How to Approach Challenging Necks with Off-the-shelf Solutions

Dr Vikram Puttaswamy
Head of Department
Vascular Surgery
Royal North Shore Hospital
Sydney, Australia

Content from Medtronic Hostile Neck Club and recently presented by Prof J.P. DeVries, CX 2020.
The Proximal Neck

• The single most difficult problem that we face when treating AAA, is to treat patients with complex proximal necks
  – Increased chance of Type 1A endoleak
  – More complex procedures are needed to achieve proximal seal
  – Higher rates of re-intervention

• Differentiate between concept of proximal neck length vs seal zone

• Identify the rationale in best treatment options for those AAA with hostile necks vs those with an inadequate seal zone
Not All Necks Are the Same

NECK LENGTH and SEALING ZONE

INFRARENAL NECK LENGTH
Length over which neck diameter remains within 10% of infrarenal diameter (Core Lab definition)
- Anatomy related
- NOT Stent Graft dependent

INFRARENAL SEALING ZONE
Length over which a correctly (per IFU) oversized stent graft is circumferentially apposed against the aortic wall
- Anatomy related
- Dependent on SG oversizing
- Dependent on SG deployment accuracy

- Diameter < 10% of infrarenal
- Diameter > 10% of infrarenal or Neck > 28mm or Infrarenal angle > 60° but graft apposition maintained
- Diameter > 20% of infrarenal, no graft apposition
### Not All Necks Are the Same

#### THE SEALING ZONE CHALLENGE

<table>
<thead>
<tr>
<th>INFRARENAL NECK LENGTH</th>
<th>NECK LENGTH</th>
<th>NECK LENGTH</th>
<th>NECK LENGTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length over which neck diameter remains within 10% of infrarenal diameter (Core Lab definition)</td>
<td>LONG</td>
<td>SHORT</td>
<td>SHORT</td>
</tr>
</tbody>
</table>

If we just evaluate the Neck Length, we may call SHORT two different things.

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## Not All Necks Are the Same

### THE SEALING ZONE CHALLENGE

<table>
<thead>
<tr>
<th>INFRARENAL SEALING ZONE</th>
<th>NECK LENGTH</th>
<th>SEALING ZONE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ADEQUATE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HOSTILE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>INADEQUATE</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**INFRARENAL SEALING ZONE**
Length over which a correctly (per IFU) oversized stent graft is circumferentially apposed against the aortic wall.

The graft is expected to have limited/no circumferential apposition in a hostile sealing zone.

The graft is expected to be apposed circumferentially in a healthy sealing zone.

The graft is expected to be apposed circumferentially in a hostile sealing zone.

Evaluating the Sealing Zone, we can isolate different needs.
### Not All Necks Are the Same

#### THE SEALING ZONE CHALLENGE

<table>
<thead>
<tr>
<th>INFRARENAL SEALING ZONE</th>
<th>ADEQUATE</th>
<th>HOSTILE</th>
<th>INADEQUATE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NEEDS</strong></td>
<td>SEAL</td>
<td>SEAL +</td>
<td>SEAL +</td>
</tr>
<tr>
<td>Use all the existing seal</td>
<td></td>
<td>STRENGTH</td>
<td>LENGTH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Use all the existing seal and maintain the seal over time</td>
<td>Extend the seal above the renals</td>
</tr>
</tbody>
</table>
The graft is expected to have **circumferential apposition** along the min IFU length.

- Infrarenal sealing zone is sufficient (longer than min neck recommended per IFU of the standard graft alone) to seal infrarenally.
- Infrarenal sealing zone is considered hostile (conical).

### CASE EXAMPLE

<table>
<thead>
<tr>
<th>Neck Length</th>
<th>Sealing Zone</th>
<th>Neck Diameter</th>
<th>Angulation Infrarenal</th>
<th>Angulation Suprarenal</th>
<th>% Thrombus</th>
<th>% Calcium</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 mm</td>
<td>10 mm</td>
<td>24 mm</td>
<td>20°</td>
<td>10°</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Courtesy of Prof. De Vries, Groningen, Netherlands*
Hostile Sealing Zones – Add Strength to Seal

CASE EXAMPLE

<table>
<thead>
<tr>
<th>NECK LENGTH</th>
<th>SEALING ZONE</th>
<th>NECK DIAMETER</th>
<th>ANGULATION INFRA</th>
<th>ANGULATION SUPR</th>
<th>% THROMBUS</th>
<th>% CALCIUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 mm</td>
<td>10 mm</td>
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<td>20°</td>
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<td>0%</td>
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ESAR (ENDURANT + HELI-FX)

- STRENGTHEN THE SEAL
- AVOID RENAL CANNULATION

Less is better, no need for renal cannulation if infrarenal seal zone can be strengthened

Courtesy of dr. Tinelli, Rome, Italy
Inadequate Sealing Zones – Add Length to Seal

CASE EXAMPLE

- The graft is expected to have limited/no circumferential apposition
- **Infra**renal sealing zone is not sufficient (shorter than min neck recommended per IFU of the standard graft alone) to seal infrarenally

<table>
<thead>
<tr>
<th>Neck Length (mm)</th>
<th>Sealing Zone (mm)</th>
<th>Neck Diameter (mm)</th>
<th>Angulation (°)</th>
<th>%Thrombus</th>
<th>%Calcium</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>30</td>
<td>15</td>
<td>10</td>
<td>0%</td>
</tr>
</tbody>
</table>

Courtesy of Prof. De Vries, Groningen, Netherlands

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Inadequate Sealing Zones – Add Length to Seal

If the infrarenal sealing zone is inadequate, a healthier one should be found above the renals.

