From the Western Vascular Society

Prospective, multicenter experience with the Ventana Fenestrated System for juxtarenal and pararenal aortic aneurysm endovascular repair

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Objective: **This study assessed preliminary results of the Ventana Fenestrated System (Endologix, Irvine, Calif) as an off-the-shelf integrated device for juxtarenal aortic aneurysm (JAA) or pararenal aortic aneurysm (PAA) endovascular repair.**

Methods: **From November 2010 to April 2012, seven centers enrolled 31 patients with JAAs or PAAs in an international clinical trial of the Ventana Fenestrated System. Clinical and laboratory evaluations were done predischarge and at 1 month, with continuing follow-up through 5 years. Core laboratory computed tomography imaging assessments were performed at 1 month and at each subsequent follow-up.**

Results: **Patients (mean age, 73 years; 90% male) presented with mean aneurysm sac diameter of 6.0 cm. One patient with a short, reversed tapered infra-superior mesenteric artery (SMA) neck was enrolled under a protocol waiver. Among the 31 patients, one of five Ventana device models was used to preserve main renal arteries, the SMA, and celiac arteries; 20 patients (65%) received the same Ventana device (aligned fenestrations, 28-mm diameter). Median fluoroscopy and procedure times were 49 and 197 minutes, respectively; median hospital length of stay was 3.0 days. The 1-month clinical success rate was 94% (29 of 31), with no perioperative mortality. One intervention on day 26 was done to resolve limb kink/occlusion. A type IA endoleak and renal occlusion secondary to procedural device damage led to a reintervention on day 52 and dialysis at 5 months. During follow-up to 23 months, three non-aneurysm-related deaths occurred. No aneurysm rupture or conversion to open repair has occurred. One late migration with endoleak and covered renal stent fracture/occlusion occurred at 8 months in the patient with a short, reverse tapered infra-SMA neck performed under a protocol waiver, which was managed successfully with bilateral renal bypasses and endovascular repair of the endoleak. Another patient underwent late endovascular interventions to resolve bilateral renal stenosis.**

Conclusions: **The multicenter experience of the Ventana Fenestrated System supports its safety and early-term to midterm effectiveness for the endovascular repair of JAAs and PAAs. This off-the-shelf integrated system permits endovascular treatment of JAAs or PAAs; however, further expanded clinical experience and longer-term follow-up are needed to more fully assess this device system. (J Vasc Surg 2013;58:1-9.)**

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Lower morbidity and mortality after endovascular repair of abdominal aortic aneurysms has encouraged the application of available device technology outside of the manufacturer's labeled indications.[1,2] Whereas the use of ancillary techniques to deal with unfavorable or hostile proximal seal zones (eg, short, irregular, angulated, thrombus-laden) has had reasonable early success, a higher risk of adverse outcomes (eg, type IA or type III endoleak, migration, rupture) has been reported in the midterm and longer term.[2,3] The goal of extending an endovascular option for aneurysms with short or no infrarenal necks or visceral artery involvement, or both, has encouraged the development of more standardized techniques to preserve visceral flow, taking advantage of a seal zone in the more proximal, usually healthier aorta below the superior mesenteric artery (SMA).

Essentially two approaches have evolved: chimney and snorkel techniques involving the combination of covered

stents to the visceral branches parallel to and outside an infrarenal endograft[4-6] or customized devices using covered stents through patient-specific main endograft fenestrations to the visceral arteries.[6-9] Intuitively, the latter seems preferable because it may achieve a more predictable seal at the endograft–visceral stent interface. Historically, the main disadvantages of the fenestrated approach are that the surgeon must design and create the endograft by altering a commercially available device (time-consuming, quality-control issues, liability) or it is custom-produced by the manufacturer for the particular patient's anatomy (delay in treatment, cost). These limitations have naturally led to the search for off-the-shelf endograft design platforms for these more complex aneurysms.

The Ventana Fenestrated System (VFS) consists of an integrated endovascular stent graft system deployed as a proximal extension to the currently Food and Drug Administration-approved AFX (Endologix, Irvine, Calif) infrarenal endograft. A generous proximal scallop preserves blood flow to the SMA and celiac arteries. In situ movable fenestrations with preloaded sheaths are used to place covered stents into the renal arteries to complete aneurysm exclusion. It has been designed as an off-the-shelf system for the treatment of juxtarenal aortic aneurysms (JAAs) or pararenal aortic aneurysms (PAAs).

We present the early-term to midterm results of a multicenter clinical trial using the VFS for the management of high-risk patients with JAAs or PAAs.

METHODS

Study design and patient selection. Seven international centers with experience in infrarenal endovascular aortic stent grafting, complex open surgical repair, and visceral artery interventional techniques participated in this trial. Each site obtained ethical approval for human investigation and necessary government authorization, and written patient informed consent was obtained. Preoperatively, a high-resolution, contrast-enhanced computed tomography (CT) scan assessment of the descending thoracic and abdominal aorta was conducted by an independent core laboratory (Cleveland Clinic Foundation Peripheral Vascular Core Lab, Cleveland, Ohio). An independent physician reviewed the CT scan and core laboratory assessment, as well as angiography, if available, to determine anatomical eligibility for enrollment.

