◆CLINICAL INVESTIGATION ──────────────── ◆

Graft Inflow Stenosis Induced by the Inflatable Ring Fixation Mechanism of the Ovation Stent-Graft System:
Hemodynamic and Clinical Implications

Christos V. Ioannou, MD, PhD[1]; **Nikolaos Kontopodis, MD**[1,2]; **Eleni Metaxa, PhD**[2];
Yannis Papaharilaou, PhD[2]; **Efstratios Georgakarakos, MD, PhD**[3]; **Alexandros Kafetzakis, MD**[1];
Elias Kehagias, MD[4]; **and Dimitrios Tsetis, MD, PhD**[4]

[1]Vascular Surgery Unit, Department of Cardiothoracic and Vascular Surgery, and [4]Interventional Radiology Unit, Department of Radiology, University of Crete Medical School, Heraklion, Crete, Greece. [2]Institute of Applied and Computational Mathematics, Foundation for Research and Technology-Hellas, Heraklion, Crete, Greece. [3]Vascular Surgery Department, ''Demokritus'' University of Thrace Medical School, Alexandroupolis, Greece.

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Purpose: To investigate the observed inflow stenosis at the O-rings of the Ovation stent-graft and evaluate its hemodynamic and clinical impact.
Methods: The study involved 49 consecutive patients (48 men; mean age 71.2±7.7 years) treated successfully with the Ovation abdominal aortic stent-graft between June 2011 and January 2014 at a single center. Cross-sectional area and radius measurements of the infrarenal aorta just proximal to the sealing mechanism, as well at the site of stenosis, were measured from 3D reconstructions of the 1-month postoperative computed tomographic angiograms. Based on Poiseuille's law, the predicted pressure drop was calculated for each patient based on the length of the stenosis. Invasive blood pressure measurements at 3 levels (proximal to the inflatable rings, halfway inside the stenosis, and distal to the stenosis) were obtained in 10 patients intraoperatively. Ankle-brachial index (ABI) values preoperatively were compared to those after the procedure for all patients to assess the clinical impact of this phenomenon.
Results: Median internal cross-sectional area at the site of the stenosis was significantly reduced compared to the area just proximal to the O-rings [57% reduction: 123 mm^2 (range 28–254) vs. 283 mm^2 (range 177–531), respectively; p<0.001]. The same was observed for the radius [6.5 mm (range 3–9) vs. 9.5 mm (range 7.5–13), respectively; p<0.001]. Based on the median 15 mm length of the stenosis (range 13–17) observed in the study population, a median pressure drop of 0.13 mmHg (range 0–0.25) along the stenosis was calculated. Invasive blood pressure measurements indicated a non-significant pressure change along the stenosis (e.g., 0.7 mmHg between the proximal level and halfway inside the stenosis). ABI remained practically unchanged postoperatively.
Conclusion: The advantages of the Ovation device's unique sealing mechanism come at the expense of a median area inflow stenosis of ∼60%. This stenosis does not cause a hemodynamically significant pressure drop. Future modification of the graft ring design may be needed in order to reduce this stenosis.

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Corresponding author: Christos V. Ioannou, MD, PhD, Assistant Professor of Vascular Surgery, Head of Vascular Surgery, Department of Cardiothoracic and Vascular Surgery, University of Crete Medical School, PO Box 1352, 711 10 Heraklion, Greece. E-mail: *ioannou@med.uoc.gr*

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Endovascular aneurysm repair (EVAR) has revolutionized the treatment of infrarenal abdominal aortic aneurysms (AAAs). Currently in the US, it is estimated that 60% of AAAs are repaired by EVAR[1]; however, limitations to the endovascular approach remain.[2] Notably, recent large population studies suggest that only ~65% of patients may be eligible for EVAR,[2,3] so stent-grafts that can accommodate difficult anatomies without sacrificing durability are needed to increase the applicability of this technology.

