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Current Status of Endovascular Devices to Treat Abdominal Aortic Aneurysms

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Abstract: The introduction of endovascular abdominal aortic aneurysm (AAA) repair has revolutionized the therapeutic approach to patients with AAA. Due to an on-going and prolific collaboration between vascular interventionalists and biomedical engineers, the devices used to perform endovascular AAA repair have also changed dramatically. The purpose of this publication is to provide an overview of the currently available and upcoming options for endovascular AAA repair.

Keywords: AAA, EVAR, endograft, aortic stent, endovascular, aneurysm, future technology

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Introduction

An abdominal aortic aneurysm (AAA) is a localized dilatation of the abdominal aorta that measures greater than 3.0 cm in diameter.¹ The main risk of an untreated AAA is progressive expansion, rupture and death. AAA rupture risk increases with increasing aortic diameter and this catastrophic event is associated with a mortality of 50% to 80%.²⁻⁴ Due to the excessive mortality associated with emergent repair, the mainstay of AAA management is early diagnosis and elective repair prior to rupture. The traditional open surgical repair involves a large incision in the abdomen and exclusion/replacement of the aneurysm with a synthetic fabric graft. An alternative treatment, first described in 1986,⁵ is endovascular aneurysm repair (EVAR). This minimally invasive technique involves insertion of a fabric covered stent to re-line the aneurysmal aorta via the femoral and iliac arteries. The function of the stent-graft is to exclude the weakened aortic aneurysm wall from the systemic blood pressure and hence rupture. The introduction of EVAR has revolutionized the therapeutic approach to patients with AAA. Furthermore, the last decade has witnessed a rapid progression in the techniques and devices engineered to perform endovascular AAA stent grafting in an attempt to decrease graft-related complications and re-interventions. The purpose of this publication is to provide an overview of the currently available and upcoming device options available for endovascular AAA repair.

Basic Stent Graft Construction

Over the last two decades, there has been rapid innovation and increasing device diversity due to collaboration between vascular interventionalists and bioengineers. The first commercially available devices were launched in 1994 and since this time continuous modifications have been made. At present, numerous new endoprostheses exist with varied stent material, graft fabric, fixation, deployment precision, ease of use, delivery sheath size, and flexibility. Polyethylene terephthalate (PET; eg, Dacron) or polytetrafluoroethylene (PTFE; eg, Teflon) are the graft materials used in construction of all currently available aortic stent grafts. Both of these polymers are high strength, resilient, and lightweight, necessary properties for material that is subject to constant wear against metallic stent components and the pulsatile stress of

the arterial blood flow. The composition of the stent skeleton also varies depending on the graft. Current options include stainless steel, nitinol (a nickel and titanium alloy), or cobalt chromium alloys. The choice of material used in stent cage construction must balance strength, conformability, and compressibility to maximize aneurysm repair durability and device deliverability through challenging aortic and iliac artery anatomy. Similarly, the method by which the stent graft is attached to the aortic wall varies between device manufacturers and is achieved by active fixation using hooks, barbs, anchors, or staples that embed into the aortic wall, or by anatomical fixation in which the stent graft rests on the aortic bifurcation as a means of stabilization. Active fixation is further subdivided into supra- or infra-renal, depending on the relationship of the anchoring mechanism to the renal arteries. The suprarenal aortic neck may be more resistant to aneurysmal degeneration but concerns have been raised about the use of suprarenal fixation and long term kidney dysfunction.⁶ Currently, no consensus exists regarding the influence of supra- or infra-renal fixation on long term kidney function.

Currently Available Devices

Cook Zenith Flex and Zenith Fenestrated

The Cook Zenith Flex device with Flex Iliac Limbs and Z-Trak Introduction System (COOK Medical, Bloomington, IN, USA) is the latest generation Zenith device available for use in the United States. The traditional modular bifurcated design with woven polyester graft material is supported by stainless steel Z-stent bodies hand sutured to the fabric.⁷ The newer Flex Iliac Limbs contain shorter stents with greater fabric space between them to improve flexibility and conformability in tortuous iliac arteries. The main body component can be deployed with pinpoint accuracy allowing precise repositioning until the top cap is released which deploys the barbed suprarenal fixation stent. Main body devices range in size from 22 to 36 mm delivered through 18- to 22-French sheaths (1-French = 3.14 mm inner diameter).⁸ Flared iliac limbs go up to 24 mm in diameter. Current graft specific indications include a non-aneurysmal infra-renal aortic neck of at least 15 mm with an angle ≤ 60 degree relative to the aorta (Fig. 1).

