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Apposition and Positioning of the Nellix EndoVascular Aneurysm Sealing System in the Infrarenal Aortic Neck

Kim van Noort, MSc[1,2], Simon P. Overeem, MSc[1,2], Ruben van Veen, MSc[1,2], Jan M. M. Heyligers, MD, PhD[3], Michel M. P. J. Reijnen, MD, PhD[4], Richte C. L. Schuurmann, PhD[1,2], Cornelis H. Slump, PhD[2], Rogier Kropman, MD, PhD[1], and Jean-Paul P. M. de Vries, MD, PhD[1]

Abstract

Purpose: To investigate the initial proximal position and seal of the Nellix EndoVascular Aneurysm Sealing (EVAS) system in the aortic neck using a novel methodology. **Methods:** Forty-six consecutive patients who underwent elective EVAS for an abdominal aortic aneurysm were retrospectively selected and dichotomized into an early (n=23) and a late (n=23) group. The aortic neck morphology and aortic neck surface (ANS) were determined on preoperative computed tomography (CT) scans; the endograft position and nonapposition surface (NAS) were determined on the 1-month CT scans. The position of the proximal endobag boundary was measured by 2 experienced observers to analyze the interobserver variability for the EVAS NAS measurements. The shortest distance from the lowest renal artery to the endobag (shortest fabric distance) and the shortest distance from the endobag to the end of the infrarenal neck (shortest sealing distance) were determined. The intraclass correlation coefficients (ICCs) are presented with the 95% confidence interval (CI). Continuous data are presented as the median and interquartile range (IQR: Q3 – Q1). **Results:** There were no differences between the early and late EVAS groups regarding aortic neck morphology except for the neck calcification circumference [41° (IQR 33°) vs 87° (IQR 60°), respectively; p=0.043]. Perfect agreement was observed for the NAS (ICC 0.897, 95% CI 0.780 to 0.956). The NAS as a percentage of the preoperative ANS was 47% (IQR 43) vs 49% (IQR 49) for the early vs late groups, respectively (p=0.214). The shortest fabric distances were 5 mm (IQR 5) and 4 mm (IQR 7) for the early and late groups, respectively (p=0.604); the shortest sealing distances were 9 mm (IQR 13) and 16 mm (IQR 17), respectively (p=0.066). **Conclusion:** Accurate positioning of the Nellix EVAS system in the aortic neck may be challenging. Despite considerable experience with the system, still around half of the potential seal in the aortic neck was missed in the current series, without improvement over time. This should be considered during preoperative planning and may be a cause of a higher than expected complication rate. Detailed post-EVAS nonapposition surface can be determined with the described novel methodology that takes into account the sometimes irregularly shaped top of the sealing endobags.

Keywords

abdominal aortic aneurysm, aortic neck, apposition, endobags, endovascular aneurysm sealing, position, stent-graft

Introduction

Large clinical studies of endovascular aneurysm repair (EVAR) and the technique of endovascular aneurysm sealing (EVAS) have documented the clinical outcomes and occurrence of type Ia endoleaks and/or migration after abdominal aortic aneurysm (AAA) repair.[1-5] For both techniques, however, adequate positioning and seal of the endografts in the aortic neck play major roles in sustaining long-term clinical success. It is thus of utmost importance to determine changes in post-EVAR and post-EVAS seal at follow-up imaging.

[1]Department of Vascular Surgery, St Antonius Hospital, Nieuwegein, the Netherlands
[2]MIRA Institute for Biomedical Technology and Technical Medicine, University of Twente, the Netherlands
[3]Department of Vascular Surgery, Elisabeth TweeSteden Hospital, Tilburg, the Netherlands
[4]Department of Vascular Surgery, Rijnstate Hospital, Arnhem, the Netherlands

Corresponding Author:
Kim van Noort, Department of Vascular Surgery, St Antonius Hospital, Koekoekslaan 1, 3435 CM, Nieuwegein, the Netherlands.
Email: k.van.noort@antoniusziekenhuis.nl

During EVAR stent-graft deployment, radiopaque markers on the proximal margin of the fabric ensure the visibility of the device in the aortic neck relative to the renal artery orifices. Moreover, these radiopaque markers are also visible on follow-up computed tomography angiography (CTA). Therefore, position and apposition of EVAR devices in the aortic neck can be determined rather easily. A previous study from Schuurmann and coworkers[6] validated a novel CTA methodology for accurate determination of position and apposition after EVAR. The methodology used a 3-dimensional (3D) mesh of the aortic lumen, the radiopaque markers, the CT scan coordinates of the renal artery positions, and the center lumen line (CLL) to calculate the 3D position of the endograft in the aortic neck and the apposition surfaces.