The modular Ovation Stent-Graft is a new device designed to deal with a broad range of aortoiliac characteristics, navigate convoluted iliac and femoral accesses, and provide seal in complex proximal infrarenal aortic neck morphology.[4–6] It utilizes an original mechanism for proximal aortic neck seal that includes a network of inflatable channels and sealing rings filled during deployment with a low-

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viscosity, radiopaque polymer that conforms to the aortic neck. This mechanism creates an uninterrupted concentric seal reminiscent of an O-ring or gasket that represents a unique concept in EVAR technology. Because of this feature, the Ovation stent-graft is the only one approved to treat proximal necks <10 mm provided that the proximal neck at the level of the inflated sealing ring (13 mm below the lowest renal artery) does not exceed 30 mm. This feature alone might increase EVAR eligibility by about 10%.[2] Furthermore, it has been conjectured that the polymer-filled O-rings do not exert the kind of chronic outward force on the aorta that is seen with systems employing oversized, self-expanding stents to achieve seal. This constant radial force has been correlated with progressive aortic dilatation.[7–10]

To date there are 4 published series evaluating the safety and effectiveness of the Ovation stent-graft for treatment of AAAs,

including the pivotal study conducted by Mehta et al.[4] These show promising results,[4,5,11,12] with excellent safety and effectiveness in patients with AAA, especially in those with challenging anatomical characteristics who would be ineligible for treatment with other approved stent-grafts.

Over the last couple of years in which we have used the Ovation system to treat AAA patients, we have observed an inflow stenosis at the site of the inflatable O-rings after implantation. The degree and ramifications of such an abnormality are unknown, and we believe they deserve to be investigated if the Ovation stent-graft is to be the definitive solution for EVAR as De Donato et al.[13] recently opined. Thus, we conducted a retrospective analysis of our patients who underwent implantation of the Ovation stent-graft to quantify the degree of inflow stenosis caused by the inflatable O-rings and evaluate its potential hemodynamic and clinical impact.

METHODS

Study Design and Patient Cohort

The records of all 50 patients treated for an AAA utilizing the Ovation Stent-Graft System (TriVascular Inc., Santa Rosa, CA, USA) in a single center during a 30-month period (June 2011 to January 2014) were retrospectively reviewed. Patients had been selected for EVAR based on current guidelines: maximum AAA diameter ≥55 mm, growth rate ≥10 mm/year, and/or symptomatic aneurysms. AAAs with maximum diameter ≥40 mm and concomitant common iliac artery aneurysms with maximum diameter ≥30 mm were also repaired. Patient suitability for implantation of the specific endograft was based on the manufacturer's anatomical requirements of (1) a proximal neck length ≥7 mm and an inner diameter between 16 and 30 mm, (2) a juxtarenal aortic neck angulation ≤60° if the proximal neck length was ≥10 mm or ≤45° if the proximal neck length was <10 mm, and
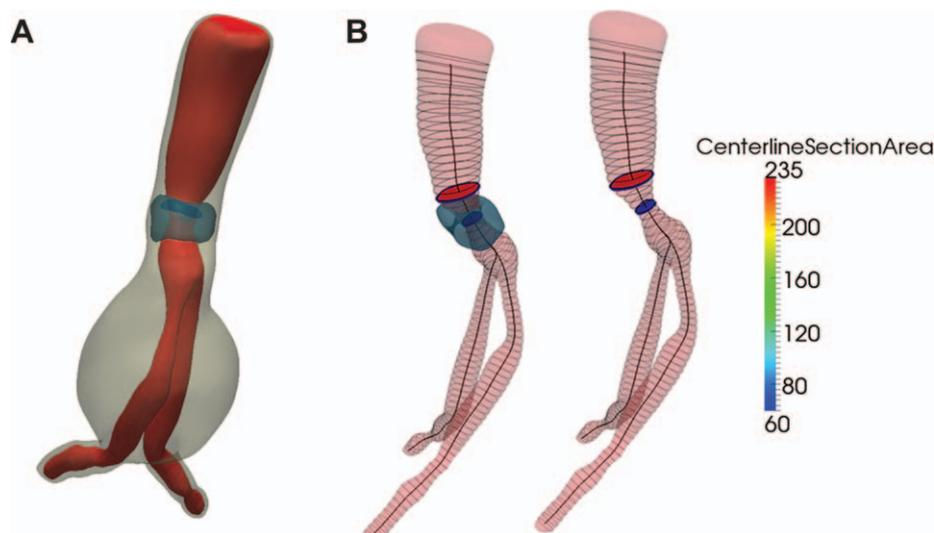
Figure 1 ◆ (**A**) 3D reconstructed model of the AAA wall (gray), lumen inside the aorta and endograft (red), and inflatable rings (blue). (**B**) Aortic lumen (pink) and wireframes of the cross sections perpendicular to the centerline with and without the inflatable rings. The cross section 1 mm proximal to the inflatable rings (red) and the one halfway between the rings (blue) are presented. The color scale indicates an area reduction of 74% for this patient (color scale is displayed in mm^2). A color version is available online at *www.jevt.org*.

