Early outcomes of the Conformable endograft in severe neck angulation from the Triveneto Conformable Registry

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ABSTRACT

Objective: The study reports retrospective evaluation of early outcomes from a multicentric experience with the Excluder conformable endograft with active control system (CEXC Device) in the treatment of abdominal aortic aneurysms. Its design allows more flexibility, given by proximal unconnected stent rows and a bending wire within the delivery catheter enables control of proximal angulation. This study specifically focuses on the severe neck angulation (SNA) subgroup (≥60°).

Methods: All patients treated with CEXC Device in nine vascular surgery centers of Triveneto area (Northeast Italy) between January 2019 and July 2022 were enrolled prospectively and analyzed retrospectively. Demographic and aortic anatomical characteristics were evaluated. Endovascular aneurysm repair in SNA were selected for analysis. Major investigated outcomes were technical success, endoleaks, morbidity, mortality, and reinterventions at 30 days and during follow-up. Endograft migration and postoperative aortic neck angulation changes were also analyzed.

Results: A total of 129 patients were enrolled. An infrarenal angle of ≥60° was observed in 56 patients (43%) (SNA group) and their data analyzed. The mean patient age was 78.9 ± 5.9 years and median abdominal aortic aneurysm diameter 59 mm (range, 45-94 mm). Median aortic infrarenal neck length, angulation and diameter were 22 mm (range, 13-58 mm), 77° (range, 60°-150°), and 22.0 ± 3.5 mm respectively. Analysis revealed a technical success rate of 100% and perioperative major complication rate of 1.7%. Intraoperative and perioperative morbidity and mortality rates were 3.5% (one buttock claudication and one inguinal surgical cutdown) and 0%, respectively. No perioperative type I endoleaks were observed. The median follow-up was 13 months (range, 1-40 months). Five patients died during follow-up from aneurysm-unrelated causes. Two reinterventions occurred (3.5%): one conversion for a type IA endoleak and one sac embolization for a type II endoleak. Aneurysm sac shrinkage was observed in 15 patients (26%) and aneurysm stability in 35 patients (62%), respectively. Estimated freedom from reinterventions at 24 months was 92%. Aortic neck median postoperative angulation was 75° (range, 45°-139°).

Conclusions: The Triveneto Conformable Registry shows good early results of the CEXC device in severely angulated aortic infrarenal necks. These data need confirmation on longer follow-up and a wider cohort of patients to further increase endovascular aneurysm repair eligibility in SNA. (J Vasc Surg 2023;78:954-62.)

Keywords: EVAR; Abdominal aortic aneurysm; Severe neck angulation; Technical success; Early results

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Endovascular aneurysm repair (EVAR) has become the standard of care for infrarenal abdominal aortic aneurysms (AAAs), owing to decreased mortality and morbidity compared with open surgical repair.[1,2]

Despite continuous endovascular technological evolution, one-third of patients are not suitable to EVAR because of anatomical limitations, mainly related to hostile neck anatomy.[3]

Availability and confidence with last-generation endografts both enlarged applicability of EVAR within the recommended instructions for use (IFU) and expanded its application outside the IFU, even if results in this last scenario seem worse in terms of success rate and need for secondary procedures.[3,4]

Recently, the Excluder Conformable endograft was approved for indication in patients with angulated proximal sealing zones. Its technical features, such as proximal stent graft design, repositionability, and active angulation system are created precisely to increase the graft's adaptability and extend the range of treatment to severe angulated infrarenal necks (≤60° with neck length of ≤10 mm, ≤90° with a neck length of 15 mm according to the European IFU).[5]

The aim of this study was to analyze the early outcomes of EVAR with the CEXC graft focusing on results in the severe neck angulation (SNA) subgroup in a real-world cohort of patients collected in the Triveneto Conformable Registry (TriCoRe).

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter, observational, retrospective review of prospectively collected data from the Triveneto Conformable Registry
- **Key Findings:** Endovascular aneurysm repair with the Conformable endograft in severe neck angulation group of 56 patients (β angle ≥60°) resulted in 100% technical success, a low perioperative major complication rate (1.7%), and low mortality (0%). Two reinterventions occurred, one significant (type IA endoleak), during a median follow-up of 13 months.
- **Take Home Message:** This multicenter study shows good, early, real-life results of the conformable device in endovascular aneurysm repair with severely angulated infrarenal necks.

METHODS

All patients with AAA and submitted to EVAR using the Gore Excluder Conformable endograft (CEXC Device, W. L. Gore & Associates, Flagstaff, AZ) from January 2019 to July 2022 in nine Triveneto vascular centers were enrolled prospectively in the registry. Clinical data were entered in a standardized database and analyzed retrospectively. The institutional review board requirements were waived for the present descriptive and retrospective study. All included patients provided written informed consent.

