A nighttime photograph of a cityscape with a bridge over water. The city lights are reflected in the water, and the bridge is illuminated. The title text is overlaid on the top half of the image.

Identifying Complications and Its Management of Open and Endovascular Repair

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Presenter Disclosure Information

Name: RICHARD R. HEUSER M.D.

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

- QuantumCor, Major Stock Holder/Medical Director;*
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- Spectranetics, Abbott, Medtronic, Bard, Abiomed, Honorarium and*
- Medtronic, Abbott, AngioScore, Speaker*

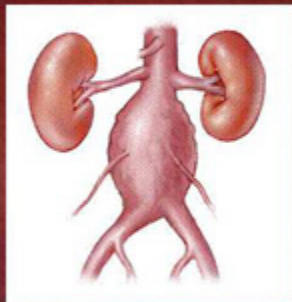
Patents -- *RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure*



Abdominal Aortic Aneurysms

Risk factors

- Age (peak incidence 70 yrs)
- Family History
- Peripheral Aneurysm
- Smoking
- Coronary Artery Disease
- Hypertension



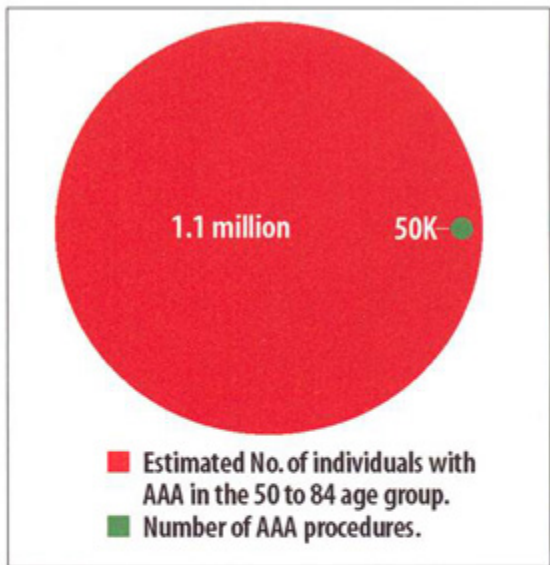
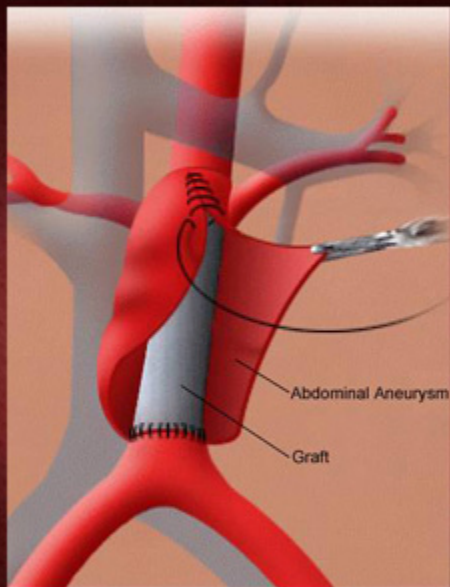


Figure 1. Of the 1.1 million people between ages 50 and 84 diagnosed with an AAA, approximately 50,000 undergo aneurysm repair. Created with information from Kent KC, et al. *J Vasc Surg.* 2010;52:539-548.¹





AAA

Surgical Repair



Abdominal Aortic Aneurysm

Scope of Problem

- 40,000 surgical repairs annually*
- Operative mortality 1-5% in good surgical risk patients*
- Operative mortality $\geq 10\%$ in higher risk surgical candidates*
- Significant operative morbidity: 15-30% incidence of major post operative complications*





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





EVAR Trial

- ***Patients*** **900**
- ***Over Recruited*** **1082**
- ***EVAR*** **543**
- ***Open Repair*** **539**

Lancet 2004;364;843-8



EVAR Trial

- *30 Day Mortality*
- *EVAR* *1.7%*
- *Open* *4.7% P<.05*

Lancet 2004;364;843-8



ORIGINAL ARTICLE

Endovascular vs. Open Repair of Abdominal Aortic Aneurysms in the Medicare Population

Marc L. Schermerhorn, M.D., A. James O'Malley, Ph.D., Ami Jhaveri, M.D., Philip Cotterill, Ph.D., Frank Pomposelli, M.D., and Bruce E. Landon, M.D., M.B.A.

ABSTRACT

BACKGROUND

Randomized trials have shown reductions in perioperative mortality and morbidity with endovascular repair of abdominal aortic aneurysm, as compared with open surgical repair. Longer-term survival rates, however, were similar for the two procedures. There are currently no long-term, population-based data from the comparison of these strategies.

METHODS

We studied perioperative rates of death and complications, long-term survival, rupture, and reinterventions after open as compared with endovascular repair of abdominal aortic aneurysm in propensity-score-matched cohorts of Medicare beneficiaries undergoing repair during the 2001–2004 period, with follow-up until 2005.

RESULTS

There were 22,830 matched patients undergoing open repair of abdominal aortic aneurysm in each cohort. The average age of the patients was 76 years, and approximately 20% were women. Perioperative mortality was lower after endovascular repair than after open repair (1.2% vs. 4.8%, $P < 0.001$), and the reduction in mortality increased with age (2.1% difference for those 67 to 69 years old vs. 8.5% for those 85 years of older, $P < 0.001$). Late survival was similar in the two cohorts, although the survival curves did not converge until after 3 years. By 4 years, rupture was more likely in the endovascular-repair cohort than in the open-repair cohort (1.8% vs. 0.5%, $P < 0.001$), as was reintervention related to abdominal aortic aneurysm (9.0% vs. 1.7%, $P < 0.001$), although most reinterventions were minor. In contrast, by 4 years, surgery for laparotomy-related complications was more likely among patients who had undergone open repair (9.7% vs. 4.1% among those who had undergone endovascular repair, $P < 0.001$), as was hospitalization without surgery for bowel obstruction or abdominal-wall hernia (14.2% vs. 8.1%, $P < 0.001$).

CONCLUSIONS

As compared with open repair, endovascular repair of abdominal aortic aneurysm is associated with lower short-term rates of death and complications. The survival advantage is more durable among older patients. Late reinterventions related to abdominal aortic aneurysm are more common after endovascular repair but are balanced by an increase in laparotomy-related reinterventions and hospitalizations after open surgery.

