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Initial Clinical Experience With a New Conformable Abdominal Aortic Endograft

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Initial Clinical Experience With a New Conformable Abdominal Aortic Endograft: Aortic Neck Coverage and Curvature Analysis in Challenging Aortic Necks

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Abstract

Objectives: Aim of this work was to investigate precision of deployment and conformability of a new generation GORE EXCLUDER Conformable Endoprosthesis with active control system (CEXC Device, W.L. Gore and Associates, Flagstaff, AZ, USA) by analyzing aortic neck coverage and curvature. **Methods:** All consecutive elective patients affected by abdominal aortic aneurysm or aortoiliac aneurysm treated at our institution between November 2018 and June 2019 with the new CEXC Device were enrolled. Validated software was adopted to determine the available apposition surface area into the aortic neck, apposition of the endograft to the aortic wall, shortest apposition length (SAL), shortest distance between the endograft fabric and the lowest renal arteries (SFD) and between the endograft fabric and the contralateral renal artery (CFD). Pointwise centerline curvature was also computed. **Results:** Twelve patients (10 men, median age 78 years (71.75, 81.0)) with available pre- and postoperative computed tomography angiography (CTA) were included. Technical success was obtained in all the cases. Preoperative median length of the proximal aortic neck was 16.1 mm (10.7, 21.7) and suprarenal (α) and infrarenal (β) neck angulation were, respectively, 28.9° (15.7°, 47.5°) and 75.0° (66.9°, 81.4°). Postoperative median apposition surface coverage was 79% (69.25%, 90.75%) of the available apposition surface. SFD and CFD were 1.5 mm (0.75, 5.25) and 7 mm (4.5, 21.5), respectively. Average curvature over the infrarenal aorta decreased from 25 m⁻¹ (21.75, 29.0) to 22.5 m⁻¹ (18.75, 24.5) postoperatively ($p=0.02$). Maximum curvature did not decrease significantly from 64.5 m⁻¹ (54.25, 92.0) to 62 m⁻¹ (41.75, 71.5) ($p=0.1$). **Conclusions:** Our early experience showed that deployment of the CEXC Device is safe and effective for patients with challenging proximal aortic necks. Absence of significant changes between pre- and postoperative proximal aortic neck angulations and curvature confirms the high conformability of this endograft.

Keywords

abdominal aortic aneurysm, apposition, endovascular treatment, geometric analysis, sealing

Introduction

Continuous evolution of endovascular aortic repair (EVAR) allowed to make this option the treatment of choice in patients affected by infrarenal abdominal aortic aneurysm (AAA), whenever anatomically feasible and in presence of reasonable life expectancy.^{1,2}

Nevertheless, the presence of a short and angulated proximal aortic neck remains a challenge for standard EVAR due to the increased risk of type IA endoleak and reinterventions. On the other hand, poor endograft conformability in tortuous and angulated anatomies, with significant aorto-iliac remodeling, is a challenge to the long-term performance resulting

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in loss of seal at attachment sites, limb disconnection, kinking, and occlusion.

Only very recently, the introduction of a new generation endograft with active control technology, combined with technological improvement based on advanced planning software, is pushing the boundaries of EVAR in “hostile” anatomies.³ The GORE EXCLUDER AAA Endoprosthesis with active control system (CEXC Device) was engineered to offer angulation control, improved conformability and precise placement of the proximal endograft in challenging anatomies.

The purpose of this preliminary experience is to investigate precision of deployment and conformability of the CEXC Device by analyzing aortic neck endograft apposition and aortic curvature changes at different aortoiliac segments.

Materials and Methods

All consecutive elective patients affected by AAA or aortoiliac aneurysm who were treated at our institution between November 2018 and June 2019 with the CEXC Device were prospectively enrolled. The clinical, procedural, and follow-up data were prospectively collected and recorded into a dedicated database. The study was approved by the local institutional review board.

Indication for EVAR was based on multidisciplinary evaluation of individual subject’s comorbidities, life expectancy, and personal preference. All patients underwent preoperative assessment with high-resolution computed tomography angiography (CTA) of the thoraco-abdominal aorta and iliac-femoral axis with post-processing analysis using the Aquarius Intuition Software (TeraRecon Inc, Foster City, CA, USA) as part of the routinely practice to determine anatomic eligibility for endovascular treatment. Clinical and imaging follow-up with duplex and CTA scans examination were performed according to the local standard protocol, including examination at 1, 6, and 12 months after the procedure and yearly thereafter.

