

# Place of Percutaneous Fistula Devices in Contemporary Management of Vascular Access

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*Clin J Am Soc Nephrol* 14: ●●●–●●●, 2019. doi: <https://doi.org/10.2215/CJN.00980119>

Half a century ago, the surgically created dialysis arteriovenous fistula (AVF) was conceived. Although the useable AVF is considered the preferred form of hemodialysis vascular access, assuming it matures sufficiently for use, persistently poor maturation rates and early failure have long signaled the need for any change that could yield improved outcomes.

For a particular patient subset, that time seems to have arrived with the FDA approval of two devices that create AVF *via* percutaneous catheter-guided techniques. These devices function to avoid aspects of surgically created AVFs that can contribute to complications, such as poor incisional site healing and vessel clamping and dissection, as well as demonstrating superior AVF maturation, earlier cannulation, and fewer short-term complications (1–4).

## The Devices

There are two available technologies, both of which create a side-to-side AVF, a configuration believed to be associated with minimal wall shear stress, less development of intimal hyperplasia, and more favorable flow characteristics compared with an end-to-side configuration. Both are designed around the vascular anatomy in the proximal forearm, making it a prerequisite to preoperatively assess the upper extremity vasculature using duplex ultrasound mapping to determine patient suitability. An AVF is created between either the proximal radial or ulnar arteries and an adjacent deep vein that then drains to the upper arm superficial veins (1–3,5).

The Ellipsys endovascular arteriovenous fistula (endoAVF) system is a single-catheter vascular access system that uses direct heat and pressure to fuse the arterial and venous wall, creating a percutaneous AVF between the proximal radial artery and the deep communicating vein in the proximal forearm (see <https://www.youtube.com/watch?v=kPFTDaTQLa0>) (2). Under continuous ultrasound guidance, a single, retrograde venous puncture is made to the median basilic or median cephalic vein, continues to the deep communicating vein, and is then advanced into the adjacent proximal radial artery, followed by a wire and sheath. The Ellipsys catheter is then introduced, the sheath is retracted, and the device is advanced and positioned to capture the radial artery and perforating vein walls, pulling them together. The device is then

activated using thermal energy, and seconds later, a side-to-side elliptical anastomosis is formed between the perforator vein and the proximal radial artery, followed by balloon angioplasty to reduce the post-anastomotic stenosis observed in earlier studies (2).

The WavelinQ endoAVF system is a dual, magnet-lined catheter system that uses radiofrequency energy to create an anastomosis between the ulnar artery and adjacent ulnar vein in the proximal forearm (see <https://vimeo.com/295441830>). Under fluoroscopic guidance, the brachial vein and brachial artery are each cannulated (newer devices allow for radial access), and a magnetic catheter is passed to the ulnar vein and ulnar artery, respectively. After catheter alignment, the magnets attract one another, pulling the ulnar artery and vein together as a radiofrequency electrode is released, creating a side-to-side anastomosis. The brachial vein is then coil-embolized to direct flow toward the superficial veins (1).

## Patient Selection

Each of the device pivotal studies were single-arm, prospective multicenter, nonrandomized, open-label studies in patients CKD who needed vascular access, and were designed to evaluate safety and efficacy of the creation of an endoAVF (1,3). The primary endpoints were a >4 mm vein diameter by ultrasound measurement and brachial artery flow of >500 ml/min at 90 days. Each included patients with (1) nontortuous target vessels  $\geq 2$  mm, (2) the presence of a  $\geq 2$  mm perforator vein, and (3) and patent cephalic and basilic draining veins in the target upper extremity, as assessed by screening ultrasound examination. Candidates for a surgical radial-cephalic AVF were excluded, as were those with central outflow occlusion. Interventional nephrologists and interventional radiologists performed the procedure under ultrasound in the Avenu (Ellipsys) pivotal study (1), whereas surgeons and interventional radiologists performed the procedures in a fluoroscopy suite in the Novel Endovascular Access Trial (WavelinQ) study (3). Conscious sedation with local or regional anesthesia was used.

A total of 28% of the 251 patients evaluated in the Ellipsys trial and 25% of the 183 patients evaluated in the WavelinQ trial had unsuitable anatomy for an endoAVF.

