◆ TECHNICAL NOTE ◆

Ventana Fenestrated Stent-Graft System for Endovascular Repair of Juxtarenal Aortic Aneurysms

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Purpose: To describe the initial use of an off-the-shelf fenestrated stent-graft system for endovascular repair of juxtarenal abdominal aortic aneurysms.

Technique: The off-the-shelf Ventana fenestrated stent-graft system consists of a 25-mm IntuiTrak self-expanding bifurcated stent-graft implanted at the aortic bifurcation. A Ventana self-expanding fenestrated proximal extension stent-graft is overlapped with the bifurcated body distally and sealed proximally in the visceral segment with a 4-cm-long scallop below and around the SMA and celiac artery, obviating the need for an infrarenal neck. Movable, non-reinforced, 3-mm fenestrations for the renal arteries can be expanded to 10 mm. The 22-F delivery system includes 6.5-F guide sheaths pre-inserted through the stent-graft fenestrations so that the renal arteries are cannulated before the fenestrated stent-graft is deployed. The Xpand renal stent-grafts, with a proximal segment intended for flaring in the aorta, are delivered on 5-F or 6-F balloon catheters through the 6.5-F guide sheaths.

The technique is illustrated in 2 patients (76 and 77 years of age) with significant comorbidities and juxtarenal aortic aneurysms measuring 5.9 and 7.4 mm, respectively, who were enrolled in an ongoing prospective trial (*www.ClinicalTrials.gov* identifier NCT01348828) of this new device. Patient 1 had a 28-mm fenestrated stent-graft system with the aligned fenestration configuration deployed, while the stent-graft in Patient 2 was 32 mm in diameter and had offset fenestrations to accommodate the renal artery geometry. Mean fluoroscopy times were 27 and 35 minutes, and the contrast volumes were 72 and 67 mL. Total procedure times were 84 and 71 minutes. The aneurysms were effectively excluded in uneventful procedures, with no migration, endoleak, or renal dysfunction at 6-month follow-up.

Conclusion: There exists an unmet clinical need for a broadly applicable endovascular option for repair of more complex juxtarenal or pararenal aortic aneurysms. These cases suggest that endovascular repair of such aneurysms using the Ventana fully integrated off-the-shelf stent-graft system is safe and feasible.

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Key words: abdominal aortic aneurysm, endovascular aneurysm repair, stent-graft, fenestrated endograft, renal stent, juxtarenal aortic aneurysm

Endovascular repair of abdominal aortic aneurysm (AAA) in patients with suitable infrarenal neck anatomy has been shown in multiple trials to have lower perioperative morbidity and mortality compared to open surgical repair.[1,2] Anatomical unsuitability for infrarenal endografting is reported in 30% to 40% of AAA patients, primarily due to unfavorable proximal neck anatomy.[3] Interventionists who have attempted to place infrarenal endografts in

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anatomies without an adequately long proximal seal zone, generally accepted for most devices as ≥15 mm, have reported increased incidences

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of migration, type I or III endoleak, and aneurysm rupture.[4,5] To address this limitation, patient-customized endografts with fenestrations and scallops to preserve blood flow to the visceral and renal arteries in short infrarenal aortic necks have been used with favorable outcomes.[6] However, because substantial time is required for the individual planning, manufacture, and delivery of these devices, there remains an unmet need for a true off-the-shelf endograft system to use in the repair of these more complex AAA anatomies.[7,8]

We describe our initial experience with treating juxtarenal AAAs as part of a feasibility and safety evaluation of a new off-the-shelf fenestrated stent-graft system and considerations for patient selection, device selection, and implant technique.

TECHNIQUE

Our center is one of several involved in a 5-year prospective, nonrandomized, feasibility and safety evaluation of the Ventana fenestrated stent-graft system (Endologix, Inc, Irvine, CA, USA) in AAA patients with proximal neck anatomy unsuitable for commercially available endografts (*www.ClinicalTrials.gov* identifier NCT01348828). Patients were eligible for the study if they met the general inclusion criteria: (1) life expectancy of at least 1 year; (2) written informed consent and a willingness to comply with the follow-up schedule; (3) no contraindication to contrast media or to device materials; (4) not pregnant; (5) no bleeding or connective tissue disorders or active infection; (6) no mycotic, ruptured, or leaking aneurysm, aortic dissection, or thoracic aneurysm; (7) serum creatinine ≤2.0 mg/dL; (8) no prior renal transplant; and (9) renal arteries ≥13 mm long and without significant occlusive disease (<70% stenosis).