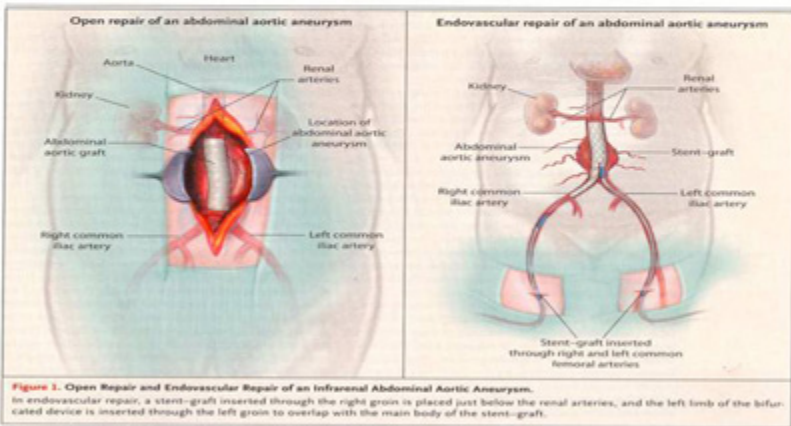


SINCE THE FIRST REPORT OF ENDOVASCULAR repair of abdominal aortic aneurysm in 1991, the technique has become a mainstay in the repair of abdominal aortic aneurysm, accounting for over 40% of elective repairs of abdominal aortic aneurysm in 2003 (Fig. 1).^{4,5} Randomized trials have shown a perioperative survival benefit of endovascular repair over open repair, with fewer complications and a shorter recovery.^{6,7}

There are concerns, however, that longer-term outcomes of endovascular repair may not be as durable as those of open repair, with endovascular repair increasing the risk of late rupture of the abdominal aortic aneurysm and necessitating more frequent reinterventions — including conversion to open repair — to preserve the integrity of the aneurysm repair.⁸ The risks of complications and death, as well as the expense,

associated with these additional procedures may offset the initial survival benefit observed with endovascular repair.^{7,9} In addition, patients enrolled in the clinical trials were highly selected and were generally treated at high-volume referral institutions. Therefore, the experience in those trials may not reflect that in actual practice.

Currently, there are limited data regarding long-term reintervention and rupture after open repair^{10,11} or endovascular repair.^{6,7,12,13} In addition, there are few data on laparotomy-related reinterventions for problems such as bowel obstruction and abdominal-wall hernia that arise as late complications of open repair. In this study, we used data from the Medicare program to compare short-term and long-term outcomes among matched cohorts of patients with abdominal aortic aneurysm who underwent open or endovascular repair during the 2001–2004 period.



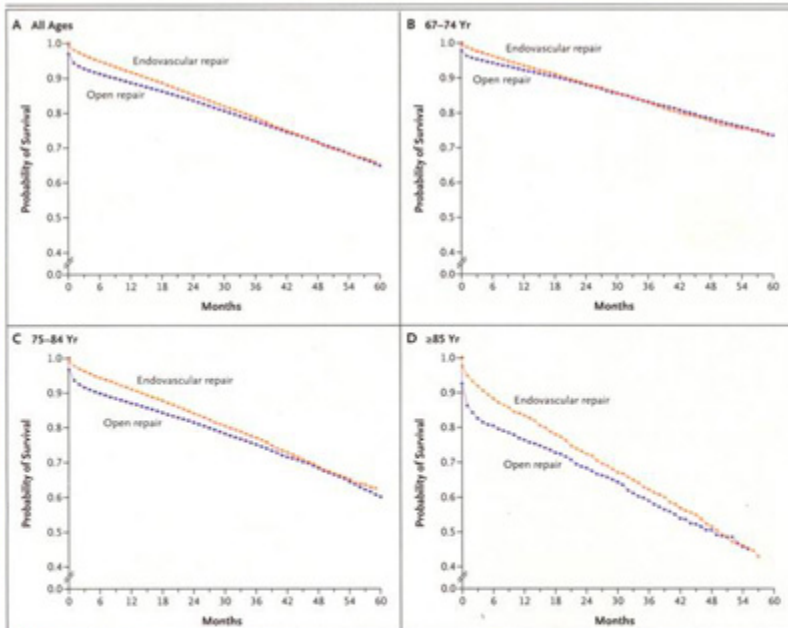


Figure 2. Survival of Patients Undergoing Endovascular Repair or Open Repair of Abdominal Aortic Aneurysms, Overall and According to Age. Data are shown for all patients (Panel A), for those 67 to 74 years of age (Panel B), those 75 to 84 years of age (Panel C), and those 85 years of age or older (Panel D).



TABLE 2. PERIOPERATIVE OUTCOMES AFTER ENDOVASCULAR REPAIR OR OPEN REPAIR*

Perioperative Outcomes	Endovascular Repair (N = 22,830)	Open Repair (N = 22,830)	P Value	Relative Risk Associated with Open Repair (95% CI)
Death (% of patients)				
All ages	1.2	4.8	<0.001	4.00 (3.51-4.56)
67-69 yr	0.4	2.5	<0.001	6.21 (4.98-7.73)
70-74 yr	0.8	3.3	<0.001	4.12 (3.51-4.84)
75-79 yr	1.3	4.8	<0.001	3.69 (3.25-4.19)
80-84 yr	1.6	7.2	<0.001	4.49 (4.02-5.02)
≥ 85 yr	2.7	11.2	<0.001	4.14 (3.80-4.52)
Medical Complications (% of patients)				
Myocardial Infarction	7.0	9.4	<0.001	1.34 (1.26-1.42)
Pneumonia	9.3	17.4	<0.001	1.89 (1.79-1.98)
Acute Renal Failure	5.5	10.9	<0.001	2.00 (1.87-2.14)
Renal Failure Requiring Dialysis	0.4	0.5	0.047	1.33 (1.00-1.75)
Deep-vein Thrombosis or Pulmonary Embolism	1.1	1.7	<0.001	1.51 (1.29-1.76)
Surgical Complications (% of patients)				
Conversion to Open Repair	1.6			
Acute Mesenteric Ischemia	1.0	2.1	<0.001	2.19 (1.87-2.56)
Reintervention for Bleeding	0.8	1.2	<0.001	1.50 (1.24-1.80)
Tracheostomy	0.2	1.5	<0.001	7.46 (5.48-10.14)
Thrombectomy	0.4	0.2	<0.001	0.50 (0.35-0.71)
Embolectomy	1.3	1.7	<0.001	1.29 (1.11-1.50)
Repair of Infected Graft or Graft-enteric Fistula	0.01	0.09	<0.001	7.00 (2.09-23.46)
Major Amputation	0.04	0.13	0.002	3.00 (1.47-6.14)



TABLE 2. PERIOPERATIVE OUTCOMES AFTER ENDOVASCULAR REPAIR OR OPEN REPAIR*

	Endovascular Repair	Open Repair	P Value	Relative Risk Associated with Open Repair
Complications Related to Laparotomy				
Lysis of Adhesions Without Resection	0.1	1.2	<0.001	13.05 (8.37-20.33)
Bowel Resection	0.6	1.3	<0.001	2.17 (1.77-2.65)
Ileus or Bowel Obstruction Without Resection or Lysis of Adhesions	5.1	16.7	<0.001	3.25 (3.05-3.46)
Mean Length of Hospital Stay (No. of Days)	(3.4±4.7)	9.3±8.3	<0.001	
Discharged Home (% of patients)				
All ages	94.5	94.5	<0.001	0.87 (0.87-0.88)
67-69 yr	97.8	97.8	<0.001	0.95 (0.95-0.95)
70-74 yr	96.8	96.8		0.92 (0.91-0.92)
75-79 yr	94.4	94.4	<0.001	0.85 (0.84-0.86)
80-84 yr	90.6	90.6	<0.001	0.75 (0.74-0.75)
≥85 yr	84.6	84.6	<0.001	0.67 (0.66-0.68)

*Plus-minus Values are Mean± SD.

