Custom-made Scallop thoracic stent-graft to extend short proximal landing zones without revascularization

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Disclosures

Consultant: Bolton Medical/ Medtronic/W.L. Gore/ Cordis/ Aptus /iVascular/Lombard

Proctor: Cook Medical/ Bolton Medical/ Medtronic/ W.L. Gore/Lombard/Aptus/Cordis

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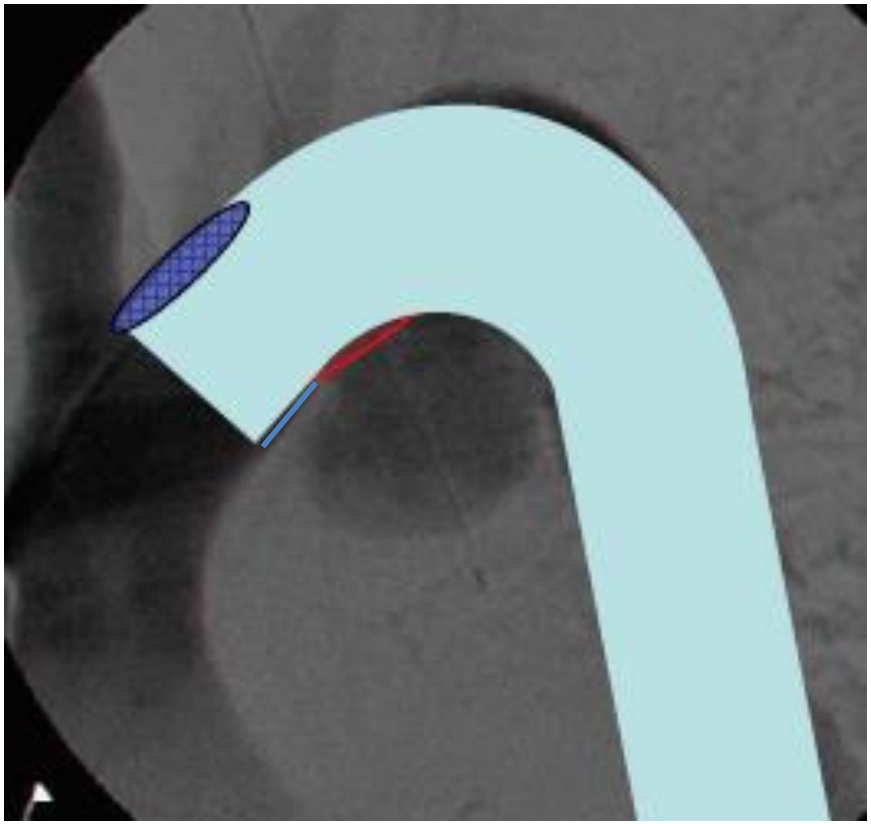
Concept of Proximal Scallop



- Increase proximal landing zone
- Improve proximal sealing (inner curvature)
- Keep SAT perfused
- Avoid debranching, single branch or chimney

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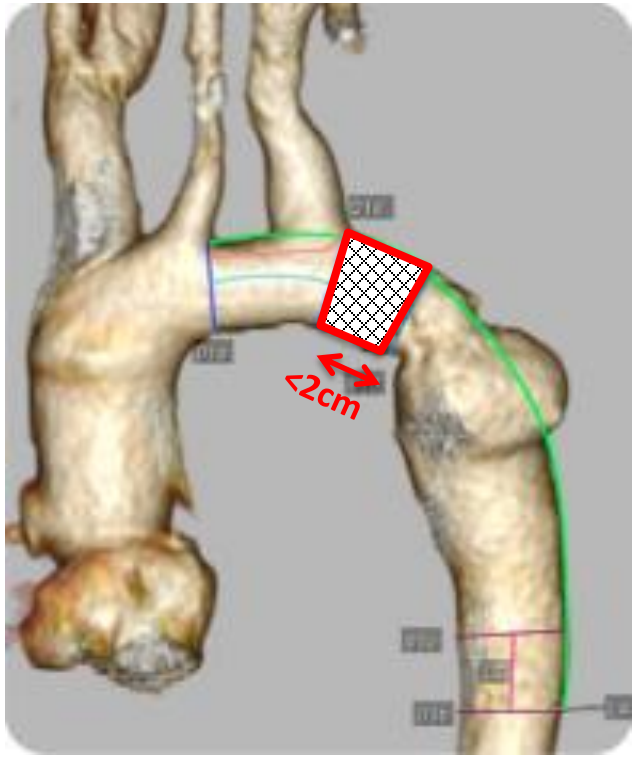
Patient Anatomical Requirements

- Patients with a thoracic aortic aneurysm with a proximal landing zone of <20 mm (inner curvature)

- Patients with a significant angulation of the arch that need a longer length of landing zone for adequate graft apposition and seal



