



# Endograft with scallop for aortic arch disease

Vincent Riambau, MD, PhD  
Professor and Chief of Vascular Division  
Hospital Clinic, University of Barcelona



# 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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# Bolton solutions for the arch

AORTA

## State-of-the-Art Review

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## Application of the Bolton Relay Device for Thoracic Endografting In or Near the Aortic Arch

Vincent Riambau, MD, PhD\*

Vascular Surgery Division, Thorax Institute, Hospital Clinic of Barcelona, Barcelona, Spain

### Abstract

Endovascular correction of aortic arch pathology remains a challenge, with a variety of techniques proposed over the years to minimize complications and enhance the probability of a successful result. A variety of approaches have been developed in order to deal with the aortic arch pathology and its idiosyncrasies. We review potential interventional techniques for the repair of aortic arch pathologies, beginning with conventional aortic arch surgery, followed by hybrid treatments and those along the endovascular spectrum (parallel and fenestrated endografts, scalloped endografts, and ascending and new branched endografts). We finish with an overview of all the Bolton Medical (Barcelona, Spain and Sunrise, FL, USA) thoracic platforms. Endovascular techniques show acceptable results in selected cases. Both proximal Bolton Relay configurations (with and without a bare stent) offer conformability and accuracy on deployment with very low rates of stroke. Fenestrated and scalloped designs are also useful for selected cases. Ascending and branched Bolton devices are very promising platforms for a serious, full endovascular approach to the aorta.

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### Key Words

Arch • Endovascular treatment • Endograft

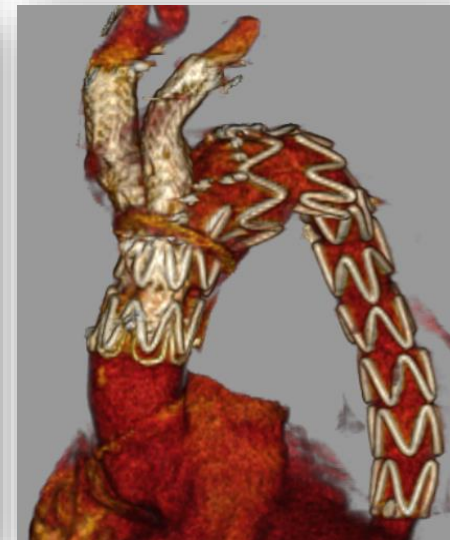
### Introduction: Aortic Arch-Related Pathologies

There are an increasing number of patients with thoracic aortic pathology. Enlargement of the thoracic aorta is an increasingly recognized condition that

is usually diagnosed incidentally on imaging studies performed to evaluate unrelated conditions. Main pathologies of the thoracic aorta, including the arch section, include aneurysms (and sometimes pseudoaneurysms), dissections, penetrating ulcers, and intramural hematomas (IMHs).

Aneurysms along the arch often develop over many years without symptoms; however, they are a serious pathology, with an incidence around 5 to 10 cases per 100,000 patients/year [1]. Arch aneurysms are dangerous health issues, which often require urgent surgical interventions. The prevalence of arch aneurysms may be at least 3–4% of patients older than 65 years. Aortic aneurysms are the 18th leading cause of death in the USA and the 15th among individuals older than 65 years. Aortic aneurysms cause about 13,000 deaths per year in the USA [2]. Thoracic aneurysms are mainly caused by atherosclerosis and other degenerative diseases of the aorta, and have been historically treated with highly invasive surgery. Due to the significant risks associated with thoracotomy, alternative approaches to treat aortic disease have been developed.

Aortic dissections are relatively uncommon, with a documented incidence of 10–20 cases per million population per year [3]. However, aortic dissection is a serious health condition, with extremely high mortality rates, affecting both young and elderly people. Reported incidence rates are probably underestimates of the true incidence, because of difficulties in diagnosis (symptoms of aortic dissection may mimic those of other diseases, often leading to



