Catheter based Aortic Interventions

Innovations in Endovascular Aortic Aneurysm Repair

Shirling Tsai, M.D.
Assistant Professor of Surgery
Dallas Veterans Affairs Medical Center
University of Texas Southwestern
Department of Surgery
Division of Vascular and Endovascular Surgery

VA NORTH TEXAS HEALTH CARE SYSTEM
Changing lives. One Veteran at a time.

UT SOUTHWESTERN MEDICAL CENTER

Disclosures

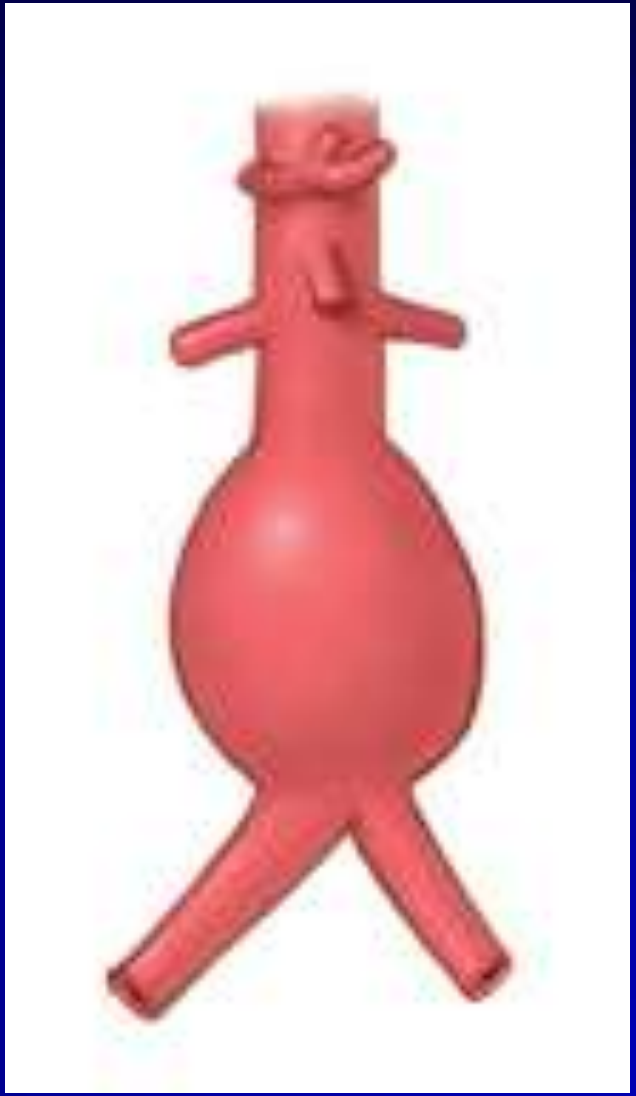
- None

Outline

- Abdominal Aortic Aneurysm - background
- Management options for infrarenal AAA
- Outcomes after open repair vs. EVAR
- Devices for EVAR
- Complex AAA repair

Abdominal Aortic Aneurysms

- Definition
  - Exceeds normal aortic diameter by >50%
  - >3cm
- Nearly all involve infrarenal aorta
- Most are isolated to infrarenal aorta



AAA epidemiology

Table 1 | Prevalence of AAA in screened populations

Study (population)	Screened population	Number of scans	Number of AAAs*	Prevalence of AAA
Ashton *et al.* for the MASS group (UK)[10]				
Norman *et al.* (Western Australia)[12]				
Lindholt *et al.* (Viborg, Denmark)[13]				
Ashton *et al.* (Chichester, UK)[43]				
Scott *et al.* (Chichester, UK)[44]				

Table V. Prevalence of small and medium AAAs among 73,451 US military veterans between 50 to 79 years†

Race	*Gender*	*Smoking status*	*AAA ≥3cm (%)*	*AAA ≥4cm (%)*
White	Male	Smoker	5.9	1.9
		Nonsmoker	1.9	0.4
White	Female	Smoker	1.9	0.3
		Nonsmoker	0.6	0
Black	Male	Smoker	3.2	0.8
		Nonsmoker	1.4	0.1

- Older patients
- Predominantly male

Nordon IM et al. *Nat Rev Cardiol.* 2011; 8: 92-102.

Indications for repair

- Rupture risk is related to AAA size
  - Associated mortality 50-80%

AAA diameter	Rupture risk per year
< 4.0 cm	< 0.5%
4.0 – 4.9 cm	0.5 – 5%
5.0 – 5.9 cm	3 – 15%
6.0 – 6.9 cm	10 – 20%
7.0 – 7.9 cm	20 – 40%
>= 8.0 cm	30 – 50%

When should AAA be repaired?

- Two large randomized control trials
  - ADAM
  - UK Small Aneurysm Trial
- No benefit to early aneurysm repair
- Elective repair of AAA > 5.5cm

History of Aneurysm Repair

THE USE OF TUBES CONSTRUCTED FROM VINYON "N" CLOTH IN BRIDGING ARTERIAL DEFECTS—EXPERIMENTAL AND CLINICAL*

ARTHUR H. BLAKEMORE, M.D. AND ARTHUR B. VOORHEES, JR., M.D.

NEW YORK, N. Y.

FROM THE DEPARTMENT OF SURGERY OF THE PRESBYTERIAN HOSPITAL AND THE COLLEGE OF PHYSICIANS AND SURGEONS OF COLUMBIA UNIVERSITY

- Annals of Surgery 1954
- Series of 17 patients

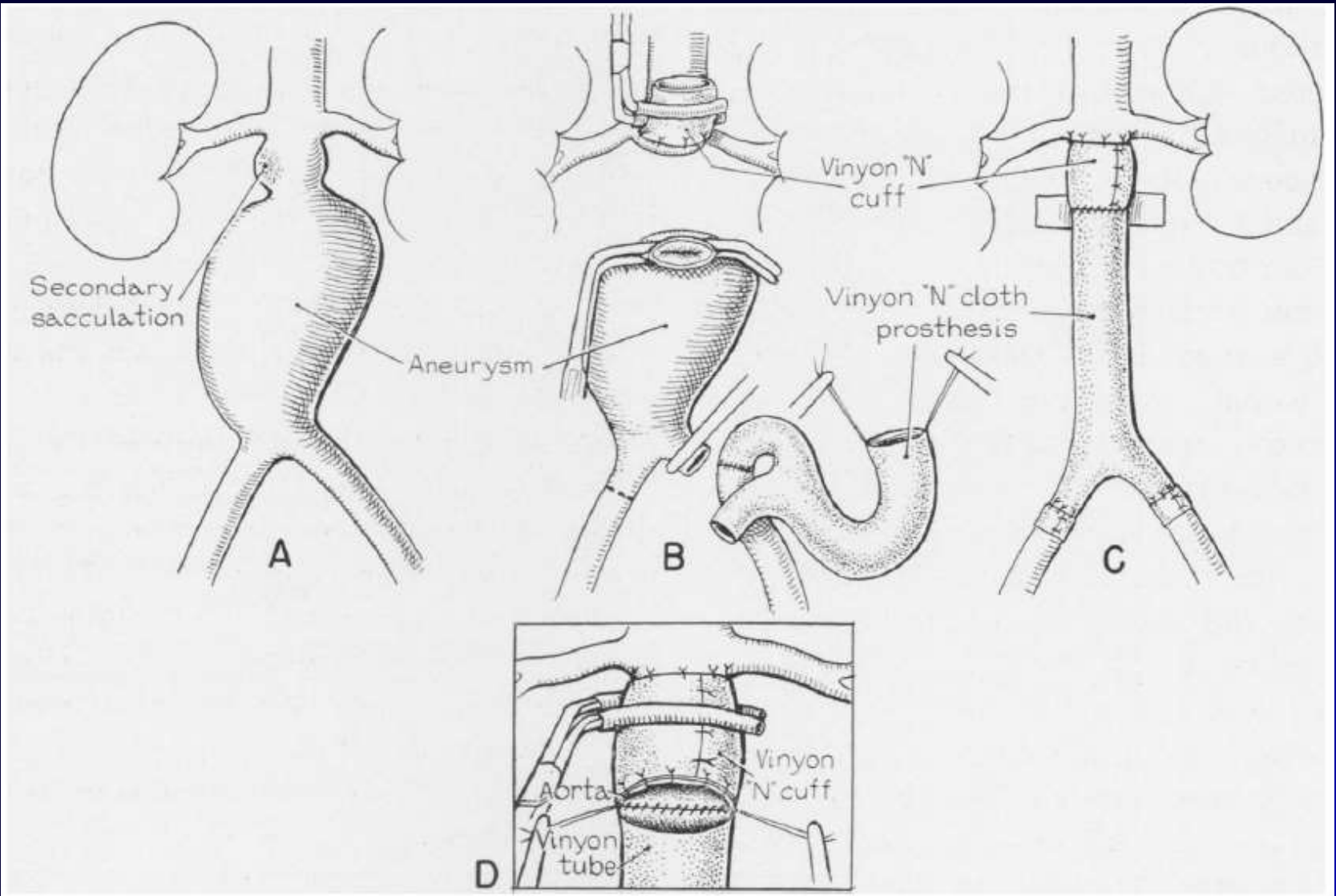


FIG. 4. The diagrammatic sketch of the case of E. P. demonstrates how secondary sacculations, or weakened areas of the aorta, may be reinforced by a cloth cuff. In this case the sacculation did rupture when the clamp was applied, but the cuff brought the hemorrhage under immediate control.

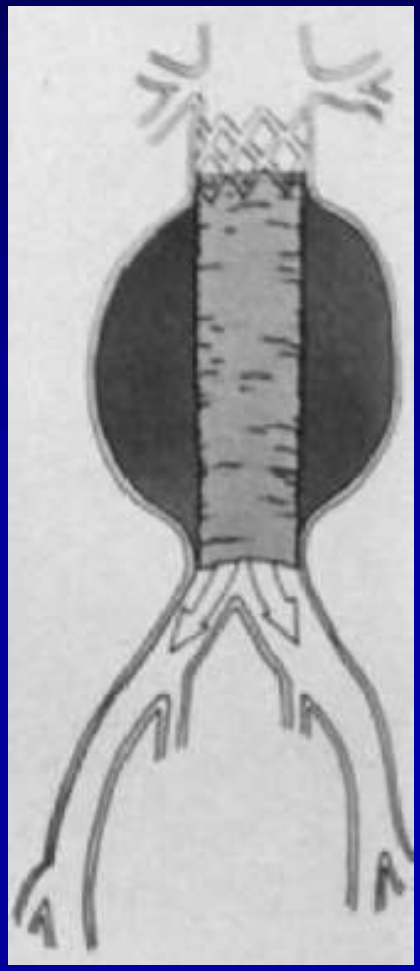
Blakermore AH and Voorhees AB. Ann Surg 1954.

