Assessment of Thoracic Endovascular Aortic Repair Using Relay Proximal Scallop: Results of a French Prospective Multicentre Study

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Short title: Proximal Scallop for Simpler Endovascular Treatment in the Aortic Arch

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WHAT THIS PAPER ADDS

Proximal scalloped endograft may allow endovascular repair in the aortic arch in a select patient population with minimal supra-aortic vessel and wire manipulation without compromising longer term durability. This multicentre prospective study evaluates the safety and efficacy at one year of the Relay proximal scallop stent graft. Treatment in 40 patients from 10 centres with a patients per centre median of 2, of whom 50% targeted aortic arch zone 0 and 35% had associated supra-aortic revascularisation, resulted in 95% primary technical success, 10% 30 day mortality, 5% stroke, and 2.5% type Ia endoleak at one year. Overall mortality at one year was 17.5%.

Objective: A proximal scallop design allows aortic arch repair without complex endovascular manipulation in the aortic arch. The aim was to assess the safety and efficacy at one year of the Relay proximal scallop stent graft.

Methods: A prospective multicentre study evaluated consecutive patients treated with the Relay proximal scallop stent graft in 10 French aortic centres. All consecutive patients eligible for elective thoracic endovascular repair with proximal scallop in the 10 participating centres between January 2015 and July 2018 were included. Primary endpoints were 30 day mortality, stroke, and spinal cord ischaemia (SCI) rates. Outcomes including safety and efficacy, technical and clinical success, all cause mortality, neurological events, vessel patency, and device specific complications were analysed. Survival and survival without severe complications were estimated using Kaplan–Meier estimates.

Results: Ten aortic centres treated 40 patients for thoracic aortic aneurysm (45%), penetrating atherosclerotic aneurysm (30%), and dissection (25%). Half of the procedures (50%) targeted zone 0 of the aortic arch (zone 0 in 17.5% and zones 0/1 in 32.5%), 37.5% targeted zone 2 (35% zone 2 alone; 2.5% zones 1/2), and 15% targeted zone 1 (12.5% zone 1 alone). Median follow up was one year. Thirty day mortality, stroke, and SCI rates were 10%, 5%, and 0% respectively. Primary technical success was 95%. Type Ia, Ib, and III endoleaks rates were 5.4%, 0%, and 0% respectively at one month. Overall mortality rate at one year was 17.5%. Aneurysm expansion was > 5 mm in one case at one year

associated with type Ia endoleak (3%). There was no supra-aortic trunk thrombosis, one (2%) graft kink, and no migration.

Conclusion: One year outcomes showed that the Relay proximal scallop stent graft is an acceptable answer to aortic thoracic disease to deal with short proximal landing zones.

<H1>INTRODUCTION

Thoracic endovascular aortic repair (TEVAR) has become the first line treatment of thoracic aortic aneurysm and type B aortic dissection, particularly in high risk patients.[1–3] This technique is associated with drastic reduction of early morbidity and mortality compared with open surgical repair, particularly if the proximal landing zone does not include the supra-aortic trunk (SAT).[4] Nevertheless, up to 40% of patients will have lesions extending to or involving the orifice of the left subclavian artery (LSA) and may require coverage for adequate stent graft sealing.[5] Open repair remains the reference standard in medically fit patients, despite a peri-operative mortality rate of 7 – 12% reported for elective cases.[3,6,7] Aortic arch anatomy is subject to many variations and tortuosity as well as greater pulsatile forces, making it a very challenging segment for endovascular repair. During the last decade, short neck issues in TEVAR led surgeons to develop alternative techniques, such as hybrid arch repair with supra-aortic debranching,[8,9] chimneys,[10,11] fenestrations,[12] and branches.[13–17] However, complex endovascular manipulations in the aortic arch increase the theorical risk of embolisation and stroke and SAT debranching may also have a risk of stroke and nerve palsy.[8,9,18]

A simpler endovascular device design allowing proximal sealing in the aortic arch while maintaining perfusion to one or more of the SAT vessels and limiting additional endovascular or open revascularisation should therefore be considered. The custom made Relay proximal scallop device (Terumo Aortic, Sunrise, FL, USA) (Fig. 1) has a bare stent and a graft cut away design to preserve follow to one (or more) of the SAT vessels. This device is based on the standard Relay platform known for its dual sheath delivery system that allows the descending thoracic aorta and aortic arch to be reached using a soft, inner sheath.[19] A pre-curved catheter goes along the length of the stent graft, providing longitudinal support to accurately place the scallop systematically on the upper side of aortic arch.

