Historical Aspects and Evolution of Fenestrated and Branched Technology

1

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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.

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

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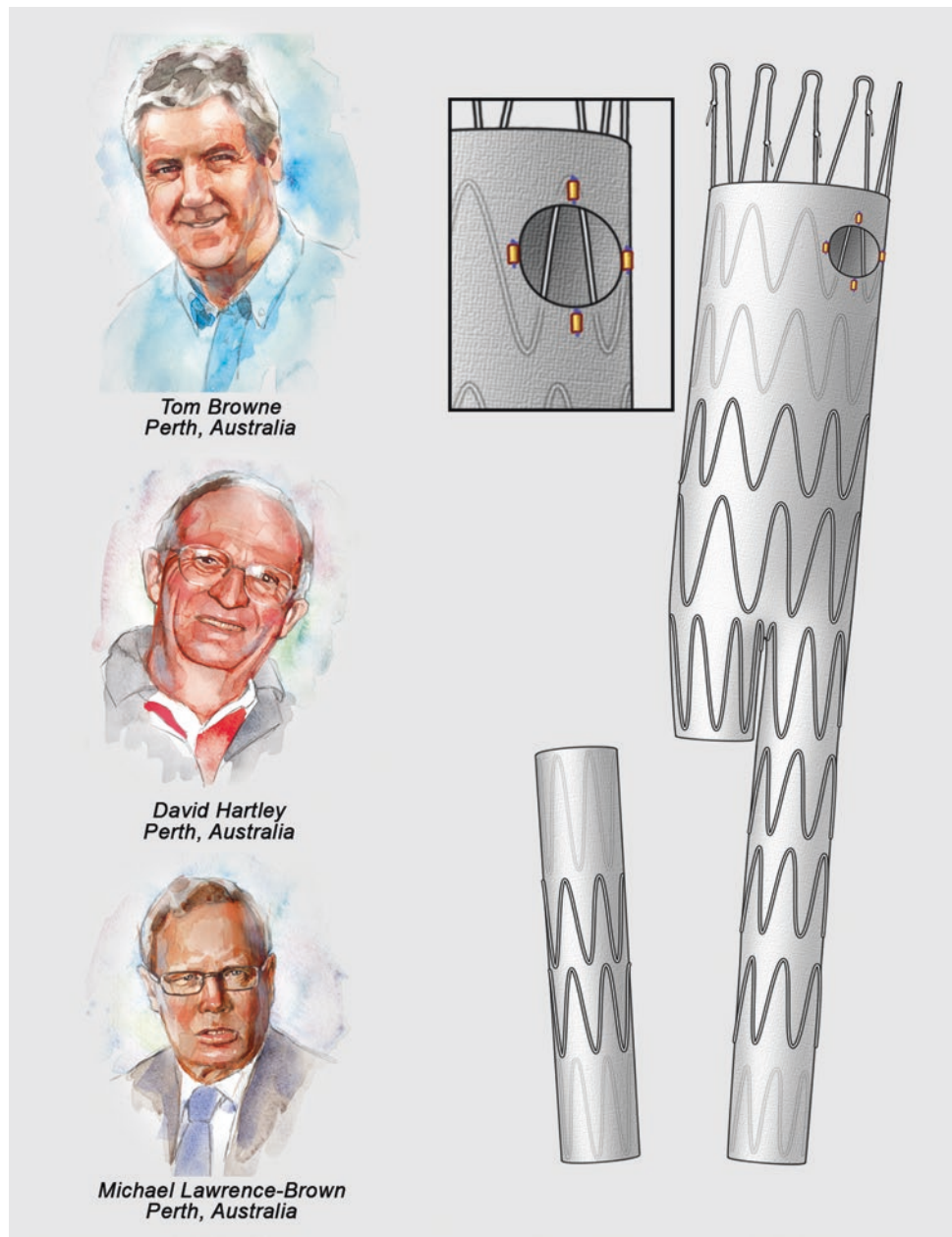
fenestrations from a contralateral approach added additional challenge to the procedure over a standard infrarenal AAA repair. In addition, the need to place the stents from a contralateral approach limited applicability of the fenestrated technique in patients without bilateral access. Towards these 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 rely-

