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Radiofrequency In Situ Fenestration for Aortic Arch Vessels During Thoracic Endovascular Repair

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Abstract

Purpose: To report the first clinical application of a novel technique using radiofrequency puncture to create retrograde in situ fenestrations during thoracic endovascular aortic repair (TEVAR). **Methods:** Between June 2011 and December 2013, 40 TEVAR procedures were performed in our facility, including 10 cases in which in situ fenestration was planned. Two thoracic stent-graft models were deployed: the Valiant (n=5) and the Zenith TX2 (n=5). A 0.035-inch PowerWire radiofrequency guidewire delivered from a brachial approach was used to fenestrate the grafts covering a left subclavian artery (LSA) in 9 cases and a left common carotid artery in one. The fenestrations were serially dilated to 6 mm, and self-expanding Advanta V12 covered stents were positioned in the target arteries. **Results:** Technical success was achieved in 6 of the 10 planned cases. Of the remaining 4 cases, stent-grafts were deployed in zone 3 in 2 cases (one received a chimney to the LSA). Another stent-graft was deployed in zone 2 without endoleak after fenestration was abandoned (the LSA had good filling via the vertebral artery). In the last case, the fenestration was unsuccessful in double-layered (proximal extension overlap) stent-grafts; a carotid-axillary bypass was required. There were no fenestration-related complications, but overall surgical complications included a case of paraparesis that resolved following spinal drainage and a death from a preexisting aortoesophageal fistula. There were no postoperative strokes. All fenestrations remained patent, and there were no endoleaks at a mean 12-month follow-up (range 1–33). **Conclusion:** Radiofrequency puncture is a viable alternative to needle or laser punctures for in situ fenestration during TEVAR. Early clinical results suggest technical feasibility and acceptable early outcomes.

Keywords

in situ fenestration, thoracic endovascular aortic repair, aortic arch, thoracic aneurysm, radiofrequency, cutting balloon, self-expanding stent-graft, covered stent, common carotid artery, left subclavian artery

Introduction

There are several methods of revascularizing the arch vessels when performing thoracic endovascular repair (TEVAR), particularly in zone 2. The high cost and considerable time delay associated with custom-made fenestrated devices have prompted the development of more versatile on-site modifications of stent-grafts. Several techniques for on-site modification have been reported,[1–7] each with their advantages and disadvantages. We report the first clinical application of a novel technique of radiofrequency puncture[8] to facilitate retrograde in situ fenestration for zones 1 and 2 during TEVAR.

Methods

Between June 2011 and December 2013, 40 TEVAR procedures were performed in our facility, including 10 cases in which in situ fenestration was planned. The baseline medical comorbidities for the 10 planned in situ cases are shown

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Table 1. Baseline Characteristics and Operative/Perioperative Details of 10 Patients With Planned Radiofrequency Puncture for In Situ Fenestrations During TEVAR.[a]

Baseline characteristics	
Age, y	74 (54–85)
Men	7
Hypertension	8
Current/previous smoker	5
Dyslipidemia	3
Renal insufficiency	1
Congestive heart failure	1
COPD	5
Diabetes mellitus	0
Coronary artery disease	4
Peripheral artery disease	0
History of arrhythmia	6
Known connective tissue disorder	0
Operative details	
Proximal diameter, mm (median)	42 (28–44)
Proximal landing zone 0/1/2/3	1/2/5/2
Percutaneous brachial access	1
Retrograde sheath size, F	7 (7–9)
Fenestrations achieved/patent	6/6
Branch covered stent diameter, mm	9 (8–10)
Endoleak	0
Operative time, min	288 (162–440)
Fluoroscopy time, min	30.8 (12.6–54.4)
Contrast, mL	172 (50–270)
Perioperative details	
Stepdown unit stay, d	1.8 (1–7)
Length of stay, d	4 (2–10)
Stroke	0
Death	1

Abbreviations: TEVAR, thoracic endovascular aortic repair; COPD, chronic obstructive pulmonary disease.
[a]Continuous data are presented as the means (ranges) unless stated otherwise; categorical data are given as counts.

