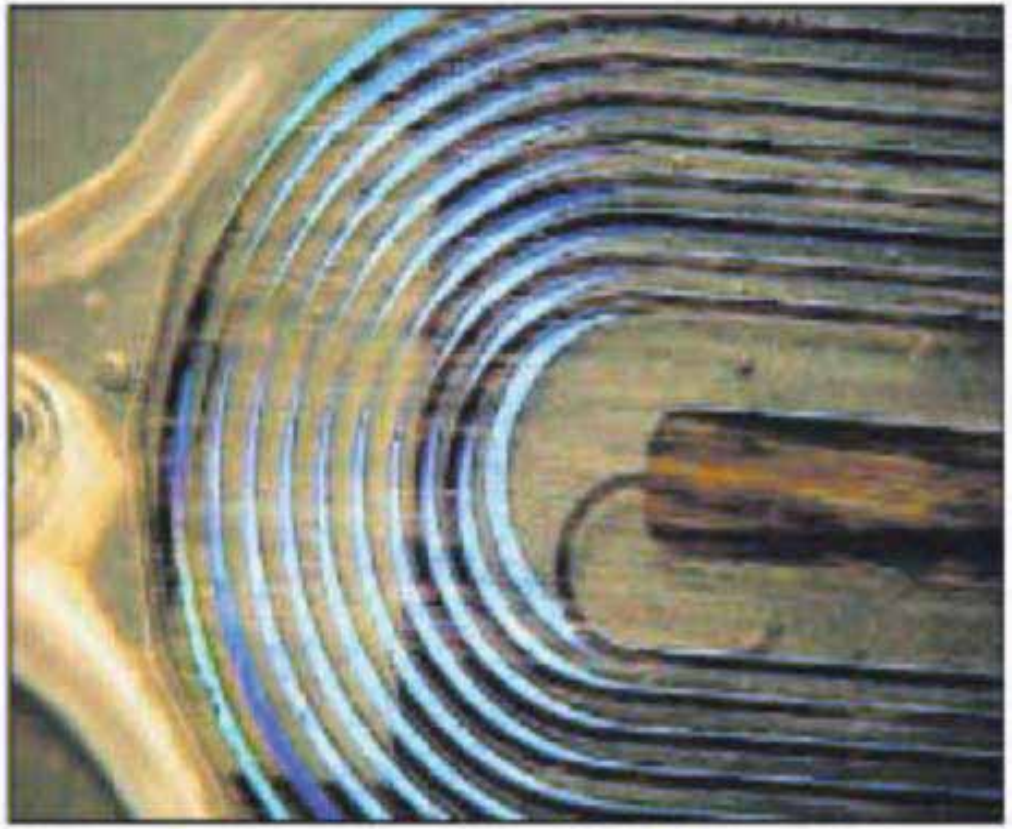


Figure 2. Closeup view of the CardioMEMS pressure sensor. MEMS allows the fabrication of precise components on the micron scale.

CardioMEMS (micro-electro-mechanical-systems) pressure sensor

CardioMEMS Pressure Sensor

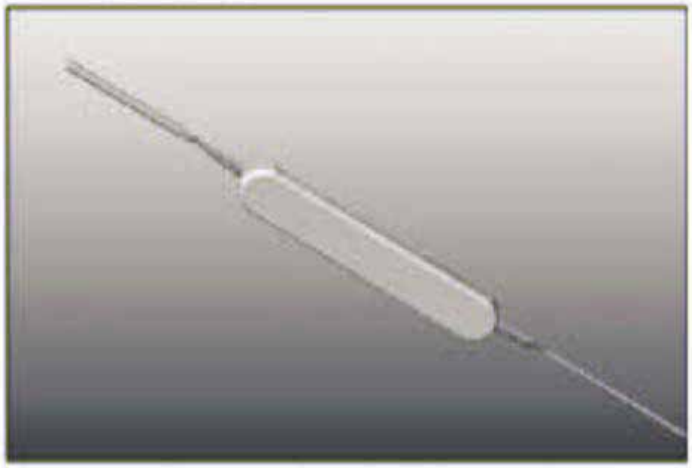


Figure 4. The AAA pressure sensor on a tether system.

