Concerns for the durability of the proximal abdominal aortic aneurysm endograft fixation from a 2-year and 3-year longitudinal computed tomography angiography study

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Objective: **To provide a long-term perspective on the durability of the proximal abdominal aortic aneurysm endograft fixation from a single device series with perpendicular neck measurements in two groups of patients with complete 2- and 3-year follow-up.**
Design: **This was a prospective study of postoperative, radiologic images.**
Setting: **The study used a referral center, institutional practice, and ambulatory patients.**
Subjects: **From January 1994 until May 1998, 37 endografts were implanted for abdominal aortic aneurysm. In the first postoperative year, there were four unrelated deaths and six conversions, leaving 27 patients with complete 24-month data and 13 with complete 36-month data.**
Main Outcome Measure: **Computed tomography angiograms were processed on a work station to measure the neck perpendicular to the central lumen line of the aorta. The surface area at the proximal endovascular anastomosis was recorded at each follow-up interval and related to the postoperative size at the same level.**
Results: **Significant dilatation of the surface area was found: 20% (16% to 27%) at 24 months ($c^2 = 30$; $P < .001$, Friedman) and 23% (18% to 28%) at 36 months ($c^2 = 27$; $P < .001$, Friedman). This increase in neck size was continuous and linear, with a yearly rate of approximately 10% surface area; translated into diameter, this approximates 1 mm/y.**
Conclusion: **A continuous aortic enlargement of approximately 1 mm/y at the level of the proximal endovascular anastomosis was found. Because of the practice of oversizing the endograft relative to the infrarenal aortic neck, a loss of the endovascular seal may not become apparent until several years after endovascular abdominal aortic aneurysm repair is performed. (J Vasc Surg 2001;33:S64-9.)**

The long-term performance of a vascular graft depends on the durability of the anastomoses and graft material. Satisfactory long-term results after conventional repair of an abdominal aortic aneurysm (AAA) have been reported.[1-6] With the development of endovascular aneurysm repair (EAR), distinct deviations from the conventional type of anastomosis and graft materials have evolved. It is clear that these new features are not necessarily as durable as conventional aneurysm repair. Currently, results of EAR are available only for the short- and mid-term. One crucial distinction between the conventional and the endovascular method is the fixation of the graft to the proximal aortic neck. Most of the available endografts are secured in the proximal neck by radial force. Few devices rely on hook fixation, which has been demonstrated to better resist pulling forces in bench tests.[7] However, with continued dilation of the proximal neck after EAR, both radial force and hook fixation attachment systems are theoretically at risk for long-term failure.

Size changes of the proximal neck after EAR have been the subject of several earlier studies.[8-10] Unfortunately, the results of these studies are inconsistent, and several limitations preclude valid conclusions: short-term follow-up, small patient numbers, and inaccurate measurements.[11]

The aim of this study was to provide a long-term prospective on the durability of proximal AAA endograft fixation in two groups of patients with complete 2-year and 3-year follow-up.

PATIENTS AND METHODS

In May 2000 patients with complete follow-up of at least 24 months were identified. From January 1994 until May 1998, 37 patients received an endovascular graft for an infrarenal AAA at the University Medical Center

