Historical Aspects and Evolution of Fenestrated and Branched Technology

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Introduction

Endovascular repair of aortic aneurysms (EVAR) has been disseminated worldwide since the first report by Juan Parodi in 1991 (Fig. 1.1). Since this initial disclosure, several innovators have worked on broadening the indications of EVAR to treat patients with complex anatomy. The Zenith AAA Endovascular Graft resulted from the collaboration of a global team of innovators. This team shared a common philosophy that the endovascular repair must seal in healthy aorta to provide a durable repair over the life of the patient. As a result of this philosophy, the Zenith was the first endovascular graft to incorporate proximal fixation and a modular three-piece system in combination with a delivery system that allowed for precise deployment. This enables the physician to place the graft in a position that takes advantage of all the available healthy aortic seal zone possible, while active fixation acts to maintain the seal over a prolonged period, ultimately resulting in a durable endovascular repair. Subsequently, nearly every commercially available endovascular graft for abdominal aortic aneurysm (AAA) repair has evolved to incorporate proximal fixation, modularity, and delivery systems offering more control of graft placement.

As experience grew in the early days of endovascular stent graft repair, it was quickly realized that not all patients were suitable candidates for standard infrarenal or thoracic endovascular grafts. These grafts were limited to the repair of lesions between the renal arteries and internal iliacs, or between the left subclavian and the celiac artery, where a suitable proximal and distal sealing zone remained without coverage of any major aortic branches. As disease encroached towards these branches, the options were to either compromise on the quality of the seal zones or incorporate the branches in order to have seal zones in healthy aorta. Driven by the aforementioned philosophy that the endovascular repair must land in a healthy segment of aorta to provide a durable repair, the group embarked upon developing the ability to incorporate critical branches into the seal zone. Ultimately these developments resulted in the possibility of treating patients with branches in the seal zones and branches arising from the aneurysm itself, making repair of complex thoracoabdominal (TAAA) and arch pathologies possible.

This chapter details the development of fenestrated and branched endografts from the first prototypes and clinical cases with simple fenestrated grafts in the late 1990s to the most recent developments where patients can be offered the possibility of endovascular treatment of the entire aorta from the sino-tubular junction to the internal and external iliacs.

Development of the Zenith Fenestrated Graft

The simplest structure that can be added to an endovascular graft to allow blood flow to a branch vessel is a fenestration (or hole) through the graft material. Challenges arise from the need to align the fenestration with the branch vessel during deployment, and in maintaining alignment with the vessel during the life of the endovascular repair, to ensure long-term branch patency. The need for three-dimensional precise alignment is the primary challenge in fenestrated endovascular repair when compared to infrarenal AAA repair. The Zenith AAA Endovascular Graft has a delivery system that allows for precise placement and proximal fixation to reduce migration and provide an ideal basis for incorporation of fenestrations.

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Fig. 1.1 Parodi, Palmaz, and Barone from Argentina reported in 1991 (Ann Vasc Surg 1991(6): 491–499) their initial animal experiments and clinical experience with endovascular aortic aneurysm repair. By permission of Mayo Foundation for Medical Education and Research. All rights reserved