Endograft selection was based on the instructions for use (IFU) of this specific device that include AAA patients with infrarenal aortic neck diameter range of 16 to 31 mm, minimum aortic neck length of 10 mm, when proximal aortic neck angulation is $<60^\circ$, and minimum aortic neck length of 15 mm when proximal aortic neck angulation is $<90^\circ$. Iliac artery diameter in range 8-25 mm and iliac distal vessel seal zone length of at least 10 mm were also required; iliac and femoral axes must be adequate for 12- to 18-F introducer sheaths. In presence of aortoiliac aneurysm the decision to use a Gore Iliac Branch Endograft in combination with the bifurcated graft was at discretion of the surgeon team, being considered an outside IFU procedure.

Device Description and Technique

The new device is characterized by a design that switches from a continuous sinusoidal pattern to independent stents

with it supposed to facilitate the nesting and thus the angle of the device. The device is characterized by an additional sleeve that allows repositionability with partial deployment of the graft and its complete closure with the C3 system. In the previous version of the device only the first stent could be closed. The new active control system allows the folding of the angulation wire into the delivery system, making it possible to angle and reposition the device to achieve precise placement orthogonal to the lumen centerline.

Definitions and Outcomes

Patients’ comorbidities were evaluated accordingly to the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery/International Society for Cardiovascular Surgery (SVS/ISCVS). Preoperative risk assessment was based on the American Society of Anesthesiologists (ASA) classification. Study outcomes, defined according to SVS reporting standards, included intraoperative and 30-day technical success, survival, absence of type IA endoleak, limb kinking/thrombosis, and reintervention.

The contact surface of the endograft with the infrarenal aortic neck was evaluated with Vascular Image Analysis (VIA) prototype software (Endovascular Diagnostics BV, Utrecht, the Netherlands), which was developed and validated to quantify and visualize the contact surface area, as well as shortest length of apposition of the endograft fabric with the aortic neck. The software also calculates the endograft geometry within the aortic neck, including the renal artery-to-fabric distances over the curve of the aorta, proximal graft diameter and tilt.^{4,5}

A vessel centerline was constructed semiautomatically in the 3mensio Vascular Workstation (Pie Medical Imaging, BV, Maastricht, the Netherlands). Centerline coordinates, coordinates of the renal artery orifices and coordinates of the edge of the graft fabric were imported into the VIA software to compute (1) neck surface area, that is, the surface area available for sealing in the aortic neck (Figure 1A); (2) apposition surface area, that is, the surface contact of the fabric with the aortic neck (Figure 1B) and the related neck coverage percentage; (3) shortest apposition length (SAL), that is, the shortest distance between the proximal circumference of the stent fabric and the first slice perpendicular to the centerline where circumferential apposition of the fabric to the aortic neck is lost (Figure 1C); (4) endograft inflow diameter and percentage of proximal endograft diameter expansion in the aortic neck calculated as the ratio between expanded endograft diameter and the original main body diameter; (5) the shortest fabric distance (SFD), that is, the shortest distance between the endograft fabric and one of the renal arteries (Figure 1C); (6) the contralateral fabric distance (CFD), that is, the distance between the endograft fabric and the contralateral renal artery (Figure 1C); and (7) the tilt angle between the axis of the proximal endograft

