The Current State of Fenestrated and Branched Devices for Abdominal Aortic Aneurysm Repair

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Abstract

Keywords

- fenestrated
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- stent graft
- abdominal aortic aneurysm
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Endovascular abdominal aortic aneurysm repair (EVAR) provides an attractive alternative to traditional open techniques. Endovascular repair is frequently limited by aortic aneurysm neck angulation, the absence of an adequate infrarenal neck, and the need for internal iliac preservation. Several devices have been created to incorporate visceral artery segments as well as preserve the internal iliac artery, thus broadening the patient population suited for endovascular repair. This article will provide a review of the current literature regarding fenestrated devices, branch devices, off-the-shelf devices, and physician-modified devices. It will also highlight the iliac branch stent grafts currently on trial for internal iliac artery preservation. Data thus far have suggested that these devices will be both a safe and effective option for anatomically challenging abdominal aortic aneurysms.

Objectives: Upon completion of this article, the reader will be able to identify the current devices being used in the treatment of anatomically-challenging abdominal aortic aneurysms.

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It has been well documented that endovascular repair of abdominal aortic aneurysms (EVAR) offers many advantages over open abdominal aortic aneurysm (AAA) repair.^{1–4} However, up to 40% of patients are unsuitable candidates for traditional EVAR secondary to factors such as a short infrarenal

neck, proximal neck angulation, inclusion of visceral vessels, and inadequate vascular access.^{5–8} To overcome these limitations, several devices have been developed to incorporate the visceral vessels into the proximal seal zone, making previously nonstentable disease amenable to endovascular repair. This article will review the current products available for hostile aortic anatomy including fenestrated stent grafts, off-the-shelf stent grafts, physician-modified devices, and branch grafts. This article will also address internal iliac preservation with a discussion of the internal iliac artery branch graft devices currently on trial.

Cook Zenith Fenestrated Stent Graft

The only fenestrated stent graft currently approved by the FDA is the Zenith fenestrated endovascular (ZFEN) stent graft (see ►Fig. 1). The modular system comprises a proximal body graft, a distal bifurcated graft, and one iliac limb. The graft components are made of woven polyester fabric sewn to self-expanding Cook-Z stents. Fixation is achieved via barbs that are located on the bare suprarenal stent of the proximal body graft. Fenestrations are available in small, large, or scallop (cutouts of

Fig. 1 The Zenith fenestrated endovascular (ZFEN) stent graft is a modular system that consists of a proximal body graft, a distal bifurcated graft, and one iliac limb. Permission for use granted by Cook Medical Incorporated, Bloomington, IN.

the proximal margin) configurations. Stenting is recommended for small fenestrations, optional for scallops, and is not recommended for large fenestrations (Cook Medical, Bloomington, IN).

The safety and efficacy of the device has been established in many countries, and two manuscripts summarizing the intermediate and long-term results of a multicenter prospective trial in the United States have been published.^{4,8-18} The intermediate results of the trial involving 30 patients were published by Greenberg et al in 2009. At 24-month follow-up, there were no aneurysm ruptures, conversions to an open procedure, or aneurysm-related deaths. Aneurysm size decreased in 69.6% of patients, and no patient had an increase in aneurysmal size of greater than 5 mm. Type 2 endoleaks were identified in 26.1% of subjects at 1-year follow-up and 20% at 2-year follow-up. There were eight renal events, namely, four renal artery stenoses, two renal artery occlusions, and two renal infarcts. There was one case of graft migration, one case of renal artery stent fracture, and one case of fixation barb separation in which only the migrated graft required a secondary intervention. The study concluded that the trials intermediate data were similar to other previous single-

center studies, and that the fenestrated endograft was a safe and effective option for juxtarenal AAA repair.^{8,10,15,19-22}