The first fenestrated repair was reported by Park in 1996 using a device modification to incorporate an accessory renal artery in a patient with infrarenal aneurysm. In 1997, Dr. Tom Browne (Fig. 1.2) with the research team in Perth led by Michael Lawrence-Brown and David Hartley demonstrated deployment of an endovascular graft in an animal model in which a fenestration was aligned both longitudinally and rotationally to perfuse an aortic branch, which would otherwise have been covered [1]. This was achieved by deploying the fenestration over a balloon placed in the orifice of the target vessel. The first successful clinical fenestrated endovascular aneurysm repair (Fig. 1.3) was completed the next year by Dr. John Anderson in Adelaide, Australia. The first case was not aligned by stent in the fenestration. Later, John Anderson and the Perth team ensured long-term alignment by placing a balloon-expanded stent to hold tight the fenestration and target orifice. The technique was quickly disseminated through workshops run in Perth to the rest of Australasia, Europe, and Southeast Asia. Wolf Stelter (1998) in Germany suggested a composite body to the stent graft with a tubular upper module and a separate distal bifurcated component (Fig. 1.4). The upper tubular module was adapted for the fenestrations in Australia and in the USA Roy Greenberg (2001) energetically took up the technology and, by the force of large numbers of cases, excellent data, and concise presentations, demonstrated to the world that it was a viable method of treatment. Michael Denton performed the first thoracoabdominal repair using the fenestrated endograft to incorporate the celiac axis and superior mesenteric artery (Fig. 1.5). In the initial version of the device, two wires were used to constrain, and reduce the diameter of the device in its posterior wall. Today, fenestrated grafts with up to five fenestrations and scallops are routinely placed to treat short-neck AAA, juxtarenal AAA, pararenal AAA, and type IV TAAAs.

The simple hole in the graft material evolved to include nitinol rings on the margins of the fenestration to make a more durable connection with the stent (Fig. 1.6a), and covered balloon-expandable stents replaced bare stents (Fig. 1.6b) as they proved a more durable repair [2]. The use of covered stents also facilitated bridging small gaps between the endograft and aortic wall without the endoleak that would otherwise occur through the bare stent and into the aneurysm.

As the technique developed, there were several deployment-related improvements that enhanced the Zenith system to better facilitate fenestrated endovascular repair. Gold radiopaque markers were added to demonstrate the margins of the fenestration under fluoroscopy and facilitate location and alignment of the fenestrations with their respective target arteries (see Fig. 1.6a). Diameter-reducing ties were added to partially constrain the graft following release of the graft from the delivery sheath (Fig. 1.6c). In this way, some repositioning of the endovascular graft to perfectly align the fenestrations was possible. Further, the "composite" design wherein the body of the graft was manufactured in two parts, the proximal fenestrated component being a tube, and a separate distal component being bifurcated, simplifies the procedure by allowing alignment of the fenestrations during deployment of the proximal fenestrated component independent of the positional requirements of the bifurcation. It is also perceived that the sliding connection between the proximal and distal components reduces displacement forces applied to the fenestrations and connecting stents in the event of movement of the bifurcated component.

These developments above are all features of the commercially available Zenith Fenestrated AAA Endovascular, which was CE marked in 2005 and following a prospective trial of 67 patients at 14 centers in the USA was approved by FDA in 2012. The trial reported 100 % technical success, and no aneurysm ruptures or conversions during a mean follow-up of 37 ± 17 months (range, 3–65 months), and patient survival was 91 ± 4 % at 5 years [3]. Patient follow-up will continue through 5 years.

Regardless of the clinical success of the fenestrated platform, the need to cannulate branch vessels through fenestrations in the graft and placement of stents through these

