



Results from the Italian Nexus aRCH endovascular repair registry for endovascular aortic arch repair

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ABSTRACT

Objective: The aim of this study is to evaluate the safety, efficacy, and clinical outcomes of endovascular aortic arch repair using the Nexus and Nexus Duo endograft systems.

Methods: A multicenter, retrospective study with prospectively collected data was conducted as part of the Italian Nexus Aortic aRCH Endovascular Repair Registry (INARCHER) between 2019 and 2024. Nexus platforms include an off-the-shelf bimodular single branch endograft and a custom-made double-branch device. Patients who underwent endovascular aortic arch repair with the Nexus and Nexus Duo endograft systems at participating centers were included. The study addressed both aortic arch aneurysm and dissection. Data collection included baseline patient characteristics, procedural details, and follow-up results. The primary endpoints were early (30 days) major adverse events, major stroke, and mortality. Secondary endpoints included the need for device-related reintervention and the device-related endoleak.

Results: We collected 31 cases from 11 centers. The mean age was 73.4 ± 7.32 years, and 77.4% were male. Thirteen patients had a degenerative aneurysm, three had a pseudoaneurysm after prior surgical repair, two had penetrating aortic ulcers, and 13 had an aortic dissection (subacute, $n = 1$; chronic, $n = 12$). Prior ascending aorta replacement was present in 15 cases (48.4%). Seven patients (22.6%) received urgent treatment. Twenty-five cases were treated with complete supra-aortic trunks debranching and Nexus, six cases with left subclavian artery-left common carotid artery debranching and Nexus Duo. The mean operative time was 230 ± 73 minutes. Technical success was achieved in 97% of procedures owing to one case of type IA endoleak. Perioperative mortality was 6.5%, related to a massive pulmonary embolism and a cardiac arrest. Major strokes occurred in 6.5%. The major adverse event rate was 22.6%. The mean follow-up period was 29.7 ± 24.9 months. Beyond 30 days, there was no aortic-related mortality, and freedom from related reintervention was 97% (95% confidence interval, 91%-100%).

Conclusions: The use of the Nexus and Nexus Duo endograft systems appears to be a safe option for the treatment of aortic arch dissection and aneurysm, with complication rates consistent with existing literature for such high-complexity cases. Endovascular aortic arch repair remains a challenging procedure with non-negligible neurologic complication, requiring ongoing improvements to enhance patient outcomes. (J Vasc Surg 2025;82:1137-45.)

Keywords: Aneurysm; Aortic arch; Endovascular; Off-the-shelf

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Presented as the 2025 Vascular Annual Meeting of the Society for Vascular Surgery, New Orleans, LA, June 4-7, 2025.

Additional material for this article may be found online at www.jvascsurg.org.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

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<https://doi.org/10.1016/j.jvs.2025.05.201>

The management of aortic arch pathologies remains a challenge due to the region's complex anatomy and critical hemodynamic characteristics. Traditionally, open surgical repair has been the gold standard of treatment, although it is often associated with significant risk and morbidity.^{1,2} In recent years, the endovascular techniques have transformed the therapeutic landscape, offering minimally invasive alternatives that reduce surgical trauma, enhance recovery, and expand the accessibility of treatment to patients that had been traditionally excluded from open surgery owing to high surgical or medical risks.

Endovascular repair of the ascending aorta and aortic arch, however, remains technically demanding. These procedures require meticulous planning and a deep understanding of the vascular anatomy of the arch. Custom-made endovascular devices have become the preferred approach due to their tailored fit. The introduction of off-the-shelf solutions has enriched current practice. These standardized devices offer simplified procedures and immediate availability.

The Nexus platform has been specifically designed for the endovascular treatment of the aortic arch. The device consists in an off-the-shelf, bimodular single-branch, nitinol endograft. The Nexus endograft is the only CE approved endograft for the treatment of the aortic arch, and it is currently under investigation in the United States with the TIOMPHE clinical trial (NCT04471909). The Nexus Duo is a patient-specific device derived from the standard Nexus and sharing the same main characteristics, with the addition of one retrograde inner branch that can be targeted to the left subclavian or carotid artery.

Although promising data have been reported with the Nexus platform, only limited experiences have been reported in the literature.^{3,4} The aim of this study is to report the procedural and clinical outcomes of the endovascular treatment of aortic arch pathologies using the Nexus and Nexus Duo endografts.

