

Fenestrated Endovascular Graft Repair of Abdominal Aortic Aneurysms

Matthew J. Sideman, M.D.

Vascular Surgeon, University of Texas Health
Science Center (UTHSCSA)

San Antonio, Texas

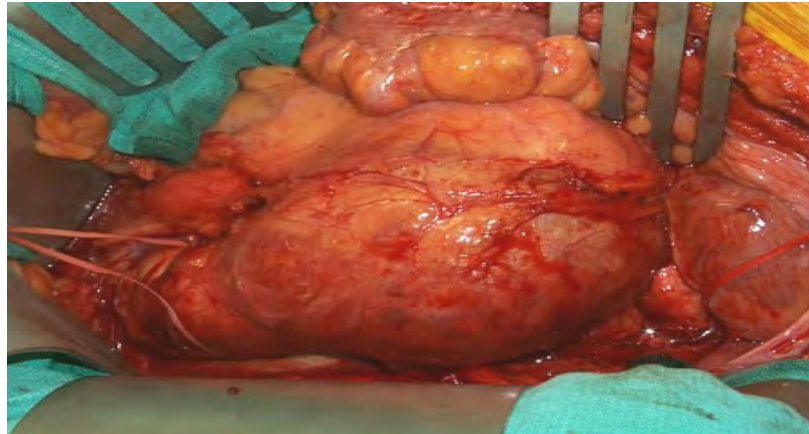
RUC Advisor for SVS

Vice-Chair of the SVS Health Policy Committee

Disclosure

- The Society for Vascular Surgery (SVS) has paid for my travel expenses to present at this meeting.

Aortic Aneurysms



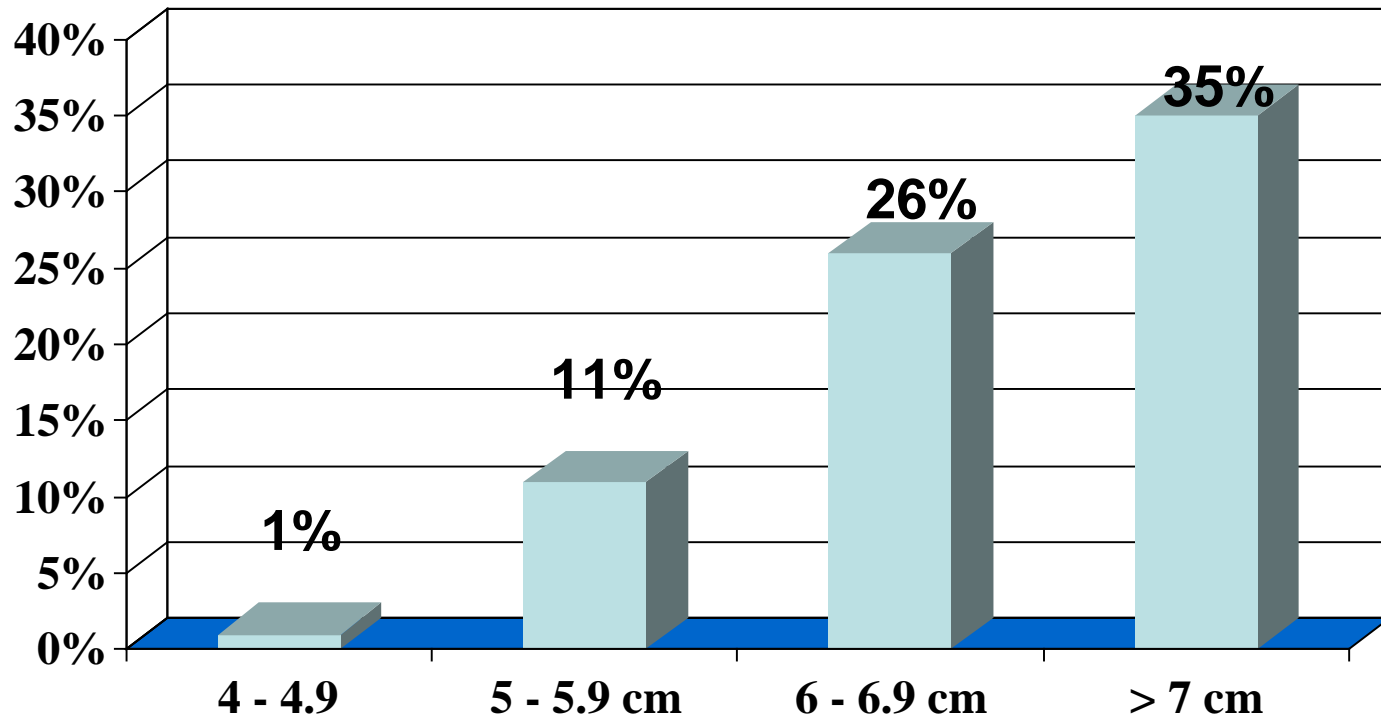
- Aneurysm: a circumscribed dilation of an artery, greater than 1.5x its normal diameter
- Ruptured aortic aneurysms (mostly abdominal) estimated to cause over 15,000 deaths each year in U.S.
- Etiology is multi-factorial. Risk factors include age, smoking, gender (males), high blood pressure, family history, and certain connective tissue disorders