Angiography was selectively done to assess the degree of stenosis if a significant renal artery lesion was seen on the CT scan. Key considerations were quality of the proximal infra-SMA neck (ie, <20% diameter change over the most proximal 15-mm neck length without severe plaque or thrombus) and renal arteries (ie, <70% ostial stenosis with suitable diameter and length for covered stent placement). Ankle-brachial index (ABI) and blood laboratory evaluations, medical history, and physical examination were performed. These baseline assessments were used to determine patient suitability for enrollment (Table I).

Device description. The VFS consists of the commercially available AFX 22- or 25-mm bifurcated stent graft seated at the aortoiliac bifurcation, the Ventana fenestrated proximal extension stent graft, and Xpand (all Endologix) balloon-expandable covered renal stents (Fig 1). All are manufactured and packaged in individual catheter-based delivery systems as ready-to-use, sterile medical devices.

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 on the preoperative CT scan)
- 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° (clock face)
- Celiac artery-to-SMA angle ≤60° (clock face)
- 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 ≥3 cm

CT, Computed tomography; *SMA,* superior mesenteric artery.

The bifurcated stent graft is a unibody self-expanding cobalt chromium alloy endostent with a multilayer expanded polytetrafluoroethylene (ePTFE) graft that is attached to the stent proximally and distally using surgical suture. The Ventana stent graft has the same stent element design as the bifurcated stent graft; it is continuous in the proximal and distal sections, with anterior and posterior stent elements connecting these segments (Fig 2). Its multilayer ePTFE graft is a one-piece design attached to the stent proximally and distally, incorporating an oversized midsection with two fenestrations. There is no stent interference with the fenestrations (Fig 2). An ample proximal 4-cm-length scallop encompasses the SMA and celiac arteries, with sizes available to treat aortic diameters from 18 to 34 mm. The 28-mm-diameter distal segment permits substantial overlap (≥3 cm) with the bifurcated device body. Radiopaque markers identify the scallop margins, center, and circumference of each fenestration. The fenestrations are expandable from their nominal 3-mm-diameter to 10 mm and are movable in situ longitudinally and circumferentially to accommodate renal arteries spaced ±30 mm longitudinally and 90° to 210° (clock face).

The 22F profile delivery system incorporates preloaded guide sheaths transfenestration for simplified renal artery cannulation and covered renal stent delivery. The Xpand device is a balloon-expandable, multilayer ePTFE-covered cobalt chromium alloy stent premounted on a 115-cm-length nylon balloon catheter that is compatible with

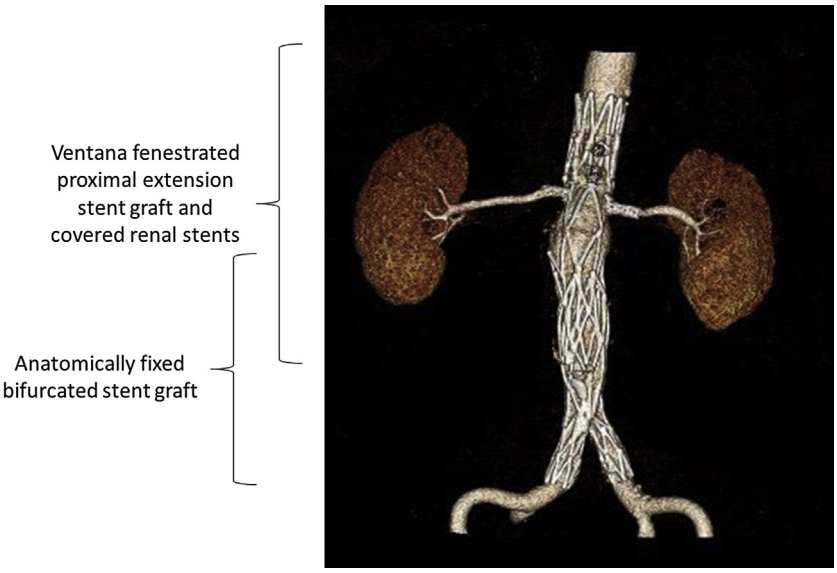

Fig 1. The Ventana Implant. Note the bifurcated unibody stent graft anatomically fixed at the aortic bifurcation, the Ventana fenestrated proximal extension stent graft, and the balloon-expanded covered renal stents.

0.035-inch guidewires and the Ventana 6F guide sheaths. The proximal segment of the covered stent, available in 18-, 25-, or 35-mm lengths, is designed to be flared in the aorta after implant across the fenestration. Selective angiographic catheters that have various tip configurations with 120-cm length, compatible with the Ventana delivery system guide sheaths, are used.

Definitions. JAA is defined as an aneurysm encroaching upon but not involving the renal arteries. PAA is defined as an aneurysm involving one or both of the renal arteries. Renal failure is defined as serum creatinine increase >0.5 mg/dL on two consecutive assessments or need for temporary or permanent dialysis. Renal dysfunction is defined as reduction in estimated glomerular filtration rate (eGFR) >30% from baseline. Major adverse events (MAE) include all-cause mortality, bowel ischemia, myocardial infarction, paraplegia, renal failure, respiratory complication, stroke, and blood loss ≥1000 mL. Procedure technical success was defined as successful device delivery and deployment, with resulting patency of all visceral arteries and no type I or III endoleak at the completion of the procedure. The primary end point, treatment success, is defined as successful device delivery and deployment with resulting patency of all visceral arteries and absence of type I or III endoleak at 1 month.

