


Abdominal Aortic Aneurysm Volumetric Evaluation During Mid-term Follow-Up After Endovascular Sealing Using the Nellix™ Device

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Abstract

Objectives—To analyze the volumetric evolution of abdominal aortic aneurysms after endovascular sealing (EVAS) with the Nellix™ device during follow-up.

Methods—Patients who underwent elective EVAS in our institution in 2014 and 2015 were retrospectively reviewed. Preoperative, postoperative and 1-year scans were processed. A custom software was conceived to assess semi-automated measurements of the aneurysm sac and the endograft sizes including volume, maximum diameter, sectional area and perimeter. Thrombus volume, aneurysm length, mean distance between the stents inside the polymer-filled sacs and endograft migration were also estimated. Manual maximum diameters were measured for comparison. Inter and intra-observer variability of the proposed semi-automated method was evaluated.

Results—Pre-EVAS, post-EVAS and last follow-up scans of 12 patients were finally analyzed during a mean follow-up of 17 ± 5 months. No endograft migration or endoleak were detected. During follow-up, aneurysm volume and perimeter slightly increased compared to post-EVAS scans (+ 1 and + 5%, respectively, $p < 0.05$). A systematic 6% enlargement of the endobag volume was also observed (range 1–15 mL, $p < 0.001$). Endobag maximum diameter, area and perimeter increased 4, 8, and 8%, respectively (all $p < 0.01$). Mean plane-by-plane distance between stents increased 4% ($p < 0.05$). Mean thrombus volume did not change during follow-up, although a high variability was observed. Aneurysm and thrombus volume changes were highly correlated ($r = 0.93$, $p < 0.001$). No associations were observed between aneurysm and endobag volume changes. Intra- and inter-observer variability was below 1.7 and 2.4% for diameter and volume measurements, respectively. The automated measurements of post-EVAS aneurysm diameter and

volume were higher than preoperative ($p < 0.05$). Maximum diameters measured manually did not differ between scans. **Conclusion**—Small aneurysm volume enlargement detected during a mid-term follow-up was associated with thrombus size change, whereas systematic endograft expansion resulted independent from the aortic growth. Volumetric measurements using a semi-automated method could quantify small changes in aneurysm, endograft and thrombus sizes not detected by manually defined maximal diameters.

Keywords—Abdominal aortic aneurysm, Aneurysm sizing, Endograft follow-up, Aneurysm volume, Endovascular sealing system.

INTRODUCTION

The success of endovascular exclusion of an aortic abdominal aneurysm (AAA) is usually defined by the overall shrinkage of the aneurysm sac or by the absence of aneurysm growth without any detectable endoleak^{10,18} between the covered stent graft and the aortic wall. Besides the fact that accurate endoleak detection modalities and management is still under debate, morphologic follow-up of aortic aneurysms after endovascular aortic repair (EVAR) appears to be the most objective way to diagnose aneurysmal growth. Follow-up recommendations after EVAR are based on maximal orthogonal diameter measurement.¹⁴ However, the accuracy of this two-dimension parameter seems to be insufficient to detect variations of the whole AAA size that has a three-dimension (3D) morphology.^{16,28} Accordingly, a volumetric follow-up has been proposed.^{1,2,11,16,17,20,28,29}

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Endovascular aortic sealing (EVAS) has been recently introduced as a new concept for AAA treatment.¹² It consists of two expandable stents surrounded by dual endobags filled with a polymer to ensure a total sealing of the aneurysmal sac.^{4,7,12} Each stent is positioned between the infrarenal aorta and the iliac artery. The EVAS system claims to present a lower risk of endoleak and to be less prone to migration compared to standard devices with proximal and distal fixations.²⁶ The EVAS technique relies on the assumption that endobags volume occupying the whole aneurysm lumen remain stable and then the aneurysm shrinkage would depend on the surrounding thrombus evolution. However, a mild but significant increase in polymer volume was detected in subjects without visible endoleaks at 1-year follow-up after EVAS.²⁵ In the same study, mean thrombus volume tended to shrink during 1-year follow-up but significance was not reached probably due to the high variability in the volume values. A non-significant increase in total aortic volume was also detected after 1-month and at long term follow-up. On the first post-EVAS scan, small but significant aneurysm sac growth has been reported by our team and others authors in patients without any detectable endoleak.^{6,9,21} Since the configuration of the EVAS system is unique, the classification of proximal endoleaks and the device migration had to be recently revised.^{24,27} Volumetric analyses of the change in aneurysm, thrombus and endobag sizes after EVAS are scarce, whereas their correlation at mid-term seems to be essential to detect complications.

The aims of this retrospective study were (1) to quantify the aneurysm, thrombus and endobags volumes before and after EVAS and (2) to assess the potential impact of changes in thrombus and endobag volumes on the aneurysm size at mid-term follow-up. All geometric quantifications after EVAS were assessed using a custom software that included tools to estimate longitudinal migration of the Nellix endoframe and stent-to-stent distance changes.

