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BRANCHING OUT

Experts share their views on advancing endovascular technology.


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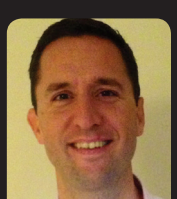
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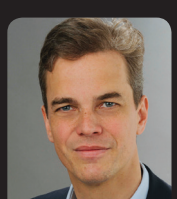
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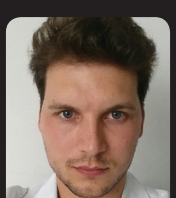
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Roy K. Greenberg, MD: A Legacy of Innovation

It is a privilege and honor to organize and present the first Roy Greenberg Session of the 31st Annual Meeting of the German Society of Vascular Surgery and Medicine, which was the inspiration for this supplement. This initiative was the least that we could do to pay tribute to a great innovator, a master surgeon, and a unique teacher. Dr. Roy K. Greenberg died almost 2 years ago at the age of 49. We do not think that the pain of losing such a great pioneer and friend will go away. His colleagues and friends everywhere in the world carry on his legacy, thriving to refine endovascular therapy and pushing the limits of knowledge. As with many of his friends and colleagues, we did not have a chance to say goodbye. Therefore, let's find comfort in the precious memories we have and reevaluate some of his important messages.

Dr. Greenberg's contributions are legion. With the increasing complexity of endovascular procedures, Roy developed creative solutions in the treatment of aortic pathologies with involvement of fenestrations and aortic branches. Nowadays, aortic aneurysms from the ascending aorta to the external/internal iliac arteries can be successfully repaired from a totally endovascular approach. The journey started in 2001 with the first fenestrated devices and continued to reinforced fenestrations, a helical iliac branch device, helical visceral branch, arch branch device, bifurcated-bifurcated device, and, finally, with the off-the-shelf endograft for juxtarenal abdominal aortic aneurysms, the so-called p-Branch endograft (Cook Medical). He always aimed for a durable solution that would reduce perioperative morbidity and last for the patient's life span.

Keeping this principle in mind, we have invited a group of experienced aortic specialists, all of them good friends or brilliant students of Roy, to provide their personal experience and perspectives on current aortic endovascular techniques and to address the impact of his innovations on advanced endovascular aortic programs worldwide.

Tara M. Mastracci, MD, FRCSC, from The Royal Free London NHS Foundation Trust in London, United Kingdom, begins with the iliac branch device. In her article, Dr. Mastracci shares an overview of the current indications for treatment with this device and highlights the reasons that the iliac side branch is a major advance and a safe solution in the treatment of aortoiliac aneurysm disease.

In the context of advancing medicine, another equally great innovator and pioneer in the field of endovascular aortic aneurysm repair, Timothy A.M. Chuter, MD, from the University of California, San Francisco, shares his thoughts and experience in regard to the "Achilles heel" of branched technology, renal branch failure.

Next, Gustavo S. Oderich, MD, and Bernardo Mendes, MD, from the Mayo Clinic in Rochester, Minnesota, provide an excellent overview of the anatomical criteria, techniques of implantation, and results achieved with the Zenith t-Branch multibranched stent graft (Cook Medical), the first off-the-shelf endoprosthesis for the treatment of thoracoabdominal aortic aneurysms.

Speaking about off-the-shelf endografts and the legacy of Roy Greenberg, we invited Tim Resch, MD, PhD, from Skane University Hospital in Malmö, Sweden, to give us a current update of his unique experience with Roy's last achievement, the Zenith p-Branch endoprosthesis (Cook Medical), the off-the-shelf endograft for juxtarenal abdominal aortic aneurysms. This article describes the preoperative planning, device selection, and technical considerations involved when using the new endograft.

Nikolaos Tsilimparis, MD, PhD, FEBVS; Krassi Ivancev, MD, PhD; and Tilo Kölbel, MD, PhD, from Hamburg, Germany, describe their current experience with the treatment of aortic arch aneurysms and provide new insights on the future of this technique.

Last but not least, we couldn't overlook the experience of Stéphan Haulon, MD, PhD, with coauthors Adrien Hertault, MD; Jonathan Sobocinski, MD, PhD; and Richard Azzaoui, MD, from the Hôpital Cardiologique–CHRU Lille in Lille, France, who share various strategies, from room setup to good radiological practice, to reduce radiation dose during endovascular aortic procedures.

Whether you currently use one or more of these devices and technologies, are considering starting to treat complex aortic pathologies, or just want to stay up to date on the latest achievements in this field, we hope this supplement will provide a snapshot of the current technology and devices. However, behind all of these innovations, a great pioneer should be acknowledged and never forgotten, Dr. Roy K. Greenberg.

We thank the authors for their contributions, and we hope you will enjoy this supplement and the session. ■

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Iliac Branch Devices

An overview of these devices from bifurcated to helical configurations.

BY TARA M. MASTRACCI, MD, FRCSC

Although, on the surface, the development and introduction of iliac branch devices (IBDs) to treat pathologies in the iliac territory may seem like an incremental step in the evolution of treatment for aortic diseases, this advance actually heralded a major change in the approach and conceptualization of endovascular devices. At that point in history, the major strength of open surgery was the ability of the surgeon to create bespoke repairs that responded to any pathology that might be present in an individual patient. Unfortunately, this ability did not transfer to endovascular repair. Until branch devices became available, endovascular surgeons had a prosaic approach to aneurysm repair, relying heavily on the stars aligning for perfect landing zone anatomy, meaning that there were many anatomic exclusions or "off-label" implantations.

Fenestrated devices allowed for expansion of the proximal seal zone above the renal arteries, but there was a need to incorporate branches in more tortuous areas of the aorta, namely large thoracoabdominal aneurysms, supra-aortic trunks, and iliac arteries. It quickly became apparent to thought leaders like Roy Greenberg, MD, among others, that a branch solution was required if surgeons wanted to expand the indications of repair. In addition to this, early use of complex devices was restricted to high-volume centers, implying that a superspecialized skill set was required to use this new technology and that endovascular surgeons had limited opportunity to learn the platform without a dedicated training period. The introduction of IBDs for pathologies in the iliac arteries both proved the concept that a branch could be used and provided a platform by which any endovascular surgeon could begin incorporating more complex technology in his or her own practice.

INCIDENCE

Solitary iliac artery aneurysms likely comprise 0.5% to 1.9% of all intra-abdominal aneurysms,[1,2] but concurrent iliac artery aneurysms can complicate infrarenal aneurysms in 40% of patients.[3] Most agree that the indication for repair is iliac artery aneurysms > 3.5 cm when found in isolation,[4] but iliac aneurysms are commonly repaired when the aortic aneurysm reaches an operative threshold, even if this is before they mature. In modern practice and parlance, iliac arteries are considered ectatic when they become too large for the largest endovascular device—which on some platforms can be as large as 24 mm.

Early experience with endovascular aortic repair began to reveal that larger iliac landing zones compromised the durability of the repair.[5-7] The high incidence of type Ib endoleaks with early devices both demonstrated the need for a technology to deal with ectatic iliac arteries and created a market for a device that could rescue earlier devices that had failed. In addition, the higher incidence of short common iliac arteries in very specific populations[3] made routine endovascular repair challenging, often requiring internal iliac artery coil embolization or transposition as a matter of course, which was less than ideal. In all of these scenarios, the IBD was the next logical step.

EARLY TECHNIQUES

Prior to the use of custom devices in the iliac territory, there were different approaches to dealing with ectatic iliac arteries that can be classified in two categories: occlusive and inclusive. Perhaps the most commonly used approach was occlusive. For these techniques, some form of occlusion was placed in the internal iliac, after which the device limb was then extended down into the external iliac. The use of both coils and plugs were described, with the general consensus now being that a patent internal iliac must have some form of occlusive device placed because failure to do so would lead to a type II endoleak.[8] Occlusion of the iliac territory was very commonly associated with buttock claudication in patients who were ambulatory[9] and could be associated with more nefarious complications such as rectal or bowel ischemia and lumbar plexopathy.[10,11]

In one study of 71 patients who had undergone internal iliac artery occlusion, the incidence of fatal pelvic ischemia was 2.8%, and buttock claudication occurred in 25%.[11] In addition, it is thought that occlusion of the internal iliac may have some bearing on erectile function, although this has not been proven in patients with aneurysmal diseases.

The category of inclusive techniques for dealing with iliac arteries included "bell-bottom" devices and chimney grafts. Fashioning larger iliac devices from aortic cuffs or other larger-diameter devices allowed the surgeon to keep the internal iliac artery in circulation, while still achieving seal. However, this approach ultimately failed, as

it was later found that landing in an unhealthy iliac artery was associated with early device failure.[12,13] The use of chimney devices was described in early experiences, but no long-term experience has been published to determine the durability of this approach.[14]

THE MOVEMENT TO "GENTRIFY" THE ILIAC TERRITORY

The presence of ectatic iliac arteries, and their risk of rupture, is only one consideration in the development of IBDs. As the endovascular movement gained a greater foothold and more complex aneurysms were being treated with endovascular devices, the importance of preserving the iliac territory to prevent spinal cord injury became imperative. In the early endovascular era, many surgeons opted to embolize internal iliac arteries on one or both sides in order to achieve seal in "healthier-looking" external iliac arteries. Although this improved the ease of implantation, longer-term follow-up began to reveal that the occlusion of territories during a previous surgery had immediate and long-term functional consequences, including decreased mobility due to buttock claudication and an increased proclivity to spinal cord ischemia if further aortic surgery was needed.[15,16]

Interest in the iliac territory also coincided with a need to find a more robust solution for thoracoabdominal aneurysms. At the time, fenestrations had proven the concept that endovascular repair could be used for complex aneurysms, but the effectiveness of a fenestration with a mating branch stent was questioned in thoracoabdominal aortic aneurysm cases. Developing a branch for the iliac territory provided a testing ground for branch-based systems for the thoracoabdominal aorta. Specifically, development of the helical branch for the internal iliac allowed the engineers an in vivo platform for testing these branches. Between 2002 and 2005, the biomedical engineering lab run by Dr. Greenberg produced an iterative succession of helical limbs, with the aim of finding solutions to both the iliac and thoracoabdominal challenges. Certainly, loss of the iliac bed, although not ideal, would be far more tolerable than loss of the mesenteric bed in early device experience.

CURRENT DEVICES

Iterations of various IBDs have resulted in three main configurations that are available for clinical use today.

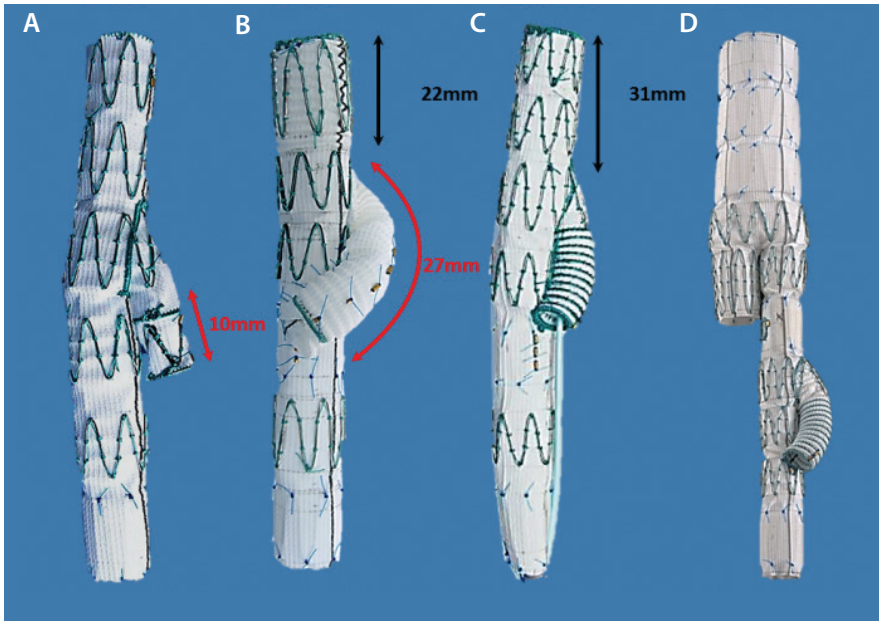

Figure 1. Iliac branch device configurations: straight IBD (A), helical IBD (B), helical limb from the contralateral side (C), and bifurcated-bifurcated device (D).

Broadly, these include the straight branch, helical branch, and bifurcated-bifurcated devices.

Straight IBD

The straight IBD (Figure 1A) is available from multiple manufacturers. The general concept of this device is that a straight branch comes off the main body of the limb and is mated to a stent that bridges to the internal iliac artery. The length of the branch is constricted by the diameter and length of the common iliac artery. For the Zenith Branch Iliac Graft* (Cook Medical), this length is 14 mm. For the Excluder iliac branch endoprosthesis (Gore & Associates), the length of overlap is 25 mm, and the diameter of the internal iliac branch is up to 14.5 mm. Experience with this device configuration is growing, and recent publications show promising results, with some limb-related complications.[17] For the Cook device, a two-center experience with up to 5 years of follow-up showed a freedom from reintervention rate of 81.4%, a branch patency rate of 91.4%, and a technical success rate of 95%.[18]

Helical IBD

The helical IBD (Figure 1B) was developed by Dr. Greenberg to address concerns that there was insufficient overlap in the straight branch configuration to accommodate a self-expanding stent, with the theoretical assumption that a self-expanding stent would be better suited to the tortuous angles that exist within the pelvis. The length of overlap between the mating stent and branch is 2.7 cm.

Bifurcated-Bifurcated Device

After early experience with IBDs, the indications were refined, and it became clear that the pitfalls of the devices were related to use in severely calcified internal iliac arteries, as well as in short common iliac arteries. The need for a long common iliac artery can be difficult to meet in certain populations in which short common iliac arteries are more typically seen. The bifurcated-bifurcated device grew out of this perceived challenge, and as it gained use in some centers, it became apparent that it was also quite useful in long common iliac aneurysms to provide a more stable platform for repair and to decrease the use of multiple additional pieces.[19]

As its name suggests, this device is a bifurcated infrarenal device that has a helical branch on the ipsilateral limb. Cannulation of the helical branch is made possible through the introduction of a self-sealing fenestration, developed by Dr. Greenberg, that permits access to the helical limb from the contralateral side (Figure 1C). This element overcame the need for brachial access and standardized the implantation procedure to be similar to that of existing IBDs. Thus, device delivery involves introduction of the device into the infrarenal position, cannulation of the helical branch, stenting of the internal iliac artery, and then cannulation of the gate and placement of the contralateral limb. By removing the joint between the iliac device and the main body, the bifurcated-bifurcated device creates a far more stable repair (Figure 1D).