Abdominal Aortic Aneurysm

- AAA is a prevalent disease
 - Men >65yo: 6% (95% CI 5 – 6)
 - Women >65yo: 1% (95% CI 1 – 2)
- The rationale for surgical intervention is to avoid the risk of spontaneous rupture and death

Lindholt JS et al. BMJ 2005
Ashton HA et al. Lancet 2002
Norman PE et al BMJ 2004
Scott RA et al. EJVES 2001

AAA: Yearly Risk of Rupture



Hallett et al (Mayo Clinic) 1989, 1997

Indications for Treatment

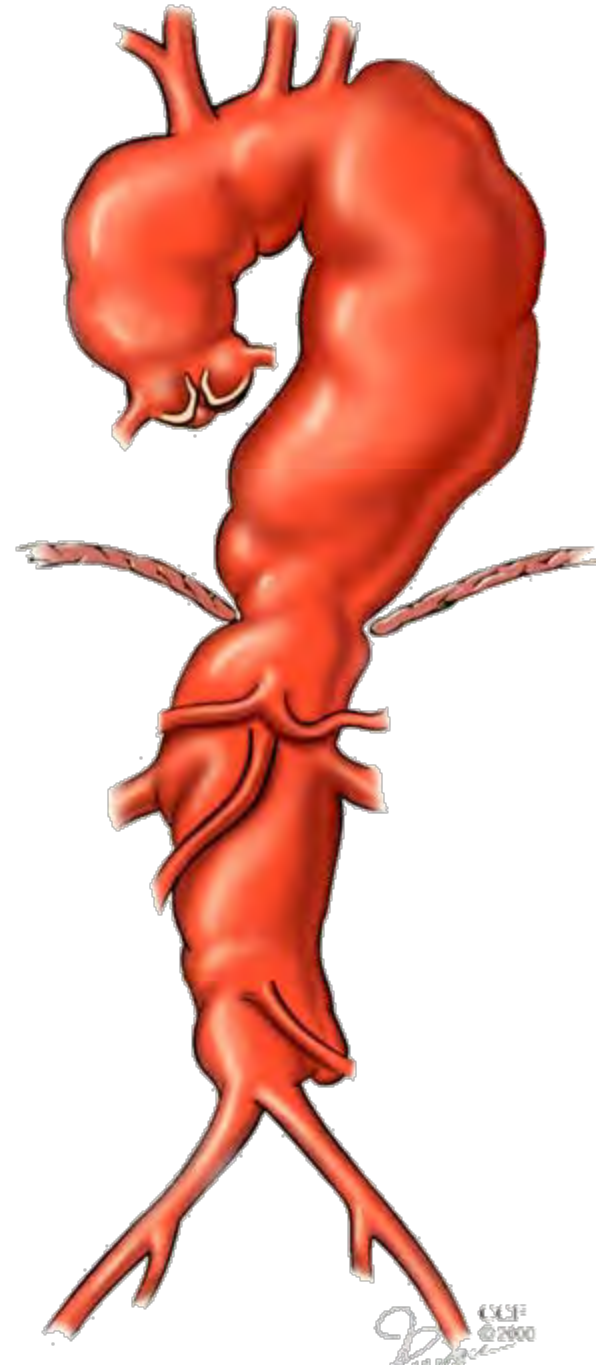
- The primary objective in the treatment of aneurysms is to prevent death from rupture
 - The probability of rupture correlates with the size of the aneurysm at the initial diagnostic exam
 - The larger they grow, the greater the chance for rupture
- Indications for treatment include:
 - Aneurysm > 5 to 5.5 cm (AAA) or > 5 to 6 cm (Thoracic)
 - Rapidly growing aneurysms
 - Symptomatic and/or ruptured aneurysms

