

# Influence of aortic neck characteristics on successful aortic wall penetration of EndoAnchors in therapeutic use during endovascular aneurysm repair



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## ABSTRACT

**Objective:** This study sought to quantify EndoAnchor (Medtronic Vascular, Santa Rosa, Calif) penetration into the aortic wall in patients undergoing endovascular abdominal aortic aneurysm repair and to assess predictors of successful penetration and its relationship to postprocedural type IA endoleak.

**Methods:** A subset of patients from the Aneurysm Treatment Using the Heli-FX Aortic Securement System Global Registry (ANCHOR) were included if they met the following criteria: the indication for EndoAnchor use was to treat a type IA endoleak, and postprocedure contrast-enhanced computed tomography (CT) scans of sufficient quality were available for core laboratory review. Patients undergoing implantation of cuffs or stents during the EndoAnchor implantation procedure were excluded. Baseline anatomic characteristics were recorded. The cohort was divided into patients with and without persistent type IA endoleaks at the first postoperative CT scan. Penetration of each EndoAnchor measured on this CT scan was defined as good penetration when the EndoAnchor penetrated  $\geq 2$  mm into the aortic wall, borderline penetration when EndoAnchor penetration was  $< 2$  mm or a gap remained between the endograft and aortic wall, or no penetration when the EndoAnchor did not penetrate into the aortic wall. Differences between the groups were analyzed with the Mann-Whitney *U* test or Fisher exact test. Multivariate analyses were performed to identify independent predictors of EndoAnchor penetration, and procedural success was defined by absence of type IA endoleak.

**Results:** Eighty-six patients of the primary ( $n = 61$  [71%]) and revision ( $n = 25$  [29%]) arms of the ANCHOR registry were included. There were 53 (62%) without and 33 (38%) with persistent type IA endoleaks on the first postprocedural CT scan. The median number of EndoAnchors with good penetration was significantly greater in the cohort without endoleaks, 4 (interquartile range, 3-5) vs 3 (interquartile range, 1.5-4), respectively ( $P = .002$ ). A multivariate model for EndoAnchor penetration identified use of a Medtronic Endurant endograft as a factor associated with good penetration ( $P = .001$ ), whereas poor penetration was associated with a larger aortic neck diameter 10 mm distal to the lowest renal artery ( $P < .001$ ) and greater proximal neck calcium thickness ( $P = .004$ ). EndoAnchor penetration was the only variable that attained significance ( $P < .001$ ) in the multivariate model for successful treatment of a type IA endoleak.

**Conclusions:** Adequate EndoAnchor penetration into the aortic wall is less likely when the aortic neck diameter is large or when the neck contains significant mural calcium. No penetration of the EndoAnchor was the only factor predictive of postprocedural type IA endoleak. This study stresses the importance of careful selection of patients based on preoperative assessment of the infrarenal neck on CT angiography and emphasizes careful deployment of EndoAnchors into the aortic wall to improve successful treatment of type IA endoleaks. (*J Vasc Surg* 2018;68:1007-16.)

**Keywords:** EndoAnchor; Endovascular aneurysm repair; Abdominal aortic aneurysm; Type IA endoleak; Aneurysm neck

Despite advances in endograft technology, complications such as endoleaks and migration still occur in the long term after endovascular aneurysm repair (EVAR). Challenging proximal aortic neck anatomy leads to insufficient sealing or fixation and strongly influences the occurrence of neck-related complications, such as type IA endoleak and endograft migration.<sup>1-3</sup>

The Heli-FX EndoAnchor System (Medtronic Vascular, Santa Rosa, Calif) was developed to increase migration resistance and to improve sealing of endografts in the aortic neck. Experimental studies demonstrated that EndoAnchors can significantly improve proximal fixation and sealing by securing the proximal endograft to the aortic wall.<sup>4,5</sup> By circumferentially deploying the helically

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shaped EndoAnchors through the endograft fabric into the aortic wall, the strength of a surgical hand-sewn anastomosis is approximated.<sup>6,7</sup> However, this strength may be achieved only by evenly divided EndoAnchors over the circumference of the aortic wall and is dependent on the successful deployment and penetration of each individual EndoAnchor.<sup>4,5,7,8</sup> To be successfully deployed, the EndoAnchor should penetrate at least 2 mm into the aortic wall.<sup>6,9,10</sup>

Previous clinical studies validated the preclinical findings, with good results with the use of EndoAnchors<sup>11-13</sup> that were employed to optimize proximal fixation and sealing as well as in the therapeutic setting<sup>6,14-18</sup> to treat migration and type IA endoleaks evident at the time of the initial endograft deployment or during follow-up. Jordan et al<sup>11</sup> reviewed failures in their study and observed that not all EndoAnchors penetrated the aortic wall, resulting in type IA endoleaks. In sum, the preclinical and clinical data support the importance of sufficient penetration of each EndoAnchor. To date, no study has directly assessed the relationship of aortic neck characteristics with EndoAnchor penetration and outcome, the main subject of this analysis.

## METHODS

### Selection of patients

Patients from the Aneurysm Treatment Using the Heli-FX Aortic Securement System Global Registry (ANCHOR; NCT01534819) were included in this analysis. Informed consent was obtained of every patient, and the study was conducted according to the Declaration of Helsinki. The inclusion criteria were an indication for use of EndoAnchors to treat type IA endoleak and an available postprocedure contrast-enhanced computed tomography (CT) scan of sufficient quality. Hence, patients with CT artifacts due to metal or glue, for example, in patients treated for type II endoleaks, or CT slice thicknesses >3 mm were excluded because proper analysis of the implanted EndoAnchors was not possible.

