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Determination of Endograft Apposition, Position, and Expansion in the Aortic Neck Predicts Type Ia Endoleak and Migration After Endovascular Aneurysm Repair

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Abstract

Purpose: To describe the added value of determining changes in position and apposition on computed tomography angiography (CTA) after endovascular aneurysm repair (EVAR) to detect early caudal displacement of the device and to prevent type Ia endoleak. **Methods:** Four groups of elective EVAR patients were selected from a dataset purposely enriched with type Ia endoleak and migration (>10 mm) cases. The groups included cases of late type Ia endoleak (n=36), migration (n=9), a type II endoleak (n=16), and controls without post-EVAR complications (n=37). Apposition of the endograft fabric with the aortic neck, shortest distance between the fabric and the renal arteries, expansion of the main body (or dilatation of the aorta in the infrarenal sealing zone), and tilt of the endograft toward the aortic axis were determined on the first postoperative and the last available CTA scan without type Ia endoleak or migration. Differences in these endograft dimensions were compared between the first vs last scan and among the 4 groups. **Results:** No significant differences in endograft configurations were observed among the groups on the first postoperative CTA scan. On the last CTA scan before a complication arose, the position of the fabric relative to the renal arteries, expansion of the main body, and apposition of the fabric with the aortic neck were significantly different between the type Ia endoleak (median follow-up 15 months) and migration groups (median follow-up 23 months) compared with the control group (median follow-up 19 months). Most endograft dimensions had changed significantly compared with the first postoperative CTA scan for all groups. Apposition had increased in the control group but had decreased significantly in the type Ia endoleak and migration groups. **Conclusion:** Progressive changes in dimensions of the endograft within the infrarenal neck could be detected on regular CTA scans before the complication became urgent in many patients.

Keywords

3D imaging, 3D reconstructions, abdominal aortic aneurysm, aneurysm neck, endograft, endovascular aneurysm repair, geometry, migration, stent-graft, type I endoleak

Introduction

Endoleaks (types I and III) and endograft migration are the leading causes of rupture after endovascular aneurysm repair (EVAR).[1,2] New-onset endoleaks and migration may occur at any time after EVAR, demanding life-long surveillance.[3]

Migration (>10 mm) and type Ia endoleaks may develop progressively from continuous changes in endograft position and decreasing apposition of the endograft fabric within the infrarenal aortic neck. Diagnosis of these often-subtle changes on regular computed tomography angiography (CTA) images is difficult, even with centerline reconstructions on a vascular workstation. Therefore, the

focus of current EVAR surveillance is on the detection of aneurysm growth, endoleaks, and migration and less on the prediction and prevention of such complications.[4,5] Plain radiography may capture endograft migration, but subtle changes can be overlooked.

A novel CTA methodology based on new proprietary software that enables precise and accurate determination of endograft (ap)position and expansion in the aortic neck, as well as neck morphology, has been detailed and validated in previous publications.[6,7] The current study sought to determine the predictive value of this new methodology in a retrospective EVAR cohort by associating the endograft dimensions in the aortic neck and changes during follow-up with the development of later failure of seal and fixation.

Methods

Study Protocol

A retrospective cohort study was performed to determine the value of 5 dimensions of infrarenal endograft deployment on the early detection of seal and fixation failure in the proximal seal zone. These validated dimensions[6,7] include (1) the shortest distance between the endograft fabric and the renal arteries, (2) the angle (tilt) between the axis of the proximal endograft fabric boundary and the directional vector of the centerline, (3) the percentage of proximal endograft diameter expansion in the aortic neck, (4) the shortest apposition length between the proximal circumference of the fabric and the first slice perpendicular to the centerline where circumferential apposition of the fabric with the aortic neck is lost, and (5) the surface contact of the fabric with the aortic neck (endograft apposition), calculated as the percentage of the entire infrarenal aortic neck surface. Additionally, change in maximum aneurysm diameter was determined and compared to the preoperative diameter. Figure 1 presents an analysis of the preoperative aortic neck morphology and post-EVAR endograft dimensions in a patient with a late type Ia endoleak.

Patient Selection

A database of 150 electively treated EVAR patients was available from 3 high-volume EVAR centers [Yale School of Medicine (New Haven, CT, USA), University of Alabama, (Birmingham, AL, USA), and St. Antonius Hospital (Nieuwegein, the Netherlands)] that were part of a matched control cohort for the Aortic Securement System Global Registry (ANCHOR; *ClinicalTrials.gov* identifier NCT01534819). Part of the ANCHOR cohort has been used in previous studies to determine preoperative anatomical predictors of seal failure.[8–10]

Figure 2 presents an overview of the patient selection. Of the 150 EVAR patients, 85 had a pre-EVAR CTA scan, an early postoperative CTA scan (<100 days after the procedure), and a late postoperative CTA scan. Eight patients were excluded because additional materials were used, such as bare metal stents, extension cuffs, or chimneys. Five patients were excluded because the endograft was deliberately deployed lower than directly distal to the lowest renal artery. Eight patients were treated with devices without a clear proximal planar edge of fabric (6 Ovation and 2 Aorfix) and were excluded.

Information from the ANCHOR core laboratory analysis (Syntactx, New York, NY, USA) in the 64 remaining patients noted 7 patients with a type Ia endoleak, of which 4 were identified on the first postoperative CTA scan; in addition, 2 patients had migration (>10 mm), 16 patients had a type II endoleak, 1 patient had a type Ib endoleak, and 1 patient had a type III endoleak. The 4 patients with a type Ia endoleak on the first postoperative CTA scan and the 2 patients with type Ib and type III endoleaks were excluded from the current analysis.