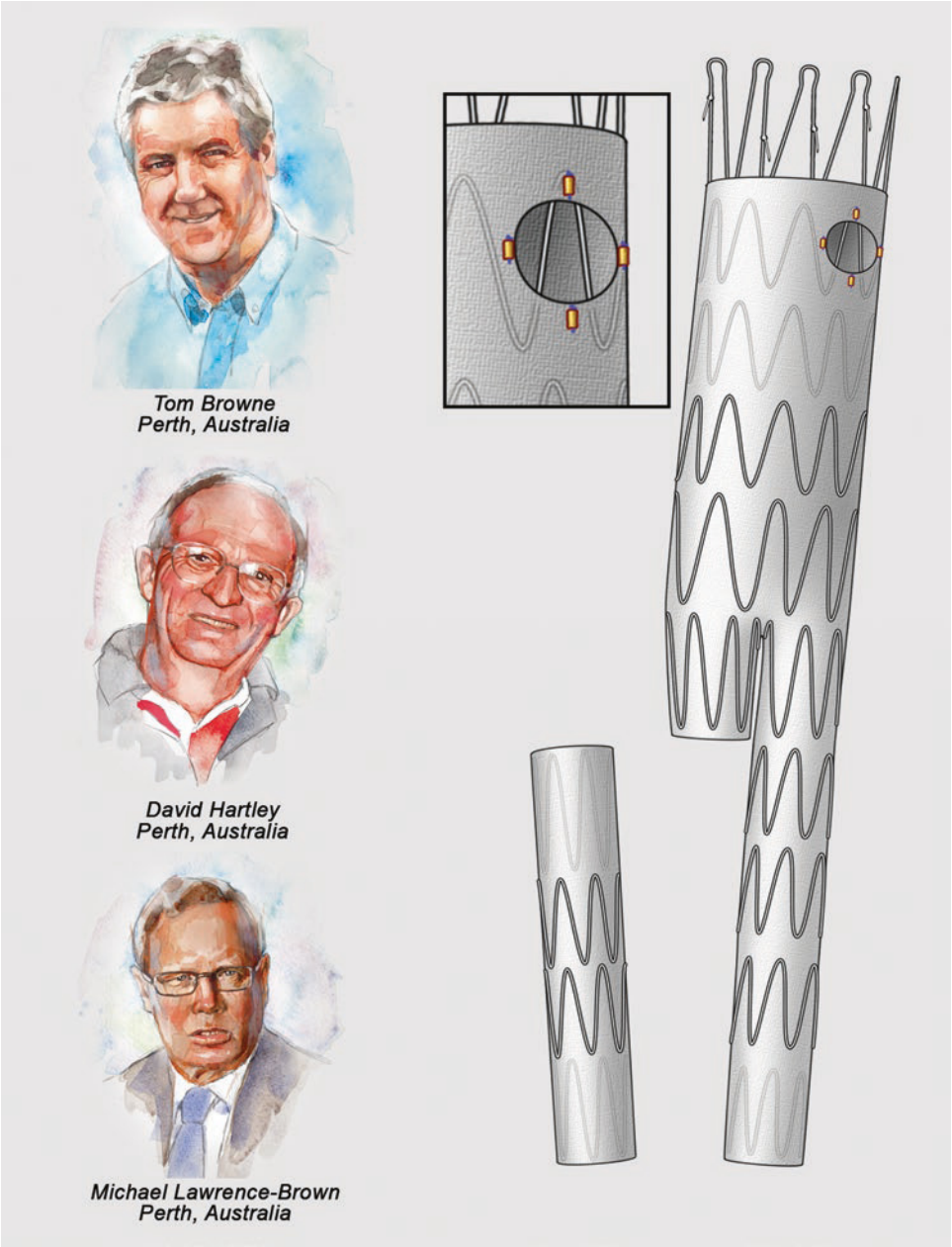

Fig. 1.2 The Perth research team of Tom Browne, David Hartley, and, led by, Michael Lawrence-Brown were instrumental in the initial animal experiments. The initial graft design was based on the Zenith Bifurcated Stent with suprarenal fixation. The fenestration was not reinforced and had radiopaque markers. Stent struts are noted across the fenestration, which at the time was not intended to be stented. The detailed designs and prototypes for the majority of the subsequent Cook production fenestrated and branched devices evolved out of the Perth R&D facility. By permission of Mayo Foundation for Medical Education and Research. All rights reserved

fenestrations from a contralateral approach added additional challenge to the procedure over a standard infrarenal AAA repair. In addition, the need to place the stents from a contralateral approach limited applicability of the fenestrated technique in patients without bilateral access. Towards these ends, and as suggested by Krassi Ivancev (Sweden), a novel preloaded delivery system (Fig. 1.7) was developed with its first use by Dr. Brendan Stanley in Perth, in May 2007, closely followed by Drs. Greenberg (USA), Ivancev (Sweden), Ferreira (Brazil), and Haulon (France), all of whom recognized the potential of the system to simplify procedures and contributed to its development. Rather than relying on contralateral access for targeting branch vessels, ports were added to the fenestrated delivery system to allow ipsilateral access with preloaded guide wires and sheaths for cannulation of target vessels and placement of the branch stents. The added inherent stability and control offered by the system simplifies vessel cannulation and placement of stents through the fenestrations.