Following ethics committee approval of the protocol and patient consent form, prospective patients were offered study participation and gave written informed consent.

Anatomical eligibility was determined by a core laboratory (Cleveland Clinic Peripheral Vascular Laboratory, Cleveland, OH, USA) and independent physician assessment of contrast-enhanced computed tomographic angiography (CTA) of the distal descending thoracic aorta to the lesser trochanter of the femur. Patients were enrolled in the study if they met the anatomical criteria: (1) aneurysm sac diameter ≥5.5 cm or ≥4.5 cm and at risk of rupture due to rapid growth; (2) infrarenal neck length <15 mm; (3) non-aneurysmal proximal neck relative to the superior mesenteric artery (SMA) with length ≥15 mm, diameter 18 to 34 mm, and angle to the aneurysm sac ≤60°; (4) renal arteries with reference diameters of 4 to 8 mm that are 0 to 35 mm below the SMA and within each other ±30 mm (axially) and 90° to 210° (clock face); (5) celiac artery to SMA angle ≤60° (clock face); (6) most caudal renal artery to aortoiliac bifurcation length ≥70 mm; (7) dispensable inferior mesenteric artery; and (8) suitable distal iliac anatomy with ability to preserve at least 1 hypogastric artery.

Device Design and Procedure Planning

The Ventana system components include a 25-mm (proximal diameter) IntuiTrak self-expanding bifurcated stent-graft implanted at the aortic bifurcation to achieve distal seal and extend proximally to within 1 to 3 cm below the most caudal renal artery; the Ventana self-expanding fenestrated proximal extension stent-graft with a 28-mm distal diameter to overlap (≥3 cm) the bifurcated endograft; and the Xpand balloon-expandable renal stent-grafts.

All these devices are constructed from a cobalt chromium alloy continuous stent with expanded polytetrafluoroethylene (ePTFE) graft cover attached with surgical suture. The fenestrated stent-graft component is a single-piece, highly conformable graft with movable, non-reinforced, 3-mm-diameter fenestrations that have circumferential radiopaque markers. Unique to this device, the stent does not interfere with the fenestrations, which can be expanded to 10 mm. The 22-F (outer diameter) Ventana delivery system includes 6.5-F guide sheaths that are pre-inserted through the stent-graft fenestrations so that renal

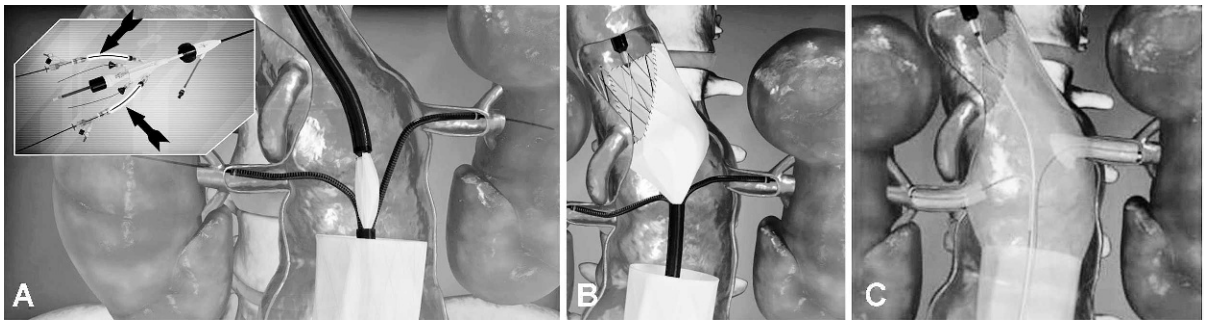

Figure 1 ◆ (**A**) Illustration of the Ventana system's renal artery cannulation. The fenestrated stent-graft remains constrained during renal artery cannulation. The Ventana delivery system with integrated 6.5-F guide sheaths (arrows) is shown in the inset. (**B**) Illustration of the Ventana system's proximal segment deployment. The scallop is placed below and around the SMA to ensure continued perfusion. (**C**) Final implant configuration (transparent for illustration purposes). The conformable graft material enhances the seal zone in the proximal segment and around the renal arteries. Flaring of the renal stent-grafts completes the procedure and aneurysm sealing.