Aortic Aneurysm Types

Thoracic Aorta ↗ ascending
 → arch
 ↘ descending

Thoraco-abdominal

Abdominal Aorta ↗ suprarenal
 → juxtarenal
 ↘ infrarenal



Treatment Options and ICD-9 Codes

Thoracic Aortic Aneurysm	Abdominal Aortic Aneurysm	Thoraco-abdominal Aortic Aneurysm
Open repair (38.45)	Open repair (38.44)	Open repair (38.45 + 38.44)
“Standard” endovascular repair (39.73)	“Standard” endovascular repair (39.71)	“Standard” endovascular (39.71 + 39.73?)
Fenestrated/branched endovascular repair (39.78)	Fenestrated/branched endovascular repair (39.78)	Fenestrated/branched endovascular repair (39.78)

38.44 Resection of vessel with replacement; abdominal aorta

38.45 Resection of vessel with replacement; thoracic vessel

39.71 Endovascular implantation of graft in abdominal aorta

39.73 Endovascular implantation of graft in thoracic aorta

39.78 Endovascular implantation of branching or fenestrated graft(s) in aorta

Treatment Options and ICD-10 Codes

Thoracic Aortic Aneurysm	Abdominal Aortic Aneurysm	Thoraco-abdominal Aortic Aneurysm
Open repair (02VW0DZ)	Open repair (04V03DZ)	Open repair (02VW0DZ + 04V03DZ)
Standard or Fenestrated/branched endovascular repair (02VW3DZ)	Standard or Fenestrated/branched endovascular repair (04V00DZ)	Standard or Fenestrated/branched endovascular (02VW3DZ + 04V00DZ)

02VW0DZ – Restriction of Thoracic Aorta with Intraluminal Device, Open Approach

02VW3DZ – Restriction of Thoracic Aorta with Intraluminal Device, Percutaneous Approach

04V03DZ – Restriction of Abdominal Aorta with Intraluminal Device, Open Approach

04V00DZ – Restriction of Abdominal Aorta with Intraluminal Device, Percutaneous Approach

AAA Treatment Options

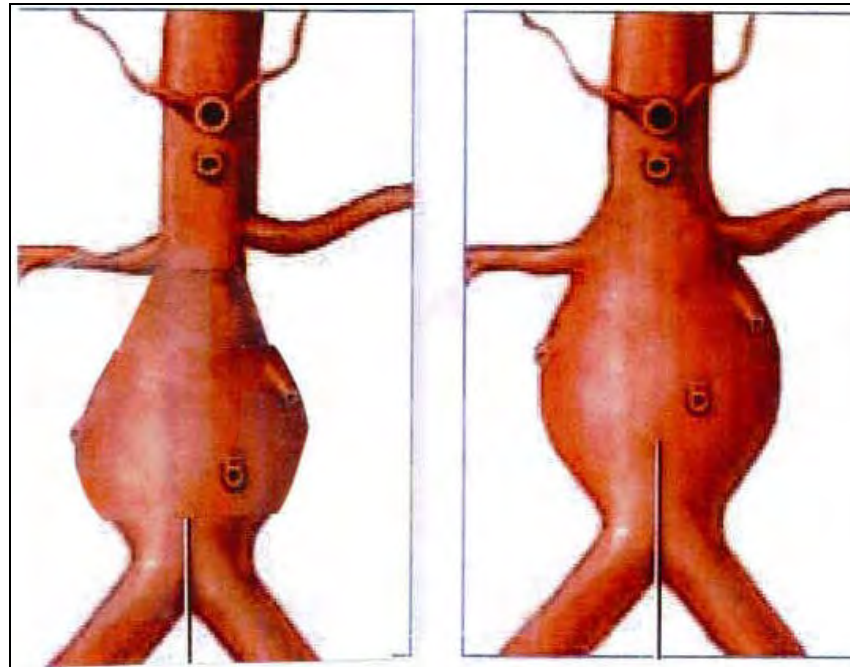
- Open surgical repair is the historical gold standard
- Endovascular aortic repair (EVAR) became available in the late 1990s (first device commercially available in U.S. in 1999)
- EVAR has become the much more common treatment option in the traditional Medicare population
- ICD-9 procedure code “39.71 Repair, endovascular graft implantation, aneurysm, abdominal aorta”

