Cardiovasc Intervent Radiol (2019) 42:1–9
https://doi.org/10.1007/s00270-018-2037-6

REVIEW

A Review of the Current Status of Percutaneous Endovascular Arteriovenous Fistula Creation for Haemodialysis Access

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Received: 30 January 2018 / Accepted: 13 July 2018 / Published online: 20 July 2018

Abstract Surgical fistulas were first described over 50 years ago and have revolutionized the outlook for millions of dialysis-dependent patients. Despite many developments, results remain sub-optimal with high rates of primary failure and re-intervention to maintain patency. Surgical fistulas are known to fail in part due to intimal hyperplasia leading to stenosis, and vessel manipulation during anastomosis creation can be contributory. New technology is emerging that allows the endovascular creation of fistulas with minimal vessel trauma and the initial results demonstrate encouraging outcomes with high technical success rates, low re-intervention, and failure rates and good usability for hemodialysis. Two such device systems are currently available, and here, we provide an overview of the current global status of endoAVF, patient selection criteria, trial results, technical aspects, re-interventions, and outlook for the future.

Keywords Endovascular · Dialysis fistulas · Renal failure · Interventional radiology · AVF creation

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Background

Surgical AVF are fraught with problems in that around 20% thrombose acutely, mean maturation times range from 4 to 9 months, and failed maturation rates are 20–60% [1–6]. Up to 3–4 interventions per year are required to maintain functional patency in AVF and thrombotic occlusion rates are as high as 25% [7]. Loss of patency is associated with a significant morbidity and subsequent reliance on dialysis catheters, which have been associated with increased morbidity and mortality [8].

In recent years, new technology has emerged that has the potential to provide a minimally invasive alternative to open surgical creation of AVF. These devices have been developed to address many of the shortcomings of surgical fistulas that result from skin incision, vessel dissection and translocation, and the sutured anastomosis, which may result in prolonged healing, complications, and a low rate of functional fistula creation [9]. Early experience in percutaneous endovascular creation of AV fistulas (endoAVF) appears promising, and may offer improved fistula outcomes and lower morbidity without compromising the traditional surgical sites for AVF creation. These new devices utilize image-guided catheter-based technology to create proximal forearm fistulas. There are currently two such devices in use, which have predominantly been used in clinical trials [10–15]. The endoAVFs can be created in the day-case/outpatient setting with local or regional anesthesia and sedation, and do not require the use of the operating theatre. Here, we provide a current overview and commentary on the status of these devices in AV access creation and use.

Anatomy and Devices

Mapping of the perforating veins in dialysis patients has demonstrated that 88% of patients have a perforating vein greater than 2 mm diameter [16]. The presence of the perforating vein allows the creation of a fistula between a deep artery and vein to provide flow to the superficial venous system for dialysis. The other important anatomical detail enabling percutaneous endoAVF creation is that all of the arteries in the arm typically have two adjacent parallel veins, which can be used to create a side-to-side arteriovenous fistula. The perforating vein is the essential gateway between the deep and superficial venous system enabling the creation of an in situ fistula (Fig. 1). The perforating vein has been used to create surgical fistulas since 1977, when this was first described by Toledo-Pereyra and Gracz in separate publications [17, 18]. Each EndoAVF system takes advantage of the antecubital anatomy in a slightly different manner. Device properties of both systems are summarized in Table 1.

