

Endovascular Management of Abdominal Aortic Aneurysms: Devices Available and Evidence for Use

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INTRODUCTION

Since Juan Parodi,¹ performed the first endovascular aneurysm repair (EVAR) more than two decades ago, there has been continuous attempts to work towards developing an ideal stent graft. This is evidenced by the regular releases of new devices as well as updated older devices on to the market. Unfortunately, no device at present has all the characteristics that would make it an ideal stent graft.²

An ideal stent graft should:

1. Be easy to deploy
 - Low profile
 - Easy to cannulate contralateral gate or do away with the need to
 - Have excellent marker visibility
2. Be able to adapt to adverse aortic anatomy (angulated neck, tortuous iliacs, thrombus etc.)
3. Be able to reduce the risk of endoleaks and thus guarantee prevention of rupture and eliminate the need for secondary re-interventions.
4. Be inexpensive.

Most current stent grafts do not fulfil one or more of the above characteristics. The search for the holy grail thus continues!³

Most large volume vascular units adopt either a 'horses for courses' approach, where a device that suits the patient's aortic anatomy is chosen or use the units favoured 'work horse' on most occasions accepting the fact that on many occasions the usage is outside the manufacturer's instructions for use.

The devices that have been included in this chapter are all CE marked,⁴ FDA approved⁵ or both. The list is thus not comprehensive as several locally manufactured devices in countries like China, South Korea, Brazil and the Czech Republic are not CE marked or FDA approved and are not widely available for use outside their countries of manufacture.

BASIC DESIGN AND PRINCIPLES OF ENDOVASCULAR STENT GRAFTS FOR ABDOMINAL AORTIC ANEURYSM (AAA) REPAIR

While details of the instruction for use of every stent graft is beyond the scope of this chapter, there are some basics that most, if not all, stent grafts used for treating AAAs adhere to.

- All AAA stent grafts have a metal skeleton of either Nitinol or stainless steel.
- All AAA stent grafts have a covering of either Dacron, Polyester or ePTFE.
- All stent grafts come in a delivery system that can be retrieved after deployment of the graft.
- All stent grafts used to treat AAAs need good access vessels, i.e. the common femoral and iliac arteries should be of reasonable caliber (between 5 and 8 mm), depending on the size of the delivery system.
- All stent grafts need good proximal (from 7 to 15 mm of good quality aorta below the lowest renal artery) and distal landing zones.
- All stent grafts (especially the ones without hook or barb fixation), work better when there is minimal thrombus in the landing zones.
- All stent grafts (except the uni-iliac variety), need adequate space at the aortic bifurcation, to avoid compression and potential for limb occlusion.
- Severe aortic neck angulation and iliac vessel tortuosity are predictors of stent graft failure to prevent AAA rupture.⁶
- All stent grafts need to be oversized (between 10 and 15%), compared to the diameter of the aortic landing zones.
- All stent graft repairs need adequate follow up to pick up potential problems before they escalate into aneurysm rupture.

Commonly Used AAA Repair Stent Grafts

As mentioned above there are a large number of stent grafts that are commercially available. Some (or their previous iterations) have been around for more than 10–15 years while some have only recently been commercially available. This means that there is potentially a larger body of evidence around the older grafts. The author makes no attempt to pick one over the other, as all have their strengths and weaknesses.

Most Commonly Used Modular Bifurcated Grafts

The Zenith[®] and Zenith flex[®] (Cook Medical), the Endurant[®], Endurant 11s (Medtronic) and the Gore[®] Excluder (W L Gore) have been in use for much longer than most other stent grafts. The Zenith[®] grafts have supra renal fixation and an excellent track record.^{7,8} There seems to be a reduction in number of secondary re-interventions over the years⁹ with increasing experience with the Zenith. The Zenith[®] platform also comes with and iliac branched device which can be used to address the issues surrounding ectatic or aneurysmal common iliac arteries (Fig. 1).¹⁰

The Endurant[®] and Endurant 11s[®] from Medtronic,¹¹ are arguably the most widely used endografts round the world. Its ease of use and 'physician friendly'