(3) a distal seal zone ≥ 10 mm long and between 8 and 20 mm in diameter. The endograft was successfully implanted in 49/50 patients (98% success rate). Open conversion was necessary in 1 case due to inability to catheterize the contralateral limb because of limb collapse and bending, leaving 49 subjects (48 men; mean age 71.2±7.7 years) for retrospective review. Our center's follow-up protocol includes clinical evaluation, ankle-brachial index (ABI) measurements, color duplex ultrasound, and computed tomographic angiography (CTA). The institutional ethics committee approved this research protocol.

Image Acquisition and Measurements

According to AAA management guidelines[14] and our practice, all patients underwent a postoperative (1-month) CTA with a slice thickness of at least 2 mm, and these data were employed in the current analysis. The degree and length of maximum inflow stenosis at the site of the inflatable O-rings was determined with respect to the proximal non-aneurysmal infrarenal abdominal aorta as described below. Realistic 3D models of the

aortic lumen following endograft implantation were reconstructed from 2D images using a semiautomatic segmentation protocol and the open source software ITK-SNAP.[15] Initially, the AAA lumen entry and exit points were identified by the user, while the rest of the procedure was automated; segmentation was based on identification of intensity regions with an active contour-based process. Manual corrections were performed by the user, if needed. The reconstructed 3D lumen surface of each case was then processed using the vascular modeling tool kit (VMTK) open source software.[16]

After smoothing the surface, the centerline was computed, and perpendicular cross sections were extracted at 1-mm intervals. Using orthogonal plane measurements (postulated to more accurately represent the actual vessel size than the axial plane, which may overestimate the size[17]) the internal and external surface cross-sectional areas (Aint and Aext, respectively) were recorded at the site of the inflatable rings, as were the corresponding radiuses at the same sites (Rint and Rext, respectively). Moreover, surface area and radius (Fig. 1A,B) were also recorded with regard to the last perpendicu-

lar cross section (1 mm proximally) before the inflatable O-rings to obtain the normal values of these variables relative to the infrarenal aorta for each patient (Aaort and Raort). Furthermore, the length of the stenosis was measured for all patients, and a median value for the cohort was calculated. The endograft size in each case, as well as the degree of oversizing, were recorded and displayed against the stenosis grade to examine possible causality.

Theoretical Model

Poiseuille's law describes the viscous energy losses occurring in an idealized rigid pipe with steady flow as $P1–P2=Q*8nL/\pi R^4$, where $P1–P2$ represents the drop in potential energy between 2 points along a distance L; Q is the volume flow in a tube with an internal radius R. In our study, values for n were obtained from the literature (n=0.035), while a value of 20 cm^3/s was assumed for Q based on magnetic resonance studies measuring blood flow in the infrarenal abdominal aorta.[18,19] The length L was recorded from the patient data as previously described. Using these values, the pressure drop was computed and plotted against radius and surface area reduction for values of R between 0.1 and 1.5 cm, which allowed us to estimate the pressure drop at the stenosis in our series. These values were recorded for each case under examination.