Scallop length and width can be 10 – 30 mm and 13 – 22 mm, respectively, and depend on graft diameter. Custom Relay diameters can be between 20 and 50 mm and allow tapering. Finally, distal scallop designs are also possible.[20] Previous studies have reported its feasibility and showed satisfying early and midterm results.[20–23]

The REP (*Relay Echancrée en Proximal*) study is the first prospective, multicentre study to assess the Relay proximal scallop configuration in terms of security and efficacy.

<H1>MATERIALS AND METHODS

<H2>*Study design and population*

The study was non-interventional, non-randomised, and single arm. Ethics approval for this study was given by the CCTIRS (*Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé*) and the Île-de-France CPP (*Comités de protection des personnes* IDF2). Regulatory approval was from the ANSM (*Agence nationale de sécurité du médicament et des produits de santé*, DR-2014-435).

In accordance with French guidelines for TEVAR, participating aortic centres were required to have expertise in both open and endovascular aortic repairs. Choice of TEVAR with a proximal scallop was determined by each centre after multidisciplinary team meetings of each case. All French centres that used Relay proximal scallop devices during inclusion period were included in the study. All consecutive patients in 10 participating French aortic centres with appropriate anatomy and who were deemed eligible by the centre for TEVAR with a proximal scallop configuration were prospectively included. Patients needed to have life expectancy greater than one year. Urgent procedures that would not allow the procedure to be deferred for three weeks without increasing the medical risk to the patient were excluded to allow at least three weeks for device manufacture. Informed written consent for the study was obtained from all patients. Indications for TEVAR with a proximal scallop were maximum aneurysm diameter > 6 cm or rapid aneurysm growth (>5 mm/6 months or 1 cm/year), symptomatic aneurysm <6 cm without rupture complication, type B aortic dissection without malperfusion or rupture signs, grade I or II isthmic rupture, saccular aneurysm,

penetrating aortic ulcer (PAU), type Ia endoleak post-standard TEVAR; proximal TEVAR landing zone in the aortic arch requiring at least LSA coverage and distal sealing in the descending thoracic aorta without coverage of the coeliac trunk; and proximal sealing from the proximal end of the stent graft ≥ 2 cm

Also excluded were infectious aneurysms and patients unexpected to be able to comply with clinical or radiological follow up.

<H2>*Peri-operative and post-operative follow up*

All management options were discussed at multidisciplinary team meetings with vascular and cardiac surgeons. All clinical preoperative and peri-operative data, as well as follow up data were prospectively collected. All procedures were performed under general anaesthesia. Peri-operative management followed the French Society of Anaesthesiology standards.[24] Patients underwent intravenous induction and maintenance with either volatile agents or total intravenous anaesthesia with a target controlled infusion of sufentanil and propofol and orotracheal intubation. The anaesthesiologist monitored the patient during the entire procedure. In addition to fluid therapy, noradrenaline (norepinephrine) support was added for a target mean arterial pressure of 65 mmHg. Heparin administration was not standardised and dose administered at the beginning of the procedure could vary between centres (between 50 and 100 IU/kg). Devices were flushed with 60 cc of heparinised saline. The scalloped TEVAR procedure followed recommendations that have been previously described.[25] Post-operative follow up included clinical assessment and computed tomography (CT) or magnetic resonance imaging (MRI) imaging evaluation at one month, six months, and one year (CT or MRI choice was left to the discretion of centres).

<H2>*Endpoints*

The primary endpoints were 30 day mortality, stroke, and spinal cord ischaemia (SCI) rates. Secondary endpoints were technical success, all cause mortality, symptomatic left arm ischaemia, phrenic paralysis, SAT patency, per-operative conversion, early post-operative local surgical complications, TEVAR-related complications, re-intervention, and associated complications. Severe complications were defined

as all cause mortality, ischaemic stroke/transient ischaemic attack (TIA), SCI, peripherical ischaemia, nerve injury, SAT thrombosis, type I/III endoleak, any secondary intervention, and post-operative dialysis.

<H2>*Statistical analysis*

All data were collected in a secured electronic data capture platform (S4 Research, OpenClinica platform, version 3.4). A descriptive analysis was performed. Quantitative variables were expressed as mean ± standard deviation or median (interquartile range [IQR]), as appropriate, and qualitative variables as number (percentage).

Survival curves were constructed using the Kaplan–Meier method. All statistical analyses were performed with SAS, statistical and analytic software version 9.4 (SAS institute inc., SAS Campus Drive, Cary, NC, USA) and R statistical software version 4.1.1 (R foundation for Statistical Computing, Vienna, Austria).

