Initial experience with the Ventana fenestrated system for endovascular repair of juxtarenal and pararenal aortic aneurysms

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Objective: Customized fenestrated endovascular stent grafts have been investigated as an alternative to open surgery for repair of more complex juxtarenal aortic aneurysms (JAAs). The substantial time required to design and manufacture these devices has led to the desire for a standardized fenestrated endovascular system. We report the initial pilot study results of a potential "off-the-shelf" fenestrated device system to assess its initial safety and feasibility for endovascular repair of JAAs and pararenal aortic aneurysms (PAAs).

Methods: Following ethics committee approvals, consenting patients were evaluated for eligibility. Patients with aneurysms abutting or including the renal artery orifices who were not candidates for standard infrarenal endograft placement because of proximal aortic neck morphology were further assessed for anatomic suitability for this "off-the-shelf" device. There were a number of anatomic requirements, the most important being a stable infra-superior mesenteric artery aortic neck length ≥15 mm. Patients are assessed in-hospital and in follow-up at 1, 6, and 12 months, and annually thereafter to 5 years for adverse events and using contrast-enhanced computed tomography angiography with Core Laboratory interpretation of renal perfusion, device integrity, migration, endoleak, and aneurysm morphology.

Results: Fifteen patients (87% male) with JAAs (93%) or PAAs (6.7%) presented at mean age of 77 years (range, 66-85 years) and with mean sac diameter of 5.9 cm (range, 5.1-7.9 cm). Four Ventana fenestrated stent graft models having aligned fenestrations (three models) or offset fenestrations (one model) and renal stent grafts were successfully implanted among the patients, and all renal and visceral arteries were preserved. Mean endovascular procedure time was 108 minutes (range, 71-212 minutes) with mean contrast usage and fluoroscopy time of 254 mL (range, 67-420 mL) and 55 minutes (range, 27-104 minutes), respectively. Five patients received blood products. Mean time to hospital discharge was 3.3 days (range, 2-9 days). In follow-up to 6 months and 1 year, no rupture, conversion to open repair, migration, type I/III endoleak, or renal loss/infarcts were observed. Two late nonaneurysm-related deaths have occurred. One secondary procedure for iliac limb kinking/occlusion and one secondary procedure for renal artery stenosis have been performed.

Conclusions: Early experience supports procedural and initial postprocedural safety and demonstrates proof of concept for the off-the-shelf Ventana fenestrated system for the endovascular repair of JAAs and PAAs in selected patients. Continued follow-up and expanded multicenter clinical experience is warranted. (J Vasc Surg 2013;■:1-11.)

Endovascular repair of infrarenal abdominal aortic aneurysm (AAA) in patients with suitable nonaneurysmal proximal neck and distal anatomy is shown to reduce perioperative morbidity and mortality compared with open surgical repair.[1,2] Anatomic unsuitability for standard endovascular AAA repair is reported in 35% to 45% of patients, primarily because of short or otherwise unfavorable infrarenal neck anatomy.[3,4] Attempts to extend the application of standard endografts to anatomies outside

of the clinically tested parameters, including a short proximal seal zone length, have been reported to increase the risk of device failure manifested as clinically significant migration, type I or III endoleak, and aneurysm rupture.[5,6] To address this limitation, a patient-customized fenestrated endograft designed for short infrarenal neck (juxtarenal) aortic anatomy has been used. Published results report favorable outcomes in selected patients.[7,8] However, because substantial time is required for the individual planning, manufacture, and delivery of these devices, there remains an unmet need for a standardized, readily available off-the-shelf endograft system for repair of more complex aortic aneurysm anatomies.

This article reports the initial results from the first prospective pilot study of the Ventana fenestrated system (Endologix Inc, Irvine, Calif).

METHODS

Study design. A prospective, single-arm pilot study (NCT01437215) of the Ventana fenestrated system was conducted at two centers in Chile and New Zealand having experience in infrarenal endovascular stent grafting, open surgical repair, and visceral artery interventional techniques.

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An initial case report from this experience is available.[9] This is the first human clinical use of the device system; accordingly, this study is intended to determine whether expanded clinical investigation is warranted. Each site obtained local approval for human investigation, and written patient informed consent was obtained. The primary safety assessment is the incidence of major adverse events (MAEs) at 30 days. MAEs include all-cause mortality, bowel ischemia, myocardial infarction, paraplegia, renal failure, respiratory complication, stroke, and blood loss ≥1000 mL. The primary feasibility assessment is successful device delivery and deployment, with endograft patency and absence of type I/III endoleak at 30 days. Other assessments include core laboratory evaluations of computed tomography (CT) scans; renal function via estimated glomerular filtration rate (eGFR); and distal perfusion evaluation via ankle-brachial index (ABI) determination.