The Nellix EVAS system (Endologix Inc, Irvine, CA, USA) uses balloon-expandable stent frames surrounded by polymer-filled endobags to ensure complete seal of the aneurysm. Contrary to conventional aortic stent-grafts, the Nellix endobags lack radiopaque markers; only the stent frames are visible on digital subtraction angiography during the EVAS procedure. However, these frames are in the center of the aortic neck lumen and do not play a role in the sealing process itself. The endobags can be visualized during prefill if contrast is added, but the polymer itself is not radiopaque. Furthermore, the shape of the proximal part of the endobags depends on the fill volume of the polymer and the fill pressure. Ideally, the top of the endobags should be horizontal from the stent frames toward the aortic wall. However, sometimes the shoulders of the endobags are drooping and the outer surface of the endobags is lower compared with the central part attached to the stent-graft frames. Therefore, it might be difficult to position the proximal endobag boundary directly distally to the renal arteries for proper apposition in the aortic neck.

This study employed this new methodology[6] to investigate the deployment and sealing accuracy of EVAS in the aortic neck. Moreover, EVAS procedures in the early and late experience at a single center were compared to elucidate the learning curve for physicians as regards deployment and positioning accuracy.

Methods

Study Design

Patients for this retrospective analysis were part of the Dutch EVAS Study (DEVASS),[7] and approval for the retrospective analyses of the CT scans and clinical data were obtained from the local ethics committee. Between February 2014 and December 2015, 119 patients were treated with EVAS in our center. Ruptures, isolated common iliac artery aneurysms, and chimney-EVAS cases were excluded, leaving 90 consecutive, electively treated AAA patients. The first 13 patients were excluded due to a protocol refinement. Patient numbers #13–43 and #82–119 were assigned to the early and late cohorts, respectively, with the removal of all nonelective patients. Four of the 50 selected patients were excluded due to missing preoperative CT scans, resulting in 23 patients each in the early (median age 75 years; 21 men) and late (median age 75 years; 21 men) cohorts. Baseline patient characteristics and aortic neck morphology are shown in Table 1.

CT Protocol

All pre- and post-EVAS CT scans were acquired as part of regular protocols on a 256-slice CT scanner (Philips Healthcare, Eindhoven, the Netherlands) with acquisition parameters of 120-kV tube potential, 200-mA·s tube current time product, 0.75-mm increment, 0.9-mm pitch, 125×0.625-mm collimation, and 1.5-mm slice spacing. Contrast medium (Xenetix 300; Guerbet, France) was administered intravenously in the arterial phase using bolus triggering a rate of 4 mL/s before (100 mL) and after (60 mL) EVAS.

CT Measurement Protocol

The aortic neck morphology and the aortic neck surface (ANS) were defined on the preoperative CT scan. EVAS position and the nonapposition surface (NAS) were determined on the 1-month CT scans. Pre- and postoperative measurements were performed by an experienced observer on a 3Mensio vascular workstation (V8.1; Pie Medical, Maastricht, the Netherlands). The position of the endobags was also determined by a second observer to test the interobserver variability of these particular measurements. A CLL was semiautomatically drawn through the lumen of the aorta, covering the trajectory from the superior mesenteric artery to the aortic bifurcation.

Aortic Morphology Measurements. Neck length, neck diameter, neck angulation, neck thrombus thickness and circumference, neck calcification thickness and circumference, and maximal preoperative AAA diameter were measured to determine if the aortic neck morphology was inside the manufacturer's 2016 refined instructions for use (IFU).[8] According to the refined IFU 2016, the proximal aortic neck criteria were (1) diameter 18 to 28 mm, (2) minimum length ≥10 mm, and (3) angulation ≤60°. Other IFU characteristics were (4) aortic aneurysm blood lumen diameter ≤60 mm, (5) ratio of maximum aortic aneurysm diameter to maximum aortic blood lumen diameter <1.4, and (6) distal iliac artery seal zone ≥10 mm long and from 9 to 35 mm in diameter.[8]

Aortic neck diameter was determined at the distal boundary of the lowest renal artery (baseline). Neck length

Table 1. Baseline Characteristics of Patients Treated With Endovascular Aneurysm Sealing in the Early and Late Periods.[a]

