

## Mid-term Fixation Stability of the EndoVascular Technologies Endograft\*

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**Aim of the study:** to determine the positional stability of the EndoVascular Technologies (EVT) endograft after endovascular aneurysm repair during morphologic changes of the abdominal aorta during follow-up.

**Patients and methods:** all patients treated worldwide with an EVT endograft with an adequate postoperative and at least 12 months postoperative CT scan were included (n=125). Endograft migration was investigated by recording the position of the endograft attachment systems relative to the renal arteries and the aortic or iliac bifurcations. The vertical body axis served as a scale to quantify migration.

Aortic cross-sectional areas were measured in the suprarenal aorta and in the proximal and distal aneurysm necks. Length changes of the infrarenal aorta during follow-up were measured, comparing the distance between the left renal artery and the aortic bifurcation.

**Results:** the median follow-up was 24 months (range 12–48 months). Graft migration was identified in 4 out of 125 patients (3%).

Significant infrarenal aortic dilation was observed at the proximal and distal aneurysm neck during follow-up. However, aortic neck dilation was not associated with endograft migration. The length of the infrarenal aorta did not change significantly after endovascular repair.

**Conclusion:** fixation by stents containing hooks of the EVT design appear to be effective in preventing migration of endografts with an unsupported trunk for up to four years. A stable position was maintained in spite of changes in cross-sectional areas of the aneurysm neck.

**Key Words:** Endograft; Endovascular aneurysm repair; Migration; Hooks.

### Introduction

Endovascular aneurysm repair can be performed effectively.<sup>1–8</sup> In order to compete with transabdominal aneurysm surgery, this new technique must also provide long-term exclusion of the abdominal aneurysm. The essential difference between the two techniques is the fixation of the graft to the aortic wall; a hand-sewn suture under direct visual control can only be achieved by open aneurysm repair. A number of systems have been developed to provide a durable fixation of the endograft to the aortic attachment areas. Three principles are applied to keep the endograft in position: outward radial forces of the stents, columnar strength of fully stented endografts, and hooks penetrating the aortic wall.

A number of late complications have been encountered following the endovascular repair, particularly late endoleaks caused by migration of the

entire endoprosthesis or one of its components.<sup>9</sup> Migration may result from insufficient fixation of the endoprosthesis to the aortic wall or by changing morphology of the abdominal aorta during follow-up. Dilation of the proximal and distal aneurysm necks has already been demonstrated, but the relationship to graft migration remains to be proven.<sup>2,8,10</sup>

The attachment systems of the EndoVascular Technologies (EVT) endografts have been designed to prevent graft migration by inserting hooks into the aortic wall<sup>11–14</sup> (Fig. 1). The aim of this study is to investigate the long-term efficacy of this system in preventing endograft migration in the perspective of the morphologic changes that affect the abdominal aorta during follow-up.

### Patients

All patients treated worldwide with a first or second generation EVT endograft from the start in February 1993 up to October 1996 were candidates for this study

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**Fig. 1.** Hook/stent assembly of a second generation EVT endograft. Four V-shaped shanks containing two hooks each are sewn to the polyethylene graft, in-between the limbs of the zigzag stent.

( $n = 186$ ). The data and image material retrieved from the trial databases on EVT endografts represent initial experience with endovascular aneurysm repair from 21 U.S.A., one Australian and five European centres.

As this study focuses on long-term durability of endograft fixation, only those with a first-to-third postoperative day and at least a 12-month follow-up CT scan available for measurements were included ( $n = 125$ ).

The reasons for exclusion of the remaining 61 patients were recorded by the independent core lab for the EVT trials (Cleveland, U.S.A.). In 12 patients immediate conversion to open aneurysm repair was performed due to technical failures. Five patients were converted within six weeks following operation because of massive endoleaks. Another four patients were converted in the first postoperative year for persistent early endoleaks and aneurysm growth. Four patients were converted because of hook breakage in completely excluded aneurysms based on the physicians' decisions.