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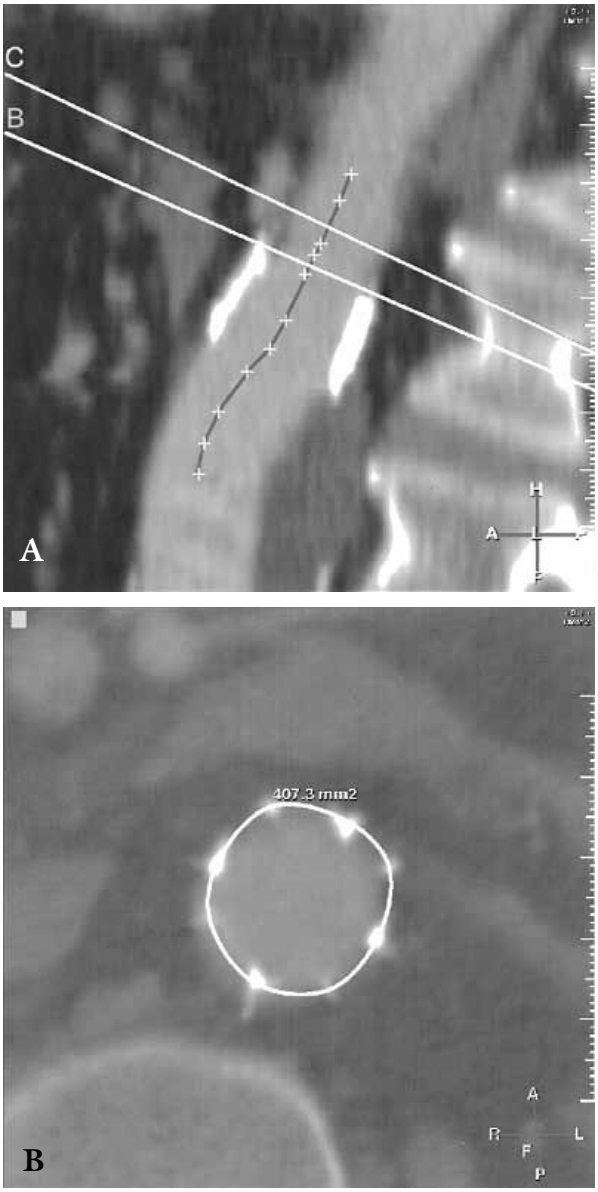

Fig 1. A, Saggital reconstruction of spiral CTA of pararenal aorta after endovascular AAA repair. Cross-marked line represents central lumen line. *Lines B* and *C* represent planes perpendicular to central lumen line at level of proximal endovascular anastomosis and at level immediately distal to lower-most renal artery, respectively. These planes are depicted in **B** and **C**. **B,** Spiral CTA reconstruction of plane perpendicular to central lumen line, at level of proximal endovascular anastomosis, with standard window level (60 HU) and width (4000 HU) settings for measurement. Contour has been drawn manually through tips of all eight struts/hooks of attachment system and encloses cross-sectional surface area. **C,** Spiral CTA reconstruction of plane perpendicular to central lumen line immediately distal to lower-most renal artery (left, in this case). Distance between plane **B** and **C** along central lumen line is distance between renal artery and attachment system.

Utrecht. Ten patients were excluded: four died of unrelated causes, and six were converted (two in the first month, the other four in the rest of the first year; all for persisting endoleak). This resulted in study group A consisting of 27 patients (24 male and 3 female) with a median age of 68 years (IQ range, 63 to 71). Six aortoaortic, three aortomonoiliac, and 18 bifurcated EVT/Ancure (Guidant, Menlo Park, Calif) endografts were implanted. In 13 (11 male and 2 female) of these 27 patients, 36-month data were also available (group B), with a median age of 68 years (IQ range, 63 to 69), with six tube and seven bifurcated grafts.

Helical computer tomography angiography (CTA) was performed on all patients at discharge, 6 months, 12 months, and yearly thereafter. All scans were obtained according to a standardized acquisition protocol on a Philips CT scanner (SR7000 or SR8000/AV-EP, Philips Medical Systems, Best, The Netherlands). An amount of 140 mL of intravenous contrast was administered at an injection rate of 3 mL/s, starting 30 seconds ahead of scanning. Scanning started at the level of the twelfth thoracic vertebra, which is the presumed position of the celiac trunk; 50 to 70 rotations of 1 second each were made. The collimation was set at 5 mm/s and the table speed at 5 mm/s, resulting in a pitch of 1. The length of the scanned volume was therefore at least 25 cm.