Variables	Early (n=23)	Late (n=23)	p
Demographics			
Age	75 (11)	75 (13)	0.700
Men	21	21	
Perioperative parameters			
Procedure time, min	75 (25)	76 (33)	0.651
Blood loss, mL	100 (100)	100 (100)	0.964
Polymer fill, mL	75 (42)	77 (51)	0.750
Fill pressure, mm Hg	186 (15)	183 (20)	0.825
Aortic morphology			
Neck length, mm	16 (19)	24 (20)	0.078
Neck diameter, mm	22.7 (3.6)	23.0 (3.1)	0.999
Neck angulation, deg	19.4 (19.2)	20.4 (25.7)	0.368
Neck thrombus	5	4	
Thickness, mm	2.4 (2.8)	2.9 (2.5)	0.730
Circumference, deg	83 (83)	140 (184)	0.413
Neck calcification	9	8	
Thickness, mm	1.8 (1.0)	1.8 (0.4)	0.697
Circumference, deg	41 (33)	87 (60)	0.043
AAA diameter, mm	60 (9)	56 (4)	0.148
Aortic neck surface, mm^2	1152 (1012)	1743 (1807)	0.132
Inside the IFU			
Aortic neck	19	18	
All IFU criteria	4	5	

Abbreviations: AAA, abdominal aortic aneurysm; IFU, instructions for use.
[a]Continuous data are presented as the median and interquartile range (Q3 − Q1); categorical data are given as the counts.

was measured as the distance over the CLL between baseline and the distal end of the neck, defined as the point where there is a 10% increase in neck diameter compared with the diameter at baseline. Neck angulation was measured as the angle between 3 fixed points on the CLL: the lowest renal artery, the distal end of the neck, and 40 mm distal of the aortic neck.

Mural neck thrombus thickness >1 mm over the circumference of the aorta was measured 5 mm distal to baseline. The mural neck thrombus circumference was measured 5 mm distal to baseline as the total degree of neck circumference covered by thrombus. Neck calcification thickness and circumference were measured similarly.

Position and Apposition Measurements. Preoperative ANS, EVAS position, and NAS were measured with the use of dedicated software developed in MATLAB 2015a (The MathWorks, Natick, MA, USA). The methodology was previously described and validated for position and apposition measurements in EVAR.[6] The surface over a 3D mesh of the aortic lumen was computed using coordinates from 3Mensio of the CLL, the renal arteries, and 4 manually placed markers on the proximal boundary of the endobags. These 4 endobag markers were placed clockwise at 3, 6, 9, and 12 hours at the circumferential position where the endobags are in contact with the aortic wall.

The ANS was determined on the pre-EVAS CTA and was calculated as the surface over the aortic mesh between the renal arteries and the distal end of the aortic neck (Figure 1A) as defined previously (>10% increase in the neck diameter compared to the diameter at the lowest renal artery).

The EVAS position was defined by the shortest fabric distance (SFD), the contralateral fabric distance (CFD), and the shortest sealing distance (SSD) in the aortic neck (Figure 1B). The SFD and CFD were calculated as distance over the CLL between the coordinates of the lower boundaries of the renal artery orifices to the circumferential position of the respective proximal endobag boundary. The SFD and CFD were independent of which renal artery was more proximal on the CLL reconstruction. The SSD in the aortic neck was the shortest distance between the proximal endobag boundary and the distal end of the neck.

The NAS for EVAS was similar to the apposition calculation for EVAR only with different boundaries. The proximal apposition boundary of the endograft was the location where the endobags were in contact with the aortic wall. The NAS was determined as the surface between the renal arteries and the proximal boundaries of the endobags (Figure 1C). Ideally, this surface is 0 mm^2 for complete seal of the aortic neck with the Nellix endosystem.

The NAS was calculated as a percentage of the preoperative ANS. The positions of the proximal endobag boundary