cannulation occurs before the fenestrated stent-graft is deployed, providing ample room for maneuvering. There is a generous 4-cm-long proximal scallop with radiopaque side and central markers for placement below and around the SMA and celiac artery during final deployment. With the seal zone defined with reference to the SMA, this device does not require an infrarenal neck. Mounted on 5-F or 6-F balloon catheters, the radiopaque Xpand renal stent-grafts with proximal and distal markers have a proximal segment intended for flaring in the aorta after implantation.

There are 8 fenestrated stent-graft models with aligned fenestrations available to treat patients with proximal neck diameters ranging from 18 to 34 mm; additional devices are available with offset fenestrations if needed. Endograft oversizing of 10% to 15% is required. Provided the renal arteries have reference diameters of 4 to 8 mm, are at or below the SMA $\leq$35 mm, and are within 30 mm of each other axially and 90° to 210° radially, the patient can be considered for treatment with this system.

Deployment Procedure

Bilateral femoral artery access is achieved per the standard institutional procedure. The bifurcated stent-graft delivery system can be advanced from either femoral artery depending upon physician preference after considering anatomical features and angulations. Contralateral femoral artery cannulation is used only for imaging with an angiographic catheter and is not required for fenestrated stent-graft deployment or renal artery cannulation, as this is done completely through the delivery system in the ipsilateral access site.

After heparin administration, the 25-mm IntuiTrak bifurcated stent-graft system is delivered and deployed at the aortic bifurcation. The delivery system is removed ipsilaterally, and a Coda balloon (Cook Medical, Inc., Bloomington, IN, USA) is positioned in the contralateral limb through a 12-F sheath and inflated during ipsilateral advancement of the Ventana fenestrated stent-graft delivery system. The balloon is exchanged for a pigtail catheter, which is advanced into the visceral aorta.

After positioning the fenestrated delivery system, the outer sheath is retracted to expose the 6.5-F guide sheaths below the renal arteries. The distal radiopaque markers serve to identify and differentiate the guide sheaths under fluoroscopy. After access is obtained, each renal artery is cannulated with a combination of an appropriate catheter (usually C2 or VS1) and a stiff Glidewire (Terumo Medical, Somerset, NJ, USA). The Glidewires are then exchanged for Rosen wires (Cook Medical).

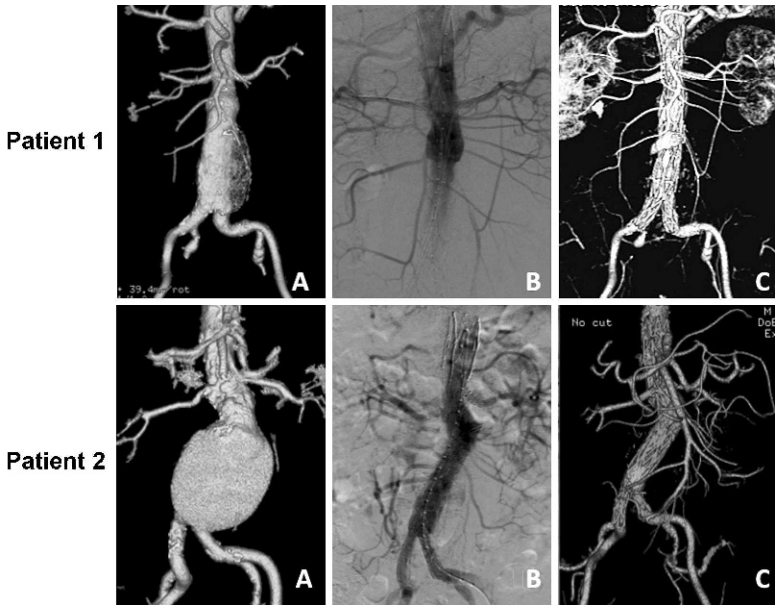

Figure 2 ◆ (**A**) Preoperative CTA, (**B**) post-implant angiography, and (**C**) 6-month post-implant CTA in patients 1 and 2. Imaging confirms successful aneurysm exclusion, no endoleak, and preserved visceral perfusion.