Current management of infrarenal AAA

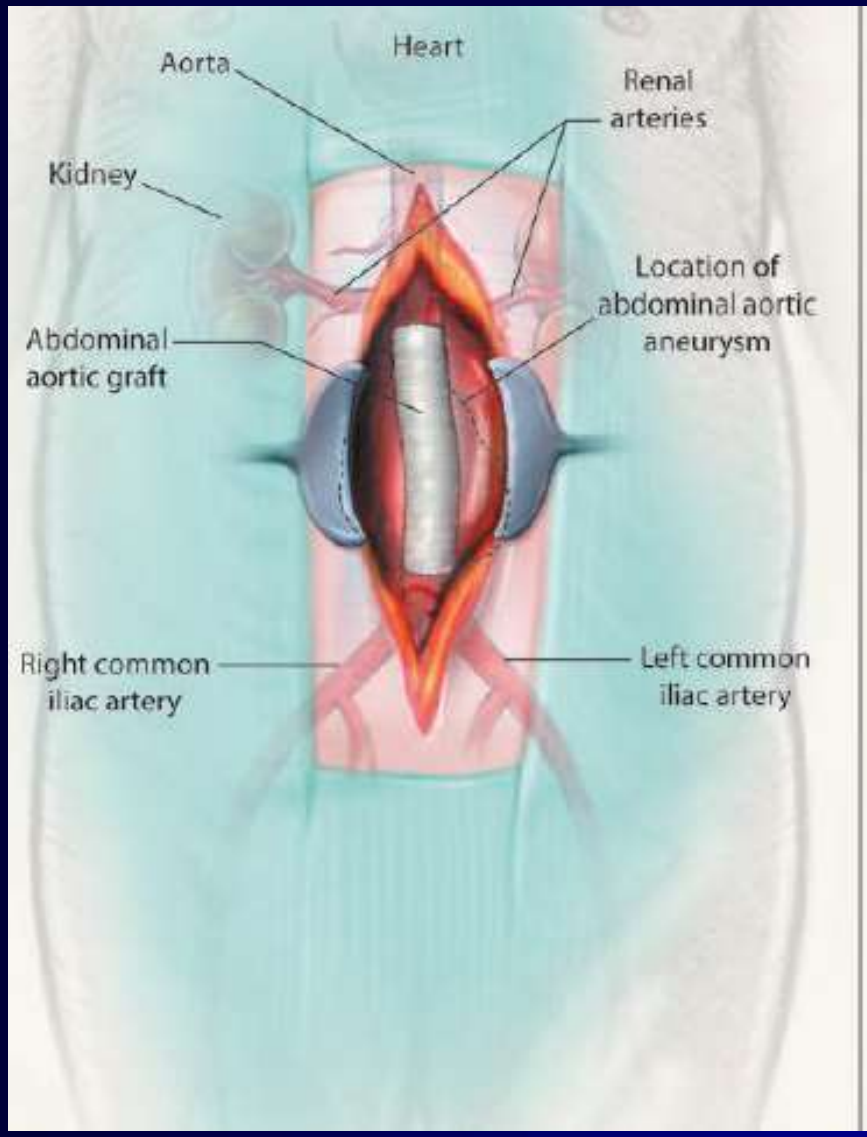
Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms

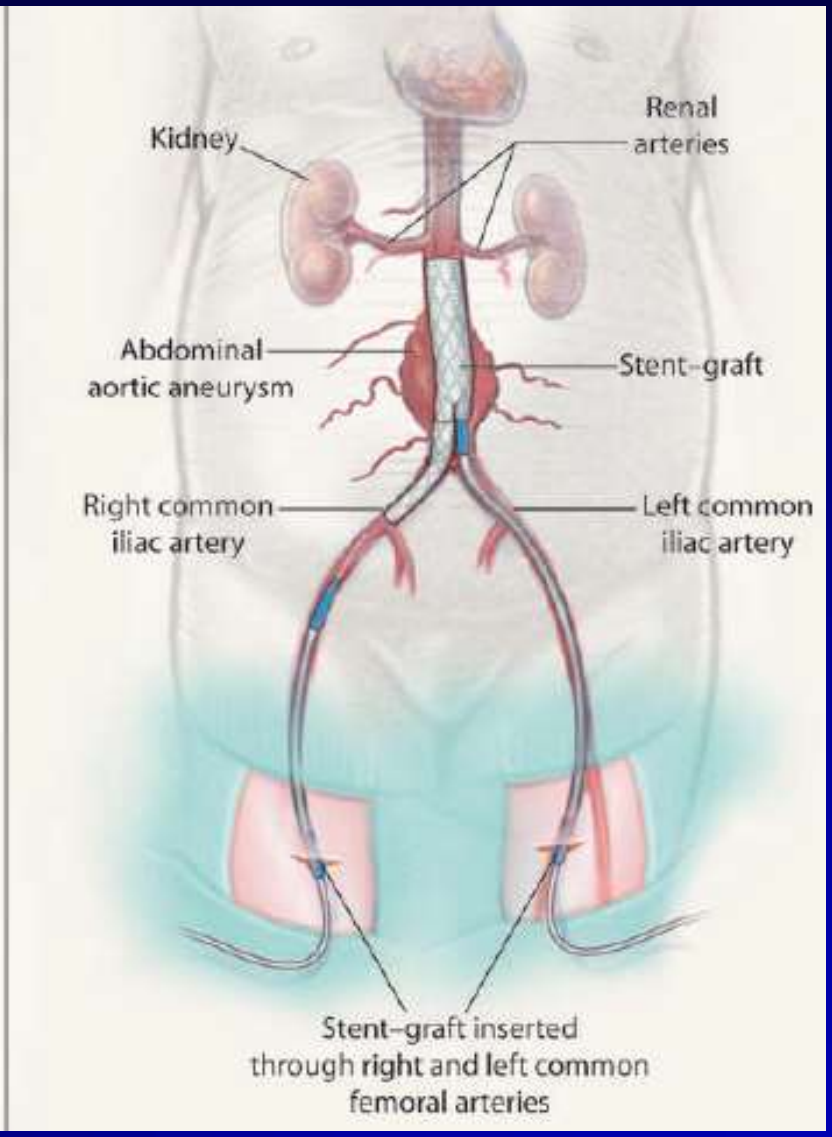
J.C. Parodi, MD*, J.C. Palmaz, MD†, H.D. Barone, PhD, *Buenos Aires, Argentina, and San Antonio, Texas*

This study reports on animal experimentation and initial clinical trials exploring the feasibility of exclusion of an abdominal aortic aneurysm by placement of an intraluminal, stent-anchored, Dacron prosthetic graft using retrograde cannulation of the common femoral artery under local or regional anesthesia. Experiments showed that when a balloon-expandable stent was sutured to the partially overlapping ends of a tubular, knitted Dacron graft, friction seals were created which fixed the ends of the graft to the vessel wall. This excludes the aneurysm from circulation and allows normal flow through the graft lumen. Initial treatment in five patients with serious co-morbidities is described. Each patient had an individually tailored balloon diameter and diameter and length of their Dacron graft. Standard stents were used and the diameter of the stent-graft was determined by sonography, computed tomography, and arteriography. In three of them a cephalic stent was used without a distal stent. In two other patients both ends of the Dacron tubular stent were attached to stents using a one-third stent overlap. In these latter two, once the proximal neck of the aneurysm was reached, the sheath was withdrawn and the cephalic balloon inflated with a saline/contrast solution. The catheter was gently removed caudally towards the arterial entry site in the groin to keep tension on the graft, and the second balloon inflated so as to deploy the second stent. Four of the five patients had heparin reversal at the end of the procedure. We are encouraged by this early experience, but believe that further developments and more clinical trials are needed before this technique becomes widely used. (*Ann Vasc Surg* 1991;*5*:491–499).



Open repair vs. EVAR





Schermerhorn ML et al. NEJM 2008;358:464.

The benefits of EVAR

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 14, 2004 VOL. 351 NO. 16

	EVAR	Open repair	Odds ratio (95% CI)				p
			Crude	p	Adjusted*	p	
Outcome by intention to treat (number of patients)	531	516					
30-day mortality (number of deaths)	1·7% (9)	4·7% (24)	0·35 (0·16–0·77)	0·009	0·37 (0·17–0·83)	0·016	
In-hospital mortality (number of deaths)	2·1% (11)	6·2% (32)	0·32 (0·16–0·64)	0·001	0·30 (0·14–0·62)	0·001	
Median (IQR) length of hospital stay (days)†	7 (5–10)	12 (9–16)					<0·0001‡
Median (IQR) length of operation (min)†	215	300 (155–240)					<0·0001‡
Secondary interventions either during 30 days or during the primary admission							
Conversion to open repair	10						
Correction of endoleak	18						
Re-exploration of open repair	1						
Other surgery	21	14					
Unknown	2	0					
Total	52 (9·8%)	30 (5·8%)					0·02§

30 Mortality
4.7% (open AAA) vs. 1.7% (EVAR)

Two year follow-up data

The NEW ENGLAND JOURNAL of MEDICINE

ORI

Two-Year Outc
or Endovascul
Aor

Jan D. Blankensteijn, M.D., Sjor
Arie C. van der Ham, M.D., Jaap
Hence J.M. Verhagen, M.D., Erik
for the Dutch Randomiz
(D

