Upsides (Advantages) And Downsides (Disadvantages) of Low Profile Devices For EVAR And TEVAR: There Are Tradeoffs

Michel S. Makaroun MD
Co-Director, UPMC Heart and Vascular Institute
Professor and Chair, Division of Vascular Surgery
University of Pittsburgh School of Medicine

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Aortic Advisory Board: Medtronic/ W.L. Gore
National PI for the TAMBE early Feasibility trial
National PI for the US IDE InCraft study

Advantages of Lower Profile
1. Easier delivery
2. Navigates tortuous vessels better
3. Usable in smaller calcified iliac vessels
4. Less iliac injuries
5. More Applicable to women
6. Makes more patients candidates for EVAR
7. Safer and easier percutaneous access
15/11/2018

MC: 82 y woman with severe iliac disease

14 Fr INCRAFT Case with severe Iliac Tortuosity

Courtesy of Dr Takao Ohki, co-PI

IS: 68 yo 6 wk post Ascending Aortic Aneurysm Rx

Zenith Alpha: No Conduits
28 mm (16 Fr) and 34 mm (18 Fr) devices

How often do iliac arteries limit EVAR?

<table>
<thead>
<tr>
<th>Management of Difficult Access during Endovascular Aneurysm Repair</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yona Ebrani,7, Anad Belg,4, Paul J. Flory,1 Grace J. Wang,2 Edward Y. Wey,3 Jeffrey P. Carpentier,4 Ronald M. Fairman,1 and Benjamin H. Jackson,1 Methodist New York, Philadelphia, Pennsylvania, Washington, DC, and Graebker, New Jersey</td>
</tr>
<tr>
<td>2009-2013 400 EVAR’s</td>
</tr>
<tr>
<td>191 difficult access 48% Low profile may help</td>
</tr>
<tr>
<td>35 needed adjuncts 8.7% Low Profile would help</td>
</tr>
<tr>
<td>2 cases aborted because of iliac access</td>
</tr>
<tr>
<td>7 iliac ruptures, 3 limb ischemia, 7 limb thrombosis</td>
</tr>
</tbody>
</table>

Patients Excluded such as Women may become Candidates!

Endovascular vs. Open Repair of Abdominal Aortic Aneurysms in the Medicare Population

Marc L. Schmerlhorn, M.D., A. James O’Malley, Ph.D., Arjinder Jhussel, M.D., Philip Cotterill, Ph.D., Frank Pompoufello, M.D., and Bruce E. Landon, M.D., M.B.A.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unmatched Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endovascular Repair (N=29,942)</td>
<td>Open Repair (N=32,056)</td>
</tr>
<tr>
<td>% of patients Male sex</td>
<td>83.2</td>
</tr>
</tbody>
</table>
**Is there a point of diminishing return?**

**Probably yes.**

- A size less than 14-16 Fr is unlikely to
  - increase applicability of EVAR or
  - reduce complications further or
  - Simplify the procedure significantly

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**Disadvantages:**

Does Lowering Profile interfere with Outcomes and durability?

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**Are Recent Recalls and Cancelled Projects Related?**

Cook Medical Inc. Recalls Zenith Alpha Thoracic Endovascular Graft for the treatment of Blunt Traumatic Aortic Injury (BTAI) Due to the Potential Formation of Thrombus Inside the Device After Implantation

- The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

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**Are Recent Recalls and Cancelled Projects Related?**

FierceBiotech

Incidence and Outcomes of Anaphylactic Reaction Related to Polymer Leak With the Ovation Abdominal Stent Graft System


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**How is Profile Reduced?**

1. Reduce graft thickness and volume
2. Lower gauge Nitinol wires.
3. Smaller carriers
4. Decrease number of stent peaks
5. Decrease overlap of stents. Tri-fab configurations.

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**Excluder: Thinner Constraining Sleeve**

Same Implant but ePTFE sleeve made stronger, denser and thinner to constrain components at smaller diameter

- Released Early 2013

**Reduced profile 2.4 Fr size**

- 31 and 35 mm Main body down to 18 Fr Profile ID
- 16, 18 and 20 mm contra leg down to 12 Fr ID
- 23 contra leg down to 14 Fr / 27 mm down to 15 Fr ID
- 23-28.5 Aortic Extenders down to 16 Fr ID
- 32 mm Aortic Extender 17 Fr and 36 mm down to 18 Fr ID

Future Design Target includes much lower profile
Ovation: Modular Change

- Reduced profile further by 2 Fr sizes
  - 16Fr OD → 14 Fr OD

Changes from original Trivascular graft:
- Modular instead of Unibody
- Tri fab: three pieces
- Smaller proximal stent

Incraft: Stent design and Thin Polyester

- First Nitinol Polyester design to manage a 14 Fr OD profile based on Different stent design
- Thin Dacron Polyester Fabric Tri-Fab design

Zenith LP: Nitinol Replaces Stainless Steel

- Mostly New Device
  - Nitinol instead of Stainless
  - New suprarenal stent design
  - New capless constraint
  - New Stent configuration
  - Woven polyester fabric
  - New Dilator tip and Cannula

- 18-22 Fr ID → 16 Fr ID

Endurant evo: Thinner Dacron Fabric

- Change the Dacron weave
- Change to Tri-Fab
- Minor modifications to deployment System and top cap

- Reduced profile by 4 Fr sizes
  - 18-20 Fr OD → 14-16 Fr OD

Price to Pay for aggressive profile reduction:
- Limbs Vulnerable for compression/occlusion
  - Flexible Limbs
  - Smaller Overlap Diameter
  - Tendency to Use in Disadvantaged Limbs

Strata Fabric on Endologix AFX

- Unfortunately we are not always successful And require multiple iterations to get it right

Overlap Zones and Narrowed Areas Must be Ballooned

Caution: Investigational Device / Limited by United States Law to Investigational Use
There is clearly a price to pay from aggressive attempts at reducing profile!

1. Endurant eva project terminated because of fractures
2. InCraft is still not approved by the FDA for similar problems despite no untoward clinical effects at 4 years
3. Zenith LP project on hold because of limb issues
4. Zenith Alpha small sizes removed because of thrombotic complications. Trauma indication withdrawn
5. Endurant AFX was recalled and lost CE mark in Dec 2016 because of type III endoleaks from fabric holes
6. Ovation biopolymer leaks with anaphylaxis

Summary

1. Low Profile devices are already here. 14 Fr OD
2. Devices between >18 Fr are all undergoing changes to reduce their profile.
3. This trend will increase applicability of EVAR and reduce some complications
4. Most benefit expected with TEVAR
5. Aggressive profile reduction however may carry some disadvantages including reduced durability