<H1>RESULTS

<H2>*Baseline characteristics of the patients*

A total of 40 patients underwent scalloped TEVAR between January 2015 and July 2018 in 10 French aortic centres (patients per centre was median of 2; IQR 1, 15). The majority were men (82.5%, 33/40); mean age was 70.6 ± 14.1 years. Patient baseline characteristics and pre-operative conditions are described in Table 1. Indications for treatment were $n = 18$ (45%) atherosclerotic thoracic aortic aneurysms, three of which were symptomatic, one (2.5%) was a Kommerel diverticulum and $n = 8$ (20%) were saccular aortic aneurysms; $n = 12$ (30%) PAU; $n = 10$ (25%) aortic dissection. Four procedures (10%) were secondary interventions for failure of prior standard TEVAR (proximal endoleak): two in type B aortic dissection, one in PAU, and one in atherosclerotic aneurysm. Three symptomatic cases involved dysphonia and dysphagia ($n = 1$), back pain ($n = 1$), and nerve compression ($n = 1$). All procedures were elective or semi-elective.

Half of the interventions (50%, 20/40) targeted aortic arch zone 0, one-third (35%, 14/40) zone 2, and 15% zone 1 (6/40). For two patients, proximal landing zone presented concentric or circumferential calcium plaque. One-third of patients (n = 12, 30%) had had prior standard TEVAR.

Device details along with anatomical and procedural characteristics are described in Tables 2 and 3. With the exception of the eight cases treated after previous ascending aortic surgery with neo-brachiocephalic trunk (BCT), one-third of patients (n = 14, 35%) had planned concomitant SAT revascularisation. Scallop characteristics are presented in Figure 2.

<H2>*Peri-operative results*

Mean procedural and fluoroscopy times were 188.7 ± 107.8 minutes (112.5 – 228.5) and 12.7 ± 8.9 minutes (7.0 – 17.0) respectively. Mean procedural time was 267.7 ± 127.6 minutes in the subgroup with concomitant SAT revascularisation and 142.3 ± 59.6 minutes in the subgroup without additional procedures. Rapid pacing was used for one patient. Overall technical success was obtained in 97.5% of cases (39/40). For one patient, stent graft maldeployment was followed by antegrade dissection and aortic rupture that was treated by adding proximal extension. No open conversion was needed. For one patient, type Ib endoleak was noticed and treated by an additional stent graft distally.

Additional details on devices and concomitant revascularisations are provided in Table 3.

In hospital death was 5% (two patients). One patient died from respiratory complications, the other from a gastric haemorrhage with pneumoperitoneum. Two patients presented with neurological complication (5%): the first underwent TEVAR with proximal landing in zone 1 and concomitant revascularisation by bilateral carotid–subclavian bypass for the artery of Lusoria. He presented an occipital lobe stroke in the early post-operative period. The second was treated for PAU in arch zone 2. At day 1 he presented with a stroke of the anterior cerebral territory with complete occlusion of the right anterior cerebral artery. Lower limb weakness was the only symptom. A coagulation test revealed the presence of lupus anticoagulant.

There was no SCI. One patient presented with dysphonia and swallowing problems without identified aetiology as no SAT bypass was needed for this case. Three days after the procedure, one patient presented an acute leg ischaemia treated by femoral–femoral bypass.

<H2>*Follow up results*

The median follow up period was 12.02 months (IQR 8.84, 15.39). Four patients (10%) died within one month or before discharge and a further three died within 12 months. Of the five patients who died after discharge, two died within one month, one within six months, and two within 12 months. For these cases, no identified causes of death were reported (no autopsy) and clinical and imaging evaluations during the last follow up before the event were normal. All cause mortality at one year was 17.5%. Kaplan–Meier estimate of freedom from all cause mortality at one year was 82.5% (95% CI 80.5 – 84.50 (Fig. 3).

One patient presented TIA. One patient presented extension of its dissection to the abdominal aorta. One patient presented an iliac stenosis that was treated by stenting. One patient with severe chronic respiratory failure was hospitalised for check up. One patient presented with severe renal insufficiency with permanent dialysis, and one patient presented a problem of healing of the wound in the groin. There were no local complications related to revascularisation. Freedom from severe complications at one year was 65% (95% CI 62.1 – 67.9) (Fig. 3).

Aneurysm exclusion at one year was obtained in 86.2% of cases (26/30, three missing). There were no scallop positioning changes, stent graft migration, or kink noticed during follow up. No SAT thrombosis was reported at one year. One patient, who underwent subsequent elective TEVAR for chronic aortic dissection and had post-operative renal artery malperfusion treated by stenting, presented renal stent thrombosis. Endoleak complications details during follow up are presented in Table 4.