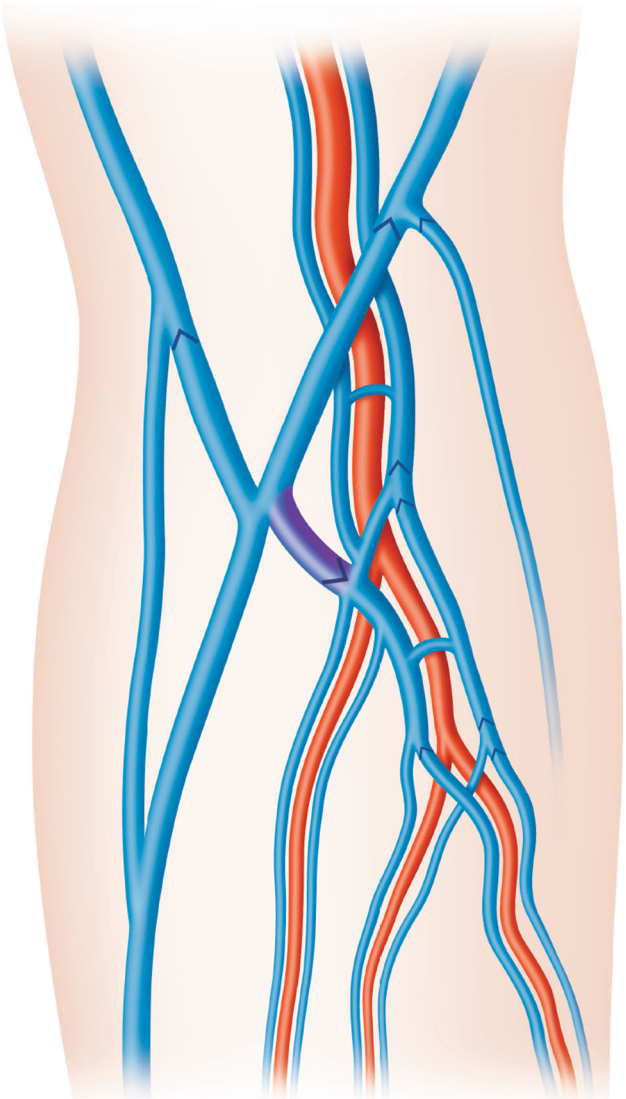

Fig. 1 Diagram of target zone anatomy. The perforator vein is represented as the purple section. This demonstrates the anatomical relationship of the deep and superficial venous system of the proximal forearm and the target site for endoAVF creation using the TVA EverlinQ device system

The EverlinQ endoAVF system [TVA Medical, Austin, TX, USA] is a dual catheter-based system, which is used to create a fistula between the closely applied deep arteries and veins of the proximal forearm. The endoAVF is typically created between the common ulnar artery and adjacent ulnar vein, which is the anatomical segment between the brachial artery bifurcation and the origin of the interosseous artery, although the deep radial vessels can also be utilized for fistula creation using the device. The superficial veins then receive arterialized blood flow via the perforating vein.

The key elements of the EverlinQ endoAVF system are two endovascular catheters (one arterial and one venous) both containing magnets to enable correct catheter alignment, a radiofrequency electrode on the venous catheter, and a radiofrequency generator. This technology was first conceptualized from the recognition of findings in patients with penetrating injuries and subsequent development of post-traumatic AV fistula with no evidence of extravasation or hematoma that often remain patent for long periods unless endovascular embolization or corrective surgery is undertaken [10]. This analogy was then applied in a more directed-and-controlled fashion in the development of this technology.

The endoAVF procedure is carried out under conscious sedation and local anesthesia and does not require an overnight stay in hospital. The patient is positioned prone on the fluoroscopy table with the arm abducted and secured on a specific arm board with wrist straps. Retrograde above-elbow brachial vein access followed by antegrade brachial artery access is performed under sonographic guidance. The 6Fr first generation device requires a 7Fr sheath in the vein and a 6Fr sheath in the artery, but a rapid exchange 4Fr 0.014” system is now available (EverlinQ 4 endoAVF system, TVA Medical, Austin, TX) that is compatible with 4/5Fr Terumo vascular access sheaths. Once arterial and venous access has been achieved, angiography of the antecubital fossa and forearm is performed. Using the angiographic roadmap, a 0.018” wire is positioned in the ulnar artery. This is used as a visual guide to enable catheterization of the adjacent ulnar vein, again using an 0.018” wire and catheter (e.g.: Bolia, Terumo). The relationship between the ulnar veins, arterial wire, and perforator vein at the target site is seen in Fig. 1. Once parallel wire position is obtained at the target site, the EverlinQ catheters are introduced. The magnetic catheters attract each other when positioned in the adjacent ulnar (or

