# 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.





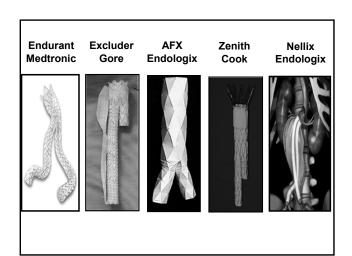
### Juan Parodi, M.D. - EVAR

- 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.

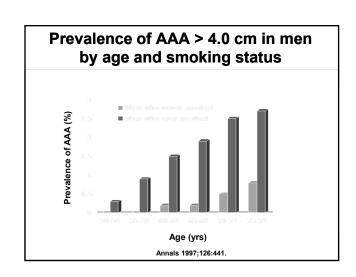


# **AAA** risk factors

- 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		



# **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 nondiseased 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**

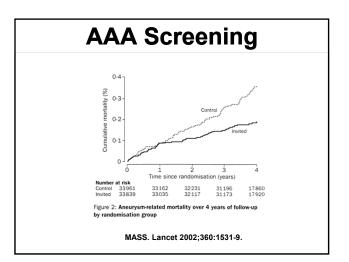
- Intervention: Half (33,839) were invited for ultrasound (US) screening. US results were sent to family physicians
- Primary Outcome: Death from AAA
- Secondary outcome: all-cause mortality, ruptured AAA, and quality of life

# **AAA** Screening

- < 3.0 cm: not rescanned</li>
- 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**

- 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 onetime 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

# **EVARI**

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

- 1082 patients with AAA pts randomly assigned to surgery vs open repair.
- 30 day day mortality 1.7% EVAR and 4.7% open repair (p<.001).</li>
- · 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).</li>
- Complication 4% EVAR and 9% open. (p<.001).</li>
- At <u>4 years</u>, 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 répair, 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 <u>not</u> 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 <u>no</u> difference in all cause mortality between the groups.
- No benefit for EVAR found during follow up for any age.

### **OVER Trial**

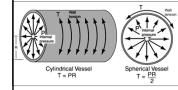
JAMA, October 14, 2009—Vol 302, No. 14 1535-42. N Engl J Med 2012:367:1988-97.

- 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 openrepair 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

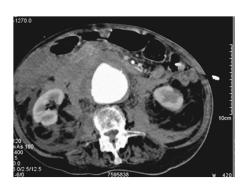


For a given vessel radius and internal pressure, a spherical vessel will have half the wall tension of a cylindrical vessel.

# 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 (3<sup>rd</sup> 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

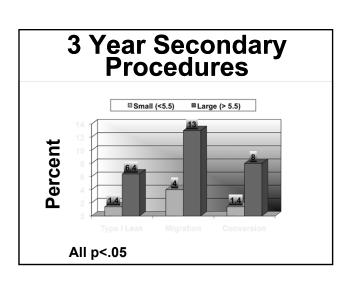
- · The open vs. observation trials (UK-SAT and ADAM) demonstrated <u>similarity or</u> <u>superiority</u> of surveillance compared to early repair.
- These findings were documented despite a perioperative mortality rate\* of 5.4% in UK-SAT and 2.1% in ADAM.
  - CCF data has mortality rates of < 1.8%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

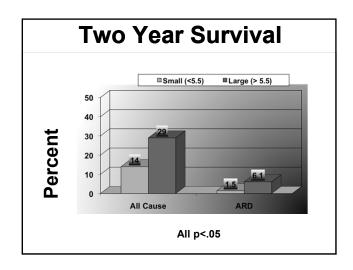
# Logic Behind Endovascular AAA Repair for 4 - 5.5 cm Aneurysms

