CLINICAL INVESTIGATION



# **Evaluation of Aneurysm Neck Angle Change After Endovascular Aneurysm Repair Clinical Investigations**

Trong Binh Le<sup>1</sup> · Mi Hyoung Moon<sup>1</sup> · Yong Sun Jeon<sup>2</sup> · Kee Chun Hong<sup>3</sup> · Soon Gu Cho<sup>2</sup> · Keun-Myoung Park<sup>3</sup>

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#### Abstract

*Purpose* To evaluate the aneurysm neck angle changes and post-endovascular aneurysm repair (EVAR) complications.

*Methods* We retrospectively analyzed 72 cases of elective EVAR for abdominal aortic aneurysm among 109 consecutive cases from December 2005 to April 2014. Patients were divided into angulated and non-angulated groups. The angulated group was defined as neck angulation  $\geq 60^{\circ}$ . Neck angle was evaluated pre- and post-EVAR during short- (within 1 month), mid- (3–6 months), and long-term (>1 year) follow-up. Aneurysm sac diameter change, aneurysm neck morphology other than angulation, endoleaks, and other post-procedural complications were also documented.

*Results* A total of 34 patients were enrolled in the angulated group. There were no statistical differences in age, sex, follow-up duration, and aneurysm neck profile between the two groups (p > 0.05). Both groups showed statistically significant and consistent decreases in angulation during the follow-up period (p < 0.01). The angulated group revealed 22.45 % more straightening than the non-angulated group. Recoil of the Endurant device occurred in the angulated group. No statistically significant intergroup

⊠ Yong Sun Jeon radjeon@inha.ac.kr

- <sup>1</sup> Endovascular Training Center, Inha University Hospital, Incheon, Republic of Korea
- <sup>2</sup> Department of Radiology, Inha University Hospital, Inha University School of Medicine, 7-206 Sinheung-dong 3-ga, Jung-gu, Incheon, Republic of Korea
- <sup>3</sup> Department of Vascular Surgery, Inha University School of Medicine, Incheon, Republic of Korea

differences were observed in any endoleaks, complications, or re-intervention rates (p > 0.05). Pre-EVAR angle was the only predictor for post-procedural angle change (p < 0.001).

*Conclusion* EVAR is applicable for patients with highly angulated aneurysm neck and provides consistent neck straightening over long-term follow-up. Recoil was evident in the angulated group using the Endurant device.

**Keywords** Endovascular aneurysm repair · Abdominal aortic aneurysm · Proximal neck angulation · Endoleak

## Introduction

Abdominal aortic aneurysm (AAA) is one of the underlying causes of sudden death worldwide with the reported prevalence of 1.7–12.7 % [1]. Since it was first introduced by Parodi et al. in 1991, endovascular aneurysm repair (EVAR) has become a revolutionary approach to the treatment of infrarenal AAA. EVAR has proven salient advantages in perioperative mortality and morbidity, hospital stay length, operative time, and blood loss compared to open repair [2–6]. However, EVAR may not always be the optimal treatment option since not all patients are eligible for it. A hostile neck, consisting of severe angulation, a short, reverse taper and severe calcification and thrombus, remains a leading anatomical limitation of EVAR.

The proximal neck anatomy is a major limiting factor in the determination of a patient's suitability for EVAR [1, 3, 7]. These factors were initially estimated to exclude 20–40 % of patients [8–11]. Among them, angulation is possibly the most important characteristic of the aneurysmal neck [12]. In fact, the implantation of endografts in patients with highly angulated proximal neck anatomy results in considerable intraprocedural technical problems and adverse short-term clinical outcomes [1]. However, recent stent-graft design improvements and diversifications as well as the availability of operators who are more skilled in stent grafting techniques allow standard stent grafts to be implanted for shorter, more highly angulated, and wider aortic necks. Changes in aortic angulation over time after EVAR may affect the proximal sealing and fixation zone; therefore, they are considered a potential risk of late complications and adverse outcomes [12]. This raises the need to understand the post-procedural configuration of the angulated neck and identify complications during followup. In this series, we aimed to compare the proximal aneurysm neck angulation changes and EVAR clinical outcomes in patients with angulated and non-angulated necks.