The sheaths are advanced and parked distally in both renal arteries (Fig. 1A).

The side and central markers of the proximal scallop are then positioned at the SMA using a full lateral projection, with fluoroscopic verification in anteroposterior and lateral views. Axial and lateral movement and orientation of the scallop are freely allowed by the oversized PTFE fabric unattached to the stents where the renal fenestrations are located. The proximal end of the fenestrated stent-graft is then deployed by advancing the inner core with the scallop to immediately below the SMA and incorporating the celiac artery (Fig. 1B); perfusion to both the SMA and celiac artery is verified. The distal end of the stent-graft is deployed by retracting the outer sheath. Both fenestrations are moved toward the renal ostium using the delivery system fenestration pushers on either side. This simple mechanism permits placement of the fenestration with attached graft into the renal artery, essentially creating the basis for a branched graft. Each Xpand renal stent-graft is advanced through the corresponding guide sheath. Both stent-grafts are expanded to 5 to 7 mm at nominal pressure; the proximal ends protruding into the aorta are flared with a 10×20-mm Powerflex balloon (Cordis Corporation, Bridgewater, NJ, USA), completing the repair and effectively establishing a stable seal (Fig. 1C).

Illustrative Cases

A 76-year-old Caucasian man presented with a history of hypertension, hypercholesterolemia, lymphoma in remission, peripheral vascular disease, prior abdominal surgery, and a smoking habit. CTA revealed a juxtarenal AAA measuring 5.9 cm in diameter; the infrarenal proximal neck was 9 mm long with moderate angulation and thrombus and mild calcification (Fig. 2A). The infra-SMA proximal neck length and diameter were 45 and 23 mm, respectively, and the renal arteries were aligned axially and spaced 155° radially. Although off-label use of an infrarenal system was considered for treatment, a fenestrated graft was deemed more appropriate.

A 77-year-old Caucasian man presented with a history of chronic obstructive pulmonary disease (COPD), diabetes, and renal function deterioration. His 7.4-cm juxtarenal

AAA (Fig. 2A) had a short 6.5-mm infrarenal proximal neck with moderate angulation and thrombus and mild calcification. The infra-SMA proximal neck length and diameter were 36 and 26mm, respectively; the renal arteries were 5.6 mm in diameter and spaced 18 mm axially and 177° radially.

Patient 1 had a 28-mm fenestrated stent-graft system with the aligned fenestration configuration deployed, while the stent-graft in Patient 2 was 32 mm in diameter and had offset fenestrations (left more proximal) to accommodate the renal artery geometry (Fig. 2B). The renal artery cannulation times were 13 and 10 minutes, respectively. Both patients had a self-expanding Smart stent (Cordis Corporation) deployed to solve a severe angulation at the left endograft to common iliac junction. The fluoroscopy times and contrast volumes were 27 minutes and 77 mL in Patient 1 and 35 minutes and 67 mL in Patient 2; total endovascular procedure times were 84 and 71 minutes, respectively. The patients tolerated the procedure well. Patient 1 was discharged from the hospital on postoperative day 2, but Patient 2 developed a mild, transient increase in serum creatinine that resolved without sequelae. He was kept in hospital to receive therapy for his pre-existing COPD and was discharged on postoperative day 6. Core laboratory evaluation of the CT scans at 1 and 6 months (Fig. 2C) documented sustained perfusion of the renal and visceral vessels, and no endoleak, migration, or device defect.