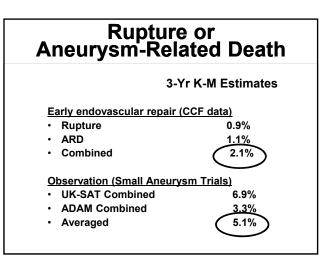
- If a procedure could be performed with a lower peri-operative mortality rate, that procedure might be able to "beat" surveillance in patients with smaller AAA.
- Results of EVAR trial of endovascular vs. open surgery in larger aneurysms: 30 d mortality significantly lower with endo repair (1.9 vs.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

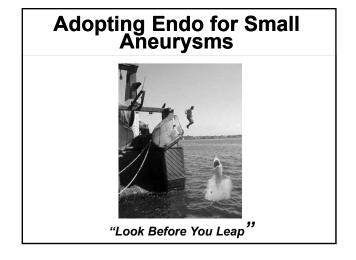
# **Cleveland Clinic Study:**Endo Repair Performs Best in Smaller AAA

- 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

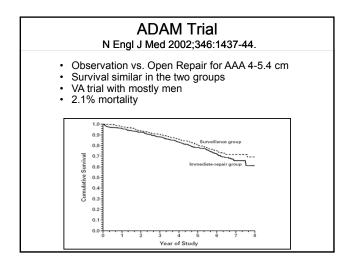


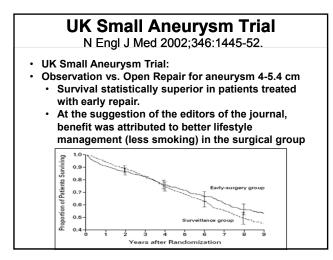


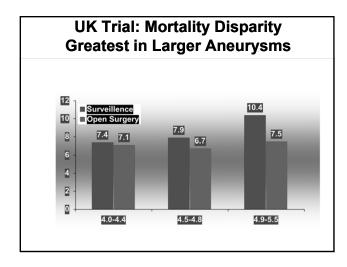


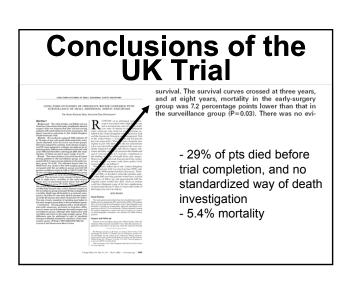


Level One Data Two Studies: 4 - 5.5 cm AAA









## Will Observed Patients Undergo Repair Anyway? 70% - Both the UK (top) and ADAM (bottom) trials documented the need for eventual repair in approximately <u>70%</u> of patients initially managed with surveillance 70%\_\_\_ - 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

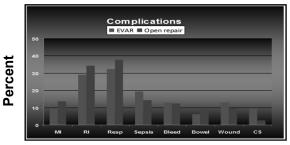




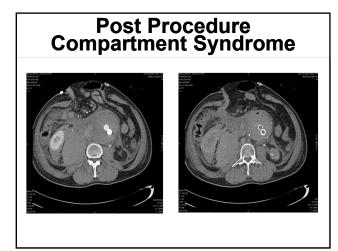
Fast deployment and inflation of a balloon.

### Postoperative data

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

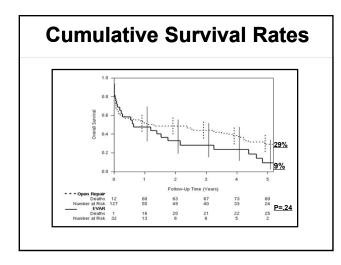


- Mortality similar between open and end (30%)
- There was no difference in complications between EVAR and open repair.
- · ICU stay: 6 days; hospital stay: 12 days



# **Mortality Rates**

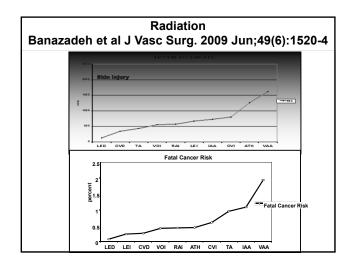
	Overall	EVAR	Open repair	p.
Intraoperative	5.6 %	0	7 %	.03
30 day/in- hospital	31.9 %	32 %	31.2 %	.93



