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Mid-Term Results of EVAR in Severe Proximal Aneurysm Neck Angulation

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WHAT THIS PAPER ADDS

Proximal neck angulation is a risk factor for adverse events following endovascular aneurysm repair (EVAR). The first study to assess mid-term outcomes and morphology changes in the proximal neck in patients with severely angulated proximal neck treated with a late-generation endograft is presented. This study shows that clinical outcome following EVAR in patients with severe proximal neck angulation is not significantly different from those patients with more favorable proximal anatomy.

Objective: To determine if mid-term outcome following endovascular aneurysm repair (EVAR) with the Endurant Stent Graft (Medtronic, Santa Rosa, CA, USA) is influenced by severe proximal neck angulation.

Methods: A retrospective case–control study was performed using data from a prospective multicenter database. All measurements were obtained using dedicated reconstruction software and center-lumen line reconstruction. Patients with neck length >15 mm, infrarenal angle (β) >75°, and/or suprarenal angle (α) >60°, or neck length >10 mm with β >60°, and/or α >45° were compared with a matched control group. Primary endpoint was primary clinical success. Secondary endpoints were freedom from rupture, type 1A endoleak, stent fractures, freedom from neck-related reinterventions, and aneurysm-related adverse events. Morphological neck variation over time was also assessed.

Results: Forty-five patients were included in the study group and were compared with a matched control group with 65 patients. Median follow-up time was 49.5 months (range 30.5–58.4). The 4-year primary clinical success estimates were 83% and 80% for the angulated and nonangulated groups ($p = .42$). Proximal neck angulation did not affect primary clinical success in a multivariate model (hazard ratio 1.56, 95% confidence interval 0.55–4.41). Groups did not differ significantly in regard to freedom from rupture ($p = .79$), freedom from type 1A endoleak ($p = .79$), freedom from neck-related adverse events ($p = .68$), and neck-related reinterventions ($p = .68$). Neck angle reduction was more pronounced in patients with severe proximal neck angulation (mean $\Delta\alpha$ −15.6°, mean $\Delta\beta$ −30.6°) than in the control group (mean $\Delta\alpha$ −0.39°, mean $\Delta\beta$ −5.9°) ($p < .001$).

Conclusion: Mid-term outcomes following EVAR with the Endurant Stent Graft were not influenced by severe proximal neck angulation in our population. Despite the conformability of the device, moderate aortic neck remodeling was identified in the group of patients with angulated neck anatomy on the first computed tomography scan after implantation with no important further remodeling afterwards. No device integrity failures were encountered.

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INTRODUCTION

Proximal neck anatomical features, such as angulation, have been associated with increased risks of aneurysm-related complications and have restricted suitability for endovascular aneurysm repair (EVAR).[1] Owing to an expected increase of risk following EVAR in the presence of very angulated necks, different thresholds of proximal neck angulation have been set by each manufacturer's instructions for use (IFUs), reflecting the different extent to which each endograft is expected to perform in these challenging anatomies.

The Endurant Stent Graft (Medtronic, Santa Rosa, CA, USA) is a late-generation endograft that has been

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specifically designed to treat more challenging anatomy by increasing conformability, proximal seal, and fixation, allowing the treatment of a broadened group of patients.[2] Some data suggest that these features are well suited for the treatment of severely angulated proximal anatomy,[3] but long-term data are lacking.

The hypothesis of this study is that severe proximal neck angulation has no influence on mid-term outcome after EVAR with the use of the Endurant Stent Graft System.

METHODS

One hundred and ten patients who were included in a previously published case—control study that reported on 30-day outcomes after EVAR with the Endurant Stent Graft in severely angulated proximal aneurysm necks were reviewed.[4] This study was based on a prospectively maintained database from three high-volume centers in the Netherlands (St. Antonius Hospital, Nieuwegein, University Medical Center, and Utrecht and Erasmus University Medical Center). This study complied with the principles of the Declaration of Helsinki. Informed consent was not required according to institutional policy on retrospective research.

Patient population

Study design and patient selection have been reported previously, in detail.[4] In summary, in the period 2008—09, 418 patients with abdominal aortic aneurysms (AAAs) were treated in the three centers. Of these, 271 patients electively received an Endurant Stent Graft for a degenerative AAA. Patients with mycotic aneurysms or prior aortic reconstructive surgery were excluded. The treatment decision and type of repair offered were individualized according to anatomical determinants, health status, and history of previous abdominal surgery (hostile abdomen). Patient preference was also taken into account before obtaining informed consent. All patients with severely angulated proximal anatomy selected for endovascular repair were treated consecutively solely with an endurant bifurcated endograft.

Angulation measurement has been reported previously.[4] Briefly, following three-dimensional image reconstruction, the aorta is turned 360° perpendicularly to the center lumen line (CLL) flexure, and then rotated along its longitudinal axis until the sharpest angle is found. The alpha angle is formed between the suprarenal aorta and the aneurysm neck, and the beta angle between the aneurysm neck and sac. Angulation inclusion criteria were defined according to the maximum proximal neck angulation described in Medtronics' IFUs for the Endurant Stent Graft.[5] Accordingly, patients were included in the angulated group if one of the following two combinations occurred: a neck length >15 mm with an infrarenal angle (β) >75°, and/or suprarenal angle (α) >60°, or neck length >10 mm with β >60° and/or α >45°. Forty-five (16.5%) of the patients electively receiving an Endurant Stent Graft were included in the angulated group and thus treated outside the device's IFUs. Twenty-three (51.1% of the angulated group) patients were included owing to β angulation, 14 (31.1%) owing to both α and β angulation, and eight (17.8%) owing solely to α angulation. A control group matched for baseline clinical characteristics of 65 patients was selected from the remaining elective infrarenal EVAR patients from the same hospitals in the same time period using the same Endurant endograft.[4]

Postoperative surveillance

Follow-up protocols consisted of a contrast-enhanced computerized tomography angiography (CTA) at 1 and 12 months, and annually thereafter. According to the treating physician's expectation, in selected patients with expected lower risk of complications or renal function impairment, CTA was replaced by colored-duplex ultrasound or by noncontrasted CT.