METHODS

Study Population

In 2014 and 2015, twenty-six patients with infra renal AAA underwent EVAS in our institution (Cardiovascular surgery Department, Hôpital Européen Georges Pompidou, Paris, France) using the Nellix™ system (Endologix, Irvin, California, USA). According to French recommendations, a computed tomography angiography (CTA) follow-up was scheduled during the first month after the procedure, after 6 months and

every year afterwards. Clinical and morphological data were reviewed retrospectively to find patients with a pre-EVAS, post-EVAS and a 12 months CTA scan available in our database. Twelve patients were finally included in this retrospective study. The rest of the patients were excluded due to the absence of a minimum 1-year follow-up or whether preoperative CTA scan was made outside our institution. In one case, a patient was excluded due to the poor image quality of his 1-year follow-up scan that did not allow a correct visualization of the endobag borders. The Georges Pompidou European Hospital Ethics Committee approved this retrospective study and waived the need for individual patient consent. All patients gave informed consent to each procedure.

EVAS Procedure and Follow-Up

As previously described, the EVAS procedure included the implantation of two 10-mm balloon-expandable covered stents between the infra renal aorta and each iliac artery.⁴ Briefly, stents were deployed by inflating the balloons. In the meantime, the surrounding endobags were first filled with a saline solution until the endobags pressure reached 180–200 mmHg. The complete exclusion of the aneurysm and the correct positioning of the stents regarding to renal arteries level were assessed with an aortic angiogram. Then, this saline solution was withdrawn from the endobags to evaluate precisely the required polymer volume to fill the aneurysm sac. Finally, definitive filling with polymer was performed slowly until the endobags pressure was stabilized around 180 mmHg. An additional filling could be performed if the final angiogram showed a residual type I endoleak.

Imaging and Aneurysm Size Assessment

All scans were performed with a 64-slice scanner (Light-speed VCT; GE Health care, Milwaukee, Wisconsin, USA). Matrix size was 512×512 and slice thickness was 1 mm or less. Acquisition was performed before and after contrast injection, from the coeliac artery to both femoral arteries, using a non-ECG-gated scanning. DICOM images were imported and analyzed with a custom software exclusively developed in C++ for this study by biomedical engineers of the Favaloro University (M.E.C and D.C). It included interactive tools to manually contour the aneurysm/endobag borders at several axial planes and to extrapolate the volumetric information. For contouring, the user was asked to manually set several points around a border while the software interpolated these points using a spline.³⁰ Maximum diameter was automatically estimated by searching the farthest away

points of the border curve. The cross-sectional area inside a contour was computed oversampling the curve to ~ 2000 points and computing the polygonal area by triangle summation.¹⁹ Two specific tools to estimate the mean stent-to-stent distance and stent frames migration from the renal arteries were also integrated into the software. The proposed method to measure each patient's aneurysm morphology before and after the endograft implantation is described hereafter.

For each scan, the observer defined two fiducial axial planes: one at the most caudal edge of the lowest renal artery and a second one at the aortic bifurcation level. Measurements were done in the aortic portion enclosed between these planes (Fig. 1a). Planes were reconstructed using a trilinear interpolation every 2 cm distance between the two fiducial planes, raising a total of ~ 10 planes to cover the entire aneurysm. Two additional planes, one at the top level of the endobag and another one at the level of the aortic bifurcation were set and also measured. Moreover, the user could also choose to add intermediate planes in the presence of rapid diameter changes (e.g., near the shoulder regions of the lesion). In each reconstructed plane, the user manually contoured the outer wall border of the aneurysm using a custom tool (red curves in Fig. 1b). As shown, usually 5-to-10 landmark points were required to build a smooth interpolated contour curve to connect them. The aortic lumen (for the preoperative scan) or the prosthetic endobags (for the postop-

erative scan) were also manually contoured using the same semi-automated tool (green curves in Fig. 1b). In postoperative studies, the centre of each stent was also manually selected by the user in each reconstructed plane (blue markers in Figs. 1b and 1d).

All these measurements resulted in an external and an internal closed curve for each reconstructed plane inside the aneurysm. As shown in Fig. 1c, the following five parameters were calculated by the software for each contour curve: (i) the maximum diameter, computed as the distance between the farthest points within the external curve, (ii) the perimeter, (iii) the enclosed cross-sectional area (CSA), (iv) the geometrical center and (v) the enclosed volume inside the current and the subsequent slice, computed as the mean enclosed area between two slices (dotted line in Fig. 1c) times the inter-slice distance.