AAA Treatment Options (cont.)

- “Fenestrated” and/or “branched” endovascular repair procedures have developed for aortic aneurysm patients with certain anatomic limitations
- These procedures recognized by ICD-9 with creation of procedure code “39.78 Endovascular implantation of branching or fenestrated graft(s) in aorta” in FY2012 (the descriptor for “standard” repairs was modified to “endovascular implantation of other graft in abdominal aorta”)
- In 2013, nearly 2400 Medicare beneficiaries underwent procedure 39.78 (approximately 10% of total endovascular AAA repairs)

Infrarenal (IR) vs. Juxtarenal (JR) Aneurysms

- By definition, these two types of AAA differ anatomically
- These two types of aneurysms also differ pathophysiologically



Infrarenal (IR) vs. Juxtarenal (JR) Aneurysms (cont.)

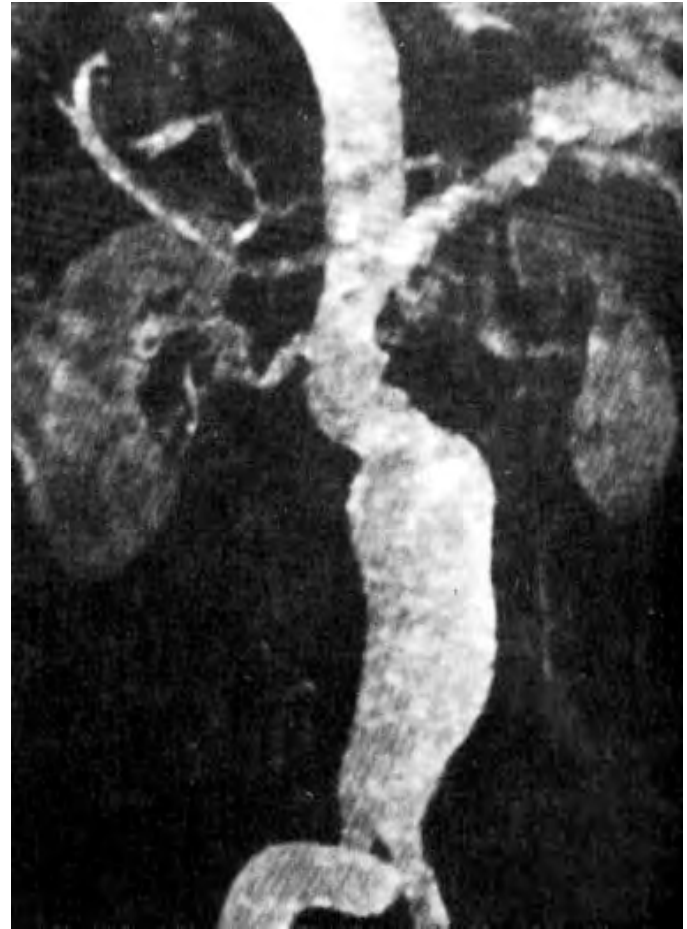
- Open surgical repair of JR aneurysms also differs from IR: surgery is more complicated; patients experience higher morbidity and mortality
- Endovascular repair had historically *not* been an option for treating JR aneurysms
- Through the development of “fenestrated” and/or “branched” endovascular stent-grafts, endovascular procedures have become an option for treating JR aneurysms