Patients from both the primary and revision arms were included. The primary arm had EndoAnchors deployed for treatment of an intraoperative type IA endoleak observed at the initial implantation of the endograft. Patients in the revision arm had previously undergone an EVAR procedure and received EndoAnchors as a secondary procedure to treat a type IA endoleak.<sup>18</sup>

ANCHOR patients undergoing implantation of adjunct aortic extension cuffs or giant stents during the EndoAnchor implantation procedure were excluded from the current analysis. The reasons for this are multiple. First, EndoAnchors are not intended to fixate two graft components together, without the intention of penetrating the aortic wall.<sup>7</sup> The sequence of deploying additional materials (eg, cuffs, stents, or EndoAnchors) was unknown. Furthermore, deployment of these

## ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of prospectively collected data of the Aneurysm Treatment Using the Heli-FX Aortic Securement System Global Registry (ANCHOR) of 86 patients treated for type IA endoleaks
- **Take Home Message:** In 53 (62%) patients where the type IA endoleak was resolved, a significantly greater percentage of good penetrating EndoAnchors was observed. Poor EndoAnchor penetration was associated with a greater risk of type IA endoleaks and was seen with wide infrarenal necks and great calcium thickness.
- **Recommendation:** This study suggests that EndoAnchors should be used with caution in large infrarenal aortic necks and in those with great calcium thickness.

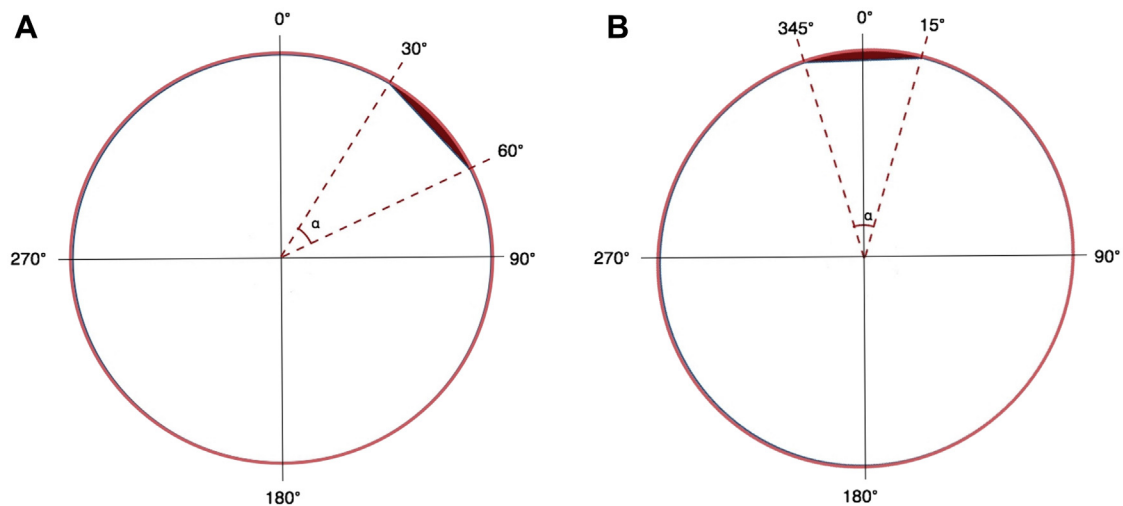
devices can result in artifacts that challenge assessment of EndoAnchor penetration.

The study cohort was divided into patients without and with persistent type IA endoleak at the first postoperative CT scan after implantation of EndoAnchors (ie, no-endoleak group vs type IA endoleak group). Procedural success was defined as the absence of a type IA endoleak on the first post-EVAR CT scan in the primary arm and first CT scan after the EndoAnchor secondary procedure in the revision arm.

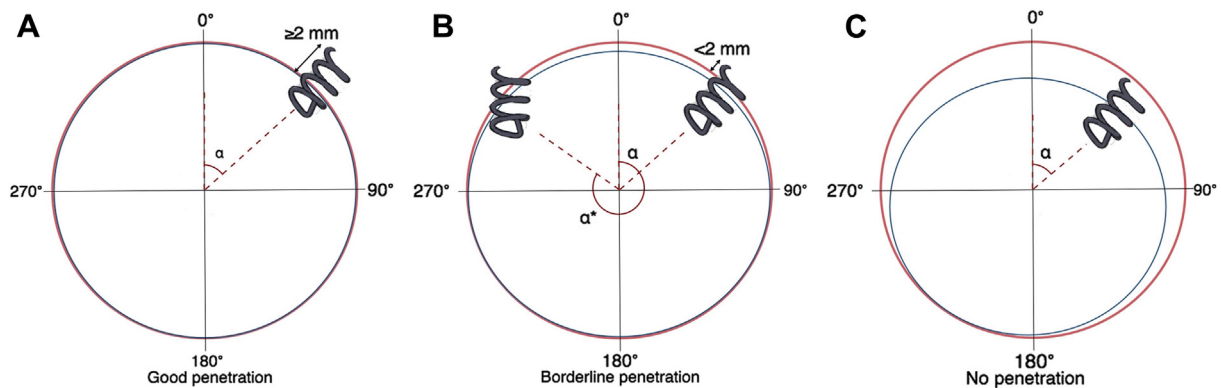
### Imaging studies and measurement protocol