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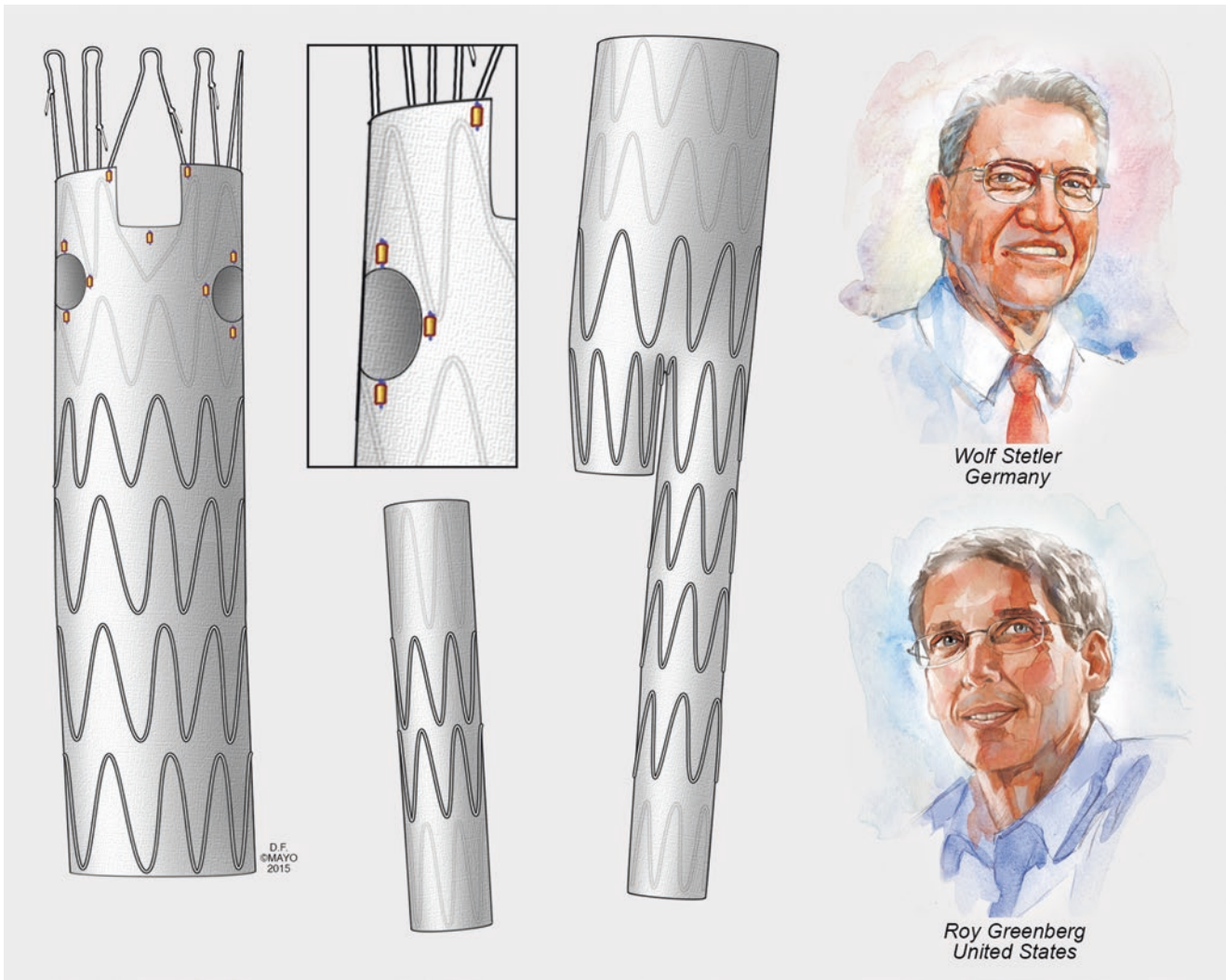
Fig. 1.4 Progress in the design of the fenestrated graft is credited to Wolf Stelter in Germany who suggested the concept of a separate tubular component with the fenestrations and a distal bifurcated component. Roy Greenberg in the USA is credited with applying the technology to wide clinical use, treating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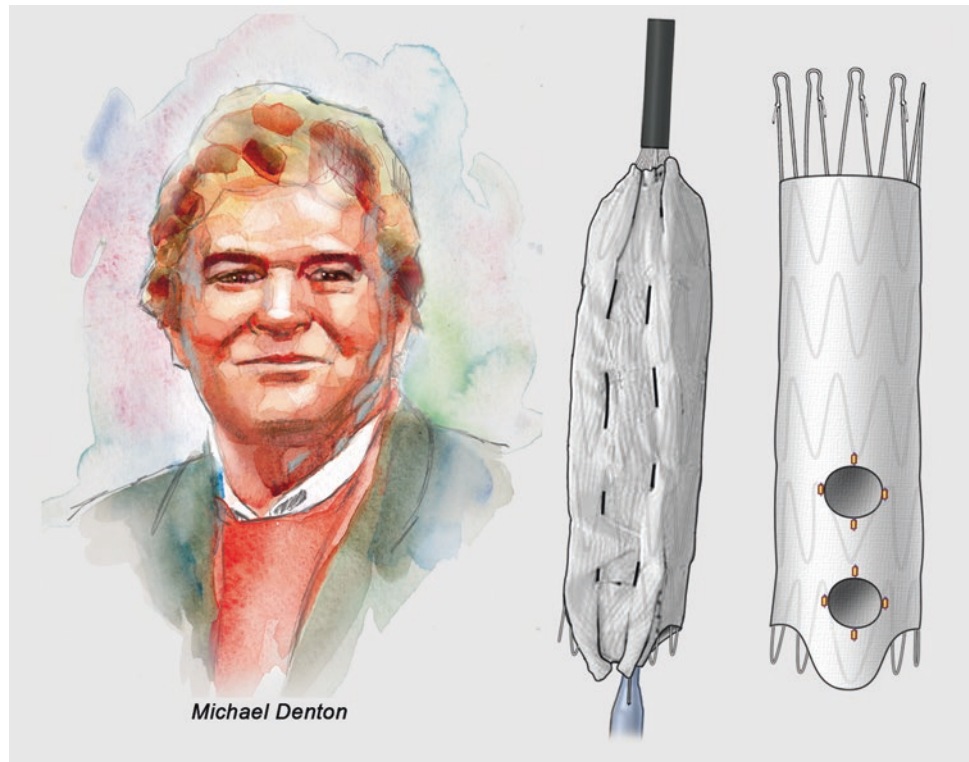 anatomy with multiple fenestrations and scallops in a large number of patients. The fenestrations at this point were not reinforced, but the design had evolved to avoid struts across the fenestrations, with the intention to align the fenestration to the target vessel with an "alignment" stent. By permission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

shelf components to accommodate a wide range of iliac artery anatomy and simplified the procedure by allowing implantation in a staged fashion. When the use of fenestrated grafts to save renal arteries began in 1997, it was a small step forward to use a covered stent in the fenestration, and turn it into what was effectively a side branch.