N. Eng J Med 338:5, January 31, 2008, p. 469



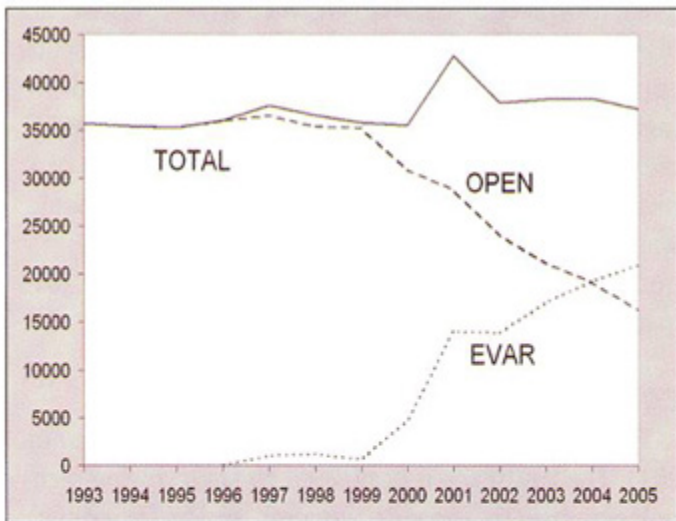


Figure 4. Total, open, and endovascular repairs of intact aortic aneurysms from 1993 to 2005. Reprinted from the *Journal of Vascular Surgery*, 49/3, Giles et al, 543-550, Copyright 2009, with permission from Elsevier.¹⁴





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Figure 100-7 Transabdominal aortic aneurysm exposure, vascular clamps in place, incising the aneurysm.



It is not appropriate for me to describe the complications after open repair

- I am not a surgeon
- So few patients that I see go for open repair
- Since pseudo-aneurysm and endoleaks do occur any patient post AAA open repair the patient does need follow up if not by CT, at least with abdominal ultrasound



Abdominal Aortic Aneurysm Endograft Repair

OPEN REPAIR COMPLICATIONS

- I do not deal with them
- I am not a surgeon but...long term follow up is important





SCIENCEPHOTOLIBRARY

Ruptured AA Aneurysm Endovascular Repair

- More common
- You need a dedicated team
- You need emergency CT capabilities
- You need to immediately get groin access or upper arm access
- You need to have large balloons in stock



What about the one true emergency during endovascular repair?

- Hypotension and shock...think rupture
- Large balloon
- Good imaging
- Cell saver?



Table 52-4 Complications Specific to Endovascular Grafts

Early

X-ray radiation exposure

Potential risk to patients and staff

Trauma to access arteries

Perforation, dissection, or thrombosis of femoral or iliac artery

Microembolization

Due to dislodgment of mural components or thrombus from the AAA sac

Graft displacement or misplacement

Occlusion of major branch arteries

Renal artery, accessory renal arteries, mesenteric arteries

Endoleak

AAA rupture

Postimplantation syndrome

Fever, backache, malaise

Graft limb compression, stenosis, occlusion

Contrast allergy or renal failure

Late

Graft migration

Endoleak

Endotension

Late stenosis, kink, or thrombosis of graft or graft limb

Graft tear or failure, material fatigue, stent or wire form breakage

AAA rupture

AAA, abdominal aortic aneurysm.



- 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.







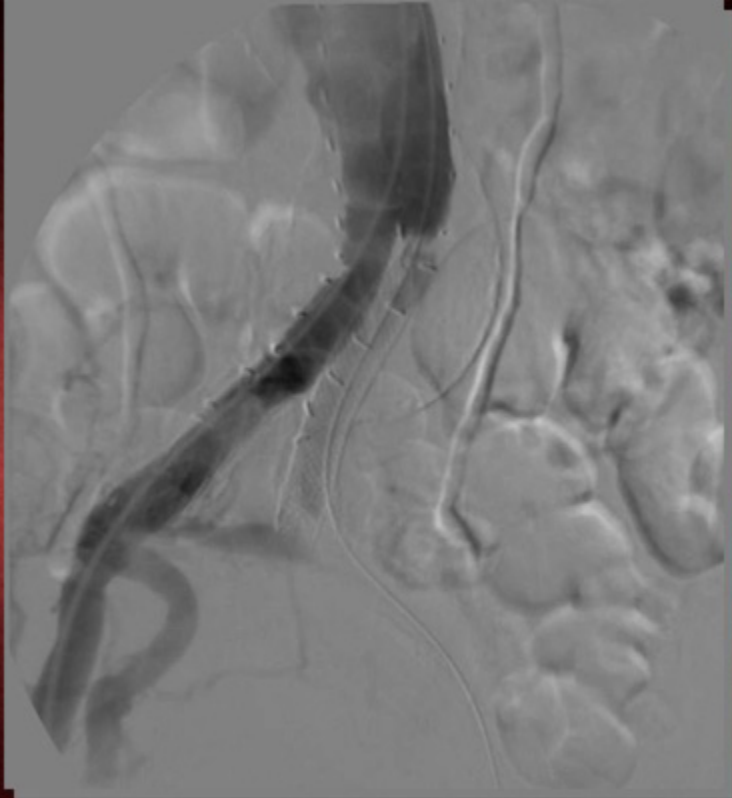
Catheter Introducer System
Patent # 7,166,088
Issue Date 1/27/07





Catheter Introducer System
Patent # 7,166,088
Issue Date 1/27/07





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)

