VASCULAR AND ENDOVASCULAR TECHNIQUES

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Practical points of attention beyond instructions for use with the Zenith fenestrated stent graft

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Fenestrated stent grafting for endovascular repair (F-EVAR) aims to treat patients with abdominal aortic aneurysms that are unsuitable for standard EVAR because of a short or absent infrarenal neck. F-EVAR has been used initially in patients with higher surgical risk with pararenal abdominal aortic aneurysms, but F-EVAR is now increasingly considered a treatment alternative to open surgery in anatomically suitable patients. F-EVAR has benefitted from ongoing technical refinements and accumulating clinical experience but remains a relatively complex procedure. Correct indication, accurate preoperative planning, and meticulous execution are the key to long-term success. Considering the growing interest in F-EVAR worldwide, including the United States, we discuss current indications and provide advice for planning and technical execution on the basis of the senior authors' 13 years of experience. (J Vasc Surg 2014;60:246-52.)

Fenestrated stent grafting for endovascular repair (F-EVAR) was developed to treat patients with abdominal aortic aneurysms (AAAs) featuring a short or absent infrarenal neck. Fenestrated stent grafts are provided with custom-made fenestrations and scallops for the visceral arteries, which allow extension of the proximal sealing zone to the suprarenal aorta.[1] During the past decade, F-EVAR has evolved in terms of technical refinements. Published series demonstrate high initial technical success, safety, and durability (97%-100% operative target vessel preservation, 0%-3.5% early mortality, 96%-99% target vessel patency during follow-up).[2-5] Nevertheless, F-EVAR remains a relatively complex procedure requiring correct indication and accurate preoperative planning and execution. The procedure requires not only precise positioning and deployment of the stent graft but also careful catheterization and stenting of the visceral target vessels. A detailed step-by-step approach of the procedure was published at an early stage, and the manufacturer (Cook Inc, Bloomington, Ind) issued clear instructions for use.[6] However, technical and anatomic challenges can occur and do require ad-hoc solutions. On the basis of the experience of more than 650 fenestrated and branched endovascular procedures by the senior author, current anatomic and clinical indications of F-EVAR are discussed, and advice for planning and advice for correct technical execution of F-EVAR are suggested.

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INDICATIONS

Current anatomic and clinical indications for primary F-EVAR include short-necked, pararenal, and some suprarenal AAA. F-EVAR can also be used to repair previous failed open surgery or EVAR.[7,8] F-EVAR is currently used in high-risk and normal-risk surgical patients.

The absence of a neck is not a limiting factor because fenestrations can be added to move the graft upward to find a stable sealing zone above the renal arteries (RAs). Compared with standard EVAR, F-EVAR requires a better access vessel because the graft must be repositioned and reoriented to achieve successful catheterization of the target vessels. The anatomy of the target vessels must be adequate to achieve insertion and sealing with a covered stent. Therefore, diseased (<4 mm) and early bifurcated target vessels are not suitable. Sharp downward take-off target vessels represent an unfavorable anatomic characteristic because catheterization is more difficult.

Beyond anatomic limitations and technical difficulties, custom-made fenestrated grafts have no role in acute patients because of the required 4- to 6-week device customization process. Fenestrated stent grafts available "off-the-shelf" are currently under investigation.