However, for the sake of clarity, branched endovascular grafts are now distinguished from their fenestrated counterparts by having a tubular protrusion arising from the main lumen of the endovascular graft. The rationale for using such a connecting structure is that when self-expanding bridging stents are used to bridge the gap across an aneurysm space, it provides more surface area for seal and security. It can also direct the bridging stents, aligning them towards the target vessel in a direction that matches native anatomy, and allows more latitude in the positioning of these bridging stents.

Initial development of branched endovascular grafts was focused in two areas: (1) a branch for the internal iliac artery in patients with iliac or aorto iliac aneurysms and (2) branches for the visceral vessels in patients with extensive TAAA. Today, branched stent grafts have evolved to include the treatment of aortic arch disease.

Iliac Branch Device

The first use of an iliac branch device to maintain flow to the internal iliac artery was performed successfully by Dr. Marcel Goodman in 2001 (Perth, WA). Professor Wolf Stelter (Frankfurt, Germany), also involved in the development of the iliac branch device (Fig. 1.9), completed the first large series of cases soon after that [6]. Initial attempts at iliac branch repair paralleled early approaches to complete infrarenal AAA repair with a unibody (single piece) bifurcated endovascular prosthesis. Similar to the experience with AAA repair, the device implantation was simpler and the required device sizes required to treat varying patient anatomy were reduced by a modular approach.

Ultimately, the graft design was similar to that of a standard iliac leg extension with a small branch added a few centimeters from the proximal end of the graft. Two unique versions of the device were developed. The first version had a straight branch that was designed to be used in combination with a balloon-expandable covered stent to bridge to the internal iliac artery. The second version, pioneered by Roy Greenberg (see Fig. 1.9), had a helical branch that intended to align the branch with the internal iliac and use a self-expandable covered stent to connect to the internal iliac. The philosophy behind the helical device was to better manage the often angulated takeoff of the internal iliac and narrowing in the iliac bifurcation [7].

The iliac branch device is intended to be the first component placed in the repair. The graft seals distally in the external iliac artery and can land proximally at or below the aortic bifurcation. A preloaded catheter facilitates placement of a femoral-to-femoral through-wire that further
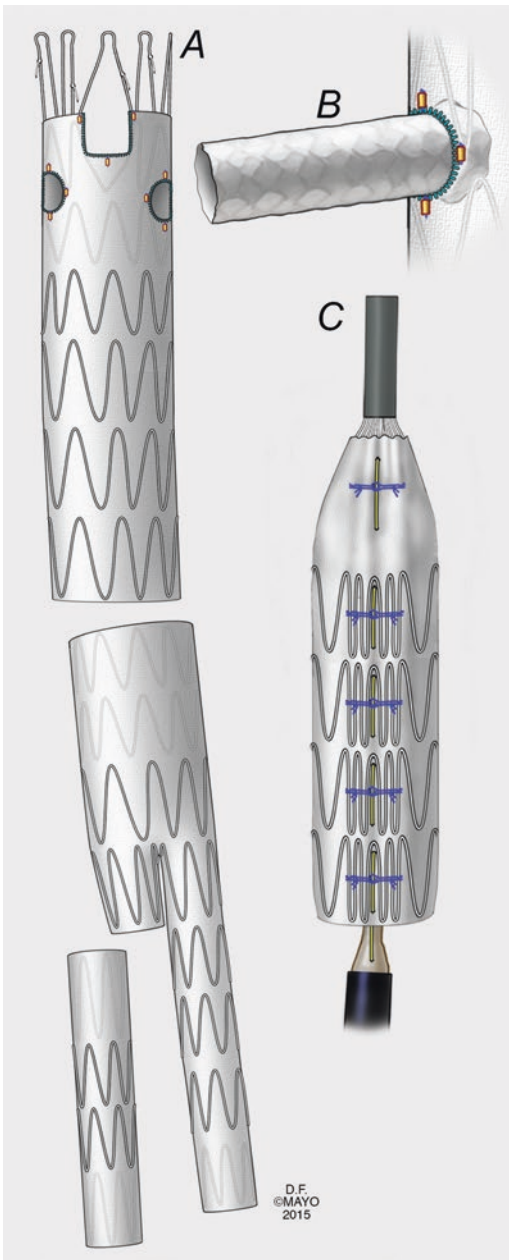
Fig. 1.6 Evolution of the Zenith fenestrated graft included the addition of a nitinol-reinforced ring and gold radiopaque markers (**a**), the use of covered stents to replace bare metal stents for alignment of fenestrations (**b**), and diameter-reducing ties (**c**). By permission of Mayo Foundation for Medical Education and Research. All rights reserved

facilitates access to the branch, stability during cannulation of the internal iliac artery, and placement of the bridging stent from a contralateral approach. The repair is completed with a bifurcated device deployed above the iliac branch device and short limb connecting the short limb of the bifurcated device to the proximal end of the iliac device prosthesis. The Zenith Branch Endovascular Graft was CE marked in 2006 with the helical version approved in 2007. The pivotal US trial completed enrollment in early 2015. FDA approval is expected in 2016.