# **Materials and Methods**

This study was approved by our institution's institutional review board. Data were retrieved from the hospital's database. Between December 2005 and June 2014, 109 consecutive patients with EVAR were treated for infrarenal AAA. Exclusion criteria included EVAR for pseudoaneurysm, ruptured AAA, aortic dissection, penetrating ulcer, and previous aortic surgery. Ultimately, 72 patients (60 men) who underwent elective EVAR for AAA were enrolled in this study. The patients were then divided into the angulated (n = 34) and non-angulated (n = 38) groups according to the aneurysmal neck angulation ( $\geq 60^{\circ}$  or  $<60^{\circ}$ , respectively). Follow-up duration was 1–85 months

(mean, 18 months). Patient demographics, aneurysm profile (including aneurysm diameter, neck length, and neck diameter), endoleaks, complications, and re-intervention rate in both groups were also documented and compared. Four types of stent grafts were used in our series, including 31 Zenith (Cook Medical, Bloomington, IN, USA), 21 Endurant (Medtronic Vascular, Santa Rosa, CA, USA), 11 Excluder (WL Gore and Associates, Flagstaff, AZ, USA), and 9 Seal (S&G Biotech, Seongnam, Korea). Subgroups of the Zenith and Endurant device groups were also analyzed, while those of the Excluder and Seal were not due to small sample sizes. The indications for EVAR required consensus between vascular surgeons and interventional radiologists and considered each patient's age, clinical condition, and imaging findings as well as the instructions for use (IFU) of specific stent grafts. Informed consent was obtained from all patients. All of the procedures were performed by one interventional radiologist with over 10 years of experience of EVAR.

The definition and measurements of aneurysm neck angulation (Fig. 1) were based on the method described by Hoshina et al. [6]. All patients underwent baseline computed tomography angiography (CTA) for the aneurysm anatomical evaluation before EVAR and follow-up CTA at 1 month, 6 months, 1 year, and every year after EVAR. The CTA and 3-D reconstruction images were obtained according to standard institutional protocols using 64-slice multidetector CT. Helical scan data were acquired from the xyphoid process to feet in the supine position with a detector coverage of 40 mm, a gantry rotation time of 0.6 s, a scan thickness of 1.25 mm, image reconstruction interval of 2.5 mm, and an effective tube current–time product of 300–400 mAs and 140 kVp. Nonionic contrast media (Bonorex Iohexol 300, CMS, Seoul,



Fig. 1 Measurement of aortic neck angulation before (A) and after (B) endovascular aneurysm repair (EVAR)

**Table 1** Patient characteristicsand neck anatomy of angulatedand non-angulated group

Variables	Angulated $(n = 34)$	Non-angulated $(n = 38)$	p value
Demographics			
Age (years)	$75.59 \pm 11.35$	$72.34 \pm 9.75$	0.196
Sex (male)	24 (71)	36 (95)	0.006
Comorbidity			
Smoking	12 (35)	17 (45)	0.754
Hypertension	24 (70)	29 (76)	0.817
Coronary artery disease	9 (26)	11 (29)	0.791
Diabetes mellitus	11 (32)	12 (32)	0.548
Cerebrovascular disease	7 (21)	8 (21)	0.684
Chronic renal failure	4 (12)	3 (8)	0.241
Hyperlipidemia	14 (41)	16 (42)	0.758
Aneurysm diameter (mm)	$59.89 \pm 9.23$	$58.65 \pm 10.71$	0.600
Neck anatomy			
Diameter (mm)	$26.23 \pm 8.47$	$26.46 \pm 3.89$	0.883
Length (mm)	$36.36 \pm 15.41$	$33.59 \pm 17.14$	0.474
Short neck (<15 mm)	0	4	
Follow-up (months)	$14.4 \pm 17.9$	$21.7 \pm 24.0$	0.149

Korea) were used in all patients with the average dose was 2 ml/kg of body weight. The contrast medium was administered intravenously through a mechanical power injector (Stellant, Medrad, Pittsburgh, PA, USA) at a rate of 5 ml/s. The computer-assisted bolus-tracking software was used to determine the optimal scan delay for the arterial phase in each patient. All the CT images were reviewed at a workstation with the PACS (Maroview 5.4, Infinitt, Seoul, Korea). 3D images were reconstructed using AW Volume Share 4 software (GE, Milwaukee, WI, USA).