Dr. Greenberg's team reported their 5-year experience with the helical IBD and bifurcated-bifurcated device, which revealed a technical success rate of 94% and 5-year branch patency rate of 81.8%.[19] The population of patients reported in this series included 35% who had internal iliac aneurysms. Also, 45% of treated patients had narrow common iliac arteries (< 16 mm), an exclusion criterion with the use of the straight IBD in earlier studies. Lessons learned from this experience include that technical success was lower if an internal iliac stenosis existed, but that, overall, these devices fared well in difficult anatomy.

CONCLUSION

Although not commonly acknowledged, IBDs have been a major advance in the treatment of aortic disease because they proved the concept that branched devices could be durable, provided an "entry level" platform for incorporating branches into aortic repair and removed a common criterion for anatomic exclusion. Dr. Greenberg's contribution to the devices used to treat this territory is present at every stage. Currently, IBDs are available either commercially or through investigative trials in most jurisdictions and should be considered when iliac arteries are short or ectatic. Treating iliac arteries with branch grafts when pathology exists serves the patients well, as they preserve important territory for future repair and restore functional capacity to ambulatory patients despite the presence of complex pelvic pathologies. ■

**The Zenith Branch Iliac Graft is an investigational device in the United States. Limited by United States law to investigational use. It is CE Mark approved with indications for use in the endovascular treatment of patients with an aortoiliac or iliac aneurysm, an insufficient distal sealing site within the common iliac artery, and having morphology suitable for endovascular repair.*

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Is Renal Branch Occlusion the Achilles Heel of Endovascular TAAA Repair?

A look at the causes of and possible solutions to this lingering complication.

BY TIMOTHY A.M. CHUTER, MD

There is no shortage of candidates for the title "Achilles heel of endovascular thoracoabdominal aortic aneurysm (TAAA) repair." For all of its advantages, endovascular TAAA repair has many potential failure modes. However, the more common complications (eg, type II endoleak) tend to be relatively benign, whereas those that are more life-threatening or disabling (eg, paraplegia) tend to be rare.[1,2] Only renal branch failure (thrombosis, fracture, or dislocation) is late occurring, difficult to predict, difficult to treat, potentially life-threatening, and seen in as many as 20% of patients, depending on the length of follow-up and the exact method of branch construction.[1-6]

Although early reports[2] suggested that most cases of renal branch occlusion occurred within 6 months of repair, later studies (with longer follow-up) have shown a steady accumulation of new cases long after stent graft implantation.[3,5] As other barriers to the widespread application of endovascular TAAA repair diminish, the rising rate of renal branch failure after this procedure could become a limiting factor. It is still difficult to advocate endovascular TAAA repair in patients who are healthy enough to undergo open repair, and the prospect of long survival after endovascular repair might paradoxically raise the risk of late-occurring renal branch failure.

TYPES OF BRANCHED STENT GRAFTS

All of the currently available modular systems for endovascular TAAA repair combine an aortic stent graft with multiple (usually four) covered stents. The site of branch attachment is either a wire-reinforced hole in the wall of the stent graft (fenestration) or a short axially oriented branch (cuff).

As a rule, fenestration-based branches are created from balloon-expandable covered stents. Cuff-based branches are more variable: some are created from self-expanding covered stents, and some are created from balloon-expandable covered stents. Regardless of type, covered stents are often lined with self-expanding stents to minimize infolding and kinking, smooth the transition from the stiff stented portion of the renal artery to the flexible unstented portion, and stabilize branch attachment by providing a site for arterial ingrowth. Commonly used covered stents include iCast (Maquet; balloon expandable), Jostent (Abbott Vascular; balloon expandable), Viabahn (Gore & Associates; self-expanding), and Fluency (Bard Peripheral Vascular, Inc.; self-expanding). Commonly used uncovered stents include Zilver (Cook Medical) and Wallstent (Boston Scientific Corporation).

Some investigators prefer fenestrations,[5-8] some cuffs,[1-4] and some a mixture of the two.[9,10] The resulting heterogeneity of stent graft design both helps and hinders the study of renal branch failure. Differences in the rate and form of renal branch failure between branch types and locations may suggest possibly various risk factors, but statistically meaningful analysis is complicated by low event rates and the need to stratify results by different stent graft constructs. Analysis is also hindered by unclear naming conventions, most of which reflect the evolutionary origins of the field. Some studies[6] fail to distinguish between simple fenestrations (anchored by uncovered stents) and fenestration-based branches; others[5] use terms like "branched stent graft" (meaning a stent graft with cuff-based branches) and "fenestrated stent grafts" (meaning a stent graft with fenestration-based branches).

MECHANICAL DIFFERENCES BETWEEN GRAFT TYPES

The basic methods of fenestrated stent graft implantation were developed in the late 1990s and were reported in 2001.[11] This approach employed constraining ties to maintain a state of partially expanded stent graft, a bridging catheter to help guide the fenestration to the arterial orifice, and a bridging stent to keep the fenestration anchored. The substitution of a balloon-expandable covered stent for the original uncovered bridging stent changed a fenestration into a branch. Whereas the uncovered stent of a simple fenestration relies on direct apposition between the stent graft and the aorta for sealing, the covered stent of a fenestration-based branch has an impervious wall, which means it can bridge a gap between the stent graft and aorta, thereby providing inflow to branches that originate

from a pararenal or thoracoabdominal aneurysm.[12] For a fenestration-based branch to work without leakage (type I endoleak), there must be hemostatic connections between the fenestration and the covered stent proximally, as well as between the covered stent and the lumen of the target artery distally.

A stable hemostatic connection between a covered stent and the wire-reinforced rim of a typical fenestration requires near-perfect transaxial orientation of the branch relative to the long axis of the stent graft, which in turn requires near-perfect alignment between the fenestration and the target artery orifice. Only the so-called pivoting fenestration[13] has enough tolerance for nonperpendicular branch orientation to accommodate renal/fenestration misalignment. The stability of the fenestration-to-branch connection also depends on the high local forces generated where the nitinol-reinforced margin of the fenestration contacts the outer surface of an unyielding balloon-expandable stent (self-expanding stents do not provide the necessary force required in this scenario). Because balloon-expandable stents take the shape of the balloon (and balloons straighten forcibly on inflation), fenestration-based branches tend to be both straight and stiff.

Cuff-based branches were originally designed and specifically used for treating TAAAs.[14] Although they come in a variety of forms (helical or straight, external or internal), all have a substantially axial alignment (they point up or down along the stent graft) and all provide a cylindrical (not merely circular) implantation site on the stent graft for overlap with the covered stent.[15] The intrinsic stability of an intercomponent overlap allows for the use of relatively compliant self-expanding covered stents. The axial orientation allows covered stents to pass obliquely up or (more often) down the aorta at a variable angle for a variable distance before turning into the target artery orifice.[16] Self-expanding stents may be more flexible than balloon-expandable stents, but they are still more stiff than the typical native renal artery.

RENAL BRANCH OCCLUSION AFTER ENDOVASCULAR TAAA REPAIR

Based on the experience at University of California, San Francisco,[3] approximately 10% of cuff-based renal branches occlude, which translates to a per-person rate of approximately 20%. For cuff-based branches, the risk factors for occlusion include sex (men), aneurysm extent (not Crawford type II aneurysms), a history of myocardial infarction, and renal artery length. Notably absent from this list are aortic diameter (< 30 mm at the level of the renal orifices), renal artery diameter, renal artery angle, and branch angle. In the majority of cases, each branch combined a Fluency covered stent with a slightly oversized vascular Wallstent. The stiffness of the resulting branch was an intentional design feature, the goal being to stabilize the multibranched construct and help prevent both migration and component separation.

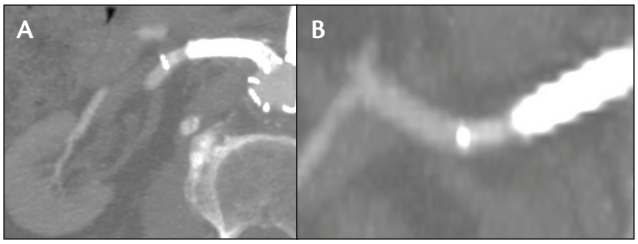

Figure 1. Follow-up CT angiography demonstrating how a relatively stiff Fluency stent creates angulation of the distal renal artery despite the presence of a slightly less stiff Zilver stent (A). Incipient hyperplasia and stenosis are seen just distal to the Fluency stent (B).

In this experience, most cases of renal branch occlusion go unheralded by observable changes in luminal diameter, probably because the causative lesion is located just distal to the end of the branch where markers on the Fluency stent create a starburst effect on follow-up CT (Figure 1). It is even possible to miss established branch occlusion because the downstream artery may be patent through adrenal collaterals and flow may be sufficient to maintain the size of the affected kidney, especially when the contrast bolus is poorly timed. Under these circumstances, the potential for preservation of viable renal function is sufficient to justify an attempt at aspiration thrombectomy, transcatheter thrombolysis, and stent implantation.

Compared to cuff-based branches, fenestration-based branches appear to be less likely to occlude but more likely to fail in other ways, such as fracture and disconnection.[5,6] All in all, fenestration-based branches have a failure rate of approximately 10%, which is basically the same rate of failure seen in cuff-based renal branches. Kaplan-Meier and exponential decay curves show rates of branch failure and reintervention as high as 20% at 5 years.

RENAL ARTERY ANATOMY AND MOVEMENT BEFORE AND AFTER ENDOVASCULAR TAAA REPAIR

The proximal renal arteries rarely originate at right angles to the aorta. Most are caudally oriented, especially on the left.[16-18] The presence of an aneurysm changes the renal artery orientation by altering the position of the pararenal aorta. Crawford type IV aneurysms lengthen the infrarenal aorta and push the renal orifices up, causing the renal arteries to be more caudally oriented. Crawford type II and III aneurysms lengthen the suprarenal aorta and push the renal orifices down, causing the renal arteries to be more cranially oriented.

The renal arteries are seldom straight, especially proximally, although they may appear so on antero-

posterior angiography. In the absence of heavy calcification, the proximal 2 cm of the renal artery is often mobile, bending up and down, back and forth, to accommodate the effect of diaphragm descent on the position of the kidneys.[18]

After endovascular TAAA repair, the proximal 1 to 3 cm of each renal artery is occupied by a covered stent. The effect on renal anatomy depends on the length, stiffness, and orientation of the stent, which varies according to operator preferences. Most fenestration-based branches are inserted from below (transfemoral), and their presence rotates the proximal renal artery into a more cranially oriented position.[6] Most cuff-based branches are inserted from above, and their presence rotates the proximal renal artery into a more caudally oriented position. Fenestration-based branches are all balloon-expandable, which means that they are stiff and straight. Cuff-based branches are usually self-expanding, which means that they are less stiff than fenestration-based branches, but still more stiff than unstented renal arteries.

With both branch types, the stented portion of the renal artery goes from curved, flexible, and mobile to straight, stiff, and immobile. However, the stented portion of the flow lumen with its robust impermeable lining is not the portion most at risk for compression, kinking, hyperplastic ingrowth, or anything else that might constrict the lumen. The greatest risk is where the stiff branch meets the flexible renal artery, creating an abrupt mechanical discontinuity. Postimplantation CT scans show this to be the site of acute angulation (Figure 1). Because endovascular TAAA repair does nothing to arrest the kidneys' respiratory motion, the renal artery continues to bend with every breath, and due to the presence of the stiff branch, bending is isolated to the distal end of the branch, which becomes a discrete hinge point.

Thus, we hypothesize that acute angulation and repetitive microtrauma at the distal end of a stiff renal branch cause hyperplasia, leading to stenosis and eventual occlusion.

THE FUTURE

If this hypothesis is correct, the use of a flexible covered stent should help reduce the stiffness mismatch between the stented and unstented portions of the renal artery, thereby reducing angulation and repetitive microtrauma. With this in mind, we at the University of California, San Francisco have switched from Fluency to Viabahn covered stents. The early results of this change were marred by cuff-induced infolding of the Viabahn, which went unrecognized because completion angiography was performed with the tip of the catheter well into the branch. Currently, we routinely line the Viabahn with a Zilver stent, dilate the entire branch to iron out irregularities, and perform completion angiography using a 5-F sheath placed just inside the proximal end of the branch.

None of the renal branches inserted since we made this change (a little over 2 years ago) have occluded. This is not to say that we believe the Viabahn device to be the ideal covered stent for this application. For example, neither of the available lengths (5 and 10 cm) are ideal. The 5-cm version is too short to allow for a 2-cm overlap proximally, a 2-cm overlap distally, and the usual central gap (of 2 cm or more) between the cuff and the target artery. The 10-cm version, on the other hand, protrudes too far into the renal artery and the trunk of the stent graft and can curve through the aneurysm sac between widely spaced attachment points. The latter is a concern because the central segment of the Viabahn covered stent can shorten, lengthen, or bend in an uncontrolled way that, in theory, deprives both the branch and the stent graft of stability. In practice, we have never seen stent graft migration or branch dislocation, perhaps because the celiac and superior mesenteric branches still consist of a (relatively stiff) Fluency/Wallstent combination.

Again, if the previously stated hypothesis is correct, fenestration-based branches would also benefit from a higher degree of flexibility—the limiting factor being the intrinsic rigidity of the balloon-expandable stent. One possible solution involves the combination of a PTFE graft with multiple short balloon-expandable stents. Nothing of the sort currently exists, at least not in sizes compatible with renal use.