Fax +1 203 785 3552  
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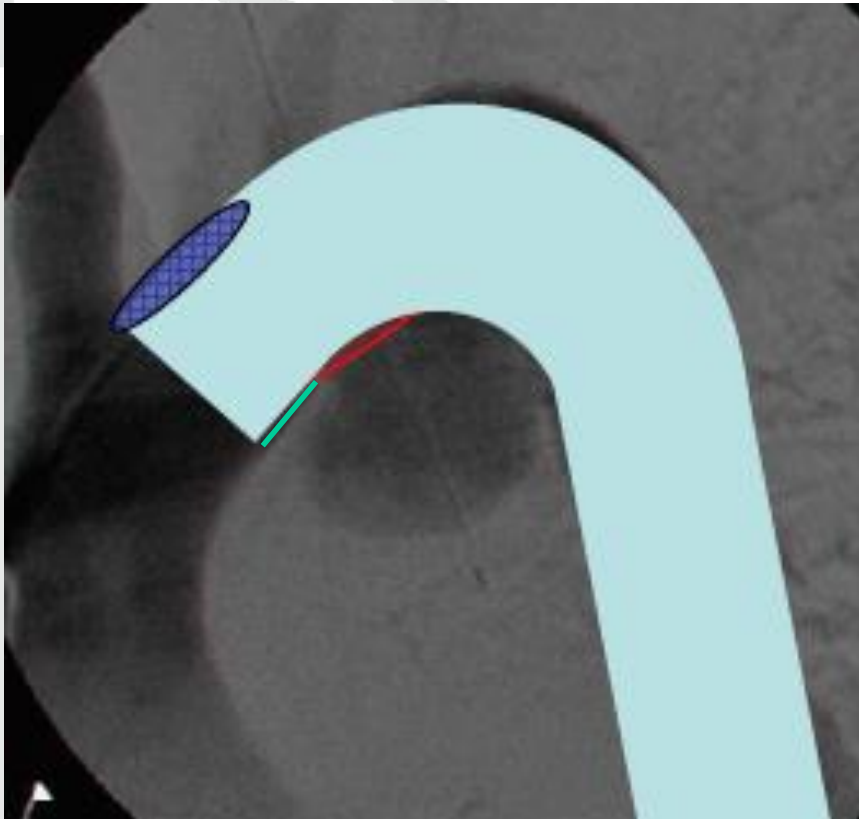
\* Corresponding Author:  
Vincent Riambau, MD, PhD  
Thorax Institute, Hospital Clinic  
University of Barcelona  
Villarroel 170, 08036 Barcelona, Spain  
Tel: +34 932275315, Fax: +34 932275740, E-mail: [vrriambau@gmail.com](mailto:vrriambau@gmail.com), [vrriambau@clinic.ub.es](mailto:vrriambau@clinic.ub.es)



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# Concept of Proximal Scallop



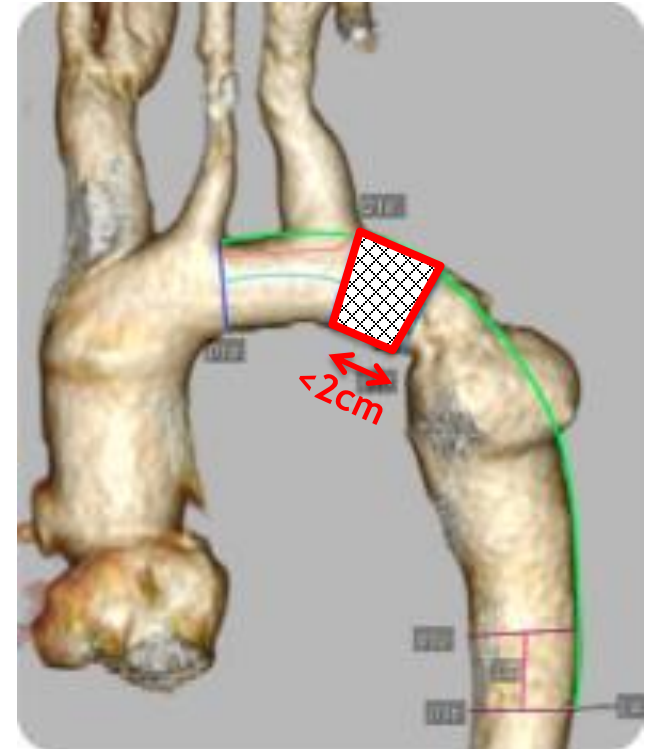
- Increase proximal landing zone
- Improve proximal sealing (inner curvature)
- Keep SAT perfused
- Avoid debranching, single branch or chimney