Device description. The Ventana fenestrated system consists of the commercially available bifurcated stent graft, the Ventana fenestrated proximal extension stent graft, and the Xpand renal stent grafts (Endologix Inc) (Fig 1). The bifurcated device is a unibody self-expanding cobalt chromium alloy endostent with an expanded polytetrafluoroethylene (ePTFE) graft attached proximally and distally using surgical suture. The stent graft is constrained within a catheter-based delivery system. The Ventana fenestrated stent graft has the same stent elements as the bifurcated stent graft. Its ePTFE graft is continuous, incorporating an oversized midsection having two 3-mm diameter fenestrations. There is no stent interference with the fenestrations. The proximal stent graft segment varies in diameter from 24 to 38 mm depending upon model and is ePTFE covered except for a 4-cm-length anterior bare stent scallop intended to encompass the superior mesenteric artery (SMA) and celiac arteries. The 28-mm diameter distal stent graft segment is intended to attain substantial overlap with the bifurcated stent graft body. Radiopaque markers identify the proximal scallop margins and the fenestrations circumferentially (Fig 2). The fenestrations are expandable to 10 mm in diameter and are movable in situ longitudinally and circumferentially to accommodate a wide range of renal artery anatomies. Sizing of this device is relative to the length and diameter of the nonaneurysmal aorta immediately inferior to the SMA, relative locations of the visceral arteries, and aortic length. A total of 24 models are indicated for neck diameters of 18 to 34 mm, with eight having aligned fenestrations (renal arteries spaced longitudinally ± 15 mm) and 16 having offset fenestrations (renal arteries spaced >15-30 mm, with either left or right fenestration superior). The delivery system (Fig 3) has 22F outer diameter profile, incorporating 6.5F guide sheaths preloaded through the fenestrations for rapid renal artery cannulation and stent graft delivery. Fenestration pushers are short segments of hollow tubing that ride over the renal guide sheaths with a monorail handle, which permit the operator to advance the fenestrations to and/or into the renal artery as desired. The Xpand renal stent graft consists of a premounted balloon-expandable cobalt chromium
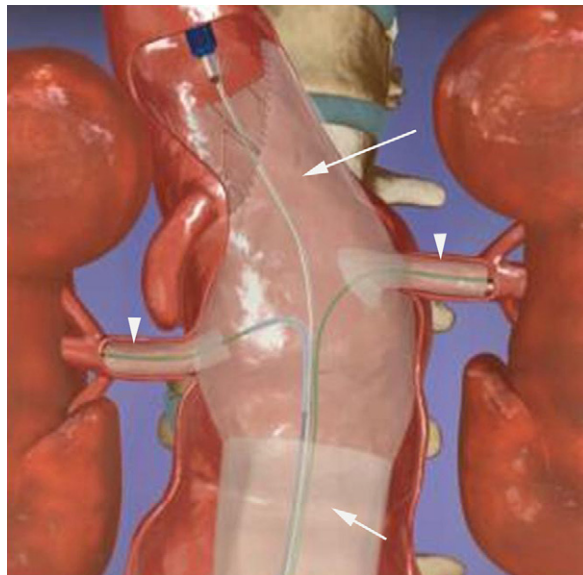

Fig 1. Anatomic illustration of the implant. Note the bifurcated unibody stent graft (*short arrow*), anatomically fixed at the aortic bifurcation; Ventana fenestrated/scalloped proximal extension stent graft (*long arrow*); Xpand renal stent grafts (*arrowheads*).
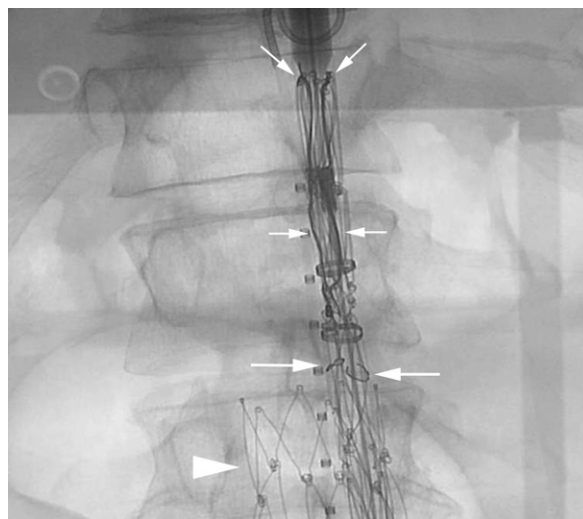
Fig 2. Ventana stent graft system fluoroscopic image. The Ventana stent graft is constrained within its delivery system, which is advanced through a deployed bifurcated stent graft (*arrowhead*). Note the "U" shaped radio-opaque marker outlining the visceral scallop (*short arrows*) and the right and left fenestration circumferential markers *(long arrows)*. Front sheath, outer sheath, and renal guide sheath markers are also visible.

alloy endostent with an ePTFE graft cover, intended for renal artery lumen diameters of 4 to 8 mm. The most proximal 5 mm is designed to protrude from the fenestration into the aorta where it can be flared using a separate balloon.

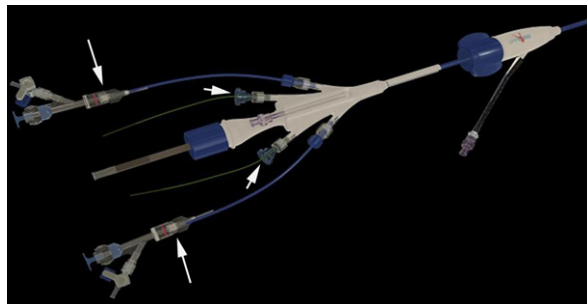**Fig 3.** Ventana delivery system user interface. The central handle is bounded on the left and right by the 6.5F guide sheaths (*long arrows*) and fenestration pushers (*short arrows*).