Table 1 Device properties

	Ellipsys	EverlinQ	Surgery
Catheter	Single	Dual	NA
Energy	Thermal resistance	Radiofrequency	NA
Controller	Microprocessor	Electrocautery unit	NA
Imaging guidance	Ultrasound	Fluoroscopy	Ultrasound used in some cases
Anesthesia	Local or regional and sedation	Local or regional and sedation	Local or regional, sedation, general
Positioning	Ultrasound	Magnets	Dissection
Anastomosis	Tissue fusion	Precise slit	Suture
Maturation procedures	Two-stage process: additional procedures to adjust and direct flow	Brachial vein embolization during index procedure	Single and two stages
Inflow artery	Proximal radial	Ulnar (or radial)	Multiple
Conduit	Single-target vein, though multiple-vein possible	Multiple vein	Single-target vein

radial) artery and vein (Fig. 2). This magnetic attraction holds the artery and vein together and simultaneously aligns the radiofrequency (RF) electrode in the venous catheter and the ceramic backstop in the arterial catheter. As a result of this, correct catheter alignment is ensured. The radiofrequency electrode on the venous catheter is energized for 2 s via a hand-held switch in the circuit between the RF generator and venous catheter. This creates a channel between the artery and vein using radiofrequency energy to vaporize the tissue and thereby creating the AV anastomosis in a side–side configuration (Fig. 3).

Arterialized flow is then seen from the deep ulnar vein, through the adjacent perforator vein and into the superficial veins (Fig. 3). Arterialised outflow is also seen in the deep brachial veins above the elbow, and in view of this, typically, the brachial vein used for access is coil embolized during in the same index procedure to limit arterialized flow in the deep brachial veins (Fig. 4). This augments flow to the superficial veins contributing to maturation.

The FLEX and NEAT trials both utilized the 6 French system and access was from the brachial artery (antegradely, over the wire) and brachial vein (retrogradely, rapid exchange) over 0.018" wires [13, 15]. The new 0.014" rapid exchange 4 French system (EverlinQ 4 endoAVF system, TVA Medical, Austin Texas, USA) has improved visual markers and square magnets for optimizing alignment prior to RF energy release (0.7 s compared to 2 s with the 6Fr system). While still targeting the same forearm site for endoAVF creation, this smaller calibre system has expanded the access options to enable the wrist vessels to act as access points. Multiple approach options are, therefore, available, including ulnar and radial arteries and their associated veins if they are of adequate diameter; or the 'antiparallel' approach where a wrist artery is

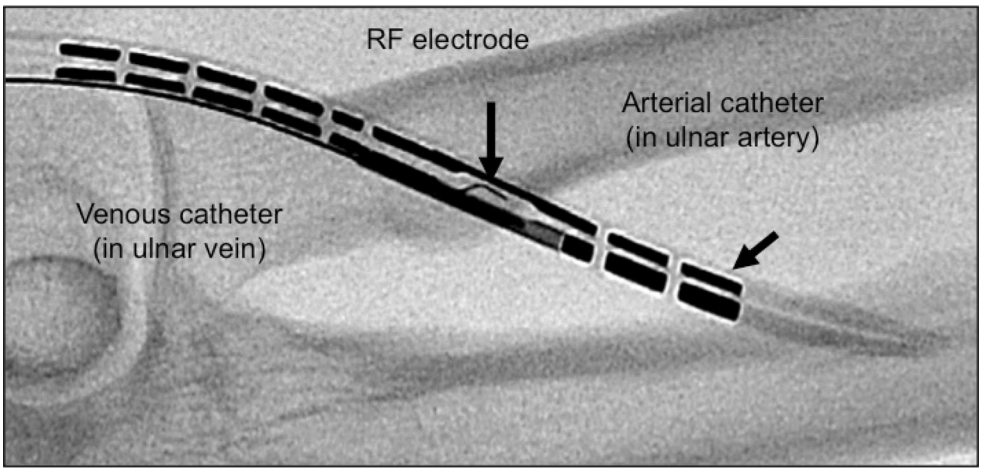

Fig. 2 Fluoroscopic image of the 6 French EverlinQ endoAVF catheters aligned in the ulnar artery and vein at the target site prior to RF energy release and endoAVF creation. Both catheters have been positioned from upper arm access and the wires removed