Standard EVAR: Procedural Description

- Bilateral femoral artery cutdowns to obtain femoral artery access
- Bilateral catheterization of aorta
- Endovascular (catheter-based) deployment of stent-graft components to exclude the aneurysm
- Components – typically two or three – are deployed under fluoroscopic guidance
- Cutdowns closed

EVAR Anatomical Requirements

- EVAR has specific anatomic requirements
 - Appropriate femoral/iliac arteries to access aorta with endovascular device
 - Limited angulation of the aneurysm and adjacent aorta
 - Adequate/appropriate infrarenal neck diameter and morphology
 - ADEQUATE INFRARENAL NECK LENGTH

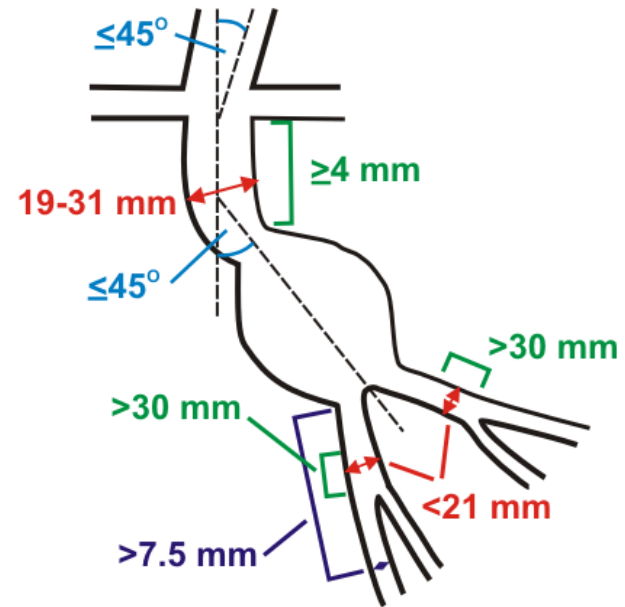


Standard EVAR Limitations

- Standard EVAR requires infrarenal neck length ≥ 10 to 15 mm
- 10 to 50% of AAAs do NOT have adequate neck length for standard EVAR
- Surgical repair of these juxtarenal/pararenal AAAs poses higher risks
- This same patient subset also has higher incidence of co-morbidities, further arguing against open surgical repair

Fenestrated Endograft Repair of AAAs

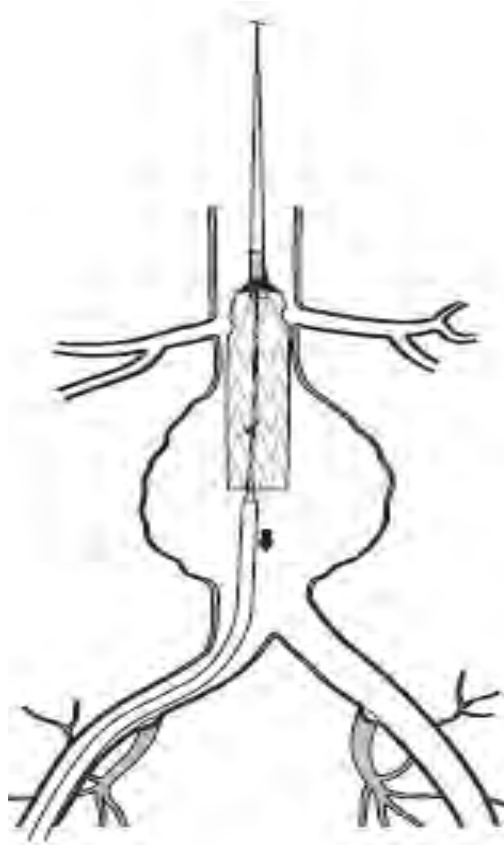
- A new device design results in a new procedure
- Allows treatment of shorter infrarenal necks
- Maintains flow to aortic branches/visceral vessels



