

ASK THE EXPERTS

Where Do You See Percutaneous Arteriovenous Fistula Creation Fitting Into Practices in the Next Several Years?

Experts offer their outlook for the future of percutaneous arteriovenous fistula access creation.

**WITH SANFORD ALTMAN, MD; ERIC K. PEDEN, MD; MARK TURCO, MD;
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When I first learned about percutaneous arteriovenous fistula (AVF) creation, I was intrigued. After all, if it could be performed safely and effectively at a patient's access center, it could prove to be a beneficial treatment option. I am a believer that life's "why nots" help to move us forward. As an early specialist in dialysis access interventions in the early 90s, it was the "why not" that led me to develop a mobile access intervention service providing care to dialysis patients in more than 300 dialysis centers in eight states. Oftentimes taking that chance on a "why not," backed by sound medical research, can propel us forward, as was the case with moving access intervention from in-hospital care to the outpatient arena as we see it today.

As an access specialist, I have always been searching for the ideal access—one that is easy to place, easy to use, has high patency rates, and few complications. The question is, will percutaneous AVF get us closer to the ideal access, or is it a feeble attempt at providing interventionalists untrained in open surgical techniques a means of creating substandard fistulas? After all, how could percutaneous sutureless creation, limited by anatomic considerations, create fistulas superior to those created by a skilled access surgeon?

Having performed more than 40,000 dialysis access interventions, I know fistula creation and maturation rates > 90% are achievable when working with skilled surgeons using appropriate mapping and maturation techniques. In addition, in our diverse referral-based practice with > 67% fistulas, it seemed to me that there would be many patients with vasculature not suitable for such a percutaneous approach. So, I faced the question: Why should I place a percutaneous AVF? Doing so would likely upset my referring surgeons. Would it really improve the care provided to my patients?

To answer these questions, I turned to the data available in current medical literature. Although new, innovative procedures often have minimal data to accompany

them, the limited available data suggest that percutaneous AVF creation is successful where it is in use, and it seems to be safe. The reported advantages include a true percutaneous sutureless placement, no foreign material, no need for sutures or staples, and it does not require traditional incision. As such, lower surgical site complication rates have been reported. In addition, there appears to be a significantly shorter time to maturation when compared with traditional fistulas, with an amazing 97% technical success rate and a 96% 6-month patency, as shown in the single-center FLEX study. It also appears to be cost-effective, if not cost-advantageous, when compared with traditional AVF creation considering the costs associated with higher failure rates, longer maturation times, poorer patency, and prolonged catheter use seen with the traditional approach.

One potential disadvantage is related to patient age. The average age for patients enrolled in the FLEX trial was 51 years, significantly lower than the average age of patients on hemodialysis as reported by the United States Renal Data System. As a result, this raises several questions: Is this a procedure for younger dialysis patients? Are the high success and patency rates related to lower patient age? Are these rates achievable on a larger scale?

Even with these questions, the early data on percutaneous AVF are more than encouraging. It appears that for at least a subset of patients, this “why not” could help get us closer to the ideal access, one that is easy to place, has a high surgical success rate with a short maturation time, a high patency rate, and a low complication rate. Best of all, patients could have their access conveniently placed at their local access center.



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Unfortunately, dialysis access surgery has evolved very little over the past few decades. Creation and maintenance of dialysis access remains one of the biggest problems for dialysis providers and patients alike. Autogenous fistulas remain the preferred dialysis access choice, and there is a variety of prosthetic grafts to choose from. The original fistula described a half century ago remains the first choice for dialysis access surgery.

More recently, percutaneous techniques for fistula maintenance have become mainstream and are the preferred techniques for rescue, maturation augmentation, maintenance, and salvage of dialysis access. This has moved much of the dialysis access procedures from the hospital to outpatient settings. However, this has occurred at a cost: an increase in the need for multiple repeat procedures. Dialysis grafts have not proven to be superior to fistulas and generally have shown little differentiation between the varieties in terms of durability.

The ability to create fistulas with a percutaneous technique has the potential to be one of the most sig-

nificant advances in dialysis access. The early reports of outstanding maturation rates are remarkable; however, it remains to be seen if these early results can be duplicated with equally good outcomes and freedom from significant complications in the hands of many providers. Some patients will still need open surgery for various procedures such as lipectomy, transposition, and revisions after percutaneous fistula creation. Patients will likely flock to centers that can offer this fistula creation technique with no surgical incisions. The exact percentage of patients who will be good candidates for these procedures remains to be determined. These procedures will provide new challenges for surgeons, including a decision of whether to offer them as part of their practice, managing complications associated with the technique, and perhaps most challenging, handling the failures of these procedures. The complexity of the communication between the arterial and venous systems during cases where these accesses are abandoned and require ligation will likely be quite challenging. Ligating these connections will likely be mandatory before creating an access in the same arm.