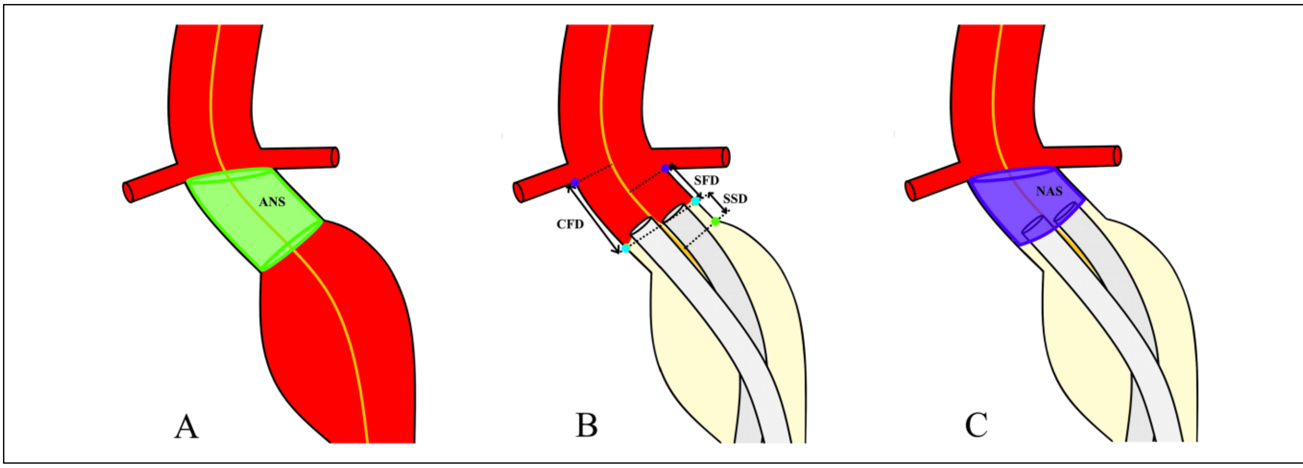

Figure 1. Schematic representation of Nellix position and apposition. (A) Aortic neck surface (ANS): the available preoperative neck surface area available to seal, with the renal arteries as proximal boundaries and the distal end of the aortic neck as the distal boundary. (B) Shortest fabric distance (SFD): shortest distance between the lowest renal artery (dark blue dot) and the proximal boundary of the endobags (light blue dots); contralateral fabric distance (CFD): distance between the contralateral renal artery and the proximal boundary of the endobags; shortest sealing distance (SSD): distance between the proximal boundary of the endobags and the distal end of the aortic neck (green dot). (C) Nonapposition surface (NAS): the postoperative aortic neck surface where there is no apposition of the endobags to the aortic neck. Proximal and distal boundaries are the renal arteries and the proximal boundaries of the endobags, respectively.

of the early EVAS patients were measured by 2 experienced observers (K.N. and J.V.) to analyze the interobserver variability for the EVAS NAS.

Statistical Analysis

Normality was not anticipated for a large part of the data because of the small numbers, so the data are displayed as median with interquartile ranges (IQR; Q3 − Q1). Statistical differences between the early and late groups were tested with the nonparametric Mann-Whitney *U* test. The interclass correlation coefficient (ICC) was determined for the NAS measurements in a 2-way mixed model by absolute agreement; the mean difference is presented with the 95% confidence interval (CI). ICC values are scored as poor (0–0.20), fair (0.21–0.40), moderate (0.41–0.60), good (0.61–0.80), or perfect agreement (0.81–1). The repeatability coefficient was calculated as 1.96 times the standard deviation of the differences between the NAS measurements of the 2 observers. A 2-tailed p<0.05 was considered significant. Statistical analysis was performed with SPSS software (version 23; IBM Corp, Armonk, NY, USA).

Results

Group Comparison

There were no significant differences between the early and late cohorts as regards demographics, perioperative parameters, or aortic morphology (Table 1) except for the neck calcification circumference [41° (IQR 33°) vs 87° (IQR 60°), respectively; p=0.043]. The median neck length was 8 mm longer in the late group (p=0.078). Aortic neck morphology alone complied with the refined IFU 2016 in 19 and 18 patients of the early and late groups, respectively, while only 4 and 5 patients, respectively, where entirely in compliance with the refined IFU 2016.

There was no significant difference regarding the median (IQR) time intervals between the EVAS procedure and the first follow-up CT scan comparing the early and late groups [31 (4) vs 32 (14) days, respectively; p= 0.427]. Clinical follow-up in the early group was significantly longer than in the late group [29 (11) vs 15 (17) months, respectively; p<0.001].

Clinical Outcomes

In the early group 2 patients underwent Nellix explantation during follow-up, one (inside the refined IFU) due to a secondary infected endosystem at 10 months and one owing to occlusion of both stent-grafts at 28 months, respectively. One patient died at 27 months due to a nonvascular cause. A type Ia endoleak was found in 2 patients (both inside the refined IFU) at 16 and 33 months, respectively; both were treated with a proximal extension. Two patients showed migration >5 mm at 12 and 8 months, respectively, without sequelae.