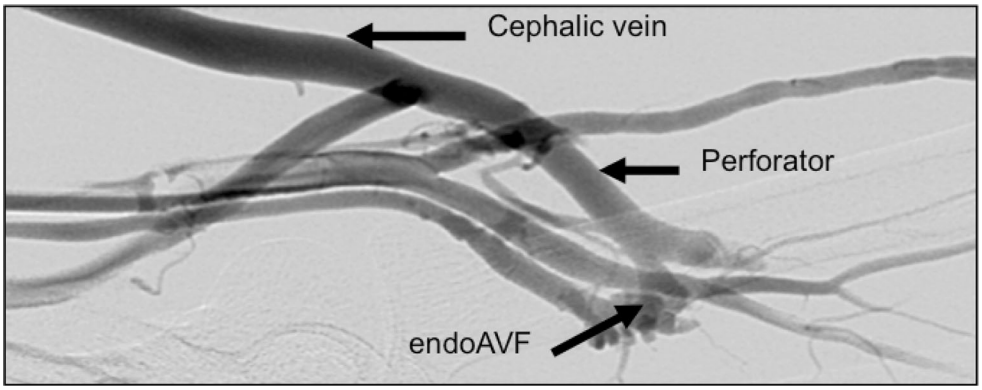

Fig. 3 Arteriogram from injection in brachial artery access sheath taken immediately post-endoAVF creation with the EverlinQ device. The level of the AVF can clearly be seen between the ulnar artery and vein with arterialized flow in the brachial and cephalic veins

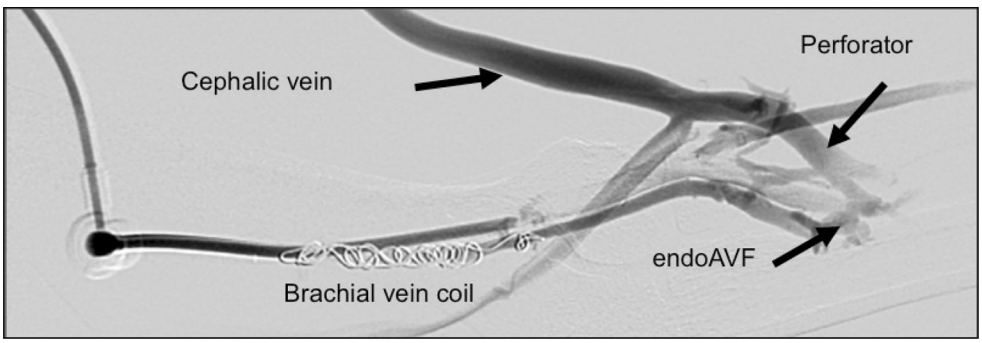

Fig. 4 Arteriogram taken following coil embolisation of the brachial vein during the same procedure. Note that flow is now predominantly into the superficial cephalic vein via the perforator

accessed and a brachial vein from above is accessed thereby utilizing the bi-directional properties of the system and simplifying arterial hemostasis (Fig. 5). All procedures are carried out with full heparin anticoagulation and anti-spasmodic medication as required.

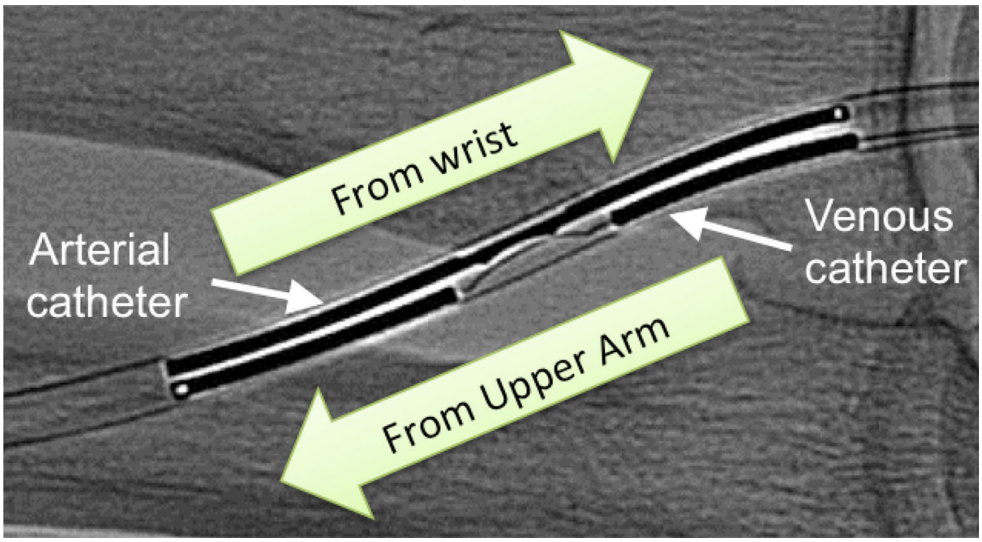

Fig. 5 Fluoroscopic image demonstrating the 'antiparallel' approach of the EverlinQ 4 French system. The arterial catheter is positioned at the target zone from access in the ulnar artery and the venous catheter from above via the brachial vein. Also note the new configuration of the venous RF electrode in the 'saddle-shaped' arterial catheter backstop

The Ellipsys endoAVF system (Avenu Medical, San Juan Capistrano, CA, USA) is a single-catheter venous access system to create an endoAVF between the adjacent proximal radial artery and perforating vein. The perforating vein drains directly into the superficial veins.