CONCLUSION

There is no denying that renal branch thrombosis is the most common failure mode in the endovascular repair of TAAA, but I would argue that this is a product of the current technology, not the technique itself. If this is true, the rate of branch occlusion may be amenable to changes in device design. Although this observation applies to both fenestration-based branched and cuff-based branches, the underlying problems and solutions may be different. In the case of cuff-based branches, the most important cause is mechanical discontinuity between the stiff branch and the flexible native artery, and the most important change would be an increase in the flexibility of the branch. Ideally, this change would occur with the development of covered stents specifically designed for this purpose. In the meantime, we have opted to use the most flexible self-expanding covered stent available (Viabahn), and medium-term results suggest that we may be moving in the right direction. If so, we may have reached the point at which endovascular repair of TAAA really has no Achilles heel, and the technique may be ready to assume the role of first-line treatment. ■

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Endovascular Repair of TAAAs With the t-Branch Multibranched Stent Graft

The technical aspects and clinical applications of this approach.

BY GUSTAVO S. ODERICH, MD, AND BERNARDO MENDES, MD

Visceral artery incorporation using fenestrations and directional branches has gained widespread acceptance. Multiple clinical series and systematic reviews have shown high technical success rates and lower morbidity and mortality rates compared to historical open surgical reports. Characteristics of an ideal visceral branch include short length, long overlap with the aortic attachment site, and vector alignment with the target artery. Although fenestrations allow the placement of short, transversely oriented alignment stents that result in low occlusion rates, disconnections and associated type III endoleaks limit its use for branch vessels that originate from a large aortic lumen. In this scenario, directional branches provide a longer overlap between the bridging stent and the attachment site, minimizing the risk of disconnections and type III endoleaks. This article summarizes the anatomical criteria, techniques of implantation and results obtained with the Zenith t-Branch multibranched stent graft* (Cook Medical) for the treatment of thoracoabdominal aortic aneurysms (TAAAs).

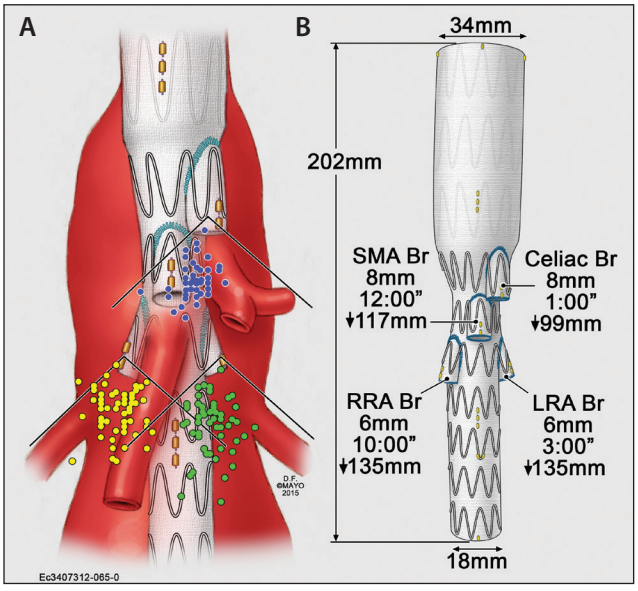

Figure 1. The t-Branch stent graft with four directional branches (A). The SMA is placed in a fixed point. Note the locations of the celiac axis (blue dots), right renal artery (yellow dots), and left renal artery (green dots). Standard diameter and length measurements (B).

DEVICE DESCRIPTION

The t-Branch stent graft consists of a tapered woven polyester stent graft sutured to a stainless steel Z-stent exoskeleton. The mid-portion of the device contains four short (18 mm) axially oriented, caudally directed cuffs for attachment of covered stents, which serve as the branches for visceral vessel incorporation. The cuffs are situated in the external surface of the stent graft, and their positions are based on predictable locations of the visceral vessels as depicted in Figure 1. The device has a diameter of 34 mm at the top and 18 mm at the bottom, with a length of 202 mm. The celiac artery and superior mesenteric artery (SMA) cuffs are each 8 mm in diameter and are axially located in the 1 and 12 o'clock positions, respectively. The right and left renal artery cuffs are each 6 mm in diameter and are located in the 10 and 3 o'clock positions, respectively. The device is delivered through a 20-F system.

ANATOMICAL FEASIBILITY

Anatomical feasibility of the t-Branch stent graft has been assessed in a few studies. Sweet et al[1] evaluated aortic anatomy in 66 patients treated by multibranched stent grafts. In that study, 88% of patients met all of the anatomical criteria proposed in Figure 2, suggesting that a standardized multibranch stent graft has wide applicability. Park et al[2] analyzed the shape and length of branches in a patient series treated with patient-specific multibranched stent grafts. Although all of the branches were inserted as intended and without migration, disconnection, or kink, 23% of the branches had > 30° misalignment, suggesting that the design was quite forgiving for errors of implantation or variations in patient anatomy.

A follow-up study by Gasper et al[3] analyzed the applicability of multibranched stent grafts in a broader study population of 201 potential candidates for repair of TAAAs. Anatomic suitability was assessed for

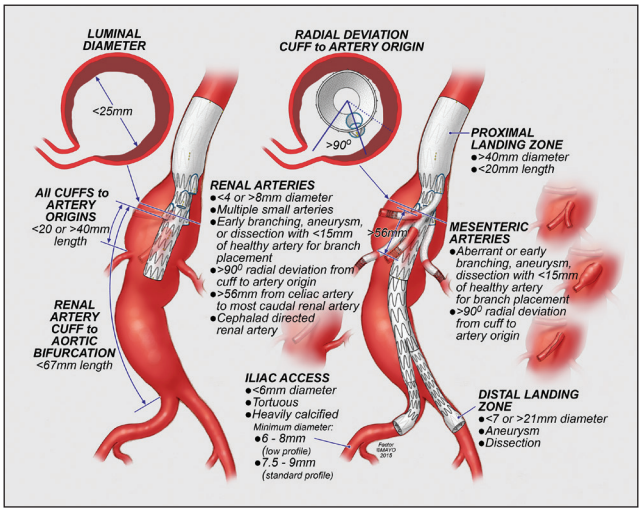

Figure 2. Anatomical criteria for the t-Branch stent graft. Important considerations are the minimal luminal diameter of 25 mm, ability to incorporate all vessels within a 90° angle to each cuff, and the target vessel diameter of 4 to 8 mm for the renal arteries.

patient-specific or an off-the-shelf version with either a standard (22 F) or lower-profile (18 F) device. Of the 201 patients, 58% were candidates for repair in a single-stage procedure, and another 29% could be candidates for repair with adjunct procedures to provide a suitable landing zone. Women were significantly more likely to require a conduit, which was less frequently needed with the lower-profile design. Patients with chronic dissections were significantly less likely to qualify for repair due to involvement of the iliac arteries, compressed true lumen, or aberrant vessel anatomy. Although the off-the-shelf design has the advantages of eliminating the need to wait for customization, only 94 patients (< 50%) qualified for the use of this device.

Variations in target vessel configuration remain the main limitation to widespread use of off-the-shelf multibranched designs. Conway et al[4] evaluated the angles of implantation of the renal arteries according to different aneurysm anatomies. In that study, patients with a predominance of abdominal disease (type IV TAAA) more often had a downward orientation of the renal arteries as compared to those with a predominance of thoracic disease (types II and III), who more often had a neutral or "up-going" configuration. Incorporation of up-going renal arteries with down-going branches is not ideal and may lead to kinking, stenosis, or branch thrombosis. Conversely, down-going branches are very well suited for vessels with a down-going configuration, which is frequently the case for the celiac axis and SMA. Our approach has been to individually adapt the best design to the patient anatomy, whenever possible, with the use of directional branches and/or fenestrations in patient-specific or off-the-shelf designs.

SPINAL CORD INJURY PREVENTION

Spinal cord injury is the most devastating complication of endovascular TAAA repair. We have adopted a standardized approach, which includes the following measures.

Blood Pressure Management

Vasodilator antihypertensive medications are discontinued or decreased in dose a week prior to the operation through up to 4 to 6 weeks after the procedure. A mean arterial pressure (MAP) of ≥ 80 mm Hg is targeted intraoperatively and for the first 72 hours. If there are changes noted in neuromonitoring or the physical exam, MAP goals are raised to 100 mm Hg. Transfusion of blood products is indicated in the first 48 hours after the procedure to maintain a target hemoglobin level of ≥ 10 mg/dL and a normal coagulation profile.

Cerebrospinal Fluid Drainage

Routine, prophylactic cerebrospinal fluid (CSF) drainage is used in all patients with a pressure control system and a baseline spinal pressure of 10 mm Hg. If there were changes in neuromonitoring or the physical exam, the CSF pressure is decreased to 0 to 5 mm Hg. Spinal fluid drainage is continued for 24 hours in patients with type IV TAAAs and for 48 to 72 hours in those with type I to III TAAAs.

Lower Limb Reperfusion and Conduits

Early lower limb reperfusion is used whenever possible. Temporary iliac artery conduits are indicated in patients with small iliac arteries. Femoral conduits anastomosed end-to-side to the common femoral artery have also been selectively used to allow restoration of lower extremity flow in patients with challenging anatomy or severe internal iliac and femoral artery disease. The use of femoral conduits minimizes lower extremity ischemia during visceral branch stenting by allowing the aortic device sheath to be retracted into the conduit.

Intraoperative Neuromonitoring

Intraoperative neuromonitoring is routinely used in all patients to trigger specific maneuvers depicted in Figure 3. A > 75% consistent reduction from baseline in the evoked potential amplitude triggers standardized maneuvers to optimize lower extremity and spinal cord perfusion, including incremental changes in MAP and CSF pressure. The MAP is raised with vasopressors along with a simultaneous decrease in CSF drainage pressure. In patients who improve after the maneuvers, the procedure is completed in a standard fashion. In those with no change or deterioration, flow is restored to the pelvis and lower extremities as quickly as possible. In patients with normalization of evoked potentials after lower extremity flow is restored, the procedure is completed. If

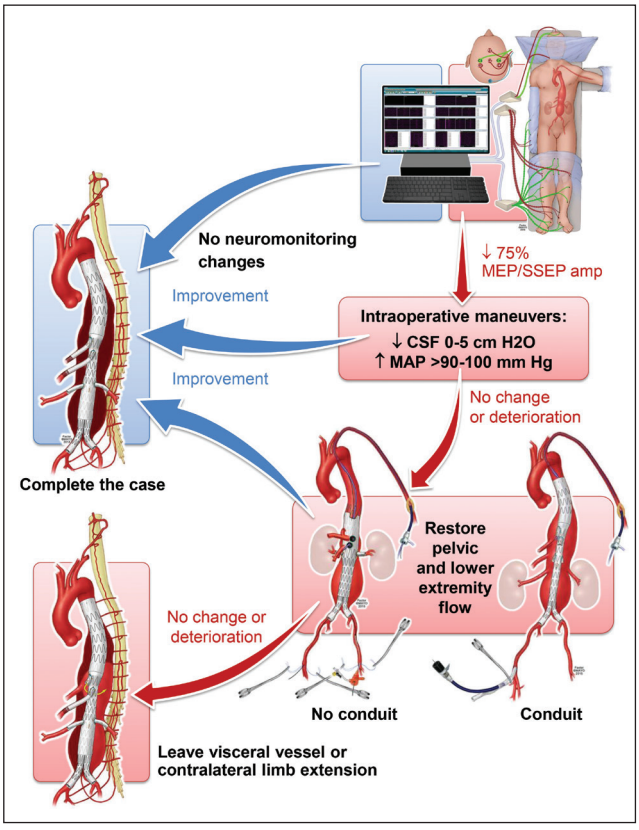

Figure 3. The placement of electrodes for monitoring motor-evoked potentials (MEP) and somatosensory-evoked potentials (SSEP) during complex endovascular aortic repair. A significant change is defined by a > 75% decline in the amplitude in MEP or SSEP. Standardized maneuvers and protocol are triggered by changes in MEP and SSEP.

the changes persist, the procedure is left incomplete by leaving either the celiac branch or contralateral iliac limb open, whenever possible.

Staged Procedures

A staged endovascular approach has been used in all patients with type I or II TAAAs. The most common technique is coverage of the thoracic aorta up to the celiac axis in the first stage of the procedure, followed by completion of the endovascular repair using a thoracoabdominal fenestrated and/or branched stent graft 6 to 8 weeks later.

TECHNIQUES

Ancillary Tools

These procedures require advanced endovascular skills and a comprehensive endovascular inventory with a wide range of catheters, balloons, and stents. Dedicated training in fenestrated and branched techniques is highly recommended for physicians who are already very experienced with other types of endovascular procedures.

Perioperative Measures

Preadmission should be considered in patients with chronic kidney disease (estimated glomerular filtration rate < 60 mL/min/1.73 m^2), advanced age, and very complex anatomy. Patients undergo gentle bowel preparation, intravenous hydration with bicarbonate infusion, and oral administration of acetyl-cysteine. Acetyl-salicylic acid is started or continued prior to the operation, but clopidogrel is discontinued at least 10 days beforehand. Patients are instructed to shower with liquid skin cleanser (chlorhexidine gluconate 4%) the day prior to the procedure to reduce bacterial counts. In obese patients, the skin over the groin crease needs to be inspected several days before the procedure, and any fungal infection is treated. Antibiotics are intravenously administered prior to the incision and continued up to 24 hours after the procedure.

General Approach

Optimal imaging is recommended using a hybrid endovascular suite with a fixed imaging unit and, ideally, fusion cone-beam capability. Most procedures are performed using general endotracheal anesthesia, although select cases can also be done under local or regional anesthesia. Intraoperative blood salvage ("cell salvage") may be considered if one anticipates difficulty or a prolonged operating time. A useful tip is to create large pockets within the surgical drapes to allow for the blood to be collected via cell salvage. The use of iodinated contrast is minimized throughout all of the steps of the procedure. Our preference has been to use small hand injections of 10 mL of diluted contrast at 30% (3 mL of contrast in 7 mL of saline) to locate the side branches. Completion aortography is performed after all of the stents are placed, with the use of diluted contrast at 50%.

Positioning

Patients are positioned supine, with the left arm abducted and the imaging unit oriented from the head of the table (Figure 4). Arterial access most often includes a bilateral femoral and left brachial approach. Just prior to prepping the patient, the brachial artery is imaged to select the incision site, which is typically high in the axilla, unless the artery is small (< 4 mm); in these cases, exposure is performed at the infraclavicular fossa. Electrocardiography leads, the urinary catheter, and other monitoring cables and lines should be taped or secured so that they are not in the path of the x-ray beam of the fluoroscopic unit or do not get caught during movement of the C-arm gantry.