Aortic neck morphology on the preprocedure and postprocedure contrast-enhanced CT scans was obtained from an electronic data capture system, as measured by an independent core laboratory (Syntactx, New York, NY). Anatomic characteristics have been described in previous publications and included aortic neck diameter and length, infrarenal and suprarenal angulation, maximum aneurysm diameter, and aortic neck calcium and thrombus.<sup>8,18,19</sup> The median time between the procedure and first postprocedure CT imaging was 36 days (25-47 days). The median slice thickness of postprocedure CT scans was 2 mm (range, 0.6-3 mm).

**Endoleak analysis.** The CT images were loaded into a 3mensio vascular workstation V7.2 (Pie Medical Imaging BV, Maastricht, The Netherlands) for analysis. First, a center lumen line (CLL) was semiautomatically drawn from the celiac trunk to the aortic bifurcation. If necessary, the CLL was adjusted manually. The measurements were performed on orthogonal images perpendicular to the CLL. The locations of the orifices of the renal arteries, aortic bifurcation, and endograft markers were identified. A type IA endoleak was expressed as the clock face range and width (degrees) as well as the distance (millimeters) from the lowest renal artery (Fig 1). The endoleaks of all patients were normalized such that the



**Fig 1.** Example of the analysis and normalization of endoleaks. **A**, The endoleak in this example has a range of 30 to 60 degrees and width ( $\alpha$ ) of 30 degrees as measured on the orthogonal image perpendicular to the center lumen line (CLL). **B**, The normalized endoleak shows the middle of the endoleak at 0 degrees.



**Fig 2.** Schematic depiction of the three EndoAnchor penetration possibilities;  $\alpha$  represents the clockwise location of the EndoAnchor, and 0 degrees is anterior on the orthogonal image. **A**, Optimal EndoAnchor placement of at least 2 mm through the endograft (blue circle) and the aortic wall (red circle). **B**, The EndoAnchor penetrates the aortic wall  $<2$  mm or there is a gap between the endograft and the aortic wall. **C**, The EndoAnchor does not penetrate the aortic wall.

center of each endoleak was translated to 0 degrees. This normalization allowed the comparison between the preprocedure and postprocedure endoleaks of patients from the revision arm. In addition, the normalization enabled comparison of all EndoAnchors with respect to the center of the endoleak.

**EndoAnchor analyses.** EndoAnchor analyses were performed on the first postoperative CT scan after EndoAnchor deployment. The location of the EndoAnchors was reported as clock face orientation (degrees) on the orthogonal view. The distance from the top of the endograft fabric to the middle of the EndoAnchor (millimeters) and the distance from the inferior border of the lowest renal artery to the middle of the EndoAnchor (millimeters) were measured on the reconstructed stretched vessel view. Based on the EndoAnchor dimensions, the penetration of each EndoAnchor was defined as good

penetration when the EndoAnchor penetrated  $\geq 2$  mm into the aortic wall, borderline penetration when the EndoAnchor penetration was  $< 2$  mm or when a gap remained between the endograft and the aortic wall, or no penetration when the EndoAnchor did not penetrate the aortic wall (Fig 2). The stretched vessel view was used to verify the penetration of the EndoAnchors. Two experienced observers (S.R.G. and K.N.) independently performed the classification of EndoAnchor penetration. In case of interobserver discrepancy, a third reviewer's (J.-P.P.M.V.) measurement was used as a tiebreaker.

### Statistical analysis

Statistical analyses were performed with SPSS 24 software (IBM Corp, Armonk, NY) and SAS software (version 9.4; SAS Institute, Cary, NC). Normal distributions were

**Table I.** Baseline anatomic characteristics of the type IA endoleak and no-endoleak groups

Variable <sup>a</sup>	Type IA endoleak group (n = 28)	No-endoleak group (n = 52)	P value
Endograft size, mm	28 (26-30.8)	28 (25-32)	.839
Oversizing, %	4.8 (-2.6 to 18.2)	13.9 (-1.8 to 23)	.101
Suprarenal aortic diameter, mm	26.6 (25.5-29.5)	26 (23.4-28.4)	.153
Aortic diameter at lowest renal, mm	26.6 (24.5-28.9)	26 (23.0-28.4)	.188
Aortic diameter 5 mm below lowest renal, mm	27.6 (25.8-31.3)	26.0 (22.7-29.8)	.053
Aortic diameter 10 mm below lowest renal, mm	30.1 (26.8-33.8)	26.7 (24.1-32.1)	.020
Proximal neck length, mm	9.6 (7.0-16.8)	15.1 (8.7-27.0)	.039
Neck tortuosity index	1.1 (1.0-1.1)	1.1 (1.0-1.1)	.408
Maximum sac diameter, mm	60.1 (52.1-74.6)	59.1 (53.7-69.3)	.610
Suprarenal angulation, degrees	11.5 (4.3-21.3)	16 (10-23)	.080
Infrarenal angulation, degrees	18.5 (12.3-34.8)	20 (11.5-29)	.920
Infrarenal angulation to bifurcation, degrees	37.5 (23.3-43.8)	37.5 (27.3-47)	.565
Neck thrombus average thickness, mm	0 (0-0)	0 (0-1)	.392
Neck thrombus circumference, mm	0 (0-0)	0 (0-49.3)	.312
Neck calcium average thickness, mm	0 (0-2)	0 (0-1.8)	.821
Neck calcium circumference, mm	0 (0-40.0)	0 (0-18.4)	.693

