

# Endovascular Arteriovenous Fistula Creation: A Review

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## Abstract

### Keywords

- ▶ endovascular AVF
- ▶ percutaneous fistula creation
- ▶ WavelinQ
- ▶ Ellipsys
- ▶ dialysis
- ▶ interventional radiology

Endovascular arteriovenous fistula (endoAVF) creation offers a minimally invasive method for the formation of arteriovenous shunts utilized for hemodialysis. Currently, there exist two similar yet unique devices: WavelinQ and Ellipsys. This review analyzes the anatomy, pre- and postoperative considerations, fistula creation methods, and outcomes associated with endoAVF. Currently, data are limited with regard to clinical efficacy of endoAVFs when compared to surgical AVFs. However, early data suggest endoAVFs are a useful technique in the creation of AVFs.

Arteriovenous fistulas (AVFs) are often considered the preferred vascular access for patients requiring long-term hemodialysis.<sup>1</sup> Their superior patency rates combined with their low infection and reintervention rates compared to central venous catheters (CVCs) and arteriovenous grafts make them an ideal choice for access for many patients with end-stage renal disease. Traditionally, AVFs have been surgically created. However, with the development of two systems—WavelinQ (Becton, Dickinson and Company; Franklin Lakes, NJ) and Ellipsys (Medtronic, Minneapolis, MN), endovascular AVF (endoAVF) creation represents a novel, minimally invasive alternative to surgical fistula creation.

## Relevant Anatomy

Surgical fistulas for hemodialysis are most commonly created in the upper extremity between the radiocephalic, brachiocephalic, and brachial–basilic systems.<sup>2</sup> EndoAVF utilizes the radial artery and radial vein, ulnar artery and ulnar vein, or the radial artery and a venous perforator in the distal upper extremity depending on the device used to create the fistula.

## Perforator Veins

The upper extremity venous drainage consists of two systems: the superficial and deep venous systems. The superficial venous system is primarily composed of the basilic and cephalic veins in the forearm and upper arm. The deep venous system includes paired radial, ulnar, and interosseous veins in the forearm which drain into the brachial vein in the upper arm. These two systems communicate via a perforator vein in the forearm, located just distal to the antecubital fossa. The presence of a perforator vein is essential for successful endoAVF creation using both WavelinQ and Ellipsys devices, as it serves as the conduit for arterialized venous blood from the deep venous system to reach the superficial venous system. Without this superficialization of flow, there would be no veins suitable for cannulation of hemodialysis.

## Fistula Sites

The WavelinQ system creates a fistula between the radial artery and vein or the ulnar artery and vein.<sup>3</sup> The radial and ulnar artery/veins are targeted due to ease of percutaneous access and their close proximity to one another; that is, the

radial artery closely follows the path of the radial vein and the ulnar artery closely follows the path of the ulnar vein. This proximity facilitates alignment of the magnetic components used to form the fistula with the WavelinQ system. An added benefit is that their location in the distal upper extremity spares proximal vessels should future fistula attempts be required.

The Ellipsys system connects the proximal radial artery (PRA) with the deep communicating vein (DCV), the venous perforator of the distal upper extremity.<sup>4</sup> The PRA and DCV are selected using the Ellipsys system, which, due to their proximity, allows for direct puncture of both vessels using a single needle and fistulization through direct radiofrequency (RF) energy application.

## Preprocedure Considerations

### Patient Selection

Given the minimally invasive nature of endoAVF compared to surgical AVF (sAVF) creation, endoAVF represents an ideal option for patients who would prefer to avoid surgery or with contraindications to surgery. EndoAVF may also be indicated in patients for whom a radiocephalic (Breccia–Cimino) fistula is not feasible. EndoAVF creation should not be performed in patients with severe arterial or venous flow limitation. Specifically, endoAVF creation should not be attempted in patients with thrombosed cephalic or basilic veins or in patients with flow-limiting transmural arterial calcification.

### Timing

Whether fistulas are created surgically or endovascularly, the maturation process may require several weeks to months rendering the fistula unusable over this time frame.<sup>1</sup> Anticipating the need for hemodialysis preemptively allows the fistula to mature by the time it is required. Coordination among providers may facilitate timely fistula creation and can curb the need for CVC placement.