METHODS

Study design. We conducted a multicenter, retrospective study with prospectively collected data as part of the Italian Nexus Aortic aRCH Endovascular Repair Registry (INARCHER). This is a clinician-initiated, not sponsored spontaneous registry collecting consecutive patients treated between 2019 and 2024 in 11 high-volume participating centers. Patients who consecutively underwent endovascular aortic arch repair with the Nexus and Nexus Duo endograft systems at participating centers were included. The study addressed any aortic arch pathology eligible for endovascular treatment (aneurysm, pseudoaneurysm, and dissection). Inclusion criteria were not standardized but were based on the endograft instructions for use (IFU) and were at the

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter retrospective analysis of prospectively collected data
- **Key Findings:** In this real-life multicenter study, the Nexus arch endograft was used for the treatment of aortic arch pathologies both in the elective (77%) and urgent (23%) setting, with a 97% technical success rate. The perioperative mortality rate was 6.5%, and major stroke occurred in 6.5%. The major adverse events rate was 22.6%.
- **Take Home Message:** The use of the Nexus and Nexus Duo endograft systems appears to be a valid option for the treatment of aortic arch dissection and aneurysm, with complication rates consistent with existing literature for such high-complexity cases.

discretion of each center. Ethical committee and patients' consensus approval were obtained.

Nexus endograft. The Nexus Endospan arch branch stent-graft (Endospan) is the only off-the-shelf endograft for the endovascular treatment of the aortic arch. The detailed endograft characteristics and procedural steps had been reported elsewhere.⁵ It is a bi-modular device with a main module for the aortic arch and descending aorta with an incorporated side branch for the target supra-aortic trunk (SAT) and an ascending module for the ascending aorta (Fig 1). The two modules connect through a side-facing dock and lock. Both the main and ascending modules require a 20 Fr delivery system. The device has a preshaped delivery system to enhance deliverability and alignment with the aortic arch. The main module delivery system has an S-shape to facilitate reaching the designated supra-aortic trunk, typically the brachiocephalic trunk (BCT), whereas the ascending module shaft has a C-shape to better accommodate the great curvature of the aortic arch towards the ascending aorta. The main module is 180 mm long, and its diameter is determined based on the descending aorta. The minimum distal landing zone length is 30 mm, with a diameter ranging from 26 to 40 mm. The single branch can be sized according to the diameter and length of the target supra-aortic vessel. The supra-aortic target vessel must have a diameter from 11.5 to 18.5 mm, with a minimum landing zone of 20 mm and a take-off angle from the arch more than 125 degrees. The ascending module has a length ranging from 40 to 70 mm and can be sized based on the length and diameter of the ascending aorta. The proximal landing zone should be at least 30 mm long in the ascending aorta, with a diameter ranging from 29 to 39 mm, to ensure effective sealing. In native aorta, proximal landing zone should be as straight and proximal as possible, aiming to reduce the risk of

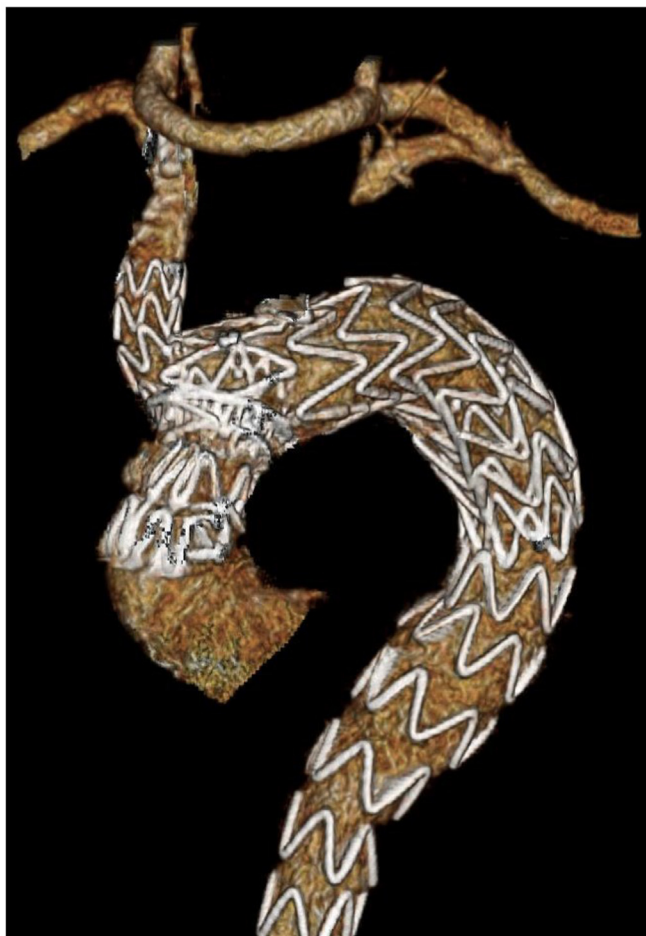


Fig 1. Three-dimensional reconstruction of a computed tomography (CT)-angiogram of a patient with residual chronic dissection after ascending aorta replacement undergone to endovascular aortic arch repair with the off-the-shelf Nexus endograft. The side branch has been delivered in the brachiocephalic trunk (BCT) and blood supply to the left common carotid artery (LCC) and left subclavian artery (LSA) is guaranteed by supra-aortic trunk (SAT) debranching.

retrograde dissection. This does not apply in case of patients with previous ascending aorta replacement.