With this complete set of automated measurements for each curve, the following five morphological variables were calculated by the software to describe the aneurysm and the lumen (in preoperative scan) or endobags size (in postoperative scan): (i) the maximum diameter, calculated as the maximum diameter value across all the curves, (ii) the maximum CSA, calculated as the maximum area across all the curves, (iii) the maximum contour perimeter, calculated as the maximum perimeter across all the curves, (iv) the total volume, calculated as the sum of enclosed volumes for subsequent slices, (v) The aneurysm length, computed

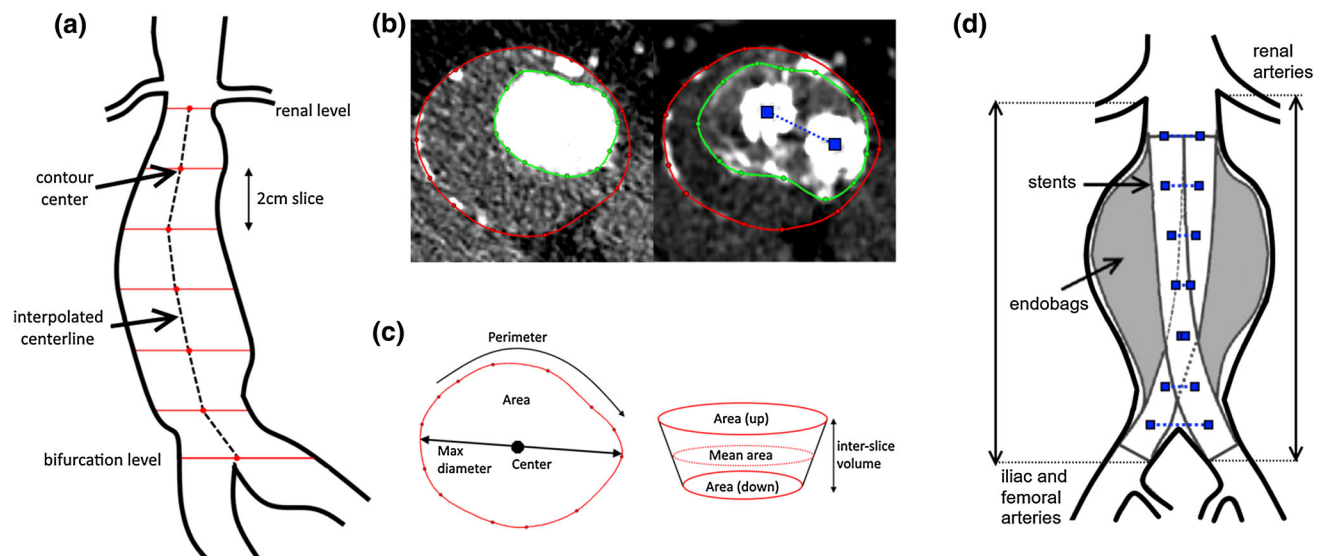


FIGURE 1. Computer-assisted evaluation of abdominal aorta aneurysm and endobag sizes. (a) Several CT planes were reconstructed between the renal artery and the aortic bifurcation every 2 cm to cover the entire aneurysm volume. (b) The user manually contoured the external border of the aortic wall (red curves), the aortic lumen in preoperative scans or the prosthetic endobag after EVAS (green curves). The center of each stent was also manually set (blue markers). (c) For each contour curve, maximum diameter, cross-sectional area, perimeter and the contour center were automatically calculated. The volume between subsequent contours was estimated as the mean area between them (dotted lines) times the inter-slice distance. (d) Mean stents distance was calculated averaging the distances of the center of each stent in a plane-by-plane basis (blue markers). The migration of the endoframe was calculated as the mean distance between the renal arteries and the distal end of each stent (see arrows).

as the sum of the distances between geometrical centers (Fig. 1a). Longitudinal and stent-to-stent migrations were also quantified. The averaged distance between stents was calculated as the mean distance between the stents centreline points in a plane-by-plane basis (Fig. 1d) and longitudinal displacement was measured as the vertical distance from the lower renal artery to the averaged distal border of the two stents at the iliac arteries. Lastly, the thrombus volume was estimated as the difference between the aneurysm volume and the lumen volume (in preoperative scans) or endobags volume (in postoperative cases). Similarly, the thrombus CSA was also calculated at the maximum diameter level.

Study Measurements and Statistical Analysis

For each preoperative scan, a single expert measured the maximum aneurysm diameter, maximum CSA, maximum perimeter and length using the proposed method. The expert was a senior vascular an endovascular surgeon and was blinded to any radiology report or clinical notes, including those mentioning the aneurysm dimensions. Volumes of the aneurysm sac, lumen and thrombus were also calculated. For postoperative and—follow-up scans, the same expert quantified the endobag size and the stents distances. For comparison with the semi-automated method, maximum diameters were measured manually for the aneurysms and the endobags using a standard caliper tool (distance between two points).

Variables with normal distribution were summarized as mean \pm standard deviation (SD) and categorical variables as frequencies and percentages. Postoperative measurements were considered as reference values to calculate absolute and percentage changes of every morphologic variable compared to preoperative and last follow-up scans. Paired *t* student tests were used to assess significant differences compared to the postoperative reference values. A *p* value < 0.05 was considered significant. Changes in thrombus, endobag and aneurysm volume were correlated and expressed using the linear regression slope (β) and the Pearson coefficient (*r*).