In the late group, 2 patients also underwent Nellix endosystem explantation, one for a type Ia endoleak (inside the refined IFU) at 23 months and one owing to substantial

Table 2. Position and Nonapposition Parameters of the Patients Treated With Endovascular Aneurysm Sealing in the Early and Late Periods.[a]

Parameters	Early (n=23)	Late (n=23)	p
Position			
Shortest fabric distance, mm	5 (5)	4 (7)	0.604
Contralateral fabric distance, mm	10 (6)	10 (5)	0.774
Shortest infrarenal neck seal distance, mm	9 (13)	16 (17)	0.066
Nonapposition			
Surface, mm^2	668 (366)	637 (367)	0.423
Surface of the aortic neck surface, %	47 (43)	49 (49)	0.214

[a]Data are presented as the median and interquartile range (Q3 − Q1).

migration (>5 mm) at 24 months, respectively. One type Ia endoleak was found at 18 months incidentally in a patient with critical bowel ischemia that resulted in death 1 day after diagnosis. One patient had a right stent-graft stenosis 2 months post EVAS; the stent-graft was relined. One other patient (inside the refined IFU) showed migration >5 mm at 9 months without sequelae.

Position and Nonapposition

Perfect agreement was observed for the NAS measurements [ICC 0.897 (95% CI 0.780 to 0.956)], with a mean difference between the observers of 7.4 mm^2 (95% CI −266.12 to 251.32) and a repeatability coefficient of 259. Table 2 shows the position and nonapposition parameters of the early and late groups. There were no significant differences in position and nonapposition parameters between the groups. The SFDs were 5 and 4 mm (p=0.604) for the early and late groups, respectively. The median SSD in the early group was 9 mm (IQR 13), which is mainly due to the short necks in combination with low positioning of the endobags relative to the renal arteries. In the late group the median SSD was 16 mm (IQR 17) due to the longer necks treated. Due to the low positioning of the endobags in the aortic neck, the NAS as a percentage of the preoperative ANS was high: 47% and 49% for the first and last groups, respectively, with a large IQR for both groups.

Discussion

This study has shown that around half of the potential seal in the aortic neck was missed in both the early and late EVAS groups, indicating no improvement after the learning curve. The shortest fabric distance did not decrease significantly (median 5 vs 4 mm, respectively). This unused seal length was substantial, considering a 10- to 15-mm infrarenal neck length is present in the majority of AAA patients in the modern endovascular era.

One explanation for the substantial missed seal might be the lack of markers on the top and sides of the sealing part

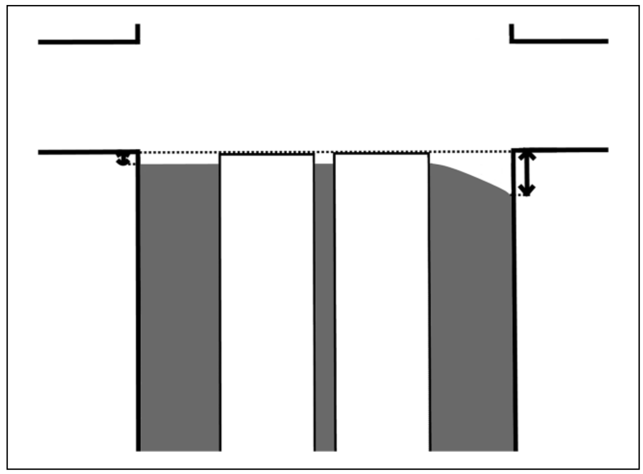

Figure 2. Schematic representation of the Nellix in the infrarenal abdominal aorta. Example of differences between the top of the stent frame and the top of the left endobag (flat shoulder) and right endobag (drooping shoulder).

of the EVAS device, the endobags. Moreover, the endobags surrounding the stent-graft frames often have so-called drooping shoulders (a rounded rather than flat top almost perpendicular to the axis of the stent-graft frame; Figure 2), so the stent frames must be positioned 5 mm above the lower boundary of the renal arteries instead of below, which is counterintuitive compared with EVAR procedures.

Other tips may increase positioning accuracy for EVAS. Contrast in the prefill is needed to identify the boundaries of the endobags during the procedure. If the position is not satisfying, removal of the prefill and repositioning of the stent frames could result in precise positioning of the endobags just beneath the renal arteries. Contrast use in the prefill should not be limited to challenging aortic neck anatomy. The endobag filling should also be sufficient to make sure the endobag shoulders are horizontal and to avoid an irregular surface of the endobags that also may induce lack of seal. According to the IFU, the fill pressure should be at least 180 mm Hg (or higher in case of perioperative type Ia endoleaks), and the physician must be aware that at this fill pressure the top of the endobag is not always flat. Leaving the angioplasty balloons inflated during the endobag filling phase may prevent intraprocedural migration and endobag unfurling before stent deployment can improve endobag apposition.

