Device Evolution and New Concepts to Preserve Renal Artery Patency in Challenging Infrarenal Aortic Necks

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At the beginning of the endovascular aortic repair (EVAR) era, a large number of patients were denied endovascular treatment due to challenging aortoiliac anatomy. In particular, short and angulated neck (so-called complex neck) and narrow access vessels were responsible for EVAR ineligibility in more than 50% of cases [1–5], with women deriving less benefit from EVAR when compared to men [6].

Simultaneously, stent-graft technology has evolved rapidly, limitations of earlier-generation devices have been overtaken, and EVAR eligibility has increased enormously.

Traditional EVAR technology has aimed to both anchor and seal using stents combined with fabric, with neither optimized for their roles and each forced to compete for the same space within their delivery catheters, which inevitably led to larger profile of the delivery system.

The Ovation Prime Abdominal Stent Graft System (TriVascular, Inc., Santa Rosa, CA) is a tri-modular device, designed with the aortic body

delivered via a flexible, hydrophilic-coated, ultra-low-profile catheter (14 F outer diameter—OD).

The aortic body is provided with a suprarenal nitinol stent with anchors that provide active fixation, while a network of rings and channels that are inflated with a low-viscosity radiopaque polymer during stent-graft deployment provides effective sealing.

The technical revolution of the Ovation endograft includes the idea of truly uncoupling the stages of stent-graft fixation and seal during the procedure. In the Ovation endograft platform, stent and fabric are not competing for the same space within the delivery system, and an ultra-low-profile delivery can be achieved without compromise. With such a low-profile delivery catheter, approximately 90% of men and 70% of women with AAA have access vessel diameters considered fit for endovascular repair [7, 8].

This chapter focuses on the evolution over the years of endografts in terms of profile and adaptability to challenging infrarenal aortic neck. The final section of the chapter is dedicated to the VENT procedure, a particular EVAR technique that combines the Ovation endograft implantation with open bare-metal stent in the renal arteries and offers a treatment option for patient with unfit challenging neck for traditional endograft.

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7.1 The Evolution of Endograft Delivery Catheter: From 27 to 14 F Profile

More than 25 years ago, Juan Parodi developed a handmade device made of a tube-shaped aorto-aortic graft sutured at each end to a balloon-expandable stent based on the design of radiologist Julio Palmaz. This kind of device was implanted in a human body for the first time on September 7, 1990, in Buenos Aires, Argentina. At that time, the delivery system of this handmade endograft was primitive and extremely rigid, measuring a bulky 27 French (F).

By 1994, the first commercially available devices were launched on the market.

Gradually, they became narrower and much more flexible, allowing for improved access in tortuous vessels, while stent-graft material and design changed in various ways to improve conformability, reduce fracture, and minimize rates of device migration.

The first endograft to enter clinical trials in the United States and the first product to be approved by the FDA in the treatment of abdominal aortic aneurysm was the Ancure Stent Graft (Guidant Corporation). It was made of Dacron, and most of the fixating device was made of Elgiloy, a special alloy produced by CMC of Chicago that was extremely fatigue-resistant. It was a large, bulky, and nonmodular endoprosthesis that required a large (25 F) and complicated delivery system: it was a challenge to implant even in a relatively healthy iliac and femoral anatomy.

Guidant recalled the Ancure endograft due to FDA warnings that this device damaged the already weakened arterial walls and led to complications. The lesson learned was that if it were to reduce endoprosthesis profile, this device would have to be modular.

The AneuRx device (Medtronic AVE, Santa Rosa, CA, USA) was the first endoprosthesis that introduced the concept of “modularity”: the flow divider was separated from the contralateral endoleg, therefore reducing the profile to 21 F. The graft consisted of a Dacron mesh, structurally supported by nitinol mesh which was self-expanding upon delivery; moreover AneuRx graft was positioned using radiopaque markers strategically

located on the stent graft, combined with orientation indicators on the delivery system.

Soon thereafter, the Talent stent graft (Medtronic AVE, Santa Rosa, CA, USA), which was initially 23 to 24 F, underwent an evolution to a lower-profile device. It consisted in a series of serpentine nitinol stents embedded into woven Dacron fabric. The stents were spaced discontinuously along a full-length nitinol spine. Salient features of talent device included the proximal bare spring (uncovered nitinol stent) and custom manufacturing to fit a wide range of aortoiliac sizes and configurations, as determined preoperatively by CT imaging and angiography.

