The AneuRx stent graft: Four-year results and worldwide experience 2000

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Objective: The objective was to review the current results of endovascular abdominal aortic aneurysm repair with the AneuRx stent graft and to determine the effectiveness of the device in achieving the primary objective of preventing aneurysm rupture.

Methods: The outcome of all patients treated during the past 4 years in the U.S. AneuRx clinical trial was determined, and the worldwide clinical experience was reviewed.

Results: A total of 1192 patients were treated with the AneuRx stent graft during all phases of the U.S. Clinical Trial from June 1996 to November 1999, with follow-up extending to June 2000. Ten (0.8%) patients have had aneurysm rupture, with most ruptures (n = 6) occurring in 174 (3.4%) patients treated with an early stiff bifurcation stent graft design used in phase I and in the initial stages of phase II. Since the current, flexible, segmented bifurcation stent graft design was introduced, four (0.4%) ruptures have occurred among 1018 patients treated. Of these, one was during implantation, two were placed too far below the renal arteries, and one patient refused treatment of a type I endoleak. Kaplan-Meier analysis of all 1192 patients treated with the AneuRx stent graft including both stent graft designs revealed the patient survival rate to be 93% at 1 year, 88% at 2 years, and 86% at 3 years, freedom from conversion to open repair to be 98% at 1 year, 97% at 2 years, and 93% at 3 years, and freedom from secondary procedure to be 94% at 1 year, 92% at 2 years, and 88% at 3 years. Freedom from aneurysm rupture with the commercially available segmented bifurcation stent graft was 99.7% at 1 year, 99.5% at 2 years, and 99.5% at 3 years. The presence or absence of endoleak on contrast computed tomography scanning after stent graft placement was not found to be a significant predictor of long-term outcome measures. Worldwide experience with the AneuRx device now approaches 10,000 patients.

Conclusions: Endovascular management of abdominal aortic aneurysms with the AneuRx stent graft has markedly reduced the risk of aneurysm rupture while eliminating the need for open aneurysm surgery in 98% of patients at 1 year and 93% of patients at 3 years. The device was effective in preventing aneurysm rupture in 99.5% of patients over a 3-year period. The overall patient survival rate was 93% at 1 year and 86% at 3 years. (J Vasc Surg 2001;33:S135-45.)

The primary objective in treating patients with aortic aneurysms is to prevent aneurysm rupture and death from aneurysm rupture. The effectiveness of any treatment of abdominal aortic aneurysms must be balanced against the risk of the treatment itself and the risk of no treatment, that is, the natural history of the aneurysm to rupture. Open repair with direct exposure of the aneurysm and transmural suture fixation of a prosthetic graft is generally effective in preventing aortic aneurysm rupture but requires major abdominal surgery and is associated with significant morbidity and mortality.\(^1\,2\) The long-term aneurysm-related risk after open repair is greatly reduced but persists with the potential for subsequent anastomotic or true aneurysmal degeneration. Endovascular aneurysm repair with endoluminal placement of a stent graft provides a less invasive alternative to standard open surgery with reduced morbidity and more rapid patient recovery.\(^3\,4\) However, the long-term effectiveness of this approach compared with that of open surgery or with observation and no treatment is not well defined. This report will review the current clinical results of abdominal aortic aneurysm treatment with the AneuRx stent graft and consider issues related to its effectiveness against open surgery and the natural history of abdominal aortic aneurysms. We will also provide a current perspective on the worldwide use of the AneuRx stent graft for the treatment of patients with abdominal aortic aneurysms.

