Challenges in the treatment of infrarenal aneurysm & considerations for a durable repair

Nilo J Mosquera, MD.

Head of Department
Angiology and Vascular Surgery.
CHUO Hospital. Ourense. Spain
Disclosure

Speaker name:

Nilo J Mosquera, MD.

I have the following potential conflicts of interest to report:

✓ Consulting: Lombard Medical, Cook Medical, WL Gore, JOTEC-Cryolife, Terumo Aortic, CORDIS-Cardinal Health

Employment in industry

Stockholder of a healthcare company

Owner of a healthcare company

✓ Other(s): Spanish National Health Service Employee

I do not have any potential conflict of interest
A Closer Disclosure Report

Speaker name:

Nilo J Mosquera, MD.

I have the following potential conflicts of interest to report:

✓ I HAVE CONFIDENCE IN COOK AORTIC PRODUCTS
Aortic Disease Can Progress AFTER Repair

- Resulting in:
  - Stent migration
  - Endoleaks
  - Secondary interventions
  - Sac enlargement
Aortic anatomy and off label treatment are clearly related with failure in durable aortic repair

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Complication</th>
<th>Conclusion</th>
</tr>
</thead>
</table>
| Schanzer A, Greenberg RK | 10228 patients US multicentric data | 41% patients with sac enlargement 5 years FU | ONLY 42% PATIENTS ANATOMY COMPLIED WITH IFU  
Aortic neck angle >60°  
Aortic neck diameter >28mm  
Neck shorter than 15mm  
Independent risk factor during FU period |
| Wyss TR, Greenhald RM | 217 patients US multicentric data | 53 patients had graft related complication at FU  
Mean 3.6y | ITI had the strongest relation (hazard ratio) with complications AFTER EVAR.  
Neck angulation, and calcification are independent risk factors |

Aortic neck angulation and length
Keys to a Durable Repair?
A mantra for EVAR surgeons

① Resistance to Endoleaks and Migration
② Personalized Solutions
③ Precise and Controlled Deployment
④ A Seal in Healthy Tissue
Endoleak and Migration Resistance

Resistance is based on three components:

**Active fixation**: barbs to anchor securely in healthy tissue

**Radial force**: stents that help support the aorta and provide graft-to-vessel apposition

**Columnar strength**: a balance of length, stability and flexibility

“The long main body of the Zenith device may also play a role, as it has a higher amount of columnar support.”

“The Zenith, a modular 3-piece bifurcated device with suprarenal support and 3 mm long fixation barbs, displayed the maximum proximal fixation capability.”
① Endoleak and Migration Resistance

Active fixation: barbs to anchor securely in healthy tissue
Radial force: stents that help support the aorta and provide graft-to-vessel apposition

**Stability and Fixation are mandatory for a durable repair**
Personalized Solutions

Devices need to be tailored to the patient’s individual vasculature to help ensure the best seal. Modularity and range of sizes allows for patient-specific device configuration.

Now-a-days three piece strategy has been adopted by many EVAR device manufacturers!!!!

“I have to conclude that modular stent-grafts have overwhelming advantages, whereas the only advantage of unibody design is a reduced potential for type III endoleak. There are no components to separate. However, a properly designed modular stent-graft, with relatively short limbs and a locking mechanism between components, virtually eliminates the risk.”

Modularity is critical to take the advantage of the maximum sealing zone using any single millimeter from the renal to both hypogastric arteries.
Precise and Controlled Delivery

Modularity is nothing without control!!!

We agree every millimeter of healthy tissue in a seal zone is invaluable to a durable repair.

Accurate device deployment is critical to helping to ensure a seal in healthy tissue.

“It is important to have some means of determining and controlling the orientation of the stent-graft. The best devices have prominent markers and a 1:1 response to externally applied torque.”
“A durable EVAR requires a stable proximal aortic segment that is not wide, angulated, thrombus lined, calcified, conical-shaped or a combination of these features.”
Why Durability is so important?

EVAR started in the 90’s

Parodi’s initial EVAR device in 1990
Why Durability is so important?
Why Durability is so important?

But now it is 2019!!!!

And 2019 is cooler!

We have clearly proven EVAR is feasible (at least outside UK)

We have clearly proven EVAR is safer for the patient and NHS (again at least outside UK)

We need to be sure that our new gold standard is durable
Is durability so critical as we think and promote?

Even tested and designed endografts for regular therapy can fail.
Is durability so critical as we think and promote?

Even tested and designed endografts for regular therapy can fail.

2011: 1y FU  
2012: 2y FU  
2014: 4y FU  
2015: 5y FU
Is durability so critical as we think and promote?