Implant procedures. Each principal investigator underwent didactic training and performed in vitro implants using the integrated VFS in a pressurized flow model of a replica juxtarenal aneurysmal anatomy with only fluoroscopic visualization. A trained proctor attended each case. Device delivery and deployment has been previously described.[10] The implantation is performed through femoral artery access or iliac conduit, as indicated. Briefly, after bifurcated device anatomic fixation, the VFS is advanced ipsilaterally over the stiff 0.035-inch guidewire. Outer sheath retraction exposes the precannulated renal guide sheaths. Importantly, the proximal and distal stent graft segments remain fully constrained within the delivery system, maximizing maneuverability within the visceral segment (Fig 3). Cannulation of the renal arteries occurs at this time using physician-selected angiographic catheters and guidewires introduced through the transfenestration guide sheaths. Ventana deployment proximally then distally is performed. Integrated pushers may be used to advance the fenestrations to or into the renal ostia. The covered renal stents are advanced through the guide sheaths and into the renal arteries, where they are deployed and then flared in the aorta with a separate 10-mm balloon.

Follow-up evaluations. Before hospital discharge, patients underwent a clinical and laboratory examination. Follow-up is at 1 month, 6 months, 1 year, and annually to 5 years. History and physical examination, blood laboratory evaluations, ABI determinations, and contrast-enhanced CT scans are conducted at each visit. Duplex ultrasound imaging is performed at site discretion. Core laboratory evaluation of the CT scans is the basis for device performance and efficacy determinations.

Data analysis. Baseline and procedural continuous, ordinal, and categoric variables are presented descriptively. An independent Clinical Events Committee adjudicates adverse events for analysis, and oversight reviews by an independent Data Safety Monitoring Board occur periodically. Early (≤30 days) and late (>30 days) MAEs, endoleak, and aneurysm data are presented descriptively. Primary end point analysis is done using the exact binomial distribution. Statistical significance is considered for $P < .05$. Analyses are performed using SAS 9.1 software (SAS Institute, Cary, NC).

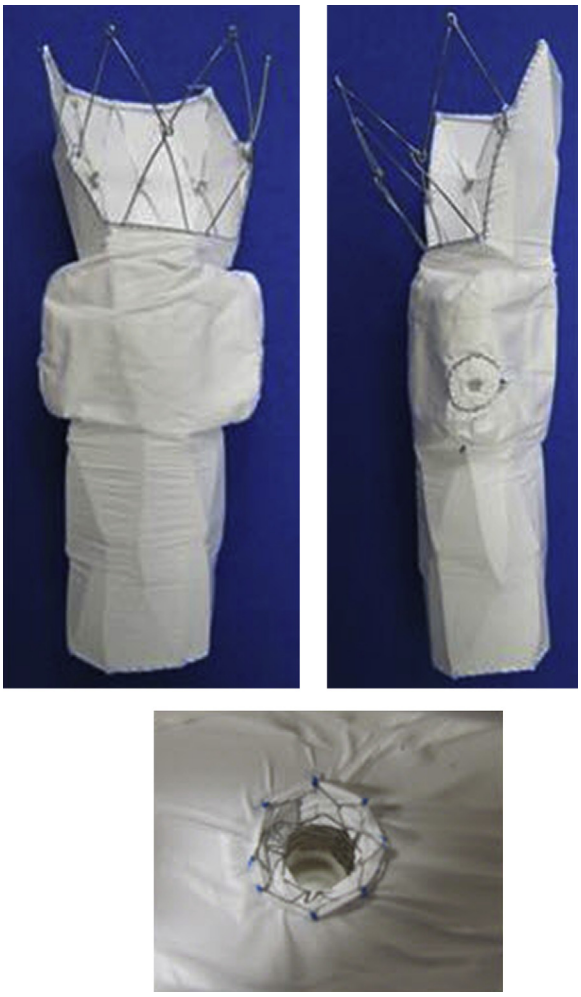

Fig 2. Ex vivo images show front (*left*) and side views (*right*) of the Ventana stent graft and the flared renal stent graft–fenestration interface (*bottom*).

RESULTS

Enrollment and procedural outcomes. Fifty-one patients were consented and screened, with 31 found eligible and enrolled between November 2010 and April 2012, which includes a 6-month period while several sites were awaiting government approvals. Primary reasons for screen failure included inadequate infra-SMA neck length, inadequately sized access vessels, and unsuitable renal artery diameter or length. One patient was excluded because the screening showed a long (>35 mm) distance from the SMA to the renal artery. One patient with a short (9-mm length), reverse tapered infra-SMA proximal neck was accepted for enrollment under a protocol waiver. Table II summarizes the preoperative patient demographics, risk factors, and baseline aneurysm characteristics. Patients were a mean age of 73 years, and 91% were men. Medical history and risk factors were typical of this population with aneurysmal disease.

