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Early and mid-term outcomes of a novel Endovascular Aneurysm Sealing (EVAS) system in patients with infrarenal Abdominal Aortic Aneurysms

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Abstract:

Background: Endovascular aneurysm sealing (EVAS) using the Nellix system is a promising technology for Abdominal Aortic Aneurysm (AAA) treatment. Long-term data is unavailable regarding the potential modifications of the EndoBags and their content, and the polymer behavior over time. We present our initial clinical experience with this sac anchoring endoprosthesis in 24 patients with a maximum 12 months follow-up.

Methods and Results: From December 2013 to March 2015, 24 patients with an infrarenal AAA were treated with the Nellix™ System. Computed Tomography Angiography (CTA) scan control was performed at 30 days, and follow-up Magnetic Resonance Angiography (MRA) and ultrasounds were performed at 30 days, 6 and 12 months. Median and peak systolic velocities in the suprarenal aorta were measured preoperatively and during follow-up using phase contrast sequences and Argus (Siemens, Erlangen, Germany) software of the MRA. We achieved 100% technical success, 0% aneurysm-related mortality and 0% endoleaks. One patient (4%) experienced early acute thrombosis of a single Nellix stent, successfully treated with thrombolysis. Sac shrinkage occurred in 80% of cases with 12 months follow-up.

Conclusions: Our preliminary clinical experience is promising, with 100% early technical success and satisfactory sealing of the aneurysm sac. Post-procedural controls during 1-year-follow-up revealed no morphologic changes of the aneurysm wall, stable device and endobag position, and gradual dissolution of the air initially trapped within the EndoBags. Aneurysmal sac shrinkage occurs and probably is due to the remodeling of the thrombus around the EndoBags and the dissipation of the air bubbles into the EndoBags.

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Keywords: Nellix system, endovascular aneurysm sealing (EVAS), abdominal aortic aneurysm (AAA), endovascular aortic procedure, Magnetic Resonance Angiography (MRA) control

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Introduction

Aortic endografting using currently available devices has reduced procedure-related mortality and morbidity compared with open repair in elective and emergency settings[1,2]. Nevertheless concerns persist regarding the outcomes of these procedures. Endoleaks, and especially type II endoleak, are often described as the Achilles heel of conventional endovascular aneurysm repair (EVAR)[3].

The Nellix Endovascular Aneurysm Sealing (EVAS) system[4,5], has completely modified the way in which we address aneurysmal pathology. Rather than excluding the aneurysm sac as achieved with EVAR, EVAS seals the entire aneurysmal sac. The Nellix endoprosthesis consists of a biostable polyethylene glycol (PEG)-based polymer that is injected into dual EndoBags for complete aneurysm seal and endoleak reduction, and two expanded polytetrafluoroethylene (ePTFE)-covered, cobalt chromium (CoCr) alloy balloon-expandable stents provide adequate flow from the infrarenal aorta to the iliac arteries. The polymer is injected in a low viscosity liquid state and cures to a solid state at body temperature, thus conforming to the proximal and distal seal zones and aneurysm.

Nevertheless questions arise about the polymer behavior over time. Given that Nellix is still a relatively new technology in clinical practice, it is too early to establish long-term data, regarding the potential modifications of the EndoBags and their content. How do the EndoBags interact with the aneurysmal sac? The EndoBags are filled under carefully controlled and monitored pressure; does this pressure decrease in time? Will we see aneurysm sac shrinkage in these patients or maybe future aortic wall inflammation due to the interaction with the endobags? And, will the presence of this endoprostheses filling the infrarenal part of the aorta cause hemodynamic modifications just above it? Will these modifications be responsible for future suprarenal dilatations in patients? Although compute

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tomography angiography (CTA) is widely considered to be the most appropriate method for surveillance after EVAR, magnetic resonance angiography (MRA) may be a reliable diagnostic tool for EVAS follow-up due to its excellent soft-tissue contrast to evaluate the morphological features of aortic wall, the endoleaks and to measure flow velocities.