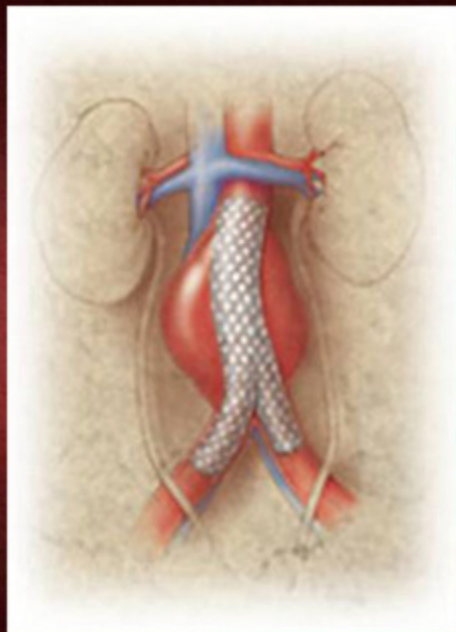






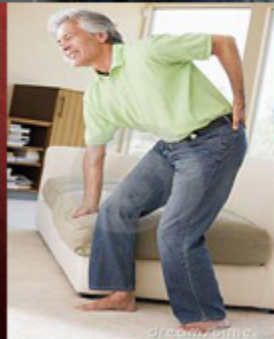






EVAR





Post Implant Syndrome

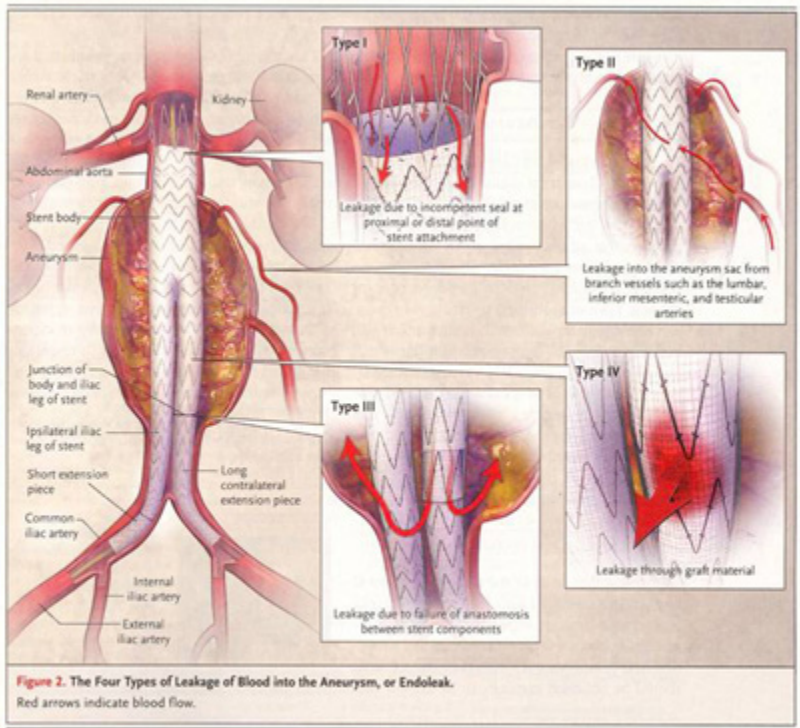
- Back pain
- Fever
- 50% of cases
- 2-3 days (up to 7)
- Negative cultures
- No increase in white blood count
- Usually benign



Endoleak

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





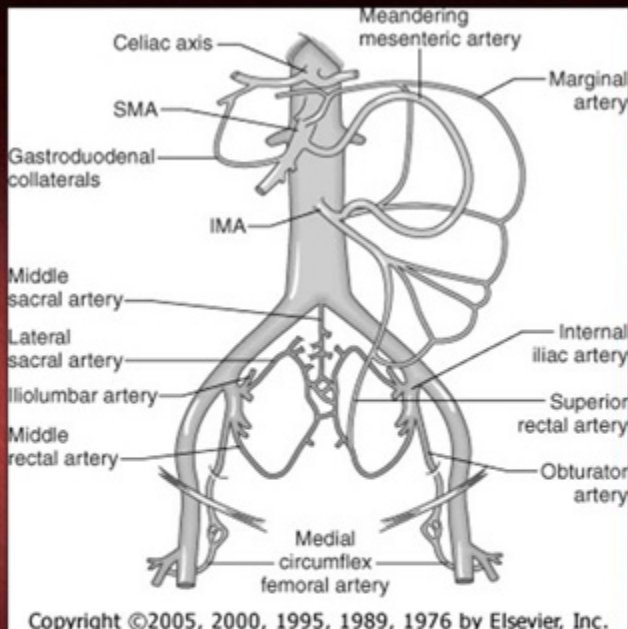


Figure 100-13 Important collateral pathways for the sigmoid colon and pelvis. IMA, inferior mesenteric artery; SMA, superior mesenteric artery. (From Bergman RT, Gloviczki P, Welch TJ, et al: The role of intravenous fluorescein in the detection of colon ischemia during aortic reconstruction. *Ann Vasc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



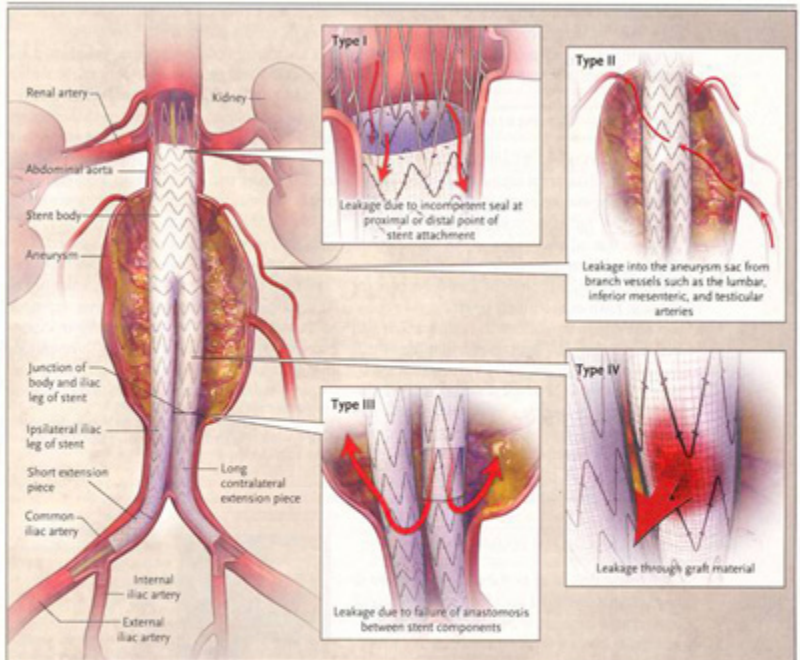


Figure 2. The Four Types of Leakage of Blood into the Aneurysm, or Endoleak.
Red arrows indicate blood flow.