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### Advantages/Disadvantages

Despite its superior characteristics, the traditional surgical AVF is not without problems. Data derived from published studies suggest that these problems can be minimized or eliminated with an endovascularly created AVF. Because of the steps involved, a period of several months may be required to progress from surgical referral for access creation to a functional, surgically created AVF (6). This delay can significantly influence the proportion of patients starting dialysis with a central venous catheter rather than an AVF or graft. By placing endovascularly created AVFs in the hands of the interventionalist, the problem of delays and scheduling for office visits and presurgical procedures can be greatly diminished. In the outpatient facility in which these physicians work, patients can often be seen the same day or within no more than a few days of referral (7).

Achieving and maintaining a functional AVF is a challenge. Failure to mature is an intractable problem that has been reported as high as 60% (4). This problem results in prolonged central venous catheter use for dialysis with their inherent risks and additional interventions in an attempt at salvage. Even after maturation, early patency loss of AVFs can occur and has been shown to be directly associated with increased patient mortality (8). In a study using propensity score matching of 3764 patients with a traditional surgically created AVF, it was found that a cohort of 60 patients with an endoAVF required fewer postcreation procedures and had lower associated mean costs within the first year (9). In one report of 33 individuals, all were either used or usable at 4–6 weeks (2). The cumulative patency rate at 1 year has been reported to be in the range of 80% to 86.7% (1,3), which is significantly superior to that reported for traditional, surgically created AVFs. It has been suggested that this improved patency and fewer interventions are related to the fact that the anatomy associated with the AVF has not been disturbed, the vasa vasorum remains intact, and that the only change is physiologic (2).

In addition to the medical and economic advantages of this approach, the emotional impact of decreased morbidity of AVF creation on patients cannot be overstated. The procedure can be done with regional or local anesthesia, a surgical incision is not required and the need for additional interventions is minimized.

### Differences in the Dialysis Process

Several important differences exist between percutaneous and surgically created AVFs. First, an endoAVF has no surgical scar to identify the anastomotic site, and there is a Y-shaped AVF, rather than the single AVF channel typically present in a surgical AVF. Cannulation location will vary according to development of the superficial outflow veins, requiring individualization of the cannulation technique.

Given the available data, several unanswered questions remain. First, with endoAVF expansion, it remains to be seen whether sufficient education will be provided to dialysis units around proper cannulation technique and to patients about percutaneous AVF anatomy, to avoid inadvertent use of the AVF and ipsilateral limb for non-dialysis purposes. Second, although neither of the pivotal

observational studies reported dialysis prescription variables, a smaller subsequent study reported that the pump blood flow speed used was between 300 and 350 ml/min, whereas AVF blood flow (as measured in the brachial artery) increased over time from 670 ml/min at 3 months to 800 ml/min at 1 year (10). Therefore, it remains to be seen whether percutaneous AVFs will provide United States standard blood pump speeds of 400–500 ml/min, or whether an increase in dialysis time may be required to achieve the prescribed dialysis dose. In addition, it is unknown what the extent of secondary interventions will be needed to maintain AVF function long term, how surgical transposition may affect AVF function, or what impact endoAVF may have on subsequent AV access creation. Therefore, although reported observational outcomes at 1 year are promising, data beyond 12 months will be informative.

### Conclusions

Overall, percutaneous AVF outcomes look encouraging and appear to result in improved primary patency, as well as lower associated first-year costs compared with surgically created AVFs (9). They confer the advantage of eliminating surgical variation in outcomes, and offer select patients with suitable anatomy a less invasive option and the avoidance of general anesthesia, utilized for more complex surgical AVF procedures. Moreover, the anatomic location of the AVF fits nicely into the algorithm of Kidney Disease Outcomes Quality Initiative guidelines, which recommend that arteriovenous access placement starts distally and then move proximally, without sacrificing the opportunity for secondary upper arm arteriovenous access creation.

Yet, the actual creation of an endoAVF may turn out to be the easiest part, as to be successfully adopted, its advantages and disadvantages must be understood by nephrologists, and it must be placed in the right patient, be able to be cannulated, and provide the prescribed dialysis dose. For this to occur, sufficient education and training of the patient, dialysis staff, nephrologist, interventionalist, and surgeon must accompany its wider use. In short, a multidisciplinary approach is needed in which providers communicate as a team, and this will require a major paradigm shift.

### Acknowledgments

The content of this article does not reflect the views or opinions of the American Society of Nephrology (ASN) or the *Clinical Journal of the American Society of Nephrology* (CJASN). Responsibility for the information and views expressed therein lies entirely with the author(s).

### Disclosures

Dr. Wasse reports other funding from TVA Medical, outside the submitted work.

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Published online ahead of print. Publication date available at [www.cjasn.org](http://www.cjasn.org).