Device delivery and deployment. Following bilateral vascular access, a 12F tear-away introducer sheath is inserted into the ipsilateral femoral artery and a 9F introducer sheath is inserted contralaterally. The commercially available 25-mm bifurcated device is selected such that the proximal edge of the anatomically fixed body is 1 to 3 cm below the most caudal renal artery after implant, and limbs are of suitable diameter (available range, 13-16 mm) and length (available range, 30-55 mm) to preserve at least one hypogastric artery. Bifurcated device implant steps have been previously described.[10] After deployment, the delivery system is removed. The Ventana delivery system is then inserted ipsilaterally over the .035-inch guidewire; a compliant balloon may be inflated in the contralateral limb of the bifurcated device to maintain its secure positioning during delivery system advancement. The system is advanced through until the radiopaque markers on the ends of the 6.5F sheaths are visualized approximately 1 to 2 cm below the lowest renal artery. Retraction of the delivery system handle exposes the 6.5F sheaths while constraining the proximal and distal segments of the fenestrated stent graft. An angiographic catheter and guidewire (.035 inch or smaller) is inserted into each 6.5F sheath and tracked for renal artery cannulation (Fig 4). While pinning each angiographic catheter, the corresponding 6.5F sheath is advanced over the angiographic catheter and into the renal artery (Fig 5). The Ventana delivery system is then advanced, and the central radiopaque marker of the SMA scallop aligned several millimeters above the SMA (Fig 6). The SMA scallop side radiopaque markers are also visualized in the frontal projection (Fig 7, *A*). Once the proper alignment is verified, the pusher rod is advanced to deploy the Ventana proximal segment. The system can then be retracted caudally so the SMA and celiac artery are within the boundaries of the scallop (Fig 7, *B*). Retraction of the outer sheath deploys the Ventana distal segment within the bifurcated stent graft body (minimum overlap, 3 cm). In patients with long or tortuous infrarenal anatomies or at physician discretion, a standard infrarenal extension can be placed at the junction of the bifurcated and Ventana stent grafts. The fenestration pushers are used to advance the fenestrations to the renal ostia. Balloon dilatation of attachment sites is performed if desired. After removal of
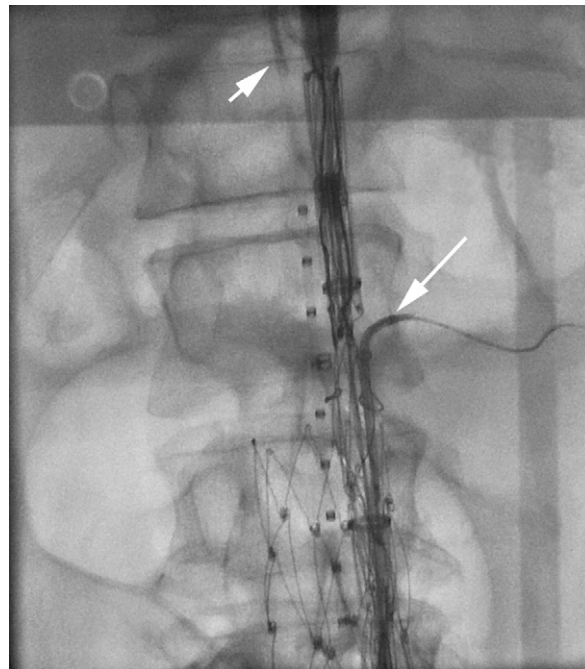

Fig 4. Initial renal artery cannulation. A downward-seeking catheter (*long arrow*) has been introduced through the right renal sheath allowing cannulation of the right renal artery. Note the control pigtail catheter introduced from the contralateral femoral artery (*short arrow*). Angiographic catheters with guidewires (*black arrows*) are advanced into renal artery ostia.

the angiographic catheters placed within the renal arteries, the renal stent grafts (oversized 5%-20% relative to the artery lumen diameter) are advanced over the guidewires through the renal sheaths (Fig 8) and positioned with approximately 5 mm length protruding into the aorta. The remaining lengths extend through the fenestrations into the renal arteries. The stents are expanded and the angioplasty balloons removed.

Subsequently, a separate angioplasty balloon (8-10 mm diameter) is advanced through each 6.5F sheath and used to flare the aortic renal stent graft segments. Angiographic imaging in both lateral and anterior-posterior projections is conducted to ascertain device position, apposition to the aortic wall, vessel patency, and absence of endoleaks (Fig 9). The delivery system and guidewires are then removed, and closure of the groins performed in usual fashion.

Patient and device selection. Patients with juxtarenal aortic aneurysms (JAAs) or pararenal aortic aneurysms (PAAs) (Table I) underwent high-resolution CT angiography and clinical baseline evaluations. Core Laboratory (Cleveland Clinic Peripheral Vascular Laboratory, Cleveland, Ohio) and independent physician (D.C.) analyses of CT scans determined anatomic eligibility. Devices were selected based on these anatomic measurements. The fenestrated device was selected to allow 10% to 20% oversizing relative to the infra-SMA aortic diameter. Iliac extensions were selected per physician discretion.

Fig 5. Renal guide sheath advancement. After successful renal artery cannulation, 6.5F renal guide sheaths are advanced into each renal artery.

Follow-up evaluations. Prior to hospital discharge, patients underwent a physical examination, blood laboratory evaluations (serum creatinine, blood urea nitrogen, hematocrit, and hemoglobin), and ABI determinations. Protocol-specified continued follow-up is at 1 and 6 months and annually to 5 years. At each visit, clinical evaluations and contrast-enhanced CT scan analyses with core laboratory assessment are conducted. All patients completed 1-month follow-up (Fig 10); eight patients have reached 6-month follow-up; and three patients have reached 1-year follow-up. Paired comparisons of proportions and of continuous variables were assessed using Fisher exact test and two-sided *t*-test, respectively.

Definitions and data analysis. JAA is an aneurysm encroaching upon but not involving the renal arteries. PAA is an aneurysm involving one or both of the renal arteries. Endoleak is the presence of contrast material within the aneurysm sac and outside of the graft material. Migration is >10 mm movement of the infra-SMA edge of the stent graft. Renal failure is an increase in serum creatinine >0.5 mg/dL on two consecutive assessments, or need for temporary or permanent dialysis. Renal dysfunction is a reduction in eGFR >30% from baseline. Respiratory complication is pneumonia or need for intubation after 24 hours postprocedure.