The preloaded delivery system facilitated the most recent evolution of fenestrated repair: an off-the-shelf device to treat short-neck AAA, juxta-renal AAA, and pararenal AAA. Planning, manufacturing, and delivery of a fenestrated device built for a specific patient can take several weeks.

Fig. 1.3 The first clinical implant of a fenestrated stent using the Cook Zenith platform was performed by Dr. John Anderson in Adelaide, Australia. This illustration based on the actual case depicts a single left renal fenestration. The patient had been previously treated for a high-grade left renal stenosis by placement of a bare metal stent, which was carefully deployed inside the vessel. Note that the fenestration was non-reinforced and was not aligned by stent. By permission of Mayo Foundation for Medical Education and Research. All rights reserved

This delay limits the potential for this technology in patients who experience a rupture, are symptomatic, or have a large aneurysm. The Zenith p-Branch is an off-the-shelf fenestrated device. The device includes a large scallop for the celiac artery, a standard fenestration for the superior mesenteric artery, and two pivot fenestrations for the renal arteries (Fig. 1.8). The device is deployed as a standard fenestrated graft, with focus on alignment of the SMA fenestration with its target. The dome-shaped pivot fenestrations are designed to allow for offset of the renal arteries from the renal fenestrations. In this way, a singular device can be used to treat a range of patient anatomies. The additional stability and control afforded by the preloaded fenestration delivery system, which is part of the p-Branch package, help to offset possible challenges in cannulation of renal arteries from the fenestrations. Tim Resch followed by Stephan Haulon completed the first p-Branch cases in 2011 [4, 5] and pre-approval clinical studies are currently under way (see Fig. 1.8).

Preservation of Normal Anatomy

Another key philosophy from surgery translated into endovascular techniques is the preservation of normal anatomy whenever possible. It is possible to restore blood flow to critical branches via surgical bypasses in combination with standard endovascular grafts that cover and occlude blood flow the native vessel ostia or via so-called parallel grafts. Although such "hybrid techniques" were a critical step in treating more patients by endovascular approaches, they most definitely do not preserve normal anatomy and hybrid techniques have the further downside of necessitating surgical intervention in combination with the endovascular repair. Fenestrations are the foremost example of preservation of normal anatomy in endovascular aortic repair that incorporate blood flow to branch vessels. In fenestrated repair, the structure of the combined endovascular graft and covered bridging stent placed in the branch vessel often replicates the

