Evolution of Endografts for EVAR

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Bolton, Lombard, Trivascular
New EVAR Device
2015

Commercialization allowed a rapid evolution

- Improved delivery
- Improved deployment
- Improved durability
- Improved design

Expanded Applications
What have we learned from older generation of endografts?

1. Longer Durability is Needed!
EVAR Success

Abdominal aortic aneurysm repair: long-term follow-up of endovascular versus open repair

Gabriele Piffaretti¹, Giovanni Mariscalco², Francesca Riva³, Federico Fontana⁴, Gianpaolo Carrafiello⁵, Patrizio Castelli⁶

50-60% of patients are still Alive at TEN YEARS

Rupture After EVAR should be Eliminated

- Reported with all types of grafts in up to 2% / year
- Severity of presentation is variable
- Associated with endoleaks and pressurization of sac

AneuRx 4 years / Zenith 5 years / Ancure 7 years

Device Durability is an Essential Component
Fabric Tears: Type III Endoleak

OLD Devices have been Replaced
New devices have stronger fabrics
Metal Fatigue: Fractures

Aug 02

Dec 02

Fractures

Some Devices Never Made it to Market
Better design of stent apices
Material Fatigue: Suture Miniholes

Sutures to grafts revised

Courtesy of K. Ouriel
Poor Overlap Zone: Limb Disconnection

We need long overlap zones with friction.
No Active Fixation: Migration / complications

Treated with New Endograft inside first one

We learned the value of Active Fixation
What have we learned from older generations of endografts?

1. Longer Durability is Needed!
2. Preclinical Testing Critical!
Improved Pre Clinical testing

- Analysis and testing of cyclic motion and deformation, FEP stresses, wires, angles, deployment, abrasion...
What have we learned from older generations of endografts?

1. Longer Durability is Needed!
2. Preclinical Testing Critical!

Testing sets the performance boundaries and limits of the IFU that should be respected.
Disregarding IFU can be problematic!

- Do not Undersize
- DO NOT OVERSIZE Excessively over recommendation

19 mm Narrowing

32 mm Zenith

Neck Rupture

1 month later

> 50% oversizing
Beyond IFU: Challenging Neck Anatomy

Some devices can work outside the IFU in selected cases
Beyond IFU: Challenging Iliac Anatomy

Some devices can work outside the IFU in selected cases.
Results Not Always Acceptable in Hostile Anatomy

Iliac Rupture
Results Not Always Acceptable in Hostile Anatomy

- 17 mm Calcified Neck
- 23 mm Device
- Fold because of Oversizing
Results Not Always Acceptable in Hostile Anatomy

3 years later
Migration
Occlusion of The right limb
Emergency Fem fem
Late conversion
10228 patients (1999-2008)
59% <5.5 cm

✓ Compliance with EVAR device guidelines was low
✓ Post EVAR sac enlargement was high

❖ 41% had Sac enlargement @ 5 years
❖ ONLY 42% of EVAR’s had anatomy that fit guidelines

Conclusion—In this multicenter observational study, compliance with EVAR device guidelines was low and post-EVAR aneurysm sac enlargement was high, raising concern for long-term risk of aneurysm rupture. (Circulation. 2011;123:2848-2855.)
What have we learned from older generations of endografts?

1. *Longer Durability is Needed!* 
2. *Preclinical Testing Critical!* 
3. *We need devices that fit the AAA anatomy rather than the other way around!*
Trends in new devices besides Durability

1999 Ancure Sheath 27 F OD

2013 Ovation Sheath 14 F OD

Decreasing Profile

Increasing Flexibility
Potential Benefits 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
MC: 82 y woman with AAA + severe iliac disease
MC: 82 y woman with AAA + severe iliac disease

14 Fr Device
Most Modern EVAR devices have a low enough profile for percutaneous use!!

New 14 Fr devices will encourage more users
How is Profile Reduced?

1. Reduce graft thickness
2. Lower gauge Nitinol wires.
3. Decrease number of stent peaks
4. Decrease overlap of stents
5. Tri-Fab Construction

All These changes must balance low profile with Durability of AAA exclusion
What makes up profile?