<sup>a</sup>Denominators are smaller than the group size because of missing values. Data are represented as median (interquartile range).

not assumed, and variables were expressed as median and interquartile range (IQR). Differences in continuous variables were assessed with the Mann-Whitney *U* test, and categorical variables were evaluated with the Fisher exact test. The weighted  $\kappa$  statistic was used to determine the interobserver agreement of the scoring of the EndoAnchors. Binary logistic regression was performed to identify independent predictors of both the EndoAnchor penetration and procedural success. Two regression models were tested; the first model was performed for each EndoAnchor to identify predictors of EndoAnchor penetration. The second model was applied on a per patient basis to identify predictors of procedural success. Anatomic variables were included if  $P < .2$ . A stepwise process was used, removing variables until the significance of all variables was  $< .1$ .  $P$  values were considered significant when the two-tailed  $\alpha$  was  $< .05$ .

## RESULTS

The study cohort consisted of 86 patients with an indication for EndoAnchors to treat type IA endoleaks (81.4% male); among these, 61 patients (71%) were treated with EndoAnchors at the time of the initial endograft procedure (primary arm) and 25 (29%) were treated with EndoAnchors as a secondary procedure for proximal neck complications (revision arm). Of the 86 included patients, 53 patients had no endoleak after EndoAnchor treatment, whereas a type IA endoleak persisted in the remaining 33 patients. The median preoperative type IA endoleak width of the 25 patients in the revision arm was 113 degrees (IQR, 98-143 degrees), which decreased to 60 degrees (IQR, 0-120 degrees) after

EndoAnchor treatment. Of these 25 patients, 16 had a persistent type IA endoleak. The median preoperative endoleak width of these 16 patients compared with the 9 patients with procedural success was 113 degrees (IQR, 80-145 degrees) vs 113 degrees (IQR, 112-142 degrees), which was not significantly different ( $P = .329$ ).

The baseline maximum aneurysm sac diameter was not significantly different between the persistent type IA endoleak and no-endoleak groups ( $P = .610$ ). Aortic diameter 10 mm below the lowest renal artery was significantly greater in the persistent type IA endoleak group ( $P = .020$ ), and the aortic neck length was significantly shorter ( $P = .039$ ). There was no significant difference in the amount of neck thrombus ( $P = .392$ ) or calcium ( $P = .821$ ) between the two groups. The baseline anatomic characteristics are reported in Table I. The endograft size ( $P = .839$ ) and oversizing ( $P = .101$ ) were not significantly different between the two groups. The types of endografts for both cohorts are displayed in Table II. Because of the small number per type of stent graft, subgroup analyses were not performed and  $P$  values were not calculated.

### Evaluation of EndoAnchor penetration

A total of 580 EndoAnchors were implanted, 333 EndoAnchors (median, 6 [IQR, 4-8] per patient) in 53 patients in the no-endoleak group and 247 EndoAnchors (median, 8 [IQR, 4-10] per patient) in 33 patients in the persistent type IA endoleak group. The two reviewers were in agreement on deployment success in 412 (71%) of the 580 EndoAnchors, accounting for a good strength of agreement with a weighted  $\kappa$  of 0.628 (95% confidence interval, 0.576-0.679;  $P < .001$ ; Table III). The

**Table II.** Types of endografts

Variable	Type IA endoleak group (n = 33)	No-endoleak group (n = 53)	Total
Endograft type			
Cook Zenith	8 (24.2)	4 (7.4)	12 (14)
Cook Zenith LP	0	1 (1.9)	1 (1.2)
Cordis Incraft	1 (3)	0	1 (1.2)
Gore Excluder	12 (36.4)	19 (35.8)	31 (36.0)
JOTEC E-vita	1 (3)	0	1 (1.2)
Medtronic AneuRx	0	2 (3.8)	2 (2.3)
Medtronic Endurant	8 (24.2)	26 (49.1)	34 (39.5)
Medtronic Talent	2 (6.1)	0	2 (2.3)
Other	1 (3)	1 (1.9)	2 (2.3)

Data are represented as number (%). Percentages are per column.

median number of EndoAnchors with good penetration was larger in the no-endoleak group, numbering four (IQR, three to five) vs three (IQR, two to four;  $P = .002$ ), whereas the median number of borderline and nonpenetrating EndoAnchors was significantly lower in the no-endoleak group (Table IV). Seven of the 172 nonpenetrating EndoAnchors were errantly deployed proximal to the margin of the endograft fabric. One of these seven EndoAnchors was fractured during the intervention but remained within the aortic wall and was not removed. The aortic diameter at the lowest renal artery exceeded the graft diameter in 24 patients. The median number of good and nonpenetrating EndoAnchors was significantly different between the type IA endoleak group and no-endoleak group (Table V).

