The Relationship between Temporal Changes in Proximal Neck Angulation and Stent-Graft Migration after Endovascular Abdominal Aortic Aneurysm Repair

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Background: In recent years, endovascular abdominal aortic aneurysm repair (EVAR) for treating abdominal aortic aneurysms (AAA) has become quite prevalent in Japan. Though little information is available about temporal changes in proximal neck angulation due to the difficulties encountered in measuring the angle. Therefore, we examined temporal changes in proximal neck angulation and its relationship to stent-graft migration after EVAR.

Methods: Between June 2007 and March 2010, 159 patients underwent EVAR for treatment of fusiform AAAs at our hospital. This study focuses on the 80 patients among this group whose treatment sites and subsequent stent grafts were examined by contrast computed tomographic angiography before surgery, directly after surgery (within 4 days), as well as 1 year and 2 years thereafter. We created curved planar reconstruction (CPR) images and measured the length of migration and neck angle using our method.

Results: At 2 years after EVAR, the average length of proximal landing zone was 21.4 ± 9.2 mm. The average length of stent migration after 2 years was 1.41 ± 2.68 mm. The average neck angle was 33.9° preoperatively and 29.9° directly after surgery yielding a significant difference. However, 1 and 2 years after surgery the average neck angle was 28.2° and 28.4°, respectively. The number of patients experiencing a change >6° in the angle of the proximal neck between the preoperative condition and that directly after surgery was 16 (34.8%) with the use of Zenith stent grafts ($n = 46$) and 14 (41.2%) with the use of Excluder stent grafts ($n = 34$). There was no correlation between the proximal neck angle and migration of the proximal stent graft. In addition, there was no correlation between the changes in proximal neck angle and the secondary intervention rate and the occurrence of endoleak.

Conclusions: There was a significant change in the neck angle between the preoperative condition and the immediate postoperative condition. However, there was no clear relationship found between the angle of the neck and the proximal stent-graft migration. Postoperative changes in the proximal neck angle just after EVAR and subsequent temporal changes during a 2-year follow-up period do not appear to predict stent-graft migration, secondary intervention rates, or the occurrence of endoleak.

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INTRODUCTION

In recent years, endovascular abdominal aortic aneurysm repair (EVAR) for treating abdominal aortic aneurysms (AAA) has become quite prevalent with tortuous shapes in Japan.[1,2] Though it is recognized that the force exerted on the stent graft (displacement force) is influenced by the angle of stent graft, little information is available about temporal changes in proximal neck angulation due to the difficulties encountered in measuring the angle.[3–5] Some author reported that 12% of the patients for whom EVAR was not suitable had large neck angles.[6] The temporal change of the neck angle with after EVAR is important for the indication and prognosis of EVAR. However, traditional methods of evaluating the angle were open to question in terms of the possibility of determining the extent of the change of the angle. Therefore, we examined temporal changes in proximal neck angulation and its relationship to stent graft migration after EVAR.

METHODS

Between June 2007 and March 2010, 159 patients underwent EVAR for treatment of fusiform (spindle-shaped) AAAs at our hospital. This study focuses on the 80 patients among this group whose aneurysms and subsequent stent grafts were examined by contrast computed tomographic angiography (CTA) at 1-mm intervals before surgery, directly after surgery (within 4 days), as well as 1 and 2 years thereafter. Using the contrast CTA data, we created curved planar reconstruction images (CPR images) and measured the length of migration and neck angle. The migration was measured at the proximal stent-graft position, which is the stent graft distal from the proximal edge, because it seems to be the most fixed part of the endograft.

The items considered included the length of migration, changes in the neck angle as defined in this study, the ratio between the proximal neck diameter and the implanted device diameter, and the length of the landing zone. Additionally, we examined the type II endoleak rate as well as the rate of secondary intervention.

As this study contained only deidentified data, the study is not subject to Institutional Review Board approval. However, we obtained all patients consent about using patient data and images.

