Update On Advantages Of Custom-Made Precurved Fenestrated Endograft For Arch Lesions:
Durable Long-Term Results Are Better Than with Other Endo Techniques

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Disclosure
none

Latest Case: 2015 Nov. 13 at TWMU Customized PCFE

Pre-curved fenestrated endograft
Clinical Trial

Multi-center clinical trial
All devices designed by Yokoi M.D.

Follow up of clinical outcome
~60 months
Jan. 2009 ~

Thoracic aortic aneurysm (n=78)
Gender (m:f) 59 : 19
Age 72.9 (52-86)

Comorbidities
- Hypertension 89.7%
- Smoking 76.1%
- Heart disease 41.9%
- Cerebrovascular disease 29.1%
- Pulmonary disease 28.2%
- Renal dysfunction 12.8%
Landing Zones
Thoracic aortic aneurysm (n=78)

Early Results
- Procedural time
  136±53 min
- 30 day survival
  98.7%
- Device deployment
  98.7%
- Prox. Type I Endoleaks (n = 4)
  5.3%
- Branch occlusion
  0%
- Migration > 5 mm (n=2)
  2.6%
- Stroke (n=6, no symptom remains: 4)
  7.9%

Proximal end of Device

Long-term Results
Type I Endoleaks

Follow-up with CT
n =
30day 1y. 2ys. 3ys. 4ys. 5ys.
78 71 64 53 46 39

Long-term Results
Change in Aneurysm Size

Follow-up with CT
1y. 2ys. 3ys. 4ys. 5ys.
71 64 53 46 39

Follow-up with CT
71 64 53 46 39

Follow-up with CT
71 64 53 46 39

Follow-up with CT
71 64 53 46 39

Changes of aneurysm size with morphological changes
5 of 7 Enlargement cases without Endoleak

All-cause Mortality
K-M estimates at 5 years
F-TEVAR : 16.5%
TAA-Related Mortality

K-M estimates at 5 years
F-TEVAR : 7.7%

- Low mortality in All-cause and TAA related
- Low stroke rate in these high risk patients
- No branch occlusion
- No device related stroke
- No retrograde aortic dissection
- No device migration to distal side
- Endoleak and enlargement rate are relevant

PCFE “Najuta”  Designed by Yokoi M.D.
1st year(Jun.2013~May.2014) post-marketing surveillance

- N = 123
  Early results
  - 30 day survival 98.4 %
  - Stroke ( n=4 ) 3.1 %
  @ 1 year
  - Prox. Type I Endoleaks ( n=4 ) 3.9%
  - Branch occlusion 0 %
  - 1 Fracture caused by bird beak

Long-term Results summary

- Low mortality in All-cause and TAA related
- Low stroke rate in these high risk patients
- No branch occlusion
- No device related stroke
- No retrograde aortic dissection
- No device migration to distal side
- Endoleak and enlargement rate are relevant

Early (perioperative~30day) Result
Precurved Fenestrated vs Branched Device

<table>
<thead>
<tr>
<th>Period</th>
<th>N of Pt</th>
<th>Mortality</th>
<th>Endoleak</th>
<th>stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCFE clinical trial</td>
<td>Jan.2008~Aug.2009</td>
<td>78</td>
<td>1.3%</td>
<td>11.4%</td>
</tr>
<tr>
<td>Cook inner branch</td>
<td>Sep.2009~May.2013 (Following 28)</td>
<td>38</td>
<td>13.2%</td>
<td>NA</td>
</tr>
<tr>
<td>Bolton arch branch</td>
<td>~Aug.2014</td>
<td>26</td>
<td>11.5%</td>
<td>3.0%</td>
</tr>
<tr>
<td>PCFE post-marketing surveillance</td>
<td>Jun.2013~May.2014</td>
<td>123</td>
<td>1.6%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Early (perioperative~30day) Result
Precurved Fenestrated vs Chimney and hybrid

<table>
<thead>
<tr>
<th>Period</th>
<th>N of Pt</th>
<th>Mortality</th>
<th>Endoleak</th>
<th>stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCFE clinical trial</td>
<td>Jan.2008~Aug.2009</td>
<td>78</td>
<td>1.3%</td>
<td>11.4%</td>
</tr>
<tr>
<td>Chimney technique</td>
<td>2012~published</td>
<td>Over 10cases</td>
<td>3.8~16.6%</td>
<td>0~31%</td>
</tr>
<tr>
<td>Hybrid repair</td>
<td>2012~published</td>
<td>Over 10cases</td>
<td>3~11%</td>
<td>0~16%</td>
</tr>
<tr>
<td>PCFE post-marketing surveillance</td>
<td>Jun.2013~May.2014</td>
<td>123</td>
<td>1.6%</td>
<td>NA</td>
</tr>
</tbody>
</table>

Long-term (over 2y~) Results
Precurved Fenestrated vs Chimney and hybrid

<table>
<thead>
<tr>
<th>mean f/u</th>
<th>N of Pt</th>
<th>Mortality</th>
<th>TAA Related</th>
<th>Type 1 Endoleak</th>
<th>Additional intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCFE clinical trial</td>
<td>42 months ~60months</td>
<td>78</td>
<td>16.5%</td>
<td>7.7%</td>
<td>3.5%</td>
</tr>
<tr>
<td>Mangiardi et al</td>
<td>38.8 months ~131months</td>
<td>26</td>
<td>19.2%</td>
<td>3.8%</td>
<td>23.1%</td>
</tr>
<tr>
<td>Zerwees et al</td>
<td>48.3 months ~62months</td>
<td>50</td>
<td>30%</td>
<td>NA</td>
<td>4%</td>
</tr>
<tr>
<td>Chiesa et al</td>
<td>27.3 months ~94months</td>
<td>179</td>
<td>9.5%</td>
<td>2.2%</td>
<td>Not clearly reported</td>
</tr>
</tbody>
</table>

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**Discussion**

*Simplified arch repair with precurved fenestrated endograft*

- Perioperative mortality and morbidity of fenestrated arch repair are better than other endo technique.
- Long-term effectiveness is almost same with other intervention.
- No long-term migration (to distal side) without branch occlusion suggests pre-curved design and Zone 0 landing secure the device stability in the aortic arch.

**Latest Device : Customized PCFE based on Najuta**

**Critical case AoD : 57 M**

Pre-operative 3D-CT

**Critical case AoD : Design of device**

Pre-operative 3D-CT