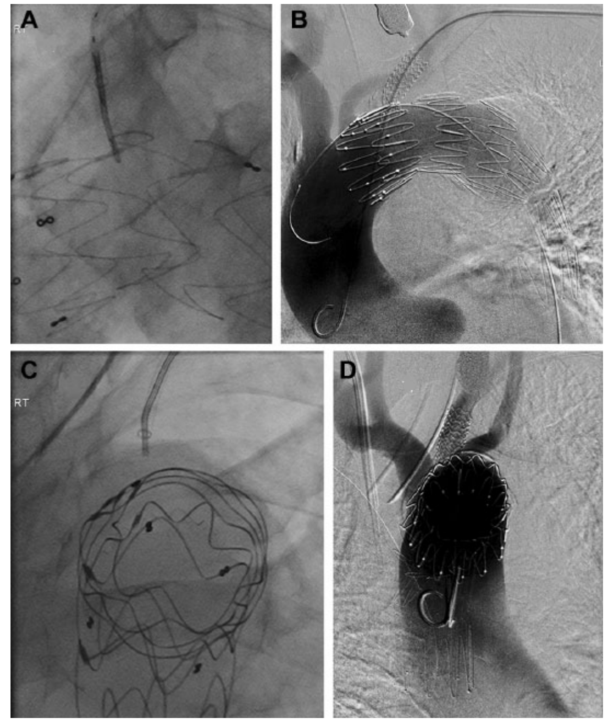

Figure 1. (A) Steep left anterior oblique view of thoracic endovascular aortic repair (TEVAR) during in situ fenestration. Note that it is difficult to determine whether the catheter is in front of or behind the thoracic stent-graft. (B) Typical completion angiography in this projection. (C) Steep right anterior oblique view of TEVAR during in situ fenestration. (D) Completion angiography in this projection demonstrates the variation in the relationship of the proximal great vessels to the aortic arch.

in Table 1. Two of the cases were performed for symptoms of new back pain in the presence of an aortic aneurysm. One case was performed for aortoesophageal fistula after previous open repair of type B dissection. Two of the aneurysms were saccular in nature, and all other aneurysms were >6 cm in diameter. One case was performed after a previous TEVAR with subsequent occlusion of an adjunctive carotid-subclavian bypass, resulting in debilitating arm claudication. Half of the patients received a Valiant stent-graft (Medtronic Vascular, Santa Rosa, CA, USA) and the other half a Zenith TX2 device (Cook Medical, Bloomington, IN, USA). Nine of the cases involved a left subclavian artery (LSA) fenestration (zone 2) and one had a left common carotid artery (LCCA) fenestration (zone 1).

Techniques

For zone 2 TEVAR, left brachial access is achieved either percutaneously or by a small cutdown. A 7- or 8-F, 45-cm hockey stick Pinnacle Destination sheath (Terumo, Somerset, NJ, USA) is introduced and advanced over a guidewire to the origin of the LSA. The thoracic endograft is deployed across the LSA orifice, and a 5-F Kumpe catheter (Cook Medical) is advanced until it reaches the endograft. [A coaxial technique with a 7-F, 55-cm renal double curve guiding sheath (Cordis Corp., Bridgewater, NJ, USA) is used occasionally to achieve more angulation and directional control.] The guidewire is exchanged for a 0.035-inch PowerWire radiofrequency guidewire (Baylis Medical Company, Mississauga, ON, Canada). After adjusting the fluoroscopic projection from a steep left anterior oblique view (Figure 1A) to a steep right anterior oblique view (Figure 1B), the graft is punctured using a 2-second duty cycle on the "high" setting of the radiofrequency puncture generator (Baylis Medical Company). Minimal mechanical force is applied. After breaching the graft material, the PowerWire is advanced down the descending thoracic aorta (Figure 2A). The Kumpe catheter is advanced and used to exchange the 0.035-inch PowerWire for a 0.018- or 0.014-inch V18/V14 ControlWire (Boston Scientific, Natick, MA, USA), which