# Patient Clinical Requirements

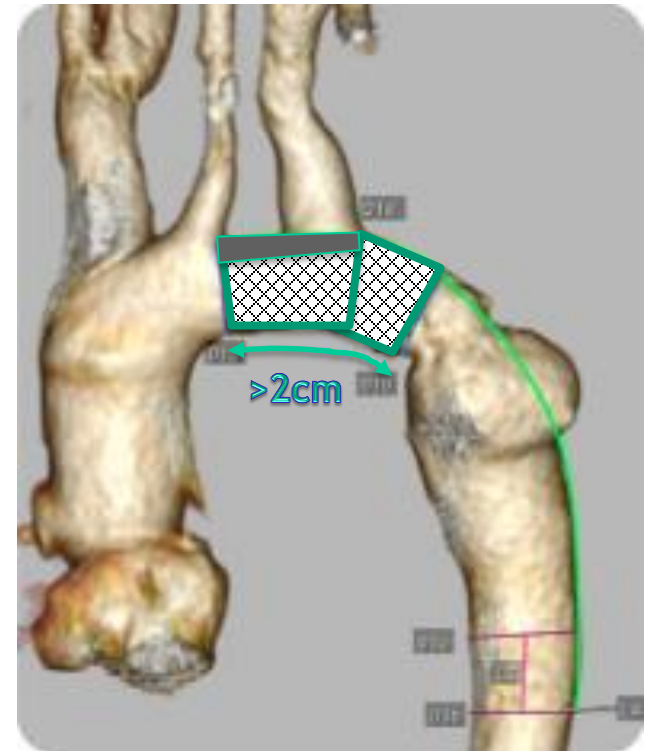
- Patients with a thoracic aortic aneurysm with a proximal landing zone of  $<20$  mm (inner curvature)
- Patients with a significant angulation of the arch that need a longer length of landing zone for adequate graft apposition and seal





# Patient Clinical Requirements

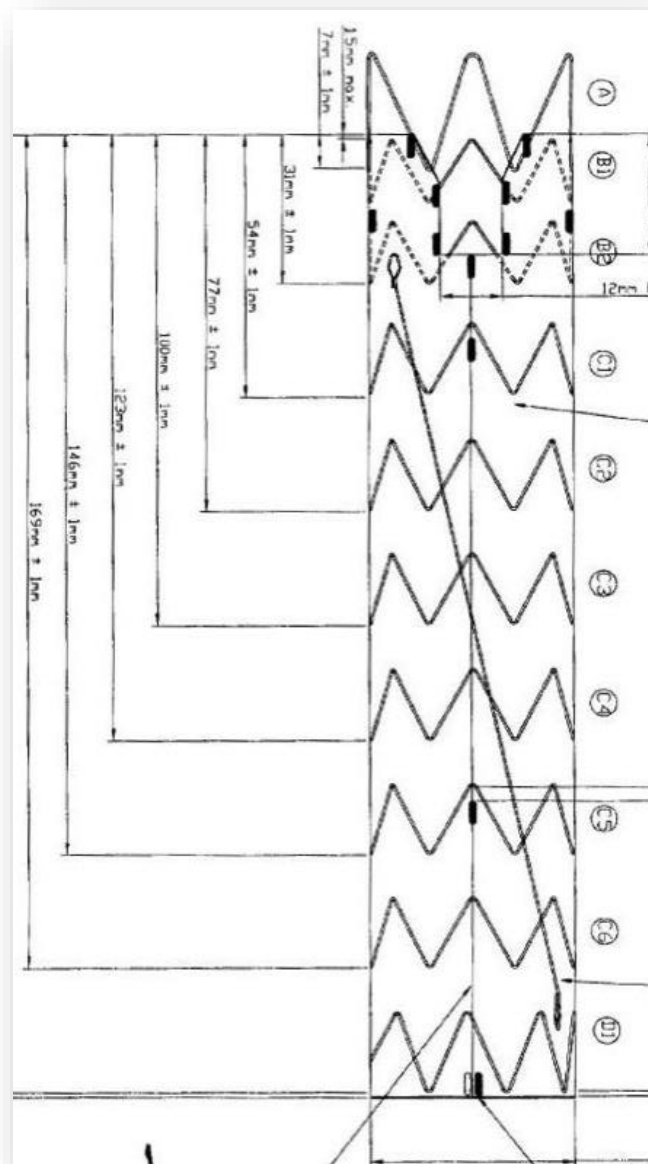
- Patients with a thoracic aortic aneurysm with a proximal landing zone of  $<20$  mm (inner curvature)
- Patients with a significant angulation of the arch that need a longer length of landing zone for adequate graft apposition and seal



# Scallop graft technology

- **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



The background of the slide features a large, semi-transparent image of a scallop graft delivery system. It consists of a long, white, flexible catheter with a scallop-shaped stent graft at the tip. The stent graft is made of a mesh-like material and is designed to be deployed into the thoracic aorta. The catheter has a handle and a control knob. The overall appearance is that of a medical device used for minimally invasive aortic repair.