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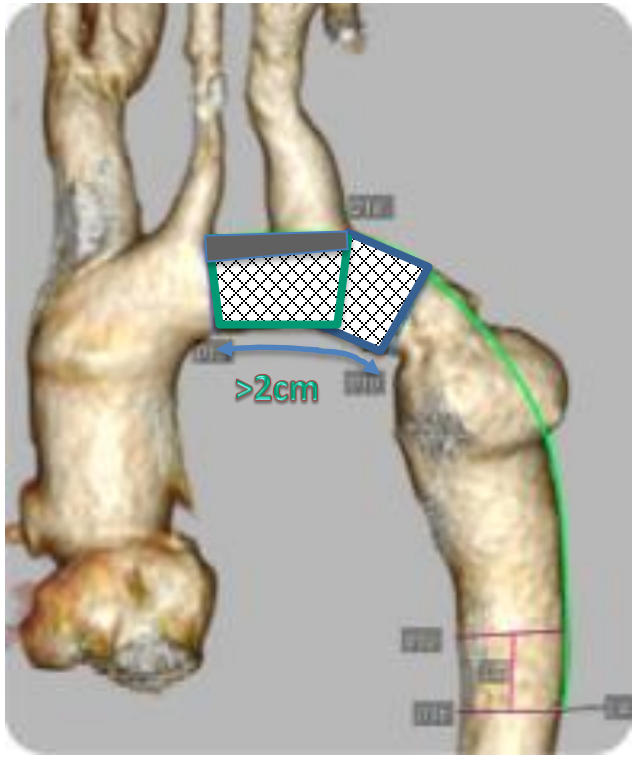

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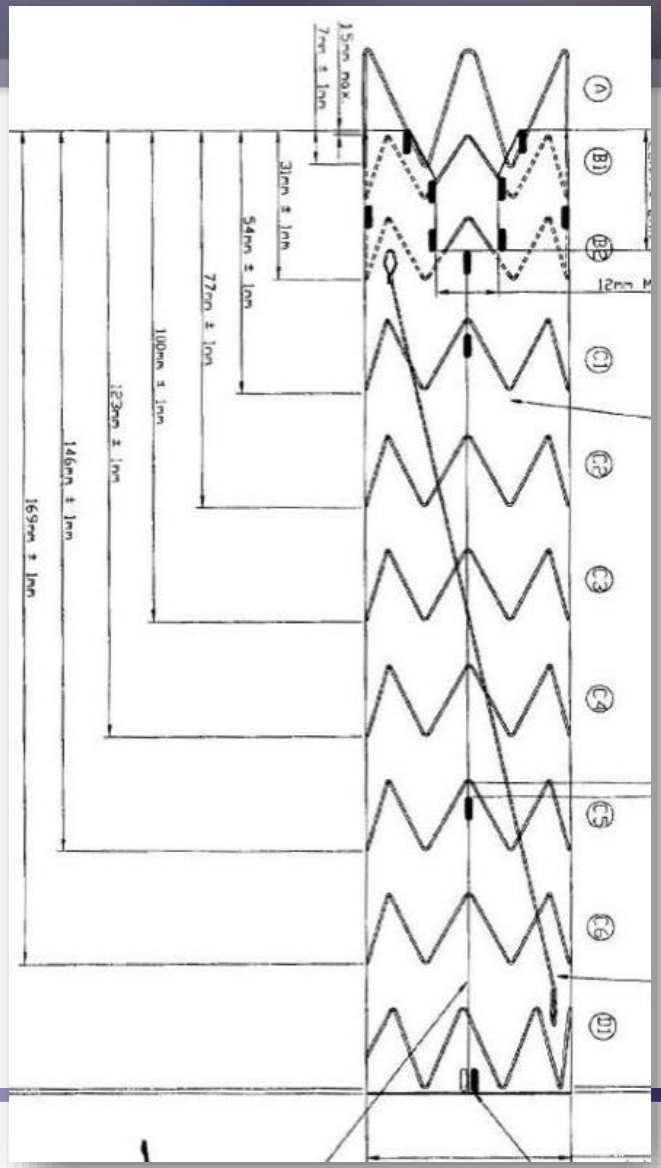
Scallop Graft Features

- **Stent graft** based on the CE-marked custom-made Relay Plus scalloped stent grafts:
  - Self-expanding nitinol stents sutured onto polyester vascular graft fabric with a curved nitinol spine along the length of the graft to provide support
  - Radiopaque end markers and in addition are four more markers delineating the position of the scallop
  - Scallop width up to 22mm
  - With or Without Proximal bare stent
  - Diameter Up to 50mm



