STATUE OF ZFEN FEVAR: ADVANTAGES, EFFECT OF OUTSIDE ITS IFU, LIMITATIONS & FUTURE DIRECTIONS

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STATUS OF ZFEN FEVAR: ADVANTAGES, EFFECT OF OUTSIDE ITS IFU, LIMITATIONS & FUTURE DIRECTIONS

NEW YORK, NEW YORK

DISCLOSURE

- Consulting fees (All paid to Mayo)
  - Cook Medical Inc., WL Gore, GE Healthcare

- Research grants (All paid to Mayo)
  - Cook Medical Inc., WL Gore, GE Healthcare

- Off label technique
  - Up and over IBD deployment

ZENITH® FENESTRATED
FDA approval in April 2012

- Infrarenal neck ≥4 mm and <15 mm
- Max 3 fenestrations, 2 of same type

US ZENITH® FENESTRATED TRIAL

- Prospective, non-randomized trial
  - 67 patients
  - Mean FU, 37 months
  - 30-day mortality, 1.5%
  - No rupture, conversion or dialysis
  - 4 renal stent occlusions (3%)
  - 1 late type I endoleak at 3 years (1.5%)
  - 11 patients (16%) had secondary interventions

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FINAL 5-YEAR RESULTS

- Mean follow up 46 ± 22 months
- 95% of eligible patients had imaging:
  - 19.5% type A endoleak, 19.5% type B endoleak, 2 (3%) device migration and 4 (6%) sac enlargement

- 5-year estimates
  - Freedom from all-cause mortality 89 ± 4%
  - Freedom from aneurysm-related mortality 97 ± 4%
  - Primary renal target patency 83 ± 6%
  - Secondary renal target patency 88 ± 2%
  - Freedom from secondary interventions 63 ± 7%

FEVAR DISSEMINATION

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>n</th>
<th>Technical Success</th>
<th>30-day Mortality</th>
<th>Major Events</th>
<th>Reintervention</th>
<th>Follow-up (months)</th>
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<tbody>
<tr>
<td>Wang et al., 2018</td>
<td>100</td>
<td>98%</td>
<td>1.9%</td>
<td>10%</td>
<td>22%</td>
<td>20.8</td>
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<tr>
<td>Vemuri et al., 2014</td>
<td>57</td>
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<td>1.8%</td>
<td>15%</td>
<td>4%</td>
<td>6</td>
</tr>
<tr>
<td>Oderich et al., 2014</td>
<td>67</td>
<td>100%</td>
<td>1.5%</td>
<td>18%</td>
<td>22%</td>
<td>37</td>
</tr>
</tbody>
</table>

Marcelo Ferreira
J. Anderson
Adelaide
Author, Year n Technical Success
30 day mortality Major Events Reintervention Follow-up (mo)
ZFEN ANNUAL DEVICE REQUESTS

8,620 ZFEN endografts ordered since approval!

Year Since Approval

Number of Devices

2012 2013 2014 2015 2016 2017 2018

500 1000 1500 2000

3 Fen 2 Fen + 1 Sc Other

36% 45% 19%

VOLUME OF CASES PER SURGEON

85% perform less than 5 cases/year
Only 1% perform >20 cases/year

Physicians (no.)

Average number of devices/year

≤5 6-10 11-20 >20

CLINICAL APPLICATION OF ZFEN

Maximum of 3 fenestrations

- 4-14mm neck
- 2/3 patients with complex AAAs do not qualify for ZFEN due to insufficient neck length

PHYSICIAN MODIFICATIONS OF ZFEN

Courtesy of Jesse Manunga, Minneapolis MN

PHYSICIAN MODIFICATIONS OF ZFEN

Courtesy of Jesse Manunga, Minneapolis MN
“in the last two years, all ZFENs have been modified to lengthen landing zone…”
CONCLUSION

- ZFEN has expanded the indications for EVAR, but its real applicability (under IFU, without modifications) is limited by design constraints, extent of aortic disease and physician preference to achieve longer sealing zones.
- Upcoming clinical trials (ZFEN+, Thoraco+, TAMBE, etc) will address this issue and further expand indications to patients with suprarenal and TAAAs.