Built on the proven Zenith platform, the Cook Zenith Fenestrated AAA Endovascular graft is a

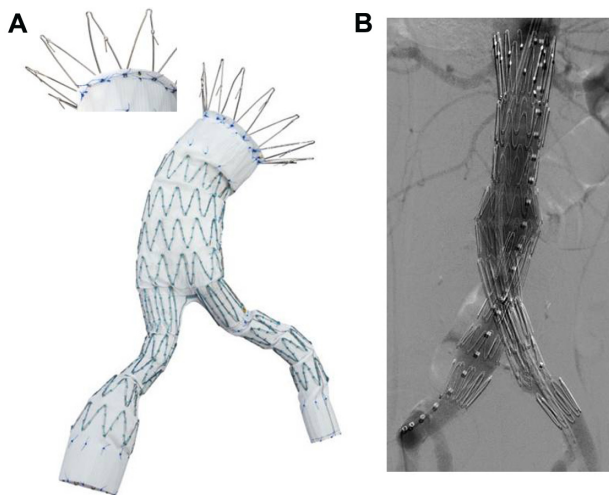


Figure 1. Cook Zenith Flex device (COOK Medical, Bloomington, IN, USA) (A) View of the Cook Zenith stent grafts (Permission for use granted by Cook Medical Incorporated, Bloomington, Indiana). Three-piece modular bifurcated design with woven polyester graft material supported by stainless steel Z-stent bodies hand sutured to polyester fabric. A series of barbs that engage the aortic wall provide active fixation. Additional iliac and aortic extender cuffs are available. (B) Completion aortogram showing successful AAA exclusion following Cook Zenith Flex deployment (Implantation of the Cook Zenith device performed by the authors).

currently available endovascular option for patients who have a non-aneurysmal infra-renal aortic neck as short as 4 mm. These patients are, at present, not able to undergo endovascular repair with any other commercially available device. The Cook Fenestrated device is able to exclude these AAA's by incorporating up to three precisely located holes (ie, fenestrations) and/or cut-outs from the proximal margin (ie, scallops) of the graft material. The fenestrations/scallops allow the proximal graft material to be placed above the level of the renal arteries and therefore allow patients with shorter aortic necks to undergo endovascular repair. It is important to note, these grafts are custom-made and require careful planning of fenestration/scallop placement using advanced processing of computed tomography images. The Cook Zenith Fenestrated system consists of three components: a proximal body graft, a distal bifurcated body graft, and one iliac limb. The graft modules are identical to the materials used to construct the standard Zenith AAA endovascular graft, with the exception of the new Zenith Fenestrated device having a nitinol wire ring around the graft fenestrations (Fig. 2).

Medtronic Endurant II

The Medtronic Endurant II device (Medtronic Cardiovascular, Santa Rosa, CA, USA) is the latest