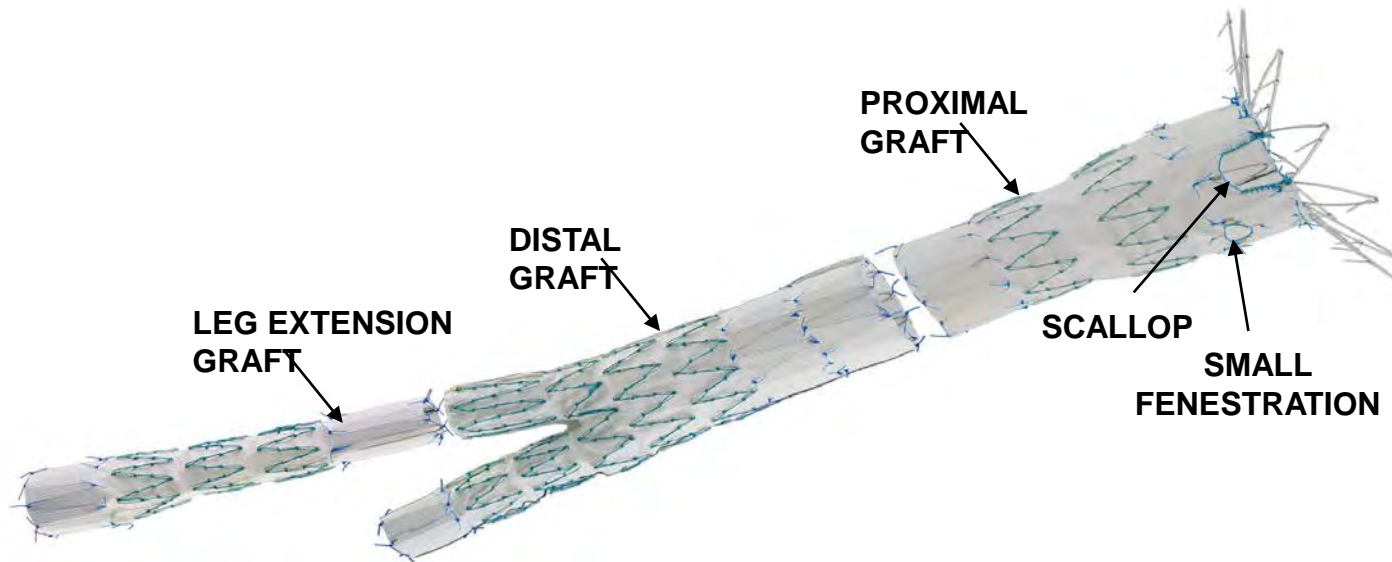
Fenestrated Device Description

- Customized for each individual patient's anatomy
- Utilizes holes (“fenestrations”) and/or scallops to maintain flow to branch vessels such as renal arteries and superior mesenteric artery
- Procedure typically requires placement of covered metal stents through fenestrations into branch vessels

Fenestrated Device Description (cont.)



Procedural Description

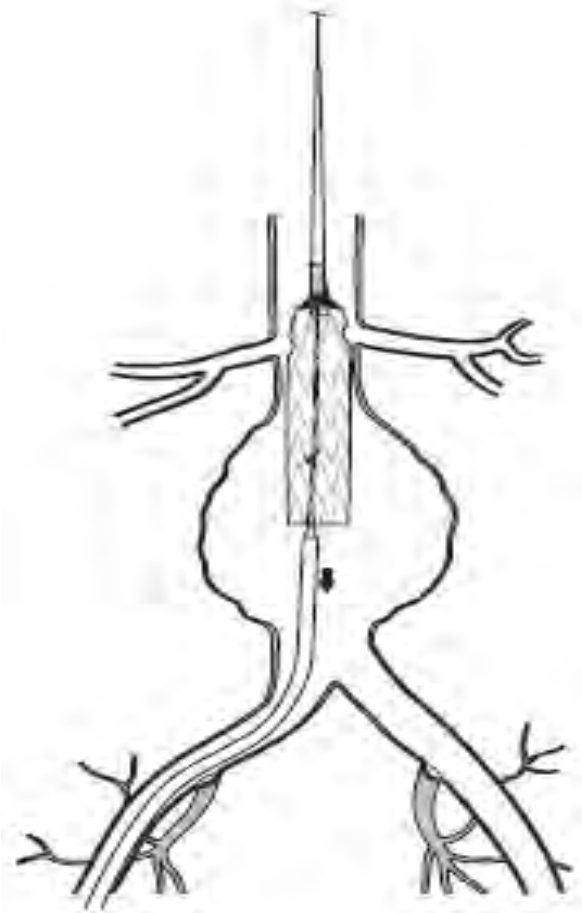


- Performed in operating room or dedicated endovascular suite
- Femoral artery cutdowns (typically) to obtain vascular access
- Bilateral catheterization of aorta