Dataset. The TriCoRe arise from an independent collaborative network of nine vascular surgery units located in the Triveneto area in northeast Italy. The proprietary company did not participate in the present work. Since 2019, the registry prospectively collected data of all patients treated with CEXC device at the participating centers.

All preoperative and follow-up computed tomography (CT) scans were analyzed by a referring senior vascular surgeon in each of the involved centers to verify quality of inserted data. A single site was responsible of merging the data from each center. Records were then sent to the referral center where the database was created and analyzed.

Patient selection. All patients who had undergone elective EVAR with the CEXC endograft were prospectively enrolled in the TriCoRe. EVAR in SNA were then selected. Device was chosen by the operating physician of each single center in accordance with measurements and anatomic morphology assessment. Inclusion criteria were maximum AAA diameter of ≥5 cm for women and ≥5.5 cm for men or rapid AAA growth (increase of >0.5 cm in 6 months or 1 cm <1 year) or EVAR procedures for iliac aneurysm >3.5 cm in diameter.

Treatment and definitions. Demographic baseline characteristics, risk factors, and preoperative medical therapy data were obtained by the operating physician at the time of treatment. Recorded cardiovascular risk factors were hypertension, dyslipidemia, chronic obstructive pulmonary disease, chronic kidney disease, diabetes, cardiopathy, arrhythmia, and a history of coronary artery revascularization (coronary artery bypass graft, percutaneous transluminal coronary angioplasty, or stenting). Data on medical therapy were also collected (single or double antiplatelet, anticoagulant, and/or statin therapy).

Preoperative imaging studies were routinely performed using CT angiography (CTA) of the thoracoabdominal aorta with a 1-mm slice thickness. The evaluation of aortic disease and the presence of severe anatomic and morphologic characteristics (aortic neck angle, conic neck, neck thrombus, neck calcification, iliac tortuosity) was based on the Society for Vascular Surgery (SVS) reporting standards.[6,7] The suprarenal (α) and infrarenal (β) aortic neck angles, infrarenal aortic neck length, and diameter were assessed with reference to a standardized technique proposed using 3D reconstruction.[8] SNA, in absence of standardized definition,[9] was identified in cases with a β angle of ≥60° for all patients enrolled in the study. All patients with a β angle of >90° (outside the IFU) were treated with EVAR if considered at

excessive risk for open surgery (American Society of Anesthesiologists class 3 or 4).

All procedures were performed by experienced vascular surgeons in a dedicated vascular room.

Delivery of this endograft in SNA and short neck could be associated with adjunctive technical maneuvers (through-and-through with soft hydrophilic guidewire, precannulation of the distal renal artery) to optimize a precise graft delivery.[10]

Every participating center had no specific indications regarding the intraoperative deployment technique and selection of eventual adjunctive maneuvers, which were planned according to personal expertise.

Recorded intraoperative data for all patients were operative time, type of anesthesia, type of arterial access and percutaneous closure device, use of axillary-femoral through-and-through, graft repositioning maneuvers (specifically regarding direction and number) and need for adjunctive procedures. Technical success was defined according with the SVS reporting standards on an intent-to-treat basis and required successful deployment of the device in the absence of surgical conversion or mortality, type I and III endoleaks, or graft occlusion.[6]

The follow-up schedule was assessed by the operating physician on the single-center protocol basis, but at least two CT scans were required, one in the early postoperative period (within 30 days) and one during follow-up (within 1 year). All procedure-related complications were confirmed by a CTA scan and categorized in accordance with the SVS reporting standards for EVAR.[6] Endoleaks were defined according with the SVS and European Society for Vascular Surgery reporting standards.[11,12]

Primary endpoints were technical success, mortality, morbidity, endoleaks, and freedom from reinterventions at 30 days and during follow-up. The distance between the lowest renal artery and the proximal edge of the endograft was defined on the postoperative and follow-up CT scans and migration assessed. The infrarenal aortic neck was evaluated for postimplantation β angle changes. Mortality was validated using a regional inter-hospital database. Data analysis and outcomes evaluation specifically focused on the CEXC graft performance in SNA group.

Device details. The CEXC device has been available in Europe since 2018. It is a last-generation modular endograft with active infrarenal fixation and fits a wide range of neck diameters (proximal neck from 16 to 32 mm). Its design allows more flexibility, given by proximal unconnected stent rows and renewed delivery system. A bending wire within the delivery catheter allows control of proximal angulation, which can be used both before and after the first deployment stage. According to this delivery system, the endograft conforms to severe proximal aortic neck angulation of ≤90°. This feature, associated with the repositionability system (recostraining of the proximal end) and a new secondary constrainment sleeve system (which maintains main body partial collapse), allows optimal and aggressive juxtarenal deployment in complex anatomies (Fig 1). It can also be associated with a new Excluder Conformable Aortic Extender with active control.