# Scallop graft technology

- **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





# Published Clinical Experience (1)

## Endovascular treatment of thoracic aortic aneurysms with a short proximal landing zone using scalloped endografts

Ali Alsafi, MBBS, BSc (Hons),<sup>a</sup> Colin D. Bicknell, MD, FRCS,<sup>b,c</sup> Nung Rudarakanchana, PhD, MRCS,<sup>b,c</sup> Erika Kashef, FRCR, MRCS,<sup>b</sup> Richard G. Gibbs, MD, FRCS,<sup>b,c</sup> Nicholas J. Cheshire, MD, FRCS,<sup>b,c</sup> Michael P. Jenkins, BSc, MS, FRCS, FRCS (Gen Surg), FEBVS,<sup>b,c</sup> and Mohamad Hamady, FRCR, EBIR,<sup>b,h,c</sup> London, United Kingdom

**Background:** The suitability of the proximal landing zone remains one of the main limitations to thoracic endovascular aortic repair (TEVAR). The advent of custom-made scalloped stent grafts widens the endovascular options for patients with challenging anatomy. The objective of this study was to present our early and midterm results of custom-made scalloped thoracic stent grafts.

**Methods:** Prospectively acquired data relating to patient demographics, procedure details, clinical outcome, and complications were analyzed. In addition, we analyzed preoperative and postoperative computed tomography scans to evaluate aneurysm morphology, graft placement, side-vessel patency, and endoleaks.

**Results:** Twenty-one patients with a median age of 71 years (range, 35-81 years) underwent custom-made scalloped TEVAR, eight of whom had a concomitant hybrid repair. Procedural success was achieved in all cases. Proximal seal was achieved in all cases, with no type I endoleaks. There were no cases of retrograde dissection and no conversions to open repair. The median follow-up period was 36 weeks (range, 3-183 weeks). Two patients died in the hospital. Three patients suffered a stroke. Three patients had a type II endoleak, one of whom had significant sac enlargement requiring reintervention. One patient had a type III endoleak requiring reintervention. There were no cases of graft migration.

**Conclusions:** Our midterm results show that custom-made scalloped TEVAR is an acceptable treatment of thoracic aortic aneurysms with a short proximal landing zone. Longer term outcome data are required to establish wider use of scalloped thoracic endografts. (J Vasc Surg 2014;■:1-8.)

Thoracic endovascular aortic aneurysm repair (TEVAR) is an established treatment of thoracic aortic disease in both the acute and elective setting.<sup>1</sup> TEVAR is associated with lower early mortality and morbidity compared with open surgical repair, making it an attractive therapeutic option.<sup>2-4</sup>

From the Department of Interventional Radiology<sup>a</sup> and Imperial Vascular Unit,<sup>b</sup> Imperial College Healthcare NHS Trust, St Mary's Hospital; and the Department of Surgery and Cancer, Imperial College London.<sup>c</sup> This study was funded in part by the Imperial College Healthcare Trust and the National Institute for Health Research through the Comprehensive Biomedical Research Centre.

**Author conflict of interest:** C.D.B. received presentation, travel, and conference fees from Bolton Medical. N.R. received presentation, travel, and conference fees from Bolton Medical. R.G.G. received presentation, travel, and conference fees from Bolton Medical. M.H. is an advisory consultant to Bolton Medical.

Presented as a poster at the British Society of Interventional Radiology, Birmingham, United Kingdom, November 13-15, 2013; and partial results presented as an e-poster at Controversy and Updates in Vascular Surgery, Paris, France, January 23-24, 2014.

**Reprint requests:** Ali Alsafi, MBBS, BSc (Hons), Department of Interventional Radiology, Imperial College Healthcare NHS Trust, St Mary's Hospital, Praed St, London W2 1NY, United Kingdom (e-mail: Ali.alsafi03@alumni.imperial.ac.uk).

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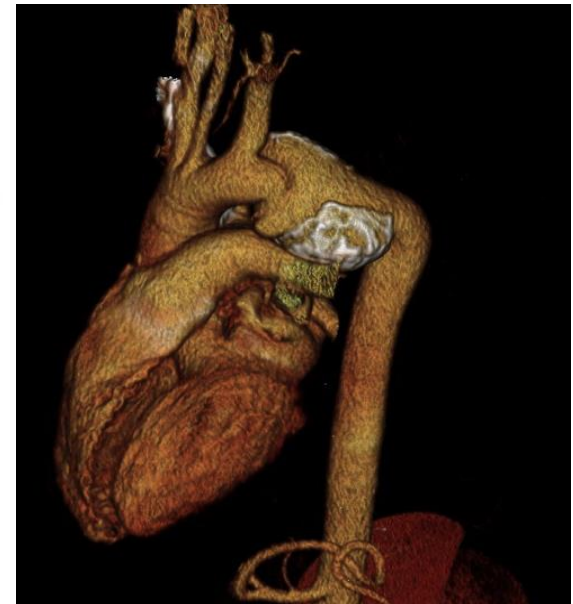
The feasibility of TEVAR is determined by several anatomic factors, including landing zones. Adequate proximal and distal landing zones of healthy aorta are mandatory for endovascular treatment to prevent stent graft migration and to reduce the risk of endoleak.