The resulting 173 CTA data sets were evaluated in random order by one observer. A central lumen line was drawn manually through the aorta by positioning points in the center of the lumen with the axial, sagittal, and coronal reformats on an EasyVision work station (release 4, Philips Medical Systems, Best, the Netherlands). With this central lumen line, a curved linear reformatted image was created representing a plane perpendicular to this line at

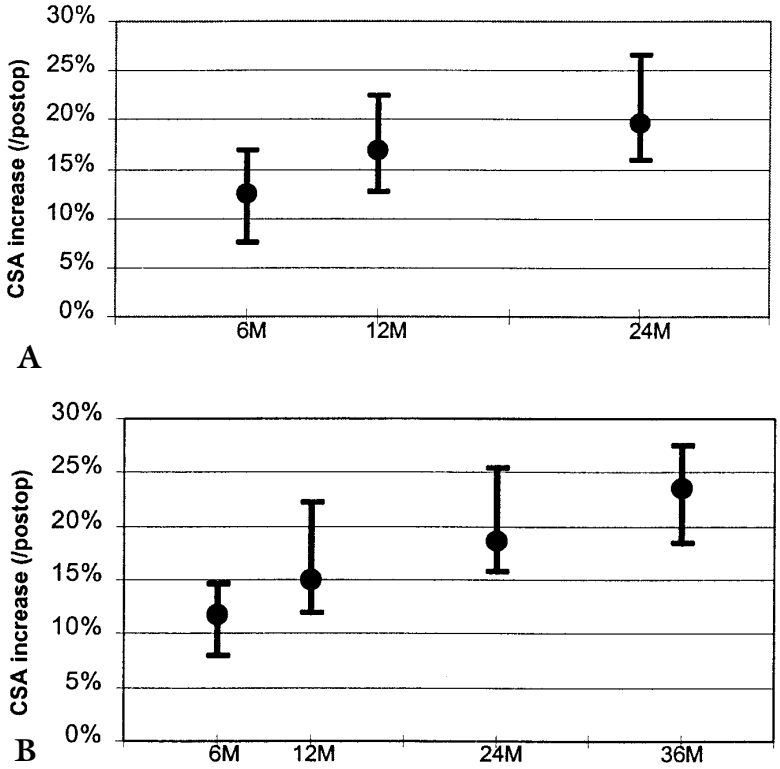

Fig 2. A, Median (quartile range) changes of proximal neck cross-sectional surface area in group A: 2-year follow-up complete (n = 27). **B,** Median (quartile range) changes of proximal neck cross-sectional surface area in group B: 3-year follow-up complete (n = 13).

each level (Fig 1, *A*). This allowed the measurement of the cross-sectional surface area (CSA) perpendicular to the central lumen line at the level of the proximal endovascular anastomosis (PEA level). This appears to be the most relevant area to follow in the Ancure endograft, and it also allows reproducible measurements, because it can be reproduced accurately at each follow-up CT scan. The PEA level was determined as follows: starting in the midportion of the proximal attachment system, the curved linear reformatted images were assessed in a 1-mm stepwise fashion, moving cephalad in the direction of the renal arteries. The last image at which all eight hooks of the proximal attachment system were visible was designated the PEA level (Fig 1, *B*). Window level and window width was set at 60 HUs and 4000 HUs, respectively. Because this method is based on the position of the attachment frame, it cannot be used before the operation. Therefore enlargement of the CSA at the PEA level over time was calculated with the discharge CSA at the same level as the baseline.

In addition, the distance between the PEA level and the most distal renal artery was measured along the central lumen line (Fig 1, *C*).

The nominal CSA of the attachment system was calculated with the nominal diameters: 20 mm, 22 mm, 24 mm, and 26 mm amount to 314 mm^2, 380 mm^2, 452 mm^2, and 513 mm^2, respectively. Graft oversizing relative to the proximal neck (oversize ratio) was calculated by dividing the nominal CSA by the follow-up CSA. CSA increase and oversize ratios are expressed as median (quartile range).

The Institutional Review Board approved the protocol and informed consent, and all patients gave signed informed consent.

Nonparametric tests for related samples (Wilcoxon signed rank and Friedman) were used to assess significance of the changes in CSA. The correlation coefficient between CSA enlargement and neck size, oversize ratio, presence or absence of endoleak, and the distance between the PEA level and the most distal renal artery was calculated with the Spearman test. A value of $P < .05$ was considered statistically significant.