DEVELOPMENT OF THE ANEURX STENT GRAFT

The AneuRx stent graft was designed and engineered by Dr. Thomas J. Fogarty and Fogarty Engineering in 1993.\(^5\,6\) The device and delivery system were perfected by AneuRx, Inc (Sunnyvale, Calif), and animal experi-
ments were concluded at Stanford University and Harbor UCLA in 1995. European CE mark was granted in March 1997. U.S. clinical trials, in accord with Food and Drug Administration (FDA) guidelines, were begun in 1996. The first AneuRx device implanted in the United States was by Dr. Rodney White at Harbor UCLA on June 3, 1996. The first AneuRx device in Europe was implanted by Dr. Frans Moll in the Netherlands in September 1996. AneuRx, Inc. was acquired by Medtronic, Inc (Minneapolis, Minn) in 1996 and is now operating as a part of Medtronic AVE (Santa Rosa, Calif).

The U.S. phase II clinical trial comparing the AneuRx stent graft with standard open surgical aneurysm repair began in April 1997 and was carried out at 13 clinical sites throughout the United States. The 1-year results were reviewed on June 23, 1999, by the FDA Advisory Panel, which recommended approval. The FDA granted market approval for the AneuRx device on September 28, 1999.

THE ANEURX STENT GRAFT SYSTEM

The AneuRx stent graft is a modular, bifurcated endovascular device designed to treat infrarenal aortic aneurysms. Each stent graft module consists of a thin-walled, noncrimped, woven polyester graft that is joined to a nickel-titanium (Nitinol) exoskeleton by numerous individual polyester sutures. The self-expanding Nitinol stent rings provide both radial and columnar structural support throughout the length of the graft, and the polyester graft provides a smooth, impervious blood flow conduit. Each individual stent graft module is loaded inside a delivery catheter, which is introduced over a stiff 0.035-inch guidewire and positioned with x-ray fluoroscopic control.

The primary aortic bifurcation module is contained in a 21F (OD) delivery catheter, and the iliac modules are contained in 16F delivery catheters. A nosecone orientation marker and radio-opaque markers on the stent graft allow radial and longitudinal orientation of the stent graft under fluoroscopic guidance. The self-expanding stent graft is deployed by retraction of the delivery catheter-covering sheath with a deployment handle. A new tapered nosecone and new integrated deployment-delivery system is being introduced and will eventually replace the two-component delivery system.

In April 1998, early in the AneuRx clinical trial, the FDA approved a manufacturing change of the bifurcation stent graft module. The initial bifurcation stent graft mod-

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**Fig 1.** AneuRx stent graft composed of Nitinol exoskeleton joined to woven polyester graft with multiple polyester sutures. **A,** Original bifurcation module included single 5-cm long, unbending bifurcation stent. **B,** Currently available device is constructed with individual 1 cm long stent rings throughout its length and provides flexibility throughout length of stent graft.
ules were manufactured with a single-unit Nitinol bifurcation stent, 5 cm in length, coupled proximally and distally to individual 1 cm long Nitinol rings joined together end to end (Fig 1, A). After April 1998, the entire length of the bifurcation stent body was constructed with individual 1 cm long Nitinol rings joined together end to end (Fig 1, B). The segmented body construction resulted in flexibility of the bifurcated graft throughout the length of the stent graft and eliminated the stiff, unbending 5 cm long proximal bifurcation segment (Fig 2). The commercially available AneuRx stent graft has the segmented body construction.

U. S. MULTICENTER CLINICAL TRIAL

The AneuRx Stent Graft System was evaluated under the FDA Investigational Device Exemption (IDE) Application Number G960016 for Endovascular Stent Graft and Delivery Catheter. The study was designed in three phases. Phase I began in June 1996 and was designed as a feasibility study involving 40 patients at four study sites. Only one follow-up year was required, but most patients in this phase continue to be monitored. Phase II began in April 1997 and was a prospective, non-randomized, controlled clinical investigation comparing endovascular repair using the AneuRx stent graft with standard open surgical repair. Phase II included 13 study sites and included a 1-year follow up, which has been extended to 5 years for the patients receiving stent grafts. Phase III began in August 1998 and included additional patients with stent grafts treated at a total of 19 clinical sites (13 phase II sites and 6 new sites). These patients will be monitored for 5 years. The clinical study sites are listed in the Appendix.