Blood Pressure Measurements

After the inflow stenosis at the level of the inflatable O-rings had been observed in our initial cases, a protocol was initiated to record intra-aortic blood pressure measurements at the time of endograft implantation to determine the hemodynamic impact of this abnormality. The methodology of invasive intra-aortic blood pressure measurement has been described elsewhere.[20] Pressure measurements were performed using a 6-F, multi-hole, fluid-filled diagnostic pigtail catheter. After the final angiogram, the tip of the catheter was placed at 3 positions inside the aorta and the endograft: (1) just proximal (~1–2 cm) to the inflatable rings

where the aortic diameter is normal (level A); (2) midway inside the rings (usually between the first and second ring), which refers to the level of maximum inflow stenosis (level B); and (3) distal to the sealing mechanism halfway in the main body of the endograft (level C). Small injections of contrast were used to verify the correct catheter position fluoroscopically. Subsequently, the catheter was calibrated and connected to the pressure transducer to record values at peak systole at all 3 levels.

ABI Measurements

In order to further examine whether the observed stenosis was significant from a hemodynamic standpoint, we searched for a purely clinical parameter that would display compromise in blood pressure and flow and reflect patient symptoms. Therefore, we recorded lower limb pulse palpation and ABI measurements for all patients both preoperatively and postoperatively before discharge from the hospital. These measurements were routinely obtained for all cases and were retrospectively reviewed for the current study. Patients who had conditions that could affect the ABI, such as limb stenosis or thrombosis, were excluded from these measurements since it was the intention to examine the effect that the sealing mechanism alone may have on ABI values.

Statistical Analysis

Area and radius measurements are given as the median values and range. Differences between measurements were tested for statistical significance using the Wilcoxon signed rank test for related samples. Similarly, pressure drop, invasive blood pressure measurements, and ABIs are given as the median values. Endograft size and degree of oversizing were stratified; for graft size, the subgroups were 23 mm (5/49), 26 mm (20/49), 29 mm (12/49), and 34 mm (12/49), while oversizing was grouped as ≤10% (7/49), 11%–20% (13/49), 21%–30% (16/49), and >30% (13/49). Median stenosis was calculated and compared using the Kruskal-Wallis test.

TABLE 1
Measurements of Cross-Sectional Area and Radius

	Measurements	% Reduction	p (vs. internal)
Internal cross-sectional area, mm^2	123 (28–254)		
Cross-sectional area proximal to the O-rings, mm^2	283 (177–531)	57%	<0.001
External cross-sectional area, mm^2	380 (201–804)	68%	<0.001
Internal radius, mm	6.5 (3–9)		
Radius proximal to the O-rings, mm	9.5 (7.5–13)	32%	<0.001
External radius, mm	11.0 (8–16)	41%	<0.001

Measurements are given as the median (range).
Internal and external measurements at the level of the inflatable O-rings.

RESULTS

Area and Radius Measurements

Area and radius measurements were obtained for all patients, and these results are summarized in Table 1. Median Aint (123 mm^2) was significantly smaller (both p<0.001) than both Aaort (283 mm^2) and Aext (380 mm^2). The same was observed for the Rint (6.5 mm) radius measurements [Raort 9.5 mm (p<0.001) and Rext 11 mm (p<0.001)]. For cross-sectional areas (Figs. 2–4), median Aint reduction with reference to the proximal normal aorta (Aaort) was 57% (range 10%–80%).

Median stenosis for the 4 endograft size groups (Table 2) were 68% (23 mm), 59% (26 mm), 59% (29 mm), and 59% (34 mm). Differences between groups were not statistically significant (p=0.932). Relative to the degree of oversizing (Table 2), the median stenosis measurements were 57% (7/49), 59% (13/49), 62% (16/49), and 70% (13/49); differences between groups were not significant (p=0.837).

Pressure Calculations and Invasive Measurements

The pressure drop along the stenosis due to the inflatable O-rings was calculated for all cases. Using the median 15 mm length of the stenosis (range 13–17) observed in the study population, a median pressure drop of 0.13 mmHg (range 0–0.25) along the stenosis was calculated. For the patient with the most severe stenosis (80% reduction of cross-sectional area), a pressure change of 0.25 mmHg was calculated. Figure 5 displays the curve that Poiseuille's law predicts between the pressure drop and radius as well as values predicted for cases in this study.

Invasive blood pressure measurements were obtained intraoperatively in 10 patients studied after realizing the inflow stenosis caused by the O-rings. Differences between pressures at the 3 levels of interest were practically nonexistent for all 10 patients: the median difference in pressure between levels A (proximal) and B (maximum stenosis) was 0.7 mmHg, while the median difference between levels B and C (distal) was 1.1 mmHg. These differences were neither statistically significant (p=0.9) nor clinically relevant.