Data management

Baseline clinical, anatomic, and intraoperative data were acquired at the time of surgery. All subsequent long-term follow-up data were prospectively obtained upon outpatient clinical visits.

Image analysis and measurements

All measurements (diameters, length, and volume) were performed using semiautomatically generated CLL reconstruction on a workstation with dedicated reconstruction software (3Mensio Vascular 4.2; Medical Imaging B.V., Bilthoven, the Netherlands). All long-term imaging data were obtained by a single observer with experience in image analysis (N.F.G.O.). In previous reports, our group demonstrated high rates of interobserver agreement in respect to aneurysm diameter, neck diameter, neck length, and proximal seal length measurements,[6—8] obtained according to this methodology. Aneurysm volume was measured according to previously validated methodology.[7] Angulation measurements were executed in a standardized and previously validated method.[9]

Definitions

Reporting was performed according to the guidelines from the Society for Vascular Surgery/American Association of Vascular Surgery ad hoc Committee for Standardized Reporting Practices in Vascular Surgery.[10] Clinical success, primary clinical success, primary assisted clinical success, and secondary clinical success were defined accordingly.[10] Oversizing was determined by dividing the difference between the implanted main body diameter and the reference neck diameter in the first 15 mm of the infrarenal neck by the latter. Proximal seal length was defined as the extension of complete circumferential apposition between the endograft and the aortic wall, and was determined according to a previously published method.[8] The length of the neck was defined as the distance between the most distal point of the origin of the lowermost renal artery and the beginning of the aneurysm. For proximal seal

determination and barb detachment, center lumen markers were placed from the origin of superior mesenteric artery and at every 2 mm, and progressed caudally until reaching the flow divider. Distance from the lowermost renal artery to the endograft was measured on CLL reconstruction as the distance between a tangent horizontal plan passing through the most distal point of the circumference of the lowermost renal artery ostium and the first covered stent of the endograft on last imaging available. Migration was defined by subtracting the distance from the lowermost renal artery to endograft measured on first postoperative imaging from last available imaging exam.

Sac growth was defined as a >5% increase in aneurysm sac volume or as a >5 mm increase in sac diameter.[10] Long-term sac dynamics were defined as the difference in maximum diameter between the first (within 30 days) and the last postoperative imaging examinations. Barb detachment was defined on CLL reconstruction as nonapposition of a proximal uncovered stent barb to the aortic wall and distance of detachment was measured between the outer surface of the barb and the inner limit of the aortic wall. Posterior neck bulging was defined by the increase of neck diameter in quadrant defined by the convexity of the suprarenal angle, despite maintenance of adequate endograft apposition to the aortic wall in the remaining quadrants on surveillance imaging.

AAA-related adverse events were defined as a composite of the following: direct (type 1 or 3) or undetermined type endoleaks, aneurysm sac growth, migration >10 mm, device integrity failure, AAA-related death, late post-implantation AAA rupture, or any AAA-related secondary intervention. Undetermined endoleak was considered if contrast was identified within the aneurysm sac but outside the endograft and if its origin could not be imputed to failure of proximal or distal seal or patent aortic branch vessels. Secondary interventions were considered if performed to resolve or prevent a possible complication, and included endovascular procedures (proximal cuff and stent implant, distal extension implant, catheter-based thrombolysis, iliac angioplasty, coil or glue embolization of aortic branch vessels), as well as surgical procedures (balloon thrombectomy, femoro-femoral crossover, conversion to open repair, open or laparoscopic ligation of collaterals).

Endpoints

The primary study endpoint was primary clinical success. Secondary endpoints were freedom from rupture, freedom from type 1A endoleak, freedom from neck-related reinterventions and aneurysm-related adverse events. Additional individual elements of the latter composite endpoint—aneurysm expansion (diameter ≥5 mm, volume ≥5%), type 1 B and type 3 endoleaks, graft or limb thrombosis, graft infection, conversion to open repair or death as a result of aneurysm-rupture or aneurysm-related treatment—were also explored separately. Variation of neck-related morphological features and device-related outcomes in the proximal neck were also assessed.

Statistical analysis

Categorical variables are presented as count and percentage, and were compared using the Pearson's chi-square test. Continuous variables are presented as mean, SD, median, interquartile range (IQR), and range. Differences between groups were analyzed using the Mann—Whitney *U* test for independent samples with non-normal distributions, with the Student *t* test and significance with the independent samples test for nonrelated variables with normal distributions, and the paired Student *t* test for paired variables. Survival curves for primary clinical success and freedom from neck-related reinterventions were estimated by Kaplan—Meier methods, and equality was evaluated with the Mantel—Cox log-rank test. Long-term outcome variables were assessed by Cox hazards regression models. Multivariate regression was performed to include the most significant morphologic features determined by previous univariate analysis (neck diameter and neck length). Confidence intervals (CIs) of 95% were used and statistical significance was considered if $p < .05$. All statistical analysis was performed using SPSS 21.0 (IBM, Armonk, NY, USA).