We present our preliminary experience with 3 Tesla MRA controls about these concerns.

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Materials and methods:

From December 2013 to March 2015, the Nellix EVAS system was successfully implanted in 24 non consecutive patients (all male), mean age 72 years, 30% classified as American Society of Anesthesiologists score (ASA) II and 70% as ASA III (Table I). All patients presented with an infrarenal abdominal aortic aneurysm (AAA), fusiform and sacciform, and were studied with pre-operative CTA scans with 1 mm slice thickness and MRA exams. All procedures were performed electively. Five (21%) presented two pair of lumbar arteries arising from the aneurysmal sac, ten (42%) three pair, eight (33%) four pair and one (4%) 5 pair. Seventy five percent (75%) of patients presented a patent Inferior Mesenteric Artery (IMA) (Table II). Our inclusion criteria were according to the Nellix Instructions For Use (IFU) and required a non-aneurysmal aortic neck length of ≥ 10 mm, non aneurysmal aortic neck diameter of 18-32 mm, maximum aortic blood flow lumen diameter of ≤ 60 mm, and common iliac artery diameter of 8-35 mm. All patients were fit for the Nellix device and the anatomical aortic features are summarized in Table II. Pre-operatory aneurysm diameters of the patients with major follow-up are summarized in Table III. All procedures were performed in the operating room using a C-arm unit (Philips); thirteen cases were performed under general anesthesia, nine under epidural and two under local anesthesia. In all cases both femoral arteries were exposed and used as access vessels. In all cases the polymer filling step was performed under >180 mmHg pressure to achieve an optimal filling of the EndoBags (Table II). Commercially available iliac extenders were used in two patients (8.3%), all of which were VIABAHN stents (W. L. Gore & Associates, Flagstaff, Arizona, USA) employing the same diameter of the Nellix stents (Figure 2). Mean procedural time was 120 minutes, and mean contrast volume was 70 ml. CTA scan control was performed at 30 days (22 patients), 6 months (5 patients) and 12 months (1 patient). Follow-up Magnetic Resonance Angiography (MRA) were performed at 30 days (19 patients), 6 months (12

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patients) and 12 months (10 patients). High resolution Duplex scans (Toshiba Aplio ™ 500) supported by Fly Thru application and contrast enhancement were scheduled before the discharge and at 30 days, 6 and 12 months. Ultrasound controls were aimed to detect potential endoleaks by echo-enhancement within the aneurysm sac. Duplex scanning with Fly Thru application to visualize luminal walls was also employed to identify eventual stent compressions by the endobags (Figure 1). In 5 patients (21%) follow-up was not possible with MRA due to claustrophobia or the presence of pacemakers. In these cases CTA served as the designated control. In this first phase of our experience with EVAS we thought useful to modify our usual protocol including both CTA and MRA besides ultrasound controls. We choose MRA6 as a follow-up exam using a 3 Tesla device to better understand the evolution of the polymer over time, to study eventual interactions between the aneurysmal wall and the peri-aortic tissue with the EndoBags previously filled under pressure, to study the behavior of the air bubbles detected within the EndoBags during the saline pre-fill and polymer-fill procedure steps, to better access intraluminal thrombus changes and, recently, as a second endpoint, to measure suprarenal flow velocities using phase contrast sequences and Argus (Siemens, Erlangen, Germany) software. For this last purpose we performed MRA as a pre-operatory exam too. We are just in the beginning, calculating suprarenal mean velocities before, after and in the follow-up of these patients. At the moment we have the data of just 7 patients (Table IV), with three of them studied at 30 days and 6 months follow-up.

