

The Endovascular

# ARTERIOVENOUS FISTULA

A Clinical Update



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## Background

The recently updated Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline for Vascular Access considers all hemodialysis (HD) access options viable if they align with each patient's end stage kidney disease Life-Plan and access needs (ESKD-PLAN). The updated guidelines find it reasonable to suggest that for both incident and prevalent HD patients, an arteriovenous fistula (AVF) or arteriovenous graft (AVG) is generally preferred over a central venous catheter (CVC). Furthermore, when there is adequate preparation time and patient circumstances are favorable, an AVF is generally preferred over an AVG.<sup>1</sup> When feasible, an AVF is considered the optimal vascular access because of its superior durability, lower risk of infection, and decreased number of interventions to maintain patency.<sup>2,3</sup>

Disappointingly, in 2018, 80.8% of U.S. patients were reported using a catheter at HD initiation, while 65.2% of incident ESKD patients either did not have an AVF or AVG placed, or did not have one that was ready for use by their first outpatient HD treatment. As recently as 2017, 68% of U.S. patients were still using a CVC 90 days after the initiation of HD.<sup>4</sup> This high rate of dependence on CVCs is associated with risks for infection, hospitalization, and mortality, as compared with other types of vascular access.<sup>1,2</sup> The reasons for a low AVF start rate include long wait times for surgery (3-10 weeks),<sup>5,6,7</sup> extra time and planning needed for preoperative visits, patients refusing surgery, surgical risks, and early thrombosis of 12% to 26%.<sup>5,8,9</sup>

AVFs can also have difficulty maturing, which is associated with the need for bridging catheters, and exposure to an average of 1.5 to 3.3 procedures to make an AVF functional.<sup>10,11,12,13</sup>

According to the United States Renal Data System (USRDS), of the AVFs created between June 2014 and May 2016, 39% failed to mature enough to support HD. For those that did mature sufficiently, the median time to first use was 108 days.<sup>2</sup> Due to a combination of primary surgical and maturation failures, 36.2% of AVFs in the United States were not viable.<sup>2,14</sup> These barriers to AVF creation increase patient reluctance to submit to AVF surgery, especially in patients with a previously failed AVF.<sup>5,15</sup>

Similar to the improved outcomes achieved by transitioning other traditional open vascular surgeries to an endovascular approach, surgeons thought that an endovascular AVF (endoAVF) could potentially address certain of the barriers to successful AVF creation by decreasing vessel trauma and intimal hyperplasia that impedes AVF maturation, decreasing morbidity from open wounds and re-interventions, and ultimately, increasing patient acceptance of AVFs.<sup>5,16</sup> In the pursuit of endoAVF technology, two devices were developed to provide a minimally invasive percutaneous alternative to the open surgical approach. These devices could help to solve some of the problems associated with surgical AVFs that can arise from incisions, vessel dissection and translocation, and the sutured anastomosis, which may cause delayed healing, infections, and a low rate of functional AV fistula creation.<sup>16,17</sup>

The endoAVF technologies currently in use include the WavelinQ™ EndoAVF System and the Ellipsys® Vascular Access System. Both systems use image-guided catheter-based technology to create proximal forearm fistulas in the outpatient setting with local or regional anesthesia and conscious sedation. Most experience with these devices has been obtained through clinical trials,<sup>5,18,19,20,21,22</sup> but efforts are underway to expand their usage and to monitor their long-term outcomes.<sup>16</sup> This clinical update provides a brief overview of these innovative technologies and their impact thus far.

## Key Components for EndoAVF Creation

### Vascular Considerations

The endoAVF is created within the deep vasculature of the proximal forearm, close to or slightly distal to the perforating vein, and, either between the ulnar artery and adjacent ulnar vein, or between the radial artery and adjacent radial vein.

**Figure 1** indicates the locations for endoAVF creation sites. The adjacent vessels are connected to the perforating vein in the area of the cubital fossa to allow for direct outflow to the superficial veins.<sup>23,24</sup> The perforating vein is the essential conduit between the deep and superficial vessels; it should be at least 2 mm in diameter, and it is most favorable if it lies straight in relation to either the cephalic or basilic vein.