RESULTS

Clinical and anatomical baseline characteristics are presented in Table 1. At the time of surgery, the mean age of the patients was 73.9 ± 7.9 years, and 86.4% were men. Both groups were not significantly different regarding comorbidities. Anatomic characterization has been exhaustively described elsewhere.[4] Mean α angles were 51.4 ± 21.1 and 17.9 ± 17.0, and mean β angles were 80.8 ± 15.6 and 35.4 ± 20.0 for the angulated and control groups, respectively. Intraobserver variability for neck angulation measurements was tested for a sample of 44 patients, with very good agreement (Pearson's correlation coefficient, α angle −0.965, $p < .01$; β angle −0.932, $p < .01$), and Bland—Altman plots were created (Fig. 1).

Patients in the angulated group presented significantly larger aneurysms, with a mean aneurysm volume of 309.5 ± 30.1 cc ($p < .001$) and shorter proximal neck lengths (mean 27.2 mm ± 14.8; $p < .01$). Procedural-related and early outcomes have been previously reported.[4]

Median follow-up time was 49.5 months (IQR 30.5—58.4; range 0.43—67.1 months). Follow-up time differed between groups, with median of 45.3 months (range 1.5—61.6 months) for the angulated group and a median of 52.1 months (range 0.4—67.1 months) for the nonangulated group ($p = .03$).

Early postoperative mortality occurred in one patient in the study group and two patients in the control group as previously reported.[4] Of the remaining 107 patients, postoperative CTAs were available for 44 (98.0%) patients of the angulated group and 62 (95.0%) patients in the control group. Only one patient did not undergo postoperative CTA owing to impaired renal function and an uneventful follow-up. A 1-year CTA was obtained for 91, a 2-year CTA for 77, a 3-year CTA for 52, and a 4-year CTA for 36 patients.

Table 1. Baseline clinical and anatomic characteristics.

Characteristic	Angulated ($n = 45$)	Nonangulated ($n = 65$)	p
Age (y), mean (SD)	75.6 (6.5)	72.7 (8.5)	.49
Male	36 (80.0)	59 (90.8)	.11
Smoking	32 (71.1)	51 (78.5)	.38
Hypertension	25 (55.6)	35 (53.8)	.70
Cardiac disease	22 (48.9)	27 (41.5)	.45
Diabetes	6 (13.3)	15 (23.1)	.20
COPD	14 (31.1)	13 (20.0)	.18
Creatinine clearance <60 mL/min/1.73 m^2	16 (35.6)	20 (30.8)	.60
Cerebrovascular disease	4 (8.9)	12 (18.5)	.16
Peripheral arterial disease	11 (24.4)	15 (23.1)	.87
ASA class III/IV	33 (73.3)	43 (66.2)	.42
AAA Ø (mm), mean (SD)	68.6 (14.2)	58.8 (7.6)	$<.01$
AAA volume (cc), mean (SD)	309.5 (30.1)	187.4 (8.2)	$<.01$
Proximal neck Ø (mm), mean (SD)	25.2 (4.2)	25.5 (4.5)	.71
Proximal neck length (mm), mean (SD)	27.2 (14.8)	32.6 (13.1)	.05
Neck thrombus $>25\%$ of circumference	8 (17.8)	10 (15.4)	.74
Neck calcification $>25\%$ of circumference	3 (6.7)	1 (1.5)	.16
α Angle (degrees), mean (SD)	51.4 (21.1)	17.9 (17.0)	$<.01$
β Angle (degrees), mean (SD)	80.8 (15.6)	35.4 (20.0)	$<.01$

Note. Values given as *n* (%) unless otherwise indicated. COPD = chronic obstructive pulmonary disease; ASA = American Society of Anesthesiologists; AAA = abdominal aortic aneurysm.

Clinical success

Primary clinical success was obtained in 86 (78.2%) patients. Forty of these patients had angulated proximal anatomy (88.9%) and 46 had less challenging necks (70.8%) ($p = .02$). Kaplan–Meier survival estimates for primary clinical success were not different for patients with or without proximal angulated anatomy ($p = .42$; Fig. 2A). The 2- and 4-year estimates for primary success rates were 93% and 83% for the angulated group, 92% and 80% for the control group. On multivariate regression analysis, patients with severe proximal neck angulation were not at increased risk of presenting worse primary clinical success compared with the control group (Hazard ratio [HR] 1.56, 95% CI 0.55–4.41; $p = .40$). Overall primary-assisted and secondary clinical success were not different among both groups (Table 2).

Freedom from late aneurysm rupture

Late aneurysm rupture occurred in three (2.7%) patients, one in the angulated group (2.2%) and two in the nonangulated group (3.1%) ($p = .79$) and resulted in the death of one patient in each group (1.8%) ($p = .79$; Table 3). In the nonangulated group, one patient developed an infection of the endograft with subsequent type 1a endoleak and aneurysm rupture. Despite undergoing a proximal cuff insertion, this patient died 26 days after reintervention. The other patient from the nonangulated group presented a type 1b endoleak with rupture, which was successfully treated with a limb extension. In the angulated group, one patient presented with aneurysm rupture due to a type 1b endoleak.