Nexus Duo endograft. The Nexus Duo arch stent graft is a custom-made device based on the Nexus platform with an additional customizable pre-cannulated retrograde inner branch for the left subclavian artery (Fig 2).

Data collection. Data collection included baseline patient characteristics, aortic arch anatomical features, procedural details, and follow-up results. Demographic and clinical data included cardiovascular risk factors based on the Society for Vascular Surgery reporting standards⁶⁻⁸ and any previous cardiac or vascular surgery. Baseline anatomical measurements and follow-up were based on computed tomography angiography (CTA) scans and included diameters, lengths, and angle of the ascending

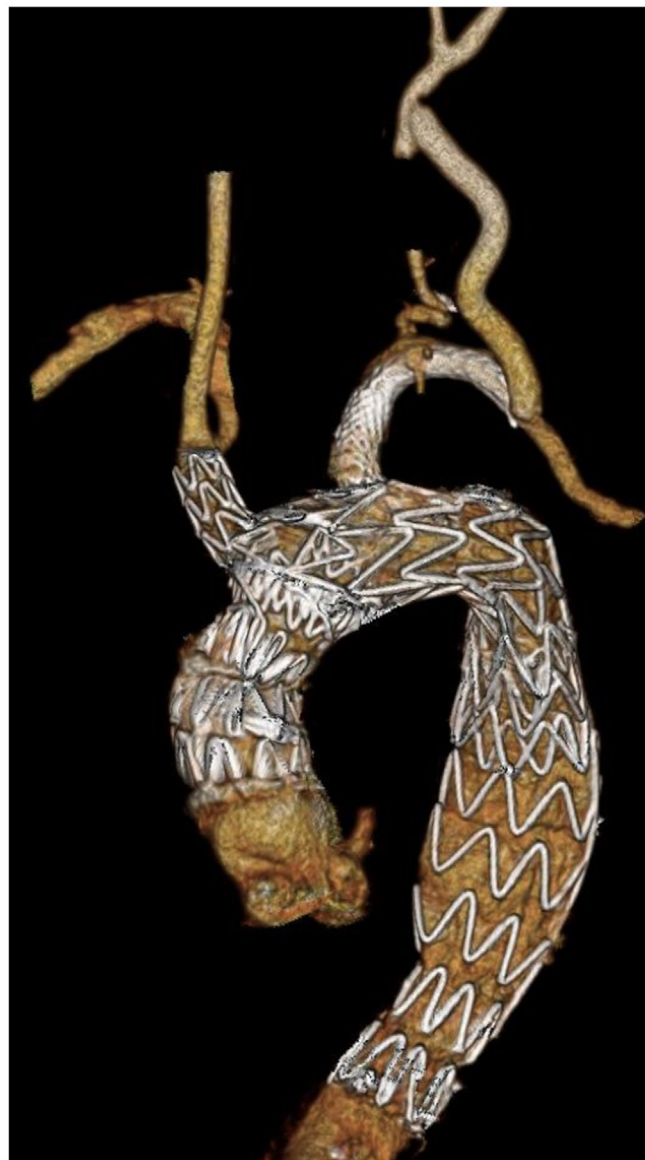


Fig 2. Three-dimensional reconstruction of a computed tomography (CT)-angiogram of a patient with chronic residual thoracoabdominal dissection with previous ascending aorta replacement successfully treated with Nexus Duo endograft. One side branch supplies the brachiocephalic trunk (BCT) and the inner branch guarantees blood flow to the left subclavian artery (LSA). It required LSA-left common carotid artery (LCC) bypass.

aorta, target SATs, and descending aorta. Procedural detail assessed primary technical success, any additional maneuver, SAT debranching technique and timing, and operative time. A technical success implies successful access to the arterial system using a remote site, successful deployment of the endoluminal graft at the intended location, absence of a type I or III endoleak (angiographically detected), and patent endoluminal graft without severe obstruction.⁷ The primary endpoints considered any neurologic and cardiac event, mortality,

and major adverse events (MAEs), which included severe acute kidney injury, new onset dialysis, myocardial infarction, respiratory failure requiring prolonged mechanical ventilation or reintubation, paraplegia, stroke, bowel ischemia requiring surgical resection or intensive medical care, and estimated blood loss >1 L. Secondary endpoints included the need for device-related reintervention and the presence of endoleak. Both primary and secondary endpoint were classified based on their onset in early (<30 days) and late (>30 days). Follow-up was based on imaging protocol with CTA at 1, 6, 12, and 24 months.