**Multivariate analysis**

**Predictors of EndoAnchor penetration.** The binary logistic regression identified 15 candidate variables for inclusion in the multivariate analysis of the EndoAnchor penetration (Table VI). The stepwise process yielded three variables that were significant predictors for successful EndoAnchor penetration. The use of a Medtronic Endurant stent graft ( $P = .001$ ) was associated with better EndoAnchor penetration, whereas the aortic diameter 10 mm below the lowest renal ( $P < .001$ ) and average thickness of mural neck calcium ( $P = .004$ ) were risk factors for poor EndoAnchor penetration. Thus, the multivariate analysis showed that every millimeter increase in diameter at the aortic diameter 10 mm below the lowest renal artery decreased the odds of good EndoAnchor penetration by 11.6%.

**Predictors of procedural success.** The binary logistic regression identified 16 candidate variables to be included in the multivariate analysis of procedural success (Table VII). Borderline and nonpenetrating EndoAnchors were significant independent risk factors for a persistent type IA endoleak. The risk of a type IA endoleak increased 76.7% and 68.4%, respectively, for

every borderline and nonpenetrating EndoAnchor. Patients with a larger number of nonpenetrating EndoAnchors were associated with a greater risk of persistent type IA endoleak ( $P < .001$ ).

**DISCUSSION**

This study describes a classification scheme for aortic wall penetration of EndoAnchors. Significant differences in EndoAnchor penetration were found in patients with and without persistent type IA endoleak. Multivariate analysis identified three significant predictors of EndoAnchor penetration: a Medtronic Endurant stent graft ( $P = .001$ , protective), the aortic diameter 10 mm below the lowest renal artery ( $P < .001$ , risk factor), and the average thickness of mural neck calcium ( $P = .004$ , risk factor). In multivariate analysis to identify predictors of type IA endoleak, the number of nonpenetrating EndoAnchors was the only significant risk factor for type IA endoleak ( $P < .001$ ).

The median aortic diameter 10 mm below the lowest renal artery was 30 mm in the cohort with persistent endoleaks. Moreover, the median oversizing of the endografts in this group was only 4.8% of a recommended 15%. The aortic neck diameter at the lowest renal artery exceeded the endograft diameter in 11 patients from this group. This kind of undersizing of an endograft can never be overcome by the use of EndoAnchors as the maximum diameter of the endograft cannot be increased. The combination of a large aortic diameter 10 mm below the lowest renal artery and low percentage of oversizing may lead to undersized endografts with a gap between the endograft and the aortic wall, precluding good EndoAnchor penetration in this group. In addition, the median distance from the lowest renal artery to where the EndoAnchors were deployed was slightly greater in the type IA endoleak group (9 mm [6-13 mm] vs 8 mm [4-13 mm];  $P = .006$ ). This distance corresponds to the usual level of EndoAnchor deployment reported by Tassiopoulos et al.<sup>8</sup> This difference in distance between groups is small, and it may be difficult to make this distinction during the intervention. EndoAnchors should be deployed close to the proximal margin of the fabric of the endograft (<10 mm) to maximize the chance of adequate aortic wall penetration.

In this study, the failure rate exceeds that observed in the overall ANCHOR study cohort.<sup>18</sup> This higher rate of failure reflects the selection of a subset of revision patients that systematically excluded patients with deployment of aortic extension cuffs, giant bare-metal stents, and other adjunctive procedures, including embolizations. The use of EndoAnchors is mainly to stabilize the neck and to enhance sealing. The use of extension cuffs is indicated to extend the sealing zone in the neck (for instance, in case of migration). Combinations of both extension cuffs and EndoAnchors are useful in patients with migrated endografts in combination

**Table III.** The interobserver agreement shows an exact agreement in 71% of all the evaluated EndoAnchors

	EndoAnchors, No.	Observer 2			Total
		Good penetration	Borderline penetration	No penetration	
Observer 1	Good penetration	281	78	11	370
	Borderline penetration	18	26	14	58
	No penetration	7	40	105	152
Total		306	144	130	580

**Table IV.** EndoAnchor characteristics of the type IA endoleak and no-endoleak groups

Variable <sup>a</sup>	Type IA endoleak group		No-endoleak group		Total	P value
EndoAnchors, No.	247 (42.6)	8 (4-10)	333 (57.4)	6 (4-8)	580 (100)	.060
Good penetration	98 (39.7)	3 (2-4)	235 (70.6)	4 (3-5)	333 (57.4)	.002
Borderline penetration	43 (17.4)	1 (0-2)	32 (9.6)	0 (0-1)	75 (12.9)	.003
No penetration	106 (42.9)	3 (1-5)	66 (19.8)	1 (0-2)	172 (29.7)	<.001
Distance from LRA, mm		9 (6-13)		8 (4-13)		.006
Fabric distance, mm <sup>b</sup>		7.5 (4.5-11.8) <sup>b</sup>		7.3 (4.3-10.3) <sup>b</sup>		.118
Clock face location, degrees		158 (90-278)		188 (98-285)		.273

LRA, Lowest renal artery.  
<sup>a</sup>Data are represented as number (%) and median (interquartile range).  
<sup>b</sup>Seven EndoAnchors were deployed above the fabric, four in the persistent type IA endoleak group and three in the no-endoleak group.

