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Advanced Stent Graft Treatment of Venous Stenosis Affecting Hemodialysis Vascular Access: Case Illustrations

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Abstract

Surgically placed dialysis access is an important component of dialysis replacement therapy. The vast majority of patients undergoing dialysis will have surgically placed accesses at some point in the course of their disease, and for many patients these accesses may represent their definitive renal replacement option. Most, if not all, arteriovenous fistulae and grafts will require interventions at some point in time. Percutaneous angioplasty is the typical first treatment performed for venous stenoses, with stents and stent grafts being reserved for patients in whom angioplasty and surgical options are exhausted. In some salvage situations, stent graft placement may be the only or best option for patients. This article describes, using case illustrations, placement of stent grafts in such patients; a focus will also be made on the techniques utilized in such salvage situations.

Keywords
- interventional radiology
- percutaneous angioplasty
- stent grafts

Objectives: Upon completion of this article, the reader will be able to identify the role of stent graft placement in patients with salvage situations requiring treatment for dialysis access failure, as well as some of the technical considerations for such treatment in this special patient population.

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Stents and stent grafts have been used in the treatment of venous stenoses involving dialysis access circuits for many years. Until recently, the use of stent grafts for hemodialysis access stenoses was considered to be an off-label use. In 2010, the RENOVA trial demonstrated that the FLAIR stent graft (Bard, Tempe, AZ) improved primary graft patency in patients with venous anastomotic stenoses at 6 months when compared with percutaneous transluminal angioplasty (PTA) alone.[1] The REVISE trial also demonstrated improved primary graft patency for venous anastomotic stenoses using Viabahn stent grafts (Gore Medical, Flagstaff, AZ) at 6 months when compared with angioplasty alone.[2] Currently, the FLAIR and Viabahn stent grafts are the only FDA-approved stent grafts for use in hemodialysis access. Although the conditions in which stents and stent grafts provide the most benefit are open for debate, many interventional radiologists will use such devices in instances where the patient has severely limited access options. The following case illustrations represent such examples where stent grafts were used in salvage situations, and discusses when such devices should be considered for this challenging patient population.

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Case Series

Case No.1: Stent Graft Placement via Diminutive Collateral

A 55-year-old African American man, with a past medical history of asthma and hypertension, was evaluated in a general medicine clinic in 2012 with complaints of fatigue and cramping. Laboratory values demonstrated a serum creatinine level of 31.0 mg/dL, and he was admitted to the hospital for acute renal failure. During admission, it was determined that his uropathy was secondary to bladder outlet obstruction from benign prostatic hypertrophy. He was initiated on hemodialysis via a tunneled internal jugular catheter; however, despite best medical treatment, his renal function did not recover. One month later, he began a peritoneal dialysis (PD) regimen. After several PD catheter-related complications, including an umbilical hernia requiring surgical repair and several episodes of peritonitis, the patient decided to abort PD in favor of hemodialysis. A left radiocephalic fistula was created.

Three months after the creation of fistula, the patient was referred to interventional radiology (IR) for fistulography for a non-maturing fistula. A fistulogram demonstrated occlusion of the cephalic outflow vein at the elbow with visualization of two large competitive outflow veins (►**Fig. 1a**). The dominant competitive vein reconstituted via the basilic vein. The occlusion was crossed with standard catheter-wire technique, and a 6 mm × 5 cm Viabahn stent graft was placed and balloon expanded to 6 mm. The patient had a good angiographic response (►**Fig. 1b**), and coil embolization was performed of the dominant competitive vein. A 1 month follow-up fistulogram was scheduled for evaluation of the stent graft patency and the need for further competitive vein embolization.

On follow-up fistulogram 1 month later, a palpable thrill was present over the fistula, and pre-procedural ultrasound demonstrated a patent fistulous connection. Fistulography demonstrated no flow-limiting stenoses (not shown).

Follow-up fistulogram 1 month later demonstrated patency of the fistula with persistent occlusion of the embolized competitive veins. Additional smaller veins were visualized but were deemed too small to embolize (►**Fig. 1c**).

The patient continued to receive hemodialysis through his catheter. A follow-up fistulogram was scheduled for 1 month later; however, the patient did not present for his procedure until 3 months later. The patient was then able to successfully receive dialysis through the fistula and the tunneled hemodialysis catheter was removed. The patient was lost to follow-up at this point in time.