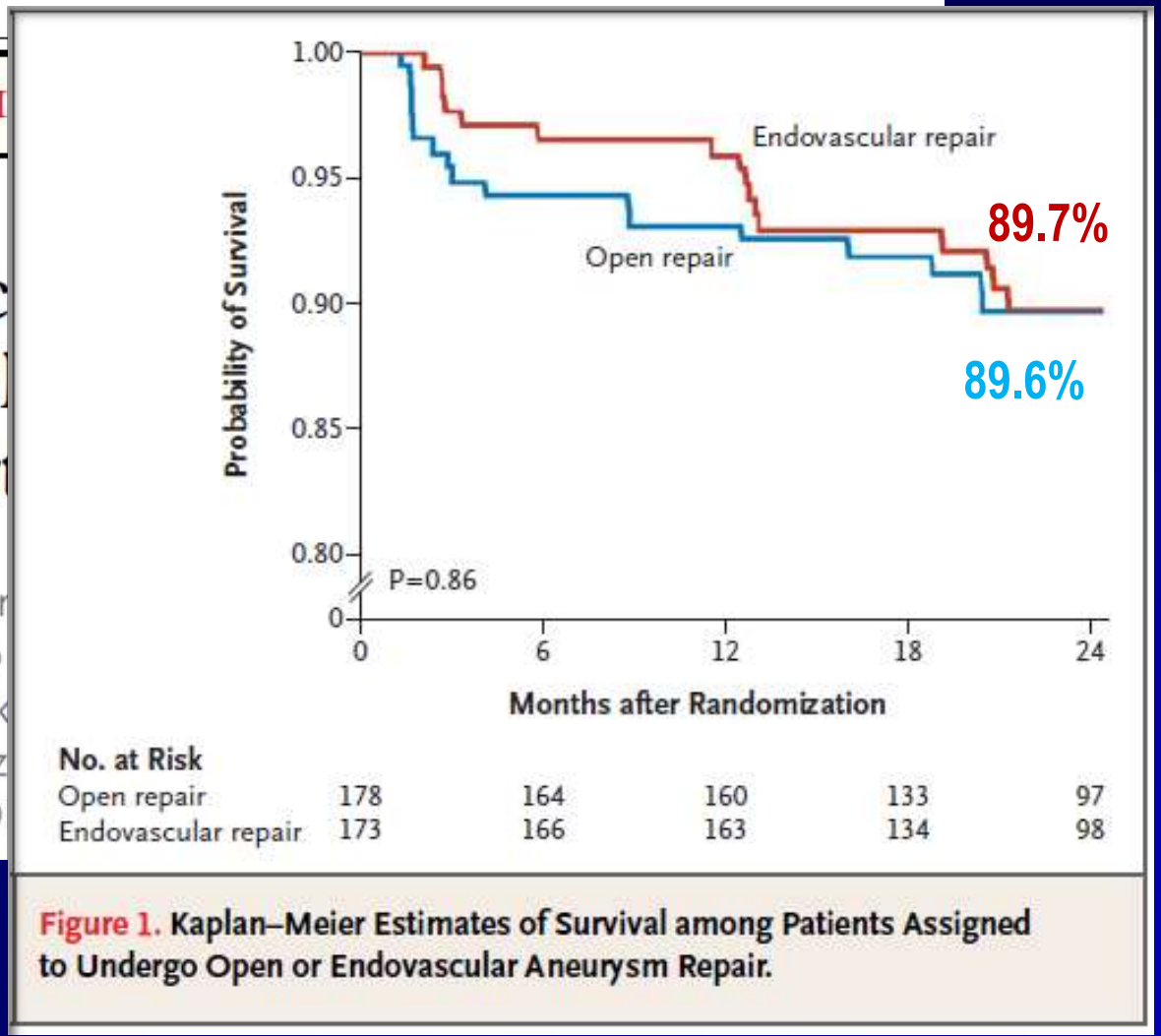
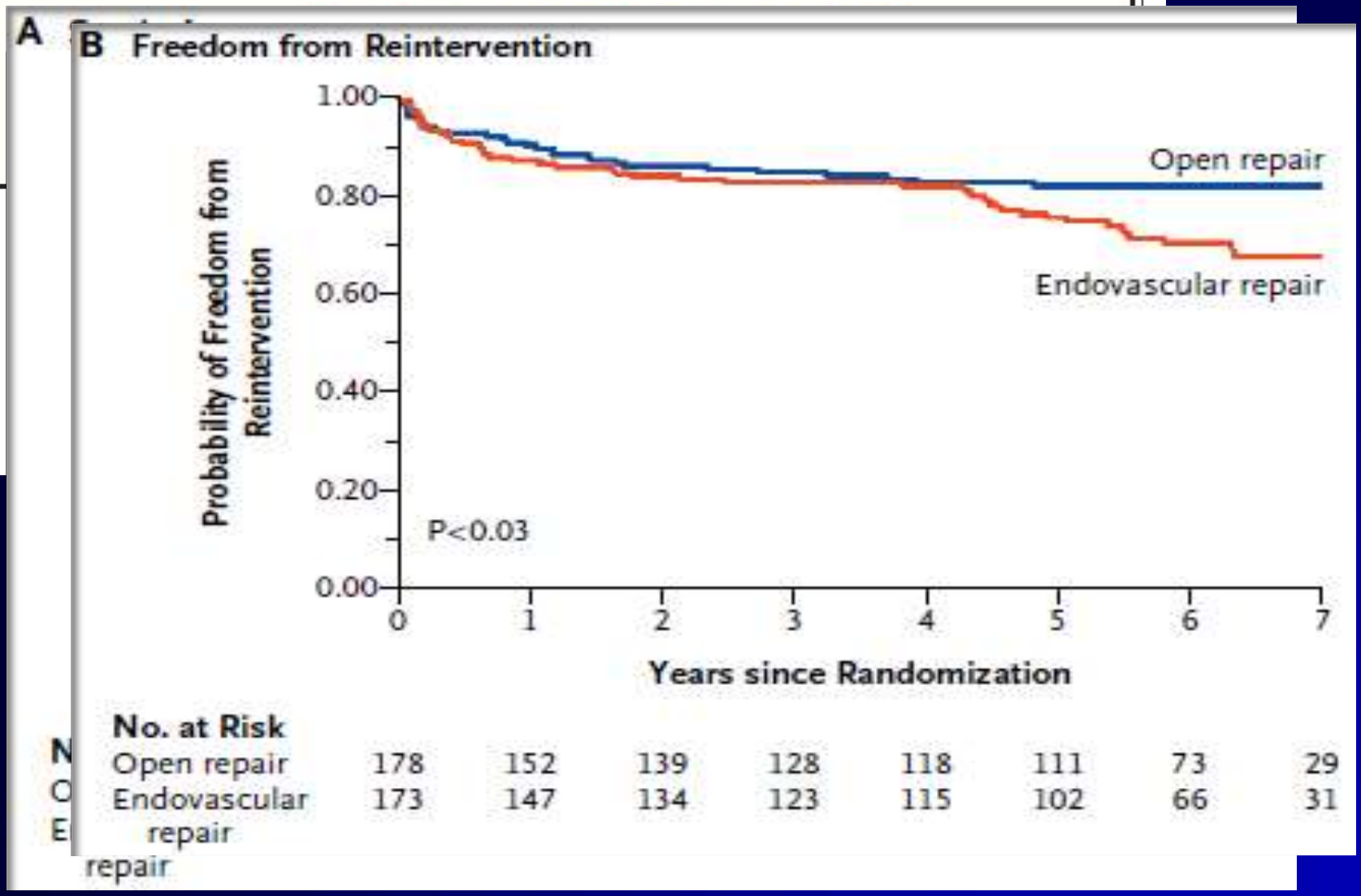
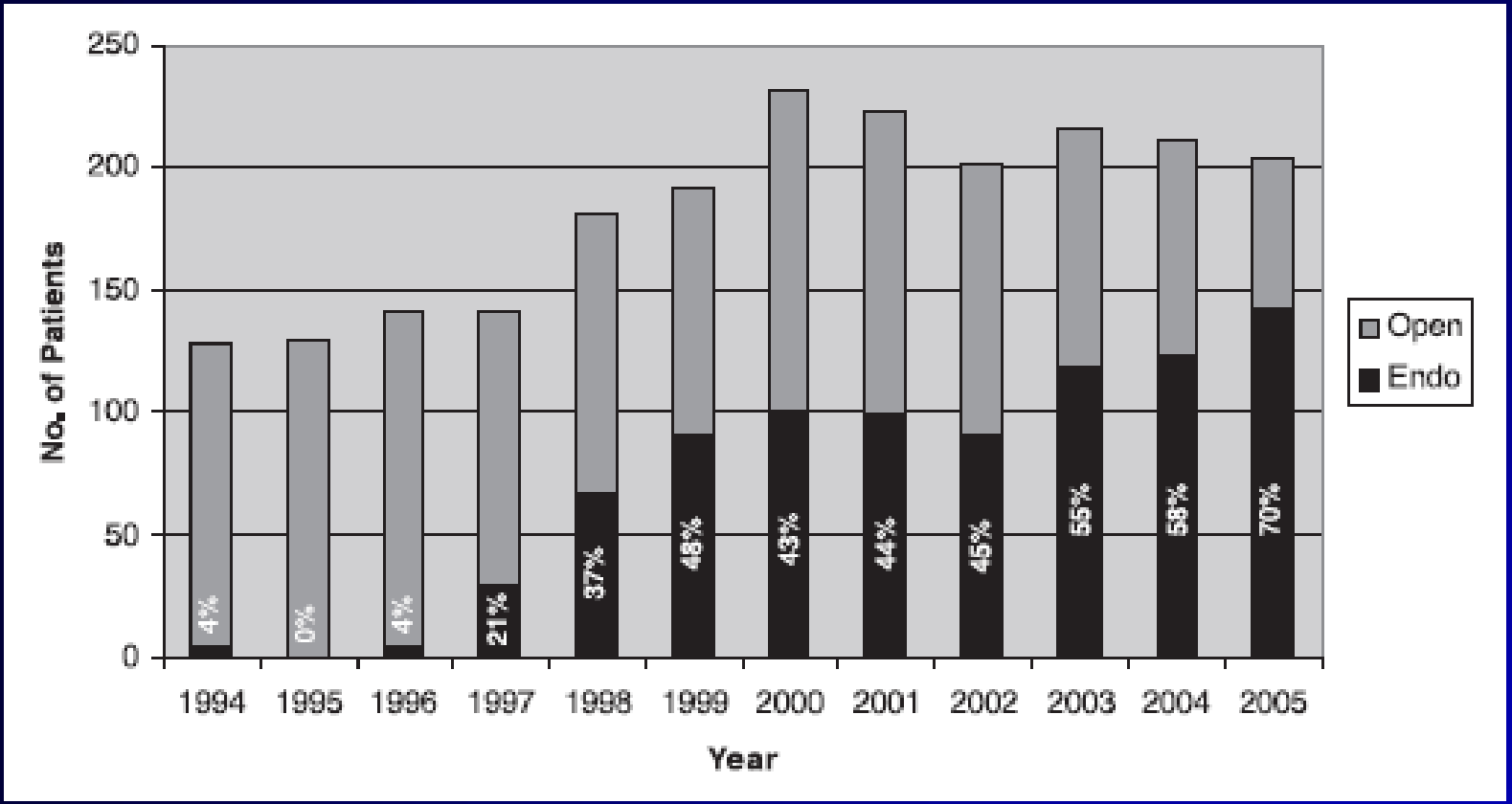


Figure 1. Kaplan–Meier Estimates of Survival among Patients Assigned to Undergo Open or Endovascular Aneurysm Repair.

