Preliminary results from an Italian National Registry on the outcomes of the Najuta fenestrated aortic arch endograft

Giacomo Isernia, MD, PhD,[a] Gioele Simonte, MD, PhD,[a] Matteo Orrico, MD,[b] Roberto Silingardi, MD,[c] Andrea Gaggiano, MD,[d] Tea Covic, MD,[c] Michelangelo Ferri, MD,[d] Massimo Lenti, MD, PhD,[a] *and* Nicola Mangialardi, MD,[b] On behalf of the Italian Najuta Registry study group,* *Perugia, Rome, Modena, and Turin, Italy*

ABSTRACT

Background: Arch pathology represents one of the last frontiers in aortic aneurysm endovascular management. Several companies recently developed dedicated branched and fenestrated endografts specifically designed for the aortic arch, aiming to overcome some of the issues associated with standard thoracic endograft and supra-aortic vessels extra-anatomic debranching. This study aimed to evaluate early outcomes obtained with a custom-made fenestrated endograft approved for thoracic aortic aneurysms exclusion.

Methods: All consecutive patients treated with the Najuta endograft (Kawasumi Laboratories, Inc, Tokyo, Japan) in Italy were enrolled prospectively and included in the study population. Anatomic characteristics and perioperative data were analyzed retrospectively. Study end points were technical success, 30-day clinical success, overall survival, supra-aortic vessel patency, endoleak, and need for reintervention or surgical conversion.

Results: Between 2018 and 2022, 76 patients received a Najuta endograft in Italy and were enrolled in the study. The median patient age was 72 years (interquartile range, 69-76 years) and 80.3% were male. Most of the patients received treatment for atherosclerotic aneurysms (80.3%); others were treated for postdissection aneurysms (7.9%), penetrating aortic ulcer (9.2%), or type I endoleak correction after previous thoracic endovascular repair (2.6%). Overall, 161 supra-aortic vessels were preserved through a dedicated fenestration. Technical success was achieved in 74 of 76 procedure (97.4%); both failures were associated with endoleak detection at final angiography (one type I and one type III endoleak). Two distal migrations occurred during the implanting procedure. Clinical success at 30 days was 94.7%. Two early reinterventions were needed within 30 days after index procedure: in one case, an aortic false lumen coils embolization was performed, because distal re-entry caused enlargement of the postdissection thoracic aneurysm. The other procedure consisted of a femoral pseudoaneurysm repair. The median follow-up was 7 months (interquartile range, 3-15 months); no supra-aortic vessel occlusions occurred and no patients needed surgical conversion.

Conclusions: Early results suggest that, in selected patients with aortic arch pathology needing a proximal landing, an endovascular approach with the Najuta system is safe and effective, especially for those at high surgical risk. A strict follow-up with high-quality computed tomography angiography images and eventual evaluation for long-term complications is needed to confirm these initial experience findings. (J Vasc Surg 2023;77:1330-8.)

Keywords: Aortic arch repair; Fenestrated endograft; Custom made; Endovascular repair; Multicenter study; Minimally invasive aortic repair

Despite continuous evolution in surgical techniques, the aortic arch remains for cardiac and vascular surgeons one of the most challenging locations to treat either in case of open or endovascular repair. Considering the impossibility of using standard endografts in the aortic arch, hybrid procedures combining surgical and endovascular techniques to achieve aortic aneurysm exclusion were developed recently and rapidly became widespread, decreasing

From the Vascular and Endovascular Surgery Unit, S. Maria della Misericordia University Hospital, Perugia[a]; the Department of Vascular Surgery, San Camillo-Forlanini Hospital, Rome[b]; the Department of Vascular Surgery, Ospedale Civile di Baggiovara, Azienda Ospedaliero-Universitaria di Modena, University of Modena and Reggio Emilia, Modena[c]; and the Vascular and Endovascular Surgery Unit, Mauriziano Umberto I Hospital, Turin.[d]

*A complete list of the Italian Najuta registry collaborators is provided in the Appendix (online only).

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Correspondence: Matteo Orrico, MD, Department of Vascular Surgery, San Camillo Forlanini Hospital, Circonvallazione Gianicolense 87, Rome, Italy (e-mail: najutaitalianregistry@gmail.com).

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invasiveness and perioperative complications in selected patients if compared with standard open repair.[1-4]

Meanwhile, several companies developed dedicated custom-made branched and fenestrated endografts for the aortic arch, aiming to overcome anatomic issues associated with standard thoracic endograft (transthoracic endovascular aortic aneurysm repair [TEVAR]) and supra-aortic vessels extra-anatomic debranching. Despite these technological improvements, any type of aortic arch repair requiring supra-aortic vessel manipulation remains demanding with undeniable stroke and death risks. Thus, the custom-made Najuta fenestrated stent-graft (Kawasumi Laboratories, Inc, Tokyo, Japan) was designed to obtain a proximal landing between Ishimaru aortic arch zones 0 and 2 while preserving supra-aortic vessels antegrade flow, averting need for additional maneuvers in target arteries or adjunctive components deployment. This study aimed to investigate the preliminary technical and safety outcomes obtained using the Najuta system for aortic arch repair collected through a multicenter, prospective Italian registry.