Both of these steps similar/identical to standard EVAR repair

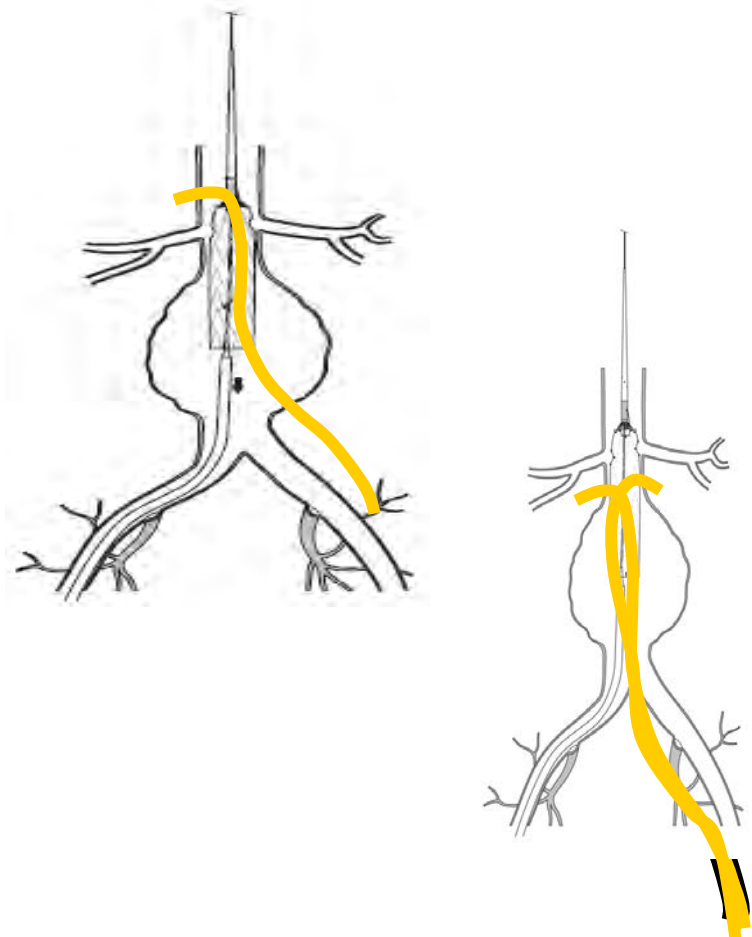
Procedural Description (2)

- Deployment of fenestrated/scalloped main body component
- Differs significantly from standard EVAR procedure
- Requires precise alignment of fenestrations and scallops with ostia of branch vessels



