

Global Experience With the Zenith p-Branch Device

Outcomes of this novel device for treating juxtarenal or pararenal abdominal aortic aneurysms.

BY TIM RESCH, MD, PhD



Endovascular repair of abdominal aortic aneurysms (EVAR) has become the primary treatment option in morphologically suitable patients. Stent graft systems for infrarenal aneurysm repair have undergone significant development and refinement since the

commercial introduction of EVAR in the mid-1990s. Current technology allows for the treatment of a wide range of infrarenal aneurysms presenting with challenging anatomical features in the iliac arteries, such as tortuosity and narrowing. The main obstacle to EVAR continues to be a challenging proximal sealing and fixation zone, especially in patients with a short infrarenal aortic neck or when the aneurysm encroaches upon the renal arteries. This is true in the short term, where an unfavorable proximal sealing zone can lead to acute type I endoleaks and failed aneurysm repair, but is more significant in the long-term follow-up, where continuing aortic dilatation in the paravisceral segment of the aorta can cause late endograft failure and, ultimately, rupture. Many bailout techniques are used to overcome immediate and short-term failures, such as the use of adjunctive balloon-expandable stents, endoanchors, or chimney repairs. The durability of these maneuvers in the long-term remains questionable in the face of progressive aortic disease.

Anderson et al first described the concept of fenestrated aortic stent grafts for juxtarenal aortic aneurysms in the late 1990s.¹ Incorporation of one or more visceral arteries into the aortic repair was utilized to allow a more extensive proximal seal of the stent graft while maintaining flow to the visceral arteries. Roy Greenberg, MD, was the first to show the effectiveness and durability of this approach in a large cohort of patients and championed fenestrated EVAR, even for true thoracoabdominal aortic aneurysms. Over the past decade, multiple literature publications have demonstrated this technology to be safe, effective, and durable for the treatment of these challenging patients.^{2,3}

One obstacle to the widespread use of fenestrated EVAR has been the need to customize the device according to the individual patient anatomy to achieve an optimal fit. This process includes detailed planning and device manufacturing, both of which contribute to a time of 4 to 6 weeks between diagnosis and patient

treatment. This treatment delay makes the technology unavailable to patients with very large aneurysms (with a higher likelihood of interval rupture), as well as emergent patients. Therefore, an off-the-shelf (OTS) device is needed for juxtarenal or pararenal aneurysm repair. This could potentially lead to simplified planning and the availability of devices when needed.

ZENITH P-BRANCH DEVICE

The Zenith p-Branch device* (Cook Medical) is based on the CE Mark and US Food and Drug Administration approval of the Zenith fenestrated platform, but with some significant modifications, primarily in the proximal tubular component containing the fenestrations. By default, the p-Branch device has two fenestrations for the renal arteries, one fenestration for the superior mesenteric artery (SMA), and a scallop for the celiac artery. To accommodate variability between the renal fenestration and target vessel position in an OTS setting, the renal fenestrations are dome-shaped (Figure 1), with an inner diameter of 6 mm and an outer diameter of 15 mm. These “pivot fenestrations” have nitinol wire reinforcements in the inner ring, outer ring, and dome. This design allows for catheterization of renal arteries that fall within the 15-mm outer diameter while keeping the inner 6-mm fenestration for mating the stent seal. The SMA fenestration is an 8-mm-diameter standard single-ring fenestration.

Based on anatomical studies of patients treated with fenestrated stent grafts, positioning of the fenestrations on the p-Branch device allow for treatment of approximately 60% to 80% of aneurysms with only two device configurations, called “A” and “B.”



Figure 1. The p-Branch proximal component displaying a celiac artery scallop, SMA fenestration, and right renal artery pivot fenestration. Note the dome structure of pivot fenestration, which has a preloaded catheter.

In the p-Branch device, the renal fenestrations have been fitted with a preloaded 0.018-inch-diameter wire to obviate the need for catheterization of the fenestrations and to facilitate cannulation of the target vessels during the procedure. In addition, the preloaded wire runs through the stent graft on the delivery side using a modified delivery handle that can accommodate two 6-F introducers alongside it. The preloaded wire passes through a side port on the delivery handle, through the main body of the graft, out through one renal fenestration, across the graft, into the other renal fenestration, through the main body of the graft, and finally out through the second sideport on the delivery handle.

During planning, the center of the SMA is always used as a reference point with respect to the locations of the renal arteries and celiac artery. The longitudinal and circumferential positions of the renal arteries and the celiac artery in relation to the SMA are mapped out on a grid. An overlay template is positioned on the grid to determine which configuration, A or B, is most appropriate.

During the procedure, once the fenestrated component had been placed and mating stents extended into the target vessels, the case is then completed by placing a distal bifurcated unibody and iliac limb extensions, similar to a standard fenestrated case.

RESULTS

The first report on the use of a device similar to the p-Branch was published by myself and colleagues in 2012.⁴ We described the use of stent grafts utilizing the preloaded delivery system, as well as the renal pivot fenestrations, in a small cohort of seven elective patients. The devices were tailored to each patient in the same way as a Zenith fenestrated device, but took advantage of the new features incorporated into the p-Branch design. Technical success was 100%, and the 30-day mortality was 0%.

In a report from 2013,⁵ Greenberg et al reported early clinical outcomes of the first use of the p-Branch device. Sixteen patients, including two with ruptures, were enrolled in a physician-sponsored investigational device exemption trial at the Cleveland Clinic in Cleveland, Ohio. Technical success was 100%, and no aortic-related deaths were reported. A single renal artery occlusion was found during follow-up and was successfully treated by endovascular recanalization.

