

Update on Abdominal Aortic Aneurysms

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History

- **1888 – Matas – first successful treated AAA with ligation**
- **1951 – Dubost – first repair with a homograft**
- **1952 - Voohres - he treated the first ruptured AAA in a human with Vinyon cloth.**
- **1953 – Sir Charles Rob reported doing the same in a injured soldier**
- **1954 Debakey and his group developed the the knitted Dacron.**



Juan Parodi, M.D. - EVAR

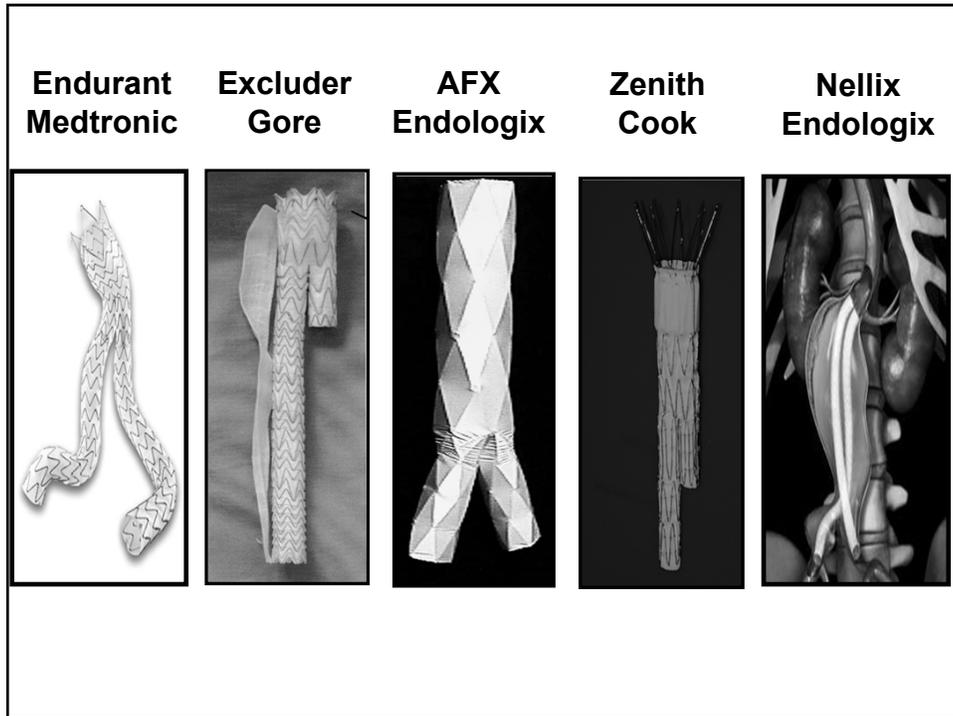
- **Developed the concept as a junior resident at Cleveland Clinic, after he observed 3 mortalities in a few days from ruptured AAAs.**
- **Initial project done on stray dogs in Argentina.**
- **On September 7, 1990, Dr. Parodi implanted the first endograft in Buenos Aries.**
- **Today \$1.8 billion dollar/year worldwide market.**



Demographics Facts

- **1.7% of women and 5% of men have abdominal aortic diameter greater than 3 cm after age 60, and the prevalence increases 6% per decade thereafter.**
- **150,000 abdominal aortic aneurysms repaired/year.**
- **Rupture causes 9,000 deaths/yr (15th leading cause of death in US)**
- **It is estimated that 80% of ruptures never make it to the hospital**
- **Small AAA enlarge 0.2-0.3 cm in diameter/yr and remain asymptomatic till rupture**
- **Approximately 70% amenable to endovascular repair.**
- **Cost of devices about \$9K and graft \$800.**
- **There are currently 5 commercially available grafts.**

4



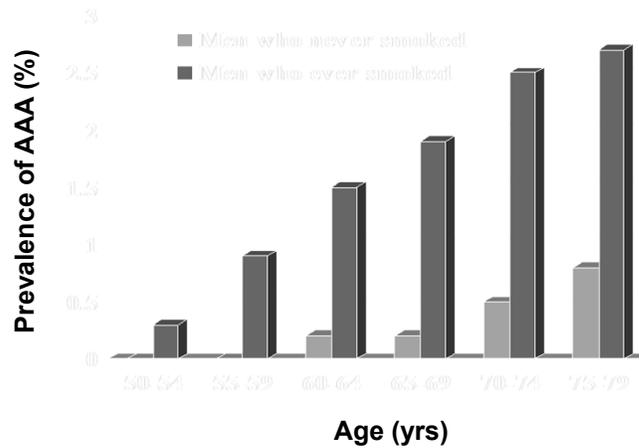
AAA risk factors

1. Size
2. Hypertension
3. COPD
4. Tobacco
5. Family History
6. Age
7. PVD and CAD

**Aneurysm in Detection and Management (ADAM)
VA Cooperative Study (Annals 1997;126:441-449)**

Risk Factors	Odds ratio of aortic diameter ≥ 4.0 vs. < 3.0 cm
H/O smoking	5.57
Family history	1.95
Age (per 7-yr interval)	1.65
H/O CAD	1.62
High cholesterol	1.54
COPD	1.28
H/O CVD	1.19
Hypertension	1.16

**Prevalence of AAA > 4.0 cm in men
by age and smoking status**



Annals 1997;126:441.

AAA Screening

- **Ultrasound is preferred method**
 - **Sensitivity and specificity nearly 100%**
 - **Low cost**
 - **Patient accepted**
 - **Lack of radiation exposure**
 - **Widely available**

Effectiveness of screening

- **Screening programs need to target the most likely to benefit to maximize cost-effectiveness and minimize inconvenience and risk to the non-diseased population.**
- **Most published screening programs and randomized trials have been limited to men**
- **Screen at age at 65**
 - **95% of pts. dying from rupture are > 65 yo**
 - **Future death from AAA rupture rare after a negative US at 65 yo**
- **Smokers**
 - **3-5x likely to have AAA at screening**

Screening studies

- **Four randomized trials of AAA screening**
 - Lindholdt JS et al. (Eur J Vasc Endovasc Surg 2002)
 - Scott RA et al. Br J Surg 1995
 - Vardulaki et al. (Br J Surg 2002)
 - Norman et al. (Br J Surg 2003)
 - Ashton HA et al. (MASS). (Lancet 2002)

AAA Screening

The Multicenter Aneurysm Screening Study Group. The Multicenter Aneurysm Screening Study (MASS) into the effect of abdominal aortic aneurysm screening in men: a randomized controlled trial. Lancet 2002;360:1531-9. (11/16/02).

AAA Screening

- Purpose:
 - to assess whether or not ultrasound (US) screening is beneficial
 - Screening does not adversely affect quality of life
- Design/method:
 - Randomized, blinded (data collectors and outcome assessors) controlled trial
 - Mean follow-up of 4.1 years at 4 screening and 4 academic centers in England, UK

AAA Screening

- Patients:
 - **67,800 men, age 65 to 74 (mean 69.2 yrs.)**
 - **Exclusion:**
 - men with serious illness,
 - history of AAA repair, or
 - unfit to be screened
 - **Mortality follow-up was 99%**

AAA Screening

- **Intervention: Half (33,839) were invited for ultrasound (US) screening. US results were sent to family physicians**
- **Primary Outcome: Death from AAA**
- **Secondary outcome: all-cause mortality, ruptured AAA, and quality of life**

AAA Screening

- **< 3.0 cm: not rescanned**
- **3.0-4.4 cm: scanned yearly**
- **4.5-5.5 cm: scanned q 3 months**
- **> 5.5 cm: referred to vascular surgery**

- **80% of men invited agreed to US**
- **1,333 AAA detected (4.9% scanned)**

AAA Screening

- Results:
 - Deaths from AAA and ruptured AAA were **lower** in the invited group
 - More elective surgery and less emergent surgery in invited group
 - 30-day mortality not stat. sig.
 - No difference in all-cause mortality, anxiety, depression, or health status measure

AAA Screening

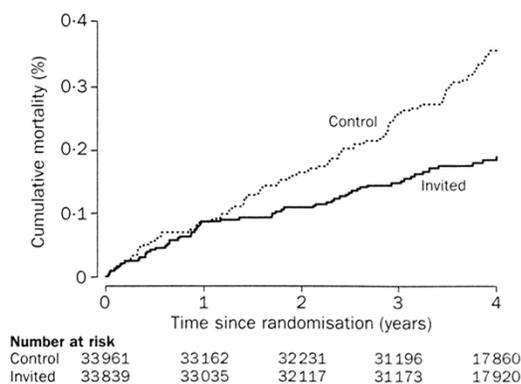


Figure 2: Aneurysm-related mortality over 4 years of follow-up by randomisation group

MASS. Lancet 2002;360:1531-9.

AAA Screening

- **Conclusion:**
 - In older men, US screening for AAA reduced death from AAA without any detectable reduction in quality of life
 - 712 NNS to prevent one aneurysm-related death
 - Not applicable to women and men age 65-74
- **Are we ready to screen all men older than age 65?**

AAA Screening – Take home message

Lederle concludes that “it would be reasonable to offer one-time US screening to men ages 65-79 who have ever smoked, especially if elective repair can be reserved for AAA 5.5 cm or larger.”

Lederle FA. Ann Intern Med 2003;139:516-22. (9/16/03)

SAAVE Act

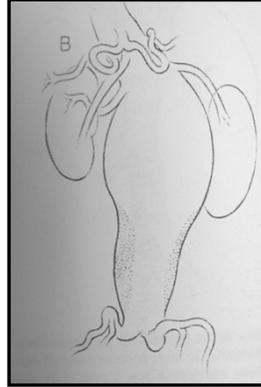
Screen for Abdominal Aortic Aneurysms

- Under the law, Medicare covers a one-time ultrasound scan screening of men aged 65 to 75 years of age who ever smoked in their lifetime or men and women who have a family history of AAA disease as part of a “Welcome to Medicare” package.
 - In 2007, this led to only a fraction (1%) of eligible beneficiaries actually receiving screening ultrasound
- The Society for Vascular Surgery recommends one-time ultrasonography screening for AAAs in men aged 55 years or older with a family history of AAA, all men aged 65 years or older, and women aged 65 years or older who have smoked or have a family history of AAA .