Since this left only 3 patients with type Ia endoleak and 2 with migration, the dataset was enriched with 40 patients who had undergone reintervention for type Ia endoleak (n=33) or migration (n=7) at 6 Dutch high-volume EVAR centers. Only patients with the availability of at least 1 postoperative CTA scan without type Ia endoleak or migration were selected. This augmentation produced 36 patients with

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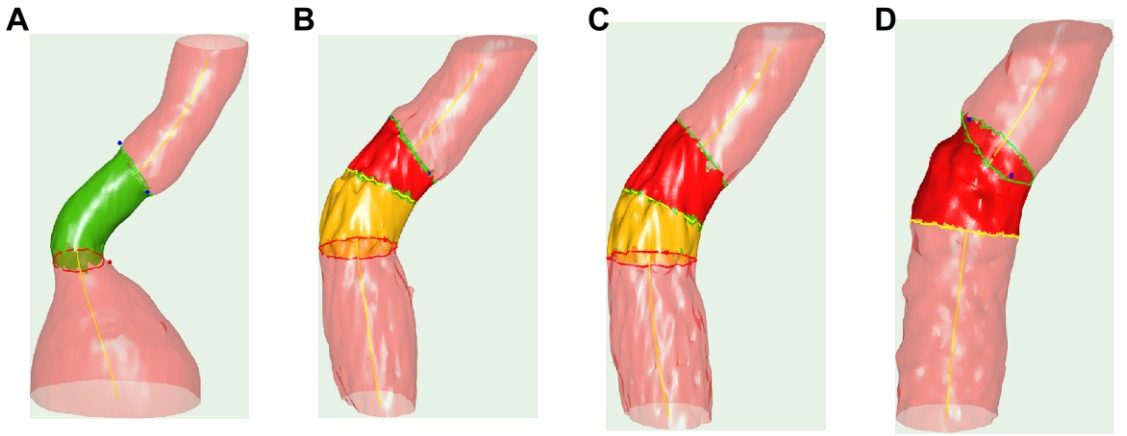

	A	B	C	D
	Pre-EVAR: 1 month	**Follow-up:** 1 month	**Follow-up:** 8 months	**Follow-up:** 75 months
Neck:				
Length	39 mm	33 mm	34 mm	8 mm
Diameter				
⌀ 0	23 mm	21 mm	21 mm	26 mm
⌀ -5	24 mm	24 mm	24 mm	28 mm
⌀ -10	25 mm	24 mm	25 mm	29 mm
⌀ -15	26 mm	26 mm	25 mm	33 mm
Surface	2777 mm^2	3112 mm^2	3098 mm^2	859 mm^2
Thrombus:				
Circumference	117°			
Thickness	1.7 mm			
Calcification:				
Circumference	0°			
Thickness	0 mm			
Device main body:				
Diameter	26 mm			
Oversized	18%			
Aneurysm:				
Diameter	72 mm			
Apposition:				
Length		14 mm	10 mm	0 mm
Surface		1884 mm^2 (61%)	1342 mm^2 (43%)	0 mm^2 (0%)
Top of fabric:				
SFD		10 mm	15 mm	17 mm
CFD		21 mm	25 mm	35 mm
Diameter		23 mm (90%)	26 mm (99%)	26 mm (100%)
Tilt		14°	4°	5°
Aneurysm:				
Diameter		74 mm (102%)	72 mm (100%)	42 mm (58%)

Figure 1. A sample analysis of computed tomography angiography (CTA) scans from an elective endovascular aneurysm repair (EVAR) patient with a type Ia endoleak. (A) Preoperative anatomical characteristics measured in 3mensio, including a large thrombus burden in the aortic neck. (B) On the first postoperative CTA scan 1 month after EVAR, low deployment (10 mm below the renal artery) of the endograft resulted in a small percentage of neck coverage (61%), with sufficient apposition length (14 mm). (C) The second follow-up CTA scan showed no change of the neck characteristics. Caudal displacement of the device (4 mm) resulted in reduced neck coverage (43%) and apposition length (10 mm). The 26-mm endograft main body was fully expanded (99%). The maximum aneurysm diameter remained unchanged (72 mm). (D) The CTA scan at 75 months demonstrated type Ia endoleak; the neck diameter had expanded, apposition was lost, and the endograft had migrated into the aneurysm. The maximum aneurysm diameter had shrunk to 42 mm.

a type Ia endoleak, 9 with migration without an endoleak, 16 with a type II endoleak, and 37 controls without endoleak or failure of seal/fixation. The patients had been treated with a variety of endografts (Table 1): Endurant (Medtronic Cardiovascular, Santa Rosa, CA, USA), Talent (Medtronic), Zenith (Cook Medical, Bloomington, IN, USA), and Excluder (W.L. Gore & Associates, Flagstaff, AZ, USA).

The groups were not matched, but the goal was to include a substantial number of patients within the selection criteria. A preoperative CTA scan was not available for 7 patients in the type Ia endoleak group and 2 patients in the migration group. A postoperative CTA scan within 100 days after the procedure was not available for 12 patients in the type Ia endoleak group and 3 in the migration group. Figure 3 shows the median duration of CTA follow-up for each of the groups.

CTA Analysis

Differences in preoperative anatomy between the groups were determined on the preoperative CTA scans. Accuracy of the deployment, short-term migration, and adaptive neck