Arterial Access

Percutaneous bilateral femoral access is used in all cases, whenever possible, except for in patients with high femoral bifurcations, dense calcifications, or anterior plaque. The

concept that percutaneous access leads to prolonged time of lower extremity ischemia is misleading and erroneous. In fact, we immediately remove the sheaths and tighten the sutures without tying the knots, once all of the steps are completed via the femoral approach. This allows restoration of flow to the lower extremity faster than with primary arterial closure. Access can be done by reintroduction of the sheath using the guidewire, if needed. We have not experienced any significant bleeding complications or hypotension related to access issues.

The patient is systemically heparinized with an intravenous bolus of heparin (80–100 units/kg), which is administered immediately after the femoral and brachial access is established. The activated clotting times are rechecked every 30 minutes, and additional heparin needs to be administered if the activated clotting time is < 250 seconds. A continuous drip of heparin (500–1000 units/h) is also started, and diuresis is induced with intravenous mannitol and/or furosemide.

Device Deployment

The sequence of steps for stent deployment can vary slightly depending on the proximal extent of the aneurysm.

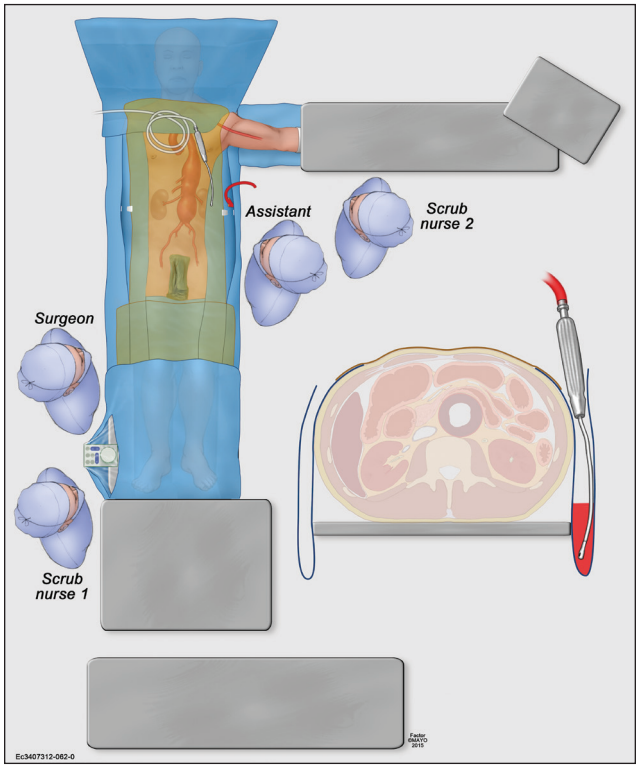

Figure 4. The patient is positioned supine with the left arm abducted. Standard brachial artery access sites include a small incision close to the axillary hairline for larger-diameter sheaths (12 F) or a small incision just above the antecubital crease for smaller-diameter sheaths (7 or 8 F). Occasionally, an incision can be made at the deltopectoral crease or infraclavicular area in patients with very small upper brachial arteries (< 4 mm).

In general, the repair starts with deployment of a proximal thoracic TX2 stent graft (Cook Medical), if needed, followed by deployment of the t-Branch stent graft. One of the advantages of using directional branches is that there is room to use selective catheters between the cuffs and target vessels; therefore, implantation does not need to be performed with the extreme degree of precision that is required with fenestrated stent grafts. Our preference is to deploy the distal bifurcated component and limb extensions, leaving placement of the bridging self-expandable stents as the last step of the procedure after closure of the femoral arteries. A modification of this technique—staggered deployment—may be needed in difficult cases with a narrow aortic lumen.

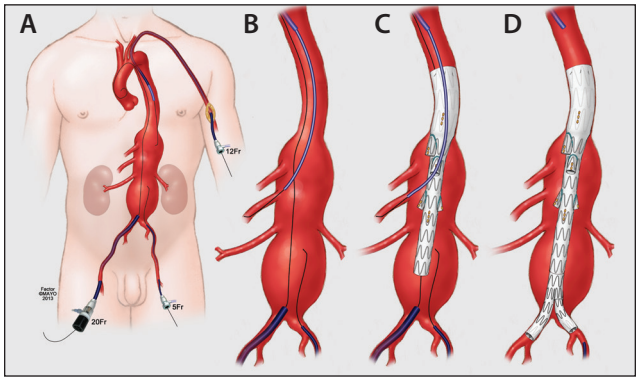

Figure 5. The t-Branch multibranched stent graft is designed with four directional branches for the celiac axis, SMA, and both renal arteries. The operation is performed using bilateral femoral and left brachial access (A). One of the target vessels is catheterized (B) to guide deployment of the multibranched stent graft (C). The distal bifurcated device and iliac limbs are added, and flow is restored to the lower limbs (D).

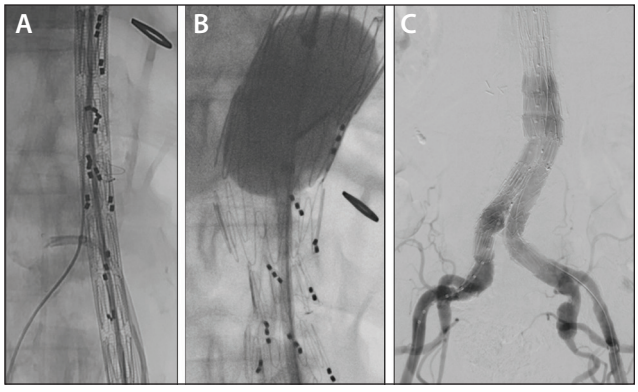

Figure 6. The t-Branch stent graft is oriented and positioned with each cuff above its intended target vessel (A). Note the SMA was catheterized with a sheath to indicate the location of the vessel. The t-Branch stent graft is deployed, followed by placement of the distal bifurcated stent graft and iliac limbs. The proximal and distal landing zones are dilated with a Coda balloon (Cook Medical; B), and limited distal angiography is performed to document adequacy of the distal landing zone (C).

Precatheterization of the renal arteries is typically not needed. However, it is critical that the distal edge of each of the branches is deployed 1.5 to 2 cm above its intended target vessel (Figure 5). Ideally, the minimum internal aortic diameter should be > 25 mm to allow space for catheter manipulation. Review of the anatomy is important to understand the lengths and clock positions of the branch vessels. For example, the device may need to be somewhat rotated during deployment to better align the renal cuffs in relation to the renal arteries. To guide deployment of the t-Branch component, we usually catheterize one of the vessels. The t-Branch stent graft is oriented extracorporeally, introduced via the femoral approach, and deployed with the directional branches located proximal to its intended target vessel (Figure 6). Next, the distal universal bifurcated stent graft and contralateral iliac extensions are placed. One important tip is to avoid aggressive dilatation of the aortic bifurcation in these patients because the aneurysm sac is still perfused, and inadvertent rupture of the aortic bifurcation can be catastrophic. The femoral arteries are closed at this point, restoring flow into the lower extremities. If the procedure is performed percutaneously, this can be done in an expeditious manner by leaving the guidewires in place along with a small sheath.

A 12-F Ansel I sheath (Cook Medical) is advanced via the left brachial approach and positioned inside the t-Branch component in the descending thoracic aorta. A 0.014-inch guidewire is then advanced with a through-and-through approach from the left brachial to femoral artery (Figure 7), preventing movement of the 12-F sheath in the aortic arch. Each side branch is individually catheterized in a sequential fashion, starting with the renal arteries (Figure 8) and

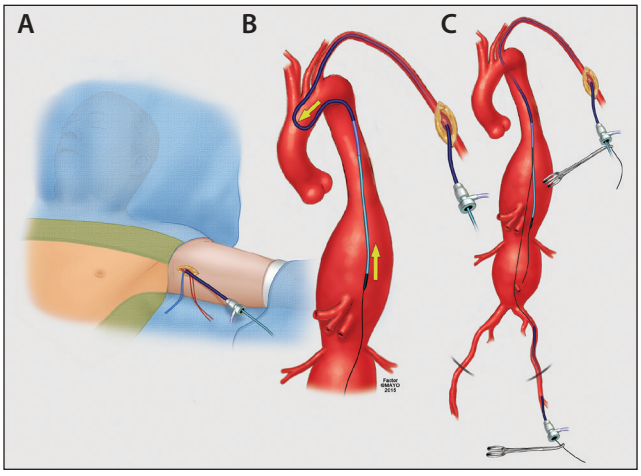

Figure 7. An upper brachial artery exposure is usually adequate for access (A). The through-and-through maneuver with placement of a 0.014-inch guidewire from the 12-F brachial artery to the 5- to 8-F femoral artery avoids the problem of the sheath protruding into the ascending aorta and arch (B) with each manipulation, thus securing the sheath in a more stable position (C).

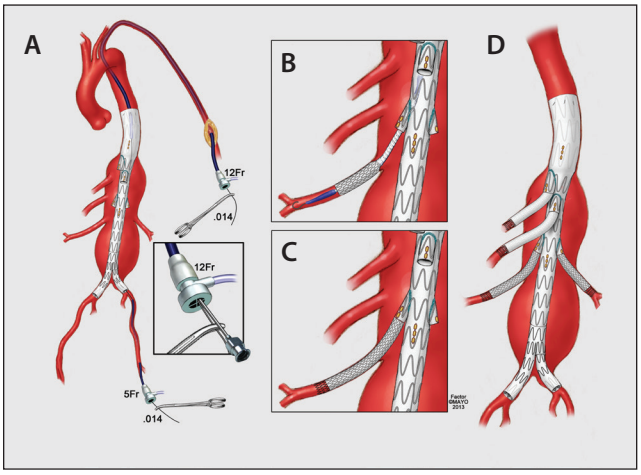

Figure 8. Once all of the aortic components are deployed, flow is restored to the lower extremities, and only a small sheath is maintained in one of the femoral arteries (A). Each branch is accessed via the brachial approach and bridged to the target vessel by placing self-expandable stent grafts (B). A self-expandable bare-metal stent is added to void kinking at the distal edge (C). The repair is completed by placing all of the four side branch stents (D).

followed by the SMA and celiac axis. A 5-F MPA or Kumpe catheter (Cook Medical) is used to access the directional branch and target vessel. Once the vessel is catheterized, the soft Glidewire (Terumo Interventional Systems) is exchanged for a stiff guidewire (Rosen or short-tip Amplatzer, Cook Medical), which is positioned in the target vessel. Before the stent is deployed, it is critical to confirm that the guidewire is placed into the correct cuff. This requires moving the imaging projection in different oblique views to visualize the guidewire and the cuff.

A Rosen guidewire is used for the renal arteries. For bridging stents, our preference is to use Viabahn stent grafts (Gore & Associates) for the renal arteries (Figure 9) due to their excellent conformability and possibly superior patency rates. However, these stents are limited by their length being either too short (5 cm) or too long (10 cm), as well as difficult deployment. Therefore, one needs to be careful not to pull the stent out of the vessel during deployment. This can be prevented with slow deployment while leaving the sheath inside the proximal half of the stent, and then once the stent engages the vessel, the sheath is pulled, and the deployment is slowly completed. If the stent is too short or a 5-mm diameter is used, our preference is to use a proximal balloon-expandable covered stent to track the Viabahn device into the cuff. The distal edge of the Viabahn device is reinforced by placing a self-expandable bare-metal stent. This is followed by balloon dilatation of all stents to profile and, at last, completion angiography.

Catheterization of each cuff can be facilitated by keeping the stiff wire inside the branch (Figure 10) while working

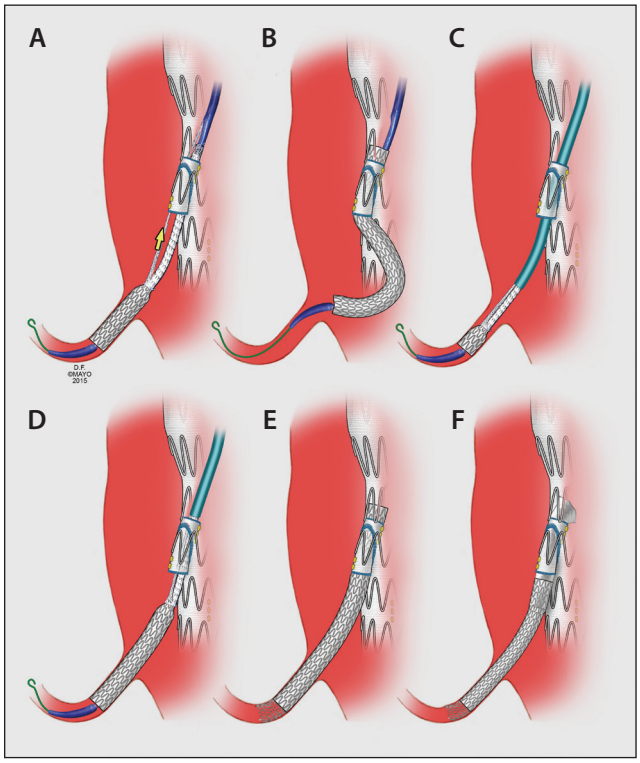

Figure 9. Deployment of Viabahn stent grafts into the branches is done carefully to avoid dislodgement. Because the deployment mechanism of the Viabahn device is done through a suture string (A), which when removed, opens a sleeve that constrains the stent, the stent can be pulled out of the intended target vessel (B). A useful technique is to keep the sheath in the middle portion of the stent graft (C) while the stent graft is slowly being deployed to that level. The sheath is then retracted (D), and the deployment is completed (E). If needed, a proximal balloon-expandable covered stent or an additional Viabahn stent graft is deployed to connect to the branch cuff (F).