Statistical analyses. Statistical analysis was performed using the R software/environment (version 4.2.2, R Foundation for statistical computing, Vienna, Austria). Continuous data were assessed for normality with the Shapiro-Wilk test. Continuous variables were expressed as mean ± standard deviation when distributed normally, and otherwise as median and range. Categorical data are reported as frequencies and proportions. The survival and reintervention-free probability rates were calculated using Kaplan-Meier curves, truncated at 36 months for excessively low number at risk. *P* value were considered significant when <.05.

RESULTS

Patient selection. During the study period, 129 patients who had undergone AAA repair with CEXC endograft were collected in the registry. Fifty-six patients were analyzed (SNA group). The distribution of cases per institution involved is summarized in Supplemental Table I (online only). The median age in the SNA group was 78.9 ± 5.9 years and most patients were male (n = 45 [80.3%]). Baseline demographic characteristics, including comorbidities and oral therapy are listed in Supplemental Table II (online only).

Preoperative morphological characteristics. Preoperative aortic morphological details are summarized in Table I. The SNA group β angle distribution was 30 (53%) >75° and 14 (25%) >90°. All 14 patients treated outside the IFU (β > 90°) were considered high risk for open surgery. In severely angulated necks, 12 (21%) had conic neck; calcifications and thrombus apposition were considered not severe. No issues regarding femoro-iliac arteries were reported.

Procedure results. Intraoperative technical findings in SNA group are listed in Table II. Thirty-seven patients (67%) were treated under general and 19 (33%) with local anesthesia through a total percutaneous approach in 80% of cases. The preferred closure system, performed in almost all cases (94%) was Proglide (Abbott Vascular, Redwood City, CA) with the Preclose technique.[13] An angulation system was used in 100% of cases. The endograft was deployed in the correct intended position in 4 cases (7.2%) and the repositioning system was used in 52 cases (92.8%), with a median of 1 maneuver (range, 1-5 maneuvers). Preferential direction for graft repositioning was upward (25 vs 18; 9 up and down). Repositioning maneuvers were performed over a hydrophilic