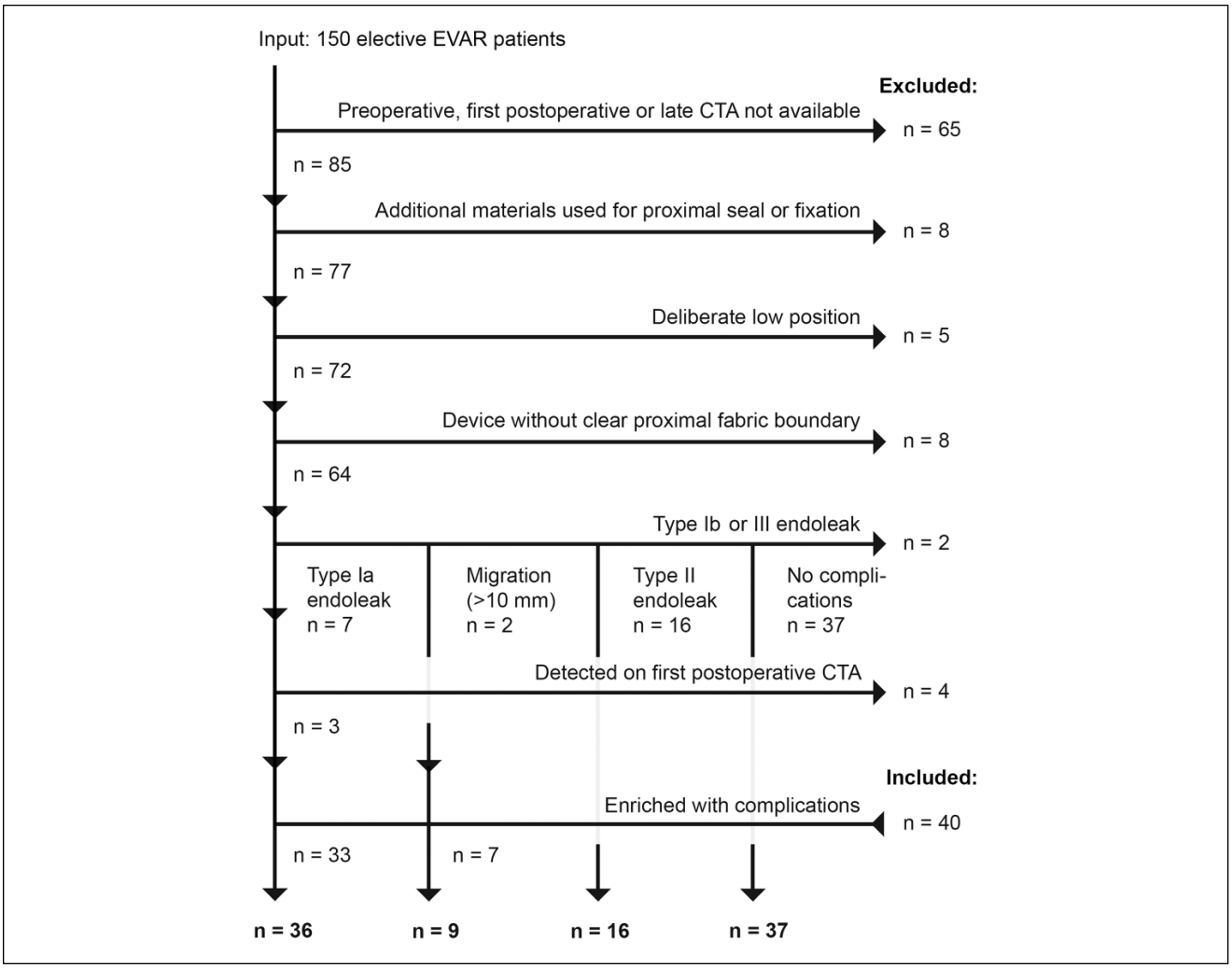

Figure 2. Criteria for patient selection.

Table 1. Anatomical Characteristics From the Preoperative Computed Tomography Angiography Scan in the 4 Study Groups.[a]

	Type Ia Endoleak (n=36)[b]	Migration (n=9)[b]	Type II Endoleak (n=16)	Controls (n=37)
Interval between CTA and EVAR, mo	1.1 (0.1, 1.9) p=0.605	1.1 (0.7, 2.4) p=0.553	2.0 (0.4, 2.4) p=0.201	1.0 (0.6, 1.6)
Neck diameter, mm	24.2 (21.7, 27.2) p=0.132	27.1 (22.7, 28.6) p=0.875	23.1 (20.1, 26.5) p=0.649	23.2 (21.3, 25.6)
Endograft diameter, mm	28 (26, 32) p=0.082	30 (28, 36) p=0.049	28 (25, 28) p=0.937	26 (25, 32)
Intended oversizing, %	20 (10, 27) p=0.964	20 (3, 26) p=0.925	19 (10, 25) p=0.931	20 (10, 26)
Neck length, mm	14.0 (6.5, 29.1) p=0.065	15.0 (9.0, 39.0) p=0.683	33.0 (16.5, 38.0) p=0.114	21.0 (15.0, 30.5)
Aneurysm diameter, mm	62.0 (57.6, 73.3) p<0.001	60.2 (54.8, 71.6) p=0.024	51.1 (43.8, 61.8) p=0.300	54.3 (51.0, 57.3)
Endografts	p=0.003	<0.001	p=0.528	
Endurant	12	1	8	24
Talent	14	6	1	1
Zenith	6	1	3	6
Excluder	2	0	4	4
Other	2	1	0	2
Within IFU, %	48 p=0.259	43 p=0.341	63 p=0.981	62

Abbreviations: CTA, computed tomography angiography; EVAR, endovascular aneurysm repair; IFU, instructions for use.
[a]Data are presented as the median (interquartile range Q1, Q3); p values are vs controls.
[b]A preoperative CTA scan was not available for 7 patients in the type Ia endoleak group and 2 patients in the migration group.