RESULTS

All patients showed an increase of the CSA over time, with a median increase of 20% (16% to 27%) at 24 months in group A ($\chi^2 = 30$; $P < .001$, Friedman) and 23% (18% to 28%) at 36 months in group B ($\chi^2 = 27$; $P < .001$, Friedman). The trend in group A appeared to indicate a decrease of the growth rate with a plateau at approximately 20% at 2 years (Fig 2, *A*). Group B, however, demonstrated a continuous increase of the CSA at 3 years: 19% at 24 months versus 23% at 36 months ($Z = -3.0$; $P = .03$, Wilcoxon, Fig 2, *B*).

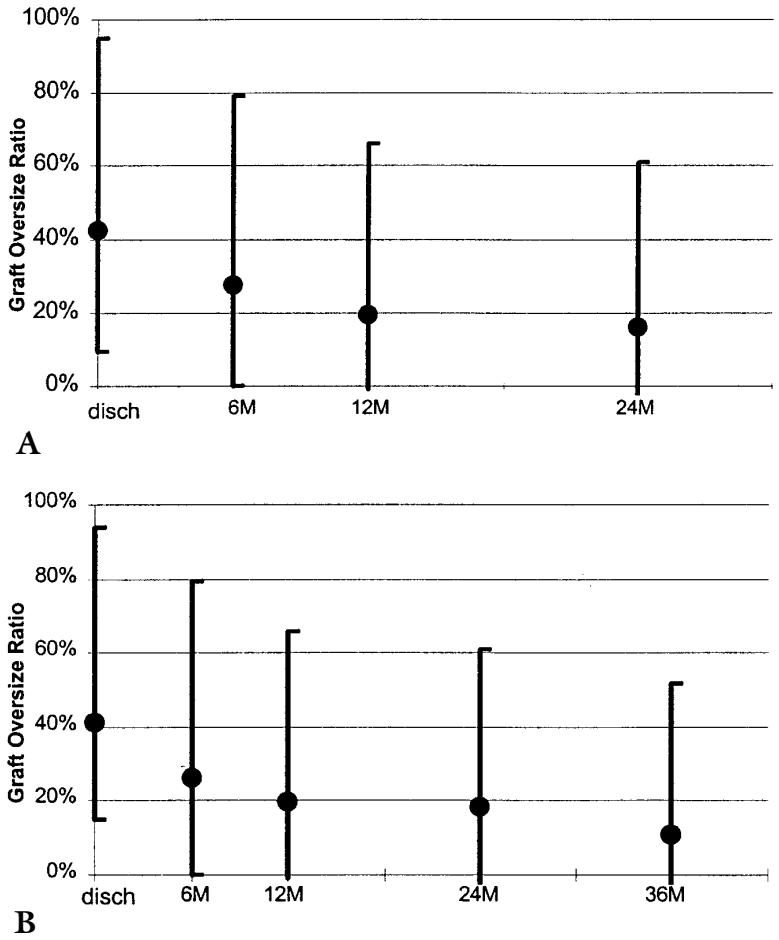

Fig 3. A, Median (absolute range) graft oversize ratio of proximal neck relative to nominal endograft cross-sectional surface area in group A: 2-year follow-up complete (n = 27). **B,** Median (absolute range) graft oversize ratio of proximal neck relative to nominal endograft cross-sectional surface area in group B: 3-year follow-up complete (n = 13).

When presenting the neck changes relative to the nominal size of the implanted endograft, similar changes can be demonstrated in terms of the oversize ratio (Fig 3). At discharge a median oversize ratio of 43% (maximum 95%, minimum 9%) was found, declining to a median of 16% at 24 months in group A ($Z = -4.5$; $P < .01$, Wilcoxon). In group B the discharge median oversize ratio of 41% decreased to a median of 11% at 36 months ($Z = -3.2$; $P < .01$, Wilcoxon). In four patients negative oversize ratios were found at 36 months (1% to 5%), indicating the error margins of these measurements as an Ancure attachment system cannot be expected to dilate beyond its nominal size.