Scalloped endografts are one strategy in overcoming the problem of a short proximal landing zone. These are custom-made covered stent grafts with a scallop designed to accommodate the origin of a supra-aortic vessel, which would otherwise be covered or require revascularization. Most often, the proximal scallop is to the left subclavian artery (LSCA), but it has also been successfully used to accommodate common carotid and innominate vessels either with extra-anatomic bypass for covered vessels or by use of fenestrated grafts as an alternative.<sup>5-7</sup> Distal celiac and superior mesenteric artery scallops have also been described.<sup>8-10</sup>

In this paper, we discuss our early and midterm outcomes using TEVAR with a proximal scallop or fenestration in treating thoracic aortic disease with inadequate proximal landing zones.

### METHODS

All cases were discussed at our specialist vascular multidisciplinary team meeting before their surgery. Our protocol was to select TEVAR with a custom-made scalloped stent graft in patients with a thoracic aortic aneurysm with a proximal landing zone of <20 mm (as measured



# Demographics and comorbidities

N = 21	
Age years, (range)	71 (35-81)
Sex	
Male	9
Female	12
Hypertension	14; 67%
Smoking history	12; 57%
Diabetes mellitus	1; 5%
COPD	5; 24%
Renal insufficiency	4; 19%
Coronary artery disease (CAD)	4; 19%
Previous MI	1; 5%
Previous cardiac surgery/intervention	9; 43%
Initial presentation with acute aortic syndrome	5; 24%
Previous infrarenal aortic surgery	2; 10%
Previous open thoracic aortic surgery	3; 14%

<sup>1</sup>Alsafi A, Bicknell CD, Rudarakanchana N, Kashef E, Gibbs RG, Cheshire NJ, Jenkins MP, Hamady M. J Vasc Surg. 2014 Dec;60(6):1499-506. doi: 10.1016/j.jvs.2014.08.062.



# Overall Results

**N = 21**

- **Technical success 100%**
- **30 day mortality 9.5%** (2 cases with hybrid procedure)
- **Seal and endoleaks:**
  - **100% seal** achieved in all cases
  - **Endoleak:**
    - Type I → 0/21
    - Type II → 2/21 (one treated at 52 weeks / 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%**

# Results in patients with Scallop TEVAR only

**N = 13**

- Follow- up → median 53 weeks (6-120)
- Technical success 100%
- Seal and endoleaks: 100% seal & 0% endoleaks
- Migration 0%
- Stroke & death at 6 months → 1/13 (7.7%)
- Paraplegia 0%
- 30-day Mortality 0%
- Conversion or re-intervention rate 0%
- Vessel patency 100%
- Retrograde dissection 0%



# Published Clinical Experience (2)

ARTICLE IN PRESS

Eur J Vasc Endovasc Surg (2015) ■, 1–7

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

I. Ben Abdallah<sup>a</sup>, S. El Batti<sup>a,c</sup>, M. Sapoval<sup>b,c</sup>, M. Abou Rjelli<sup>a,c</sup>, J.-N. Fabiani<sup>a,c</sup>, P. Julia<sup>a,c</sup>, J.-M. Alsac<sup>a,c,d</sup>

<sup>a</sup>Service de Chirurgie Cardiaque et Vasculaire – Hôpital Européen Georges Pompidou, AP-HP, Paris, France

<sup>b</sup>Service de Radiologie Interventionnelle – Hôpital Européen Georges Pompidou, AP-HP, Paris, France

<sup>c</sup>Université Paris-Descartes, Faculté de Médecine, Paris, France

### WHAT THIS PAPER ADDS

Proximal scalloped stent grafts appear to be an effective additional tool for TEVAR when dealing with short or angulated proximal necks. More prospective and multicentre studies have been initiated to confirm these results.

**Objective:** To evaluate initial experience with a custom made proximal scalloped stent graft for thoracic endovascular aortic repair (TEVAR) of aortic aneurysms involving the arch.

**Methods:** Between September 2012 and November 2014, patients presenting with a thoracic aortic aneurysm (TAA) with short or angulated neck were selected for treatment by custom made proximal scalloped Relay Plus stent grafts (ABS Bolton Medical, Barcelona, Spain). Prospectively acquired data relating to patient demographics, procedure details, clinical outcomes, and complications were analyzed retrospectively.