RESULTS

Enrollment and procedural outcomes

Two sites screened 23 patients, with eight screen failures attributable to inadequate infra-SMA neck, renal ostial stenosis >70%, or severe proximal neck angulation. The remaining 15 patients were enrolled between November
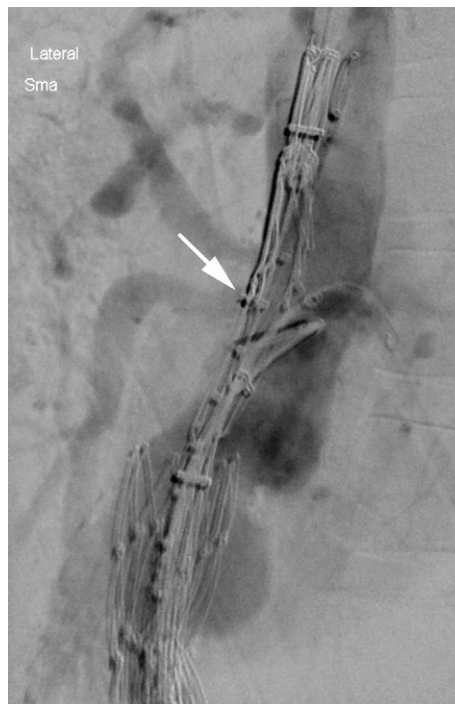

Fig 6. Proximal scallop to superior mesenteric artery (*SMA*) alignment. The central scallop marker (*arrow*) is oriented a few millimeters above the base of the SMA as viewed in a lateral projection. The scallop can be lowered into optimum position after the proximal graft segment has been deployed.

2010 and August 2011 (New Zealand, eight; Chile, seven), with continuing follow-up for all patients scheduled through 5 years. Baseline characteristics are shown in Table II (demographics and risk factors) and Table III (anatomic characteristics). Enrolled patients included 13 males (87%) and two females (13%) with mean age of 77 years and comorbidities typical of this population. The mean aneurysm sac diameter was 5.9 cm (range, 5.1-7.9 cm). All patients had an infrarenal neck length <15 mm (mean, 6.9 mm; range, 0-14 mm). Spacing of the renal arteries was 0 to 18 mm longitudinally and 122° to 204° (clockface).

Per the Society for Vascular Surgery reporting standards,[11] procedural technical success was achieved in 100% of patients. Anesthesia selection was general (80%) or regional (20%). Bifurcated stent grafts used in the study had 22 or 25 mm aortic body diameter with length 80 or 100 mm (total length 120 or 140 mm). Four Ventana stent grafts were used; 14 patients received the device with aligned fenestrations (24 mm [n = 4]; 28 mm [n = 9]; 32 mm [n = 1]). One patient having renal arteries longitudinally spaced 18 mm received the 32-mm fenestrated device with the left superior fenestration. One patient with a long and tortuous infrarenal aorta received an infrarenal extension at the junction of the bifurcated and Ventana stent grafts to provide added stability. Three patients underwent hypogastric embolization prior to the implant procedure and received limb extensions. Because of the timing
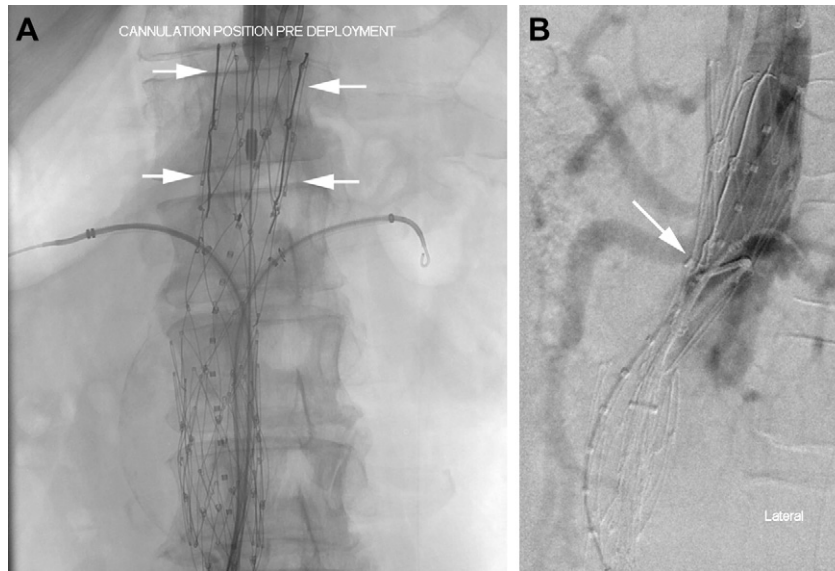
Fig 7. Deployed proximal segment of Ventana stent graft. **A,** Frontal projection: The radiopaque markers along the sides of the visceral artery scallop (*arrows*). **B,** Lateral projection: The graft has been retracted caudally to position the radiopaque marker at the base of the visceral artery scallop immediately below the superior mesenteric artery (SMA) (*arrow*).

Fig 8. Xpand renal stent graft catheter placement. The most proximal 5 mm of the renal stent graft remains in the aorta for flaring (*arrows*).

of product availability, the first five patients enrolled received Advanta V12 covered stents (Atrium Medical, Hudson, NH) to maintain the patency of the renal arteries; the last 10 patients received the Xpand device.

Mean fluoroscopy time was 55 minutes (range, 27-104 minutes), and mean contrast volume was 254 mL (range, 67-420 mL). From initial bifurcated system introduction, the mean time to complete renal artery cannulation was 40 minutes. In one patient having a highly tortuous right renal artery and a sharply downward posterior geometry

on the left, difficulties in renal artery cannulation were encountered that required several angiographic catheter and guidewire exchanges (Fig 11). A mild renal artery dissection occurred because of the manipulations, which spontaneously resolved at 1 month. The mean (range) of endovascular procedure time, total (skin to skin) procedure time, and anesthesia time were 108 minutes (range, 71-212 minutes), 211 minutes (range, 130-377 minutes), and 244 minutes (range, 153-398 minutes), respectively. Mean estimated blood loss was 628 mL (range, 200-1500 mL); five patients received blood products. Patients were discharged from the hospital at a mean of 3.3 days (range, 2-9 days). In evaluation of the renal cannulation time, fluoroscopy time, and endovascular procedure time (Table IV) among the last five patients compared with the first 10 patients treated, a trend toward reduced times appears suggestive of a learning curve.