Statistical analysis. Results are reported as number and percentage for categorical variables and as mean $\pm$ standard deviation or median and interquartile range for continuous variables. Continuous variables were compared with the Wilcoxon rank sum test or *t*-test, as appropriate. Pearson's χ^2 test and Fisher's exact test were used for analysis of categorical variables. Time-dependent variables were estimated using Kaplan-Meier curves. A *P* value of .050 was used to determine statistical significance. R 4.3 software (R Foundation for Statistical Computing) was used for statistical analysis.

RESULTS

A total of 31 patients underwent aortic arch endovascular repair using either the Nexus (*n* = 25; 80.6%) or Nexus Duo (*n* = 6; 19.4%) endograft. The mean age was 73.4 $\pm$ 7.3 years, and 77.4% were male. Comorbidities were common, with hypertension present in 96.8%, hypercholesterolemia in 71.0%, chronic obstructive pulmonary disease in 41.9%, and coronary artery disease in 41.9%. Prior aortic interventions included open ascending aortic repair in 48.4%, endovascular thoracic aortic repair in 13.9%, endovascular abdominal aortic repair in 13.9%, and open abdominal aortic repair in one case (3.2%). No patients had known genetically triggered aortic disease (Table I).

Degenerative aneurysm was the most frequent indication for repair (41.9%), followed by chronic dissection (38.7%), pseudoaneurysm (9.7%), intramural hematoma/penetrating aortic ulcer (6.5%), and acute/subacute dissection (3.2%). Dissection cases were 13: one case of non A/non B dissection and 12 cases of residual type A dissection after previous ascending aorta replacement. Aortic arch anatomy varied, with Type II arches being most common (51.6%), followed by Type III (29.0%) and Type I (19.4%). Bovine arch configuration was observed in 19.4% of patients. Mean ascending aorta diameter and length were 33.3 $\pm$ 5.1 mm and 73.3 $\pm$ 23.8 mm, respectively (Table II).

In seven cases (22.6%), the intervention was performed in an urgent setting; four of them presented >70 mm aneurysm, one case had sub-acute dissection, and two cases had high-risk pseudoaneurysm. All patients

Table I. Clinical data of the 31 patients enrolled in the Italian Nexus Aortic aRCH Endovascular Repair Registry (INARCHER)

Clinical data	Total (N = 31)
Age, years	73.4 $\pm$ 7.32
Male sex	24 (77.4)
Hypertension	30 (96.8)
Diabetes mellitus	5 (16.1)
Tobacco use	20 (64.5)
Hypercholesterolemia	22 (71.0)
COPD	13 (41.9)
Chronic kidney injury	11 (35.5)
Coronary artery disease	13 (41.9)
Stroke or TIA	7 (22.6)
SVS score	0.9 $\pm$ 0.3
Prior open ascending aorta repair	15 (48.4)
Prior endovascular aortic repair	8 (25.8)
Genetically triggered aortic disease	0 (0)
COPD, Chronic obstructive pulmonary disease; SVS, Society for Vascular Surgery; TIA, transient ischemic attack. Data are presented as number (%) or mean $\pm$ standard deviation.	

underwent total supra-aortic debranching. The most frequent configuration was right common carotid (RCC)—left common carotid (LCC) and LCC—left subclavian artery (LSA) bypass (48.4%), followed by RCC—LSA with LCC reimplantation (32.3%) and LSA—common carotid artery (CCA) bypass (19.4%). Debranching was performed concomitantly with endografting in 16.1% of cases, whereas 83.9% had it performed prior to the procedure. Rapid ventricular pacing was used in 93.5% of cases. The mean operative time was 218 $\pm$ 74 minutes. LSA embolization was performed in 35.1% of patients. Technical success was achieved in 96.8% of cases, with one patient showing a residual type Ia endoleak at final angiogram. No access-related complications were reported (Table III).

The 30-day mortality rate was 6.5% (*n* = 2), with one death due to pulmonary embolism and one due to acute myocardial infarction. MAEs occurred in 22.6% of patients and included myocardial infarction (6.5%), major stroke (6.5%), pulmonary embolism (3.2%), respiratory failure (3.2%), and spinal cord injury (3.2%). The case of spinal cord injury occurred in a patient with prior open abdominal aortic repair. There were also two cases of minor stroke that fully recovered prior to discharge.