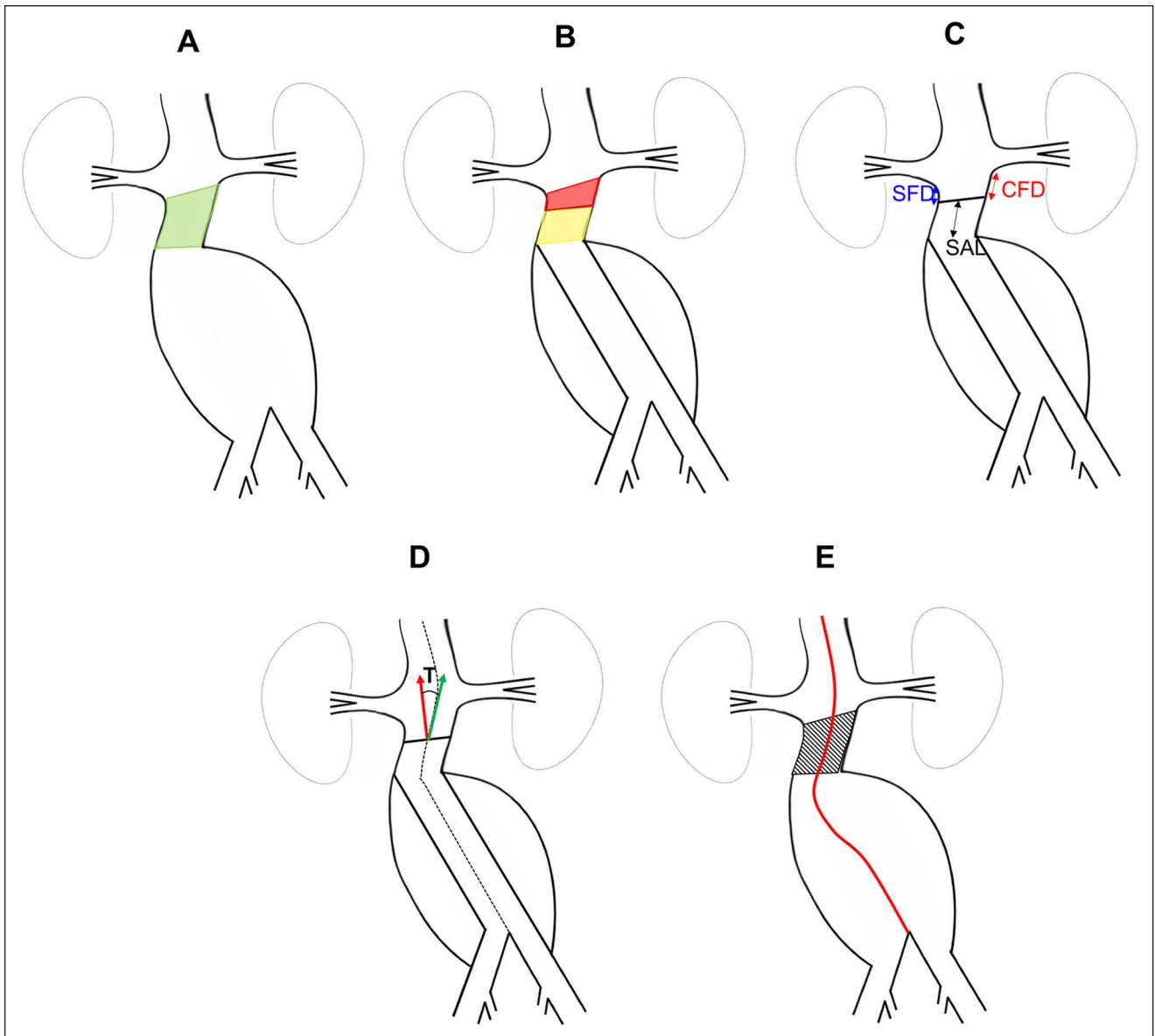


Figure 1. Schematic representation of computed parameters concerning 3-dimensional position of the endograft: (A) proximal aortic neck surface area (green zone); (B) postoperative apposition surface (yellow) and nonapposition surface area (red); (C) shortest apposition length (SAL), shortest fabric distance (SFD), contralateral fabric distance (CFD); (D) tilt angle (T) between the endograft axis and the aortic neck; and (E) centerline curvature (red).

fabric boundary and the directional vector of the centerline (Figure 1D).

Aortic curvature analysis was performed on the centerlines of the preoperative and 30-day postoperative CTA scans. Aortic curvature assessment has been described and validated in previous publications, and has been associated with intraoperative, as well as late type IA endoleak, and late endograft migration (>10 mm).⁶⁻⁸ Mean and maximum curvature values were computed along the centerline (Figure 1E). At each point, curvature is defined as the inverse of the osculating circle, that is, the circle that

approximates the centerline at the given point. Punctual curvature values were then averaged to compute mean curvature over the infrarenal aorta on the preoperative CTA scan or the stent main body on the postoperative CTA scan. The maximum curvature value of these segments was extracted as well.⁸

Statistical Analysis

All data were collected into a prospectively maintained database. Continuous variables were expressed as median

Table 1. Demographics.

Characteristics	
Age (years), median (interquartile range) (mm)	78 (71.75, 81.0)
Sex (male:female), n	10:2
Smoking history, n (%)	6 (50.0)
Hypertension, n (%)	11 (91.6)
Hyperlipidemia, n (%)	7 (58.3)
Diabetes, n (%)	1 (8.3)
CAD, n (%)	4 (33.3)
Arrhythmia, n (%)	3 (25.0)
Oral anticoagulant therapy, n (%)	4 (33.3)
CVD, n (%)	2 (16.6)
PAD, n (%)	2 (16.6)
COPD, n (%)	4 (33.3)
CKD (score III to V), n (%)	5 (41.6)
ASA class of III-IV, n (%)	10 (83.3)

Abbreviations: ASA, American Society of Anesthesiologists; CAD, coronary artery disease; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CVD, cerebrovascular disease; PAD, peripheral artery disease.

and interquartile range (Q1, Q3) and their variations were compared using paired-sample Student *T* test. Categorical variables were listed as numbers and percentages and compared with the χ^2 test. Statistical significance was assumed when the *p* value was <0.05 .