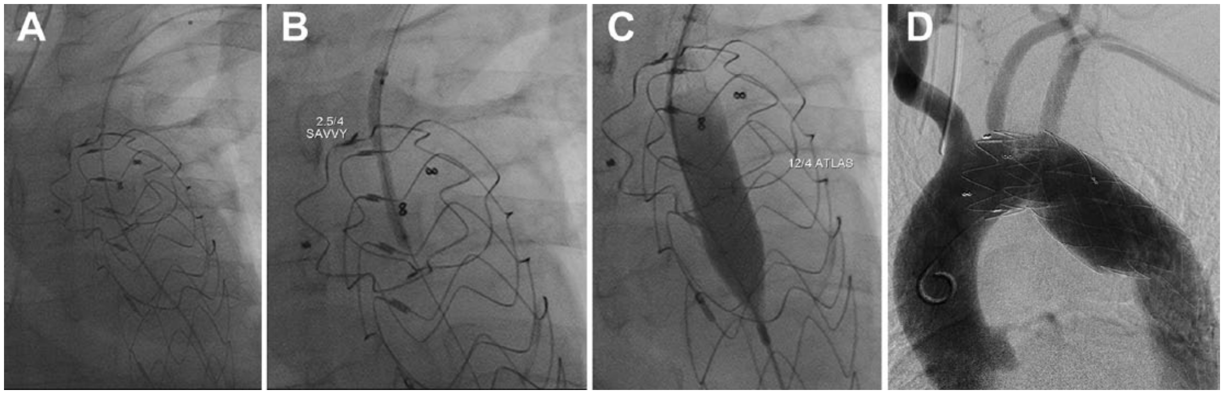

Figure 2. (A) Fluoroscopic image of a PowerWire that has been advanced from the subclavian artery through the fenestration and down the descending aorta. (B) Dilation of fenestration using a 2.5-mm angioplasty balloon. (C) Flaring of the covered stent using a 12-mm angioplasty balloon. (D) Completion angiography after LSA in situ fenestration of a thoracic stent-graft. Note the optimal arch configuration that allowed a near perpendicular approach.

is used to support balloon dilation with either a low-profile balloon for Valiant stent-grafts or a cutting balloon for the Zenith TX2 devices. The fenestration is dilated incrementally up to 6 mm using serially-larger balloons and inflating the balloon slowly to nominal pressure to allow the fabric yarns to accommodate (Figure 2B). The V18/V14 ControlWire is then exchanged for a 0.035-inch Amplatz wire (Cook Medical), over which is deployed an Advanta V12 covered stent (Maquet Cardiovascular, Hudson, NH, USA) sized to the LSA diameter. A 10- or 12-mm diameter angioplasty balloon is typically used to "flare" the intra-aortic portion of the Advanta V12 subclavian extension (Figure 2C). Completion angiography is then carried out to evaluate target vessel patency and rule out endoleaks (Figure 2D).

For zone 1 deployments, a left carotid-subclavian (C-S) bypass is first performed through a left supraclavicular incision. Proximal to the carotid anastomosis, a short 9-F sheath is inserted directly into the LCCA and directed toward the aortic arch in a retrograde fashion. A clamp is placed between this sheath and the C-S bypass to prevent embolization; at this point, left cerebral inflow is derived from the C-S bypass. Via the right femoral artery, the thoracic endograft is deployed across the orifice of the LCCA and then a single directional catheter is advanced through the carotid sheath until it reaches the endograft. The PowerWire is used to puncture the graft fabric, and the procedure is completed in a similar fashion as for zone 2, with dilation of the graft and stent placement. After final Advanta V12 deployment and flaring, the LCCA is temporarily clamped distal to the C-S bypass so that any debris is flushed out of the bypass or down the LSA. An Amplatzer plug (St Jude Medical, St Paul, MN, USA) is then deployed in the proximal LSA to prevent a retrograde endoleak.