Long term follow-up

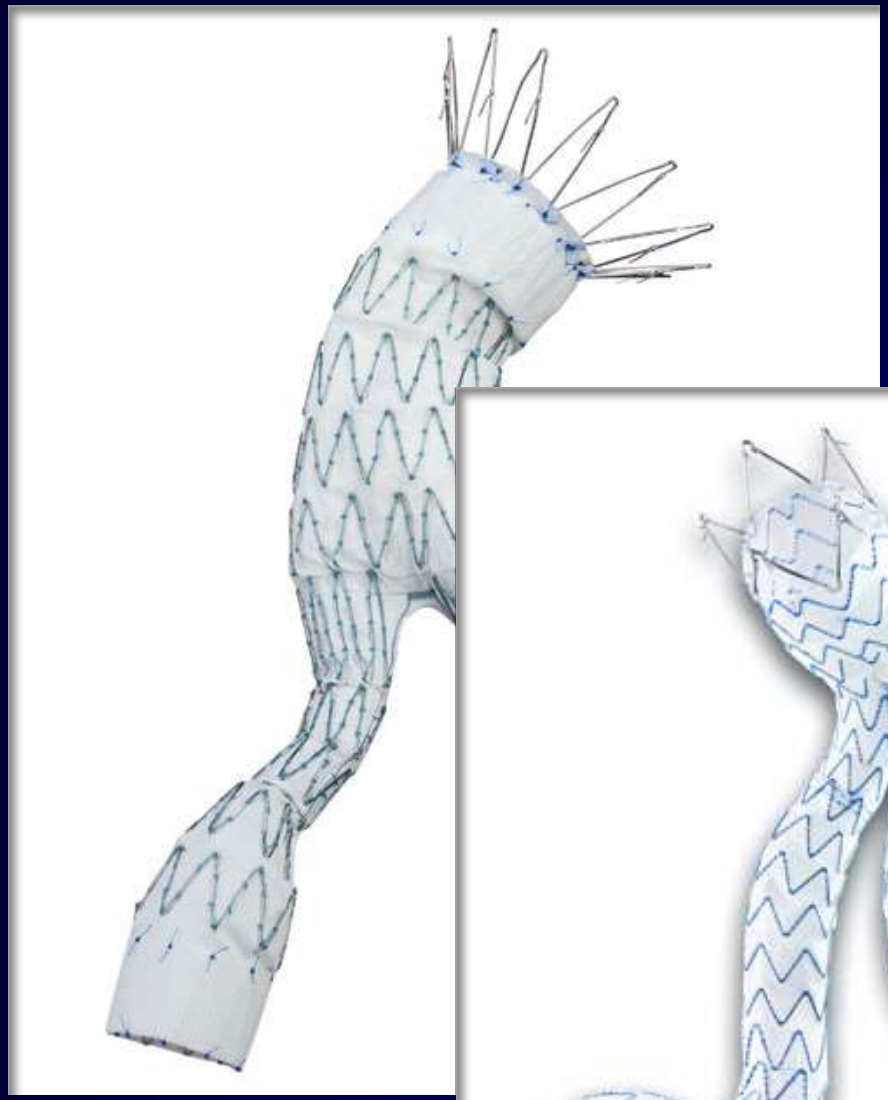


Trend in management of infrarenal AAA



Brewster DC et al. Ann Surg 2006; 244: 426.

CURRENT EVAR DEVICES



Length	≥ 15 mm nonaneurysmal infrarenal neck
Aortic Fixation Site Diameter	18-32 mm (measured outer wall to outer wall)
Angulation/	• Angle < 60 degrees relative to the long axis of the aneurysm.

INDICATIONS FOR USE

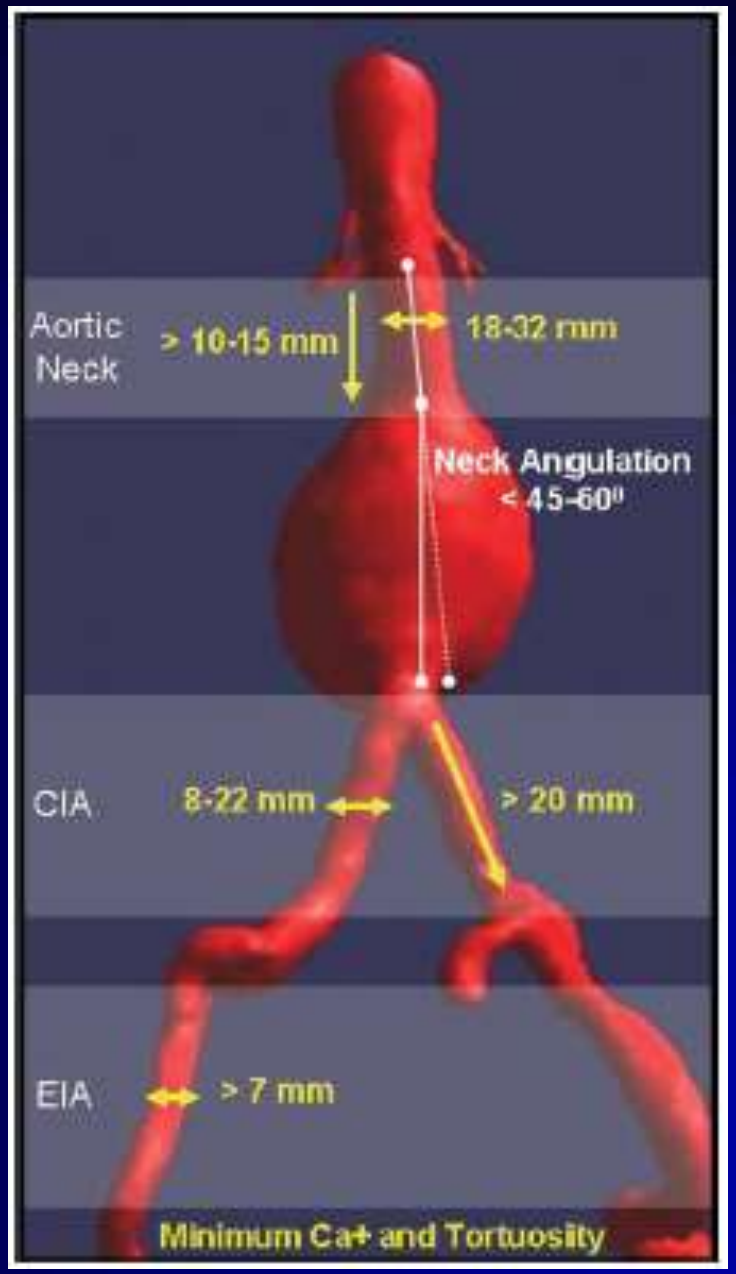
Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis Components

The GORE® EXCLUDER® AAA Endoprosthesis is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below:

- Adequate iliac / femoral access
- Infrarenal aorti
  aortic neck leng
- Proximal aortic
- Iliac artery treat
  zone length of

Indications for Use:

- **Proximal neck >= 10mm**
- **Infarenal neck angulation <= 60 degrees**
- **Aortic neck diameter 19-32mm**
- **Distal fixation length >= 15mm**
- **Iliac diameters 8-25mm**



Schanzer A et al. *Circulation* 2011;123:2848-2855.

Outcomes following endovascular abdominal aortic aneurysm repair (EVAR): An anatomic and device-specific analysis

Thomas A. Abbruzzese, MD, Christopher J. Kwolek, MD, David C. Brewster, MD, Thomas K. Chung, MS, Jeanwan Kang, MD, Mark F. Conrad, MD, Glenn M. LaMuraglia, MD, and Richard P. Cambria, MD, *Boston, Mass*

Objective: We performed a device-specific comparison of long-term outcomes following endovascular aneurysm repair (EVAR) to determine the effect(s) of device type on early and late clinical outcome impact of performing EVAR both within and outside of specific instructions for use (IFU) for each de commercially available stent graft devices. Study outcomes included perioperative (≤30 days) mortal technical complications and need for adjunctive procedures, aneurysm rupture, aneurysm-related morta open repair, reintervention, development and/or resolution of endoleak, device related adverse e thrombosis, or kinking), and a combined endpoint of any graft-related adverse event (GRAE). Send correlated by aneurysm morphology that was within or outside of the recommended device IFU. χ^2 a methods were used for analysis.

Results: Grafts implanted included 177 Cook Zenith (CZ, 31%), 111 Gore Excluder (GE, 20%), and AneuRx (MA, 49%); 39.3% of grafts were placed outside of at least one IFU parameter. Mean follow- months and was shorter for CZ (20 months CZ vs 35 and 31 months for GE and MA, respectively; P lower number of graft migration events (0 CZ vs 1 GE and 9 MA); however, there was no difference bet actuarial 5-year freedom from aneurysm-related death, reintervention, and GRAE was similar among d actuarial analysis. Combined GRAE was lowest for CZ (29% CZ, 35% GE, and 43% MA; $P = .01$). outside of IFU was associated with similar 5-year freedom from aneurysm-related death, migration, and ($P > .05$), but a lower freedom from GRAE (74% outside IFU vs 86% within IFU; $P = .021$), likely rela incidence of graft thrombosis (2.3% outside IFU vs 0.3% within IFU; $P = .026$). The differences in out placed within vs outside IFU were not device-specific.

Conclusion: EVAR performed with three commercially available devices provided similar clinically relevant years, although no graft migration occurred with a suprarenal fixation device. As anticipated, applicat anatomically specific IFU variables had an incremental negative effect on late results, indicating that adh IFU guidelines is appropriate clinical practice. (J Vasc Surg 2008;48:19-28.)