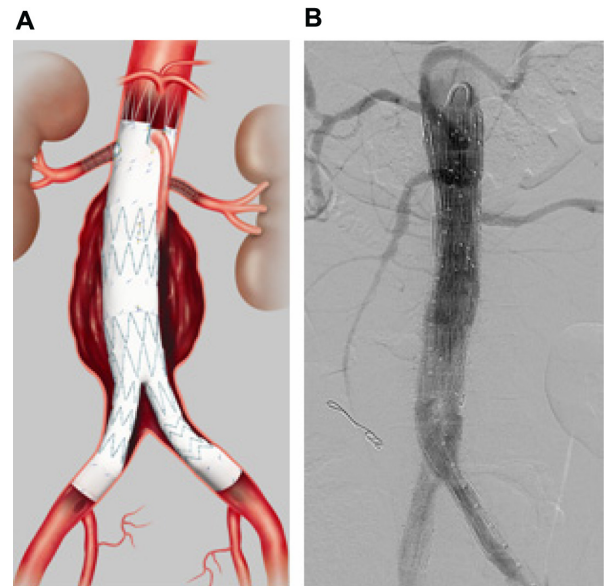


Figure 2. Cook Zenith Fenestrated AAA Endovascular graft (COOK Medical, Bloomington, IN, USA). (A) The Cook Zenith Fenestrated system consists of three components: a proximal body graft, a distal bifurcated body graft, and one iliac leg (Permission for use granted by Cook Medical Incorporated, Bloomington, Indiana). The graft modules are constructed of full-thickness woven polyester fabric sewn to self-expanding stainless steel Cook Z stents with braided polyester and monofilament polypropylene suture. Incorporation of scallops or fenestrations into the graft design allows EVAR to be performed in patients with more challenging anatomy. Graft design as shown in (A) include a scallop for the superior mesenteric artery and a fenestration for each renal artery. (B) Completion aortogram showing successful juxta-renal AAA exclusion following Cook Zenith Fenestration deployment (Implantation of the Cook Zenith Fenestrated AAA Endovascular graft performed by the authors). Graft design (as shown in (B)) includes one fenestration for the left renal artery and one scallop for the superior mesenteric artery (patient had previous hepatorenal bypass).

generation of the Endurant device available for use in the United States.⁹ It is a low profile (23–36 mm main body sizes deployed through 18-French access) device with a unique sheathless hydrophilic delivery system. Precise deployment is achieved using the controlled release system which allows separate deployment of the barbed suprarenal fixation stent apart from the main body. The modular bifurcated device is composed of self-expanding nitinol stents mounted on high density polyester fabric.¹⁰ Multiple lengths and diameters are available for the iliac limbs with the largest flared limb measuring 28 mm. The device is approved for aortic necks at least 10 mm in length with angulation ≤ 60 degrees. Compared to the previous generation Medtronic device, the Endurant II is made with a shorter and wire-formed M-shaped body stent which allows it to accommodate more angulated aortic necks (Fig. 3).¹¹

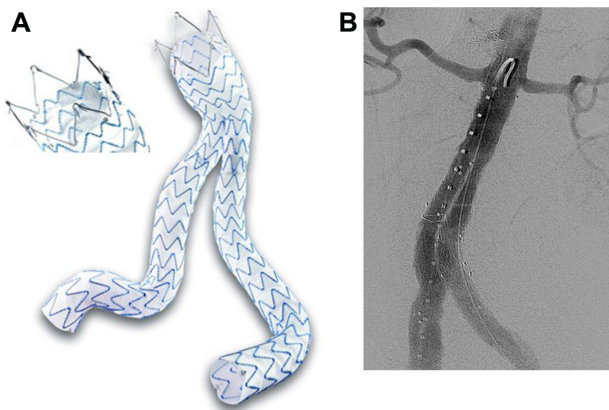


Figure 3. The Medtronic Endurant II device (Medtronic Cardiovascular, Santa Rosa, CA, USA). **(A)** The modular bifurcated device is composed of self-expanding nitinol stents mounted on polyester fabric (Permission for use granted by Medtronic Cardiovascular Santa Rosa, CA, USA). Multiple lengths and diameters are available for the iliac limbs with the largest flared limb measuring 28 mm. The device is approved for aortic necks at least 10 mm in length with angulation < 60 degrees. **(B)** Completion aortogram showing successful AAA exclusion following Medtronic Endurant II deployment (Implantation of the Medtronic Endurant II device performed by the authors).