All the automated measures were repeated by an independent user and by the same expert after one-week. Intra-observer and inter-observer repeatability were analyzed with Bland–Altman residues plots and by calculating the coefficients of variation (CV) for repeated measures using the root mean square method. Manual and semi-automated measurements of maximum aneurysm diameters were correlated and expressed using the Pearson *r* coefficient. Follow-up scans measurements were repeated using a 1 cm distance between fiducial planes. Measures for these

additional planes were performed by the same expert. Diameters, areas and volumes were recalculated. Measures resulting from 2 to 1 cm plane distances were compared using the same method used for intra- and inter-observer repeatability. Statistical analysis was performed with JMP software (SAS Institute Inc, Cary, NC, USA).

RESULTS

Demographic and clinical data of the 12 patients included in this study are reported in Table 1. They were mostly hypertensive men that were followed during 17 ± 5 months. EVAS procedure was conducted 4 ± 2 months after the preoperative scan. In 50% of the cases, the procedures were outside the original endograft instructions for use (IFU) introduced in 2013, mainly due to a short aneurysm neck length. The device was successfully placed in all patients and no visible endoleak was detected during the CTA follow-up used for our study. Each measurement was performed by the same expert in a range of 5–10 min. Taking a 2 cm distance between fiducial planes raised an average of 10 ± 2 planes to cover the entire aneurysm. In order to refine the segmentation in the presence of rapid diameter changes, the user chose to add a total of 12 additional planes among all CT scans (less than 1 additional plane per study). In Table 2, measurements of the aneurysm, endobag and thrombus sizes at preoperative (pre-EVAS), postoperative (post-EVAS) and last follow-up scans are compared. Mean volumetric values are plotted in Fig. 2 and individual changes during the last follow-up compared to post-EVAS measurements are shown in Fig. 3.

Maximum aneurysm sac diameter and volume were significantly higher at post-EVAS compared to pre-EVAS ($p < 0.05$), whereas maximum CSA and perimeter remained stable (Table 2). During the last follow-up, aneurysm sac perimeter and volume increased +1 and +5% compared to post-EVAS measurements, respectively ($p < 0.05$). Aneurysm length remained unchanged.

TABLE 1. Population description.

Number of patients	12
Age, years	77 ± 10
Male gender, <i>n</i> (%)	11 (92)
Hypertension, <i>n</i> (%)	11 (92)
Diabetes, <i>n</i> (%)	1 (8)
Dyslipidemia, <i>n</i> (%)	8 (67)
Smoking, <i>n</i> (%)	6 (50)
Coronary pathology, <i>n</i> (%)	7 (64)
Peripheral artery disease, <i>n</i> (%)	5 (42)

TABLE 2. Geometrical absolute dimensions: matched pairs comparison (N = 12) between preoperative (PRE), postoperative (POST) and last CT follow-up (17 ± 7 months) measurements.

	Pre*	Post ⁺	Follow-up	Mean follow-up % change	Mean follow-up % change/month
Aneurysm geometry					
Maximum diameter, cm	5.64 ± 0.51	5.74 ± 0.49*	5.83 ± 0.45	2	0.1
Maximum cross-sectional area, cm ²	22.0 ± 3.4	22.2 ± 3.1	23.5 ± 3.3	6	0.7
Perimeter, cm	16.8 ± 1.4	17.0 ± 1.3	17.2 ± 1.2 ⁺	1 ⁺	0.2 ⁺
Volume, mL	154 ± 23	158 ± 23*	166 ± 19** ⁺	5 ⁺	0.5 ⁺
Length, cm	13.6 ± 1.2	13.7 ± 1.3	13.8 ± 1.2	1	0.2
Endobag geometry					
Maximum diameter, cm		4.51 ± 0.88	4.71 ± 0.90 ⁺⁺	4 ⁺⁺	0.4 ⁺
Maximum cross-sectional area, cm ²		13.8 ± 5.2	14.9 ± 5.3 ⁺⁺	8 ⁺⁺	0.9 ⁺⁺
Perimeter, cm		13.3 ± 2.8	14.4 ± 3.1 ⁺⁺	8 ⁺⁺	0.8 ⁺⁺
Volume, cm ³		97 ± 28	103 ± 31 ⁺⁺⁺	6 ⁺⁺⁺	0.6 ⁺⁺⁺
Mean stents distances, cm		1.36 ± 0.12	1.42 ± 0.13 ⁺	4 ⁺	0.5 ⁺
Distance from renal artery to distal stent, cm		14.8 ± 1.9	14.7 ± 1.8	- 1	0.0
Thrombus size					
Cross-sectional area, cm ²	7.9 ± 4.4	8.4 ± 3.8	8.6 ± 4.3	2	0.4
Volume, cm ³	60 ± 25	61 ± 21	63 ± 22	3	0.4

Follow-up percentage change and percentage change per month were calculated with respect to POST.

p* < 0.05, *p* < 0.01, with respect to pre.

