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GEOMETRIC ANALYSIS OF THE GORE EXCLUDER CONFORMABLE ENDOPROSTHESIS IN THE INFRARENAL AORTIC NECK: 1-YEAR RESULTS OF THE EXCEL REGISTRY

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ABSTRACT

Objective

The Gore Excluder Conformable Endoprosthesis (CEXC) is designed to treat challenging infrarenal anatomy because of its active angulation control, repositionability, and enhanced conformability. This study evaluated 30-day and 1-year position and apposition of the CEXC in the infrarenal neck.

Methods

Patients with an available 30-day computed tomography angiography (CTA) were selected from four hospitals in a prospective registry. Endograft apposition (shortest apposition length [SAL]) and position (shortest fabric distance [SFD]) were assessed on the 30-day and 1-year CTAs. Maximum infrarenal aortic curvature was compared between the preoperative and postoperative CTAs to evaluate the conformability of the CEXC.

Results

There were 87 patients with a 30-day CTA, and for 56 of these patients, the 1-year CTA was available. Median preoperative neck length was 22 mm (15–32), and infrarenal angulation was 52° (31°–72°). Median SAL was 21.2 mm (14.0–29.3) at 30 days for all included patients. The SAL in 13 patients (14.9%) was <10mm at 30 days, and one had a SAL of 0mm and a type 1a endoleak. The SAL significantly increased by 1.1 mm (−2.3−4.7; *p*=.042) at 1 year. The SAL decreased in 7 patients (12.5%), increased in 13 (23.2%), and remained stable in 36 (62.2%). Median SFD was 2.0 mm (0.5–3.6) at 30 days, which slightly increased by 0.3 mm (−0.5−1.8; *p*=.019) at 1 year. One patient showed migration (SFD increase ≥5mm). Median endograft tilt was 15.8° (9.7°–21.4°). Preoperative maximum infrarenal curvature was 36 m^{-1} (26–56) and did not significantly change thereafter.

Conclusion

In most patients, the CEXC was implanted close to the renal arteries, and sufficient (≥10mm) postoperative apposition was acquired at 30 days, which slightly increased at 1-year. Postoperative endograft tilt was relatively low, and aortic geometry remained unchanged after implantation of the CEXC, probably due to its high conformability.

INTRODUCTION

Abdominal aortic aneurysms (AAAs) remain a significant health concern, with rupture posing a substantial risk of death.[1] Endovascular aneurysm repair (EVAR) has emerged as an alternative to open surgical repair due to its minimally invasive nature, which reduces perioperative morbidity and length of hospital admision.[2,3] However, EVAR outcomes are notably compromised in patients presenting with challenging neck anatomy characterized by short, angulated, wide, or severely calcified infrarenal necks, which increase the risk of endograft migration, type 1a endoleak, and subsequent reinterventions.[4–6] Current guidelines recommend determining the optimal treatment based on aortic neck anatomy, life expectancy, anaesthetic risk, and comorbidities.[7–9]

The Gore Excluder Conformable AAA Endoprosthesis with active control system (CEXC; W.L. Gore and Associates, Flagstaff, AZ, USA) is designed to address the endeavours associated with challenging neck anatomy.[10] The CEXC combines enhanced conformability with an active control mechanism, aiming to optimize graft positioning and allowing repositioning and angulation control to ultimately enhance maximal apposition in the infrarenal neck.[11,12] Results regarding short-term effectiveness and safety are promising, even in angulated neck anatomy.[12–15] The current study evaluated 30-day and 1-year position and apposition of the CEXC. In addition, the conformability of the CEXC was evaluated by comparing preoperative and postoperative aortic curvature.

METHODS

Study design

This multicentre study adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines and the principles of the Declaration of Helsinki.[16,17] Patients were drawn from the "Assessment of the GORE EXCLUDER Conformable AAA Endoprosthesis In the Treatment of Abdominal Aortic Aneurysms" (EXCeL) registry.[18] Approval for the EXCeL registry was obtained from the Medical Research Ethics Committees United (MEC-U 2015.78), after which approval from each participating centre was acquired. Informed consent was obtained from all patients.