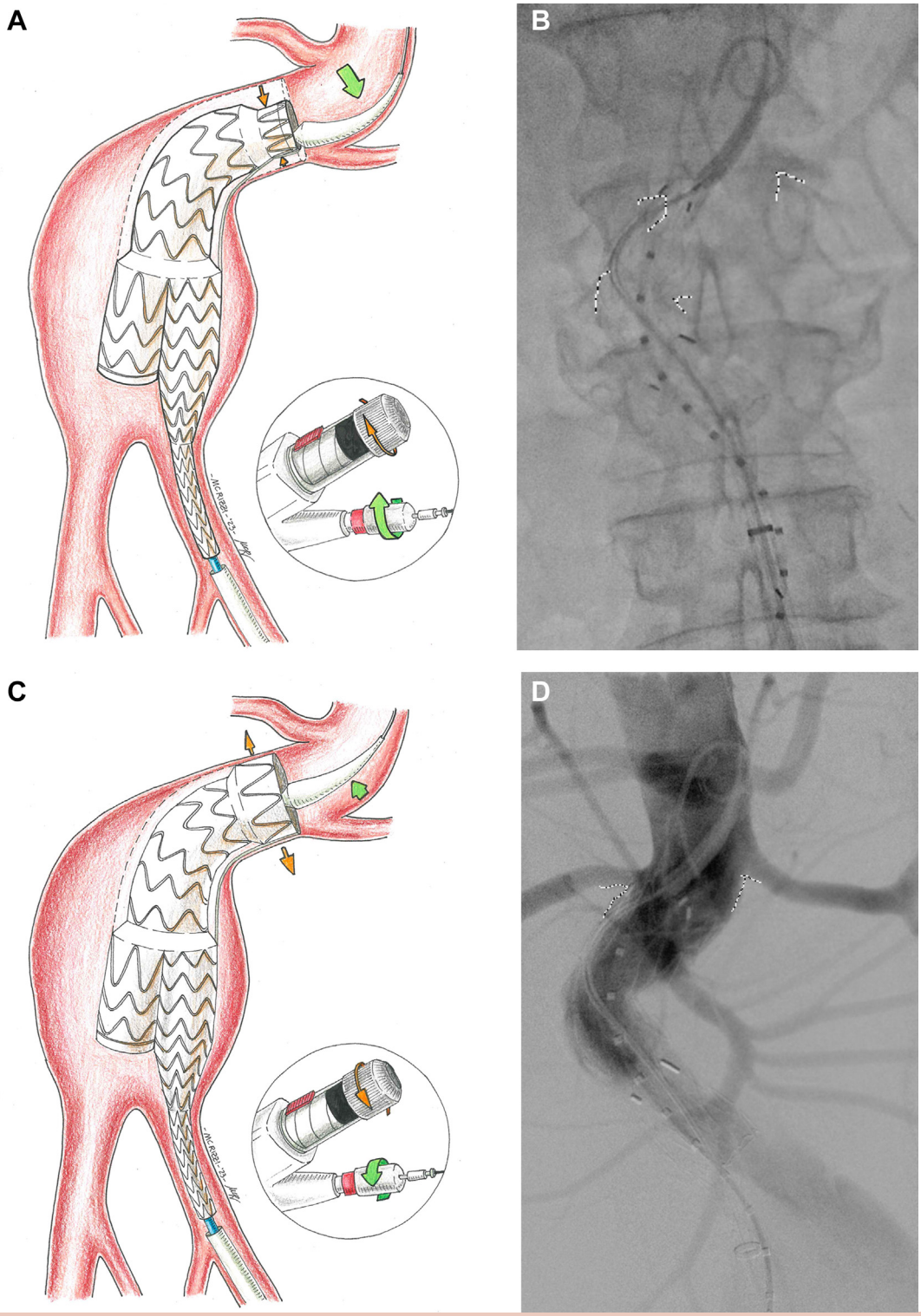

Fig 1. The Conformable Excluder Endoprosthesis (CEXC) and deployment stages with intraoperative images. **(A)** Angulation while restrained for upward repositioning. **(B)** Intraoperative corresponding image. **(C)** Proximal constrainment released and angulation removed before complete deployment. **(D)** Intraoperative angiogram evidencing precise infrarenal positioning in severely angulated neck.

Table I. Anatomical findings from preoperative computed tomography (CT) angiography scans, focusing on severe anatomic characteristics in severe neck angulation (SNA) group (n = 56)

Variable	Median (range), mean ± SD, or No. (%)
Aneurysm maximum diameter, mm	60 (45-94)
Proximal neck diameter, mm	22 ± 3.5
Proximal neck length, mm	22 (13-58)
Right CIA diameter, mm	15 (8.6-39)
Left CIA diameter, mm	15 (7-44)
Severe anatomic characteristics	
Aortic neck α angle, °	53 ± 33.3
Aortic neck β angle, °	77 (60-150)
Aortic neck β angle ≥75°	30 (53.5)
Conick neck	12 (21.4)
Neck calcifications ≥25%	4 (7.1)
Neck thrombus ≥25%	1 (1.7)
Aortic bifurcation <18 mm	7 (12.5)
Iliac tortuosity index >1.5	36 (64.2)
Iliac artery calcifications >50%	5 (8.9)

CIA, Common iliac artery; *SD*, standard deviation.

Table II. Intraoperative technical characteristics in the severe neck angulation (SNA) subgroup (n = 56)

Variable	Median (range) or No. (%)
Operative time, minutes	143 (52-360)
Technical success	56 (100)
Type of anesthesia	
Local	18 (32.1)
General	37 (66)
Spinal	1 (1.7)
Access	
Open surgical	3 (5.3)
Hybrid[a]	8 (14.2)
Percutaneous	45 (80.3)
Percutaneous closure device (n = 53)	
Proglide	50 (94.3)
Prostar	3 (5.6)
Axillary artery-femoral artery through-and-through	18 (32)
Renal artery precannulation	8 (14.2)
Repositioning	52 (92.8)
Upward	25 (48)
Downward	18 (34.6)
Up and down	9 (17.3)
Main body guidewire	
Soft hydrophilic	18 (32.1)
Extra stiff	38 (67.8)
Oversizing, %	28 (16-44)

[a]Hybrid: percutaneous femoral access + surgical axillary cutdown.

guidewire when supported by a femoral-axillary through-and-through (18/56 [32%]) and on extrastiff guidewire in the remnants. The lower renal artery was precannulated in eight cases (14%), all with an extremely angulated (≥75°) and short (≤15 mm) infrarenal neck. Device delivery was then completed following standard procedural steps. The median proximal diameter of the main body was 28 mm (range, 20-36 mm), with a median oversize of 28% (range, 16%-44%). Adjunctive procedures and intraoperative complications are listed in Table III. Thirteen patients (23%) underwent preventive intraoperative aortic sac embolization for being considered at high risk of a type II endoleak, four (7%) hypogastric embolization, and two (3%) polar renal artery embolization. Patients with common iliac artery aneurysms were treated with hypogastric branches in eight cases (14%), two of them with a bilateral iliac branch. Technical success was achieved in all 56 (100%) patients. In three cases, a proximal unplanned aortic cuff was positioned to extend proximal sealing after unintended caudal deployment of the graft evidenced at final angiography even if no type IA endoleak was detected. At the completion angiography no cases of type I/III endoleak or unintended renal artery coverage were recorded. One external iliac artery dissection (1.7%) was diagnosed and treated in the same operating session. Two patients (3.5%) underwent percutaneous femoral access surgical conversion.