The correlation of aortic neck length to early and late outcomes in endovascular aneurysm repair patients

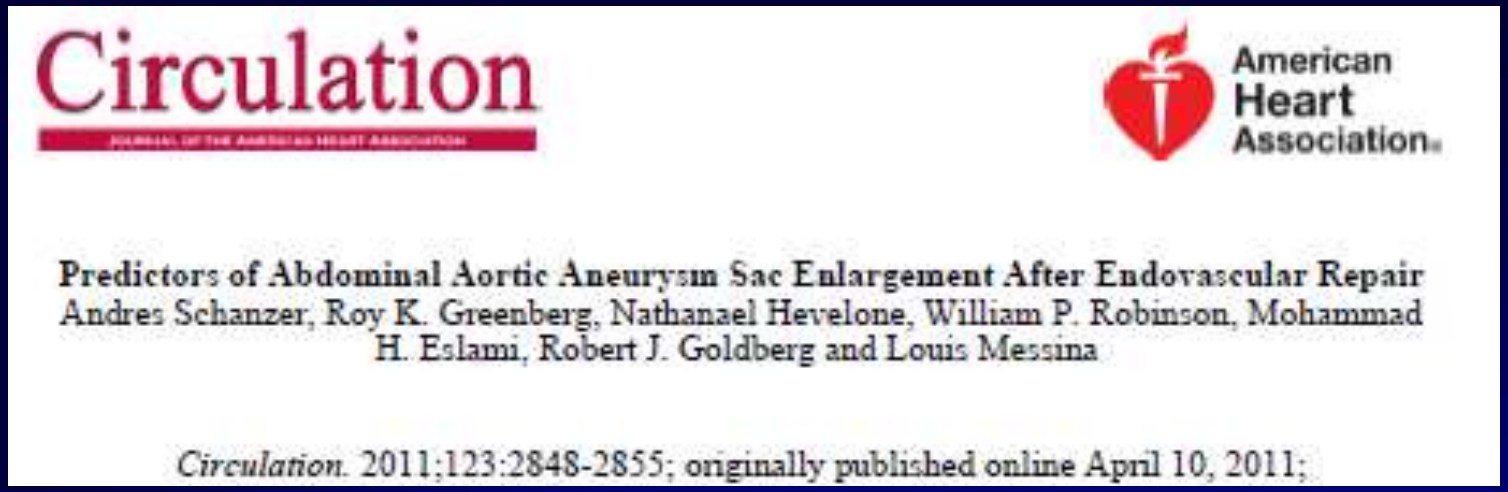
Ali F. AbuRahma, MD,[a] John Campbell, MD,[a] Patrick A. Stone, MD,[a] Aravinda Nanjundappa, MD,[a] Akhilesh Jain, MD,[a] L. Scott Dean, PhD, MBA,[b] Joseph Habib, MD,[a] Tammi Keiffer, RN,[b] and Mary Emmett, PhD,[b] *Charleston, WV*

Background: Initially, patients with a short angulated aortic neck were considered unfit for endovascular aneurysm repair (EVAR). Recently, however, more liberal use of EVAR has been advocated. This study analyzes the correlation of aortic neck length to early and late outcomes.

Methods: We analyzed 238 patients who underwent EVAR during a recent 7-year period. All patients were followed up clinically and underwent postoperative duplex ultrasound imaging or computed tomography angiography, which were repeated every 6 months. Aortic neck length was classified into ≥15 mm (L1, n = 195), 10 to <15 mm (L2, n = 24), and <10 mm (L3, n = 17). Kaplan-Meier methods were used to estimate freedom from late endoleak, early and late reintervention, and survival.

Results: Analyzed were 49 Ancure, 47 AneuRx, 104 Excluder, and 38 Zenith grafts. The mean follow-up was 24.7 months (range, 1-87 months). The initial technical success was 99%. The perioperative complication rates for groups L1, L2, and L3 were 13%, 21%, and 24%, respectively ($P = .289$). Proximal type I early endoleaks occurred in 12%, 42%, and 53% in groups L1, L2, and L3, respectively ($P < .001$). Intraoperative proximal aortic cuffs were needed to seal proximal type I endoleaks in 10%, 38%, and 47% in L1, L2, and L3 groups, respectively ($P < .0001$). However, the rate of late reintervention was comparable in all groups. Postoperatively, the size of the abdominal aortic aneurysm decreased or remained unchanged in 95%, 94%, and 88% in L1, L2, and L3 groups, respectively ($P = .660$). Rates of freedom from late type I endoleak at 1, 2, and 3 years were 84%, 82%, and 80% for L1; 68%, 54%, and 54% for L2; and 71%, 71%, and 53% for L3 ($P = .0263$). Rates of freedom from late intervention at 1, 2, and 3 years were 96%, 94%, and 92% for L1; and 94%, 83%, and 83% for L2; and 93%, 93%, and 93% for L3 ($P = .5334$).

Conclusions: EVAR can be used for patients with a short aortic neck; however, it was associated with a significantly higher rate of early and late type I endoleaks, resulting in an increased use of proximal aortic cuffs for sealing the endoleaks. (J Vasc Surg 2009;50:738-48.)

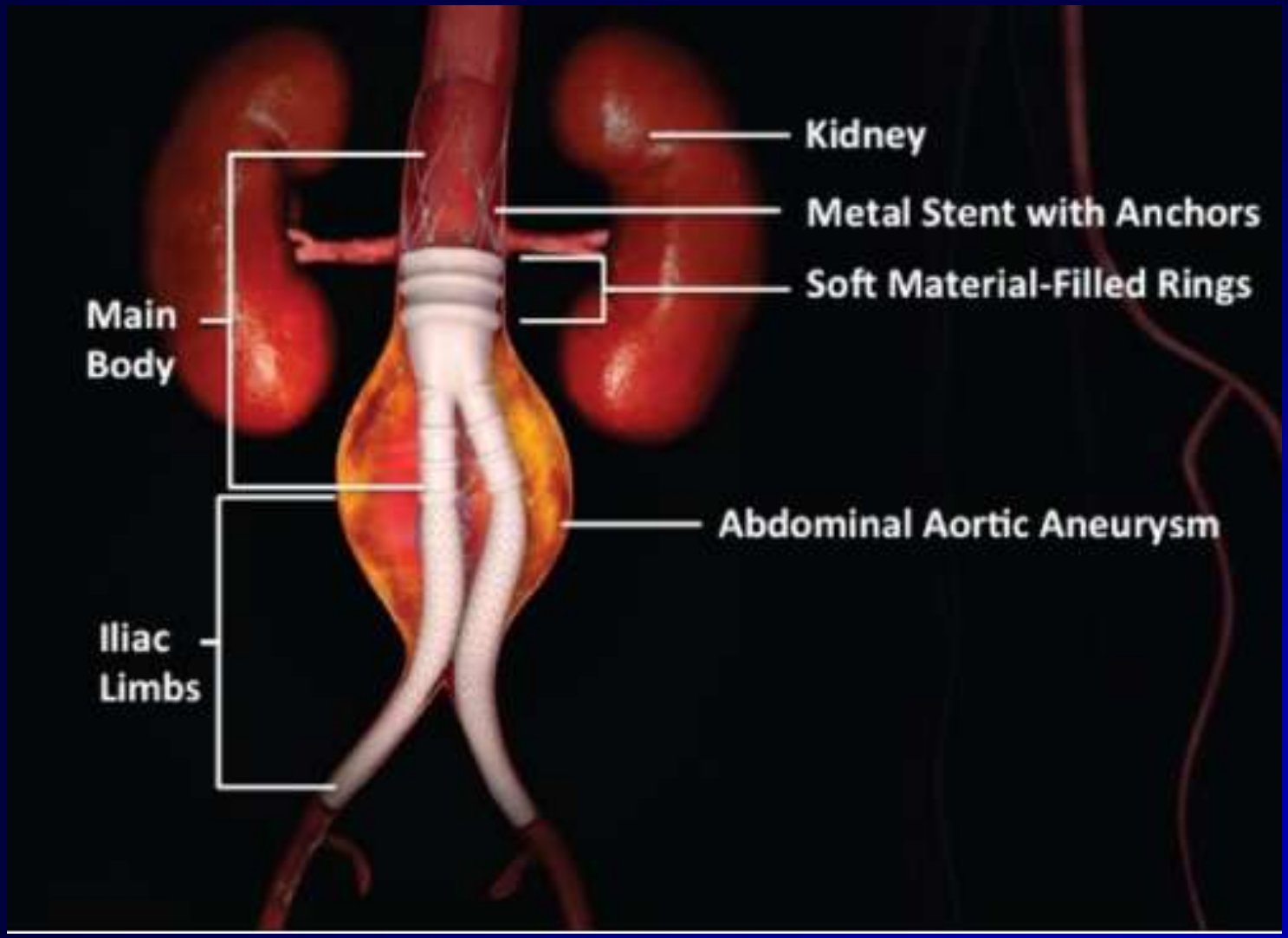


- Over 10,000 EVAR patients from 1999-2008
- 31.1% outside of most liberal IFU
- At 5 years, 41% of patients developed AAA sac enlargement
- Incidence of sac enlargement was significantly higher in patients treated outside of IFU

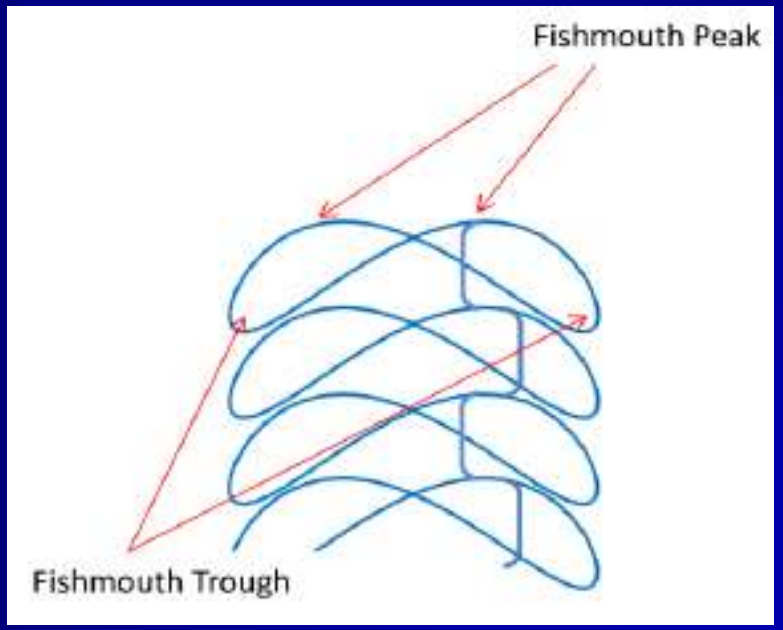
Schanzer A et al. *Circulation* 2011;123:2848-2855.