<H1>DISCUSSION

This study presents the prospective multicentre results of scalloped TEVAR for 40 patients in 10 French aortic centres. Satisfactory results were observed with technical success of 97.5% (39/40) and rate of

type Ia endoleak of 3.0% at one year (1/33), suggesting that, despite a relatively large proximal scallop (mean length and width 31.6 mm and 18.8 mm, respectively), there was sufficient stent radial force for adequate sealing. The concept of large scallops in combination with or without debranching remains controversial with concerns about proximal sealing and durability. Sealing requirements are determined by the interaction of the aortic wall and the stent graft in the treated area. Shahcheraghi *et al.* demonstrated that the higher haemodynamic pressure in the aortic arch is along the outer wall near the SAT.[26] Unlike visceral abdominal aortic aneurysms, where stent graft is deployed in the middle of the sac, leaving a large gap between stent graft and aortic wall, in the aortic arch, haemodynamic forces and angulation align the deployed stent graft against the greater curvature. This could explain the relatively low rate of type Ia endoleaks.

The results are consistent with the literature. Since the first case series of four patients demonstrating the feasibility and safety of the technique in 2011,[25] several studies have reported early and mid-term experience with technical success in 100% of cases, 30 day mortality rate of 3 – 10%, post-operative stroke rate of 3 – 14.3%.[20,21,27,28] One study reported long term durability in a retrospective review of 38 patients operated on in a single centre with median follow up of 4.5 years.[23] Technical success was 98%, and freedom from thoracic reintervention was 92%. Thirty day mortality was 5%, post-operative stroke 8%, and type Ia endoleak 5%. Further prospective data are needed to establish long term sealing and durability.

Most TEVAR failures are caused by proximal endoleaks originating from the smaller curvature of the aortic arch.[29] To obtain a sufficient sealing zone for apposition in the inner curvature, a longer length needs to be covered in the outer curvature. Recently, numerical and clinical studies assessed the Modified Arch Landing Areas Nomenclature (MALAN classification) to predict proximal endograft failures and showed that classification as a valuable tool in the preoperative decision process.[30,31] Aortic arch types were not analysed in this study. The use of such classification could help to better understand in which aortic anatomy scalloped TEVAR is safest.

Fifty per cent of cases had anatomy compatible with landing zone in Ishimaru zone 0. The alternative to scalloped TEVAR would have been aortic arch replacement surgery on cardiopulmonary bypass, with significant associated morbidity and mortality, particularly in high risk patients. In recent years, high volume centres have adopted fenestrated and branched TEVAR (f/b-TEVAR) with encouraging results, especially in aortic dissection pathologies.[16,32] Recent studies have reported b-TEVAR results with 30 day mortality between 0% and 16.6%, stroke 11 – 25%, endoleaks 6 – 18.5%, and technical success 96 – 100%.[13,33,34] A recent study on 108 consecutive patients treated with f-TEVAR in six experienced European vascular centres was reported by Tsilimparis in 2021.[12] The cohort was quite similar to ours with 15% previous ascending aortic repair, 16% PAU, 39% post-dissection, and 36% degenerative aneurysms. Proximal landing zone was in zone 0, 1, or 2 in 19.4%, 42%, and 39% of cases, respectively. A proximal scallop was used in conjunction with fenestration in 59% of cases. They reported similar results with 30 day mortality, stroke, and late type Ia endoleaks, and technical success rates of 3.7%, 7.5%, 3.8%, and 99%. However, f/b-TEVAR is technically complex, time and contrast consuming, and requires advanced skills and experience. In particular, a significant learning curve associated with the procedure has been reported.[13] Moreover, multiple endovascular manoeuvres for catheterisation or snaring of wires to access the SAT ostia could be associated with a higher risk of stroke. In pre-loaded f-TEVAR, a high rate of wire entanglement has been reported (near 30%) that have been successfully managed by experienced operators but can increase manipulation in the arch.[12] When anatomy allows, scalloped TEVAR seems to be much simpler and therefore more accessible to vascular surgeons. This study is the first to prospectively report the mid-term results of scalloped TEVAR. All the aortic French centre that used the Relay proximal scallop device included patients with a median of two patients per centre and the eligibility criteria were not limited in order to best represent the population treated, with a heterogeneous group of patients in terms of aortic diseases morphologies and aetiologies. Moreover, no medical proctoring was required. Systematic positioning of the scallop in the outer curvature is obtained with its pre-curved nitinol catheter and the operator should only focus on the distal marker of the scallop, which can be easily identified and positioned at the distal level of the SAT. Only one case used rapid pacing in this cohort. All these elements underline

252 that scalloped TEVAR technique is less technically demanding than modular stent grafts, resulting in
253 potentially fewer complications.