The statistical analyses were performed with the MATLAB 2019b—Statistics and Machine Learning Toolbox—software (The Mathworks, Inc., Natick, MA, USA).

Results

During the study period, 36 patients were treated at our unit with elective EVAR for AAA and aortoiliac aneurysm. The following abdominal stent grafts were adopted: the EXCLUDER and the CEXC Device (W.L. Gore and Associates, Flagstaff, AZ, USA), the Endurant II (Medtronic Vascular, Santa Rosa, CA, USA), the Zenith Alpha (Cook Medical, Bloomington, IN, USA), and the AFX (Endologix, Inc, Irvine, CA, USA). In 12 (33.3%) of these, we implanted the CEXC Device.

Ten patients were male and the median age was 78 years (71.75, 81.0). Demographics characteristics are listed in Table 1. Incidence of atherosclerotic risk factors reflected the standard distribution observed in patients affected by AAA. ASA class III or IV was identified in 83.3% of the patients. There was a high incidence of preoperative chronic kidney disease (CKD) and one patient was on dialysis. Anatomical characteristics of patients are reported in Table 2. The median preoperative proximal aortic neck length was 16.1 mm (10.7, 21.7) and was ≤ 15 mm in 6 (50%) patients.

Table 2. Anatomic Characteristics of the AAA.

Measurements	Median (IQR Q1, Q3)
Neck diameter (mm)	22.1 (19.4, 23.3)
Neck diameter at 15 mm (mm)	22.2 (19.5, 26.1)
Neck length (mm)	16.1 (10.7, 21.7)
AAA diameter (mm)	53.6 (39.4, 57.2)
Right CIA diameter (mm)	19.2 (14.7, 26.5)
Right IIA diameter (mm)	9.7 (8.5, 11.0)
Left CIA diameter (mm)	19.4 (16.6, 20.9)
Left IIA diameter (mm)	10.6 (8.9, 12.3)
α angle (deg)	28.9 (15.7, 47.3)
β angle (deg)	75.0 (66.9, 81.4)

Abbreviations: AAA, abdominal aortic aneurysm; CIA, common iliac artery; IIA, internal iliac artery; IQR, interquartile range.

The suprarenal (α) and infrarenal (β) angles were, respectively, 28.9° (15.7°, 47.3°) and 75.0° (66.9°, 81.4°). The β angle was $>60^\circ$ in 10 (83.3%) patients.

Technical success was obtained in all cases, without the need for adjunctive procedures. Active control system technology was adopted in 9 of 12 cases; an example of device placement optimization is shown in Figure 2. Seven (58.3%) patients received a total percutaneous EVAR under local anesthesia. Five patients required an iliac side-branch for a concomitant iliac and/or hypogastric aneurysm. Data regarding implanted endograft characteristics are shown in Table 3. In 9 (75%) patients, we got a C-shaped configuration of the main body. At the intraoperative angiographic control, the complete exclusion of the aneurysm with any type I endoleak or endograft kinking was documented for all cases. Fluoroscopy time and dose area product DAP were 31:46 (17:37, 41:13) minutes:seconds and 16694.5 (10713.5, 27766.8) cGy·cm², respectively.

Median length of hospital stay was 7.5 days (5, 14.5). Two major nongraft-related complications occurred during the recovery. At 1-month CTA control we observed 5 type II endoleaks with no need for reintervention. The overall mortality was 8.3%.

Analysis of Aortic Endograft Apposition

Figure 3 presents an analysis of pre- and postoperative aortic neck apposition parameters. Apposition parameters for all patients are reported in Table 4 (and Supplementary Figure 1).

The median preoperative aortic neck surface area was 2050.5 mm². Median aortic neck surface area at follow-up examination was 2525.5 mm². Postoperative apposition and nonapposition surface area were 1630.5 mm² and 422.0 mm², respectively, indicating that the median aortic neck coverage was 79% (69.25%, 90.75%) of the available aortic neck sealing surface. The median shortest apposition length

