Endograft Migration: Incidence, Causes, and Clinical Significance

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Endovascular device migration is approximately 2% at 1 year using each of the Food and Drug Administration-approved devices (Medtronic AneuRx, Gore Excluder, Cook Zenith). In this report, we review the incidence, causes, and clinical importance of endograft migration over a 5-year period after endovascular aneurysm repair with the AneuRx stent graft. In a multicenter United States clinical trial of the AneuRx device, migration was identified in 8% (94/1119) of patients over a mean follow up time of 30 ± 11 months. A Kaplan-Meier analysis determined migration rates were 1.4% at 1 year, 6.6% at 2 years, and 18.8% at 3 years. The significant factors in device migration appeared to be proximal fixation length (P = .005), renal artery to stent-graft distance (P = .001), and the clinical site (P < .001). Preimplantation aortic neck length, neck diameter, degree of device oversizing, device type (stiff vs flexible), placement of proximal extender cuffs at the original procedure, and postprocedure endoleak were not significant predictors of migration. These results highlight the importance of technical precision in stent-graft deployment as critical in preventing late AneuRx stent graft migration.

Key words: endovascular aneurysm repair, AneuRx, device migration

Introduction

Endovascular strategies to treat infrarenal abdominal aortic aneurysms have been shown to be effective in preventing aneurysm rupture, with reduced patient morbidity and mortality compared with open surgical repair. However, the migration of endoluminal devices has been noted following successful endovascular repair, raising concerns about long-term durability of endovascular repair. Continuous downward displacement forces are exerted on all aortic devices by the pulsatile nature of blood flow, with cumulative effects over time. Thus, it is not surprising that migration has been noted with all current endovascular devices and configurations, including those with modular design, unibody design, infrarenal fixation, suprarenal fixation, hook and barb fixation, longitudinal columnar support, and flexible designs. Migration has also been noted with prosthetic aortic grafts placed at open surgery. The risk of migration increases with time and can result in the loss of device fixation proximally, dis-
tally, or at modular junctions, resulting in aneurysm rupture.\textsuperscript{11-15}

To minimize potential failures of endograft repair of aortic aneurysms, migration must be identified and minimized. Unfortunately, the reported incidence of endograft migration varies widely between studies, and this may be due to different definitions of endograft migration and the follow-up period may vary.\textsuperscript{4}

### The Definition and Incidence of Migration

In a recent report of a 5-year review of patients treated during the multicenter US AneuRx (Medtronic, Minneapolis, Minn) clinical trial, endograft migration was defined as any postimplantation movement or displacement of the stent-graft in relation to the native aorta or renal arteries as documented by computed tomographic (CT) scans, abdominal radiographs, angiograms, or pathologic analysis (Figure 1).\textsuperscript{16} Migration rates and factors that may predispose to migration along with clinical outcome were evaluated in 1119 patients treated at 19 clinical sites on the basis of more than one postimplant imaging study to allow assessment of migration.

Preoperative, postoperative, and follow-up clinical and imaging data from each clinical site was reported to a centralized data registry and audited by external monitors. An independent core laboratory evaluated preoperative and postoperative CT scans and abdominal radiographs from 13 clinical sites during phase II of the trial and was blinded as to patient information.

Stent-graft migration occurred at some time during the follow-up period in 94 of 1119 (8.4%) patients, with no migration reported in 1025 patients. Mean time following implantation was 30 ± 11 months (range 0.5 to 61 months). The Kaplan-Meier analysis for freedom from migration was 98.6% at 1 year, 93.4% at 2 years, and 81.2% at 3 years (Figure 2).

### Predictors of Migration

Univariate Cox proportional hazard results revealed that proximal fixation length (\( P = .005 \)) and renal to stent-graft distance (\( P = .001 \)) were significant predictors of the risk of stent-graft migration. Factors that were not found to be significant predictors of migration by univariate and

![Figure 1](image1.png)

Figure 1. A plain radiograph of the abdomen demonstrates caudal migration of the stent-graft 1 year after implantation. Bony landmarks are used as reference points for the stent-graft as the projection, penetration, and position of the patient can vary.
multivariate analysis included age, gender, risk factors, comorbidities, preimplant aortic aneurysm size, preimplant aortic neck length, preimplant aortic neck diameter, the degree of device oversizing or undersizing, correct versus incorrect oversizing, device type (stiff vs. flexible), the use of extender cuffs at the time of implantation, and the presence of postprocedure endoleak.

A multivariate analysis that included both proximal fixation length and renal to stent-graft distance yielded P values of .04 and .01 and hazard ratios of 0.975 and 1.058, respectively. This result indicates that both of these factors are independently predictive of migration and that each millimeter increase in the length of fixation decreases the hazard of migration by 2.5% and each millimeter increase in renal to stent-graft distance increases the hazard of migration by 5.8%. However, significant differences in migration rates were also found between clinical centers, which suggest inherent technical considerations in stent-graft implantation.

