

# Preserving the Aortic Neck

Why the O-ring sealing technology of the Ovation Prime® System does not contribute to aortic neck dilatation.

BY SEAN P. LYDEN, MD

Most of you have probably never heard of an O-ring, but they make everyday life possible, as they are used in engines, pumps, pipelines, auto-claves, compressors, reactors, hydraulics, HVAC (heating, ventilation, and air conditioning), and aerospace uses. As you can see, O-rings are one of the most common seals used in machine design because they are inexpensive, easy to make, reliable, and have simple mounting requirements.

## O-RING MECHANISM OF ACTION

An O-ring is a torus, or a doughnut-shaped object, generally made from an elastomer designed to be seated in a groove and compressed between two or more parts, creating a seal at the interface (Figure 1). The O-ring may be used in static applications or in dynamic applications where there is relative motion between the parts and the O-ring. Dynamic examples include rotating pump shafts and hydraulic cylinder pistons.<sup>1</sup> The amazing quality of an O-ring is that it can seal tens of thousands of pounds per square inch of pressure.

Now, how does the O-ring apply in the context of vascular surgery? The two main challenges in endovascular aneurysm repair are fixation and sealing.<sup>2</sup> For devices with-

out suprarenal stents, fixation and sealing occur at the same level. Devices with suprarenal stents use the paravisceral segment of the aorta to enhance fixation. Sealing for most endovascular aneurysm repair devices approved by the US Food and Drug Administration (FDA) is achieved via radial force from (nitinol or stainless steel) stents pushing fabric (either polyester or polytetrafluoroethylene) against the aneurysm wall. The exception is the Ovation Prime stent graft (TriVascular, Inc.), which uses an O-ring for seal (Figure 2).

## O-RING SEALING WITH THE OVATION PRIME DEVICE

The TriVascular Ovation Prime device gained FDA approval based on data from a prospective, multicenter, single-arm trial in which 161 patients were treated.<sup>3</sup> The Ovation Prime device is unique in that the fixation and sealing mechanisms are separated. The device uses a suprarenal nitinol stent with integral anchors for active fixation. To achieve seal, a polymer fills an O-ring that, once cured, does not exert chronic outward force on the aortic wall. The midpoint of the primary sealing O-ring is located 13 mm below the top of the fabric on the Ovation Prime device. A secondary sealing ring is located 20 mm below the top of the fabric.



Figure 1. A basic O-ring design.



Figure 2. The Ovation Prime stent graft with sealing O-ring.

The prospective, multicenter, single-arm trial utilized an independent imaging core laboratory (M2S, Inc.). The imaging core lab analyzed all CT scans and radiographs in that study. Measurements were obtained by the core laboratory at 15 mm below the lowest renal artery. The 15-mm measurement should approximate the location of the sealing O-ring. The core lab data noted a 0.18-mm decrease (-0.55 to 0.18 mm; 95% confidence interval) in mean diameter at 15 mm below the lowest renal arteries at 24 months after placement (data on file at TriVascular, Inc.). The lack of significant neck dilation at 15 mm below the lowest renal artery at 24 months supports the concept that the aorta is not subjected to chronic outward force applied to the aorta at the sealing location. The regression of aortic diameter and lack of proximal endoleaks found in the multicenter trial, as well as a single-center trial, also support the concept of durability of an O-ring seal in the aorta.<sup>3,4</sup>

The lack of neck dilation at 24 months due to the Ovation Prime sealing ring is likely due to its unique design. Unlike the Ovation Prime device, all prior FDA-approved endovascular abdominal aneurysm devices use self-expanding stents that perform the combined function of fixation and sealing in the aortic neck. Endovascular aneurysm repair devices without active fixation rely on chronic outward force generated by the Z-stent design to hold it in place. The type of self-expanding stent metal used (nitinol vs stainless steel), thickness of the metal, height of the strut, strut design, and amount of oversizing all have an impact on the amount of chronic outward force generated. These factors affect the force required to displace a stent graft from its fixation on the aortic wall.<sup>5</sup>

Several studies have noted neck dilatation with self-expanding stent grafts.<sup>6-10</sup> In many cases, the aortic neck dilates to a diameter approaching the device diameter.<sup>11</sup> The growth of the aortic neck can upset the delicate balance that a self-expanding stent graft needs to maintain fixation.<sup>12</sup> The continued expansion in proximal neck diameter raises concern for the risk of developing late migration and/or proximal endoleak. To date, self-expanding stent grafts have demonstrated neck enlargement and thus confer this limitation.<sup>6-12</sup> The addition of active fixation with hooks and/or barbs or screws has been shown to increase the pull-

out force required to displace a device.<sup>13-15</sup> The additional methods of active fixation employed by some devices could explain the lack of device migration seen clinically when aortic neck growth occurs.<sup>11</sup>

## CONCLUSION

Aortic neck dilation occurs with endovascular aneurysm repair using self-expanding stent grafts. The Ovation Prime device does not use self-expanding stents for sealing and therefore does not put chronic outward force on the aorta. The separation of fixation from sealing with the Ovation Prime device has proven durability throughout this follow-up period.

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