Initial clinical experience with a sac-anchoring endoprosthesis for aortic aneurysm repair

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Objective: All current aortic endografts depend on proximal and distal fixation to prevent migration. However, migration and rupture can occur, particularly in patients with aortic necks that are short or angulated, or both. We present our initial clinical experience with a new sac-anchoring endoprosthesis designed to anchor and seal the device within the aneurysm sac.

Methods: The initial worldwide experience using a new endoprosthesis for the treatment of aortic aneurysms (Nellix Endovascular, Palo Alto, Calif) was reviewed. The endoprosthesis consists of dual balloon-expandable endoframes surrounded by polymer-filled endobags designed to obliterate the aneurysm sac and maintain endograft position. Clinical results and follow-up contrast computed tomography (CT) scans at 30 days and 6 and 12 months were reviewed.

Results: The endograft was successfully deployed in 21 patients with infrarenal aortic aneurysms measuring 5.7 ± 0.7 cm (range, 4.3-7.4 cm). Two patients with common iliac aneurysms were treated with sac-anchoring extenders that maintained patency of the internal iliac artery. Infusion of 71 ± 37 mL of polymer (range, 19-158 mL) into the aortic endobags resulted in complete aneurysm exclusion in all patients. Mean implant time was 76 ± 35 minutes, with 33 ± 17 minutes of fluoroscopy time and 180 ± 81 mL of contrast; estimated blood loss was 174 ± 116 mL. One patient died during the postoperative period (30-day mortality, 4.8%), and one died at 10 months from non-device-related causes. During a mean follow-up of 8.7 ± 3.1 months and a median of 6.3 months, there were no late aneurysm- or device-related adverse events and no secondary procedures. CT imaging studies at 6 months and 1 year revealed no increase in aneurysm size, no device migration, and no new endoleaks. One patient had a limited proximal type I endoleak at 30 days that resolved at 60 days and remained sealed. One patient has an ongoing distal type I endoleak near the iliac bifurcation, with no change in aneurysm size at 12 months.

Conclusion: Initial clinical experience with this novel intrasac anchoring prosthesis is promising, with successful aneurysm exclusion and good short-term results. This new device platform has the potential to address the anatomic restrictions and limitations of current endografts. Further studies with a longer follow-up time are needed. (J Vasc Surg 2011;53:574-82.)

In 1989, Dr Juan Parodi ushered in the era of endovascular aneurysm repair (EVAR) as a less invasive alternative to open surgical repair. Using a transfemoral, endoluminal approach, he delivered a standard prosthetic surgical graft to open surgical repair.1

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current U.S. Food and Drug Administration (FDA)-approved devices, including suprarenal stents, hooks, barbs, radial force, and columnar support. These are supported by in vitro experimental studies using linear pull-out force analysis that demonstrate increased resistance to longitudinal endograft displacement by penetrating hooks and barbs. In addition, in vivo experimental studies have shown that iliac fixation increases the resistance to downward displacement, and clinical studies have confirmed the importance of iliac fixation in preventing migration. Nonetheless, migration has been reported with each of the currently available EVAR devices, regardless of the proximal and distal fixation mechanisms.

In contrast, little attention has been focused on the middle portion of the endograft, which is unsupported within the aneurysm sac. Aneurysm sac diameter reduction and shrinkage may lead to device fractures and tears. Rafii et al recently showed that lateral movement of the endograft within the aneurysm sac, as seen on cross-sectional computed tomography (CT) scan images at 1 year, was an indicator of endograft instability and late adverse clinical events. In addition, the risk of lateral endograft movement was higher in patients with large aneurysms.

Three-dimensional (3D) computational analysis has revealed that the in vivo displacement force acting on endografts is not in the downstream direction of blood flow, as is commonly assumed, but rather is in a lateral or sideways direction perpendicular to the direction of flow. None of the commercially available aortic stent grafts are designed to oppose this lateral displacement force and all are prone to device migration. We describe a new endovascular aneurysm device designed to withstand the lateral displacement forces acting on endografts, while at the same time obliterating the aneurysm sac lumen. The device consists of two independent flow channels, one to each iliac artery. Each flow channel is surrounded by a polymer-filled bag that expands to fill the aneurysm sac, thus providing positional stability of the endograft and sealing side branch flow. This article describes the initial, worldwide clinical experience, outside the United States, using this new endovascular device for the treatment of aortic aneurysms.