METHODS

Data from all consecutive patients treated in Italy with the Najuta endograft since its commercial launch in 2017 were included in a prospective electronic database after patient consent to a voluntary, observational, multicenter data collection (Italian Najuta Registry). The study was approved by a local institutional review board (Comitato Etico Lazio 1). According to the European General Data Protection Regulation, all cases were deidentified with a coding number and clustered into a dedicated shared electronic database. No funding was obtained from companies or other institutions for this research. Each patient signed a written consent form for anonymous use of data regarding surgery and follow-up for scientific purposes.

Anatomic characteristics, patient demographics, and preoperative clinical data were gathered, including comorbidities and indications for treatment, according to the Society for Vascular Surgery reporting standards.[5] All patients were considered at high risk for open repair based on their anatomy, age, and comorbidities. This decision was taken in each case after multidisciplinary discussion and anesthesiologic assessment at the treating center. A broad spectrum of aortic arch pathologies was treated, including degenerative aneurysmal disease, penetrating atherosclerotic ulcer, postdissection aneurysm, and type Ia endoleak on previous TEVAR.

A thin-sliced computed tomography angiography (CTA) of the thoracoabdominal aorta was analyzed in each case both from the referring vascular institute and Kawasumi Laboratories planning center to assess aortic arch characteristics along with aortoiliac vascular accesses. The custom-made graft was projected based on the CTA measurements aiming to seal at least in a proximal 20-mm-long neck in case of aneurysm treatment. Shorter proximal necks were considered acceptable in case of penetrating aortic ulcers and chronic dissections. Before endograft manufacturing, an in vitro simulation test was carried out, aiming to evaluate device conformability to the proper aortic arch to be treated. Endograft apposition to the actual vascular anatomy to be treated was estimated taking advantage of a stiff three-dimensional printed plastic model. This simulation was primarily focused on fenestrations matching with supra-aortic target vessels and eventual proximal endograft bird beak.

All procedures were performed in an operating room, angio-suite, or hybrid vascular operating theater equipped with a C-arm or a ceiling-mounted x-ray imaging system, depending on the vascular department. An experienced surgeon with at least three former Najuta device implants performed as operator attended each case, whether as proctor or directly as operator. In case of aortic pathology involving proximal arch portions, the repair was conceived with the intention to cover left subclavian artery or left carotid artery (LCA) origins with graft fabric. In these cases, an extra-anatomic supra-aortic surgical debranching was performed before or simultaneously with the endovascular procedure. Completion angiography was obtained in two different projections for all patients to confirm target vessels patency and aneurysm exclusion.

The follow-up protocol consisted in a CTA performed within 30 days after index procedure (Fig 1), one at 6 months, and yearly thereafter. During the follow-up, eventual aneurysm sac modifications (ie, growth >5 mm), endoleaks, stent graft fracture, and/or migration were systematically assessed.

Graft description. The Najuta device is a custom-made endograft with single or multiple nonsupported fenestrations created along its greater curvature to secure blood supply via the arch vessels (Fig 2). The graft is individually crafted using a three-dimensional CTA assessment to properly fit patients' aortic anatomy. It is made of five stainless steel stents sutured to three layered polytetrafluoroethylene only at both ends.

This endograft, aiming to enhance proximal sealing in case a proximal neck beyond left subclavian artery is not available, finds specific indication in case of saccular arch aneurysms or penetrating aortic ulcers and in general when dilatation does not involve supra-aortic vessels origin. Because epiaortic vessels perfusion is guaranteed through fenestrations measuring 11.5 to 18.0 mm and no additional bridging is needed, aortic lesion exclusion expects circumferential graft apposition at the level of each fenestration, in addition to precise matching between target vessels ostia and fenestrations.

The delivery system (21F-23F, depending on endograft diameter) comes with four possible precurved configurations, allowing easy positioning and accurate fenestrations

self-orientation at the supra-aortic arteries ostia. Fenestrations are meant for preserving target vessel perfusion without the need to place additional covered or uncovered stents.

Implant procedure. The Najuta endograft deployment sequence expects device advancement from a femoral access over a femoral-right brachial through and through wire. The graft is constrained inside a 21F to 23F outer diameter hydrophilic coated delivery sheath. The system reaches the innominate artery ostium, taking advantage of the tension obtained continuously pulling each guidewire end. Once this target position is achieved, tension is lost and a loop is formed inside the aortic root to facilitate delivery system sliding until intended deployment position, obtained after matching the highly visible radiopaque markers with target vessels ostia. At this stage, the endograft can be unsheathed through a pull-back maneuver relying on the unique fenestration self-orientation system features (Fig 3).