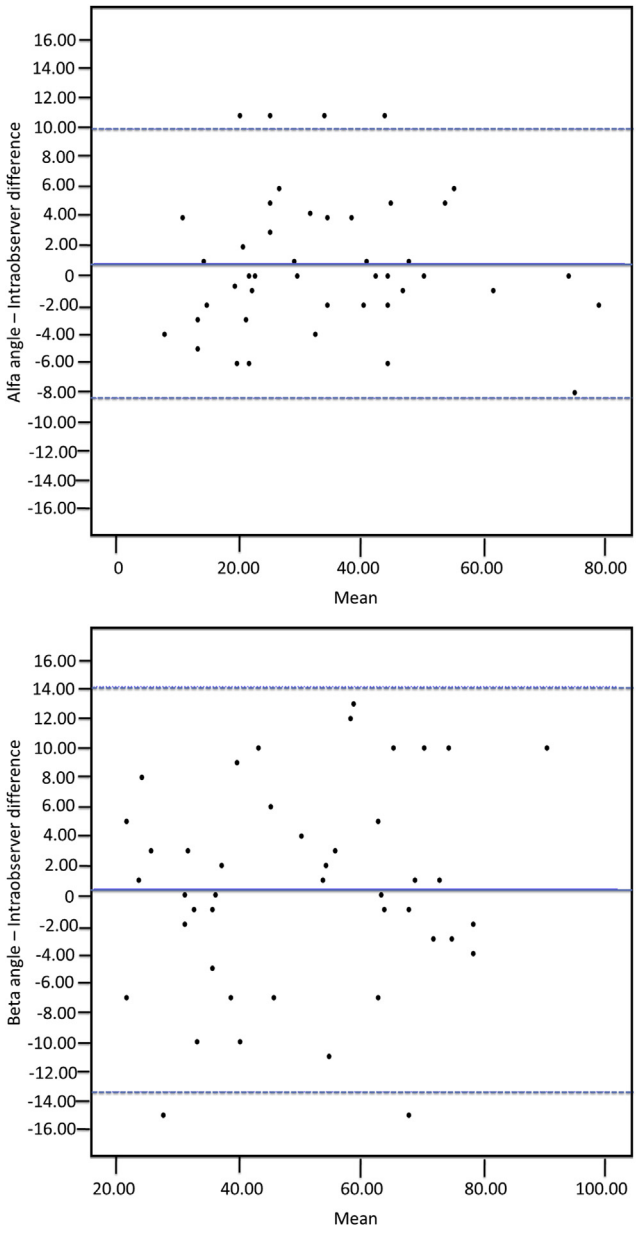
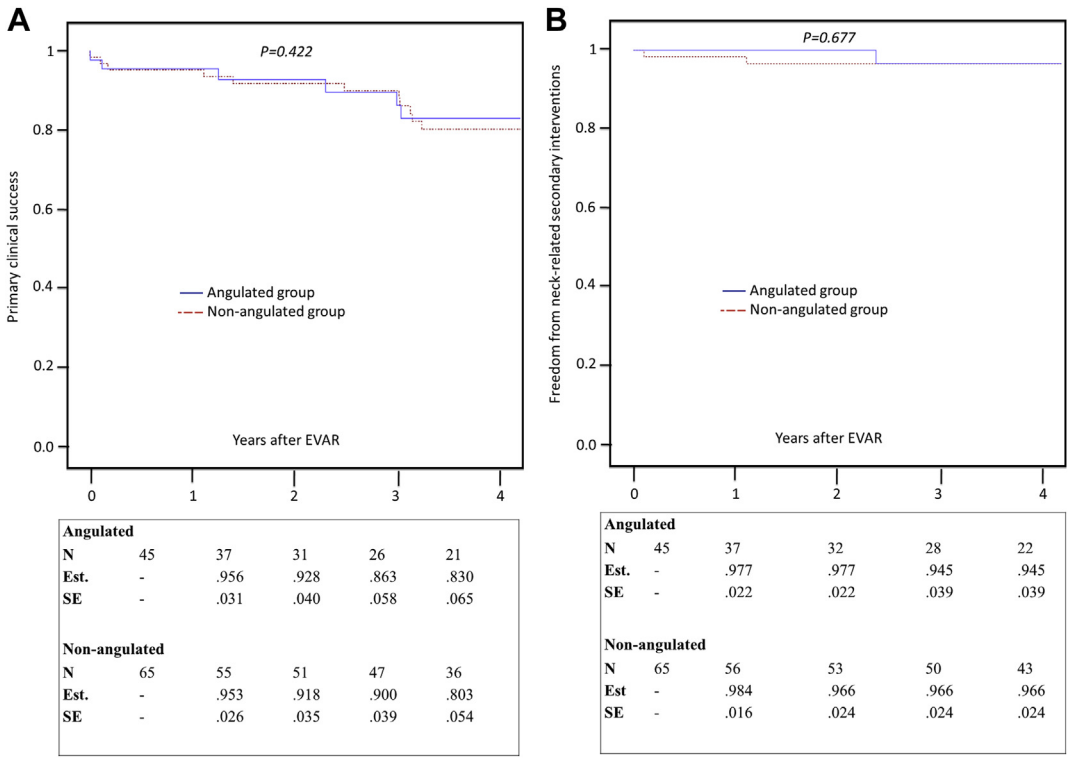


Figure 1. Bland–Altman plots showing intraobserver variability for suprarenal (top) and infrarenal (bottom) neck angulation on last imaging available in a group of 44 patients.