METHODS

Device description. The Nellix sac-anchoring endoprosthesis (Nellix Endovascular, Palo Alto, Calif) consists of two identical catheter-based systems, one for each side. Each system has four components:

1. The endoframe: This is a stainless steel, balloon-expandable endoskeleton designed to support the flow channel that is mounted on a balloon and deployed by inflating the balloon. Two endoframes are positioned in a kissing configuration at the aortic neck proximally and each extends into the common iliac artery distally.

2. The endobag: This is made from a nonporous expanded polytetrafluoroethylene-based material that surrounds the endoframe and acts as a containment system for the polymer, which fills and conforms to the aneurysm sac providing a seal at the aortic and iliac ends. An injection system accesses the bottom of the endobag through fill conduits and valves, including a mechanical safety mechanism to prevent accidental delivery of uncured polymer into the bloodstream.

3. Fill material or polymer: This is a biocompatible, nonbiodegradable polyethylene glycol-based solution, mixed with a radiopaque contrast agent that is visible under fluoroscopy and cures to a solid ≤5 minutes at 37°C. Filling is achieved by an injection system that includes a handle with a controlled mechanism to monitoring fill volume and pressure.

4. Delivery catheter: The current tapered-nose cone delivery system has an outer diameter of 21F and contains the balloon-mounted endoframe with surrounding endobag and conduits for fill material injection, along with ports for guidewire insertion, balloon inflation, and angiography. Device components in the undeployed state and after deployment inside a synthetic aneurysm model are shown in Fig 1.

Animal studies. Before the clinical studies were initiated, extensive bench and animal studies were conducted. Finite-element stress analysis was used to ensure that endoframe design would withstand loads from balloon expansion, endobag filling, and intra-arterial blood pressure loading. The device was tested in vitro for long-term durability equivalent to 10 years of in vivo life. The deployment system was tested in flow models using realistic human aneurysm models that simulated the conditions of intended clinical use.

Animal studies were conducted in a patch-aneurysm ovine model to evaluate the safety of the device delivery and deployment system and the success of aneurysm exclusion. Long-term results, with animals surviving >2 years, showed effective long-term aneurysm exclusion and lumen patency as demonstrated on CT and angiographic imaging. Histologic studies showed minimal trauma and low inflammation.

Clinical experience. The initial clinical experience using the Nellix endoprosthesis at four international medical centers in Latvia, New Zealand, Venezuela, and Colombia during the past 2 years was reviewed. The study protocol was approved by the Institutional Review Board at each clinical site, and each patient signed an approved informed consent written in his or her native language.

Preoperative, implant, and follow-up data were collected real-time according to prospectively defined protocol parameters. All patients were deemed to be appropriate candidates for open aortic aneurysm repair with suitable anatomy for endovascular repair using the sac-anchoring endoprosthesis. Patients with iliofemoral arteries unable to accommodate a 21F outer diameter delivery catheter were excluded. All patients were studied with preoperative contrast CT scans with 1- to 3-mm slice thickness and 3D image analyses. If anatomic criteria were met, they were...
enrolled into the study after signing institutionally approved informed consent.

All team members involved with the clinical device deployment underwent didactic and hands-on training using patient-specific silicone cast aneurysm flow models before undertaking patient treatment. At least one investigator at each clinical deployment had extensive prior in vivo experience with the device in experimental animal aneurysm models before human implantation experience.

**Procedure.** Bilateral transfemoral sheath and 0.035-inch guidewire access was obtained using standard surgical techniques. Under fluoroscopic and angiographic control, the device delivery catheters were advanced and positioned across the aneurysm sac. The covering sheath was retracted, and the catheters were positioned at the desired location with respect to the renal arteries. The endoframes were expanded by simultaneous inflation of the deployment balloons. Both endobags were then filled with contrast-enhanced saline under fluoroscopic guidance while the pressure inside the endobag was monitored. This determined the volume required to completely fill the aneurysm sac.

An aortogram using subtraction angiography was obtained with the endobags filled to confirm that the aneurysm had been successfully excluded. The contrast solution was aspirated from the endobags. The endobags were then filled by injecting the same volume of polymer under fluoroscopy and pressure control. Endobag fill pressures were within the range of physiologic blood pressure, with a mean fill pressure about 50 mm Hg greater than the patient’s systolic pressure, not >200 mm Hg. After 5 minutes, the polymer was cured, and the delivery catheters were released from the implant and removed from the patient. A completion aortogram was obtained. A typical deployment sequence is shown in Fig 2.