Angle Measurement Techniques

''Neck angle'' was defined as the crossed-axes angle between the body axis and aortic neck and was defined for each device. The body axis was considered to be the axis perpendicular to the normal CT section. We measured these angles on anterior and lateral views using a three-dimensional (3D) CT. The 2 angles were calculated for one 3D angle using a calculation method (Fig. 1):

$$\theta(\text{degree}) = \tan^{-1}\left((\tan^2 X + \tan^2 Y)\hat{}0.5\right)$$

where X is the angle of anterior view and Y the angle of lateral view.[7]

With the Zenith device, the aortic neck was defined as one stent structure from the proximal edge of the stent graft (without the bare stent) to one stent below. With the Excluder device, the aortic neck was defined as the area from the proximal edge of the stent graft to 15 mm below. And we connected one point on the centerline of the proximal edge and the other point on the centerline of the distal edge. This line was defined as neck axis, and the angle was measured as these 2 crossed-axes angle. During the follow-up period, the neck angle was measured from the same location of the first CT after EVAR from the lower renal artery by measuring along the vessel centerline (by along the centerline). Contrast CTA was used to capture 1 mm slices of the arterial phase and curved planar reconstruction images (CPR images) were created.

Defining Migration

The migration length was defined as the difference between the distance from the bottom of the lower renal artery to the edge of proximal stent on the centerline obtained by CT measurement immediately after EVAR and the distance obtained when measuring the same section by CT 2 years later.

The Accuracy of Angle Measurement

The proximal neck angle at 6 months was measured twice by one observer. The observer was the same vascular surgeon. A plot was fabricated using the difference on the vertical axis and the average of angles on the horizontal axis (Bland–Altman Plot). This ±1.96 standard deviation (SD) area is the possible measurement error (intraobserver variability) range. An angular variation $\geq 6°$ was defined to be significant (Fig. 2A).[3]

The Accuracy of Measuring Migration

By a similar method, the migration length at 6 months was measured twice. A Bland–Altman plot was created with the differences in the 2 measurements plotted on the vertical axis and the

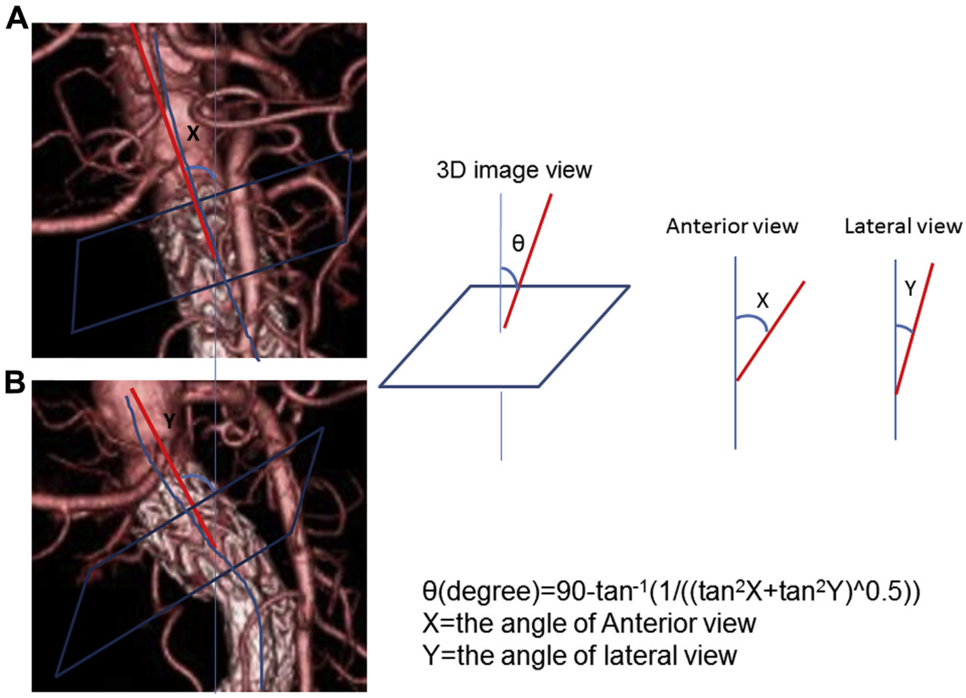

Fig. 1. Measurement techniques. At the plane including the proximal neck, measuring the angle of the body axis and center line in the anterior view **(A)** and lateral view **(B)**, which were synthesized in the following way. $\theta = 90 - \tan^{-1}(1/((\tan^2 X + \tan^2 Y)^{0.5}))$. X is the angle of anterior view and Y is the angle of lateral view.