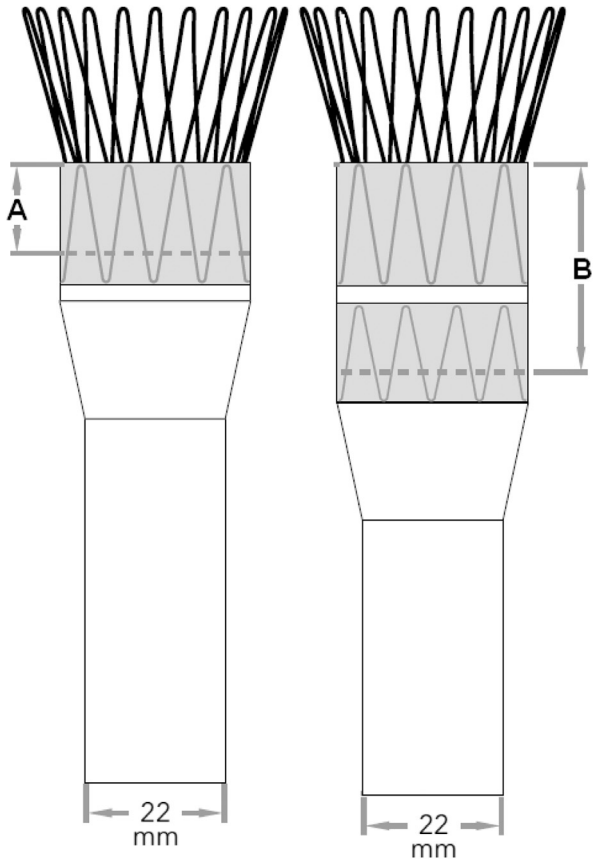

Fig 1. Schematic diagram of the first tube-graft that includes the scallop and fenestrations. Proximally, the stent graft contains either one **(A)** or two **(B)** internal sealing stents; below this/these, it starts tapering down to 22 mm.

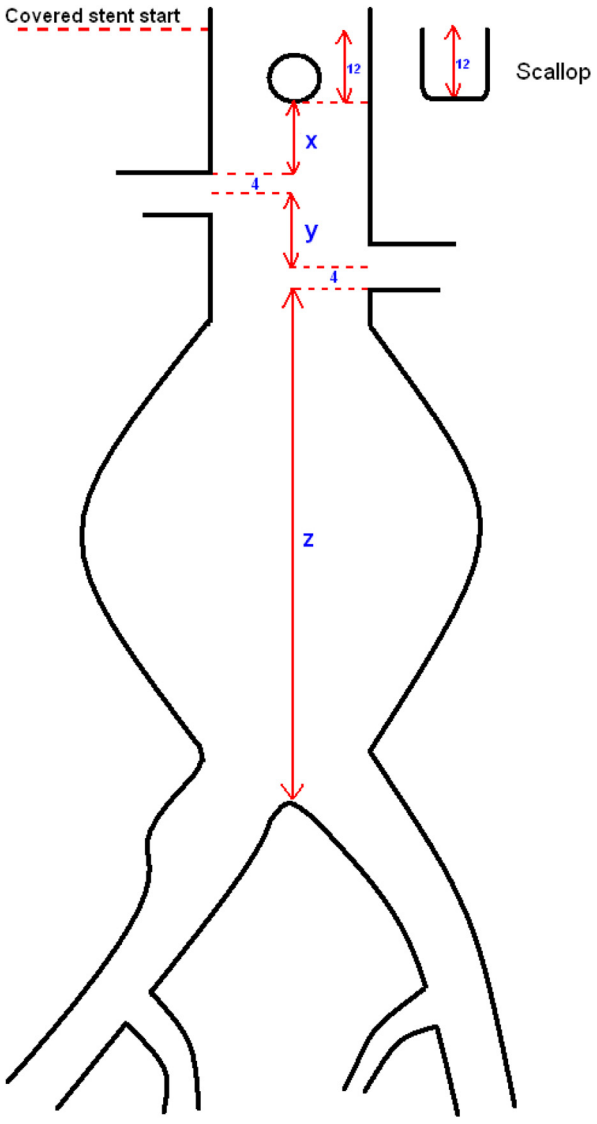

Fig 2. Schematic diagram demonstrating the distances measured for planning of a standard two-fenestration graft and a scallop for the superior mesenteric artery (SMA).

STENT GRAFT PLANNING AND SIZING

General configuration. The stent graft is based on the Zenith delivery system (Cook Inc) and is custom-made for each patient on the basis of preoperative computed tomography angiography measurements. It usually consists of a composite three-part system, with a proximal fenestrated tube, a distal bifurcated component, and a contralateral limb. The reason behind this composite three-part system is to allow for some sliding between the fenestrated tube and the bifurcation. This helps to avoid traction on the fenestrations with subsequent risk of squashing the RA stents. A fenestrated tube is also easier to reposition and safer to reorient to position each fenestration in front of the ostium of the target vessel during each catheterization.