**(Figure 2)** The superficial veins should have a minimum diameter of 2.5 mm along their entire length, and target artery should have two adjacent parallel veins to create a side-to-side anastomosis,<sup>16</sup> a configuration thought to cause less shear stress on vessel walls, less intimal hyperplasia, and better blood flow dynamics than one that joins the end of one vessel to the side of another.<sup>25</sup>

Based on early clinical data, 72%–75% of patients studied had suitable anatomy for endoAVF creation.<sup>26</sup> If vascular requirements are met, both pre-dialysis and dialysis patients can be appropriate candidates. This includes those with previously failed surgical AVFs, since the target site is different from the previous surgical site, which was most likely at the wrist or above the elbow, rather than the proximal forearm. Conversely, a subsequent surgical AVF can be placed if an endoAVF fails to mature or lose patency.

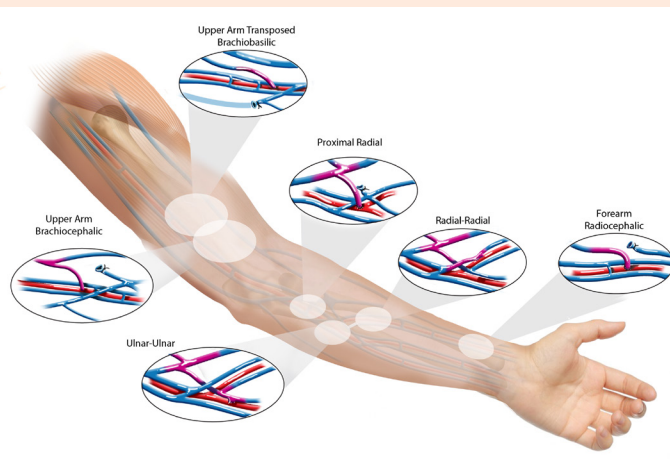
## EndoAVF Systems and Devices

The WavelinQ™ EndoAVF System uses two 4F magnetized catheters and radiofrequency energy to create an anastomosis between either the ulnar artery and adjacent ulnar vein or the radial artery and adjacent radial vein in the proximal forearm. Brachial artery and multiple vein access options (brachial, radial or ulnar) can be used to get access to the vessels, allowing for procedural flexibility for varying patient anatomies. The catheters are advanced to the targeted artery and vein and magnets are used to align the devices. Radiofrequency energy is delivered to the electrode in the venous device, creating a channel between the vessels. To allow blood flow to the superficial veins, it is recommended to coil-embolize one of the brachial veins at the end of the procedure.<sup>5,25</sup>

The Ellipsys® Vascular Access System uses one 6F catheter that applies direct heat and pressure to fuse the proximal radial artery and the deep communicating vein in the proximal forearm. A needle puncture is made in 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 catheter is then inserted, the sheath is retracted, and the catheter is advanced further to draw the radial artery and perforating vein walls together. Thermal energy is then applied to form a side-to-side anastomosis between the perforating vein and the proximal radial artery, followed by balloon angioplasty to reduce post-anastomotic stenosis observed in early studies.<sup>22,25</sup>

As with open surgeries, pre-operative duplex ultrasound vessel mapping is required prior to any endoAVF procedure to determine patient suitability. An important benefit of these procedures is that the vessels are not clamped, mobilized, or dissected, and are not anastomosed by sutures.<sup>23</sup> Characteristics of both systems are listed in **Table 1**.