The Ellipsys endoAVF is created with an ultrasound guided, single, 6 French tissue fusion catheter from an access into the cubital or brachial vein. The catheter is designed to create a side-to-side anastomosis using tissue fusion to weld and cut an elliptical anastomosis between artery and vein (Figs. 6, 7). Tissue fusion requires both heat and pressure to be applied simultaneously at the site of tissue fusion. The triple helix of collagen Ia at the boundary layer between the artery and vein is unwound during heating. The unwound triple helix fibrils in the respective artery and vein entangle each other when under pressure creating a molecular bond along the entire circumference of the anastomosis. The intact anastomosis is confirmed by imaging showing fistula flow, without separation between artery and vein, pseudoaneurysm, hemorrhage, or hematoma (Figs. 8, 9).

The Ellipsys endoAVF procedure is performed with local or regional anesthesia and conscious sedation as required under ultrasound guidance. The patient is positioned with arm abducted to allow comfortable access for operator and ultrasound machine. Retrograde venous access is obtained at the cubital or brachial vein. The access needle is advanced through the vein (with ultrasound guidance) to reach the point of contact between the perforating vein and proximal radial artery. The radial artery is entered and a radial artery sheath is placed over a wire. Through the sheath the catheter is positioned between the artery and vein with the catheter open. The sheath is retracted into the vein. The artery and vein walls are captured in the device and closed. The device is activated in 10 s cycles. The processor notifies the user when the jaws of the device are completely closed, indicating that the anastomosis has been created. The device is removed from the sheath and Doppler ultrasound exam is performed to evaluate for flow volume in the brachial artery and spams in the perforating vein. Spasm or brachial artery flow volume < 500 ml/min are immediately treated with balloon dilation under ultrasound guidance, typically with a 5 mm balloon [14]. Upon completion of the procedure the sheath is removed and hemostasis is achieved with light manual pressure.

Patient Selection

The majority of the criteria in terms of patient selection to date have been under the auspices of clinical trials, and these criteria are likely to evolve with continued experience and technological advancement. In principle, all candidates eligible for a surgical AVF are also potential candidates for endoAVF with caveats being placed on (1) the presence of a perforator vein (Fig. 1) and (2) Minimal 2 mm diameter access and target vessels to maintain consistency as used in both the EverlinQ and Ellipsys series [10–14]. These criteria are readily and rapidly assessed by screening Doppler/Ultrasound examinations.

Pre-dialysis and dialysis patients are suitable candidates alike. Those with the previous failed surgical AVF are not excluded and are likely suitable for endoAVF creation as the target anatomical site is distinct from the previous surgical AVF location, which is likely to have been at the wrist or above the elbow, rather than the proximal forearm.