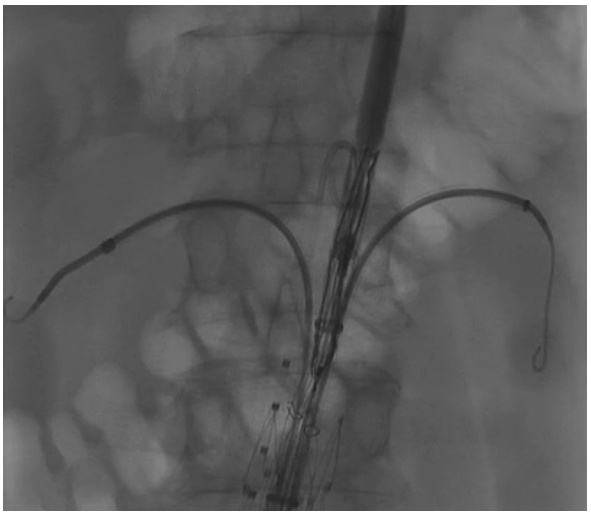

Fig 3. Angiographic image shows renal cannulation. The Ventana fenestrated proximal extension stent graft is constrained, maximizing maneuverability within the visceral segment.

Five Ventana models were used: 30 patients received the device with aligned fenestrations, with 20 receiving the 28-mm device. One patient whose renal arteries were longitudinally spaced at 18 mm received the 32-mm device with the left superior fenestration. The Core Laboratory characterized the infra-SMA neck shape as funnel or reverse funnel in 26% of patients, with all but one having <20% diameter change over the first 15-mm infra-SMA neck length. The visceral morphology of the 31 patients is shown in Fig 4, illustrating the range of anatomy treated.

Intraoperative angiography verified that in each patient, the Ventana scallop was placed accurately below and about the SMA and celiac arteries with no obstruction. The first five patients enrolled received Advanta V12 covered renal stents (Atrium Medical, Hudson, NH). Preplanned concomitant procedures include stenting of the SMA (n = 1), bypass of an external iliac artery to the hypogastric artery (n = 1), conduit placement due to inadequate access vessel size (n = 4), and unilateral hypogastric artery embolization (n = 6).

Technical success was achieved in 30 of 31 patients (97%). Procedural results, including complications and clinical utility outcomes, are summarized in Table III. In one patient, the device implants were completed successfully. At final angiography, the physician was uncertain whether an endoleak was present, and elected to balloon model the implant. Renal sheaths had been removed, and renal artery reaccess was attempted but could not be gained. Inadvertent compression of the implanted covered renal stents occurred during balloon modeling of the proximal segment. Upon final angiography, partial occlusion of the left covered renal stent and malpositioning of the Ventana device appeared to result in an incomplete seal at the proximal segment.

In another patient, procedure time was prolonged (566 min) secondary to significant renal ostial stenosis

Table II. Baseline demographics and risk factors

Characteristic	*No. (%) or mean ± SD (range) (n = 31)*
Demographics	
Male sex	28 (91)
Age, years	73 ± 7.5 (55-85)
GFR, mL/min[a]	68 ± 21 (42-125)
Risk factors	
Arrhythmia	7 (23)
Cancer	9 (29)
Coronary artery disease	10 (32)
Chronic obstructive pulmonary disease	6 (19)
Diabetes	6 (19)
Family history of AAA	1 (3.2)
Gastrointestinal abnormality[b]	6 (19)
Hypertension	21 (68)
Hypercholesterolemia	25 (82)
Peripheral arterial disease	3 (9.7)
Prior abdominal surgery	7 (22)
Prior myocardial infarction	4 (13)
Prior CABG or PCI	6 (19)
Smoking (ever)	16 (52)
Aneurysm characteristics	
Aneurysm sac diameter, cm	6.0 ± 0.9 (4.9-10)
Irregular infra-SMA neck[c]	8 (26)
Infra-SMA neck diameter, mm	25 ± 2.8 (21-30)
Infra-SMA neck length, mm	27 ± 11 (9-35)
Infra-renal neck length, mm	6.9 ± 3.4 (0-14)
Angulation,°	
Suprarenal aorta to renal artery	57 ± 11 (42-83)
Infra-SMA neck to sac	36 ± 12 (20-53)
SMA to celiac artery (clock face)	14 ± 9.0 (0.8-30)
SMA to aortic bifurcation length, mm	145 ± 17 (122-186)

AAA, Abdominal aortic aneurysm; *CABG,* coronary artery bypass grafting; *GFR,* glomerular filtration rate; *PCI,* percutaneous coronary intervention; *SD,* standard deviation; *SMA,* superior mesenteric artery.
[a]Estimated by the Cockroft-Gault equation.
[b]Includes stomach ulcer, Crohn disease, ulcerative colitis, and nonspecific irritable bowel conditions.
[c]Funnel or reverse taper, defined as length with 11% to 20% change in neck diameter.