DISCUSSION

Open surgical repair of juxtarenal or pararenal aortic aneurysms has been shown to result in significantly increased operative mortality compared to infrarenal AAA, due to suprarenal cross-clamping, renal impairment, and increased blood loss.[9] In an analysis of outcomes using different endovascular devices from the EUROSTAR registry, Leurs et al.[4] reported that a short infrarenal neck or significant neck angulation predicted type I endoleak. Because of the increased risk of open repair, along with the limitations of infrarenal endografts, physicians have sought an endovascular approach for these more complex aneurysms. Clinical results with customized fenestrated endografts designed for short infrarenal necks (juxtarenal) employing commercially available renal stents have been favorable.[6] However, the time and cost required to design and manufacture the customized fenestrated stent-graft, the need for an accurately manufactured device for the individual patient, and the challenging implantation procedure limit the widespread applicability of this technique. Additionally, we find that the lack of an integrated covered renal stent to be a limitation of this approach. To work around these problems, methods have been devised in which renal stenting is done with concomitant ''chimney'' or ''snorkel'' stent-grafting techniques using combinations of commercially available devices in an off-label manner,[10] but data on performance outcomes and durability of such approaches are limited. Clearly, the time has come for a more elegant solution.[7,8]

The integrated Ventana fenestrated stent-graft system has made a true off-the-shelf endovascular approach a reality. Our initial experience with the Ventana system was technically feasible and acceptable, providing initial proof of concept for the design. Implantation of the unibody bifurcated stent-graft at the aortic bifurcation provides a firm foundation for the endovascular repair, which has been shown in clinical trials involving infrarenal aneurysms to effectively seal the aneurysm from blood flow and prevent migration.[11] We found sizing and the procedure to be straightforward, yet as with all endografts, validation is necessary with multiple investigators and patient characteristics in a clinical trial, which is now underway.

Conclusion

Endovascular repair of more complex juxtarenal/pararenal aortic aneurysms using the Ventana fully integrated fenestrated stent-graft system with preservation of visceral/renal artery patency is feasible. By providing an easy-to-size, off-the-shelf system, case planning is simplified, and broad application to various patient anatomies is potentially

possible. Further patient accrual and continued case follow-up will assess performance and safety.

REFERENCES

1. United Kingdom EVAR Trial Investigators, Greenhalgh RM, Brown LC, et al. Endovascular versus open repair of abdominal aortic aneurysm. *N Engl J Med*. 2010;362:1863–1871.
2. Lederle FA, Freischlag JA, Kyriakides TC, et al. Outcomes following endovascular vs open repair of abdominal aortic aneurysm: a randomized trial. *JAMA*. 2009;302:1535–1542.
3. Carpenter JP, Baum RA, Barker CF, et al. Impact of exclusion criteria on patient selection for endovascular abdominal aortic aneurysm repair. *J Vasc Surg*. 2001;34:1050–1054.
4. Leurs LJ, Kievit J, Dagnelie PC, et al. Influence of infrarenal neck length on outcome of endovascular abdominal aortic aneurysm repair. *J Endovasc Ther*. 2006;13:640–648.
5. AbuRahma AF, Campbell J, Stone PA, et al. The correlation of aortic neck length to early and late outcomes in endovascular aneurysm repair patients. *J Vasc Surg*. 2009;50:738–748.
6. Greenberg RK, Sternbergh WC, 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.e1.
7. Nordon IM, Hinchliffe RJ, Manning B, et al. Toward an ''off-the-shelf'' fenestrated endograft for management of short-necked abdominal aortic aneurysms: an analysis of current graft morphological diversity. *J Endovasc Ther*. 2010;17:78–85.
8. Bicknell CD, Cheshire NJ. Commentary: ''Off-the-shelf'' fenestrated endografts for short-necked abdominal aortic aneurysms: an attractive prospect that may be viable with advances in technology. *J Endovasc Ther*. 2010;17:86–88.
9. Martin M, Giles K, Pomposelli FB, et al. National outcomes after open repair of abdominal aortic aneurysms with visceral or renal bypass. *Ann Vasc Surg*. 2010;24:106–112.
10. Donas KP, Torsello G, Austermann M, et al. Use of abdominal chimney grafts is feasible and safe: short-term results. *J Endovasc Ther*. 2010;17:589–593.
11. Carpenter JP, Garcia MJ, Harlin SA, et al. Contemporary results of endovascular repair of abdominal aortic aneurysms: effect of anatomical fixation on outcomes. *J Endovasc Ther*. 2010;17:153–162.