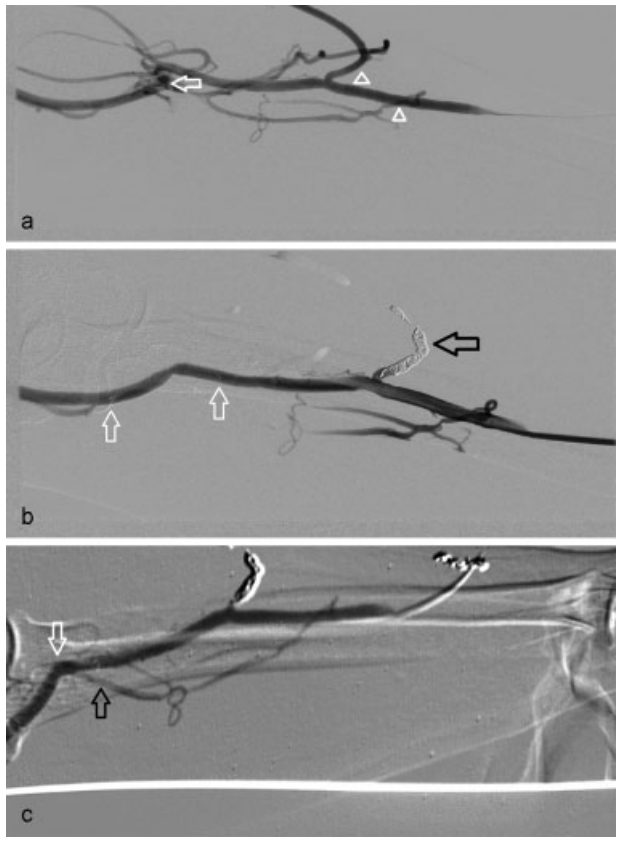

Fig. 1 Stent graft placement via a diminutive collateral vein. (**a**). Fistulogram demonstrates the region of the primary outflow vein occlusion with collateral formation into another outflow vessel (arrow). Arrowheads denoted competitive outflow veins. (**b**). Post–stent graft placement and coil embolization of the dominant competitive outflow vein. (**c**). Fistulogram performed 2 months following the initial stent graft placement and coil embolization ×2 demonstrates widely patent stent graft (white arrow) and small competitive outflow vein (black arrow) deemed clinical insignificant.

Case No. 2: Heparin-Bonded Stent Graft Placement in a Patient with a Heparin Allergy

A 57-year-old African American man with numerous chronic medical conditions including hypertension, atrial fibrillation requiring anticoagulation, peripheral vascular disease, and CHF presented to IR for fistula evaluation in mid-2015. He had required hemodialysis since 2008. The patient was allergic to heparin as documented in the electronic medical record; however, according to the dialysis center, the only known adverse reaction was bleeding; for this reason, heparin was being withheld during his dialysis sessions. This bleeding while on heparin was later considered to be his "allergy," but at the time of the procedure described later, the severity of the allergy was unknown.

In 2009, a left brachial-basilic fistula was created for access. Since that time he had multiple stents placed at an outside hospital, and developed a known central in-stent stenosis. He presented to the emergency department at the authors' institution in mid-2015 with left upper extremity pain and swelling over the fistula after receiving hemodialysis. A pseudoaneurysm (PSA) of the arteriovenous fistula (AVF) was suspected and he was admitted for surgical ligation of the access. Prior to ligation, the patient was referred to the IR service for possible fistula salvage.

Preliminary images of the left upper extremity fistulogram demonstrated several endovascular stents throughout the left subclavian vein extending into the brachiocephalic vein and superior vena cava (SVC). An endovascular stent was also noted proximally in the left

basilic vein, with a small segment of intervening normal vein (►**Fig. 2a**). Focused sonographic evaluation of the left upper extremity AVF aneurysm was performed, and a diffuse PSA with no nonaneurysmal vein was identified between the visible aneurysm and the actual AVF.

Fistulography demonstrated multifocal left subclavian intrastent stenoses (►**Fig. 2b**). These stenoses were considered hemodynamically significant, as evidenced by multiple collateral vessels arising upstream from the stents. The extensive stenoses across the length of the overlapping stents were initially treated with serial angioplasty with a 10 mm × 6 cm high pressure balloon (Mustang; Boston Scientific, Marlborough, MA). Postplasty venography demonstrated mild improvement of intrastent vascular flow; however, residual stenoses were noted.