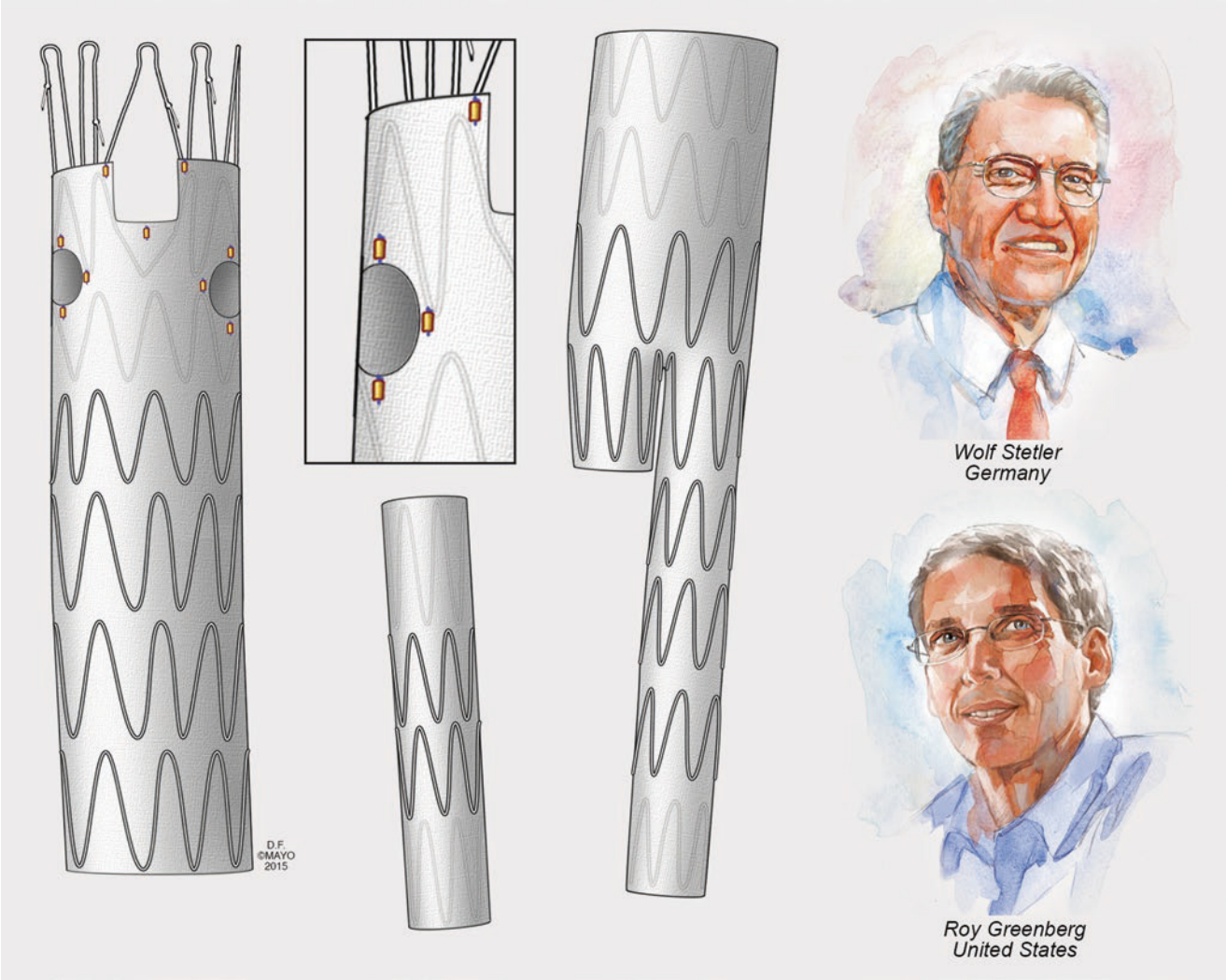

Fig. 1.4 Progress in the design of the fenestrated graft is credited to Wolf Stelter in Germany who suggested the concept of a separate tubular component with the fenestrations and a distal bifurcated component. Roy Greenberg in the USA is credited with applying the technology to wide clinical use, treating complex anatomy with multiple fenestrations and scallops in a large number of patients. The fenestrations at this point were not reinforced, but the design had evolved to avoid struts across the fenestrations, with the intention to align the fenestration to the target vessel with an "alignment" stent. By permission of Mayo Foundation for Medical Education and Research. All rights reserved

native anatomy to within a millimeter or two. In some instances, blood flow may even be optimized as any stenosis in the orifice may be resolved by the stents. Angulation and tortuosity of branches may provide additional challenges to branch stent conformance to the anatomy leading to distortion at the junction of the stents with the arteries or kinking of the stents. In practice, additional self-expanding stents are often added to help address these transitions and to provide long-term branch patency. The transition at the end of the distal end of the connecting stent in the target vessels remains a challenge with some of these procedures.

Directional Branches

Endovascular branched grafts used to maintain blood flow to critical aortic branches were not an independent innovation but rather a continued evolution of previous designs. The Chuter unibody bifurcated abdominal aortic graft in 1993 was the first example of a branch device, to preserve native anatomy and patency of both iliac arteries, when the common practice at the time was to employ an aorto-uniiliac graft and a surgical fem-fem crossover procedure. This was followed by modular bifurcated branch devices with off-the-

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