30-Day results. No intraoperative or perioperative death was recorded. Perioperative complications occurred in two patients (3.5%). One buttock claudication secondary to hypogastric embolization was evidenced (1.7%) and treated conservatively, and one patient experienced an inguinal surgical cutdown on the first postoperative day for acute femoral occlusion. The freedom from reintervention rate was 98%. There were no cases of pulmonary or cardiac morbidity or severe postoperative renal function worsening. Median hospitalisation time was 3 days (range, 1-17 days). All patients underwent postoperative CTA within 30 days. No postoperative type I/III endoleaks were observed; a type II endoleak was detected in seven patients (12%). The median distance between lower renal artery and the proximal endograft at that time was 2 mm (range, 0-6 mm). The median aortic infrarenal postoperative angle was 75° (range, 45°-139°).

Follow-up results. All 56 patients with SNA had >30 days follow-up, with a median of 13 months (range, 1-40 months); 23 (41%) had a follow-up of ≥12 months and 3 (5%) of ≥24 months. Follow-up results in the SNA

Table III. Adjunctive intraoperative procedures and complications in the severe neck angulation (SNA) subgroup (n = 56)

Variable	No. (%)
Adjunctive procedure	
Proximal aortic cuff	3 (5.3)
Aortic sac embolization	13 (23.2)
Hypogastric artery embolization	4 (7.1)
Polar renal artery embolization	2 (3.5)
Iliac side branch	8 (14.2)
Bilateral iliac branch	2 (3.5)
Intraoperative complications	
EL IA	0
EL IB	0
EL III	0
EL II	4 (7.1)
Renal artery coverage	0
Iliac branches malpositioning	0
External iliac artery dissection	1 (1.7)
Groin hematoma	2 (3.5)

EL, Endoleak.

Table IV. Follow-up results in the severe neck angulation (SNA) group (n = 56), complications, and reinterventions

Variable	Median (range), No. (%), or %
Distance lowest renal artery-graft, mm	2 (0-6)
Aortic infrarenal angle, °	75 (45-139)
Follow up-time, months	13 (1-40)
≥12	23 (41)
≥24	3 (5)
Early complications (30 days)	
Early mortality	0
Freedom from reintervention	98.2
Buttock claudication	1 (1.7)
Femoral occlusion	1 (1.7)
EL IA/III	0
EL II	7 (12.5)
Hospitalization, days	3 (1-17)
Complications during follow-up	
Mortality at 12 months	1 (1.7)
Mortality, aneurysm related	0
Freedom from reintervention	96.5
EL IA	1 (1.7)
EL II + sac growth	1 (1.7)
Reinterventions	
EL II embolization (transfemoral)	1 (1.7)
Surgical conversion	1 (1.7)
Endograft migration	0
Aortic infrarenal angle, °	75 (45-139)
AAA sac stability	35 (62.5)
AAA sac shrinkage	15 (26.7)
AAA sac growth	2 (3.5)

AAA, Abdominal aortic aneurysm; *EL*, endoleak.

group are listed in Table IV. Fifty patients (89%) have at least two follow-up CT scans. One patient died at 12 months (5 overall during follow-up) for causes unrelated to the treatment of the AAA. No patient was lost to follow-up.

During the follow-up period, two patients required reintervention. One was treated with transarterial sac embolization for a persistent type II endoleak and aneurysm sac enlargement (>5 mm in 6 months). One patient underwent surgical conversion for a type IA endoleak and AAA sac enlargement detected at the 1-year CT scan. An analysis of CT images revealed aortic neck enlargement and endograft caudal migration in a severely conical neck. No further type I or III endoleaks occurred during the follow-up period. Lower renal to endograft distance remained stable in all other patients, as well as the aortic neck β angle. Aneurysm sac shrinkage was observed in 15 patients (26%) and aneurysm stability in 35 patients (62%), respectively. The follow-up data were analyzed using Kaplan-Meier estimates and data are reported in Supplemental Table III (online only). The Kaplan-Meier estimates of overall mortality and freedom from reintervention at 24 months were 90.2% (95% confidence interval, 71.3%-96.9%) and 92.1% (95% confidence interval, 71.8%-97.9%) (Fig 2).

DISCUSSION

EVAR has become the standard of care for AAA treatment, according to its low invasiveness and good early and midterm results. Complex anatomies remain the main challenge regarding technical success and long-term results of the technique.[14] The presence of severe aortic neck angulation could represent a limitation for endovascular repair and condition lower results in terms of complications and durability, mainly in angulations >75° and 90°.[9,15] In these situations, aortic endografts are generally used outside IFU.[3,16] To address this issue, the Excluder Conformable device, an infrarenal repositionable endograft with a flexible proximal configuration and active control system, was designed to extend EVAR eligibility in severely angulated or short aortic necks.