Other access options were considered and discussed with the surgical service at this point in time. These options included a right-sided AVF or graft creation, or HeRO graft (CryoLife; Kennesaw, GA) placement on the left. A venogram was performed on the right, which demonstrated complete occlusion of the right subclavian vein with large collaterals (►**Fig. 2c**); for this reason, a right-sided access was deemed unreasonable. A left-sided HeRO graft placement was considered unfavorable owing to a short length of nonstented vein as the only venous access in the upper arm, as well as the patients' body habitus. As a salvage procedure, it was elected to place a 13 mm × 10 cm Viabahn stent graft through the balloon-resistant central stenosis.

Given the patients reported allergy to heparin, which could be neither confirmed nor refuted at the time of the procedure, the Viabahn stent graft manufacturer representative was contacted. The representative determined that the stent contains approximately 200 units of chemically bound heparin that may or may not elute into the bloodstream over many years after stent placement. The risks were considered minimal given the possible benefit of intervention, and it was elected to proceed with stent graft placement. The stent graft was deployed successfully and balloon expanded to 12 mm (►**Fig. 2d**).

Although the procedure was considered angiographically successful, the fistula was never again accessed for dialysis and was surgically ligated 2 days later because of risk of exsanguination secondary to PSA rupture due to overlying

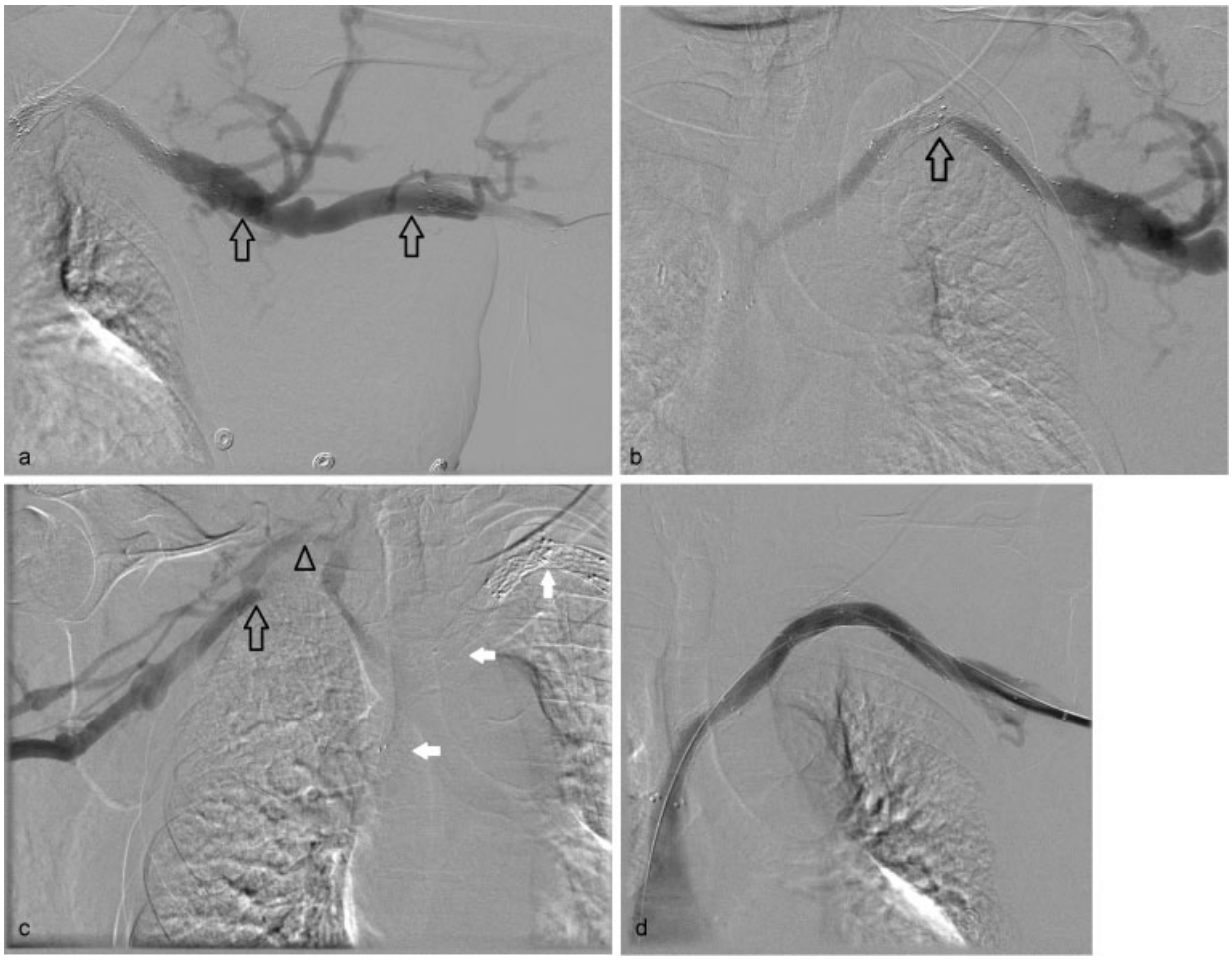

Fig. 2 Heparin-bonded stent graft placement in a patient with a heparin allergy. (**a**). Fistulogram demonstrates basilic outflow vein with short length of vessel (arrows) without indwelling stents. (**b**). Fistulogram demonstrates significant intrastent stenosis (arrow). (**c**). Venogram of the right arm and central vessels demonstrates occlusion of the subclavian vein (arrow) and significant collateral formation around the occlusion (arrowhead). White arrows demonstrate the intravascular stent complex extending centrally in the superior vena cava. (**d**). Fistulogram post–stent graft placement demonstrating resolution of intrastent stenosis.