Procedural complications. In one patient having highly calcified access vessels, an ipsilateral femoral artery localized dissection occurred, leading to distal occlusion observed while in recovery. Immediate vessel repair via femoral endarterectomy and patching was performed. No thrombosis or limb ischemia was observed, and ABI was improved at 1 month. Other complications attributed to the procedure include hematoma development at the access site, resolved spontaneously (n = 2); and minor renal artery dissection attributable to angiographic catheter/guidewire manipulation, resolved intraoperatively with angioplasty (n = 1) or not treated (n = 1). Both renal artery dissections occurred early in the study and in patients with highly tortuous renal arteries, and there have not been residual sequelae to current follow-up.
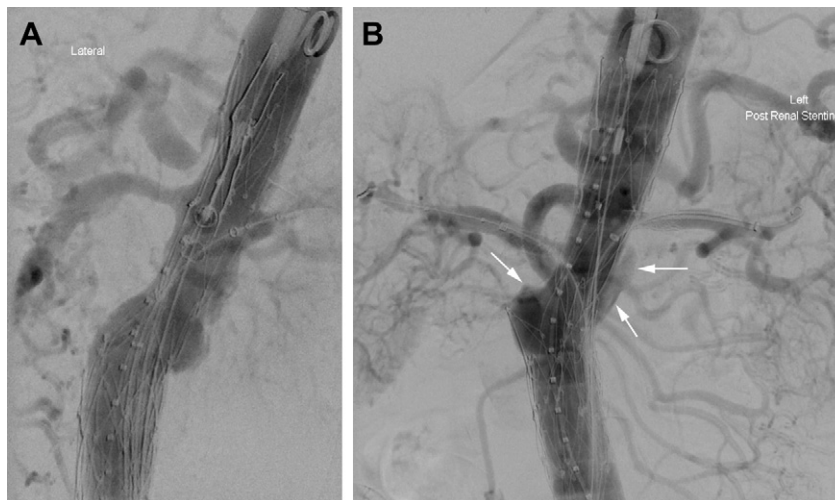
Fig 9. Final angiographic runs. **A,** Lateral projection showing a patent superior mesenteric artery (SMA). **B,** Frontal projection shows the oversized graft (*arrows*) in the visceral segment creating extended seal zones with the aortic anatomy.

Table I. Patient selection criteria

- Iliac/femoral artery access vessel diameter compatible with delivery systems
- Renal arteries with length ≥13 mm and without significant occlusive disease (<70% stenosis)
- Absence of essential accessory renal artery (ie, one that supplies >25% of the renal parenchyma)
- Mural thrombus in suprarenal segment ≤5 mm in thickness over ≤60% of circumference
- Infrarenal neck length <15 mm
- Nonaneurysmal proximal neck relative to the SMA with length ≥15 mm, diameter 18 to 34 mm, and angle to the aneurysm sac ≤60°
- 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 (longitudinally) and 90° to 210° (clockface)
- Celiac artery to SMA angle ≤60° (clockface)
- SMA to aortoiliac bifurcation length ≥90 mm
- Common iliac artery diameter 10 to 23 mm with seal zone length ≥15 mm
- Ability to preserve at least one hypogastric artery
- Fenestrated stent graft overlap with bifurcated stent graft ≥3cm

SMA, Superior mesenteric artery.

Primary study assessments

MAEs. Procedurally to within 30 days (Table V), no death occurred. Blood loss >1000 mL with transfusion occurred in two patients (13%). One patient with localized access vessel dissection described above underwent vessel repair, and in the other, a delivery system valve hub was inadvertently broken, and a delivery system exchange was done to place an infrarenal extension at the bifurcated-fenestrated stent graft junction. Both patients were discharged in satisfactory condition.

Clinical success. All endovascular procedures were completed successfully. Core Laboratory evaluations of CT scans revealed stable, properly placed devices without type I or III endoleak at 1 month. One patient (6.7%) reporting claudication postdischarge underwent magnetic resonance imaging on day 21 revealing right external iliac artery occlusion because of a kink in the bifurcated device right limb and high grade stenosis on the left side. Femoral to femoral bypass with stent placement was performed on day 26 to resolve the findings. Upon re-review of the intraoperative angiography, the bifurcated limb device kink was present but not recognized at the time.

Additional assessments

Late MAEs. After 30 days and to current follow-up (Table V), two nonaneurysm-related deaths have occurred (13%). One was due to subdural hematoma and cerebral hemorrhage secondary to a witnessed accidental fall at 3.3 months postoperatively. The other was due to left parietal intracerebral hemorrhage at 5.7 months postprocedure in a patient with chronic atrial fibrillation. No other late MAEs have occurred.

Other adverse events. Two patients developed postprocedural groin hematomas that spontaneously resolved. One patient developed in-hospital urosepsis requiring intravenous antibiotics; she also developed atrial tachycardia secondary to the infection. Both resolved prior to her discharge from the hospital on postoperative day 8.

Renal function. Compared with preoperative values, mean eGFR values are similar at 1 month (60 vs 58 [n = 15]) and 6 months (56 vs 52 [n = 8]). Renal function has been well maintained in these patients, with no renal infarcts observed.