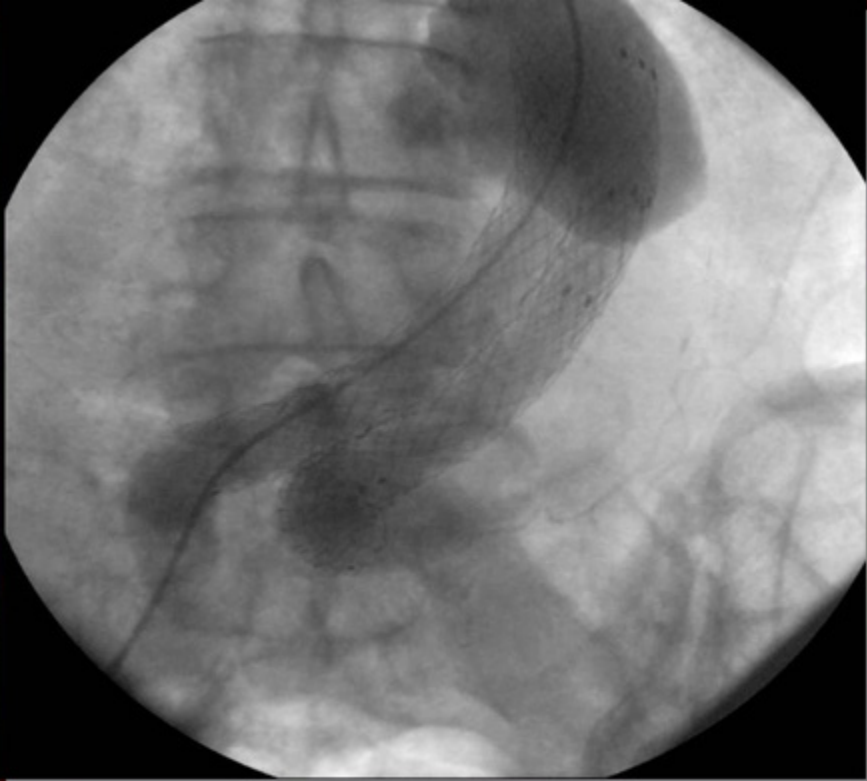


Type I Leak

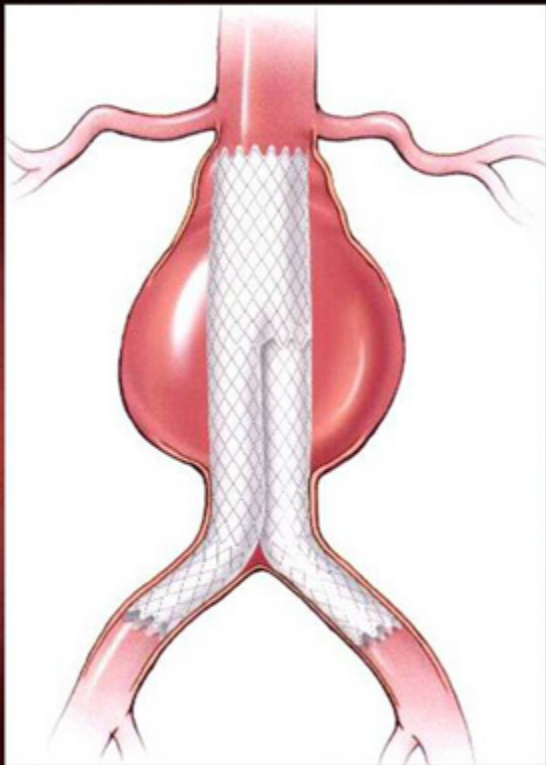
All should be treated

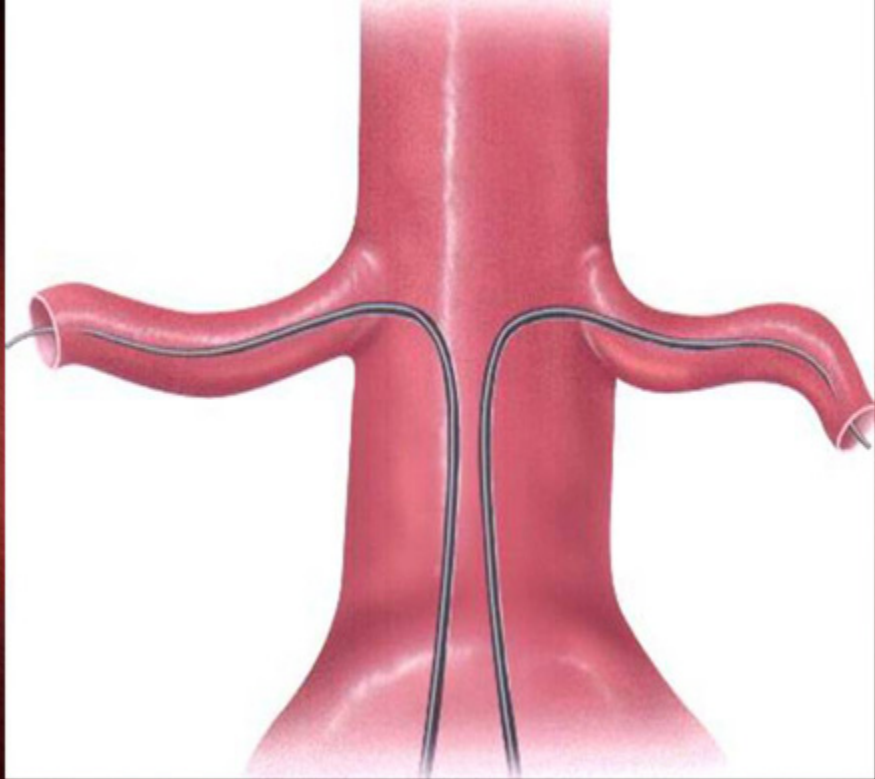
- Extension cuff with noncompliant balloon
- When close to renal artery and persists a Palmaz stent
- Distal leaks can be repaired usually with extension limbs or cuffs (sometimes to the external iliac with coil embolization to the hypogastric)