OVERCOMING ANATOMIC LIMITATIONS

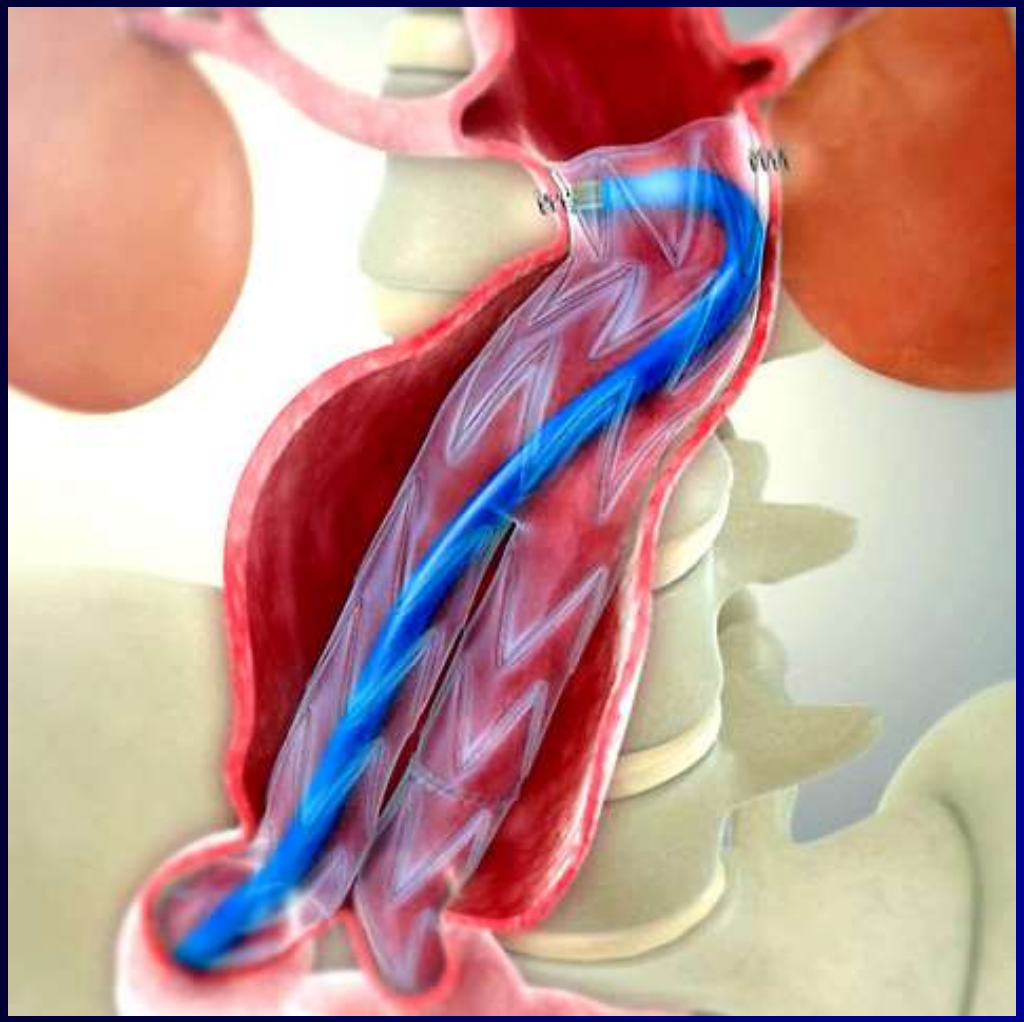
TriVascular Ovation®



Aorfix™



Aptus Heli-FX™ EndoAnchor System



3.0mm diameter x 4.5mm length helix

16Fr OD delivery device

Compatible with Cook, Medtronic, and Gore endografts

Devices in Clinical Trials

- Gore Iliac branch device
  - CE Mark
  - Hypogastric preservation

- Endologix Nellix
  - CE Mark
  - Fills and seals aneurysm sac
  - Goal to decrease device migration and endoleak

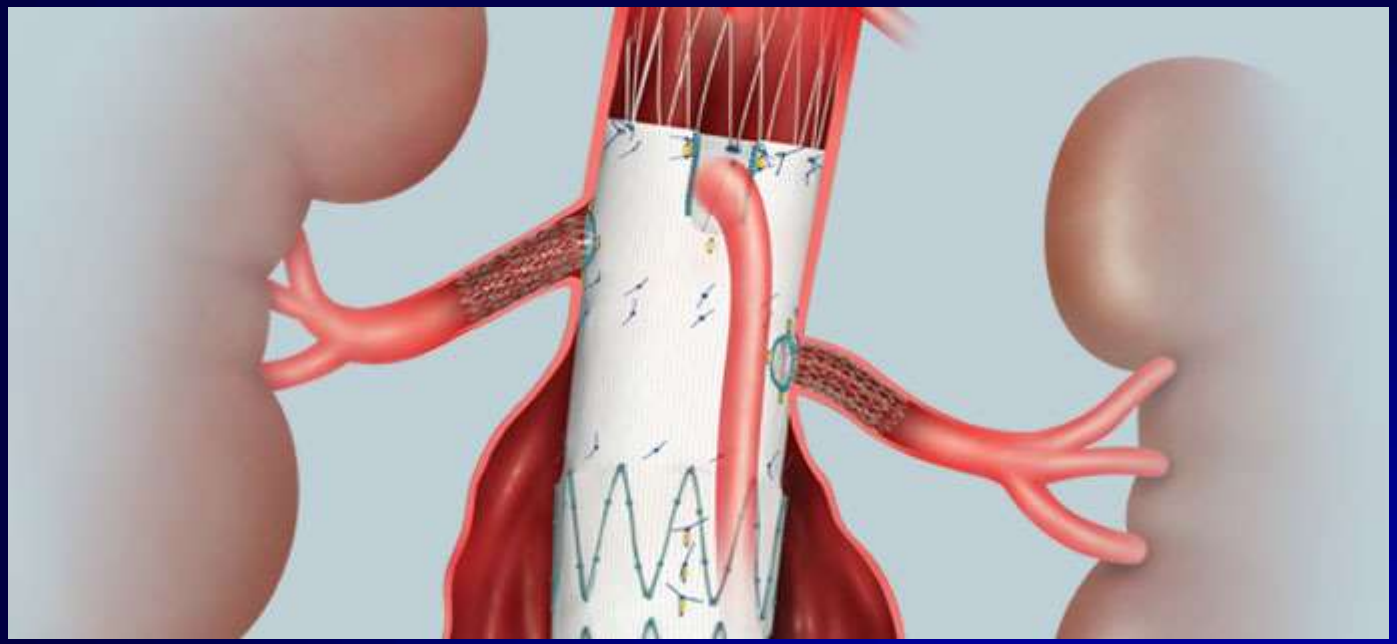
- Cordis INCRAFT
  - Only investigational
  - Very low profile (13Fr)

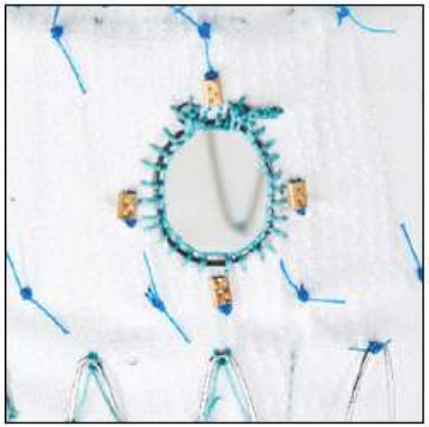
VA NORTH TEXAS HEALTH CARE SYSTEM
Changing lives. One Veteran at a time.