**Figure 1. AV Fistula Access Creation Sites**



## EndoAVF Cannulation

EndoAVF cannulation is very similar to cannulation of surgical AVF, with minor, but important differences. Therefore, clinicians should be educated about endoAVF anatomy and proper cannulation methods, while patients should also be informed about endoAVF anatomy to avoid inadvertent use of the AVF and ipsilateral limb for non-dialysis purposes.<sup>25,26</sup>

The endoAVF does not have a surgical scar or the prominent landmark of an end-to-side anastomosis to help locate the anastomotic site, and the AVF has a Y-shape, rather than a single conduit usually seen with a surgical AVF.<sup>25</sup> And because it is multi-outflow, dominance varies between the arterialized cephalic and basilic veins, rendering each AVF unique, so that cannulation sites will vary according to development of the superficial outflow veins, requiring an individualized cannulation approach.<sup>16</sup>

Rope ladder cannulation is appropriate for most patients, with buttonhole cannulation used in selected patients, per KDOQI guidelines. Expert cannulators note that an endoAVF feels softer as the needle tip enters the vessel and that blood flashback is often less forceful than an upper arm surgical AVF, and therefore, wet needle cannulation may be helpful. With a tourniquet in place, cannulation should proceed with light pressure to avoid vessel collapse and backwall injury. Vessel depth determines the needle angle, and a 20–35° angle is usually used for endoAVF cannulation. The cannulation zone length must be clearly delineated. While standard metal fistula needles come in 1-inch or 1¼-inch lengths, a shorter, 3/5-inch metal fistula needle may be more appropriate. Plastic cannulae are often used outside the United States to cannulate endoAVFs. The venous needle direction should always point toward the venous return to the central system. The arterial needle can point toward the

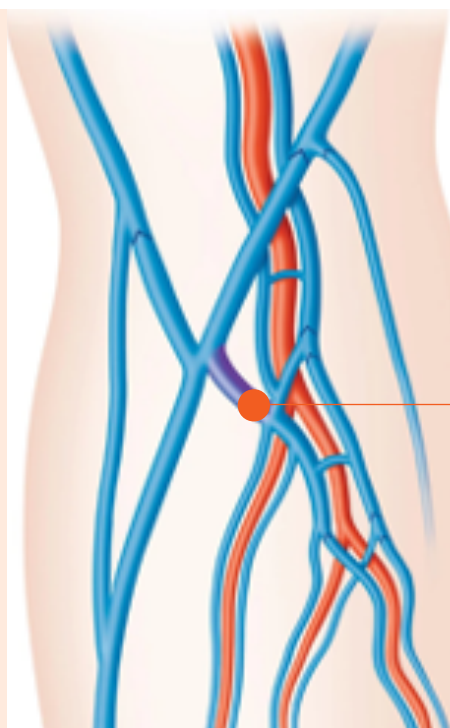
inflow (retrograde) or toward the venous return (antegrade), depending on the cannulation zone length and unit-specific policy/procedures. The arterial and venous pressures should be monitored in these moderate flow endoAVFs, paying close attention to the arterial pressure, as it may become too negative to support a standard blood pump speed.<sup>27</sup>

Lok et al. recommended that clinicians first refer to the physician who created the endoAVF for guidance on cannulation sites. This physician should follow-up with the patient prior to first cannulation, mark the cannulation zone, and review this information with both the patient and the dialysis nurse, as with surgical vascular access patients. Ultrasound should be used to guide cannulation at least for the first cannulation, particularly for obese patients, and a tourniquet should be used at the time of puncture to facilitate vessel access.<sup>26</sup>

## EndoAVF Outcomes

### WavelinQ™ EndoAVF System

Results from studies of the WavelinQ™ EndoAVF System include a feasibility trial of 33 patients (FLEX),<sup>18</sup> a prospective, multicenter trial with 60 patients (NEAT),<sup>5</sup> and a single-center study of 8 patients.<sup>20</sup> All three studies demonstrated high technical success rates of 97–100% in creating endoAVFs. Technical success was defined as visualizing blood flow through the endoAVF via a fistulogram before the patient left the procedure room<sup>5</sup> or by angiography as a flow between the proximal ulnar artery and the adjacent vein.<sup>18,20</sup> The WavelinQ™ EndoAVF System was referred to as everlinQ™ endoAVF System in the FLEX and NEAT studies. **Table 2** summarizes the technical approach and outcomes of endoAVF creation.