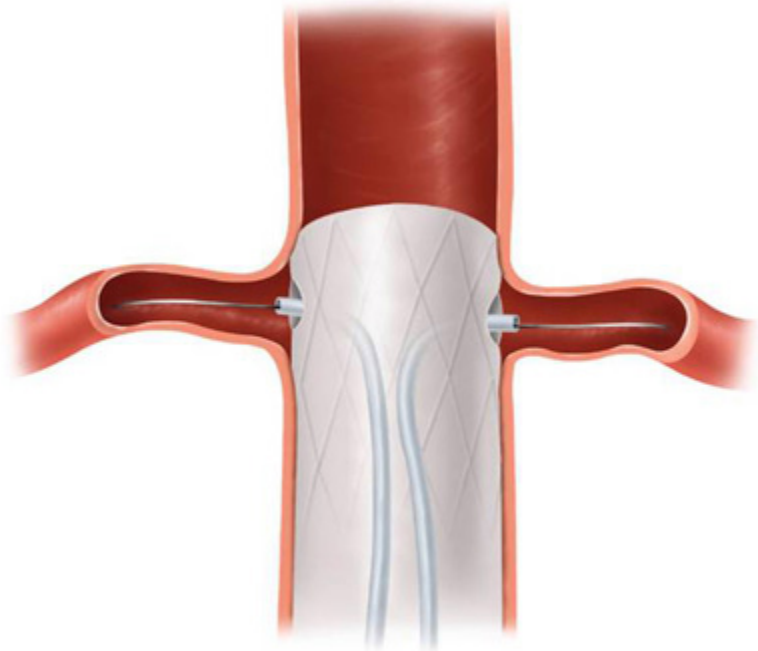


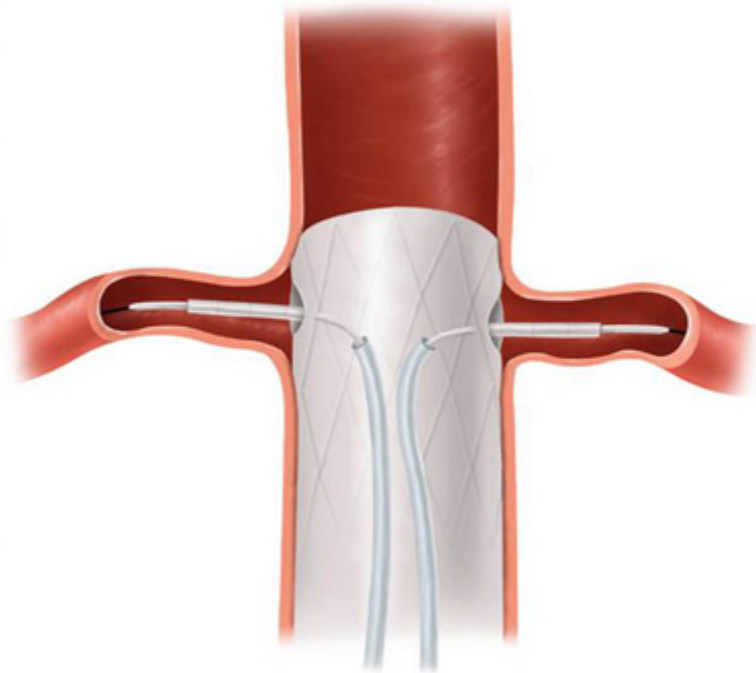


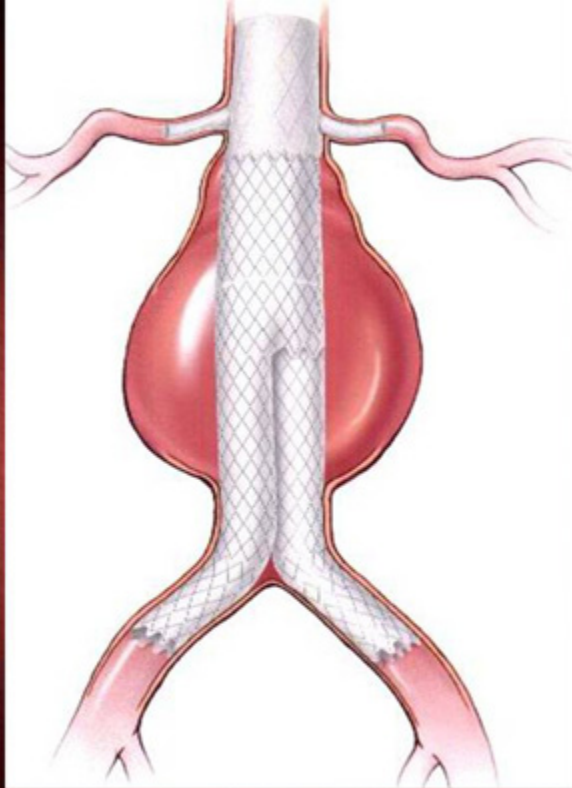








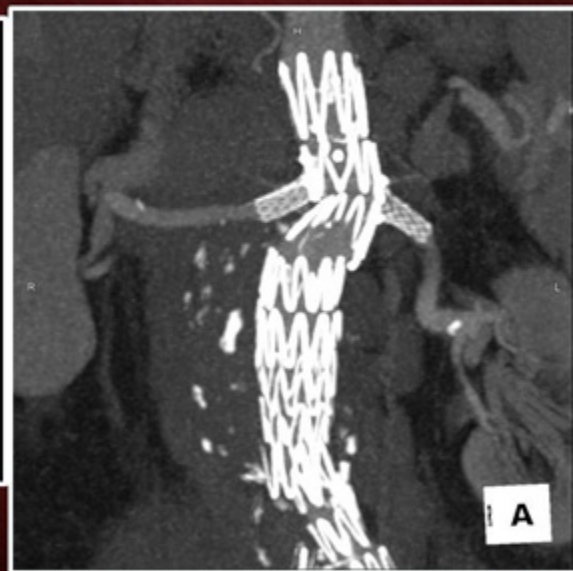




Juxtarenal: Zenith® Fenestrated



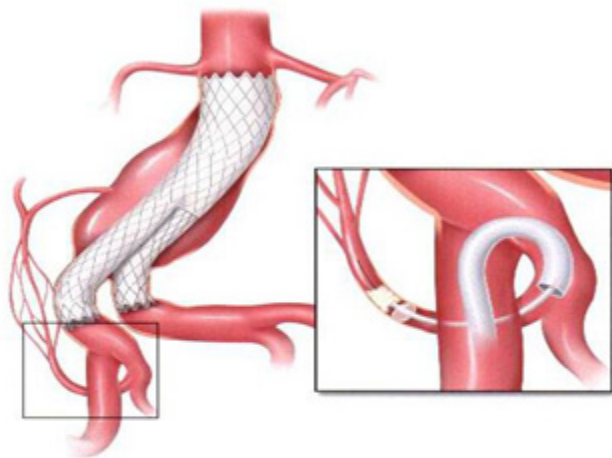
Juxtarenal: Zenith® Fenestrated



Type II Leak

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

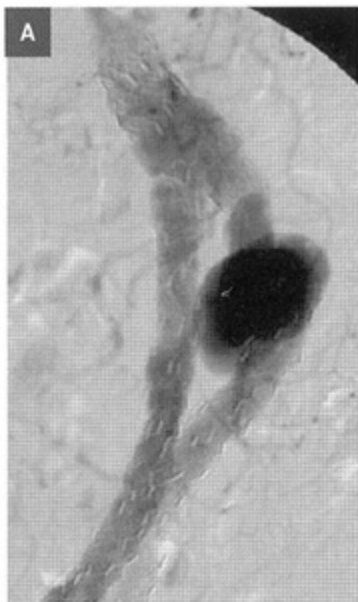




Type III Leak

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





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 IV Leak

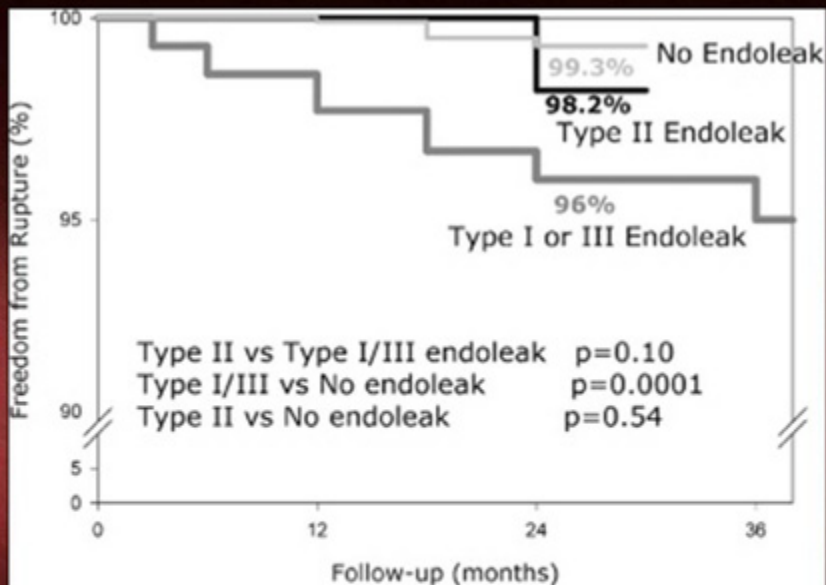
- Heparin off
- Usually no Rx



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





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Figure 101-3 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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Figure 100-1 CT scan of abdominal aortic aneurysm shows contrast-filled lumen (*) surrounded by thrombus (T) within the aneurysm sac.



(Images courtesy of respective manufacturers.)

<i>September 1999</i>	<i>November 2002</i>	<i>May 2003</i>	<i>October 2004</i>	<i>April 2008</i>	<i>December 2010</i>	
Ancure Guidant	AneuRx Medtronic	Excluder Gore	Zenith Cook	Powerlink Endologix	Talent Medtronic	Endurant Medtronic
						

Figure 2. A timeline of FDA approvals for EVAR stent grafts.