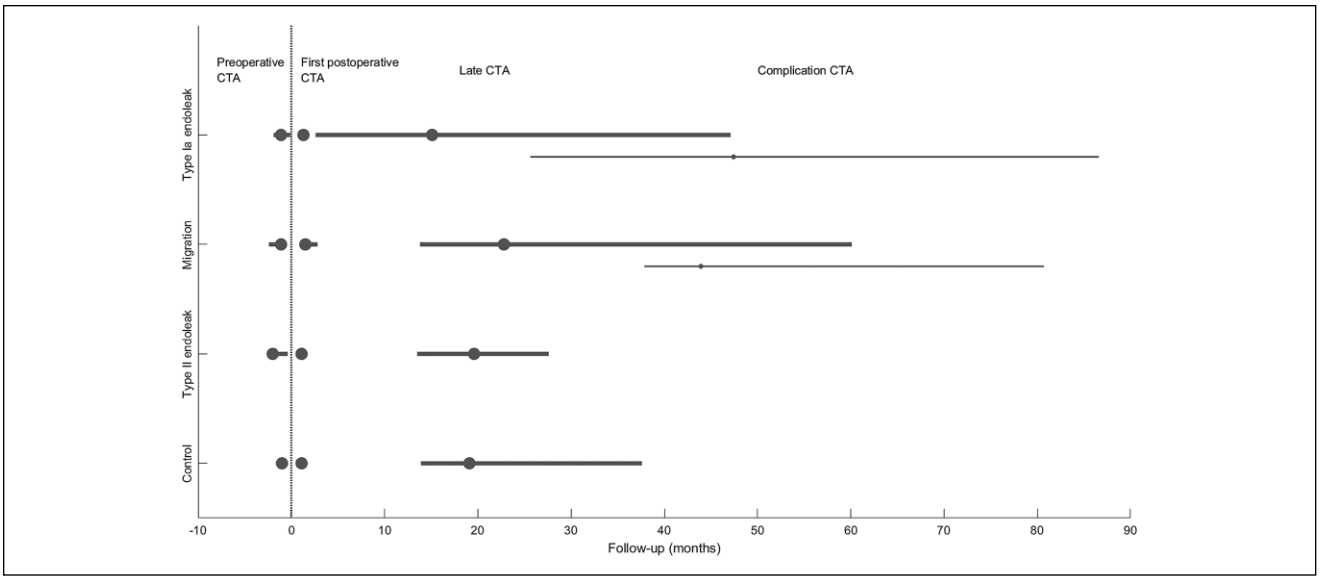

Figure 3. Follow-up duration of the preoperative, first postoperative, and late computed tomography angiography (CTA) scans for the 4 groups of patients. The procedure is marked by a dotted line. For the type Ia endoleak and migration groups, the additional follow-up duration is also given for the CTA that showed the complication. Data are given as the median (dot) and interquartile range (bar).

enlargement were determined on the first postoperative CTA scan (within 100 days post-EVAR) in all patients. The groups of patients with type Ia endoleak and migration both represent the population with failure of seal and fixation in the infrarenal aortic neck. For these patients, changes in aortic neck morphology and endograft dimensions were determined on the follow-up CTA scan that was performed previous to the CTA on which the complication was diagnosed in order to determine the predictive value of the proprietary software. The group of patients with a type II endoleak was included to verify if type II endoleak affects changes in aneurysm size and possibly reduction of apposition in the neck from the distal end. For patients with a type II endoleak and the control group, all aortic and endograft measurements were done on the last available CTA scan during follow-up. Eventual changes in endograft dimensions were compared to the first postoperative CTA scan.

Measurement Protocol

Measurements were performed by 3 experienced observers on a 3mensio vascular workstation (version 8.1 research edition; Pie Medical Imaging BV, Maastricht, the Netherlands). A single centerline was constructed semiautomatically through the aortic lumen from 20 mm proximal to the highest renal artery to the aortic bifurcation. On postoperative CTA scans, the distal end of the centerline was constructed between the limbs of the endograft to the level of the native aortic bifurcation.

Preoperative anatomical characteristics included neck diameter, neck length, and maximum aneurysm diameter. Neck diameter was measured from adventitia to adventitia in 2 orthogonal planes at the most caudal level of the lowest renal artery orifice; in necks with substantial thrombus load, the inner neck diameter was measured instead. Neck length was measured as the centerline distance between the lowest renal artery baseline and the first slice perpendicular to the centerline where the average aortic diameter exceeded 10% of the diameter at the lowest renal artery baseline. The maximum aneurysm sac diameter was located on the slices perpendicular to the centerline over the length of the aneurysm. On 3 scans, the centerline reconstruction was distorted due to large angulation; in these cases, the maximum aneurysm diameter was determined on the axial slices of the preoperative and postoperative scans as the average of 2 orthogonal diameters measured from adventitia to adventitia. Sac growth or regression was determined as the change in maximum aneurysm diameter compared with the preoperative aneurysm diameter.

The diameter of the endograft main body was obtained from the procedure reports. This information was not available for 13 patients; in these cases, the device diameter was measured perpendicular to the centerline on the postoperative CTA scans at the level of the aneurysm sac, where full expansion of the endograft could be expected. Intended oversizing was defined as the percentage of the main body diameter that exceeded the diameter of the aortic neck at the level of the lowest renal artery on the preoperative CTA scan.

In addition to the 5 endograft dimensions from the previous validation study,[7] the current study also included the calculation of the endograft expansion rate as the *expanded endograft diameter* / *original main body diameter* × 100

Table 2. Aneurysm and Endograft Dimensions From the First Postoperative Computed Tomography Angiography Scan in the 4 Study Groups.[a]

	Type Ia Endoleak (n=24/36)[b]	Migration (n=6/9)[b]	Type II Endoleak (n=16)	Controls (n=37)
Follow-up, mo	1.3 (1.1, 1.8) p=0.041	1.5 (1.0, 2.8) p=0.122	1.1 (1.0, 1.5) p=0.676	1.1 (1.0, 1.3)
Sac enlargement / regression, mm	0.7 (0.2, 1.5) p=0.119	1.1 (−0.4, 3.2) p=0.206	0.1 (−1.5, 1.2) p=0.831	0.2 (−0.9, 1.2)
Shortest fabric distance, mm	1.6 (−1.0, 5.1) p=0.647	3.7 (1.9, 4.6) p=0.060	2.8 (0.5, 4.7) p=0.261	1.4 (−0.4, 3.3)
Endograft expansion, %	89 (82, 96) p=0.069	91 (80, 98) p=0.262	87 (80, 95) p=0.328	83 (77, 90)
Tilt, deg	14.4 (6.4, 21.1) p=0.745	9.4 (6.6, 22.1) p=0.572	17.7 (9.6, 22.7) p=0.085	13.4 (8.7, 17.5)
Endograft apposition, % of neck area	75 (67, 84) p=0.976	71 (49, 81) p=0.694	75 (62, 83) p=0.907	75 (61, 86)
Shortest apposition length, mm	14.7 (8.6, 23.1) p=0.965	10.4 (7.7, 26.3) p=0.986	17.5 (8.7, 23.6) p=0.771	18.0 (6.4, 21.4)

[a]Data are presented as the median (interquartile range Q1, Q3); p values are vs controls.
[b]A postoperative computed tomography angiography scan within 100 days after the procedure was not available for 12 of the 36 patients in the type Ia endoleak group and 3 of the 9 patients in the migration group.

and the endograft apposition as *apposition surface* / *neck surface* × 100. Three-dimensional coordinates of the renal artery orifices, the proximal edge of the fabric, and the distal end of the seal were obtained from the 3mensio workstation. The distal end of the seal was defined as the first slice perpendicular to the centerline where circumferential apposition of the fabric to the aortic wall was interrupted. Centerline coordinates, a mesh of the contrast-rich aortic lumen, and the coordinates of the renal arteries, proximal fabric boundary, and distal apposition boundary were imported into dedicated proprietary software to calculate the shortest fabric distance, tilt, endograft expansion, neck coverage, and apposition length.