The rationale behind this unique implanting procedure is based on the preshaping of the delivery system: although this feature allows to easily advance the graft to the intended deployment position without needing a rigid support, it requires cautious tension maintenance during iliac and aortic graft crossing to avoid vessel damage and hinderance during progression. Because the device is very stable during deployment and blood flows through fenestrations with the partially unsheathed endograft, cardiac output modification maneuvers are not needed with Najuta arch repair

End points. Procedural technical success was defined as effective stent-graft placement without evidence of type I or III endoleak and supra-aortic vessels patency at completion angiography. Clinical success was defined as technical success in addition to the absence of important disabling clinical sequalae (perioperative death, aortic rupture, conversion to open repair, permanent paraplegia, major stroke, or renal failure requiring dialysis). Aortic-related death was defined as any death occurring within 30 days from the primary or from any secondary aortic arch intervention or because of aortic rupture. Study end points were technical success, 30-day clinical success, overall survival, supra-aortic vessels patency, endoleak, and the need for reintervention or surgical conversion.

Statistical analyses. Continuous data are expressed as median and interquartile range (first quartile and third quartile [Q1, Q3]) and categorical variables as number of patients and percentages. A Kaplan-Meier estimate was used to assess survival during follow-up considering a standard error measuring less than .10 as acceptable. All statistical analyses were performed with computed software SPSS software version 26 (IBM, Armonk, NY).

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter, national registry involving all patients treated with the fenestrated Najuta arch endograft in Italy
- **Key Findings:** During 4-year timeframe, 76 patients underwent aortic arch endovascular repair with the Najuta endograft across 21 centers in Italy, with 161 supra-aortic arteries ostia planned to be preserved through endograft fenestrations. Procedural technical success was 97.4% (74/76) and clinical success at 30 days was 94.7% (72/76). One perioperative death and one major disabling stroke were recorded. At a median of 7 months of follow-up, no supra-aortic vessel occlusion had occurred and no patients needed surgical conversion.
- **Take Home Message:** Aortic arch repair with the Najuta fenestrated endograft seems to represent a safe procedure in selected patients, expanding the possibility of undergoing a minimally invasive endovascular treatment to patients at high risk for open surgery requiring proximal sealing in the ascending aorta.

RESULTS

From March 2018 to June 2022, a total of 76 patients were treated with the Najuta endograft for aortic arch disease repair in Italy, over 21 different vascular centers, and included in the study cohort. Participating facilities and relative numbers of cases performed are detailed in the Supplementary Material (online only). The median age at the time of index procedure was 72 years (interquartile range [IQR], 69-76 years) and most of the treated patients (80.3%) were male. Patients presented the typical atherosclerotic comorbidities, as reported in Table I.

The indication for treatment was settled for degenerative aneurysm sealing in 80.3% cases; the remaining patients underwent endovascular arch repair after postdissection aneurysm (7.9%), penetrating aortic ulcer (9.2%) or proximal type I endoleak on previous TEVAR (2.6%). The proximal neck length was evaluated by the Kawasumi lab planning center as the shortest distance between the posterior edge of the more distal supra-aortic vessel ostium to be preserved and the origin of the aortic lesion (Fig 4). Median length in the study population measured 20.0 mm (IQR 15.6-23.0 mm). Arch aortic lesions involved Ishimaru zone 1 in 19.7% of the cases, zone 2 in 63.2% and zone 3, without a suitable proximal sealing zone for standard TEVAR in the remaining 17.1%. An extra-anatomic surgical debranching was needed in 71.1% of the cases. Among these cases, it was carried out as a first procedural step in 59.3% and performed during the same procedure in the remaining.