After these early experiences, a movement began to develop lower-profile devices. The challenge became how to deliver the same amount of fabric and supporting frame in a progressively smaller delivery catheter. This required changes in the design and construction of the device, without compromising the performance and durability of the device. There were two clear ideas on how to accomplish this: either to change the basic design and the materials used or to work with the same materials and reengineer the device.

The first effort to dramatically lower the delivery profile was made by Cordis in 1999 with a AAA device (Cordis Corporation, Bridgewater, NJ) that had a tri-modular design with two 13 F endolegs. It incorporated a polyurethane (Bioseal) sealing gasket in its three-piece design, which was intended to promote a biological seal at the proximal attachment site. Unfortunately, after first clinical development, it was clear that the polyurethane of the sealing gasket was not mechanically robust and did not provide the same effectiveness in a human aorta compared to animal implants. Moreover, the endolegs achieved a lower profile simply by increasing the size of each stent cell (which however became more rigid) and reducing their total number; this led to an increase in the kinkability and torsion of the limbs in tortuous anatomy.

Further efforts to develop a low-profile device involved the planning of new aortic endoprosthesis manufactured with traditional materials and characterized by a new concept of sealing and/or fixation.

Different companies developed their endograft with reduced profile (18–20 F): Zenith Flex LP (Cook Medical Inc., Bloomington, IN), Excluder (Gore & Associates, Flagstaff, AZ), and Endurant (Medtronic Vascular, Inc., Santa Rosa, CA). These new technical solutions consisted in modular low-profile devices which combined a series of barbs or hooks to engage the aortic wall and to provide active fixation, with radial force from self-expanding stent for stability and optimal graft to vessel apposition, and a main body with columnar strength that mimics the natural anatomy of the aorta.

Afterward, a new concept of fixation separated from sealing was expressed for the first time by the low-profile endoprosthesis Powerlink and AFX (Endologix, Inc., Irvine, CA). It combines in a unibody design a highly conformable material (that moves independently from the stent to maximize wall contact, conform to anatomical irregularities, and enhance sealing) with anatomical fixation (that inhibits migration and limb competition). This endograft was delivered through a 17 F introducer sheath (19 F OD).

Further efforts to develop a low-profile device were based on the concept of changing the basic design and the materials used and planning an endoprosthesis without the traditional metallic stent frames to support the fabric. TriVascular (TriVascular Inc., Santa Rosa, CA) developed the first generation of endograft, called eNovus, which was a nonmodular device, presenting a delivery profile of 16 F OD. The device was made of a unique PTFE sleeve with channels for a biocompatible fill polymer as the endoframe for the device and used nitinol stents only for suprarenal and distal endoleg attachments. Unfortunately, the clinical trials revealed some cases of fracture of the suprarenal stent. It was seen that the load created by anatomical flexing was concentrated across a small number of points, leading to a higher potential for fatigue. This problem was rapidly solved with a new design of more uniform strut width that achieves the goal of spreading stress-strain loads more evenly across the stent, thereby significantly improving the resistance to fatigue.

With these design improvements, TriVascular was able to launch the first generation of a new

endograft, the Ovation, preserving the unique sealing mechanism of the inflatable sealing rings. Moreover, the other significant improvement in stent design made by TriVascular was that a three-piece modular design with two nitinol endolegs was adopted with a further reduction of profile from 16 F OD to 14 F OD.

Incorporating traditional materials and a three-piece design, the Cordis INCRAFT (Cordis Corporation, a Johnson & Johnson company; Warren, NJ) has recently proposed an ultra-low-profile endograft (14 F). The INCRAFT includes the technologies and designs Cordis acquired from the TERAMed AAA device (also known as Forton) in the design of its endolegs, although the bifurcated component is entirely new. It is made of a low-porosity polyester graft with segmented nitinol stents and a suprarenal fixation: the number of crowns in the suprarenal stent was reduced to a minimum, and instead stent hooks are designed to be fracture-resistant while still affording excellent anchoring with high pullout forces. Moreover, to reduce the profile and increase the durability of the fabric, the attachment of the stent rings to the fabric was modified, minimizing the wear force of attachments and reducing the metal fabric interaction.