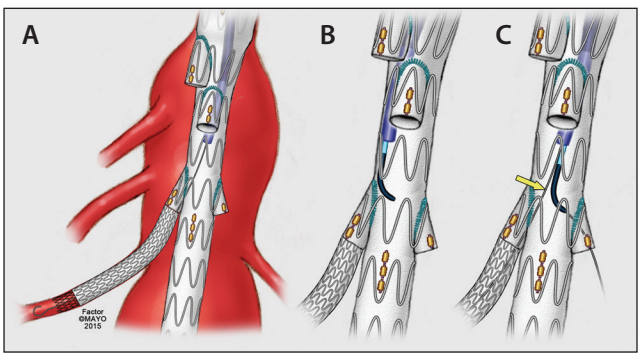

Figure 10. A useful maneuver to facilitate branch catheterization is to keep access into one of the branches using a 0.035-inch guidewire (A). Note that if the guidewire is removed, the catheter tends to be displaced to the lateral wall of the stent graft (B). Instead, keeping the guidewire in the branch and using a buddy catheter (C) facilitates catheterization of the next intended branch.

with a buddy catheter to catheterize the next intended target branch. As previously mentioned, it is critical to ensure that the catheter is in the correct branch before deploying the bridging stent. One can easily misjudge the SMA for the celiac cuff and place the stent into the incorrect branch, compromising the entire repair. For stenting of the celiac and SMA, a 9-F, 70-cm Flexor sheath (Cook Medical) is advanced coaxially within the 12-F sheath. Each target vessel is stented with a self-expandable stent graft (Viabahn or Fluency, Bard Peripheral Vascular, Inc.). The stent graft should be oversized by 1 to 2 mm and should provide at least a 2-cm distal landing zone in the target vessel, extending 2 to 5 mm into the aortic lumen of the t-Branch device. Our preference is to use Fluency stent grafts for the celiac and SMA because of the smaller-profile sheath and larger-diameter stents with greater availability of lengths. To prevent kinks in the transition between the stent graft and the target artery, each self-expandable stent graft is reinforced by a second self-expandable stent, which is deployed 1 cm beyond the distal edge of the stent graft. Selective completion angiography is performed for each sequential branch. Next, completion angiography of the arch and thoracoabdominal aorta is performed after all bridging stent grafts are deployed. Figures 11 and 12 illustrate a case in which a patient was treated with a multibranched thoracoabdominal stent graft.

DISCUSSION

The ideal off-the-shelf stent graft should combine wide anatomical applicability, ease of technical implantation, and durable branch-related outcomes. Although there is controversy with respect to which design is best suited for most patients with TAAAs, experts agree that directional branches are ideal for down-going vessels that originate from large aortic lumens, whereas fenestrations

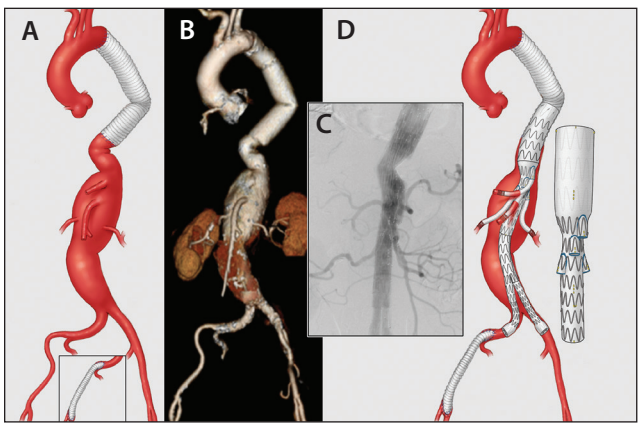

Figure 11. A patient who was treated with the multibranched stent graft. The aneurysm distal to thoracic aortic graft (A) and preoperative CT angiography of a large TAAA (B). Completion angiography showed no endoleaks (C), and the repair was completed using a four-vessel multibranched stent graft (D).

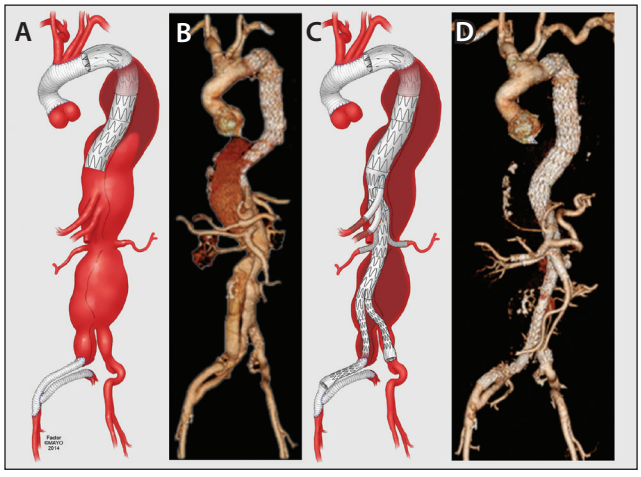

Figure 12. Rationale of staged thoracoabdominal repair is based on the concept of an extensive collateral network to the spine circulation. The staged procedure can be performed with sequential coverage (A, B) with placement of stent grafts in the proximal thoracic aorta. This is followed by a second-stage procedure with placement of the multibranched stent graft (C, D).

may be preferred for vessels that originate from the sealing zone or narrow aortic segments.[5,6] The advantage of a multibranched stent graft relies on the ability to implant the device without a high degree of precision, which is needed for fenestrated stent grafts.[7]

The choice between fenestrations and branches varies greatly between centers. Our preference has been to select patient-specific stent grafts with mixed configurations using directional branches and fenestrations. Renal fenestrations have an exceptionally low rate of occlusion compared to recent reports of multibranched stent grafts (< 2% and 7%–10%, respectively), but some disadvantages exist, including higher rates of type III endoleaks and branch disconnection, particularly when fenestrations are applied for renal arteries that originate from large aortic segments.[5,7-9] In addition, patient-specific stent grafts require an average delay of approximately 8 weeks for customization, which is not ideal in patients with excessively large aneurysms (> 8 cm) and prevents their use in patients with symptomatic and ruptured aneurysms.

The t-Branch stent graft represents an evolution from the original multibranched design proposed by Chuter et al in 2001.[10] It is estimated that > 50% of the TAAA population are suitable for the device in a single procedure, with even greater suitability with staged procedures.[3] The most frequent limitations include inadequate renal arterial anatomy (small diameter, multiple accessory renal arteries, early bifurcation), difficult access, or lack of a proximal landing zone. Whereas some of the proposed anatomical criteria are flexible, such as the distance or angulation between the branch and the target, it is likely that these factors may affect branch-related events and reinterventions. Similarly, there is no agreement in terms of selection of the ideal bridging stent for branches. Investigators have used a wide combination of self-expandable stent grafts and balloon-expandable covered stents, with or without reinforcement with a self-expandable bare-metal stent. Selection of the bridging stent also likely plays a role in branch occlusion rates, although this has not yet been confirmed by convincing data. Our preference has been to use Viabahn stent grafts for the renal arteries with minimal (1 mm) oversizing because of its excellent flexibility; we often reinforce the distal transition point with a self-expandable bare-metal stent to prevent kinking. For the celiac and SMA, we use Fluency stent grafts because of its lower-profile sheath, larger-diameter stents, and wider availability of stent lengths.

Most reports describing endovascular TAAA repair do not report outcomes by specific device designs. The University of California, San Francisco group has used primarily patient-specific or off-the-shelf stent grafts with directional branches. In their most recent report of 81 patients, the 30-day mortality rate was 3.7%, and renal branch occlusion occurred in 9%.[7] The Cleveland Clinic group has exclusively used fenestrations for the renal arteries and reported a 2% rate of renal occlusion within 5 years.[5] Others have assessed both patient-specific and off-the-shelf stent grafts and found a 30-day mortality rate of 0% and a renal occlusion rate of 14% for the off-the-shelf t-Branch group and a 30-day mortality rate of 8% and renal occlusion rate of 0% for the patient-specific group, respectively.[11-13]

CONCLUSION

Fenestrated and branched stent graft techniques continue to evolve. Advantages of the t-Branch device include its wide clinical versatility and high technical success for repairing large TAAAs. Key technical points include extensive physician planning, case selection, and meticulous perioperative techniques. There have been important contributions from large clinical series, which demonstrate the benefit of staging extensive TAAAs and early restoration of lower extremity perfusion, whenever possible. ■

**The Zenith t-Branch multibranched stent graft is an investigational device in the United States. Limited by United States law to investigational use. It is CE Mark approved with indications for use in the endovascular treatment of patients with an aortoiliac or iliac aneurysm, an insufficient distal sealing site within the common iliac artery, and having morphology suitable for endovascular repair.*

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Global Experience With the Zenith p-Branch Device

Outcomes of this novel device for treating juxtarenal or pararenal abdominal aortic aneurysms.

BY TIM RESCH, MD, PHD

Endovascular repair of abdominal aortic aneurysms (EVAR) has become the primary treatment option in morphologically suitable patients. Stent graft systems for infrarenal aneurysm repair have undergone significant development and refinement since the commercial introduction of EVAR in the mid-1990s. Current technology allows for the treatment of a wide range of infrarenal aneurysms presenting with challenging anatomical features in the iliac arteries, such as tortuosity and narrowing. The main obstacle to EVAR continues to be a challenging proximal sealing and fixation zone, especially in patients with a short infrarenal aortic neck or when the aneurysm encroaches upon the renal arteries. This is true in the short term, where an unfavorable proximal sealing zone can lead to acute type I endoleaks and failed aneurysm repair, but is more significant in the long-term follow-up, where continuing aortic dilatation in the paravisceral segment of the aorta can cause late endograft failure and, ultimately, rupture. Many bailout techniques are used to overcome immediate and short-term failures, such as the use of adjunctive balloon-expandable stents, endoanchors, or chimney repairs. The durability of these maneuvers in the long-term remains questionable in the face of progressive aortic disease.

Anderson et al first described the concept of fenestrated aortic stent grafts for juxtarenal aortic aneurysms in the late 1990s.[1] Incorporation of one or more visceral arteries into the aortic repair was utilized to allow a more extensive proximal seal of the stent graft while maintaining flow to the visceral arteries. Roy Greenberg, MD, was the first to show the effectiveness and durability of this approach in a large cohort of patients and championed fenestrated EVAR, even for true thoracoabdominal aortic aneurysms. Over the past decade, multiple literature publications have demonstrated this technology to be safe, effective, and durable for the treatment of these challenging patients.[2,3]

One obstacle to the widespread use of fenestrated EVAR has been the need to customize the device according to the individual patient anatomy to achieve an optimal fit. This process includes detailed planning and device manufacturing, both of which contribute to a time of 4 to 6 weeks between diagnosis and patient treatment. This treatment delay makes the technology unavailable to patients with very large aneurysms (with a higher likelihood of interval rupture), as well as emergent patients. Therefore, an off-the-shelf (OTS) device is needed for juxtarenal or pararenal aneurysm repair. This could potentially lead to simplified planning and the availability of devices when needed.

ZENITH P-BRANCH DEVICE

The Zenith p-Branch device* (Cook Medical) is based on the CE Mark and US Food and Drug Administration approval of the Zenith fenestrated platform, but with some significant modifications, primarily in the proximal tubular component containing the fenestrations. By default, the p-Branch device has two fenestrations for the renal arteries, one fenestration for the superior mesenteric artery (SMA), and a scallop for the celiac artery. To accommodate variability between the renal fenestration and target vessel position in an OTS setting, the renal fenestrations are dome-shaped (Figure 1), with an inner diameter of 6 mm and an outer diameter of 15 mm. These "pivot fenestrations" have nitinol wire reinforcements in the inner ring, outer ring, and dome. This design allows for catheterization of renal arteries that fall within the 15-mm outer diameter while keeping the inner 6-mm fenestration for mating the stent seal. The SMA fenestration is an 8-mm-diameter standard single-ring fenestration. Based on anatomical studies of patients treated with fenestrated stent grafts, positioning of the fenestrations on the p-Branch device allow for treatment of approximately 60% to 80% of aneurysms with only two device configurations, called "A" and "B."

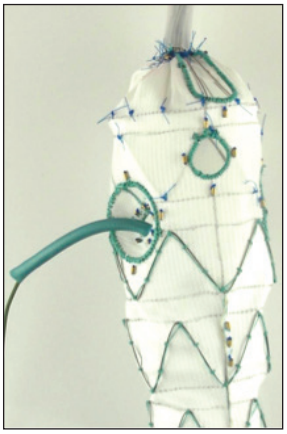

Figure 1. The p-Branch proximal component displaying a celiac artery scallop, SMA fenestration, and right renal artery pivot fenestration. Note the dome structure of pivot fenestration, which has a preloaded catheter.

In the p-Branch device, the renal fenestrations have been fitted with a preloaded 0.018-inch-diameter wire to obviate the need for catheterization of the fenestrations and to facilitate cannulation of the target vessels during the procedure. In addition, the preloaded wire runs through the stent graft on the delivery side using a modified delivery handle that can accommodate two 6-F introducers alongside it. The preloaded wire passes through a side port on the delivery handle, through the main body of the graft, out through one renal fenestration, across the graft, into the other renal fenestration, through the main body of the graft, and finally out through the second sideport on the delivery handle.

During planning, the center of the SMA is always used as a reference point with respect to the locations of the renal arteries and celiac artery. The longitudinal and circumferential positions of the renal arteries and the celiac artery in relation to the SMA are mapped out on a grid. An overlay template is positioned on the grid to determine which configuration, A or B, is most appropriate.

During the procedure, once the fenestrated component had been placed and mating stents extended into the target vessels, the case is then completed by placing a distal bifurcated unibody and iliac limb extensions, similar to a standard fenestrated case.

RESULTS

The first report on the use of a device similar to the p-Branch was published by myself and colleagues in 2012.[4] We described the use of stent grafts utilizing the preloaded delivery system, as well as the renal pivot fenestrations, in a small cohort of seven elective patients. The devices were tailored to each patient in the same way as a Zenith fenestrated device, but took advantage of the new features incorporated into the p-Branch design. Technical success was 100%, and the 30-day mortality was 0%.

In a report from 2013,[5] Greenberg et al reported early clinical outcomes of the first use of the p-Branch device. Sixteen patients, including two with ruptures, were enrolled in a physician-sponsored investigational device exemption trial at the Cleveland Clinic in Cleveland, Ohio. Technical success was 100%, and no aortic-related deaths were reported. A single renal artery occlusion was found during follow-up and was successfully treated by endovascular recanalization.

