EVAR Using the Nellix Sac-anchoring Endoprosthesis: Treatment of Favourable and Adverse Anatomy


Pauls Stradins Clinical University Hospital, Riga, Latvia
Auckland City Hospital, Grafton, New Zealand
Instituto de Clinicas y Urologia Tamanaco, Caracas, Venezuela
Harbor/UCLA Medical Center, Torrance, CA 90502, USA
University of Utrecht, Utrecht, The Netherlands
Baptist Cardiac and Vascular Institute, Miami, FL 33176, USA
Department of Surgery, Stanford University Medical Center, Palo Alto, CA 94304, USA

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Endovascular aortic aneurysm repair;
Novel sac-anchoring endoprosthesis;
Adverse aortic anatomy;
Clinical results of EVAR with new endovascular device;
New device for EVAR

Abstract  Objective: The study aimed to review the results of endovascular aneurysm repair (EVAR) using a novel sac-anchoring endoprosthesis in patients with favourable and adverse anatomy.
Design: This is a prospective, multicentre, clinical trial.
Materials: The Nellix endoprosthesis consists of dual, balloon-expandable endoframes, surrounded by polymer-filled endobags, which obliterate the aneurysm sac and maintain endograft position.
Methods: The study reviewed worldwide clinical experience and Core Lab evaluation of computed tomography (CT) scans.
Results: From 2008 to 2010, 34 patients (age 71 ± 8 years, abdominal aortic aneurysm (AAA) diameter 5.8 ± 0.8 cm) were treated at four clinical sites. Seventeen patients (50%) met the inclusion criteria for Food and Drug Administration (FDA)-approved endografts (favourable anatomy); 17 (50%) had one or more adverse anatomic feature: neck length <10 mm (24%), neck angle >60° (9%) and iliac diameter >23 mm (38%). Device deployment was successful in all patients; iliac aneurysm treatment preserved hypogastric patency. Perioperative mortality was 1/34 (2.9%); one patient died at 10 months of congestive heart failure (CHF); one patient had a secondary procedure at 15 months. During 15 ± 6 months follow-up, there were no differences in outcome between favourable and adverse anatomy patients. Follow-up CT extending up to 2 years revealed no change in aneurysm size or endograft position and no new endoleaks.

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* Corresponding author.
E-mail address: zarins@stanford.edu (C.K. Zarins).
Endovascular aneurysm repair (EVAR) has markedly reduced procedure-related mortality and morbidity compared with open repair. However, significant concerns persist regarding the long-term durability and effectiveness of endovascular repair due to endoleaks, aneurysm enlargement, endograft migration, the need for secondary procedures and ongoing computed tomography (CT) surveillance. Many of these concerns are related to the design of currently available endografts, which are dependent on proximal and distal fixation to exclude blood flow to the aneurysm sac. The aneurysm sac itself remains untreated, thus leaving a large space where blood flow may continue, with potential endoleaks from proximal or distal fixation zones, from the device itself or from side-branch vessels. In addition, the untreated aneurysm sac space provides an opportunity for the endograft to move sideways within the aneurysm sac, resulting in angulation and displacement of the proximal or distal fixation zones leading to new onset of endoleaks and stent-graft migration. Indeed, sideways movement of the endograft within the aneurysm sac is a predictor of endograft migration and late adverse events.

Moreover, not all patients with abdominal aortic aneurysms are candidates for endoluminal repair due to the need for a suitable aortic neck and non-aneurysmal iliac arteries for endograft fixation and seal. The specific anatomic requirements of the aortic neck and iliac arteries for proper patient selection are contained in the instructions for use (IFU) of each aortic endograft. These requirements exclude up to 50% of patients with aortic aneurysms from endovascular repair, leaving surgical repair as the only treatment option. Patients with adverse anatomic features, such as large aortic aneurysms and short, angulated aortic necks have inferior short- and long-term outcomes for use.

The initial prospective, multicentre trial to evaluate the performance of the Nellix endoprosthesis was conducted at four clinical sites (Latvia, New Zealand, Venezuela and Colombia) from 2008 to 2010. Ethical approval of study protocol was provided by the Institutional Review Board (IRB) at each site and each patient signed an approved informed consent written in his/her native language. All patients were deemed to be appropriate candidates for the Nellix sac-anchoring endoprosthesis. Early results are promising but longer-term studies are needed.