The most commonly used configuration includes small, 8- × 6-mm fenestrations for the RAs and a scallop (10 mm wide, 12 mm deep) for the superior mesenteric artery (SMA). The RAs are always stented and the scallop usually is not stented. The reinforced 10-mm scallop should fall into position once the two renal fenestrations have been stented. This is not the case in a one fenestration + one scallop configuration. Indeed, because of the diameter reducing ties, the scallop can land in a different orientation than planned when not fixed by two or three fenestrations. We have therefore completely abandoned this configuration. If needed, we would advise the use of an additional fenestration for the SMA, and, if needed, a scallop for the celiac artery. In other words, if a scallop is used, one must ascertain that this one will fall into position, based on the fenestrations.

One or two internal sealing stents. The proximal fenestrated tube can feature one or two internal sealing stents. The graft starts to taper to 22 mm below this/these internal sealing stent(s) (Fig 1). Choosing two internal sealing stents, whenever possible, is better for two reasons. First, it increases fixation of the stent graft in maximal use

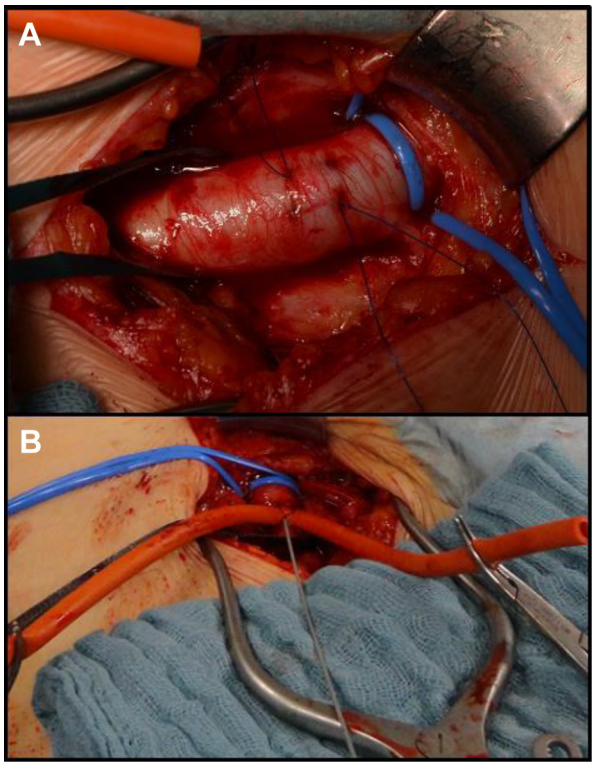

Fig 3. Double purse-string sutures at the common femoral artery before puncture **(A)**. After removal of the delivery system of the proximal body, both purse-string sutures are pulled and snugged around a stiff guide wire, enabling blood flow restoration to the ipsilateral lower limb while stenting the target vessels **(B)**.

of the available neck. Second, it allows positioning of the fenestrations in the second sealing stent with better apposition to the aortic wall. With one internal sealing stent, some fenestrations would end up in the tapered part of the stent graft, which increases the risk of type III endoleak through the fenestrations. The sole advantage of one internal sealing stent is having one extra stent distally (for the same graft length), allowing for more overlap/sealing distally with the bifurcated graft. However, this is rarely needed in our patient population.

Small fenestration type and bridging stent. Small fenestrations can be either 6 × 6 mm or 6 × 8 mm. The second option is preferred because it allows for easier catheterization of the fenestration and softens the effects of small imperfections in planning, especially in angulated necks. To avoid endoleaks, it is advisable to use covered balloon-expandable stents (eg, iCast V12; Atrium Medical Corporation, Hudson, NH). After deployment, these can easily be flared with a larger balloon on the inside of the main stent graft. It is important to deploy the covered stents with exact tangential view on the fenestration. This allows two stent rows (4-5 mm) to be left inside the aorta for flaring. Covered stents have demonstrated better long-term patency rates than have noncovered stents in fenestrated stent grafting.[9]