Open vs Endovascular and Outcomes

Early Comparison of Open vs Endovascular Repair for AAA

- Infrarenal CCF Data
 - Open (*Hertzer et al. JVS 2002;6:1145-54*)
 - 1.2% 30 day mortality
 - EVAR (*Ouriel et al. JVS 2003;5:991-8*)
 - 1.7% 30 day mortality
 - Juxtarenal AAA
 - 6-10% of all open infrarenal repairs. Neck < 1 cm.
 - 2.5% mortality (*Sarac et al. J Vasc Surg. 2002 Dec;36(6):1104-11*)



Early Technology Issue

- Endoleaks - 10-20%
- Migration – 3-6%
- Limb Compression and occlusion 2-10%
- Stent Fractures
- Rupture - 0.5-1%
- Mortality rates equivalent to open repair



The Trials

- DREAM Trial
- EVAR I and II
- UK Small Aneurysm Trial and ADAM Trial
- Small Aneurysm
- Ruptured AAA
 - Improve Trial
 - Retrospective series
- SAAVE

EVAR I

Lancet 2004;364:843-8.
Lancet 2005;365:2179-86.

- 1082 patients with AAA pts randomly assigned to surgery vs open repair.
- 30 day mortality 1.7% EVAR and 4.7% open repair (p<.001).
- Complication 4% EVAR and 9% open.
- At 4 years aneurysm related mortality for EVAR one less than open repair (4% vs 7%), but over all mortality 26% vs 29% (no difference).
- Cost of EVAR 10% higher.

EVAR I

Lancet 2005;365:2179-86.

- 1082 patients with AAA were randomly assigned to surgery vs open repair.
- 30 day mortality: 1.7% EVAR vs 4.7% open (p<.001).
- Complication 4% EVAR and 9% open. (p<.001).
- At 4 years, aneurysm related mortality for EVAR was less than open repair (4% vs 7%), but not over all mortality 26% vs 29% (p=ns).
- Conclusions: compared with open repair, EVAR offers no advantage with respect to all-cause mortality and long term quality of life, but it does result in a 3% better aneurysm-related survival.
- Cost of EVAR 10% higher.

DREAM Trial

Prinssen et al. NEJM 2004;1607-1618.

Blankenstein et al NEJM 2005;352;2398-405.

- 351 patients with AAA > 5 cm randomly assigned to EVAR vs open repair.
- 30 day mortality was significantly less for EVAR (1.2% vs 4.6%)
- Aneurysm related death less for EVAR (2.1% vs 5.7%).
- Two years after randomization, cumulative survival was 89.6% for open and 89.7% for EAVR.
- Overall survival was equivalent at 2 years and benefit for open surgery recently reported at 5 years.
- Conclusion – peri-operative survival advantage for EVAR not sustained after first year.

EVAR II

Lancet 2005; 365:2187-2192.

- 388 patients older than 60 years not candidates for open repair randomly assigned for EVAR or observation.
- 30 day mortality - 9% for EVAR.
- The “No treatment group” had a rupture rate of 9/100 years.
- There was no difference in all cause mortality between the groups.
- No benefit for EVAR found during follow up for any age.

OVER Trial

JAMA, October 14, 2009—Vol 302, No. 14 1535-42. N Engl J Med 2012;367:1988-97.

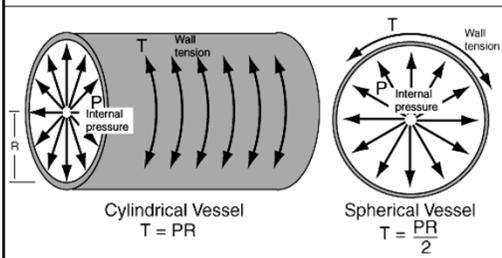
- A randomized trial of 881 veterans comparing EVAR vs open repair for abdominal aortic aneurysms.
 - No difference in all-cause mortality, or aneurysm related mortality .
 - The early reduction in perioperative mortality with EVAR was not sustained after 3 years.
 - 6 aneurysm ruptures were confirmed in the endovascular-repair group versus none in the open-repair group (P=0.03).
- Conclusions - Endovascular repair and open repair resulted in similar long-term survival. The perioperative survival advantage with endovascular repair was sustained until 3 years, but rupture after repair remained a concern.

Small Aneurysms – Does Size Matter?

Risk of Aneurysm Rupture

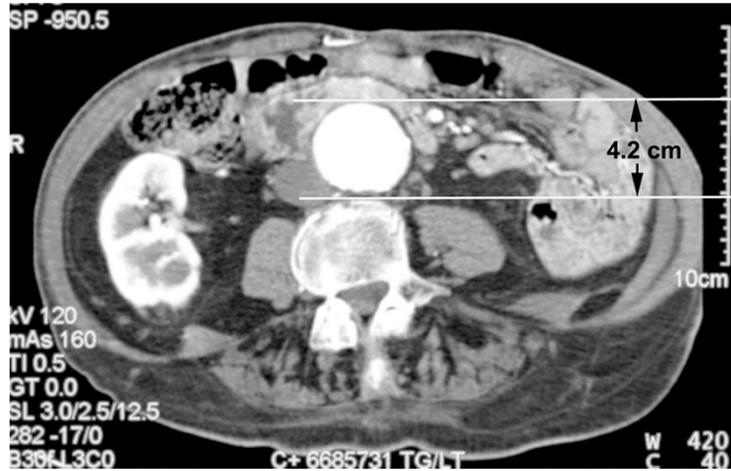
- Greatest risk factor for rupture is size.

LaPlace's Law $T=PR$
The larger the vessel radius, the larger the wall tension required to withstand a given internal fluid pressure

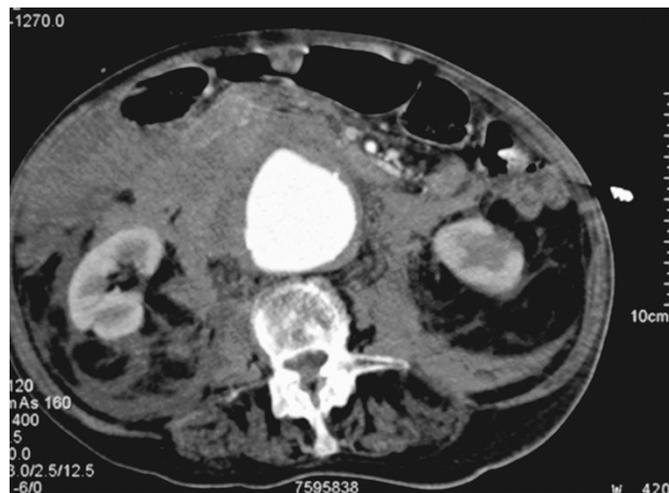


For a given vessel radius and internal pressure, a spherical vessel will have half the wall tension of a cylindrical vessel.

Small AAA: Recommendation- *q6m* *ultrasounds??*



2 Weeks Later...



Early Small Aneurysm Data

Ouriel et al. JVS 1992;15:12-20

- **100 AAA ruptures**
 - 5.1% of all ruptures occur below 5 cm
 - 1.9% of all ruptures occur below 4 cm
 - Aortic diameter is dependent on age and gender.
 - Standardization of AAA diameter to patient size (3rd vertebral body) was best predictor of rupture.

Critique

- **ADAM trial**
 - VA trial with mostly men
 - 2.1% mortality
- **UK SAT**
 - 29% of pts died before trial completion, and no standardized way of death investigation
 - 5.4% mortality

Logic Behind Endovascular AAA Repair for 4 - 5.5 cm Aneurysms

- The open vs. observation trials (UK-SAT and ADAM) demonstrated *similarity or superiority* of surveillance compared to early repair.
- These findings were documented despite a perioperative mortality rate* of 5.4% in UK-SAT and 2.1% in ADAM.
 - CCF data has mortality rates of < 1.8% for both EVAR and open repair.
- 4 to 5.5 is a 28% difference in size.

Logic Behind Endovascular AAA Repair for 4 - 5.5 cm Aneurysms

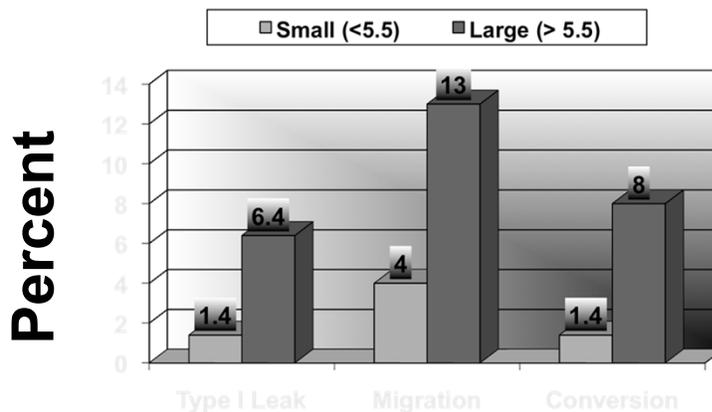
- If a procedure could be performed with a lower peri-operative mortality rate, that procedure might be able to “beat” surveillance in patients with smaller AAA.
- Results of EVAR trial of endovascular vs. open surgery in larger aneurysms: 30 d mortality significantly lower with endo repair (1.9 vs. 4.7%).