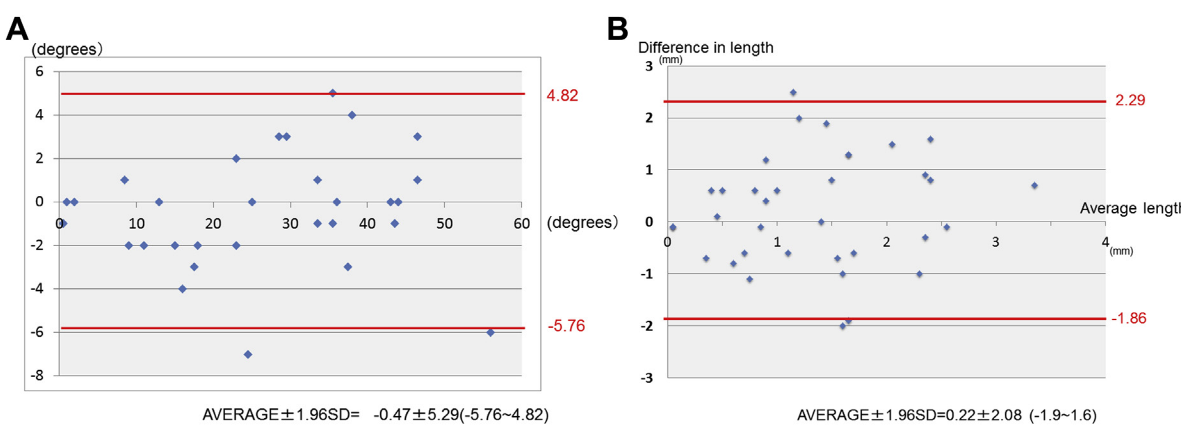

Fig. 2. **(A)** The accuracy of measuring the angle: the proximal neck angle at 6 months was measured twice for evaluation of intraobserver variability (Bland—Altman plot). An angular variation ≥6° was defined to be significant. **(B)** The accuracy of measuring the migration: the migration length at 6 months was measured twice. A Bland—Altman plot was created and the measurement error was set to be within 3 mm of CPR length.

average of length plotted on the horizontal axis. The region shown on the plot shows the measured error range and the measurement error was set to be with 3 mm of CPR length.[8] We defined the variation in migration from the deployment site to the distal side as a positive direction (Fig. 2B).

The proximal landing zone was defined as the area that device was adhering to native vessel and it is smaller than device's initial proximal diameter. The length of this area was measured by using CPR images.

All data in this study were measured using AquariusNET Viewer (TeraRecon, Inc., San Francisco,

Table I. Patient characteristics and baseline morphology

	Zenith (n = 46)	Excluder (n = 34)	P value
Age	77.5 ± 4.95	75.4 ± 4.95	0.099
Gender: male	39 (84.8%)	29 (85.3%)	0.949
Comorbidity			
Diabetes	4 (8.7%)	2 (5.9%)	0.830
Hypertension	24 (52.2%)	15 (44.1%)	0.637
Ischemic heart disease	7 (15.2%)	5 (14.7%)	0.553
Renal insufficiency	5 (10.9%)	3 (8.8%)	0.762
AAA morphology			
Angle of neck (degrees)	30.3 ± 6.98	38.8 ± 8.08	0.019
Length of neck (mm)	27.4 ± 15.4	29.0 ± 11.9	0.552

Chi-squared test used for categorical variables and *t*-test used for continuous variables.

CA) with vascular surgeons serving as intraobserver. Statistical analyses were carried out using chi-squared tests for categorical variables and *t*-tests for continuous variables. Statistical significance was set at a P value of $\leqq 0.05$.