A third iliac branch device, the bi-branch was developed in collaboration with Dr. Stephen Cheng in Hong Kong and Roy Greenberg and is currently under clinical evaluation at the Cleveland Clinic (see Fig. 1.9). The device incorporates the branch for the internal iliac in the leg of a bifurcated prosthesis rather than in a leg extension. The repair is completed with a proximal cuff landing below the renal arteries and a contralateral iliac leg extension. The concept was originally developed for use in patients with short common iliac arteries, because removal of two modular connections between the aortic graft bifurcation and the internal iliac branch shortened the overall length of the device. The device also found favor in use for preservation of internal iliac arteries in combination with other composite systems such as fenestrated or TAAA repairs. Preservation of internal iliac arteries is critical in TAAA repairs to minimize the risk of paraplegia.

Thoracoabdominal Multibranch Repair

Dr. Tim Chuter (Fig. 1.10) implanted the first multibranched device for TAAA repair [8]. The branched component had four branches (Fig. 1.10a), and was physician-manufactured and constructed of Z-stents sewn to Dacron fabric and remarkably similar to the design of visceral branched grafts manufactured today with two 8 mm braches for the SMA and celiac arteries and two 6 mm branches for the renal arteries.

The first Cook-manufactured side branch was in the form of a short extension (Fig. 1.10b), only a few millimeters long, attached to the outside of a fenestration in a thoracoabdominal fenestrated endovascular graft. This graft was placed by John Anderson in 2002. The axis of these early cuffs was orthogonal to the long axis of the graft but soon evolved in accordance with the principle of the Chuter design to have the cuffs arise from the graft at a lesser angle, nearly parallel to the graft itself (see Fig. 1.10b). In a further development of the original Chuter design, the side branches were manufactured to minimize profile, and strategically placed above each target vessel such that they could be cannulated and stents placed in an antegrade fashion (Fig. 1.10c). The graft evolved to its current design (t-Branch stent graft) with four directional branches as an off-the-shelf alternative (Fig. 1.10d).

An alternative configuration conceived and most commonly used by Roy Greenberg had helical branches to preserve flow to the celiac and SMA and fenestrations with covered stents to provide flow to the renal arteries. Although use of helical branches in the treatment of TAAA is less common than straight branches, device strategies that primarily combine branches for the SMA and celiac and fenestrations for the renal arteries are commonplace today.

Key design principles for the ideal branch are as follows: the branches should be short in length, long-overlap is essential for a stable repair and long-term durability, and the trajectory of
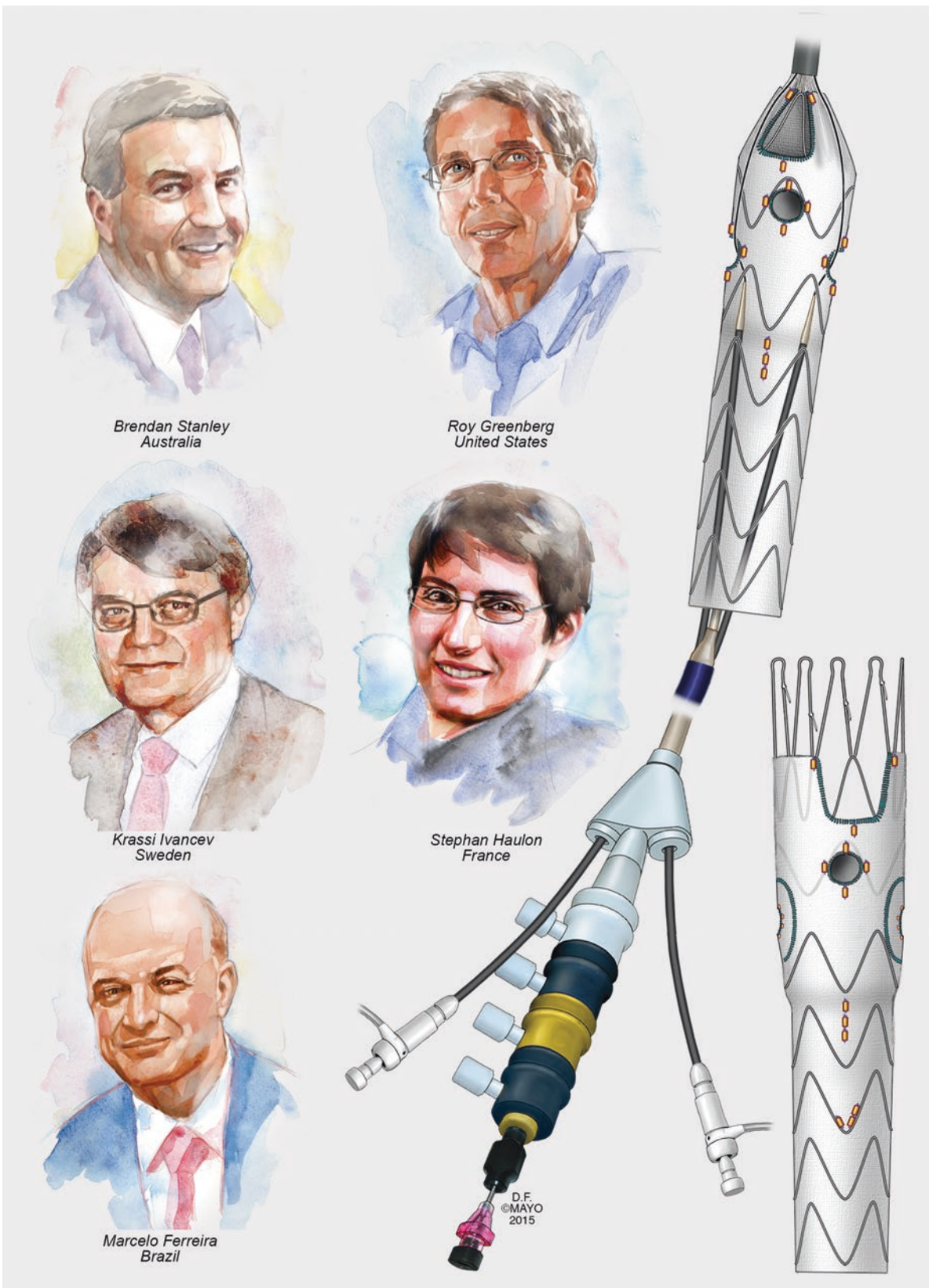
Fig. 1.7 Development of the preloaded delivery system to facilitate fenestrated repair was first suggested by Ivancev, and became a collaboration of multiple investigators including Drs. Stanley (Australia), Greenberg (USA), Ivancev (Sweden), Haulon (France), and Ferreira (Brazil). By permission of Mayo Foundation for Medical Education and Research. All rights reserved