Percutaneous fistula creation has great potential to play a major role in dialysis access procedures. Further technical advances will almost certainly make the procedure easier. We can expect that more than half of patients getting a new fistula creation will be candidates for this procedure. Outcomes and patient demand will likely drive reimbursement for this procedure and associated devices.

Overall, I believe percutaneous fistula creation is very exciting, and I look forward to its evolution and its impact on dialysis access and patient care.


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With any new technology, we look at areas of unmet need and opportunity. Specifically in the vascular access space, the costs alone of vascular access-related complications equate to about \$3 billion to the Centers for Medicare & Medicaid Services (CMS). There's a significant need to improve on current treatments for patients with end-stage renal disease, especially in the world of value-based health care.

Until recently, physicians have had very little available to them in terms of innovation for patients with dialysis access needs. It has been nice to see some developments in percutaneous vascular access, as well as in other technologies related to vascular access. Obviously, any new technology needs to positively affect outcomes, but it also needs to be cost-effective. For vascular access specifically, this means reducing repeat interventional rates and graft failure rates. Additionally, the ability for early maturation of the access site is desired.

Percutaneous AVF technologies will move through the regulatory path for approval in the United States and begin to become commonplace. We need to continue to evaluate the clinical trial data to really assess the adoption rates by vascular surgeons and other providers in this area. If we continue to see improved maturation, improved patency, and reduced reintervention rates, then certainly I see a paradigm shift where vascular surgeons, interventional radiologists—all providers in this space—would move toward more minimally invasive opportunities. Over time, percutaneous technologies will also become lower profile and easier to use, which in turn, will lead to increased adoption rates of the technology. Outside of the clinical data, the biggest hurdle would be to ensure CMS reimbursement for percutaneous access technologies. This will certainly be a high-profile area for CMS to look at given how large this market is.

As we continue to transition from current surgical treatments to percutaneous options in the vascular access space, research needs to continue. Are there opportunities to combine what we know in the coronary space and the other areas of drug/device combinations? Are there ways to use any antiproliferative agents to improve patency and maturation rates? I'm excited to see the interest in the development of newer treatment options for this complex subset of patients from a time in the past when there was little in the way of innovation.


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I started doing independent vascular care at an outpatient hospital in 2002. At that time, patients required excellent care as usual, but they were receiving horrendous customer care. If they awoke to a clotted access, the dialysis clinic would still try to access their fistula or graft, causing a fresh puncture that would have to be addressed later at the time of primary revascularization. This often led to temporary dialysis access catheter placement. Before the declot, patients waited for same-day surgery or were admitted to the hospital for hemodialysis via a temporary access because they had missed their previously scheduled dialysis due to a clotted access. If the patient went for surgical declot, the clot would be removed, but often

the causative lesion was not treated. The repair usually occurred with a second declotting and a possible surgical patch angioplasty.

Percutaneous therapies evolved and became the better option because they treated the causative lesion and restored access patency through a minimally invasive approach, via lyse-and-wait or lyse-and-go techniques, or with primary mechanical thrombectomy techniques, which I prefer. In mechanical thrombectomy, not only are the clot and the platelet plug removed and treated, but then, during the same session, the causative lesion is treated with angioplasty and/or a stent as needed. This enables the patient to return for same-day dialysis. This care migration has been a great move for patient quality of life, while also saving hospitals Medicare dollars each year. Same-day procedures also prevent hospital admissions and obviate the need for temporary dialysis access and in-hospital emergent dialysis, which is expensive. A thrombectomy rarely fails, but when it does, a patient still needs an access conduit. In those instances, we place either a temporary or permanent catheter access so the patient can be dialyzed but, depending on the schedule, a

new percutaneous access could be started if the schedule and anticoagulation status and patient informed consent were in alignment.

Regardless of when a new percutaneous access is initiated, such as a new primary access or after a failed thrombectomy, the opportunity to vein map properly and choose the circuit pathway and conduit allows for optimal anatomic anastomoses. Although maturation and healing time is needed after a successful percutaneous access placement, at least the long-term planning for the patient's access needs are underway.

Another factor in access creation is who will be the vascular access conduit expert leaders: vascular surgeons, interventional radiologists, or interventional nephrologists? As outpatient end-stage renal disease care moves from a

primarily office-based procedure setting to an ambulatory surgery center setting, access creation will be properly incentivized in this setting for both classic open and percutaneous access creation. Comprehensive vascular care for a patient with chronic kidney disease/end-stage renal disease is an entire spectrum involving dialysis access, peripheral artery disease, and cardiac care, necessitating access placement planning all the way through to noninvasive vascular monitoring, and then even minimally invasive procedures, followed by open surgery as needed. Any procedure physicians can develop or improve upon for patients that trends toward minimally invasive medicine and procedures, augments safe and effective patient care, and promotes high-quality care will be a good evolution for patients we treat with chronic diseases. ■