Value of conformability for the success of aortic endovascular repair in the short and long-term

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Disclosures

• Consulting: Abbott, Cook, Cordis, Medtronic, WL Gore & Associates, Terumo Aortic
Conformability affects short and long-term EVAR outcomes

- Proximal neck: Malpositioning and risk of Type I EL
- Aneurysm shrinkage and risk of type II EL and limb kinking/occlusion
- Distal iliac seal: all of the above
Conformability as the way to respect the natural course of the aorta
Let Nature...
...take its course
Let Nature…
...take its course
Conformability in standard anatomies
Conformability in standard anatomies

Ten-year outcome analysis of the Italian Excluder Registry with the Gore Excluder endograft for infrarenal abdominal aortic aneurysms

Giovanni Pratesi, MD, Gabriele Piffaretti, MD, PhD, Fabio Verzini, MD, Giovanni De Blasis, MD, Patrizio Castelli, MD and Carlo Pratesi, MD, Rome, Varese, Perugia, Avezzano, and Florence, Italy

J Vasc Surg 2017
Conformability in challenging proximal and distal anatomies
Secondary Procedures Following Iliac Branch Device Treatment of Aneurysms Involving the Iliac Bifurcation: The pELVIS Registry

Konstantinos P. Donas, MD\textsuperscript{1,2}, Mirjam Inchingolo, MD\textsuperscript{1,2}, Piergiorgio Cao, MD\textsuperscript{3}, Carlo Pratesi, MD\textsuperscript{4}, Giovanni Pratesi, MD\textsuperscript{5}, Giovanni Torsello, MD\textsuperscript{1,2}, Georgios A. Pitoulias, MD, PhD\textsuperscript{6}, Ciro Ferrer, MD\textsuperscript{3}, Gianbattista Pariani, MD\textsuperscript{7}, and Fabio Verzini, MD\textsuperscript{7}, on behalf of the pELVIS Registry collaborators

650 iliac branch in 575 Pts between 2005 and 2015 mean follow-up 32.6±9.9

- 621 Cook ZBIS, 29 Gore IBE
- Overall postop reintervention rate 8.9%
- 30 (4.6%) EIA or CIA occlusion
- 28 (4.3%) type I EL

Conclusion

This large midterm experience with placement of IBDs has shown a low incidence of secondary procedures due to type I endoleaks and occlusions. The main reasons for reinterventions seem to be a short proximal aneurysm sealing zone and the poor conformability of the ZBIS device in elongated EIAs, respectively.
Conformability in challenging distal anatomies
A propensity score-matched comparison of two commercially available iliac branch devices in patients with similar clinical and anatomic preoperative features

Fabrizio Masciello, MD, Aaron Thomas Fargion, MD, Giovanni Pratesi, MD, Walter Dorigo, MD, and Carlo Pratesi, MD. Florence and Rome, Italy
Conformability in challenging proximal anatomies: does it affect short and long-term success?

EVAR standard

EVAR (+Anchors)

BEVAR

FEVAR

CHEVAR

YES, definitively it does
Long-term outcomes of standard endovascular aneurysm repair in patients with severe neck angulation

Nelson F. G. Oliveira, MD, Fredericko Bastos Gonçalves, MD, PhD, Sanne E. Hoeks, PhD, Marie Josee van Rijn, MD, PhD, Klaas Ultee, PhD, José Pedro Pinto, MD, Sander Ten Raa, MD, PhD, Joost A. van Herwaarden, MD, PhD, Jean-Paul P. M. de Vries, MD, PhD, and Hence J. M. Verhagen, MD, PhD.

A higher rate of EL1A was identified among patients with severely angulated necks at 7 years of follow-up (11.4 vs 3.2)

*J Vasc Surg 2018*
Challenging proximal aortic anatomies: is a complex endoTx always necessary?

- Short (< 10 mm)
- Angulated (>60°)
- Wide (>30 mm)
- Conical
- Thrombus
- Calcification
EXCLUDER® Conformable AAA Endoprosthesis with ACTIVE CONTROL System

CONFORMABLE STENT GRAFT:
• Individual stent rows facilitate stent row nesting
• Temporary attachment fiber, once removed, allows conformability at the trunk bifurcation

ENHANCED DEVICE POSITIONING:
• Secondary sleeve over trunk body enhances device repositioning
• GORE ® C3 ® Delivery System functionality included

OPTIONAL ANGULATION CONTROL:
• Angulation wire designed to adjust proximal device angle to optimize seal within flow lumen
• Available when trunk is fully constrained on catheter or partially deployed on catheter
Conformability in challenging proximal anatomies: EXCLUDER® Conformable AAA Endoprosthesis
Conformability in challenging proximal anatomies: EXCLUDER® Conformable AAA Endoprosthesis
Proximal neck
Diameter 16-31 mm
Length ≥ 10 mm if PN angulation is < 60°
Length ≥ 15 mm if PN angulation is < 90°

Iliac artery
Diameter 8–25 mm
Distal seal zone length ≥ 10 mm
Axes adequate to accept 12-18 F introducer sheaths
Complex anatomies in abdominal aorta:
EXCLUDER® Conformable AAA Endoprosthesis
Importance of Clinical Data

FDA Pivotal Study

Patient Enrollment:
190 patients up to 56 US sites (ongoing) 28 pts

BSET-CLEVAR UK Registry – British Society for Endovascular Therapy- Conformable EndoVascular Aneurysm Repair Registry