Cleveland Clinic Study:

Endo Repair Performs Best in Smaller AAA

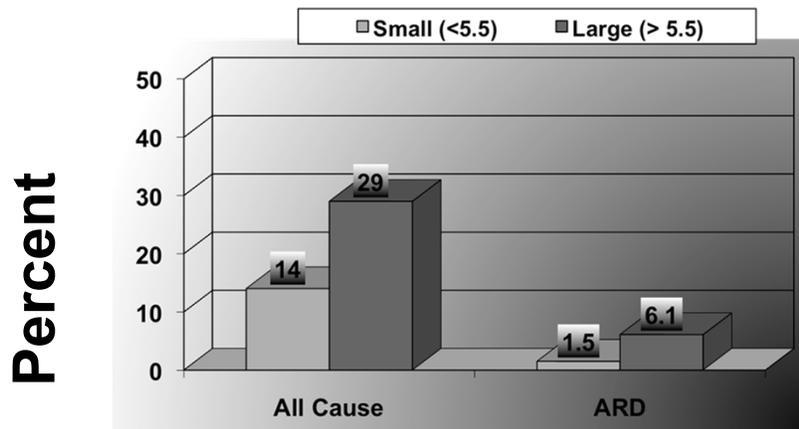
- 700 repairs between 1996-2002
 - <5.5 cm- 59%
 - >5.5 cm- 41%
- No differences in
 - rate of Type II endoleaks
 - change in sac diameter over time
 - rupture

3 Year Secondary Procedures



All $p < .05$

Two Year Survival



All p<.05

Rupture or Aneurysm-Related Death

3-Yr K-M Estimates

Early endovascular repair (CCF data)

- Rupture 0.9%
- ARD 1.1%
- Combined 2.1%

Observation (Small Aneurysm Trials)

- UK-SAT Combined 6.9%
- ADAM Combined 3.3%
- Averaged 5.1%

Adopting Endo for Small Aneurysms



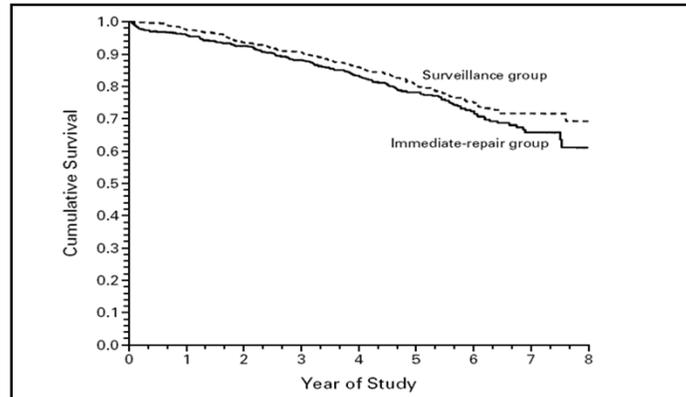
“Look Before You Leap”

Level One Data
Two Studies: 4 - 5.5 cm AAA

ADAM Trial

N Engl J Med 2002;346:1437-44.

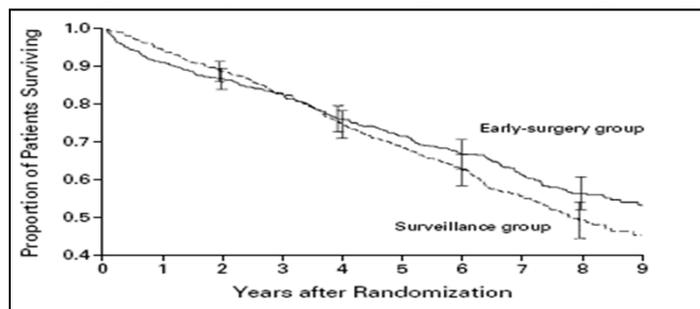
- Observation vs. Open Repair for AAA 4-5.4 cm
- Survival similar in the two groups
- VA trial with mostly men
- 2.1% mortality



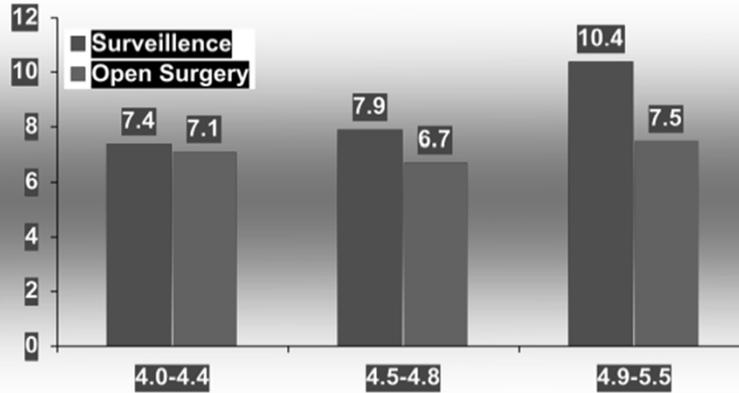
UK Small Aneurysm Trial

N Engl J Med 2002;346:1445-52.

- **UK Small Aneurysm Trial:**
- **Observation vs. Open Repair for aneurysm 4-5.4 cm**
 - **Survival statistically superior in patients treated with early repair.**
 - **At the suggestion of the editors of the journal, benefit was attributed to better lifestyle management (less smoking) in the surgical group**



UK Trial: Mortality Disparity Greatest in Larger Aneurysms



Conclusions of the UK Trial

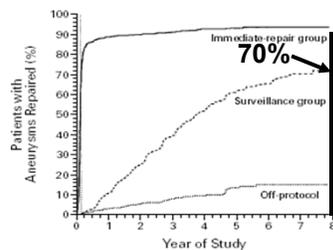
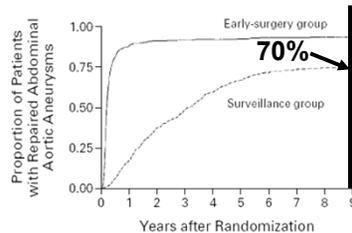
LONG-TERM OUTCOMES OF SMALL ABDOMINAL AORTIC ANEURYSMS
 LONG-TERM OUTCOMES OF IMMEDIATE REPAIR COMPARED WITH SURVEILLANCE OF SMALL ABDOMINAL AORTIC ANEURYSMS
 THE UNITED KINGDOM SMALL AORTIC ANEURYSM TRIAL PARTICIPANTS*

ABSTRACT
Background: Ten clinical trials, one British and nine American, have shown that early prophylactic elective surgery does not improve five-year survival among patients with small abdominal aortic aneurysms. We report long-term outcomes in the United Kingdom Small Aneurysm Trial.
Methods: We randomly assigned 5000 patients, 60 to 74 years of age, with small abdominal aortic aneurysms (diameter, 4.0 to 5.5 cm) to one of two groups: 503 were assigned to undergo early elective surgery, and 527 were assigned to undergo surveillance by ultrasonography. Patients were followed in the trial until June 1993 and thereafter until August 2007; the mean duration of follow-up was 8 years (range, 0 to 40).
Results: The mean duration of survival was 6.5 years among patients in the surveillance group, as compared with 6.2 years among patients in the early surgery group ($P=0.25$). The adjusted hazard ratio for death from any cause in the early surgery group as compared with the surveillance group was 0.82 (95% percent confidence interval, 0.69 to 0.99). The 30-day operative mortality among patients in the early surgery group was 2.2 percent, and the mortality at eight years, mortality in the early surgery group was 7.2 percent, which was lower than that in the surveillance group ($P=0.03$). There was no difference in mortality between the two groups if the mortality in the surveillance group increased 20-day postoperative mortality. Death was attributable to a ruptured aneurysm in 13 of the 61 men who died in the early surgery group and in 12 of the 60 men who died in the surveillance group. The rate of early operation of aneurysm was higher in the early surgery group than in the surveillance group.
Conclusion: Among patients with a small abdominal aortic aneurysm, we found no long-term difference in mean survival between the early surgery and surveillance groups, although after eight years, total mortality was lower in the early surgery group. This difference may be attributed in part to beneficial changes in health-related behaviors in the early surgery group. (N Engl J Med 2002;348:1445-52.)
 Copyright © 2002 Massachusetts Medical Society.

survival. The survival curves crossed at three years, and at eight years, mortality in the early-surgery group was 7.2 percentage points lower than that in the surveillance group ($P=0.03$). There was no evi-

- 29% of pts died before trial completion, and no standardized way of death investigation
- 5.4% mortality

Will Observed Patients Undergo Repair Anyway?

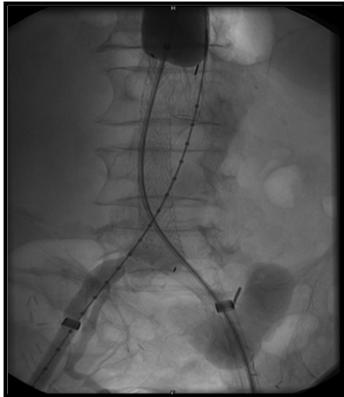


- Both the UK (top) and ADAM (bottom) trials documented the need for eventual repair in approximately 70% of patients initially managed with surveillance
- These studies were pre-EVAR

EVAR for Ruptured AAA

- Despite improvements in technology, screening programs and early intervention, mortality of ruptured infrarenal AAA remains high.
- The first reported case of EVAR for ruptured AAA was by Dr. Parodi in Buenos Aries, and Frank Veith in the US.
- Who do we perform the procedure on?
 - Imaging has helped.