The CSA increase did not correlate with postoperative neck size ($r = -.18$; $P = .38$), nominal graft size ($r = .34$; $P = .84$), and the presence or absence of early ($r = .22$; $P = .26$) or late endoleak ($r = -.08$; $P = .69$). A weak but statistically significant correlation was found between CSA increase and oversize ratio at discharge ($r = .55$; $P = .03$). Finally, no correlation was found between CSA increase and the distance between the PEA level and the most distal renal artery ($r = .01$; $P = .97$).

Two patients were suspected to have secondary failure of the proximal endovascular anastomosis. The first patient was treated with a 24-mm graft in an 18-mm neck. The attachment frame accidentally landed too far distal (17 mm below the renal arteries) and tilted relative to the axis of the proximal aortic neck. The postoperative CTA scan revealed a type 1 endoleak at the proximal anastomosis, but this endoleak spontaneously sealed after 11 days. Subsequently, the thrombus volume decreased by 50% at the 2-year follow-up visit, and the proximal neck CSA increased by 43%. At the 3-year follow-up visit, a recurrent type 1 endoleak was found, and the thrombus volume had regained its preoperative volume. In the second patient successful EAR was followed by a decrease of the thrombus volume of almost 80% at 3 years. At the same time the proximal neck CSA had increased by 24%. It is surprising that through the 4- and 5-year follow-up visits, the thrombus volume almost returned to the preoperative value without evidence of an endoleak. On close

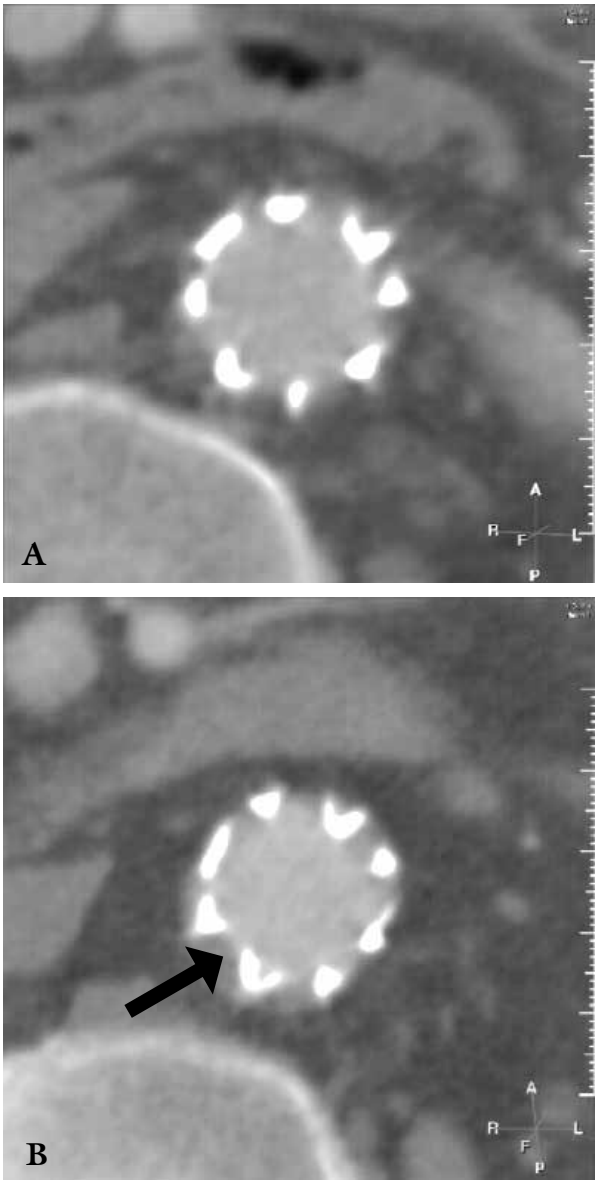

Fig 4. A, Spiral CTA reconstruction of plane perpendicular to central lumen line, at level of the proximal endovascular anastomosis, 1 day after EAR. **B,** Spiral CTA reconstruction of plane perpendicular to central lumen line, at level of proximal endovascular anastomosis of same patient as in **A**, 5 years after EAR. Note darker area outside contour of attachment system but inside aortic neck (*arrow*), probably representing thrombus lining between attachment system and aortic wall.

examination of the proximal neck, however, a circumferential layer of thrombus, not present earlier, was noted between the aortic wall and the attachment frame (Fig 4). Both patients were converted to conventional AAA repair.