ABI Measurements

Three patients were excluded from the ABI study because they had limb collapse and stenosis (n=2) and limb thrombosis that could affect pulse palpation and ABI. In the 46 patients examined, preoperative and postoperative femoral pulses were similar. Median ABI was 0.91 in the right and 0.84 in the left limb preoperatively and 0.88 and 0.86, respectively, after the procedure. Differences were not statistically significant (p=0.89 and p=0.92, respectively). Taking into account that a >0.10 ABI change is considered relevant from a clinical point of view, there were no patients who presented deterioration after endograft implantation, even in those cases with the most severe inflow stenosis.[21]
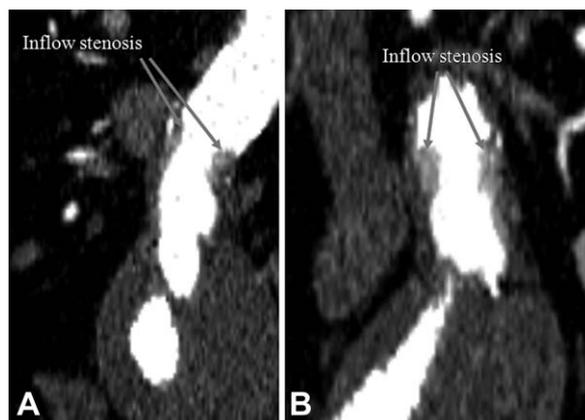
DISCUSSION

Besides being ultra low profile (14-F delivery system), the Ovation endograft is a next-
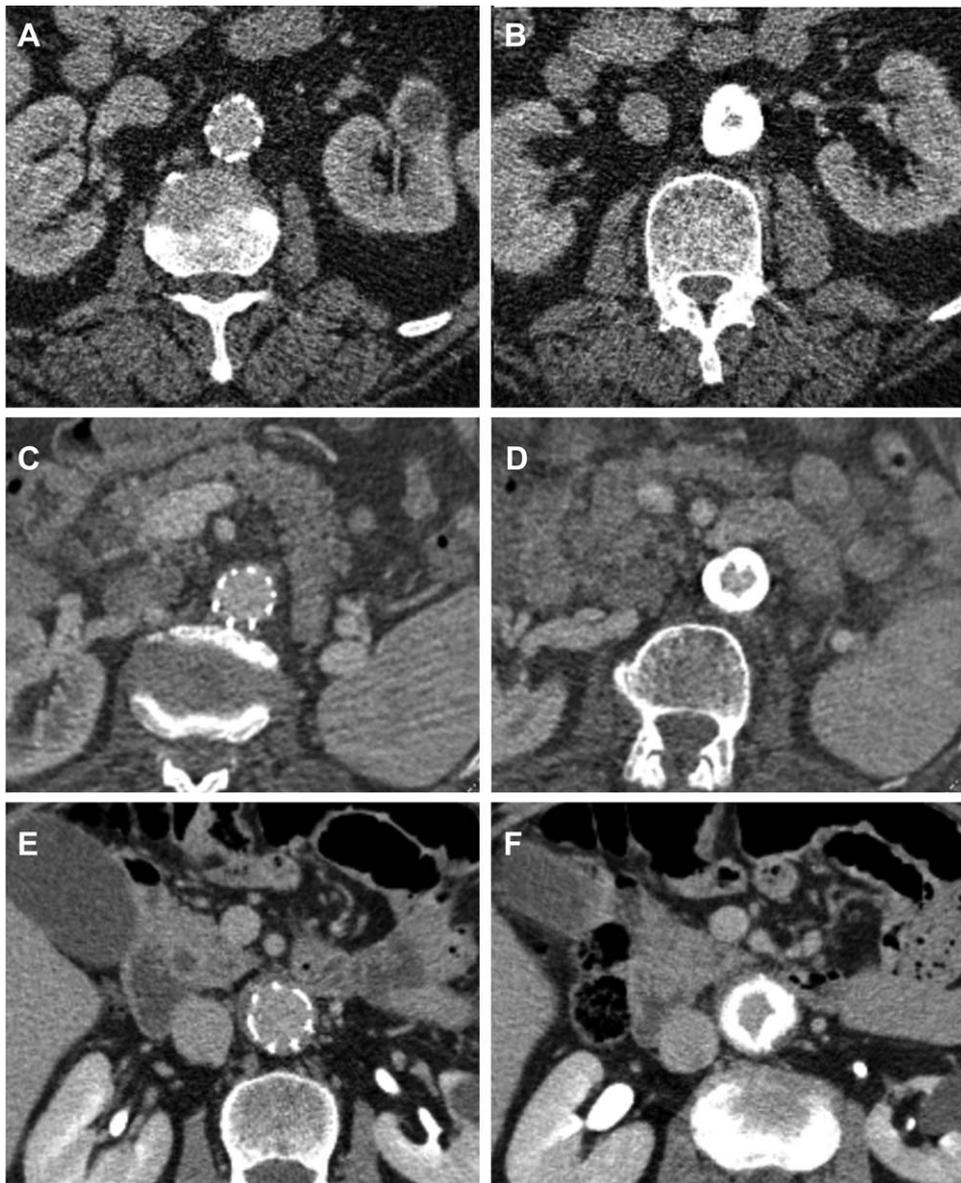
Figure 2 ◆ CT slices just proximal to the inflatable O-rings (**A,C,E**) and at the site of maximum cross-sectional area reduction (**B,D,F**) in 3 representative cases: (**A,B**) an 80% inflow stenosis, (**C,D**) a 65% inflow stenosis, and (**E,F**) a 52% inflow stenosis. It is worth noting that graft oversizing was 31% (neck diameter 26 mm, graft size 34 mm) for the first, 22% (neck diameter 23 mm, graft size 29 mm) for the second, and 35% for the third case (neck diameter 25 mm, graft size 34 mm).