Gore Excluder

The Gore Excluder stent graft (W.L. Gore and Associates, Flagstaff, AZ, USA) is a recent generation AAA endoprosthesis with a long history of efficacy, safety, and durability.¹² This modular stent graft consists of a bifurcated main body with a single docking limb used in combination with an assortment of iliac limbs and proximal extensions to tailor the repair to the aneurysm anatomy. The Gore Excluder is composed of expanded polytetrafluoroethylene (ePTFE) combined with a thin, non-permeable layer of fluorinated ethylene propylene, all of which is attached to a nitinol stent frame. The graft provides active infra-renal fixation through the use of nitinol barbs at the proximal neck of the main body. In late 2010, the Gore Excluder deployment system was modified to allow for more precise and controlled deployment. This new delivery system, deemed the C3 delivery system, is a three-step process that allows the operator to reposition the Excluder after deployment but before release of the active fixation stent. This technique is useful if deployment of the main body is too far above or below the lowest renal artery. The Excluder device is currently approved to treat infra-renal aortic neck diameters ranging from 19 to 29 mm with a minimum aortic neck length of 15 mm and a proximal aortic neck angulation $\leq 60^\circ$. To ensure safe delivery and adequate seal, iliac artery diameters must range from

8 to 25 mm and iliac distal vessel seal zone length must be at least 10 mm (Fig. 4).

Endologix AFX

The AFX Endovascular AAA System (Endologix, Inc., Irvine, CA, USA) is a unique device in many aspects. First, it is the only device to utilize anatomical fixation, wherein a unibody graft straddles the native aortoiliac bifurcation as its means of stabilization. Second, it is the only self-expanding stent cage that is composed of a cobalt chromium alloy. To this stent cage, a thin-walled, a low porosity ePTFE graft is attached proximally and distally with polypropylene suture to the outside of the stent cage. This proprietary ePTFE graft material, termed Strata graft technology, is highly conformable, averages 20 layers of ePTFE, and offers exceptional strength and impermeability through multilayer processing and bonding. The remainder of the system consists of proximal and distal limb extensions to accommodate the patient's specific aortic anatomy. Lastly, the AFX AAA system takes a unique approach to achieving proximal seal of the AAA. The proximal extension achieves aneurysm exclusion (ie, seal) due to the outward radial force of the stents (traditional seal) but also due to movement of the graft material outside of

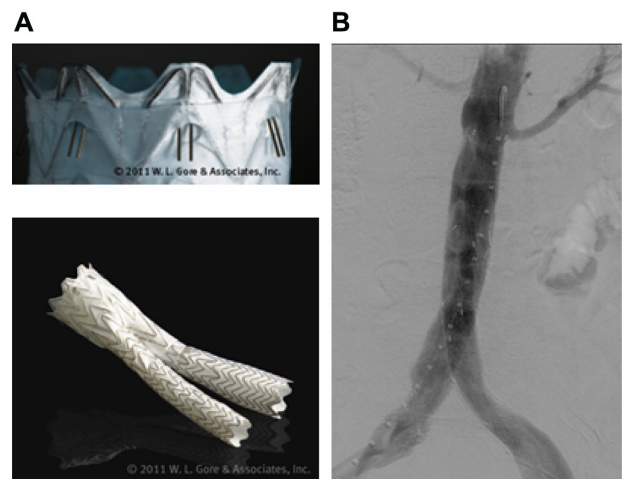


Figure 4. Gore Excluder stent graft (W.L. Gore and Associates, Flagstaff, AZ, USA). **(A)** Modular stent graft design consisting of a bifurcated main body with a single docking limb used in combination with an assortment of iliac limbs and proximal extensions (Permission for use granted by W.L. Gore and Associates, Flagstaff, AZ, USA). The Excluder is composed of ePTFE attached to a nitinol stent frame. The graft provides active infra-renal fixation through the use of nitinol barbs at the proximal neck of the main body. **(B)** Completion aortogram showing successful AAA exclusion following Gore Excluder deployment (Implantation of the Gore Excluder stent graft performed by the authors).

the stent. This enhanced seal, termed ActiveSeal with STRATA™, is due to the placement of attachment sutures at only the proximal and distal ends of the graft material which allows independent movement of the graft material to provide more wall contact. The AFX delivery system consists of a 17-French hydrophilic introducer sheath with a hemostatic valve and a 9-French contralateral percutaneous access and is approved for aneurysms with 15 mm neck length and less than 60 degree neck angulation (Fig. 5).