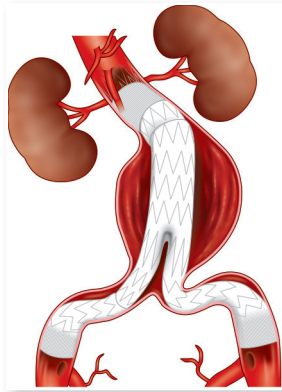


Figure 1: Zenith® stent graft

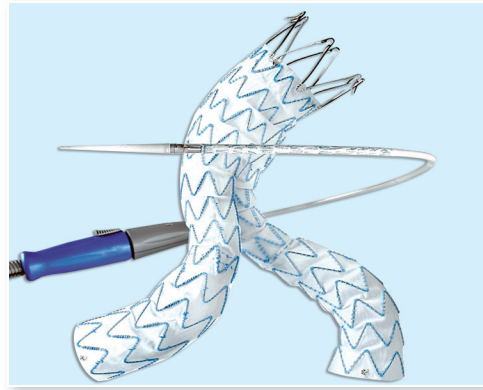


Figure 2: Endurant® Stent graft

delivery system has led to this being used with excellent results.^{12,13} Although, unlike the Cook device it does not have an iliac branched or fenestrated iteration, the Endurant® has been used to repair perirenal aneurysms using the chimney or snorkel technique with reasonable success (Fig. 2).¹⁴

The Gore Excluder®,¹⁵ is another in this series of modular bifurcated grafts that has a large volume of evidence behind it.^{16,17} It differs from the Endurant® and Zenith® in that it has a covering of ePTFE rather than Polyester or Dacron. Its C3 variant is repositionable and an iliac-branched device is available.^{18,19}

The E-tegra® (Jotec GmbH), stent graft is similar to the grafts from Cook and Medtronic and performs very well within its instructions for use. The E-tegra® can be used along with Jotec's E-iliac® iliac branched device to treat aorto-iliac aneurysms. The Treovance® (Bolton Medical) is very similar in design to the above grafts and has a reasonable body of evidence regarding its performance (Fig. 3 and Table 1).^{20,21}

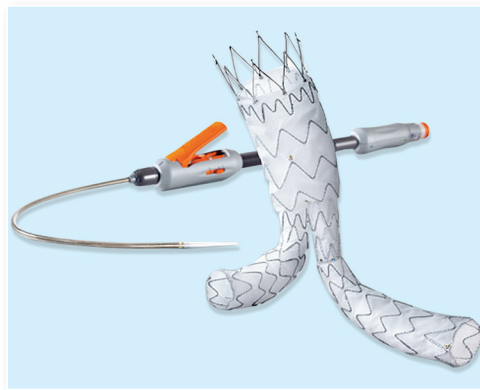


Figure 3: Jotec E-Tegra® stent

Table 1: Endovascular stent grafts used to repair abdominal aortic aneurysms and their main characteristics

Device name	Type of graft	French size main body	Max proximal diameter of stent (millimeters)	Largest available flared limb diameter (millimeters)	Iliac branch available	IFU neck length (millimeters)	IFU aortic neck angle (degrees)
Zenith® Zenith Flex® (Cook)	Modular bifurcated	18–22	36	24	Yes	15	Up to 60
Endurant® Endurant 11s® (Medtronic)	Modular bifurcated	14–20	36	28	No	10	Up to 60
Gore Excluder® (W. L. Gore)	Modular bifurcated	16–18	35	27	Yes	15	Up to 60
Incraft® (Cordis)	Modular bifurcated	14–16	34	24	No	15	Up to 60
Aorfix® (Lombard Medical)	Modular bifurcated ring stent	22	31	20	No	15	Up to 90
Anaconda® (Vascutek Terumo)	Modular bifurcated ring stent	20–22	34	23	No	15	Up to 90

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Device name	Type of graft	French size main body	Max proximal diameter of stent (millimeters)	Largest available flared limb diameter (millimeters)	Iliac branch available	IFU neck length (millimeters)	IFU aortic neck angle (degrees)
Ovation® (Endologix)	Modular bifurcated polymer ring seal.	14–15	34	28	No	7	Up to 60
E-tegra® (Jotec GmbH)	Modular bifurcated	18–20	36	25	Yes	15	Up to 60
Treovance® (Bolton Medical)	Modular bifurcated	18–19	36	24	No	10	Up to 60
AFX® (Endologix)	Non-modular bifurcated	19	34	25	No	15	Up to 60
Nellix® (Endologix)	Parallel stents polymer filled endobags	17	Parallel 10 mm stents. Can treat up to 32 mm aortic neck	Endobags fill the iliac artery	No	10	Up to 60
Altura® (Lombard Medical)	Parallel double D stents	14	30	21	No	15	Up to 60

Other Modular Bifurcated Stent Grafts

The Aorfix™ (Lombard Medical) and Anaconda™ (Vascutek Terumo), stent grafts have ring stents as opposed to Z stents and this makes them able to conform to tortuous anatomy much better. The Aorfix™ was the first to get CE marked and FDA approved for use in angulated aortic necks up to 90 degrees.²²⁻²⁵ It has also proven itself in adapting to tortuous iliac anatomy.²⁶ The Aorfix™ has no suprarenal fixation but has a fish-mouth appearance proximally. If the renal arteries are placed in the trough of the fish mouth some amount of the covered portion will extend to the supra renal region of the aorta. The superior mesenteric artery thus needs to be at least 10 mm above the lowest renal artery (Fig. 4).