Nellix aortic devices were available in various sizes and lengths to treat aortic neck diameters of 22 to 28 mm, iliac diameters of 8 to 12 mm, sac lengths between 130 and 150 mm, and aneurysm blood lumen diameters of ≥60 mm, independent of sac diameter. Nellix iliac extender devices were able to treat iliac aneurysms with blood lumen diameters of <30 mm independent of sac diameter and available in 60-mm length. Fillable Nellix extender devices were not available during the beginning of this clinical experience. Therefore, commercially available iliac extenders were used in patients who needed distal iliac extenders during the initial phase of this clinical study.

Patients were monitored postoperatively with clinical evaluation and noncontrast CT scans and at 1, 6, and 12 months.

**RESULTS**

**Patient population.** Results for 21 patients (19 men, 2 women) were collected, representing the entire worldwide clinical experience to date using the Nellix device. Patients were a mean age of 69.7 ± 8.3 years (range, 53-84 years). All patients were deemed to be suitable candidates for open surgical repair (Table I). Preoperative aneurysm diameter was 5.7 ± 0.7 cm (range, 4.3-7.4 cm), with aneurysm blood lumen diameter of 4.0 ± 0.6 cm (range, 3.0-5.0 cm). Infrarenal aortic neck diameter was 25.7 ± 3.7 mm (range, 16-28 mm), with a neck length of 24.9 ± 14.3 mm (range, 0-59 mm); neck angle was 39° ± 15° (range, 10°-66°). Common iliac diameter was >20 mm in 14 patients, >25 mm in 4, and 6 had bilateral iliac enlargement >20 mm.

**Device implantation.** Nellix endoprostheses were successfully implanted in all 21 study patients. The time required to insert, implant, and remove the Nellix devices averaged 76 ± 35 minutes (range, 33-139 minutes; Table II). Fluoroscopy time averaged 33 ± 17 minutes (range, 17-71 minutes), with contrast use averaging 180 ± 81 mL (range 110-350 mL). Mean blood loss was 174 ± 116 mL (range, 65-400 mL). The mean total volume of polymer
infused into the endobags was 71 ± 37 mL (range, 19-158 mL). There were no access problems or iliac injuries. In three patients, commercially available iliac extenders were used, and in two patients, common iliac aneurysms were treated with Nellix sac-anchoring iliac extenders. The endobag in one patient covered and excluded a hypogastric artery, without any clinical consequence.

The treatment of a large aneurysm with minimal thrombus and a large blood-lumen volume is shown in Fig 3. The aneurysm was treated with two devices deployed side-by-side, each with its own lumen. The top images are 3D reconstructions before and after treatment, and the bottom images are cross-sectional images at various times. Preoperative CT scan measurements included a maximum aneurysm sac diameter of 6.6 cm and aneurysm blood lumen diameter of 5.7 cm. Aortic neck diameter was 18 mm, common iliac diameter was 12 mm, and predicted total endobag fill volume was 135 mL. The endoframes were expanded by two lumen-shaper balloons, and each endobag was filled with 74 mL of polymer (total polymer infused was 148 mL). Completion angiogram demonstrated complete aneurysm exclusion. Postprocedural CT scans to the 1-year follow-up revealed no change in aneurysm size, stable device and endobag position, and gradual dissolution of contrast from the polymer.

The treatment of a 6.4-cm aneurysm with a sharply angulated aortic neck is shown in Fig 4. The endoprosthesis was positioned at the top of the aneurysm sac rather than extending it to the level of the renal arteries to avoid the neck angulation. Conventional abdominal aortic aneurysm (AAA) stent grafts require device placement in the neck, below renal arteries, for aortic fixation. Here, the endoframes were held in place by the polymer-filled endobags, and the completion angiogram demonstrated complete aneurysm exclusion with no endoleak. The CT scan at 30 days demonstrated contrast filling of a small portion of the proximal aneurysm sac just below the aortic neck. This spontaneously sealed, with no evidence of a type I endoleak.