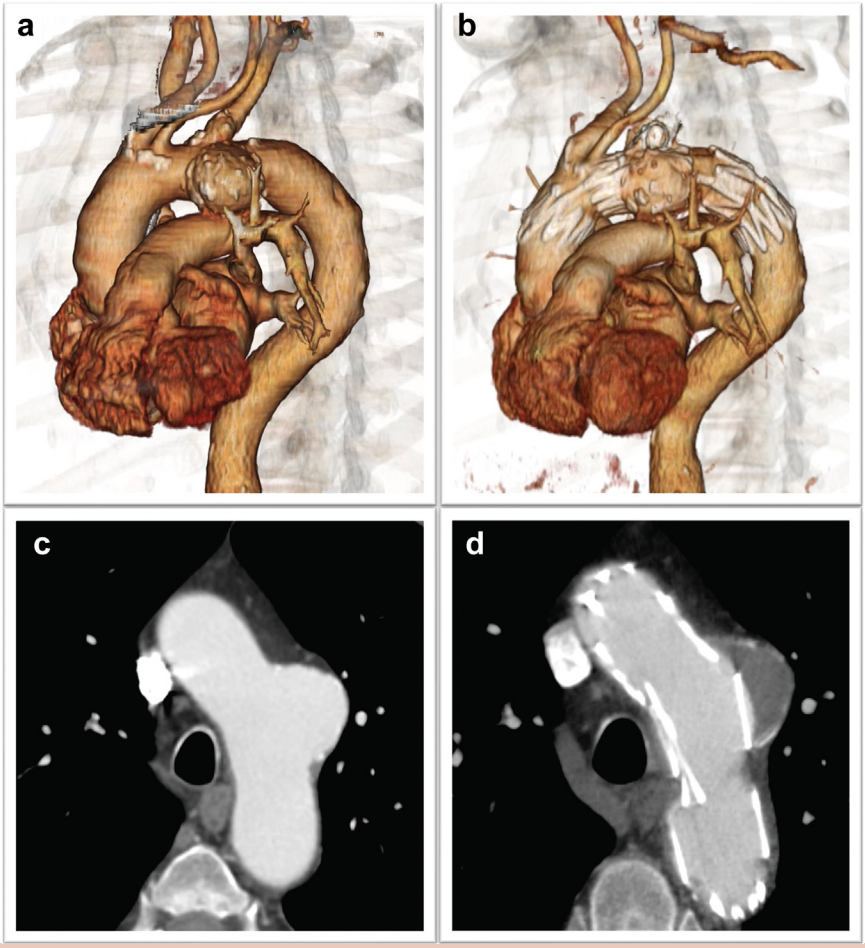

Fig 1. Preoperative and postoperative computed tomography scan in a patient who underwent Najuta endograft implantation for saccular aneurysm correction. Three-dimensional reconstruction **(A and B)** and axial images **(C and D)** before and after treatment. Note in image **C** how contrast media spreads outside the metallic stents. This image is typical and is caused by the mutual stent and fabric position (with fabric being outside of the stent and free to expand under blood pression).

Median interval between supra-aortic debranching and Najuta endografting was 8.5 days (IQR 5-60 days). Epi-aortic vessel rerouting was obtained in 8 cases via carotid-carotid-subclavian bypass and in 46 with left carotid to subclavian bypass.

Overall, 161 supra-aortic arteries ostia were planned to be preserved through endograft fenestrations (mean of 2.1 vessels per patient). Proximal endograft edge landing reached Ishimaru zone 0 in 92.1% of the cases and zone 1 in the remaining. The median procedural time was 90 minutes (IQR, 60-200 minutes), the median fluoroscopy time was 21.5 minutes (IQR, 13-30 minutes), and the median volume of contrast media used was 120 mL (IQR, 100-195 mL) (Table II). In five cases (6.6%), the fenestrated arch endograft was implanted under local anesthesia, whereas in all the others the operating team opted for general anesthesia.

In three cases a planned adjunctive procedure with surgical prosthetic iliac conduit was needed to properly advance the delivery system with the intention to overcome diseased external iliac and common femoral vascular accesses. The endograft was advanced through a percutaneous common femoral access in 56.6% of the cases.

Because the Najuta graft is designed with a standard length of 175 mm, a distal thoracic extension is sometimes needed to refine aneurysm sealing. In the study cohort, this additional TEVAR was performed in 27.6% of the cases. Because Kawasumi does not provide thoracic extensions, these adjunctive grafts were in all cases coming from a different manufacturer.

A prophylactic cerebrospinal fluid drain was positioned in eight cases deemed at high risk for spinal cord ischemia by the local operating team. In six of these cases, aortic coverage was planned to be extended distally beyond the Najuta graft with a different thoracic endograft.

Technical success was obtained in 97.4% of the procedures (74/76), with the two failures being due to a proximal type I endoleak that occurred after graft migration and

Fig 2. External appearance of a fenestrated Najuta arch endograft.