**Results:** Ten selected patients (50% male, mean age  $77 \pm 8$  years) were treated using a thoracic custom made Relay Plus stent graft, three of whom underwent additional cervical supra-aortic trunk revascularizations. TAA were fusiform in four cases, saccular in three, and three patients were treated for proximal type I endoleaks after previous standard TEVAR. The graft was landed in zone 2 in 3 cases, in zone 1 in 4 cases, and in zone 0 in 3 cases. The custom made scallop was designed to preserve flow in the left subclavian artery in three patients, in the left common carotid artery in four, and in the innominate artery in three. No proximal type I endoleak occurred and proximal sealing was achieved in all cases, with a technical success rate of 100%. All targeted vessels were patent. During a mean follow up of  $12 \pm 5$  months, no conversion to open surgical repair and no aortic rupture occurred. One patient died post-operatively from myocardial infarction and one patient suffered a stroke with complete recovery. One patient had a distal type I endoleak on the 6 month CT scan and is scheduled for distal extension. No paraplegia, retrograde dissection and no other aortic related complications were recorded.

**Conclusions:** Proximal scalloped stent grafts appear to be an effective additional tool for TEVAR of TAA when dealing with short or angulated proximal necks.

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**Keywords:** Aortic, Arch, Aneurysm, Endovascular repair

### INTRODUCTION

Although thoracic endovascular aortic repair (TEVAR) is now an established treatment for descending aortic aneurysms,<sup>1</sup> it is not so clear when considering the aortic arch. Management of the proximal landing zone remains challenging in cases of short proximal neck and severe angulation of the

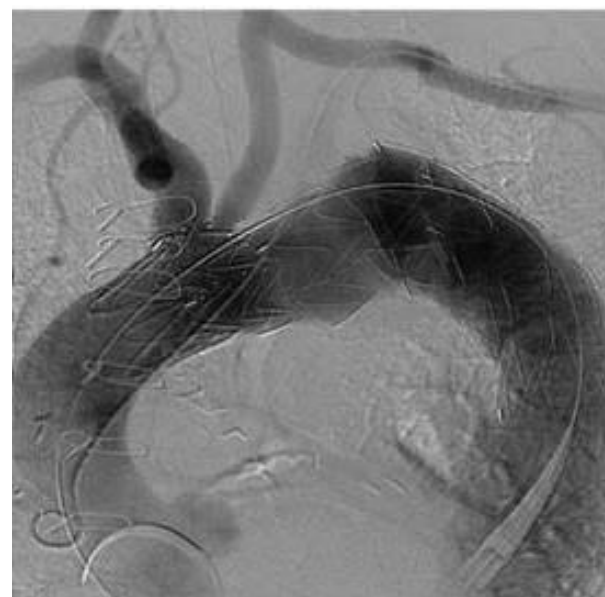
arch. During the last decade, short neck issues in TEVAR led surgeons to develop alternative techniques, such as hybrid arch repair with supra aortic debranching,<sup>2</sup> chimneys,<sup>3</sup> fenestrations,<sup>4</sup> and branches.<sup>5</sup> However, these procedures are still under evaluation and their results have been controversial.<sup>6,7</sup> In the era of exclusive endovascular solutions for aortic arch lesions, stent grafts designed with a proximal scallop may provide an interesting approach. The concept of the proximal scallop aims to increase the proximal landing zone in the inner curvature of the arch without compromising supra aortic trunk (SAT) patency, thereby reinforcing proximal sealing at its weakest point. This study reports a single center experience using a custom made proximal scalloped stent graft for TEVAR of aortic aneurysms involving the arch.

\* Corresponding author: MCL-PH en Chirurgie Vasculaire, Service de Chirurgie Cardiaque et Vasculaire, Hôpital Européen Georges Pompidou 20, rue Leblanc – 75908 Paris Cedex 15, France.

E-mail address: jean-marc.alsac@egp.aphp.fr (J.-M. Alsac).

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# Demographics and comorbidities

**Table 1.** Patient demographics and comorbidities,  $N = 10$  (%).

Median age (range), years	77 (66–90)
Sex	
Male	5
Female	5
Comorbidity, $n$ (%)	
Hypertension	10 (100)
Diabetes mellitus	1 (10)
Smoking history	4 (40)
CAD	2 (20)
COPD	1 (10)
Chronic renal failure	3 (30)
Previous open thoracic aortic surgery	2 (20)
Previous TEVAR (3 type I endoleak)	4 (40)
Previous infra renal aortic surgery	3 (30)