### Vessel Mapping

Assessment of vessel anatomy and patency should be performed to determine whether the patient is a candidate for endoAVF creation. Criteria for endoAVF eligibility depend on the device used, but are similar for both WavelinQ and Ellipsys systems. Eligible candidates using the WavelinQ system must have cephalic and basilic vein with diameters  $\geq 2.5$  mm without flow-limiting central stenosis, a patent perforator with diameter  $\geq 2$  mm, brachial artery and vein with diameter  $\geq 2$  mm, an ulnar artery/vein pair with diameter  $\geq 2$  mm, or a radial artery/vein pair with diameter  $\geq 2$  mm.<sup>3</sup> Additionally, there must be less than 2 mm of separation between the target vessels. Multiple access sites including the brachial artery/vein, ulnar artery/vein, or the radial artery/vein can be used as long as they are sufficiently wide ( $\geq 2$  mm) to accommodate the WavelinQ system.

With the Ellipsys system, eligible patients must have a PRA and perforator vein with diameter  $\geq 2$  mm and with less than 1.5 mm of separation between the target artery and

vein.<sup>4</sup> The proximity of the vessels is essential to successful fistula creation due to the mechanism of the Ellipsys system (i.e., single, direct puncture of the adjacent target vessels).

## Technique

Currently, two endoAVF devices exist, the WavelinQ and Ellipsys systems. Each system utilizes different technologies and is performed using different techniques, though both rely on the presence of a perforator vein to superficialize flow to the cephalic and basilic veins. With the WavelinQ system, a radial artery–radial vein or ulnar artery–ulnar vein fistula, is created, while with the Ellipsys system a PRA–venous perforator fistula—is formed.

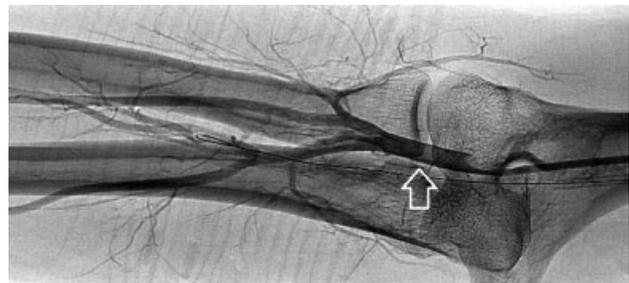
### Anesthesia

EndoAVF creation is typically performed with local anesthesia and moderate sedation (midazolam and fentanyl). A brachial plexus block can also be particularly beneficial, as it induces intraprocedural arterial and venous dilation, which may potentially facilitate improved short-term fistula patency. Additionally, brachial plexus block may also minimize patient discomfort and movement during the RF pulse application when using the WavelinQ system.

### WavelinQ

Using the WavelinQ system, the brachial artery and vein are accessed each using a micropuncture kit.<sup>3</sup> Care should be used to avoid stimulation or injury to the median nerve during access. Vascular sheaths are then inserted into the brachial artery and vein under fluoroscopic guidance. A guidewire is passed through both vessels and directed toward the ulnar artery and vein (or radial artery and vein) with the aid of an angled catheter. Of note, an ulnar–ulnar fistula is preferred by the authors, as the proximity of the ulnar vein to the perforator vein may improve flow to the superficial venous system. Advancing the wire using a brachial approach may also prove challenging due to the presence of venous valves. As such, using a stiffer guidewire may aid in navigation.

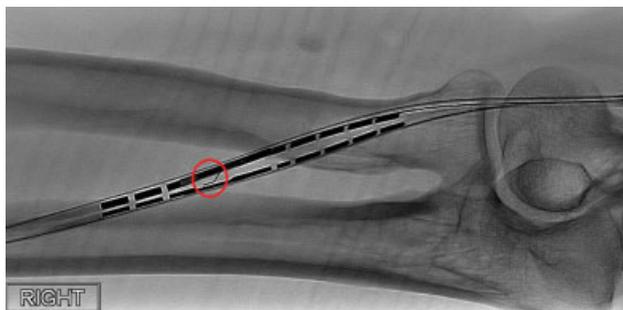
Digital subtraction angiography is performed to depict the arterial (→ Fig. 1) and venous anatomy (→ Fig. 2) of the upper extremity and to identify the location of the perforator vein. The WavelinQ catheters are inserted into the brachial artery and vein and then advanced distal to the perforator



**Fig. 1** Arteriography pre-fistula formation. Contrast injected through the brachial artery (arrow).



**Fig. 2** Venography pre-fistula creation. Contrast injected simultaneously with brachial vein compression to image superficial venous system.