skin erosions. The patient is subsequently receiving dialysis via a tunneled hemodialysis catheter.

Case No. 3: Stent Graft Placement across the Elbow for a Clotted Graft and Diminutive Vein

A 39-year-old obese African American man presented with a history of long-standing poorly controlled type 2 diabetes mellitus, hypertension, and hyperlipidemia; his chronic medical conditions had caused multiple transient ischemic attacks, coronary artery disease, and severe peripheral vascular disease. His chronic medical conditions also caused ESRD, for which he required hemodialysis since 2010. After missing dialysis for 2 weeks, he was referred to the interventional radiology department for a declot procedure of a left upper extremity dialysis access graft.

No palpable thrill was felt on exam and preprocedure ultrasound documented complete thrombosis of the graft. The graft underwent a standard declot procedure using pharmacomechanical techniques. PTA of the venous anastomosis was performed using a 7-mm high-pressure balloon catheter (Mustang; Boston Scientific). Arteriography demonstrated persistent stenosis in the venous anastomotic region of the graft and native vein. In addition, the native vein beyond the anastomosis across the elbow was diminutive (►**Fig. 3a**). This downstream native brachial vein was resistant to 7-mm balloon angioplasty (►**Fig. 3b**); as a salvage procedure, two 8 mm × 10 cm Viabahn stent grafts were placed across the small veins and balloon expanded to 8 mm (►**Fig. 3c**). Minimal residual clot was treated with intragraft injection of 3,000 units of heparin and 2 mg tPA, which resulted in patent flow throughout the graft.

The patient received dialysis through his graft for 1 month, at which time he presented with a rethrombosed graft. He underwent a repeat pharmacomechanical declotting procedure, at which point a stenosis was noted in the downstream aspect of the brachial vein stent graft complex (►**Fig. 3d**). This was successfully treated with angioplasty, as was a central subclavian vein stenosis, using an 8-mm balloon (►**Fig. 3e**). Following this intervention, the patient was lost to follow-up.

Discussion

The three cases presented earlier describe placement of stent grafts during salvage situations, in patients with very limited

