

ISET 2020

Hollywood, FL

January 23, 2020

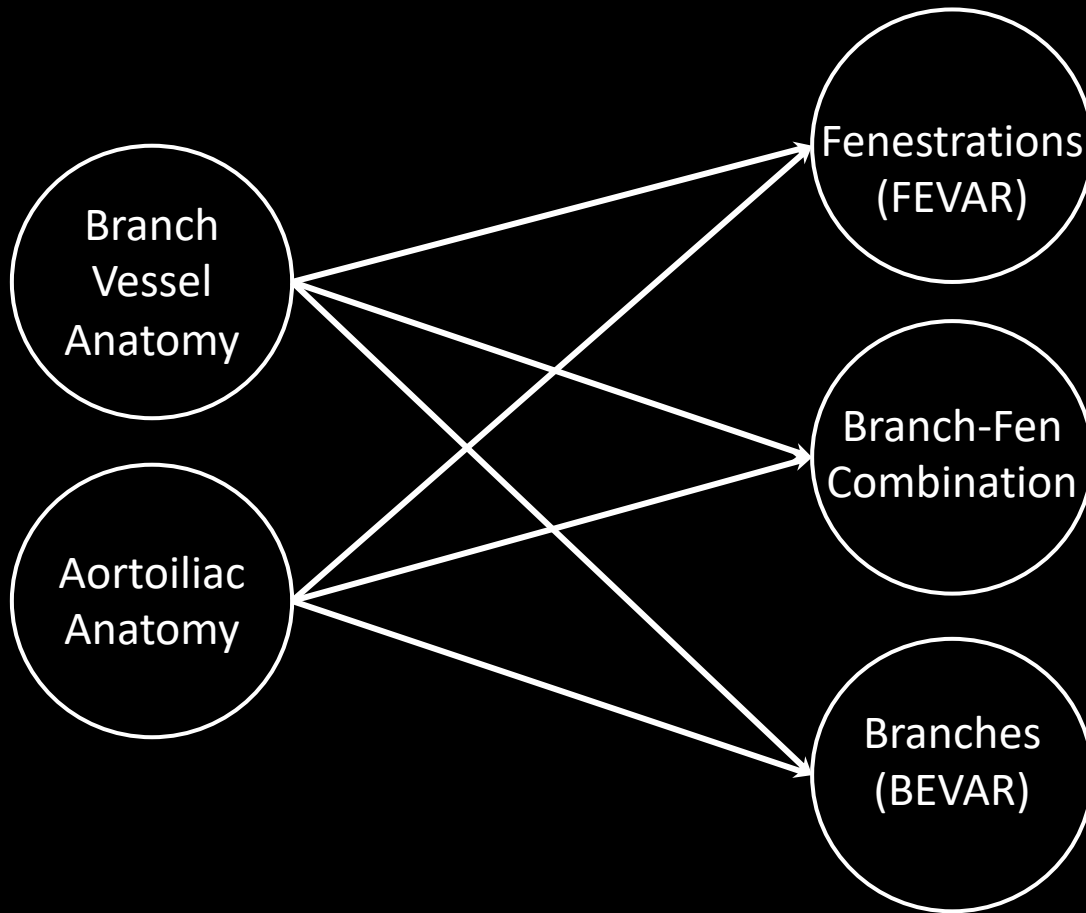
FEVAR IN EVAR: WHAT SHOULD WE EXPECT?