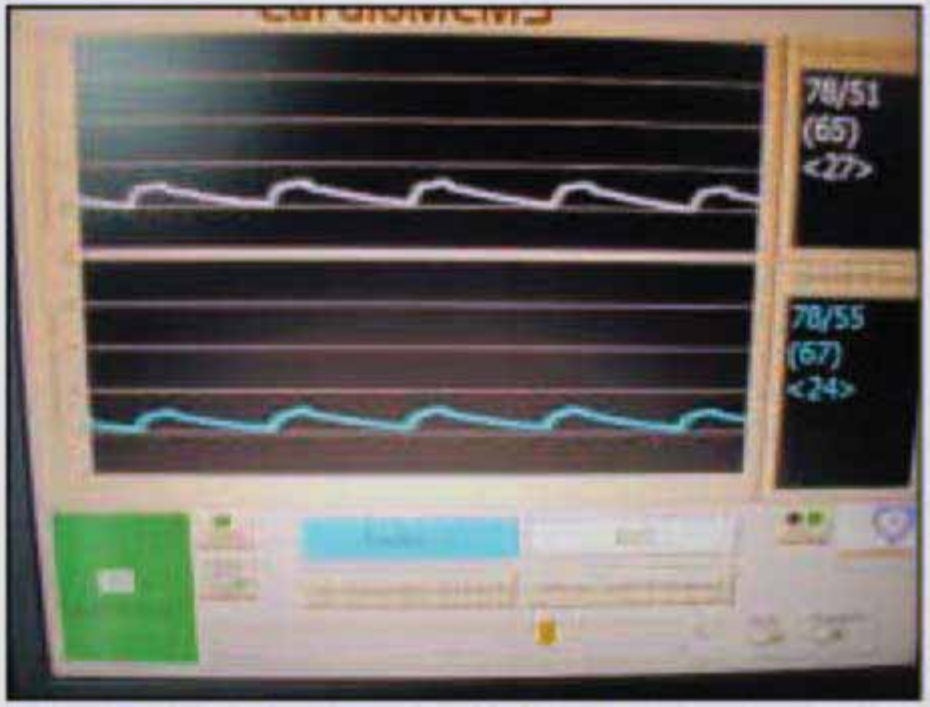


Figure 5. Note the excellent correlation between the catheter and the CardioMEMS wireless sensor readings.

First in man experience – sensor delivered into the aneurysm sac successfully in 5 patients

T. Ohki. Endovascular Today 2004

Aneurysm Sac Pressure Measurement

Figure 6. Aneurysm sac pressure measurement in a patient who underwent EVAR and CardioMEMS pressure implantation 4 hours earlier. The signal can be readily acquired with the antenna. Note the pressure wave form within the excluded sac is still pulsatile.