All data were entered into an electronic spreadsheet (Microsoft Excel; Microsoft Corporation, Redding, WA) and statistical analysis was performed with SPSS 16.0 (SPSS, Inc. Chicago, IL). The relationship was tested using the Pearson's correlation coefficient and simple linear regression analysis. Bland—Altman analysis was undertaken to assess the mean error for measurements of angles and diameters. Range of agreement was defined as bias ±2 SDs.[3,8]

All CT angiographies were performed on an multiple detector computed tomography scanner with 64 detectors (Aquilion; Toshiba, Tokyo, Japan). The CT protocol was carried out with the Aquilion, using 1.0-mm collimation, 15.0 pitch, 120 kV peak, and 0.5 s rotations with a helical exposure of 10—25 s. Nonionic contrast (370 mgI/mL) was given intravenously at a rate of 3.5 mL/s (range of total dose 70—80 mL). Scanning was performed using a bolus-tracking technique to ensure optimal contrast enhancement.

We also examined other factors involved in migration, namely the ratio of the diameter of the implanted device to the vessel diameter immediately after surgery as well as the correlation between the neck length and migration. Furthermore, we divided the patients into 2 groups according to whether or not the preoperative neck angle was greater or less than 40° (the patients >40° were 22.5%) and then examined and compared the results. The neck angles became the new defined angles. This was carried out under the assumption that the larger the preoperative neck angle was, the greater the proximal displacement force would be.

RESULTS

The stent grafts in this study comprised 46 Zenith® (Cook Medical, Inc.) devices and 34 Excluder® (W. L. Gore & Associates, Inc.) devices. The study excluded EVAR using other devices, cases of ruptured AAA, and cases involving saccular aneurysms.

Patient demographics, comorbidity risks, including diabetes, hypertension, ischemic heart disease, and renal insufficiency, and baseline morphology of their AAA in the Zenith group and Excluder group were compared and are presented in Table I. The 2 groups had a similar age and gender distribution, but the mean preoperative neck angle tended to be significantly larger in the Excluder group than in the Zenith group (38.8 ± 8.08° in Excluder vs. 30.3 ± 6.98° in Zenith, $P = 0.019$). In relation to the other factors, no significant differences were observed between the 2 groups.

The average length of peripheral migration was 1.41 ± 2.68 mm, and landing length was 21.4 ± 9.2 mm 2 years after EVAR was performed.

The preoperative angle was defined as zero to provide the basis for the number of degrees in negative and positive change of the angle. The mean change of the angle was −4.0° 3 days after EVAR, −6.2° 1 year after EVAR, and −5.9° 2 years after EVAR for patients receiving the Zenith stent graft. For patients receiving the Excluder stent graft, the mean change in the angle was −4.3° 3 days after EVAR, −5.0° 1 year after EVAR, and −4.9° 2 years after EVAR. There was a significant difference between the pre-EVAR angles and the angles 2 years after EVAR using both devices ($P < 0.01$). Subsequent changes occurring after EVAR were not significant (Table II).

The preoperative angle had increased 2 years after EVAR in 2 patients (5.9%). There was no increase in the angle between the immediate postoperative measurement and the measurement taken 2 years after

Table II. The change in neck angulation from preoperative state

	Postoperative		Year 1		Year 2	(from preoperative)
Zenith	-4.0		-6.2		-5.9	
		$P = 0.08$		$P = 0.57$		
Excluder	-4.3		-5.0		-4.9	(degrees)
		$P = 0.57$		$P = 0.94$		

This table shows the average change in neck angulation from preoperative state in the 2 groups.

EVAR in any patient. Between the preoperative period and immediate postoperative period, the angle decreased over 6° or more in 16 Zenith patients (35%) and 14 Excluder patients (41%) (Table III).

Migration over 3 mm occurred in 9 patients (11%). The preoperative proximal neck length was significantly different ($P = 0.02$, *t*-test) between the migration group (migration >3 mm) and nonmigration group (migration <3 mm). However, for each device, the neck length was not significantly different between migration group and nonmigration group. Furthermore, the ratio of the diameter of vessel to the nominal diameter was not significantly different for all patients and for each device (Tables IV and V).

