Stent Graft Use in AV Access Maintenance: What We've Learned

Leading clinical researcher Ziv J. Haskal, MD, discusses ideal application, pitfall avoidance, and long-term results.

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What is your current algorithm for selecting a stent graft as treatment for hemodialysis access stenoses?

One of the trends that warms this editor's heart is the methodical increase in prospective, higher-level studies of what interventional radiologists do daily. Research quality is simply improving. In hemodialysis, which is an area of medical care that costs us billions of dollars in the United States, such evidence must be the basis with which we make interventional treatment choices. For stent grafts, we have such evidence, in the form of multiple unique or replicative controlled trials. They all emphasize the primary benefit of revision of prosthetic access grafts at first diagnosis of stenosis or later—the FLAIR, RENOVA, and REVISE studies all strongly support this. Other trials are in the pipeline.

The benefits of prosthetic access graft revision are less clear in other applications. The RESCUE study has shown that revision of stenotic bare-metal stents in the access circuit provided clear improvements in patency compared with angioplasty. Hopefully, use of bare-metal stents will mostly disappear from peripheral access circuits. Stent grafts can be used for pseudoaneurysms in the access circuit and even in some native fistulae, provided that treatment decisions are made in concert with nephrology and surgical colleagues. Equally, degenerating, mature, native fistulae can occasionally be managed with stent grafts with some advantages. Naturally, all venous ruptures are readily solved with stent grafts. I recently placed a stent graft in a malignant compression of an external iliac vein that ruptured after a bare-metal stent. Problem simply solved, and the leg is normal 4 weeks later.

In which cases are stent grafts best avoided?

Primary use of expanded polytetrafluoroethylene (ePTFE) stent grafts in central venous stenosis is not yet supported by high-level evidence—and devices are not "mission ready" in my opinion. That said, I've salvaged many central vein restenoses with existing large ePTFE stent grafts. I do think superior vena cava syndrome is undertreated in dialysis patients. We need to be more aggressive about providing patients more lasting treatments. Recoil, recurrence, and restenosis are bigger problems than we might believe.

Placing a stent graft in a location that might prevent the surgical creation of a future secondary fistula (eg, at the elbow) should be avoided if possible. Stent grafts may also be avoided in potentially infected accesses, cellulitic arms, or pseudoaneurysms at higher risk of infection.

Finally, a cautionary note—while some data have shown that devices provide better outcomes in cephalic arch stenoses, this is a very tricky place to precisely land a device. If the stent graft is placed too short, the stenotic valve is undertreated. If it is placed too far, the axillary vein can be inadvertently covered, leading to a problematic arm deep vein thrombosis. We need more studies involving larger cohorts of patients to confirm these results. Caveat medicus.

What are some of the key lessons that have been learned about stent graft covering materials and inflammatory response in this setting, and how have these been applied in current devices?

At this point, the material that is front and center is ePTFE. There's no positive evidence for the use of any other material (eg, polyethylene terephthalate), although there is evidence against their use. It is unclear whether there's any advantage in carbon- or heparin-bonded ePTFE or differences in internodal distance between the materials. Likely, those issues are too small to register, given the overall long-term advantage of the devices over balloon angioplasty.

AVOIDING COMMON PITFALLS

- Respect size criteria to avoid excessive oversizing and potential encroachment upon device lumina, especially for overlapping devices. Oversize by 1 or 2 mm maximum.
- Know the deployment characteristics of your devices and use every "easy" deployment opportunity to practice precise landings and adjustments, so that more critical central or cephalic applications become reliable.
- Be familiar with multiple devices; they all have unique value.
- Practice evidence-based medicine. Where data are good, use them to drive daily decisions.
- Learn to love (and respect) access interventions. Satisfying, important, and valuable work.
- Seek opportunities to provide more durable outcomes in central vein stenoses. There are far more patients suffering with chronic undertreated central vein stenoses in dialysis centers than we realize.
- Remain vigilant in innominate and superior vena cava interventions. Ruptures and life-threatening complications occur, especially with larger-than-needed balloons. Be prepared.

Do you think the longer-term effectiveness observed to date has influenced initial decision making related to the placement of access grafts in any way?

The Fistula First initiative has been a fabulous boon to hemodialysis patients in the United States by bringing them native fistulae in far greater numbers. This is a public good. But we now see the downsides of forcing these onto all patients. There are older age groups, high-risk patients, or patients with comorbidities, etc., in which maturation is more problematic and secondary catheter use becomes prolonged. The economic benefits of fistulae decrease and risks of catheter use increase, such as venous thromboses and catheter-related bloodstream infections. When you balance this against the improved graft patency rates we can now achieve, prosthetic graft use will find an increasing and rightful place.