Both cases of major stroke presented a history of neurologic events (one stroke and one transient ischemic attack). One was treated for aneurysm and one for chronic. In all cases, the stroke was ischemic with onset upon awakening: neurologic evaluation with neck and head CTA was performed in all cases with no indication to embolic material retrieval. The case of pulmonary embolism caused a cardiac arrest with need of

Table II. Anatomical data of the 31 patients enrolled in the Italian Nexus Aortic aRCH Endovascular Repair Registry (INARCHER)

Anatomical data	Total (N = 31)
Aortic pathology	
Degenerative aneurysm ^a	13 (41.9)
Acute/subacute dissection	1 (3.2)
Chronic dissection	12 (38.7)
Pseudoaneurysm	3 (9.7)
IMH/PAU	2 (6.5)
Aortic anatomy	
Arch type 1	6 (19.4)
Arch type 2	16 (51.6)
Arch type 3	9 (29.0)
Bovine arch	6 (19.4)
Ascending aorta diameter, mm	33.3 ± 5.1
Ascending aorta length, mm	73.3 ± 23.8
Arch thrombus ^b	6 (19.4)
Arch calcification ^b	3 (9.7)
BCT diameter, mm	15.6 ± 4.4
BCT length, mm	39.5 ± 8.8
BCT take off angle, °	134.5 ± 12.6
BCT, Brachiocephalic trunk; IMH/PAU, intramural hematoma/penetrating aortic ulcer. Data are presented as number (%) or mean ± standard deviation. ^a Two cases treated for type I endoleak of previous thoracic endovascular aortic repair. ^b Moderate/severe according to Society for Vascular Surgery reporting standard. ³	

cardiopulmonary resuscitation (CPR), at urgent CTA, side branch thrombosis was detected. Debranching-related complications occurred in 9.7% of patients and were limited to dysphonia, which fully resolved in two cases and was permanent but non-disabling in one. No debranching thrombosis were recorded. Four patients (13%) required early reintervention to treat a type II endoleak from the LSA. Two patients presented type Ia endoleak (6.5%). One case spontaneously resolved at 6 months follow-up, the other is under follow-up with no signs of sac enlargement. No type III endoleak were reported (Table IV).

The mean follow-up time was 29.7 ± 24.9 months. The estimated survival was 83% (95% confidence interval, 71%-97%) (Fig 3). Beyond 30 days, there was no aortic-related mortality, and freedom from related reintervention was 97% (95% confidence interval, 91%-100%) (Fig 4). Two patients were lost at follow-up with a follow-up rate of 93.5%.

DISCUSSION

The Nexus endograft system has emerged as a promising off-the-shelf solution for endovascular repair of complex aortic arch pathologies requiring proximal landing in Zones 0 or 1. Our experience, along with

Table III. Procedural data of the 31 patients enrolled in the Italian Nexus Aortic aRCH Endovascular Repair Registry (INARCHER)

Procedural data	Total (N = 31)
Urgent timing	7 (22.6)
Debranching	31 (100)
RCC-LSA with LCC reimplantation	10 (32.3)
RCC-LCC and LCC-LSA	15 (48.4)
LSA-CCA	6 (19.4)
Debranching timing	
Prior	26 (83.9)
Concomitant	5 (16.1)
Operative details	
Nexus endograft	25 (80.6)
Nexus DUO	6 (19.4)
LSA embolization	11 (35.1)
Rapid pacing	29 (93.5)
Operative time, minutes	218 ± 74
Technical success ^a	30 (96.8)
Access-related complication	0 (0)
CCA, Common carotid artery; LCC, left common carotid artery; LSA, left subclavian artery; RCC, right common carotid artery. Data are presented as number (%) or mean ± standard deviation. ^a One case presented type Ia endoleak.	

previously published series, confirms its favorable technical performance and safety profile, particularly in patients deemed unsuitable for open surgical repair.

In a multicenter study by Planer et al,³ 28 patients with aortic arch aneurysms or chronic dissections were treated with the Nexus device, achieving 100% technical success. At 1 month, 96.1% of cases showed complete exclusion of the pathology, with no device-related deaths. The 30-day mortality and stroke rates were 7.1% and 3.6%, respectively, with all strokes being non-disabling. Over the first year, reintervention was required in 10.7% of patients, primarily for type II endoleaks treated with LSA embolization. A longer-term follow-up at 3 years⁴ demonstrated overall survival rates of 89% and 71% at 1 and 3 years, respectively, with no device- or procedure-related deaths. Importantly, no new neurologic deficits, myocardial infarctions, or aortic valve complications were reported, highlighting the device's mid-term durability.

Similarly, Squizzato et al⁵ presented a single-center experience involving eight patients treated with Nexus, reporting 100% technical success and a 12% stroke rate. Two patients required reintervention for type II endoleaks from the LSA. These outcomes further reinforce the Nexus system's viability in high-risk patients ineligible for open repair.