Table I. Patient demographics and comorbidities

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. (%)</th>
<th>Mean (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients, total</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Age, y</td>
<td>69.7 (53-84)</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>19 (90.5)</td>
<td></td>
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<tr>
<td>Female</td>
<td>2 (9.5)</td>
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</tr>
<tr>
<td>Hypertension</td>
<td>15 (71)</td>
<td></td>
</tr>
<tr>
<td>CAD (MI/stent)</td>
<td>11 (52)</td>
<td></td>
</tr>
<tr>
<td>CABG</td>
<td>2 (10)</td>
<td></td>
</tr>
<tr>
<td>Renal insufficiencya</td>
<td>1 (5)</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>2 (10)</td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>12 (57)</td>
<td></td>
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</tbody>
</table>

CABG, Coronary artery bypass grafting; CAD, coronary artery disease; MI, myocardial infarction.

*Defined as a serum creatinine level >2 mg/dL.

Table II. In-hospital outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. (%)</th>
<th>Mean (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients, total</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 days</td>
<td>1 (4.8)</td>
<td></td>
</tr>
<tr>
<td>1 year</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Conversion to surgery</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Total procedure time, minutes</td>
<td>127 (80-148)</td>
<td></td>
</tr>
<tr>
<td>Nellix indwelling time, minutes</td>
<td>76 (33-139)</td>
<td></td>
</tr>
<tr>
<td>Fluoroscopy time, minutes</td>
<td>33 (13-71)</td>
<td></td>
</tr>
<tr>
<td>Contrast volume, mL</td>
<td>180 (110-350)</td>
<td></td>
</tr>
<tr>
<td>Amount of polymer infused, mL</td>
<td>71 (19-158)</td>
<td></td>
</tr>
<tr>
<td>Estimated blood loss, mL</td>
<td>174 (50-400)</td>
<td></td>
</tr>
<tr>
<td>Length of stay, days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td>4.3 (2-11)</td>
<td></td>
</tr>
<tr>
<td>Intensive care unit</td>
<td>0.7 (0-3)</td>
<td></td>
</tr>
</tbody>
</table>

The treatment of a large aneurysm with minimal thrombus and a large blood-lumen volume is shown in Fig 3. The aneurysm was treated with two devices deployed side-by-side, each with its own lumen. The top images are 3D reconstructions before and after treatment, and the bottom images are cross-sectional images at various times. Preoperative CT scan measurements included a maximum aneurysm sac diameter of 6.6 cm and aneurysm blood lumen diameter of 5.7 cm. Aortic neck diameter was 18 mm, common iliac diameter was 12 mm, and predicted total endobag fill volume was 135 mL. The endoframes were expanded by two lumen-shaper balloons, and each endobag was filled with 74 mL of polymer (total polymer infused was 148 mL). Completion angiogram demonstrated complete aneurysm exclusion. Postprocedural CT scans to the 1-year follow-up revealed no change in aneurysm size, stable device and endobag position, and gradual dissolution of contrast from the polymer.
on multiplane angiography at 60 days and no evidence of endoleak on contrast CT at 6 months.

The treatment of a 3-cm common iliac aneurysm with preservation of the hypogastric artery is shown in Fig 5. After deployment of the aortic endoprosthesis and removal of the Nellix delivery system, the distal end of the endoframe was flared using a 20-mm noncompliant balloon. A Nellix iliac extender endoframe was deployed, and the surrounding endobag was filled with polymer. This excluded the common iliac aneurysm and preserved blood flow to the internal iliac artery.

Obliteration of retrograde branch flow into the aneurysm sac is shown in Fig 6. The filled endobag expands to obstruct the orifices of the inferior mesenteric and lumbar arteries, thus significantly reducing the likelihood of type II endoleaks.

Early results. Twenty of 21 patients (95%) recovered from the implant procedure uneventfully. One patient died postoperatively from multisystem organ failure, for a 30-day mortality rate of 4.8%. The patient was a 74-year-old man with a 7.4-cm aneurysm and chronic renal insufficiency with a history of hypertension, chronic obstructive pulmonary disease, hypertensive cardiomyopathy, and lower extremity occlusive disease. This was the first clinical implant using this device, and the endoframe balloon expanders were kept inflated throughout the endobag inflation and the prefill and polymer filling procedure, resulting in a prolonged aortic occlusion time. The postimplant premortem imaging studies revealed an intact aneurysm, patent renal arteries, and a widely patent endoluminal device. The postmortem examination with device explanation revealed no evidence of aneurysm or vascular rupture, an intact endograft with patent lumens, intact endobags, and no evidence of polymer extravasation. The implant procedure was modified after this first case, and in all subsequent patients, the endoframe deployment balloons were deflated immediately after full endoframe expansion with an aortic occlusion time of <2 minutes.