Freedom from proximal type 1 endoleaks and neck-related reinterventions

Secondary interventions due to neck-related adverse events occurred in three patients. In the angulated group, one patient who had received a limb relining owing to a type 3 endoleak became symptomatic 5 months later, without



Angulated					
N	45	37	31	26	21
Est.	-	.956	.928	.863	.830
SE	-	.031	.040	.058	.065
Non-angulated					
N	65	55	51	47	36
Est.	-	.953	.918	.900	.803
SE	-	.026	.035	.039	.054

Angulated					
N	45	37	32	28	22
Est.	-	.977	.977	.945	.945
SE	-	.022	.022	.039	.039
Non-angulated					
N	65	56	53	50	43
Est	-	.984	.966	.966	.966
SE	-	.016	.024	.024	.024

Figure 2. (A) Kaplan–Meier analysis of long-term primary clinical success. (B) Kaplan–Meier analysis of freedom from neck-related reinterventions. *Note*. EVAR = endovascular aneurysm repair.

rupture, and was converted to open repair. Intraoperatively a position-dependent type 1a endoleak reported. In the nonangulated group, two patients required proximal cuffs: one patient who developed an endograft infection and consequent proximal type 1 endoleak, as reported above; the other patient was treated for a secondary type 1a endoleak with a proximal cuff but required also a proximal Palmaz stent 1 year later owing to progressive neck dilatation and endoleak relapse. No differences between Kaplan–Meier survival curves were demonstrated for proximal neck-related reintervention ($p = .68$) (Fig. 2B). The 2- and 4-year estimates for freedom from neck-related reinterventions were 98% and 95% in the angulated group, while in the control group they were both 97%. In addition to these three patients listed, one further patient with severe proximal neck angulation developed a proximal type 1 endoleak but died before receiving treatment for the endoleak owing to unrelated medical complications following refractory lower intestinal bleeding. Patients in the angulated group did not present more proximal type 1 endoleaks when compared with the control group ($p = .79$).

Table 2. Long-term clinical outcomes.

	Angulated ($n = 45$)	Nonangulated ($n = 65$)	p
Primary clinical success	40 (88.9)	46 (70.8)	.02
Assisted primary clinical success	42 (93.3)	60 (92.3)	.84
Secondary clinical success	43 (95.6)	63 (96.9)	.71
Late aneurysm-related mortality	1 (2.2)	1 (1.5)	.79
All-cause mortality	11 (24.4)	11 (16.9)	.33

Note. Values given as *n* (%).

AAA-related adverse events

During the follow-up period, aneurysm-related adverse events were registered in 23 (20.9%) patients, six (13.3%) of whom had severely angulated necks; the remaining 17 did not (26.2% of the control group) ($p = .10$; Table 3). Patients with severe proximal angulation were not at increased risk for adverse events (HR = 1.65, 95% CI 0.57–4.75; $p = .35$).

Patients in the angulated group underwent less secondary interventions than in the control group ($p = .04$). On multivariate analysis, an increased risk of having a secondary intervention could not be identified among the study group (HR = 1.19, 95% CI 0.35–4.02; $p = .78$).

Sac growth >5 mm did not occur in the angulated group but was identified in six (9.7%) patients in the nonangulated group ($p = .03$). Type 2 endoleak was considered the cause of sac growth in three patients; two of these patients underwent glue/coil embolization, which did not prevent progressive sac growth. The remaining cases of sac growth occurred in the presence of direct endoleaks.

Device-related outcomes in the proximal neck

Postoperative CTAs were available for 44 (98.0%) patients in the angulated group and 62 (95.0%) patients in the control group.

Table 3. Abdominal aortic aneurysm (AAA)-related events.

	Angulated ($n = 45$)	Nonangulated ($n = 65$)	p
AAA-related adverse events, patients	6 (13.3)	17 (26.2)	.10
Aneurysm rupture	1 (2.2)	2 (3.1)	.79
Late aneurysm-related mortality	1 (2.2)	1 (1.5)	.79
Secondary endoleaks			
Type 1a—patients	2 (4.4)	2 (3.1)	0.79
Type 1a—events	2	3	
Type 1b	2	8	
Type 2	3	7	
Type 3	1	0	
Sac growth	0 (0)	6 (9.7)	.03
Sac shrinkage ≥10 mm	17 (38.6)	22 (35.5)	.74
Graft infection	0	1	
Limb thrombosis, events	1	7	
Endograft occlusion	1	0	
Buttocks claudication	0	1[a]	
Access artery thrombosis	1[a]	0	
Migration	0	0	
Device failure	0	0	
Secondary interventions—patients	4 (8.9)	16 (24.6)	.04
Secondary interventions—events	5	22	
Proximal stent/cuff	0	3	
Limb extension	2	9	
Coil/glue embolization	0	4	
Relining	0	0	
Conversion to open repair	1	0	
Conversion to aortouniiliac	0	0	
Open/laparoscopic fenestration	0	0	
Thrombolysis and iliac PTA	2	4	
Isolated iliac PTA	0	2	

Note. Values given as *n* (%). PTA = percutaneous transluminal angioplasty.

[a] No intervention took place in these patients.

Mean distance from the lowermost renal artery was not significantly increased in patients with angulated anatomy (4.9 ± 3.9 mm) when compared with the patients without severe proximal angulation (3.9 ± 3.5 mm) ($p = .15$) on last CTA. Mean endograft migration distance measured between the first and the last postoperative imaging available did not differ significantly among groups (Table 4).