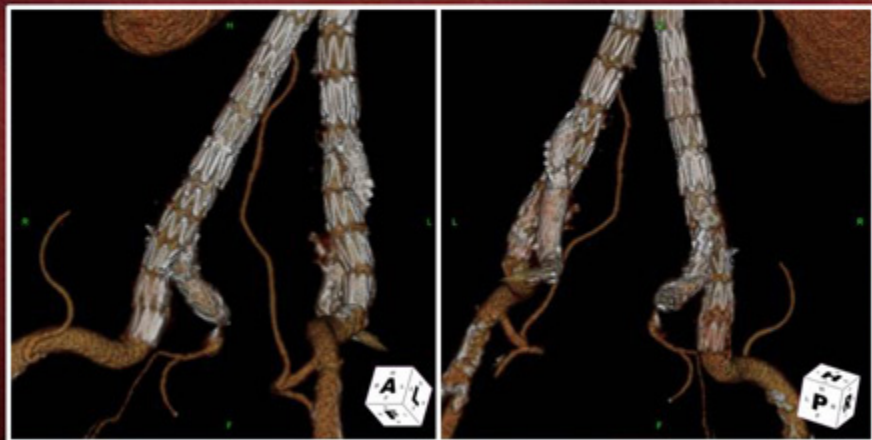
*Common Iliac:
Zenith® Branch Iliac Endovascular Graft*

- Bifurcated Branch



Common Iliac: Zenith® Branch Iliac Endovascular Graft

- Helical Branch



Aneurysms

- 1st successful open repair of aneurysm repair was in 1951 by Dr. John Freeman's group as iliac vein graft

Charles Dubost used an aortic homograft to replace the aneurysm

- 1st Complete Repair Occurred September 2, 1954 -- Michael DeBakey

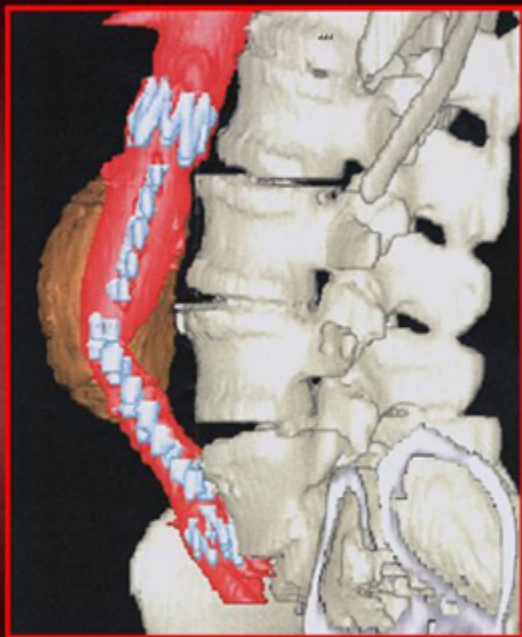
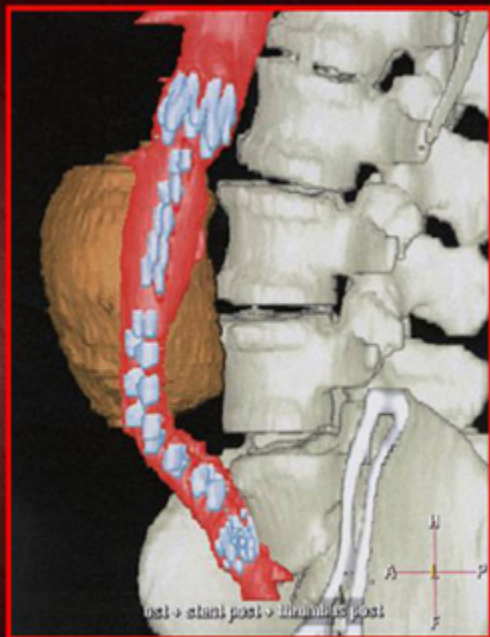
SUBJECTED TO LEVEL 1 EVIDENCE



OPEN REPAIR

- Does Require Intensive Follow Up and Surveillance
- 51.8% **WHO HAD OPEN REPAIRS** Have Endoleaks or Pseudoaneurysms
- Only 64% Fully Ambulatory Post Open Repair **WOULD NOT HAVE IT AGAIN**



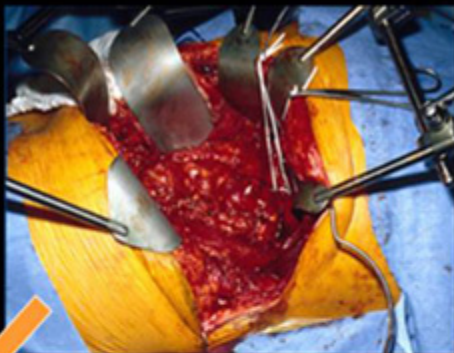


Endoluminal Stent-Graft Demonstrated Advantages

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

Patient Preferred Treatment





Transfemoral intraluminal graft implantation for abdominal aortic aneurysms

Parodi JC, Palmaz JC, and Barone HD.

Ann Vasc Surg. 1991 Nov;5(6):491-9.

- Demonstrated the new trend in vascular therapies
- What was once a disease process treated exclusively by the surgeon can now be treated less invasively by other non-surgeons



Impact of EVAR on Open AAA Repair in the United States

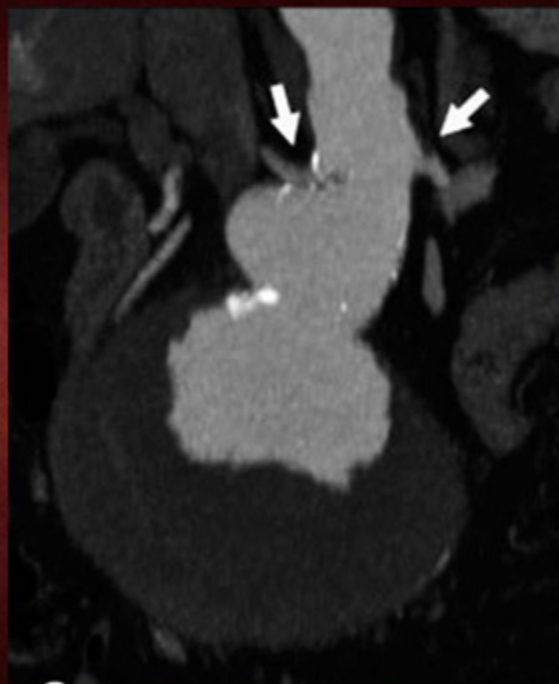
- Open Repair Volume Decreasing
- Open Repair More Challenging



Impact of EVAR on Open AAA Repair in the United States

- Anatomy Unsuitable for EVAR
- Circumferentially Calcified Neck
- Short Aneurysm Neck
- Excessive Neck Angulation
- Suprarenal AAA
- Juxtarenal AAA





Juxtarenal AAA



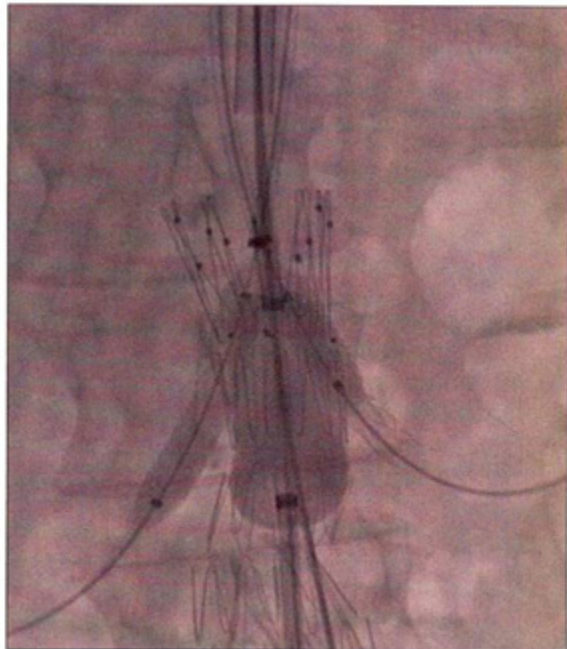


Figure 4. Bilateral renal chimney stents during endovascular repair of a juxtarenal aneurysm.