At the Vascular Annual Meeting in 2014, Mark Farber, MD, presented the 1-year aggregated outcomes from four prospective, single-center, investigational device exemption studies (conducted in the United States and Europe) of the Zenith p-Branch device.[6] Results from 59 patients (52 elective, seven emergent) were reported. The mean patient age was 72 years and 67 years for elective and emergent patients, respectively. The maximum aneurysm diameter was 62 mm in elective patients and 70 mm in emergent patients. In approximately 60% of elective patients, device configuration A was used, whereas device configuration B was used in approximately 60% of the emergent patients. Technical success was 100%, with an immediate target vessel patency rate of 98.8%.

In two of the emergent patients, a single renal vessel was not catheterized; in one patient treated for rupture, a renal artery was intentionally covered (this renal artery was outside the defined treatment region), and in a second patient, a renal artery was successfully stented on postoperative day 8 (the stent graft achieved effective sealing at the index procedure without renal stenting). There was no 30-day mortality and no renal failure that required dialysis in the 59 patients presented. During a mean follow-up of 13 months, there was one death attributed to coronary artery disease. One emergent patient experienced a type I endoleak in the distal aspect of an SMA stent, which was treated by mating stent extension and embolization.

Of the 59 patients, 40 were available for 1-year follow-up. Target vessel patency at 1 year was 96% for elective patients and 95% for emergent patients. Five renal artery occlusions were identified, and four of these were successfully treated by endovascular means. An additional two cases of renal artery stenosis were found and treated by percutaneous angioplasty and stenting.

DISCUSSION

Fenestrated stent grafting for juxtarenal or pararenal abdominal aortic aneurysms has become a well-established treatment option. Thousands of implants and numerous publications support this as an effective and durable repair option. However, the problems of complex planning, as well as device availability, have driven the development of more standardized OTS stent grafts.

With the current p-Branch device, planning has been radically simplified. Because the device only comes in two configurations, device choice becomes quite straightforward. The unique design of the renal pivot fenestrations provides a much more extensive range of inclusion than standard renal fenestrations. As has been previously shown, device planning, even in experienced hands, has a degree of variability. This, in combination with the need to align the fenestrations precisely with the target vessels during implantation, can make a procedure somewhat challenging. With the p-Branch device, this has significantly changed. Flexibility in accommodating a suboptimal fit is incorporated in the device design. As the results show, the short-term technical success is high, even in emergent cases. The long-term outcomes are yet to be determined.

The OTS p-Branch device also solves the problem of device availability. The proximal p-Branch component that comes with two configurations and five diameters (26, 28, 30, 32, and 36 mm) can easily be kept on the

shelf in limited numbers. The distal bifurcated body is uniform in design and also only comes in four lengths. Finally, the procedure is completed with the standard iliac extension limbs used for an infrarenal Zenith device. Thus, keeping five proximal diameters available in both the A and B configurations, as well as four different lengths of bifurcated devices, a total of 14 devices in stock will cover most anatomies within the instructions for use.

An added benefit of the device is the preloaded delivery system, which obviates the need for a large sheath in the contralateral femoral artery during the target vessel catheterization phase of the procedure. Instead, an 8- to 12-F sheath is placed in the contralateral groin to allow for catheterization of the SMA fenestration. This provides continuous flow to the contralateral lower limb during the majority of the procedure as well as flow in the contralateral internal iliac artery, which can provide some collateral flow to the ipsilateral lower limb where the femoral artery is largely occluded by the main delivery sheath. Obviously, a preloaded system is also favorable in patients who exhibit limited or no access from one femoral artery. ■

**The Zenith p-Branch is an investigational device in the United States and Europe. It is not FDA or CE Mark approved at this time.*

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Endovascular Aortic Arch Repair

An update on the devices and techniques available to treat this challenging anatomy.

BY NIKOLAOS TSILIMPARIS, MD, PHD, FEBVS; KRASSI IVANCEV, MD, PHD; AND TILO KÖLBEL, MD, PHD

Today, open surgery is considered the gold standard in treating the ascending aorta and the aortic arch. However, conventional surgical techniques for managing the aortic arch are invasive and frequently associated with a significant systemic inflammatory response syndrome and related complications. Therefore, patients with multiple comorbidities are often classified as high risk and are denied open repair.

Over the past 10 years, thoracic endovascular aneurysm repair (TEVAR) has prevailed as the treatment of choice for pathologies of the descending aorta and aortic arch up to Ishimaru zone 2. The superiority of TEVAR in comparison to open repair in reducing perioperative and long-term severe morbidity has been demonstrated in a prospective comparative study.[1] In high-volume centers and in patients at low risk, surgical techniques such as complete open repair of the aortic arch or the hybrid (frozen) elephant trunk have been associated with a mortality rate of up to 9% and a stroke rate of 4% to 12%.[2-4] Minimally invasive treatment of aortic arch pathologies faces a number of technical challenges. First, the supra-aortic branches perfuse the brain, which has a low ischemic tolerance. Furthermore, the aortic arch is wide, angulated, pulsatile, and is further away from the typical access vessels, the femoral arteries. In addition, the presence of plaque and thrombus in the aortic arch (ie, "shaggy aorta") increases the risk for brain embolism.[5]

ENDOVASCULAR HYBRID TECHNIQUES

The hybrid approach to treating the aortic arch consists of bypasses from the ascending aorta (Figure 1) to the supra-aortic vessels or cervical debranching of the supra-aortic vessels with carotid-carotid bypass and/or carotid-subclavian bypass (or left subclavian artery [LSA] transposition). This technique has shown good results over the last 10 years and has expanded the options for repair of aortic arch pathologies in patients who are considered unfit for open surgery.[6,7] However, a meta-analysis by Antoniou et al reported that this technique is still associated with a 30-day mortality rate of 13% and a 30-day morbidity rate of 35%.[7] Patients who underwent aortic arch debranching and proximal sealing in Ishimaru zones 0 and 1 had higher morbidity rates compared to those with more distally located landing zones.[8] Chiesa et al confirmed these results and concluded that most of the deaths occurred due to strokes in patients with stent grafts in Ishimaru zones 0 and 1.[6]

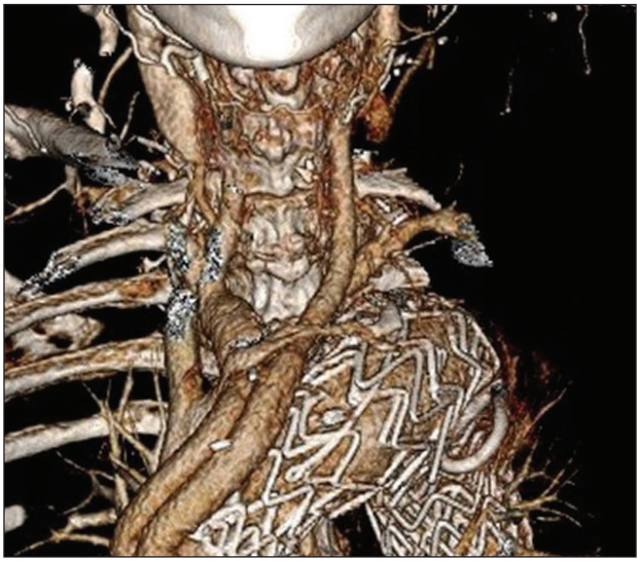

Figure 1. Three-dimensional reconstruction of CT angiography (CTA) of a patient with debranching of the aortic arch with bypasses from the ascending aorta to the innominate and LCCA.

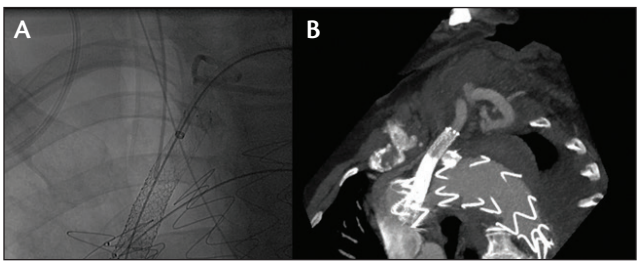

Figure 2. Intraoperative angiography of a patient with implantation of a Zenith Alpha endograft (Cook Medical) and a chimney endograft (Advanta, Maquet) for the LCCA (A). Maximal intensity projection reconstruction of a CTA from the same patient (B).

CHIMNEY PROCEDURES

The practice of using parallel or chimney stent grafts has increasingly been reported for the aortic arch in recent

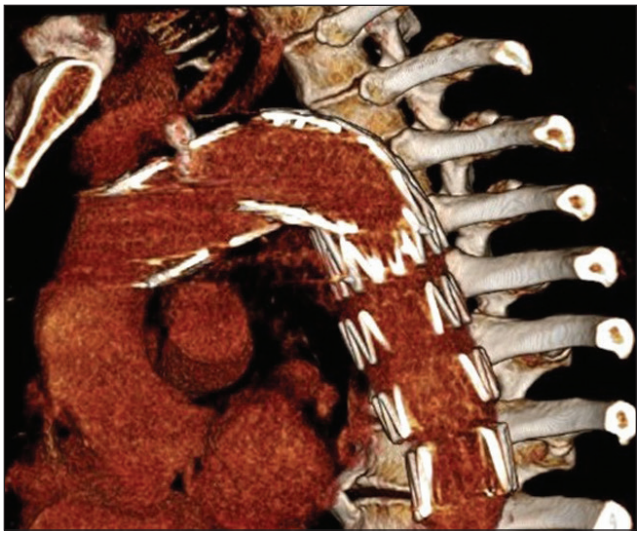

Figure 3. Three-dimensional reconstruction of a CTA in a patient with in situ laser fenestration of the LCCA.

years (Figure 2). Although this technique has typically been used for revascularization of the LSA, the feasibility of the chimney technique for all major supra-aortic branches has been demonstrated.[9] A recent meta-analysis reported that the incidence rates of type Ia and II endoleaks were 11% and 8%, respectively, thus representing a major drawback of this technique. Although the perioperative mortality rate was reported to be only 5%, the perioperative stroke rate was still 4%.[10]

IN SITU FENESTRATED AORTIC ARCH ENDOGRAFTS

The technique of retrograde or antegrade in situ fenestration of stent grafts for the thoracic aorta is well described as a bailout technique for emergent situations.[11,12] In 2013, Redlinger et al published the largest series to date, in which favorable results were observed in 22 patients who underwent TEVAR with laser fenestration of the left subclavian artery.[13] In our experience, the laser fenestration procedure was successfully used as a bailout procedure in a case with accidental overstenting of the left common carotid artery (LCCA) (Figure 3).[14]

Although laser fenestration can achieve quick perfusion to the target arch vessel, the technique can be demanding and is associated with significant risk, especially when material damage is poorly controlled. Although polytetrafluoroethylene stent grafts are easier to puncture and dilate compared to Dacron stent grafts, they are also more prone to material damage.

CUSTOM-MADE FENESTRATED AND BRANCHED STENT GRAFTS

As far back as 11 years ago, Chuter et al envisioned the endovascular treatment of the aortic arch and introduced branched arch stent grafts.[15-17] Since the initial use of

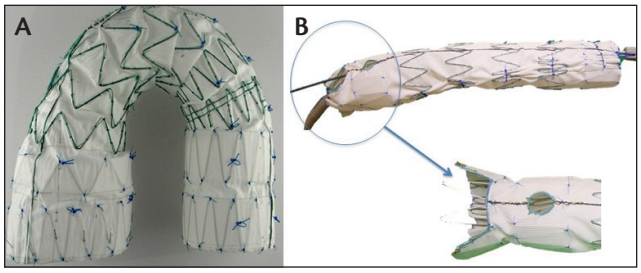

Figure 4. The Zenith arch branched endograft* (A) and the Zenith arch fenestrated endograft (B), both by Cook Medical.

fenestrated and branch stent grafts in the aortic arch, the technique has evolved considerably and has now reached the stage of clinical implementation on a large scale. This is evident by the number of companies that manufacture or develop fenestrated and branch stent grafts for the aortic arch. Although Cook Medical was the first to produce fenestrated and branch stent grafts for the arch, other companies such as Bolton Medical and Medtronic have produced endografts for the aortic arch. Medtronic is conducting a clinical trial on the single-branched stent graft Valiant Mona LSA, which has a funnel-shaped inverted window ("volcano") for the LSA. Similarly, Gore & Associates and MicroPort Endovascular are in the development and clinical trial phase for single-branch endografts for the LSA.

Cook Medical has two main stent graft designs that address the specific characteristics of the aortic arch: a fenestrated endograft and an arch branch endograft (Figure 4). Both endografts are custom-made according to a patient's specific anatomy. Fenestrated or branched arch endografts typically come in longer delivery systems compared with standard thoracic endografts and are precurved to facilitate self-alignment of the endograft in the aortic arch during introduction and deployment. The principle of self-alignment is essential, given that the possibility of rotational manipulation in the arch is minimal.

Fenestrated endografts in the arch typically address one to two vessels with either two fenestrations or, more commonly, one fenestration and one scallop depending on the intended landing zone. Fenestrated endografts can be manufactured with a fenestration for the LCCA and a large scallop for the innominate artery, or similarly a fenestration for the LSA and a scallop for the LCCA or the bicarotid trunk. A preloaded catheter and guidewire runs through the graft and the fenestration and is used to achieve femoroaxillary through-and-through wire access. Thus, alignment of the fenestration to the target vessel can be securely achieved. Special notice must be taken during this maneuver not to entangle the through-and-through wire in the uncovered struts of the scallop (Figure 4B), as it may complicate the procedure and require multiple manipulations in the arch.

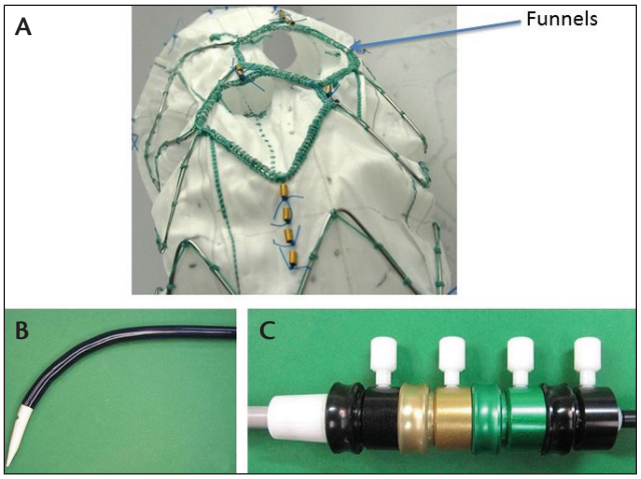

Figure 5. Funnels of the Zenith arch branch endograft at the outer curvature (A), the precurved formation of the endograft facilitating self-alignment in the aortic arch (B), and the multiple trigger wires allowing staged and controlled deployment of the arch endograft (C).