The migration was not significantly different between these 2 groups which had greater or less than 40° of preoperative neck angle ($P = 0.983$; Tables VI and VII).

We examined the relationship of the change in the angle immediately after EVAR and migration in each device (Table VII). Migration did not correlate with the change of angles over 6°.

The additional treatments were for 3 patients (6.5%) in the Zenith group and 2 patients (5.9%) in the Excluder group. Proximal type I endoleak occurred in the Zenith group and was treated by proximal cuff. Other procedures performed were leg extension (1 patient), coil embolization to type II endoleaks (2 patients), and type III endoleak treated by proximal cuff. For each device group, the occurrence of additional treatment was not significantly different in relation to changes in the neck angles.

Type Ia and type III endoleaks were treated by additional procedures and no endoleak was discovered 2 years after EVAR.

DISCUSSION

EVAR has become the main treatment for AAAs with tortuous shapes.[1,2] However, Elkouri et al.[6] reported that 12% of the patients for whom EVAR was not suitable had large neck angles. The temporal change in the neck angle after EVAR is important for the indication and prognosis of EVAR. However, traditional methods of evaluating the angle were open to question in terms of the possibility of determining the extent of the change in the angle. Most methods were preoperative measuring methods, but some articles that used these methods did not define the measuring methods, especially in terms of the lines that intersected to form the measuring angle.[3–5]

To measure an angle, we must first define at least 3 points and then also define 2 lines by these 3 points. Finally, these 2 lines intersect and form the measuring angle. In this study, one of 2 lines was fixed and the other line was defined by determining 2 points on the proximal neck. These points and lines were defined immediately after EVAR on the proximal neck and fixed on the location, which set the point on the aortic centerline. By setting these points on the proximal neck, the influence of the migration was eliminated in quantitatively evaluating the change in the angle over time. The neck angle in this study was the angle formed by the intersection of the body axis with the proximal neck axis. For example, when the middle point of the proximal neck curved widely, there were 2 options for the location of the device. One of the options was above the curved position and the other option was below the curved position. The difference in these 2 cases influenced the morphological change in the device and the proximal neck. However, these 2 cases yielded the same results by the conventional method of measuring the angle of the proximal neck.

We expressed the angle by one figure synthesized from the 2 figures of the angles that were measured from the anterior and the lateral directions. In some articles it was reported that the angles were measured from 2 directions or measured directly by using 3D reconstruction images.[9,10] Therefore, one objective

Table III. Angular variation in neck angle

	Pre to post	Post to year 2	Pre to year 2
Zenith ($n = 46$)			
Increase ≧ 6°	0	0	0
Increase < 6°	11 (23.9%)	16 (34.8%)	14 (30.4%)
Decrease ≧ 6°	16 (34.8%)	1 (2.2%)	20 (43.5%)
Decrease < 6°	19 (41.3%)	29 (63.0%)	12 (26.1%)
Excluder ($n = 34$)			
Increase ≧ 6°	0	0	2 (5.9%)
Increase < 6°	8 (23.5%)	15 (44.1%)	7 (20.5%)
Decrease ≧ 6°	14 (41.2%)	1 (2.9%)	13 (38.2%)
Decrease < 6°	12 (35.3%)	18 (52.9%)	12 (35.3%)

This table shows angular variation between the preoperative period and immediate postoperative period, and between the immediate postoperative measurement and the measurement taken 2 years after EVAR.

Table IV. Neck length and migration

Neck length	Migration ≧ 3 mm	Migration < 3 mm	*P* value
Average neck length 27.5 ± 12.1 mm ($n = 80$)	21.3 ± 6.8 mm ($n = 9$)	28.3 ± 12.4 mm ($n = 71$)	0.020
Zenith ($n = 46$)	21.7 ± 8.3 mm ($n = 6$)	26.8 ± 10.0 mm ($n = 40$)	0.244
Excluder ($n = 34$)	20.4 ± 3.1 mm ($n = 3$)	27.2 ± 7.9 mm ($n = 31$)	0.154

This table shows that preoperative proximal neck length was significantly different between the migration group (migration > 3 mm) and nonmigration group (migration < 3 mm). The ratio of the diameter of vessel to the nominal diameter was not significantly different for all patients and for each device.