Future Devices

Cook Zenith low profile (LP)

The Cook Zenith LP modular device (COOK Medical, Bloomington, IN, USA) is similar to the previously discussed Cook Zenith aortic endografts, but with an updated low profile (LP) system. The graft modules have similar construction and fixation to the previously described Zenith Flex endograft, with replacement of the Z-stent (stainless steel) bodies with self-expanding nitinol stents. The LP delivery system diameter is 16-French, 20% less than previous Cook aortic stent devices, potentially providing use in patients with smaller iliac and femoral access vessels. The deployment system is flexible and hydrophilic to provide safer percutaneous or open delivery through

small, tortuous, and calcified vessels. Currently this device is undergoing clinical trials in Europe and is not approved for use in the U.S.

Trivascular Ovation

The Trivascular Ovation stent graft (Trivascular Inc., Santa Rosa, CA, USA) is a bifurcated trimodular device with components consisting of an aortic body, iliac limbs, and iliac extensions as required. The aortic body is comprised of a proximal stent for suprarenal fixation, polytetrafluoroethylene (PTFE) graft material, and a self-expanding nitinol stent cage. Proximal seal and support are achieved by a network of inflatable rings filled with a proprietary low viscosity biocompatible liquid polymer that solidifies during deployment. The iliac limbs/extensions are comprised of a nitinol stent encapsulated in PTFE. Graft components are preloaded into separate delivery catheters. During deployment, the device is positioned and the sheath is retracted. The proximal stent is then deployed using stent release knobs located on the delivery handle. The fill polymer is then delivered through the fill connector port using an Autoinjector. The contralateral and ipsilateral iliac limbs are each deployed via delivery catheters. The delivery sheaths are removed after the fill polymer has cured. The fill polymer includes three components that are mixed prior to injection. Upon injection into the graft, the components form a radiopaque polymer filling the sealing rings and channels in the wall of the aortic body.¹³ Aortic anatomical elements affecting aneurysm exclusion include proximal neck angulation $> 60^\circ$, proximal aortic neck length < 7 mm, distal iliac landing zone < 10 mm, and/or aortic neck/iliac inner wall diameter inappropriately sized to the stent graft.

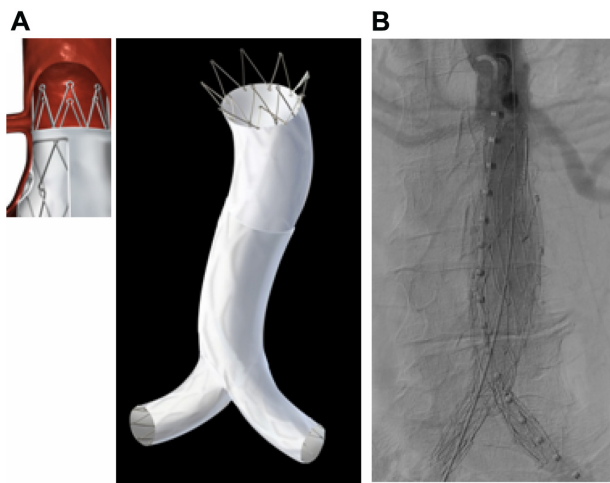


Figure 5. AFX Endovascular AAA System (Endologix, Inc., Irvine, CA, USA). (A) A unibody graft design that straddles the native aortoiliac bifurcation as its means of stabilization (Permission for use granted by Endologix, Inc., Irvine, CA, USA). The stent cage is composed of a cobalt chromium alloy to which ePTFE fabric is attached proximally and distally with polypropylene suture to the outside of the stent cage. The manufacturer hypothesizes that movement of the graft material outside of the stent leads to enhanced proximal seal. (B) Completion aortogram showing successful AAA exclusion following Endologix AFX deployment (Implantation of the AFX Endovascular AAA System performed by the authors).