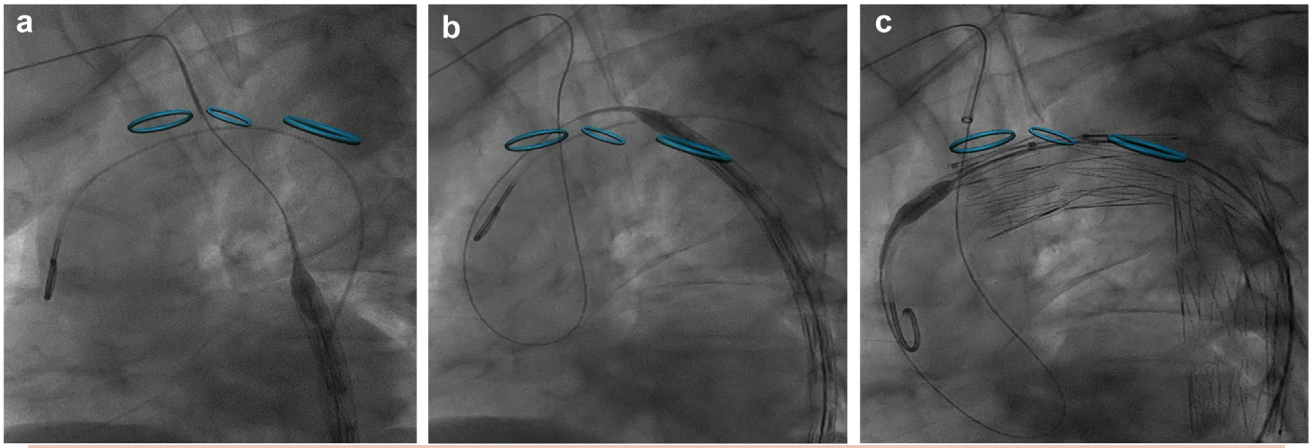

Fig 3. Intraoperative steps. The endograft is advanced up to the arch on a femoral-right brachial through and through **(A)**, guidewire tension is lost and a loop created in the ascending aorta once the proximal graft's end reaches the innominate artery ostium **(B)**, the device is advanced into the ascending aorta and fully deployed **(C)**. Fusion technology circle markers indicate supra-aortic vessels origins.

one type III endoleak occurring after inadequate overlap between the Najuta graft and a distal thoracic component. In two patients, the endograft migrated distally during the procedure after complete and proper deployment. In the first, the proximal graft end was indented to be released in front of the innominate artery ostium, properly deployed, then immediately moved distally, ending up in front of the LCA origin. As a consequence of the migration, the endograft fabric partially covered the LCA ostium and so a self-expandable bare metal stent was deployed with complete blood flow recovery. Despite this graft displacement, the aneurysm was effectively excluded and postoperative CTA confirmed technical success. This patient was followed up for 2 years and no endoleak or clinical sequelae developed. The procedure was thoroughly reviewed by the operating team along with Kawasumi lab engineers analyzing intraoperative angiographic images and postoperative CTA. In this particular case, the endograft failed to obtain a stable proximal sealing because of a bird beak inferiorly along with the presence of a wide common origin of the Innominate Artery and LCA superiorly. Therefore, a proper wall apposition was obtained in less than 50% of the first stent axial section, only in its lateral portions. The debriefing concluded that preoperative planning was inadequate and the endograft should have been manufactured with the intention to land more proximally into the ascending aorta.

In the second case of migration, a chronic postdissection aneurysm was treated by implanting a distal thoracic endograft before Najuta deployment. Because both endografts remained significantly compressed at

Table I. Preoperative risk factors in the study cohort

	No.	Percent
Male sex	60	78.9
Age, years	72 (IQR, 69-76)	
Hypertension	60	78.9
Diabetes	6	7.9
Smoker	45	59.2
Dyslipidemia	45	59.2
Chronic renal failure (>1.20 mg/dL)	14	18.4
Coronary artery disease	19	25
Chronic obstructive pulmonary disease	34	44.7
Previous ischemic stroke	7	9.2

IQR, Interquartile range.

the aortic isthmus where the true lumen was really narrow, the operators decided to postdilate with a large compliant aortic balloon. During this maneuver, the grafts slipped back approximately one stent length, resulting in a type Ia endoleak.

The other recorded complications were in all cases vascular access related. In two patients, external iliac artery damage developed during graft advancement; one was treated with a surgical iliofemoral bypass and the other by implanting a covered stent. Three right brachial and one common femoral pseudoaneurysms were detected after percutaneous artery access. All target vessels were preserved as planned and no patient needed conversion to open surgery.

One perioperative death occurred in hospital 28 days after index procedure, for acute respiratory failure in a patient with severe chronic obstructive pulmonary disease. Three neurological complications were recorded, all immediately resolving upon awakening—two minor strokes and one major disabling stroke (National Institutes of Health Stroke Scale score). The latter was clinically, and after imaging, identified as a right hemispheric cerebral ischemia, probably provoked by embolization from the aortic arch during the procedure. There were no cases in which spinal cord ischemia or renal failure requiring dialysis occurred. Clinical success at 30 days after the procedure was, therefore 94.7%, (72/76).

Two reinterventions were needed during the perioperative period. In one case, an aortic false lumen coil embolization was performed, because distal reentry caused enlargement of the postdissection thoracic aneurysm. The other procedure consisted of a femoral pseudoaneurysm repair.

The median follow-up was 7 months (IQR, 3-15 months). During the observational period, a total of seven deaths, including the already mentioned perioperative one, occurred. No late aortic-related deaths were reported. Kaplan-Meier analysis estimated an 83.4% cumulative survival rate at 24 months after the procedure. Two late TEVAR reinterventions were performed successfully to fix the endoleaks that determined technical failures, 2 and 6 months after the index procedure.