Table V. Neck diameter and stent diameter ratio

Postoperative	Migration ≧ 3 mm	Migration < 3 mm	*P* value
Neck diameter/stent diameter 0.883 ± 0.051 ($n = 80$)	0.866 ± 0.054	0.885 ± 0.051	0.311
Zenith ($n = 46$)	0.849 ± 0.057	0.885 ± 0.055	0.149
Excluder ($n = 34$)	0.900 ± 0.035	0.885 ± 0.046	0.588

This table shows that preoperative proximal neck length was significantly different between the migration group (migration > 3 mm) and nonmigration group (migration < 3 mm). The ratio of the diameter of vessel to the nominal diameter was not significantly different for all patients and for each device.

Table VI. Preoperative neck angle and migration

Preoperative	Migration ≧ 3 mm	Migration < 3 mm	*P* value
Proximal neck angle ≧ 40 ($n = 18$)	2	16	0.983
Proximal neck angle < 40 ($n = 62$)	7	55	

The number of patients with more than 40° of proximal neck angle was18.

parameter was measured by this synthesis and the error of measurement for the selection of the direction to measure the angle on the 3D reconstruction image was avoided in this study. We also eliminated the axis of aneurysm, because the influences of the aneurysmal changes were reduced. Therefore, this method of measuring the angle of the neck was more suited for temporal evaluation.

There were no significant differences between the Zenith group and the Excluder group. Only the neck angle between these 2 devices was significantly different ($P = 0.019$). The patients with large

Table VII. Angular variation and migration

Postoperative	Migration ≧ 3 mm	Migration < 3 mm	*P* value
Zenith ($n = 46$)			
Angular variation ≧ 6°	2/16	14/16	
Angular variation < 6°	4/30	26/30	0.093
Excluder ($n = 34$)			
Angular variation ≧ 6°	1/14	13/14	
Angular variation < 6°	2/20	18/20	0.772

neck angles were more suitable for using the Excluder, and the patients in this study included patients with large neck angles using the method of ''pull-through'' or locating the stent graft by pushing the devices for setting along the proximal neck.[11,12] It has generally been believed that large proximal necks, such as in the case of these patients, lorded larger force to return the preoperative shape than proximal necks with smaller angles. Therefore we assumed that the proximal neck with large angle would return to the preoperative shape. However, in fact the change in the angle did not reach the defined significant difference 2 years after EVAR (significant difference was ≥6°; Tables IV and V) in all patients regardless of which of the 2 devices was used. Keulen et al. reported that the angle of the neck decreased after EVAR.[4] The angles also decreased in our study, and none of the angles in any of the patients increased more than the significant difference. The change in the angle was the greatest between the preoperative angle and the angle immediately after the operation. Because the enhanced CT for the immediate postoperative period was performed 3 or 4 days after EVAR, we considered that the angle of the neck had already changed during this period. These changes in the angle were not significantly different between the Zenith and Excluder groups in contradiction to the difference in the rigidity between 2 devices.

Our purpose in this study was to analyze the relationship between the variable temporal change in neck angle with the variable length of stent-graft migration, necessity of additional procedures, and occurrence of endoleaks. Therefore, we had to examine other factors or variables, besides temporal change in the neck angle, that have been reported to or have been assumed to be related to stent-graft migration. One of these factors is the ratio of the diameter of the vessel to the diameter of the neck, and when it was examined no relationship with stent-graft migration was found.[13,14] Similarly, no relationship was found between the neck length and stent-graft migration (Tables VI and VII). Furthermore, because some articles asserted that large neck angles lead to greater stress on the device leading to greater migration,[1,8,15] we analyzed the 2 groups that comprised patients with preoperative angles under 40° and over 40°, as measured by our method. Nevertheless, contrary to the reports mentioned above, there were no significant differences in these 2 groups, not only in relation to stent-graft migration, but also in relation to the necessity of additional procedures, and the occurrence of endoleaks.