The INCRAFT System is approved for investigational device use only, and it is not for sale anywhere in the world. It was initially tested in a phase I-type European study (INNOVATION) with favorable early patient outcomes. The pivotal multicenter US INSPIRATION clinical trial is under way.

7.2 Technical Notes of Endograft Design to Reach Ultra-Low Profile

One of the most frequent reasons for EVAR ineligibility is connected to access. With its ultra-low profile of 14 F OD, the Ovation stent graft allows access in 90% of men and 70% of women with AAA, based on data from the Characterization of Human Aortic Anatomy. In contrast, needing a minimum iliac diameter of 6 mm, many other stent grafts accommodate access in only 70% of men and 40% of women.

From a technical point of view, how can a stent-graft aortic body be packaged in a delivery system with a profile of only 4.66 mm (14 F OD)?

The answer has to be found in a substantial shift in EVAR technology, based on a suggestive change in the conceptual process of two important steps of procedure: the fixation and the sealing.

Actually, the technical revolution of the Ovation endograft includes the idea to truly uncouple the stages of stent-graft fixation and seal during the procedure. This EVAR solution dictated the use of a corresponding segmentation by function, location, and time for the system architecture and its elements. According to this new EVAR technology, a seal is created that must only seal and not be burdened with the additional task of fixation, and a deployed anchor must only hold the implant securely in place and not be asked to do anything more. Additionally, because these components can preferentially engage separate locations within the anatomy, they are not superimposed within the delivery catheter, and their constituents are not all delivered simultaneously.

As a result, in the Ovation endograft platform, stent and fabric do not compete for the same space within the delivery system, and an ultra-low-profile delivery can be achieved without compromise.

The previous EVAR technology has aimed to both anchor and seal using stents combined with fabric, with neither optimized for their roles and each forced to compete for the same space within their delivery catheters, which inevitably led to larger profile of the delivery system.

With the Ovation stent graft, the fixation is acquired by a quite long suprarenal nitinol stent (35 mm), which uses integrally formed anchors. The proximal stent and the anchors are delivered in a staged way, allowing precise placement that is particularly important in short-neck anatomies.

Once the endograft fixation phase is complete, the sealing phase begins. The aortic body is provided with a network of inflatable channels and sealing rings that are filled with a low-viscosity, nonembolic, radiopaque fill polymer. This polymer-filled ring network conforms to the patient's aortic neck, creating an uninterrupted concentric seal reminiscent of O-ring or gasket-like seals that have long been considered the gold standard in other sealing applications. Providing a simple,

precise, and reliable seal in a variety of applications and function by introducing a calculated mechanical stress between the O-ring itself and the surface that the ring is in contact with, this kind of design is typically used to prevent the passing of air or fluid between two surfaces.

Being casted in situ to form a custom-molded O-ring seal at the margin of the aneurysm, the polymer guarantees a very high seal conformability of the Ovation to irregular surfaces, such as in the presence of calcium or thrombus.

The polymer-filled O-rings do not apply the kind of chronic outward force on the aorta, which is typically seen with other endografts that employ oversized, self-expanding stents to achieve seal in proximal aortic necks.

Furthermore, the delivery system profile is not affected by the amount of polymer required, since the material is injected in a liquid state and subsequently solidifies in 20 min.

All these technical details explain how it was possible to package this endograft in a delivery catheter of only 4.66 mm.

7.3 Endograft Design and Aortic Neck Dilatation

At the beginning, very little was known about the role of device design on early procedural success and long-term durability. The idea was just to create endograft simulating those used for open surgical repair, replacing the aortic suture line with stents to achieve fixation.

But how could the device stay in place and guarantee to seal off the aneurysm for years? Of course, a radial force applied by a stent at the proximal aortic neck is needed.

Unfortunately, already in the late 1990s, it was clear that the wall of the aortic neck is never a completely healthy arterial segment, but rather it has to be considered a delicate and weaken area. A significant dilatation of the proximal aortic neck may be experienced in up to one-third of patients following open repair, questioning the efficacy of EVAR over time [1, 2] when a chronic outward force is applied on the proximal neck.

