Low Profile Endografts: Current Status

Low Profile Endografts: Current Status

Clinical Professor of Radiology and Surgery
Associate Dean for Clinical Affairs Baptist Health
FEU Herbert Wertheim College of Medicine

Low Profile Devices: Potential Benefits

- Increase number of patients who can benefit from EVAR
- Improved Deliverability:
  - Trackability
  - Pushability
  - Controlability
- Implant compromise:
  - Thinner fabric
  - Durability

Artery on a Stick

Approx. 70% is graft material

What Makes up Profile?

- Stent
- Delivery System
- Graft

Disclosures

- Advisory Boards
  - WL Gore
  - Boston Scientific
  - Medtronic Vascular
  - Philips Healthcare
- Endowed Chair: Cook Medical

Artery on a Stick

Courtesy of Peter Taylor and Rachel Clough, London, UK

What Makes up Profile?

Graft
Delivery System
Stent

Approx. 70% is graft material

Courtesy D. Boekler, MD Heidelberg
Device Profiles

TABLE 1. EXAMPLES OF EVAR DELIVERY DEVICE DIAMETERS

<table>
<thead>
<tr>
<th>Low-Profile EVAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have low-profile endografts modified our practice and outcomes?</td>
</tr>
<tr>
<td>By Rachel E. Clough, MD, PhD; Adrien Hertault, MD; Richard Azzouz, MD; Jonathan Sobocinski, MD, PhD; and Stephan Haulon, MD, PhD</td>
</tr>
<tr>
<td>Low-profile balloon catheters are used to deploy the endograft in the iliac artery.</td>
</tr>
<tr>
<td>Total diameter of 18F indwelling sheath.</td>
</tr>
</tbody>
</table>

The INCRAFT® Stent Graft System

- Modular Tri-Fab system
- Polyester graft fabric
- Electro-polished Nitinol stents
- Active suprarenal fixation barbs
- 12 F Sheath Size

InSitu Length Adjustments

Limbs are flexible with 2-3 cm In-Situ length adjustment that allows accurate distal landing.

Limited Number of Parts (23)

<table>
<thead>
<tr>
<th>Few Fits Most</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 Main Body diameters</td>
</tr>
<tr>
<td>5 Iliac Limb diameters</td>
</tr>
<tr>
<td>22-26-30-34</td>
</tr>
<tr>
<td>10-13-16-20-24</td>
</tr>
<tr>
<td>17-31</td>
</tr>
<tr>
<td>7-22</td>
</tr>
<tr>
<td>OD 14 12</td>
</tr>
</tbody>
</table>

The INSPIRATION Pivotal Study

30 Day Results

- Mortality: 0.5% (1/190)
- Major Adverse Event (MAE): 3.2% (6/190)
- Myocardial Infarction: 0.5% (1/190)
- Renal Failure: 0.0% (0/190)
- Respiratory Failure: 0.0% (0/190)
- Stroke: 0.5% (1/190)
- Bowel Ischemia: 0.0% (0/190)
- Procedural Blood Loss ≥ 1000cc: 2.1% (4/190)

- No Limb occlusions in the first 30 days

INSPIRATION Study:
Primary Safety Endpoint was met
MAE < 20% (3.2%)

US: 4.5% Japan: 0%
Type IV Endoleaks in 16% (31/190)
Do not affect Long Term Outcomes but may require Procedural Troubleshooting (similar to other grafts)

Illustrative case: ES/ 72 Year Old Woman

Possible Vulnerability of Limbs
- Flexible Limbs
- Smaller Overlap Diameter (11 mm)
- Tendency to Use in Disadvantaged Limbs

Overlap Zones and Narrowed Areas Must be Ballooned

Summary and Conclusions
- The INCRAFT® Device for EVAR
- The Incraft® is a very low profile device that allows In-Situ limb length adjustments and safe use in patients with small external iliac arteries
- The INSPIRATION trial is the first EVAR regulatory device trial conducted simultaneously in the US and Japan
The INSPIRATION Pivotal Study

**Imaging: Size Changes up to 1 Year**

Size Changes ≥ 5mm considered significant

**INSPIRATION Study**

- Mean AAA size:
  - 1 Month: 56 mm
  - 6 months: 53 mm
  - 1 year: 51 mm
- Enlargement > 5mm @ 1 year: 0%

---

**Results up to 360 days**

**INSPIRATION Study:**

Primary Effectiveness Endpoint was met
Successful Treatment * >80%  (87.3%)

*Defined as Absence of enlargement, migration, conversion to open surgery, rupture, type I or III endoleaks, or Graft occlusion*

---

**FU to 360 days**

- One year Survival: 96.7%
- 7 deaths: Cardiac including MI: 3, Stroke: 1, Head Trauma: 1, Cancer: 2
- 4 Strokes and 6 MI's
- 11 Re-Interventions: All for Occlusion or stenosis, None for Endoleaks

---

**Enrolment:** July 2012 to Aug 2013
- 190 patients: 134 from US, 56 from Japan
- 32 sites: 27 from US, 5 from Japan
- All Imaging reviewed by a Core Lab (M2S)
- Clinical Events Committee (CEC) with 3 Independent members adjudicated all untoward events

**Safety and Efficacy endpoint Targets:**

"Performance goals"

---

**INSPIRATION Case From Japan with Iliac Tortuosity**

GR / 79 year old woman

**INSPIRATION STUDY:**

44% of patients with iliac access < 7 mm bilaterally
No iliac ruptures or significant injuries reported

---

Courtesy of Dr. Takao Ohki, co-PI

Miami Cardiac & Vascular Institute
Nellix EndoVascular Aneurysm Sealing System (EVAS)

- Next generation technology
- Designed to seal the entire aneurysm using a contained biostable polymer
- Non-modular design with complete fixation
- Potential to overcome issues associated with conventional endografts

EVAS Procedural Steps

1. Evacuate Endobags and visualize anatomy
2. Advance 17Fr Catheters
3. Align and Expand Stents
4. Angiographically confirm seal; aspirate
5. Refill to 180 mmHg
6. Angiographically confirm seal; remove delivery systems
7. Polymer fill to 180 mmHg

Nellix System Overview

- Both friendly and hostile anatomies
- Short common iliac artery
- Common iliac artery aneurysm
- Tortuous aorta

Effect on Lumbar Arteries that can Lead to TII EL

Anatomies well suited for Nellix
May also be adverse for EVAR

- Common iliac artery aneurysm
- Tortuous aorta

Case Example: Infrarenal AAA
Case Example: Challenging Proximal Neck

Case Example: Tortuous AAA

Global Registry Includes more Complex Anatomies

Current Status

Conclusions

- Two next generation devices are under investigation with data begin accumulated
- One, low profile, thinner graft material and nitinol skeleton bringing advantages of flexibility, applicability to women, and tortuosity, but perhaps some limitations in implant design
- One, low profile (16F), employing totally different concepts and treatment strategies
- The field is maturing after 25 years with continually improving technology
- Also, incremental improvement of existing, proven devices: Endurant, Conformable Excluder, Zenith
- Ultimate market acceptance will be dependent on durability, ease of use, and other benefits
- Moving toward EVAR as an outpatient procedure?