Materials and Methods

Device description

The Nellix endoprosthesis consists of dual, balloon-expandable endoframes, each surrounded by an endobag, which is filled with an in situ curing polymer. As illustrated in Fig. 1, each endoframe supports the blood-flow lumen through the aneurysm sac to the iliac arteries. The polymer-containing endobags surround the flow lumen and fill the aneurysm sac, blocking retrograde flow from side branches. They thus eliminate the space for potential blood flow in the aneurysm (endoleak), while anchoring the device within the aneurysm sac to provide positional stability. Full details of the device and clinical procedure are described in a previous publication. Design device evolved during the course of the study to include longer length devices and fillable iliac extenders to treat common iliac aneurysms. Commercially available iliac extenders were used in three patients, who were treated before Nellix iliac extenders were available.

Clinical study

The initial prospective, multicentre trial to evaluate performance of the Nellix endoprosthesis was conducted at four clinical sites (Latvia, New Zealand, Venezuela and Colombia) from 2008 to 2010. Ethical approval of study protocol was provided by the Institutional Review Board (IRB) at each site and each patient signed an approved informed consent written in his/her native language. All patients were deemed to be appropriate candidates for the Nellix sac-anchoring endoprosthesis.
open aortic aneurysm repair with suitable anatomy for endovascular repair using the sac-anchoring endoprosthesis. Inclusion criteria for the study included one or more of the following: aneurysm size 4.5 cm or greater, aneurysm size twice the diameter of the infrarenal neck and documented rate of aneurysm enlargement >10% in 1 year with aortic neck length 10 mm or greater. After review of the clinical results from the first 21 patients, the study protocol was modified to allow inclusion of patients with shorter aortic necks (5 mm or greater). The study now includes a total of 34 patients with complete 1 year follow-up in all patients. These data have been submitted for CE mark approval.

Data analysis

Preoperative, implant and follow-up data were collected according to prospectively defined protocol parameters. Clinical results were maintained in a central registry. Contrast CT scans were performed on all patients prior to treatment and within 30 days of treatment. Follow-up CT scans were performed at 6, 12 and 24 months.

DICOM (Digital Imaging and Communications in Medicine) data sets of all pre- and postoperative CT scans were sent for independent Core Laboratory image analysis. Patients with one or more of the following anatomic measures on the preoperative CT scan were defined as having adverse anatomy: aortic neck length <10 mm, aortic neck angle >60° and common iliac artery diameter >23 mm. Follow-up CT scan measurements included aneurysm diameter and cross-sectional area and endograft position with respect to the superior mesenteric artery (SMA) and vertebral body reference points. The first post-procedure CT scan (within 30 days) was used as the baseline for comparison of quantitative morphological changes on follow-up CT scans. Results are presented as the mean ± standard deviation. Statistical comparison of individual measures was performed using the paired t-test or Fisher’s exact test and significance was assumed at p < 0.05.

Results

Patient population

A total of 34 patients were enrolled and treated from 2008 to 2010. Patients included 31 (91%) men and three (9%) women with a mean age of 71 ± 8 years (range 53–84 years). Patient comorbidities are shown in Table 1.

Aneurysm morphology

Preoperative aneurysm diameter was 5.8 ± 0.8 cm (range 4.3–7.6 cm), with aneurysm blood lumen diameter of 4.2 ± 0.8 cm (range 3.0–6.0 cm). Infrarenal aortic neck diameter was 24 ± 3 mm (range 18–31 mm) with a neck length of 21 ± 12 mm (range 5–50 mm); neck angle was 37 ± 15° (range 9–72°). Common iliac diameter was >23 mm in 13 patients. Six patients had bilateral iliac enlargement.