ChEVAR-FEVAR

- EXTEND THE SEAL IN HEALTHY AORTA
- ADD LENGTH

<table>
<thead>
<tr>
<th>NECK LENGTH</th>
<th>SEALING ZONE</th>
<th>NECK DIAMETER</th>
<th>ANGULATION INFRArenal</th>
<th>SUPRArenal</th>
<th>%THROMBUS</th>
<th>% CALCIUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 mm</td>
<td>15 mm</td>
<td>30 mm</td>
<td>15°</td>
<td>10°</td>
<td>0%</td>
<td>0%</td>
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</table>

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Minimize Hospital Resource Impact

**ESAR**
- No waiting time
- OR time\(^2\)
- Fluoro time\(^2\)
- Total cost\(^4,5\)
- Reinterventions\(^6\)

**FEVAR**
- 4-6 week wait time\(^3\)
- 2X OR time\(^1,4\)
- 2X fluoro time\(^3\)
- 2X total cost\(^4,5,8\)
- 3X reintervention rate\(^7\)

**CHEVAR**
- No waiting time
- Total cost\(^8\)

**REFERENCES**
2. Average total procedure time from ANCHOR registry 2019 data cut, on file at Medtronic.
5. List prices for Heli-FX and Endurant II main body and Endurant II 124cm limb.
6. ANCHOR 2-year Short Neck Cohort Data.

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Off-the-shelf Options and Sealing Zones Framework

WHAT TO USE AND WHEN

*User experience and hospital resources* play a crucial role in defining a customized therapy algorithm.

<table>
<thead>
<tr>
<th>EVAR</th>
<th>ESAR</th>
<th>CHEVAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treat standard cases using all the seal zone, adapting to it and maintaining it over time</td>
<td>Treat hostile necks off-the-shelf, without involving the renals, securing the seal zone</td>
<td>Treat short necks off-the-shelf, extending the seal zone above the renals</td>
</tr>
</tbody>
</table>

**EFFECTIVE INFRARENAL SEALING ZONE**

<table>
<thead>
<tr>
<th>ADEQUATE</th>
<th>HOSTILE</th>
<th>INADEQUATE</th>
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ESAR + Endurant™ II/IIIs Stent Graft

✓ ADD STRENGTH TO THE SEAL

ANCHOR Registry data demonstrates favorable outcomes of Heli-FX™ EndoAnchor™ system in hostile AAA sealing zones

<table>
<thead>
<tr>
<th></th>
<th>ANCHOR Primary AAA Arm 4-Yr Data¹ (N=716)</th>
<th>Endurant™ II/IIIs AAA stent graft system + Heli-FX™ EndoAnchor™ system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type Ia endoleak</td>
<td>3.4% (4/117)</td>
<td>0.0% (0/32)</td>
</tr>
<tr>
<td>Migration</td>
<td>0.0% (0/57)</td>
<td>0.0% (0/32)</td>
</tr>
<tr>
<td>Sac Regression</td>
<td>62.1% (64/103)</td>
<td>64.7% (22/34)</td>
</tr>
</tbody>
</table>

¹Hostile necks described as: <15mm, >28mm, >60°, Conical, Ca2+/Thrombus >50%.
1 ANCHOR 4-yr Full Primary AAA Cohort. 2019 data cut. Medtronic data on file.
2 ANCHOR 2-yr Short Neck Cohort Data. 2018 data cut. 2 and 3 year Medtronic data on file.

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ChEVAR + ENDURANT™ II/IIIs Stent Graft

✓ ADD LENGTH TO THE SEAL

128 PATIENTS ENROLLED
24.6 ± 17.4 MONTHS MEAN RADIOLOGIC FOLLOW UP

100% TECHNICAL SUCCESS
1.5 TARGET VESSELS PER PATIENT
4.7 mm PREOPERATIVE NECK LENGTH
18.7 mm NEW PROXIMAL NECK SEAL ZONE

Results from the PROTAGORAS study

PROTAGORAS study shows robust outcomes of standardized use of ChEVAR in inadequate IR sealing zones

1.6% New onset Type Ia endoleaks
95.7% Primary patency of chimney grafts
68% Sac Regression
93.1% Freedom from chimney graft-related reinterventions


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FEVAR remains gold standard for “above the renal” treatment if patient selection is carefully respected, but ...

Health care systems are driving to decrease resource utilization and increase patient throughput

ESAR and ChEVAR are off-the-shelf, allowing immediate care for hostile and short necks
Thank you

Dr Vikram Puttaswamy
Head of Department
Vascular Surgery
Royal North Shore Hospital
Sydney, Australia