The United States Zenith Fenestrated AAA Endovascular Graft Trial continued to enroll patients through 2012, and Oderich et al recently published the results of 67 patients. There was one perioperative death related to bowel ischemia leading to an early mortality rate of 1.5%. At 5 years, freedom from all-cause mortality was 91% ($\pm 4\%$) and freedom from major adverse events was 79% ($\pm 6\%$). Major adverse events included death in five patients, congestive heart failure, bowel ischemia, myocardial infarction, stroke, and bowel obstruction; only four of these complications were attributed to the actual procedure. Five-year primary renal artery patency was 81% ($\pm 5\%$) and secondary renal artery patency was 97% ($\pm 2\%$). There was no observed difference in rates of occlusion or stenosis in bare-metal versus covered stents, though other studies have reported higher patency rates for covered stents.^{6,23} There was only one type 1 endoleak, and freedom from any endoleak at 5 years was 63% ($\pm 6\%$). Stent migration occurred in two patients, likely related to proximal aortic disease progression, and the overall rate of secondary interventions in all patients was 22%. The trial concluded that the Zenith fenestrated stent graft is both safe and effective as well as durable for use in the United States.⁴

Anaconda Fenestrated Stent Graft

The fenestrated Anaconda stent graft (Vascutek, Inchinnan, United Kingdom) is not FDA-approved for use in the United States; however, it is commercially available in Europe. The system consists of an aortic endograft and two separate iliac limbs. The proximal end of the main body consists of two separate nitinol ring stents and four pairs of nitinol hooks that aid in sealing. The main body itself does not contain any stents, allowing for flexibility in fenestration placement. Furthermore, the design is unique in that it can be fully repositioned after deployment. The device also offers a magnetically assisted limb cannulation system that can decrease contralateral limb cannulation time. The stent graft is custom designed for each patient.^{5,24-26}

Four studies to date have assessed the efficacy of the fenestrated Anaconda stent graft. The initial study by Bungay et al in 2011 evaluated four patients in whom there were no perioperative deaths or differences in preoperative and postoperative serum creatinine levels. At 1-month follow-up, all target vessels remained patent; however, one of the four patients did have a type 1b endoleak requiring balloon angioplasty of the right iliac graft component.⁵ Rolls et al evaluated 13 patients with juxtarenal, pararenal, and type 4 thoracoabdominal aneurysms and reported no 30-day mortalities. Two endoleaks were identified and addressed intraoperatively, four type 2 endoleaks were noted on discharge, and one type 2 endoleak was identified at the most recent follow-up.²⁵ Dijkstra et al published their results on 25 patients undergoing fenestrated endovascular abdominal aortic aneurysm repair (FEVAR) between 2011 and 2013 for juxtarenal and short-neck AAA. Three type 1 endoleaks (12%) and seven type 2 endoleaks (28%) were identified on

completion angiography; however, at 1-month follow-up all endoleaks had resolved with conservative management only. Primary patency rates of cannulated vessels at 1 month were 96%. The reposition feature of the stent graft was used in 64% of patients. Though this feature does have its advantages, it was felt that repositioning led to embolization of thrombotic material and renal failure in one patient.²⁶ Finally, Shahverdyan et al described a novel approach combining the Anaconda fenestrated stent graft with the Zenith iliac side-branched device to treat aortoiliac aneurysms. Three patients underwent this hybrid procedure without any intraoperative or postoperative endoleaks, stent migration, dislocation, or stenosis.²⁴

Off-the-Shelf Devices

Off-the-shelf devices are stent grafts that are available for immediate use and are designed to accommodate the majority of the general population with a finite number of configurations and a modular design. Current waiting time for individualized, customized devices ranges from 3 to 4 weeks. Since not all patients are able to wait for a customized graft, trials have sought out to investigate the feasibility, safety, and efficacy of off-the-shelf devices.²⁷ Two off-the-shelf devices have been investigated in the United States: the Cook p-Branch (Cook Medical, Bloomington, IN) and the Endologix Ventana (Irvine, CA) stent graft. The Ventana device study, however, has been placed on hold by Endologix and the FDA given difficulties with the durability and patency of the renal artery stent graft components.

