Total Endovascular Repair of Thoracoabdominal Aortic Aneurysm: Lessons Learned

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D. Loschi, B. Fiorucci, T. Cambiaghi, E. Centonza, and F. Verzini

23.1 The Origins of Total Endovascular Repair of Complex Aortic Aneurysms

Fenestrated endovascular aneurysm repair (fEVAR) has been introduced into the clinical practice to treat patients with abdominal aortic aneurysms (AAAs) with inadequate infrarenal neck, where visceral vessels need to be included in the endovascular reconstruction. The first fenestrated repair has been described by Park in 1996 using a device modification to incorporate an accessory renal artery, in a patient with infrarenal aortic aneurysm [1]. Since these pioneeristic experiences, the technique has dramatically evolved over time. The main body of the endograft was improved after bifurcated endografts for the endovascular treatment of AAAs were proposed in the late 1990s by Stelter and afterward widely adopted. The success of these experiences led to the development of a tubular upper module

associated to a separate distal bifurcated component, similar to the contemporary unibody, to treat inadequate aortic necks. Gold radiopaque markers were added to highlight fenestration margins under fluoroscopy and facilitate identification and alignment of the fenestrations with their respective target vessels. The openings in the graft material were reinforced with nitinol rings around the fenestrations to create a more stable and durable connection with the stent. To facilitate endograft alignment, diameter-reducing ties were added to partially constrain the graft following unsheathing, to avoid adhesion of the graft to the aortic wall and allow rotation of the device along the vertical axis and movement to a more proximal/distal level.

Also covered stents available for bridging of visceral arteries have been significantly upgraded to improve stability within fenestrations and avoid endoleaks which could occur between the aortic wall and the fenestrated endograft. Anderson et al. published in 2001 a case series of 13 patients treated by means of fEVAR with implantation of balloon-expandable stents for the superior mesenteric artery (SMA) and renal arteries [2]. Technical success was achieved in all cases and no conversion to open surgery was needed. This permitted to demonstrate the feasibility and safety of a fenestrated endograft design to achieve adequate proximal sealing in case of inadequate neck.

With the increasing expertise and with developments of new technologies, more and

D. Loschi · T. Cambiaghi
Division of Vascular Surgery, IRCCS San Raffaele
Scientific Institute, Milan, Italy

B. Fiorucci · E. Centonza
Unit of Vascular and Endovascular Surgery,
Hospital S. M. Misericordia, University of Perugia,
Perugia, Italy

F. Verzini (✉)
Vascular Surgery Unit, Department of Surgical
Sciences, Turin University, A.O.U. Città della Salute
e della Scienza, Molinette Hospital, Turin, Italy

more proximal segments of the aorta have been involved in the reconstruction with management of all visceral vessels in the treatment of thoracoabdominal aneurysms (TAAAs). Nevertheless, TAAAs with a large lumen at the level of visceral arteries would require long bridging stents in fenestrated designs, which could impair stability and long-term patency. For this reason, multibranched devices (branched endovascular repair, bEVAR) have been developed. The first experience with a multibranched endograft has been reported by Chuter in 2001, who implanted in a TAAA an on-table-modified four-vessel-branched endograft [3]. bEVAR designs consist of a tubular endograft with downward-oriented side branches to be extended into visceral vessels with self-expanding stents. The branches need to be accessed from an upper extremity access, either the axillary or the brachial artery.

23.2 Current Endografts

23.2.1 Custom-Made Grafts

Several endograft designs have been proposed by different companies for the management of thoracoabdominal aneurysms. Whenever construction time is not an issue (i.e., elective repairs), most operators rely on custom-made devices (CMDs): just like physician-modified grafts were created to fit patient anatomy, CMDs are designed and built based on aneurysm morphology (aortic neck diameters, lengths, and especially visceral vessel origin and orientation) identified at preoperative CT angiography.

The currently available custom-made endograft is commercialized by Cook (Zenith Fenestrated), Vascutek (Fenestrated Anaconda), and Jotec (E-Xtra Design).

