Relay Custom-made endografts (Terumo) for TEVAR, Scalloped: When and Why are they advantageous and do they still have a role in view of other new endografts?

Michael Jenkins
St Mary's Hospital
Imperial College, London
Imperial College London

Disclosures

- Industry relationships with:
  - WL Gore
  - Terumo Aortic
  - Medtronic
  - Bayer
  - Philips
  - InHealth

What do we know?

- TEVAR is complicated by a stroke risk

Eur J Vasc Endovasc Surg. 2017 Feb;53(2):176-184. doi: 10.1016/j.ejvs.2016.10.025. Epub 2016 Dec 18.

Editor's Choice - Incidence of Stroke Following Thoracic Endovascular Aortic Repair for Descending Aortic Aneurysm: A Systematic Review of the Literature with Meta-analysis.

von Allmen RS[1], Gahl B[2], Powell JT[2].
Author information

Abstract

OBJECTIVE: Stroke is an increasingly recognised complication following thoracic endovascular aortic repair (TEVAR). The aim of this study was to systematically synthesise the published data on perioperative stroke incidence during TEVAR for patients with descending thoracic aneurysmal disease and to assess the impact of left subclavian artery (LSA) coverage on stroke incidence.

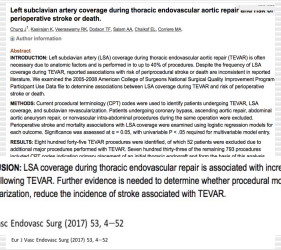
METHODS: A systematic review of English and German articles on perioperative (in-hospital or 30 day) stroke incidence following TEVAR for descending aortic aneurysm was performed, including studies with ≥50 cases, using MEDLINE and EMBASE (2005-2015). The pooled prevalence of perioperative stroke with 95% CI was estimated using random effect analysis. Heterogeneity was examined using I^2 statistic.

RESULTS: Of 215 studies identified, 10 were considered suitable for inclusion. The included studies enrolled a total of 2594 persons (61% male) between 1997 and 2014 with a mean weighted age of 71.8 (95% CI 71.1-73.6) years. The pooled prevalence for stroke was 4.1% (95% CI 2.9-5.5) with moderate heterogeneity between studies (I^2 = 49.8%, p = .04). Five studies reported stroke incidences stratified by the management of the LSA, that is uncovered versus covered and revascularised versus covered and not-revascularised. In cases where the LSA remained uncovered, the pooled stroke incidence was 3.2% (95% CI 1.0-6.5). There was, however, an indication that stroke incidence increased following LSA coverage, to 5.3% (95% CI 2.6-8.6) in those with a revascularisation and 8.0% (95% CI 4.1-12.9) in those without revascularisation.

CONCLUSION: Stroke incidence is an important morbidity after TEVAR, and probably increases if the LSA is covered during the procedure, particularly in those without revascularisation.

What do we know?

- TEVAR is complicated by a stroke risk
- TEVAR with LSA coverage increases the risk



Left subclavian artery coverage during thoracic endovascular aortic repair ... perioperative stroke or death.

Chung J, Kaesmann K, Vanneyaenv RK, Dodson TF, Geisen AA, Chaikof EL, Connem MA.

Author information

Abstract

INTRODUCTION: Left subclavian artery (LSA) coverage during thoracic endovascular aortic repair (TEVAR) is often necessary due to anatomic factors and is performed in in up to 40% of procedures. Despite the frequency of LSA coverage during TEVAR, reported associations with risk of perirocedural stroke or death are inconsistent in reported literature. We examined the 2005-2008 American College of Surgeons National Surgical Quality Improvement Program Participant Use Data file to determine associations between LSA coverage during TEVAR and risk of perioperative stroke or death.

METHODS: Current procedural terminology (CPT) codes were used to identify patients undergoing TEVAR, LSA coverage, and subclavian revascularization. Patients undergoing coronary bypass, ascending aortic repair, abdominal aortic aneurysm repair, or nonvascular intra-abdominal procedures during the same operation were excluded. Perioperative stroke and mortality associations with LSA coverage were examined using logistic regression models for each outcome. Significance was assessed at α = 0.05, with univariable P < .05 required for multivariable model entry.

RESULTS: Eight hundred forty-five TEVAR procedures were identified, of which 52 patients were excluded due to additional major procedures performed with TEVAR. Seven hundred thirty-three of the remaining 793 procedures included CPT codes indicating primary placement of an initial thoracic endograft and form the basis of the analysis.