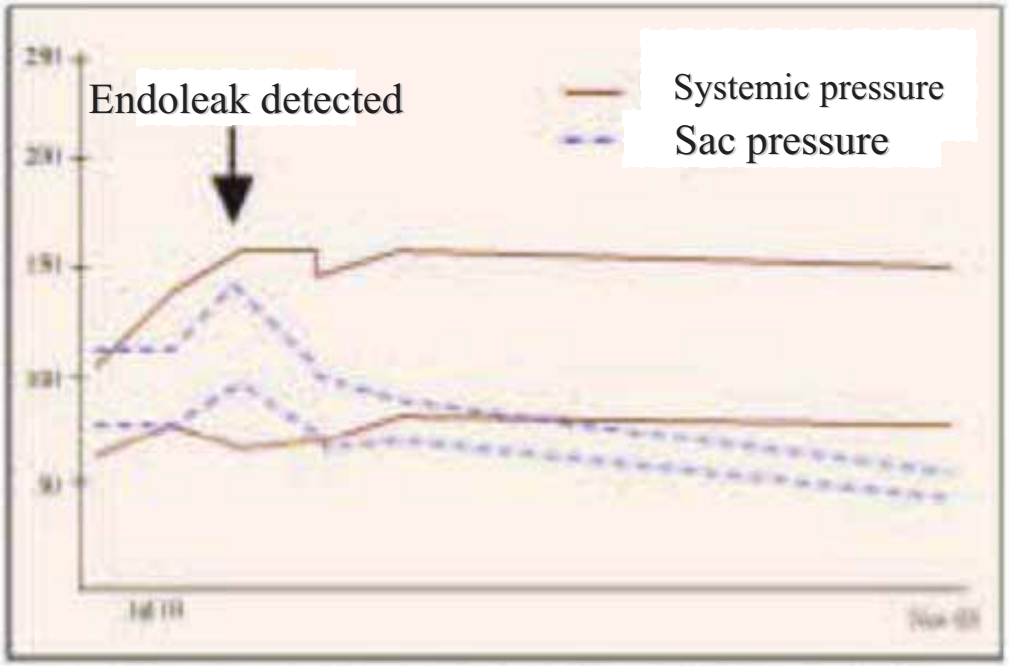
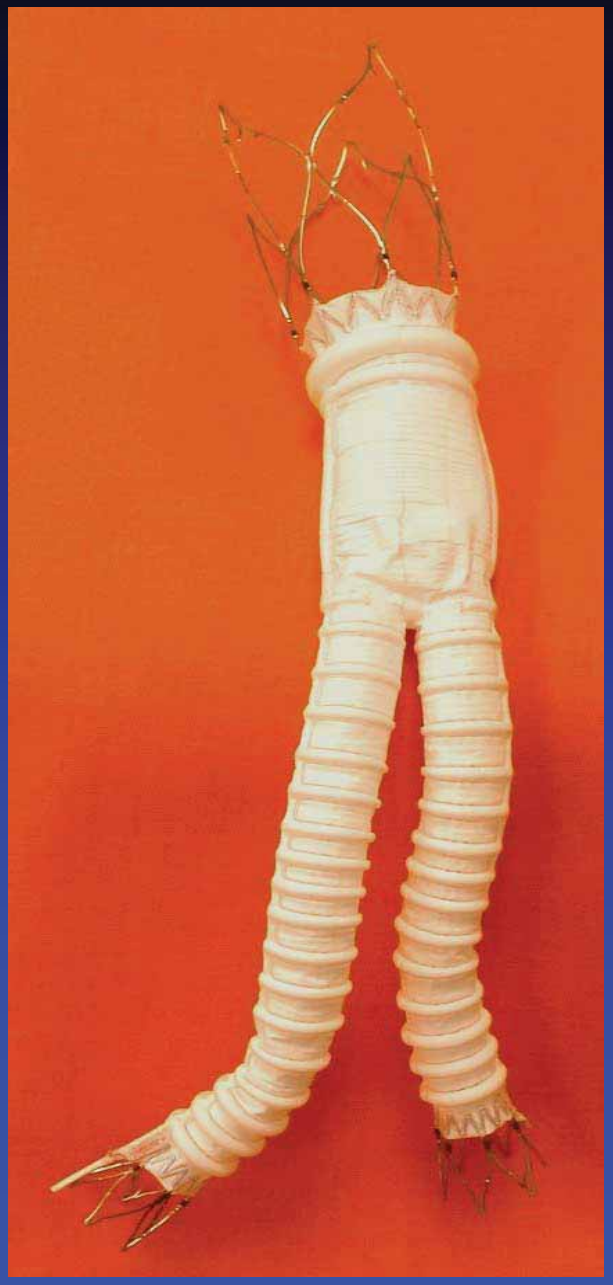


Figure 7. A Remon pressure sensor was implanted in a patient undergoing EVAR. The sac pressure was initially high. Follow-up MRA detected a distal type 1 endoleak, which was treated with an extension cuff. While the systemic pressure remained stable, the sac pressure gradually decreased during the next 3 months (modified from Lookstein R et al[12]).

T. Ohki. Endovascular Today 2004



TriVascular Stent Graft

Inflatable sealing cuffs

Suprarenal positive fixation

Distal positive fixation

Unibody graft designed for:

- ***Kink resistance***
- ***Conformance to anatomy***
- ***Mechanical integrity***

Conclusions

- Exclusion of AAA with endoluminal grafts is in its earliest stages
- Considerable improvement in device design and deployment techniques
- Each of the devices can be deployed with high technical success rates and low operative mortality/morbidity