Patient selection

Inclusion criteria for the EXCeL registry were (1) an AAA combined with one of the following: maximum aneurysm diameter ≥50 mm, aneurysm growth >5 mm in 6 months, or the presence of clinical symptoms; (2) adequate aortic anatomy: adequate iliac or femoral access, aortic neck diameter 16 to 32 mm, distal iliac seal zone ≥10 mm, and an iliac artery diameter between 8 and 25 mm; (3) capability of adhering to the follow-up protocol; and (4) age >18 years and life expectancy >2 years.[18] The most important exclusion criteria were (1) mycotic, ruptured, or saccular aneurysm; (2) presence of a concomitant thoracic aortic aneurysm necessitating surgical intervention; (3) renal insufficiency, with a glomerular filtration rate <30 mL/min/1.73 m^2; and (4) systemic infection or connective tissue disease.[18] The full list of inclusion and exclusion criteria is available in the EXCeL protocol (ClinicalTrials.gov identifier NCT03743142).[18]

The study included all patients in the EXCeL registry in the Catharina Hospital Eindhoven, Rijnstate Hospital Arnhem, and Elisabeth TweeSteden Hospital Tilburg, The Netherlands, and the San Martino Hospital, Genoa, Italy, between September 2018 and September 2022. These hospitals were selected because of the high volume of enrolment in the EXCeL registry.

Because the aim of this study was to analyse apposition of the CEXC, patients without an available 30-day computed tomography angiography (CTA; ~1 – 90 days postoperatively) to

assess baseline apposition were excluded. Patients with adjuncts to fixate the proximal part of the endoprosthesis were excluded. Patients treated with a Gore aortic extender were not excluded, because this is an optional component of the CEXC. For each included patient, the preoperative, 30-day, and (if available) the 1-year CTA (~275 – 455 days postoperatively) were requested. If patients underwent a reintervention in the proximal neck (e.g., for type 1a endoleak or migration), the succeeding CTA was excluded from apposition analysis. Follow-up data were last updated in June 2023.

Clinical characteristics

Patient characteristics were gathered using an electronic case report form. Preoperative aortic characteristics were assessed by the core laboratory after centre lumen line (CLL) reconstruction. Neck diameter was measured from adventitia to adventitia at the inferior border of the lowest renal artery. Neck length was defined as the CLL distance between the lowest renal artery and the point where the diameter of the neck increased by 10%.[19] Infrarenal angulation was defined as the CLL angle between the longitudinal axis of the aortic neck and the aneurysm sac. Suprarenal angulation was defined as the CLL angle between the longitudinal axis of the suprarenal aorta and the aortic neck.[20] Intended oversizing was calculated as (*nominal endograft diameter*/*pre-EVAR neck diameter*) × 100%.[21]

Patients were assigned to inside instructions for use (IFU) or outside IFU subgroups based on neck length and infrarenal neck angulation. To classify as inside IFU, one of the following criteria were met: (1) neck length ≥15 mm and infrarenal angulation ≤90 mm, or (2) neck length ≥10 mm and infrarenal angulation ≤60 mm. The aim of this study was to analyse geometric results of the CEXC. A comprehensive overview of clinical results of the EXCeL registry will be published in a later phase.

Analysis of endograft position and apposition

Endograft apposition and position were calculated using VIA software (Endovascular Diagnostics BV, Bussum, The Netherlands) according to published and validated protocols.[11,22] Each CTA was preprocessed by an experienced observer (R.Z.) using a 3mensio Vascular Workstation (Pie Medical Imaging BV, Maastricht, The Netherlands). A CLL reconstruction

was created, coordinates were placed at the orifice of the renal artery, the endograft fabric markers, and the end of circumferential apposition, and a mesh of the aortic lumen was created. The CLL, the coordinates, and the mesh were exported to VIA to calculate aortic and endograft dimensions. The shortest apposition length (SAL), shortest fabric distance (SFD), contralateral fabric distance (CFD), and endograft tilt were computed. An example of postoperative VIA output is shown in Figure 1.