### **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.

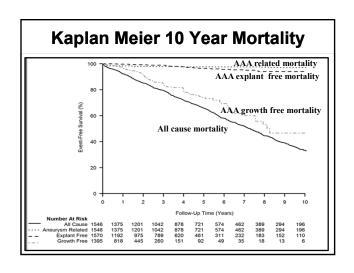


# Long Term Outcomes Beyond 5 Years

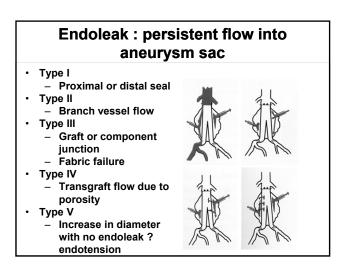
- Our interest in this study came from curiosity in what happened to the patients who had endografts beyond 5 years.
- We retrospectively reviewed our results of patients undergoing <u>non trial</u> EVAR between 1999 and 2011. During this time 1570 non trial EVARs were performed.
- Various outcome measures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

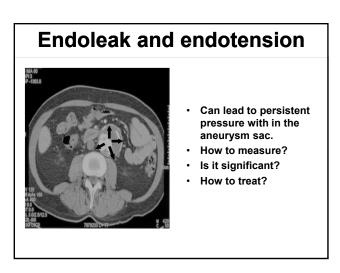
### Overall Long Term Outcomes Beyond 5 Years

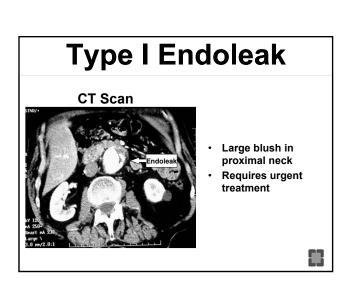
- 9.4% sac growth , 56.7% sac shrinkage, 33.9% no change (90.6)
- Known AAA Rupture = 0.7%
- Graft migration 4.6%
- Limb Disunion 3.6%
- Limb Occlusion 3.6%
- Conversion to open repair 2.3%
- Overall endoleak 26.1%
- Secondary intervention Rates 17.1%
- All cause mortality 53.9%, but aneurysm related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



# Endoleaks THE CLEVELAND CLINIC ROUNDARION IN

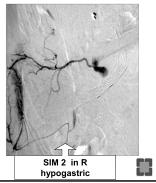






# Type II endoleak

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



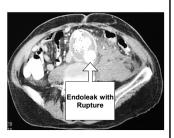
# **IMA Endoleak**

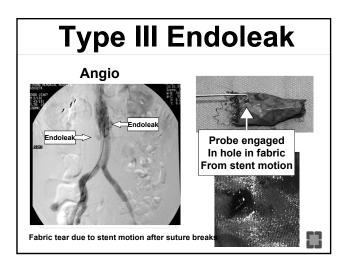


- •5F sheath placed into SMA
- •Catheter engaged into middle colic artery (right).
- •Microcatheter advanced over a 0.018" or 0.014"into the IMA
- •Glue injected into AAA sac and orifice of IMA
- •Completion angiogram demonstrating stagnant flow