23.2.1.1 Cook Zenith Fenestrated

Intro: The Cook Zenith custom-made fenestrated and branched endografts have been introduced in the European market in 2005 [4]. The whole device consists of a proximal main component with scallops, fenestrations, and/or branches for the visceral vessels, to be completed by a distal

bifurcated component (and related iliac limb). The proximal portion of the main component has a bare metal stent for proximal fixation and one or two Z-stents long (27–54 mm) sealing component ($\varnothing$ 24–36 mm) tapering distally to a diameter of 22 mm to achieve sealing with the 24 mm distal bifurcated component.

Regardless of the branched/fenestrated design, the graft includes gold markers at the proximal edge of the fabric, a check/tick marker (✓) to assess anteroposterior orientation, and three anterior vertical markers which combined to three posterior horizontal markers aid in identifying correct rotation with respect to C-arm position (Fig. 23.1). Each fenestration is identified by four radiopaque markers, at the top, bottom, and both sides of the opening. The branches instead have three markers on the proximal por-

Fig. 23.1 Intraoperative fluoroscopy demonstrating the markers of a fenestrated EVAR. Fenestrations are shown through four small gold markers. Gold markers at the proximal edge of the fabric, a check/tick marker at the distal edge to assess anteroposterior orientation, and three anterior vertical markers combined to three posterior horizontal markers are used to identify correct orientation of the graft

tion, on the inner side (closer to main graft fabric), and two markers at the distal end on the outer side (closer to the aortic wall).

Small fenestrations (6×6 mm and 6×8 mm), because of constructional constraints, need to be placed at least 15 mm lower than the proximal edge of the fabric, while large fenestrations can be designed >10 mm from the edge. On the European market, all fenestrations are reinforced and without struts crossing the opening (contrary from the US FDA-approved version).

The novel helical branches were proposed to increase mating length with the bridging stents and provide less sharp entry angles into the visceral vessels, while inner branches can be designed to deal with small residual aortic lumen (i.e., dissection or thrombotic wall apposition) when fenestrations are not preferred (Fig. 23.2).

In patients with a renal artery arising too close to the aortic bifurcation (e.g., prior EVAR or aortoiliac graft), a distal bifurcated component with an inverted iliac limb can be requested in order to deploy it lower onto the bifurcation.

Manufacturer: Cook Medical Inc.,
Bloomington, IN

Platform: Zenith Flex

Stent material: self-expanding stainless steel

Graft material: woven polyester

Available designs: downward/upward branches ($\varnothing$ 6 mm and 8 mm, 18/21 mm long), fenestrations ($\varnothing$ 6×6 mm, 6×8 mm, 8×8 mm, 10×10 mm, 12×12 mm), scallops (10 mm wide, 6–12 deep), helical branches, and inner branches

Application: thoracoabdominal, pararenal, and juxtarenal aneurysms

Available diameters: 24–36 mm

Delivery system diameter: 20 Fr (up to 34 mm $\varnothing$) and 22 Fr (36 mm $\varnothing$)

Peculiarities: diameter-reducing ties (single, double), preloaded catheters/sheaths, and free-flow

Limitations: construction time 4–6 weeks

23.2.1.2 Vascutek Fenestrated Anaconda

Intro: The Fenestrated Anaconda endograft was released on the market in 2011 and is significantly different from other available grafts in many aspects. The bifurcated nature of this graft

Fig. 23.2 Postoperative computed tomography angiography (CTA) of a patient treated with a combined fenestrated and branched endograft for a thoracoabdominal aneurysm

requires completion only by iliac extensions, but the lack of dedicated proximal thoracic components limits its application in extensive thoracoabdominal aneurysms since its sealing within currently available thoracic endografts has been reported to be suboptimal.

Manufacturer: Vascutek, Renfrewshire, Scotland

Platform: Anaconda AAA

Stent material: nitinol

Graft material: woven polyester

Available designs: fenestrations and augmented valley (comparable to a scallop)

Application: extent IV TAAA and pararenal and juxtarenal aneurysm

Available diameters: up to 34 mm

Delivery system diameter: 20–23 Fr

Peculiarities: repositionable, flexible (no supporting metal stents), no top cap (facilitates access from the upper extremities), magnetic iliac gate cannulation, and case rehearsal with 3D model and prototype

Restrictions: lack of dedicated proximal thoracic component for management of extensive thoracoabdominal aneurysms and construction time 3 weeks

The key characteristic of the graft is the lack of metal stents along the middle portion, where fenestrations are located, which confers extreme flexibility and conformability to tortuous anatomies and, we can assume, would be more forgiving in case of misalignment between fenestration and target ostium.