Results

Of the 10 planned fenestrations, technical success was achieved in 6 cases. Operative and perioperative details are given in Table 1. Of the 4 unfenestrated cases, 2 had stent-grafts deployed in zone 3 without any endoleak (one received a chimney graft for encroachment on the LSA). One case that was abandoned after a brief attempt at fenestration had the stent-graft landed in zone 2 without endoleak in an emergent symptomatic patient with good LSA filling via the vertebral artery. The last case was unsuccessfully attempted in a double-layered graft (a proximal extension had been added), necessitating a carotid-axillary bypass.

There were no fenestration-related complications, but overall perioperative complications included urinary retention, gout exacerbation, blood transfusion, transient creatinine elevation, transient troponin elevation, paraparesis that resolved with insertion of a spinal drain, and the death of the patient with a preexisting aortoesophageal fistula, which eroded through the distal anastomosis of a previous open repair of type B aortic dissection (remote from the TEVAR site).

The range of follow-up was 1 to 33 months (mean 12). None of the patients had a stroke, no endoleak was observed, and all fenestrated vessels were patent, either clinically or by postoperative imaging.

Discussion

The first clinical case of in situ fenestration was published by McWilliams et al[1] in 2004. This was achieved with the stiff end of a glidewire, followed by a needle and cutting balloon angioplasty. Since that time, there have been further reports using a needle for graft puncture.[2–5] However, a needle requires the application of mechanical force in the appropriate direction, and as Riga et al[9] observed, the angle of approach is very important. Therefore, cases using a needle have in some instances required adjunctive surgical techniques, such as an incision in the supraclavicular fossa in order to obtain as straight and short a path as possible.[2] Surgical exploration of this anatomical area may not be desirable if other techniques are available, such as a through-and-through wire to deal with a difficult angle between the stent-graft surface and the LSA.[2]

Another method of graft puncture that avoids the need for direct mechanical force is the use of a laser delivered through a flexible, directable catheter.[6,7] This allows the puncture to be more independent from the direction/guidance action. The disadvantages of the laser are the cost, the limited number of clinicians familiar with the use of the laser, and the safety requirements surrounding it.

A radiofrequency wire similarly takes advantage of an energy source rather than direct mechanical force to achieve the puncture. However, the operation and safety of a radiofrequency wire is more familiar to surgeons compared to a laser. Its handling is the same as that of a standard surgical cautery, with a remote grounding pad applied to the skin and energy applied at the tip of the device. Radiofrequency wires and generators are used routinely by electrophysiologists for crossing the interatrial septum and by interventional radiologists for traversing chronic total occlusions. Therefore, the equipment is available in many institutions, obviating the need for an additional expenditure.

While radiofrequency puncture has been shown to be feasible in animal[8] and cadaver models,[10] no one has, to the best of our knowledge, reported the clinical application of this technique. Our group has been deliberately careful in adopting in situ fenestration into clinical practice. We have been involved in both bench[11] and animal[8,12] work to better understand in situ fenestration and optimize the technique and workflow. In our opinion, the radiofrequency wire is a reasonable alternative to laser and needle punctures and has become our preferred technique.

Our first case was a simple, low-risk case of a chronically occluded C-S bypass with disabling arm claudication in a patient with an optimal anatomical configuration of the aortic arch (Figure 3). Subsequent cases were progressively more challenging, with higher risk of perioperative complications. Our second case proved most interesting and deserves elaboration. Our center has been involved in the use of endovascular aneurysm repair as an adjuvant maneuver for aggressive oncological resections that involve the aortic wall.[13,14] In case 2, a zone 2 deployment with in situ fenestration was carried out prior to resection of a squamous cell lung carcinoma that was invading the chest wall, vertebral bodies, nerve roots T4-8, and the lateral side of the thoracic aorta. The LSA was preserved because of the long length of thoracic aortic coverage required and to ensure