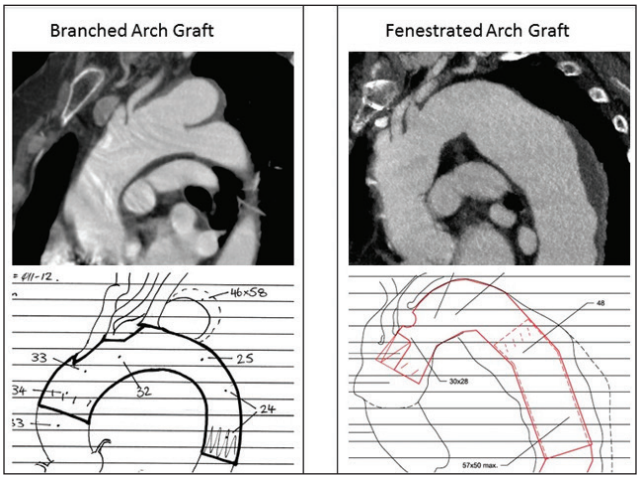

Figure 6. Sagittal reconstructions of CTA and preoperative planning sketches of patients with arch aneurysms planned to undergo fenestrated or branched TEVAR.

However, just as in the visceral aorta, large aneurysms or post–type A dissection aneurysms involving the entire arch cannot be effectively treated by fenestrated endografts alone. The distance between the fenestration and the target vessel in combination with the strong pulsation of the arch would expose the bridging stents to extreme mechanical stress and compromise seal at the fenestrations. Therefore, branched arch devices are more suitable for these cases. Cook Medical has developed an arch branch device, which is composed of a stent graft with two internal branches.* In contrast to previous branched devices, retrograde catheterization of the internal branches is performed through large funnel-shaped orifices that are oriented at the outer curve of the aortic arch (Figure 5A). The two inner branches typically address the innominate and the LCCA.

Given that endograft rotation and deployment at the intended rotational position in the arch are more complicated than in the visceral aorta, the introduction of inner branches connected to the funnels represents an ingenious characteristic that makes branch catheterization and the entire procedure easier to perform. Furthermore, this prosthesis is made of very thin but high-density Dacron and has a self-alignment system, as well as a controlled-release mechanism (Figure 5B and 5C).

After deploying the main stent graft in the arch, bridging stent grafts are inserted over (1) the right common carotid artery, to which access has been achieved through cutdown; and (2) the left carotid artery via a previously established carotid-subclavian bypass.

Haulon et al published the initial international experience, which describes 38 patients deemed medically unfit for surgical repair who underwent placement of this arch branch stent graft. The authors concluded that these results support the feasibility of treating patients with arch pathologies using this device, and the early results after overcoming the learning curve appear favorable (30-day mortality: 30% in the first 10 patients vs 7% in the last 28; $P = .066$). A diameter of > 38 mm in the landing zone was associated with increased risks for early morbidity and stroke.[18]

In our own experience from 2012 through the end of 2014, 29 patients underwent fenestrated or branched TEVAR (66 ± 9 years, 9 women). No differences in comorbidities were reported between fenestrated TEVAR patients (n = 15) and branched TEVAR patients (n = 14) (Figures 6 and 7).[19] Previous cervical debranching was performed in only six (40%) fenestrated TEVAR patients compared to all patients who underwent branched TEVAR. In all patients who underwent branched TEVAR, two arch vessels were targeted (innominate artery = 13, LCCA = 14, LSA = 1), whereas in patients who underwent fenestrated TEVAR, 1.6 ± 0.5 arch vessels were targeted (bovine trunk = 4, LCA = 11, LSA = 8). Fenestrated endografts landed proximally in zone 0 in 33% of the cases, while all branched endografts landed in the ascending aorta.

Technical success was achieved in all but one case of a fenestrated endograft that was displaced, resulting in major stroke and death. Strokes occurred in two fenestrated TEVAR patients and one branched TEVAR patient (P = nonsignificant), thus still representing a serious clinical consequence of aortic arch interventions. The 30-day mortality rate in this high-risk cohort was 20% in those who underwent fenestrated TEVAR (n = 3) versus 0% in patients who underwent branched TEVAR (P = nonsignificant). The causes of early mortality were major stroke (n = 1), access complication (n = 1), and myocardial infarction (n = 1). Mean follow-up was 8 (range, 1–35)

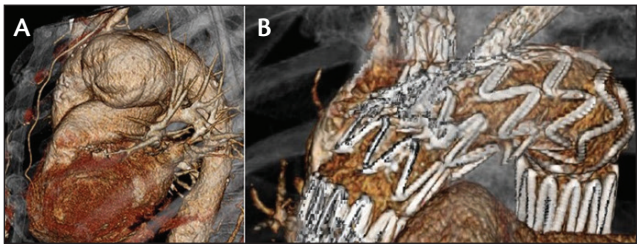

Figure 7. Preoperative (A) and postoperative (B) CTA imaging of a patient with an aortic arch aneurysm who underwent implantation of the Zenith arch device with branches for the innominate artery and LCCA.

and 10 (range, 2–22) months for fenestrated or branched TEVAR, respectively. No branch occlusions occurred, and two patients underwent coil embolization for endoleaks (*P* = nonsignificant). One patient was readmitted with an infected branched endograft 4 months after intervention and has so far been successfully treated with aneurysm sac drainage and antibiotics. There was one late, nonaneurysm-related death in each group.

DISCUSSION

The special hemodynamic and anatomic characteristics of the aortic arch make manipulation in this region challenging. Inaccuracy of stent graft placement can have fatal consequences for the patient and increase the risk of endoleaks and stroke. Precise preoperative planning to achieve optimal stent graft dimensions and implantation tactics are essential to avoid complications (Figure 6). Further, careful patient selection for aortic arch stent grafts is essential. An interdisciplinary conference with cardiologists and heart surgeons is crucial to match the right patient with the right therapy.

The future of fenestrated and branched TEVAR in the aortic arch is promising, and as technology evolves and experience grows, more and more patients will be considered for this technique (Figures 7 and 8). There are some problems that still need to be addressed, specifically arch repair, which is mostly restricted by the absence of an adequate landing zone in the ascending aorta due to its large diameter.

Currently, endovascular repair of the arch is reserved for patients with a landing zone distal to the coronary arteries or in the presence of at least an open repair with a graft long enough to provide a landing zone that can facilitate further endovascular repair. The next challenge for both academic and industry innovators is the combination of an aortic valve and an ascending graft with preservation of the coronary arteries, which would make a complete endovascular repair, starting from the heart, possible.

CONCLUSION

Hybrid interventions can be a good alternative to open surgery in high-risk patients. Endoleaks are a relevant problem during chimney procedures in the aortic arch due to the high hemodynamic forces involved. Custom-made fenestrated and branched stent grafts provide an excellent option for high-risk patients and represent a potential future option for more patients with aortic arch disease. ■

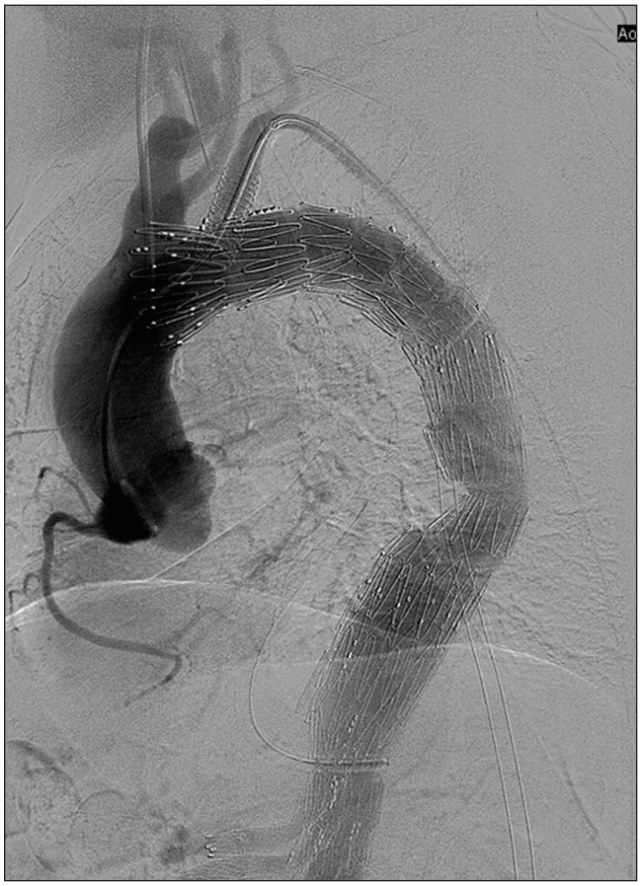

Figure 8. Intraoperative final angiography of a patient with a thoracoabdominal aortic aneurysm after implantation of a fenestrated Zenith arch device with a fenestration for the left subclavian artery and a scallop for the bicarotid trunk.

**The Zenith arch branched device is an investigational device in the United States and Europe. It is not FDA or CE Mark approved at this time.*

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How to Reduce Radiation Exposure During EVAR

Tips and tricks to minimize radiation exposure during EVAR procedures.

BY STÉPHAN HAULON, MD, PHD; ADRIEN HERTAULT, MD; JONATHAN SOBOCINSKI, MD, PHD; AND RICHARD AZZAOUI, MD

During the last 2 decades, technical improvements in biomaterials have enabled minimally invasive treatment of most vascular diseases. Endovascular aneurysm repair (EVAR) is now a large part of vascular surgeons' daily practice. Initially reserved for high-risk patients and expert centers, EVAR is now commonly performed as the first-line treatment in most hospitals. However, these procedures require x-ray guidance, which is associated with biological risks for both physicians and patients. Potential consequences range from skin burns to the development of solid cancers and leukemia. When following good practices, it is possible to achieve excellent clinical outcomes with a simple workflow and a low x-ray exposure level.[1] This article suggests various strategies—from room setup to good radiological practices—to reduce radiation dose during endovascular aortic procedures.

RADIATION FUNDAMENTALS

X-ray imaging is based on the seemingly simple physics of the interaction of x-rays with matter. X-rays are both electromagnetic waves and particles (photons) that move along straight lines in a vacuum. They are powerful enough to deeply penetrate in matter and are able to cross it in certain conditions. A shadow image is seen because certain parts of the body are more transparent to x-rays than others. In all cases, some x-rays are absorbed (entirely or partially) by the body. This absorption effect is called the *radiation dose,* and therefore, it is inherent to x-ray imaging to supply a radiation dose to the patient.

Air kerma (AK, in Gy; *kerma* refers to the kinetic energy released per unit mass) is the absorbed dose and is computed at the interventional reference point, defined as 15 cm from the system isocenter toward the anode, which is a good estimation of the patient skin entrance position. It is well correlated to the peak skin dose (in Gy), which is defined as the highest dose delivered to any portion of the patient's skin, including backscattered radiation during a procedure, and is used to assess the risk of deterministic effects, such as skin injuries. A threshold of 2 to 3 Gy is commonly considered to be at risk.[1] The dose area product (DAP, in Gy cm²) is the product of the AK by the exposed area. The DAP accumulated during the procedure is linked to the stochastic effect (ie, the increased risk of cancer) and can be converted in a first approximation to the effective dose (in Sv) using a conversion factor.[2] However, there is no consensus on the method used to compute this conversion factor. Since DAP was introduced on fluoroscopy equipment a long time ago, it has been widely used for comparing doses among procedures performed in the same anatomic region and between different institutions.

TECHNIQUES TO REDUCE RADIATION DOSE

The risk-benefit ratio of x-ray use in medical practice has to be considered for each patient and procedure in order to obtain sufficient image quality at a minimum dose while allowing for safety and efficacy.[3] This concept is referred to as the "as low as reasonably achievable" (or ALARA) principle. To achieve this goal, different strategies should be combined, from x-ray system technical settings optimization to good and advanced clinical practice. When available, non–x-ray procedures need to be considered.

Room Setup and Dose Awareness

Because x-rays are undetectable by the human eye, passive protection and alerts are needed to help the operator protect himself or herself, the staff, and the patients at all times.

Distance and shielding. The main source of radiation to the operator is scattered radiation. Levels of scattered radiation decrease by the inversed squared distance from its main source, the patient. Therefore, a longer distance from the main beam (eg, by working with longer sheaths) can help decrease occupational exposure.

Scattered radiation is more important at the entrance point of the beam into the patient—under the table. Most x-ray energy deflected upward will be absorbed by the

patient's tissues, but x-rays deflected downward will not encounter any obstacle. Thus, radiation levels are higher at the operator's legs, reinforcing the need for table-mounted lead skirts. Consequently, the tube should always be positioned under the table to avoid the highest scattered radiation being directed at the operator's head. Likewise, in lateral angulations, operators should preferentially stand on the side of the detector, and ceiling-mounted shields need to be used.[4,5]

Monitoring patient exposure. Modern interventional fluoroscopy systems are capable of displaying a number of metrics related to patient dose, including the fluoroscopy time, the DAP, and the cumulative AK (CAK). These metrics do not directly measure patient dose, but are intended to provide enough information in real time to allow the physician to decide to stop the procedure or change strategy.

Fluoroscopy time can be useful as a quality assurance tool for assessing the efficiency of a physician in completing a procedure, but it has shown poor correlation with the other dose indicators, as it does not take into account any of the x-ray system settings. Moreover, its definition varies and can either represent total pedal time or x-ray pulse duration. Therefore, this indicator should be used carefully and only if no other metric is available.

DAP correlates poorly with the skin dose for individual patient procedures but is more reliable as an estimator of energy imparted to the patient and, therefore, of stochastic risk.

Last, monitoring AK provides a practical way for estimating the dose at the patient's skin in order to avoid deterministic effect due to high-dose radiation during the procedure. However, CAK has limitations related to the size and position of the patient. In addition, CAK and DAP measures ignore the effect of the backscatter from the patient.