**Table V.** EndoAnchor characteristics for patients in whom the aortic neck diameter at the lowest renal artery (LRA) exceeded the stent graft diameter

Variable <sup>a</sup>	Type Ia endoleak group (n = 11)		No endoleak group (n = 13)		Total (N = 24)	P value
EndoAnchors, No.	91 (47)	8 (8-10)	103 (53)	8 (7-10)	194 (100)	.680
Good penetration	33 (36)	2 (1-5)	59 (57)	4 (2-6)	92 (47)	<.001
Borderline penetration	14 (15)	1 (1-2)	16 (16)	1 (0-2)	30 (15)	.564
No penetration	44 (48)	3 (2-7)	28 (27)	2 (1-3)	72 (37)	<.001
Distance from LRA, mm		10 (5-13)		8 (2-14)		.085
Fabric distance, mm		9 (4.4-16.1) <sup>b</sup>		9.3 (5.5-14.1)		.696
Clock face location, degrees		165 (94-267)		203 (135-285)		.037

<sup>a</sup>Data are represented as number (%) and median (interquartile range).  
<sup>b</sup>Three EndoAnchors were located above the fabric.

with type IA endoleaks and may be important in revision patients with challenging aortic neck features. In daily practice, adjunct procedures, such as extension cuffs and even chimney or fenestrated cuffs, will be used if the aortic neck has to be extended for additional seal length. EndoAnchors can stabilize the neck but not extend the neck. The use of EndoAnchors as primary treatment of type IA endoleaks is indicated in patients in whom the endograft fabric is just below the renal artery and no extension is possible with standard cuffs. If the EndoAnchors are not successful in overcoming the type IA endoleak, chimney or fenestrated cuffs are the next option (besides explantation of the endograft). In case of a type IA endoleak due to migration of a primary endograft, the EndoAnchors are helpful in fixation of this endograft to the remaining aortic wall to

prevent persistent migration. After the implantation of EndoAnchors, an extension cuff can be deployed to extend the seal (whether infrarenal or juxtarenal). However, adjunctive tools could have influenced the procedural success and may otherwise have affected the multivariable model. In addition, adjunctive devices cause too much scattering to enable careful determination of EndoAnchor penetration, and therefore these cases were excluded in the current analysis.

In the type IA endoleak group, 17% of the implanted EndoAnchors had borderline penetration and 43% did not penetrate the aortic wall whatsoever. The difference in odds ratios between the borderline and nonpenetrating EndoAnchors was small, suggesting that full EndoAnchor penetration is necessary for remediation of type IA endoleaks. Our findings corroborate those of other studies that

**Table VI.** Binary logistic regression and multivariate analysis of the EndoAnchor penetration

Predictors of successful EndoAnchor penetration (binary)	Coefficient	SE	OR <sup>a</sup>	P value
Univariate logistic regressions				
EndoAnchor				
Distance from lowest renal artery, mm	0.00586	0.00929	1.006	.528
Clock face location, degrees	0.000053	0.000840	1.000	.949
Type of endograft				
Cook Zenith	-0.2467	0.3019	0.982	.414
Cook Zenith LP	-1.2092	1.0268	0.375	.239
Cordis Incraft	-0.3337	0.6936	0.900	.630
Gore Excluder	0.4086	0.2633	1.891	.121
JOTEC E-vita	-1.2092	0.7446	0.375	.104
Medtronic AneuRx	1.8816	0.7260	8.248	.010 <sup>b</sup>
Medtronic Endurant	1.0934	0.2703	3.750	<.001 <sup>b</sup>
Medtronic Talent	-1.0268	0.6333	0.450	.105
Other	0.8703	1.1200	3.000	.437
Endograft size, mm	-0.0113	0.0217	0.989	.601
Oversizing, %	2.4983	0.5162	12.162	<.001 <sup>b</sup>
Suprarenal aortic diameter, mm	-0.0948	0.0235	0.910	<.001 <sup>b</sup>
Aortic diameter at lowest renal, mm	-0.1226	0.0220	0.885	<.001 <sup>b</sup>
Aortic diameter 5 mm below lowest renal, mm	-0.1111	0.0192	0.895	<.001 <sup>b</sup>
Aortic diameter 10 mm below lowest renal, mm	-0.1193	0.0208	0.888	<.001 <sup>b</sup>
Proximal neck length, mm	0.00970	0.00777	1.010	.212
Neck tortuosity index	5.0233	2.2391	151.915	.025 <sup>b</sup>
Maximum sac diameter, mm	-0.00020	0.00547	1.000	.970
Suprarenal angulation, degrees	0.00413	0.0108	1.004	.703
Infrarenal angulation, degrees	0.00250	0.00595	1.003	.675
Infrarenal angulation to bifurcation, degrees	0.00385	0.00575	1.004	.503
Neck thrombus average thickness, mm	-0.7096	0.1573	0.492	<.001 <sup>b</sup>
Neck thrombus circumference, mm	-0.0134	0.00293	0.987	<.001 <sup>b</sup>
Neck calcium average thickness, mm	-0.5701	0.1483	0.565	<.001 <sup>b</sup>
Neck calcium circumference, mm	-0.0205	0.00543	0.980	<.001 <sup>b</sup>
Multivariate logistic regressions with stepwise method				
Type of endograft				
Cook Zenith	-0.3137	0.3220	1.027	.330
Cook Zenith LP	-1.4788	1.0192	0.320	.147
Cordis Incraft	-0.6146	0.6937	0.761	.376
Gore Excluder	0.00367	0.2813	1.411	.990
Medtronic AneuRx	1.3802	0.7292	5.590	.058
Medtronic Endurant	0.9739	0.2953	3.724	.001 <sup>b</sup>
Medtronic Talent	0.6317	0.8103	2.645	.436
Other	-0.2415	1.1208	1.104	.829
Aortic diameter 10 mm below lowest renal, mm	-0.1123	0.0252	0.894	<.001 <sup>b</sup>
Neck thrombus average thickness, mm	-0.4301	0.2477	0.650	.083
Neck calcium average thickness, mm	-0.5756	0.2001	0.562	.004 <sup>b</sup>

OR, Odds ratio; SE, standard error.