Despite its encouraging clinical results, the Nexus system's anatomical applicability remains limited. Retrospective analyses have shown that only 19% to 38% of patients undergoing aortic arch repair meet the

Table IV. Procedural data of the 31 patients enrolled in the Italian Nexus Aortic aRCH Endovascular Repair Registry (INARCHER)

Outcome data <30 days	Total (N = 31)
Death ^a	2 (6.5)
Any MAEs	7 (22.6)
EBL >1000 mL	0 (0)
Myocardial infarction	2 (6.5)
Respiratory failure	2 (6.5)
Major stroke	2 (6.5)
Any spinal cord injury ^b	1 (3.2)
Debranching-related complications ^c	3 (9.7)
Reintervention needed	4 (13)
Unplanned reintervention	0 (0)
Endoleak	
Type I ^d	2 (6.5)
Type II	4 (13)

EBL, Estimated blood loss; MAEs, major adverse events. Data are presented as number (%).

^aOne case related to pulmonary embolism, one case of acute myocardial infarction.

^bThis case had prior open abdominal aortic repair.

^cDysphonia. Two cases fully recovered, one case permanent but non-disabling.

^dOne endoleak spontaneously resolved at 6 months computed tomography angiography follow-up, one case in follow-up with no sac enlargement.

anatomical criteria for Nexus deployment,⁹ primarily due to its requirements for landing zone dimensions and supra-aortic vessel configuration. Nevertheless, Bisdas et al¹⁰ reported successful use of Nexus outside its IFU in 13 patients with complex arch aneurysms, achieving 100% technical success with no perioperative major cardiovascular or cerebrovascular events and a 1-year survival rate of 79%. These findings suggest that the current IFU may be overly restrictive, and that, with careful patient selection, the device could serve a broader population. In our series, just one case was performed outside IFU with ascending aortic diameter of 40 mm (IFU range is 29-39 mm).

Comparatively, multi-branched arch repair systems such as the Terumo RelayBranch and Cook Zenith Arch Branched Graft offer greater anatomical flexibility by incorporating two or more internal branches for supra-aortic vessels. However, these systems require custom manufacturing and more complex implantation techniques, which may delay treatment and increase procedural risks.

The RelayBranch system, evaluated in multiple prospective studies, has demonstrated technical success rates ranging from 93% to 100%. Thirty-day mortality rates vary from 7.1% to 10%, with stroke rates reported between 7% and 18%.¹¹⁻¹³ In the RelayBranch arm of the pivotal GREAT registry, the 1-year survival was approximately 84%, with reintervention rates of 10% to 15%, depending on the indication. The higher stroke risk

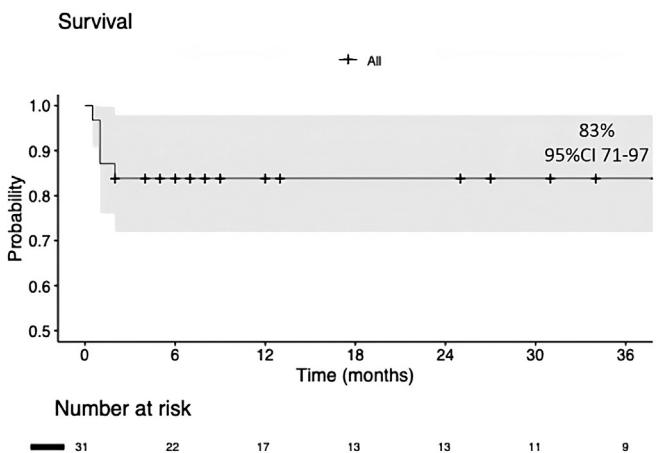


Fig 3. Kaplan-Meier survival curve showing the overall survival. CI, Confidence interval.

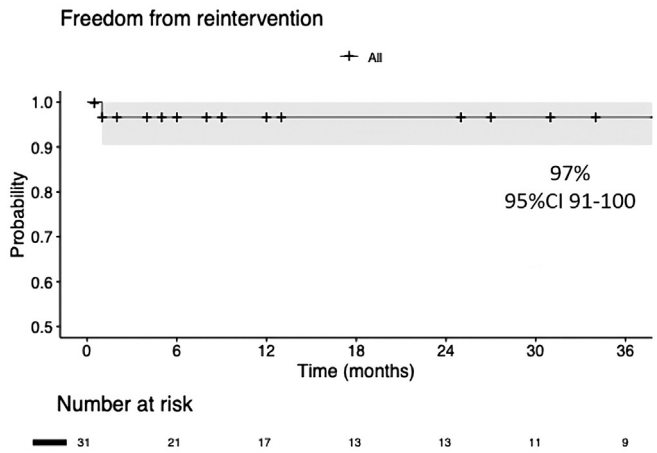


Fig 4. Kaplan-Meier survival curve showing the overall freedom from reintervention. CI, Confidence interval.

may reflect the technical complexity and longer procedural times associated with dual branch manipulation.