Mean proximal seal length was significantly shorter for the angulated group (16.7 mm) in comparison with the nonangulated patients (23.7 mm) ($p < .01$) on last imaging available. Moreover, patients with severe proximal neck angulation were at higher risk of presenting short (<10 mm) proximal seal lengths (HR 4.91, 95% CI 1.58—15.31; $p < .01$). However, significant differences were already present on the first postoperative CT, where mean proximal seal length was 16.8 ± 8.5 mm in the angulated group and 22.1 ± 8.8 mm in patients without proximal neck angulation ($p = .01$) and were not dissimilar from the proximal seal lengths measured on the last imaging for both angulated ($p = .18$) of nonangulated ($p = .36$) groups.

Stent fracture was not identified among any of the groups. Barb detachment was encountered in 13 (11.8%) patients: eight (17.8%) in the study group and five (7.8%) in the control group, which was not significantly different ($p = .12$). Mean distance from wall to barb was also not significantly different among groups (angulated patients: 3.6 ± 2.2 mm; controls 2.2 ± 0.65 mm [$p = .13$]). On multivariate regression, patients with very angulated proximal neck anatomy were found to be at a higher risk of presenting barb detachment (HR 3.59, 95% CI 1.14—11.33; $p = .03$). Multiple barb detachment was not identified in our population.

Proximal neck morphological outcomes

Suprarenal and infrarenal angles remained significantly different between the two groups ($p < .01$) after EVAR. Angle reduction was significantly more pronounced in patients with severe proximal neck angulation when compared with the control group (Table 4). However, when comparing the last available CTA with the first postoperative one, the suprarenal and infrarenal angles did not change significantly in either angulated or nonangulated neck patients (Fig. 3).

Mean baseline neck diameter was 25.2 ± 4.2 mm in the severe neck angulation group and 25.5 ± 4.5 mm in the

Table 4. Long-term morphologic and device-related outcomes in the proximal neck.

	Angulated ($n = 44$)	Nonangulated ($n = 62$)	p
Migration distance (mm), mean (SD)	1.9 (2.6)	1.1 (1.6)	.22
Proximal seal length on last imaging (mm), mean (SD)	16.7 (9.3)	23.7 (10.9)	<.01
α Angle on last imaging (degrees), mean (SD)	35.5 (17.6)	16.7 (12.1)	<.01
β Angle on last imaging (degrees), mean (SD)	50.4 (19.4)	29.8 (16.7)	<.01
$\Delta\alpha$ Angle compared with 30-d CTA (degrees), mean (SD)	−1.1 (11.9)	−1.6 (10.8)	.81
$\Delta\beta$ angle compared with 30-d CTA (degrees), mean (SD)	−1.0 (21.0)	4.3 (15.9)	.14
Neck dilatation compared with baseline (mm), mean (SD)	3.0 (2.0—5.0)	4.0 (1.0—5.3)	.55

Note. CTA = computerized tomographic angiography.

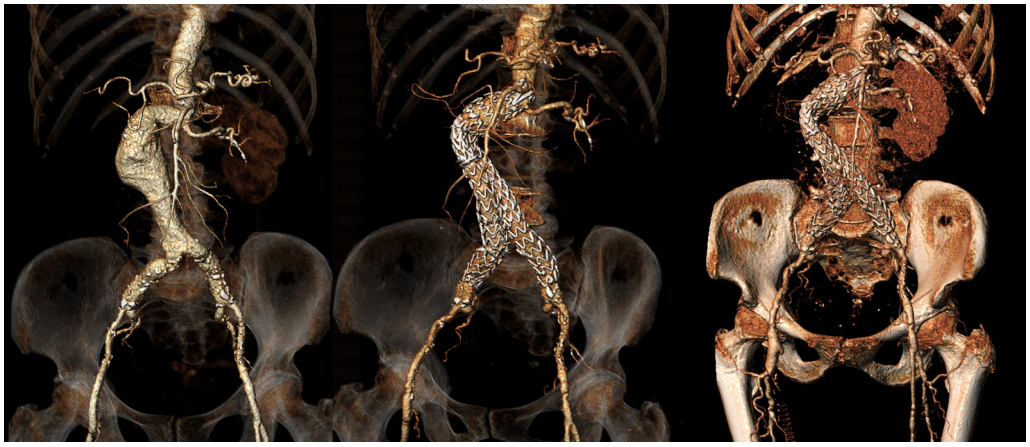


Figure 3. Evolution of proximal aneurysm neck angulation following endovascular aneurysm repair with the Endurant Stent Graft (left, baseline, middle 30-d imaging; right, 4-year follow-up).

control group. Patients with angulated proximal necks had shorter neck lengths (27.2 ± 14.8 mm) when compared with the control group (32.6 ± 13.1 mm) ($p = .05$). Mean neck dilatation was 12.6 ± 12.5% and 13.8 ± 10.7% when compared with baseline diameters among patients with and without severe proximal neck angulation, respectively, and did not differ significantly ($p = .59$). Mean device oversizing was 21.4 ± 10.2% in the angulated group and 16.1 ± 9.4% in the control group ($p = .01$). Posterior bulging occurred in three patients (6.8%) in the angulated group and in one patient (2.2%) without angulated anatomy, which was not significantly different between both groups ($p = .17$). However, in one of the patients in the angulated group it was associated with a proximal type 1 endoleak but no intervention took place as this patient died in the sequence of lower intestinal bleeding, as reported above.

DISCUSSION

The present study is the first to evaluate mid-term outcome and morphology changes of patients with severely angulated proximal neck treated with a late-generation endograft. Despite concerns over implantation accuracy and durability after EVAR in angulated proximal aneurysm necks, our results suggest that EVAR with the Endurant Stent Graft in adequately selected patients with severe proximal neck angulation results in acceptable mid-term outcomes. In our study, secondary interventions were unexpectedly more frequent in the control group and were mostly performed owing to complications unrelated to the proximal neck (distal type 1 endoleaks, type 2 endoleaks, limb occlusion).