Fourteen patients died. One patient died on the first postoperative day due to perioperative complications. During the first postoperative year, six patients died of unrelated causes and seven patients of unknown cause. Twenty-two patients were excluded for protocol violation due to unavailability of CT investigations.

The median follow-up period of the included patients was 24 months (range 12 to 48 months). Sixty-one patients had a follow-up period of 1 to 2 years, 42 patients a period of 2 to 3 years and 22 patients a

period of 3 to 4 years. One hundred and eleven patients were male, the median age at the time of operation was 71 years (range 41–87 years). The median aneurysm diameter at the time of the operation was 53 mm (range 35–77 mm). All patients had been enrolled in prospective clinical studies: 101 patients in the phase 1 and 2 U.S.A. trials and 24 patients in an international trial. An EVT endograft of the first generation had been inserted in 87 patients and a second generation graft in 38.<sup>13,14</sup> Tube and bifurcated endografts were used in 106 and 19 cases, respectively.

## Methods

The same investigator performed all measurements. The immediate postoperative contrast-enhanced CT images were used as a reference; the last available follow-up images were applied for comparison.

### *Investigation of endograft migration: definition of the reference levels and the position of the proximal and distal attachment systems*

Registration of the position of the attachment systems was performed by measuring the distance between anatomic and prosthetic landmarks, using the vertical axis as a scale.

The ostium of the left renal artery was used as the reference level for defining the position of the proximal attachment system. When the ostium of the left renal artery was projected on more than one axial CT image, follow-up images were compared to the postoperative CT images showing the closest morphologic resemblance. When the left renal artery could not be identified on the postoperative or the follow-up CT images, the right renal or superior mesenteric artery was used as a reference. The most cephalic CT image showing any part of the attachment-system frame or hooks was used to define the most cephalic position of the proximal attachment system.

The aortic bifurcation was utilised as the reference level for the distal attachment system of the tube endograft. The aortic bifurcation was defined as the first image demonstrating complete separation of the left and right common iliac arteries. The most caudal image showing part of the frame or hooks was used to mark the most caudal position of the distal attachment system of a tube endograft. A similar method was applied to define the position of the distal attachment systems of a bifurcated endograft; the most cephalic images showing complete separation of the left and right external and hypogastric arteries were used as reference levels.

The distance between the reference levels and the levels of the proximal and distal attachment systems on the postoperative scans was compared to the corresponding measurements on the last follow-up scans, in order to investigate downward migration of the proximal parts and upward migration of the distal parts of the endografts.

*Investigation of morphologic changes of the abdominal aorta: methodology and definition of the levels of measurement*

Size changes of the abdominal aorta were investigated by measuring the aortic cross-sectional area in the axial plane at 3 levels on the immediate postoperative and last follow-up scans; the suprarenal aorta at 10 mm above the most cephalic renal artery, the proximal aneurysm neck at 10 mm below the most caudal renal artery and the distal aneurysm neck at 10 mm cephalic to the aortic bifurcation (tube endografts only). Assessment of the cross-sectional area was performed by outlining the outer aortic circumference of scanned CT images. Automated computer-calibrated cross-sectional area measurements were subsequently obtained using UTHSCSA Image Tool (University of Texas Health Science Center, San Antonio, TX, U.S.A.). Infra-renal aortic length was measured by selecting the axial CT images that revealed the level of the ostium of the left renal artery and the aortic bifurcation respectively. The number of CT cuts multiplied by slice thickness represents the infrarenal aortic length measured along the vertical body axis. Only those cases that had comparable images of the postoperative and follow-up CT scans available for measurement were included. Changes in the suprarenal aorta and proximal aneurysm neck were investigated in 80 and 111 patients respectively. Changes in the distal neck in tube-graft cases were determined in 86 patients. Changes in length could be studied in all cases.