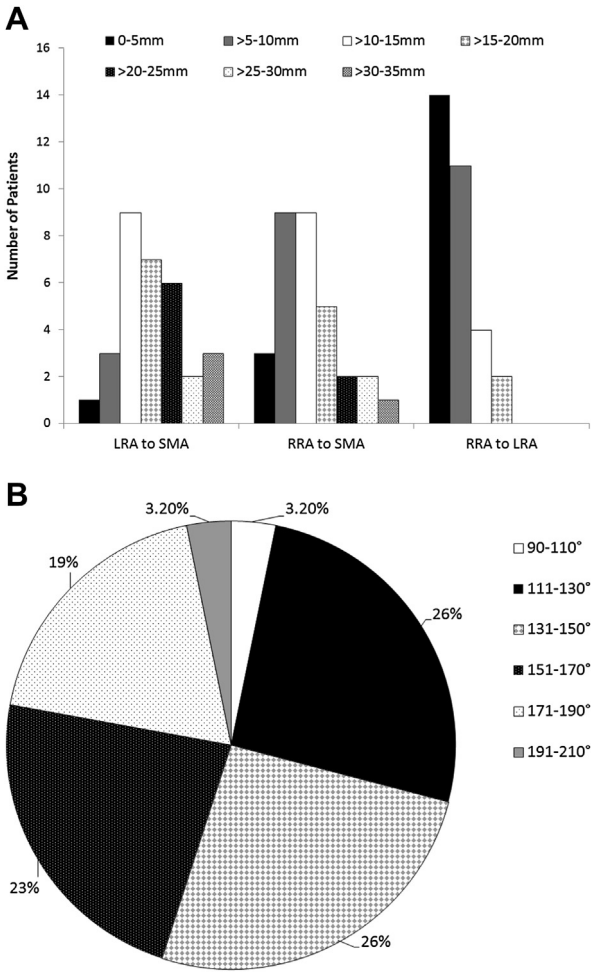

Fig 4. Visceral morphology of the 31 study patients. **A,** Distribution of centerline lengths: superior mesenteric artery (*SMA*) to left renal artery (*LRA*); SMA to right renal artery (*RRA*); and LRA to RRA. **B,** Distribution of clock face angle between the LRA and RRA.

(~80%) not recognized on the preoperative CT scan. Renal stent placement was eventually accomplished to address the stenosis. The Ventana implant was then successfully delivered and deployed. Experience with this patient led to a protocol revision requiring angiographic evaluation of renal artery stenosis when suspected on CT scan before inclusion in the trial.

Complete 1-month follow-up data are available for all 31 patients. After 30 days to 6 months, three patients died; 6-month data are available on the 28 survivors. Longer-term follow-up is available to a maximum of 23 months in 11 patients. The mean follow-up is 1.3 years.

Primary end point results. Within 1 month, one iliac occlusion and one renal occlusion with endoleak occurred, yielding a treatment success rate of 94% (29 of 31; $P = .01$, binomial distribution). The former was a right external iliac artery occlusion due to a kink in the bifurcated device right limb, and the patient underwent successful femoral-to-femoral bypass on day 26. The renal occlusion occurred in the patient with intraoperative ballooning over the unprotected covered renal stents. Renal occlusion and ischemia and endoleak of unknown origin were reported. Onyx liquid (Covidien, Irvine, Calif) embolic sac embolization via catheter introduction behind the Ventana scallop was performed on day 52 to resolve the endoleak, and no renal intervention was performed.

Mortality and MAEs. No early deaths occurred. After 30 days and within 6 months, three non-aneurysm-related deaths occurred secondary to a witnessed accidental fall, left parietal intracerebral hemorrhage in a patient with chronic atrial fibrillation (both with autopsy), and cardiopulmonary arrest secondary to pre-existing chronic obstructive pulmonary disease. All were adjudicated as non-aneurysm-related.

Pneumonia on postoperative day 12 in one patient was treated medically without sequelae. Four patients (13%) were observed procedurally with blood loss ≥1000 mL due to access vessel injury or to first-generation delivery

Table III. Procedural and in-hospital outcomes

Parameter	*No. (%) or median (range) (n = 31)*
Anesthesia type	
General	26 (84)
Regional	5 (16)
Ventana device usage	
Aligned fenestrations	30 (97)
24 mm	4 (13)
28 mm	20 (65)
32 mm	5 (16)
36 mm	1 (3.2)
Offset fenestrations (32 mm)	1 (3.2)
Procedural complications[a]	
Access vessel repair	2 (6.5)
Access site hematoma	3 (9.7)
Minor renal artery dissection angioplasty	1 (3.2)
Clinical utility outcomes[b]	
Renal cannulation time, min	18 (8-92)
Endovascular device time, min	97 (71-490)
Total procedure time, min	197 (115-566)
Estimated blood loss, mL	500 (49-1500)
Fluoroscopy time, min	49 (27-104)
Contrast volume, mL	189 (50-500)
Time to hospital discharge	3.0 (2-9)

[a]All complications were resolved.

[b]Renal cannulation time is defined as the time from bifurcated delivery system introduction to cannulation completion of both renal arteries. Endovascular device time is defined as the time from bifurcated delivery system introduction to Ventana delivery system removal. Total procedure time is the skin-to-skin time.

system valve breakage. Late nonfatal MAE to 23 months are reported in three patients. The patient with procedural covered renal stent damage and compression became dialysis-dependent at 5 months, and a myocardial infarction at 1 month subsequently was treated with percutaneous coronary intervention. Pneumonia with concomitant congestive heart failure was treated medically in another patient at 6 months. Lastly, the patient enrolled with a short infra-SMA neck length presented in renal failure with bilateral renal occlusion and covered renal stent fractures at 8 months, and temporary dialysis was initiated to maintain renal function. Extranatomic renal bypasses were performed successfully, with restoration of renal function.