Distal perfusion. Compared with preoperative values, mean ABI are similar at 1 month (1.05 vs 1.03 [n = 15]) and 6 months (1.05 vs 1.05 [n = 8]). Distal perfusion is well maintained.
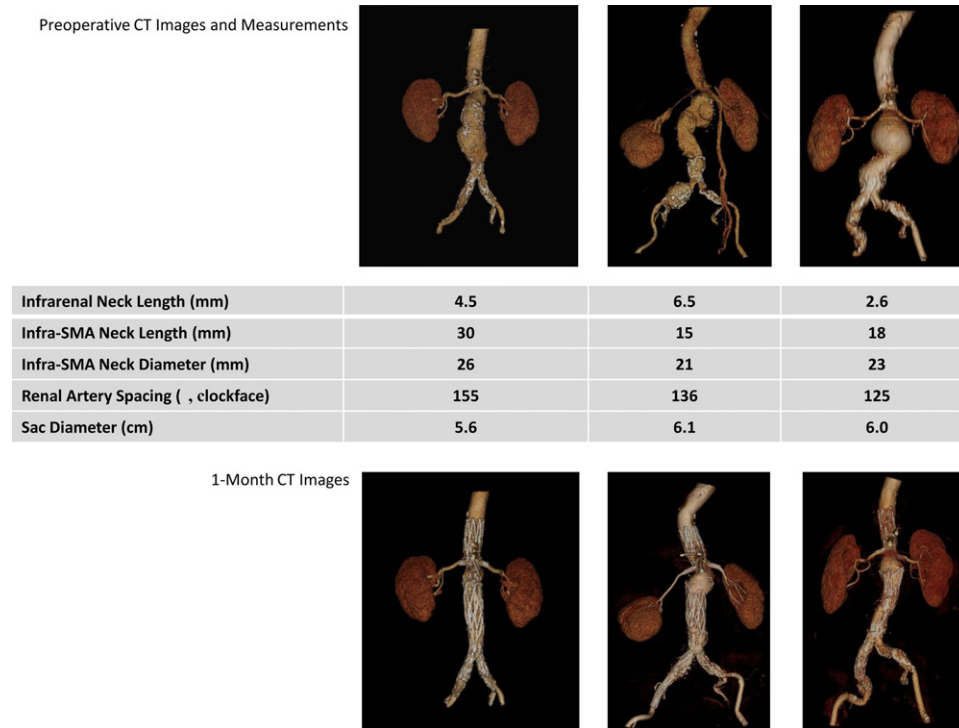
Fig 10. Examples of preoperative and 1-month case computed tomography (*CT*) images. *SMA,* Superior mesenteric artery.

Device integrity. The Core Laboratory assessed CT scans to evaluate device integrity and to determine the incidence of stent fracture, graft fatigue/failure, migration, limb occlusion, and renal stenosis/occlusion. No stent fractures, graft fatigue/failures, or migrations have been observed. No aneurysm rupture or conversion to open repair has occurred. One limb occlusion was repaired as noted above. One patient is identified with late bilateral renal artery stenoses at the distal junctions with the implanted 5-mm renal stent grafts attributed to implant of undersized renal stent grafts at the index procedure. The stenoses were successfully resolved with implantation of 7-mm Precise stents (Cordis Corporation, Miami Lakes, Fla).

Endoleaks and sac morphology. Core Laboratory assessment revealed no type I, type III, or type IV endoleaks through current follow-up. Three patients (20%) were identified with mild type II endoleaks at 1 month that are continuing at 6 months. Through current follow-up, all sac diameters are stable or decreasing, and no secondary procedure for endoleak has been performed.

DISCUSSION

Open surgical repair of more complex JAAs or PAAs requires suprarenal or supraceliac aortic clamping and eventual renal artery reconstruction, leading to renal ischemia and increasing the risk of mortality and morbidity, including bleeding, renal failure, and associated sequelae compared with infrarenal aortic aneurysm surgical repair.[12,13] As such, efforts have been made to develop potential options to extend the perioperative benefits observed following endovascular stent graft repair of infra-renal aneurysms[14] to these more complex aortic aneurysms. Multicenter studies of one patient-customized fenestrated stent graft used in conjunction with various bare or covered stents have demonstrated positive outcomes.[7,8] Encouraging initial experience among eight patients with another patient-customized fenestrated endograft has been made available.[15] Access to these custom fenestrated devices has been limited to selected centers because of the substantial time required for custom device planning and manufacture, technical challenges of custom device deployment, and the ability of centers to support customized technology with adequate training and resources.[16] In the most recent meta-analysis of custom fenestrated endografting of JAAs and PAAs from 2001 to 2010 (n = 629), Linsen and colleagues[16] reported a pooled estimate for technical success of 90.4%, and pooled estimates of 93.2% for branch vessel patency, 22.2% for renal impairment, and 17.8% for secondary intervention in follow-up ranging from 15 to 25 months. More recently, a retrospective analysis of 100 patients treated with a custom fenestrated endograft at a single center found that 72% could theoretically be treated by one of two standardized model designs having more flexible fenestration elements.[17] The availability of published clinical data will serve to validate this promising anatomic analysis.

Table II. Baseline demographics and comorbidities

Characteristic	Result
Male sex	13 (87)
Age, years	77 ± 5.6
Serum creatinine, mg/dL	1.2 ± 0.2
Arrhythmia	5 (33)
Cerebrovascular disease	1 (6.7)
Coronary artery disease	1 (6.7)
Chronic obstructive pulmonary disease	3 (20)
Diabetes	4 (27)
Gastrointestinal abnormality	2 (13)
Hypertension	12 (80)
Hypercholesterolemia	12 (80)
Peripheral arterial disease	1 (6.7)
Prior abdominal surgery	3 (20)
Prior myocardial infarction	2 (13)
Prior coronary artery bypass grafting	1 (6.7)
Renal failure	1 (6.7)
Smoking (ever)	9 (60)

Results reported as n (% of 15) or mean ± standard deviation.