Fig. 1.8 The p-Branch fenestrated graft evolved as an off-the-shelf alternative to treat juxta-renal abdominal aortic aneurysms. The device has a double-wide scallop for the celiac axis, a fenestration for the superior mesenteric artery, and two pivot fenestrations for the renal arteries. The initial clinical experience was by Tim Resch in Sweden and Stephan Haulon in France. By permission of Mayo Foundation for Medical Education and Research.
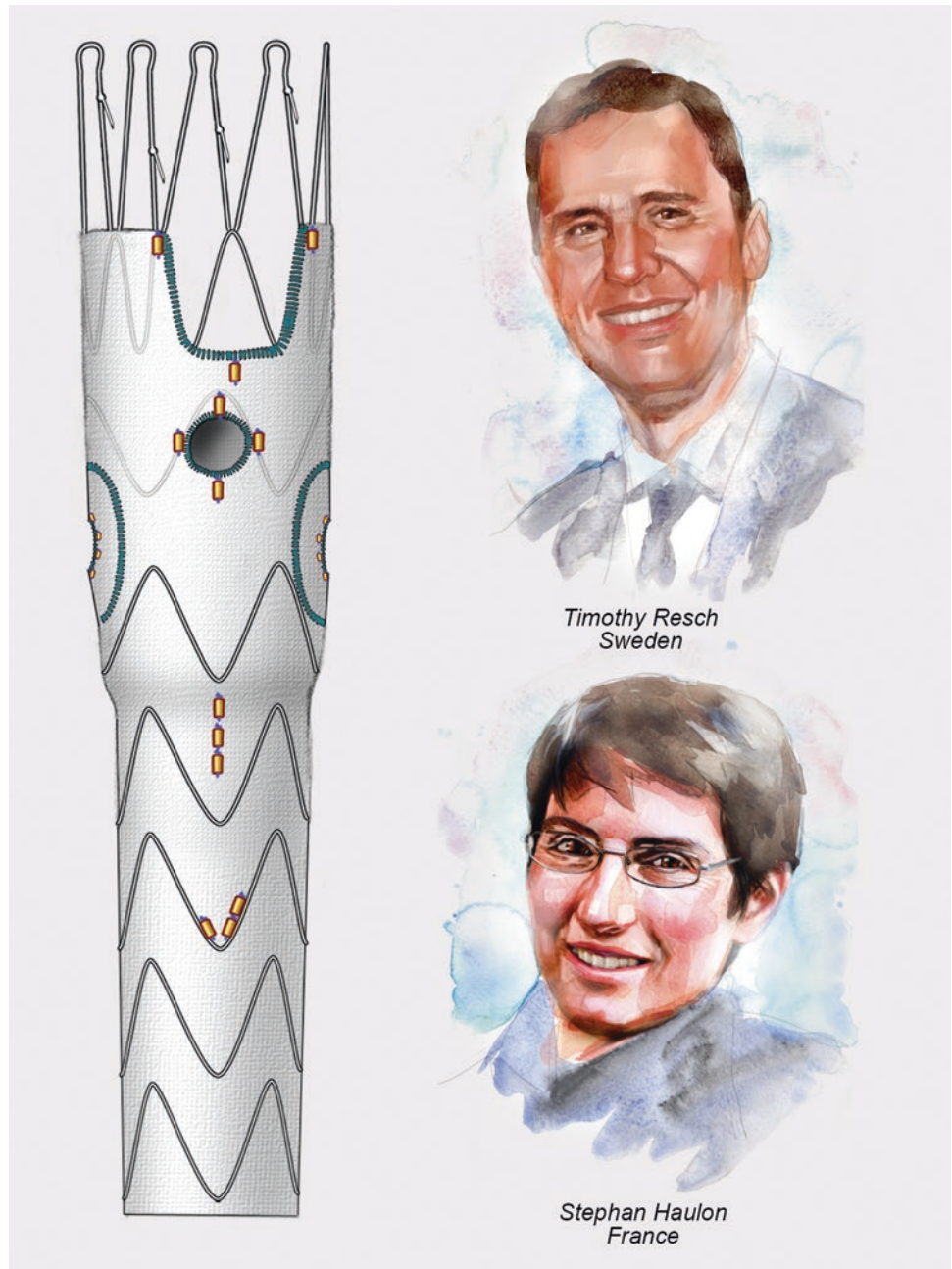
the branch as it arises from the graft should be aligned with the target vessel. In this way, angulation of the branch stent and tendency towards kink is greatly reduced. Regardless of branch configuration, these principles provide a solid foundation for design of fenestrated and branched endovascular repairs.