Other treatment effectiveness evaluations

Renal function. Preoperatively, eGFR was <60 mL/min in 15 of 31 patients (48%) and ≥60 mL/min in 16 (52%). Only one patient in the latter group was observed with renal dysfunction at 1 month, attributed to covered renal stent compression procedurally. Paired comparisons of eGFR in late follow-up vs baseline reveals similar results at 6 months (59 ± 21 vs 66 ± 19 mL/min; n = 28; $P = .23$) and 12 months (60 ± 22 vs 57 ± 14 mL/min; n = 10; $P = .72$). The Core Laboratory has not identified any renal infarcts among the cohort.

Visceral artery patency. Preoperatively, four patients had a unilateral renal artery stenosis; no stenosis was observed at 1 month in these patients. Visceral artery patency was 98% at 1 month. One patient with a procedural complication described previously, who did not have a preexisting renal stenosis, was observed with severe renal stenosis at 1 month, with >30% reduction in eGFR.

Secondary procedures. In the patient in whom inadvertent implant damage occurred procedurally, liquid embolic embolization of the sac via catheter introduction at the scallop was performed on day 52 postoperatively. Intervention for late renal artery stenosis was reported in two patients. One received a 5-mm Advanta V12 covered renal stent, and distal stenoses developed and was treated on day 235 with an 8-mm self-expanding stent; in-stent stenosis was later treated on day 383. In another patient, who received a 6-mm covered renal stent and a self-expanding stent due to severe renal artery angulation, in-stent stenosis with occlusion at 5 months was treated with lysis, angioplasty, and stent placement. One late implant failure occurred at 8 months in the patient with a short, reverse-tapered infra-SMA neck (protocol waiver). The patient presented in renal failure, and temporary dialysis was initiated. Lateral device movement, bilateral covered renal stent fracture, and endoleak between the left covered renal stent and fenestration were treated with renal bypasses and extension placement across the existing aortic devices to resolve the endoleak.

Endoleaks. Eight patients (26%) were observed with type II endoleak at 1 month. Two patients were found with endoleak of unknown origin: one with inadvertent damage to the implant procedurally (possible type II or type IA) and one with an inferior mesenteric artery occluded at its origin and reconstituted distally (possible type II). No intervention was performed. No type I, type III, or type IV endoleaks have been observed through current follow-up in suitably selected patients (this of course excludes the patient enrolled under the protocol waiver). Type II endoleak was observed in five patients at 6 months and persisted in 2 patients at 1 year.

Device stability and aneurysm sac morphology. Among the 30 patients enrolled with suitable anatomy, no migration has been reported by the Core Laboratory through current follow-up. All SMA and celiac arteries remain preserved. Aneurysm sac diameters were stable at 6 months (5.8 ± 0.7 cm) and 1 year (5.6 ± 0.3 cm), with no sac expansion.

DISCUSSION

Understandably, an attempt has been made to extend the benefits of endovascular repair to patients with anatomy outside of labeled indications, recognizing that, even in these cases, benefit may be derived. Unfortunately, ancillary techniques are affecting repair durability, increasing the risk of late adverse outcomes compared with patients treated within the instructions for use.[11]

Two approaches have been advocated for endovascular repair of aneurysms with short infrarenal necks or JAAs. The chimney and snorkel technique first described by Greenberg et al[12] uses available devices by creating parallel channels with covered stents to maintain visceral perfusion.

The potential for a type I endoleak through the "gutters" created by the stent graft outside the main endograft is reduced by creating two chimneys with a 20-mm seal zone length.[4] Bruen et al[4] compared 21 chimney-treated patients with 21 anatomically matched open surgery patients. Operative mortality (4.8%) was similar. Acute renal dysfunction was high in the endovascular group (29%) due to planned renal artery coverage in some patients. Nonetheless, permanent dialysis occurred only in open surgery patients (9.5%). Others reported their 10.7-month experience with the chimney technique in 28 consecutive JAA patients. Complications included permanent dialysis (7.1%), type I or III endoleak (14%), and one occlusion (3.5%).[13] Although a chimney technique may be an appealing alternative for high-risk patients not suitable for standard endovascular JAA repair, its off-label nature, need for brachial access, and unclear long-term durability has limited widespread adoption.

The fenestrations in patient-customized devices may be a reinforced opening or a short branch intended to lengthen the proximal aortic endograft-branch stent seal zone.[14] Surgeon-modified devices start with a partially deployed commercial endograft that is modified on a back table while the patient is being prepared for surgery. Once prepared, the modified device is reloaded into its delivery system. Great care must be taken to avoid damage to the device or subsequent patient injury during attempted delivery, deployment, and implant. Although technically challenging, several centers have reported acceptable early-term to midterm results with this approach.[7,15,16] The disadvantages of this surgeon-modified graft approach are that creation of the device is time-consuming and presents quality control challenges. Reimbursement for these procedures is a nonresolved issue and may limit the ability of many institutions to sustain the effort. The main disadvantage of commercially customized devices is the device planning and production time (~8 weeks) along with an estimated risk of interval rupture of 1.1% to 3.8%, depending on aneurysm size.[17] Both procedures are technically demanding, requiring advanced visceral interventional skills and experience.

