ZFEN-Advantages and Limitations

And a wish list for ZFEN+

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US Device Overview
- Indication: 4-14mm infra renal
- Stainless steel stents
- Polyester fabric
- Graft diameters: 22-36
- 20-22Fr introduction system

Custom Fenestrations Allow Increased Seal Zone
- Scallop: Scallops along the graft's proximal edge are 10 mm wide and 6, 8, 10 or 12 mm high.
- Small Fenestration: Small fenestrations are 6 mm wide and 6 or 8 mm high.
- Large Fenestration: Large fenestrations are 8, 10 or 12 mm in diameter

ZFEN Creates the Longest Seal Zone

Juxtarenal AAA 2010-current
104 snorkel, 159 ZFEN

Since Sep 2012
Juxtarenal AAA 2010-current
104 snorkel, 159 ZFEN

USA
ZFEN approval

ZFEN Creates the Longest Seal Zone

ACTUAL SEAL ZONE
CREATED SEAL ZONE

Neck Length ≠ Seal Zone
Neck Length = Seal Zone

0 5 10 15 20 25 30 35 40
Trivascular Talent Endurant Flex ZFEN

0 20 40 60 80 100
Snorkel ZFEN

2018

20 40 60 80 100
Snorkel ZFEN
ZFEN Pivotal Data

- Technical success was achieved in all patients
- All 178 visceral vessels were patent at completion angiography

Procedural Results

<table>
<thead>
<tr>
<th>Procedure</th>
<th>n or mean ± SD</th>
<th>% or range</th>
</tr>
</thead>
<tbody>
<tr>
<td>General anesthesia</td>
<td>52 78</td>
<td></td>
</tr>
<tr>
<td>Total percutaneous access</td>
<td>9 13</td>
<td></td>
</tr>
<tr>
<td>Total anesthesia time (min)</td>
<td>298 ± 74 177 - 623</td>
<td></td>
</tr>
<tr>
<td>Total procedure time (min)</td>
<td>236 ± 81 104 - 554</td>
<td></td>
</tr>
<tr>
<td>Device implantation time (min)</td>
<td>164 ± 69 50 - 448</td>
<td></td>
</tr>
<tr>
<td>Estimated blood loss (ml)</td>
<td>526 ± 493 50 - 2400</td>
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- Technical success was achieved in all patients
- All 178 visceral vessels were patent at completion angiography

Early Outcomes (Within 30 Days)

- 30-day mortality: 1.5% (1/67)
- Bowel ischemia (procedure-related)
  - Major adverse events: bowel ischemia in 2 other patients
  - Both had complete resolution after medical treatment
- No conversion, rupture, or renal function deterioration
- Pre-discharge CTA
  - All target arteries patent
    - No type I or II endoleaks
    - 16 patients (28%) had type II endoleaks
  - Mean hospital stay: 3.3 ± 2.1 days (range, 1-14 days)

Late Outcomes

Mean follow-up: 37 ± 17 months (range, 3-65 months)

- 4 late deaths not related to aneurysm
  - 5 late major adverse events not related to aneurysm
  - No late rupture, conversion to open repair, or dialysis
  - No type III endoleak, only 1 case of type I endoleak
  - Renal outcomes
    - Mean hospital stay: 3.3 ± 2.1 days (range, 1-14 days)

Patency of Targeted Renal Arteries

<table>
<thead>
<tr>
<th>Years</th>
<th>Primary Patency (%)</th>
<th>Secondary Patency (%)</th>
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<tbody>
<tr>
<td>1</td>
<td>97 ± 5%</td>
<td>91 ± 5%</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
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<tr>
<td>3</td>
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<td>4</td>
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<td>5</td>
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</table>

Patency measures defined as:
- Primary patency: uninterrupted patency from index procedure until occlusion or reintervention for renal stent stenosis
- Secondary patency: time to occlusion or reintervention for renal stent stenosis

Renal outcomes:
3 patients with renal function deterioration
- 4 renal stent occlusions (3% of targeted renal arteries)
- 12 renal stent stenoses (9% of targeted renal arteries)
- Re-interventions were needed in 15 patients (22%)
- 11 for renal stenosis/occlusion
- 4 for endoleak (2 for type II endoleak; 1 for type I endoleak)

FDA approval 2012- early postmarket outcomes

Postapproval outcomes of juxta renal aortic aneurysms treated with the Zenith fenestrated endovascular graft


Objective: To evaluate data from the 1,295 patients who underwent fenestrated endovascular aneurysm repair (FEVAR) and were enrolled in the post-market study. Patients were stratified into 2 groups based on the number of fenestrations to the iliac arteries: group A (1-2 fenestrations) and group B (3-4 fenestrations). The primary outcome assessed was freedom from device-related complications and secondary outcomes included freedom from repeat endovascular repair and freedom from death. The cohort was also compared with the Zenith thoracic aortic stent graft experience (ZTACS) study. Results: Freedom from device-related complications was 92.6% (95% confidence interval [CI], 91.6-93.8) for group A and 91.4% (95% CI, 90.1-92.6) for group B (p=0.4). Freedom from repeat endovascular repair and death was 89.8% (95% CI, 88.5-91.1) for group A and 89.5% (95% CI, 87.6-91.4) for group B (p=0.5). The ZTACS experience was compared with both groups and found to be similar to group A but worse than group B (p<0.001 for both). Conclusions: FEVAR is associated with excellent outcomes in patients with juxta renal aneurysms. The outcomes are similar to those of the ZTACS experience, with better results in the group with 3-4 fenestrations. FEVAR could be a good alternative to open repair in high-risk patients with juxta renal aneurysms, but further studies are needed to confirm these findings.
Clinical Data

Postapproval outcomes of juxtarenal aortic aneurysms treated with the ZFEN fenestrated endograft.

- First 100 patients since ZFEN approval
- 388ml EBL, 59min fluoro, 98% technical success
- 15% endoleak (60% type 2), 20% reintervention rate, 98% branch patency at 1.7 years

Real World Data

Institutional experience with the Zenith fenestrated endovascular graft.

- First 100 patients since ZFEN approval
- 388ml EBL, 59min fluoro, 98% technical success
- 15% endoleak (60% type 2), 20% reintervention rate, 98% branch patency at 1.7 years

Access limitations - Iliac conduits - need 20F for FEVAR

Renal Cannulation Angles

Impact of Renal Access Angulation on Endograft Efficiency During Fenestrated Aneurysm Repair

Not enough holes? Some design limitations?

71 yo male WITH 9.3 cm AAA
- Double angle with downgoing renal
- SMA at same level as R renal and very close to L renal

SMA/renal distances?

75 yo female 6.6 cm AAA
- Ulcer at juxtarenal neck
- SMA lower than highest renal

Future devices may answer some of the limitations

Wait time/OTS?
renal angulations

Wish list:
smaller access branch stents?

p-Branch Device

- Off-the-shelf
- SMA fenestration and CA scallop
- Renal pivot fenestrations
- Nitinol and stainless steel Cook-Z® stents
- Polyester graft fabric (Zenith Flex)
- Active fixation
- 2 configurations

Conclusions

- ZFEN is a durable, well-performing, custom solution for juxtarenal aaaa's
  - Wait time
  - Angulated necks
  - Some anatomic limitations
- P-branch off the shelf has performed well in feasibility and is over halfway enrolled in pivotal trial
- ZFEN+ is in the works, which will provide additional 4th fenestration
  - Concept of increasing seal zone
Thank you!