At the Vascular Annual Meeting in 2014, Mark Farber, MD, presented the 1-year aggregated outcomes from four prospective, single-center, investigational device exemption studies (conducted in the United States and Europe) of the Zenith p-Branch device.⁶ Results from 59 patients (52 elective, seven emergent) were reported. The mean patient age was 72 years and 67 years for elective and emergent patients, respectively. The maximum aneurysm diameter was 62 mm in elective patients and 70 mm in emergent

patients. In approximately 60% of elective patients, device configuration A was used, whereas device configuration B was used in approximately 60% of the emergent patients. Technical success was 100%, with an immediate target vessel patency rate of 98.8%.

In two of the emergent patients, a single renal vessel was not catheterized; in one patient treated for rupture, a renal artery was intentionally covered (this renal artery was outside the defined treatment region), and in a second patient, a renal artery was successfully stented on postoperative day 8 (the stent graft achieved effective sealing at the index procedure without renal stenting). There was no 30-day mortality and no renal failure that required dialysis in the 59 patients presented. During a mean follow-up of 13 months, there was one death attributed to coronary artery disease. One emergent patient experienced a type I endoleak in the distal aspect of an SMA stent, which was treated by mating stent extension and embolization.

Of the 59 patients, 40 were available for 1-year follow-up. Target vessel patency at 1 year was 96% for elective patients and 95% for emergent patients. Five renal artery occlusions were identified, and four of these were successfully treated by endovascular means. An additional two cases of renal artery stenosis were found and treated by percutaneous angioplasty and stenting.

DISCUSSION

Fenestrated stent grafting for juxtarenal or pararenal abdominal aortic aneurysms has become a well-established treatment option. Thousands of implants and numerous publications support this as an effective and durable repair option. However, the problems of complex planning, as well as device availability, have driven the development of more standardized OTS stent grafts.

With the current p-Branch device, planning has been radically simplified. Because the device only comes in two configurations, device choice becomes quite straightforward. The unique design of the renal pivot fenestrations provides a much more extensive range of inclusion than standard renal fenestrations. As has been previously shown, device planning, even in experienced hands, has a degree of variability. This, in combination with the need to align the fenestrations precisely with the target vessels during implantation, can make a procedure somewhat challenging. With the p-Branch device, this has significantly changed. Flexibility in accommodating a suboptimal fit is incorporated in the device design. As the results show, the short-term technical success is high, even in emergent cases. The long-term outcomes are yet to be determined.

The OTS p-Branch device also solves the problem of device availability. The proximal p-Branch component that comes with two configurations and five diameters (26, 28, 30, 32, and 36 mm) can easily be kept on the

shelf in limited numbers. The distal bifurcated body is uniform in design and also only comes in four lengths. Finally, the procedure is completed with the standard iliac extension limbs used for an infrarenal Zenith device. Thus, keeping five proximal diameters available in both the A and B configurations, as well as four different lengths of bifurcated devices, a total of 14 devices in stock will cover most anatomies within the instructions for use.

An added benefit of the device is the preloaded delivery system, which obviates the need for a large sheath in the contralateral femoral artery during the target vessel catheterization phase of the procedure. Instead, an 8- to 12-F sheath is placed in the contralateral groin to allow for catheterization of the SMA fenestration. This provides continuous flow to the contralateral lower limb during the majority of the procedure as well as flow in the contralateral internal iliac artery, which can provide some collateral flow to the ipsilateral lower limb where the femoral artery is largely occluded by the main delivery sheath. Obviously, a preloaded system is also favorable in patients who exhibit limited or no access from one femoral artery. ■

**The Zenith p-Branch is an investigational device in the United States and Europe. It is not FDA or CE Mark approved at this time.*

Tim Resch, MD, PhD, is with the Vascular Center, Department of Hematology and Vascular Diseases at Skane University Hospital in Malmö, Sweden. He has disclosed that he is a consultant to Cook Medical. Dr. Resch may be reached at +46 40331000; timothyresch@gmail.com.

1. Anderson JL, Berce M, Hartley DE. Endoluminal aortic grafting with renal and superior mesenteric artery incorporation by graft fenestration. *J Endovasc Ther.* 2001;8:3-15.
2. Greenberg RK, Sternbergh WC 3rd, Makaroun M, et al. Intermediate results of a United States multicenter trial of fenestrated endograft repair for juxtarenal abdominal aortic aneurysms. *J Vasc Surg.* 2009;50:730-737.
3. Mastracci TM, Greenberg RK, Eagleton MJ, Hernandez AV. Durability of branches in branched and fenestrated endografts. *J Vasc Surg.* 2013;57:926-933.
4. Resch TA, Dias NV, Sobocinski J, et al. Development of off-the-shelf stent grafts for juxtarenal abdominal aortic aneurysms. *Eur J Vasc Endovasc Surg.* 2012;43:655-660.
5. Kitagawa A, Greenberg RK, Eagleton MJ, Mastracci TM. Zenith p-Branch standard fenestrated endovascular graft for juxtarenal abdominal aortic aneurysms. *J Vasc Surg.* 2013;58:291-300.
6. Farber MA, Eagleton MJ, Mastracci TM, et al. Off-the-shelf fenestrated stent graft: one-year prospective results from multiple p-Branch single-center clinical trials. Presented at the Vascular Annual Meeting; June 7, 2014; Boston, Massachusetts.