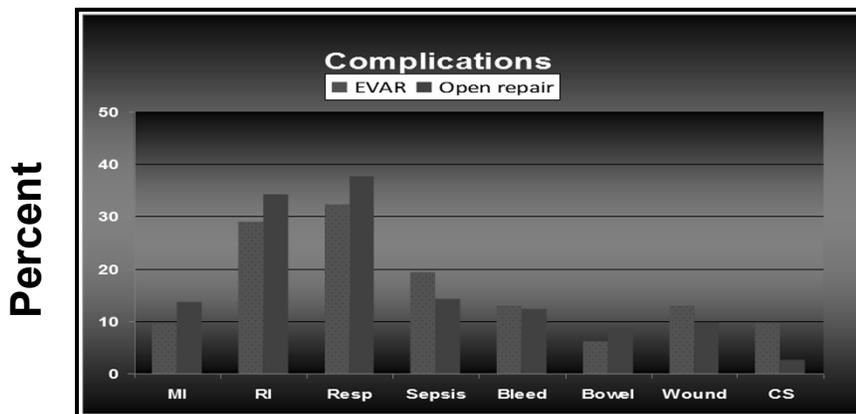
Proximal Control Needs Quality Imaging and a Great Team



Fast deployment and inflation of a balloon.

Postoperative data

Sarac et al. Ann Vasc Surg. 2011 May;25(4):461-8



- Mortality similar between open and end (30%)
- There was no difference in complications between EVAR and open repair.
- ICU stay: 6 days; hospital stay: 12 days

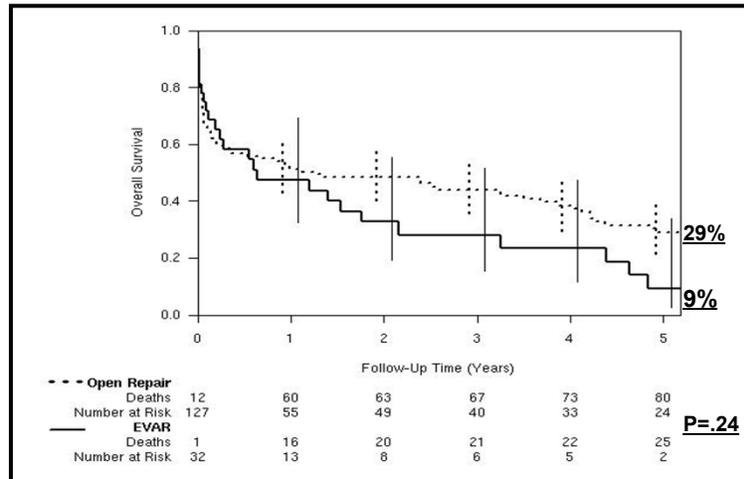
Post Procedure Compartment Syndrome



Mortality Rates

	Overall	EVAR	Open repair	<i>p.</i>
Intraoperative	5.6 %	0	7 %	.03
30 day/in-hospital	31.9 %	32 %	31.2 %	.93

Cumulative Survival Rates



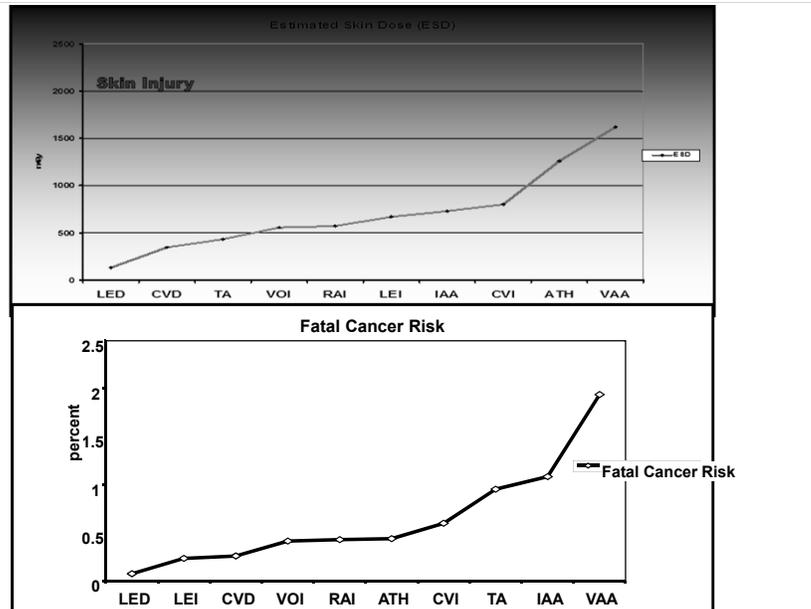
Improve Trial

BMJ 2014; 348

- 316 patients were randomized to the endovascular surgery and 297 to open repair.
- 30 day mortality was 35.4% (in the endovascular strategy group and 37.4% in the open repair group.
- More patients in the endovascular strategy than in the open repair group were discharged directly to home (189/201 (94%) v 141/183 (77%); $P < 0.001$).
- Average 30 day costs were similar between groups.
- A strategy of endovascular repair was not associated with significant reduction in either 30 day mortality or cost.

Radiation

Banazadeh et al J Vasc Surg. 2009 Jun;49(6):1520-4



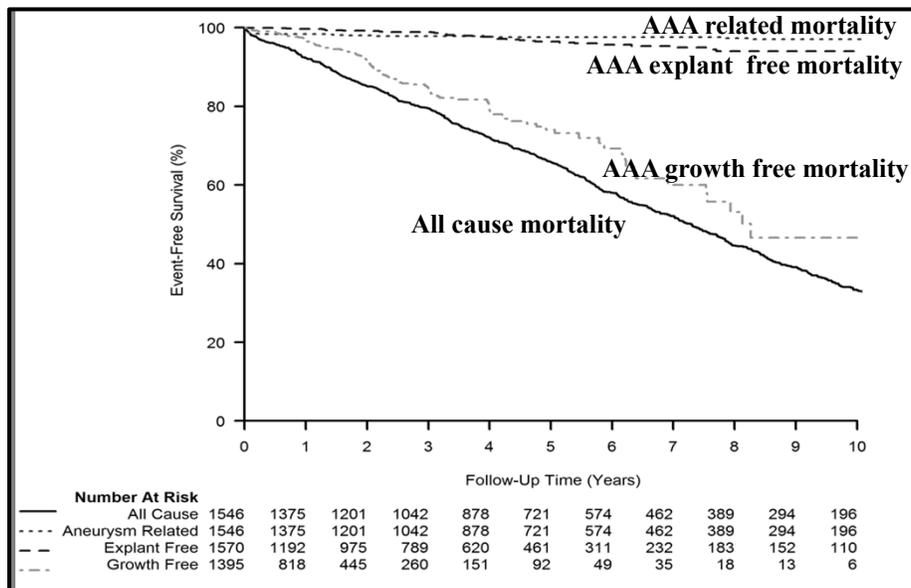
Long Term Outcomes Beyond 5 Years

- Our interest in this study came from curiosity in what happened to the patients who had endografts beyond 5 years.
- We retrospectively reviewed our results of patients undergoing non trial EVAR between 1999 and 2011. During this time 1570 non trial EVARs were performed.
- Various outcome measures analyzed with respect to stent graft type, demographics, operative procedure, and long term follow up data.

Overall Long Term Outcomes Beyond 5 Years

- 9.4% sac growth , 56.7% sac shrinkage, 33.9% no change (90.6)
- Known AAA Rupture = 0.7%
- Graft migration – 4.6%
- Limb Disunion – 3.6%
- Limb Occlusion – 3.6%
- Conversion to open repair – 2.3%
- Overall endoleak – 26.1%
- Secondary intervention Rates – 17.1%
- All cause mortality 53.9% ,but aneurysm related mortality 2.3%.

Kaplan Meier 10 Year Mortality

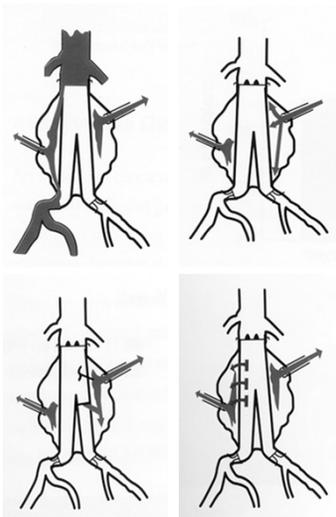


Endoleaks

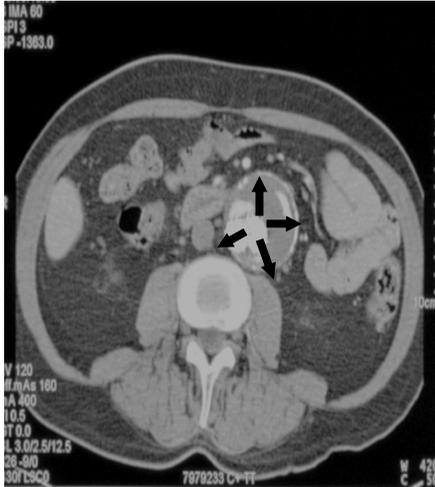
THE CLEVELAND CLINIC
FOUNDATION 

Endoleak : persistent flow into aneurysm sac

- Type I
 - Proximal or distal seal
- Type II
 - Branch vessel flow
- Type III
 - Graft or component junction
 - Fabric failure
- Type IV
 - Transgraft flow due to porosity
- Type V
 - Increase in diameter with no endoleak ?
 - endotension



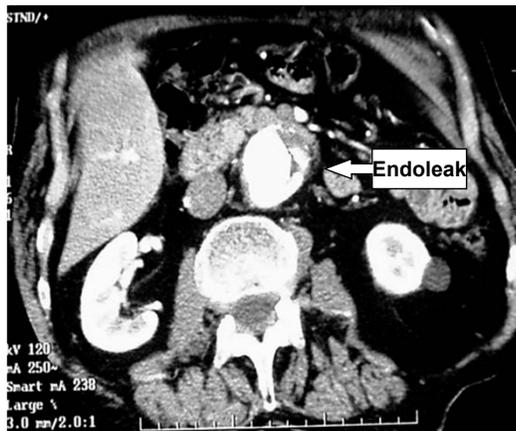
Endoleak and endotension



- Can lead to persistent pressure with in the aneurysm sac.
- How to measure?
- Is it significant?
- How to treat?