#### **Statistical Analysis**

Continuous data are presented as mean  $\pm$  standard deviation, while categorical data are given as counts and percentages. Independent two-sample *t* test and repeated measure analysis of covariance were used to compare data between the two groups. All analyses were performed using R software version 3.1.2 (R Core Team, R Foundation for Statistical Computing). *p* values <0.05 indicate statistical significance for all comparisons.

## Results

There were no differences in age, aneurysm neck morphology, number of comorbidities, or follow-up duration between the two groups. A short aneurysmal neck (<15 mm) was observed in 4 patients of the non-angulated group (mean neck length,  $36.36 \pm 15.41$  mm), while it was not evident in any patients of the angulated group (mean neck length,  $33.59 \pm 17.14$  mm). The mean follow-up duration was  $14.38 \pm 12.31$ 

17.86 months (range, 1–67 months) for the angulated group and  $21.74 \pm 24.04$  months (range, 1–85 months) for the nonangulated group (Table 1). Both groups showed significant decreases in neck angulation immediately after EVAR and remained consistent during the follow-up period (Table 2). The angulated group had a 22.45 % greater average degree of straightening than the non-angulated group (Fig. 2); however, the final angulations were still higher in the angulated group. Regarding device-specific evaluation, recoil was noted in 5 patients of the angulated group in whom the Endurant was used, whereas straightening was consistently seen in patients in the angulated group in whom the Zenith was used. No difference was seen in late configuration between the two devices in the non-angulated group (Fig. 3). The mean aneurysmal sac diameters of the angulated group at baseline, 1 month, 3–6 months, and >1 year were  $59.89 \pm 9.23$ ,  $57.47 \pm 9.93$ ,  $53.87 \pm 11.40$ , and  $50.2 \pm 15.42$  mm, while the mean aneurysmal sac diameters of non-angulated group were  $58.65 \pm 10.71$ ,  $55.60 \pm 10.49$ ,  $53.68 \pm 11.92$ , and  $51.70 \pm 17.98$  mm, respectively. No intergroup difference in diameter was seen at any of the checkpoints (p > 0.05); however, a slight sac regression tendency was evident (Fig. 4).

The endoleaks, complications, and re-intervention rates are presented in Tables 3 and 4. The overall incidence of endoleaks was 30.6, 29.4, and 30.6 % at 1 month, 6 months, and 1 year, respectively. At these time points, the incidence of type I endoleak was 1 of 34 patients, 0 of 22, and 0 of 16 in the angulated group and 3 of 38, 1 of 29, and 0 of 20 in the non-angulated group, respectively. We encountered 5 cases of type I endoleak (1 in the angulated and 4 in the non-angulated groups), of which 4 cases were Table 2Aneurysm neckangulation change before andafter EVAR with device-specific analysis

Time		Angulated $(n = 34)$	Non-angulated $(n = 38)$	p value
Pre-EVAR (°, mean	± SD)	$81.27 \pm 19.81$	37.93 ± 12.19	< 0.001
1 month (°, mean $\pm$	SD)	$52.85 \pm 14.30$	$28.24 \pm 14.30$	< 0.001
3-6 months (°, mean	$1 \pm SD$	$49.70 \pm 15.29$	$25.42 \pm 12.31$	< 0.001
$\geq$ 12 months (°, mean $\pm$ SD)		$48.01 \pm 19.20$	$27.61 \pm 18.77$	0.002
Zenith				
Time	Angula	ted $(n = 16)$	Non-angulated $(n = 15)$	p value
Pre-EVAR	73.86	± 11.73	36.06 ± 10.79	< 0.001
1 month	48.63	± 10.64	$26.66 \pm 11.74$	< 0.001
3-6 months	43.18	$\pm 11.87$	$22.81 \pm 11.87$	< 0.001
$\geq 12$ months	43.26	± 16.27	$22.57 \pm 13.89$	< 0.001
Endurant				
Time	Angula	ted $(n = 10)$	Non-angulated $(n = 11)$	p value
Pre-EVAR	100.2 =	± 24.08	37.41 ± 11.45	< 0.001
1 month	63.13 =	± 13.20	$28.8 \pm 11.27$	< 0.001
3-6 months	61.72 =	± 15.83	$23.24 \pm 10.59$	< 0.001
$\geq 12$ months	70.65 =	± 10.68	$21.27 \pm 24.01$	0.078