In this study, 56 of the 129 patients (43%) had a severe proximal neck angle (≥60°). Despite this anatomical issue, technical success in the SNA group was 100%, with no evidence of type IA endoleak at final angiogram or accidental intraoperative renal artery loss. The majority of these procedures were conducted under general anesthesia (66%), but the same results were achieved in patients treated with local or spinal anesthesia.

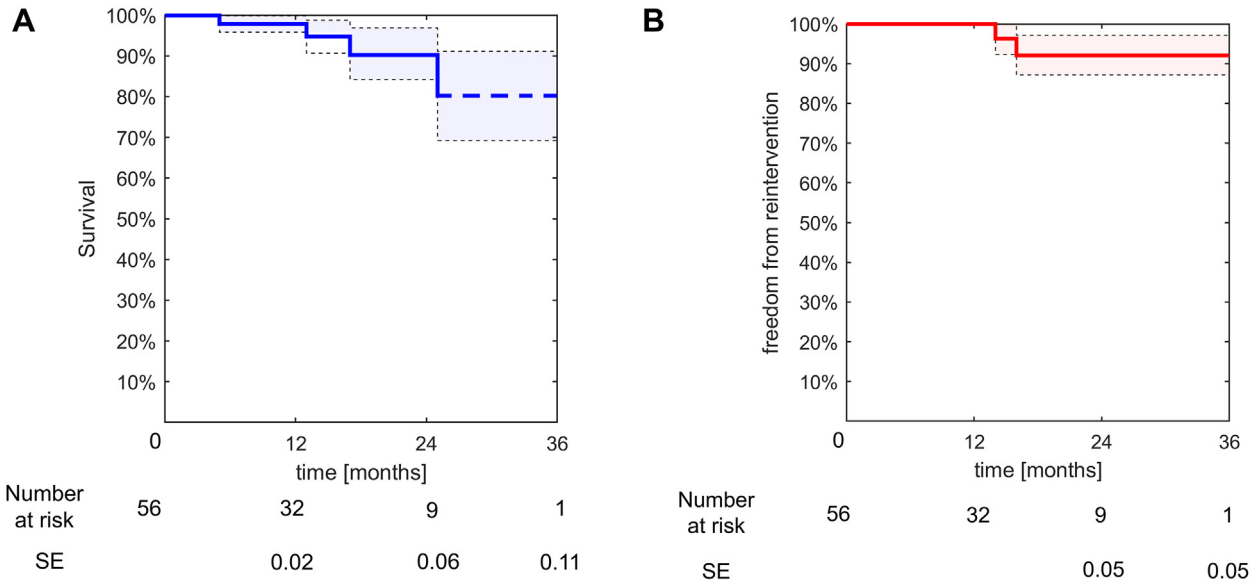

Fig 2. Kaplan-Meier curve for **(A)** survival and **(B)** freedom from reinterventions with confidence intervals at 95%. Curves are truncated at 36 months, given low number at risk.

According to data in the SNA group, the repositioning system was used in most cases (92%), showing its usefulness in these anatomies. The authors observed slight differences in the delivery setting between the contributors, mainly regarding the guidewire used during deployment and active control or repositioning maneuvers. Thus, no general suggestions could be inferred.

A recent single-center report suggested to release the graft over a stiff hydrophilic guidewire or the floppy portion of an extrastiff guidewire, to match the need for support and allow flexibility in angulated necks.[17]

A previous preliminary experience described routinely through-and-through axillary-femoral approach in SNA, using a floppy hydrophilic guidewire together with preventive cannulation of the lower renal artery if a short neck (<15 mm) was associated.[10] According to the authors, the use of these tools could combine flexibility, releasing tension on the guidewire during graft deployment, with pushability and support when returning wire tension during repositioning, mainly if performed cranially.

These maneuvers were not used frequently in the reported registry, respectively, in 18 of 56 (32%) and 7 of 56 (12%) cases, but were limited to patients with SNA associated with a short neck. Nevertheless, another report underlined this maneuver is not mandatory, showing good results in SNA without the need for these technical tricks.[17] These authors suggest aggressive deployment of the graft above the lowest renal artery, eventually repositioning it, pulling downstream rather than pushing cranially. However, a TriCoRe analysis revealed a need for upward repositioning in extreme SNA, suggesting these adjunctive maneuvers could be reserved to these specific situations.

An unplanned aortic cuff was necessary intraoperatively in three cases (5%) for unintended graft distal landing observed at final angiography. In all cases, the proximal extension was deployed to expand the proximal sealing zone, even if no type IA endoleak was detected. Cuffs were deployed in different centers at the beginning of each experience. This evidence is probably higher than expected by single contributors and could be explained by a learning curve effect.