Multivariate predictors were chosen by stepwise procedure using an entry criterion of .2 with a stay criterion of .1.

<sup>a</sup>Indicates the increased odds for good EndoAnchor penetration per unit increase in the covariate. Every increased millimeter of neck thrombus average thickness decreases the odds of good EndoAnchor penetration by 50.8%, whereas every millimeter increase in neck thrombus circumference decreases the odds of good EndoAnchor penetration by 1.3%.

<sup>b</sup>Significant P value.

**Table VII.** Binary logistic regression and multivariate analysis of procedural success

Predictors of endoleak (binary)	Coefficient	SE	OR <sup>a</sup>	P value
Univariate logistic regressions				
Type of endograft				
Cook Zenith	-0.5524	189.2	>999.999	.998
Cook Zenith LP	-14.5270	710.5	1	.984
Cordis Incraft	12.0656	720.4	>999.999	.987
Gore Excluder	-1.7050	189.2	>999.999	.993
JOTEC E-vita	12.0656	720.4	>999.999	.987
Medtronic AneuRx	-14.5270	519.9	1	.978
Medtronic Endurant	-2.4242	189.2	>999.999	.990
Medtronic Talent	12.0656	526.6	>999.999	.982
Other	12.0656	720.4	>999.999	.987
Oversizing, %	-1.4216	1.2926	0.241	.271
Suprarenal aortic diameter, mm	0.0889	0.0612	1.093	.147
Aortic diameter at lowest renal, mm	0.0790	0.0534	1.082	.139
Anatomic neck length (10% threshold), mm	0.0718	0.0486	1.074	.139
Aortic diameter 5 mm below lowest renal, mm	0.1030	0.0478	1.108	.031 <sup>b</sup>
Aortic diameter 10 mm below lowest renal, mm	0.0838	0.0502	1.087	.095
Proximal neck length, mm	-0.0496	0.0247	0.952	.045 <sup>b</sup>
Visual neck length, mm	-0.0279	0.0192	0.972	.146
Neck tortuosity index	0.1732	5.0333	1.189	.973
Maximum sac diameter, mm	0.0157	0.0151	1.016	.298
Suprarenal angulation, degrees	-0.00414	0.0276	0.996	.881
Infrarenal angulation, degrees	0.0137	0.0151	1.014	.366
Infrarenal angulation to bifurcation, degrees	0.00316	0.0144	1.003	.827
Neck thrombus average thickness, mm	0.5525	0.3445	1.738	.109
Neck thrombus circumference, mm	0.00737	0.00583	1.007	.206
Neck calcium average thickness, mm	0.5434	0.3658	1.722	.137
Neck calcium circumference, mm	0.0109	0.0133	1.011	.412
No. of EndoAnchors	0.1920	0.0920	1.212	.037 <sup>b</sup>
Good penetration, No.	-0.3440	0.1225	0.709	.005 <sup>b</sup>
Borderline penetration, No.	0.5695	0.2241	1.767	.011 <sup>b</sup>
No penetration, No.	0.5214	0.1398	1.684	<.001 <sup>b</sup>
Good penetration, %	-3.5078	0.9018	0.030	<.001 <sup>b</sup>
Borderline penetration, %	2.6326	1.4883	13.909	.077
No penetration, %	3.3944	0.9859	29.798	<.001 <sup>b</sup>
Multivariate logistic regressions with stepwise method				
No penetration, No.	0.5386	0.1508	1.714	<.001 <sup>b</sup>

OR, Odds ratio; SE, standard error.  
 Multivariate predictors were chosen by stepwise procedure using an entry criterion of .2 with a stay criterion of .1.  
<sup>a</sup>Indicates the increase in risk for type IA endoleak per unit increase in the covariate. Every millimeter increase in proximal neck length decreases the risk by 4.8%, whereas every millimeter increase in aortic diameter 5 mm below the lowest renal artery increases the risk by 10.8%.  
<sup>b</sup>Significant P value.

identify the necessity of  $\geq 2$ -mm EndoAnchor penetration depth to achieve sealing.<sup>6,9,10</sup> Ours is the first study, however, to objectively demonstrate EndoAnchor penetration as an independent predictor for successful treatment of type IA endoleak.

The observation that borderline penetrating EndoAnchors, like nonpenetrating EndoAnchors, are ineffective lies in the fact that full apposition of the endograft to the aortic

wall is necessary. Subsequent attempts to appose the endograft circumferentially to the aortic wall (for instance, with a giant bare-metal stent) will fail because a portion of the EndoAnchor lies between endograft and aortic wall, providing persistent channels (gutters) for flow into the sac.