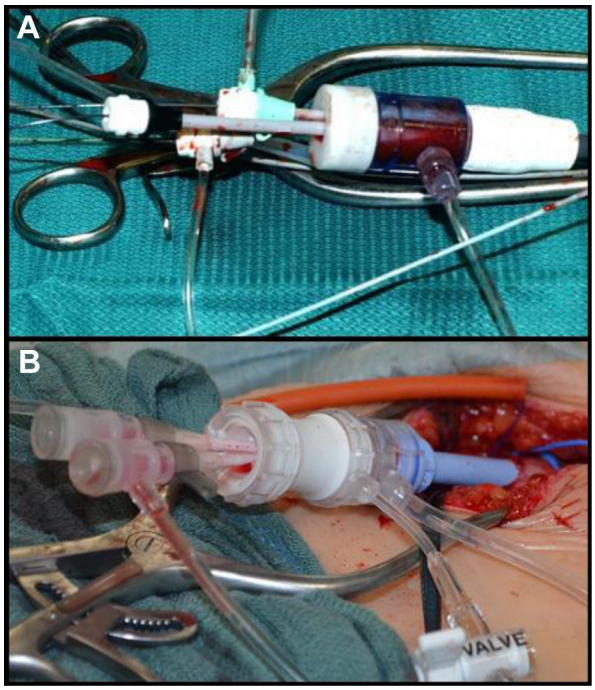

Fig 4. Separate 5F sheaths for each target vessel catheterization inserted in the valve leaflets of a large 20F Cook sheath through contralateral femoral access **(A)**. An 18F Gore Dry-seal sheath is used, which can be easily fitted by two or more 5F sheaths without blood loss **(B)**.

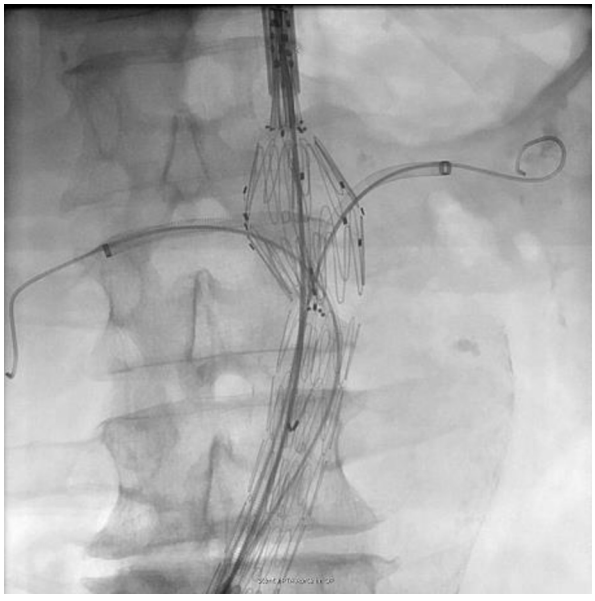

Fig 5. Guiding sheaths (7F) advanced into the renal arteries (RAs) before complete opening of the fenestrated tube stent graft.

Sizing of the fenestrated tube. Oversizing and length measurements are not different from standard EVAR, but one must take into consideration that a part of the graft