generation stent-graft that offers a totally new perspective on the sealing-fixation philosophy. The polymer-filled ring network conforms to the aortic neck, creating a stable concentric seal as opposed to the chronic outward force of stent-graft systems that employ self-expanding stents to achieve seal. It ha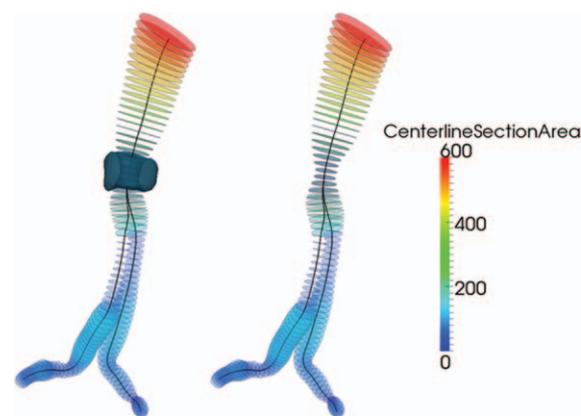s been suggested that the constant force exhausts the elastic recoil of the degenerating aortic wall and results in enlargement of the aortic neck, with subsequent risk for type Ia endoleaks and/or device migration.[22] Moreover, the Ovation endograft seems to overcome limitations relevant to conical aortic necks since adequate sealing depends only on the first inflatable ring (provided the neck

Figure 3 ◆ Sagittal and coronal views of an aneurysm with cross-sectional area reduction of 64%.

TABLE 2
Median Stenosis According to Main Body Size and Graft Oversizing

	N	Stenosis	p
Stent-graft size, mm			
23	5	68% (50%–80%)	0.932
26	20	59% (29%–72%)	
29	12	59% (10%–79%)	
34	12	59% (36%–80%)	
Oversizing			
<10%	7	57% (53%–65%)	0.837
11%–20%	13	59% (29%–79%)	
21%–30%	16	62% (50%–75%)	
>31%	13	70% (10%–80%)	

Data are given as the median (range).

diameter 13 mm below the lowest renal artery does not exceed 30 mm); thus, diameter discrepancies along the aortic neck length do not compromise sealing unlike some other endografts.[23]