254 Stroke remains a major concern of thoracic endovascular repair of the aortic arch, with rates up
255 to 14%, probably less risky in aortic dissection pathology because of less atheroma ratio.[16,32,35–38]
256 TEVAR for descending aortic aneurysm is associated with stroke rate up to 5%.[39] Theses rates could be
257 underestimated, with a 50% incidence of silent brain infarction reported in endovascular arch procedures
258 in a recent study.[40] Guidewire manipulation should be reduced to the minimum to limit the risk.
259 Moreover, according to Rylski *et al*., the dual sheath design seems to be effective in reducing the
260 clinically relevant volume of gas released that can trigger cerebral embolisation by compartmentalising
261 the total volume into two quantities, only one of which represents a relevant risk for cerebral embolic
262 events.[19] The cohort was a high risk population for stroke complication. Indeed, the landing zone was
263 in Ishimaru zone 0 or 1 in 65% of cases (26/40) and 75% of cases (30/40) presented atheromatous aortic
264 arch disease. Finally, the rate of post-operative stroke was 5%, similar to stroke rate reported for
265 descending aorta TEVAR.

266 Another complication is the risk of stroke and ischaemia associated with LSA coverage and the
267 Society of Vascular Surgery and the European Society for Vascular Surgery guidelines recommend
268 revascularisation of the LSA for patients considered at risk.[1,4] Long term permeability of LSA bypass
269 or transposition is up to 97%, but this surgery can be also responsible for early complications such as
270 haematoma, stroke, and phrenic nerve palsy.[41,42] Moreover, complications are reported to be even more
271 relevant in left common carotid artery (LCCA) and BCT debranching. A stent graft design able to
272 provide comfortable proximal sealing at the level of the aortic arch and endovascular SAT perfusion
273 while limiting SAT debranching would reduce risk of complications. In the study, 35% of patients
274 (14/40) required SAT debranching, 25% concerning the LSA (n = 10), and 17.5% the LCCA (n = 7).
275 No nerve injury related to SAT debranching was noticed.

276 TEVAR carries lower in hospital morbi-mortality than open repair in emergency situations.[43]
277 However, the time to manufacture a custom made device is not compatible with emergent aortic repair.

Alternatives to open surgery, such as parallel grafting and physician modified endografts (PMEGs), were presented as the answer for that kind of situation. Chimneys carry a high risk of proximal endoleak due to gutters between the main stent graft and the parallel graft(s). PMEGs involve deployment of a conventional stent graft device *ex vivo*, creation of customised fenestrations and placing it back into the delivery system. The main limits are the uncertainties about long term resistance of the home made customised fenestrations.[44,45] Consequently, an off the shelf device available in the operating area inventory setting with the most frequent aortic arch anatomies could provide an appropriate response to urgent situations. Although no real consensus on a standard method to analyse aortic arch anatomy exists, evaluation of arch morphology and applicability of off the shelf devices has been previously published.[46–48] Similar results were found with previous study of the Relay proximal scallop with 70% and 85.5% of cases compatible with a scallop of 22 mm in width and 30 – 40 mm in length, respectively and 75% of TEVAR with proximal and distal diameters between 34 and 44 mm and 30 and 40 mm, respectively. The device is not yet available in emergency situations but its production for limited range of diameters seems to be feasible.

There limitations to this study, including the heterogeneity of patients in terms of aortic disease morphologies and aetiologies. Despite being a prospective protocol, one patient was lost to follow up at one year and five patients died during follow up with no identified causes. The specific reason why the scalloped TEVAR was selected (as opposed to alternatives such as f/b-TEVAR or hybrid repair) was left to the discretion of centres, potentially creating selection bias and potential confounding by indication. Moreover, the prospective protocol may result in missing data that were not initially defined as criteria of the study, such as the use of cerebrospinal fluid drainage or femoral access modalities. Interpretation of outcomes of supra-aortic revascularisation is limited by the small number of cases.

This study showed that scalloped TEVAR is an acceptable answer to aortic thoracic disease to deal with short proximal landing zones. An off the shelf device should be developed to enhance the range of possibilities for endovascular specialists dealing with complex thoracic aortic pathology in emergency situations. Long term data are required to confirm durability and safety. More detailed

anatomical analysis, such as the MALAN classification and possibly numerical simulation, could help to establish in which type of arch anatomy scalloped TEVAR is safest.

CONFLICT OF INTEREST

All authors were investigators in the Relay proximal scallop study sponsored by the manufacturer. J.M.A. is a consultant and proctor for Terumo Aortic.

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Figure 1. (A) Image of the custom made Relay proximal scallop device (Terumo Aortic, Sunrise, FL, USA). (B) Supra-aortic trunk scallop target vessels according to Ishimaru arch zones.