Altered blood flow patterns due to severe angulation proximal neck angulation have been found to increased drag forces on endografts, increasing the risk of graft migration.[11] Additionally, the inability of many devices to cope with severe neck angulation resulting in asymmetrical device deployment may render the endograft more susceptible to migration.[12] Consequently, neck angulation has been associated with an increased risk of adverse aneurysm-related events in the short and midterm.[13] Moreover, owing to these concerns, patients with severe proximal anatomy were excluded from several major trials and, consequently, outcomes in this particular subgroup have not been easily assessable. In a EUROSTAR-based report from Hobo et al. with a mean (SD) follow-up of 19.9 (17.9) months ($n = 1,152$), patients with severe proximal angulation were at increased risk of presenting a proximal type 1 endoleak (HR 1.80, 95% CI 1.25−2.58).[14]

Recent devices have been specially designed to broaden EVAR applicability particularly in more challenging proximal neck anatomies. Weale et al. reported their prospective experience with the use of the Aorfix (Lombard Medical, Didcot, UK),[15] a US Food and Drugs Administration-approved device for the treatment of patients with AAA with up to 90° angulated necks. In a group of 30 patients with a mean infrarenal angle of −81.2° [range 63°−110°], two (6.7%) cases of primary proximal type 1 endoleaks were found to persist at the 6-month follow-up, despite intraoperative ballooning of the proximal stent. The Anaconda AAA stent graft system (Vascutek, Terumo, Inchinnan, UK) has also claimed a role in the management of patients with AAA with angulated proximal anatomy. Rödel et al. reported recently on the 4-year outcomes of this device in a group of 36 patients with proximal neck angulation >60°.[16] Primary clinical success had been sustained in 25 (69%) patients. Two endograft occlusions were reported along with five limb occlusions, particularly, according to the authors, in the presence of increased neck angulation. Additionally, one patient presented a migration of the device with proximal type 1 endoleak. In a retrospective analysis of 519 patients treated with the Endologix graft (Endologix, Irvine, CA, USA), Qu et al. reported,[17] in a subgroup of 36 patients with neck angulation >60°, one (2.8%) secondary proximal type 1 endoleak during an overall mean follow-up of 2.6 years (range 4.0 months to 5.0 years). Nevertheless, 25 (69.0%) of these patients had required additional proximal cuffs or Palmaz stents during the primary intervention. In the sample in the present study, only one (2.2%) patient in the study group required an additional proximal extension intraoperatively.[4]

Morphological neck changes and proximal device fixation of the Endurant Stent Graft were evaluated in the sample presented herein. Barb detachment may result from the inability of the barb to follow the lesser aortic curvature in very angulated necks. In the current sample, patients with severe neck angulation presented a 3.7-fold increased risk of single barb detachment. However, multiple barb detachment was not identified and barb detachment did not increase over time. Moreover, this finding does not represent device failure as significant migration was not identified among the present population.

Increased device oversizing has been used to ensure adequate proximal seal, particularly in situations prone to eccentric deployment, such as in the presence of severe proximal neck angulation, which was also identified among the present study group. However, other morphologic features also differentiated significantly the study group: neck length was shorter ($p = .05$; Table 1), aneurysms were larger ($p < .01$), and, as reported previously, patients in the study group presented a greater variability in neck conformation, assuming more frequently a noncylindrical form.[4] It is hypothesized that in patients with cylindrical proximal aneurysm necks, increased oversizing may not be warranted as unlike devices with columnar strength, the high conformability of the Endurant Stent Graft enables it to follow intimately the aneurysm neck curvature in severely angulated anatomy. EVAR has been found to induce dynamic morphologic remodeling of the neck, as reported by van Keulen et al.,[17] particularly with the deployment of endografts with columnar strength. Hoshina et al. found that in a group of 46 patients with proximal neck angulation $>60°$,[18] 41 (89.0%) presented significant and straightening immediately after endograft deployment. Moreover, the rate of further straightening during follow-up was graft-dependent. Statistically significant reductions were also identified in both suprarenal and infrarenal neck angles, which were more pronounced in the angulated group, despite the high flexibility of the device deployed. However, when comparing suprarenal and infrarenal angle variation on the last available CTA to the first postoperative one, the present data suggest that significant angle reduction occurred only immediately after device deployment and did not modify, as the Endurant Stent Graft remained adapted to the underlying anatomy. The authors hypothesize that the increased flexibility of this device, which leads to a more concentric deployment of the endograft and enduring conformation to an unstrained aortic neck in the mid-term, may result in decreased morphologic neck modification, which, in turn, may contribute to a decreased risk of neck dilatation, proximal type 1 endoleak, or device migration.

Noticeable limitations to the present study include its retrospective design, which is subject to selection and reporting bias, thus contributing to the significantly different mean follow-up time among groups. Nevertheless, all patients were treated in a consecutive fashion with the same endograft, followed prospectively, and life-table analysis was performed showing no difference in any of the endpoints. Additionally, case volume may limit the reproducibility of the findings at other centers. However, as all patients received the same endograft, the conclusions may be clinically relevant to many centers where this device is currently available. Finally, the sample size may limit revealing of more subtle differences between groups. However, this report represents the largest study to date reporting on clinical outcomes following EVAR in patients with severe proximal neck angulation during a median follow-up of 4 years.