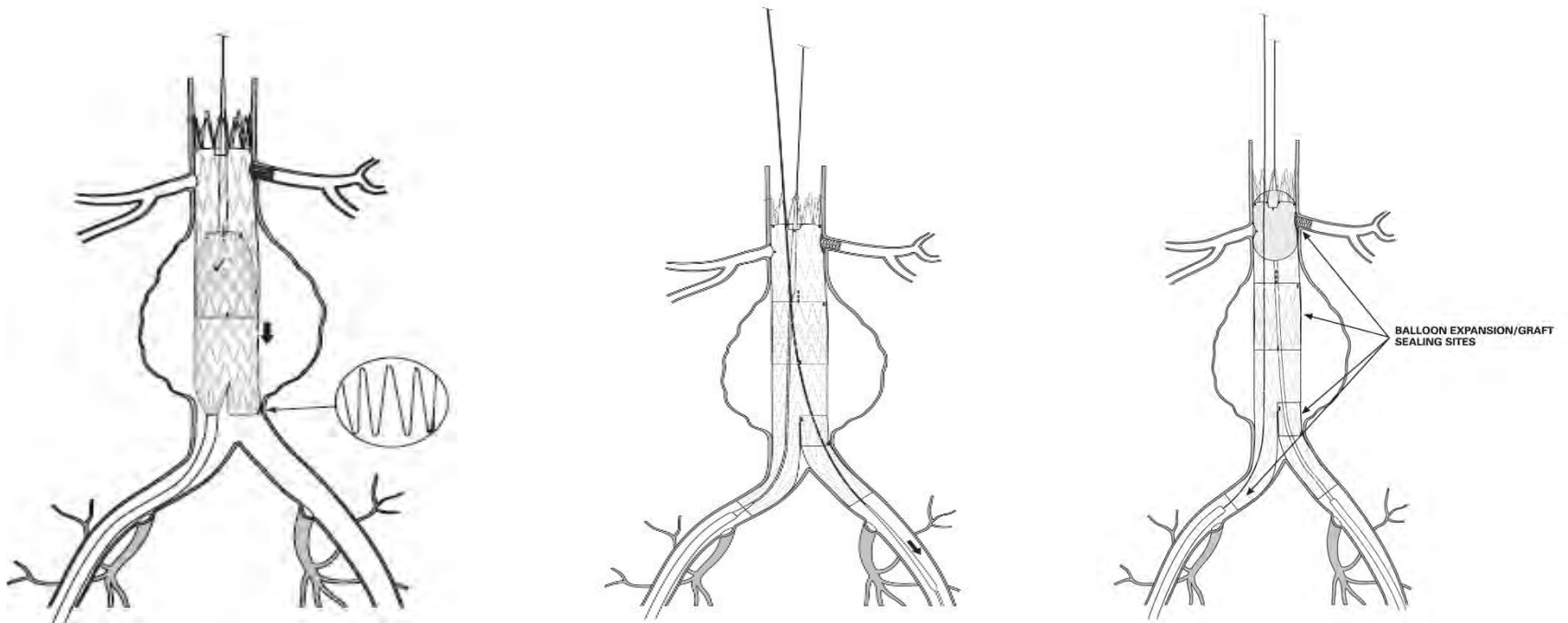
Procedural Description (3)

- Catheterization of branch vessels required
- Not a typical requirement for standard EVAR
- Following main body deployment, covered stents are often placed in branch vessels (most commonly renal arteries)



Procedural Description (4)

- Additional components and limbs added
- Overlapped stents and sealing sites ballooned as needed
- These steps similar to standard EVAR



Fenestrated vs. Standard EVAR

	Standard EVAR ^a	Fenestrated Procedure ^b
Procedural Time	153.2 +/- 56.3 min	227 +/- 76 min (48% increase)
Fluoroscopic Time	29.5 +/- 25.5 min	56 +/- 22 min (90% increase)
X-ray Contrast Required	162 +/- 7 ml	179 +/- 53 ml (10% increase)

^a Reported in Cook Zenith AAA Endovascular Grant pivotal study to obtain FDA approval

^b Reported by O'Neill, et al in 119-patient series at the Cleveland Clinic (largest published series on Fenestrated AAA procedures to date)

Alternative Device Options

- Commercially available fenestrated device
(Cook Medical Zenith Fenestrated AAA
Endovascular Graft)
- Physician-modified devices
- Investigational devices

Summary

- AAAs are major cause of morbidity and mortality in the Medicare population
- Endovascular repair (EVAR) has become the predominant treatment option for AAA
- A significant number of patients with juxtarenal aortic aneurysms are not candidates for standard EVAR due to anatomical limitations

Summary (2)

- Fenestrated endovascular repair offers a treatment option for patients with short infrarenal necks
- Endovascular repair with a fenestrated device is distinctly different from standard EVAR
 - Patients often sicker
 - Procedure significantly more complicated: longer procedural time, more and more complex device components required, more resources utilized

Summary (3)

- A unique ICD-9 procedure was developed and implemented on October 1, 2011 for the Fenestrated/Branched Endograft Repair of Abdominal Aortic Aneurysms
- ICD-10 does not currently distinguish between “standard” and “fenestrated/branched” endovascular repairs

Summary (4)

- For administrative and clinical research purposes, it is important that ICD-10 contain unique coding to uniquely identify these procedures
- It is important that this coding update be concurrent with the switch from ICD-9 to ICD-10, and not delayed until October 1, 2016