The Ventana fenestrated system (VFS) is designed to treat patients with juxtarenal and pararenal aortic aneurysms. It consists of the FDA-approved AFX bifurcated infrarenal stent graft, the proximal Ventana fenestrated stent graft extension, and Xpand balloon-expandable renal stents (Endologix, Irvine, CA). The stent grafts consist of a self-expanding cobalt-chromium alloy endostent with a multilayer expanded polytetrafluoroethylene (ePTFE) graft. There is a large scallop that permits flow to the celiac and superior mesenteric arteries (SMAs), as well as fenestrations with precannulated sheaths that aid in renal artery stenting (see ►Fig. 2).²⁸

A prospective multicenter trial involving 31 patients was conducted between November 2010 and April 2012 to demonstrate early and mid-term results of the Ventana system for juxtarenal and pararenal aortic aneurysms. All patients were treated with one of five Ventana stent graft models. Technical success was achieved in 97% of patients perioperatively. At 1 month, there were one iliac artery occlusion and one renal artery occlusion with a resultant endoleak, leading to a technical success rate of 94%. There were no perioperative deaths and the incidence of early major adverse events was only 16%. Type 2 endoleaks were identified in eight patients (26%) at 1 month, five patients at 6 months (17.5%), and two patients (6.5%) at 1 year. Visceral artery patency was 98% in the early period and 94% at late follow-up (mean follow-up 1.3 years). The study concluded that the Ventana device showed promising early to mid-term data; however, future studies with

Fig. 2 The Endologix Ventana fenestrated system consists of two scallops for the superior mesenteric artery and celiac artery as well as two fenestrations for the renal arteries.

longer-term follow-up were needed to verify its safety, efficacy, and durability.²⁸

The Zenith pivot branch device (Cook Medical, Bloomington, IN) is an off-the-shelf device that integrates polyethylene terephthalate fabric with a proximal stainless steel uncovered barbed supraceliac stent and several nitinol z-stents that include a scallop for the celiac artery, a strut-free fenestration for the SMAs, and two renal pivot fenestrations (see ►Fig. 3). The graft can be produced with two variations for renal artery fenestration placement. One device has both renal arteries originating at the same level, while the other device has the left renal artery originating slightly lower than the right renal artery. The graft can be used either as a single component when building up from a prior aortic repair or as a proximal component in combination with other Zenith devices. The device is appropriate only if there is a 4 mm or greater neck below the SMAs and the aorta in the proximal seal zone has a diameter of 32 mm or less.²⁹

Kitagawa et al published the early clinical outcomes of 16 patients enrolled in a physician-sponsored investigation device exemption study. The patients underwent repair with the off-the-shelf Zenith p-Branch device between August 2011 and September 2012 for juxtarenal aneurysms. Two of the patients were repaired for rupture. The authors reported no aortic-related deaths, aneurysm ruptures, or open surgical conversions. Their technical success rate was 100% and no type 1 or type 3 endoleaks were identified. One patient did require additional placement of a nitinol stent in the setting of lower extremity ischemia in the perioperative period. The only late complication reported was a renal stent

Fig. 3 The Zenith pivot branch device includes a scallop for the celiac artery, a strut-free fenestration for the SMAs, and two renal pivot fenestrations. Permission for use granted by Cook Medical Incorporated, Bloomington, IN.

occlusion at 3 months, and it was successfully treated with ballooning and distal nitinol stent placement. The study concluded that although early clinical data were favorable, strict attention would be required for proper patient selection and assessment of the proximal landing zone as well as configuration of the aorta near branch points.²⁹