CONCLUSION: LSA coverage during thoracic endovascular repair is associated with increased risk of perioperative stroke following TEVAR. Further evidence is needed to determine whether procedural modifications, including LSA revascularization, reduce the incidence of stroke associated with TEVAR.

Eur J Vasc Endovasc Surg (2017) 53, 4–52

Eur J Vasc Endovasc Surg (2017) 53, 4–52

What don't we know?

- Is LSA coverage just a surrogate for more proximal disease?
- Are strokes embolic or hypoperfusion related?
- Are they anterior or posterior territory?
- Are they disease related?

What we are told

Eur J Vasc Endovasc Surg (2017) 53, 4–52

Editor's Choice — Management of Descending Thoracic Aorta Diseases

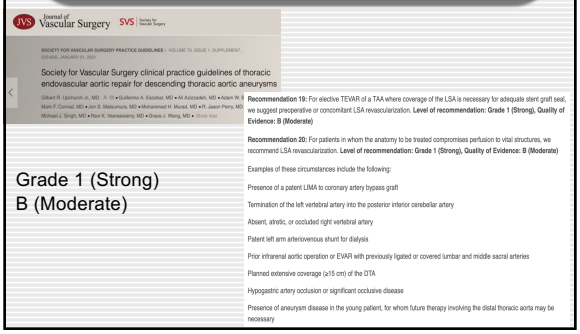
Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS)

Writing Committee † V. Riambau, D. Böckler, J. Brunkwall, P. Cao, R. Chiesa, G. Coppi, M. Czerny, G. Fraedrich, S. Haulon, M.J. Jacobs, M.L. Lachat, F.L. Moll, C. Setacci, P.R. Taylor, M. Thompson, S. Trimarchi, H.J. Verhagen, E.L. Verhoeven, ESVS Guidelines Committee ‡ P. Kolh, G.J. de Borst, N. Chakfé, E.S. Debus, R.J. Hinchliffe, S. Kakkos, I. Koncar, J.S. Lindholt, M. Vega de Ceniga, F. Vermassen, F. Verzini, Document Reviewers † P. Kolh, J.H. Black III, R. Busund, M. Björck, M. Dake, F. Dick, H. Eggebrecht, A. Evangelista, M. Grabenwöger, R. Milner, A.R. Naylor, J.-B. Ricco, H. Rousseau, J. Schmidli

Keywords: Clinical practice, Descending thoracic aorta, Descending thoracic aortic management, Guideline, Recommendations, Thoracic aorta abnormalities, Thoracic aorta diseases, Thoracic aorta disorders, Thoraco-abdominal aorta

Recommendation 11	Class	Level of evidence	References
In elective thoracic endografting cases when it is planned to intentionally cover the left subclavian artery, in patients at risk of neurological complications, preventive left subclavian artery revascularisation should be considered	IIa	C	44

What we are told



Journal of Vascular Surgery | SVS

Society for Vascular Surgery clinical practice guidelines of thoracic endovascular aortic repair for descending thoracic aortic aneurysms

Recommendation 19: For elective TEVAR of a TAA where coverage of the LSA is necessary for adequate stent graft seal, we suggest preoperative or concomitant LSA revascularization. **Level of recommendation: Grade 1 (Strong), Quality of Evidence: B (Moderate)**

Recommendation 20: For patients in whom the anatomy to be treated compromises perfusion to vital structures, we recommend LSA revascularization. **Level of recommendation: Grade 1 (Strong), Quality of Evidence: B (Moderate)**

Examples of these circumstances include the following:

Presence of a patent LIMA to coronary artery bypass graft

Termination of the left vertebral artery into the posterior inferior cerebellar artery

Absent, atretic, or occluded right vertebral artery

Patent left arm arteriovenous shunt for dialysis

Prior infrarenal aortic operation or EVAR with previously ligated or covered lumbar and middle sacral arteries

Planned extensive coverage (≥15 cm) of the DTA

Hypogastric artery occlusion or significant occlusive disease

Presence of aneurysm disease in the young patient, for whom future therapy involving the distal thoracic aorta may be necessary

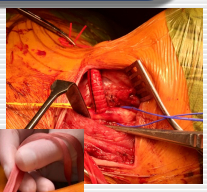
Grade 1 (Strong)
B (Moderate)