Patient enrollment:
200 patients from up to 30 UK sites

EXCeL Registry - EXcluder Conformable real Life

Patient Enrollment:
150 patients from 10 European sites

Clinic of Vascular and Endovascular Surgery
Ospedale Policlinico San Martino - HSM
University of Genoa
Chief: Prof. D. Palombo
Gore Excluder Conformable with active Control: Genoa Experience

- October 2018 – December 2019
- 27 patients, Median age 78 years (range 58-94)
- Mean Neck length: 17.3 mm ± 8.6
- Mean Infrarenal neck angulation: 60.5 ° ± 21.6

Aortic-bisiliac

17 pts

Aortic-bisiliac + iliac branch

9 pts

Aortic-bisiliac + bilateral iliac branch

1 pts
Outcomes

Mean follow-up duration: 5.16 months ± 3.9 (range 1-12)

<table>
<thead>
<tr>
<th>Intraoperative</th>
<th></th>
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<tbody>
<tr>
<td>Time of intervention, mean ± SD</td>
<td>116 ± 41.1</td>
<td></td>
</tr>
<tr>
<td>Fluoroscopy time, mean ± SD</td>
<td>33:58 ± 17:45</td>
<td></td>
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<tr>
<td>DAP, mean ± SD (cGy.cm²)</td>
<td>19325.8 ± 20231.1</td>
<td></td>
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<tr>
<td>Total pEVAR under local anaest</td>
<td>15 (55.5%)</td>
<td></td>
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<tr>
<td>Concomitant IBE</td>
<td>10 (37.0%)</td>
<td></td>
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<tr>
<td>Angulation control</td>
<td>14 (51.8%)</td>
<td></td>
</tr>
<tr>
<td>Repositionability</td>
<td>7 (25.9%)</td>
<td></td>
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<thead>
<tr>
<th>Early outcomes</th>
<th>n</th>
<th>%</th>
</tr>
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<tbody>
<tr>
<td>Technical success</td>
<td>27</td>
<td>100</td>
</tr>
<tr>
<td>Type I endoleak</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Type II endoleak</td>
<td>7</td>
<td>25.9</td>
</tr>
<tr>
<td>Limb occlusion</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Reintervention</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Non graft-related complication</td>
<td>2*</td>
<td>7.4</td>
</tr>
<tr>
<td>Mortality</td>
<td>1</td>
<td>3.7</td>
</tr>
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*1 Respiratory complication, 1 fatal IMA
Conformability in challenging proximal anatomies:
EXCLUDER® Conformable AAA Endoprosthesis
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Conformability in challenging proximal anatomies: EXCLUDER® Conformable AAA Endoprosthesis
Conformability: a fashionable word
Conformability analysis in abdominal aorta: need to upgrade from 2D to 3D approach

- Planning
- Intraoperative
- Follow-up
3D planning upgrade: proximal neck angle measurement method

Step #1
Place a centerline on the 3D reconstruction. Rotate the image to maximize the projected angle.

Step #2
Place three markers on centerline per guidance:
- one marker at the angle inflection point within the proximal aortic neck
- a second marker proximal to the inflection point at the lowest renal artery or distal to lesser angle in the proximal aortic neck
- a third marker at the level distal to inflection point and proximal to any angle in the aneurysm

Step #3
Measure the angle using the 3 points identified. If multiple angles exist, identify the largest one.
3D intraoperative upgrade: 3D-fusion and cone-beam CT scan
A new methodology was validated to quantify and visualize position, apposition, and expansion of the endograft within the aortic neck after EVAR.

Accurate post-EVAR analysis of these endograft dimensions is feasible and reproducible.
Aim of the study

To analyze precision of deployment and conformability of the GORE® EXCLUDER® Conformable Endoprosthesis with active control system in AAA patients.

Aortic neck endograft apposition and aortic curvature changes analysis at different aorto-iliac segments.

Comparison between preoperative and 30-day CTA after EVAR for AAA.
Apposition analysis

Pre-operative available aortic neck surface area
2495.25 mm²

Post-operative apposition & non-apposition surface area
1760.17 mm² & 542.17 mm²

- Mean aortic neck coverage (apposition/total)
  78.92% ± 16.44%

- Mean shortest apposition length
  23.5 mm
Curvature analysis

<table>
<thead>
<tr>
<th>Curvature</th>
<th>Pre-operative mean [range]</th>
<th>Post-operative mean [range]</th>
</tr>
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<tbody>
<tr>
<td>Main body, average, m⁻¹</td>
<td>23.9 [9-30]</td>
<td>21.3 [9-28] p=.02</td>
</tr>
<tr>
<td>Main body, max, m⁻¹</td>
<td>68.7 [16-107]</td>
<td>56.7 [18-102]</td>
</tr>
<tr>
<td>Infrarenal neck, average, m⁻¹</td>
<td>25 [21 – 29]</td>
<td>23 [18 - 26]</td>
</tr>
<tr>
<td>Infrarenal neck, max, m⁻¹</td>
<td>65 [51 – 92]</td>
<td>62 [41 - 77]</td>
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Conclusions

• The new GORE® EXCLUDER® Conformable AAA Endoprosthesis with Active Control has been designed to provide repositionability, conformability, and, for the first time, optional angulation control.

• Effectiveness of conformability in the short and highly angulated neck is under clinical evaluation to provide safety and efficacy in the short and long term.

• Multidisciplinary integrated team-approach is mandatory for an accurate clinical and engineered conformability 3D analysis.
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