Statistical Analysis

Normality could not be assumed for a large part of the data because of boundaries and small numbers; thus, the data are displayed as medians with interquartile ranges (Q1, Q3). The type Ia endoleak group, the migration group, and the type II endoleak group were compared with the control group. Statistical differences in anatomical baseline characteristics, the change in sac diameter, and endograft dimensions were assessed with the nonparametric Mann-Whitney *U* test. Differences in implanted devices were tested with cross tabulation and the Pearson chi-square test. The significance of changes of the endograft dimensions during follow-up was assessed with the 1-sample *t* test against the null hypothesis of zero change. All tests were 2-tailed; the threshold of statistical significance was $p<0.05$. Statistical analysis was performed with SPSS software (version 23; IBM Corporation, Armonk, NY, USA).

Results

Group Comparison

The preoperative anatomical characteristics of the 4 groups are displayed in Table 1. The median time between the preoperative CTA scan and the EVAR procedure was not significantly different between groups. The neck lengths of the patients in the complication groups were shorter compared with the control group, although not statistically significant. The aneurysm sizes were significantly larger at baseline for the type Ia endoleak and migration groups. The percentage of intended oversizing of the endograft main bodies was the same for all groups. The implanted devices were significantly different in the type Ia endoleak and migration groups compared with the control group. These groups included more former generation devices compared with the controls, with more Talent endografts in the type Ia endoleak and migration groups.

First Postoperative CTA Scan

Sac enlargement and endograft dimensions at the first postoperative CTA scan are displayed in Table 2 and Figure 4. The time interval between the EVAR procedure and the first postoperative CTA scan was longer for the type Ia endoleak group compared with the control group [1.3 (1.1, 1.8) vs 1.1 (1.0, 1.3) months, respectively]. The endografts were positioned lower in the migration group compared with the controls, although the difference was not statistically significant [3.7 (1.9, 4.6) vs 1.4 (−0.4, 3.3) mm]. The endograft expansion was not statistically different between the patients with late seal failures and the control group. A similar proportion of the neck was covered by fabric in all groups, resulting in comparable lengths of apposition.

Late Follow-up CTA Scan

Sac enlargement and the endograft dimensions at the late CTA scan are displayed in Table 3 and Figure 5. The time interval between the procedure and the late CTA scan was not significantly different among the groups [15.1 (2.6, 47.1), 22.8 (13.8, 60.1), 19.6 (13.5, 27.6), and 19.1 (13.9, 37.6) months for the type Ia endoleak, migration, type II endoleak, and control groups, respectively. The median time

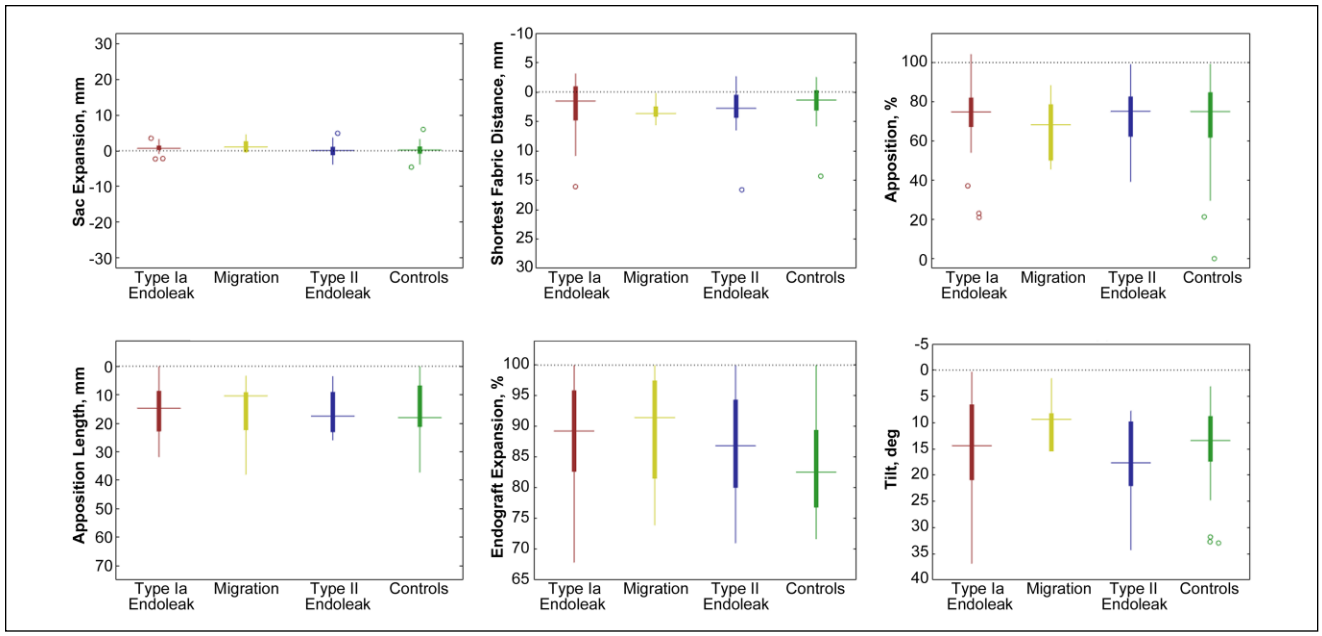

Figure 4. Aneurysm and endograft dimensions at the first postoperative computed tomography angiography (CTA) scan.