The numbers of patients treated in the clinical trial as of June 3, 2000, are as follows: phase I - 40 patients, phase II stent graft - 424 patients, phase II surgical control - 66 patients, and phase III stent graft - 641 patients. In addition, 87 patients during phases II and III were treated with the AneuRx stent graft on a compassionate use/high-risk basis. The total number of patients treated with the AneuRx stent graft during all phases of the clinical trial was 1192.
Patient selection. Patients with nonruptured infrarenal aortic and aortoiliac aneurysms were candidates for the trial if the aneurysm met one of the following criteria: larger than 5 cm in diameter, between 4 and 5 cm in diameter with a documented increase in diameter of 0.5 cm in the past 6 months, twice the diameter of the infrarenal neck, or saccular. Additional requirements included an infrarenal neck between 18 and 26 mm in diameter with a length below the most inferior renal artery of at least 1 cm. Patient exclusions included ruptured or leaking aneurysms and suprarenal, thoracic, and inflammatory aneurysms.

Patient selection criteria in the clinical trial were the same for patients in both the stent graft and surgical control groups. Patients were evaluated with preoperative and postoperative computed tomography (CT) scans and Duplex ultrasound scanning and were monitored at intervals of 1 month, 6 months, and 12 months and annually thereafter with clinical evaluation, plain abdominal x-ray evaluation, and CT scans.

Data at each study site are managed by a study coordinator and externally audited with interval site visits. Data are entered into a central database. A data safety and mon-
itoring board reviews adverse event information. Imaging data from patients in phase II of the study (CT scans and abdominal x-ray evaluations) are independently evaluated by a Radiologic Core Laboratory with expertise in radiologic imaging and with no affiliation to any of the study sites or investigators. Statistical analysis of the data is overseen by D.A.B. of the Stanford University Medical Center, Department of Health Research and Policy.

**Early results.** The initial experience of 190 patients treated with the AneuRx stent graft (patients in both phase I and phase II) was compared with that of 60 patients in a surgical control group with 1-year follow-up and was presented to the International Society for Cardiovascular Surgery in June 1998 and published in 1999. There were no significant differences in preoperative risk factors of comorbidities between the patients in the surgical control and stent graft groups. Stent graft deployment was successful in 97% of patients. There was no difference in operative mortality between the groups (0% in the surgery group and 1% in the stent graft group). Patients who underwent stent graft repair had 60% less blood loss compared with patients who underwent open surgery \( (P < .001) \), and these patients required 80% less blood transfusion \( (P < .05) \). There was a marked reduction in the time to extubation, discharge from the intensive care unit, ambulation without assistance, and eating a regular diet in the stent graft group compared with the surgery group. Major morbidity was reduced by 50% in the stent graft group \( (P < .05) \), and hospital length of stay was reduced from 9.3 to 3.4 days \( (P < .001) \).

**Phase II clinical trial.** The phase II controlled trial of 416 patients in the stent graft group compared with 66 patients undergoing open aneurysm repair was presented to the FDA Advisory Panel on June 23, 1999. The results did not differ significantly from the previously published results and demonstrated the following. Successful graft deployment was achieved in 98% of patients, and the surgical conversion rate was 1.5%; there was no difference in the 30-day mortality rate between patients in the stent graft group (2%) and those in the surgical group (0%). There was a 50% reduction in major morbidity compared with open repair, a 66% reduction in blood loss, and a 63% reduction in hospital length of stay. Patients recovered

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**Fig 4.** Survival after endovascular aneurysm repair. Kaplan-Meier analysis.
more quickly and had earlier return to function compared with patients undergoing open surgery. The physician-reported endoleak rate at the time of hospital discharge was 38%, which was reduced to 13% at 1 month, 16% at 6 months, and 11% at 12 months. Two (0.5%) patients had aneurysm rupture, one during the implantation procedure and one 14 months after implantation of a stiff bifurcation stent graft. These ruptures are included in the later analysis in this article. Five percent of patients required a secondary endovascular procedure for endoleak, and 2% required a secondary procedure for nonpatency of the stent graft. The primary graft patency rate was 98%, and the secondary graft patency rate was 99%.