Apparently, early results from clinical studies using this device seem to be excellent regarding technical success, effectiveness, and safety. Mehta et al.[4] in the Ovation global pivotal study report successful implantation in 100% of patients (50% treated percutaneously), without any access failures, type I or III endoleaks, stent-graft migration, explantation, or aneurysm rupture. Furthermore, at 1 year, there were no migrations, type I or III endoleaks, or conversions to open surgery. There was a 6% AAA-related secondary reintervention rate.[4] Similarly, Carrafiello et al.[5] in a 3-center study, which included initial results from our institution, reported a technical success rate of 100%; none of the patients required conversion to open surgery. Furthermore, midterm results reported no aneurysm enlargement, rupture, fracture, migration, or type I, III, or IV endoleaks.[5]

Despite advantageous features of the Ovation stent-graft and the promising early results from clinical studies, we were troubled by an inflow stenosis that became clear

Figure 4 ◆ Cross sections perpendicular to the vessel centerline and a color scale with reference to cross-sectional area with and without the inflatable rings. The aortic lumen stenosis at the site of the inflatable rings is obvious (color scale is displayed in mm²). A color version is available online at *www.jevt.org*.
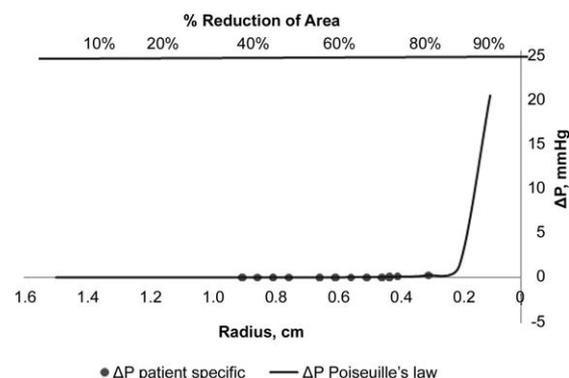

Figure 5 ◆ The curve that Poiseuille's law predicts for specific n, Q values obtained from the literature, and L measured in the study cohort is plotted against the change in pressure for all patients in our study (dots); all values are practically zero. ΔP is change in pressure.

following accumulated experience with this device. Our investigation of this phenomenon indicate that there was an actual reduction in cross-sectional area with respect to the infrarenal aorta just proximal to the inflatable O-rings (median 57% ranging to 80%) at the 1-month follow-up. We did not obtain longer follow-up measurements since the polymer's radiopacity dissipates over time and may not be visible on fluoroscopy, radiography, or CT beyond 1 to 2 months post implantation.[6] Such a stenosis could be assumed to be due to an inward expansion of the polymer rings and is not expected to change over time.

Our calculations of the pressure drop that such a stenosis would cause indicated that this pressure reduction is insignificant. Invasive blood pressure measurements obtained intraoperatively in a 10-patient sample, as well as the ABI measurements in 46 of 49 patients also did not display any remarkable differences. It should be emphasized that all patients included in the current analysis, even those with most severe inflow stenosis, presented unremarkable ABI changes, but further follow-up of these patients will be performed.

The explanation for the absence of a significant pressure drop after the inflow stenosis is based on Poiseuille's law, which states that energy losses are inversely proportional to the fourth power of the radius and therefore plots of pressure change against radius are sharply curved. Apparently, as the diameter of a vessel is reduced, there is little effect on the pressure gradient until a certain degree of narrowing is reached. Further reductions in diameter beyond that point cause the pressure gradient to rise rapidly, which is the concept of critical arterial stenosis.[24] It is important to note that critical arterial stenosis is not a constant number but varies directly with the effective cross-sectional area of the artery and inversely with the flow rate. Thus, a lesion producing a particular reduction in cross-sectional area for a large artery may not result in any compromise in blood flow, but the same percentage reduction in cross-sectional area of a smaller vessel may exceed the critical stenosis level for that artery.[25] Subsequently a lesion of the abdominal aorta does not become hemodynamically significant until 90% cross-sectional luminal narrowing exists, while for medium-sized arteries, such as the iliac vessels, hemodynamic changes occur at a smaller cross-sectional luminal narrowing.[26,27]

On the other hand, Poiseuille's law applies only to steady (nonpulsatile) laminar flow in a straight cylindrical tube with rigid walls. Thus, the strict conditions required by Poiseuille's law are seldom, if ever, present in the human circulation. In addition, energy losses during fluid flow are almost never totally viscous, and in many situations, viscous losses are equally significant to inertia-related energy losses. Nevertheless, although actual energy losses may be greater than those predicted here, this was not confirmed by invasive pressure measurements obtained in this study.