Table 3. Aneurysm and Endograft Dimensions From the Late Follow-up Computed Tomography Angiography Scan[a] in the 4 Study Groups and Change From the First Postoperative Scan.[b]

	Type Ia Endoleak (n=36)	Migration (n=9)	Type II Endoleak (n=16)	Controls (n=37)
Follow-up, mo	15.1 (2.6, 47.1) p=0.153	22.8 (13.8, 60.1) p=0.628	19.6 (13.5, 27.6) p=0.691	19.1 (13.9, 37.6)
Sac enlargement / regression, mm	0.3 (−1.9, 3.7) p<0.001	4.1 (0.0, 8.1) p<0.001	−1.0 (−6.6, 2.0) p<0.001	−10.2 (−13.7, −5.5)
Change, mm	−0.1 (−5.1, 9.5) p=0.991	2.2 (−2.6, 7.9) p=0.327	−0.9 (−5.2, 1.6) p=0.491	−9.9 (−14.6, −6.0) p<0.001
Shortest fabric distance, mm	4.9 (0.8, 14.0) p=0.042	8.4 (6.5, 13.5) p<0.001	4.1 (1.0, 7.3) p=0.175	2.3 (0.8, 4.4)
Change, mm	2.0 (0.9, 4.7) p=0.018	6.6 (3.4, 10.8) p=0.012	2.1 (−0.5, 4.7) p=0.007	0.9 (−0.2, 2.0) p=0.004
Endograft expansion, %	94 (88, 100) p=0.050	99 (93, 100) p=0.022	92 (87, 97) p=0.461	90 (83, 97)
Change, %	7 (0, 17) p=0.002	1 (−2, 19) p=0.224	6 (0, 10) p=0.036	4 (−1, 12) p=0.001
Tilt, deg	12.3 (5.1,18.5) p=0.627	8.9 (6.7, 14.8) p=0.935	15.8 (7.9, 21.3) p=0.085	10.4 (5.6, 15.8)
Change, deg	−2.9 (–4.9, 0.8) p=0.212	−0.6 (–6.8, 4.0) p=0.606	−2.1 (–5.0, 0.8) p=0.123	−2.4 (–7.2, 3.2) p=0.041
Endograft apposition. % of neck area	65 (22, 82) p=0.055	42 (29, 57) p=0.002	68 (53, 87) p=0.684	75 (61, 85)
Change, %	−7 (−55, 3) p=0.016	−29 (−45, −9) p=0.026	−3 (−14, 4) p=0.178	0 (−6, 3) p=0.830
Shortest apposition length, mm	9.2 (0.0, 27.1) p=0.033	10.2 (4.2, 14.4) p=0.040	16.3 (8.4, 24.3) p=0.548	18.6 (11.5, 26.5)
Change, mm	−2.8 (−13.6, 2.8) p=0.213	−2.0 (−15.1, 3.4) p=0.368	1.3 (−4.4, 3.8) p=0.379	2.2 (−0.5, 6.4) p=0.019

[a]Last scan before diagnosis of type Ia endoleak or migration (>10 mm); last available CTA scan for the type II endoleak and control groups.
[b]Data are presented as the median (interquartile range Q1, Q3); p values are vs controls for the endoleak and migration groups.

interval between the precomplication scan and the next CTA scan on which the complication was reported was 24.6 (12.2, 36.3) months.

Sac regression (>0 mm) was observed for 13 (36%), 2 (22%), 12 (75%), and 34 (92%) patients in the type Ia endoleak, migration, type II endoleak, and control groups, respectively, while aneurysm growth (>5 mm) was observed for 7 (19%), 4 (44%), 3 (19%), and 0 patients. The type Ia endoleak, migration, and type II endoleak groups showed large variations in maximum aneurysm diameter change; the median diameter of these groups had not changed significantly compared with the first postoperative CTA scan. Further duplex ultrasound follow-up after the last CTA scan was available for 6 of the type II endoleak cohort and 7

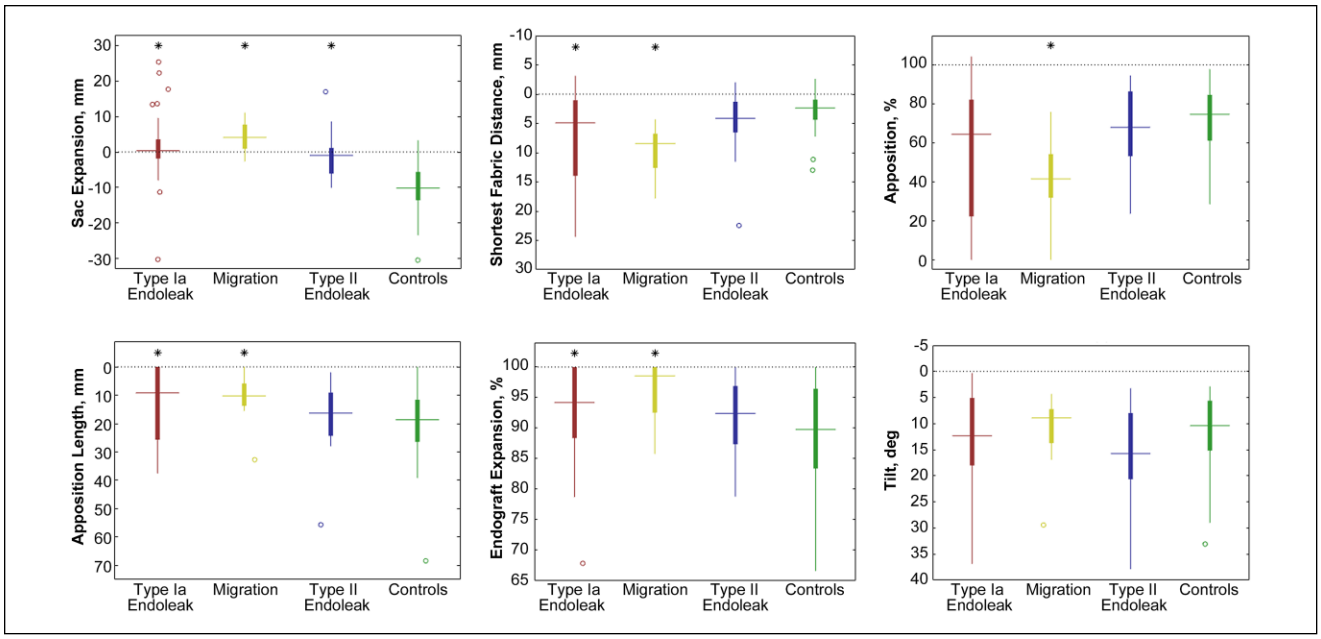

Figure 5. Aneurysm and endograft dimensions at the late computed tomography angiography (CTA) scan, with comparable duration of follow-up for all groups.

controls, with an additional follow-up duration of 15 (12, 38) and 32 (25, 49) months, respectively. These duplex images showed no endoleaks and no increase in maximum aneurysm diameter in both groups.