Figure 2. Scallop characteristics and stent graft diameters distribution. (A, B) Length and width of the scallop. (C, D) Proximal and distal diameter of the proximal stent graft.

Figure 3. (A) Cumulative Kaplan–Meier (KM) estimate of freedom from all cause mortality after scalloped thoracic endovascular aortic repair (TEVAR). (B) Cumulative KM estimate of freedom from complication related to scalloped TEVAR.

Table 1. Patient (*n* = 40) demographics, characteristics, and indication for treatment.

Variable	**Patients**
Age – y	70.6 ± 14.1 (28–89)
Female	7 (17.5)
Hypertension	31 (77.5)
Smoker	22 (55.5)
Dyslipidaemia	16 (40.0)
Peripheral artery disease	12 (30.0)
Former TEVAR	12 (30.0)
Cardiopathy	11 (27.5)
Chronic obstructive pulmonary disease	7 (17.5)
Chronic renal failure	5 (12.5)
Diabetes mellitus	4 (10.0)
Stroke	2 (5.1)

Previous ascending aortic surgery with neo-BCT	8 (20)
Atherosclerotic aortic aneurysm	18 (45)
Including saccular aortic aneurysm	8 (20)
Penetrating aortic ulcer	12 (30)
Aortic dissection	10 (25)
Type Ia endoleak (post standard TEVAR)	4 (10.0)

457 Data are *n* (%) or mean ± standard deviation (min–max). TEVAR = thoracic endovascular aortic repair;

458 BCT = brachiocephalic trunk.

Table 2. Anatomical characteristics of treated patients.	
Variable	**Patients (*n* = 40)**
Length from LSA to lesion – mm	3.0 ± 6.6 (–10 – 24)
Length from LCCA to lesion – mm	15.1 ± 9.4 (7–22)
Length from BCT to lesion – mm	28.7 ± 14.7 (8–67)
Length from neo-BCT to lesion (*n* = 8) – mm	17.0 ± 22.0 (0–62)
Diameter of proximal landing zone – mm	34.0 ± 5.9 (25–48)
Length of proximal landing zone – mm	28.5 ± 6.5 (11–41)
Diameter of distal landing zone – mm	31.4 ± 6.1 (22–49)
Length of distal landing zone – mm	39.1 ± 15.5 (15–72)
Maximal diameter of total aorta – mm	56.0 ± 15.1 (25–99)
Lateral angle between branches and aortic arch – °	32.2 ± 20.1 (0–74)
Posterior lateral angle	23 (57.5)

Data are mean (± standard deviation) (min–max) or *n* (%). BCT = brachiocephalic trunk; LCCA = left common carotid artery; LSA = left subclavian artery; RCCA = right common carotid artery; SD = standard deviation.

Table 3. Device/scallop characteristics.

Variable	**Patients (*n* = 40)**
Stent graft proximal diameter – mm	39.0 ± 5.6 (28–50)
Stent graft distal diameter – mm	35.2 ± 6.4 (25–50)
Stent graft length – mm	161.5 ± 34.6 (90–200)
Scallop length – mm	31.6 ± 10.4 (10–55)
Scallop width – mm	18.8 ± 2.2 (12–22)
Additional stent graft(s)	18 (45.0)
1	15 (37.5)
2	2 (5.0)
3	1 (2.5)
Concomitant revascularisation	14 (35.0)
LSA to LCCA transposition/bypass	10 (71.4)
LCCA to RCCA bypass	5 (35.7)
Other	4 (28.6)

Data are mean (± standard deviation) (min–max) or *n* (%). BCT = brachiocephalic trunk; LCCA = left common carotid artery; LSA = left subclavian artery; RCCA = right common carotid artery.

Table 4. Outcomes of patients undergoing scalloped thoracic endovascular aortic repair.

Variable	**1 month (*n* = 37)**	**6 months (*n* = 35)**	**12 months (*n* = 33)**
Lesion exclusion			
Yes	32 (86.5)	25 (83.3)	25 (86.2)
No	5	5 (16.7)	4 (13.8)
Missing	0	5	4
Maximum diameter of lesion – mm	51.3 ± 18.8	50.5 ± 17.9	49.7 ± 17.9
	53.0 (38.0–64.5)	50.0 (36.0–65.0)	50.0 (35.0–60.0)
Change from baseline – mm	–4.5 ± 9.7	–8.0 ± 10.8	–6.6 ± 10.3
	0.0 (–8.0, 0.0)	–5.0 (12.0, 0.0)	–5.0 (–11.0, 1.0)
Total aortic diameter change			
Increase ≤5 mm	11 (30.6)	13 (48.1)	12 (48.0)
Stable	24 (66.7)	13 (48.1)	12 (48.0)
Decrease >5 mm	1 (2.8)	1 (3.7)	1 (4.0)
Missing	1	8	8
Endoleaks			
Any	5 (13.5)	5 (14.3)	4 (12.1)
Type Ia	2 (5.4)	0 (0.0)	1 (3.0)
Type Ib	0 (0.0)	0 (0.0)	1 (3.0)
Type II	3 (8.1)	4 (11.4)	1 (3.0)
Type III	0 (0.0)	1 (2.9)	1 (3.0)