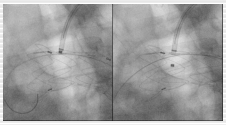
Ideal scenario

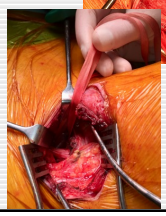
- Conformable stent that deploys accurately
- Gets maximum coverage in to the arch
- With minimum manipulation/cannulation
- Maintains L subclavian (and vertebral) perfusion
- Flexibility to include L carotid if needed

Options

- Carotid - L SCA bypass
- In situ laser fenestration

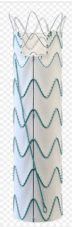


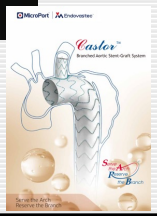




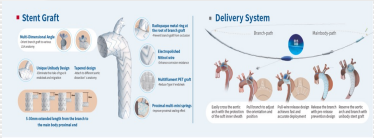
Options

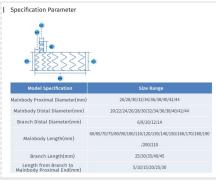
- Scallop
- Fenestration
- Branch



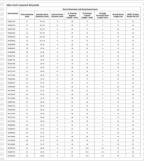


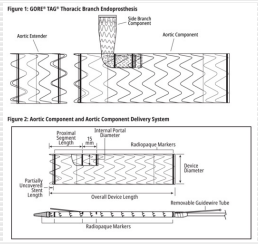
Options - Castor





Options – Gore TBE





Relay series

Four-year results of the Bolton relay proximal scallop endograft in the management of thoracic and thoracoabdominal aortic pathology with unfavorable proximal landing zone

Lydia Hanna, MRCS,[1,2] Ammar Abdullah, MRCS,[1,2] Eilika Kashef, FRCR,[1,2] Celia Riga, MD, FRCS,[1,2] Michael Jenkins, MD, FRCC, FEBVS,[1,2] Colin Bicknell, MD, FRCS,[1,2] Richard Gibbs, MD, FRCS,[1,2] and Mohammad Hamady, MD, FRCR, EBIR[1,2] *London, UK*

ABSTRACT

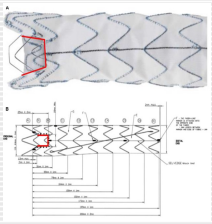
Background: Thoracic endovascular aortic repair with a scallop design (scallop-TEVAR) is a useful treatment strategy to extend the proximal landing zone (PLZ), while maintaining perfusion to one or more of the supra-aortic trunks (SATs) when treating aortic pathology with an unfavorable PLZ. The durability of this approach with the Bolton Relay scallop endograft (Terumo Aortic, Sunrise, Fla) has not been established.

Methods: A retrospective review of prospectively collected data on consecutive patients that received scallop-TEVAR in zones 0 to 2 at a tertiary aortic unit was undertaken. The main outcome was durability, characterized by survival estimates, freedom from reintervention to the thoracic aorta and PLZ, migration and aneurysm sac regression.

Results: Between 2008 and 2019, 38 patients (71% male; median age, 70 years) underwent scallop-TEVAR for thoracic aortic pathology (n = 28, 74%) or as a part of thoracoabdominal aneurysm repair (n = 10, 26%). The use of scallop-TEVAR significantly extended the PLZ (median, 5 mm preoperative PLZ vs 26 mm extended PLZ, *P* = .0001). A total of 41 SATs were perfused with a scallop, including the left subclavian artery (n = 25), left common carotid artery (n = 6), neoinnominate artery (n = 4), left subclavian artery, and vertebral artery (n = 1), innominate artery, and left common carotid artery (n = 2) in conjunction with 15 extra-anatomical bypasses. The PLZ was at Ishimaru zone 0 and 1 in 6 cases (16%), respectively, and zone 2 in 28 cases (68%). Technical success was 98%. The 30-day mortality was 5% (2/38, 1 death from myocardial infarction and 1 from multiorgan failure). A minor stroke occurred in three patients (8%) and temporary spinal cord ischemia in two patients (5%). The median follow-up was 4.5 years (range, 0-10.53 years) during which two patients (5%) developed type Ia endoleak and required intervention to the PLZ (one from device-related migration and one from disease progression). All-cause and aorta-related survival were 72% and 85% and freedom from thoracic and PLZ reintervention was 92% and 97%, respectively. There were no cases of early or late thoracic aortic rupture, retrograde type A aortic dissection or SAT occlusion.

Conclusions: Scallop-TEVAR offers a less invasive treatment option to extend the seal zone in selected patients with an unfavorable PLZ, allowing for a durable repair in terms of overall survival and reintervention. Periprocedural stroke remains a principle concern. (J Vasc Surg 2021;74:1447-58.)