*Definition of measurement accuracy*

Axial CT images represent a volume of the scanned subject, projected in a two-dimensional plane. The

anatomic and prosthetic landmarks may be positioned anywhere along the vertical axis of this volume. Therefore, the inaccuracy of the investigation of both endograft migration and length changes is determined by the slice thickness of the postoperative and follow-up CT images. A maximum slice thickness of 2 to 3 mm was encountered in 35 patients; a maximum thickness of 4 to 5 mm in 37 and of 6 to 10 mm in 53. Migration was defined as a change between the level of anatomic landmark and the level of the attachment system, exceeding the maximal slice thickness.

A change in distance between the renal artery and the aortic bifurcation exceeding the maximal slice thickness of both the postoperative and the follow-up images was interpreted as lengthening or shortening; length changes within the maximum slice thickness were regarded as "no change". The intraobserver variability of cross-sectional area registration was based on randomly repeated measurements of 30 axial images, using the method described by Bland and Altman.<sup>15</sup> The 95% confidence interval for cross-sectional area assessment was  $\pm 9\%$ . Changes between the postoperative and follow-up images smaller than 9% of the postoperative cross-sectional area were regarded as non-significant and defined as "no change". An increase of 9% or more was regarded as neck dilation, a decrease of 9% or more as shrinkage. Any tendency of size changes of the abdominal aorta based on the described length and cross-sectional area measurements were tested for statistical significance using the Wilcoxon rank test.

## Results

### *Endograft migration*

Migration of the endograft attachment systems was found in 4/125 patients (3.2%; Table 1). Downward migration of the proximal attachment system was encountered 1/125 cases (Fig. 2; 0.8%). The proximal

**Table 1.** Description of cases demonstrating migration of the endograft.

Case	Diagnosis (months p.o.)	Generation device	Attachment system	Migration (mm)	Probable cause	Outcome
A	24	First	Distal	13	Incorrect deployment, late endoleak	Conversion 24 months p.o.
B	24	First	Distal	16	Persistent endoleak	Conversion 24 months p.o.
C	15	First	Distal	20	Incorrect deployment, late endoleak	Conversion 25 months p.o.
D	15	First	Proximal	11	Multiple hook breaks	Conversion 17 months p.o.

p.o. = post operative.

**Table 2. Changes in cross-sectional area (CA) during follow-up. Cross-sectional areas are presented in square millimetres and expressed as a median value (range).**

Level of measurements	Postoperative CA	Final CA	Change in absolute values	Change in % yearly
Suprarenal aorta	458 (290 to 762)	462 (286 to 780)	0 (−187 to 157)	−0.7% (−18 to 36%) n.s.
Proximal aneurysm neck	456 (200 to 689)	475 (242 to 677)	37 (−208 to 158)	4.1% (−19 to 47%)***
Distal aneurysm neck	394 (186 to 1428)	425 (235 to 1199)	27 (−502 to 334)	5.3% (−22 to 62%)***

\*\*\*:  $p < 0.001$ ; n.s. = not significant.

attachment system of this first generation endograft was deployed 20 mm caudal to the renal arteries, in a long proximal aneurysm neck. Migration followed multiple fractures of the stent. This was presumed to be the cause of migration and was the indication for converting the patient to transabdominal aneurysm repair. Upward migration of the distal attachment system of a tube endograft was found in 3/106 patients (2.8%). In 2/3 cases, the distal attachment system was positioned at 8 to 10 mm proximal to the aortic bifurcation in a wide distal aneurysm neck (both 500 mm<sup>2</sup>, maximal diameter 27 and 29 mm respectively; Fig. 3). Inaccurate positioning during deployment of the distal stent appeared to be the cause of migration in these two cases. A third case was associated with a persistent distal endoleak.

The design of the EVT attachment systems was thoroughly revised after detection of hook breaks. Neither endograft migration nor attachment system breaks were encountered in patients with second generation endografts ( $n = 38$ ).

#### *Changes in aortic cross-sectional area*

No significant changes in aortic cross-sectional area were found in the suprarenal aorta ( $z = 0.32$ ,  $p = 0.8$ ; Table 2).

