TREO: From Evidence to Clinical Practice

Dr Andrew Winterbottom
Disclosure

Speaker name: Dr Andrew Winterbottom

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☑️ Other(s) speaking, proctor, travel

☐ I do not have any potential conflict of interest
TREO®
ABDOMINAL STENT-GRAFT SYSTEM

Bolton Medical
A WerfenLife Company
Treo a real 3 piece system with multiple size options for treatment VERSATILITY
The benefit of longer bodies is to achieve less displacement forces in the stent-graft structure and an easier cannulation.

Length bodies / displacement forces correlation in abdominal aorta

Adjustable zones allows you to maximise the iliac fixation length which has been demonstrated as significant predictor for endograft migration. 

Adjustable leg landing zones for versatile treatment and adjustment to the distal landing zone

10mm Contralateral Adjustable Zone

30mm Ipsilateral Adjustable Zone
The overlap of the two first proximal stents provides optimal sealing even in tortuous anatomies

- TREO is indicated in neck lengths of:
  - 10 mm or greater with an infrarenal angle of less than 60 degrees
  - 15 mm or greater with an infrarenal angle between 60 and 75 degrees
Range of Cuffs sizes

**GRAFT DIAMETER**

20.22.24.26

28.30.33.36 mm

**TRANSRENAL SEGMENT**

17 mm

**LENGTHS**

40.55.70 mm
TREO is the only EVAR graft designed with both suprarenal and infrarenal active fixation.

**SUPRARENAL FIXATION**
Suprarenal laser cut barbs allow for primary proximal fixation once deployed.

**INFRARENAL FIXATION**
Infrarenal laser cut barbs provides supplemental fixation. Forces increases proportionally with the infrarenal angulation.
The infrarenal barbs highly contribute to migration resistance in large angulated necks.

**Infrarenal Barb Contribution Alone**
(Suprarenal Barbs Cut Off Stent for Test)

<table>
<thead>
<tr>
<th>Straight</th>
<th>Small Angle</th>
<th>Large Angles</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.9 N</td>
<td>6.41 N</td>
<td>9.75 N</td>
</tr>
<tr>
<td>9.75 N 50% Increase</td>
<td>12.88 N 100% Increase</td>
<td></td>
</tr>
<tr>
<td>1-2 Barbs Engaged</td>
<td>1-2 Barbs Engaged</td>
<td></td>
</tr>
</tbody>
</table>

Bolton Medical
A WerfenLife Company
Superior **FIXATION** within stent modules with the unique Lock-Stent to avoid modular disconnection

**LOCK STENT TECHNOLOGY**
Rounded barbs located at the base of main body lock stent are designed specifically to engage with leg extensions to add resistance against module disconnection and deliver safe variable distal adjustment.
INTRODUCER SHEATH
Low profile sheath with hydrophilic coating and flexible tip and for easier navigation.

PROXIMAL CLASPING
The clasp mechanism keeps control on the deployment allows cranial and caudal adjustment before the bare stent is released for precise placement.

PRECISE DELIVERY SYSTEM
The mechanical deployment provides controlled and stable stent-graft deployment.

<table>
<thead>
<tr>
<th>MAIN BODY D.S.</th>
<th>LEG EXTENSION D.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 to 36mm</td>
<td>20 to 28mm</td>
</tr>
<tr>
<td>19 F. (OD)</td>
<td>18 F. (OD)</td>
</tr>
<tr>
<td>30 to 36mm</td>
<td>20 to 28mm</td>
</tr>
<tr>
<td>19 F. (OD)</td>
<td>18 F. (OD)</td>
</tr>
<tr>
<td>30 to 36mm</td>
<td>20 to 28mm</td>
</tr>
<tr>
<td>19 F. (OD)</td>
<td>18 F. (OD)</td>
</tr>
<tr>
<td>30 to 36mm</td>
<td>20 to 28mm</td>
</tr>
<tr>
<td>19 F. (OD)</td>
<td>18 F. (OD)</td>
</tr>
<tr>
<td>30 to 36mm</td>
<td>20 to 28mm</td>
</tr>
<tr>
<td>19 F. (OD)</td>
<td>18 F. (OD)</td>
</tr>
</tbody>
</table>
LOW PROFILE DELIVERY SYSTEM