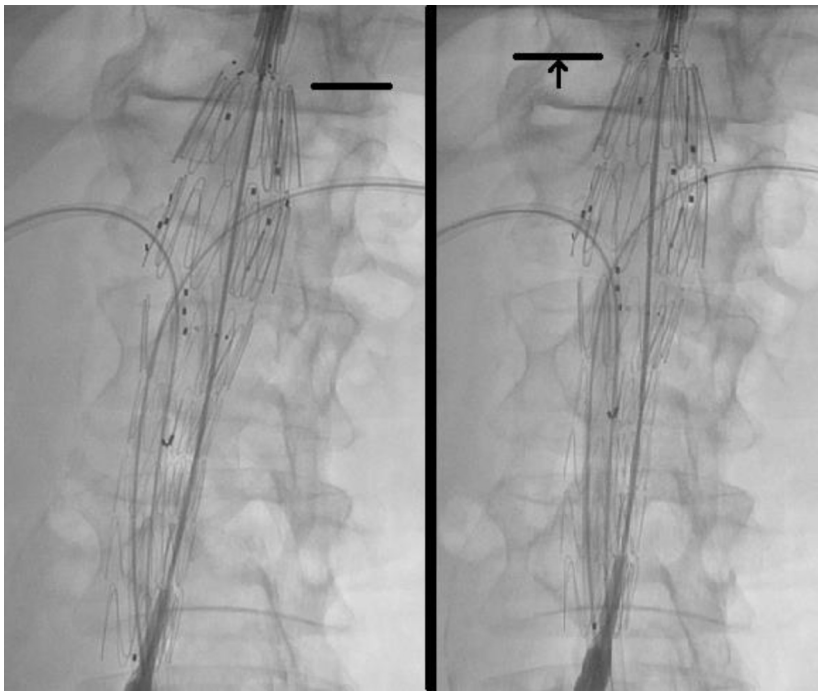

Fig 6. Pushing up of the stent graft, aiming to position the fenestrations as high as possible before removal of the diameter-reducing ties and release of the top cap. This maneuver compensates for a 1- to 2-mm downward migration of the graft after opening caused by encroachment of the hooks and barbs.

will lay above the RAs. After defining the clockwise position of the target vessels, on the basis of the axial computed tomography angiography sections, starting from proximal to distal (celiac artery, SMA, RAs), a decision must be made to use two, three, or even four fenestrations. The advice is clearly to create a healthy sealing zone of at least 25 mm in length. If the sealing zone is shorter, one should add a fenestration. For a standard two-fenestration graft and a scallop for the SMA, we measure the following distances: bottom SMA to top highest RA (x), highest to lowest RA (y), and bottom lowest RA to aortic bifurcation (z) (Fig 2). Starting with a 12-mm-deep scallop to increase the sealing length to the maximum, one adds x + 4 mm (=12 + x + 4) to determine the level of the middle of the highest RA fenestration (8 mm high, therefore 4 mm to the middle). The level of the second RA fenestration is then 12 + x + 4 + y. The graft length above the RAs (12 + x + 4 + y + 4) should be added to the infrarenal working length (z) to determine the length of the fenestrated tube, but with subtraction of 30-35 mm to allow for room for the 23-mm-long contralateral limb of the bifurcated graft (for catheterization).

Fenestrations can be added if a higher position of the main graft is required or if accessory RAs must be involved. Vessels with diameters smaller than 3 mm should not be used because experience in all large-volume centers has invariably shown occlusions, even after initial technical success.

Overlap between the proximal tube and the distal bifurcated stent graft. A maximum overlap between the proximal fenestrated tube part and the second bifurcated stent graft is mandatory. Two-stent overlap, especially in an angulated aorta, carries a risk of disconnection. Therefore, the longest possible bifurcated graft should be used because this will result in a three- to four-stent overlap. The length of the bifurcated graft (including the contralateral limb) should be chosen approximately 2 cm shorter than the measured length from the lowest RA to the aortic bifurcation (z).

PROCEDURE

Surgical access. The importance of good surgical access is often underestimated. Especially in more complex advanced endovascular procedures, access and blood flow to the limbs become more important. In our institution, the open femoral approach with double purse-string sutures is the standard of care (Fig 3, *A*). For the purse-string sutures, we use Prolene 4/0 and fit these with a snugger. This allows complete removal of the delivery system of the proximal body while stenting the target vessels from the contralateral side. This restores blood flow to the ipsilateral limb with only a stiff guide wire in position, which secures safe introduction of the bifurcated graft later (Fig 3, *B*).

Fenestrated tube deployment. The fenestrated tube is correctly oriented before insertion (three longitudinal markers and a tick marker) and deployed after angiography.