Monitoring staff occupational exposition. The effective dose to the operator can be reported in Sv. Passive dosimeters do not provide direct readouts and operate without any active means. As opposed to a passive dosimeter, active dosimeters provide a direct display of the accumulated dose and dose rate, as well as some additional functions, such as alarm threshold settings for dose or dose rate values. The active dosimeter allows the medical staff to adjust their behavior and avoid unnecessary occupational radiation exposure.

Longitudinal dose analysis. Collecting and storing dose data allows for continuous self-evaluation and thus helps to manage and control the risk to patients and staff in the long term. Dose information tracking systems, called *dose archiving and communication systems* (eg, DoseWatch, GE Healthcare), are currently available. They can automatically collect dosimetric information from different x-ray modalities, perform statistical analysis, manage patient dose history, and send alerts.

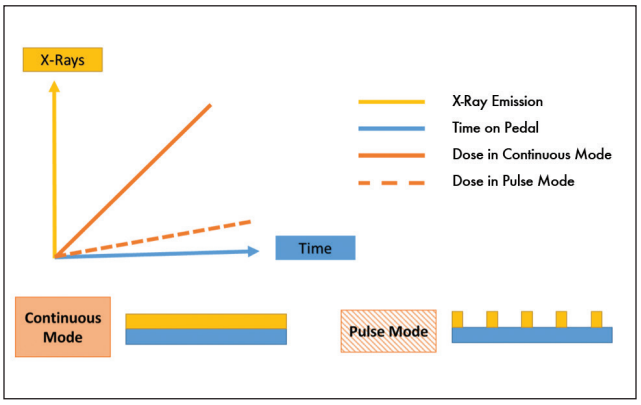

Figure 1. In continuous mode, x-rays (in yellow) are continuously emitted while the foot stays on the pedal (in blue); however, x-rays are only emitted during short pulses in pulse mode. Therefore, the delivered dose rises faster in continuous mode (continuous orange line) than in pulse mode (dashed orange line).

Optimizing X-Ray System Technical Settings

Modern fixed angiography systems come with smart designs and technology, delivering the best image quality at low radiation levels. It is important to understand these designs and technology to better optimize their use in daily practice.

Flat panel detector technology. Flat panel detector technology, which is widely used in liquid crystal display monitors, achieves a high level of radiographic performance thanks to a high signal-to-noise ratio, wide dynamic signal range, limited geometric distortion, and high uniformity of performance across the field of view (FOV). Evidence in the literature suggests that this technology can be associated with a reduction in radiation exposure of up to 30% when compared with the previous generation of devices using image intensifiers.[6]

Pulse mode. Any modern angiography system is now equipped with a pulsed mode, where images are obtained via multiple short x-ray pulse emissions, as opposed to continuous fluoroscopy (Figure 1). Digital image display at a constant frame rate is then used to compensate the loss of temporal resolution and to obtain a smooth shift between each image. At a typical frame rate of 7.5 images per second in a pulsed mode, a 90% reduction of produced images is achieved compared with the continuous mode (typically 30 images per second). Therefore, the frame rate must be lowered and adjusted to each procedure type.

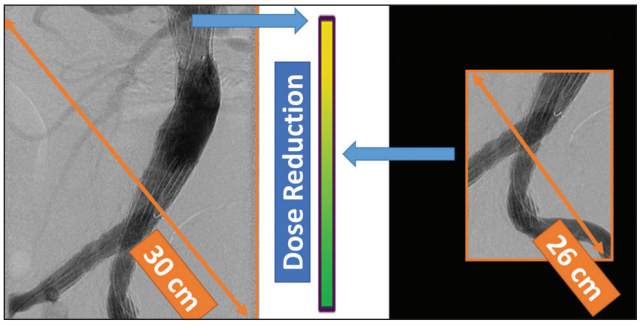

Figure 2. Optimal collimation on the area of interest allows significant dose reduction (proportional to the image reduction).

Auto exposure settings. In modern angiography systems, x-ray exposure is automatically adjusted in real time to deliver constant image quality at the lowest dose via continuous patient thickness estimation. Image quality can then be adjusted with the help of the manufacturer to each physician's specific daily practice and preference, so that procedures systematically start with the lowest settings that provide sufficient image quality. Easy upgrade of these settings must be available at any time from tableside if higher image quality is required at specific times during the procedure.

Low-dose setting. Most of the commercially available imaging systems now offer half and/or low-dose modes. Experimental studies on phantoms have demonstrated that routine use of the half-dose setting is associated with an entrance skin dose reduction of almost half without impairment of the image quality compared with full dose.[7]

Antiscatter grids. Antiscatter grids are commonly used to increase image quality by reducing scatter-induced background noise. However, the introduction of an additional matter thickness leads to significant dose increment. Removal of the grid is possible but would allow dose savings only in very specific cases such as very small anatomies or pediatric patients.

Good Radiological Practice

Time on the pedal. It is obvious that the foot pedal should be engaged only when information is required. It is important to disengage the pedal as soon as data acquisition is no longer relevant.

Digital subtraction angiography (DSA) versus fluoroscopic mode. DSA allows high-quality loop acquisition with subtraction of nonvascular structures. It is commonly used for diagnosis or documentation purposes. However, DSA requires substantial additional radiation exposure compared with standard fluoroscopy. Therefore, the use of fluoroscopy must be preferred and DSA runs limited where possible.[8] Digital storage of fluoroscopic loops can replace most DSA runs.

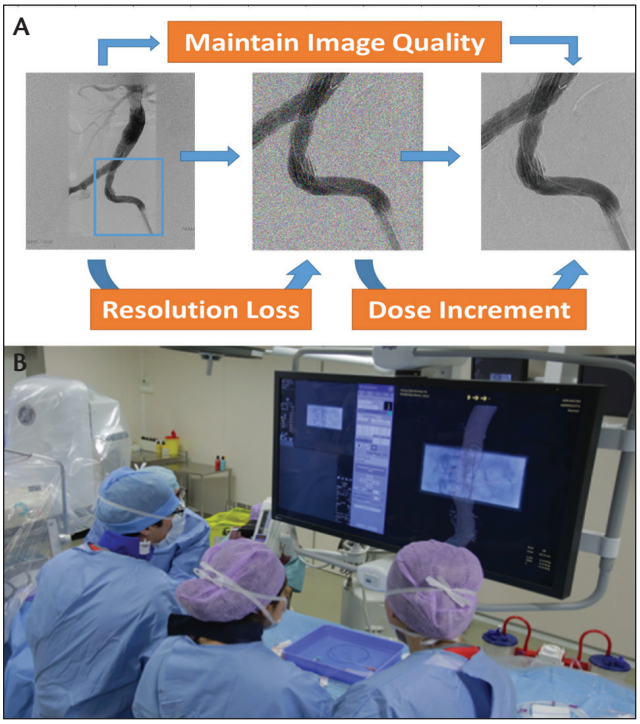

Figure 3. Magnification increases the dose (A), but this can be avoided by using large display monitors (B).

Collimation. Reduction of the FOV through appropriate vertical, horizontal, or iris collimation allows one to focus on the area of interest. It reduces scattered radiation and therefore increases image accuracy. Moreover, it limits the exposure of surrounding tissues. Radiation exposure is decreased in proportion to the reduction of image size (Figure 2).[9] The use of virtual collimation, when available, can help with positioning the collimation leaves without fluoroscopy.

Magnification. Magnification is sometimes used to achieve better visibility by using a smaller FOV (Figure 3). Zooming is applied to the image, making it easier to see the objects because they are bigger and also because monitors are used at relatively long distances compared with their display capability. Collimation is automatically adapted to protect surrounding tissues, which also has an effect on removing scattered radiation, thus improving the image contrast. In general, to compensate for the loss in resolution by magnification, the equipment is designed to increase the dose rate with the reduction in FOV, either approximately linearly or in a quadratic way with the magnification factor. Typically, flat panels and corrected image intensifiers would experience an approximate linear increase of the dose rate with the magnification factor. The need for magnification can be limited by digital zooming and the use of large display monitors.

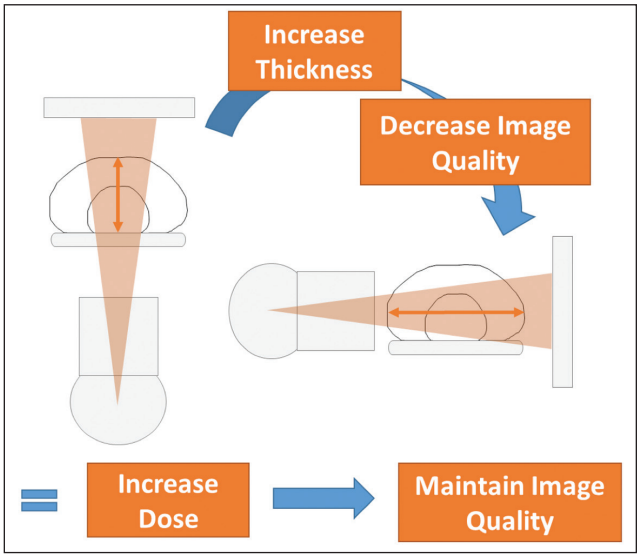

Figure 4. Whenever possible, angulations should be avoided. In lateral (or craniocaudal) angulations, x-rays cross more tissues, which increases attenuation and decreases image quality. To compensate, the system increases the beam energy to maintain image quality.

Limit angulations. An exponential increase of scattered radiation is observed when the gantry position is > 30° in left or right anterior oblique angulation or 15° in cranial angulation (Figure 4). Angulation increases staff exposure, and image quality deteriorates. Extreme gantry angulations should be avoided or used in short increments with adequate collimation when required.

Imaging chain geometry. The detector must be placed as close to the patient as possible to avoid beam energy dispersion and acquisition of a lowered signal, which would result in an increase of dose production settings by generators (Figure 5). Table height must be adjusted so that the operator's head and chest are not too close to the patient, who is the main source of scatter radiation.

Advanced Techniques to Reduce Radiation During EVAR

Operator-controlled imaging. Additional exposure can be induced by a misunderstanding or incorrect coordination between radiographers and operators. A dose reduction of approximately 30% has been reported during EVAR procedures with complete operator-controlled imaging from the tableside compared with radiographer-controlled imaging.[10]

Preoperative image analysis. Meticulous planning of the EVAR procedure with preoperative imaging analysis on a three-dimensional (3D) workstation allows for the assessment of access routes and for selecting specific angulations and working positions. Consequently, direct

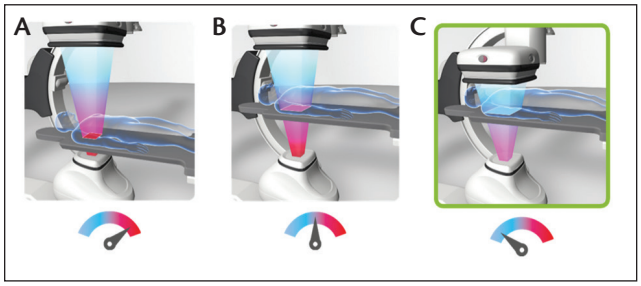

Figure 5. When the table is too low, the FOV will decrease, and the dose delivered to the patient's skin will increase (A). If the table is too high, the operator's head and chest are too close to the patient and are exposed to scattered radiation (B). The detector must be placed as close as possible to the patient to limit background noise (more scattered radiations will reach the captor) (C).

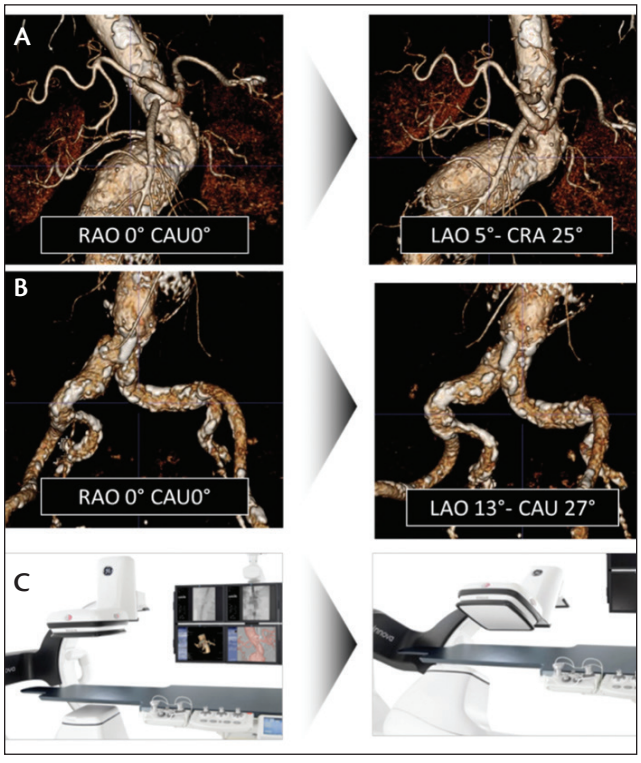

Figure 6. Proximal (A) and distal (B) sealing zones are analyzed on a dedicated workstation before the intervention in order to appropriately position the gantry during the intervention (C) and avoid unnecessary radiation.

positioning of the gantry at the proper angulation can be performed during the procedure, thus minimizing fluoroscopy or DSA runs (Figure 6). The old-fashioned "diagnostic" run at the beginning of interventional procedures is no longer required.

Advanced imaging applications. Advanced imaging applications, such as fusion imaging, are available in most hybrid rooms. Several methods are described to register a

3D volume, either from the preoperative CT angiography or a contrast-enhanced cone-beam CT acquired during the procedure, such as Innova Vision (GE Healthcare). Because the fused aortic 3D model automatically follows table and detector movements, fluoroscopy is only performed once the gantry and the table are precisely positioned to visualize the working FOV. This allows consequent dose savings. A reduction of up to 70% of the procedure's total radiation has been reported in complex EVAR cases supported by this technique.[11,12]

CONCLUSION

Before, during, and after EVAR procedures, patients undergo extended exposure to x-ray and iodinated contrast, and the clinical staff is also exposed to scattered radiation on a daily basis. Specific attention must be paid to the application of regulations of radiation dose reduction and to the monitoring of patients and personnel. Specific education and training of the clinical staff, optimization of angiographic systems settings, and adherence to good clinical practice are therefore keys to reducing radiation and contrast media volume while ensuring safe and efficient EVAR procedures. ■

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