**FOUR-YEAR RESULTS OF U.S. ANEURX CLINICAL TRIAL**

All patients entered into the endovascular treatment arm beginning with the first patient in phase I (June 3, 1996) and ending with the last patient treated in phase III on November 4, 1999, were reviewed. The follow-up period extended for 4 years through June 3, 2000, with a mean of 73.4 ± 8.0 SD months. All patients were included in this analysis, with no patient exclusions for the initial learning curve, device manufacturing changes, compassionate use, or other reasons.

A total of 1192 patients were reviewed to determine long-term outcome on intent-to-treat basis. Patients included 1058 (89%) men and 134 (11%) women with a mean age of 73.4 ± 8.0 SD years (range 45 to 96 years). Patients had multiple risk factors and comorbidities, and 92% of patients had American Society of Anesthesiologists (ASA) risk classification of III or IV. The mean preoperative aneurysm diameter was 5.6 ± 0.3 SD cm. The mean aneurysm neck length was 27.3 ± 12.2 SD mm, and the mean neck diameter was 22.3 ± 2.9 SD mm. The primary end points for analysis included aneurysm rupture, death from aneurysm rupture, death from any cause, surgical conversion, and secondary procedures for endoleak/migration or graft nonpatency.

**Aneurysm rupture.** The first report of aneurysm rupture after successful AneuRx stent graft repair was in 1999. This was a patient in phase I with a 5.5-cm
aneurysm and a short angulated neck who had a rupture 23 months after endovascular repair. The main bifurcation module used in this patient was the early stiff body design, which is no longer manufactured. Since that time there have been seven additional cases of aneurysm rupture after successful AneuRx stent graft repair. Three of these patients were reported by Politz et al13 in the March 2000 issue of the Journal of Vascular Surgery. Seven of the eight patients who had rupture including the three reported by Politz et al and two additional patients who had aneurysm rupture during the implantation procedure were reported by Zarins et al14 in the May 2000 issue of the Journal of Vascular Surgery. Thus as of June 3, 2000, 4 years since the first device implantation, there have been a total of 10 aneurysm ruptures (two during the implant procedure, eight after implantation) among the 1192 (0.8%) patients entered into the endovascular treatment arm of the U.S. AneuRx Clinical Trial.

Two of the ruptures occurred during the treatment period, and both underwent successful surgical conversion. One was related to intraoperative balloon dilation of the proximal aortic neck in an attempt to seal a type I endoleak, and the other was related to instrumentation and perforation of the aneurysm sac. The eight ruptures after successful endovascular repair occurred 3 weeks to 26 months (mean 17 months) after endovascular repair. Five patients survived open surgical repair, two died in the perioperative period, and one died after refusing operation (rupture-related mortality: 0.3%).

Before rupture occurred, two patients had type I iliac endoleaks and aneurysm enlargement and refused recommended treatment with iliac extender modules. Six patients had no documented endoleak and no aneurysm enlargement. Four ruptured as a result of proximal fixation failure in angulated necks, and two ruptured as a result of aneurysm tortuosity and separation of the iliac limb from

### Table: Freedom from Secondary Procedures

<table>
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<tr>
<th>Time</th>
<th>6 months</th>
<th>1 year</th>
<th>2 years</th>
<th>3 years</th>
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<tr>
<td># at Riska</td>
<td>1192</td>
<td>1040</td>
<td>816</td>
<td>284</td>
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<td># of Eventsb</td>
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<td>15</td>
<td>13</td>
<td>7</td>
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<td>0.916</td>
<td>0.882</td>
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<td>Std Error</td>
<td>0.0064</td>
<td>0.0073</td>
<td>0.0091</td>
<td>0.0163</td>
</tr>
</tbody>
</table>

a) beginning of time interval  
b) during time interval  
c) made at end of time interval  