Table III. Preoperative aneurysm and vascular anatomy

Characteristic	Result
JAA/PAA	14 (93)/1 (6.7)
Aneurysm sac diameter, cm	5.9 ± 0.8
Infra-SMA proximal neck diameter, mm	24 ± 2.2
Aortoiliac bifurcation diameter, mm	29 ± 9.4
Infra-SMA proximal neck length, mm	25 ± 9.9
Infrarenal proximal neck length, mm	6.9 ± 5.3
SMA to aortoiliac bifurcation length, mm	144 ± 13
Left renal artery diameter, mm	5.9 ± 0.7
Right renal artery diameter, mm	5.7 ± 0.8
Left to right renal artery length (axial), mm	6.9 ± 5.6
Left to right renal artery angle (clockface), °	147 ± 23
SMA to celiac artery angle (clockface), °	17 ± 11
SMA to aorta angle, °	56 ± 14
Proximal neck to aneurysm sac angle, °	36 ± 15
Ipsilateral external iliac artery diameter, mm	9.3 ± 1.5

JAA, Juxtarenal aortic aneurysm; *PAA,* pararenal aortic aneurysm; *SMA,* superior mesenteric artery.

Results reported as n (% of 15) or mean ± standard deviation.

A prospective clinical study was conducted to evaluate the initial safety and feasibility of the Ventana fenestrated system as a potential 'off the shelf' option for the endovascular repair of JAA/PAA. Notably, this is the first study conducted using this device configuration, which builds on the anatomic fixation/proximal sealing technique established for the repair of infrarenal aortic aneurysms.[10,14] The main body stent graft seated at the aortic bifurcation provides columnar support for the larger fenestrated proximal extension stent graft. Because migration forces act predominantly on the stent graft bifurcation,[18] this implant algorithm takes advantage of the aortic anatomy to attain secure fixation to resist natural migration forces. Seal is achieved distally at the junction of the bifurcated stent graft limbs and common iliac arteries, and proximally at the junctions of the fenestrated stent graft with the infra-SMA aorta and fenestrations with the covered renal stents. A unique feature of this implant design is the visible extension of proximal seal below the scallop because of the effect of the conformable graft, which acts independently from the stent (Fig 10). Nonetheless, severe neck angulation and clinically significant renal artery ostial stenoses limit the application of any endovascular device design. Proper device selection as well as placement of the scallop at the base of the SMA is important to achieving both seal and maintaining visceral artery patency.

A major advantage of this device system is the cannulation of the renal arteries using preloaded guide sheaths whereas the fenestrated stent graft proximal and distal segments remain fully constrained within the delivery system. All necessary angiographic and guidewire exchanges occur through the indwelling guide sheaths of the Ventana system. Once renal cannulation is achieved, Ventana proximal and distal deployments are completed. Integrated fenestration pushers facilitate fenestration movement at and into the renal artery orifice, essentially creating the basis for a branched graft implant. Thereafter,

renal stent graft advancement through the guide sheaths followed by balloon expansion and flaring in the aortic segment completes the repair. Moore and colleagues suggested that the rigidity of a balloon-expandable covered renal stents may lead to difficulties in advancement into the visceral artery.[19] These authors furthermore expressed concern that a covered renal stent implant could result in suboptimal aortic flaring, potentially leading to poor seal with the fenestrated stent graft. We did not observe these particular difficulties, likely because of the flexibility of the integrated guide sheaths, the significant range of motion of the Ventana fenestrations (which have no stent constraints or interference), and the design of the renal stent grafts. Flaring in the aorta after renal stent graft implant was not complex.

Perioperatively and to current follow-up, no aneurysm-related mortality, aneurysm rupture, or conversion to open repair occurred. Procedural complications and MAEs were limited. Considering the complexity of these endovascular repairs, clinical utility outcomes were reasonable. Even with this early experience, a limited learning curve was identified, which bodes well for further physician training on this device configuration. Opportunities for improvement exist in delivery system hemostatic component design, handling, and operating techniques to reduce blood loss.

Treatment success was achieved. One limb occlusion observed because of a bifurcated device limb kink was resolved surgically. A secondary procedure to resolve renal stenoses in a patient at 6 months underscores the need for adequate oversizing of the covered renal stent to the renal artery lumen diameter.

The design of the Ventana fenestrated stent graft originated based upon a detailed retrospective review of CT scans from the Endologix infrarenal trial patient cohort. Specific measurements were made by the Core Laboratory to determine the range of geometries between the SMA,
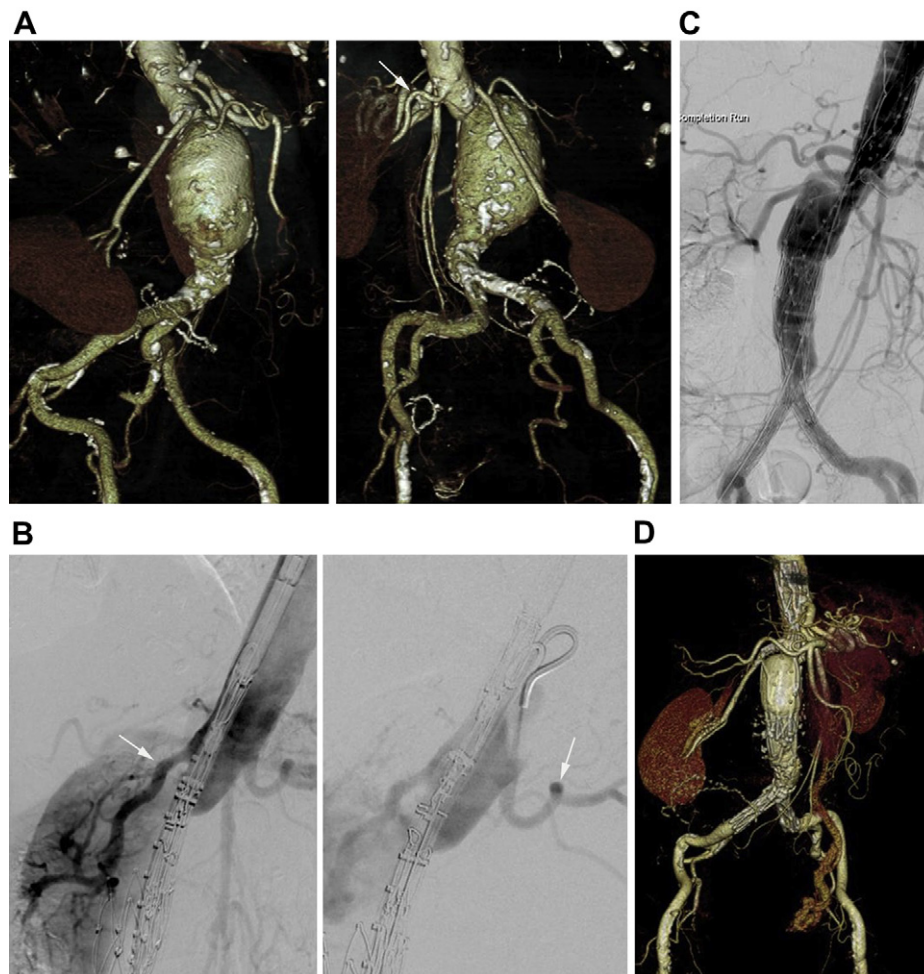
Fig 11. Challenging renal cannulation example. **A,** Preoperative computed tomography (CT) anatomy in the oblique and posterior projections (note the tortuous left renal artery [*arrow*]). **B,** Intraoperative arteriography of the renal arteries showing the irregular, downward pointing right renal artery and the tortuous left renal artery (*arrows*). **C,** Completion angiogram. **D,** CT at 1 month showing conformance of the oversized graft midsection to the anatomy.