Different approaches can be not so attractive in the mid-long term as they seem in short term.
To Summarize

1. Aortic disease is a progressive condition

2. It requires a durable repair

3. Keys to a Durable Repair Didn’t change:
   1. Resistance to endoleaks and migration
   2. Personalized Solutions
   3. Precise and controlled deployment
   4. A seal in healthy tissue
Zenith Alpha AAA™: can durable repair be facilitated?

Wider patient applicability
- Lower profile
- 3-piece modularity
- Complete range of sizes from 22-36 mm
- Can be used in conjunction with other Zenith devices, i.e. Iliac branch

Easy-to-use introduction system
- 3 simple steps for main body deployment
- Retains the precision and control of previous generation devices

Durable repair
- Active fixation, radial force and columnar strength combined in a lower profile device
## Evolution of Zenith

<table>
<thead>
<tr>
<th>Zenith® Flex Abdominal Endovascular Graft</th>
<th>Zenith® Alpha™ Abdominal Endovascular Graft</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stainless steel</td>
<td>Nitinol</td>
</tr>
<tr>
<td>Full thickness dacron (~0.25 mm)</td>
<td>Thin tightly woven dacron (~0.12 mm)</td>
</tr>
<tr>
<td>Top cap</td>
<td>No top cap</td>
</tr>
<tr>
<td>20 Fr Flexor 7.7 mm O.D. (32 mm stent-graft)</td>
<td>16 Fr Flexor 6 mm O.D. (32 mm stent-graft)</td>
</tr>
</tbody>
</table>
Zenith Alpha™ Abdominal: main features

Three-piece modular system designed to accommodate varying patient anatomies

Low-profile main body device:
  - Active suprarenal fixation
  - Gold marker at the flow divider for increased visualization under fluoroscopy

Completely new low-profile leg featuring nitinol Spiral-Z™ technology
Zenith Alpha™ Abdominal
Versatile system with many potential combination to adapt to Patient’s anatomy

<table>
<thead>
<tr>
<th>Components</th>
<th>Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main body</td>
<td>22, 24, 26, 28</td>
</tr>
<tr>
<td>Iliac leg graft</td>
<td>9, 11, 13</td>
</tr>
<tr>
<td>Main body extension</td>
<td>22, 24, 26, 28</td>
</tr>
<tr>
<td>Converter</td>
<td>24, 28, 32, 36</td>
</tr>
<tr>
<td>Iliac plug</td>
<td>14, 16, 20, 24</td>
</tr>
</tbody>
</table>

- 42 different main bodies
- 30 different leg extensions
- 14 different aortic cuffs
- 4 AUI converters

Fit the graft to the Patient, not the patient to the graft!!!
Zenith Alpha™ Abdominal

Long main bodies: maintain columnar strength in non-tortuous cases, facilitate cannulation and stable landing zone if needed in the future.

**Main body length: 70 mm**
- A 6 mm gap between the first and second stents

**Main body length: 84 mm**
- A 6 mm gap between the first and second stents and between the second and third stents

**Main body lengths: 98, 108, 118, and 128 mm**
- A 6 mm gap between the first and second, the second and third, and the third and fourth stents

**Note:** All stent lengths are measured in mm.
Zenith Alpha™ Abdominal: long main bodies

Proximal migration 3 mm above SMA

Huge type I endoleak: hook dislocated

5 mm sac expansion
REDO 4 fen plan: Design

No room even for inverted limb bifurcated!!!

1 additional sealing stent Above CT

JUST 1 sealing stent below renals!!!
18 months FU

Type 2 Endoleak

15% sac volume reduction
Zenith Alpha™ Abdominal: Familiar Design Attributes

Active suprarenal Fixation provides long-term migration resistance

Controlled delivery

Modularity
**Zenith Alpha™ Abdominal: Improved Familiar Design Attributes**

- Fixation barbs at 2 levels

<table>
<thead>
<tr>
<th>Model</th>
<th>Migration resistance</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zenith Alpha AAA</td>
<td>41.4N (Range 34.3-48.8)</td>
<td>MED TS080117, PMA submission</td>
</tr>
<tr>
<td>Zenith Flex</td>
<td>36.6 +2.4N</td>
<td>Zenith PMA Submission</td>
</tr>
</tbody>
</table>
Notable Improvements
Designed for a Simplified Deployment

1. New rotation handle
2. New Captor Sleeve
3. No trigger wires to manually remove
4. More intuitive system
5. Low-profile system.

16 Fr Sheath (17Fr for 36mm)
22-36 Diameters
Simplified Deployment

- Low-profile system for increased treatment options
- New rotational handle
  - Controlled, simple & precise deployment
- No trigger wires to manually remove
  - Trigger wires now remain contained within the new rotational handle
Simplified Deployment

- New Captor Sleeve
  - Minimized deployment forces
- No top cap to retrieve
  - Improved trackability
New features allow a Simplified Deployment: just 3 steps

1. Position device.
2. Pull back sheath.
3. Rotate handle.

Low profile & Flexor Introducer Sheath enables percutaneous access and minimize vessel trauma.