In theory, endovascular branches spanning an aneurysmal space allow some flexibility in offset of the branch from the target vessel. Taking advantage of this property, Tim Chuter's suggestion to the research team in 2008 proposed a standardized design for a TAAA branched graft [9]. This analysis determined that a majority of patient's visceral vessel anatomy could be accommodated with a single four-branch configuration, something that could potentially be available off the shelf. Ultimately the Zenith t-Branch, an off-the-shelf four-branch device to treat TAAA was CE marked in 2012 (see Fig. 1.10d).

In spite of the availability of an off-the-shelf solution, a significant portion of endovascular TAAA repairs are still completed using grafts manufactured for specific patients. Advantages to this approach include tailoring branch and potentially fenestration locations and branch graft dimensions

Fig. 1.9 Evolution of endovascular repair to extend the landing zone into the external iliac artery required creation of an iliac branch device. The initial case by Marcel Goodman (Australia) and a larger clinical experience by Wolf Stelter (Germany) using the prototype depicted in the illustration, which evolved later into the straight iliac branch device currently utilized. The helical branch pioneered by Roy Greenberg later evolved into a bifurcated-bifurcated device with a helical branch. By permission of Mayo Foundation for Medical Education and Research. All rights reserved

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to fit an individual patient's anatomy. Branches can even be included that have an upwards orientation if such a design will be a better match for the target vessel anatomy. Branch/fenestration locations that accurately match a patient's anatomy have the potential to simplify deployment and improve outcomes. Custom tailoring of graft dimensions may also reduce

the number of components required for the repair and limit the amount of coverage in the thoracic aorta. For these reasons, device usage for TAAA repair remains a split between off-the-shelf designs and grafts built for a specific patient.

The first low-profile TAAA repair was completed in early 2011 by Tim Chuter at the University of California, San
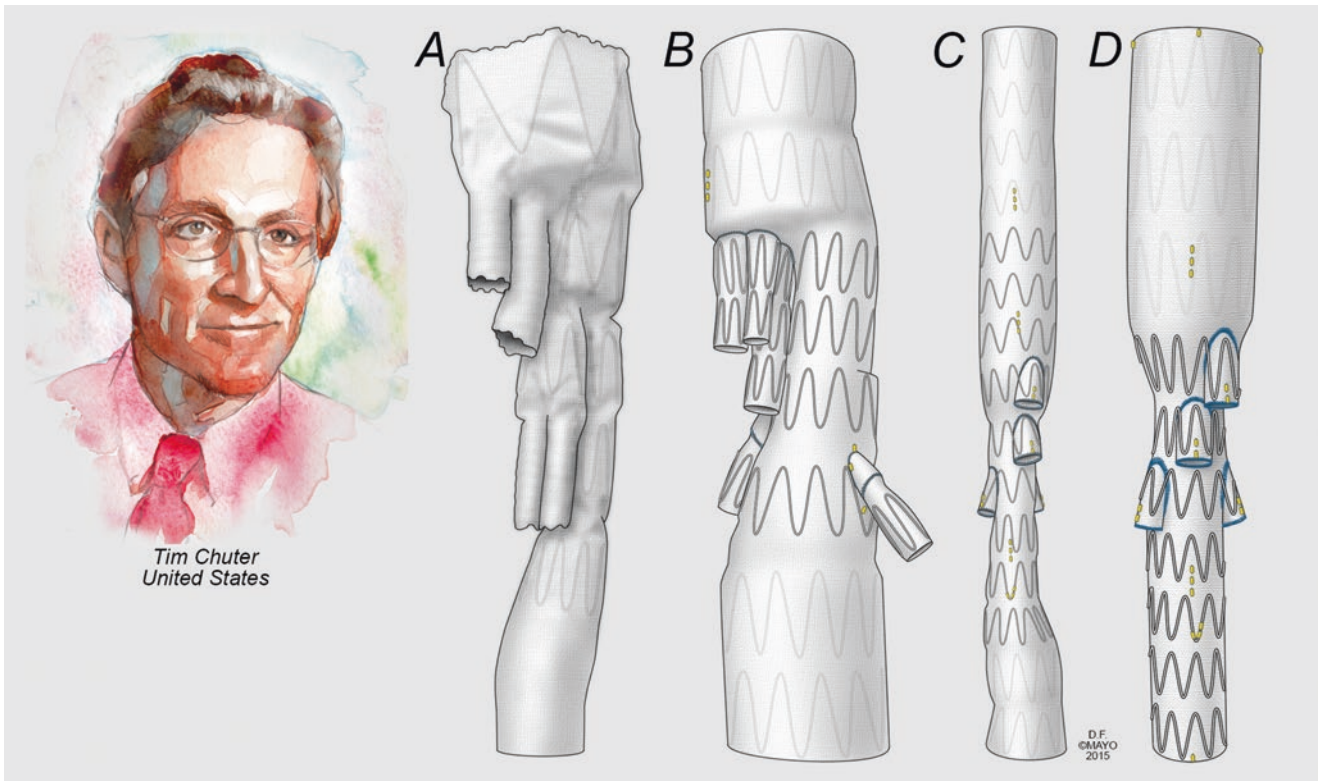
Fig. 1.10 Tim Chuter is credited for the development and first clinical use of a multibranched thoracoabdominal device. The illustration depicts evolution of the device based on photographs of the first implant (**a**), first versions of a manufactured device (**b**, **c**), and current off-the-shelf t-branch stent graft (**d**). By permission of Mayo Foundation for Medical Education and Research. All rights reserved

Francisco. The graft had four downward-facing branches similar to the Zenith t-Branch. Delivery sheath profile was reduced by 4 Fr from 22Fr to 18Fr. Low-profile systems may provide the biggest benefit in the thoracic aorta as graft delivery systems are often larger to begin with and TAAA occur at a higher rate in women who often present with access challenges.