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Disclosure

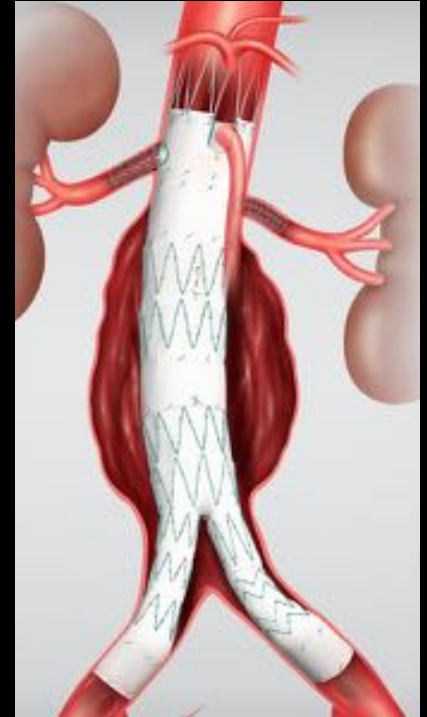
- No financial disclosures pertinent to this presentation

FEVAR \neq BEVAR



Current Status of FEVAR

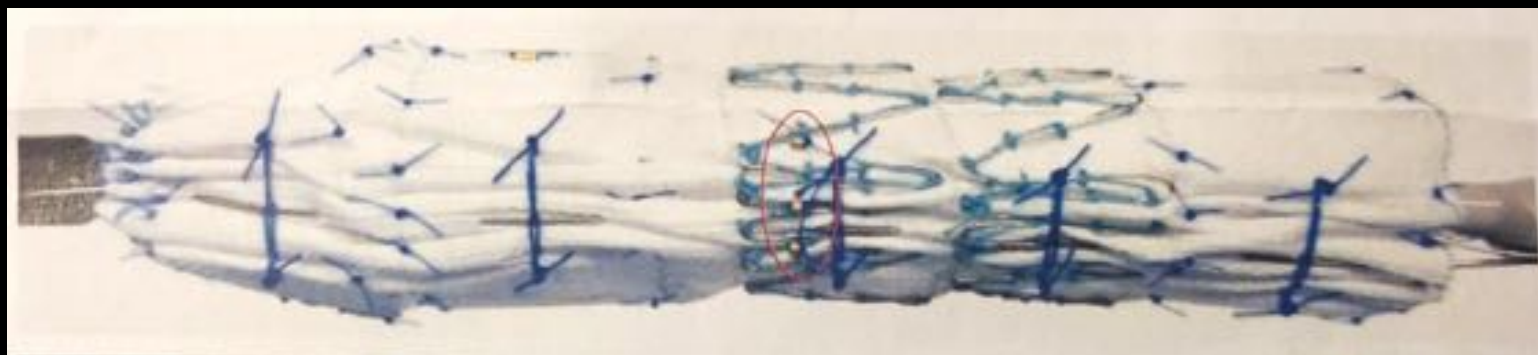
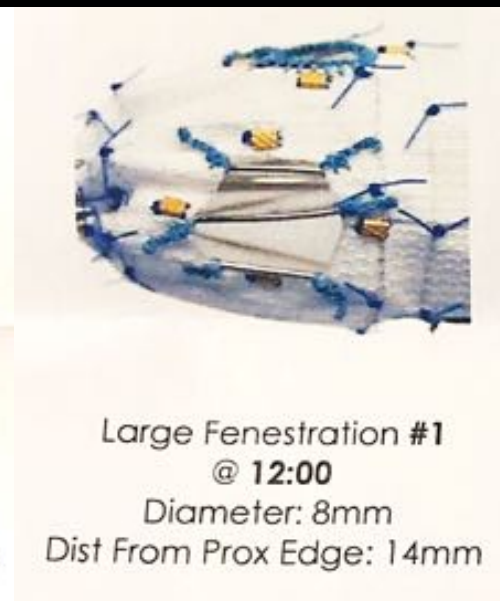
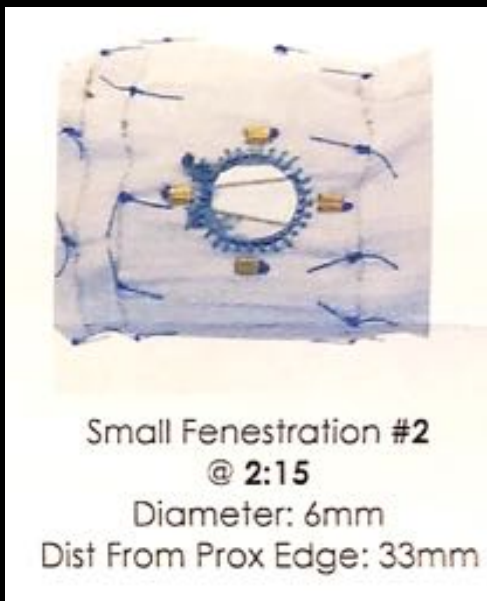
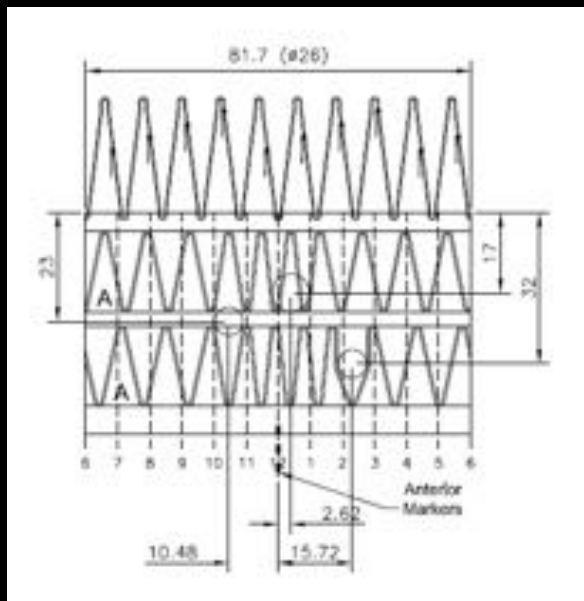
- ◎ US
 - Commercial ZFEN (Cook Medical, Bloomington, IN, FDA-approved April 2012)
 - PMEG
- ◎ OUS: Cook (Zenith CMD), Terumo (Anaconda CMD), Jotec
- ◎ Future (US)
 - pBranch (pivot fenestrations)
 - ZFEN Plus
 - CMD Fen