Beyond proximal fixation length and distance from the renal arteries, preliminary data suggest that iliac fixation length may also be important in preventing stent-graft migration. Promising results were obtained in the sheep model that evaluated iliac fixation, in which an increase in the pull down forces required to dislodge the AneuRx stent-graft was demonstrated. It is now common in our practice to place the stent-graft down to the origin of the hypogastric arteries to maximize iliac fixation length.

**Clinical Significance of Migration**

Seven ruptures occurred among the 1025 patients (0.7%) with no stent-graft migration (NS). Among the 94 AneuRx study patients with migration, 30 (32%) have been treated:

![Kaplan-Meier Curve](Kaplan-Meier Curve.png)

Figure 2. Kaplan-Meier analysis of freedom from migration. In the interval 24 months to 36 months, 427 patients were at risk at the start of the interval (24 months) and 135 patients were at risk at the end of the interval (36 months).
• 1 patient had aneurysm rupture and underwent successful open surgical repair.
• 6 patients underwent elective surgical conversion for migration with type I endoleak, with or without aneurysm enlargement.
• 23 patients (24%) underwent secondary endovascular treatment with placement of proximal modular stent-graft extenders, with or without distal stent-graft extenders.

No treatment- or aneurysm-related deaths occurred. Sixty-four patients (68%) with migration did not require treatment or secondary procedures and continue to be monitored with clinical follow-up and serial imaging studies.

In patients who require treatment, such as those with type I endoleak or aneurysm enlargement, a proximal aortic extender cuff can usually be placed to the level of the lowermost renal artery. This was true in 77% of patients with stent-graft migration in the AneuRx trial, with only 23% of treated patients needing surgical conversion.

These good results are likely due to careful and ongoing surveillance, with prompt secondary treatment as clinically indicated. It is possible that over time more patients in whom migration has been identified will require secondary treatment.

Migration Rates of Other FDA-Approved Stent-Graft Devices

Migration has been identified in all FDA-approved stent-graft devices, including the Excluder (W.L. Gore & Associates, Flagstaff, Ariz) and the Zenith (Cook, Bloomington, Ind) vascular grafts. In a prospective, nonrandomized multicenter clinical study of the Excluder, migration was identified in 3.0% of 235 patients at 6 months, 2.3% at 1 year, and 1.4% at 2 years. Migration was independently determined by the core laboratory and defined by caudal migration exceeding 10 mm on CT scan.17

Another FDA-approved device, the Zenith endovascular graft, was placed in 351 patients in a prospective multicenter FDA phase II trial. Migration was identified in 2.3% (6/261) at 12 months as defined by caudal migration exceeding 5 mm.

Earlier reports found migration to be quite rare, with no migration in 116 patients with a mean follow up of 10.3 ± 9.8 months.18 However, longer term data beyond 1 year are not yet available for either the Excluder or the Zenith endovascular grafts. Longer follow-up may be critical, as most AneuRx stent-graft migration occurred after a mean follow-up of 23 months after implantation.16 Table 1 summarizes the reported migration rates between stent graft devices.

Conclusions

The clinical experience of endovascular aneurysm repair using the AneuRx stent-graft is favorable. Three-year Kaplan-Meier analyses of the primary end points for all 1193 patients treated during the course of the AneuRx clinical trial reveal a low aneurysm rupture rate (1.6%), a low aneurysm-related death rate (3.1%), a low surgical conversion rate (5.8%) and an overall survival of 76.6%.19

Device migration following endovascular aneurysm repair using the AneuRx stent-graft appears to be largely related to the precision of deployment of the stent-graft just below the renal arteries and the length of proximal fixation achieved after device deployment rather than to preoperative neck length or aneurysm morphology. This highlights the importance of the technical aspects of stent-graft deployment.

Improved intraoperative imaging and deployment techniques, together with improved patient selection, may result in an increased length of proximal fixation at the time of device implantation.

Table 1. Migration Rates of the 3 FDA-Approved Stent-Graft Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>6 mon</th>
<th>1 yr</th>
<th>2 yr</th>
<th>3 yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic AneuRx</td>
<td>1.1%</td>
<td>2.2%</td>
<td>5.3%</td>
<td>7.1%</td>
</tr>
<tr>
<td>Gore Excluder</td>
<td>3.0%</td>
<td>2.3%</td>
<td>1.4%</td>
<td>——</td>
</tr>
<tr>
<td>Cook Zenith</td>
<td>——</td>
<td>2.3%</td>
<td>——</td>
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The AneuRx and Zenith graft migration was defined as caudal migration of greater than 5 mm and the Gore Excluder graft migration was defined as caudal migration of greater than 10 mm.
This, together with improved distal iliac fixation, may lower migration rates in the future. Most patients with device migration can be treated with endovascular placement of modular stent-graft extenders. The long-term outcome following such treatment remains to be determined.

REFERENCES