Patient examples

Examples of patients with favourable and adverse anatomy are shown in Figs. 2–4. Fig. 2 shows a patient with a 5.9-cm aneurysm with favourable anatomy. The endobags were filled with 58 ml polymer with complete aneurysm exclusion. Fig. 3 shows a patient with unfavourable anatomy. This patient had a 7-cm aneurysm with an aortic neck length of only 5 mm. Polymer volume of 67 ml was used to

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Mean</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAA diameter (cm)</td>
<td>5.8</td>
<td>4.3–7.6</td>
</tr>
<tr>
<td>AAA volume (cc)</td>
<td>177.8</td>
<td>67.5–362.7</td>
</tr>
<tr>
<td>AAA lumen diameter (mm)</td>
<td>42.3</td>
<td>30.3–60.4</td>
</tr>
<tr>
<td>Aortic neck length (mm)</td>
<td>22.1</td>
<td>5.0–50.0</td>
</tr>
<tr>
<td>Aortic neck vessel diameter (mm)</td>
<td>23.5</td>
<td>17.5–31.0</td>
</tr>
<tr>
<td>Aortic neck lumen diameter (mm)</td>
<td>20.3</td>
<td>16.0–25.0</td>
</tr>
<tr>
<td>Aortic neck angulation (°)</td>
<td>37.4</td>
<td>9.1–72.0</td>
</tr>
</tbody>
</table>

Aortic neck length was <10 mm in eight patients (24%); mean aortic neck length in these patients was 6.6 mm. Aortic neck angulation was >60° in three patients (9%). Common iliac diameter was >23 mm in one or both iliac arteries in 13 patients (38%); four patients had common iliac aneurysms >30 mm in diameter. A total of 17 patients (50%) had one or more adverse anatomic features, which have made them unsuitable candidates for EVAR using currently available Food and Drug Administration (FDA)-approved devices. Six patients (18%) had two or more adverse anatomic features. Aneurysm characteristics for all 34 patients are summarised in Table 2.

Table 1 Patient demographics and comorbidities.

<table>
<thead>
<tr>
<th>Number</th>
<th>%</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total # Patients</td>
<td>34</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>71</td>
<td>53–84</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>31</td>
<td>91</td>
</tr>
<tr>
<td>Female</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>23</td>
<td>68</td>
</tr>
<tr>
<td>CAD (MI/Stent)</td>
<td>19</td>
<td>56</td>
</tr>
<tr>
<td>CABG</td>
<td>6</td>
<td>18</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>(Creatinine &gt; 2.0 mg/dl)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>4</td>
<td>12</td>
</tr>
<tr>
<td>Smoking</td>
<td>17</td>
<td>50</td>
</tr>
<tr>
<td>MI</td>
<td>9</td>
<td>27</td>
</tr>
<tr>
<td>Abdominal surgery/Trauma</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>PVD</td>
<td>7</td>
<td>21</td>
</tr>
</tbody>
</table>

* Following enrolment of this one subject, this criterion was changed to require serum creatinine ≤2 mg/dl.

Table 2 Summary of aneurysm characteristics.

* The measurements identified in this table are provided by the Core Lab. Measurements may differ slightly from those made by the clinical site at the time of enrolment.
fill the aneurysm sac. Follow-up CT scan at 1 year shows no change in aneurysm size or device position with no change in neck morphology and no endoleak. Fig. 4 illustrates the treatment of a patient with both iliac aneurysm and adverse neck anatomy. This patient had a 37-mm right common iliac aneurysm extending to the hypogastric artery. The aortic aneurysm was treated by filling the endobags with 60 ml of polymer and the iliac aneurysm was treated with a Nellix extender device filled with 15 ml polymer. The polymer-filled endobag conformed to the contours of the iliac aneurysm and preserved blood flow in the internal iliac artery.

Procedural results

Technical success was achieved in 100% with successful deployment and implantation of the endoprostheses in all 34 patients. The time required to insert and implant the device and remove the delivery system ranged from 33 to 150 min (mean time 70 ± 32 min). Fluoroscopy time was 33 ± 17 min (range 17–71 min) and 180 ± 81 ml contrast agent was used (range 110–350 ml). Mean blood loss was 165 ± 107 ml (range 35–400 ml). Mean volume of polymer used to fill the endobags was 73 ± 33 ml (range 18–168 ml). Data are summarised in Table 3.