New Captor Sleeve reduces friction and pull-back forces for controllability.

New rotation handle simplifies deployment while maintaining controlled precision.
New Alpha Legs

• Spiral-Z stent design with improved performance characteristics:
  • Lower profile introducer system (12 Fr)
  • Nitinol z-stent material
  • Thinner, tighter-weave fabric
  • Increased separation force from main body
  • Improved columnar strength in proximal seal
New Alpha Legs

Conventional Z-Stents don’t fit for angulation

Spiral Z structure balances radial force and conformability
Flexible Low profile New Alpha Legs

The risk of Low Profile… Again

1. Crossable access but poor run-off

2. Bad planning: for final landing of the graft, landing in stenosis, steep angle, excessive oversizing...

This can not be prevented by any graft, technology is not magic: can lead to limb occlusion
how to avoid limb occlusions?

Predilatation for access.

Postdilatation to prevent compression.

Surgical iliac conduits: (add potential complications to our procedure)

Hybrid technique to improve outflow

Poor run-off IS RELATED to the patient!
how to avoid limb occlusions?

Preoperative

72h later: limb thrombosis, thrombolysis and relining

Deal with complication

Clinical failure: patient at risk

Increased cost for procedure

Poor planning IS RELATED to the surgeon!
Our first experience.

76 years old patient COPD.

53 mm Dmax AAA
5-6 mm access not calcified
32 mm healthy long neck

Length: 2.4

Length: 5.3
Our first experience with Alpha: Oct 2015.
Since My first experience with Alpha: Oct 2015.

- 29 patients treated
- 17 in combination with ZBIS
- 11 patients completed 24 months FU

- No sac enlargement
- No Stent fractures
- No type I or III
- 2 non related deaths

- 1 limb occlusion (high grade stomach cancer dx from 6 months CT scan FU died 6 months after dx)
Easy of use and integration: case 2.
Easy of use and integration: case 2.

37 mm Dmax right common Aneurysm

27 mm left common Dmax

No Aortic Aneurysm

Indication to treat?
Easy of use and integration: case 2.

Referred to us by Urology dept.

Need to perform radical oncologic surgery

Relative to our Anaesthesiology Head of Department
Easy of use and integration: case 2.

1 month FU (1 week prior to urological surgery)

Discharged 24h postop (Usual PEVAR fastrack)

No complications
Easy of use and integration: case 2.

Both hypogastric patent

Successful exclusion of Iliac aneurism
Easy of use and integration: case 2.

Accurate deployment to the milimeter!!!
Easy of use and accuracy: case 3.

73 years old patient. No special comorbidities
At ER admitted for abdominal pain.
Stable contained ruptured AAA.
Easy of use and accuracy: case 3.

Small volume paraaortic haemathoma and contrast extravasation + pain = URGENT EVAR
Easy of use and accuracy: case 3.

- Left common critic stenosis
- Infrarenal neck
- Aortic bifurcation
- Calcified iliacs
Easy of use and accuracy: case 3.

Postop CT FU: successful exclusion

Patient discharged at Postop day 5

No Complications
Easy of use and accuracy: case 3.

Accurate even in ER

Accurate for *regular-trained-user*: User friendly device

INFRARENAL DEPLOYMENT
Easy of use and accuracy: case 3.

- LEFT HYPO ACCURACY
- Accurate even in ER
- Accurate for *regular-trained-user*: User friendly device
Easy of use and accuracy: case 3.

RIGHT HYPO ACCURACY

Accurate even in ER

Accurate for regular-trained-user: User friendly device
Easy of use and accuracy: case 3.

Sac exclusion granted

Bifurcation after cracking

Iliac stenosis after cracking
Some Remarks from our initial experience

1. Alpha meets profile reduction, flexibility, modularity, deliverability and control with traditional Flexor™ sheath: great for PEVAR

2. Improved features in a demonstrated platform. Alpha limbs even more flexible than Spiral Z

3. User-friendly delivery system: are you totally sure these are Cook Grafts?

4. Precise and controlled AAA system for a durable aortic repair
Status Update on
Key Points & Beyond

27\textsuperscript{th} - 29\textsuperscript{th} MARCH 2019
Barcelona – Spain, School of Medicine, University of Barcelona
www.sitesymposium.com
Challenges in the treatment of infrarenal aneurysm & considerations for a durable repair

Nilo J Mosquera, MD.

Head of Department
Angiology and Vascular Surgery.
CHUO Hospital. Ourense. Spain