Proximal sealing is achieved by two circular nitinol rings, which can be collapsed after deployment to allow complete repositioning of the device at any stage before bridging of the visceral vessels.

The “fish-mouth” shape of the proximal component can be exploited to include an additional vessel as its valley can be employed as a scallop (Fig. 23.3).

The Anaconda graft has no top cap (i.e., Cook free-flow), and this can facilitate cannulation from an upper extremity access.

Lastly, the Vascutek Fenestrated Anaconda graft kept the magnetic cannulation tool present in the AAA device, facilitating access to the iliac gate and easing the challenge to access the fenestration from a femoral access which could be presented by the fixed bifurcated design (when compared to other straight tubular grafts).

23.2.1.3 Jotec E-Xtra Design Engineering

Intro: The Jotec E-Xtra Design Engineering graft has a tubular main body with branches/fenestrations placed in the middle portion which is tapered down to a diameter of 16 mm and then re-expands to provide sealing to a bifurcated component, if needed.

Manufacturer: Jotec, Hechingen, Germany

Platform: E-vita thoracic 3G

Stent material: nitinol

Graft material: woven polyester

Available designs: fenestrations, scallops, and branches

Application: thoracoabdominal, pararenal, and juxtarenal aneurysms

Available diameters: 24–40 mm

Delivery system diameter: 22–24 Fr

Peculiarities: E markers

Restrictions: construction time 18 days

Fenestrations are reinforced as for the Cook graft and have a diameter ranging from 6 to 12 mm, while branches have a diameter of 6–10 mm.

The anterior portion of the graft presents four “E” markers which, just like the Cook check/tick marker, provide information on anteroposterior position of the graft and its eventual rotation.

23.2.2 Off-the-Shelf Grafts

Urgent procedure seemed to be a limitation to total endovascular repair, but the introduction into the market of off-the-shelf devices has recently permitted to adopt this technique also in urgent cases.

23.2.2.1 Cook p-Branch

Intro: The p-branch was designed to manage juxtarenal aneurysms. This graft has a supraceliac fixation with a single bare steel stent, followed by one scallop for the celiac trunk, one 8-mm fenestration for the SMA, and two conical renal artery pivot fenestrations. Preloaded wires are present through both renal fenestrations. Immediately distal to the renal fenestrations, a tapered bridging stent reduces the diameter of the device to 24 mm to facilitate mating with a universal distal bifurcated body. Single diameter-reducing ties are present. Two different renal configurations are available, one with both fenestrations arising at the same height (configuration A) and one with the left renal artery (LRA) fenestration 4 mm lower than the right renal artery (RRA) fenestration (configuration B). The device is deployed through a 20-French system.

Fig. 23.3 Postoperative CTA of a patient treated with a fenestrated Anaconda stent graft

Manufacturer: Cook Medical Inc.,
Bloomington, IN

Platform: Zenith Fenestrated

Stent material: stainless steel uncovered barbed supraceliac stent and a series of nitinol Z-stents

Graft material: polyethylene terephthalate

Available designs: The tubular graft design provides a scallop for the celiac artery (CA) located at 12:30 and 11 mm lower 8-mm strut-free fenestration for the superior mesenteric artery (SMA), located at 12:00 o'clock. Two options for pivot fenestration of the renal arteries with respect to the SMA origin are available. *Configuration A:* the pivot fenestrations come off at the same longitudinal position of the device below the SMA. *Configuration B:* the right renal

fenestration is 4 mm higher than the left renal pivot fenestration. In both configurations the 6-mm right renal and left renal fenestrations are oriented at 9:30 and 2:30.