What have you observed about the cost-effectiveness of this option?

We ran a Monte Carlo cost strategy analysis on the original FLAIR trial data looking at the whole set of options—stent graft after angioplasty failure, stent graft at first presentation, repeated angioplasty only, etc. Our analysis showed that it made clear economic sense to treat a stenotic graft anastomosis with a stent graft at first presentation. I think analysis of the REVISE study data will likely show the same cost benefits. In addition, these analyses do not necessarily account for the costs of interim catheter placements, related infections, hospitalization, or complications, etc.

To what degree is edge stenosis an issue in stent grafts placed in this setting?

The main site of restenosis is definitely at the edge. I reviewed > 700 follow-up angiographic images in the original FLAIR study, determining where stenoses occurred—the dendrochronology of restenosis, if you will. The incidence of restenosis was very low, but when it did occur, it was at the distal (ie, central) end of the device, within the native vein. One of my original concerns many years ago, in conceiving and designing the FLAIR trial, was whether we would simply be moving new stenoses to the edges, resulting in telescoping stent grafts marching up the "bionic" arm. I had seen this with Wallstent (Boston Scientific Corporation)

RECOMMENDED READING

The Editor-in-Chief of the *Journal of Vascular & Interventional Radiology* shares his must-read papers on stent graft use.

Stent graft versus balloon angioplasty for failing dialysis-access grafts.
Haskal ZJ, Trerotola S, Dolmatch B, et al.
N Engl J Med. 2010;362:494–503.

Long-term results of stent-graft placement to treat central venous stenosis and occlusion in hemodialysis patients with arteriovenous fistulas.
Jones RG, Willis AP, Jones C, et al.
J Vasc Interv Radiol. 2011;22:1240–1245.

Salvage of angioplasty failures and complications in hemodialysis arteriovenous access using the FLUENCY Plus Stent Graft: technical and 180-day patency results.
Dolmatch BL, Duch JM, Winder R, et al.
J Vasc Interv Radiol. 2012;23:479–487.

Effectiveness of stent-graft placement for salvage of dysfunctional arteriovenous hemodialysis fistulas.
Bent CL, Rajan DK, Tan K, et al.
J Vasc Interv Radiol. 2010;21:496–502.

Angioplasty with stent graft versus bare stent for recurrent cephalic arch stenosis in autogenous arteriovenous access for hemodialysis: a prospective randomized clinical trial.
Shemesh D, Goldin I, Zaghal I, et al.
J Vasc Surg. 2008;48:1524–1531.

years before. But this happens very gradually with ePTFE devices. It's all related to having converted an end-to-side surgical anastomosis to an end-to-end lower shear stress laminar anastomosis.

What about thrombus formation? How often is this seen, and are there any predictors of its occurrence?

Thrombus formation is not an issue. The best device applications are "uber-endo-revisions" of an access—surgery but better: safer, faster, and more effective (vis à vis flow dynamics). So thrombosis issues are not a greater concern than in surgical procedures. Regarding outcomes, the FLAIR and RENOVA studies evaluated revision of patent but failing grafts. The REVISE study included thrombosed grafts as well and found that stent grafts were still better than balloon angioplasty, although overall outcomes were poorer than those seen with non-thrombosed patients. I've seen no issues of thrombosis after well-placed devices. Said another way, I'll place the devices at the time of declot if logical.

Which technical enhancements would you like to see in the next generation of stent graft devices?

We need devices that are on-label, precisely designed for central vein applications, and that allow for precise positioning in all critical anatomies. Veins are not arteries—they are more susceptible to distortion by ill-sized or angulated stents or stent grafts, promoting aggressive intimal hyperplasia at the edges. We need devices that match the elastic moduli of veins, handle tapering diameters, and, in critical places, can be landed on a dime's edge.

We're at the earliest part of another exciting chapter: drug-coated balloons (DCBs). Early small-scale trials suggest some positive signal. The best applications will be native fistulae, especially juxta-anastomotic segments. I'm optimistic, but we need to temper "device excitement" and let the work be done methodically in controlled trials. With respect to prosthetic grafts, a controlled trial has to compare a DCB to a stent graft; if not, it'll be a missed opportunity and short sighted. Comparing a DCB to plain old balloon angioplasty in a prosthetic graft makes little sense. ■