Conformability of new generation TEVAR device: Is there a difference?

Pr Ludovic Canaud
Montpellier, France
Angulation of the proximal landing zone

Angulation $>60^\circ$ : 80% of patients

Bortone Aet al. Circulation 2002

Endovascular repair of the thoracic aorta
Bird-peak configuration

- **Migration**  
  *Kalliafas JEVT 2002*

- **Collapse**  
  *Canaud JTCS 2009*

- **Endoleak**  
  *Dake Radiology 2010*
Thoracic stent-graft collapse: 4 cases

- **Indication:**
  - Traumatic aortic rupture: 2
  - Dissecting aneurysm: 1
  - Acute type B dissection: 1

- **Stent-graft:** Tag (Gore)

- **Treatment:**
  - Endovascular treatment:
    - Second stent-graft: 2
    - Balloon expandable stent: 1
  - Open removal of the stent-graft

_Canaud L et al._

_J Thorac Cardiovas Surg_ 2009

*Factors favouring thoracic stent-graft collapses.*
Anatomical features

- Mean proximal aortic diameter: 23.1 mm
- Mean oversizing: 24.75%
- Mean aortic arch angulation: 104.5°
- Poor apposition of the stent-graft
**Thoracic stent-graft collapse**

<table>
<thead>
<tr>
<th>Year</th>
<th>No.</th>
<th>Mortality</th>
<th>Endograft</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>1</td>
<td>0</td>
<td>Endofit (1)</td>
</tr>
<tr>
<td>2005</td>
<td>1</td>
<td>0</td>
<td>TAG (1)</td>
</tr>
<tr>
<td>2007</td>
<td>7</td>
<td>28.6% (2)</td>
<td>TAG (6) Zenith (1)</td>
</tr>
<tr>
<td>2007</td>
<td>1</td>
<td>0</td>
<td>TAG (1)</td>
</tr>
<tr>
<td>2007</td>
<td>3</td>
<td>0</td>
<td>TAG (3)</td>
</tr>
<tr>
<td>2007</td>
<td>6</td>
<td>0</td>
<td>TAG (6)</td>
</tr>
<tr>
<td>2007</td>
<td>1</td>
<td>0</td>
<td>TAG (1)</td>
</tr>
<tr>
<td>2008</td>
<td>3</td>
<td>0</td>
<td>TAG (3)</td>
</tr>
<tr>
<td>2008</td>
<td>1</td>
<td>0</td>
<td>TAG (1)</td>
</tr>
<tr>
<td></td>
<td>29</td>
<td>6.8% (2)</td>
<td>TAG (27) Zenith (1)Endofit (1)</td>
</tr>
</tbody>
</table>

Any difference of thoracic stent graft conformability?
Conformability of the first generation of SG

To assess **fixation** of 4 thoracic stent-grafts as a function of:

- **aortic arch angulation**
- **oversizing**

Canaud L et al. JEVT 2008

*Performance of thoracic stent-grafts.*
Stent-grafts

Valiant Medtronic
24, 26 mm

Zenith TX Cook
22, 24, 26 mm

Tag Gore
26 mm

Relay Bolton™
24 mm
Results

- Valiant: no lack of device wall apposition up to 140°

- Other stent-grafts:
  - Zénith from 70°
  - Relay from 80°
  - TAG from 90°
Conclusions

- Major implications of stent-graft design
  - Radial force (confirmed by macroscopic intima injuries)
  - Proximal anchorage system
    - Presence of open bare or covered stent segment
    - Hooks seems to not improve stent-graft fixation

- Increased oversizing: wrinkling of the prosthesis
Stent-Graft Evolution

- Zénith → Zénith Proform  Nov 2009
- Valiant → Valiant Captivia  Oct 2010
- Relay → Relay NBS plus  Mar 2011
- TAG → Conformable TAG  Apr 2011
Device Conformability matters in Thoracic Stenting

Any improvement in stent-graft conformability?

Conformable TAG  Zénith Proform  Relay NBS Plus  Valiant Captivia
Experimental study

- 10 Fresh non-aneurysmal human aortas
  - Mean age 41.6 years, range 18–57
  - Died a maximum of 4 days previously (mean 2.9 days)
  - The mean diameter 20.5 mm (19–24 mm)
  - Mean delay between aorta harvest and experimental procedures < 30 min

- Fresh aorta: Histological analysis
  Microscopical analysis: to ensure the presence of a 3-layer wall
Test

Measurement of the intraluminal lip length

As a function of:
Oversizing: 5 to 37%
Angulation: 70 to 140° (10°)
Results

- **Zénith Proform vs Zénith TX**
  
  Lack of device wall apposition
  - Since 110° (70°)
  - Up to 4 mm

- **C-TAG vs TAG:**
  
  Proximal Bare stent
  - Since 120° (90°)
  - Up to 2 mm
Results

- **Relay NBS Plus vs Relay**
  
  Proximal Bare stent
  - Since 110° (80°)
  - Up to 4 mm

- **Valiant Captivia vs Valiant:**

  Always apposed
Conclusion

1. Improved conformability of the last generation of Stent-Grafts

Modification of the devices and/or their deployment system

2. Valiant remains the most conformable Stent-Graft


Improvement in conformability of the latest generation of thoracic stent grafts.
Clinical impact

- Endovascular repair of acute traumatic transection
  - 2001-2011
  - 48 patients

- 2 groups:
  - First generation of TEVAR until 2007
  - Last Generation of TEVAR
## Clinical impact

<table>
<thead>
<tr>
<th></th>
<th>First Generation</th>
<th>Last Generation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>32</td>
<td>16</td>
</tr>
<tr>
<td><strong>ISS</strong></td>
<td>37 ± 5</td>
<td>34 ± 7</td>
</tr>
<tr>
<td><strong>Lesions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>False aneurysm</td>
<td>23</td>
<td>13</td>
</tr>
<tr>
<td>Hematoma</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Free Rupture</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

Statistically comparable
Results

Aortic Mortality

No aortic death groupe 1 and 2

Completed follow-up 100%
## Results

<table>
<thead>
<tr>
<th></th>
<th>First generation</th>
<th>Last generation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I endoleak</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>SG Collapse</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Inadvertent coverage</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Iliac rupture</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Morbidity</td>
<td>18.7</td>
<td>6.2</td>
</tr>
</tbody>
</table>

\[p = 0.0003\]
**Conclusion**

- *Improvement in conformability of the Stent-Grafts used*
  - Decreased morbidity
  - Disappearance of complications related to lack of device conformability:
    - Stent-Graft collapse
    - Type I endoleak

*Canaud L et al. JEVT 2011*

*Impact of stent-graft development on outcome of endovascular repair of acute traumatic transection of the thoracic aorta.*
Conclusion
Stent-graft conformability is the keystone

1 Experimental results

2 Clinical results

3 Firm’s marketing
Conformability of new generation TEVAR device: Is there a difference?

Pr Ludovic Canaud
Montpellier, France