In their review of custom fenestrated endografting in 629 PAAs, Linsen et al[18] determined a 90% technical success rate with 2.1% early mortality. Pooled estimates of visceral artery occlusion, renal impairment, and secondary intervention were 7%, 22%, and 18%, respectively.

Donas et al[19] recently reported their experience with 90 consecutive JAA patients, of whom 31 were treated with open surgery, 29 with custom fenestrated endografting, and 30 with a chimney technique. Among the custom group, 12 Palmaz bridging stents (Cordis, Miami Lakes, Fla) were required to achieve seal. Early mortality was 0% in the endovascular groups and 6.4% in the open surgery group. Permanent hemodialysis was required in 6.5% of the open surgery group.

Coscas et al[20] evaluated 50 consecutive JAA patients, of whom 38 were treated with a custom fenestrated or branched endograft and 12 with a chimney technique. Early mortality was 8%. Higher renal complications occurred in the chimney group (25% vs 13% with >50% increase in serum creatinine; 25% vs 8% renal infarction). Type I or III endoleak was 7.9% in the fenestrated group and 25% in the chimney group. The authors note that endoleak is frequent after these more complex approaches and is difficult to repair, particularly if in the proximal segment.

Table IV. Early major adverse events after juxtarenal aortic aneurysm (JAA) and pararenal aortic aneurysm (PAA) endografting, infrarenal endografting, or open repair

Major adverse event[a]	*Ventana cohort (n = 31), No. (%)*	*Infrarenal test (n = 192), No. (%)*	*Open surgical control (n = 66), No. (%)*
Patients with ≥1 event	5 (16)	16 (8.3)	44 (67)
Death	0	2 (1.0)	4 (6.1)
Bowel ischemia	0	0	6 (9.1)
Myocardial infarction	0	3 (1.5)	5 (7.6)
Paraplegia	0	0	0
Renal failure	0	2 (1.0)	6 (9.1)
Respiratory failure	1 (3.2)	2 (1.0)	5 (7.6)
Stroke	0	0	1 (1.5)
Blood loss ≥1000 mL	4 (13)	11 (5.7)	38 (58)

[a]Results shown as number of patients with event (% of total in group).

In our experience among 31 patients treated at seven international centers, the VFS accommodated a wide range of anatomies consistent with the design intent. The ability to perform renal cannulation while the Ventana stent graft remains fully constrained, in addition to incorporated preloaded transfenestration guiding sheaths, are significant differentiating design features that simplify renal cannulation. In our experience, 97% of repairs were done with aligned fenestrations and the single remaining case was with a left superior fenestration design with renal arteries longitudinally spaced by 18 mm. Two-thirds of the patients were treated with the same device (aligned fenestrations, 28-mm diameter).

The incidence of early MAEs was 16%, with no perioperative deaths. This rate is twice that observed in the test arm of the original Powerlink (Endologix) infrarenal endografting trial (Table IV)[21] but is significantly lower than the 67% observed in that trial's surgical control arm ($P < .01$) involving patients with JAAs (76%), PAAs (21%), or suprarenal aneurysms (3.0%). Delivery system improvements have been made to internalize valves without physician manipulation and thus reduce blood loss due to delivery catheter valve damage (clinical use initiated in 2012). The incidence of limb occlusion of 3.2% was similar to the 1.3% observed in the infrarenal anatomic fixation trial.[21] Two patients required permanent or temporary dialysis due to complications leading to failures that were potentially avoidable. Visceral artery patency was 98% in the early period and 94% to date in late follow-up.

The importance of adherence to anatomic guidelines is illustrated by the single major complication in a patient with, in retrospect, an unsuitable proximal infra-SMA

Table V. Comparison of outcomes with published results of open and endovascular repair of juxtarenal aortic aneurysms (JAAs) or pararenal aortic aneurysms (PAAs)

Reference	*Type*	*No.*	*Follow-up, mean months*	*Sac diameter, mean mm*	*Infrarenal neck length, mean mm*	*Technical success,*[a] *% Pts*	*30-day death, %*	*Late death, %*	*Target vessels incorporated and patency, % vessels*	*Post-op renal dysfunction,*[b] *% Pts*	*Late secondary procedures, % Pts*
Sarac,[22] 2002	OSR	138	1	64	NR	NR	5.10	—	—	22	NR
Knott,[23] 2008	OSR	126	1	NR	NR	NR	0.80	—	—	18	NR
Semmens,[24] 2006	CFE	58	17	NR	NR	83	3.40	10	116 (91)	9.50	24
Chisci,[25] 2009	CFE	52	20	60	7.5	NR	5.70	NR	NR	14	12
Greenberg,[8] 2009	CFE	30	24	61	9.2	100	0	6.70	77 (92)	20	23
Amiot,[9] 2010	CFE	134	15	56	NR	99	2.20	9.10	403 (97)	10	12
Ventana study	VEN	31	9	60	6.9	97	0	9.30	124 (94)	9.70	9.70