Significant caudal displacement was seen in all groups, including the type II endoleak and control groups, but the final position of the fabric on the late CTA scan (before diagnosis of type Ia endoleak or migration) was significantly lower for the type Ia endoleak and migration groups. Significant expansion of the endograft or dilatation of the aorta in the sealing part of the infrarenal neck was seen in all patients except the migration group, where the endograft had already expanded substantially at the first postoperative CTA scan. The final expansion of the endograft was significantly larger in the type Ia endoleak and migration groups. There was no difference between the groups in tilted position of the top of the fabric toward the aortic axis. The neck coverage remained stable in the type II endoleak and control groups, and the control group gained significant apposition length. In the type Ia endoleak and migration groups, the neck coverage had been reduced significantly, resulting in significantly lower apposition length compared to the controls at the late CTA scan.

Discussion

The software allows detailed surveillance of endograft deployment and apposition on the first postoperative CTA scan and changes therein during further CTA follow-up. Deployment accuracy and adaptive neck enlargement at the first postoperative CTA scan are important parameters and should be carefully determined. Low position of the endograft may be the result of either low initial deployment or early caudal displacement. Comparison with intraoperative imaging is required when low position is observed on the first postoperative CTA scan.

Changes in anatomy and endograft dimensions during further follow-up were clearly amplified in the type Ia endoleak and migration groups on the CTA scan before actual seal failure was detected. Aneurysm growth has often been described as an important predictor of failure, which has also been verified in this study.[11–13] However, only a few patients in the type Ia endoleak and migration groups showed >5-mm aneurysm growth on the last scan before diagnosis of the complication (19% and 44%, respectively), and some patients even showed regression of the maximum aneurysm diameter (36% and 22%, respectively). Also, aneurysm growth alone does not differentiate between potential causes of sac repressurization. Both endoleak groups showed similar changes in aneurysm diameter after similar duration of follow-up. Duplex ultrasound will not be able to appreciate the exact cause of repressurization of the aneurysm sac, so CTA surveillance is required with a focus on changes in the endograft dimensions.

Caudal displacement occurs to some extent in most patients, including the controls (Table 3), which suggests that treating patients with short necks (10–15 mm) should be performed with caution. Proximal extension or the use of additional antimigration measures or repositionable devices may be required to counteract or compensate for

caudal displacement in short necks. Moreover, because caudal displacement continues to occur in the majority of patients, long-term follow-up is mandatory after EVAR.

Radial forces of the oversized, self-expanding endograft onto the aortic neck and disease progression may cause adaptive neck enlargement after implantation and neck dilatation during follow-up, which is seen to various degrees in most patients.[14,15] Endografts expanded more in the type Ia endoleak and migration groups, suggesting this is a prominent risk factor. Radial forces of a fully expanded endograft are reduced significantly, so migration resistance will depend only on active fixation provided by hooks or pins.[16,17]

The degree of tilt was similar for the patients in all groups and slightly reduced at the late follow-up scan, indicating alignment of the endograft with the aortic wall. It seems that tilt is not a major contributor to the risk of failure of seal and fixation.

Progressive reduction of the endograft's apposition with the aortic neck may be the most important predictor of failure. Reduction of apposition during follow-up was seen in both type Ia endoleak and migration groups and may be the result of caudal displacement of the endograft or distal effacement of the neck.[17] Contrary to the proximal failure groups, an increase in apposition length was observed in the majority of the controls as a result of sac shrinkage. Bastos Gonçalves and coworkers[18] showed that a short length of apposition (<10 mm) on the first postoperative CTA scan was associated with abdominal aortic aneurysm–related adverse events. In this study, reduced apposition was not observed on the first postoperative scan but during later follow-up, which is explained by a difference in patient selection. Bastos Gonçalves et al[18] included patients with evident complications on the first postoperative CTA scan, while this study included only patients with at least 1 postoperative CTA scan without complications.

CTA surveillance is recommended at 1 and 12 months after EVAR, followed by annual color Doppler ultrasound (CDU) surveillance if endoleaks and significant aneurysm growth are not detected.[4,5,19,20] CDU has the benefit of being cheaper and less harmful in terms of nephrotoxic contrast and radiation exposure. However, CDU is less sensitive in detecting endoleaks than CTA, and the position, expansion, and apposition of the endograft in the proximal neck cannot be investigated.[21] Radiography is used to detect migration, but this technique is limited in detecting subtle 3-dimensional (3D) position changes. Therefore, 3D analysis of the endograft dimensions should be performed on CTA scans, which is possible with high accuracy and precision with the presented methodology. When the (ap)position is minimal or declining, CTA follow-up may be advised instead of CDU to monitor eventual progression of this process.

When failure of seal and fixation can be predicted by accurate follow-up of the endograft dimensions, reintervention may be indicated before a type Ia endoleak is evident. This would prevent a hazardous situation for the patient and improve treatment options with less complex solutions, for example, treatment with an extension cuff and endoanchors instead of a chimney or fenestrated procedure. This may, however, result in an excess of reinterventions, as not all patients with caudal displacement or 100% expansion of the endograft will eventually develop an endoleak. A large prospective study is required to identify relevant cutoff values to support the decision to reintervene.

The type Ia endoleak and migration groups included more patients with hostile (neck) anatomy and patients treated with Talent endografts than the other groups, which may imply that the Talent endoprosthesis is more prone to migration. The data, however, are not consecutive, and different groups of patients were treated at different centers over different periods of time. Most important is that the software enables better measurement of endograft (ap)position and expansion than standard CT scan evaluation and that changes in endograft dimensions may predict failure of seal for the individual patient, irrespective of the preprocedural anatomy and implanted device.