Four cases of a type II endoleak (arising from intercostal arteries) were recorded at control CTAs without significant aneurysmal sac enlargement; no target supra-aortic vessels occlusion or debranching bypass occlusion occurred. No retrograde type A aortic dissection was observed either during the perioperative or follow-up periods.

DISCUSSION

Endovascular treatment of descending thoracic aortic aneurysm is currently accepted as a first-line strategy when expected proximal coverage is limited to Ishimaru zones 2 to 4.[6] In cases where aortic pathology involves proximal aortic arch portions, eventually requiring zone 0 or 1 endograft sealing, endovascular treatment with standard techniques is not feasible owing to the physiological curvature and the essential need for preserving supra-aortic vessels perfusion. Historically, surgical repair represented the gold standard for aortic arch aneurysm repair despite its invasiveness and perioperative complications rate. The standard surgical approach requires sternotomy and antegrade or retrograde cerebral perfusion with deep hypothermic circulatory arrest to reduce neurological complications risks.

In a comparative study of different open surgical strategies, performed extrapolating data from the Society for Thoracic Surgeons Adult Cardiac Surgery Database, Englum et al[7] reported an 8% overall stroke rate. Furthermore, procedures conducted without cerebral protection obtained worse outcomes in terms of stroke and operative mortality when compared with those using this preauction.[7]

It is now well-established that old age and high comorbidities represent the principal factors affecting outcomes after open repair. Urbanski et al[8] published an exhaustive multicenter analysis including 1232 consecutive patients treated in 11 European cardiovascular centers with surgical aortic arch repair and at least 1 supra-aortic vessel reimplantation. In-hospital and 30-day mortality rates were 11.4% and 8.8%, respectively, ranging between 1.7% and 19% among the surgical centers. Despite a quite young patient cohort with a mean age of 64 ± 13 years, surgical risk remained significant.[8]

Investigating the role of age as a potential predictor of worse outcomes, Milewski et al[3] reported that, in cases of open arch repair, the mortality rate was four times lower in patients younger than 75 years compared with patients older than 75 (9% vs 36%; $P = .05$). To overcome some of the risks associated with open repair, a series of hybrid and endovascular alternative solutions have been proposed recently. Partial or complete aortic arch debranching initially emerged as a potential candidate for decreased invasiveness and, therefore, broader

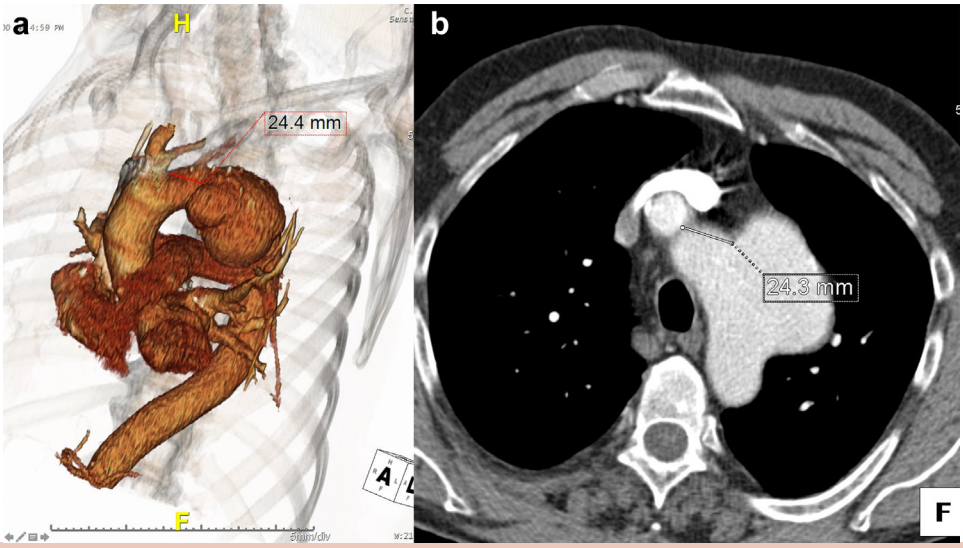

Fig 4. Axial and three-dimensional measurement of the proximal aortic neck, as evaluated by the Kawasumi lab.

Table II. Operative details in the treated population

	No.	Percent
General anesthesia	71	93.4
Percutaneous access	44	57.9
Cerebrospinal fluid drainage	8	10.5
Cardiac pacing	3	3.9
Endograft ballooning	2	2.6
Fluoroscopy time, minutes	21.5' IQR (13-30)	
Contrast medium, mL	120 ml IQR (100-195)	
Procedural time, minutes	90' IQR (60-200)	
Blood loss, mL	200ml IQR (150-300)	
Distal TEVAR component	21	27.6
LSA embolization	41	53.9

IQR, Interquartile range; *LSA*, left subclavian artery; *TEVAR*, transthoracic endovascular aortic aneurysm repair.

applicability including older and more frail patients. De Rango et al[9] in 2014 reported a series of 104 consecutive patients treated with partial or complete debranching plus TEVAR, with 5.8% and 3.8% perioperative death and stroke rates.

