The Bolton Ascending Aortic Endograft Device: Technical aspects, advantages, and limitations

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Conflicts of Interest

- Medtronic
  - Consultant
  - Speaker's bureau
- W. L. Gore
  - Proctor
- Bolton Medical
  - Scientific advisory board
  - Speaker's bureau
- Endologix / Nellix
  - Consultant
  - Proctor

Endovascular Treatment of the Ascending Aorta: How it differs from the thoracoabdominal aorta

- The aortic arch needs to be traversed:
  - Helical curvature varies with age and type of aortic lesion
- Area to be covered/excluded is relatively short
  - Coronary arteries and the brachiocephalic trunk (~ 8 cm in length)
- Access to deliver devices do not have to be transfemoral based, shorter distance to target improves control and deployment accuracy
  - Carotid, Axillary, transapical access available
- Deployment of modular branched grafts originate from target vessel not from the endoprosthesis main body

Ascending Technology with Relay® NBS

1st patient treated for Type A dissection (University of Vienna, 2006)
Most recent follow-up: No migration, endoleak, neurological sequelae, or stent fracture

1st Generation Bolton NBS for ascending exhibited oblique deployment

Deployment control and avoid retrotlex achieved through Supporting wires & V-patch configuration

Atraumatic Support Wires hold the inferior portion of the graft to avoid retrotlex

Stent-graft inside a soft 12 mm nylon sheath

Stent-graft moves towards the inner curve of the aorta & perpendicular to the aortic axis
Levers are used to stabilize and guide proximal edge of the stent-graft to make aortic wall contact.

Tip capture released with levers still holding proximal apices.

Clinical Experience with Relay® NBS

Experience in Europe:
- Spain
- France
- Germany
- England
- Austria
- Switzerland
- Hungary
- Poland
- Italy

Maximum diameter 46 mm
Length 4 – 7 cm

Pseudoaneurysm Ascending Aorta after cardiac surgery (Dr. Riambau EVT – 2014)

Oblique deployment avoided

Ascending Cases Experience

Case Experience Summary
- 25 patients implanted with revised NBS Plus design 2013-15
  - All via custom made requests throughout Europe
- All devices were implanted in Zone 0
  - Delivered via transfemoral access
- Deemed successful if the device was delivered without complication → Three cases deemed unsuccessful:
  1. Difficulty reaching treatment site
  2. Distal deployment required addition 2nd device
  3. Proximal deployment with partial coverage of the left coronary artery → Open surgical repair

Ascending Technology with Relay® NBS

Future Direction
- Early feasibility trial US
  - Expect protocol review by FDA by Q2-3 2016
  - Patient enrollment in Q4 2016
- Continue to learn from custom made experience in Europe to improve platform
- Combination with dual branch technology would allow for secure distal fixation when dealing with Type A dissections