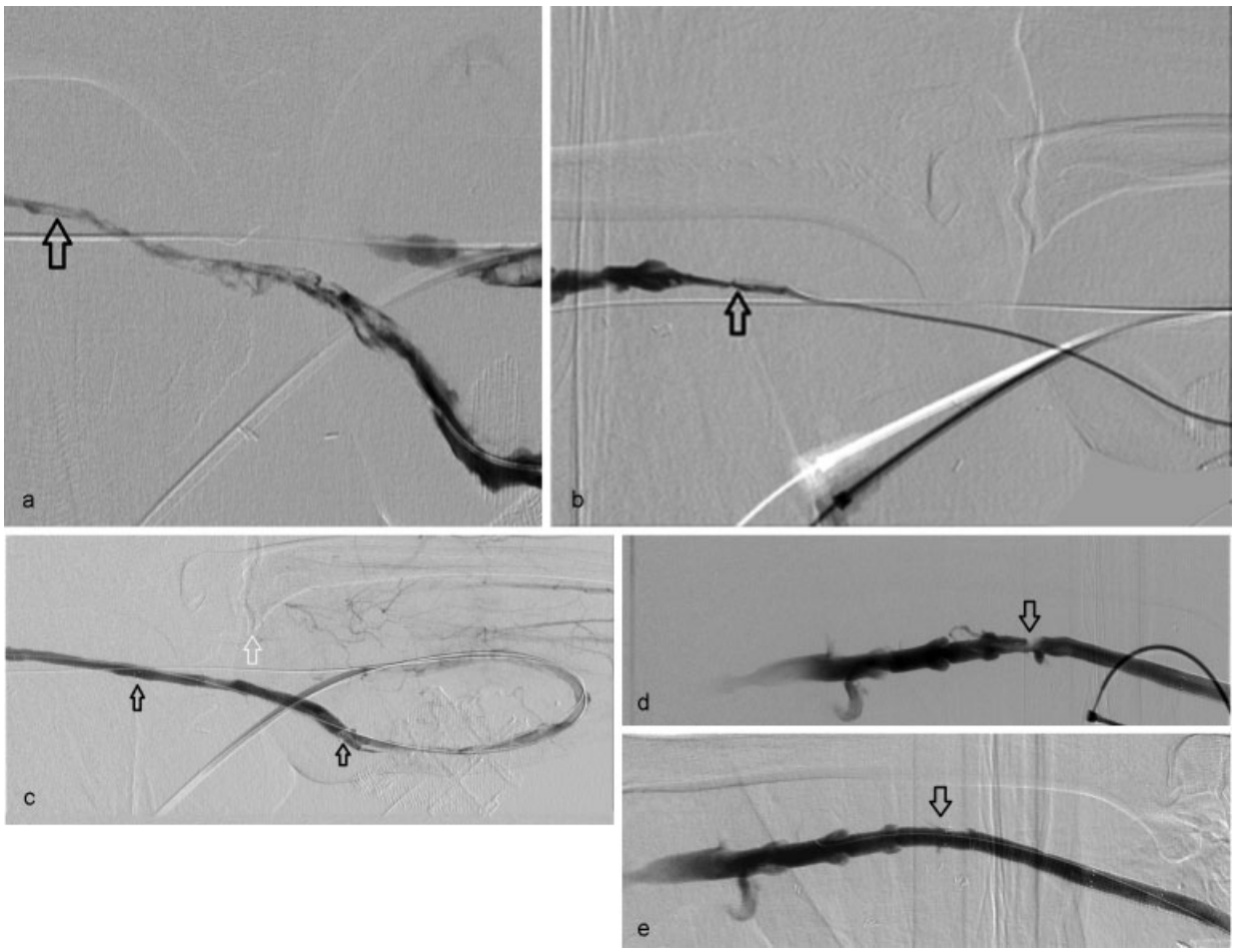

Fig. 3 Stent graft placement across the elbow joint for a clotted graft and diminutive vein. (**a**). Fistulogram demonstrating diminutive size of the outflow native vein (arrow) at the level of the elbow. (**b**). Fistulogram postangioplasty of the native outflow vein demonstrating no significant improvement in the diameter of the vein (arrow). (**c**). Fistulogram following placement of two stent grafts through the small native outflow vein (black arrows) across the elbow join (white arrow). (**d**). Stenosis noted at the downstream end of the stent graft (arrow). (**e**). Postangioplasty fistulogram demonstrating complete resolution of the stenosis (arrow) at the stent graft margin.

vascular access options. The use of such devices in these situations, particularly as opposed to other interventional options such as use of multiple repeat angioplasties; drug-eluting balloons; cutting balloons; new surgical options (e.g., creation of new access sites); or placement of long-term catheters for definitive access for dialysis, is a open for debate.[2–14] Opponents of the early use of stent grafts describe the lack of long-term outcome data, the cost of such devices, and the nonsustained benefit (>6 months) described in much of the literature as reasons against the early use of these devices. Proponents of early stent graft use counter with the argument that stent grafts provide early (6 months) benefit when compared with PTA alone, may provide added benefit when used in thrombosed grafts, and as described in these three cases may be used in salvage situations. The most recently updated National Kidney Foundation Dialysis Outcome Quality Initiative (NKF-KDOQI) guidelines do not specifically address the role of stent grafts in the maintenance of access grafts, although the most recent update was published in 2006.[15]