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Results:

Technical success was achieved in 100% of cases. No aneurysm-related mortality or endoleaks were observed or reported. All patients, but one, were discharged within five days of the index procedure. In the early post-operative period, one patient (4.1%) experienced acute thrombosis of a Nellix stents and was successfully resolved with thrombolytic therapy (Figure 3). The control exams during follow-up demonstrated widely patent endograft lumens, intact endobags and no change in device position. Near complete dissipation of any detected air bubbles within the EndoBags was documented during follow-up and aneurysmal sac shrinkage was noted in 80% of those cases (Figure 4)(Table III) with 12 month follow-up. This relates to a population of less than half of the initial patients treated. Mean sac shrinkage was of 1.9 mm with a minimum of 1 mm and a maximum of 3 mm. There were no changes noted in the suprarenal aortic diameter and no morphological changes within the aneurysmal wall and peri-aortic tissue. Also, we documented an increase in the mean flow velocity in 6 of the 7 patients studied.

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Discussion:

Traditional EVAR devices depend on the combination of radial force and anchorage with hooks or barbs for proximal sealing and fixation. Oversizing also enhances frictional forces at the aortic wall to help anchor the device. Type II endoleaks are not uncommon after EVAR, and although the relevance of type II endoleaks is still under debate, re-interventions for this indication are not rare[7]. Persistent type II endoleaks have been associated with an increased incidence of adverse outcomes, including aneurismal sac growth, repeat endovascular interventions, late open conversion and rupture[8]. Current stent-grafts are often used outside IFU and this may be associated with a greater need for secondary intervention[9]. In a study by Karthikasalingam et al many patients who had undergone endovascular repair outside the IFU of current stent grafts would have been suitable for EVAS within the Nellix device IFU[10].

The unique ability of Nellix to seal the entire aneurysm sac is a novel technology. The Nellix device is fundamentally different from conventional endovascular aneurysm repair devices, due to its ability to completely seal the entire aneurysm sac as opposed to excluding the aneurysm with seal limited to the proximal and distal landing zones. This entire aneurysm sealing mechanism may improve long-term results by way of significant reduction in endoleaks, specifically type II, prevention of migration, and overall reduction in secondary interventions.

The Nellix system is comprised of two expanded polytetrafluoroethylene (ePTFE) covered balloon expandable stents, each surrounded by an attached endobag. Each endograft flow channel is independent of the other, thus allowing 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. The raised level of the bifurcation, and the presence of the endobags around the stents, may cause hemodynamic

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modifications in the suprarenal part of the aorta, which may lead to future suprarenal dilatations.

Our early results suggest no modifications in the diameter of the suprarenal aorta and non-significant variations of suprarenal flow velocities. Data for suprarenal flow velocities are obtained in just 7 patients and these could not be consistent with the hypothesis of an increase in the shear stress at the level of the suprarenal aorta. More data, longer follow-up and comparison with patients treated with other type of endoprosthesys are necessary.

The low viscosity polymer, an aqueous polyethylene glycol (PEG) based solution, is designed to be mixed at the time of the procedure and cure in situ in approximately 3 to 5 minutes after injection into the EndoBags to form a solid biocompatible, biostable polymer. This water-soluble, nontoxic polymer has been widely used in medicine such as to improve solubility, extend serum half-life, enhance the oral bioavailability of substrate molecules etc[11].

The polymer fill step is performed under careful pressure monitoring and control until the EndoBags expand and occupy the blood lumen space within the aneurysm sac, allowing sealing of side branch flow. The Nellix device is currently indicated for use in AAA in which a maximum patent lumen diameter of 60 mm, as each endobag has a finite capacity for expansion to obliterate the aneurysm sac and this currently may limit its use in larger diameter aneurysms at present. But it has been used out of IFU too[12- 14].

There was one incident of distal stent thrombosis (Figure 3). The distal edge of the device has an 8 mm length of bare stent exposed which was deployed at the level of the iliac bifurcation and could have been the trigger for thrombosis or potential intima damage. We advise not to deploy the distal limit of the stents at the level of iliac bifurcations and rather select a shorter Nellix stent extended with a VIABAHN (W. L. Gore & Associates, inc., Flagstaff, Arizona, USA) stent.

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Our standard protocol for post-Evar surveillance consists of duplex ultrasound and contrast-enhanced ultrasound controls with CTA reserved for those individuals in whom the aforementioned modalities are inconclusive or show EVAR complications to be treated. Even though we observed an excellent correlation between CTA, MRA and ultrasound to detect post-EVAR complications[15], in this first phase of our experience with EVAS, we thought useful to modify this protocol including both CTA and MRA besides ultrasound controls in order to acquire as many information as possible about this new system.