Clinical outcomes

Mortality and clinical outcomes are shown in Table 4. One patient died during the postoperative period of multisystem organ failure. This death was not device related, as evidenced by post-procedure CT scan and post-mortem examination of the aneurysm and device. Aneurysm-related mortality was 1/34 (2.9%). In addition, one patient died at 10 months of congestive heart failure (CHF); this patient had a normal CT scan at 6 months. Contrast fill of a portion of the aneurysm sac (endoleak) was noted in two patients, and these two patients are described in detail in the previous publication.21 One patient had a proximal type I endoleak, which was seen on the 30-day CT scan and was fully resolved at 60 days. There was no endoleak on the 6-month and 12-month CT scans. The other patient had a distal type I endoleak because the device endobag was too short to fully fill the aneurysm sac and due to the non-availability of Nellix iliac extenders early in the clinical experience. This endoleak persisted with no change in
aneurysm size for 12 months. An elective secondary endovascular procedure was performed at 15 months with placement of coils and an iliac extender, resulting in complete resolution of the endoleak. Two of the four patients with major adverse events had favourable anatomy and two had adverse anatomy. There have been no other deaths, no other major adverse events and no additional secondary procedures.

During a mean follow-up of 15 ± 6 months (range 7–27 months), there have been no aneurysm ruptures, no conversions to surgery, no device migration, no aneurysm enlargement and no new endoleaks. There are no significant differences in outcomes between patients with favourable anatomy and those with adverse anatomy (p = ns, Fisher’s exact test). The one endoleak that resolved at 60 days occurred in the adverse anatomy group (neck angle) and the one persistent endoleak occurred in the favourable anatomy group (endobag too short to fully fill the aneurysm sac).

Core laboratory analysis

Results of quantitative morphologic analysis of follow-up CT scans are shown in Fig. 5. There was no change in aneurysm diameter or circumference at 30 days, 6 months, 12 months or 2 years compared with baseline. There was no change in device position relative to the SMA (longitudinal movement) or relative to the vertebral body (lateral movement) reference point. The average distance between the SMA and the top of the endoframe was 16 ± 2.7 mm (n = 33) at 30 days, 18.4 ± 2.8 mm (n = 30) at 6 months and 17.4 mm (n = 19) and 12 months. Similarly, the position of the

Figure 3  Treatment of a 7 cm aneurysm with unfavourable anatomy (5 mm, angulated neck) treated using the sac-anchoring endoprosthesis, (a,b) before and (d,e) after treatment. Oblique CT cross-sectional images show no significant change in device and endoframe position between (c) 1 month and (f) 12 months follow-up.
endoframe lumens remains unchanged relative to the vertebral reference point (Fig. 5).

**Discussion**

The Nellix sac-anchoring endoprosthesis is a novel method for the endovascular repair of aortic aneurysms. Unlike existing endografts that rely on proximal and distal fixation mechanisms to hold the endoluminal ‘bypass’ of the aneurysm sac in place, the Nellix device treats the aneurysm by filling the aneurysm sac, thus anchoring the device and eliminating the endoleak space. The polymer-filled endobags surround the blood-flow channels, providing support within the sac without the need for proximal and distal fixation mechanisms. This allows expansion of the limits of endovascular aneurysm repair to patients with aortic neck and iliac anatomy, which is not suitable for currently available aortic endografts. It also addresses two major limitations of current aortic endografts, namely endoleaks and device migration.

In this study, one-half of the patients were not candidates for endovascular repair, based on the IFU of current FDA-approved aortic endografts. Nonetheless, they were successfully treated using the sac-anchoring endoprosthesis. There was no difference in procedural success or clinical outcome between patients with favourable anatomy and those with adverse anatomy. The most common adverse anatomic feature was iliac artery diameter >23 mm, which was seen in 38% of patients. Common iliac aneurysms were readily treated with either the primary endograft device or by adding a sac-anchoring iliac extender. This filled and excluded the iliac aneurysm while preserving flow to the internal iliac artery. Aortic neck length was <10 mm in 24% of patients with an average neck length of only 6.6 mm. Neck angulation >60° was present in 9% of patients. In one case, the endograft was placed below the severe neck angulation at the top of the aneurysm sac and this resulted in a transient type I endoleak at the top of the aneurysm sac, which spontaneously sealed. There was no increase in procedure time in patients with adverse anatomy. As the device is not a bifurcated device, it does not require contralateral limb cannulation, thus simplifying the deployment procedure.

Two patients in this study were noted to have endoleaks on the first post-procedure CT scan. These patients were treated early in this trial and were described in detail in the initial publication. Both endoleaks were limited-space endoleaks, filling only a portion of the aneurysm sac and pressurising only a segment of the aneurysm wall. As tension on the aneurysm wall is directly proportional to aneurysm size, reduction of the radius of the pressurised space would be expected to significantly reduce aneurysm wall tension and stress. Thus, the clinical significance of contrast fill in the space between a sac-filling endoprosthesis and the aneurysm wall and an endoleak, which pressurises the entire aneurysm sac, such as occurs with traditional stent grafts, may be quite different. Future studies and longer follow-up will help shed light on this question.