The limitation in this study concerns the neck angle measuring error of 6°, which resulted in not being able to properly capture any changes within this 6° measuring error. Nevertheless, in this study changes over 6° were found only between the preoperative and immediate postoperative periods during which there were clear cases of significant decreases in the neck angle. We adopt an intraobserver variability as measurement error in this study. We measured these figures 2 times by one observer at intervals and calculated the average. Indeed if we use interobserver variability, it would give more consistency to the study. But in this study the measurement error (intraobserver variability) which was defined by the Bland-Altman plot was about 6°, and if we use interobserver variability the measurement error was larger and it might be difficult to evaluate the change in angle. Therefore we adopt an intraobserver variability as measurement error.

We also considered the necessity of examining the distal landing zone because the stent-graft devices were sustained by 3 zones as proximal and distal landing zones independently.[16–20] However, in the patients in this study who had migrations or large neck changes, there was no apparent migration of the distal landing zone.

There were 6 patients (13%) in the Zenith group and 3 patients (8.8%) in the Excluder group who experienced significant migration in the distal direction. However, no significant differences were found between these 2 devices including potential differences in the immediate postoperative change in the neck angle (Table VI).

During the 2-year period in which this study was carried out, additional procedures were performed on 5 patients and type Ia endoleak occurred in only one patient. This patient had no migration and no change in neck angle. Other procedures performed were coil embolization on type II endoleaks and leg extensions for type Ib endoleaks. After the 2-year period of the study, there were 8 other cases requiring additional procedures, but among these no procedure was performed on type Ia endoleak.

It has generally been believed that aneurysms with large proximal neck angles temporarily straighten upon placement of the device, due to the stiff wire in the device, and then gradually relapse to the preoperative neck angle during the follow-up period accompanied by occasional migration of the leg of these devices. However, the results in this study demonstrate that such a phenomenon of gradual relapse in the neck angle, in the case of large neck angles, does not appear to be such a common occurrence after the first week post-EVAR.

In relation to this phenomenon, when the angle of the neck is straightened by implanting the device, intra-aneurysmal pressure is considered to be a force that contributes to changing the shape of aneurysm and angle of the proximal neck. However, after the placement of stent grafts intra-aneurysmal pressure is reduced to about half of the preplacement pressure and consequently the forces acting to change the shape of aneurysm and proximal neck are also reduced proportionately.

It is often said that the greater the degree of the neck angle, the greater the ‘‘displacement force.’’ This so-called displacement force is the resultant displacement forces on the entire stent graft and the displacement force is simply calculated as the blood pressure on the whole inner surface of the device. The displacement force on the proximal neck and the displacement force on distal neck function separately. The forces on the proximal neck worked toward the distal directions and the forces on distal necks worked toward the proximal directions. These 3 forces (1 force on proximal neck and 2 forces on distal necks) did not work in alignment (unidirectional) and these lines of forces (vectors) did not cross the center of gravity of the device. Therefore, these forces did not interfere with one another and did not decrease each other. An exception to this observation, chiefly in the case of the AneuRx stent graft as well as some others, is that the force on proximal neck acting to maintain its position is a frictional force or the fixed force from the barb (mainly Zenith or Excluder and Endurant), which was down to about zero. All downward forces on the device acted on the device and especially on the distal landing zones. When this case occurred, almost all migration forces worked on the distal landing zones.

CONCLUSION

In this study, we examined the relationship between the temporal change in the proximal neck angle and the migration of the proximal stent position, which is one stent distal from the proximal edge, because it seems to be the most fixed part of the endograft. In this defined position, there were significant differences in the preoperative to postoperative angles. However, there were no significant subsequent changes in the proximal neck angle at 1 and 2 years after EVAR. The results of the study indicate that, during the 2-year period after EVAR, changes in the neck angle cannot function as a predictor of migration, secondary intervention, or endoleak.

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