Current Status of FEVAR in US

- ◎ “True” juxtarenal aneurysms
 - Pararenal neck diameter <32mm
 - Minimum branch vessel separation (axial distance + “clock” position)
 - All non-dispensable renal arteries within “normal” pararenal neck
 - Minimum juxtarenal neck/seal zone (IFU \geq 4mm)
 - Maximum combination of
 - 2 reinforced, strut-free, small (6x6mm, 6x8mm) fenestration(s) +/-
 - 1 un-reinforced, large (8-12mm) fenestration +/-
 - single wide scallop
 - Single, posterior diameter-reducing tie (DRT)

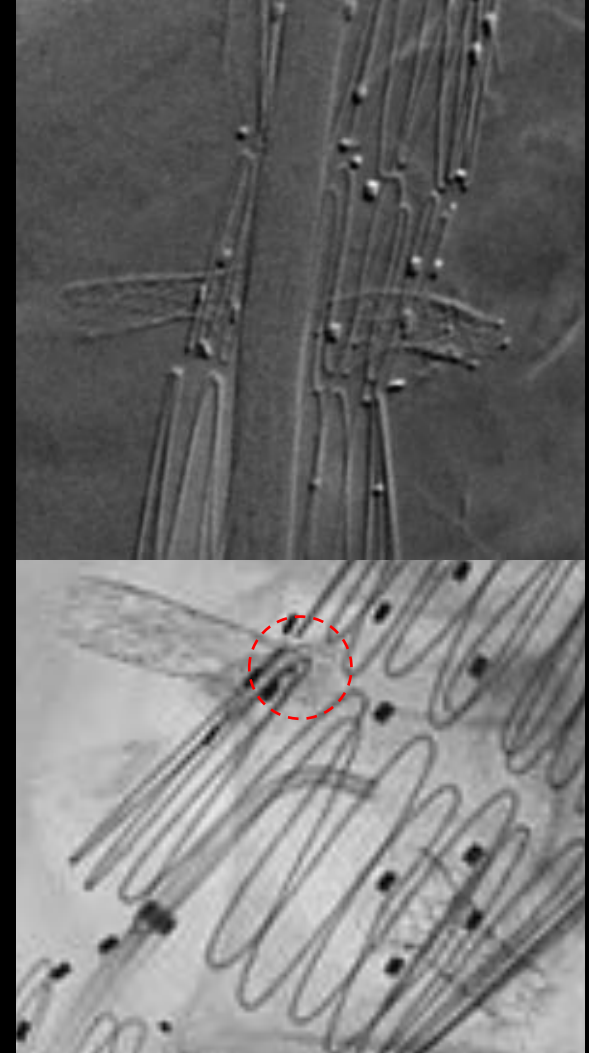
ZFEN (US)