The SAL is the shortest length between the proximal endograft fabric and the first slice where circumferential apposition between the endograft and the aortic wall is lost. The SFD is the shortest distance between the endograft fabric and the lowest renal artery. The CFD is the distance between the endograft fabric and the highest renal artery. A SAL of <10 mm was considered insufficient, because this is associated with a high risk for type 1a endoleak.[10,23,24] A SAL increase or decrease of ≥5 mm between the 30-day and 1-year CTA was classified as clinically relevant. An SFD increase of ≥5 mm was classified as clinically relevant migration. The SAL/neck length ratio demonstrates which portion of the preoperative neck length is sealed postoperatively.[21] A ratio of <1 means that the preoperative neck length is not completely sealed, whereas a ratio of >1 means that more than the preoperative neck length is sealed (probably due to larger oversizing). Tilt was defined as the angle between the axis of the proximal endograft fabric and the directional vector of the CLL.[11]

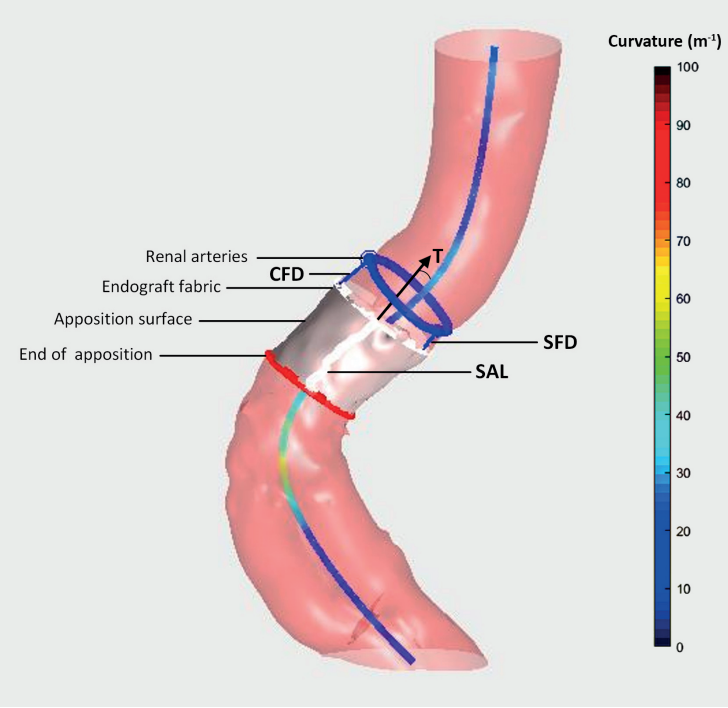

Figure 1. Example of postoperative Vascular Image Analysis (VIA) output. The blue circle marks the renal arteries, the white circle marks the endograft fabric markers, and the red circle marks the first slice where circumferential apposition is lost. The grey area represents the sealing zone (i.e., apposition surface). The white line marks the shortest apposition length (SAL), and the blue lines the shortest fabric distance (SFD) and the contralateral fabric distance (CFD). The SAL is the shortest length between the proximal endograft fabric and the first slice where circumferential apposition between the endograft and the aortic wall is lost. The SFD is the shortest distance between the endograft fabric and the lowest renal artery. The CFD is the shortest distance between the endograft fabric and the highest renal artery. The SAL quantifies the sealing zone, the SFD the proximity of the endograft to the lowest renal artery, and the CFD the proximity of the endograft to the highest renal artery. The tilt (T) is the angle between the axis of the proximal endograft fabric and the directional vector of the centre lumen line. Aortic curvature is shown as a heatmap projected over the centre lumen line (blue = low curvature, red = high curvature).

