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TITLE: Occlusive shrinkage of Ovation Endograft™ presenting as acute lower limbs ischemia: Effective endovascular management

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ABSTRACT

The aim of this report is to raise attention regarding the imagining and successful treatment of an acute shrinkage of the Ovation Abdominal Stent Graft System. The Ovation Prime system utilizes a polymer-filled sealing ring that is cast in situ at the margin of the aneurysm. The residual endograft inner volume after ring filling may reduce the volume and graft flow. Nevertheless there are no reports about severe complications. A 75-year-old male presented to our hospital for acute lower limb ischemia. The patient reported a previous endograft for abdominal aortic aneurysm one month previously, utilizing the Ovation device. Computed tomography (CT) angiography demonstrated a critical narrowing of the endograft at the site of the proximal sealing rings. We decided on urgent treatment, delivering a covered stent graft (CP STENT NUMED™). Intraoperative IVUS showed effective compaction of the proximal rings. Nine-month follow-up with CT angiography demonstrated good patency without ring recoil of the endograft. This is the first report of endovascular treatment for an acute and symptomatic shrinkage of proximal rings in the Ovation trivascular endograft. Angiographic and IVUS findings showed that covered stenting is effective and that the ring polymer is safely moldable.
INTRODUCTION

Endovascular technology has significantly changed the field of vascular surgery. However, approximately one-third of patients presenting with abdominal aortic aneurysms (AAAs) are deemed ineligible for standard endovascular aortic repair (EVAR) because of anatomic constraints, the majority of which involve inadequacy of the proximal aneurysmal neck. To cope with these challenges, different endovascular approaches have been developed, to either enhance stent graft fixation at the proximal neck or extend the proximal landing zone to allow adequate apposition to the aortic wall and thus aneurysm exclusion. Patients with aortic necks < 10 mm had a fourfold greater risk of proximal endoleak through 30 days of follow-up compared to those with necks > 15 mm. In the wide scenario of available endografts the Ovation Abdominal Stent Graft System (TriVascular Inc, Santa Rosa, Calif) is supposed to be designed to overcome the limitations of currently available stent grafts. The Ovation graft can be suitable for a broad range of aortoiliac characteristics and should provide an effective sealing in complex proximal infrarenal aortic neck morphology. However, some authors observed asymptomatic inflow stenosis at the O-rings of the Ovation stent-graft. In this paper we report the imaging and treatment of an acute complication in a patient treated for AAA with an Ovation stent-graft, leading to acute limb ischemia.

CASE REPORT

A 75-year-old male presented to our hospital for acute lower limb ischemia. Patient referred to our hospital with rest leg pain, feet numbness and hypoesthesia. One month before he was treated in another hospital for a rapidly enlarging 48 mm AAA (from 40 to 48 mm in 6 months). An Ovation Abdominal Stent Graft System was used. Sizes of the endograft are reported in Figure 1. Comorbidities were mild chronic obstructive pulmonary disease (COPD), obesity (BMI 29.3), and hypertension. Symptoms occurred a few hours before presentation to our emergency room. The patient complained of severe ankle and calf rest pain described as increasing since two hours before. The femoral arteries were pulseless, and distal bilateral acrocyanosis was present. Blood samples showed increased creatine phosphokinase (4500 U/L). Critical post-stenotic flowmetric findings were evident at ultrasound scanning of the femoral arteries. ABI was 0.22 bilaterally. Urgent computed tomography (CT) angiography was performed, showing severe narrowing of the proximal aortic neck where the endograft rings seal the AAA (Figure 1, panel B).

In consideration of the clinical and imaging findings, we decided for an urgent revascularization. We decided before proceeding with open surgery to start with an endovascular approach using a 14 French mounted covered stent with high radial force characteristics (CP STENT™, NuMED Inc., Hopkinton, NY) with a total covered length of 45mm. The aortic neck measured 20 mm and the Ovation stent graft was 29 mm (figure 1, panel 2). Circumferential calcifications surrounded the proximal aortic neck. Under general anesthesia a 4 French introducer was inserted through the left brachial artery and an angiogram performed. Intraoperative anticoagulation was achieved using 100 units/kg heparin, and the activating clotting time was maintained above 250 seconds. The right femoral artery was surgically exposed (previously used for the EVAR). An artery pouch was prepared with a 5/0 polypropylene stitch in order to close the arteriotomy at the end of the procedure. We recorded a clinically significant cycle-averaged pressure drop along the inflow stenosis and further in the endograft main body (45.5 ±15 mmHg). Mean arterial pressure dropped from 110 to 45mmHg when measured above and below the stenosis. A Visions® PV .035 Digital IVUS Catheter was placed to calculate the residual lumen and area (39.3±3.5 mm²) close to the ring and visualize the echogenicity of the polymer compared with the aortic thrombus (Figure 2). Above and below the stenosis the median area were 409 mm². The CP STENT deployment was performed in a two-stage sequence. Final delivery (Figure 3; panel
1 and 2) was obtained with high pressure second stage balloononing (10 ATM) followed by a further post-dilation with a Z-MED II™ Balloon (NuMED Inc., Hopkinton, NY). Post implantation IVUS showed good results in terms of restored area (439±22 mm²) and of reduced ring polymer volume (Figure 3). The pressure gradient along the endograft neck was eliminated. The patient recovered from limb ischemia and was discharged on the 5th postoperative day with good bilateral femoral pulses. Nine months later (fig.3; panels 3 and 4), CT angiography showed good patency of the endograft with no neck recoil. Outpatient ultrasound evaluation has shown normal flowmetric patterns.