celiac, and renal arteries. This analysis yielded a mean renal to renal (clockface) angle of 151°; mean SMA to renal (clockface) angle of 79°; and mean SMA to renal artery length of 17 mm. More than 85% of the anatomies were observed with ≤15 mm renal to renal longitudinal length; ≤35 mm SMA to bilateral renal artery length; and 90° to 210° renal to renal clockface angle. These are the design constraints of the Ventana fenestrated stent graft, suggesting that broad anatomic applicability is anticipated. The case planning that is required for this device system is more involved than the infrarenal device; however, the same principles apply, making this far easier than the planning required for a customized device. High-resolution CT scans ranging throughout the anatomic treatment area are essential to ensuring suitable anatomy for proper device selection. Focus is placed on the diameter, length, and quality of the infra-SMA nonaneurysmal neck, SMA to bifurcation length, orientation of the visceral arteries (renal to renal clockface orientation and longitudinal spacing;

renal to SMA length, SMA to celiac artery clockface orientation), and to a large extent, renal artery quality, length, and angulation/tortuosity. Because the bifurcated device serves as the foundational platform and has substantial overlap with the fenestrated device, size selection is simplified to essentially the bifurcated device limb length required to preserve at least one hypogastric artery. The significant range of motion afforded by the movable fenestrations within the conformable graft mid-segment (90°-210°) and the limited number of devices necessary to cover the full range of proximal diameters supports its 'off the shelf' characterization. The use of a single Ventana device in nine patients, with only four models used among 15 patients, 93% of which utilized the aligned fenestration configuration, supports the concept of this design. Nonetheless, the need for a healthy infra-SMA proximal sealzone cannot be overemphasized to ensure device stability in the long term. Successful initial outcomes in extending this endovascular stent graft system to these more complex

Table IV. Procedural and in-hospital measures

Parameter	First 10 patients	Last 5 patients	All patients
Fluoroscopy time, minutes	59 ± 26	48 ± 11	55 ± 22
Contrast volume, mL	273 ± 104	216 ± 171	254 ± 127
Blood loss, mL	508 ± 367	870 ± 399	628 ± 405
Blood products, % of patients	30%	40%	33%
Renal artery cannulation time, minutes[a]	45 ± 20	31 ± 9.6	40 ± 18
Endovascular procedure time, minutes[b]	116 ± 40	90 ± 18	108 ± 36
Total procedure time, minutes[c]	201 ± 39	232 ± 86	211 ± 58
Anesthesia time, minutes	244 ± 41	226 ± 32	238 ± 38
Time to hospital discharge, days	3.4 ± 2.9	3.0 ± 1.7	3.3 ± 2.5

Results shown as % or mean ± standard deviation.
[a]Time from initial bifurcated stent graft delivery system introduction to completion of bilateral renal cannulation.
[b]Time from initial bifurcated stent graft delivery system introduction to guidewire removal.
[c]Skin to skin time.

Table V. MAEs

MAE[a]	0-30 days, No. (%)	>30 days, No. (%)	Total, No. (%)
Patients with ≥1 event	2 (13)	2 (13)	3 (20)
Mortality	0	2 (13)	2 (13)
Bowel ischemia	0	0	0
Myocardial infarction	0	0	0
Paraplegia	0	0	0
Renal failure	0	0	0
Respiratory failure	0	0	0
Stroke	0	0	0
Blood loss ≥1000 cc	2 (13)	0	2 (13)

MAE, Major adverse event.
Results shown as number of patients with event (% of 15).
[a]Defined as all-cause death, bowel ischemia, myocardial infarction, paraplegia, renal failure, respiratory complication, stroke, and blood loss of >1000 mL.

aneurysms was shown among teams with substantial infrarenal endografting experience, technical skill in visceral interventional techniques, and suitable facilities with fixed imaging. A learning curve was identified, reinforcing the need for system-specific training including patient selection, case planning and device selection, and procedural techniques.

CONCLUSIONS

This report shows the initial safety, feasibility, and applicability of the Ventana fenestrated system as an 'off the shelf' option for the endovascular repair of more complex JAA/PAA. Further experience and continued

long follow-up will assess durability. Clinical validation in a broader multicenter trial is warranted.

AUTHOR CONTRIBUTIONS

Conception and design: AH, RM, AH, LM, DG
Analysis and interpretation: AH, RM, DC
Data collection: AH, RM, AH, LM
Writing the article: AH, RM, DC
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