In 2000, Wever et al. reported a 15.5% rate of dilatation of the proximal neck after EVAR [3],

which was not correlated with the graft diameter or amount of graft oversizing. At that time, this major concern was confirmed by the failure of the EVT/Ancure graft (formerly Guidant Corporation straight tube graft), which revealed that aortic growth may occur after EVAR leading to failure of aortic seal that occurred in the distal aortic seal zone [4]. This failure of endovascular aorto-aortic tube grafts led to the suggestion of preferential use of bifurcated grafts, abandoning the idea of sealing in the distal infrarenal aorta and moving to the concept of creating healthy seal zones, proximal in the aorta next to the renal arteries and distal in a normal iliac artery.

The following trials performed in the first years of the twenty-first century proved successful with EVAR, with excellent outcome [5, 9–12], although neck dilatation was still reported in single-center studies as being related to excessive device oversizing and chronic outward force applied by the self-expanding stents at the level of the proximal neck [13–17].

Contrary to self-expanding stents, balloon-expandable stents do not place continued outward force on the aortic wall. Studies reporting results on the only two endografts with balloon-expandable stents to generate fixation and sealing in EVAR (the MEGS device—Montefiore endovascular graft system—and the LifePath device, Edwards Lifesciences Corporation, Irvine, CA) revealed an extremely low aptitude to cause aortic neck dilatation. Malas et al. [18] described the complete lack of aortic neck dilatation noted in those patients who underwent AAA repair with the MEGS device. Dalainas et al. [19], studying a cohort of 200 and 42 patients after EVAR, reported a 27.5% rate of aortic neck dilatation in those treated with self-expanding stent grafts versus 7.1% in those treated with balloon-expandable stent grafts.

As well as the balloon-expandable stents, the sealing rings of the Ovation Prime device do not place chronic outward force on the aorta. Up to today, 4-year data from the premarket approval application for the Ovation device have revealed stability of the seal zone without aortic neck dilatation, migration, or proximal endoleak evolution in 100% of cases [20].

7.3.1 Device Evolution and Challenging Infrarenal Aortic Necks

Traditional self-expanding stent grafts (SESG) require an infrarenal non-aneurysmal aortic neck to adequately seal the aneurysmal sac from chronic circulatory pressures. Sealing is then procured by oversizing the stent graft (from 10 to 30%) at that level, prospecting that the chronic radial force exerted longitudinally against the aortic wall will circumferentially avert any leakage. Since the first EVAR experiences, this sealing concept has restricted the application of stent grafts [1]. Typically, the feasibility of EVAR for infrarenal AAA has mainly been related to aortic morphology, with the majority of IFU manufacturers originally requiring an adequate non-aneurysmal proximal neck of 10–15 mm, an aortic diameter <30 mm, and an infrarenal angulation <60°.

In patients with complex aortic necks, proximal graft sealing remains a challenge with traditional SESG [21–24]. As expected, applications outside of anatomically specific IFU variables have an incremental negative effect on late results [25, 26]. In a systematic review and meta-analysis of the literature, Spanos et al. [27] identified patients with large AAA and short necks as those at highest risk of graft migration after EVAR after implantation of an old-generation stent graft. Of note, neck diameter and neck angulation did not have any important influence on stent-graft migration.

With the availability of new-generation devices, an increasing number of EVARs have been performed outside IFU [28]. Violations of IFU are particularly focused on unfavorable proximal aortic neck anatomy. Out of a total of 10,228 patients from the MS2 database undergoing EVAR, only 42% of patients had anatomy that met the most conservative definition of IFU, while 69% met the most liberal definition of IFU [29].

A systematic review and meta-analysis of outcomes following EVAR in patients with hostile neck anatomy (as defined by the presence of a neck length <15 mm, neck diameter >28 mm, or angulation >60° alone or in combination)

revealed a significant increase in 30-day type I endoleaks (OR 2.92) and late type I endoleaks (OR 1.71), in comparison with patients with favorable neck anatomy [21].

There are two main consequences of an inadequate choice of the right landing zone: inappropriate fixation with high risk of stent-graft migration and failure of complete aneurysm exclusion with the presence of endoleaks that represent the most important cause of aneurysm progression and rupture.