One of the most interesting findings in this paper refers to the important correlation between proximal landing and perioperative mortality, as treatment extension to Ishimaru zone 0 represented the only independent predictor (odds ratio, 9.6; 95% confidence interval, 1.54-59.90; $P = .015$) in a multivariate analysis of 30-day mortality.[9]

Endovascular repair, whether coupled with surgical debranching or not, requires specific anatomic features that would not necessarily affect surgical feasibility. The most important of these endovascular requirements is a healthy and long enough proximal landing zone, where the endograft can seal properly. To further increase complexity, the aneurysmal pathology can present many different patterns such as a fusiform dilatation involving greater curvature and supra-aortic vessels' origin or just restrained saccular aneurysms confined to the lesser curvature.

The ascending aorta maximum diameter represents the most relevant exclusion criteria for novel endovascular techniques, as also demonstrated by Sonesson et al[10] in a feasibility study published in 2015.[10]

Branched grafts were recently developed to specifically fit in the aortic arch, proving effectiveness and acceptable mid-term branch patency in patients requiring zone 0 proximal landing.[11] This solution was enthusiastically embraced in many vascular centers and widely spread, such that inner-branched devices could be considered as the benchmark configuration in endovascular aortic arch repair. However, cerebrovascular events remain an open issue, with perioperative rates ranging from 5% to 25% after branched endovascular repair.[11-15]

The Najuta system provides a different approach, aiming to maintain supra-aortic vessel patency through dedicated fenestrations without the need for bridging stents. Effective aneurysm sealing is obtained, guaranteeing circumferential graft apposition at the fenestration level. Therefore, a Najuta endograft repair is specifically indicated in cases of aortic arch aneurysms not involving the greater curvature or the innominate artery ostium. As a result, in case of aortic pathology proximally extending to Ishimaru zone 0, a fenestrated endograft such as the Najuta is not able to provide an effective repair.

An additional unique feature characterizing the Najuta concept is in the aneurysm exclusion system itself. This outcome is actually guaranteed by the fabric expansion resulting after complete endograft release under pulsatile blood pressure. This expansion occurs because polytetrafluoroethylene is just sutured along with the stainless steel

endoskeleton at its edges and is therefore free to distend under pressure as a boat sail does when the wind blows. The implant technique and device features allow for less manipulation of the supra-aortic vessel, resulting in 1.31% major stroke and 3.9% cerebrovascular event rates in the present study. Furthermore, device advancement and deployment are generally quite straightforward, and the procedure, not requiring additional steps after graft has been released, is less demanding when compared with a branched arch reconstruction.

The Najuta endograft obtained the CE mark in 2017 and, with its availability in Europe, a few case reports have been described.[16,17] The investigated graft has been available in Japan for a significantly longer period of time and the most relevant experience reported to date using this graft was published in 2015 by Iwakoshi et al.[18] Over a total population of 32 patients treated with the Najuta graft and with its precursor Yokoi HIJ stent from 2007 to 2013, the authors reported a technical success rate of 91%. Two cases of retrograde type A dissection occurred, a complication completely missing in the Italian Najuta registry. The median follow-up was 2.5 years and the overall estimated survival rate at 3 years was 67%.[18]

This article presents the largest cohort collected to date. Although limited in follow-up length, this study may be considered as a starting point in the evaluation process to assess whether this graft could represent an effective alternative for endovascular arch treatment and to identify which patients may benefit most from a minimally invasive procedure.

The study cohort will be followed thoroughly with the intention to report also mid- and long-term results, which could be particularly interesting, in view of the peculiar and unique endograft features, aneurysm exclusion system, and unbridged fenestrated design.

Study limitations. This study was limited by its nonrandomized design and by the absence of a control group. Considering this study design, a standardized approach to patient, indications for intervention, exclusion for open surgery, and prophylactic cerebrospinal fluid drainage were not possible. However, graft planning was in each case validated by the implanting physician, a proctor supervising the case, and the Kawasumi lab planning center. Patients were in all cases excluded from open surgery after multidisciplinary discussion and anesthesiology assessment at the treating facility.

CONCLUSIONS

Early results suggest that, in selected patients with aortic arch pathology needing a proximal landing, an endovascular approach with the Najuta system is safe and effective, especially for those deemed to be at high surgical risk. Continued follow-up with high-quality CTA images and evaluation of long-term complications is needed to confirm these initial experience findings.

AUTHOR CONTRIBUTIONS

Conception and design: GI, GS, RS, AG, NM
Analysis and interpretation: GI, GS
Data collection: GI, GS, MO, RS, AG, TC, MF, ML, NM
Writing the article: GI, GS
Critical revision of the article: GI, GS, MO, RS, AG, TC, MF, ML, NM
Final approval of the article: GI, GS, MO, RS, AG, TC, MF, ML, NM
Statistical analysis: GI, GS
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Overall responsibility: GI
GI and GS contributed equally to this article and share co-first authorship.