Analysis of aortic curvature

Aortic curvature analysis was conducted in VIA on the CLL of the preoperative, 30-day, and 1-year CTAs. The protocol was previously published.[11,25] Maximum infrarenal curvature was computed along the CLL of the anticipated proximal neck for the preoperative CTA and along the CLL of the actual sealing zone for the postoperative CTAs. In addition, the distance between the lowest renal artery baseline and the point where the maximum infrarenal curvature was located was calculated.

Statistical methods

Data were analysed using IBM SPSS Statistics 28 software (IBM Corporation, Armonk, NY, USA). Normality was evaluated using histograms and quantile-quantile (Q-Q) plots. Skewed data are expressed as median with interquartile ranges (IQR; 1st – 3rd quartile). Categorical data are presented as number and percentage. Preoperative and postoperative outcomes were compared using the Wilcoxon signed rank test. Differences between the inside and outside IFU subgroups were tested using the Mann-Whitney *U* test or the Fisher exact test. A *p*-value of ≤0.05 was considered statistically significant.

RESULTS

Demographics and comorbidities

There were 156 patients enrolled in the EXCeL registry, of which 113 were from the four participating centres. Of these 113 patients, 25 were excluded due to absence of a 30-day CTA, and one patient was excluded due to use of a Cheatham Platinum (NuMED Inc, Hopkinton, NY, USA) stent. The remaining 87 patients were included. Median age was 78 years (72 – 82 years), 66 patients (75.9%) were men, and 58 (66.7%) had an American Society of Anaesthesiologists classification of ≥III.

Preoperative anatomical characteristics

An overview of anatomical characteristics is provided in Table 1. Median neck length was 22 mm (15 – 32 mm), and median infrarenal angulation was 52° (31° – 72°). In total, 72 patients (82.8%) were classified as inside IFU and 15 (17.2%) as outside IFU.

Table 1. Preoperative core laboratory-assessed anatomical characteristics

Variable	Patients (*n* = 87)
Neck diameter (mm)	21 (20 – 24)
Neck length (mm)	22 (15 – 32)
Infrarenal angulation (°)	52 (31 – 72)
Suprarenal angulation (°)	17 (11 – 35)
Maximum aneurysm diameter (mm)	59 (53 – 64)

Continuous data are presented as median with interquartile range (1st – 3rd quartile). The suprarenal angulation could not be assessed for two patients.

Procedural and follow-up details

Procedural characteristics are presented in Table 2. The angulation wire was used in 25 patients (34.7%) inside IFU, and in 11 patients (73.3%) outside IFU (p = .032). Repositioning and reconstraining were used in 37 patients (51.4%) inside IFU and in nine patients (60.0%) outside IFU (p = .815). On the completion angiography, 16 endoleaks were observed: one type 1a, one type 1b, and 14 type 2. The type 1b endoleak was left untreated, and the type 1a endoleak persisted despite remodelling and placement of an extension cuff. The assisted technical success rate was 97.7%.

Table 2. Procedural characteristics

Variable	Patients (n = 87)
Endograft diameter (mm)	28 (26 – 28)
Intended oversizing (%)	23.1 (16.7 – 35.3)
Repositioning and constraining attempts	
0	40 (46)
1	31 (35.6)
2	7 (8.0)
≥3	8 (9.1)
Unknown	1 (1.1)
Angulation wire advancements and retractions	
0	49 (56.3)
1	26 (29.9)
2	8 (9.2)
3	1 (1.1)
Unknown	3 (3.4)
Use of proximal extensions	
Yes	7 (8.0)
No	80 (92.0)
Successful deployment in planned position	87 (100)
Assisted technical success	85 (97.7)

Continuous data are presented as median with interquartile range (1st – 3rd quartile) and categorical data as n (%).