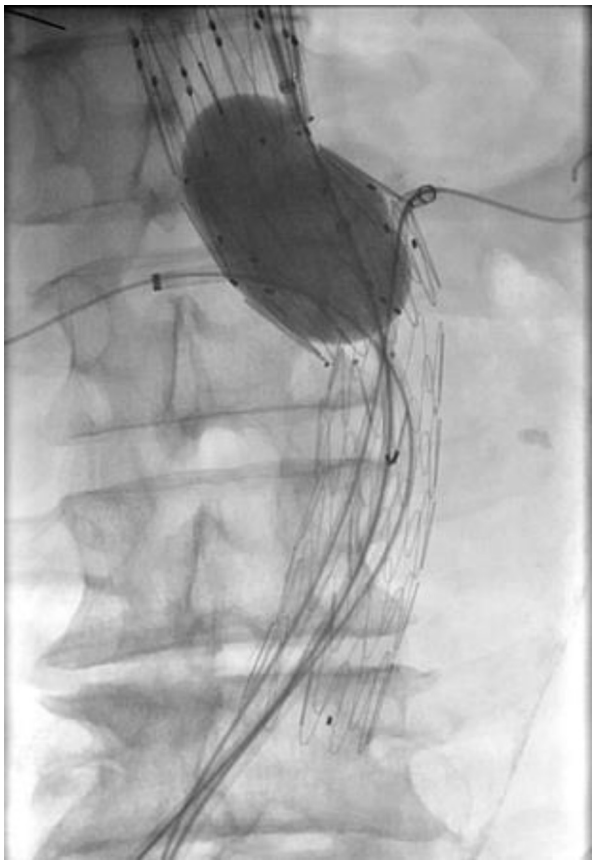

Fig 7. Balloon molding of the completely opened main stent graft with a compliant balloon before insertion of the renal covered stents. This improves apposition to the wall in the case of an angulated neck.

All fenestrations are easily visualized by four markers. It is advisable to position the graft slightly too high because repositioning and reorientation is easier downward than upward. A particular scenario is when a fenestrated cuff is used after previous EVAR or open surgery: This must be deployed slightly lower because pulling down the cuff is often difficult.

Position of a sheath from the contralateral groin. After positioning and partial deployment of the fenestrated tube, a large sheath must be positioned in the opened fenestrated tube. This allows for safe and continued access to the tube with the different wires and guiding sheaths. This sheath must be advanced over a stiff wire while keeping the fenestrated tube in correct position. A 20F Cook sheath has been used for that purpose for some time. To avoid blood loss, 5F sheaths are introduced by puncturing the valve leaflets (Fig 4, *A*). An alternative is the use of the 18F Gore Dry-seal sheath (W. L. Gore and Associates, Flagstaff, Ariz), which features a radio-opaque marker at the tip and is easily fitted with two or more small sheaths, without blood loss (Fig 4, *B*). To allow for maneuverability of the catheters, it is important not to position the large sheath too high.

Target vessel cannulation. Target vessel cannulation is performed sequentially, starting with the easiest RA. Catheterization of target vessels is a two-operator task. One operator positions the selected catheter (eg, a Cobra 1 type shaped catheter) in the fenestration. If the catheter does not fall spontaneously with its tip in the RA, the second operator aims at "opening the door" by slight repositioning of the stent graft to optimize the alignment of fenestration and target vessel. On catheterization, an angiogram should always be performed to confirm catheterization of the intended vessel and show the anatomy of the target vessel tree. This allows the operator to choose the longest branch of the visceral artery. Either a heavy-duty Rosen wire (Cook Inc) or an Amplatz super-stiff, 1-cm floppy-tip wire (Boston Scientific, Natick, Mass) is then positioned into the vessel. When catheterization is difficult, the following options are available: another type of catheter, including a reversed shaped catheter (eg, VS2, Omni-flush, SOS), more support with a 7F ANL guiding sheath, and aiming at a better angle for viewing of the RA ostium.

