# Design and Clinical Considerations for Endovascular Stent Grafts

Alexis Powell, MD, Vikram S. Kashyap, MD*

**KEYWORDS**

• Abdominal aortic aneurysm (AAA) • EVAR • Endograft • Aortic neck • Active fixation
• Radial force

**KEY POINTS**

- Endovascular treatment for aortic abnormality is an excellent alternative option for patients who are not good candidates for conventional open surgery.
- The evolution of the stent-graft design has been an exercise in expanding indications for use, safety, and miniaturization.
- The most important limitations to overcome are achieving high-quality aortic neck "healthy" landing zone, smaller diameter delivery systems, and endografts that allow for more angled aortic necks.
- New endovascular techniques were developed to accommodate endovascular repair of abdominal aortic aneurysms falling outside the above criteria in patients deemed poor open candidates.

## INTRODUCTION

Aortic aneurysms are localized dilatations of the arterial wall and most commonly affect the infrarenal abdominal aorta. Abdominal aortic aneurysm (AAA) has a multifactorial pathology, with both environmental and genetic risk factors. Occlusive atherosclerotic disease, smoking, male gender, and hypertension are known risk factors for aneurysmal degeneration. Genetic predisposition gives a relative risk of 1.9 in people with a family history.[1]

AAAs develop typically without symptoms and are commonly found incidentally on imaging for unrelated symptoms. The natural history of aneurysms is to gradually expand silently over time, and unfortunately, can commonly rupture without warning or symptoms; this often results in hemodynamic compromise and death. Aortic aneurysm rupture carries a mortality of greater than 80%, with a traditional 50% in hospital mortality after open repair.[2] Current recommendations advocate intervention for AAAs greater than 5.5 cm in diameter, symptomatic aneurysms, or ruptured.

Traditional open surgical repair uses a large intra-abdominal or retroperitoneal incision, followed by replacement of diseased aorta with prosthetic graft. The operation requires general anesthesia and is commonly associated with significant morbidity and mortality.

Endovascular treatment of aortic abnormality is an excellent alternative option for patients who are not good candidates for conventional open surgery. Multiple studies have demonstrated endovascular aortic aneurysm repair (EVAR) as an alternative to open surgery with lower perioperative morbidity and mortality, and overall long-term outcomes that rival the traditional repair. In recent years, the design of these stent grafts has evolved to adapt to

Department of Vascular Surgery and Endovascular Therapy, University Hospitals Case Medical Center, 11100 Euclid Avenue, Cleveland, OH 44106, USA
* Corresponding author.
*E-mail address:* Vikram.Kashyap@uhhospitals.org

Intervent Cardiol Clin 5 (2016) 381–389
http://dx.doi.org/10.1016/j.iccl.2016.03.003
2211-7458/16/$ – see front matter 

more and more challenging aortic abnormality and anatomic constraints.

Historically, the endovascular stent graft is associated primarily for treatment of AAAs, although they are being used more and more to treat many other different types of aortic abnormality—including dissection, atherosclerotic disease, pseudoaneurysm, and aortic trauma/transection. In addition, the grafts are now used for aneurysms of other arteries, including the thoracic aorta and iliac arteries.

## THE FIRST ENDOVASCULAR AORTIC ANEURYSM REPAIRS

Dr Nicholas Volodos and Dr Juan Carlos Parodi are credited for developing the first aortic endografts. Dr Volodos did so in the 1970s to 1980s era and developed a fabric-covered Z-stent, tested in animal models. First implantation in a human aorta was on March 24, 1987 for treatment of a traumatic thoracic aortic aneurysm. Also in 1987, Volodos and colleagues[3] performed the first EVAR in a human.

Endovascular repair of AAAs in the Western hemisphere was simultaneously underway and was initially described by Parodi and colleagues,[4] who performed their first successful EVAR in 1990. Their idea for a device initially came from coronary stenting and utilization of similar stents on a larger-size scale for the aorta.

Finally, Dr Timothy Chuter designed, made, and used the first modern-day bifurcated stent graft for AAA, the first modular system for endovascular repair of an aortic arch aneurysm, and the first modular system for bilateral iliac aneurysms.[5]

## OVERVIEW OF ENDOVASCULAR AORTIC ANEURYSM REPAIR TECHNIQUE

Although the technique of placing endovascular stent grafts has evolved since the first grafts, the basic principles remain the same. Access to the aorta is typically achieved via common femoral artery access in the groin, and fluoroscopic imaging is used to identify the anatomy of the abdominal aorta. The Seldinger technique is used to introduce catheters, sheaths, and delivery system of the stent graft into place into the aorta over a guidewire, and the endograft is deployed into position. Following complete delivery of the endograft components, a seal is achieved using balloon angioplasty at both the proximal and the distal landing zones of "healthy" aorta, excluding the aneurysm sac from circulation.

## DESIGN PRINCIPLES OF ENDOVASCULAR STENT GRAFTS

The evolution of the stent-graft design has been an exercise in expanding indications for use, safety, and miniaturization.

Original designs for endovascular aortic aneurysm exclusion devices are somewhat similar to those of today. In fact, most follow many of the same design principles—metal skeleton with graft fabric material. The early stent-graft devices were modified balloon-mounted stents sutured to a Dacron tube graft. These devices were delivered through a sheath, and the balloon-mounted stent was deployed in the neck of the aneurysm.[4] Early stent-graft designs were limited in scope of treatment, with a unibody design, and would require additional cross-femoral bypass if the aneurysm involved the aortic bifurcation or the iliac arteries.

Soon after their publication in the early 1990s, there were many modifications to the original design, including the introduction of the bifurcated stent graft designed by Dr Chuter and colleagues,[6] introduction of aortic fixation via metallic barbs and the use of self-expanding Nitinol stents for proximal fixation. Early designs and devices were based on physician modification of readily available components to create an endograft. Soon after the introduction and initial reports of success, the design of the devices was taken over by industry and underwent rapid evolution and multiple alterations.

One of the 2 first commercially available stent grafts relied on passive fixation to keep the stent graft in place as well as seal the aneurysm. Passive fixation required radial force from the stent structure pressing outward on the wall of the infrarenal aorta. In order to accomplish this, stent grafts require oversizing beyond the aortic neck diameter. This technique has been questioned in the past[7] and more recently with the introduction of gel polymer proximal seal stent grafts.[8,9] It has been hypothesized that oversizing grafts creates increased outward forces that, over time, may induce further conformational degenerative changes in the aortic wall. Isolated passive fixation devices have now largely been phased out of current use.

Although the other of the first 2 US Food and Drug Administration (FDA) -approved, commercially available grafts did use active hooks for fixation, it was fraught with problems that ultimately led to its discontinuation. Most currently available grafts use active fixation techniques in their stent grafts via metal barbs that are designed to penetrate the aortic wall and