Thirty-day endograft position and apposition

Median time between EVAR and the 30-day CTA was 42 days (29 – 69 days). Table 3 provides an overview of endograft position and apposition results on the 30-day CTA. Median SAL

was 21.2 mm (IQR 14.0 – 29.3 mm; range, 0.0 – 41.8 mm), and the median SFD was 2.0 mm (0.5 – 3.6 mm). No significant differences were found between the inside and outside IFU subgroups for SAL (p = .946), SFD (p = .167), CFD (p = .893), and tilt (p = .357). No significant difference in tilt was found for patients with angulation wire advancements vs. patients without (p = .606). SAL was <10 mm in 13 patients, of which four (30.8%) were treated outside the IFU. These 13 patients had a median SAL of 6.8 mm (5.1 – 9.3 mm), neck length of 16 mm (15 – 25 mm), and infrarenal angulation of 59.0° (35.5° – 75.5°). The SAL in one patient was 0 mm; this patient had a newly detected type 1a endoleak that was successfully treated with a proximal cuff and EndoAnchors (Medtronic Cardiovascular, Santa Rosa, CA, USA). The previously detected type 1a endoleak (at the completion angiography) had spontaneously resolved at the 30-day CTA.

Table 3. Thirty-day endograft position and apposition

Variable	Patients (n = 87)
Shortest apposition length (mm)	21.2 (14.0 – 29.3)
Shortest apposition length/neck length ratio	0.8 (0.6 – 1.2)
Shortest apposition length <10 mm	13 (14.9)
Shortest fabric distance (mm)	2.0 (0.5 – 3.6)
Contralateral fabric distance (mm)	8.1 (4.6 – 14.8)
Endograft tilt (°)	15.8 (9.7 – 21.4)

Continuous data are presented as median with interquartile range (1st – 3rd quartile) and categorical data as n (%).

One-year endograft position and apposition

For 56 patients, a 1-year CTA was analysed. Median time between EVAR and the 1-year CTA was 12.5 months (11.0 – 13.8 months). Median SAL significantly increased by 1.1 mm (−2.3 to 4.7 mm) to 24.8 mm (16.9 – 31.1 mm; p = .042). Median SFD significantly increased by 0.3 mm (−0.5 to 1.8 mm) to 2.1 mm (IQR 0.5 – 4.3 mm; p = .019). Figure 2 shows the differences between the 30-day CTA and the 1-year CTA.

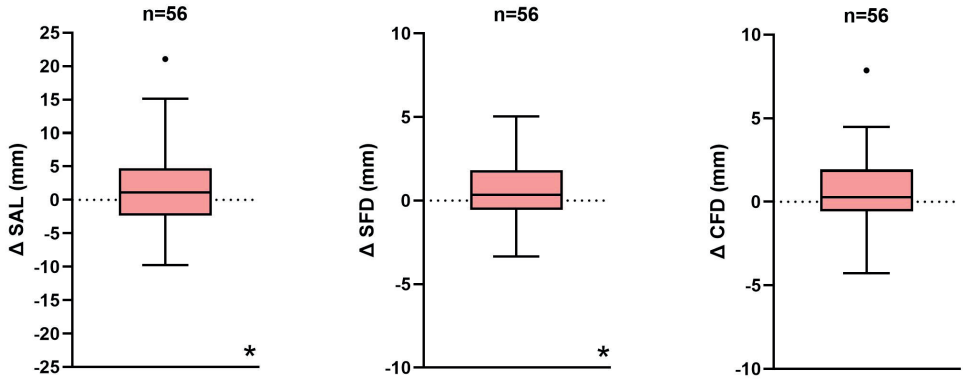

Figure 2. Difference in shortest apposition length (SAL), shortest fabric distance (SFD), and contralateral fabric distance (CFD) between the 30-day postoperative CTA and the 1-year postoperative CTA. Box-and-whisker plot: the line in the middle of each box indicates the median; the top and bottom borders of the box mark the 75th and 25th percentiles, respectively. The upper and lower whiskers extend from the hinge to the highest value and lowest value, respectively, that is within 1.5 interquartile range of the hinge, and the circles indicate outliers. *$p \leq 0.05$, indicating statistical significance.