DISCUSSION

Earlier studies of neck changes after EAR have shown contradictory results.[8-10] There are several limitations to these studies, explaining the inconsistent results. Even though a relatively large number of EAR procedures were analyzed, the number of patients available for long-term analysis (>24 months) in these studies is very small. Invariably, because of an increasing institutional yearly number of endovascular procedures over the study period, a large majority of patients in the study populations had a follow-up of less than 2 years. Therefore the mean neck diameter at the 6- and 12-month intervals was mainly determined by patients treated in the year before the analysis. As a consequence, changes in practice such as accepting larger neck diameters for EAR more frequently over time and the availability of larger endograft sizes may preclude valid comparison of the 6- and 12-month data with patients with longer follow-up. This bias, caused by so-called front-loading of the series, can be avoided by restricting the analysis to patients who have at least a 24-month follow-up. Our study describes a true longitudinal analysis of 27 patients with 24-month results and 13 patients with 36-month results.

Furthermore a substantial source of variation in the earlier reports probably results from the inaccuracy of measurements taken from axial hardcopy CTA cuts. It is important to measure in a plane perpendicular to the center line of the aortic neck, which requires postprocessing of CTA data. When electronic measurements are being used, the subject of measurement can be magnified and the window level and width can be adjusted and standardized at an optimum level. In addition, the level at which each follow-up measurement is taken can be reproduced and standardized. In some of the earlier studies a fixed distance to the renal artery was used to standardize the level of measurement. This method produces a mixture of neck sizes above and inside the attachment systems, sometimes even within one case series. In this study the neck size was always taken exactly at the level of the endovascular anastomosis, independent of the distance to the renal arteries.

One potential source of error in this study is the use of the postoperative CSA as baseline instead of the preoperative size. However, because of balloon inflation and the practice of oversizing the endograft relative to the neck, it can be assumed that the postoperative size is already larger than before surgery. Therefore this error would work in favor of the observation of the neck dilating after EAR.

Finally, an important source of variation in the earlier studies is the use of different devices and attachment systems. Neck changes may vary with the type of attachment system used. Stent fixation mechanisms with a high radial force but also balloon expandable stents are likely to attain their nominal size quickly after deployment. Because endograft attachment frames are generally oversized relative to the proximal aortic neck diameter, an (intended)

elastic stretch of the aorta at this level will occur. Over time, this elastic quality of the stented aorta may wear out, and with this the frictional forces that keep the stent in place will decline. Although this scenario is theoretical, it illustrates that size measurements at the level of a stent that already attained its maximum size will not demonstrate the loss of elastic properties. Consequently, stability of the size of such an aortic neck may falsely suggest the endograft fixation is still adequate.

In this study all of the described limitations have been avoided. An 8% to 10% yearly increase of the CSA was found. This translates into a 4% to 5% or approximate 1-mm yearly increase in neck diameter. With the current practice of oversizing the endograft to the proximal neck by 2 to 4 mm, it is important to realize that failure of the proximal attachment system may not become apparent before 3 or 4 years of follow-up have elapsed.

In most of the currently available EAR systems, endograft fixation is dependent on friction forces generated by a relatively high outward force. The attachment system of the device used in this study (Ancure) has a relatively low outward force, because endograft fixation is accomplished by hooks penetrating the aortic wall. Nevertheless, in this study no patients without proximal neck dilatation could be identified. Our findings must be validated in larger sample populations and with various types of endografts. Neck changes also vary from patient to patient. It is conceivable that risk factors of accelerated neck dilatation after EAR exist. Although the number of patients in our study is too small for a valid risk factor analysis, we have found the initial oversize ratio of endograft to neck size to be correlated significantly with CSA increase. Unfortunately, this very same factor appears to be necessary to provide an adequate proximal seal initially and to accommodate to subsequent dilatation.