⁺*p* < 0.05, ⁺⁺*p* < 0.01, ⁺⁺⁺*p* < 0.001 with respect to post.

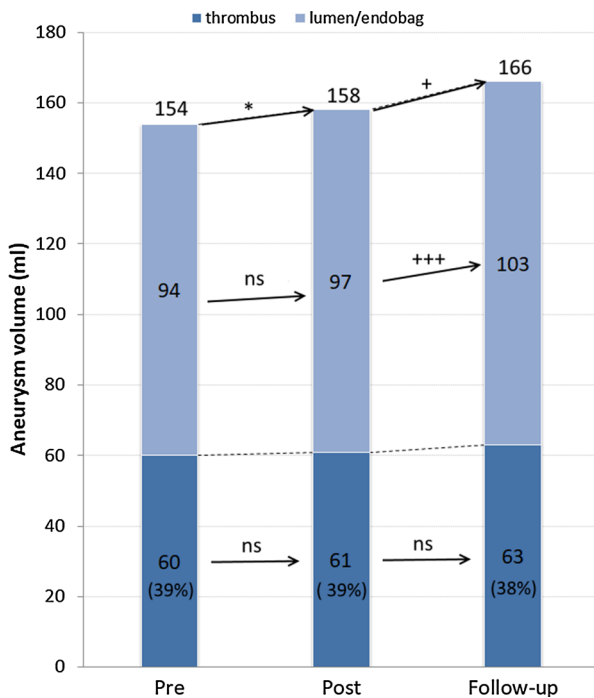


FIGURE 2. Absolute aneurysm, endobag and thrombus volumes in preoperative (pre), postoperative (post) and last follow-up scans. **p* < 0.05 pre compared to post. ⁺*p* < 0.05, ⁺⁺⁺*p* < 0.001 follow-up compared to post.

Endobag size increased at follow-up compared to post-EVAS in terms of maximum diameter (+ 4%, *p* < 0.01), maximum CSA (+ 8%, *p* < 0.01),

perimeter (+ 8%, *p* < 0.01) and volume (+ 6%, *p* < 0.001). Mean distances between stents increased 4% (*p* < 0.05) and no longitudinal migration was observed.

Mean thrombus CSA and volumes remained stable compared to post-EVAS values. Thrombus volume represented ≈ 40% of the total aneurysm volume.

To summarize the volumetric information, mean absolute volumes are shown in Fig. 2. A mild increase in the aneurysm size volume was observed between pre- and post-EVAS (*p* < 0.05). The endobag size (including the stents) was higher than the entire aneurysm lumen but this increase did not reach significance. During last follow-up, the aneurysm sac and the endobags expanded compared to the post-EVAS measurement. The thrombus mean size remained stable among the 3 scans. To better understand these evolutions, individual volume changes between post-EVAS and the last follow-up are shown in Fig. 3. During the last follow-up, we observed that (i) in 67% of the cases (8 out of 12) the aneurysm volume increased (*p* < 0.05), (ii) the endobag size was systematically higher (*p* < 0.001), and (iii) the change in thrombus size was more variable, with an expansion in half of the patients, although mean values did not differ. As shown in Fig. 4, changes in aneurysm and thrombus volumes with respect to post-EVAS were highly correlated ($\beta = 0.94, r = 0.93, p < 0.001$), whereas aneurysm and endobag volumes were not associated ($\beta = 0.55, r = 0.20, p = 0.53$). A positive