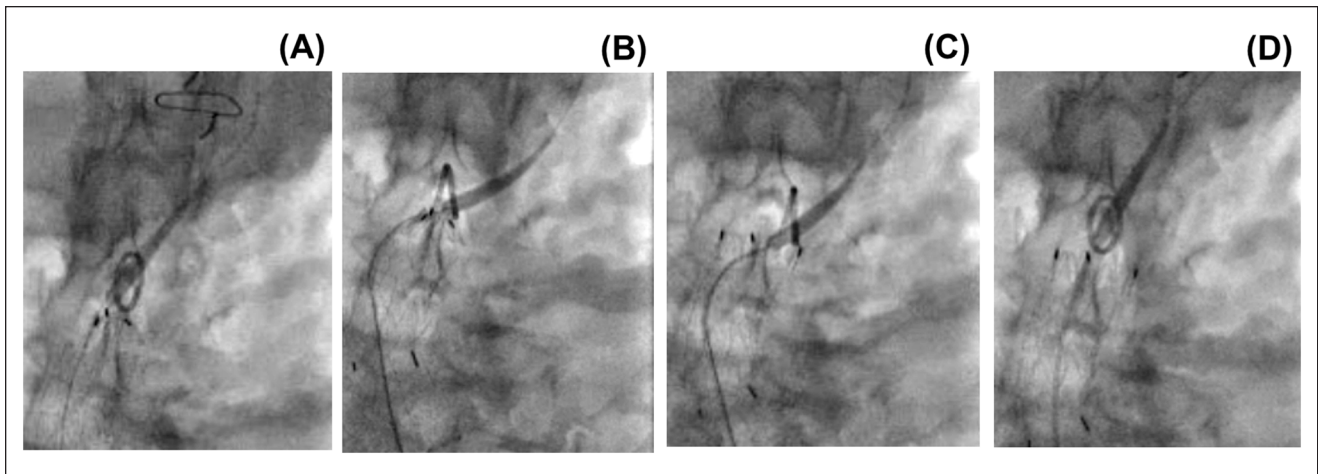


Figure 2. A case showing the sequential use of active control system during device deployment. (A) Partial deployment before and (B) with active control and angulated proximal tip. (C) Complete deployment of the main body with active control system, and (D) completion of the procedure.

Table 3. Endoprosthesis Characteristics; Median (Interquartile Range Q1, Q3).

Endograft proximal diameter (mm)	26 (23.0, 28.5)
Iliac endoprosthesis diameter (mm)	14.5 (—)
Endoprosthesis length (mm)	140.0 (120.0, 160.0)
Main body oversizing (%)	12.3 (6.0, 21.1)

at the follow-up examination was 22.5 mm, indicating an appropriate contact between endograft and aortic neck. At follow-up, median fabric distances were 1.5 mm (0.75, 5.25) and 7.0 mm (4.5, 21.5) for SFD and CFD, respectively. Partial coverage of one renal artery, without need for additional stenting, was observed in one patient and was clinically uneventfully.

The diameter of the endograft main body was obtained from the procedural planning reports. Proximal diameter expansion compared with original endograft main body diameter was 93% (88, 96).

Analysis of Aortic Curvature

Preoperative average curvature over the infrarenal aorta was 25 m^{-1} (21.75, 29.0), which decreased slightly to 22.5 m^{-1} (18.75, 24.5) postoperatively ($p=0.02$). The average curvature remained stable in half of the patients and decreased slightly in the other half after endograft implantation (all patients data are reported in Supplementary Figure 2). Maximum curvature over the infrarenal aorta was 64.5 m^{-1} (54.25, 92.0) preoperatively, and decrease to 62 m^{-1} (41.75, 71.5) postoperatively ($p=0.1$). The maximum curvature decreased in half of the patients due to aortic straightening after stent-graft implantation and increased slightly in a quarter of the patients. The distance of the maximum curvature from baseline at the lower renal artery

changed from 44.5 mm (40, 60.25) to 39 mm (23.25, 47.25). In 4 patients, the maximum angle shifted upward from the aneurysm into the aortic neck area. In one patient, the maximum angle shifted downward from the neck area toward the aneurysm, but this was a patient with almost no curvature (9 m^{-1}). Centerline curvature averaged parameters are reported in Table 5 (and Supplementary Figure 2).

Discussion

Our study showed the feasibility of EVAR with CEXC Device in hostile aortic neck and the lack of significant changes between the pre- and postoperative aortic curvature analysis. Short neck length ($\leq 10\text{ mm}$), severe angulation ($\geq 60^\circ$), and presence of calcification and thrombus are well-known predictors of negative outcome. Moreover, as noticed by Ishibashi et al,⁹ proximal neck angulation reduced greatly immediately after EVAR procedure and continued to reduce slowly and gradually. Proximal neck angulations $>60^\circ$, compared with those $<60^\circ$, had a larger angulation reduction and a smaller diameter shrinkage after the EVAR procedure. Recent studies show that aortic angulation, aortic curvature, aneurysm sac diameter, mural neck thrombus and neck length are strong predictors of late failure of endograft sealing and fixation in the aortic neck.^{8,10-12} In addition, aneurysm tortuosity has been demonstrated to be associated with increased risk of type I or III endoleaks.¹³