Mean hospital length of stay for all patients averaged 4.3 days (range, 2-11 days). No groin complications occurred. One patient was rehospitalized during the first 30 days for abdominal discomfort but was discharged in <24 hours, with resolution of symptoms and normal clinical examination.

Follow-up results. One patient died at 10 months of congestive heart failure. The CT scan at 6 months in this patient showed no change in aneurysm size, no migration, and no endoleak. There have been no ruptures, migrations, surgical conversions, or secondary interventions during the 12-month follow-up. Mean follow-up time was 7.3 ± 10.2 months. Postprocedural CT imaging data were available for 20 patients at 30 days and at 6 months and for 9 patients at 1 year. These studies demonstrated widely patent endograft lumens, intact endobags, no change in endograft position, and no change in aneurysm size. Aneurysm diameter was 5.7 ± 0.7 cm at 30 days, 5.7 ± 0.7 cm at 6 months, and 5.8 ± 0.8 cm at 12 months. Volumetric analysis showed no change in aneurysm size.

Fig 3. A-C, Pretreatment of an aneurysm with a large blood-lumen diameter and minimal thrombus, 3-dimensional reconstructions (preoperative and postoperative). D-G, Computed tomography cross-sections preoperatively and at 1, 6, and 12 months postoperatively.
Fig 4. A, Computed tomography and angiography images of an aneurysm with adverse neck anatomy treated using the Nellix device. B, The 30-day follow-up showed a limited type I endoleak, which was not visible on angiography at 60 days.

Fig 5. Angiographic images illustrate the treatment of a common iliac aneurysm using a sac-anchoring iliac extender, which preserved flow in the hypogastric artery, (left) before and (right) after treatment.
In one patient (Fig 5), the postprocedural CT scan revealed contrast fill in the space between the endobag and the proximal anterior wall of the aneurysm sac. This limited-space type I endoleak was sealed on multiplane angiography at 60 days and remained sealed on CT at 6 months.

A distal type I endoleak was seen at time of implantation in one patient. This patient had a long aneurysm sac, and the endobag lengths were too short to reach the common iliac arteries. This was early in our experience when Nellix iliac extenders were not available. Therefore, commercially available iliac extenders were deployed in both limbs. Retrograde flow from uncovered lowermost lumbar arteries filled the bottom portion of the aneurysm sac. This distal type I endoleak was visible on the 30-day, 6-month, and 12-month CT scan (Fig 7). The patient remains asymptomatic, and the aneurysm size has not changed. Endovascular repair of this endoleak is currently being entertained. No other endoleaks have been seen during the follow-up period.

In 4 of the first 10 patients, the 30-day follow-up CT scans revealed a non-contrast-enhanced ring, or halo, immediately surrounding the endoframes. At 6 months, 7 of the first 10 patients demonstrated this finding. No clinical events or aneurysm morphologic changes have been associated with this x-ray finding. The halo was attributed to the larger endobag lumen diameter relative to the endoframe. Changes were implemented to the endobag design, and the halo has not been seen on any subsequent patient CT scans. In addition, contrast within the polymer was found to dissipate over time, consistent with the known loss of iodinated contrast from polymers at variable rates, as noted by changes in
DISCUSSION

The Nellix AAA endoprosthesis represents a new conceptual approach to the endovascular repair of aortic aneurysms. It is a sac-anchoring device that does not depend on proximal and distal fixation to nonaneurysmal infrarenal aorta or iliac arteries. Rather, it is held in place by polymer-filled bags that surround the flow channels, resisting the sideways-directed or lateral displacement forces acting on the endograft.

Computational analysis reveals that in vivo displacement force acting on aortic endografts is primarily directed sideways, perpendicular to the direction of blood flow rather than downstream in the direction of blood flow. Increased curvature of the endograft increases the magnitude of sideways displacement force, and patients with angulated aortic necks and tortuous aneurysms are more prone to endograft migration. Lateral movement of the middle portion of an endograft within the aneurysm sac as seen on sequential cross-sectional CT images has been shown to be an indicator of endograft instability and a predictor of late adverse clinical events.14

Currently available endografts are designed to resist longitudinal displacement in the downward direction of blood flow.10 This device is the first endovascular device designed taking into consideration the magnitude and direction of in vivo displacement forces acting on implanted endografts. Thus, it may provide improved resistance to long-term displacement and migration.