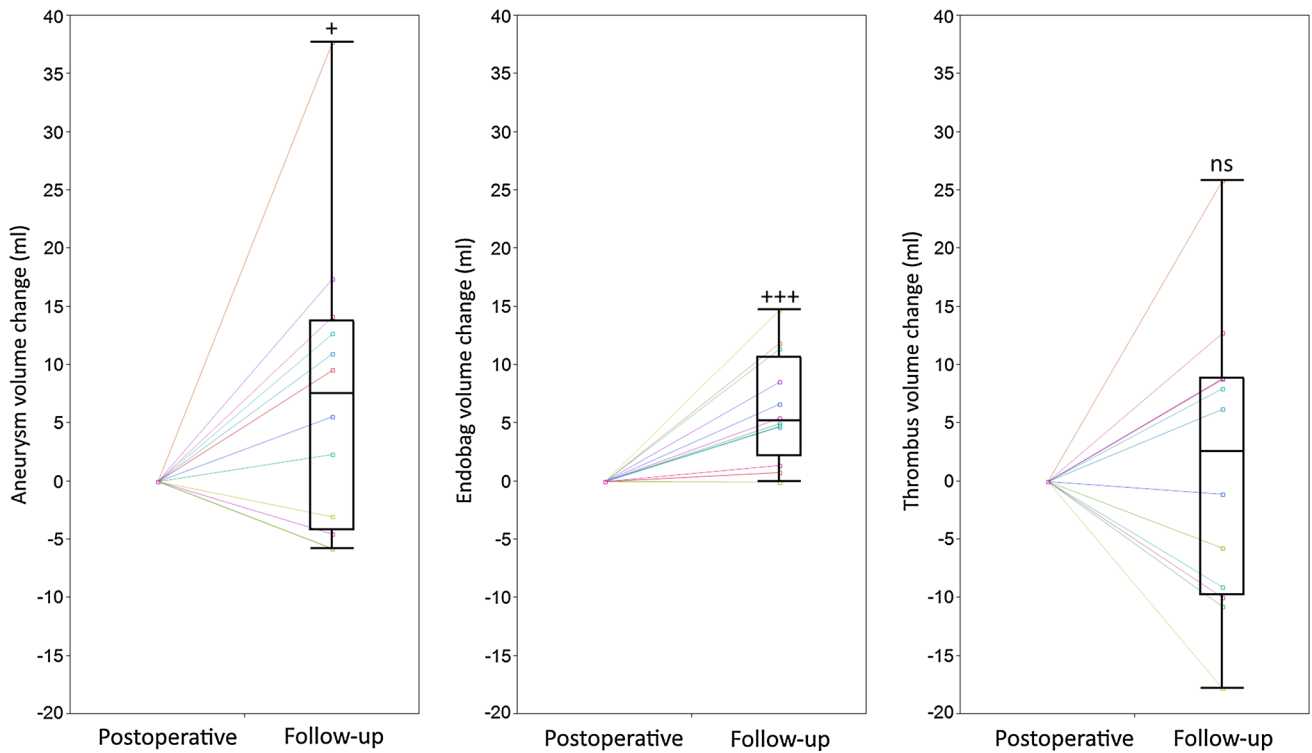


FIGURE 3. Absolute changes in aneurysm, endobag and thrombus volumes during last follow-up compared to postoperative measurements. $^+p < 0.05$, $^{+++}p < 0.001$.

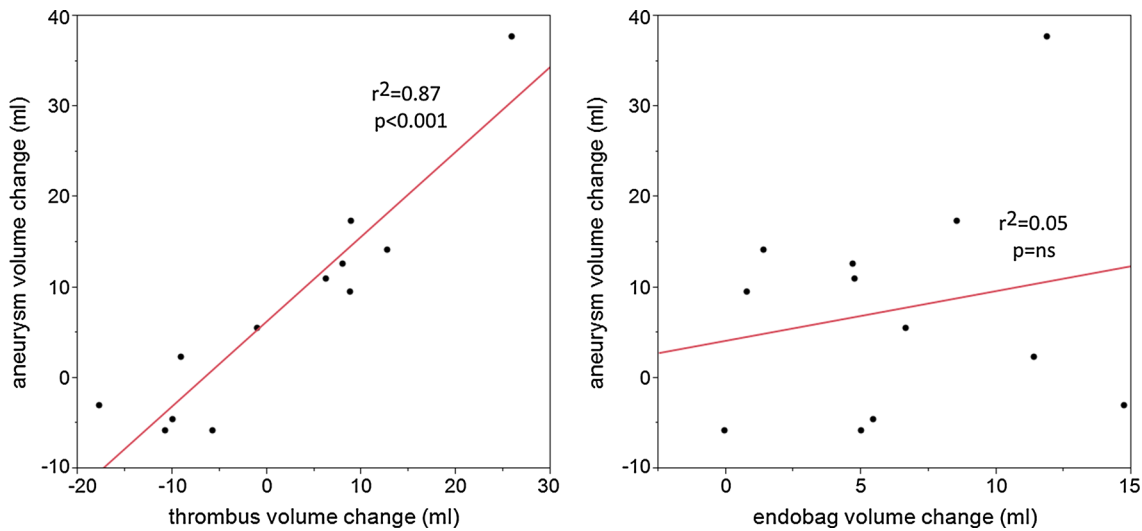


FIGURE 4. Correlation of thrombus and endobag volumes changes with aortic aneurysm volume change. Changes were calculated as differences between follow-up minus postoperative volumes.

correlation between aneurysm and thrombus volume expansion with respect to pre-EVAS was found ($\beta = 0.68$, $r = 0.71$, $p < 0.001$).

Manual and semi-automated maximum diameter values were well correlated ($r = 0.80$). Using manual maximum diameter measurements, no significant differences were observed in pre-EVAS and last follow-up compared to post-EVAS values.

Using our method, there was little intra-observer variability for aneurysm diameter and volume, with a coefficient of variation of 1.2 and 2.1%, respectively. Variations for endobag maximum diameters and volumes were 1.5 and 2.1%. Similarly, inter-observer variability for aneurysm diameters and volumes resulted in variations of 1.5 and 2.3%. For endobag diameters and volumes variations were 1.7 and 2.4%.