In most cases, CT or RM scans at 30 days demonstrated a small amount of air contained in EndoBags not seen in the subsequent controls. This has raised the concern as to whether this could lead to volume reduction over time, resulting in sub-optimal sealing of the aneurysm sac.

The presence of the polymer-filled EndoBags within the sac may prevent sac shrinkage. But our experience demonstrates that sac shrinkage is in fact possible following air bubble dissipation and mural thrombus remodeling within the aneurysmal sac.

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Conclusions:

Our initial clinical experience with this novel intra-sac anchoring prosthesis is very promising with successful aneurysm exclusion and excellent short-term results. Our early results suggest the stability of the polymer-filled EndoBags and no late endoleaks in the space between the EndoBags and aneurysm wall. More follow-up data are required to support the long-term stability of the polymer. We should continue to monitor the polymer-filled EndoBags for late endoleaks in the space between the EndoBags and aneurysm wall. Accurate volumetric analysis will be important in this monitoring process.

Disclosures: All the authors have no conflicts to disclose.

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Table legends

Table I: Patients co-morbidities (COPD: chronic obstructive pulmonary disease; ASA score: American Society of Anesthesiologists score)

Table II: Patient operative details

Table III: Follow-up

Table IV: Mean flow velocities in the suprarenal aorta

Figure legends

Figure 1: a) MRA volume rendering b) Fly-Thru application to visualize luminal walls c) Duplex ultrasoun scan (DUS), longitudinal view d) DUS, trasverse view

Figure 2: a) pre-operatory angio-CT volume rendering b) pre-operatory aneurysmal sac volume calculation c) intra-operatory post-deployment fluoroscopy d) post-operatory angio-CT volume rendering

Figure 3: a) pre-operatory volume rendering b) pre-operatory volume calculation c) successful deployment d) e) left intra-stent thrombosys f) angiography control g) 24 hours thrombolysis h) 48 hours thrombolysis

Figure 4: 12 months follow-up in 3 patients using MR exams with aneurysmal sac shrinkage

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Tables

Pt.	Age	Hyperten-sion	COPD	Diabetes	Myocardial infarction	Cardiac surgery or coronary stenting	ASA score
1	72	1	0	0	0	0	II
2	67	1	0	1	0	0	II
3	79	1	0	0	1	1	III
4	69	1	0	0	1	1	III
5	68	1	0	1	1	1	III
6	80	0	0	0	0	0	III
7	68	0	0	0	1	1	III
8	77	1	1	0	0	0	III
9	65	1	0	0	1	1	III
10	75	1	0	1	0	0	III
11	73	0	1	0	0	0	II
12	62	1	0	0	0	0	II
13	68	1	0	1	1	1	III
14	72	1	1	0	0	0	III
15	72	0	0	0	0	0	II
16	66	0	0	0	0	0	II
17	75	1	0	0	0	0	III

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18	67	1	0	0	1	1	III
19	82	1	1	0	0	0	III
20	79	0	1	0	0	0	III
21	64	1	0	0	1	1	III
22	70	0	0	0	0	0	II
23	76	1	0	0	1	1	III
24	77	0	0	0	0	0	II

Table I:

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Pt.	Max. free lumen diameter	Proximal neck angulation	Pair of lumbar arteries	Patent IMA	Nellix	Polymer used	Pressure for optimal injection	Need for iliac extensions
1	34 mm	<60°	3	Yes	R:10x150 L:10x160	45 ml	210 mmHg	No
2	45 mm	<60°	2	Yes	R:10x140 L:10x120	90 ml	220 mmHg	No
3	37.3 mm	<60°	4	Yes	R:10x140 L:10x160	45 ml	200 mmHg	No
4	45 mm	<60°	4	Yes	R:10x140 L:10x130	70 ml	210 mmHg	Yes
5	37 mm	<60°	3	Yes	R:10x180 L:10x180	64 ml	188 mmHg	No
6	34 mm	<60°	3	Yes	R:10x160 L:10x150	52 ml	200 mmHg	No
7	26 mm	<60°	2	Yes	R:10x120 L:10x130	35 ml	200 mmHg	No
8	36 mm	<60°	4	Yes	R:10x150 L:10x130	26 ml	197 mmHg	No
9	37 mm	<60°	2	No	R:10x180 L:10x170	85 ml	220 mmHg	Yes
10	34.7 mm	<60°	3	Yes	R:10x160 L:10x140	50 ml	200 mmHg	No
11	37.9 mm	<60°	4	No	R:10x110 L:10x110	42 ml	220 mmHg	No
12	34 mm	<60°	2	Yes	R:10x160 L:10x160	65 ml	195 mmHg	No
13	45.3 mm	<60°	3	Yes	R:10x160 L:10x160	82 ml	205 mmHg	No
14	44.8 mm	<60°	4	Yes	R:10x140 L:10x150	90 ml	210 mmHg	No
15	43 mm	<60°	3	Yes	R:10x170 L:10x180	52 ml	203 mmHg	No
16	37.6 mm	<60°	2	Yes	R:10x160 L:10x150	65 ml	220 mmHg	No
17	32 mm	<60°	3	No	R:10x150 L:10x150	38 ml	190 mmHg	No
18	34.5 mm	<60°	4	No	R:10x150 L:10x150	50 ml	206 mmHg	No

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19	**40.3 mm**	**<60°**	**4**	**No**	**R:10x150**	**L:10x150**	**65 ml**	**205 mmHg**	**No**
20	**36 mm**	**<60°**	**3**	**Yes**	**R:10x150**	**L:10x140**	**44 ml**	**200 mmHg**	**No**
21	**36.7 mm**	**<60°**	**4**	**No**	**R:10x140**	**L:10x160**	**60 ml**	**Pressure Transducer malfunction**	**No**
22	**38 mm**	**<60°**	**3**	**Yes**	**R:10x150**	**L:10x150**	**55 ml**	**207 mmHg**	**No**
23	**40.9 mm**	**<60°**	**5**	**Yes**	**R:10x180**	**L:10x180**	**90 ml**	**220 mmHg**	**No**
24	**45.1 mm**	**<60°**	**3**	**Yes**	**R:10x150**	**L:10x140**	**58 ml**	**205 mmHg**	**No**

Table II:

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Pt.	Pre-operatory maximum sac diameter	1 month maximum diameter	6 months maximum diameter	12 months maximum diameter
1	48 mm	48 mm	47 mm	46 mm
2	52 mm	51.7 mm	50.9 mm	50.5 mm
3	44 mm	44 mm	44 mm	44 mm
4	54.7 mm	54.2 mm	54.2 mm	53 mm
5	53 mm	53 mm	52 mm	52 mm
6	43 mm	43 mm	43 mm	43 mm
7	43 mm	43 mm	42.3 mm	41 mm
8	47.4 mm	47.4 mm	47 mm	46.4 mm
9	58.2 mm	58 mm	57 mm	55 mm
10	48 mm	48 mm	47 mm	45 mm
11	45 mm	45 mm	44 mm	-------
12	52 mm	52 mm	51 mm	-------

Table III:

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Pt.	1	2	3	4	5	6	7
Pre-operatory medium velocity	**5.87 cm/sec**	**7.02 cm/sec**	**9.40 cm/sec**	**8.58 cm/sec**	**6.18 cm/sec**	**11.31 cm/sec**	**5.38 cm/sec**
30-days medium velocity	**7.47 cm/sec**	**15.02 cm/sec**	**16.39 cm/sec**	**16.97 cm/sec**	**6.31 cm/sec**	**7.37 cm/sec**	**9.26 cm/sec**
6 months medium velocity	**7.40 cm/sec**	**8.93 cm/sec**	**10.21 cm/sec**				

Table IV:

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