Type I Endoleak

CT Scan

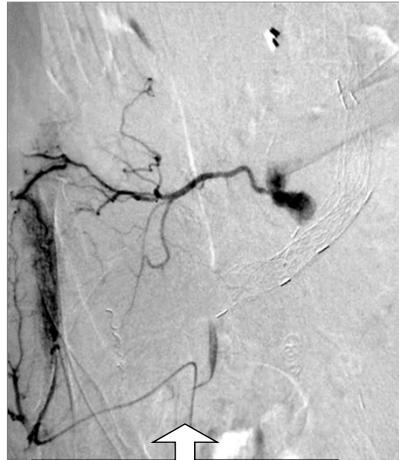


- Large blush in proximal neck
- Requires urgent treatment



Type II endoleak

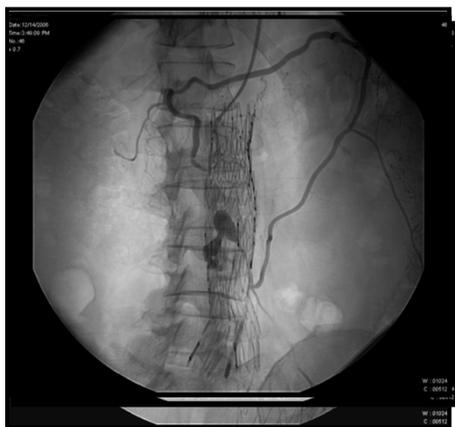
- Selective SMA injection
- Selective Hypogastric injections
- Translumbar injection
- Usually associated with an inflow and outflow source



SIM 2 in R
hypogastric



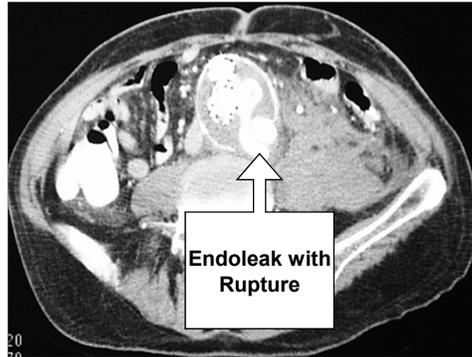
IMA Endoleak



- 5F sheath placed into SMA
- Catheter engaged into middle colic artery (right).
- Microcatheter advanced over a 0.018" or 0.014" into the IMA
- Glue injected into AAA sac and orifice of IMA
- Completion angiogram demonstrating stagnant flow

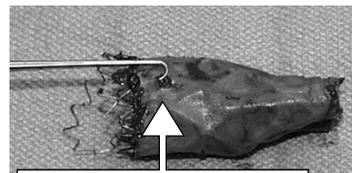
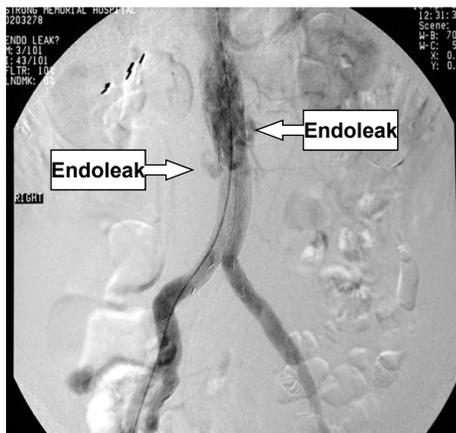
Type III endoleak

- Component Separation

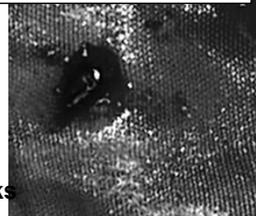


Type III Endoleak

Angio



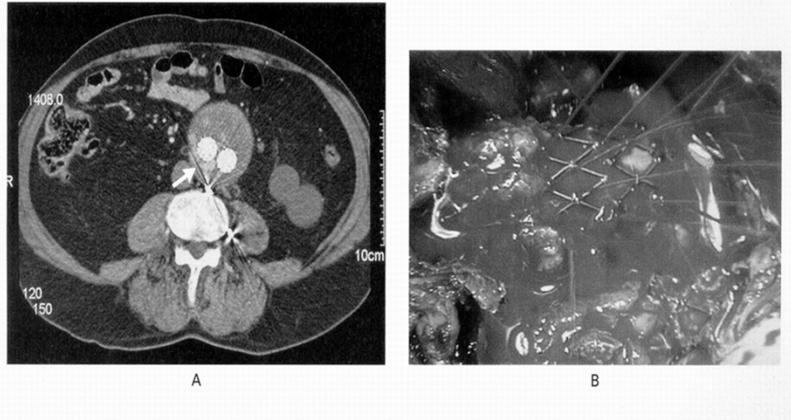
Probe engaged
In hole in fabric
From stent motion



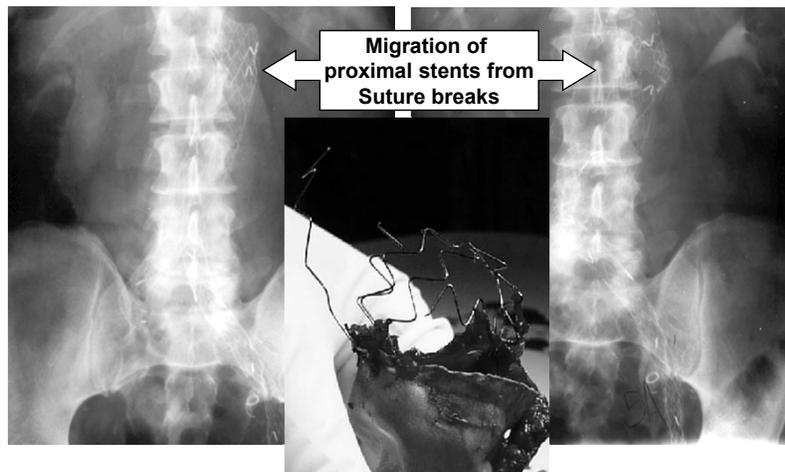
Fabric tear due to stent motion after suture breaks



Type III endoleak



Device Failure

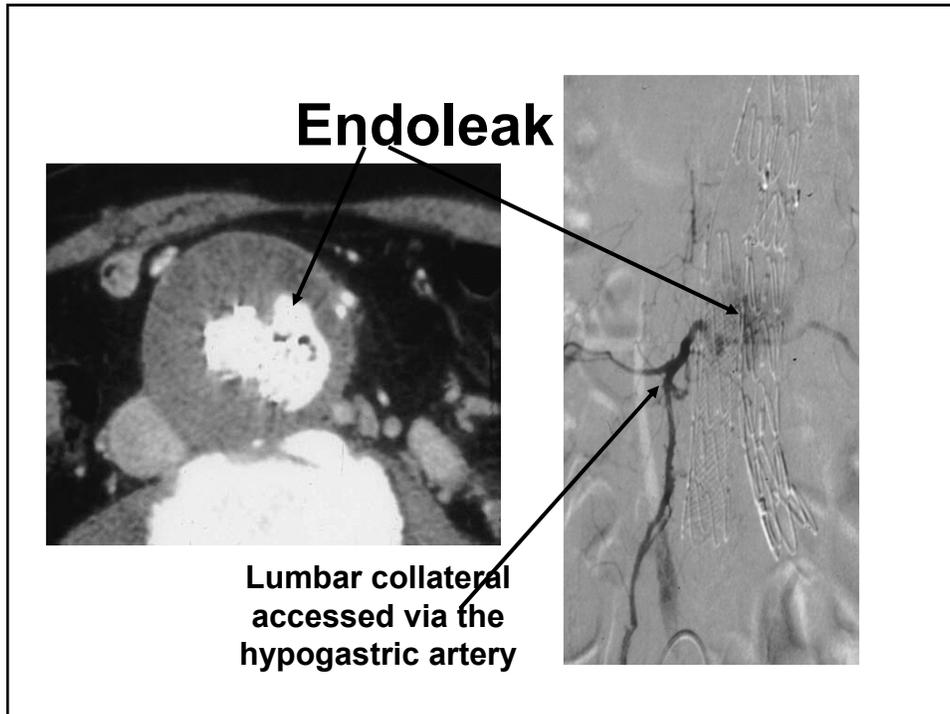


Which endoleaks should be fixed and when?

- **Type I:**
 - At initial implantation or hospitalization if detected
- **Type II:**
 - If aneurysm increases in size or ?? fails to decrease in size
- **Type III:**
 - At initial implantation or hospitalization if detected
- **Type IV:**
 - If aneurysm increases in size or ?? fails to decrease in size
- **Type V**
 - If aneurysm increases in size

Endoleaks - When Do We Treat?