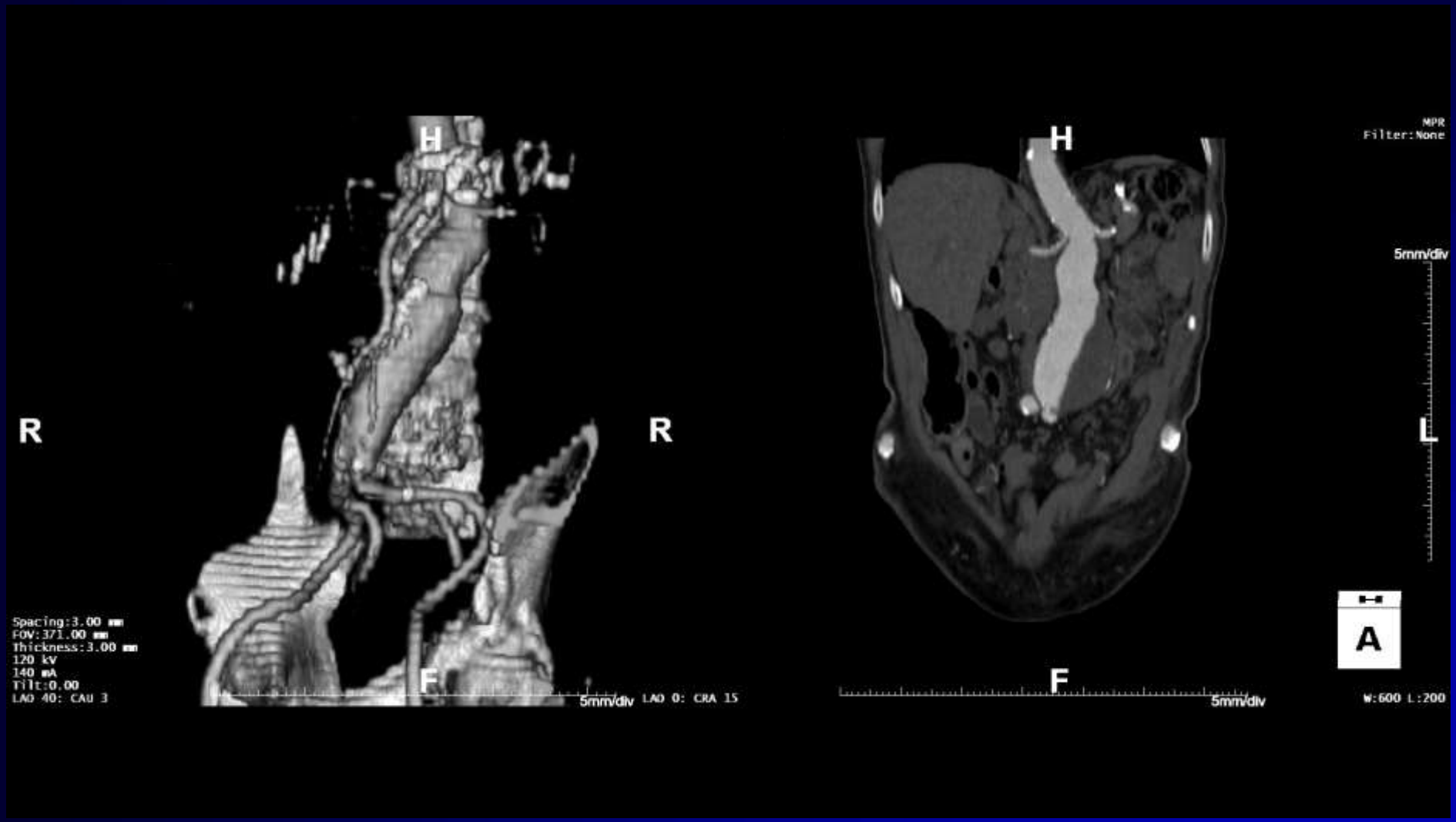
UT SOUTHWESTERN MEDICAL CENTER

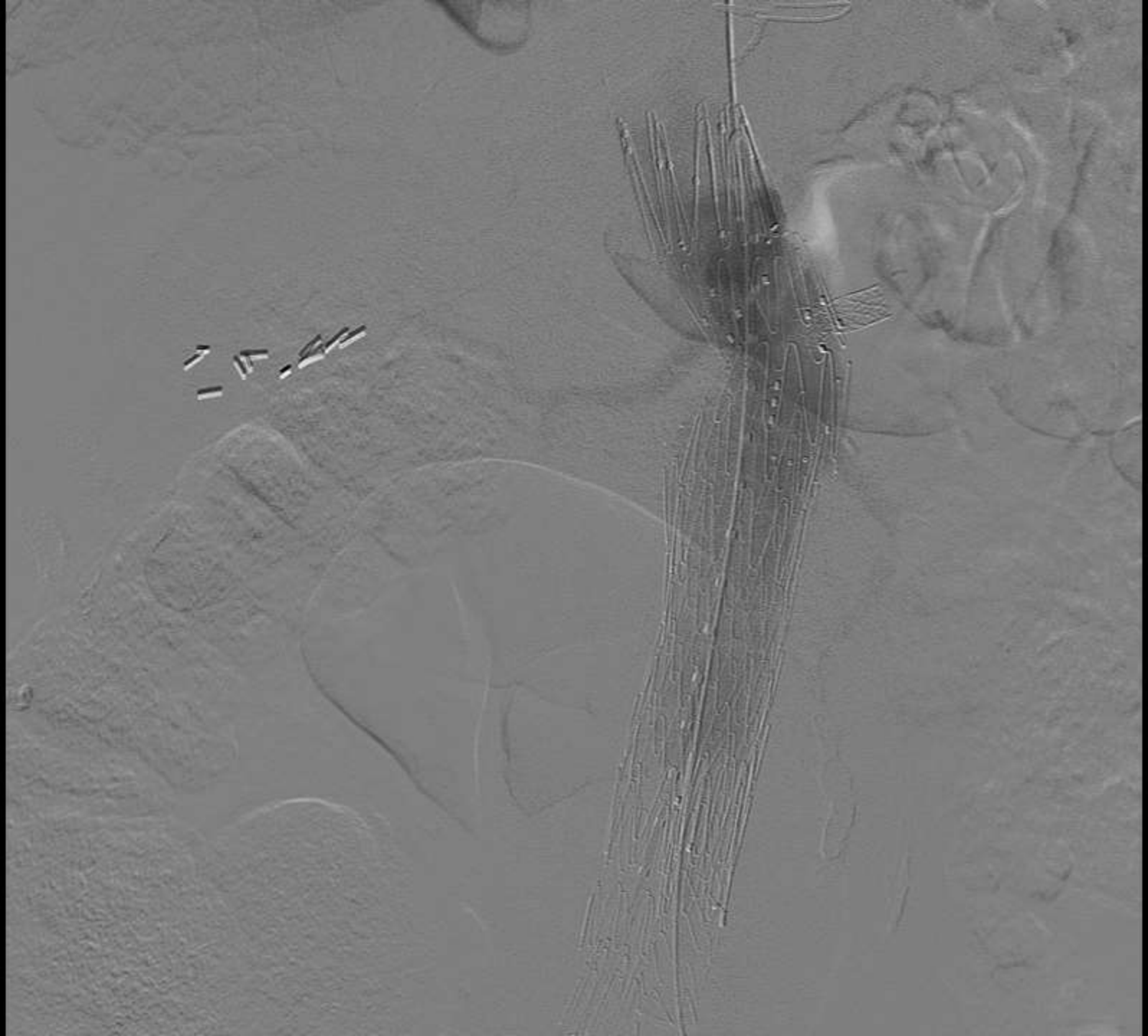
Complex aneurysm repair

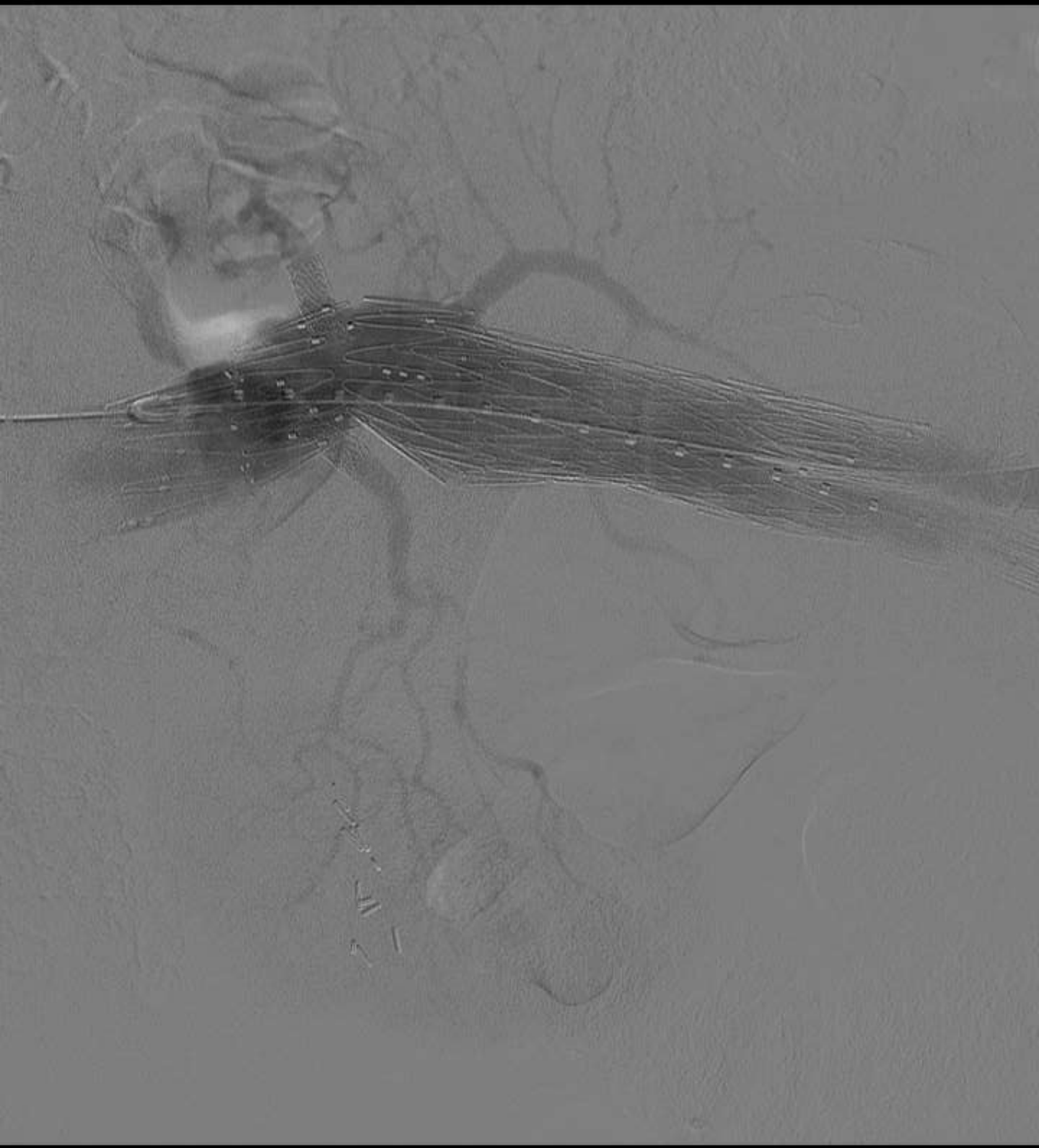
Cook Zenith® Fenestrated

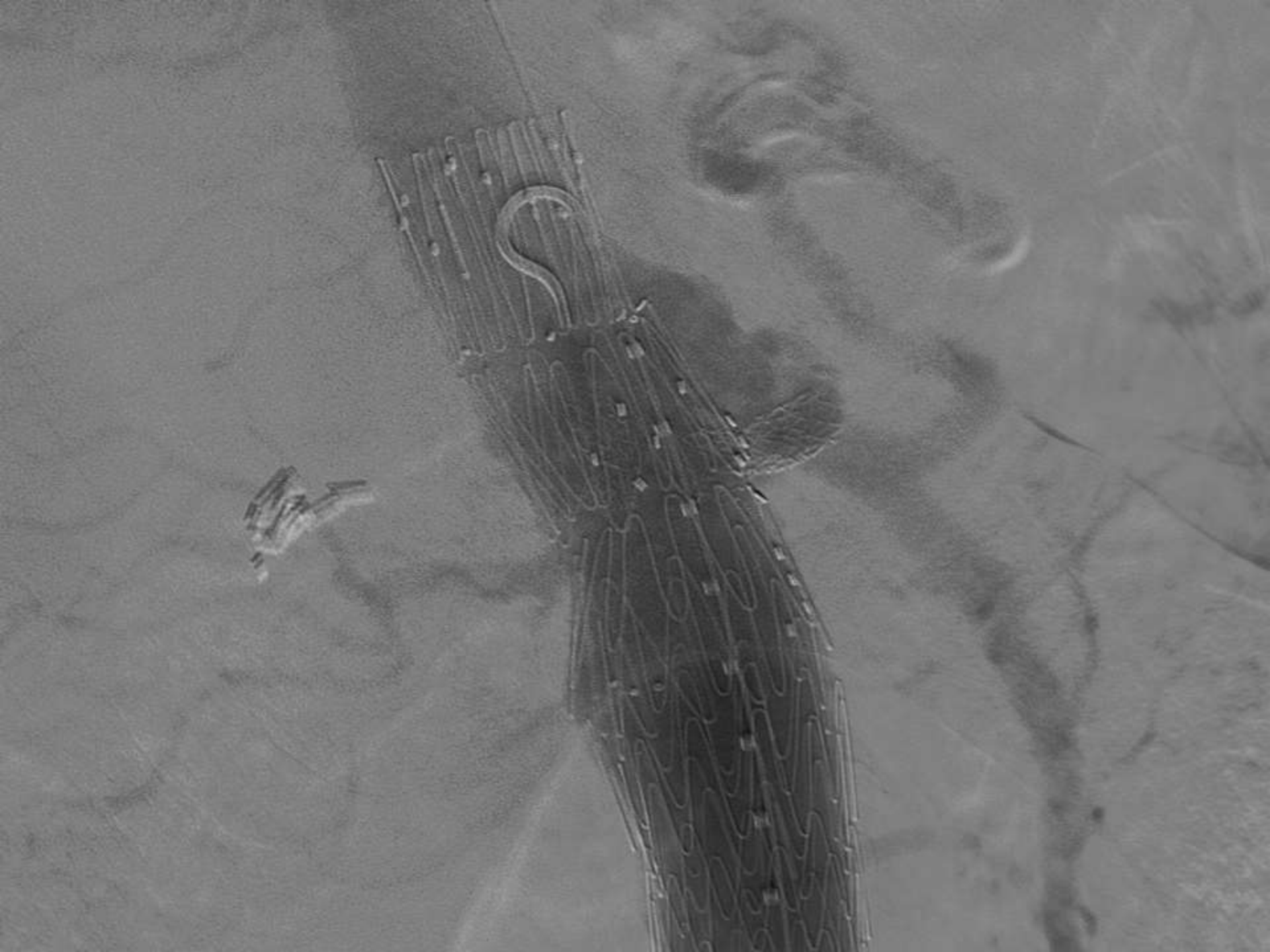