Fig 6. Freedom from secondary procedure. Kaplan Meier analysis.
the junction gate. Retrospective analysis of all patients with aneurysm rupture after successful stent graft repair revealed evidence of insecure fixation either proximally, distally, or at the junction gate, which could have been treated with stent graft extender modules before rupture.14

Single-unit versus segmented bifurcation stent body. All 40 patients in phase I were treated with the original, single-unit, stiff bifurcation body, as were 134 patients in the beginning of the phase II clinical trial. Subsequently, all patients treated with the AneuRx stent graft have received flexible, segmented bifurcation stent grafts. Thus 174 (15%) patients were treated with the stiff body stent graft, whereas 1018 (85%) patients were treated with the flexible stent graft. Among the 10 patients with rupture, six had received the stiff body stent graft, and four had received the flexible stent graft. Thus the risk of aneurysm rupture with the stiff body stent graft was much higher (6 of 174, 3.4%) than with the flexible body stent graft (4 of 1018, 0.4%). Kaplan-Meier analysis revealed a significant reduction in the risk of aneurysm rupture among patients receiving the flexible, segmented stent graft compared with those treated with the stiff body stent graft ($P < .002$, Mantel-Haenszel test, Fig 3). Freedom from aneurysm rupture with the flexible, segmented stent graft was 99.7% at 1 year, 99.5% at 2 years, and 99.5% at 3 years (Fig 3).

One of the two patients with periprocedural rupture received a stiff device, whereas the other received a flexible device. Among the eight patients with rupture after successful repair, five received the stiff body graft and three received the flexible graft. Two of the five stiff devices had been placed in aneurysms with short, angulated necks with ultimate loss of proximal fixation, and two experienced progressive anterior angulation of the stent graft over time, resulting in separation of the iliac limb from the junction gate. It is likely that the inability of the stiff bifurcation module to flex in tortuous or shrinking aneurysms exacerbated the angulation forces at either the proximal or distal end of the rigid 5 cm long segment, resulting in ultimate fixation failure. The fifth patient had a type I iliac endoleak and refused treatment. Among the three patients with flexible stent grafts who had rupture, two had severely angulated necks with initial positioning of the device low in the neck, well below the renal arteries. The third patient had a type I iliac endoleak and refused treatment.

Survival. Among the 1192 patients, a total of 119 (10%) patients have died during the 4-year time course of the study. The 30-day mortality rate was 2% (23 of 1192). Four (0.3%) patients died of aneurysm rupture after successful endovascular repair, three after emergent operation, and one refused operation. One patient died of aneurysm rupture before treatment and one of a ruptured arch aneurysm after treatment. The remaining patients died of nonaneurysm causes. The causes of death were cardiac in 49, cancer in 20, pulmonary in 19, renal in 7, gastrointestinal in 4, sepsis and multisystem organ failure in 5, stroke in 3, pulmonary embolism in 1, and mesenteric thrombosis in 1. The cause of death for four patients has not been determined. Kaplan-Meier survival analysis (Fig 4) reveals a 1-year survival rate of 93%, a 2-year survival rate of 88%, and a 3-year survival of 86%.

Secondary procedures. A total of 33 (2.8%) patients have undergone conversion to open surgical repair including the nine patients who underwent open repair for aneurysm rupture. There were 15 (1.3%) surgical conversions within the first 30 days and 18 (1.5%) late surgical conversions at an average time of 22 months after endovascular repair. The Kaplan-Meier estimate of freedom from surgical conversion is 98% at 1 year, 97% at 2 years, and 93% at 3 years (Fig 5). A total of 107 secondary procedures have been performed in 94 (8%) patients; 82 patients had one procedure, 11 patients had two procedures, and one patient had more than two procedures. Freedom from secondary procedure (Kaplan-Meier estimate) was 94% at 1 year, 92% at 2 years, and 88% at 3 years (Fig 6).