Mendes et al recently evaluated the anatomic feasibility of both the Endologix Ventana (Endologix, Irvine, CA) and Cook p-Branch (Cook Medical, Brisbane, Australia) devices in an unselected population of 390 patients with juxtarenal and pararenal aneurysms. Proximal seal was achievable in all patients with the p-Branch device and in only 61% (239/390) of patients with the Endologix Ventana device. Incorporation of all four visceral vessels was achievable in 90% of patients for the Endologix Ventana devices versus only 61% with the p-Branch device. Between the two devices, nearly 40% of patients with juxtarenal and pararenal AAAs did not meet anatomic criteria for either device.³⁰ Similar findings regarding the Endologix Ventana and Cook p-Branch device were reported by Farber et al in 2014. Between July 2012 and September 2013, 85 patients were identified as type 4 thoracoabdominal aortic

aneurysms including pararenal and juxtarenal aneurysms. Only 27% of patients were anatomically suitable for one of the off-the-shelf devices. The main constraint for the p-Branch device was the positioning of the renal arteries, while the main constraint for the Ventana device was the required neck length of 15 mm needed for a proximal seal below the SMAs. When additionally screening this population for suitability with the Cook ZFEN device, 44% of patients still did not meet criteria for any of the three stent graft devices, thus reinforcing the need for further development of fenestrated and branch stent graft technology.²⁷

Physician-Modified Endovascular Graft

Physician-modified endovascular graft (PMEG) refers to the modification, commonly known as “back-tabling,” of a previously produced device to create a device suitable for individual patient use. Often, patients that require this type of device do not have any other endovascular option or do not have the time required for a custom graft to be manufactured. Starnes conducted a retrospective, nonrandomized, single-institution study assessing the safety of physician modification of the already FDA-approved Zenith Flex aortic stent graft (Cook Inc., Bloomington, IN). They used an ophthalmic Bovie cautery device (Medtronic, Minneapolis, MN) to create fenestrations, which were reinforced with Amplatz Gooseneck Snare (ev3 Endovascular Inc., Plymouth, MN). Forty-seven patients were treated with physician-modified grafts over a 3-year period (2007–2010) for juxtarenal aneurysms. A total of 82 fenestrations were created, including 58 renal arteries, 16 SMAs, 3 celiac arteries, and 5 accessory renal arteries, with a reported technical success rate of 98%. Complications occurred in 6/47 (13%) of patients, including 3 access-related and 3 procedure-related complications (stroke, renal failure, and renal artery dissection). Endoleaks were noted in 6/47 (13%) patients. This included one type 1 endoleak that required repair and five type 2 endoleaks only, of which one required intervention. There was one in-hospital mortality related to aspiration and two deaths in the follow-up period, including one patient at day 485 who died of endograft migration and SMA occlusion.³¹

Based on these promising results, the same group performed an investigator-sponsored investigational device study (IDE) with the approval of the FDA. The study involved 26 patients who underwent 63 fenestrations (48 renal arteries and 15 SMAs) over a study period of 16 months (2011–2012) for juxtarenal aneurysms. The outcome of the study assessed major adverse events and treatment success rates. Similar to their prior data, at 30 days there were only four type 2 endoleaks (15.4%). Major adverse events occurred in 11.5% of patients at 30 days, including two myocardial infarctions and one case of respiratory failure leading to death. At 1-year follow-up, there were no major adverse device events and only one minor adverse device events (a type 3 endoleak that was successfully treated endovascularly). The primary efficacy end point was achieved in 87.5% of patients as defined by technical success (100%) and lack of migration (100%), no rupture/conversion (100%), no type 1

and 3 endoleaks (87.5%), and no sac enlargement (87.5%). The study concluded that the PMEG technique is valid, safe, and effective; however, durability has yet to be determined with no reported longer-term follow-up.³²