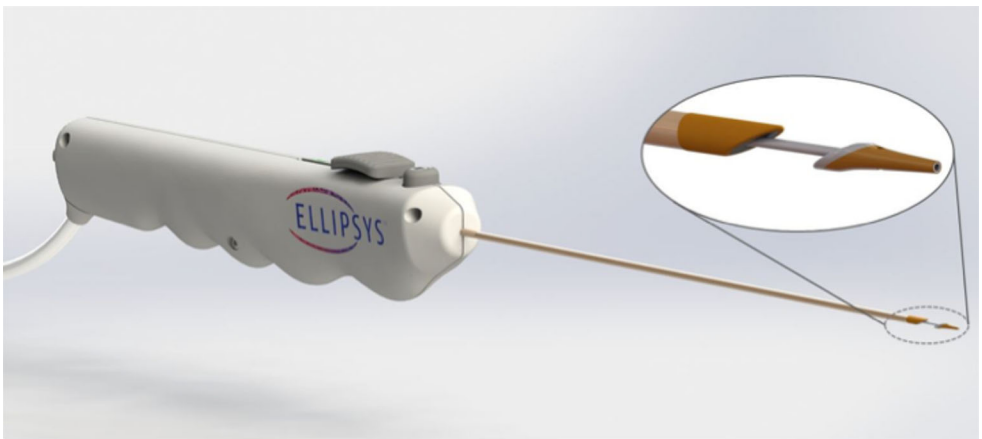

Fig. 6 Ellipsys catheter is 6 French, that operates over an 0.014" wire, through a radial artery sheath which is positioned via the venous access under ultrasound control. This illustration shows the working end or the jaws of the catheter in the open position. The catheter is opened and closed with the thumb switch on top of the handle

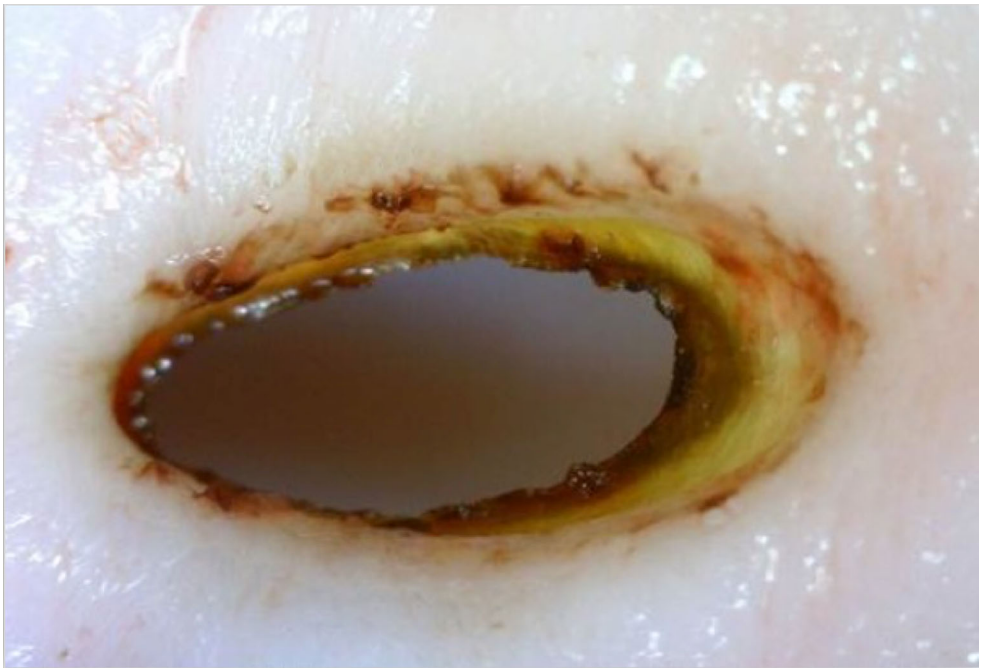

Fig. 7 Gross specimen demonstrates the artery side of the elliptical tissue-fused anastomosis created with the Ellipsys device

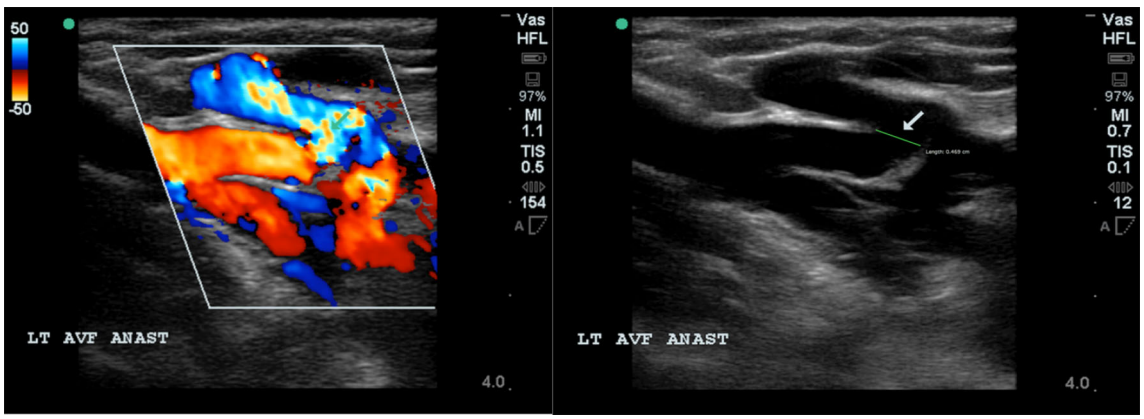

Fig. 8 Ultrasound images of an Ellipys endoAVF anastomosis (line) showing the close connection of artery to vein

Conversely, future surgical AVF creation is possible should an endoAVF fail to mature or lose patency. Therefore, the endoAVF should be viewed as a minimally invasive alternative to a surgical fistula, which does not preclude subsequent surgical AVF creation.