Aptus fortevo

The Aptus Endovascular AAA repair systems (Aptus Endosystems Inc., Sunnyvale, CA, USA) is a 3-piece modular bifurcated endograft with graft material made of a proprietary polyester material with nitinol stents that extend in a spiral fashion throughout the iliac limbs. Proximal fixation is based on an aortic securement system (HeliFx—Aptus, Sunnyvale, CA, USA). The fixation device is separate from the endograft and consists of a deflectable 16-French guide and electronically controlled applier. The endoanchor is



a 3.0-mm-diameter by 4.5-mm-long helix made of a metallic alloy (MP35N LT). The tapered needle point is designed to penetrate non-diseased vascular tissue and has a proximal cross bar devised to prevent over-penetration. The number of endoanchors and site of implantation varies depending on the proximal diameter of the endograft and aortic neck anatomy of the patient. A minimum of four endoanchors are used in the anterior, posterior and lateral positions. The modular, bifurcated endograft is delivered through the ipsilateral limb, followed by deployment, proximal anchoring, and iliac extension limbs through a low-profile delivery system (16- to 18-French).¹⁴ Although the endograft is not yet FDA approved, the endoanchoring device has recently been approved by the FDA for concomitant use with various other aortic stent grafts in the thoracic and abdominal aorta.

Cordis Incraft

The Cordis Incraft stent-graft system (Cordis Corporation, Bridgewater, NJ, USA) is a 3-piece modular system composed of a seamless, woven, polyester fabric and segmented nitinol stents. The aortic prosthesis has a short infra-renal sealing endoskeleton and proximal trans-renal flared bare metal stents with downward barbs.¹⁵ The delivery system is low profile with a 14- to 16-French built-in main body introducer sheath and 12-French delivery system for the iliac limbs. The aortic prosthesis integrated sheath introducer does not employ a cap. The iliac delivery system is similar to the aortic system, except it does not have an integrated sheath introducer. Turning the delivery system handle initiates deployment and releases the trans-renal stents. These stents remain constrained to allow precise graft positioning. Repositioning remains possible until the graft is unsheathed beyond the contralateral side markers. A fixation release wire is pulled to allow unconstrained configuration of the cranial aspect of the trans-renal stents.¹⁵ This device is investigational in Europe and the U.S.

Bolton Treovance

The Bolton Treovance Abdominal stent-graft system (Bolton Medical Inc., Sunrise, FL, USA) is a trimodular device with woven polyester material and nitinol stents. Multiple proximal fixation points are provided by suprarenal and infra-renal barbs extending from the suprarenal stent. Intra-graft fixation is provided

by 5 dull barbs within each branch of the main body. During graft deployment the proximal graft remains collapsed while the remaining distal graft expands to allow for corrections and precise placement. The device has a double-deployment mechanism allowing the option of slow motion versus the “pin and pull” method. The delivery system is low-profile, flexible, and hydrophilic with detachable sheaths.¹⁶ Sheath sizes for the main body system ranges from 18- to 19-French and iliac limb system ranges from 13- to 14-French. The device is awaiting Conformité Européenne (CE) approval and remains under investigation in the U.S.

Vascutek anaconda

The Anaconda One-Lok stent graft system (Vascutek Ltd., Inchinnan, United Kingdom) is a trimodular device with woven, polyester fabric and nitinol skeleton of separate ring stents made from a single strand of nitinol wire.¹⁷ No suprarenal fixation is present. Proximal graft fixation is based on a dual ring stent design with four pairs of nitinol hooks present on the distal ring. The main body delivery system consists of a flexible thermoplastic fluoropolymer hydrophilic-coated sheath with a repositionable deployment system that enables relocation for optimal positioning. Two control handles are located at the distal end of the sheath. One of the handles enables deployment (“sheath slider”) and the other (“control collar”) allows the operator to collapse, rotate and advance/retract the main body for redeployment. An intrinsic body system magnet wire is designed for simpler contralateral limb cannulation. The device has not been approved for use in the U.S. or Europe.

Endologix Nellix

The Endologix Nellix endoprosthesis (Endologix, Inc., Irvine, CA, USA) consists of dual, balloon expandable endoframes, each of which is surrounded by an endobag that is filled with an in situ curing polymer (polyethylene glycol). The endoframe stenting material is cobalt chromium and delivered via 17-French sheaths. Each endoframe is surrounded by PTFE and supports the blood-flow lumen through the aneurysm sac to the iliac arteries. The polymer-containing endobags surround the flow lumen and fill the aneurysm sac providing anatomical fixation.¹⁸ The Nellix device has recently been CE approved, but remains under investigation in the U.S.