Similarly, the Cook Zenith Arch Branched Graft has shown promising mid-term results; stroke rates are reported to range from 9% to 14%.^{14,15} Despite its greater adaptability, Cook's device is not yet broadly available and requires lengthy planning and manufacturing time, making it less suitable for urgent cases.

In contrast, the Nexus system's off-the-shelf design enables immediate deployment and streamlined logistics, making it an attractive option in urgent or high-risk elective scenarios.

An alternative off-the-shelf proposed solution for zone 0 is the Gore Thoracic Branch Endoprosthesis (TBE) (Gore), which is currently only approved for Zone 2 interventions.¹⁶ Ongoing experiences have reported its feasibility in more proximal landing zones,¹⁷ particularly Zone 0, but this presents higher procedural risks, particularly an increased incidence of stroke. One study¹⁸ reporting TBE use in Zone 0 reported a technical success rate of

100%, with no cases of perioperative mortality. However, the stroke rate was significantly high at 22%, reflecting the increased risk associated with arch manipulation. In these cases, supra-aortic debranching procedures, such as carotid-carotid and carotid-subclavian bypasses, were required before endograft deployment.

The suitability of the TBE for Zone 0 is further challenged by anatomical constraints. The device was initially designed to seal within a relatively stable descending thoracic aorta, but the proximal landing zone in Zone 0 is dynamic, being subject to higher shear stress due to its proximity to the heart. This may raise concerns regarding long-term durability, including risks of graft migration, component separation, and late endoleaks. The side branch is retrograde and not anatomically shaped as the Nexus and the inner portal maximum diameter is 12 mm. The introduction of the Nexus DUO—a custom-made, dual-branch variant incorporating a LSA branch—addresses some of the limitations of the original Nexus design. Although its use is still limited to select cases, the Nexus DUO holds the potential to reduce debranching complexity and broaden anatomical applicability.

In our series of 31 patients treated with either the Nexus or Nexus DUO endograft, we observed high technical success (96.8%), a 30-day mortality rate of 6.5%, and a stroke rate of 6.5%. These outcomes are in line with previously published studies, reaffirming the device's favorable safety profile. Although both the Nexus and Nexus DUO systems have specific roles shaped by anatomic and clinical constraints, their evolving design and expanding clinical experience suggest an increasing role in the treatment of aortic arch disease. Ongoing innovation and refinement of patient selection criteria will be essential to further improving outcomes and increasing adoption of these endovascular solutions.

We report a case of BCT side branch thrombosis, which is a peculiarity because no report of such an event has been published yet to our knowledge. This patient had history of hypertension, dyslipidemia, chronic obstructive pulmonary disease, and thoracic aortic aneurysm previously treated with zone 1 thoracic endovascular aortic repair and SAT debranching. He presented a proximal evolution of the aneurysmatic disease and required a Zone 0 treatment with Nexus endograft with no complications in the immediate perioperative period. After 7 days from intervention, the patient developed acute dyspnea with tachycardia and cardiac arrest; return of spontaneous circulation was achieved after effective CPR. Emergency angio-CT demonstrated diffuse pulmonary embolism and occlusion of the prosthetic branch at the origin of the right brachiocephalic artery with reduced opacification of the downstream right carotid artery, and absence of opacification in the left carotid—carotid—subclavian bypass ([Supplementary File](#), online only). Death occurred the same day. It seems that the

massive pulmonary embolism caused the cardiac arrest, and the BCT side branch thrombosis might have developed during the CPR maneuvers (three-dimensional radiologic data).

A limitation of this study is its retrospective design, which inherently introduces potential selection bias and limits the ability to establish causality. The index event for inclusion was the surgical procedure itself; therefore, there are no data on the anatomical feasibility. Furthermore, the relatively small sample size reduces the statistical power of the analysis and may limit the generalizability of the findings. Outcomes may also be influenced by center-specific practices and operator experience, which are not uniformly controlled in retrospective multicenter analyses. As such, although the results are promising, they should be interpreted with caution and validated through larger, prospective studies or randomized controlled trials.

CONCLUSIONS

The use of the Nexus and Nexus Duo endograft systems appears to be a valid option for the urgent and elective treatment of a broad spectrum of aortic arch pathologies, including patients with prior cardiac surgery. Complication rates are consistent with existing literature for such high-complexity cases. A higher number of patients and longer follow-up are still needed.

AUTHOR CONTRIBUTIONS

Conception and design: MA, AS, FS, MP

Analysis and interpretation: MA, AS, MP

Data collection: AS, EG, GP, GI, WM, LB, EM, GV, RS, FF, RC, AD, AG, FS

Writing the article: MA, AS, FS

Critical revision of the article: MA, AS, EG, GP, GI, WM, LB, EM, GV, RS, FF, RC, AD, AG, FS, MP

Final approval of the article: MA, AS, EG, GP, GI, WM, LB, EM, GV, RS, FF, RC, AD, AG, FS, MP

Statistical analysis: AS, FS

Obtained funding: Not applicable

Overall responsibility: MA

FUNDING

None.