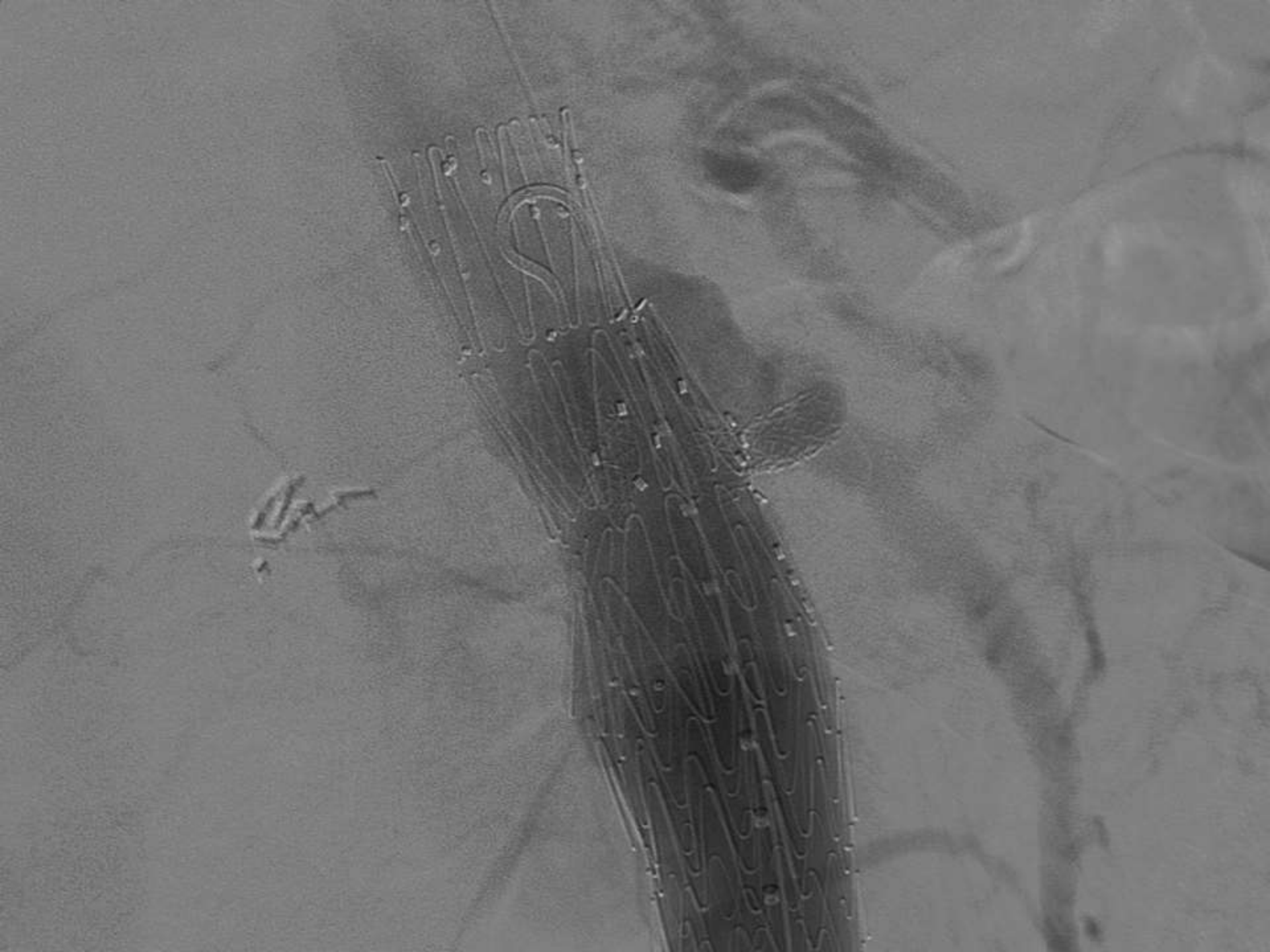


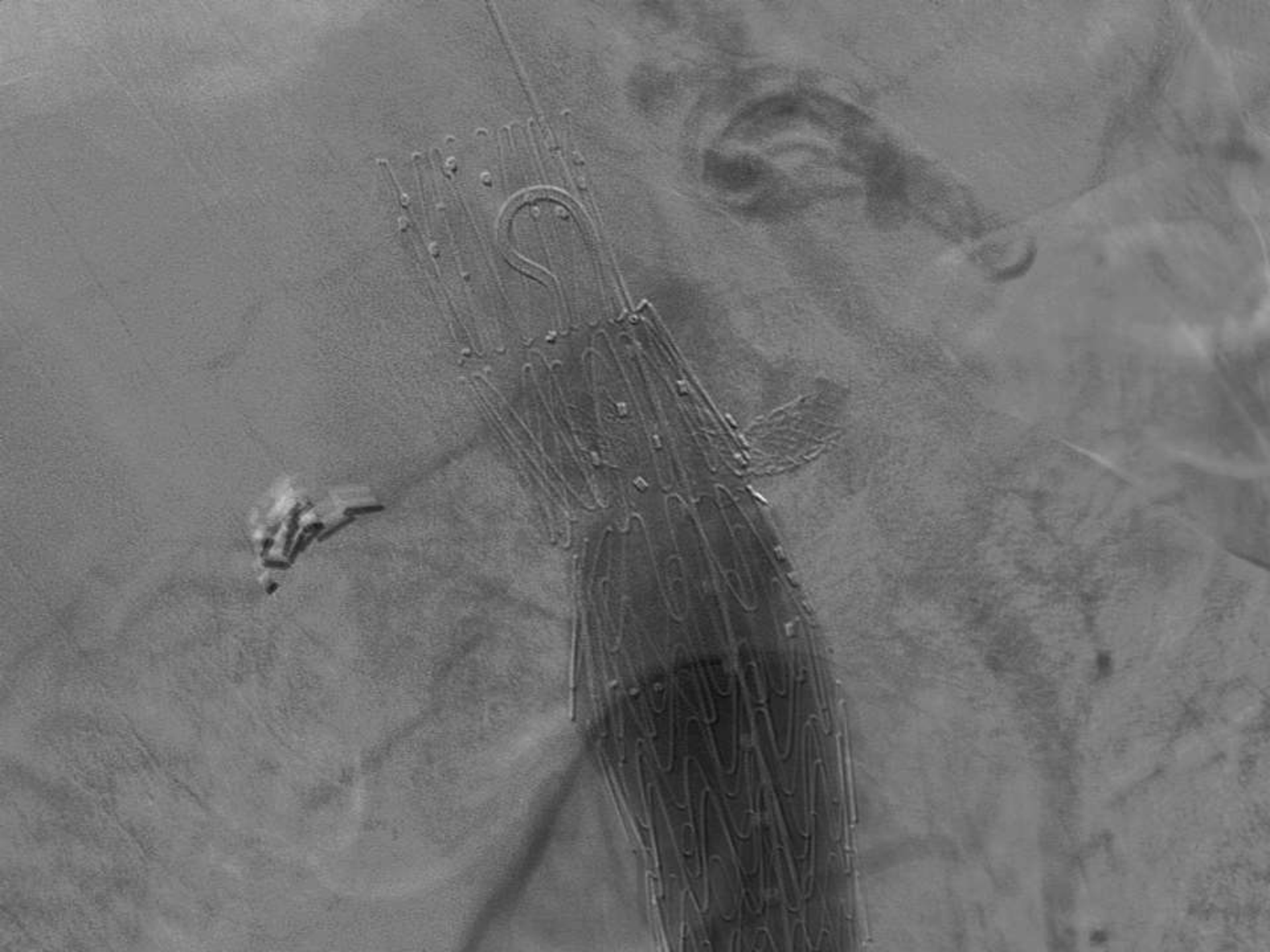

H
R
F
5mm/div
LAO 0: CRA 15
Spacing:3.00 mm
FOV:371.00 mm
Thickness:3.00 mm
120 kV
140 mA
Tilt:0.00
LAO 40: CAU 3
H
R
F
5mm/div
MPR
Filter:None
5mm/div
L
A
W:600 L:200












SOUTHWESTERN