The so-called hostile neck is typically defined as the presence of any or all of the following features [23]:

- Length <10 mm
- Angle >60°
- Diameter >28 mm
- ≥50% circumferential thrombus
- ≥50% circumferential calcified neck
- Reverse taper morphology

The “chimney” technique has been proposed to manage visceral vessel during endovascular repair of hostile neck or aortic juxtarenal aneurysms (Ch-Evar). It consists in a parallel stent-graft positioning that provides the perfusion to the branch via a stent graft between the aortic wall and aortic graft. In doing so, the sealing zone can be moved proximally, maintaining the perfusion of visceral artery originating from the part of the aorta that will be covered by the body of the aortic graft. It is called “chimney,” because the stent protrudes above the aortic endograft; the chimney graft could be also named “snorkel” when the proximal part is extended proximally or “reverse chimney” or “periscope” when stents are extended caudally. Initially, the chimney technique was used when the aortic endograft was positioned across the renal artery, either intentionally or inadvertently. Depending on the percentage of the covered ostium, the stent had to extend proximally, resulting in this peculiar appearance.

The first successes of this technique, as a bailout procedure, encouraged surgeons to use it during planned intervention for unusual or complex cases, also widening the indications for iliac internal artery, aortic arch, etc.

The complexity of this technique requires a large endovascular experience; the final outcome may vary depending on appropriate selection of patient, planning, and execution.

In order to overcome the difficulties caused by challenging anatomies of the proximal neck of abdominal aortic aneurysms, new devices have been studied and designed. In parallel, innovative endovascular techniques have been created.

The following section describes a new technique as alternative to traditional chimney EVAR to treat challenging short-neck or juxtarenal aneurysm in patients with small iliac access vessels.

7.3.2 VENT Technique

In simple terms, VENT consists of the implantation of the Ovation stent graft [Endologix™, Santa Rosa, CA] with a modified technique that includes synchronous placement of renal bare-metal stents.

To understand how the technique works, it is crucial to remark some of the peculiarities of the Ovation design. The three-modular graft provides a suprarenal fixation by a 35-mm-long nitinol stent, enriched by several hooks. This fundamental part sticks to the aortic wall in the suprarenal part, maintaining renal perfusion and assuring the stability of the entire device. The remaining part is made by a low-profile PTFE (polytetrafluoroethylene) and a network of rings, without any metallic structures. The network of inflatable rings is typically filled with a liquid polymer that solidifies during the deployment procedure.

The filling polymer consists of three different components that are mixed before the injection. Upon mixing and injection into the graft, the components form a radiopaque polymer that fills the proximal sealing rings in the wall of the aortic body graft and the ribs in the aortic body graft legs. The polymer radiopacity dissipates over time and may not be visible on fluoroscopy, X-ray, or CT beyond 1–2 months post-implant.

The low-density polymer is deployed, thanks to an auto-injector system; the “O-rings” are

filled both proximally and distally, assuring the right stability to the entire system and reducing endoleak rate.

This new kind of sealing system has been proposed to overcome complex proximal neck issue: non-cylindrical necks, with parietal thrombus and/or calcification. The sealing procedure is gradual, and there are two reasons for this: better adaptability to the aortic wall and to redistribute pressures along the entire stent graft [30].

The Ovation endograft, with its new concept of sealing by non-expansive circumferential apposition of polymer-filled rings to the aortic wall, generates no chronic outward power at the infrarenal aortic level. In August 2010, the Ovation endograft received CE Mark approval and was commercially accessible in Europe. At that time, the device-specific instructions for use (IFU) facilitated the treatment of aneurysms with a proximal aortic neck of only 7 mm, being the first device ever approved for neck shorter than 10 mm.

Currently, the sealing secured with the Ovation endograft is not longitudinal but circumferential, based on the apposition of the polymer-filled ring to the aortic wall, and, theoretically, allows the treatment of a range of aortic neck diameters independent of their length. As a result, a number of patients have been treated even in the presence of an aortic neck length <7 mm, provided that the aortic neck diameter was compatible with the endograft ring sizes.

Lately, in April 2014, the FDA approved changes to the indication statement for the Ovation Abdominal Stent Graft, and since then, it has been the only FDA-approved EVAR stent graft that is not restricted by the conventional measurement of aortic neck length in its labeling [31]. Actually, the expanded indication for use statement eliminates the minimum aortic neck length requirement. Neck length is only considered in assessing angulation: patients with a proximal neck length of less than 10 mm are indicated with an aortic angle of less than or equal to 45°; otherwise, angles up to 60° are indicated.