**Fig. 3** WavelinQ system catheters in ulnar artery and vein. Note the electrode extending from the venous catheter into the ulnar artery (circle).

site. Alternatively, if using the 4-Fr system, catheters can be inserted from the distal upper extremity through either the ulnar artery/vein or radial artery/vein. However, before proceeding with this access, a Barbeau test should be performed prior to distal forearm access to ensure patency of the radiopalmar arch. An antiparallel approach via brachial and radial or ulnar accesses can also be done.

Once the catheters are positioned at the creation site, magnets in both the arterial and venous catheters help align them. Precise alignment is achieved with microadjustments of the catheter and confirmed with an orthogonal view (→ **Fig. 3**). Once aligned, a spring-loaded RF electrode in the venous catheter is activated which momentarily contacts the ceramic backstop on the arterial catheter to form the fistula. The RF pulse takes only 0.7 seconds and causes a momentary spasm of the arm which is minimized by securing the extremity to an armboard at the start of the case. An arteriography is repeated once the anastomosis is formed with basilic and cephalic outflow indicating technical success (→ **Fig. 4**). Of note, while not required, the brachial vein is often embolized following fistula formation to aid in flow diversion to the superficial veins.

### Ellipsys

With the Ellipsys system, the median basilic or cephalic vein is accessed in the distal upper extremity with a micropuncture kit.<sup>4</sup> A guidewire is inserted through a 6-Fr vascular sheath and navigated into the perforator vein. The guidewire and sheath are positioned adjacent to the PRA to facilitate direct puncture. A micropuncture needle is advanced from



**Fig. 4** Final fistulography post-fistula creation. Note the presence of brachial vein coils (arrow) to divert flow to the basilic and cephalic veins.

the perforator into the PRA followed by the guidewire. The Ellipsys catheter is then advanced over the guidewire into the PRA. Upon activation, thermal energy is delivered by the catheter which results in formation of the fistula. A fistulogram or ultrasound study can be performed to confirm adequate fistula formation.

## Follow-up and Management

### Postprocedure Course

Given the minimally invasive nature of endoAVF, patients can be discharged shortly after the procedure, often on the same day. In the authors' practice, patients are also prescribed 1 month of aspirin and clopidogrel to decrease occurrence of fistula thrombosis.

### Fistula Maturation

Once the fistula has been formed, routine sonographic follow-up should be performed to assess fistula maturation. This is commonly performed every 2 weeks, but can vary across institutions. Flow rates  $\geq 500$  to 600 mL/min on Doppler ultrasound are considered suitable for hemodialysis.<sup>1</sup> Maturation can take anywhere from 26 to 137 days depending on the system used to create the endoAVF.<sup>3</sup> If the fistula does not achieve this target flow rate, additional endovascular interventions may be considered to assist maturation including coil embolization of a competing brachial vein or angioplasty of the fistula "anastomosis" itself (Ellipsys fistulas only), or even surgical correction.<sup>5</sup>

Doppler sonography is also important in assessing the venous outflow. EndoAVFs are multioutflow fistulas which can drain via the cephalic vein, basilic vein, or both. Flow through the cephalic vein is preferable, as its relatively superficial course tends to allow for easier cannulation without the need for surgical manipulation. In contrast, basilic-dominant flow, or even cephalic-dominant flow in larger patients, may necessitate transposition, elevation, or lipectomy.

### Cannulation

Cannulation technique with endoAVF varies slightly from the technique used for sAVF. First, routine use of a tourniquet is strongly recommended. A shallow needle angle (25–35 degrees) also facilitates successful cannulation. While cannulating, the technician should strive to apply gentle



**Fig. 5** Image of upper extremity at the conclusion of endoAVF procedure. Note the presence of only mild bruising from manual compression at the access site.

pressure to avoid injuring the back wall of the vein. Additionally, providing a diagram or photo of the cannulation zones to the technician may be useful given the absence of associated scar or skin protrusion (►Fig. 5). During early cannulation attempts with a recently created fistula, a graduated approach to cannulation may be beneficial. For example, cannulating the fistula with a single needle for arterial flow and returning blood through an existing catheter may be advantageous prior to dual-needle cannulation. Similarly, starting hemodialysis with lower pump speeds (e.g., 300–350 mL/min) can help minimize vessel trauma. As the fistula matures, higher flow rates can be attempted as tolerated.