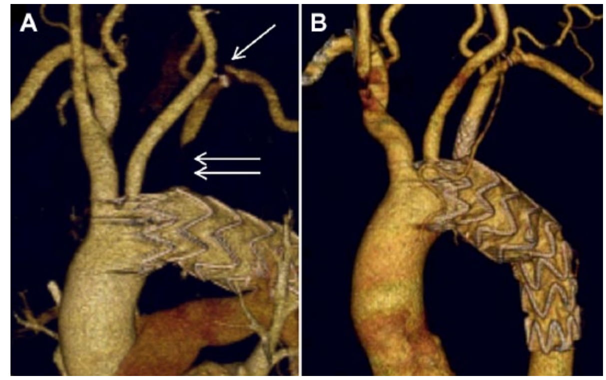

Figure 3. (A) The first case was performed for disabling arm claudication from a chronically occluded carotid-subclavian bypass. Note the ideal anatomical configuration of the arch, such that the approach from the left subclavian artery (LSA) is nearly perpendicular to the arch. The single arrow shows the stump of the occluded bypass; the double arrows show the occluded proximal LSA. (B) Volume-rendering reformat of the postoperative computed tomography scan.

the planned latissimus dorsi flap was well vascularized. Interestingly, the benefits of subclavian fenestration included the unforeseen quality of stent-graft anchoring. During the resection, portions of the aortic wall were removed with the tumor. After the tumor was removed, and at the start of the chest closure, the aortic wall defects progressively coalesced to create a large defect through which the stent-graft seemed to progressively bow outward and partially protrude. A bovine pericardial patch was sewn around the edges to prevent complete stent-graft dislodgement and exsanguination. It was felt that the LSA fenestration may have helped to anchor the stent-graft in place during the urgent repair of the wall defect.

Our last case was our first attempt at in situ LCCA fenestration for a zone 1 deployment. The unforeseen intraoperative complication of inadvertent zone 0 deployment (all great vessels were covered) greatly accelerated the urgency of the in situ fenestration. While the LCCA fenestration was created without any difficulty, we lost wire access after performing serial balloon dilation and before the deployment of the covered stent. We could not be sure that we were through the fenestration with the new wire, so we deployed the covered stent with its proximal end in front of the stent-graft (ie, in case we were not through the fenestration, we would at least have a chimney). We then performed a rapid right carotid cutdown and deployed an Advanta V12 covered stent in the innominate artery as a chimney. Fortunately, the patient did not have a stroke and was neurologically intact postoperatively and in follow-up. Subsequent imaging at 1 month showed a patent innominate chimney, a patent (albeit long) carotid fenestration, and no endoleak (Figure 4).

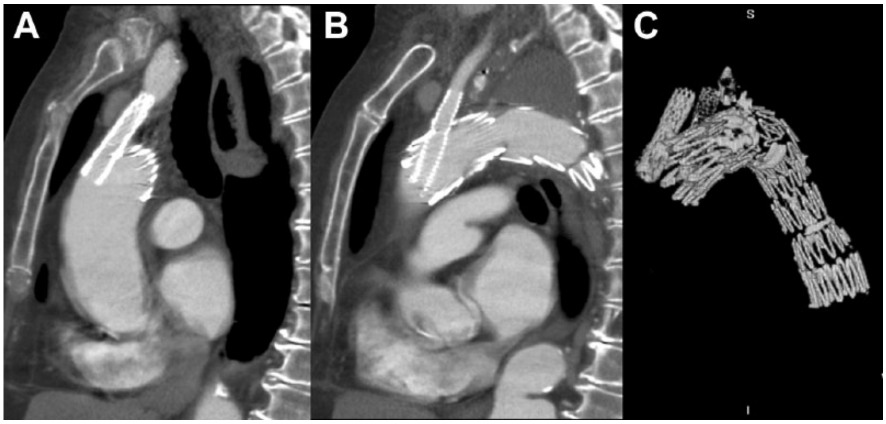

Figure 4. Postoperative computed tomography images from a case requiring in situ fenestration of the left common carotid artery (LCCA) and a chimney stent to the innominate artery for inadvertent zone 0 deployment. (A) Sagittal image of the innominate chimney. (B) Sagittal image of the "long" carotid fenestration. (C) The 3-dimensional rendering of the wireforms.