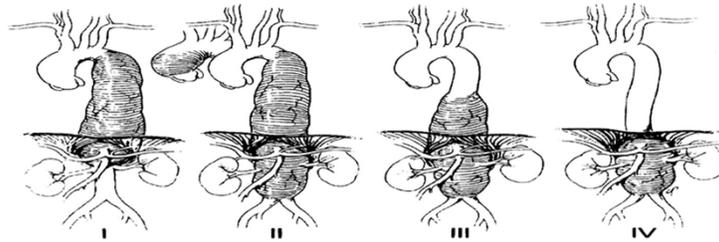
- **Treatment is initiated when there is a perceived risk of rupture**
 - type I leaks
 - type III leaks
 - persistently pulsatile aneurysm
- **How do we treat them?**
- **When do we intervene for limb migration?**



New Directions

- **Smaller Devices**
- **More Durable Devices**
- **“Radiation Friendly”**

Thoraco-abdominal Aneurysm Crawford Classification



Para-Juxtarenal Aneurysm

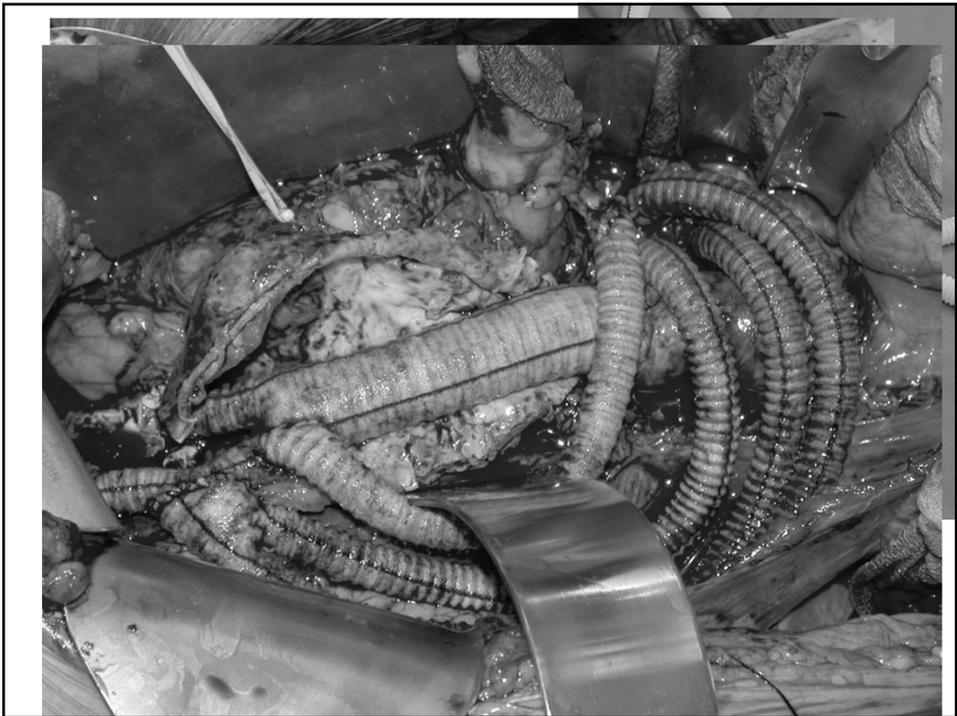
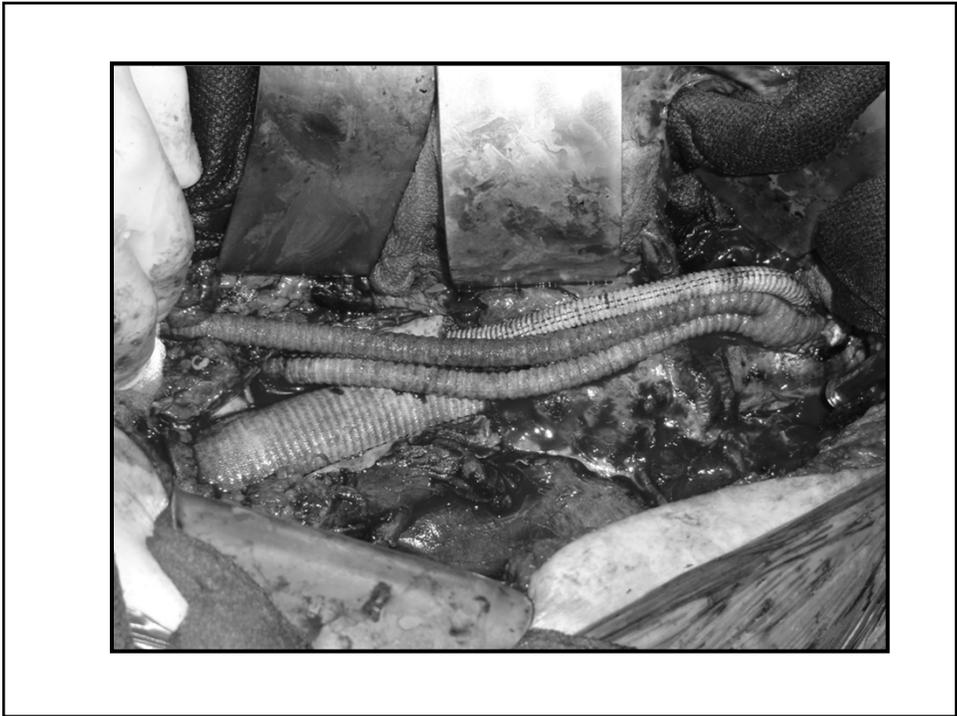


The Issues

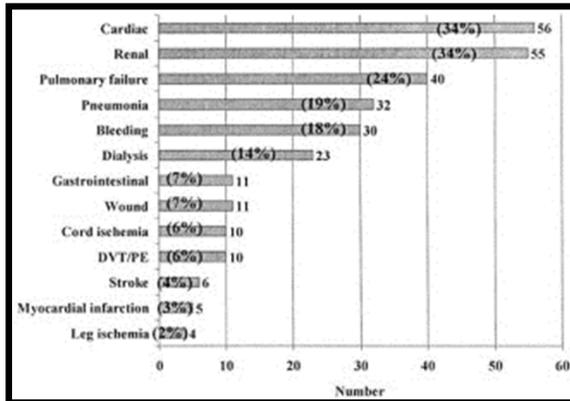
- **Type 2 and 3 TAAs**
 - The real issue is visceral ischemia and cardiopulmonary sequelae of a high clamp
 - “Organs do not do well without blood flow”
Bruce Lytle, MD
- **Juxtarenal, Suprarenal, and Type 4 AA**
 - The issue is less visceral ischemia, but still highly invasive.
- **For minimally invasive therapy, the issue is level of invasiveness vs durability.**

Open AAA vs Endovascular Aneurysm Repair

- **Type I**
 - Open - done with left heart bypass
 - Endo – now routine stent graft if visceral vessels are preserved. The first US device was approved in 2005, now there are 3 commercially available devices and 2 more soon to be added.
 - Paraplegia and mortality are higher with open than endo
 - Paraplegia 2% vs 10% and mortality 7% vs 10%
 - SVS guidelines recommend carotid-subclavian bypass if the subclavian artery is covered during TEVAR.



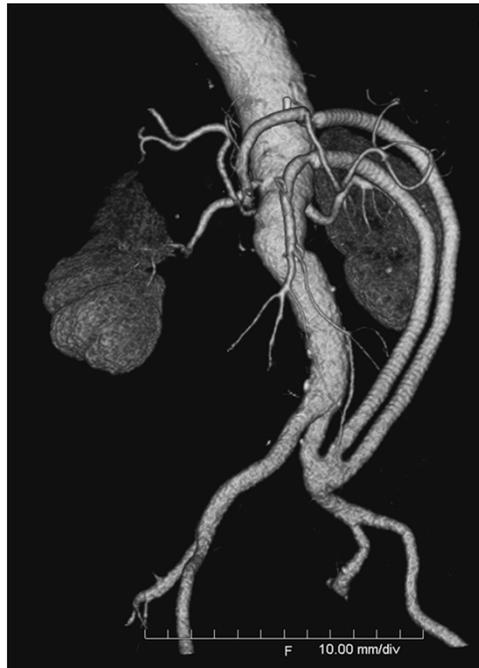
CCF Open TAA Results



Mortality
Juxtarenal – 2%
Type III – 11%
Type IV – 13%

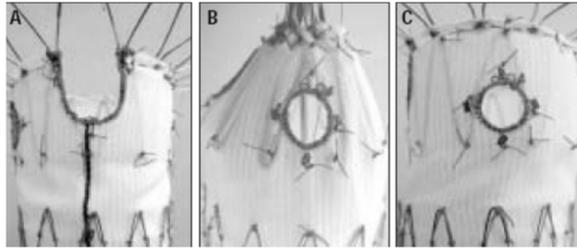
Extra-Anatomic Bypass Options

- Infrarenal aortic based
- Iliac artery based
- Thoracic aortic based



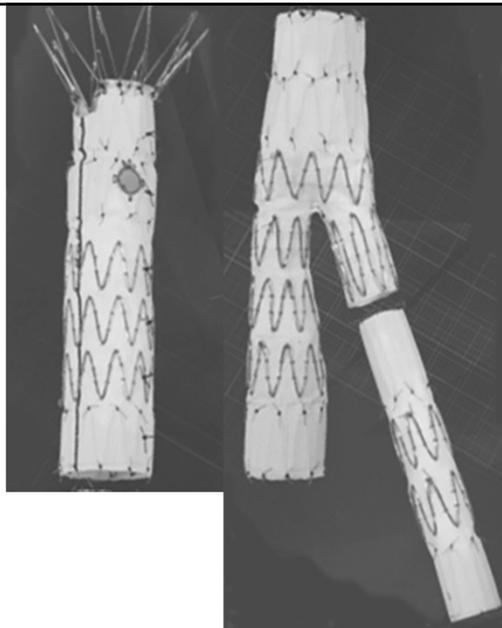
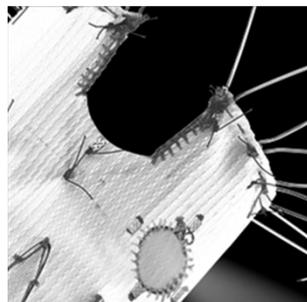
Fenestrated and Branched Endografts