The stiff wires are positioned in both RAs before inserting the guiding sheaths (7F ANL; Cook Inc) to shorten the period of renal flow impairment. The Amplatz wire is best chosen for RAs with difficult anatomy (eg, stenosis, severe angulation, sharp take-off angle, short length) and for the SMA. The guiding sheaths can be inserted, but with care not to push the dilator too far inside the RA (Fig 5). In three-fenestration grafts, two 7F guiding sheaths can be advanced in the RAs and an Amplatz guide wire only in the SMA. After stenting of each RA, the 7F guiding sheath is removed. A 7F guiding sheath is then advanced over the Amplatz wire in the SMA and the SMA is stented. This sequence avoids the need to use a 22F sheath and prolonged sheath occlusion of the SMA.

Complete opening of the fenestrated proximal tube graft. Guiding sheaths tend to slightly pull down the fenestrations. Therefore, the removal of the diameter-reducing ties and the release of the top cap should be done while firmly pushing up the whole stent graft to position the fenestrations as high as possible (even a bit higher than the target vessel) (Fig 6). After opening of the tube graft, the encroaching of the hooks and barbs may result in an initial 1- to 2-mm downward migration of the tube graft before reaching the final position. Ideal positioning of the fenestrations minimizes the stress forces on the bridging covered stents, especially from above, when a fenestration is positioned somewhat low.

In angulated necks, balloon molding of the main stent graft with a compliant balloon should be considered before insertion of the covered stents to improve apposition of the graft to the wall (Fig 7).

Target vessel stenting. Target vessel stenting should start with the highest RA to prevent damage to the contralateral lower renal stent during ballooning and flaring. Balloon-expandable covered stents (eg, iCAST V12) are preferentially used. The bridging covered stent is positioned to aim for a 4- to 5-mm protrusion in the central lumen

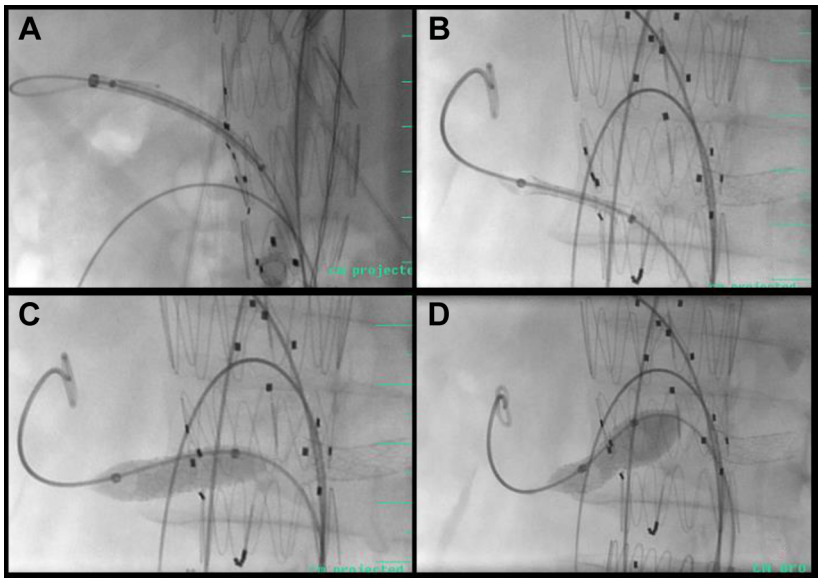

Fig 8. Positioning of the bridging covered stent within a 7F guiding sheath into the right renal artery (RA) **(A)**. Balloon inflation and deployment of the bridging covered stent under gradual upward tilting of the balloon catheter **(B** and **C)**. Circumferential flaring of the proximal protruding part of the bridging covered stent with a 12 mm × 2 cm non-compliant balloon. This is also tilted upward **(D)**.