To our knowledge, there are six published studies documenting experiences with this endograft, as summarized in Supplemental Table IV (online only). The first-in-human experience reported five cases with a single aortic neck angle of 60°. Technical success was 100% and no endoleaks were evidenced.[5] A second study analyzed aortic neck coverage and curvature changes in 12 patients with a severe aortic neck. Technical success was obtained in all cases and the absence of significant changes between preoperative and postoperative proximal aortic neck angulations and curvature was evidenced.[18]

Another preliminary experience reported results from five selected cases treated in two centers, with a highly severe proximal neck angle (>70°). Technical success was 100% and no secondary procedures were needed. Early results revealed no type IA endoleak and no migration at CTA, with a median follow-up of 5.2 months (range, 1.0-11.0 months).[10]

Rhee et al[19] recently reported 1-year results of the CEXC prothesis in the USA regulatory trial, in which 80 patients were enrolled. Of these, 23 had an aortic neck length of <15 mm. This study shows overall good results in terms of mortality and freedom from reinterventions, even though data on complex aortic necks (short or angulated) are only a small subgroup of the cohort and the angulated neck arm of the study is currently enrolling patients. The authors conclude that CEXC device performance and follow-up results in angulated necks are still pending.[19] Another paper reported good early outcomes of the CEXC endograft in 24 consecutive elective patients treated in a single center with neck length <15 mm or angulation of >60°. During 12 months of follow-up, five patients required reintervention, none for type IA endoleak.[20] A single-center study conducted by Mascoli et al[17] analyzed 25 patients with severe infrarenal aortic neck (median, 70°; range, 60°-90°]) treated with the CEXC device and a 12-month follow-up.[17] Endograft repositioning was used in 60% and active angulation system in 68% of cases. During that period no type I, II, or III endoleaks or reinterventions were detected.

The TriCoRe experience, thus, seems to be interesting regarding patients' number, severity of neck angulation and length of follow-up. To our knowledge, the TriCoRe is the largest independent postmarketing dataset analyzing the outcomes of EVAR using the CEXC in severely angulated neck.

Analysis of patient selection and preoperative characteristics in the SNA group highlighted greater anatomical complexity, specifically regarding aortic infrarenal neck angulation. As stated, 30 had a beta angle of >75° (53.5%) and 14 (25%) were treated outside the European IFU ($\beta > 90°$). TriCoRe revealed 100% use of angulation system and 92% of repositioning. These results were probably related to high anatomical complexity and intention to achieve as much sealing as possible, as confirmed by excellent results in graft distance to renal artery at postoperative CT scan.

Despite anatomical complexity, the technical success rate in our cohort was high (100%) as freedom from reintervention rate during follow-up even in complex anatomies. Accurate deployment in severe necks and graft potential to use the entire available neck was reproducible, as demonstrated by results across sites.

Follow-up seems consistent: 50 patients (89%) have at least two control CT scans, 23 (41%) patients had a follow-up of ≥12 months and 3 had a follow-up of ≥24 months. During the follow-up period only two reinterventions occurred, one of them highly significant (type IA endoleak). No other proximal sealing issues occurred in this series, except for the single conversion, mostly the result of a conical and already degenerating neck.

The median main body oversize in the TriCoRe SNA group was 28% (range, 16%-44%), higher than the IFU recommendation but similar to data highlighted in a recent article.[17] According to reported data, the choice of excessive oversizing was equally present in all the participating centers. It is the authors' opinion that an aggressive oversize could better fit anatomies with SNA, allowing the graft to adapt both to the inner and outer aortic curve, maximizing wall apposition where the graft cannot be perpendicular to the centerline.[21] Thus, a greater oversize is suggestible as the angle increases, to fit the aortic curvature at the level of maximal angulation. Indeed, despite excessive oversizing, no cases of infolding were observed on postoperative CT scans.

The absence of endograft migration and aortic neck dilatation at midterm follow-up seems to confirm suggestions from other authors and authors' practice regarding CEXC main body oversize, which seems safe and suggestible in cases of severe aortic neck angulation. Anatomical neck stability at control CTA in regards of the β angle also confirms the great endograft's flexibility, meaning that it really conforms to aortic anatomy rather than forcing it.[18] Reported results in hostile proximal neck anatomies seem encouraging and may suggest that the CEXC device could extend EVAR indications and increase eligible patients.

Limitations. The present study has some limitations. This paper reports a multicenter experience; thus, planning, patient selection, and intraoperative procedures were not standardized, leading to possible increase in terms of events related to a learning curve effect or biases in results analysis, because each center was responsible for entering their imaging results. The small number of patients selected in some centers in a relatively short period of time could be a limitation. A retrospective review was performed on a limited sample size with relatively short follow-up and no comparison group was included. The small number of events limited the power of statistical analysis and multivariable analysis could not be performed. Although the study design reflects a real-life experience with the CEXC device for AAA treatment in SNA, data on mid/long-term follow-up will be necessary to confirm the effectiveness of the treatment, especially in patients with severely angulated neck.