A significant median yearly increase in cross-sectional area of 4.1% (−19 to 47%) was demonstrated in the proximal aneurysm neck ( $z = 4.3$ ,  $p < 0.001$ ; Table 3). Aortic dilation at this level was found in 49/111 patients (44%, Table 3). Dilation of the proximal aneurysm neck was not demonstrated in the patient with migration of the proximal attachment system.

In patients with a tube endograft, a significant median yearly increase in cross-sectional area of 5.3% (−22 to 62%) was found in the distal aneurysm neck ( $z = 4.2$ ,  $p < 0.001$ ; Table 2). An increase in size was demonstrated in 41/86 cases (48%, Table 3). Significant distal neck dilation was also found in the patient with the persistent distal endoleak.

#### *Length changes of the infrarenal aorta during follow-up*

The median length of the infrarenal aorta – defined as the difference between the renal arteries and the aortic bifurcation – was 11.8 cm (8.9 to 15.9 cm) after operation and 11.8 cm (9.0 to 16.0 cm) at the last follow-up examination. The median change in length during follow-up was 0 cm (range minus 1.3 to 2.1 cm). Lengthening was seen in 17/125 patients (14%, median increase 0.8 cm (0.3 to 2.1 cm)). Shortening was found in 11/125 cases (9%; median decrease 0.9 cm (0.6 to 1.3 cm)). No significant changes were found in 97/125 cases (77%). Length changes of more than 1 cm were encountered in 8/125 patients (6%; lengthening 4, shortening 4). Migration of the endograft was not encountered in any of these patients.

## Discussion

Endovascular aneurysm repair has been introduced to provide prophylaxis against aneurysm rupture using minimally invasive surgical procedure. The feasibility and early results of endovascular aneurysm repair have been described in numerous reports on prospective studies with acceptable to excellent peri-operative morbidity and mortality.<sup>1–8,10,11,16,17</sup> Mid-term device- and technique-related complications are being reported, necessitating re-evaluation of patient selection and endograft design.<sup>8,14,16,18</sup>

One of the critical issues is prevention of endograft migration. The design of the endografts used in this study appeared effective in preventing migration. Ninety-seven per cent of the endografts retained their

**Table 3. Significant changes of cross-sectional areas during follow-up. All follow-up measurements found within  $\pm 9\%$  of the postoperative measurements were defined as “no change”.**

Level of measurements	Decrease	No change	Increase
Suprarenal aorta ( $n = 80$ )	17	46	17
Proximal aneurysm neck ( $n = 111$ )	14	48	49
Distal aneurysm neck ( $n = 86$ )	12	33	41