The two main reasons to explain the limited efficacy of standard endografts in patients with short and angulated proximal aortic necks are the inability to perform a precise and controlled endograft deployment and the scarce endograft conformability, which prevents the orthogonal placement to the main aortic axis. All these findings emphasize the necessity of a new device able to conform to changes in

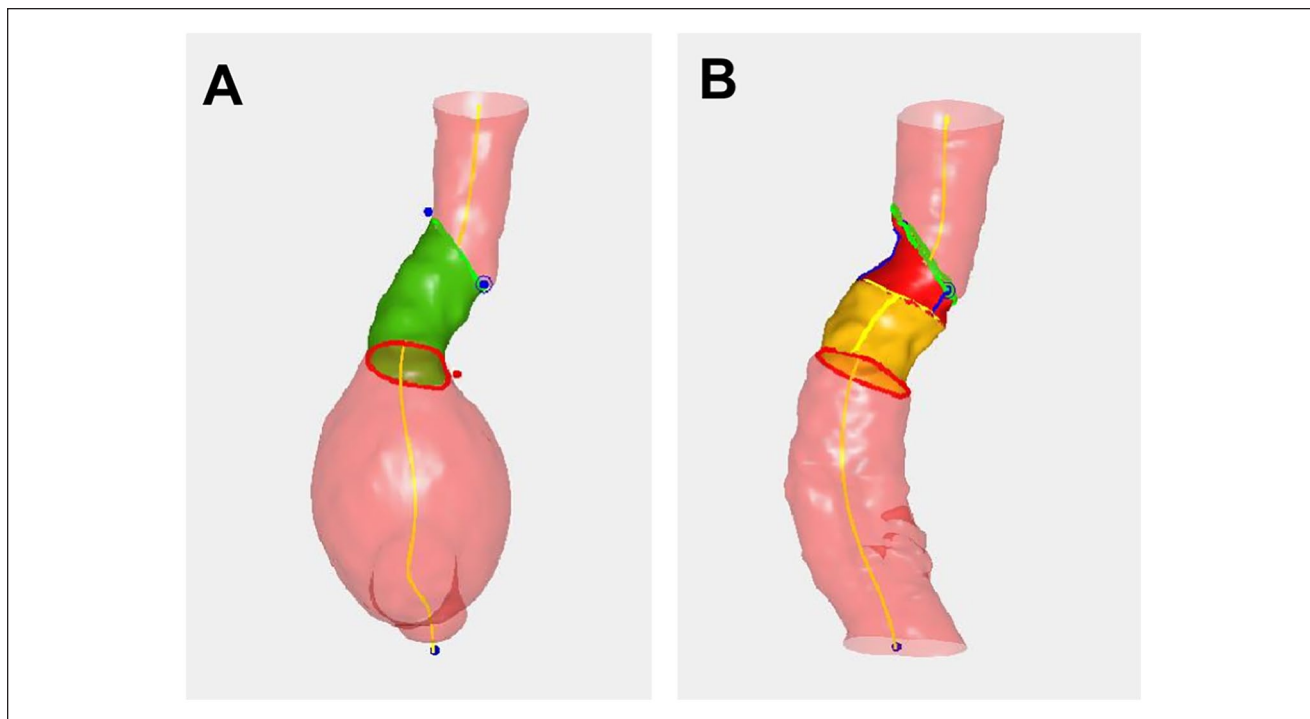


Figure 3. Apposition and position measurements for one patient: (A) preoperative neck surface area and (B) postoperative apposition (yellow) and nonapposition (red) surface.

Table 4. Apposition Parameters; Median (Interquartile Range Q1, Q3).

Apposition	Preoperative	Postoperative
Neck surface area (mm ²)	2050.5 (1467.25, 3180.25)	2525.5 (1612.25, 2620.5)
Apposition surface area (mm ²)		1630.5 (1404.0, 2116.25)
Nonapposition surface area (mm ²)		422.0 (179.75, 945.0)
Neck coverage percentage (%)		79 (69.25, 90.75)
Shortest apposition length (mm)		22.5 (19.0, 32.0)
Endograft inflow diameter (mm)		23.5 (22.75, 26.0)
Proximal diameter expansion (%)		93.0 (90.5, 98.5)
Tilt angle (deg)		13.0 (8.5, 22.0)
Shortest fabric distance (mm)		1.5 (0.75, 5.25)
Contralateral fabric distance (mm)		7.0 (4.5, 21.5)

aortoiliac anatomy, and at the same time to accommodate changes in proximal neck diameter, angulation, aortoiliac length, and iliac attachment zone diameters.