Application: juxtarenal and pararenal aneurysms, provided a healthy neck exists below the SMA

Available diameters: 26–36 mm in diameter

Delivery system diameter: 20 Fr (internal diameter)

Peculiarities: double renal pivot fenestrations configuration, single-reducing tie, and preloaded wire in both renal fenestrations

Restrictions: Proximal sealing zone should not be shorter than 4 mm below the SMA in an aorta that is ≤ 32 mm in diameter. Visceral vessels have to fit within the overlay targets of the provided planning and sizing grid.

23.2.2.2 Cook t-Branch

Intro: The off-the-shelf stent graft is built on the same platform of the custom-made devices for thoracoabdominal aneurysm but differs for its fixed design; the device proximal has a proximal diameter of 34 mm and features three sealing stents (76 mm); a covered stent at the proximal end contains barbs for additional fixation of the device. The graft then tapers down to 18 mm and gives off four downward-directed branches. Total length is 202 mm. Branches to celiac trunk and superior mesenteric artery are 8 mm in diameter and 21 and 18 mm in length, respectively, and axially located at 01:00 and 12:00 o'clock positions. Right and left renal artery branches are 6 mm in diameter, 18 mm in length, and located in the 10:00 and 03:00 clock positions, respectively. Four circumferentially placed gold markers are positioned within 2 mm of the most superior aspect of the graft. Each branch features three gold markers at the proximal internal edge and two gold markers at the distal outer edge. Three markers on the third and seventh stents and an additional thick-shaped gold marker are positioned anteriorly to ease proper orientation of the graft before deployment.

Manufacturer: Cook Medical Inc., Bloomington, IN

Platform: Zenith

Stent material: stainless steel Cook Z-stents

Graft material: woven polyester

Application: thoracoabdominal aortic aneurysm even in urgent/emergent setting

Available diameters: The device features a fixed configuration with 34 mm of proximal diameter that tapers to an 18 mm distal diameter

Delivery system diameter: 22 F internal diameter

Peculiarities: four branches for visceral vessels and off-the-shelf design

Restrictions: implantation rather higher than lower to fit higher number of anatomies

23.2.2.3 Gore TAMBE

Intro: Thoracoabdominal branch endoprosthesis (TAMBE) (WL Gore, Flagstaff, AZ) is a trimodular system with a proximal multibranched aortic component, a distal bifurcated component,

and iliac limb extensions. The multibranched component is now available in two different configurations. The original prototype featured a combination of antegrade and retrograde branches. The antegrade branches were dedicated to ensure direct flow to the celiac trunk (CT) and the superior mesenteric artery (SMA), while the retrograde branches were destined to the renal arteries. A second configuration that features four antegrade branches, one for each visceral vessel, is under investigation. The aortic component allows for placement of through-and-through preloaded guidewires to facilitate visceral vessel access, by eliminating the need for branch cannulation.

Manufacturer: WL Gore, Flagstaff, AZ

Platform: Gore® Excluder® AAA

Stent material: nitinol stent

Graft material: ePTFE

Available designs: combined antegrade (celiac trunk and superior mesenteric artery) and retrograde branch configuration (renal arteries) and fully antegrade branch configuration

Application: thoracoabdominal aortic aneurysm even in urgent/emergent setting

Available diameters: proximal diameters of 26, 31, and 37 mm, length of 215 mm, and distal diameter of 20 mm

Delivery system diameter: 22 Fr outer diameter

Peculiarities: The side branch components have CBAS® Heparin Surface, preloaded through-and-through guidewires, designed to be used with a dedicated covered balloon-expandable bridging stent Gore Viabahn BX or with the self-expandable Viabahn.

23.3 Bridging Stents

The choice of the correct bridging stents is crucial for the procedure's technical success and might play an important role in the short- and long-term clinical results in terms of occlusions, angulations, and stenosis. A large variety of stent grafts and bare metal stents are currently used in thoracoabdominal repair. Bare metal stents are usually used to reline distally a stent graft in order to obtain smoother curves and avoid kinks

and to increase distal landing zones in visceral vessels. Their application can be particularly convenient in case of poor landing zone and side branches originating from the target vessels. The following dissertation includes the most commonly used stent grafts implanted in total endovascular thoracoabdominal repair.