The comparison between 2 and 1 cm plane distance measures showed mean variations of 3.4 (range 1.5–7%) for aneurysmal length, 0.45% (range 0.1–1.9%) for aneurysmal or endobag volumes, 0.85% (range 0.1–3.1%) for aneurysmal or endobag diameters and 1.3% (range 0.2–5%) for aneurysmal or endobag cross-sectional areas.

DISCUSSION

This study evaluated the volumetric changes of the abdominal aorta and the Nellix™ endobags after implantation and at one-year follow-up. We found a mean 6% volumetric growth of the aneurysm sac and a 5% increase for the dual endobag system (that included the stents) between the post-EVAS and the mid-term follow-up (Fig. 3). Whereas aortic volumes increased in 8 subjects and decreased in 4, the small expansion of the endograft was systematic, ranging from 1 to 15 mL (Fig. 3). At first, we thought that the aneurysm growth could be explained by the expansion of the endobags, because in our study mean thrombus volume remained unchanged (Fig. 2). However, aneurysm volume change was highly correlated to thrombus volume change but not to the endograft size (Fig. 4). Thrombus has been described as an incompressible but dynamic and heterogeneous structure with large inter-patient variability.²³ Accordingly, a large variability was observed in our study (Fig. 3), where mean thrombus size increased in half of the patients (+ 9 mL) and decreased by a similar amount in the rest (– 12 mL). From our results, we could suggest that the aortic size evolution at mid-term follow-up was mostly associated with individual thrombus size, while the aneurysm volume change was independent of the endograft expansion. We also found a positive correlation between the aneurysm and the thrombus expansion normalized to the pre-EVAS values. This expansion rate per unit of original volume was lower than the one observed with respect to post-EVAS ($\beta = 0.68$ vs. $\beta = 0.94$, respectively), evidencing the complexity of thrombus deposition after EVAS. Nonetheless, more evidence is needed to assess causality effects between thrombi and aneurysm volume (i.e., if thrombus formation/reabsorption is responsible for aneurysmal lumen change, or if thrombi may be accommodating to aneurysmal wall change). This relationship could be even more intricate if thrombi is accepted to have a certain degree of compressibility, as some authors suggest.²²

At this moment, we do not have a proper explanation for the change in the endograft volume during follow-up. The average 6 mL increase found in our study is comparable with a 4 mL change after 1-year

recently reported.²⁵ Theoretically, the sacs filled with polymer cannot expand. Nevertheless, the 2 endobags that are supposed to stay coupled, are actually independent from each other. In fact, we observed that the stents drifted away 4% in terms of their average centerline distance without any longitudinal migration. Changes in stent-to-stent distance were reported elsewhere.¹³ This stent separation suggests that the endobags might suffer a mechanical deformation, artificially enlarging the external endobag perimeter. The EVAS system produces some strong mechanical forces that disturb the flow profiles at the renal artery level compared to standard EVAR devices.^{5,8} These hemodynamic alterations were used to explain longitudinal migrations¹³ or eventual endoleaks within the sacs.¹⁵ We did not observe any of those two effects in our study. Moreover, we did not find an association between stents mean distance and the endograft enlargement ($r = 0.37$, $p = 0.24$). Speculations on the air bubbles evolution inside the endobags remain controversial and could interfere in the endobag size assessment.¹⁵ Other potential reasons for the change in endobag volumes could involve slow seepage of fluid through the wall of the endobag, leak of blood/plasma between the two endobags or direct expansion of the polymer as it becomes less pressurized as the aneurysm expands. Lastly, our volumetric estimation stopped at the aortic bifurcation and did not include the iliac region, where small deformations in size and angulations were already documented during the postoperative scans.⁶ A volumetric analysis including the iliac arteries is currently being developed to clarify these issues in the near future.

The aneurysm size increase at follow-up compared to both pre- and post-EVAS was only visible using a volumetric estimation (Table 2). Previous studies have demonstrated the limitation of the diameter measurement to predict 3D morphological changes during follow-up.^{11,16,28} From our perspective, the evaluation of the aneurysm size using the maximum diameter has two main limitations. First, it is a point 2D estimation that takes into account a single plane that could easily vary during a mid-term follow-up. Second, the sectional areas of both the aneurysm wall border and the endobags were not circular, making the diameter a poor estimator for their true surfaces. Although volumetric measurements were reported to be more time consuming and less accessible in clinical routine,³ we believe that they offer a unique opportunity for the characterization of such complex morphologies as the ones observed in abdominal aneurysms. In our work, a semi-automatic method compatible with the clinical practice was conceived and implemented by biomedical engineers, adding specific tools for the surveillance of the endograft size and the stents separation/migration.

The method was reproducible and reliable to detect small changes in aortic size. If a volumetric tool is not available, we suggest to assess a manual CSA, a perimeter or at least a semi-automated diameter (calculated from the farthest points of a contoured curved) that have shown to be more sensitive to size variations than the manual maximum diameter estimation.