What Does the Future Hold?

DELIVERY SYSTEM

- ◎ Lower-profile (≤ 18 Fr)
 - Higher proportion of women in proximal aortic disease
- ◎ No need for TIP-CAPTURE
- ◎ SINGLE or DOUBLE DRT
- ◎ Choice: POSTERIOR or CONCENTRIC DRT
- ◎ Solutions for unfavorable “wire-bias”
 - SHORT nosecone for distal components
 - Centered/Fixed guidewire
- ◎ Pre-loaded catheter/guidewire delivery system



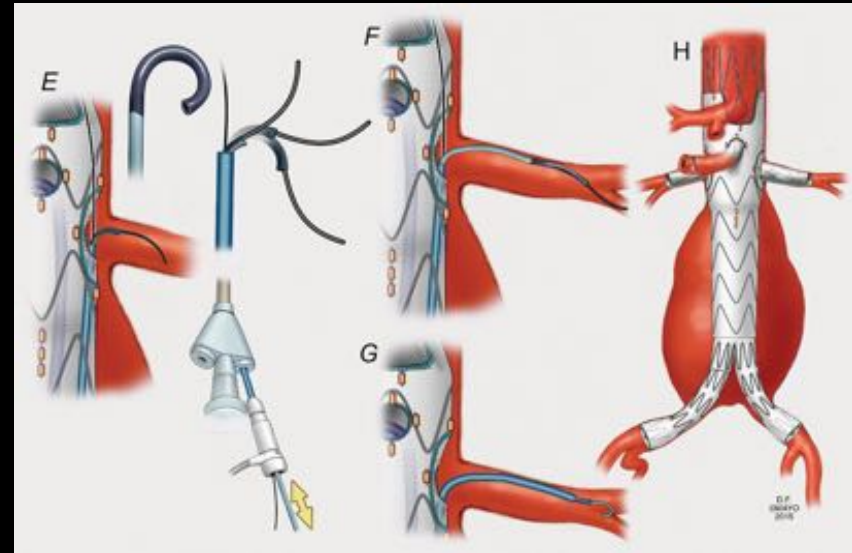
What Does the Future Hold?

ENDOGRAFT

- ◎ Choice: BARE or NON-BARE proximal fixation
- ◎ >3 fenestrations
 - Small or large, reinforced, strut-free
- ◎ Choice: 2-PIECE or 1-piece BIFURCATED aortic component
- ◎ Off-the-shelf, non-CMD device

p-Branch Endovascular Graft

- ◎ Pararenal aneurysm
 - SMA must originate from non-aneurysmal aorta
 - ≥ 4 inframesenteric seal zone
- ◎ Off-the-shelf (2 configurations)
- ◎ 4 fenestrations
 - 1 large scallop (celiac)
 - 1 large, reinforced, strut-free fenestration (SMA)
 - 2 small PIVOT fenestrations (renals)
- ◎ Pre-loaded catheter delivery system