Keywords: TEVAR; Scallop; Arch aneurysm; Thoracoabdominal aneurysm; Endovascular repair



Relay series

Table II. Procedural and operative details

Variables	No. (%) or median (range) (n = 38)
Emergency	1 (3)
Scallop operative time–only, minutes	110 (69-172)
Volume of contrast material (Omnipaque 300), mL	65 (30-100)
Fluoroscopy time, minutes	34 (16-116)
Operative technique	
Zone 0	6 (16)
IA scallop-TEVAR = BCCA-LCCA-LSA bypass	5
IA = LCCA scallop-TEVAR	1
IA = LCCA scallop-TEVAR + LCCA-LSA bypass	1
IA scallop-TEVAR = BCCA-LCCA-LSA bypass + visceral hybrid	1
Zone 1	6 (16)
LCCA scallop-TEVAR = LCCA-LSA bypass	5
LCCA scallop-TEVAR = LCCA-LSA bypass + TEVAR	1
Zone 2	26 (62)
LSA scallop -TEVAR	17
LSA = LVA scallop-TEVAR	1
LSA scallop-TEVAR = BEVAR	4
LSA scallop-TEVAR = visceral hybrid	4
Scallop vessel	
LSA	25
LCCA	6
IA	4
LSA = LVA	1
IA = LCCA	2

ENDOVAR, Tensei/modified/hand endovascular aortic repair; IA, innominate artery; RCCA/LCCA, right/left common carotid artery; LSA, left subclavian artery; LVA, left vertebral artery; TEVAR, thoracic aortic endovascular aortic repair.

- 38 consecutive patients 2009-2019
  - Zone 0 - 16%
  - Zone 1 -16%
  - Zone 2 - 68%
- TEVAR alone – 28 (74%)
- Staged TAAA repair – 10 (26%)
- 30 day mortality – 2 (5%)
- Non-disabling strokes – 3 (8%)
- 3 re-interventions:
  - FET for type 1a endoleak at 5 years
  - C-SCA bypass/extension for type 1a endoleak at 2 years
  - Coils for type II endoleak at 3 years

Relay series

Evaluation of custom-made Relay® stent-grafts for aortic arch landing zones 0 and 1: experience from two high-volume aortic centres

Vaiva Dabrovolskaite[a,b,c], Vladimir Makalovski [d,e], Harri Halavirta[a,b], Orsoya Kotelik[a], Florian S. Schoenhoff[d] and Mario Lescan[a]

[a] Department of Vascular Surgery, University Hospital of Bern, Bern, Switzerland
[b] Department of Vascular Surgery, Kuopio University Hospital, Kuopio, Finland
[c] Department of Vascular Surgery, Kaskinen Hankiavaltayhtymä, Pori, Finland
[d] Department of Cardiac Surgery, University Hospital of Bern, Bern, Switzerland
[e] Department of Thoracic and Cardiovascular Surgery, University Medical Center, Tübingen, Germany

* Corresponding author: Department of Vascular Surgery, University Hospital Bern, Inselspital, University of Bern, 3010 Bern, Switzerland. Tel: +41-31-632-59-00.
e-mail: vladimir.makalovski@insel.ch (V. Makalovski).

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Evaluation of custom-made Relay® stent-grafts for aortic arch landing zones 0 and 1: experience from two high-volume aortic centres

Summary

Early and mid-term experience with the Relay® stent-graft custom-made platform in treating 38 patients with different aortic arch pathology. We had 100% technical success rate, no 30-day mortality, low rate of perioperative stroke (5.7%) and no late strokes (>30 days postoperatively). The custom-made approach allows safe treatment with high technical success rate, low rate of perioperative stroke and favorable results during follow-up.

Legend: Three different designs used: proximal scallop, one large fenestration and branched devices

Abstract

OBJECTIVES: To report experience with a Relay® stent-graft custom-made platform in treating different aortic arch pathology in 2 high-volume aortic centres.

METHODS: A retrospective analysis of all patients treated between July 2016 and July 2023 with custom-made Relay® stent-graft (custom-made devices). Underlying aortic arch pathology was an aneurysm, penetrating aortic ulcer, and dissection. Three custom-made device designs were used: proximal scallop, fenestrations, and inner branches. The endpoints were technical success, perioperative stroke, death, and reintervention rate.

RESULTS: Thirty-five patients (89% males) with a mean age of 70 ± 11 years were treated.