One could argue that additional stenoses may be present inside the rings of the Ovation's limbs. However, these expand inside the aneurysm sac (between 50 and 80 mm from the lowest renal artery) and are not expected to cause a stenosis. Moreover, a covered stent is deployed in the limbs, and this internal support is expected to correct any possible stenosis. It should also be noted that the main body rings are intended to seal the graft at the aortic neck, whereas the limb rings are intended to offer support to the soft, floppy polytetrafluoroethylene material and to open the orifice of the limbs for catheterization.

It should be emphasized that our results regarding an outer aneurysm wall expansion at the site of the inflatable rings compared to the proximal infrarenal aorta are not by any means suggestive of neck dilatation. Previous research examining the degree of neck dilatation after endograft implantation not only takes into account the level just caudal to the lowest renal artery to define the aortic neck and obtain measurements, but also determine changes in dimensions with reference to previous CT imaging (either the preoperative or the 1-month postoperative). Moreover a threshold of 3 mm of expansion has been used to define relevant radius increase in these studies,[7,8] while a lower expansion is not considered significant. However, in the current study, expansion of the aortic wall is

indicated based on measurements midway inside the inflatable rings, which is different from how previous studies define the neck level. Moreover, we considered only one time point and did not compare with previous imaging. Finally, a median 1.5-mm difference in radius was found, which equals a diameter change of 3 mm; thus, the difference may not be relevant from a clinical standpoint. Therefore, our results are not comparable to others and do not suggest AAA neck dilatation.

The current standard of 10% to 20% oversizing appears to be relatively safe and preferable.[28] This graft oversizing is common practice with most aortic endografts and is utilized in order for the stent to exert enough radial force on the aortic wall to ensure graft stability and avoid graft migration. Along the same line, Ovation's planning instructions mandate a 15% to 20% oversizing of the main body diameter with respect to the native infrarenal aorta. In the case of the Ovation stent-graft, this practice may not be necessary. By oversizing the device, we are attempting to cramp the inflatable rings, which are designed to expand to a specific diameter, into a smaller diameter aorta. Inevitably, if these rings cannot expand outward, they will expand inward toward the lumen causing a stenosis. Furthermore, since the rings are designed to seal the graft, whereas the suprarenal metal stent is designed to fix its position against migration, maybe the manufacturer needs only to redesign the device and oversize the metal stent while decreasing ring diameter. Additionally, it should be mentioned that the use of a large caliber compliant aortic balloon across the sealing rings 20 to 40 minutes after polymer insertion is recommended by the manufacturer only if sealing is not achieved, but this additional step may routinely be necessary in all cases to conform the rings and to resolve any possible infolding causing inflow stenosis.

Finally, it could be hypothesized that despite the fact that a hemodynamic compromise is not evident from the present findings and the degree of stenosis that is observed seems unimportant from a hemodynamic standpoint, there are other aspects that such an abnormality could cause relevant to platelet aggregation and thrombus formation.

Platelet activation is closely influenced by the surrounding hemodynamic environment and frequently occurs at a locally stenosed blood vessel where recirculation and stagnate flow regions are developed.[29] Platelets have been suggested to principally use a biomechanical aggregation mechanism to promote accumulation and stabilization through local shear microgradients, which occur with changes in vessel geometry (stenosis).[30] These effects are still unknown and need to be further studied.

Conclusion

The Ovation Stent Graft System is a newly developed device that has shown very promising early results in clinical trials. It is intended to accommodate challenging anatomies and expand EVAR indications through its original characteristics, mainly its unique sealing mechanism that conforms to the aortic neck. Nevertheless, these advantages come at the cost of an almost 60% inflow stenosis at the aortic neck. This stenosis is accompanied by a hemodynamically insignificant pressure drop. Future modification of the graft ring design may be needed in order to reduce this stenosis.

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