Arch Branch Device

As with short-necked infrarenal aortic aneurysms, where fenestrations and scallops were used to move the seal to a more proximal region, the same concept was applied in thoracic grafts, with scallops and fenestrations used to extend the sealing zone proximally to the level of the innominate, left common carotid and left subclavian arteries (Fig. 1.11a). The first clinical case performed by Dr. Peter Mossop and Ian Nixon in Melbourne, Australia, occurred in 2000 and had a fenestration to preserve the flow in a left subclavian artery.

This approach required extreme accuracy in deployment to align fenestrations and scallops with target vessels. Deployment of the graft in the arch from a femoral approach makes precise positioning a challenge. Preloaded catheters were used to assist in alignment of fenestrations and scallops to the vessels, but this technique still provided a challenge especially in difficult anatomy, even for very skilled operators.

The first case of a branched endovascular graft involving all of the branches in the arch was described by Tim Chuter in 2003 [10]. This approach relied on debranching of the arch, including carotid-carotid and carotid-subclavian bypasses. The branch graft was delivered through the right carotid artery and sealed proximally in the ascending aorta and in the innominate trunk (Fig. 1.11b). A single large-diameter branch directed to the distal arch. A standard thoracic graft delivered from a femoral approach, landing in this branch, completed the repair. A primary limitation of this technique was the requirement of a large-caliber delivery sheath for the branch graft through the right carotid artery.

Early endovascular approaches described above and experience from hybrid techniques where cervical debranching and a bypass arising from the ascending aorta are used in combination with standard thoracic endograft sealing proximally in the distal ascending aorta provided the initial experience with endografts in the ascending aorta and arch. Combined, these techniques clearly demonstrated the potential benefits but also the primary challenges associated with arch endovascular repair:
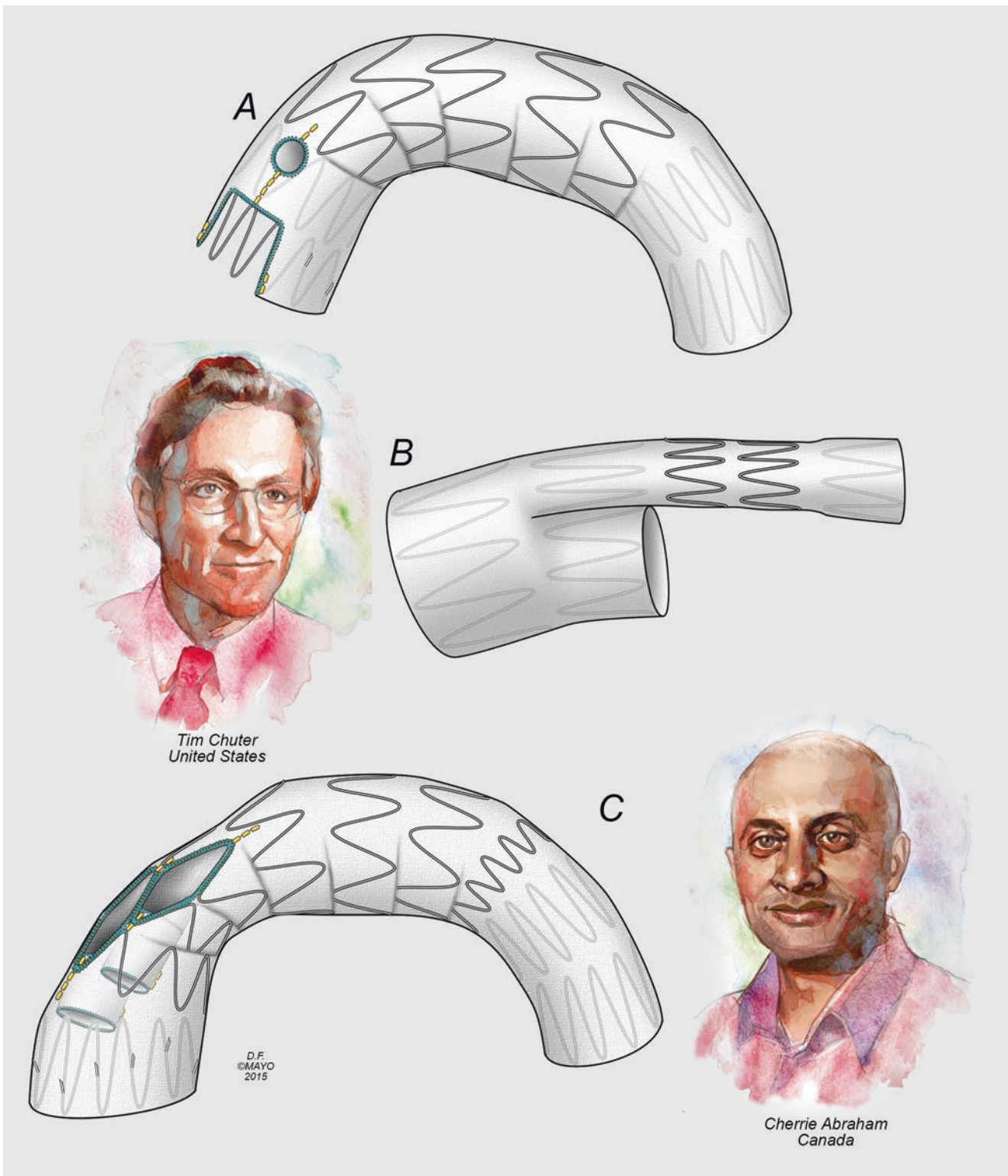
Fig. 1.11 Evolution of the arch branch device from initial experience using fenestrations and scallops (**a**) to the first full arch repair by Tim Chuter (**b**). The first clinical use of the third-generation device with diamond-shaped fenestrations is credited to Cherrie Abraham (**c**). By permission of Mayo Foundation for Medical Education and Research. All rights reserved