Cardiatis Multi-Layer Aneurysm Repair System

The Cardiatis Multi-layer Aneurysm Repair System (Cardiatis, S.A. Isnes, Belgium) is a self-expanding stent consisting of multiple layers of braided cobalt alloy wires. Available diameters for aortic aneurysms range between 20–45 mm with delivery sheath sizes of 18- to 20-French. The stent can be removed or repositioned when <80% of its length has been extruded. Deployment is initiated by fixing the metallic pusher and retracting the sheath to allow full stent expansion. Flow-diverting stents are designed to reduce the flow velocity vortex within the aneurysm and improve laminar flow in the main artery and surrounding branches.¹⁹ Computation hemodynamics suggests that stent porosity of 50%–70% will significantly reduce the aneurysm inflow rate causing a pressure drop within the aneurysm sac subsequently leading to exclusion and decreased wall tension.

Device Selection, Late Outcomes and Adjuncts

In our experience suitable anatomy, device familiarity, and cost are important factors regarding selection for endovascular repair. In general, many of the current devices used according to instructions-for-use are equivalent regarding post-operative complications, migration, and aneurysm related mortality. However, several caveats regarding device selection do exist. First, due to suprarenal fixation and graft conformability the Cook Zenith and Medtronic Endurant endografts potentially provide greater proximal exclusion as well as decreased migration in patients with shorter (10 mm), angulated aortic necks. Second, younger patients that may develop more proximal aneurysmal disease could potentially benefit from the use of infra-renal fixation. Lastly, patients with peripheral vascular disease and/or narrow aortic bifurcations may benefit from the use of the Endologix AFX device because the endograft mimics the natural aortic anatomy allowing for contralateral lower extremity interventions and deployment within narrow bifurcations.

Regarding late endovascular outcomes, any one of the aforementioned aortic stent grafts may need to be explanted for various reasons.²⁰ Devices with suprarenal fixation are typically much more difficult

to explant and carry an increased potential risk of injury to the suprarenal aorta. AAAs repaired via endovascular stent graft carry the risk of late rupture secondary to endoleaks, migration, disjunction, or infection. Type IA endoleaks, those from the proximal portion of the graft, are potentially amenable to Palmaz stent placement.²¹ The Palmaz stent is balloon expandable, stainless steel, and can be expanded up to 39 mm to aid in sealing the proximal aortic stent graft.

Conclusions

A partnership between clinicians and engineers was necessary to develop the “first generation” devices used to perform endovascular AAA repair. This cooperation across disciplines has led to many technologic advances which in turn translated into quantifiable benefits for patients with AAA. The decades that follow the “fourth generation” devices described in this manuscript will also see continued collaboration leading to innovations and enhanced performance of future endovascular devices.

Author Contributions

Conceived and designed the experiments: ER, RG, KEB. Analyzed the data: ER, RG, KEB. Wrote the first draft of the manuscript: ER, RG, KEB. Contributed to the writing of the manuscript: ER, RG, KEB. Agree with manuscript results and conclusions: ER, RG, KEB. Jointly developed the structure and arguments for the paper: ER, RG, KEB. Made critical revisions and approved final version: ER, RG, KEB. All authors reviewed and approved of the final manuscript.

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Competing Interests

Author(s) disclose no potential conflicts of interest.

Disclosures and Ethics

As a requirement of publication the authors have provided signed confirmation of their compliance with ethical and legal obligations including but not limited to compliance with ICMJE authorship and competing interests guidelines, that the article is neither under consideration for publication nor published elsewhere,



of their compliance with legal and ethical guidelines concerning human and animal research participants (if applicable), and that permission has been obtained for reproduction of any copyrighted material. This article was subject to blind, independent, expert peer review. The reviewers reported no competing interests. Provenance: the authors were invited to submit this paper.

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