Of the two limited-space endoleaks in this study, one was in a patient where the device was placed just below a severely angulated neck, leaving a small space of unfilled aneurysm sac. This proximal endoleak resolved spontaneously at 60 days and remained sealed on CT scan at 6 and 12 months. The other was in a patient where the aneurysm sac was longer than the length of the endobag and with no Nellix iliac extenders available, the lowermost portion of

<table>
<thead>
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<th>Table 3 Clinical procedural data.</th>
<th>Mean</th>
<th>Std. dev.</th>
<th>Range</th>
</tr>
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<tr>
<td>Nellix indwelling time (min)</td>
<td>70</td>
<td>32</td>
<td>33–150</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>33</td>
<td>17</td>
<td>17–71</td>
</tr>
<tr>
<td>Contrast volume (ml)</td>
<td>180</td>
<td>81</td>
<td>110–350</td>
</tr>
<tr>
<td>Amount of polymer infused (ml)</td>
<td>73</td>
<td>33</td>
<td>18–168</td>
</tr>
<tr>
<td>Estimated blood loss (ml)</td>
<td>165</td>
<td>107</td>
<td>35–400</td>
</tr>
<tr>
<td>Hospital stay (days)</td>
<td>3.8</td>
<td>2.2</td>
<td>1–9</td>
</tr>
</tbody>
</table>

Figure 4 Treatment of 6.3 cm AAA with short, funnel neck and 3.7 cm right common iliac aneurysm. (a) Pre-op 3D-CT reconstruction and (b) Post-op angiogram. (c) Post-op angiogram showing exclusion of the iliac aneurysm with preservation of internal iliac artery flow and (d) 3D-CT reconstruction of the common iliac aneurysm after treatment with complete exclusion of the aortic and iliac aneurysms.
Table 4

Summary of clinical outcomes.

<table>
<thead>
<tr>
<th>Event</th>
<th>30 days (0–30 days)</th>
<th>6 months (31–182 days)</th>
<th>1 year (183–365 days)</th>
<th>2 years (366–730 days)</th>
<th>Total (n = 34)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>2.9% (1)</td>
<td>0.0% (0)</td>
<td>3.1% (1)</td>
<td>0.0% (0)</td>
<td>5.9% (2)</td>
</tr>
<tr>
<td>Aneurysm-related mortality</td>
<td>2.9% (1)</td>
<td>0.0% (0)</td>
<td>0.0% (0)</td>
<td>0.0% (0)</td>
<td>2.9% (1)</td>
</tr>
<tr>
<td>Rupture</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Conversion to surgery</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Device migration</td>
<td>NA</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>AAA sac enlargement&lt;sup&gt;b&lt;/sup&gt;</td>
<td>NA</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Any endoleak</td>
<td>5.9% (2)</td>
<td>3.2% (1)</td>
<td>3.1% (1)</td>
<td>0% (0)</td>
<td>5.9% (2)</td>
</tr>
<tr>
<td>Secondary interventions</td>
<td>2.9% (1)</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>20% (1)</td>
<td>5.9% (2)</td>
</tr>
</tbody>
</table>

<sup>a</sup> These events occurred in the same subject; the death is considered aneurysm-related as this occurred within the 30 days following the intervention.

<sup>b</sup> Sac enlargement is defined as change greater than 5 mm.

Figure 5  Morphological changes over time (a) No change in aneurysm size and (b) No change in lateral or longitudinal endoframe position. Image shows measurement technique using vertebral body as reference point.
endoleaks, the polymer-filled endobags support and main-
aneurysm sac, obstructing side branches exiting the aneu-
aneurysm sac. The endobag adapts to the contours of the
mer, both acutely and in the long-term, while filling the
porous, malleable endobag designed to contain the poly-
gluces, but none have used a fill-containment system. The
used to fill the aneurysm sac including foams, polymers and