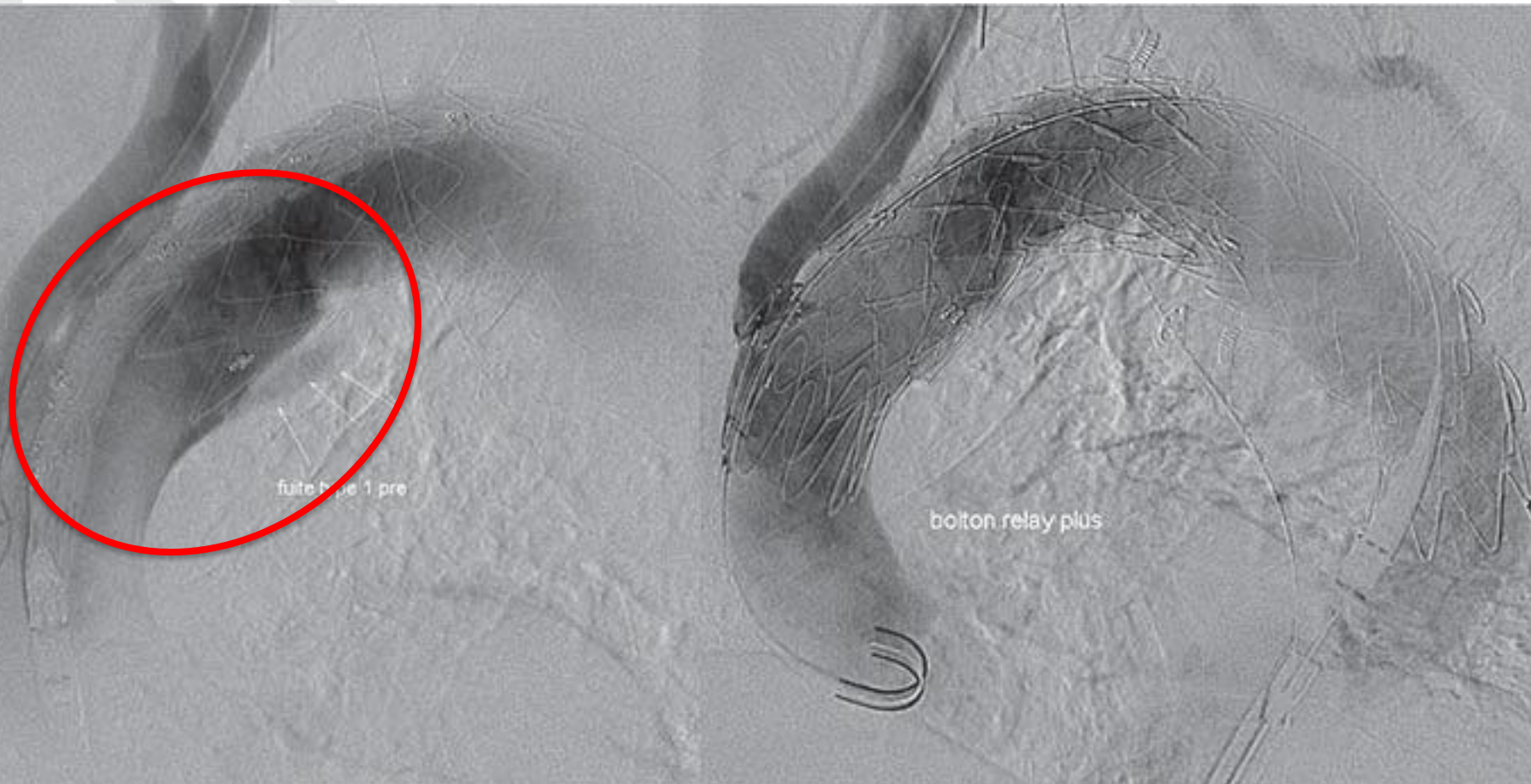


# Overall Results

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 $\pm$ SD	12 $\pm$ 5

# Overall Results

REDO surgery for a Type Ia endoleak





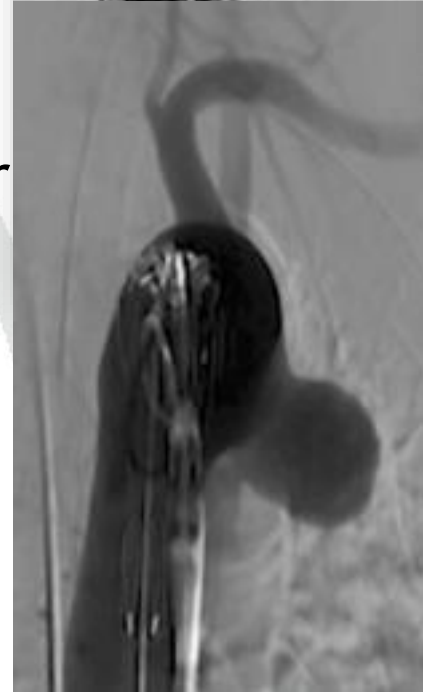
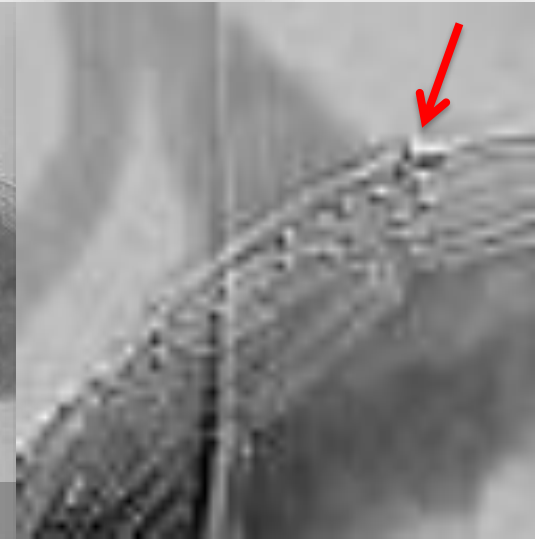
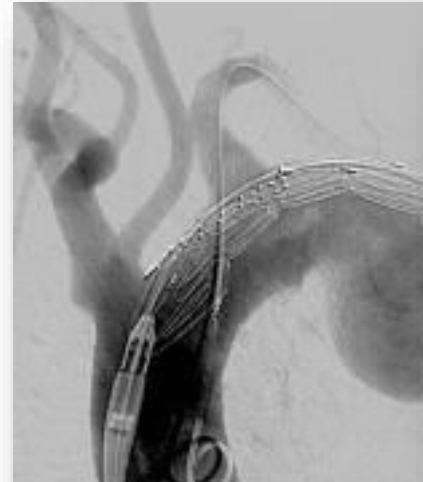