In our study, the aneurysm volume increased between the preoperative and the first postoperative scan, whereas thrombus volume remained stable and the small increment between the endograft size and the aneurysm lumen volume did not reach significance (Fig. 2). Information on the volumetric comparison between pre- and post-EVAS is scarce and showed some uneven results. In a report by Boersen *et al.* with 27 patients who underwent EVAS repair, the AAA volume remained unchanged,⁶ while in another study with 25 subjects a significant increase was observed.²¹ In both reports, thrombus shrank and the endograft size was greater than flow lumen volume. This latter result was documented in a previous report of our group, where a deformable model was proposed to accurately estimate the AAA lumen volume.⁹ In a recent multi-center report with 50 subjects and a 1-year follow-up, aortic volume increased and thrombus volume decreased after EVAS, but these tendencies did not attain significance.¹³ We can mention 3 reasons that could help to explain the discrepancies between studies. First, the time interval between the scans can significantly influence the volumetric assessments.²¹ Second, volumetric estimations include aneurysms lengthening that depend on the setting of precise landmarks. As commented before, we did not look for volumetric changes beyond the aortic bifurcation, a region identified as sensible to this type of endograft implantation.⁶ Third, the manual detection of the interface borders between the flow lumen and the endograft with the thrombotic structures is challenging and may highly depend on the custom segmentation tools. Nonetheless, our software allowed for manually enhancing the contrast (by interactively changing window width and level) in order to improve the border delineation among different structures. Another reason for the slight increases in aneurysm volume and decrease in thrombus volume immediately post EVAS could be the high pressure used to inflate the endobag, that increases load on the aneurysmal wall and might induce stress-sensitive growth and remodeling at long-term.²¹ An increase in aneurysm volume can be considered as inherent to any device deployment in the aortic lumen. Actually, an early slight increase in the aneurysm volume (3.3%) after EVAR implantation has been shown after 1 month using three different

devices.¹⁷ An increase in the aneurysm volume is usually correlated to an endoleak and then to an EVAR failure to exclude the aneurysm, even if in some cases no contrast medium is observed in the residual sac on CTA. Even if its incidence is low, we are aware that the aneurysm expansion found in our study could also be associated with an occult Is4 endoleak.²⁴ Every CTA scan in our study was carefully evaluated by a trained expert and no evidence of visible endoleaks was found. Nevertheless, maybe small endoleaks that initially escaped CTA detection should be evaluated with other techniques. Recently, a significant thrombus radio-density increase was reported after 1-year in patients without endoleaks,²⁵ indicating that alternative strategies to assess endoleaks, including other imaging modalities, should not be disregarded.

Our study has some limitations that must be addressed, including the small sample size, its retrospective design and errors related to the semi-automated measurement method. Regarding the latter, contour curves were separated every 2 cm to ensure an adequate aneurysm morphology assessment while offering a clinically compatible fast measurement. Small mean variations were found in diameter and volume measurements (below 0.5 and 0.9%, respectively) with planes separated by 1 cm. In any case, the user had a proper tool to add intermediate planes if necessary. Cross-sections were measured in true transverse planes to avoid additional manual interventions required for a centerline assessment. Probably, orthogonal cross-sections would be more accurate for diameter assessment but also more prone to measurement variability. Since volumes are calculated according to the external limits of the aneurysm, tortuosity would not directly affect these volumetric results. The dual endobags were segmented together and thus small distancing of the stents might introduce inappropriate increments in the volumetric estimation. Unfortunately, the CT spatial resolution limited the individual segmentation of the endobags in several of the scans. However, the position of each stent was assessed (using the high metallic contrast) and was used to calculate the averaged 3D distance between them. Contouring the stents border instead of selecting their center could improve the accuracy of this 3D distance estimation but would be more time consuming. Finally, the aim of this preliminary study was to introduce a semi-automated method to assess aneurysm and endograft sizes that was customized for an EVAS device. The volumetric assessment tool for aneurysm size estimation could be easily adapted to perform a similar analysis in patients who underwent EVAR in order to accurately compare the outcomes of using different devices configurations at mid-term follow-up.

CONCLUSION

This study presented a volumetric analysis of the aneurysm, endograft and thrombus sizes during a mid-term follow-up after a Nellix™ implantation. The aneurysm volume increase observed during follow-up was mostly associated with the thrombus size change, while the small but systematic endograft expansion was independent from the aortic growth. Measurements provided by our semi-automated method were reproducible, reliable and accessible in routine practice to detect small changes in the aneurysm size.

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AUTHOR CONTRIBUTIONS

Protocol/project development: SEB, MC, DC. Data collection or management: SEB, MC, DC. Data analysis, SEB, MC, DC, JMA, PJ. Manuscript writing/editing: SEB, DC, MC, JMA, EM.

CONFLICT OF INTEREST

Salma El Batti, Mariano E. Casciaro, Jean-Marc Alsac, Christian Latremouille, Pierre Julia, Elie Mousseaux, and Damian Craiem declare that they have no conflict of interest.

ETHICAL APPROVAL

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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