Data shown as mean degree (°)  $\pm$  standard deviation



**Fig. 2** Aneurysm neck angulation changes before and after endovascular aneurysm repair (EVAR). The angulated and non-angulated groups demonstrated significant angulation reductions immediately after EVAR that remained consistent during the follow-up period. The angulated group had a greater average degree of straightening than the non-angulated group

detected within 1 month and 1 within 6 months. Endotension was also documented in 2 cases (2.8 %), 1 in each group. Complications occurred in 7 patients of the



Fig. 3 Aneurysm neck angulation changes before and after endovascular aneurysm repair with device-specific evaluation. Recoiling was noted in patients in the angulated group using the Endurant device (En), whereas straightening was consistent in patients in the angulated group in whom the Zenith device (Ze) was used. No difference was seen in late configuration between the two groups

angulated group and 2 patients of the non-angulated group. The re-intervention rates were 20.6 % for the angulated group and 13.2 % for the non-angulated group. No



Fig. 4 Sac diameter changes before and after endovascular aneurysm repair. No intergroup difference in diameter was seen at any of the checkpoints; however, a slight sac regression tendency was evident during the follow-up period

Table 3 Incidence of endoleaks during follow-up

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Endoleaks	Angulated $(n = 34)$	Non-angulated $(n = 38)$	<i>p</i> value
Within 1 month	11	11	0.754
Type I	1	3	
Type II	9	8	
Type III	1	0	
3-6 months	6	8	0.528
Type I	0	1	
Type II	6	7	
Type III	0	0	
$\geq 12$ months	4	7	0.727
Type I	0	0	
Type II	3	6	
Type III	0	0	
Endotension	1	1	

statistically significant intergroup differences were observed in endoleaks, complications, or re-intervention rates (p > 0.05).

Re-intervention procedures were used to manage type I endoleaks in 3 cases by aortic extensions, 1 case in the angulated group and 2 cases in the non-angulated group (the other 2 cases of minimal endoleaks resolved spontaneously during follow-up); type II endoleaks in 2 cases by

Table 4	Complications	and re-intervention	
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	Angulated $(n = 34)$	Non-angulated $(n = 38)$	p value
Complications	7	2	>0.05
Graft occlusion	1	0	
Limb occlusion/ stenosis	4	2	
Femoral pseudoaneurysm	1	0	
Iliac artery dissection	1	0	
Re-intervention	7	5	0.235

embolization; endotension in 2 cases; and graft stenosis/occlusion in 5 cases. The 2 cases of limb occlusion in the nonangulated group were managed with femoral–femoral bypass. Four re-intervention procedures were performed within 1 month after EVAR for iliac limb stenosis/occlusion. Two cases of endotension were diagnosed during long-term followup and re-linings were performed thereafter. No patient experienced technical or clinical failure or EVAR-related death.

## Discussion

Technically, the suitability of EVAR is usually based on the manufacturer's IFU, which requires that certain criteria be respected for better outcomes. In this study, the IFU of each specific stent graft was taken into consideration whenever EVAR was indicated. As shown in Table 1, because the patients in the angulated group had relatively favorable aneurysmal neck anatomy with adequate neck length and proper neck diameter, therefore, they were candidates for EVAR after multidisciplinary discussions. The management was similar for 4 patients with short neck in the non-angulated group.

In our series, both groups demonstrated significant and consistent post-procedural angulation decreases, meaning that EVAR has a straightening effect regardless of aneurysm neck angulation degree. Moreover, the angulated group showed a 22.45 % higher mean degree of straightening than the non-angulated group, indicating that the more angulated the neck is before the procedure, the more straightening it demonstrates thereafter. An angulated aneurysm neck could be immediately straightened by the introduction of a guidewire, delivery system, and/or stent graft due to various factors such as neck anatomy and stent graft and wire design and configuration; however, the stent's radial force retains the unique and consistent impact of the aortic angle over time [6, 12, 13].