Limitations

The ability of different endografts to conform to the curve of the aortic neck varies,[22] which may impact the endograft dimensions. Also, expansion and apposition of the endograft may vary during the cardiac cycle, which can be appreciated only with dynamic CT imaging. The software is currently not optimized for the analysis of dynamic CT scans, and this study was limited to the analysis of static images. Furthermore, position, expansion, and apposition of the endograft are measured from the proximal boundary of the fabric, so devices without a clear proximal planar fabric edge cannot be analysis using this method.

This was a retrospective study, and despite efforts to include as many cases as possible, the number of patients is relatively low. Second, no long-term CDU follow-up was available for a large portion of the control patients, so some of these patients may have developed endoleaks during later follow-up. Therefore, the data are too limited to establish relevant cutoff values for each of the endograft dimensions. Future research, preferably a prospective study, should identify the predictive value of each individual endograft dimension on postoperative CTA scans.

Dedicated, proprietary software was developed and used to calculate each of the dimensions of the endograft within the proximal neck. The software is not yet licensed for medical use, making it difficult for other groups to repeat these analyses. While the software is being developed further and commercialized, standardized length and diameter measurements along the centerline in current workstations approximate the calculations of the fabric distance, apposition length, and neck diameter at level of the proximal fabric edge.

Conclusion

Detailed determination of the position, expansion, and apposition of the endograft within the infrarenal aortic neck on regular postoperative CTA scans is feasible with the presented methodology. Changes in these dimensions during follow-up are predictive of later failure of seal before urgent reintervention is required. A large prospective study is required to verify the predictive value of each of the endograft dimensions and to determine relevant cutoffs for clinical practice.

Declaration of Conflicting Interests

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References

1. Schlösser FJ, Gusberg RJ, Dardik A, et al. Aneurysm rupture after EVAR: can the ultimate failure be predicted? *Eur J Vasc Endovasc Surg*. 2008;37:15–22.
2. Antoniou GA, Georgiadis GS, Antoniou SA, et al. Late rupture of abdominal aortic aneurysm after previous endovascular repair: a systematic review and meta-analysis. *J Endovasc Ther*. 2015;22:734–744.
3. Corriere MA, Feurer ID, Becker SY, et al. Endoleak following endovascular abdominal aortic aneurysm repair: implications for duration of screening. *Ann Surg*. 2004;239:800–807.
4. Moll FL, Powell JT, Fraedrich G, et al. Management of abdominal aortic aneurysms clinical practice guidelines of the European Society for Vascular Surgery. *Eur J Vasc Endovasc Surg*. 2011;41(Suppl 1):S1–S58.
5. Chaikof EL, Brewster DC, Dalman RL, et al. The care of patients with an abdominal aortic aneurysm: the Society for Vascular Surgery practice guidelines. *J Vasc Surg*. 2009;50(4 Suppl):S2–S49.
6. 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 Cardiovasc Surg (Torino)*. 2016;57:737–746.
7. 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.
8. Jordan WD Jr, Ouriel K, Mehta M, et al; Aneurysm Treatment using the Heli-FX Aortic Securement System Global Registry ANCHOR. Outcome-based anatomic criteria for defining the hostile aortic neck. *J Vasc Surg*. 2015;61:1383–1390.
9. 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.
10. Schuurmann RCL, 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.
11. Houbballah R, Majewski M, Becquemin J-P. Significant sac retraction after endovascular aneurysm repair is a robust indicator of durable treatment success. *J Vasc Surg*. 2010;52:878–883.
12. Bastos Gonçalves F, Baderkhan H, Verhagen HJ, et al. Early sac shrinkage predicts a low risk of late complications after endovascular aortic aneurysm repair. *Br J Surg*. 2014;101:802–810.
13. Dingemans SA, Jonker FH, Moll FL, et al. Aneurysm sac enlargement after endovascular abdominal aortic aneurysm repair. *Ann Vasc Surg*. 2016;31:229–238.
14. Savlovskis J, Krievins D, de Vries JP, et al. Aortic neck enlargement after endovascular aneurysm repair using balloon-expandable versus self-expanding endografts. *J Vasc Surg*. 2015;62:541–549.
15. Monahan TS, Chuter TA, Reilly LM, et al. Long-term follow-up of neck expansion after endovascular aortic aneurysm repair. *J Vasc Surg*. 2010;52:303–307.
16. Cao P, Verzini F, Parlani G, et al. Predictive factors and clinical consequences of proximal aortic neck dilatation in 230 patients undergoing abdominal aorta aneurysm repair with self-expandable stent-grafts. *J Vasc Surg*. 2003;37:1200–1205.
17. Litwinski RA, Donayre CE, Chow SL, et al. The role of aortic neck dilation and elongation in the etiology of stent graft migration after endovascular abdominal aortic aneurysm repair with a passive fixation device. *J Vasc Surg*. 2006;44:1176–1181.
18. Bastos Gonçalves F, van de Luijtgaarden KM, Hoeks SE, et al. Adequate seal and no endoleak on the first postoperative computed tomography angiography as criteria for no additional imaging up to 5 years after endovascular aneurysm repair. *J Vasc Surg*. 2013;57:1503–1511.
19. Sternbergh WC, Greenberg RK, Chuter TA, et al. Redefining postoperative surveillance after endovascular aneurysm repair: recommendations based on 5-year follow-up in the US Zenith multicenter trial. *J Vasc Surg*. 2008;48:278–285.
20. Chaer RA, Gushchin A, Rhee R, et al. Duplex ultrasound as the sole long-term surveillance method post-endovascular aneurysm repair: a safe alternative for stable aneurysms. *J Vasc Surg*. 2009;49:845–849.
21. AbuRahma AF, Welch CA, Mullins BB, et al. Computed tomography versus color duplex ultrasound for surveillance of abdominal aortic stent-grafts. *J Endovasc Ther*. 2005;12:568–573.
22. Demanget N, Duprey A, Badel P, et al. Finite element analysis of the mechanical performances of 8 marketed aortic stent-grafts. *J Endovasc Ther*. 2013;20:523–535.