In general, a thrombosed ipsilateral cephalic and basilic vein would be a contraindication for consideration of endoAVF creation.

Outcomes of EndoAVF

Ulnar artery-to-ulnar vein fistula created with the EverlinQ system (TVA Medical, Austin Texas, USA) have been reported in a feasibility trial of 33 patients, a multicenter trial in 60 patients, and a single-center experience in 8 patients [10, 12, 13]. In all three studies, there has been high technical success of 97–100% in creating fistulas. Contrast injection is only required for an initial arteriogram and venogram and then a completion fistulogram. Therefore, large contrast volumes are not needed and can be as low as 15 ml.

The multicenter trial had 87% of fistulas mature at 90 days, the mean time to two-needle dialysis for dialysis-dependent patients was 112 days, and the 12-month cumulative patency was 84% (Table 2). Mean brachial artery flow increased from 83 ml/min at baseline to 918 ml/min at 3 months ($p < 0.001$). Twelve-month primary and cumulative patency was 69 and 84%, respectively, and exceeded rates from published large meta-analysis of surgical data of 60 and 71%, respectively [19].

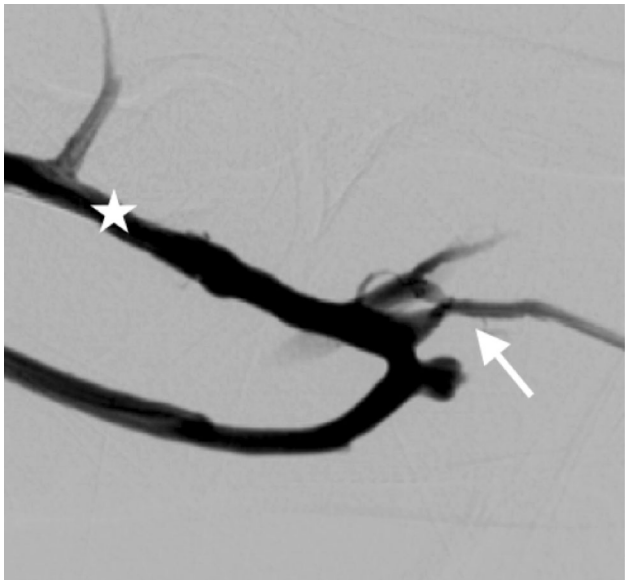

Fig. 9 Fistulogram demonstrating the fused Ellipsys anastomosis (white arrow) between the radial artery and the perforating vein. The perforating vein fills the cephalic vein (white star). The basilic vein is filling beneath and parallel to the cephalic vein. There is no filling of the deep brachial veins in this patient

There have been low rates of secondary procedures reported at 0.46 per patient per year compared to 3.6 for surgical series (Table 3) [6, 12]. During the feasibility trial, it was recognized that embolizing one of the brachial veins was desirable for most cases and this procedure was subsequently included in the index procedure [10]. In the multicenter trial, secondary procedures included 5 basilic vein transpositions, 5 coil embolisations of a tributary vein, 3 endoAVF ligations, and 2 angioplasties.

In the multicenter trial, there were 8 adverse events in 5 of 60 patients [12]. These events were primarily related to anterograde access to the mid brachial artery during the trial and included closure device embolization ($n = 2$), arterial dissection ($n = 1$), pseudoaneurysm ($n = 2$), steal syndrome ($n = 1$), and brachial artery thrombosis ($n = 2$).

Proximal radial artery to perforating vein fistulae using the Ellipsys device has been reported in three studies: a prospective feasibility study of 26 patients, a prospective, multicenter trial of 107 patients, and a retrospective, single-center case series of 34 patients [11, 14, 15]. The technical success was reported from 88 to 97%, with procedure times from 18.4 to 24 min using ultrasound guidance. In the multicenter trial, two-needle dialysis on was achieved in 88% of patients on dialysis at a mean of 114.3 ± 66.2 days [14]. The 12-month cumulative and functional patency in the same trial was 87 and 92%, respectively.