DISCLOSURES

None.

REFERENCES

1. Di Eusanio M, Berretta P, Cefarelli M, et al. Long-term outcomes after aortic arch surgery: results of a study involving 623 patients. *Eur J Cardiothorac Surg*. 2015;48:483–490.
2. Berger T, Kreibich M, Mueller F, et al. Risk factors for stroke after total aortic arch replacement using the frozen elephant trunk technique. *Interact Cardiovasc Thorac Surg*. 2022;34:865–871.
3. Planer D, Elbaz-Greener G, Mangialardi N, et al. NEXUS arch: a multicenter study evaluating the initial experience with a novel aortic arch stent graft system. *Ann Surg*. 2023;277:e460–e466.
4. D'Onofrio A, Lachat M, Mangialardi N, et al. Three-year follow-up of aortic arch endovascular stent grafting with the Nexus device: results

- from a prospective multicentre study. *Eur J Cardiothorac Surg*. 2022;63:ezac561.
5. Squizzato F, Spertino A, Grego F, D'Onofrio A, Piazza M, Antonello M. Technical tips and clinical experience with the Nexus Endospan arch branch stent-graft. *J Cardiovasc Surg (Torino)*. 2023;64:33–40.
 6. White RA, Sicard GA, Zwolak RM, et al. Society of Vascular Surgery Vascular Registry® comparison of carotid artery stenting outcomes for atherosclerotic vs nonatherosclerotic carotid artery disease. *J Vasc Surg*. 2010;51:1116–1123.
 7. Fillinger MF, Greenberg RK, McKinsey JF, Chaikof EL. Reporting standards for thoracic endovascular aortic repair (TEVAR). *J Vasc Surg*. 2010;52:1022–1033.e5.
 8. Oderich GS, Forbes TL, Chaer R, et al. Reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries. *J Vasc Surg*. 2021;73:4S–52S.
 9. Exelmans W, Mufty H, Maleux G, Verbrugghe P, Fourneau I. Anatomical feasibility of an endovascular aortic arch repair with the NEXUS endograft in patients treated with a frozen elephant trunk procedure for aortic arch pathology. *CVIR Endovasc*. 2023;6:10.
 10. Bisdas T, Zambas N, Zertalis M, et al. Early experience with the Nexus aortic arch endograft for endovascular treatment of complex aortic arch pathologies beyond standard indications. *J Endovascular Ther*. Published online February 5, 2025. <https://doi.org/10.1177/152666028251316375>
 11. Czerny M, Schmidli J, Adler S, et al. Current options and recommendations for the treatment of thoracic aortic pathologies involving the aortic arch: an expert consensus document of the European Association for Cardio-Thoracic surgery (EACTS) and the European Society for Vascular Surgery (ESVS). *Eur J Cardiothorac Surg*. 2019;55:133–162.
 12. Brown JA, Arnaoutakis GJ, Szeto WY, Serna-Gallegos D, Sultan I. Endovascular repair of the aortic arch: state of the art. *J Card Surg*. 2021;36:4292–4300.
 13. Tsilimparis N, Detter C, Law Y, et al. Single-center experience with an inner branched arch endograft. *J Vasc Surg*. 2019;69:977–985.e1.
 14. Rohlfes F, Nana P, Panuccio G, et al. A retrospective analysis of 10-year experience on branched and fenestrated endovascular aortic arch repair. *Ann Surg*. 2025;282:146–153.
 15. Nana P, Haulon S, Tsilimparis N, et al. Fenestrated or branched endovascular aortic arch repair outcomes in female patients: a retrospective multicentre analysis. *Eur J Vasc Endovascular Surg*. 2025;70:69–77.
 16. Liang NL, Dake MD, Fischbein MP, et al. Midterm outcomes of endovascular repair of aortic arch aneurysms with the gore thoracic branch endoprosthesis. *Eur J Vasc Endovascular Surg*. 2022;64:639–645.
 17. Elbayoumi EH, Farres H, Polania-Sandoval CA, Lanka SP, Erben Y. Complex zone 0 aortic arch repair using TBE device: case report and literature review. *Ann Vasc Surg Brief Rep Innov*. 2024;4:100285.
 18. Dake MD, Bavaria JE, Singh MJ, et al. Management of arch aneurysms with a single-branch thoracic endograft in zone 0. *JTCVS Tech*. 2021;7:1–6.

Submitted Apr 2, 2025; accepted May 27, 2025.

Additional material for this article may be found online at www.jvascsurg.org.

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