Instructions for use (IFU) make the Ovation Abdominal Stent Graft usable in abdominal

aortic aneurysm with adequate iliac/femoral access with:

- Proximal landing zone with an inner wall diameter of no less than 16 mm and no greater than 30 mm at 13 mm below the inferior renal artery and with an aortic angle of $\leq 60^\circ$ if proximal neck is ≥ 10 mm and $\leq 45^\circ$ if proximal neck is <10 mm
- Distal iliac landing zone: With length of at least 10 mm and with an inner wall diameter of no less than 8 mm and no greater than 25 mm

The VENT technique consists of the deployment of the sealing ring of the Ovation stent graft at between 1 and 3 mm below the lowermost renal artery rather than 13 mm as suggested by IFU (Fig. 7.1), with the proximal edge of the fabric lying above the orifice of the renal artery. Short bare-metal stent deployed simultaneously in the renal orifice (Fig. 7.2) and protruding few millimeters into the aorta allows renal patency preservation by moving the proximal edge of the

Fig. 7.1 VENT technique: modified landing zone of the first sealing ring

Fig. 7.2 VENT technique at bench test

fabric present just above the first ring (so-called collar zone).

In cases of challenging infrarenal aortic necks or juxtarenal aortic aneurysms, EVAR usually involves the use of custom-made fenestrated stent grafts, which typically require large-diameter access vessels, higher cost, and several weeks between graft planning and delivery.

These limitations with the practice of vascular surgery have been partially addressed with chimney EVAR, whose role is still controversial, largely due to concerns over gutter endoleaks. The proposed VENT technique is an alternative to traditional chimney EVAR that addresses the same limitation in treating short

challenging neck/juxtarenal aneurysm in patients, in particular in patients with small iliac access vessels.

Of note, unlike the chimney technique, bare-metal stents positioned during the VENT technique do not compete with the main graft, avoiding the appearance of the so-called gutters. Principal differences between VENT and chimney techniques are summarized in Table 7.1.

Figure 7.3 shows a typical case of a short proximal aortic neck (5 mm) treated by the VENT technique.

Landing with the sealing ring just a couple of millimeters below the lowest renal artery is planned (Fig. 7.4).

Table 7.1 Comparison between Chimney and VENT technique

Chimney	VENT
Renal covered stents (6-8 Fr)	Bare metal stents (5F)
10-15 mm protrusion outside renal arteries	2-4 mm protrusion into the aorta
Chimney & endograft competing for the same room (gutters)	Renal stents & endograft ring are not competing for the same room

Fig. 7.3 Typical case of a short proximal aortic neck (5 mm) suitable for treatment by the VENT technique

Fig. 7.4 Planning for Ovation implantation with VENT technique

Fig. 7.5 VENT technique: bare-metal stent is advanced at the level of the renal ostium from the brachial access; the main body of an Ovation endograft is advanced at the same level from the femoral access

Fig. 7.6 Simultaneous renal stent and main body endograft deployment: (a) renal stent deployment; (b) first step of the Ovation main body deployment; (c) complete

deployment of the Ovation main body deployment; (d) injection of polymer

With a percutaneous brachial access and a long 5 F introducer sheath, the bare-metal stent is positioned at the level of the renal ostium, while the main body of an Ovation endograft is advanced at the same level from the femoral access (Fig. 7.5).

Simultaneous renal stent and main body endograft deployment is shown in Fig. 7.6. The Ovation is released with the sealing ring landing exactly at the level of the short infrarenal neck.

The synchronized release of the short renal bare-metal stent (6/18 mm), which protrudes just a couple of millimeters into the aortic lumen, allows the “ventilation” of the left renal artery by moving the thin fabric of the collar zone.

Complete sac exclusion and left renal artery patency are demonstrated at final angiography. Of note, the renal stent and the first ring of the Ovation endograft are strictly in contact but do not compete for the same room. The ring is

Fig. 7.7 Final angiography: the renal stent and the first ring of the Ovation endograft are strictly in contact but do not compete for the same room. The renal stent is preserving the renal perfusion by moving the thin and flexible fabric of the collar zone

responsible for the circumferential sealing at the level of the short neck (1–3 mm below the left renal artery), while the renal stent is preserving the renal perfusion by moving the thin and flexible fabric of the collar zone (Fig. 7.7).

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