The two stent grafts most commonly used for dialysis access interventions remain the FLAIR and Viabahn stent grafts. The FLAIR device is a nitinol stent encapsulated with polytetrafluoroethylene (ePTFE). It is impregnated with carbon to reduce platelet aggregation. The device comes in both a straight and a flared configuration; the latter configuration is intended to address size mismatches between vessels in which the stent graft might be placed. The device comes in 80 cm delivery lengths, and in diameters ranging from 6 to 9 mm and lengths ranging from 30 to 70 mm. Additional sizes and diameters, however, are available in the similar FLUENCY stent graft (Bard Peripheral, Tempe, AZ). The required delivery sheath for all diameters is 9F. The Viabahn stent graft is constructed of a nitinol scaffold and an ePTFE expanded covering. The distal edge is scalloped, while the proximal end is not. The device can be obtained in 5 to 13 mm diameters, and are generally upsized by 0.5 to 1.5 mm (e.g., a 7-mm stent graft used for a 5.6–6.5 mm vessel). The stent grafts are available in lengths varying from 2.5 to 25 cm. Stent grafts ≥8 mm in diameter can be delivered via either 75 or 120 cm delivery systems, but the larger sizes can only be delivered by the 120-cm platform. The required delivery sheaths are 6 to 12F, depending on the device used. The Viabahn is available with or without the heparin bioactive surface described in this case report.

There has been one published randomized controlled trial evaluating stent graft placement versus angioplasty in the treatment of failing dialysis access grafts (RENOVA).[1] In this trial, which used the FLAIR stent graft, 190 patients with grafts and venous anastomotic stenoses were randomized to receive either angioplasty alone or angioplasty plus stent graft placement of the venous anastomotic stenosis. The results of this study reported that at 6 months, the stent graft arm demonstrated significantly better outcomes regarding both the patency of the treatment area (51 vs. 23%; $p < 0.001$) and patency of the access circuit (38 vs. 20%; $p = 0.008$) when compared with angioplasty alone. In addition, individuals in the angioplasty group required significantly more secondary interventions than individuals in the stent graft group (32 vs. 16%, respectively; $p = 0.03$).

A second prospective, randomized controlled trial has been presented in abstract form but has not yet been published.[2] This trial (REVISE) randomized 293 patients to receive either angioplasty alone or angioplasty plus stent graft (Viabahn) placement for venous anastomotic stenoses. In contrast to the study discussed earlier, thrombosed grafts were included in this patient population. Primary outcomes were assessed at 6 months; however, patients were followed for a total of 2 years. This study also demonstrated significantly improved target lesion patency compared with angioplasty alone at 6 months (53 vs. 36%, respectively; $p = 0.008$), and improved overall vascular circuit primary patency (43 vs. 29%, respectively; $p = 0.035$). Similar to the RENOVA study, the total number of interventions at 2 years was higher in the angioplasty group compared with the stent graft group both at the target lesion (3.7 vs. 2.7, respectively; $p = 0.009$) and the vascular circuit (5.1 vs. 3.7; $p = 0.053$). A cost analysis was performed that suggested that stent grafting was less expensive for maintaining patency at 24 months compared with angioplasty alone, although this cost analysis study has also not yet been published.[16]

Although the price of the stent graft itself is frequently raised as one reason to not use these devices,[17,18] to date there have been no dedicated cost or cost-effectiveness analyses evaluating overall costs of stent grafts versus other salvage treatments. All costs associated with stent graft placement compared with other procedures (such as multiple repeat angioplasties or surgical creation of a new access) must be determined to better evaluate the true cost of the procedure. It might be expected that at some point of time, due to decreased secondary interventions, the placement of stent grafts may prove to be less costly than primary repeat angioplasty procedures; this hypothesis, however, has yet to be definitively proven. In addition, one could make the same argument about the role of surgical revisions or creation of a new access when comparing these operative options to endovascular treatments.