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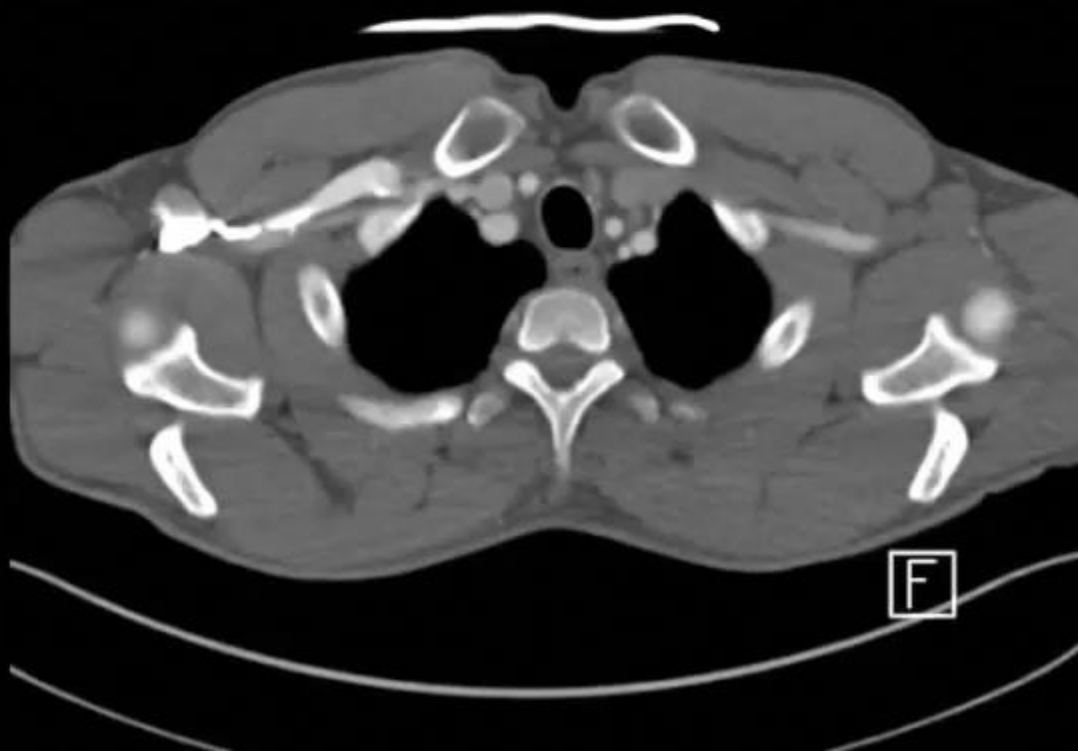
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# Technical Tips

- GA
- Cut down vs percutaneous/  
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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# 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