The angulated proximal neck leads to challenges in adequate material implantation, accurate deployment, and proper fixation [14]. The introduction of newly designed devices recently improved EVAR technical success and clinical outcomes, thus widening its indications, particularly in cases of challenging proximal neck anatomy. In this study, we compared the changes in neck angulation in the subgroup of patients in whom the Zenith and Endurant, the latest generation of stent grafts specifically designed to treat more challenging neck morphology, were used. Table 2 shows the significant decrease in angulation and lack of difference in late configuration between the two devices in the non-angulated group. Similar findings were obtained for the angulated group. Interestingly, recoil was observed in the angulated group with the Endurant device during follow-up, whereas the Zenith device showed a consistent straightening ability (Figs. 5, 6).

Recently published data regarding the use of the Endurant to treat patients with a hostile neck demonstrated

that this device is highly conformable and technically feasible, and provides acceptable results [15-22]. However, to our knowledge, this is the first study to describe recoil of the Endurant device during follow-up. This device consists of an M-shaped nitinol stent attached to a multifilament polyester graft, a highly conformable but kinkresistant main body, a suprarenal fixation, and a tip-capture delivery system. These components increase control over deployment, enhance proximal positioning, and provide potentially greater flexibility and migration resistance [15, 16]. On the other hand, the Zenith is a self-expanding stainless steel Z-stent that consists of an endoskeleton in the sealing portion of the first ring and the distal seal of the iliac limbs as well as an exoskeleton. Thus, the Zenith is more rigid and stronger and stretches the angulation for a longer period of time [8, 23]. Therefore, the Endurant was presumed to have better flexibility, whereas the Zenith showed a better straightening ability. We believe that these factors are potential hypotheses for explaining the late



Fig. 5 A 91-year-old woman with a severely angulated aneurysm neck (A) underwent endovascular aneurysm repair using the Zenith device. Neck angulation decreased immediately after 2 weeks (B) and continued to decrease consistently after 2 years (C)



**Fig. 6** A 73-year-old man with a severely angulated aneurysm neck (**A**). Endovascular aneurysm repair was performed using an Endurant device. A post-procedural computed tomography angiogram image

shows a significant decrease in angulation after 1 week (**B**). However, recoil was observed after 6 months (**C**) and 1 year (**D**)

recoil seen in patients in the angulated group treated with the Endurant device.

We noted a slight sac regression tendency during followup despite no significant intergroup difference at any time point. A similar trend in neck and sac remodeling was also described in another study [24]. However, our study findings imply a relatively comparable homogeneity of sample sizes since we found no statistically significant difference in patient number, aneurysm sac diameter, or neck morphology except for neck angulation between the two groups (Table 1). Multiple stepwise regression analysis results including all variables also indicated that preoperative neck angulation was the only predictor of an early postoperative angle change (p < 0.001), whereas sac diameter was the predictor of late angle configuration (p = 0.006).

In this study, the incidences of endoleak were in keeping with those of previous reports [10, 13, 17, 25, 26]. There was no intergroup difference in any endoleak type, including type I, during follow-up (p > 0.05). However, a meta-analysis revealed a significant increase in 30-day type I endoleaks and late type I endoleaks in patients with a hostile neck [27]. We presume that a reasonable explanation for this mismatch is that the angulated groups had relatively favorable neck anatomy (length and diameter), which could be responsible for the similarity in the endoleak rates between the two groups.

The rate of complications and re-interventions was not statistically different. In the 30-day period, we noted 4 cases of limb occlusion. These events occurred in older patients (>80 years) with underlying iliac artery risk factors such as tortuous, calcification, and stenosis. One patient had an aortoiliac aneurysm. The iliac arteries of Asian people are shorter and smaller than those of Caucasians. These factors would complicate access, impair fixation, facilitate kinking, and result in a higher incidence of access- and device-related complications [28–30].

Our study has several limitations. This was a retrospective analysis of a relatively small sample size. We also used 4 different types of stent grafts with different profiles and configurations based on physician preference. These were potential confounders that created selection bias.

In conclusion, EVAR is applicable to cases of severely angulated neck anatomy and provides consistent neck straightening over long-term follow-up. Recoil was observed in the angulated group treated with the Endurant device during follow-up, and further investigations are necessary to clarify its late configuration.

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#### **Compliance with Ethical Standards**

**Conflict of interest** All authors declare that they have no conflicts of interest.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study, formal consent is not required.

Statement of Informed Consent Inform consent was obtained from all individuals participants included in the study.

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