CFE, Custom fenestrated endograft; *eGFR,* estimated glomerular filtration rate; *NR,* not reported; *OSR,* open surgical repair; *VEN,* Ventana system.
[a]As reported by the authors. One Ventana procedure with unintended covered renal stent compression leading to renal dysfunction at 1 month is considered a technical failure.
[b]As reported by the authors. OSR reports provide the rates of renal impairment or failure; Ref 24 provides the rate of target vessel loss (% vessels); Ref 25 provides the rate of permanent renal impairment (% patients); Ref 8 provides the incidence of renal stenosis or occlusion necessitating intervention; Ref 9 provides the rate of eGFR deterioration inclusive of permanent or temporary dialysis. The present report provides the rate of renal dysfunction (>30% reduction in eGFR) inclusive of permanent or temporary dialysis.

neck anatomy who was enrolled under a protocol waiver. Root cause analysis determined this anatomy involving a short, reverse tapered infra-SMA neck led to device compromise. The observance of anatomic selection criteria and sizing recommendations is likely to be more critical as the complexity of endovascular repair increases with these more sophisticated devices.

These results with the VFS compare well with published outcomes of open or endovascular repair of JAAs (Table V).[8,9,22-25] Because these studies were performed using different patient selection criteria, procedures, and follow-up methods and durations, more specific comparisons are not appropriate.

Study limitations include the small cohort size and the available follow-up to a mean of 1.3 years. There was also possible selection bias, given 31 of 51 patients were selected based on inclusion and exclusion criteria and the opinion of a single independent physician who analyzed anatomic suitability for inclusion in the trial. Certainly, additional independent reviewers potentially could influence the final decision. These patients continue to be evaluated, according to the trial protocol, with clinical and imaging studies yearly. Lastly, this study was conducted in high-volume centers of excellence with experienced physicians, and thus, the results need to be considered in that context.

CONCLUSIONS

The Ventana fenestrated graft system is safe and appears effective in suitable patients with JAAs or PAAs. Further clinical experience and longer-term follow-up are justified and needed to establish long-term performance of this system.

The following physicians and institutions were involved in this multicenter trial: Jean-Pierre Becquemin, MD, Hôpital Mondor, Paris, France; Matthew Eagleton, MD, Cleveland Clinic Foundation, Cleveland, Ohio; Andrew Holden, MD, Auckland City Hospital, Auckland, New Zealand; Renato Mertens, MD, Pontificia Universidad Católica de Chile, Santiago, Chile; William Quiñones-Baldrich, MD, University of California at Los Angeles Medical Center, Los Angeles, Calif; Alan P. Sawchuk, MD, Indiana University, Indianapolis, Ind; and Matt M. Thompson, MD, St. George's Institute, London, United Kingdom.

AUTHOR CONTRIBUTIONS

Conception and design: WQ, AH, RM, MT, AS, JB, ME, DC
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Final approval of the article: WQ, AH, RM, MT, AS, JB, ME, DC
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DISCUSSION

Dr Timothy A. M. Chuter (*San Francisco, Calif*). In the interest of full disclosure, I have to let you know that I licensed all my patents in this field to Cook, the manufacturer of a competing fenestrated stent graft.

Based on the short-term results of this study, I would have to say that the Ventana worked pretty much as intended, barring the occasional technical misadventure. That's to be expected for three reasons. First, when was the last time anyone saw unfavorable short-term results in an industry-sponsored study? Second, many of the Ventana's features—modular construction, staged deployment, catheter-guided expansion, stent-secured alignment—have already been widely tested and refined in an extensive clinical experience going back 14 years. Third, candidates for inclusion in the current study were subjected to a rigorous selection process; for example, all the on-protocol patients in this study had some sort of infrarenal neck.

The most impressive feature of the Ventana stent graft is its versatility, which is attributable to the mobility of fenestrations in a baggy unattached segment of graft fabric. Not that this is a new idea: prototypes of such a stent graft have been around for more than a decade. They never found their way into clinical use until now, partly because we worried that a baggy graft would not protect the surrounding aorta from dilatation, leading to secondary endoleak and stent graft migration. As illustrated by the sole off-protocol case, the Ventana stent graft is highly unstable in the presence of a dilated pararenal aorta. So I have just one question: What do you think about adding some barbs to the proximal stent?

Dr William J. Quiñones-Baldrich. The early results of the Ventana clinical trial herein presented are indeed encouraging. I agree that these are short-term results in a highly selected group of patients. Certainly, this is true of all initial clinical trials of the new devices. The exciting aspect of this particular device is its unique feature of movable fenestrations, which increases the applicability of a single graft to a wide range of anatomic variance. It is important to note, however, that the baggy or unsupported portion of the device does not allow unlimited expansion; thus, if any dilation of the aorta were to occur, it would be eventually restricted.

I disagree with the characterization that this device is highly unstable in the presence of a dilated pararenal aorta. The single patient done under a protocol waiver had a proximal neck that was outside the range treatable with the largest device. It is no surprise that the graft did migrate in that patient. In response to your question, the experience to date with the Endologix infrarenal device suggests that anatomic fixation and the overlap of the proximal extension provide enough support to avoid migration. The Ventana proximal extension has, in addition, a suprasuperior mesenteric artery stent and two renal grafts through the fenestrations, which should provide additional fixation. Unless further experience suggests that these elements are insufficient, the additional barbs do not seem necessary. I would like to thank Dr Chuter for his comments and the Western Vascular Society for the opportunity to present this study.