Scallop related endoleak	0 (0.0)	0 (0.0)	0 (0.0)

Data are mean ± standard deviation, median (interquartile range), or *n* (%).

Table 1. Patient demographics, characteristics and indication for treatment	
Variable	**Patients (n=40)**
Age - y	70.6 ± 14.1 [28-89]
Female	7 (17.5)
Hypertension	31 (77.5)
Smoker	22 (55.5)
Dyslipidemia	16 (40.0)
Peripheral artery disease	12 (30.0)
Former TEVAR	12 (30.0)
Cardiopathy	11 (27.5)
Chronic obstructive pulmonary disease	7 (17.5)
Chronic renal failure	5 (12.5)
Diabetes mellitus	4 (10.0)
Stroke	2 (5.1)
Previous ascending aortic surgery with neo-BCT	8 (20)
Atherosclerotic aortic aneurysm	18 (45)
Including saccular aortic aneurysm	8 (20)
Penetrating aortic ulcer	12 (30)
Aortic dissection	10 (25)
Type Ia endoleak (post standard TEVAR)	4 (10.0)
Data are n (%) or mean ± SD [min-max]; TEVAR: thoracic endovascular aortic repair; BCT: brachio-cephalic trunk	

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Table 2. Anatomical characteristics	
Variable	**Patients (n=40)**
Length from LSA to lesion - mm	3.0 ± 6.6 [-10-24]
Length from LCCA to lesion - mm	15.1 ± 9.4 [7-22]
Length from BCT to lesion - mm	28.7 ± 14.7 [8-67]
Length from neo-BCT to lesion (n=8) - mm	17.0 ± 22.0 [0-62]
Diameter of proximal landing zone - mm	34.0 ± 5.9 [25-48]
Length of proximal landing zone - mm	28.5 ± 6.5 [11-41]
Diameter of distal landing zone - mm	31.4 ± 6.1 [22-49]
Length of distal landing zone - mm	39.1 ± 15.5 [15-72]
Maximal diameter of total aorta - mm	56.0 ± 15.1 [25-99]
Lateral angle between branches and aortic arch - °	32.2 ± 20.1 [0-74]
Posterior lateral angle	23 (57.5)
Data are mean (±SD) [min-max] or n (%). BCT, brachiocephalic trunk; LCCA, left common carotid artery; LSA, left subclavian artery; RCCA, right common carotid artery; SD, standard deviation.	

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Table 3. Device/scallop characteristics	
Variable	**Patients (n=40)**
Stent-graft proximal diameter - mm	39.0 ± 5.6 [28-50]
Stent-graft distal diameter - mm	35.2 ± 6.4 [25-50]
Stent-graft length - mm	161.5 ± 34.6 [90-200]
Scallop length - mm	31.6 ± 10.4 [10-55]
Scallop width - mm	18.8 ± 2.2 [12-22]
Additional stent-graft(s)	18 (45.0)
1	15 (37.5)
2	2 (5.0)
3	1 (2.5)
Concomitant revascularization	14 (35.0)
LSA to LCCA transposition/bypass	10 (52.7)
LCCA to RCCA bypass	5 (26.3)
Other	4 (21.1)

Data are mean (±SD) [min-max] or n (%).

BCT, brachiocephalic trunk; LCCA, left common carotid artery; LSA, left subclavian artery; RCCA, right common carotid artery; SD, standard deviation.