The CFD (p = .096), SAL/neck length ratio (p = .091), and tilt (p = .340) did not significantly change between the 30-day and 1-year CTA. Maximum aneurysm diameter did not significantly change between the preoperative and 1-year CTA (p = .703). The SAL decreased ≥5 mm in seven patients (12.5%), increased ≥5 mm in 13 patients (23.2%), and remained stable in 36 patients (62.2%). Of the 13 patients with a SAL <10 mm at the 30-day CTA, two patients had a SAL increase to ≥10 mm at 1 year. Three patients had persisting SAL <10 mm at 1 year, and they also had an increasing aneurysm diameter (≥5 mm), without the presence of a core laboratory-diagnosed endoleak. One patient required a reintervention for a type 1a endoleak, which was previously mentioned. The remaining seven patients had no 1-year CTA because follow-up was continued with duplex ultrasound imaging that showed no type 1a endoleak (4×), the 1-year CTA was omitted (1×) or not yet performed (1×), and one patient died of an unknown cause (due to loss to follow-up) during the first year after EVAR. One patient (1.8%) had clinically relevant migration (SFD increase ≥5 mm); nonetheless, the SAL increased.

Aortic curvature

Preoperative maximum infrarenal curvature was 36 m^{-1} (26 – 56 m^{-1}). Figure 3 shows the change in maximum infrarenal curvature at the 30-day CTA and 1-year CTA with respect to

the preoperative measurement. The maximum infrarenal curvature did not significantly change at the 30-day CTA (−2.0 m^{-1} [−13.0 to 7.0 m^{-1}]; p = .182) or at the 1-year CTA (−3.0 m^{-1} [−13.0 to 10.8 m^{-1}]; p = .478). The distance between the point of the maximum infrarenal curvature and the lowest renal artery did not significantly change.

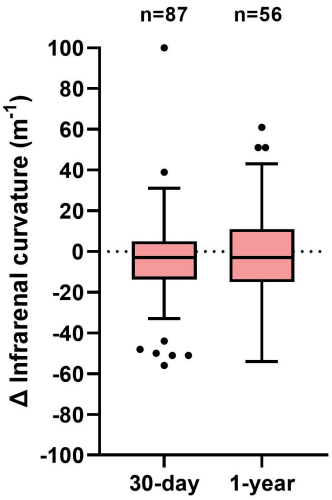

Figure 3. Change in maximum infrarenal curvature at the 30-day CTA and 1-year CTA, with respect to the preoperative CTA. Box-and-whisker plot: the line in the middle of each box indicates the median; the top and bottom borders of the box mark the 75th and 25th percentiles, respectively. The upper and lower whiskers extend from the hinge to the highest value and lowest value, respectively, that is within 1.5 interquartile range of the hinge, and the circles indicate outliers.

DISCUSSION

This study shows that the CEXC enables the achievement of sufficient SAL (≥10 mm) in 85.1% of patients and a median SFD of 2.0 mm at 30 days after the initial procedure, even in challenging anatomies. This illustrates the achievement of adequate postoperative endograft apposition to the infrarenal neck in most patients and placement of the endograft close to the lowest renal artery with a relatively low endograft tilt. At 1-year, the median SAL showed a significant increase. Aortic curvature did not change after implementation of the CEXC, which supports its claimed conformability.

Securing a sufficient infrarenal sealing zone after EVAR is crucial to prevent neck-related complications such as type 1a endoleak and migration.[24] This acquired apposition should be stable over time, because decreasing SAL is an indicator for type 1a endoleak as well.[22,26] This study found a significant increase in SAL at 1 year, and the SAL increased ≥5 mm in almost a quarter of patients. We hypothesise that this is due to ongoing endograft expansion and/or aneurysm shrinkage, which leads to collapse of the aortic wall against the endograft in the infrarenal aortic neck. This finding is consistent with a previous study regarding the CEXC.[15]

It would be interesting to investigate whether the SAL further increases over a longer period of time. In 13 patients, a SAL <10 mm was found at 30 days and/or 1 year, possibly due to the relatively challenging anatomy in this cohort. Of these patients, four had serious concerns during follow-up, of which there was one type 1a endoleak and three patients with persisting SAL <10 mm at 1 year (with simultaneous sac growth). Patients with a SAL <10 mm have a high risk of developing type 1a endoleak and should be monitored closely. Van der Riet et al found a comparable percentage of SAL <10 mm at 30 days in patients treated with the Endurant device (Medtronic).[21] The current study had a higher percentage of outside IFU treatment, and median SAL values were comparable.