Impact of EVAR on Open AAA Repair in the United States

The next generation of Endovascular devices will further increase the application of EVAR resulting in fewer Open AAA repairs being performed



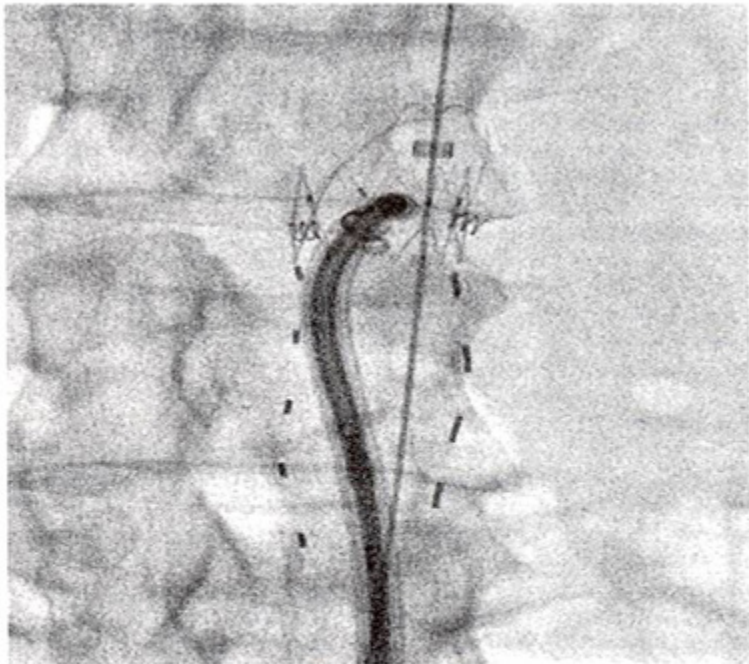


Fig. 9 Nitinol stent frame of the Aptus device in the infrarenal aorta. Endostaples can be seen affixing the graft to the vessel wall.



DEVICE FAMILIES

APTUS, INC.

- Aptus²



COOK MEDICAL

- Zenith
- Zenith Flex
- Zenith LP²



CORDIS CORPORATION

- Incraft²



ENDOLOGIX

- Powerlink
- Nellix²



GORE & ASSOCIATES

- Excluder



LOMBARD

- Aorfix²



MEDTRONIC, INC.

- AneuRx
- Talent
- Endurant



TRIVASCULAR

- Ovation²



VASCUTEK

- Anaconda²



²Investigational device in the United States.



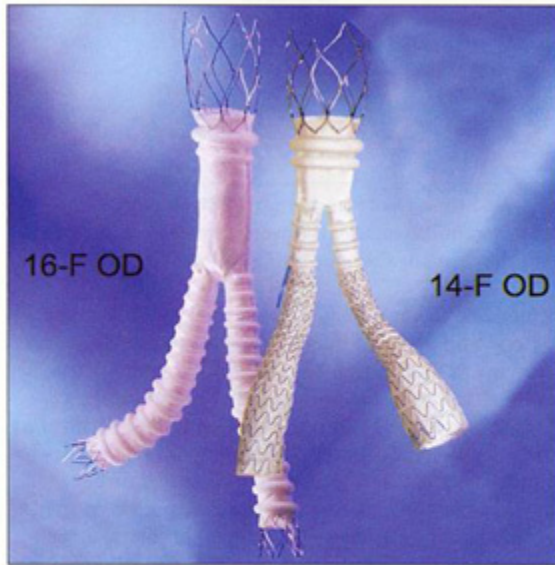


Figure 3. The TriVascular design (TriVascular, Inc., Santa Rosa, CA) evolved from a one-piece device supported entirely by an injectable polymer sleeve to a three-piece design that incorporated the injectable polymer sleeve only for the proximal sealing component. Enovus (left) and Ovation (right) endografts.





Figure 5. The Cordis Incraft endograft incorporates traditional materials and a three-piece design to achieve a 14-F OD delivery system.



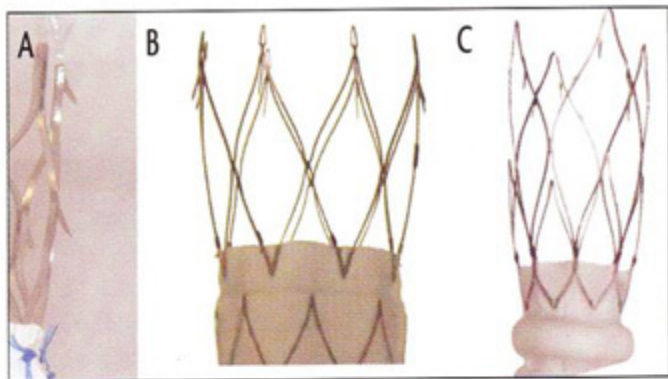


Figure 7. Next-generation suprarenal stents. The suprarenal stents have coevolved by all three manufacturers to be similar in design. All incorporate fewer nitinol crowns to achieve a lower profile and inferiorly angulated hooks for fixation. Zenith LP (A), Cordis Incraft (B), and TriVascular Ovation (C).





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Figure 100-7 Transabdominal aortic aneurysm exposure, vascular clamps in place, incising the aneurysm.



Challenges of Open Aneurysm Repair

- Maintain acceptable surgical mortality
- Continue to train vascular surgeons in Open AAA repair



Abdominal Aortic Aneurysm Endograft Repair

THE BRAVE NEW WORLD OF ENDOVASCULAR REPAIR

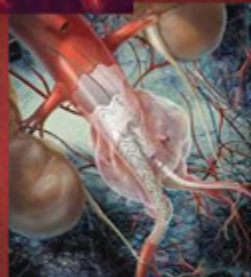
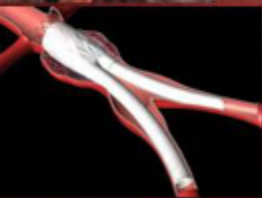
- Lower profile systems
- Endoleak monitoring with MEMS system
- Repair (stapling and glue guns)
- EVAR is taking over
- Acute rupture



CONCLUSION #1

AAA Stent Grafts

- *Exciting alternative to open surgery*
- *Continued interest despite product setbacks*
- *Industry responding with design changes*
- *Various design approaches*



CONCLUSION #2

Abdominal Aortic Aneurysm Endograft Repair

- 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