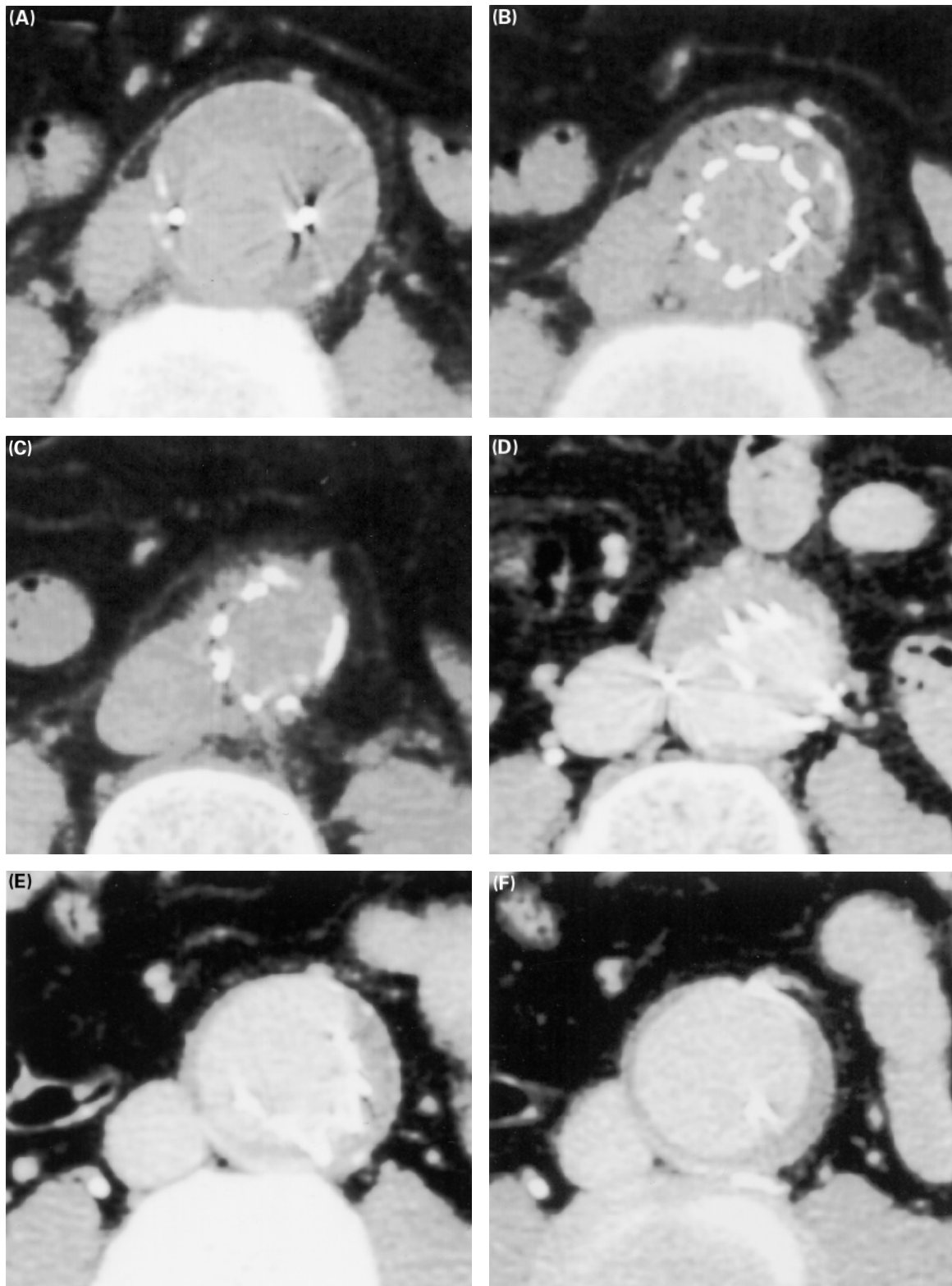




**Fig. 2.** Postoperative and last abdominal X-rays of the sole patient demonstrating migration of the proximal stent. Migration is clearly demonstrated by the insets. The inset of 15 months' X-ray (lower right) shows the remnants of the fractured hooks and a different position of the stent relative to the vertebrae.

initial position during follow-up. Three out of four cases of endograft migration concerned the distal attachment system in grafts of tubular design. No migration was demonstrated in endografts of bifurcated design. However, bifurcated grafts were not available during the first two years of EVT endograft trials. Currently, no more than 10% of all candidates for endovascular AAA repair seem to be suitable for a tube endograft because of the absence of a sufficiently

long non-dilated distal aortic neck. When a suitable neck is present, accurate positioning of the distal stent is challenging, because the endograft delivery system is difficult to position in line with the aortic axis. This is caused by the marked angle between the common iliac artery and aortic axis. Malalignment may result in endograft deployment at some distance from the aortic bifurcation, losing a few millimetres of indispensable attachment area for the distal stent. This



**Fig. 3.** Proximal migration of the distal stent of a tube endograft. The axial CT images represent the level of the maximum aneurysm size (A), the level of the center (B), and the level of the distal end of the stent (C). The postoperative image B demonstrates an incomplete stent-to-wall contact, due to incorrect deployment of the endograft.

technique-related problem was encountered in two out of three cases of distal migration in this study. One should bear in mind that the accuracy of this study to reveal endograft migration is limited by CT slice thickness, which varied from two to ten millimetres.