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APPENDIX (online only).

*Italian Najuta registry collaborators

Nicola Mangialardi, Matteo Orrico (Department of Vascular Surgery, San Camillo Forlanini Hospital, Rome, Italy)

Giacomo Isernia, Gioele Simonte, Massimo Lenti, Gianbattista Parlani, Gianluigi Fino, Luigi Baccani, Paolo Leonardi (Vascular and Endovascular Surgery Unit, Santa Maria della Misericordia Hospital, Perugia, Italy)

Roberto Silingardi, Tea Covic, Stefano Gennai (Department of Vascular Surgery, University of Modena and Reggio Emilia, Modena, Italy)

Andrea Gaggiano, Michelangelo Ferri, Emanuele Ferrero, Simone Quaglino (Vascular and Endovascular Surgery Unit, Mauriziano Umberto Hospital, Torino, Italy)

Antonio Rizza (Fondazione G. Monasterio, Ospedale del Cuore G. Pasquinucci, Massa, Italy)

Gabriele Maritati (Vascular and Endovascular Surgery Unit, Ospedale dei Castelli, Roma, Italy)

Michele Portoghese (Division of Cardiac Surgery, Ospedale Civile SS Annunziata, Sassari, Italy)

Fabio Verzini (Department of Surgical Sciences, Città della Salute e della Scienza, Torino, Italy)

Raffaele Pulli, Aaron Fargion (Vascular Surgery, Department of Cardiothoracic and Vascular Surgery, Careggi University Teaching Hospital, University of Florence, Firenze, Italy)

Stefano Bonvini (Department of Vascular Surgery, Santa Chiara Hospital, Trento, Italy)

Francesco Intrieri (Unit of Vascular Surgery, Annunziata Hospital, Cosenza, Italy)

Francesco Speziale, Wassim Mansour (Vascular Surgery Unit, Policlinico Umbero I of Rome, Roma, Italy)

Diego Moniaci (Vascular and Endovascular Surgery Unit, San Giovanni Bosco Hospital, Torino, Italy)

Raffaella Berchiolli, Nicola Troisi (Vascular Surgery Unit, Department of Translational Research and New Technologies in Medicine and Surgery, University of Pisa, Pisa, Italy)

Andrea Colli (Unit of cardiac surgery, University of Pisa, Pisa, Italy)

Stefano Camparini (Vascular Surgery Service, Cardiovascular Department, San Michele Hospital, ARNAS "G. Brotzu, Cagliari, Italy)

Giovanni Pratesi (Vascular and Endovascular Surgery Unit, Ospedale Policlinico San Martino, University of Genoa, Genova, Italy)

Francesco Massi (Department of Cardiovascular and Thoracic Surgery, Giuseppe Mazzini Hospital, Teramo, Italy)

Stefano Michelagnoli, Emanuele Chisci (Unit of Vascular and Endovascular Surgery, San Giovanni di Dio Hospital, Firenze, Italy)

Stefano Bonardelli (Unit of Vascular Surgery, Department of Surgical and Clinical Sciences, ASST Spedali Civili di Brescia, University of Brescia School of Medicine, Brescia, Italy)

Massimo Maione (Vascular Surgery Unit, Santa Croce e Carle Hospital, Cuneo, Italy)

Domenico Angiletta (Vascular and Endovascular Surgery Unit, University of Bari Aldo Moro, Bari, Italy

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Supplementary Table (online only). Participating centers with number of performed cases

Vascular center	No. of cases
San Camillo Forlanini Hospital (Rome)	16
Santa Maria della Misericordia Hospital (Perugia)	12
Civile Baggiovara Hospital (Modena)	8
Mauriziano Umberto Hospital (Turin)	8
Del Cuore G. Pasquinucci Hospital (Massa)	5
Civile SS Annunziata Hospital (Sassari)	4
Città della Salute e della Scienza Hospital (Turin)	3
Di Summa-Perrino Hospital (Brindisi)	2
San Martino Hospital (Genova)	2
Giuseppe Mazzini Hospital (Teramo)	2
San Giovanni Bosco Hospital (Turin)	2
Santa Chiara Hospital (Trento)	2
Santa Croce e Carle Hospital (Cuneo)	2
Policlinico Umberto I Hospital (Rome)	1
San Giovanni di Dio Hospital (Florence)	1
Spedali Civili Hospital (Brescia)	1
Brotzu Hospital (Cagliari)	1
Annunziata Hospital (Cosenza)	1
Policlinico Hospital (Bari)	1
Careggi Hospital (Florence)	1
Azienda Ospedaliero-Universitaria Pisana Hospital (Pisa)	1