**DISCUSSION**

The management of juxtarenal aortic aneurysms with EVAR remains controversial due to the high risks. Several endovascular techniques have therefore been proposed to ensure a secure proximal landing zone1,2,3. The morphology of the aneurysm neck is considered especially important in this process13. New technologies have expanded the applicability of endovascular aneurysm treatment to cases with anatomical adverse conditions. But, as the indications for mini-invasive techniques have expanded, complications and technical failure rates are increasing as well4,5,8.

In this case report we observed a complication starting from the technical core of the endograft. The Ovation stent graft was conceived in order to accommodate a broader range of aorto-iliac anatomy with a proximal aortic neck seal mechanism designed to conform to and accommodate the aortic neck.4-5 The aortic body contains a network of inflatable channels which fill dedicated rings during deployment with a low-viscosity, radiopaque fill polymer that remains in situ to create an effective seal to the patient’s aortic neck. Because of this design, the aortic neck size and circumferential calcification are critical issues to be evaluated before choosing this endograft. A moderate stenosis has been already described6 as a normal finding after Ovation implantation, but regarding a critical narrowing of the neck causing lower limb ischemia, ours appears to be the first report.

The sealing mechanism occurs via radial force expressed by the polymer-filled rings. This aortic volume expands externally even though a residual volume occupies the endograft lumen6,7. If the neck is heavily and circumferentially calcified, the rings may fail to expand outside and converge toward the center of the endograft, narrowing the aortic lumen. Moreover, in this case, the adequate oversizing (about 20% of the anchoring neck) was generously overcome in the pre-operative planning. If we consider the original aortic neck of 20 mm, the proper oversizing for the endograft would have been 23 mm. In this patient the proximal neck of the implanted endograft measured 29 mm. Considering all these data, we can speculate that the narrowing has two causes: the calcified neck that push the rings inward and the excessing ring oversizing that almost completely filled the device lumen.

Metha3 reported that at 1 year follow-up 2% of patients presented an aortic body stenosis without re-intervention. In other experience the authors6,7 observed 49 consecutive patients (48 men; mean age 71.2±7.7 years) treated successfully with the Ovation abdominal aortic stent-graft at a single center. They concluded that advantages of the Ovation device’s unique sealing mechanism come at the expense of a median area inflow stenosis of ~60%. Moreover some authors7 expect that the coexistence of stenotic wall regions exposed to high shear rate and post-stenotic recirculation zones may implicate platelet activation and predispose to thrombus formation and thromboembolic complications.

In our experience, we had concerns regarding the fate of rings. Do we have to deal with a dislocation or a rupture of the neck? Is the polymer fairly moldable to obtain an effective reduction of the ring volume? With
these considerations, we decided to use a covered stent for protecting the aortic neck and for keeping a long-term radial force. The solution was the Numed CP stent. Even though we are reporting an isolated experience, we do believe that aortic stenting for severe neck narrowing following the Ovation Endograft is safe and feasible. The IVUS technology substantially facilitates proper delivery of the stent and permits evaluating the final squeezing of the ring polymer.

According to the Ovation pivotal study, this stent graft may help to expand the patient population eligible for endovascular aortic repair by accommodating a wider range of aortoiliac anatomies (especially a large neck). Nevertheless, these advantages pay the fee of a median area inflow stenosis and increase the risks of thrombotic complications when the sizing of the endograft is suboptimal. The present experience shows that polymer rings are moldable and a bail-out procedure is feasible when a severe stenosis appears.

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Figure 1 Panel 1 Computed tomography angiography showing the narrowing of proximal neck. (A: bare metal stent of the endograft. B: Rings filled with polymer). Panel 2 Sizes of the endograft
**Figure 2** IVUS scanning the proximal neck

(Panel 1. A: true lumen of the upper part of the endograft just above the ring. Panel 2. A: superior ring filled with the polymer. B: endograft residual lumen. Panel 3. A: Inferior ring filled with the polymer almost occluding the lumen and the 6F IVUS occupies the residual lumen. Panel 4: A: true lumen of the lower part of the neck below the inferior ring. Aneurismal thrombus shows similar echogenicity as polymer)
Figure 3 Final result and nine months angioCT scan