A critical step in these complex procedures is the placement of bridging stent graft (BSG) in visceral vessels to connect the main stent graft with these target vessels. The commercially available BSG is either balloon-expandable or self-expandable, and none of these have been specifically approved for fenestrated or branched endovascular exclusion of TAAAs (F/BEVAR).

23.3.1 Balloon-Expandable Stents

The advantages of these stents are precision in deployment and their radial force; nevertheless, they usually lack in flexibility. Multiple balloon-expandable covered stents could be utilized for fenestrations and branches: Maquet Atrium iCAST (US market) or Advanta (EU market) stent, Bentley BeGraft, and Gore VBX stents are the three most commonly employed.

23.3.1.1 Atrium Advanta Stent

Intro: The stent structure is made up of stainless steel stent, with an open cell design, encapsulated with two layers of polytetrafluoroethylene (PTFE) (Fig. 23.4). The presence of a double layer permits on one side to avoid direct contact of the struts with the arterial wall and on the other side to reduce the shear stress with respect to the bloodstream. The balloon can be easily recognized under fluoroscopy thanks to two gold markers at the proximal and distal end. The system is 0.035"

compatible and is mounted on a noncompliant balloon and is advanced under the protection of a long introducer sheath, with a profile (6–7 Fr) depending on the balloon's diameter and length. Stent's diameter ranges from 5 to 12 mm and length ranges from 22 to 59 mm.

Manufacturer: Maquet, Getinge group, Rastatt, Germany

Stent material: stainless steel

Graft material: double layer of PTFE

Available diameters: 5–12 mm

Delivery system diameter: varies according to stent diameter from 6 to 7 Fr

23.3.1.2 Bentley BeGraft Stent

Intro: The Bentley BeGraft stent has been recently introduced in the market for fenestrated and branched endografts. The single stent structure is made of chromium-cobalt and is covered with a microporous ePTFE fabric. The device is 0.035" compatible, with stent diameters of 5–10 mm and lengths of 18–58 mm. The stent is introduced using a 6 Fr (up to 8 × 58 mm) or 7 Fr delivery sheath depending on its nominal diameter.

Manufacturer: Bentley, Hechingen, Germany

Stent material: chromium-cobalt

Graft material: ePTFE

Available diameters: 5–10 mm and lengths of 18–58 mm

Delivery system diameter: 6 Fr up to 8 × 58 mm and 7 Fr for larger stents

23.3.2 Self-Expandable Stent Grafts

The main feature of these endografts is their flexibility that renders their use ideal in tortuous vessels. Their limitation is the impossibility to be

Fig. 23.4 The Atrium Advanta balloon-expandable stent graft

flared to increase seal within the fenestrations. There are multiple self-expandable stent grafts available for peripheral vascular procedures: WL Gore Viabahn and Bard Fluency being the most used.

23.3.2.1 Gore Viabahn Stent Graft

Intro: The Gore Viabahn self-expandable stent graft (WL Gore, Flagstaff, AZ) is made up of an external nitinol stent structure and an expanded PTFE fabric (ePTFE) (Fig. 23.5), with an extremely flexible structure. A balloon-expandable version of the stent is now under development and not for clinical use yet. Both 0.018" compatible and 0.035" compatible systems are available. Stent diameters range from 5 to 13 mm while available lengths 25 to 250 mm. Its profile, depending on stent diameter, ranges from 6 to 12 Fr.

Manufacturer: WL Gore, Flagstaff, AZ

Stent material: nitinol stent

Graft material: ePTFE

Available diameters: from 5 to 13 mm

Delivery system diameter: from 6 to 12 Fr

23.3.2.2 Bard Fluency Plus

Intro: The Bard Fluency Plus (Bard Peripheral Vascular, Tempe, AZ) is a self-expanding vascular ePTFE-covered stent with a nitinol structure (2 mm uncovered at each end) and inner carbon impregnation (Fig. 23.6). It is compatible with 0.035" system. Minimum stent length is 40 and maximum is 120 mm with diameters ranging from 6 to 13.5 mm. Recommended sheath diameters are 8 to 10 Fr. It is not as flexible as the Viabahn stent graft, but its advantages are a wide spectrum of lengths and diameters and the pullback deployment system with low risk of malpositioning.