Indication for treatment was penetrating aortic ulcer in 14 patients (40%), aneurysm in 11 patients (31%) and aortic dissection in 10 patients (29%). The technical success rate was 100%. Twenty-eight patients (80%) had proximal sealing in zone 0, and 7 (20%) had proximal sealing in zone 1. Nine patients (25.6%) had proximal scallops, 9 (25.6%) had 1 big fenestration and 17 (48.8%) had a branched device; 1 with single branch, 15 with double branches and 1 with triple branches. Thirty patients (86%) had previous or simultaneous left subclavian artery revascularization. No patient died during 30 days. Two patients (5.7%) had stroke postoperatively; both recovered without disabling deficits. The mean follow-up was 35 ± 26 months. Six patients (17.1%) died during follow-up. One patient required reinforcement of the bridging stent in the left common carotid artery and one additional vascular plugging of the left subclavian artery. Three patients received distal extension.

CONCLUSIONS: The Relay® stent-graft custom-made platform showed a good performance in our study with a high technical success rate, low perioperative stroke and mortality, and low reintervention rates during the follow-up.

Keywords: Relay® • stent-graft • Design diversity • Custom-made platform • Aortic arch

Relay series

Proximal sealing in the aortic arch for inner curve disease using the Custom Relay scalloped and fenestrated stent graft

Simona Sica, MD,[1,2] Giovanni Pratesi, MD,[1,2] Giovanni Rossi, MD,[1] Marco Ferrarese, MD,[1] Luigi Lovato, MD,[3] Pietro Volpe, MD,[1] Gian Franco Fadda, MD,[1] Michelangelo Ferri, MD,[1] Antonio Rizza, MD,[1] Mario D'Oria, MD,[1] Raimondo Micheli, MD,[1] Yamume Tshomba, MD,[1,2] and Giovanni Tinelli, MD, PhD,[1,2] on behalf of the OSCAR (prOximal Sealing aortIC ARch) Collaborative Study Group. *Rome; Genoa; Lecco; Milan; Bologna; Reggio Calabria; Sassari; Turin; Pisa; Trieste; and Terni, Italy*

ABSTRACT

Objective: This study aimed to analyze early and midterm results of custom-made proximal scallop and fenestrated stent grafts for thoracic endovascular aortic repair (TEVAR) with a proximal landing zone (PLZ) in the aortic arch.

Methods: All consecutive patients treated with the custom made proximal scalloped and fenestrated Relay stent-grafts (Terumo Aortic Bolton Medical Inc.) in 10 Italian centers between January 2014 and December 2022 were included. The primary end points were technical success, incidence of intraoperative major adverse events, deployment accuracy, and rate of early neurological complications, endoleaks (ELs) and retrograde aortic dissection.

Results: During the study period, 48 patients received TEVAR with Relay custom-made endograft in Italy were enrolled. The median patient age was 70.1 years (interquartile range, 23-86 years) and 65.3% were male. The indication for treatment was atherosclerotic aneurysms in 19.2% of cases and penetrating aortic ulcer in 22.4%. The endograft configuration was proximal fenestration in 50.1% and scallop in 44.9%. The proximal landing zone was zone 0 in 25 cases (51%), zone 1 in 14 cases (28.6%), and zone 2 in 10 cases (20.4%). The supra-aortic debranching procedures were 38 (77.5%). Technical success was 97.9% (48/49) owing to one case (2.0%) of inaccurate deployment. Intraoperatively, one (2.0%) type Ia and one (2.0%) type III EL were detected. There were no cases of in-hospital mortality, major adverse events, or retrograde dissection. Three minor strokes (6.1%) (National Institutes of Health Stroke Scale score of <4) were observed. At a mean follow-up time of 36.3 ± 21.5 months the rate of types I to III ELs and reintervention was 4.1%, respectively. Four patients (8.2%) died during the follow-up period, one (2.1%) from abdominal aortic rupture and three (6.1%) from nonaortic causes.

Conclusions. Our early and midterm outcomes suggest that scalloped and fenestrated TEVAR may provide an acceptable alternative treatment option for aortic arch pathologies. Large-scale studies are needed to assess the long-term durability of this technique. (J Vasc Surg 2020;■:1-9.)