May *et al.*<sup>19</sup> reported the mid-term results using varying types of endografts. In their experience, tube endografts performed badly compared to endografts of bifurcated or monoiliac design. The management of patients with a wide or diseased distal aortic cuff should therefore preferably be performed using an endograft extending into the iliac arteries.

The majority of systems currently available use self-expanding stents to hold the endograft in its original position.<sup>13,20-25</sup> Circumferential contact of the endograft to the arterial wall relies on the outward radial forces of these stents. They are usually oversized by a few millimetres compared to the aortic diameter in order to obtain an optimally effective radial force. Dilatation of the proximal and distal aneurysm necks in the years following endovascular aneurysm repair has been reported.<sup>2,8,10</sup>

The average diameter of the infrarenal aorta increases by a few millimetres during a lifetime.<sup>26,27</sup> A much higher rate has been found after aneurysm repair by both endovascular and transabdominal methods. Matsumura *et al.* and Broeders *et al.* independently reported on a non-significant dilatation of the proximal aneurysm neck of 0.3 to 0.6 mm/year after endovascular aneurysm repair, while a significant increase in median diameter of the distal aneurysm neck of 0.9 to 1.2 mm was found.<sup>2,8</sup> Malina *et al.* found a median increase of 2 mm at the level of the proximal neck at 12 months.<sup>10</sup> These findings are confirmed by the results of this study. The exact roles of self-expanding stents and progression of aneurysmal disease on neck dilatation are unknown. A dilated proximal or distal neck is generally considered an exclusion criterion for endovascular aneurysm repair. Nevertheless, pathologic changes of the arterial wall may be present before dilatation, as experienced in open aneurysm repair. Illig *et al.*<sup>28</sup> found a mean increase of the proximal aortic cuff of 0.6 mm/yr in a group of 33 patients that underwent transabdominal aneurysm repair. Significant dilatation was found in 55% of these patients, with the amount of dilatation depending on the neck size at the time of operation. Neck dilatation experienced during follow-up may therefore be explained partly by progression of arterial disease in patients with aortic aneurysm. The outward forces of self-expanding stents will decline when the inner arterial circumference approaches the maximal stent

circumference. Theoretically, endografts not fixed by other means may be prone to dislodgement and migration when there is continuing aortic neck dilation. The long-term evaluation of attachment areas of endografts is required to evaluate the durability of endograft fixation by self-expanding stents.

Additional protection against graft migration is claimed by stenting the full length of the endograft trunk and limbs.<sup>29</sup> This provides columnar strength that will help the endograft to resist the downward forces of a pulsatile blood flow. This may indeed reinforce the vascular prosthesis, but it limits the capacity of an endograft to adapt to changes in the length and morphology of the aorta and iliac arteries during follow-up. Although upward migration of fully stented devices due to shortening of the aneurysm after exclusion is an uncommon problem, disintegration of fully stented modular systems has been associated with the changing morphology of the excluded segment of the aorta and iliac arteries.<sup>18</sup> A tendency towards shortening or lengthening of the infrarenal aorta after endovascular repair could not be demonstrated by this study. However, it should be noted that changes in length were measured along the vertical body axis, while changes in aortoiliac anatomy in aneurysmal disease occur in a multiplanar orientation. Investigation of endograft position in relation to morphologic changes of the excluded arterial segment should therefore preferably be performed by more sophisticated measurement techniques, such as analysis of central lumen lines.<sup>30-33</sup> Length changes of more than one cm were found in 8 patients (6.5%) included in this study. Graft migration was encountered in none of these cases, suggesting adequate adaptation of the non-stented endograft body. In conclusion, fixation of endografts by hooks embedded in the arterial wall provides a durable protection against migration at mid- to long-term follow-up. Although proximal and distal aneurysm necks dilate after endovascular aneurysm repair, this did not induce endograft migration in this study. Likewise, changes in the length of the infrarenal aorta were not related to displacement of the endograft.

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