### Complications

The complications associated with endoAVF creation are relatively nonspecific and are similar to those associated with sAVF or other percutaneous transarterial procedures. These include hematoma (9%), pseudoaneurysm (3%), arterial dissection (1%), and thrombosis (9%).<sup>5,6</sup> Overall, the complication rate is as low as 5.46%, with most complications correctable through minor procedures.<sup>7</sup> It is worth noting, however, that the relatively complex fistula anatomy relative to traditional sAVF can make ligation or surgical revision very challenging.

Other post-creation complications that may occur are related to the fact that the fistula is not visually prominent and lacks associated surgical scars. Consequently, vessel injury can occur during attempted cannulation, or inadvertently during phlebotomy or as a result of repeated blood pressure cuff inflation.

### Outcomes: EndoAVF versus sAVF

Given the relatively recent development of endoAVF creation, comparison with sAVF is a useful metric to assess efficacy of a percutaneous approach. While studies directly comparing endoAVF with sAVF remain limited, preliminary data suggest that outcomes with endoAVF are comparable to those with sAVF.

### Time to Maturation

Maturation times with endoAVF are comparable to those with sAVF. EndoAVF maturation times vary, but have been reported between 29<sup>8</sup> and 137 days<sup>4</sup> using the WavelinQ system and  $65.6 \pm 45.7$  days with the Ellipsys system.<sup>9</sup> Maturation with sAVF may also take 2 to 3 months<sup>1</sup> with reported mean time of 79 days.<sup>10</sup> Although few studies exist directly comparing maturation time, 6-week maturation rate with endoAVF of 65 versus 50% with sAVF has been reported.<sup>11</sup>

### Primary Patency

Primary patency rates (i.e., fistula patency prior to intervention, occlusion, or abandonment)<sup>12</sup> with the WavelinQ system of 83% at 73 days<sup>8</sup> and 69% at 1 year<sup>6</sup> have been reported. With the Ellipsys system, 1-year primary patency rate of 54% has also been reported.<sup>4</sup> A retrospective study directly comparing Ellipsys with sAVF showed a patency rate of 86% at 12 months with endoAVF versus 61% at 12 months with sAVF, a statistically significant finding.<sup>11</sup>

### Secondary Patency

Secondary patency rate measures fistula patency from creation and is inclusive of interventions used to maintain patency.<sup>12</sup> With WavelinQ, 12-month secondary patency rates between 60<sup>13</sup> and 84%<sup>6</sup> have been reported. With Ellipsys, secondary patency rates between 85 and 96% have also been reported.<sup>4,13</sup> Secondary patency rates between endoAVF and sAVF are comparable (90 vs. 91%, respectively).<sup>13</sup>

### Intervention Rate

AVFs often require intervention to promote maturation or to maintain patency. Potential interventions include angioplasty, stenting, embolization, and surgical revision. Repeated fistula cannulation results in vessel trauma which may induce neointimal hyperplasia and subsequent venous stenosis. Intervention rates between endoAVF and sAVF vary; current data suggest that sAVF often requires additional intervention compared to endoAVF. Two-year intervention rate with sAVF of 36 versus 17% has been cited.<sup>11</sup> Furthermore, intervention rates with endoAVF vary between 0.59 and 0.74 per patient year, while sAVF rates are between 3.43 and 7.22 per patient year.<sup>14,15</sup> Of note, when the costs of these interventions are calculated, endoAVF has been projected to be between \$11,240 and \$13,389 lower than sAVF.<sup>14,15</sup>

### Conclusion

EndoAVF offers a minimally invasive alternative to sAVF formation. Currently, two devices for endoAVF exist which both rely upon similar anatomical considerations—the WavelinQ system and the Ellipsys system. Data comparing endoAVF to sAVF remain limited, but preliminary data suggest that endoAVF may offer superior primary patency rates, lower intervention rate, and possibly lower overall costs compared to sAVF. Further prospective, multicenter randomized controlled trials are needed to further

characterize the indications and utility of one method over the other.

#### Conflict of Interest

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