INITIAL EXPERIENCE WITH
INCRAFT® AAA STENT
GRAFT SYSTEM

RALF R. KOLVENBACH
– Proximal landing zone issues 64%
AAA Market Segments by Patient Anatomy

Diagnosed AAAs by Aortic Neck Length
*(Distance from the lowest renal to top of Aneurysm)*

Market size based on Company estimates
NECK MATTERS

• EVAR - EVAS
• Infrarenal Fixation - Suprarenal Fixation
• Hooks
• Barbs
• Wires
• Polymer Rings
• Polymer Bags
• Flow Modulation
Suprarenal Fixation is required for EVAR

The advantages afforded with suprarenal fixation when treating abdominal aortic aneurysms.

By Benjamin M. Jackson, MD, and Ronald M. Farman, MD

Some form of anatomical fixation during endovascular aneurysm repair (EVAR) is advantageous. There is a surfeit of experiential and data illuminating the benefits of anatomic fixation in general and suprarenal fixation in particular.

**THE PROBLEM: STENT GRAFT MOVEMENT**

Stent graft migration is defined as distal movement > 10 mm or movement ≤ 10 mm when resulting in secondary intervention, according to the Society for Vascular Surgery reporting standards for EVAR. It is not surprising that migration is an Achilles’ heel of EVAR. Using cadaveric aorta, Reisch et al. showed that the tractional force required to dislodge any stent graft was much less (by a factor of 6) than that required to disrupt a sutured anastomosis. Stent graft migration is associated with type I proximal endoleak and sac pressurization; therefore, reintervention is required to avoid aneurysm growth and potential rupture. Consequently, meticulous attention to stent graft sizing, device selection, and deployment should be undertaken to minimize the risk of migration. With regard to preventing migration and proximal endoleak, two adverse outcomes that are intimately related, authorities in the field have previously advocated for transrenal bare-metal stents in aortic necks ≥ 16 mm. The Zenith endograft (Cook Medical, Bloomington, IN) (Figure 1A) was the first device approved by the US Food and Drug Administration (FDA) that has suprarenal fixation. The 5-year results of its pivotal trial demonstrated very low migration rates. Owing to its pararenal bare-metal stents, attachment hooks arising from these stents, and the availability of a 36-mm proximal sealing stent (still among the largest proximal devices available and approved for EVAR), this device is reputed to be able to treat unfavorable necks. In one single-institution study comparing the clinical results of various endografts, the Zenith device had no incidence of migration. Two Medtronic, Inc. (Minneapolis, MN) EVAR devices incorporate suprarenal bare-metal stents without hooks or barbs and are FDA approved for use in short (≤ 10 mm) aortic necks: one of only two devices with such approval. The Talent device (Figure 1B), mean-while, has both suprarenal stents, as well as hooks on these stents, and is also approved for use in short (≤ 10 mm) aortic necks. There were no migrations, ruptures, conversions, or type I endoleaks during the first year of follow-up in the United States pivotal trial of the Endurant graft. Remarkably, in a small study examining patients with hostile anatomy (including proximal necks...
The ACE Trial evaluated mid/long term outcomes of EVAR vs. Open Surgical (OSR) patients (n=299) in France.

EVAR 2nd Interventions = 16%
Open surgery = 2.4% at median f/u of 3 years

The EVAR group had significantly more 2nd interventions, and open surgery remains a ‘more durable option’.

PROXIMAL SEAL STABILITY REMAINS KEY

- Rates of 2nd interventions in EVAR are high and not improving adequately
  - Average re-intervention rate of 3.7%/yr from recent registry data\(^\text{1}\) IDE trial data demonstrate average rate of 4.1%/yr\(^\text{2}\)

- Complicated anatomy results in more Type I endoleaks & higher re-intervention risk
  - Short neck length (<15mm)\(^\text{3,4}\)
  - Neck angulation (>40°)\(^\text{5}\)

### Re-intervention-free survival\(^\text{1}\)

<table>
<thead>
<tr>
<th></th>
<th>1 yr</th>
<th>2 yr</th>
<th>5 yr</th>
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<tbody>
<tr>
<td></td>
<td>89.9%</td>
<td>86.9%</td>
<td>81.5%</td>
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### Increased odds of type I endoleak and need for re-intervention

<table>
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<tr>
<th>Risk Factor</th>
<th>OR (95% CI)</th>
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<tbody>
<tr>
<td>Neck Length &lt; 15 mm</td>
<td>2.2 (1.4-3.5)(^\text{3,†})</td>
</tr>
<tr>
<td></td>
<td>6.2 (2.9-13)(^\text{4,†})</td>
</tr>
<tr>
<td></td>
<td>4.3 (2.1-8.7)(^\text{4,‡})</td>
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<tr>
<td>Neck angulation &gt; 40°</td>
<td>5.9 (1.3-27.6)(^\text{5,*})</td>
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LIMITATIONS OF CURRENT ENDOGRAFTS

DIFFICULT ANATOMY:
- Severe neck angulations
- Conical neck structure
- Small access vessels
- Iliac or femoral occlusive disease
- Arterial tortuosity
- Significant calcification or thrombus
- Tight aortic bifurcation
- Short iliac arteries
- Short infra-renal aorta
- Accessory renal arteries
- ...

± 70% OF ALL CASES?

WHAT DO WE NEED FOR THESE AAA CASES?

- Low profile with improved flexibility of delivery system
- Precise deployment and possible re-positioning of the stent graft
- And constraint of costs (avoiding additional extensions)

INCRAFT® Online Training Modules – Module 1
CLINICAL RESULTS

Placement accuracy INNOVATION trial

- Median distance from renal artery*: 2 mm (-4†; 15mm)

†No renal artery coverage

*Accuracy Definition: distance from lowest renal to bottom of first two cranial graft edge markers

D. Scheinert et al; J Vasc Surg 2013; 57(4)):906-914
THE INNOVATION STUDY – FIRST 4Y FOLLOW-UP

<table>
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<tr>
<th>Screening</th>
<th>1MFU</th>
<th>6MFU</th>
<th>1YFU</th>
<th>2YFU</th>
<th>3YFU</th>
<th>4YFU</th>
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<tr>
<td>121.1cc</td>
<td>116.1cc</td>
<td>103.6cc</td>
<td>85.6cc</td>
<td>74.3cc</td>
<td>66.5cc</td>
<td>61.2cc</td>
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-47.3% reduction in AAA volume
STENT-GRAFT DESIGN

Bilateral in-situ length adjustment

During procedure each limb can be telescoped into the respective aortic bifurcated leg.
SHORT NECKS        CALCIFICATIONS         TORTUOSITIES
ANGLES        SMALL ACCESS
Anatomies treated with the INCRAFT® System
GRAFT FLEXIBILITY IS ESSENTIAL
CHALLENGING NECK ANATOMY
FLEXIBILITY AND LENGTH MATTERS
CHALLENGING NECK ANATOMY
NARROW BIFURCATION ADVANTAGES OF A LOW PROFILE GRAFT
Thank you
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RALF R. KOLVENBACH