Scallop Graft Features

- **Delivery System** consists of a series of coaxially arranged sheaths and catheters:
  - A “stiff” hydrophilic introducer to deliver the device through the iliac arteries
  - A flexible sheath (16mm width) containing the stent graft that allows the device to track through the tortuous course of the thoracic aorta
  - Tip capture → it helps in cases in which proximal readjustment is required
  - 22-26 F (OD) delivery system

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Global Clinical Experience

- 260 patients world wide
- All custom made devices

Alsafi A, J Vasc Surg. 2014
Ben Abdallah I, et al. Eur J Vasc Endovasc Surg, 2015

Overall Results

N = 21

- **Technical success** 100%
  - Endoleak:
    - Type I → 0/21
    - Type II → 2/21 (one treated at 52 weks / neo-innominate scallop)
- Migration 0%
- **Stroke** 3/21 (14%) - [arch hybrid, a visceral hybrid, stand-alone scalloped TEVAR]
- Paraplegia 1/21 (7,7%) - [visceral hybrid]
- **Vessel patency** 100%

Alsafi A, J Vasc Surg. 2014

Overall Results (2)

N= 10 cases

Death (MI)	1 (10)
Stroke (Full recovered)	1 (10)
Paraplegia	0 (0)
Retrograde dissection	0 (0)
Endoleaks	
Type I	
Proximal	0 (0)
Distal (Fixed)	1 (10)
Type II	0 (0)
Type III	0 (0)
Re-intervention	0 (0)
Follow up in months, median ± SD	12 ± 5

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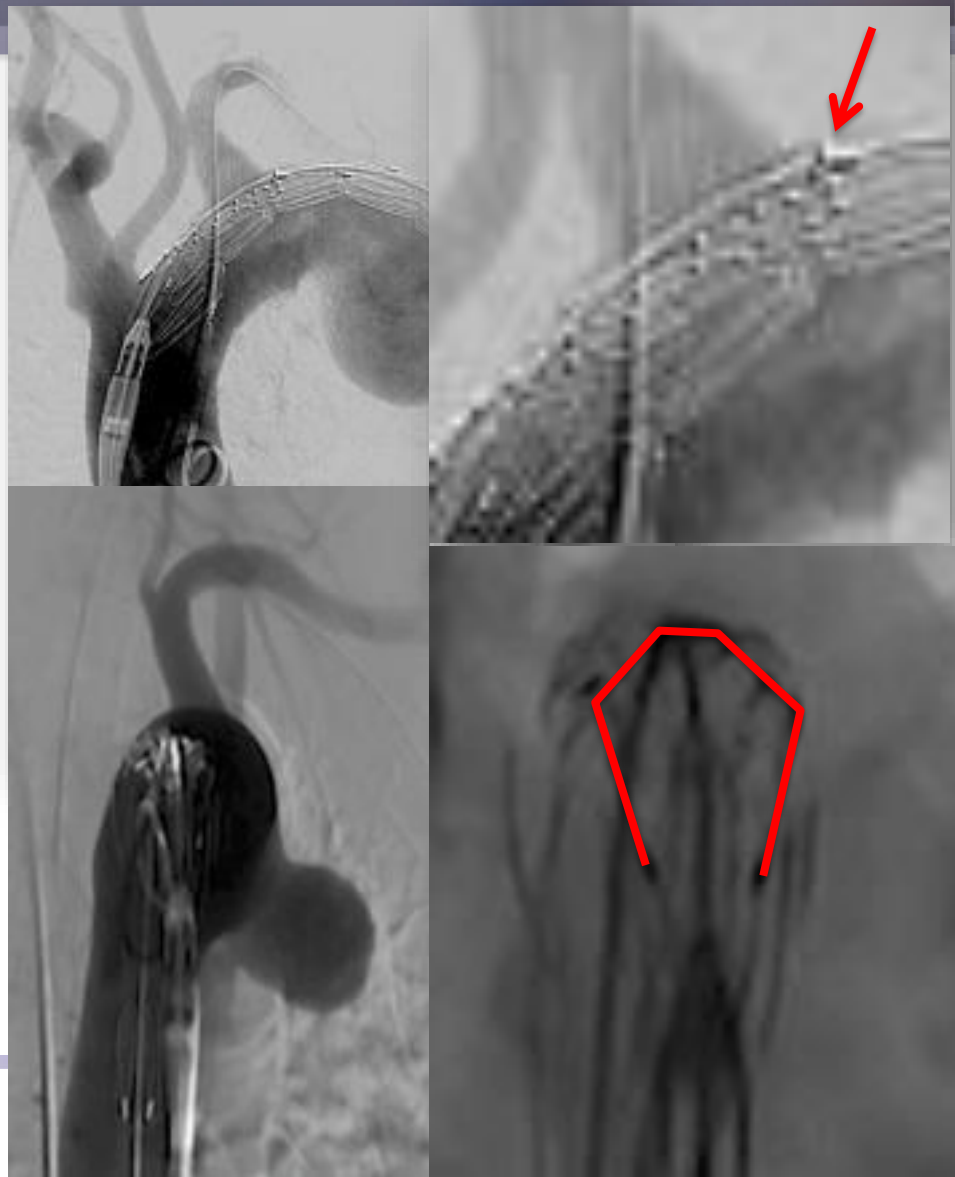
Technical Tips