It can be hypothesized that the initial distance of the endovascular anastomosis to the most distal renal artery is an important determinant of the quality of the landing zone and thereby of the subsequent neck dilatation. This factor, however, did not attain statistical significance in this analysis, most likely because of small patient numbers. It will be subject to further study.

With respect to the two patients who were suspected to have had secondary failure of the proximal attachment system, it is important to note that the loss of the endovascular seal occurred 3 or more years after the operation. At that time no more than 13 patients had been at risk for this complication. In the first patient the recurrence of the proximal endoleak in itself could be held responsible for the failure of the procedure. However, it can be hypothesized that the excessive neck dilatation of 43% had initiated the loss of the proximal endovascular seal. Although the CSA increase in the second patient was not excessive, and sufficient oversize ratio appeared to be remaining at the 4- and 5-year follow-up visits, the loss of the endovascular seal was apparent from the circumferential layer of thrombus separating the wall from the attachment system. This case illustrates the fact that an adequate endovascular anastomosis, even at 3 years, does not provide life-long security.

CONCLUSIONS

This longitudinal study demonstrates a constant and continuous aortic enlargement of approximately 1 mm/y at the level of the proximal endovascular anastomosis of the Ancure endovascular graft. As a result of the practice of a 2- to 4-mm oversize of the endograft relative to the infrarenal aortic neck, a loss of the endovascular seal may not become manifest until 3 or 4 years after endovascular AAA repair is performed. These findings must be validated in larger sample populations and with various endografts.

REFERENCES

1. Blankensteijn JD, Lindenburg FP, van der Graaf Y, Eikelboom BC. Influence of study design on reported mortality and morbidity rates after abdominal aortic aneurysm repair. Br J Surg 1998;85:1624-30.
2. Hollier LH, Plate G, O'Brien PC, Kazmier FJ, Gloviczki P, Pairolero PC, et al. Late survival after abdominal aortic aneurysm repair: influence of coronary artery disease. J Vasc Surg 1984;1:290-9.
3. Bottsford JE Jr, Bearden RC Jr, Bottsford JG. A ten year community hospital experience with abdominal aorta aneurysms. J S C Med Assoc 1983;79:57-62.
4. Crawford ES, Saleh SA, Babb JW, III, Glaeser DH, Vaccaro PS, Silvers A. Infrarenal abdominal aortic aneurysm: factors influencing survival after operation performed over a 25-year period. Ann Surg 1981;193:699-709.
5. Bernstein EF, Dilley RB, Randolph HF3. The improving long-term outlook for patients over 70 years of age with abdominal aortic aneurysms. Ann Surg 1988;207:318-22.
6. Norman PE, Semmens JB, Lawrence-Brown MM, Holman CD. Long term relative survival after surgery for abdominal aortic aneurysm in Western Australia: population based study. Br Med J 1998;317:852-6.
7. Malina M, Lindblad B, Ivancev K, Lindh M, Malina J, Brunkwall J. Endovascular AAA exclusion: will stents with hooks and barbs prevent stent-graft migration? J Endovasc Surg 1998;5:310-7.
8. Matsumura JS, Chaikof EL, Investigators ET. Continued expansion of aortic necks after endovascular repair of abdominal aortic aneurysms. J Vasc Surg 1998;28:422-30.
9. Wever JJ, de Nie AJ, Blankensteijn JD, Broeders IA, Mali WP, Eikelboom BC. Dilatation of the proximal neck of infrarenal aortic aneurysms after endovascular AAA repair. Eur J Vasc Endovasc Surg 2000;19:197-201.
10. Walker SR, Macierewicz J, Elmarasy NM, Gregson RH, Whitaker SC, Hopkinson BR. A prospective study to assess changes in proximal aortic neck dimensions after endovascular repair of abdominal aortic aneurysms [see comments]. J Vasc Surg 1999;29:625-30.
11. Wever JJ, Blankensteijn JD. Regarding "A prospective study to assess changes in proximal aortic neck dimensions after endovascular repair of abdominal aortic aneurysms" [letter; comment]. J Vasc Surg 1999; 30:1163-4.

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