Three-dimensional follow-up CT investigation of aortic endovascular procedures is important to provide a better assessment of endograft position and apposition.^{12,14} Conventional EVAR follow-up protocols may underestimate future endograft-related complications. A standardized approach based on the quantitative determination of 3-dimensional neck apposition could be more sensitive to stratify patients' risk for future complications. Moreover, information about apposition to the arterial wall and

position with regard to anatomical landmarks (ie, origin of renal arteries) could represent a powerful instrument for proper assessment of device conformability and precision of delivery with regard to preoperative planning.

However, even the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE), which represents one of the largest real-world registries for EVAR stent-grafts, does not include, at the present time, investigations regarding geometric remodeling of the sac neither conformability concepts in its 5-year outcomes.¹⁵

Our study shows that the new CEXC Device, which is specifically designed for angulated and challenging

Table 5. Centerline Curvature Parameters; Median (Interquartile Range Q1, Q3).

Curvature	Preoperative	Postoperative
Infrarenal neck, average (m^{-1})	25.0 (21.75, 29.0)	22.5 (18.75, 24.5)
Infrarenal neck, maximum (m^{-1})	64.5 (54.25, 92.0)	62 (41.75, 71.5)

anatomies, allowed to reach proper apposition in this first series of patients.

In fact, the median shortest length of stent apposition to the aortic neck was 22.5 mm with a coverage of around 80% of the available potential seal. Our results are consistent with the outcomes of a previous study performed with the same validated VIA prototype software, but in patients with less challenging aortic necks.¹² In a cohort of electively treated EVAR patients with Endurant (Medtronic Cardiovascular, Santa Rosa, CA, USA), Talent (Medtronic), Zenith (Cook Medical, Bloomington, IN, USA), and Excluder (W.L. Gore and Associates) devices, an average endograft apposition percentage of neck area of 71% to 75% (complications vs noncomplications groups) was detected with shortest apposition length of 10.4 to 18 mm.

Moreover, in our case series, median SFD, that is, the shortest distance between the endograft fabric and the lowest renal arteries, was 1.5 mm. The CFD, that is, the contralateral fabric distance, was greater (7 mm) even if it should be noted that in some cases patients present with asymmetric renal arteries origin in short straight proximal neck anatomies. SFD was greater in the first 2 patients (7 and 6 mm) indicating an improvement after an initial learning curve. Our outcomes are in line with what already observed by Schuurmann et al¹⁶ who measured 3-dimensional fabric to renal artery distances in patients with AAA treated endovascularly with Endurant, Zenith, Excluder, and Talent devices. CFD and SFD were on average 1.5 and 8 mm, respectively, suggesting that CEXC device ensures comparable performances of positioning and apposition, even with more angulated preoperative aortic neck anatomies.

A special mention concerns the 10th patient of our case series, in which even though we completed the procedure without intraprocedural complications, we did not reach a proper neck coverage (48%). This was probably related with the severe β angle and the high tortuosity index (respectively 1.5 and 2 for the aorto-iliac right and left axes).

Despite the fact that the characteristics of the hostile necks are widely described and accepted, aortic curvature analysis has been taken into account only in recent years. Schuurmann et al⁸ identified aortic curvature instead of aortic angulation as a strong predictor of late failure of endograft sealing and fixation in the aortic neck, causing late type Ia endoleak and migration. Authors analyzed curvature values of elective EVAR patients treated with standard

devices comparing patients with late complications with a control group. In our current study, the average curvature was lower. Moreover, we observed a slight decrease of mean curvature between pre- and postoperative configuration (23.91 to 21.25 m^{-1} ; $p=0.02$). Maximum curvature also decreased in our cohort ($p=0.1$) along the stent main body suggesting low risk of late failure.

In the IFU of the CEXC Device there are no specific indications for an adjunct iliac branching. As previously mentioned, we performed 5 iliac branching and we observed no further intraoperative or postoperative complications. The iliac branching is a safe and effective procedure when necessary, even if out of IFUs.¹⁷ Endovascular preservation of internal iliac arteries should be performed whenever possible to prevent complications.¹⁸

Limitations

Our work is a monocentric study with a limited number of patients, because of initial experience. We only evaluated the preoperative and postoperative 1-month CT images, without comparative data of other stent-grafts. We need a longer follow-up to investigate stability of apposition and possibility of late complications.