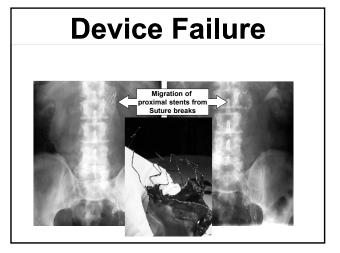
# Type III endoleak

Component Separation





# 

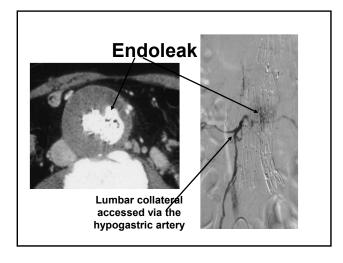


# Which endoleaks should be fixed and when?

- 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

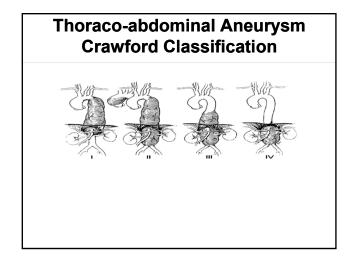
### **Endoleaks - When Do We Treat?**

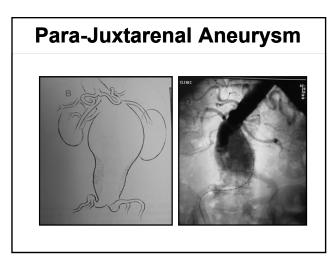
- Treatment is initiated when there is a perceived risk of rupture
  - type I leaks
  - type III leaks
  - persistently pulsatile aneurysm
- · How do we treat them?
- When do we intervene for limb migration?



# **New Directions**

- Smaller Devices
- More Durable Devices
- · "Radiation Friendly"



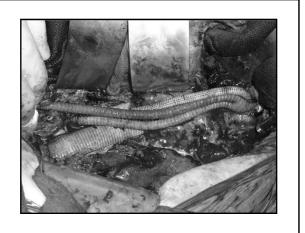


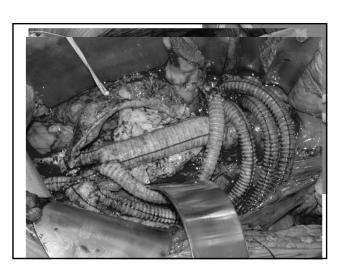
# The Issues

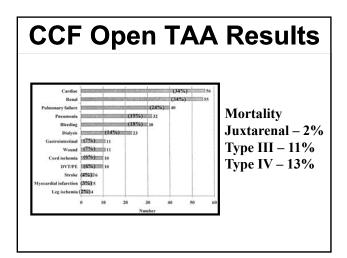
- Type 2 and 3 TAAs
  - The real issue is visceral ischemia and cardiopulmonary sequelae of a high clamp
  - "Organs do not do well without blood flow"
     Bruce Lytle, MD
- · Juxtarenal, Suprarenal, and Type 4 AA
  - The issue is less visceral ischemia, but still highly invasive.
- For minimally invasive 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-
  - SVS guidelines recommend carotidsubclavian bypass if the subclavian artery is covered during TEVAR.

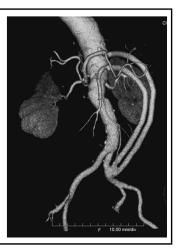






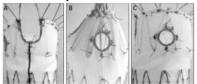
# **Extra-Anatomic Bypass Options**

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



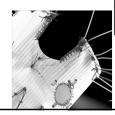
# Fenestrated and Branched Endografts

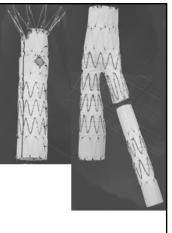
- · First venture into proximal neck issues
- Initial procedures in high-risk individuals with poor standard risk options
- · Still a patient-specific approach
- Utilizes base Cook Zenith device femestrated holes and scallops

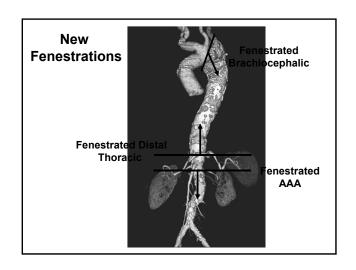


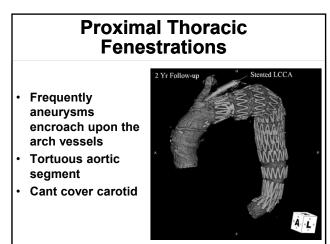
# Fenestrated AAA Device

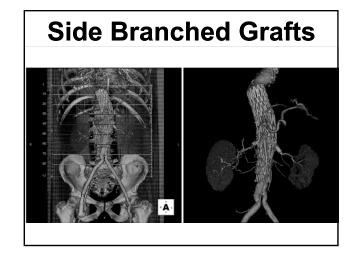
- Modular components
  - 2-piece → 3-piece evolution
    - Proximal tube, bifurcation body, and iliac