As for most procedures, patient selection is paramount for this technique. Ideally, a type I arch allows a better approach, with the puncture directed perpendicular to the graft. This decreases the likelihood that the PowerWire will slip forward proximally between the graft and aortic wall. As noted by Redlinger et al,[6] a type III arch may be better served with a chimney stent. Additionally, as per Riga et al,[9] the quality of fenestrations would be optimized with a more perpendicular approach that is offered by a type I arch anatomy.

Directing the wire to the correct position on the graft remains a challenge. In the emergent case in which we abandoned further attempts at LSA fenestration because of adequate vertebral flow, we were unable to obtain enough of an angle with a sheath, catheter, and wire. Since that case, we have added the renal double-curve guiding sheath, in addition to the sheath-catheter-wire, to create a coaxial system that can achieve a better angle. We suspect the use of a directional bendable sheath or a robotic catheter[15] may offer benefits, with the ability to tackle more acute angles and maintain a stable support system.

We have been using conventional angioplasty balloons with Medtronic thoracic endografts and cutting balloons with the Cook thoracic endografts. This practice is based on our bench studies,[11] as well as those of Riga et al,[9] in which satisfactory fenestration diameters could not be achieved with conventional balloons on Zenith stent-grafts. We have not yet tried high-pressure balloons for fenestration, but this would certainly be an alternative to cutting balloons. We had not tested radiofrequency puncture on double-layered fabric, but our failed clinical attempt at puncturing an overlap zone suggests that it is not feasible. We have not used the Gore thoracic device or any polytetrafluoroethylene (PTFE) aortic stent-grafts because we do not know how the PTFE material would behave with radiofrequency puncture. To date, we have been unable to acquire access to commercial PTFE stent-grafts for our experimental work. We have tried replicating the PTFE material for bench experiments and were unsuccessful in achieving radiofrequency puncture through this material. Therefore, at the present time, radiofrequency puncture should not be attempted in cases involving a PTFE graft; the other methods of needle and laser puncture should be considered instead.

As suggested by Redlinger et al,[6] crowding of the wire stents may present difficulties. In addition to the inability to fully dilate a fenestration, the radiofrequency wire will "short out" on the stent. When the PowerWire is in contact with stent struts, the generator detects low impedance and resets for safety.

For imaging, we have emphasized in our illustrations the importance of the steep right anterior oblique view. During attempts in the steep left anterior oblique view, it is easy for the wire to slip either in front or behind the stent-graft. The steep right anterior oblique view improves visualization and facilitates a perpendicular angle of attack. Finally, we believe that the use of a balloon-expandable covered stent and flaring are important for molding, accommodating any irregularities in the fenestration, and preventing type III endoleaks.

As physicians become more comfortable with in situ fenestration of thoracic stent-grafts in zone 2 (the more forgiving procedure), it is likely that the frequency of in situ stent-graft fenestration in zones 0 and 1 will increase (more unforgiving procedures). Work is underway with our collaborators to perform bench durability and fatigue testing, as well as animal studies for carotid and innominate fenestrations. The bench studies will focus on the issue of multiple large holes in close proximity to each other on the graft fabric; the animal studies will focus on the stroke risk, facilitated by our collaborators' animal laboratory angiosuite equipped with magnetic resonance imaging.

Conclusion

Radiofrequency puncture is a viable alternative to needle and laser punctures for retrograde in situ stent-graft fenestration during TEVAR. Early clinical results suggest technical feasibility and acceptable early outcomes.

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Declaration of Conflicting Interests

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