Manufacturer: Bard Peripheral Vascular, Tempe, AZ

Stent material: nitinol

Graft material: ePTFE

Available diameters: from 6 to 13.5 mm

Delivery system diameter: 8 to 10 Fr

Fig. 23.5 The Gore Viabahn self-expandable stents grafts in different diameters and lengths

Fig. 23.6 The Bard Fluency stent graft

23.4 Lessons Learnt

23.4.1 Custom-Made Design According to Aneurysm Morphology

23.4.1.1 Branches in Large Sac

When considering custom-made graft design, a widely accepted rule is to opt for a branch to revascularize the vessel when the distance between the wall of aneurysm and that of the opening on the endograft is >10 mm.

This is the outcome of both intraoperative and postoperative considerations. If this distance is >10 mm, it means that, at that level, we most probably have a large aneurysm with little to no thrombotic apposition, and this allows an eventual branch to expand and leaves enough room to the operator to manipulate guidewires and catheters. Furthermore, deployment of endograft in large sacs can alter the desired clock orientation of the graft, thus making a fenestrated design less ideal.

In the postoperative period, we can assume that any endograft is more mobile at the level of a large sac than at the level of close apposition to the vessel wall or parietal thrombus; this mobility in a fenestrated design could eventually translate to a superior peri-fenestration stress on the bridging stent with consequent impairment on its patency and/or sealing.

23.4.1.2 Fenestrations in Dissection

Conversely in subacute and chronic dissections, the residual true lumen is usually smaller than the lumen in an atherosclerotic aneurysm. Therefore, fenestrated design is more commonly used whenever there is not enough room for a side branch to expand and allow target vessel bridging [5].

23.4.1.3 Fenestrated Previous Thoracic or Thoracoabdominal Open Surgery

The same issue with branch expansion arises whenever the patient had been previously treated for proximal aortic pathology. If the patient had undergone open thoracic aorta repair with distal

anastomosis close (<5 cm) to the origin of the celiac trunk, there would be no room for branch expansion within the surgical graft (reminder: branches are 18–21 mm and need to be deployed 20–50 mm above the ostium of the vessel). The same problem arises in visceral aortic patch aneurysms, in which the graft ends exactly at the level of the CT and with previous endovascular management of proximal TAA, if the graft had been deployed just above the origin of the CT in a healthy portion of the aorta (e.g., 20 mm Ø).

23.4.2 Management of Hostile Visceral Vessels

23.4.2.1 Fenestrations in Upward Vessels

The optimal design for visceral vessels originating with an upward angle had been shown to be a fenestration [6]. Classic downward branches are intuitively suboptimal, both because they require the target vessel to be catheterized from an upper extremity access, making it technically more difficult, and because of the angle at which the bridging stent will bend, most likely affecting long-term patency. The idea of upward branches has been explored and offered both by Cook custom-made grafts and Gore off-the-shelf TAMBE, although the main concern of patency is still present regarding this design.

23.4.2.2 Distal Bare Stent Reinforcement

In extremely angulated visceral vessels, expert operators sometime employ distal reinforcement of the bridging stents with bare self-expanding stents to better accommodate vessel curvature. Nonetheless no data is yet available on the impact of such approach on short- and long-term patency of the bridging stents [7].

23.4.2.3 Occlusion of Small Vessels

Mastracci et al. highlighted the inferior long-term patency of renal arteries when compared to the celiac trunk or superior mesenteric artery [8]. One of the factors deemed responsible could be the smaller diameter of renal arteries which,

together with the high resistance of the target organ, might explain the high occlusion rate. Furthermore, the smallest bridging stents available on the market are 5 mm in diameter.

23.4.2.4 No Long Bridging Stents

The relationship between bridging stent length and their patency rates has already been addressed [9]. While branched designs benefit of increased flexibility of application, both in terms of clock rotation and in terms of proximal/distal positioning, any graft should not be deployed too proximally just to fit the anatomy as longer bridging stents can both occlude and disconnect. Instead the distance between the bottom of the directional branch and the ostium of the target vessel should be between 20 and 50 mm as recommended by Cook IFU.

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