The Majority is Graft Material
Excluder: Thinner constraining Sleeve

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

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

Released Early 2013
Zenith LP: Nitinol Replaces Stainless Steel

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

Mostly New Device Still in Trials in US

18-22 Fr ID → 16 Fr ID

Caution: Investigational Device / Limited by United States Law to Investigational Use
Ovation: Modular Change

Released for clinical use

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

Reduced profile further by 2 Fr sizes

16Fr OD ➔ 14 Fr OD

Rumored lower profile in near future
Available Commercial Choices in US 2015

<table>
<thead>
<tr>
<th>Talent</th>
<th>AneuRx</th>
<th>Zenith</th>
<th>Excluder</th>
<th>Powerlink</th>
<th>Endurant</th>
<th>Ovation</th>
<th>Aorfix</th>
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- Zenith (Fenestrated)
- Endurant AUI
- Zenith RENU
Available Commercial Choices in US 2015

Zenith Flex  Excluder  Powerlink  AFX  Endurant  Ovation  Aorfix  Incraft

Zenith Fenestrated  Endurant AUI  Zenith RENU
Why New Devices?

1. Commercial Interest: Attempt to gain competitive edge
2. Drive for Lower Complications
3. Improved Performance and Longer Durability
4. Expanding the Applicability of EVAR to challenging anatomies and New Aortic Segments
Devices in 2015 have Expanded the Anatomic Limits of EVAR

- Decreasing device profile makes access a non issue: 13-14 Fr devices (Incraft* / Ovation..) 12 Fr devices on Horizon

- More Size offerings can now treat smaller and larger necks of 16-32 mm (Ovation / Zenith / Excluder / Endurant…)

- Improved Accurate deployment systems can now treat shorter necks. (Endurant / C3 Excluder / Incraft*…)

- Fenestrated Grafts can treat very short to non existent necks

- Innovative seals in diseased necks (Ovation…) or Endostaplers for better fixation (HeliFX..)

- Very Flexible designs to treat very Angulated Necks (Aorfix)

- Iliac Branches to preserve Internal iliac artery flow* (Cook/Gore)

*Caution : Investigational Device / Limited by United States Law to Investigational Use
New Generation Stent Grafts better than old grafts @ 7 Yr for
Reinterventions  Conversions  AAA Growth

Active Fixation: Reduce Migration

- **Endurant**
- **Zenith**
- **Excluder**
- **Aorfix**
- **Aptus HeliFX**
- **Incraft**
- **Ovation**

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Flexible Construction: Accommodate Anatomy

- Excluder
- Endurant
- Zenith-flex
- Aorfix

Most Flexible is the Aorfix: Both Iliacs and Necks
Circular Concentric Rings Designed to Accommodate Tortuous and Angulated Anatomy

The Aorfix (Lombard)
Very Accurate and Controlled Deployment: Improve Seal Zones + Use Shorter Necks

The Endurant (Medtronic)
Based on delayed release of fixation until final position

IFU: Neck length > 10 mm
Recapture after Initial Deployment: Improve Safety and Use of Seal Zone

The C3 Excluder deployment (WLGore) Based on a constraining mechanism
TM: Reverse Taper Neck with Thrombus

Biopolymer molds to Irregularities

Diam@ Renals: 22mm

13 mm lower: 31 mm
May Prevent any Type II Endoleaks

The Nellix Endograft (Endologix)
Biopolymer Sac Filling of the Aneurysm

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Reducing Profile Further

The Medtronic Endurant IIs, EVO, Valiant LP

IIS going Trifab / Valiant LP with no proximal stent

**Caution: Investigational Device / Limited by United States Law to Investigational Use**
Controlled deployment in angled necks.

The Gore Conformable Excluder

C3 Deployment mechanism with a deflector
16 Fr for most trunks
Trial Starting in US

**Caution : Investigational Device / Limited by United States Law to Investigational Use**
Aortic Branches Represent a Major Limitation to EVAR / TEVAR

*Fenestrated and New Branched Graft solutions Provide a welcome answer*

*Internal Iliac arteries*
*Visceral Arteries*
*Thoracoabdominal pathology*
*Arch Pathology*
Allows Extension over Renal Arteries

The Zenith Fenestrated Graft
Custom Made
MV 85 year old F: Very Short Neck

Type II endoleak treated at 3 years / well at 6 years (92y)
Allows Extension over Renals *off the shelf*

The Zenith P-Branch

IDE Trial Started in US

**Caution: Investigational Device / Limited by United States Law to Investigational Use**
Allows preservation of Internal Iliac arteries

The Zenith Iliac Bifurcation Branch

IDE Trial finished enrolling in US

Caution: Investigational Device / Limited by United States Law to Investigational Use
Allows preservation of Internal Iliac arteries

The Gore IBE device

JG 75y M

IDE Trial finished enrolling in US

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The TAAA Frontier

Zenith T Branch and Gore TAMBE

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Summary

1. Endografts for EVAR have gradually evolved over the last 25 years
2. Modern grafts are more durable and apply to more patients
3. Fenestrated and branched systems will provide in the future a total aortic solution
4. Open Repair will be used less but will remain essential for some cases and for salvage