ENDOLEAKS

Evidence of blood flow in the aneurysm sac (endoleak) is commonly seen in patients after endovascular aneurysm repair. Although some have considered this to be evidence of an unsuccessful aneurysm repair,15–18 the true significance of this finding remains unclear.19,20 To determine whether evidence of blood flow in the aneurysm sac (endoleak) was a meaningful predictor of clinical outcome after successful endovascular aneurysm repair, we reviewed all patients in phase II of the AneuRx Multicenter Clinical Trial with successful stent graft implantation and predischarge contrast CT imaging. The clinical outcome of patients with evidence of endoleak was compared with that of patients without evidence of endoleak. The results were presented at the Western Vascular Society Meeting in Lake Tahoe in September 1999 and were published in the July 2000 issue of the Journal of Vascular Surgery.21

The determination of whether an endoleak was present after endovascular repair was independently determined by (1) the 13 clinical centers before hospital discharge, at 1 month, 6 months, 12 months, and 24 months, and (2) a Radiologic Core Laboratory that independently reviewed the contrast CTs at predischarge, 6 months, 12 months, and 24 months. The Centers reported endoleaks in 152 (38%) of 398 patients on predischarge CT, whereas the Core Lab reported endoleaks in 50% of these patients ($P < .001$). Follow-up extended to 2 years (mean 10 ± 4 months). There were no differences between patients with and patients without endoleak before discharge in the following outcome measures: patient survival, aneurysm rupture, surgical conversion, need for a secondary procedure, aneurysm...
enlargement more than 5 mm, and appearance of a new endoleak or stent graft migration. Despite a higher endoleak rate reported by the Core Lab, neither Core Lab-defined endoleaks nor Center-defined endoleaks at discharge were significantly related to subsequent outcome measures. The outcome of patients with type I or type II endoleaks before discharge was no different from that of patients with no endoleak.21

At 1 month the endoleak rate had decreased to 13%. Although patients with persisting endoleaks were more likely to have aneurysm enlargement at 1 year, there was no difference in patient survival, aneurysm rupture rate, surgical conversion, new endoleak, or stent graft migration between patients with and those without endoleak at 1 month. Kaplan-Meier survival of all patients undergoing endovascular aneurysm repair was 96% at 1 year and was independent of endoleak status.21

Thus the presence or absence of endoleak on CT scan after AneuRx stent graft aneurysm repair does not appear to predict long-term outcome. Although the identification of blood flow in the aneurysm sac after endovascular repair is a meaningful finding, the usefulness of endoleak as a primary indicator of procedural success or failure remains unproved. Thus all patients who have undergone endovascular aneurysm repair should be carefully monitored regardless of endoleak status.

WORLDWIDE EXPERIENCE

Since the initiation of clinical trials in the United States and the introduction of the device in Europe in 1996, use of the AneuRx stent graft has increased on an annual basis. The worldwide experience of endovascular abdominal aortic aneurysm repair with the AneuRx stent graft now approaches 10,000 patients. A total of 1192 patients were included in the U.S. clinical trial and are undergoing monitored 5-year follow-up. During the past 8 months, since FDA market approval, 895 physicians have been trained to implant the device in the United States, and 370 hospitals have begun using the AneuRx stent graft. A total of 6700 stent grafts have been shipped worldwide and include fabric tears and strut failures.27-30

As of December 1999 a total of 386 patients treated with the AneuRx graft have been entered into the Eurostar Registry from 35 European and Middle East Centers. Follow-up evaluation has been carried out on 124 patients at 12 months and 30 patients at 24 months. Patient survival at 12 months is 87% (Kaplan Meier estimate) and at 24 months is 83% (Kaplan Meier estimate). In the U.K. experience there has been one reported aneurysm rupture after AneuRx stent graft repair with successful surgical conversion.