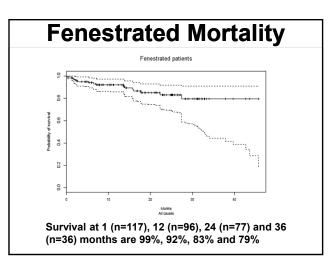


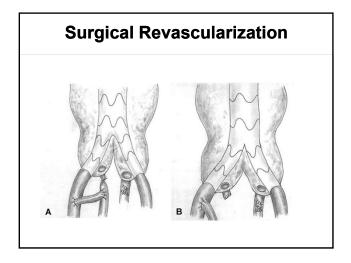


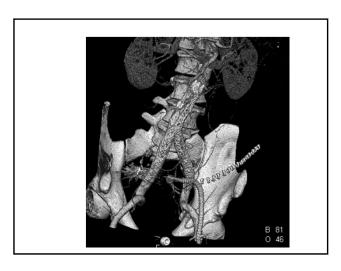






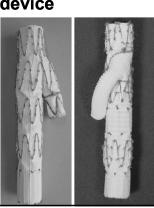


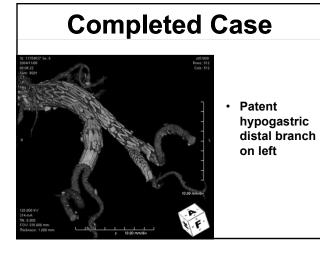


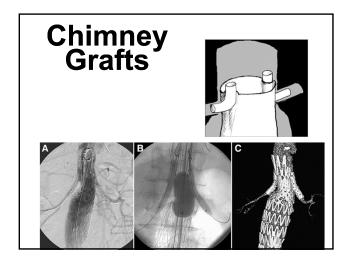




- Several designs
  - Mini-bifurcated device
  - 45° angle
  - Helical Branch







# 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
- 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 <u>"off the shelf"</u> 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
  - 8 centers did 88% of the cases
  - Type 1 endoleak rate 1.5%
  - No rupture or conversions reported with a with 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

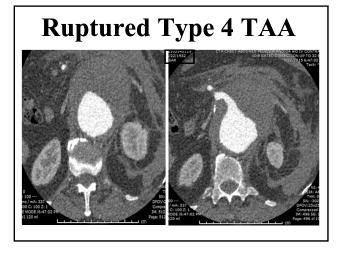
	FEVAR %	Open Surgery %	P Value
30 Day Mortality	9.5	2	.05
Any Complication	41	23	.01
Procedure Complication	21	7	.01
Graft Complication	30	2	.01

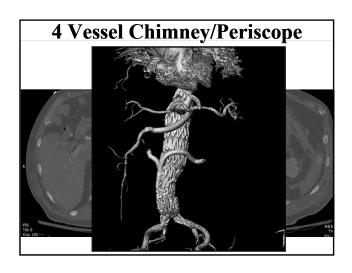
### Parallel Chimney and Periscope Grafts What We Know

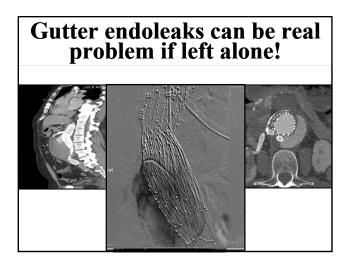
- Evolved out of need for immediate endovascular solutions to treat peri-visceral aortic aneurysms. First reported by Roy Greenberg, first case
- actually done by Dan Clair.
- The have high type 1 endoleak rates and requires multiple access points.
- For urgent use, you need a full compliment of stent 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 Streat 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.







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**