TWO WAY FLUSH PORT

DETACH MECHANISM

DETACHABLE SHEATH
The sheath detaches from the Delivery System providing less access vessel manipulation and quicker access

ADVANCED HEMOSTASIS VALVE
Double valve mechanisms, one passive and one active with 10 different positions, secures hemostasis

Bolton Medical
A WerfenLife Company
RELEASE MECHANISM
Streamlined mechanism releases proximal clasp and prepares system for removal
**SUPRARENAL FIXATION**
Suprarenal barbs are completely covered during deployment until release of the bare stent.

**INFRARENAL FIXATION**
Infrarenal barbs are obscured in “valleys” prior to final deployment.
PROXIMAL CLASPING
Allows cranial and caudal adjustment before the bare stent is released

NO TIP CAPTURE MANOEUVRE
Featuring the reliable mechanism of RELAY the clasping mechanism moves down and no tip recapture is needed

NO SNAGGING
The smooth design of the clasping mechanism avoids catheter snagging even in highly angulated anatomies

Bolton Medical
A WerfenLife Company
## Treo Phase II US Trial: Effectiveness Measures*

<table>
<thead>
<tr>
<th>Endovascular Events</th>
<th>Treatment (n = 83)</th>
<th>1 mon (n = 70)</th>
<th>6 mon (n = 39)</th>
<th>12 mon (n = 8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoleak (Type I, III, IV)</td>
<td>0% (0/83)</td>
<td>1.43% (1/70)</td>
<td>2.56% (1/39)</td>
<td>0% (0/8)</td>
</tr>
<tr>
<td>Stent-Graft Occlusion / Loss of Patency</td>
<td>0% (0/83)</td>
<td>0% (0/70)</td>
<td>0% (0/39)</td>
<td>0% (0/8)</td>
</tr>
<tr>
<td>Migration</td>
<td>N/A</td>
<td>N/A</td>
<td>0% (0/39)</td>
<td>0% (0/8)</td>
</tr>
<tr>
<td>Wireform Fracture</td>
<td>0% (0/83)</td>
<td>0% (0/70)</td>
<td>0% (0/39)</td>
<td>0% (0/8)</td>
</tr>
</tbody>
</table>

Sac size changes (relative to diameter at 1-month evaluation)

- **No change (increase/decrease ≤ 5mm)**
  - Treatment: N/A
  - 1 mon: N/A
  - 6 mon: 64.10% (25/39)
  - 12 mon: 25% (4/8)

- **Decrease (> 5 / < 10mm)**
  - Treatment: N/A
  - 1 mon: N/A
  - 6 mon: 28.21% (11/39)
  - 12 mon: 12.5% (1/8)

- **Decrease (≥ 10mm)**
  - Treatment: N/A
  - 1 mon: N/A
  - 6 mon: 7.69% (3/39)
  - 12 mon: 37.5% (3/8)

- **Increase (> 5mm)**
  - Treatment: N/A
  - 1 mon: N/A
  - 6 mon: 0% (0/39)
  - 12 mon: 0% (0/8)

- Conversion to open surgery
  - Treatment: 0% (0/83)
  - 1 mon: 0% (0/70)
  - 6 mon: 0% (0/39)
  - 12 mon: 0% (0/8)

---

*Data presented is not for the completed trial. This data was pulled June 2015 for 83 patients. US trial currently has 112 patients enrolled.
Customised solutions available within the Treo custom made program

PROGRAM DESCRIPTION
Our custom program strives to deliver you more design tools possibilities to treat patients with aortic disease.

CUSTOM SOLUTIONS
Current available designs
- Tapers
- Reverse/Extreme Tapers
- Extreme Lengths
- Scallop
- Single Fenestration

Future available designs
- Double Fenestration
- Double Fenestration w/ Scallop

DELIVERY TIME
3 weeks (From your design approval to delivery)

Custom made devices do not bear the CE mark. According to medical device law, physician prescription is required. Each custom made device is unique.
TREO: From Evidence to Clinical Practice
TREO: From Evidence to Clinical Practice

Dr Andrew Winterbottom