RUPTURE RISK OF UNTREATED ANEURYSMS

The risk of aneurysm rupture of untreated aneurysms is a continuous function of aneurysm size. The annual rupture rate is near zero for aneurysms less than 4 cm. The risk is approximately 1% per year for aneurysms 4 to 4.9 cm in diameter, 11% per year for aneurysms 5 to 5.9 cm, and 25% per year or more for aneurysms greater than 6 cm.22-24 The mean diameter for aneurysms treated in the AneuRx clinical trial was 5.6 ± 0.3 cm. Thus the 1-year risk of aneurysm rupture was reduced by more than 98% compared with the expected risk of rupture of untreated aneurysms.

Although the risk of aneurysm rupture after endovascular aneurysm repair is very low and markedly reduced compared with the likelihood of rupture of untreated aneurysms,24 the possibility of rupture persists even in patients with no endoleak after the procedure.25,26 The cause of rupture of the AneuRx stent graft can be traced to poor proximal, distal, or junctional fixation of the stent graft, with a higher risk of rupture in patients who were treated with the early stiff body prototype stent graft and who had significant aneurysm or neck angulation. Therefore all patients treated with endovascular aneurysm repair should continue to be monitored after the procedure with follow-up clinical evaluation and imaging studies. Patients with evidence of insecure stent graft fixation or evidence of aneurysm enlargement should undergo further endovascular treatment or open surgical repair. The cause of rupture of aneurysms after endovascular repair with other devices may be different from the AneuRx experience and include fabric tears and strut failures.27-30

COMPARISON TO OPEN REPAIR

Endovascular repair compares favorably to open surgical repair in the short term, with a significant reduction in morbidity, reduced blood loss, shorter hospital stay, and earlier return to function.4,7 There was no difference in 1-year patient survival between patients treated with endovascular procedures and those treated with open surgery in the phase II AneuRx clinical trial. In a similar fashion, concurrent comparison of endoluminal and open repair of aneurysms revealed no differences in survival rate.7 Long-term controlled trials comparing open with endovascular repair have not yet been reported. Although
some have assumed that patients who have undergone open surgical repair are no longer at risk of aneurysm rupture once they have recovered from the operation, this has not proved to be the case. Patients are at risk of pseudoaneurysm rupture, suprarenal and iliac aneurysm formation, graft infection, aortoenteric fistula, and graft thrombosis after open surgical repair. The risk of death from late rupture of abdominal aneurysms and pseudoneurysms after elective open surgery was 5% in three large series of 1126 patients monitored for an average of 5 years. The long-term late aneurysm-related death rate after open aneurysm repair including deaths from ruptured true and false aneurysms, aortoenteric fistula, and graft infections among 1474 patients is 6% (range 1.5% to 7.5%). Recent reports have demonstrated that “endoleaks” and ruptures can occur after conventional open aneurysm repair just as they can after endovascular repair. Thus the true differences in long-term outcome between endovascular and open aneurysm repair remain to be determined. However, the long-term risk of aneurysm rupture after endovascular treatment appears, thus far, to be no higher and perhaps to be lower than standard open surgical repair.

**SUMMARY**

The AneuRx stent graft has markedly reduced the morbidity of aortic aneurysm repair and is effective in preventing aneurysm rupture in the great majority of patients. In clinical trial follow-up extending to 4 years, the device is effective in preventing late aneurysm rupture in 99.5% of patients. Most aneurysm ruptures have occurred in patients in early clinical trials who were treated with a stiff bifurcation stent graft, which is no longer manufactured. Thus the long-term risk of rupture may be less than that suggested by early reports. The AneuRx experience suggests that endograft fixation rather than endoleak is the primary determinant of long-term results. Therefore all patients should be monitored with post-treatment imaging studies to evaluate aneurysm size and stent graft fixation.

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**REFERENCES**


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