Table 4. Outcomes			
Variable	**1 month n=37**	**6 months n=35**	**12 months N=33**
Lesion exclusion	32 (86.5)	25 (83.3)	25 (86.2)
Maximum diameter of lesion - mm	51.3 ± 18.8	50.5 ± 17.9	49.7 ± 17.9
	53.0 (38.0-64.5)	50.0 (36.0-65.0)	50.0 (35.0-60.0)
Change from baseline - mm	-4.5 ± 9.7	-8.0 ± 10.8	-6.6 ± 10.3
	0.0 (-8.0-0.0)	-5.0 (12.0-0.0)	-5.0 (-11.0-1.0)
Total aortic diameter change			
Increase ≤5 mm	11 (30.6)	13 (48.1)	12 (48.0)
Stable	24 (66.7)	13 (48.1)	12 (48.0)
Decrease >5 mm	1 (2.8)	1 (3.7)	1 (4.0)
Missing	1	8	8
Endoleaks			
Any	5 (13.5)	5 (14.3)	4 (12.1)
Type Ia	2 (5.4)	0 (0.0)	1 (3.0)
Type Ib	0 (0.0)	0 (0.0)	1 (3.0)
Type II	3 (8.1)	4 (11.4)	1 (3.0)
Type III	0 (0.0)	1 (2.9)	1 (3.0)
Scallop-related endoleak	0 (0.0)	0 (0.0)	0 (0.0)

Data are mean ±SD , median (IQR) or n (%).

IQR, interquartile range; SD, standard deviation

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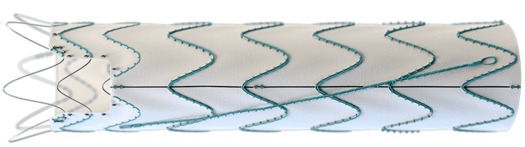
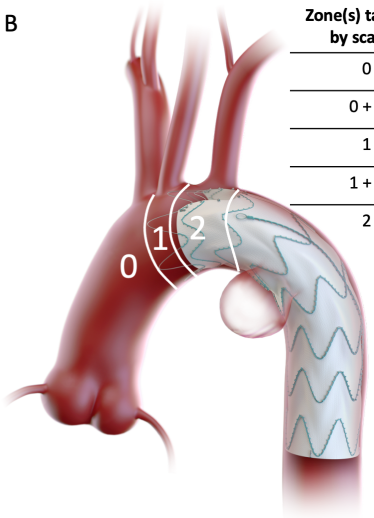
Figure 1

A



B



Zone(s) targeted by scallop	n (%)
0	7 (17.5)
0 + 1	13 (32.5)
1	5 (12.5)
1 + 2	1 (2.5)
2	14 (35)

Figure 2

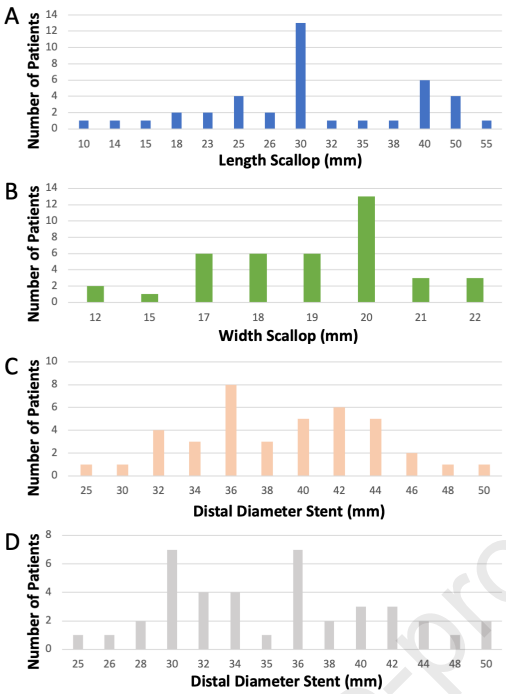
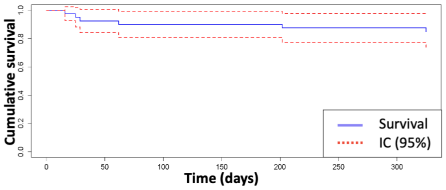


Figure 3

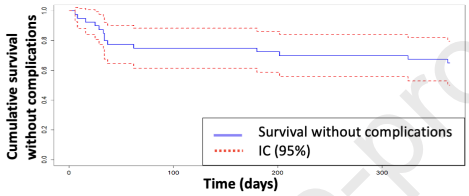
A

Time to event (days)	Number at risk	Number of events	Cumulative number of events	KM estimates
	40	-	-	**1.000**
Discharge	40	2	2	**0.950**
30 days	38	2	4	**0.900**
6 months	36	1	5	**0.875**
12 months	35	2	7	**0.825**



B

Time to event (days)	Number at risk	Number of events	Cumulative number of events	KM estimates
	40	-	-	**1.000**
Discharge	40	2	2	**0.950**
30 days	38	3	5	**0.875**
6 months	35	5	10	**0.750**
12 months	30	4	14	**0.650**



Short title: Proximal Scallop for Simpler Endovascular Treatment in The Aortic Arch

Figure 1: change n to *n*

Figure 2: follow E1 and E2

Figure 3: follow H1 and H2; change IC (95%) to 95% CI

An appendix file has been added