In addition, filling of the aneurysm sac by polymer-filled bags obliterates the aneurysm lumen and obstructs retrograde flow into the aneurysm sac from the inferior mesenteric artery and lumbar arteries. Early evidence indicates that this wall apposition of the endobag design has the potential to eliminate retrograde type II endoleaks. However, it is possible that the endobag, if not properly sized to cover the entire surface of the aneurysm sac, may not fully obstruct and obliterate all lumbar branches, as occurred in one patient early in this experience. In such circumstances, retrograde lumbar artery flow fills only a small portion of the aneurysm sac and does not pressurize the entire aneurysm sac.

Similarly, flow may enter the space between the endobag and the aneurysm wall from the proximal or distal attachment zone, as occurred transiently in one patient in this series due to placement of the device below a sharply angulated aortic neck. This small space has a much-reduced functional radius compared with the radius of the untreated aneurysm, and thus, the tension experienced by the aneurysm wall (proportional to the product of sac pressure times radius, per Law of Laplace) may be less than the tension produced by an endoleak that pressurizes the entire sac. Further studies are needed to determine the significance of contrast fill of the aneurysm sac when a sac-anchoring endoprosthesis is used.

The third unique feature of this device is that it is not a bifurcated endograft. Rather, each endograft flow channel is independent of the other, thus allowing each limb of the device to self-select the optimum flow pathway through the aneurysm sac. This reduces angulation and tortuosity to a minimum and raises the bifurcation of aortic flow to the level of the renal arteries. This may reduce iliac limb kinking and improve hemodynamic performance of the device; however, longer-term studies are needed. The fact that this is not a bifurcation device also simplifies deployment of the device because additional catheter and wire manipulation is not needed to cannulate the docking limb and deploy the contralateral iliac limb. Moreover, the balloon-expandable deployment allows for accurate device placement without the delivery challenges associated with current self-expanding stent grafts.

This device simplifies the treatment of common iliac aneurysms by providing a normal flow channel to the internal and external iliac arteries while obliterating the aneurysm sac, as shown in Fig 5. There is no need to coil embolize the internal iliac artery and extend the endovascular device to the external iliac artery. Future modifications of the Nellix iliac extender will be able to treat internal iliac aneurysms without occluding the flow lumen.

Finally, because the device does not depend on fixation to normal, nonaneurysmal aorta, it may provide the opportunity to treat aneurysms with anatomies currently not amenable to treatment with existing FDA-approved endovascular devices. Such anatomies include no-neck or funnel-neck aneurysms, severely angulated and tortuous anatomies, large-diameter aortic necks, and common and internal iliac aneurysms. Although most patients in this study had favorable anatomy with good proximal and distal landing zones, some had unfavorable anatomy and were successfully treated.

The unique design features of this device raise new questions with regard to this method of EVAR. Potential considerations include the risk of pressure transmission to the aneurysm wall causing rupture during balloon inflation and/or endobag filling and thrombus extrusion into adjacent vessels (ie, renal arteries). In addition, as with any other EVAR device, placement is critical, especially for the treatment of adverse anatomies (no-neck aneurysms, angulated necks) to prevent bag prolapse into the lumen; the kissing balloon-expandable platform requires different sizing considerations compared with current EVAR devices, and dual device extensions would be required with this platform to achieve a secure seal in the event of a persistent proximal type I endoleak.

Long-term remodeling of the aneurysm and mural thrombus, stability of the polymer-filled endobag, and the potential for late endoleaks in the space between the endobag and aneurysm wall must be evaluated. Although some of these aspects have been mitigated through device design, fill pressure control within the physiologic range, redundant fill system designs, and physician training, more studies and long-term follow-up data, including morphologic changes in well-controlled clinical trials, are needed.
CONCLUSIONS

The initial clinical experience with a new, sac-anchoring endoprosthesis is promising, with successful aneurysm exclusion and good short-term results. This new device has the potential to address the limitations of current endografts and may provide improved long-term device stability. Further studies and longer clinical follow-up are needed.

AUTHOR CONTRIBUTIONS

Conception and design: CD, CZ, RW
Analysis and interpretation: CD, CZ
Data collection: CD, DK, AH, AH, CC, JV
Writing the article: CD, CZ
Critical revision of the article: CD, CZ, DK, AH
Final approval of the article: CD
Statistical analysis: CZ, DK
Obtained funding: Not applicable
Overall responsibility: CD

REFERENCES