Ricotta and Tsilimparis looked at surgeon-modified fenestrated-branched grafts (sm-FBSGs) in high-risk patients presenting with symptomatic or ruptured complex abdominal as well as thoracoabdominal aortic aneurysms. This was a physician-sponsored IDE study approved by the FDA. The sm-FBSGs were created by modifying commercially available endovascular stent grafts (TX2 Zenith, AAA Zenith: Cook Medical, Bloomington, IN; AAA Endurant: Medtronic CardioVascular, Santa Rosa, CA) with both fenestrations and cuffed branches. The study involved 12 patients, 7 symptomatic and 5 ruptured, of which 4 aneurysms were pararenal and 8 were thoracoabdominal—there were a total of 35 branch interventions. Aneurysm exclusion was successful in all cases. Thirty-day survival was 92%, and there was no incidence of spinal cord ischemia. The early reintervention rate was 14% and no late interventions were required. Branch patency remained 100% at a mean follow-up of 9 months. Two deaths did occur secondary to contained ruptures and one type 2 endoleak is being observed. However, due to the fact that an open repair carries high morbidity and mortality in these high-risk patients, this study concluded that sm-FBSGs are a valuable option in the setting of urgent/emergent interventions for complex abdominal and thoracic aortic aneurysms.³³

Aortic Branched Devices

Branched devices consist of side arms that can be oriented axially or at an angle. The branches are primarily intended to be used with self-expanding stents grafts. The branches may be external to the graft, internal to the graft, or a combination of both. Branches are typically accessed from the axillary artery through preloaded wires to allow for quick and easier sheath cannulation.³⁴ The Cleveland Clinic has reported on a large series of patients undergoing thoracoabdominal aneurysm repair using branched side-arm devices. They utilized an external helical branch, which demonstrated an excellent patency rate. The authors reported several advantages to the helical side-arm branch, including the minimization of distance between target vessel and branch origin as well as lessening the angulation between the vessel and self-expanding stent graft.³⁵ The Cook Zenith t-Branch device, an off-the-shelf multi-branched endograft, is currently being used in Europe for the treatment of thoracoabdominal aortic aneurysms (Cook Medical, Bloomington, IN). Several studies have demonstrated promising early results, though longer-term data are pending.^{36–38} Gore has also developed an off-the-shelf device intended for thoracoabdominal aortic aneurysms, the Gore Excluder Thoracoabdominal Branch Endoprosthesis. The Gore Thoracoabdominal Aortic Aneurysm Clinical Study is evaluating a device in Brazil with hopes to begin a subsequent feasibility study in the United States (W. L. Gore & Associates, Flagstaff, AZ).

Fig. 4 The Gore Excluder Iliac Branch Endoprosthesis allows for preservation of flow to the internal iliac artery.

Internal Iliac Artery Branch Graft Devices

There are currently two iliac branch devices on trial in the United States for the preservation of internal iliac artery flow in the setting of common iliac artery aneurysms. Preservation of this flow plays an important role in the prevention of buttock claudication, gluteal necrosis, ischemic colitis, and sexual dysfunction.³⁹ The Zenith Branch Iliac Endovascular Graft has been on trial in the United States since January 2011. The trial is investigating the safety and effectiveness of the device for use in both aortoiliac and iliac artery aneurysms. Trial of the Gore Excluder Iliac Branch Endoprosthesis opened in October 2013 and is a prospective, nonrandomized, multicenter, single-arm study looking at the safety and efficacy of the device for use in both common iliac artery aneurysms and aortoiliac aneurysms (see **Fig. 4**). Early results of the Gore Excluder Iliac Branch Endoprosthesis show promising results with 100% branch patency and no 30-day mortality.⁴⁰

Conclusion

In conclusion, endovascular aortic stent grafting is a valuable alternative to traditional open aortic aneurysm repair. With recent advances in fenestrated and branched stent graft technology, endovascular approaches are becoming options

to treat patients with anatomies previously considered ineligible for stenting. The only current FDA-approved fenestrated stent graft in the United States is the Zenith fenestrated device, for which multicenter prospective trials have validated the efficacy, safety, and durability of the graft. Off-the-shelf stent grafts are currently being evaluated. Physician-modified stent grafts have also shown promising early results. Lastly, thoracoabdominal and iliac branched devices are currently under investigation and development. Overall, fenestrated and branched stent grafts have greatly broadened treatment options for aortic aneurysmal disease and their clinical use will expand as technologies are advanced.

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