ZFEN Plus (US)*

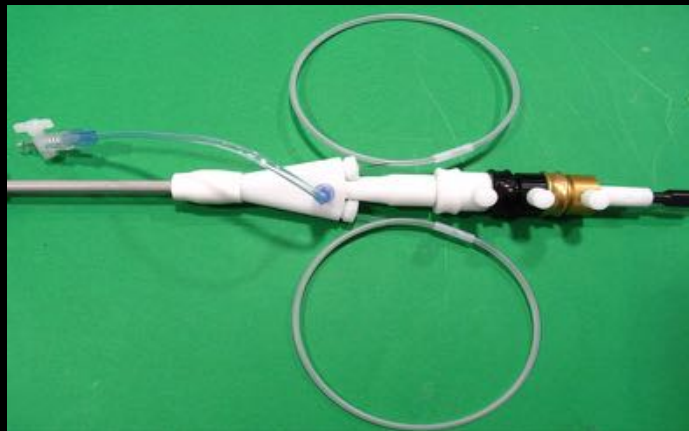
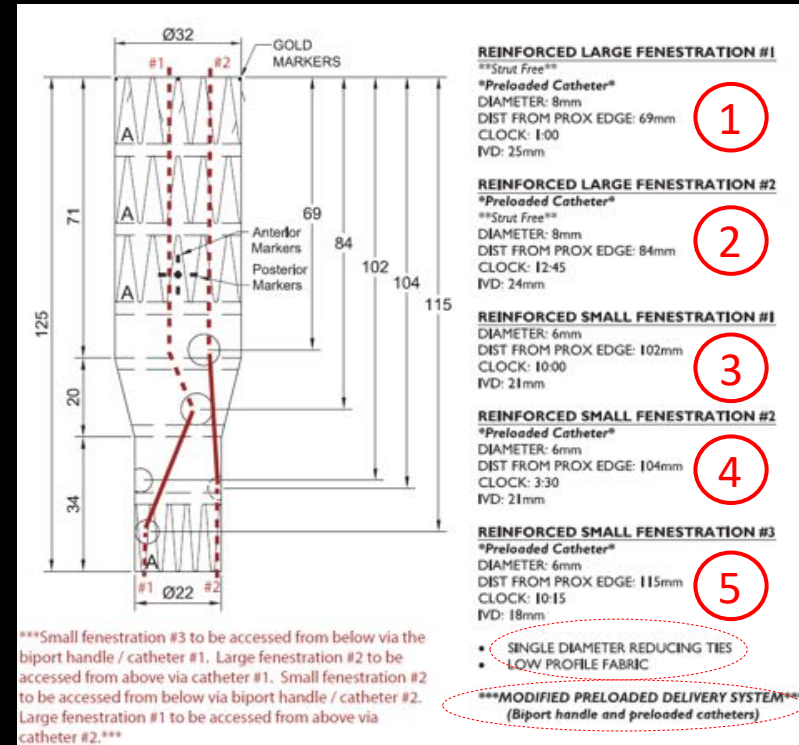
*(subject to change)

- ⦿ Increase proximal seal zone
- ⦿ ≤ 5 fenestration/scallop combination
 - Large (8mm) or small (6mm) fen
 - Single (10mm) or double (20mm) wide scallop
- ⦿ All fenestrations reinforced, strut-free
- ⦿ Optional pre-loaded delivery system
- ⦿ IDE Study initiation 2020



CMD (US-IDE, OUS)

- ⦿ Unlimited fenestrations
 - All reinforced and strut-free
- ⦿ LP fabric
- ⦿ Modified delivery system
 - Pre-loaded catheter/guidewire



What Does the Future Hold?

ANCILLARY COMPONENTS

- ◎ Therapy-specific
- ◎ Steerable/directional sheaths
 - Primary sheath vs. enabling device
 - Shape retention
 - Lower profile
- ◎ Fenestration stents
 - Flexibility + radial force
 - Fracture/fabric tear resistance
 - Pre-proximal flare
 - Improved fenestration seal mechanism