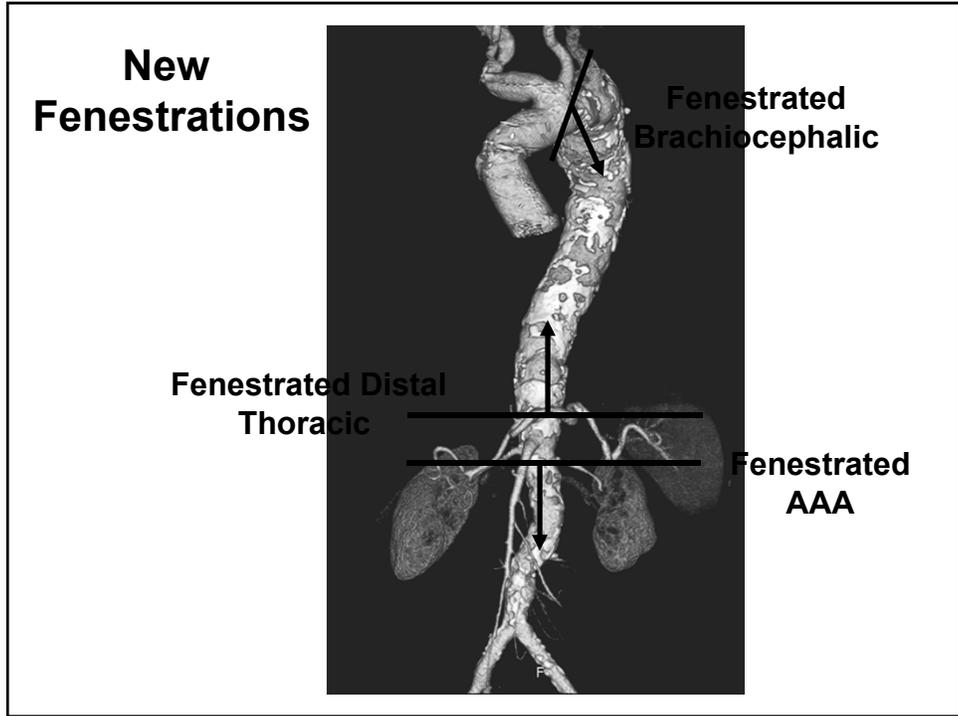
- First venture into proximal neck issues
- Initial procedures in high-risk individuals with poor standard risk options
- Still a patient-specific approach
- Utilizes base Cook Zenith device – fenestrated holes and scallops



Fenestrated AAA Device

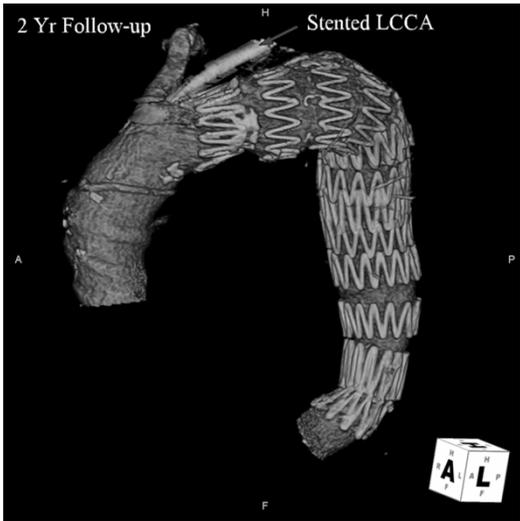
- Modular components
 - 2-piece → 3-piece evolution
 - Proximal tube, bifurcation body, and iliac limb



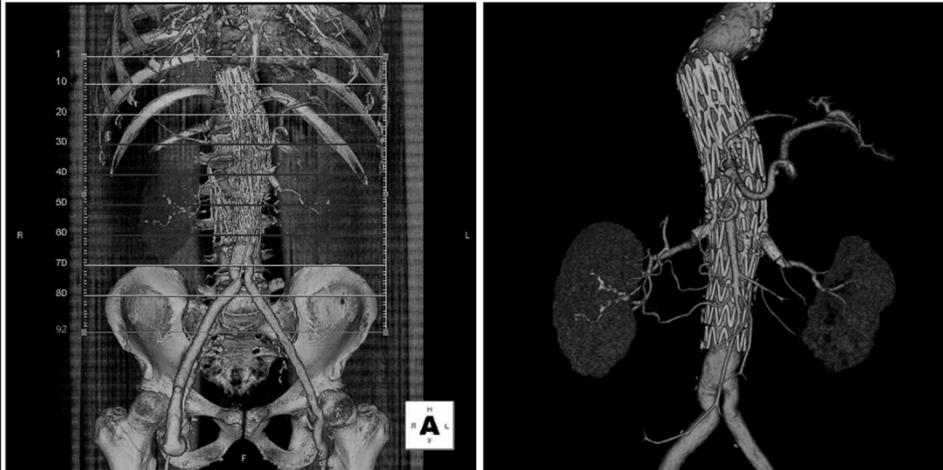


Proximal Thoracic Fenestrations

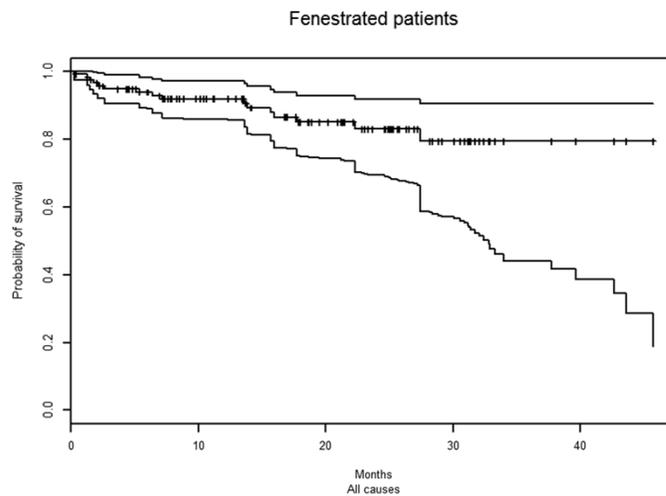
- Frequently aneurysms encroach upon the arch vessels
- Tortuous aortic segment
- Cant cover carotid



Side Branched Grafts

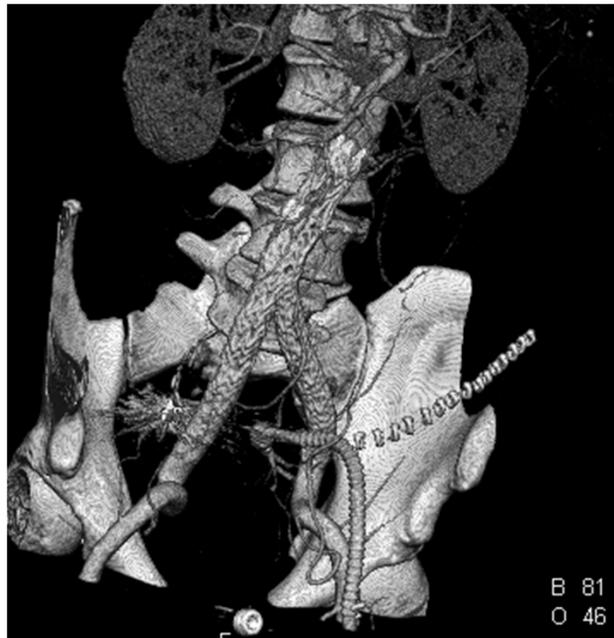
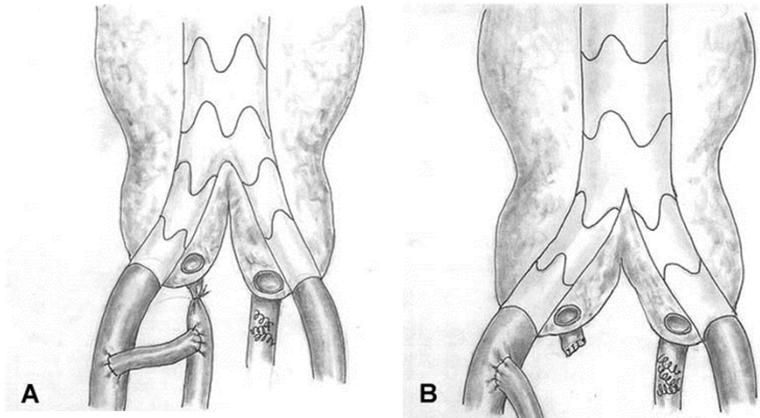


Fenestrated Mortality



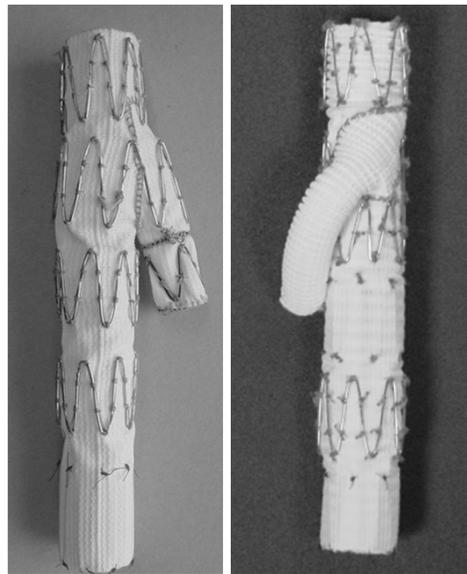
Survival at 1 (n=117), 12 (n=96), 24 (n=77) and 36 (n=36) months are 99%, 92%, 83% and 79%