accuracy in landing, conformance to the aorta, access challenges, morbidity from surgical bypasses, mortality, and stroke.

In late 2009, the first multibranched graft for a total arch repair was implanted by Cherrie Abraham (Fig. 1.11c) in Montreal, Canada, who also described the initial experience with the technique [11]. Cases soon followed using a slightly modified design including completely internal cuffs and branches with Tim Chuter, Roy Greenberg, Krassi Ivancev, Stephan Haulon, and Brendan Stanley contributing to the design. The graft is intended to land in the ascending aorta and eliminates the need for precise positioning with respect to the branches of the arch. Moreover, the introducer is designed to rotationally align the branches to the outer curve of the arch. The branches are internal to the endograft and incorporate a wide, diamond-shaped opening to facilitate retrograde cannulation. Although it was initially applied to patients with arch aneurysms, the technique has found applicability in patients with chronic type A dissection [12]. Patients with prior surgical repair of the ascending aorta often present with the need to repair the remainder of the arch. The surgical graft provides an excellent landing zone for an endovascular repair. Iterative improvements are still under way. One such modification to the delivery system allows treatment of patients with a mechanical aortic valve [13]. Results with the latest versions have been generally better than previous approaches, but clinical evaluation is still under way [14].

Dissemination of the Technique

It is important to note the significance of a global, collaborative, multidisciplinary team to translate their philosophies, ideas, and technologies into viable new devices and therapies for patients. The original collaborators were not from a single specialty. Many of the innovators undertook multidisciplinary training programs in vascular surgery and interventional radiology. One example of many is the Malmo experience where Krassi Ivancev contributed his enthusiasm and interventional radiology skills and knowledge together with the vascular surgery specialty to form a multidisciplinary endovascular unit. A measure of the success of this approach is that the unit attracted visitors such as those with the talents of Tim Chuter, and Roy Greenberg, who, along with many others trained, benefited, and contributed to the development of the technology. The global team importantly included innovative engineers and technicians who not only applied their skills in prototype manufacture development and testing, but because of their close involvement, and understanding of the clinical, technical, and regulatory requirements and opportunities, contributed significantly to the concept and detailed specification of devices for clinical research programs in countless locations around the world. Even after the field of endovascular surgery became established, embarking on repairs of the aortic arch involved collaboration with cardiac and thoracic surgeons. As a result of this collaboration, branched and fenestrated devices are now capable, in many instances of treating aneurysms and dissections of the entire aorta.

The philosophy of fenestrated and branched stent graft technology is based on a common set of fundamental principles: achieving seal in healthy aorta, matching the native anatomy whenever possible, and optimizing the endovascular repair for long-term durability. Although initially theoretical, these design philosophies have been validated with clinical data that has enabled extension of the technology from the initial treatment of a limited number of patients under compassionate use to commercially available devices that are used to treat thousands of patients each year. In summary the initial fenestrated experience from Australia [15] provided the impetus to disseminate the techniques, particularly in Europe, with CE-marked devices. In the USA, Roy Greenberg was the primary driver of clinical studies for branched and fenestrated endovascular grafts with now over 1000 patients enrolled in the studies he initiated in prospective clinical trials at the Cleveland Clinic [15, 16]. His large database and his willingness to share his experience contributed significantly in the acceptance of these techniques internationally. The many he trained, including Matt Eagleton, Stephan Haulon, Tara Mastracci, Gustavo Oderich, and Tim Resch, not only continue his studies, but have also developed comprehensive endovascular research programs around the globe (Fig. 1.12). In parallel, Eric Verhoeven has developed the largest European experience approaching 1000 fenestrated and branched cases in his centers and cases proctored in other centers. Experienced physicians proctoring new users of the technology have been critical in dissemination of fenestrated and branched devices. Finally, multicenter, prospective clinical studies have also been completed in the case of Zenith Fenestrated with more studies progressing. In aggregate, these studies prove that when designed appropriately, branched and fenestrated repairs can be safe, effective, and durable. It remains to build on these designs and further disseminate the technology so more patients may benefit in the future.

Eric Verhoeven *Stephan Haulon* *Timothy Resch*

Gustavo Oderich *Matt Eagleton* *Tara Mastracci*

Fig. 1.12 Dissemination of endovascular experience with fenestrated and branched endografts around the globe. Eric Verhoeven is credited with the largest clinical experience in Europe. Graduates of the Cleveland Clinic Aortic Program later developed extensive clinical experience and research programs, including Stephan Haulon (Lille, France), Tim Resch (Malmo,Sweden), Gustavo Oderich (Rochester, USA), Matt Eagleton (Cleveland, USA), and Tara Mastracci (London, UK). By permission of Mayo Foundation for Medical Education and Research. All rights reserved

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