endografts changes. Prior studies using computational analysis have
during follow-up with no longitudinal or lateral positional
changes. Prior studies using computational analysis have shown that the displacement force acting on aortic
endografts in vivo is primarily directed sideways, perpen-
dicular to the direction of blood flow rather than down-
stream in the direction of blood flow.8,9 Patients with
adverse anatomy often have increased angulation of the
aortic neck and iliac arteries and it is known that curvature
of the endograft increases the magnitude of sideways
displacement force. Thus, patients with short, angulated
aortic necks and tortuous aneurysms are more prone to
displacement migration and late complication of endovascular
repair using currently available devices.17–19 The Nellix
endoprosthesis resists this sideways displacement force and
is the first endovascular device designed taking into
consideration the in vivo displacement forces acting on
implanted endografts. No changes in sideways or longitudi-
dinal position of the endograft within the aneurysm sac
were seen in this study. Thus, the Nellix endograft may
provide improved resistance to time-dependent endograft
displacement and late adverse events.

Common iliac aneurysms were readily treated using the
sac-anchoring endoprosthesis with preservation of flow in
the internal iliac artery. Treatment of iliac aneurysms with
existing devices often requires coil embolisation of the
internal iliac arteries and extension to the external iliac
artery.22–24 This can result in hip and buttock claudication
as well as severe colon and pelvic ischaemia.22–24 Sac-
anchoring iliac extenders obliterate common iliac aneu-
rysms while preserving the iliac bifurcation, thus
maintaining normal blood flow to both the internal and
external iliac arteries. Furthermore, this sac-anchoring iliac
extender may be able to treat solely the common iliac
aneurysm without the need to exclude a non-aneurysmal
aorta or contralateral common iliac artery. Future modifi-
cations of the Nellix extender designs also have the
potential to treat internal iliac aneurysms with preserva-
tion of the flow lumen.

Aneurysm exclusion by filling the aneurysm space in an
effort to prevent endoleaks has been contemplated by
several research groups.25–27 Various materials have been
used to fill the aneurysm sac including foams, polymers and
glues, but none have used a fill-containment system. The
Nellix device is the first aortic endoprosthesis using a non-
porous, malleable endobag designed to contain the poly-
mer, both acutely and in the long-term, while filling the
aneurysm sac. The endobag adapts to the contours of the
aneurysm sac, obstructing side branches exiting the aneu-
rystm, thus preventing endoleaks. In addition to eliminating
endoleaks, the polymer-filled endobags support and main-
tain long-term positional stability of the endograft flow
lumens. Thus, the primary concerns regarding long-term
durability of endovascular repair, namely migration and
endoleaks, are addressed by this device.

No changes in aneurysm size were noted in this study, with
a follow-up of 2 years in five patients. While longer-term
studies are clearly needed, these initial results suggest that
the Nellix sac-anchoring endoprosthesis may allow expansion
of patient selection criteria and provide an opportunity to
treat aneurysms, which cannot currently be treated with
existing devices. Such anatomies include no-neck or funnel-
eck aneurysms, severely angulated and tortuous anato-
phies, large-diameter aneurysms and necks and common and
internal iliac aneurysms. The elimination of type II endoleaks
during the follow-up period has the potential to reduce costs
by eradicating the need for secondary interventions. In
addition, the ability to achieve long-term device positional
stability may reduce the need for annual CT scan follow-up or
may allow for the use of non-radiation, non-contrast imaging
modalities such as duplex ultrasound.

Conclusions

Patients with both favourable and adverse aneurysm
anatomy can be successfully treated using the Nellix sac-
anchoring endoprosthesis. This may expand the population
of patients who are candidates for endoluminal aneurysm
repair, may minimise or eliminate endoleaks and may
reduce the need for secondary interventions. Initial results
are encouraging but further studies with a longer follow-up
time are needed.

Acknowledgement

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Nellix Inc., Palo Alto, CA, USA. The study sponsor provided
endoprostheses to the study sites and was responsible for the
study design, data collection and data analysis. The
authors contributed to study design, data collection and
data analysis and were responsible for final data analysis
and interpretation. The authors were responsible for
writing the article and made the decision to submit the
article for publication.

Conflict of Interest

Potential conflicts of interest with respect to Nellix Inc.
include membership on the scientific advisory board (CD,
FM, BK and CZ), consulting relationship (CD and CZ), stock
option ownership (CD, BK and CZ) and research support (CD
and JS). The following have no conflicts: DK, AH and CC.

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