Surgical Revascularization

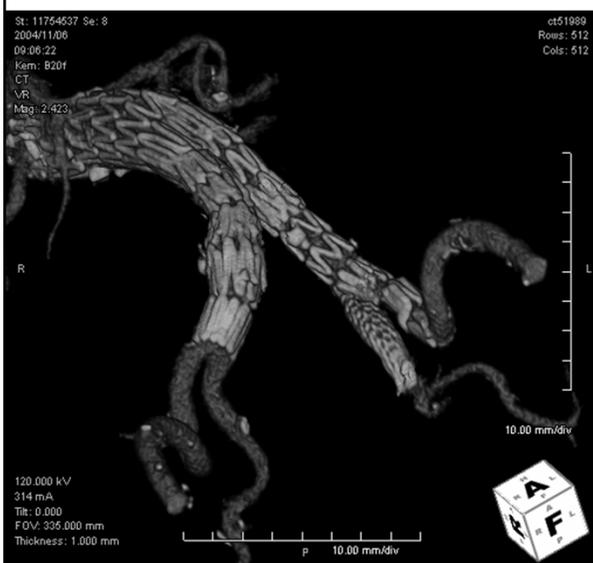


Iliac: Couple branch device with Zenith device

- Several designs
 - Mini-bifurcated device
 - 45° angle
 - Helical Branch

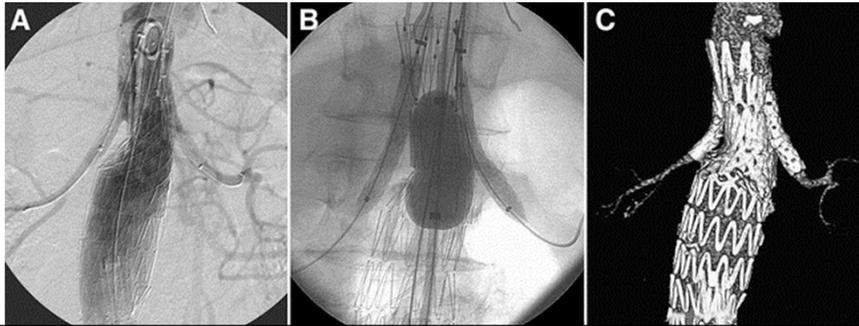
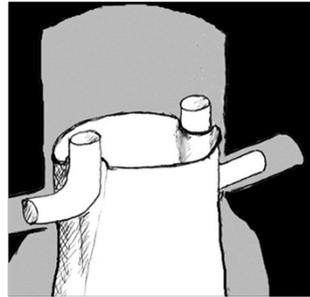


Completed Case



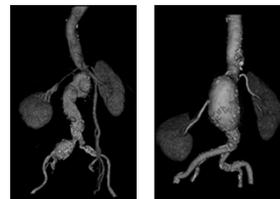
- Patent hypogastric distal branch on left

Chimney Grafts



Technology Challenges: For juxtarenal, pararenal, and infrarenal AAA not eligible for currently approved infrarenal devices

1. Broad off-the-shelf applicability
2. Unique seal in challenging anatomy
3. Stability to avoid migration
4. Fully Integrated System
5. Easy to use



***CAUTION: Investigational Device. Limited by federal (US) law to investigational use only.**

Introduction

What We Know

- Juxtarenal, pararenal and throaco-abdominal aortic aneurysms compromise 15-20% of all aneurysm repairs.
- There are several commercially available infrarenal AAA endografts, which over the past 2 1/2 decades have undergone many iterative improvements.
- Today there is only 1 commercially available fenestrated endograft in the US, which requires min 4-5 weeks to make.
- It has been 27 years since Juan Parodi, MD invented the endograft, since then only minor advances have been made.
- Fenestrated and branch vessels grafts have been in IDEs for over 15 years, require significant manufacturing time, high expertise, and are not yet available for “off the shelf” commercial use in the US.

Fenestrated Stent Grafts

What We Know

- First reported in 1999 by Brown and Hartley
- US availability – first approval in 2012
- IFU limitations
 - 15 mm landing zone between renals and sma
 - 4 mm mm of normal infra-renal aortic neck
 - Diameter of aorta < 31 mm
- Significant I aning curve
- Long radiation exposure

Fenestrated Stent Grafts

Pivotal Trial Midterm Study Results

- **Z Fen Pivotal Results J Vasc Surg 2014;60(6):1420-9**
 - Multicenter trial of 67 patients treated at 14 centers
 - 8 centers did 88% of the cases
 - Type 1 endoleak rate - 1.5%
 - No rupture or conversions reported with a mean follow up of 37 months.
 - 9% renal artery stenosis, 3% occlusions
 - 22% secondary intervention rate
 - 30 day mortality - 1.5%
 - 91% - 5 year survival

Fenestrated Stent Grafts

Real World Challenge

- **Raux et al. J Vasc Surg 2014;60:858-64**
 - Propensity matched study, 59 FEVAR/324 OSR

	FEVAR %	Open Surgery %	P Value
30 Day Mortality	9.5	2	.05
Any Complication	41	23	.01
Procedure Complication	21	7	.01
Graft Complication	30	2	.01

Parallel Chimney and Periscope Grafts

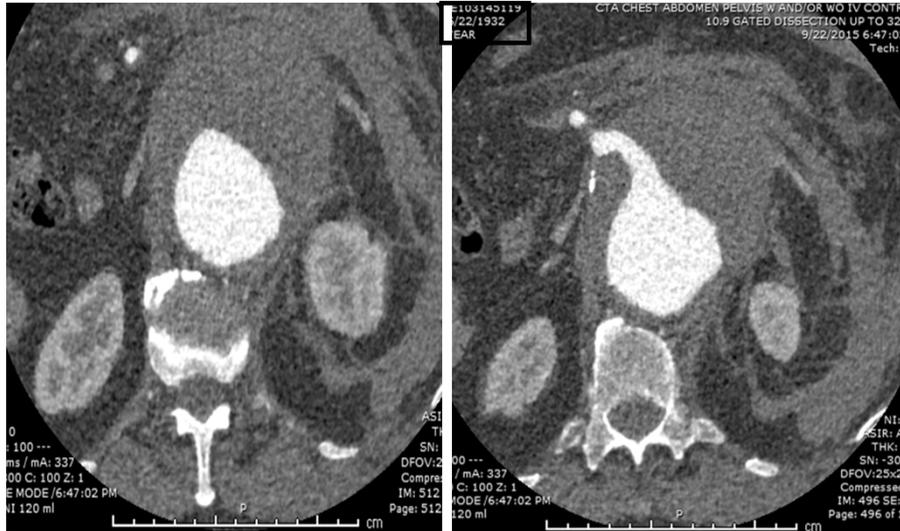
What We Know

- Evolved out of need for immediate endovascular solutions to treat peri-visceral aortic aneurysms.
- First reported by Roy Greenberg, first case actually done by Dan Clair.
- They have high type 1 endoleak rates and require multiple access points.
- For urgent use, you need a full complement of stent graft sizes which are not always readily available.
- Both balloon and self-expanding stent grafts are useful
 - Used with all AAA stent grafts
 - Viabahn Se and VBX - Gore
 - Icast - Maquet
 - Life Stent and Fluency - Baird

Chimney Endograft Technical Details

- 3-4 vessel access – bilateral femoral arteries and left axillary artery. Right axillary artery is needed in extreme cases.
- Needle puncture 120 degrees apart.
 - Axillary Artery can handle 3 – 7F sheaths.
 - We need smaller profile devices
- Consider periscopes from below and chimneys above.
- Use stent graft cuff or thoracic stent graft for proximal.
 - Suprarenal uncovered stents make it challenging for keeping chimneys straight
- Reduce fluro frames to cut down on radiation.
- Lombado sandwich technique useful for type 3 TAA
- The EVAR and chimney grafts need a minimum 2 cm sealing zone, but more is better to cut down on gutter endoleaks.

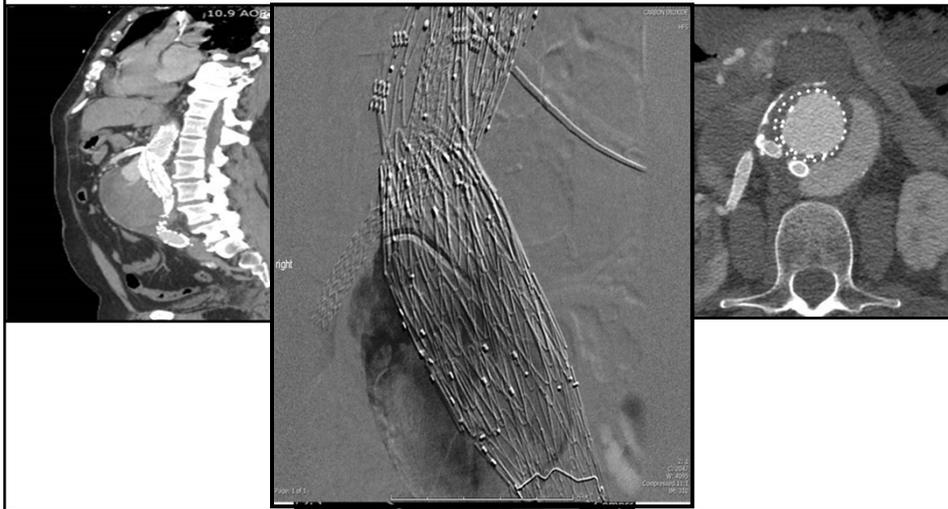
Ruptured Type 4 TAA



4 Vessel Chimney/Periscope



Gutter endoleaks can be real problem if left alone!



PAPERS OF THE 135TH ASA ANNUAL MEETING
Collected World Experience About the Performance of the
Snorkel/Chimney Endovascular Technique in the Treatment of
Complex Aortic Pathologies

The PERICLES Registry

Konstantinos P. Donas, MD, Jason T. Lee, MD,† Mario Lachat, MD,‡ Giovanni Torsello, MD, PhD, § and Frank J. Veith, MD,¶ on behalf of the PERICLES investigators*

- **Results *Ann Surg* 2015;262(3):546-53.**
 - Registry from 13 centers in US and Europe
 - 517 patients, 898 vessels
 - 8.1% - intraop type 1 endoleak, most resolved.
 - 0.6% late type 1 endoleak
 - 30 day mortality 4.9% (3.7% elective 22% rupture)
 - 3 year survival 75%
 - Early 94% primary patency
 - Cases done in high volume centers with clinical experts.

Real World Results

Real World Parallel Graft Midterm Results

- **De Beaufort et al. J Vasc Surg 2017**
 - **33 patients, 54 Chimneys**
 - **Type 1 endoleak rate was 6.1%, total 9%**
 - **Early chimney stent occlusion 6.1%**
 - **Late chimney stent occlusion 12%**
 - **Early mortality 6.1%**
 - **Two year survival 78%**

It Isn't a Poor Carpenter Who Blames His Tools