It is axiomatic that a longer proximal neck length is associated with a decreased risk for type IA



endoleaks.<sup>18-21</sup> Greater endograft oversizing was associated with better penetration of the EndoAnchors in this study. An undersized endograft or tilting of the endograft can cause a gap between the endograft and the aortic wall,<sup>7,22</sup> which is one of the contraindications to use of the EndoAnchors because of their limited length. Our results corroborate those of earlier studies that have reported the importance of thrombus and calcium for the placement of EndoAnchors.<sup>10,12,15,18,23-26</sup> In addition, the thickness and circumference of the neck thrombus and calcium are each independent risk factors for poor EndoAnchor penetration. Importantly, of these four variables, the thickness of neck calcium remains significant in the multivariate analysis, that is, there is a 44% risk of the EndoAnchor not penetrating the aortic wall for every millimeter of increased thickness of the neck calcium. Thus, to prevent maldeployment of EndoAnchors, severe thrombus and calcium should be avoided. Furthermore, implantation is contraindicated when one must overcome >2-mm gaps in undersized endografts or gaps due to dilation of the neck after EVAR.<sup>1,4,10,11,23</sup> Failure of EndoAnchor penetration will most of the time be a combination of factors causing a >2-mm gap between the endograft and aortic wall (eg, thrombus, calcium, undersized graft), and therefore a single predictor of failure of EndoAnchor penetration cannot be identified from the current analysis.

The intraoperative fluoroscopy does not visualize the aortic wall. Therefore, preoperative assessment of the infrarenal neck with CT angiography is crucial for successful EndoAnchor deployment.<sup>7,10,26</sup> Preoperatively, the proximal neck should be accurately assessed especially for the presence of thrombus, calcium, and the approximated seal length. The clock face positions where the EndoAnchors should not be deployed (in calcium and thrombus) can be calculated. Based on these calculations, it can be determined which C-arm angles should be avoided to optimize the chance of good penetration of the EndoAnchors, taking into account that the tip of the endoguide should be perpendicular to the C-arm. Moreover, it is of utmost importance to deploy the EndoAnchors in the sealing part of the main body and not below.

During EndoAnchor deployment, the physician has to rely on haptic feedback of the pressure of the tip of the Heli-FX applier/EndoAnchor against the endograft (and aortic wall) and ensure that the endoguide gets its stability from the opposite wall. At fluoroscopy, the endograft will bulge as a result of pushing the tip of the Heli-FX applier against the endograft (and thus against the aortic wall). A useful adjunct to visualize penetration of EndoAnchors in the aortic wall is the use of intravascular ultrasound. Technical details during EndoAnchor implantation might improve proper deployment with adequate wall penetration. The C-arm should be positioned such that the possible presence of localized

thrombus or calcified plaque can be visualized.<sup>10</sup> This optimal C-arm positioning is also of importance for the correct positioning of the tip of the guide (90 degrees to the fabric of the endograft).<sup>7,10,21,27</sup> In addition, a sufficiently large tip size of the Heli-FX guide of the EndoAnchor system should be selected.<sup>7,10</sup> The guide needs the support of the contralateral wall to deploy the EndoAnchor. A larger aortic diameter can result in less stability of the guide, which increases the risk of maldeployment of the EndoAnchors because of failing of the tip of the guide. Thoracic guides can be used during EVAR to deploy EndoAnchors in wider necks because they have a greater reach than the maximum 28 mm of the abdominal guides. As stated before, EndoAnchors should be deployed in a zone close to the proximal edge of the fabric to increase the chance of penetrating the aortic wall.

**Limitations.** The assessment of EndoAnchor penetration can be challenging even in high-quality CT scans. Beam hardening artifacts of the EndoAnchors can make it difficult to distinguish each individual EndoAnchor when they were implanted close together. Nevertheless, the absolute agreement between the two observers on the scoring of EndoAnchors was 71%.

A limitation to this study is the relatively small number of patients due to exclusion of those with adjuvant procedures at the EndoAnchor implantation procedure. Because of this, the number of patients per type of endograft was small, no subgroup analyses were performed, and no *P* values were calculated. The Medtronic Endurant endograft was used more in the no-endoleak group and also for primary treatment (primary arm, *n* = 29; revision arm, *n* = 5). It is not clear why this endograft was a predictor of good penetration. EndoAnchor penetration may be affected by stent graft fabric density and strut density (where strut density is higher in the Cook Zenith endograft), but this was not further investigated in this manuscript because of small subgroups. In addition, this study focused on outcome at the first postoperative CT scan, and no conclusions can be drawn about longer term success. Last, this study did not investigate correlations between EndoAnchor penetration and hospital procedure volume or learning curves.

## CONCLUSIONS

Adequate EndoAnchor penetration into the aortic wall is less likely when the aortic neck diameter is large or when the neck contains significant mural calcium. No penetration of the EndoAnchor was the only factor predictive of postprocedural type IA endoleak. This study stresses the importance of careful selection of patients based on preoperative assessment of the infrarenal neck on CT angiography and emphasizes careful deployment of EndoAnchors into the aortic wall to improve successful treatment of type IA endoleaks.

**AUTHOR CONTRIBUTIONS**

Conception and design: SG, KN, KO, CS, JV  
 Analysis and interpretation: SG, KN, KO, WJ, JP, CS, JV  
 Data collection: SG, KN  
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 Critical revision of the article: SG, KN, KO, WJ, JP, CS, JV  
 Final approval of the article: SG, KN, KO, WJ, JP, CS, JV  
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