Table. Standard endovascular materials used for F-EVAR

Material	*Manufacturer*
One hydrophilic-coated J-tip guide wire, 0.035 inch/180 cm	Terumo
One hydrophilic-coated J-tip guide wire, 0.035 inch, 260 cm	
Two Lunderquist extra-stiff guide wires, 0.035 inch, 260 cm	Cook Inc
One Amplatz super-stiff guide wire, 0.035 inch, 1-cm floppy-tip, 260 cm	Boston Scientific
Two Rosen guide wires, 0.035 inch, 260 cm	Cook Inc
Two Sheaths, 9F, 11 cm	Alternative options
Two/three sheaths, 5F, 11 cm	Alternative options
One sheath, 20F, 25/30 cm or	Cook Inc
one Dry-Seal sheath, 18F, 28 cm	Gore
Two guiding sheaths, 7F-ANL1, 55 cm	Cook Inc
One straight metric angiocatheter, 5F, 100 cm	Alternative options
One Berenstein catheter, 5F, 65 cm	Alternative options
One Cobra catheter, 5F, 65 cm	Alternative options
One aortic molding balloon	Alternative options
iCast V12 balloon-expandable covered stents (according to preoperative CTA measurements)	Atrium Maquet
One balloon dilation catheter, 12 mm × 2 cm (flaring of the covered stents)	Alternative options

CTA, Computed tomography angiography; *F-EVAR,* fenestrated stent grafting for endovascular repair.

(Fig 8, *A*). The guiding sheath is then carefully withdrawn 3-4 cm while keeping the bridging covered stent in position. Attention must be paid not to push the bridging covered stent further into the target vessel and totally out of the fenestration (because retraction over the ridge of the fenestration may be impossible). In the case of early bifurcation of a target vessel, an additional angiogram should be performed through the partially withdrawn guiding sheath to ascertain that the bridging covered stent is in correct position.

Deployment of the bridging covered stent is a two-operator task. One operator inflates the balloon while the second operator controls the positioning of the bridging covered stent and gradually tilts the balloon catheter upward (Fig 8, *B* and *C*). To flare the proximal protruding part of the bridging covered stent, a 12 mm × 2 cm non-compliant balloon is used. This balloon should also be tilted upward to achieve circumferential flaring (Fig 8, *D*).

Bifurcated component deployment and catheterization of contralateral limb. While the bifurcated component is advanced, care must be taken not to disrupt an RA stent. Before deployment, the following positions must be carefully checked: (1) the bifurcated stent is positioned below the lowest RA stent; (2) the overlap between

bifurcated and fenestrated tube stent graft is at least three stents; (3) the position and orientation of the contralateral limb are appropriate for contralateral catheterization; and (4) the ipsilateral limb is well positioned inside the common iliac artery above the iliac bifurcation. Subsequent balloon dilatation of the overlap zone is performed before insertion and deployment of the contralateral limb because this one is usually deployed slightly above the flow-divider of the bifurcated component.

Correct catheterization of the contralateral gate is the last important step and should be carefully verified to avoid wrongful position of the contralateral limb (ie, between bifurcated and tube part but outside the gate). It is advisable to have two limbs readily available to choose from (usually a ZSLE-xx-56 and ZSLE-xx-74).

The Table summarizes the standard endovascular materials that are used in F-EVAR procedures.

IMAGING SYSTEM REQUIREMENTS FOR F-EVAR

Ideally, all F-EVAR procedures should now be performed in a hybrid operating room with a fixed imaging system. This is the best possible environment in terms of ergonomics, imaging quality, and safety, both for the patient and the involved personnel. Performance of F-EVAR in a conventional operating room with a mobile C-arm is still acceptable for "simple" F-EVAR procedures (two fenestrations for the RA and a scallop for the SMA) in which longer fluoroscopy time is needed, but only in anterior or slightly oblique views. For more complex F-EVAR procedures (three or four fenestrations), the required longer fluoroscopy time, with the risk of overheating and the lateral viewing needed for catheterization of the SMA, makes the use of a mobile C-arm obsolete.[10]

CONCLUSIONS

F-EVAR is a validated method to treat anatomically suitable short-necked, juxtarenal, and suprarenal AAA by endovascular means. The procedure has been standardized during the course of the years. Nevertheless, F-EVAR remains a relatively complex procedure with a clearly operator-dependent outcome. Accuracy in stent graft planning and meticulous step-by-step execution of the procedure, following a detailed check-list, improves the technical success rate and reduces the risk of intraoperative mistakes and complications.

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