- GA
- Cut down vs percutaeous/ Heparinization/ ACT monitoring
- Left brachial catheter
- Identify the target vessel
  - LAO (level distal marker positioning)
  - Arch AP/RAO (clock orientation)
- BP control or rapid pacing



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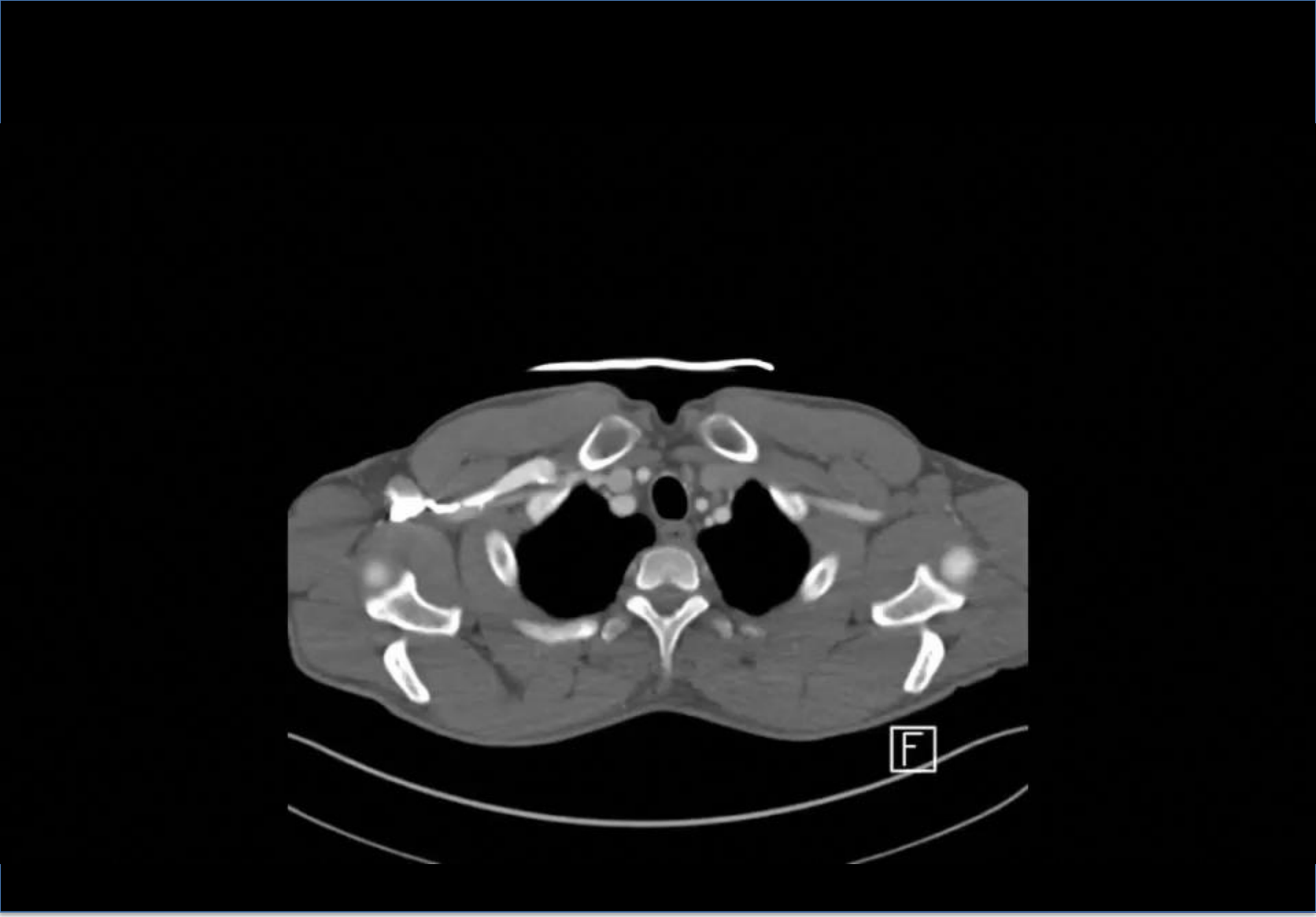
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6 month follow-up

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Summary

- Scalloped endograft represents a safe and effective endovascular alternative for arch pathology
- The technique is simple and accessible with limited maneuvers in the arch and SAT
- Long term data are required to confirm his durability