The Anaconda™ is very similar in design to the Aorfix™, but comes with suprarenal fixation and a magnetic wire to aid cannulation of the contralateral gate. Given its ring stent design it also performs well in tortuous anatomy.^{27,28} In addition the Anaconda™ is available with an 'off the shelf' fenestrated cuff. The Anaconda™ is also licensed for use in aortic neck angulation up to 90 degrees.

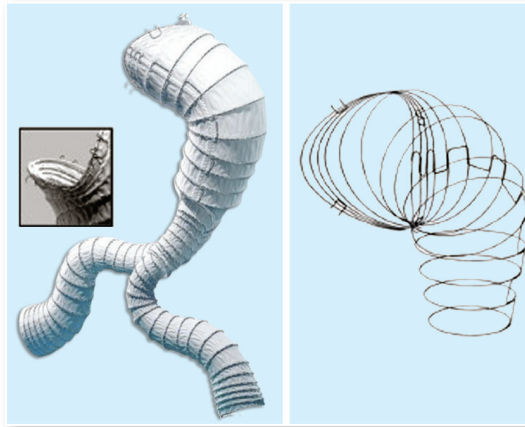


Figure 4: Aorfix™ stent graft

Low Profile Modular Bifurcated Stent Grafts

The Incraft® (Cordis), is a bifurcated modular stent graft with an ultra-low profile delivery system (14F). It lends itself well to pre-cutaneous use. It is also very useful in patients with a narrow aortic bifurcation and small access vessels as often seen in females.²⁹⁻³¹

The Ovation® (Endologix) stent graft is another ultra-low profile graft.³² Its instructions for use (IFU) lends itself to be used in short (no less than 7 mm) and conical aortic necks.³³ It has two proximal sealing rings that are filled with polymer and this along with its long suprarenal fixation allows short necks to be treated. The low profile is also useful when a per-cutaneous approach is used.³⁴ There have however been some reports regarding anaphylaxis due to polymer leakage.³⁵ There has been some work regarding aortic neck evolution following endovascular stent grafting^{36,37} and in short

conical necks where a fenestrated repair is not feasible the Ovation® could be considered (Fig. 5).

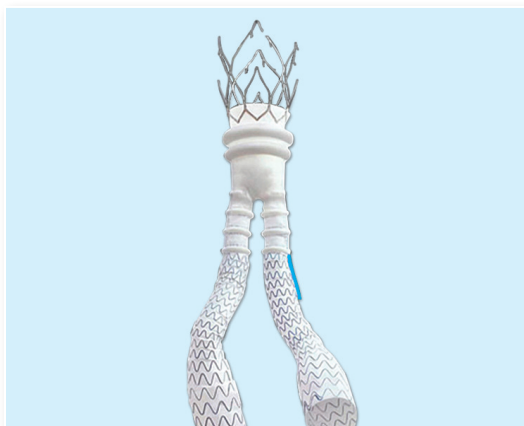


Figure 5: Ovation® stent graft

Non-modular Bifurcated Device

The AFX® (Endologix) is a bifurcated device which is non-modular, i.e. both limbs of the bifurcated graft go up one of the iliac arteries and the bifurcation of the graft is made to sit on the aortic bifurcation. Once the main body is deployed an infra-renal cuff is then deployed, (if needed), to complete the procedure and get a seal in the infra-renal position. The cuffs come with and without suprarenal fixation. This device is made of stainless steel and Endologix's proprietary ePTFE (Strata®), which is draped outside the steel skeleton. The flaring out of the Strata provides an element to the seal at the aortic neck.^{38,39} Endologix has made improvements with the top cuff by introducing the Vela® variant. The instructions for use of this states that it can be used in narrow aortic bifurcations (up to 17 mm) (Fig. 6).

