

# AneuRx Endograft: How to Avoid Early, Midterm, and Late Complications

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The AneuRx endograft was the first device approved in the United States in 1999 for the endovascular treatment of infrarenal abdominal aortic aneurysms (AAAs) at the same time as the Ancure device. The Ancure device had significant anatomic limitations and accommodated only a small proportion of patients with infrarenal AAAs. On the other hand, the AneuRx device was rapidly accepted as a user-friendly device that could be used to treat a broader range of patients. These devices were approved for the treatment of patients with AAAs that had specific anatomy proximal and distal to the infrarenal abdominal aneurysm. The AneuRx trial included patients in their endovascular group with infrarenal aortic necks > 10 mm in length and up to 25 mm in diameter. There were no limitations associated with other neck characteristics like calcification, thrombus, or plaque within the infrarenal neck. In addition, there were no limitations associated with neck angulation.<sup>1</sup>

For the initial few years after approval, the AneuRx endograft was widely used by many investigators following the original instructions for use (IFU) criteria. Over the ensuing years, multiple publications have raised concerns about the long-term durability of the endovascular reconstructions using the AneuRx device associated with the risk of graft migration and failure of aneurysm exclusion. Cao and colleagues reported 133 patients with a minimum of 24 months of follow-up after EVAR using the AneuRx graft and noted that 17 patients had distal migration of at least 10 mm.<sup>2</sup> The probability of migration by life-table analysis was 20% at 24 months and 27% at 36 months. Forty-seven percent of the patients with migration underwent secondary procedures. An even higher migration rate was reported by Connors and colleagues who reviewed the results of 91 patients that underwent AAA repair with the AneuRx graft.<sup>3</sup> They defined migration as movement of > 5 mm and reported migration rates of 20.4%, 42.1%, and 66.7% at 2, 3, and 4 years postimplantation but only had 19 and 3 patients in the 3- and 4-year groups, respectively, making the data at those time points questionable. Subsequently, Zarins reviewed 1,119 patients enrolled in the multicenter AneuRx clinical trial.<sup>4</sup> Endovascular graft migration was reported in 94 patients with estimated migration rates of 7% at 2 years and 19% at 3 years. The January 2005 clinical update for the AneuRx AAA stent-graft system published by Medtronic suggests prosthesis migration rates of 6.0%, 7.8%, and 5.4% at 3, 4, and 5 years, respectively.<sup>5</sup>

In 2003, the IFU manual for the AneuRx endovascular graft was modified to address the potential increased risk of failure if the original IFU criteria were too narrowly followed. The new IFU criteria are more consistent with the ones used for the Excluder, Zenith, and subsequent endovascular device trials based on the experiences learned by many investigators over the years. The new criteria include a 15 mm aortic neck length, oversizing between 10 and 20%, and a neck angulation of less than 45°.

To assess the risk of migration and its consequences before and after the changes in the IFU criteria, we reviewed the combined experiences of the University of North Carolina and Washington University after approval of the AneuRx endovascular graft. From October 1999 to March 2001, 595 patients underwent EVAR with the AneuRx graft at these institutions. Since long-term migration rates and their consequences were the primary interest of the study, those patients having at least 30 months of follow-up (mean 40.3 months; ranging from 30 to 55 months) were identified and underwent retrospective assessment. Eighty-four patients were identified. Seventy percent of the patients (n = 59) met the modified IFU inclusion criteria. The remaining 25 patients had characteristics that fell outside of the IFU. Life-table analysis for IFU patients at 2 and 4 years revealed a migration rate of 0% and 4.5%, respectively. These results were significantly lower (p < .0001) than the 2- and 4-year migration rates of the non-IFU patients at 24.0% and 42.1%, respectively. Statistical analysis revealed that the migrators had statistically greater neck angulation (mean angle: 26.5°; migrators: 39.5°; non-migrators: 24.1°) and devices placed farther away from the lowest renal artery (mean distance 3.4 mm; migrators: 6.5 mm; non-migrators: 2.8 mm) as compared with the non-migrators. Overall, late graft-related complications occurred in 38% of patients (IFU: 27%, NIFU: 64%; p = .003). The secondary intervention rate was 26% (IFU: 15%, NIFU: 52%; p = .0009), which included embolizations, extension cuffs, and proximal cuffs.<sup>6</sup>

Additional techniques have been recognized as important to improve the long-term results of endovascular aneurysm repair. Accurate deployment in the infrarenal neck is critical for good long-term results. The device should be deployed immediately below the lowest renal artery to have the maximal graft to neck wall apposition to improve graft stability in the long term. In the early days of endovascular aneurysm repair, there were significant concerns about renal artery occlusion or injury leading to endovascular graft deployment farther away from the lowest renal artery than was optimal. Some of the techniques that are now frequently used for accurate graft deployment just below the lowest renal artery include: slow partial deployment of the device with repeated perirenal contrast injections and changing the angle of the imaging intensifier to open the infrarenal aortic neck allowing perpendicular deployment of the endovascular graft just below the lowest renal artery. The proximal markers and the top of the partially deployed AneuRx graft can be effectively used to choose the appropriate cranio-caudal angulation that allows perpendicular visualization of the infrarenal aortic neck and accurate deployment of the device. Another important technical factor that increases graft stability in the long term as suggested by Arko and colleagues is the deployment of the limbs of the device well into the common iliac arteries.<sup>7</sup>

## Conclusions

AneuRx graft migration occurs at a relatively low rate if the device is appropriately deployed and the modified IFU criteria are followed closely. If patient selection is poor and device deployment is suboptimal, endovascular repair failure is likely to occur with any device used.

#### References

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## NOTES