Custom-Made Scallops In Relay TEVAR: Results Of The French “REP” Study

A Step Forward To An Off-The-Shelf Device

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Disclosure

Speaker name: Jean-Marc ALSAC

• Speaker, Proctor for Educational Training
  – TERUMO AORTIC
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Proximal Scallop Concept
French REP Study

« Relay Echancrées Proximales » (REP) Study : NCT : 01099215

- Safety & Efficacy Analysis Of Relay Proximal Scallop
- via Terumo Aortic custom-made program outside the US
- In non-septic, acquired disease of DTA located close to SAT

- Endpoints: Cumulative Morbidity / Mortality
  - Death all cause-Stroke-TIA-Paraplegia
  - Left brachial ischemia
- Follow-up : 30 day / 6 mo / 1 year
- January 2015 – May 2018
- Enroll 40 Patients / 10 centers
- ≈ 2 implantations / center (1 to 15)
Arch Repair Indications

• 40 patients (83% ♂, 71 ± 12 yo) - unfit for Open Arch Repair
• Indications:
  – 8 Chronic Aortic Dissection: 20%
  – 4 Type 1A Endoleaks of previous TEVAR: 12.5%
  – 13 Fusiform Atherosclerotic Aneurysms: 32.5%
  – 15 Saccular Aneurysms / Penetrating Ulcers: 35%
Targeted proximal sealing zones

Zone 2: 15 patients – 37 %
Zone 1: 18 patients
Zone 0: 7 patients – 63 %
Proximal Scallop Endografts

- Median width = 20 mm (18 to 22)
- Median length = 30 mm (10 to 55)
- Detectable by markers

Custom made Stentgraft: RELAY Plus

- Proximal Bare stent with capture
- Median Diameter = 40 / 36
- Available within 3 to 6 weeks
Technical Advantages

• **Loaded on Nitinol Pre-curved Inner Catheter:**
  
  – Tracking to the natural curvature of the arch
  
  – Enhances alignment
  
  – Scallop Self-Orientation
  
  – No SAT Canulation
  
  – No Snaring of wires in the Arch
  
  – No Need to Cross the Valve
  
  – No Need for Rapid Passing
Peroperative Results (n=40)

- 97.5% implantation success
- 13 Cervical Debranching (34%)
  - 7 RCCA-LCCA + 10 LCCA-LSA
- Procedural time = 170 min (112-228)
- Fluoroscopy time = 11 min (7-17)
- No Unexpected SAT occlusion
- No conversion to OR
- No Retrograde Aortic Dissection
In Hospital Mortality = 5 %

No Stroke / 2 TIAs = 5 %

No Paraplegia / 1 Paraparesis

No Stentgraft Migration

Endoleaks = 12.5 % (n=5)
  Type IA=1, IB=1, II=2, III=1

No Aneurysm growth or rupture
1 Year Results (n = 36)

- Mortality all causes = 17.5% (n = 7)
- No Stroke / 3 TIA = 7.5% (n=3)
- 100% patency of targeted SAT
- No Stentgraft Migration
- Endoleaks = 15% (n=6)
  IA=1, IB=1, III=1, II = 3
- 1 reintervention = Type II embolization
- 97% Decrease/Stable lesion diameter
- No Aneurysm rupture
Summary

• 1st National Multicentric Prospective Study on Relay PS
• 1st implantations for most Centers (2 / center)
• Learning curve without expert proctoring for most cases
• Safe, Precise & Reproducible Implantations (No SAT Occlusion)
• Acceptable postop rates Stroke (TIA 5%) & Mortality (10 %)
• Far less complex procedures than Branched devices:
  • Self-orientation / No SAT Canulation / No Valve Crossing
• Safe Exclusion of Distal Arch Lesions at 1 year
Endovascular treatment of thoracic aortic aneurysms with a short proximal landing zone using scalloped endografts.

Alsaifi A, Bicknell CD, Rudarakanchana N, Kashet E, Gibbs RG, Cheshire NJ, Jenkins MP, Hamacy M.

Endovascular Solutions for Thoracic Aortic Aneurysms with Challenging Anatomies.


Proximal Scallop in Thoracic Endovascular Aortic Aneurysm Repair to Overcome Neck Issues in the Arch.

Ben Abdallah I, El Batti S, Sapeval M, Abu Rieili N, Fabiani JN, Julia P, Alsaif JM.

Results From a Nationwide Registry on Scalloped Thoracic Stent-Grafts for Short Landing Zones.

van der Walde E, Bakker OJ, Tieliu IP, Zeebregts CJP, Heijmen RH.

Endovascular Treatment of Aortic Arch Lesions Using Scalloped Endografts.

Worldwide Experience

More Data to be collected …

TiGER: Terumo Aortic Global Endovascular Registry

Multi-arm, multi-center, prospective, observational registry.

Capturing the Entire Aorta:
- Thoracic - TEVAR
- Abdominal - EVAR
- Custom – FEVAR & Custom
- Other – IIAA

Enrollment Open!
- Data collection pre-op to 10 years follow up
- Minimum of 1,000 enrolled globally
- No Upper Limit
For Acute Aortic Syndromes close to SAT:
- Traumatic injuries of thoracic aorta
- Acute Type B dissections
- Ruptured DTAA or Arch PAU

Standardized proximal scallop is feasible
- Anatomical study on SAT on 35 AAS

20 / 30 mm predesigned Scallop would fit 95%