The first case presented earlier demonstrates the use of a stent graft to reestablish in-line flow from the arteriovenous anastomosis to the central veins. In this patient, occlusion of the primary outflow vein was noted several centimeters from the anastomosis itself. Flow to the upper arm was via a small collateral vein, which was subsequently crossed and through which a stent graft was placed. Multiple competitive outflow veins were also noted in this patient. Although many operators believe that competitive outflow veins can prevent a fistula from maturing and that embolization of such veins is helpful,[19–22] there is no consensus on the role of embolization of such veins in the setting of a mature fistula. While the benefit of in-line flow to the central veins has long been established for dialysis access circuits, the utility of using stent grafts to accomplish this has been described only rarely.[5,23,24] Stent grafts have traditionally been used more frequently to isolate pseudoaneurysms that occur due to repeated venipuncture, or secondary to angioplasty-induced venous ruptures.[25–27] Additionally, the use of stent grafts

placed close to the fistula itself may or may not be contraindicated due to the possibility of damaging the stent graft material during venous access for dialysis.[28]

The second case presented earlier was a much more straightforward case technically; however, it was complex due to a remote history of heparin allergy (the severity of which was unknown at the time of the procedure). The Viabahn stent graft is produced with or without a heparin bond. Unlike many other commercially available devices that have a heparin bond or coating, the Viabahn device has heparin that is bound by a process called "end-point covalent bonding," which allows the device to maintain its heparin bond without losing its bioactivity nor having significant elution into the blood stream. This allows for improved thromboresistance compared with other bonding techniques. Chemical bonding is typically used for heparin-bonded devises, but it has a weaker molecular bond than end-point covalent bonding that breaks down more easily and allows heparin to be released over time. Additionally, as the covalent bond is fairly strong, heparin does not easily leach out of the graft; in the first day, approximately 30 IU of heparin is released from the graft, after which there is minimal release of heparin with no systemic effects. The total molecular heparin in a 10 mm $\times$ 15 mm graft is $<$400 IU. However, even given the proclaimed lack of elution and the small amount of heparin bounded onto each device, the manufacturer still suggests not using the device in patients with heparin-induced thrombocytopenia.[29]

Another phenomenon noted with the second case was early in-stent stenosis of the stent graft itself, which in this patient occurred over 1 month. The narrowing was noted within 1 month of stent graft placement. Early stent graft restenosis is a known phenomenon—the reader is directed toward the article on the biology of access veins written by Misra et al in this *Seminars* issue.

The third case presented here demonstrates the use of a stent graft in a diminutive native outflow vein; similar to the first case earlier, the purpose of stent graft placement in this patient was to provide inline flow to the right atrium. Stent graft placement in native outflow veins has been described, particularly in the cephalic arch and more centrally[11,30–32]; bare metal stents have also been described in the treatment of outflow veins downstream from the fistula itself.[33,34] While early angiographic response following the placement of stent grafts is nearly always satisfying, the long-term effects of stent graft placement on the target lesion and dialysis circuit remain largely unknown. This relative paucity of data as well as other potential complications of stent graft placement (such as occlusion of veins that drain into the stent-grafted vein ["caging"]) makes routine use of stent grafts uncommon.

The final issue regarding the third case that is open for discussion is whether or not stents or stent grafts should be placed across the elbow joint. In theory, repetitive motion of a metallic device placed across a joint may lead to stent fracture and/or dysfunction. This repetitive trauma is a known phenomenon affecting stents placed in the subclavian vein (e.g., in patients with Paget-Schroetter disease), and is considered relatively contraindicated in thoracic inlet syndrome.[35,36] Although this anatomic region has less mobility than the elbow joint, the triangular space that the stent traverses in patients treated for subclavian vein stenosis is bounded by bone and ligaments, rather than softer structures as in the elbow region. This difference in anatomy may suggest that stents or stent grafts can be placed across the elbow joint without undue concern of premature fracture or dysfunction. The Viabahn device is particularly malleable when compared with other commercially available stent grafts, and has been used with success in the treatment of vascular lesions across the knee joint.[37] This malleability was one of the reasons the authors specifically chose the Viabahn in the case presented earlier.

Summary

Many dialysis patients progress to the point where their surgical access options are limited. In these challenging situations, and particularly in salvage situations, the creative use of stent grafts may be beneficial. Although most, if not all, stent grafts will eventually become stenotic, in many patients the dialysis access undergoing intervention can be salvaged for many weeks to months, providing a significant advantage that may preserve further surgical options, allow newly created access to mature, or may be used to save what may be the patient's last remaining access.

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