CONCLUSION

EVAR with the Endurant Stent Graft System is safe in patients with severe proximal neck angulation provided that a suitable proximal seal length is obtained. Mid-term outcome and freedom from neck-related reinterventions were not influenced by the severity of proximal neck angulation. Aortic neck remodeling occurred more significantly in patients with adverse neck anatomy but angulation changes were not marked and did not modify significantly during follow-up, confirming the enduring ability of this device to conform to challenging anatomies over time.

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CONFLICT OF INTEREST

J. M. de Vries, F.L. Moll, J.A. van Herwaaden, and H.J.M. Verhagen act as consultants for Medtronic. The other authors have no conflicts of interest to declare.

REFERENCES

1 Antoniou GA, Georgiadis GS, Antoniou SA, Kuhan G, Murray G. A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy. *J Vasc Surg* 2013;**57**(2):527–38.
2 van Keulen JW, de Vries JPPM, Dekker H, Gonçalves FB, Moll FL, Verhagen HJ, et al. One-year multicenter results of 100 abdominal aortic aneurysm patients treated with the Endurant stent graft. *J Vasc Surg* 2011;**54**(3):609–15.
3 Verhagen HJ, Torsello G, de Vries JP, Cuypers PH, Van Herwaarden JA, Florek HJ, et al. Endurant stent-graft system: preliminary report on an innovative treatment for challenging abdominal aortic aneurysm. *J Cardiovasc Surg (Torino)* 2009;**50**(2):153–8.
4 Bastos Gonçalves F, de Vries J-P, van Keulen JW, Dekker H, Moll FL, van Herwaarden JA, et al. Severe proximal aneurysm neck angulation: early results using the Endurant stentgraft system. *Eur J Vasc Endovasc Surg* 2011;**41**(2):193–200.
5 Rouwet EV, Torsello G, de Vries JP, Cuypers P, van Herwaarden JA, Eckstein HH, et al. Final results of the prospective European trial of the Endurant stent graft for endovascular abdominal aortic aneurysm repair. *Eur J Vasc Endovasc Surg* 2011;**42**(4):489–97.
6 Bastos Gonçalves F, Jairam A, Voûte MT, Moeiker AD, Rouwet EV, ten Raa S, et al. Clinical outcome and morphologic analysis after endovascular aneurysm repair using the Excluder endograft. *J Vasc Surg* 2012;**56**:920–8.

7 van Prehn J, van der Wal MB, Vincken K, Bartels LW, Moll FL, van Herwaarden JA. Intra- and interobserver variability of aortic aneurysm volume measurement with fast CTA post-processing software. *J Endovasc Ther* 2008;**15**(5):504—10.

8 Bastos Gonçalves F, van de Luijtgaarden KM, Hoeks SE, Hendriks JM, ten Raa S, Rouwet EV, 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**(6):1503—11.

9 van Keulen JW, Moll FL, Tolenaar JL, Verhagen HJ, van Herwaarden JA. Validation of a new standardized method to measure proximal aneurysm neck angulation. *J Vasc Surg* 2010;**51**(4):821—8.

10 Chaikof EL, Blankensteijn JD, Harris PL, White GH, Zarins CK, Bernhard VM, et al. Reporting standards for endovascular aortic aneurysm repair. *J Vasc Surg* 2002;**35**(5):1048—60.

11 Molony DS, Kavanagh EG, Madhavan P, Walsh MT, McGloughlin TM. A computational study of the magnitude and direction of migration forces in patient-specific abdominal aortic aneurysm stent-grafts. *Eur J Vasc Endovasc Surg* 2010;**40**(3):332—9.

12 Figueroa CA, Taylor CA, Yeh V, Chiou AJ, Zarins CK. Effect of curvature on displacement forces acting on aortic endografts: a 3-dimensional computational analysis. *J Endovasc Ther* 2009;**16**(3):284—94.

13 Hobo R, Kievit J, Leurs LJ, Buth J. EUROSTAR Collaborators. Influence of severe infrarenal aortic neck angulation on complications at the proximal neck following endovascular AAA repair: a EUROSTAR study. *J Endovasc Ther* 2007;**14**(1):1—11.

14 Weale AR, Balasubramamian K, Macierewicz J, Hardman J, Horrocks M. Outcome and safety of Aorfix stent graft in highly angulated necks — a prospective observational study (arbiter 2). *Eur J Vasc Endovasc Surg* 2011;**41**(3):337—43.

15 Rödel SG, Zeebregts CJ, Huisman AB, Geelkerken RH. Multicenter Angulated Neck Study with the Anaconda study participants. Results of the Anaconda endovascular graft in abdominal aortic aneurysm with a severe angulated infrarenal neck. *J Vasc Surg* 2014;**59**(6):1495—501.

16 Qu L, Raithel D. Experience with the Endologix Powerlink endograft in endovascular repair of abdominal aortic aneurysms with short and angulated necks. *Perspect Vasc Surg Endovasc Ther* 2008;**20**(2):158—66.

17 van Keulen JW, Moll FL, Arts J, Vonken EJ, van Herwaarden JA. Aortic neck angulations decrease during and after endovascular aneurysm repair. *J Endovasc Ther* 2010;**17**(5):594—8.

18 Hoshina K, Akai T, Takayama T, Kato M, Nakazawa T, Okamoto H, et al. Outcomes and morphologic changes after endovascular repair for abdominal aortic aneurysms with a severely angulated neck — a device-specific analysis. *Circ J* 2013;**77**(8):1996—2002.