CONCLUSIONS

The presence of hostile aortic neck remains a challenge for EVAR success and durability. According to the TriCoRe, the CEXC endograft demonstrated a high technical success rate and good early and midterm outcomes in patients with severe aortic neck angulation, specifically regarding low reintervention rate and aneurysm-related mortality. Further studies and long-term follow-up results could better assess our findings.

The proprietary company did not participated to the present work (neither funding, data managing or assisted writing).

AUTHOR CONTRIBUTIONS

Conception and design: SB, PF, MA, SL, ST
Analysis and interpretation: NS
Data collection: NS, PF, MA, SI, GV, DM, EG, SL, RP, ST
Writing the article: SB, NS, ST
Critical revision of the article: SB, NS, PF, MA, SI, GV, DM, EG, SL, RP, ST
Final approval of the article: SB, NS, PF, MA, SI, GV, DM, EG, SL, RP, ST
Statistical analysis: NS
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Overall responsibility: SB

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Supplemental Table I (online only). Patients with severe neck angulation (SNA) per institution of Triveneto Gore Registry (n = 56)

Institution	No. (%)
Center 1	10 (17.8)
Center 2	2 (3.5)
Center 3	11 (19.6)
Center 4	4 (7.1)
Center 5	19 (33.9)
Center 6	5 (8.9)
Center 7	3 (5.3)
Center 8	2 (3.5)

Supplemental Table II (online only). Demographic preoperative characteristics (n = 56)

Variable	Mean ± SD or No. (%)
Age, years	78.9 ± 5.9
Male sex	45 (80.3)
Risk factors	
Hypertension	45 (80.3)
Dyslipidemia	30 (53.5)
COPD	12 (21.4)
Cardiopathy	24 (42.8)
Previous PTCA	12 (21.4)
Previous CABG	3 (5.3)
Arrhythmia	16 (28.5)
CKD	16 (28.5)
Diabetes mellitus	6 (10.7)
Preoperative medical therapy	
Single antiplatelet	34 (60.7)
Double antiplatelet	4 (7.1)
Oral anticoagulant	12 (21.4)
Statin	29 (51.7)

CABG, Coronary artery bypass graft; *CKD*, chronic kidney disease; *COPD*, Chronic obstructive pulmonary disease; *PTCA*, percutaneous transluminal coronary angioplasty.

Supplemental Table III (online only). Kaplan-Meier estimates of complications and reinterventions, severe neck angulation (SNA) group (n = 56)

Complication	12 Months	24 Months	36 Months
Freedom from complications			
Mortality	97.78 (85.25-99.68)	90.21 (71.34-96.91)	80.19 (48.61-93.46)
Reintervention (any)	100	92.11 (71.88-97.97)	92.11 (71.88-97.97)
EL I-related reintervention	100	95.65 (72.93-99.37)	95.65 (72.93-99.37)
EL II-related reintervention	100	96.30 (76.49-97.47)	96.30 (76.49-97.47)

EL, Endoleak.
Values are percent (95% confidence interval).

Supplemental Table IV (online only). Studies reporting experiences with the Excluder conformable endograft with active control system (*CEXC*) device

Author, year, journal, country	No. of cases	Technical success, %	Aortic β neck ≥ 60°, n	Follow-up, months	Complications	Conclusion
Rhee et al,[5] 2019, J Vasc Surg Innov Tech, USA	5	100	1	/	/	Good performance in standard anatomies, feasibility and security in first in-human implants.
Finotello et al,[18] 2021, J Endovasc Ther, Italy	12	100	12	/	/	Deployment of the CEXC device is safe and effective for patients with challenging proximal aortic necks. Absence of significant changes between preoperative and postoperative proximal aortic neck angulations and curvature confirms the high conformability of the endograft.
Bonvini et al,[10] 2021, Vascular, Italy	5	100	5	5,2	No EL IA or reinterventions	Routine use of axillary-femoral through-and-through guidewire associated with selective precannulation of the lower renal artery allows precise deployment in difficult anatomies.
Mascoli et al,[17] 2022, J Endovasc Ther, Italy	25	100	25	12	No EL IA or reinterventions	No adjunctive maneuvers needed in SNA, no reintervention or endoleak at follow-up. Possibly increase patients' eligibility for EVAR.
Lee et al,[20] 2022, Vascular, UK	24	100	Not specified	12	Five reinterventions, no EL IA/III, no conversion	Safety and efficacy of the CEXC device in EVAR with hostile neck.
Rhee et al,[19] 2022, J Vasc Surg, USA	80	100	0	12	Two reinterventions, no EL IA/III, no conversion	CEXC device is safe and effective for EVAR with encouraging data in short necks; performance in highly angulated necks pending.

EL, Endoleak; *EVAR*, endovascular aneurysm repair; *SNA*, severe neck angulation.