Keywords: Aortic arch; TEVAR; Custom-made; Scallop; Fenestrated; Stent graft; Multicenter study

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective study of prospectively collected multicenter registry data
- **Key Findings:** In 49 patients undergoing endovascular thoracic aortic repair with custom scallop and fenestrated stent graft, the rate of in-hospital mortality, major stroke, and retrograde dissection was 0%. The indication for treatment was atherosclerotic aneurysms in 59.2% of cases. During a follow-up of 36 months, no patient died of stent graft-related causes and 8.1% required reintervention.
- **Take Home Message:** Thoracic endovascular aortic repair with a proximal landing zone in the aortic arch with custom-made proximal scallop and fenestrated stent grafts is feasible, and the results are acceptable.

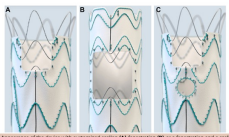


Fig 1. Appearance of the device with customized scallop (**A**), fenestration (**B**) or a fenestration and a scallop (**C**).

Flexibility

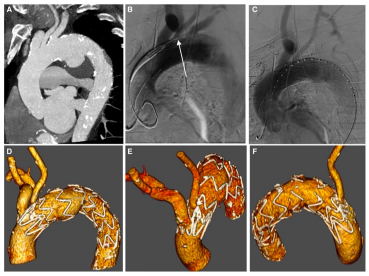


Figure 1: (**A**) Preoperative CT-angiography with PAU in the distal aortic arch, (**B**) intraoperative angiography prior to deployment of the custom-made stent-graft with scallop for the left common carotid artery (white arrow), (**C**) intraoperative final angiography with patent carotid-subclavian bypass and plugged LSA, (**D**) 3D reconstruction of CT-angiography after 2 years–side view, (**E**) 3D reconstruction with cranial/LAO view of the scallop and (**F**) 3D reconstruction with cranial/RAO view of the scallop (with truncated brachiocephalic trunk). CT, computed tomography; LAO, left anterior oblique; LSA, left subclavian artery; PAU, penetrating aortic ulcer; RAO, right anterior oblique.

Flexibility

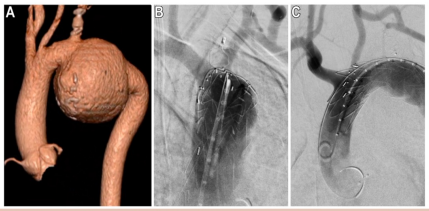
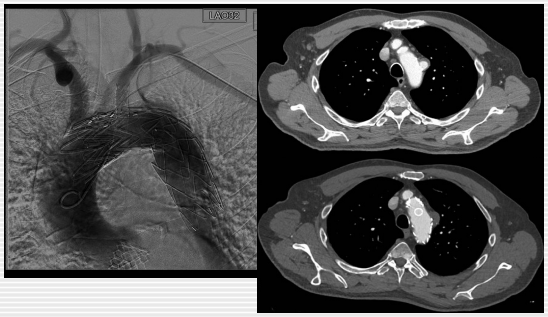


Fig 2. Preoperative three-dimensional volume rendering of post-traumatic chronic aortic isthmus pseudoaneurysm **(A)** treated with debranching and scallop thoracic endovascular aortic repair (TEVAR) in proximal landing zone (PLZ) 1 with final angiography showing the correct position of the stent graft and the patency of the supra-aortic trunks (SATs) without endoleaks (ELs) **(B** and **C)**.

Flexibility



Flexibility

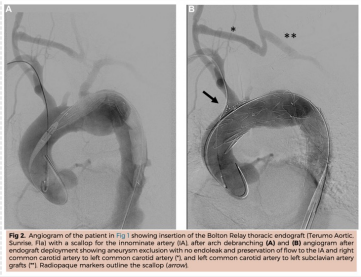


Fig 2. Angiogram of the patient in Fig 1 showing insertion of the Bolton Relay thoracic endograft (Terumo Aortic, Sunrise, Fla) with a scallop for the innominate artery (IA), after arch debranching (A) and (B) angiogram after endograft deployment showing aneurysm exclusion with no endoleak and preservation of flow to the IA and right common carotid artery to left common carotid artery (*), and left common carotid artery to left subclavian artery grafts (**). Radiopaque markers outline the scallop (arrow).

Terumo Aortic Relay Scallop:

- Relay custom TEVAR allows increased inner curve sealing
- Allows for more proximal landing without additional wire manipulation:
  - Useful for saccular aneurysms and PAUs
  - Useful for aberrant anatomy
  - Useful for aortic dissection with entry tears on inner curve

Conclusion

- Relay graft has some unique properties that make it very useful for different pathologies around zone 1 and 2
- Can work outside of the IFU of the newer devices
- Allows increased flexibility and is effectively an option between full arch branching and standard TEVAR