Conclusions

Our study shows that the use of the new CEXC Device is safe and effective in treating AAA patients with challenging proximal aortic neck as confirmed by the absence of early proximal type I endoleak in our series. Furthermore, proper apposition to the aortic neck (>2 cm coverage in most patients) is reached in this first series of patients demonstrating precision and control of endograft deployment thanks to new active control system. Finally, the absence of significant changes between the preoperative and postoperative aortic curvature analysis, confirms the high conformability of this endograft in presence of angulated necks.

Declaration of Conflicting Interests


The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Jean-Paul de Vries and Richte Schuurmann are cofounders of Endovascular Diagnostics BV, which holds patent rights to the VIA software used in this study.

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Supplemental Material

Supplemental material for this article is available online.

References

- Greenhalgh RM, Brown LC, Powell JT, et al. Endovascular versus open repair of abdominal aortic aneurism. *N Engl J Med*. 2010;362:1863–1871.
- Wanhainen A, Verzini F, Van Herzele I, et al. Editor's choice. European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. *Eur J Vasc Endovasc Surg*. 2019;57:8–93.
- Rhee R, Peterson B, Moore E, et al. Initial human experience with the GORE EXCLUDER conformable AAA endoprosthesis. *J Vasc Surg Cases Innov Tech*. 2019;5:319–322.
- Van Noort K, Schuurmann RC, Slump CH, et al. A new method for precise determination of endograft position and apposition in the aortic neck after endovascular aortic aneurysm repair. *J Vasc Surg*. 2016;57:737–746.
- Schuurmann RCL, Overeem SP, Van Noort K, et al. Validation of a new methodology to determine 3-dimensional endograft apposition, position, and expansion in the aortic neck after endovascular aneurysm repair. *J Endovasc Ther*. 2018;25:358–365.
- Schuurmann RCL, Kuster L, Slump CH, et al. Aortic curvature instead of angulation allows improved estimation of the true aorto-iliac trajectory. *Eur J Vasc Endovasc Surg*. 2016;51:216–224.
- Schuurmann RCL, Ouriel K, Muhs BE, et al. Aortic curvature as a predictor of intraoperative type Ia endoleak. *J Vasc Surg*. 2016;63:596–602.
- Schuurmann RC, Van Noort K, Overeem SP, et al. Aortic curvature is a predictor of late type Ia endoleak and migration after endovascular aneurysm repair. *J Endovasc Ther*. 2017;24:411–417.
- Ishibashi H, Ishiguchi T, Ohta T, et al. Remodeling of proximal neck angulation after endovascular aneurysm repair. *J Vasc Surg*. 2012;56:1201–1205.
- Gonçalves FB, Hoeks SE, Tejjink JA, et al. Risk factors for proximal neck complications after endovascular aneurysm repair using the Endurant stent-graft. *Eur J Vasc Endovasc Surg*. 2015;49:156–162.
- Marone EM, Freyrie A, Ruotolo C, et al. Expert opinion on hostile neck definition in endovascular treatment of abdominal aortic aneurysm (a Delphi consensus). *Ann Vasc Surg*. 2020;62:173–182.
- Schuurmann RC, van Noort K, Overeem SP, et al. Determination of endograft apposition, position, and expansion in the aortic neck predicts type Ia endoleak and migration after endovascular aneurysm repair. *J Endovasc Ther*. 2018;25:366–375.
- Chen PL, Hsu HL, Chen IM, et al. The impact of aortic tortuosity on delayed type I or III endoleak after endovascular aortic repair. *Ann Vasc Surg*. 2017;41:110–117.
- Schuurmann RC, De Rooy PM, Bastos Gonçalves F, et al. A systematic review of standardized methods for assessment of endograft sealing on computed tomography angiography post-endovascular aortic repair, and its influence on endograft-associated complications. *Expert Rev Med Devices*. 2019;16:683–695.
- Tejjink JA, Power AH, Böckler D, et al. Five year outcomes of the Endurant stent graft for endovascular abdominal aortic aneurysm repair in the ENGAGE registry. *Eur J Vasc Endovasc Surg*. 2019;58:175–181.
- Schuurmann RC, Overeem SP, Ouriel K, et al. A semiautomated method for measuring the 3-dimensional fabric to renal artery distances to determine endograft position after endovascular aneurysm repair. *J Endovasc Ther*. 2017;24:698–706.
- Schneider DB, Milner R, Heyligers JM, et al. Outcomes of the GORE Iliac Branch Endoprosthesis in clinical trial and real-world registry settings. *J Vasc Surg*. 2019;69:367–377.
- Karch LA, Hodgson KJ, Mattos MA, et al. Adverse consequences of internal iliac artery occlusion during endovascular repair of abdominal aortic aneurysm. *J Vasc Surg*. 2000;32:676–683.