**Figure 2. EndoAVF anastomosis and required vascular anatomy**

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*Purple segment indicates perforator vein.*



In the NEAT trial, the primary efficacy endpoint was that 75% of the 80 enrolled patients (n=60) have endoAVFs physiologically suitable for hemodialysis within 3 months of creation. This was defined as absence of fistula stenosis and thrombosis, with brachial artery flow  $\geq$  500 mL/min and vein diameter  $\geq$  4 mm on duplex ultrasonography<sup>28,29</sup> or successful hemodialysis treatment with 2 needles. Secondary outcomes included more detailed imaging and clinical end points, such as endoAVF primary and cumulative patency.<sup>5</sup> Eighty-seven percent (52/60) of fistulas matured at 90 days, the mean time to two-needle hemodialysis for dialysis-dependent patients was 112 days, and the 12-month primary and cumulative patency was 69% and 84%, respectively.

Primary and cumulative patency followed standardized definitions:

**Primary Patency:** Time of access creation or placement until any first intervention (endovascular or surgical) to maintain or restore blood flow, first occurrence to access thrombosis, or reaching a censored event (death, transfer to another HD unit, transfer to peritoneal dialysis, transplantation, and end of study period). It can be additionally calculated at 30 and 90 days, and at 6, 12, 18, and 24 months.<sup>30,31</sup>

**Cumulative Patency:** Time of access creation or placement until access abandonment or achievement of a censored event (death, transfer to another HD unit, transfer to peritoneal dialysis, transplantation, and end of study period), and includes all surgical and endovascular interventions.<sup>30,32</sup>

There were also low rates of secondary procedures, with 24 performed in 19 patients (0.79 procedures per fistula), compared to 209 secondary procedures performed in 63 patients (3.3 procedures per fistula) in a series of surgical AVFs.<sup>5,27</sup> There were 8 adverse events in 5 of 60 patients, which were mainly related to antegrade access to the mid-brachial artery,

including closure device embolization (n=2), arterial dissection (n=1), pseudoaneurysm (n=2), steal syndrome (n=1), and brachial artery thrombosis (n=2).<sup>5,16</sup> A single-center, prospective study of the WavelinQ™ 4F EndoAVF System with 32 patients yielded successful AVF creation in all patients, for a technical success rate of 100%. The serious adverse event rate was 3%, with 1 patient having a venous guide wire perforation that was corrected with a stent graft. Primary patency through 6 months was 83% and cumulative patency was 87%, with an intervention rate of 0.21 per patient year. Two-needle cannulation was successful in 78% (21/27) by 90 days, with a mean time to cannulation of 43  $\pm$  14 days.<sup>34</sup>

In the studies described above and below, primary and cumulative patency (time-to-event data) were analyzed with Kaplan-Meier methods and life tables to calculate and were defined as time from AVF placement to first intervention or censored event, and time from AVF placement to site abandonment, respectively.

### Ellipsys® Vascular Access System

Results from studies of the Ellipsys® Vascular Access System include a prospective feasibility study of 26 patients (TRAD),<sup>19</sup> a prospective, multicenter trial of 107 patients (PIVOTAL),<sup>21</sup> and a retrospective, single-center case series of 34 patients.<sup>22</sup> Technical success rates, as defined by creation of a fistula demonstrating flow by doppler ultrasound, ranged from 88 to 97%. In the multicenter trial, two-needle dialysis was achieved in 88% of dialysis-dependent patients at a mean of 114.3  $\pm$  66.2 days.<sup>21</sup> The 12-month cumulative patency was 87% and the functional patency was 92%, with functional patency referring to time from first cannulation to site abandonment.<sup>16,21</sup>

**Table 1. Characteristics of endoAVF systems compared with open surgery<sup>16</sup>**

|                              | Ellipsys® Vascular Access System                                 | WavelinQ™ EndoAVF System                          | Surgery                              |
|------------------------------|------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| <b>Catheter</b>              | Single                                                           | Dual                                              | NA                                   |
| <b>Energy</b>                | Thermal resistance                                               | Radiofrequency                                    | NA                                   |
| <b>Controller</b>            | Microprocessor                                                   | Electrocautery unit                               | NA                                   |
| <b>Imaging guidance</b>      | Ultrasound                                                       | Fluoroscopy                                       | Ultrasound used in some cases        |
| <b>Anesthesia</b>            | Local or regional and sedation                                   | Local or regional and sedation                    | Local or regional, sedation, general |
| <b>Positioning</b>           | Ultrasound                                                       | Magnets                                           | Dissection                           |
| <b>Anastomosis</b>           | Tissue fusion                                                    | Precise slit                                      | Suture                               |
| <b>Maturation procedures</b> | Two-stage process: additional procedure(s) to adjust/direct flow | Brachial vein embolization during index procedure | Single and two stages                |