Finally, the C-arm should always be perpendicular to the aortic neck to avoid distorted images of the position of the stent frames and endobags. To achieve this, the C-arm should be perpendicular to the stent frame configuration in the cranial-caudal direction. Moreover, an anteroposterior image, as well as a lateral image, should be acquired to make sure no loss of apposition (and type Ia endoleak) is missed, which can be overcome during the secondary fill procedure.

In the late patient cohort, all procedural steps were performed except for the standard use of contrast during prefill and unfurling of the endobags before stent deployment. This could be one of the explanations why no improvement in apposition and seal was found between the first and second cohort of patients.

The NAS methodology is a useful tool to define the position and (non) apposition of the endobags in the aortic neck. In standard CT scan reports, only the position of the stent frames is determined. No information is provided on the position of the endobags and the real seal between the endobags and the aortic wall. With the novel methodology employed in this study, the position and apposition of the endobags can be quantified, and changes in these parameters can be determined.

This measurement methodology adds more information than linear measurements alone. Unlike a standard EVAR device, the top of the sealing EVAS endobags is not a perfectly flat surface but can be irregular. Linear measurements from the orifice of the lowest renal artery to the top of the endobag do not take into account this irregularly shaped sealing. In many patients, the 2 endobags are not deployed and filled at exactly the same level, which also influences the seal in the aortic neck. Change in position and apposition of one of the endobags during follow-up may be missed with simple linear measurements.

The relationship between the polymer-filled seal and the top of the stent frames is not fixed but rather dependent on multiple factors, including the volume of polymer filling and positioning of the devices, as well as the shape and diameter of the infrarenal neck. Some patients will have a flat top of one endobag, while the other endobag has a drooping shoulder (Figure 2).

The NAS alone, however, is not a descriptive parameter for comparison between patients due to possible differences in aortic neck diameter. Therefore, the NAS is calculated as a percentage of the preoperative neck surface for direct comparison between patients. Moreover, it is of utmost importance to consider the seal of the endobags and not only the position of the stent frames, which is now common practice in standard imaging. With the use of the new software, visualization of changes in seal may be more sensitive than with standard imaging.

The use of a detailed determination of position and apposition of the Nellix device within the infrarenal neck in follow-up CT scans needs further investigation. Recent publications showed that changes in position and apposition surface after EVAR are predictive of later failure of seal.[9,10] Similar studies must be performed based on post-EVAS CT scans to appreciate the real merits of the new measurements to predict seal failures.

Complications after EVAS, however, manifest differently compared with EVAR. Loss of seal does not directly lead to endoleaks or migration due to the extended sealing of the entire aneurysm. van Veen et al[11] and Dorweiler et al[12] recently published a methodology for 3D determination of the EVAS stent frames. By visualizing these stent frames over time, migration was visible in 3 directions. This methodology combined with the NAS methodology will result in detailed understanding of stent frame and endobag behavior over time.

The incidence of complications in this cohort was higher compared with the available EVAS literature,[3–5] which might be due to the large number of patients treated outside the refined IFU. During the inclusion period of this cohort, the Nellix endosystem was also used as a bailout system for patients not suitable for other devices, which may influence the clinical outcome for these patients.

Limitations

First, the numbers of patients in the early and late groups are small. Second, the proximal endobag boundary can be difficult to determine on CTA and might not be positioned in one plane (due to bulging and folds in the endobags). Therefore, positioning of the markers at 3, 6, 9, and 12 hours was a simplification of the real proximal endobag boundary. However, the true irregularities in the proximal endobag boundary cannot be detected with the current CT scan protocols.

Conclusion

Accurate positioning the Nellix EVAS system in the aortic neck may be challenging. Despite considerable experience with the system, still around half of the potential seal in the aortic neck was missed in the current series, without improvement over time. This should be considered during preoperative planning and may be a cause of a higher than expected complication rate. Detailed post-EVAS nonapposition surface can be determined with the described novel methodology that takes into account the sometimes irregularly shaped top of the sealing endobags.

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: Jan M. M. Heyligers and Michel M. P. J. Reijnen are consultants for Endologix Inc.

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ORCID iDs

Kim van Noort https://orcid.org/0000-0002-7181-8999
Michel M. P. J. Reijnen https://orcid.org/0000-0001-7641-1322

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