The acquired postoperative sealing zone depends on many factors, of which the proximity of the device to the renal arteries is one. Landing directly below the renal arteries is extra difficult in patients with angulated aortic neck anatomy.[27] This study demonstrated that it is

possible to place the CEXC close to the lowest renal artery. Comparable SFD values were acquired in the inside and outside IFU groups. The significant increase in SFD at the 1-year follow-up was only 0.3 mm and, therefore, negligible. This was also found in previous studies with various endografts and could be due to physiological hemodynamic and mechanical forces.[22,26] Significant migration (SFD increase ≥5 mm) was found in one patient who had sufficient SAL (≥10 mm) at the 1-year CTA, without a type 1a endoleak. In addition, an endograft tilt of 0° means that the endograft is placed perpendicular to the CLL. In the current study, patients had a median tilt of 15.8°, which is comparable to previous studies.[15,22] Tilt values did not differ between the inside and outside IFU group, possibly due to the angulation control.

In previous studies, the CEXC has demonstrated promising results regarding technical success and neck-related complications in the short-term.[28] This holds true in patients with angulated anatomy.[14] The current study found no significant difference in apposition (SAL) and position (SFD) between the inside and outside IFU subgroups. This offers future possibilities for EVAR with the CEXC in patients with challenging neck anatomy. However, this should be interpreted with caution, because the preoperative aortic neck length is not necessarily equivalent to the acquired postoperative sealing zone length. Especially in patients with severely angulated anatomy, the sealing zone length at the inner or outer curve could be considerably shorter.[29] Preoperative EVAR planning in patients with a short neck length and angulated anatomy should consider the reciprocal influence of neck length and angulation.

Use of less conformable endografts during EVAR may cause straightening of the aorta, potentially resulting in tension on the endograft in the sealing zones.[30] A previous study demonstrated that the infrarenal curvature changes after EVAR, which may increase the risk for neck-related complications.[25] Moreover, most endografts cannot entirely conform to angulated anatomy.[25] The CEXC was not included in that study. The current study showed that the infrarenal curvature did not significantly change after implementation of the CEXC, probably due to its enhanced conformability. Notably, the current methodology was applied to static CTA images, whereas electrocardiogram-gated CTA offers analysis of cardiac

pulsatility-induced motion, which might provide even more insight into the conformability of the CEXC.[31,32]

Limitations and recommendations

Not all patients had an available 1-year CTA, mostly because duplex ultrasound imaging was used or the CTA was omitted or planned in the future. As a result, the 1-year CTA could not be analysed in seven patients with a SAL of <10 mm at 30 days. Future studies should investigate mid- to long-term follow-up, especially because most complications present during this period.[33] It would be interesting to update the current study after follow-up of the EXCeL registry is completed. Additionally, it would be valuable to compare the standard Gore Excluder with the CEXC to examine the SAL, SFD, and tilt to establish the added value of the angulation control. Lastly, the VIA software is not currently publicly available due to the absence of a Conformité Européenne (CE) mark. The apposition length measured along the CLL would be the best temporary substitute, although this might overestimate the actual apposition length.

CONCLUSION

In most patients who underwent EVAR with the CEXC, the device was implanted close to the renal arteries. Sufficient (≥10 mm) postoperative apposition was acquired in most patients, which remained stable at the 1-year CTA. Notably, at least four of the 13 patients with a SAL of <10 mm at the 30-day CTA had concerns at follow-up. Those patients might benefit from intensified follow-up or early reintervention. Aortic curvature remained unchanged after implementation, which suggests high conformability of the CEXC.

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