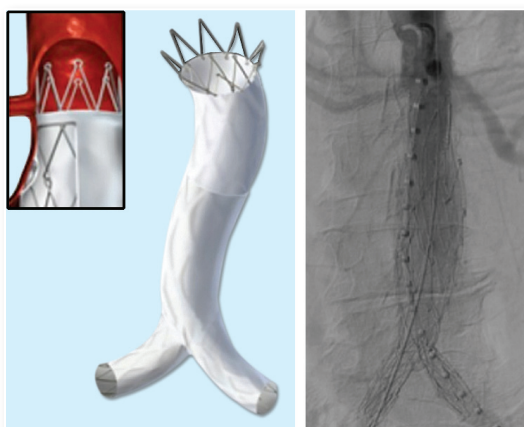


Figure 6: The AFX® stent graft

Parallel Stent Grafts

The Nellix® (Endologix) device provides endovascular aneurysm sealing (EVAS). It consists of two parallel, balloon mounted, 10 mm covered stent grafts. Each stent graft has an endobag attached to it and these are filled with polymer (polyethylene glycol) and allowed to cure during the deployment process. This leads to the aneurysm sac being completely filled by the endobags, which in theory should prevent any flow of blood into the aneurysm sac. Planning and sizing for this device is slightly different from other devices in that the volume of polymer required to fill the aneurysm sac needs to be calculated, in addition to the lengths that need to be treated. So far the results of this device are encouraging.⁴⁰⁻⁴² Some other advantages are that an iliac aneurysm can also be dealt with when treating the aorta as the endobags fill the space in an ectatic or aneurysmal iliac artery.⁴³ Given the simplicity of the deployment process (no gate cannulation), it lends itself to being used in the ruptured aneurysm situation.⁴⁴ There are also good results being reported when the chimney or snorkel technique is used with the Nellix® to treat perirenal aneurysms.⁴⁵

The concerns regarding the Nellix® center around how to deal with a type 1 endoleaks^{46,47} and reports regarding caudal migration of the graft,⁴⁸ possibly due to continuing dilatation of the aortic neck. More data are needed to clearly understand these processes (Fig. 7).

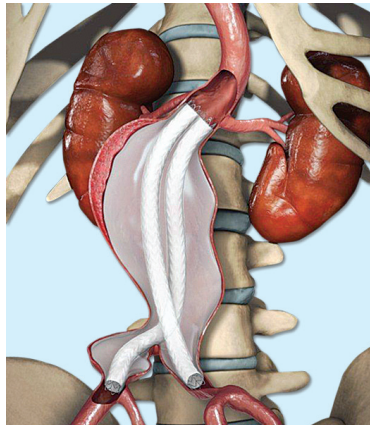


Figure 7: The Nellix® stent graft

The Altura™ (Lombard Medical) device also consists of two parallel self-expandable stent grafts. This again eliminates the need for cannulation of a contralateral gate and is quick to deploy. It also has the added advantage of retrograde deployment at the distal landing zone (i.e. the stent opens from bottom upwards), thus helping with more accurate deployment at the iliac artery bifurcation. The two stents do not have to be deployed at the same level at the top and this may help gain a little more infrarenal fixation. The Altura™ has only been commercially available for a few months and long-term real world experience is lacking (Fig. 8).

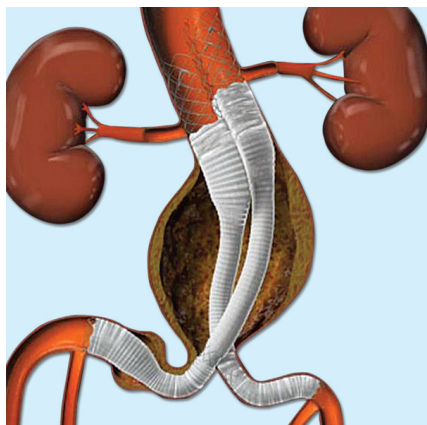


Figure 8: The Altura™ stent graft

Uni-iliac Devices

The uni-iliac device, where only a single stent graft is passed up one iliac and deployed, followed by occlusion of the contralateral iliac and a fem-fem crossover bypass is done, is rarely used. Some indications for employing this technique include (a) an occluded iliac artery, (b) a very narrow aortic bifurcation and (c) as an emergency to treat a ruptured aneurysm. Most of modular bifurcated devices mentioned above have a uni-iliac version of the graft or provide a converter whereby the bifurcated device can be converted to a uni-iliac device (Fig. 9).



Figure 9: Uni-iliac procedure

CONCLUSION

With a myriad of devices available, choosing a device can be quite confusing to those starting out to do endovascular aneurysm repairs. Although a 'horses for

courses' approach seems reasonable, it may reduce the experience that could be gained from using a 'work horse'. It would be reasonable to start with and gain considerable experience with any of the above devices that have long-term real world data. This will give the physician and the team, experience with the procedure itself, as well as an insight into how to troubleshoot or bail out if this were necessary. Cost is also a significant factor in device selection. Some of the newer stent grafts, especially the ones that use polymer are significantly more expensive than some of the well-established devices. At the end of the day there is no perfect device and personal experience, cost, patient's aortic anatomy, availability of industry support and proctoring, etc. will be the main drivers for device selection. In amongst all this one would be well advised to consider the patient's choice as well as open repair.

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