In the two studies by Hull et al.<sup>19,21</sup> secondary maturation procedures were performed on nearly all patients. In the larger multicenter trial, an average of two procedures per patient was performed for maturation, however, target endpoints of primary brachial artery flow ( $\geq 500$  mL/min) and target vein diameter ( $\geq 4$  mm) were achieved in 86% (92/107) of patients. Cumulative patency was 91.6%, 89.3%, and 86.7% at 90 days, 180 days, and 360 days. In TRAD, efficacy and safety endpoints were met, with no adverse events related to the device. At 6 weeks, 87% of AVFs (20/23) were patent and 61% (14/23) had 400 mL/min brachial artery flow.<sup>19</sup>

In the study by Mallios et al, the number of maturation procedures was reduced considerably by leaving fistulas in a multi-outflow state, and by using novel cannulation techniques.<sup>22</sup> In the multicenter trial, two hematomas were reported as serious adverse events.<sup>16,21</sup>

## Future Studies/Considerations

As with any novel procedure, education and awareness will aid in the adoption of endovascular AV fistulas. Additional long-term studies are necessary to explore the types of secondary interventions needed to maintain AVF function long-term, how surgical transposition may affect AVF function, or impact of endoAVF on subsequent AV access creation. Therefore, although observational outcomes at 1 year are positive, long-term data are needed. With continued usage of endoAVFs, further recommendations should be forthcoming.

**Table 2. Technical approaches to endoAVF creation**

|                                                          | <b>WavelinQ™ EndoAVF System</b>                          | <b>Ellipsys® Vascular Access System</b>                         |
|----------------------------------------------------------|----------------------------------------------------------|-----------------------------------------------------------------|
| <b>Number of necessary vascular accesses</b>             | 2                                                        | 1                                                               |
| <b>Possible anastomosis locations</b>                    | Ulnar vein/ulnar artery                                  | Perforating vein/radial artery                                  |
|                                                          | Radial vein/radial artery                                |                                                                 |
| <b>Access Route</b>                                      | Via brachial artery and vein                             | Via perforating vein                                            |
|                                                          | Via brachial artery and basilic vein                     |                                                                 |
|                                                          | Via brachial artery and cephalic                         |                                                                 |
|                                                          | Via brachial artery and radial vein                      |                                                                 |
|                                                          | Via brachial artery and ulnar vein                       |                                                                 |
| <b>Additional interventions in the primary procedure</b> | Coiling of the brachial vein proximal to the anastomosis | Regular PTA of the anastomosis with the perforating vein.       |
|                                                          |                                                          | Coiling of the deep vein proximal to the anastomosis, if needed |

## Conclusion

The advent of endoAVF creation could not have come at a more opportune time, when the paradigm shift toward a more patient-focused approach to access choice and planning has taken hold. The updated KDOQI vascular access guidelines emphasize the importance of devising a patient's Life-Plan for vascular access needs, so that not only is there careful planning for the initial access, but also for the types of accesses or kidney replacement modalities that may come next.<sup>1</sup> The endoAVF may help provide flexibility for adapting to changing access needs throughout life, since it can be used in patients with previously failed surgical AVFs, and conversely, in those who may need surgical AVFs as they continue through their Life-Plan.<sup>16</sup>

Factoring in the forearm location and potential patient benefits, consideration should be given to endoAVF creation prior to upper arm AVF.

The endoAVF has been shown to achieve functional usability at one year and less catheter exposure, which may improve outcomes and increase patient acceptance of AVFs.<sup>15</sup> With proper clinician and patient education, endoAVFs may provide an accepted and sustainable lifeline.

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