In the two reports by Hull et al., secondary maturation procedures were routinely performed on nearly all patients. In the larger multicenter trial, an average of two procedures per patient was required for maturation and included balloon dilation in 72%, brachial vein embolization in 32%, cubital vein ligation or embolization in 31%, and surgical transposition in 26% (Table 3). The procedures were required to increase and direct flow into single-target vein for dialysis to create an access similar to a surgical fistula for cannulation. In the European study, the rate of maturation procedures has been reduced considerably by leaving fistulas in a multi-outflow state and using novel

Table 2 Data summary

Author year	Device	Patients	Technical success (%)	Maturation 90 day (%)	Time 2-needle	Patency 12 months
Rajan (2015)	EverLinQ	33	97			NA
Lok (2017)	EverLinQ	60	98	87	112	84%
Radosa (2017)	EverLinQ	8	100			
Hull (2017)	Ellipsys	26	88			NA
Hull (2018)	Ellipsys	107	95	86	114	87%
Mallios (2018)	Ellipsys	34	97	97	35	NA

Table 3 Secondary maturation procedures. In brackets: % Patient with procedures performed in addition to anastomosis creation for maturation or flow direction

	EverlinQ [12] Lok et al.	Ellipsys [14] Hull et al.
Patients	60	107
Transposition	5(8)	28 (26)
Brachial vein embolization	5 (8)[a]	34 (32)
Cubital vein ligation	0	33 (31)
PTA	2 (3)	77 (72)

[a]100% of patients in this series had brachial vein embolization during the index procedure. The five cases here represent additional secondary embolizations

cannulation techniques [15]. Two hematomas were reported as serious adverse events in the multicenter trial [14].

EndoAVF and Dialysis Cannulation

The EndoAVFs with flow through the perforating vein create multi-outflow fistulas with flow in the cephalic and basilic veins of the upper arm and occasionally retrograde flow in forearm veins as noted in the original surgical description of the perforating vein fistula [18]. In the multicentre trial of Ellipsys endoAVF, flow was directed into a single outflow vein to mimic surgical fistulas making cannulation of the fistula familiar to staff at community dialysis centres [14]. The disadvantage of this approach was that it required additional procedures including balloon dilation, embolization, ligation, and transposition in all patients.

In the multi-outflow fistula, varying degrees of dominance are seen between the arterialized cephalic and basilic veins making each endoAVF almost unique, and this potentially serves to broaden the cannulation territory and thereby potentially shifting the paradigm for needling technique and approach. The increased useable length of fistula also serves to limit the complications of repetitive single-site cannulation. There are varying degrees of visual prominence of endoAVF and they are not particularly aneurysmal (Fig. 10) as seen with a single conduit of a surgical fistula with an end-side anastomosis, and this may pose a needling challenge initially. In the authors' experience, education at dialysis centres focussing on the understanding of the anatomy of endoAVFs has facilitated successful and sustained needling.

In summary, there is a growing body of evidence that supports endoAVF as a durable minimally invasive alternative to surgery without seemingly preventing future traditional upper limb AV access surgery, if this is required. Trends toward high rates of successful creation, patency, and usability are being observed that are comparable to and even exceed that of surgical series. Re-intervention rates differ between currently available devices but are, in general, lower than what has been observed for decades with surgically created fistulas. Low procedural complication rates are observed and what is, perhaps, most striking is the relative lack of reports of Steal syndrome in endoAVF. This in part may be due to the fact that endoAVFs are not typically high flow in nature and similar low rates of steal have been reported in surgical forearm AVF [20].

Future Direction and Controversies

The economic implications of endoAVFs can be viewed from several perspectives. The cost of care and reimbursement are not the same thing and vary widely from country to country. Yang et al. compared AVF post-creation procedures and their associated Medicare reimbursement in patients with surgical fistulas to patients with endoAVF. In this study, they extracted a 5% random sample from the US Medicare database to determine post-creation procedures and costs for surgical fistulas, and compared this to comparable information for the everlinQ device from the NEAT study [12, 19]. They estimated the average first year cost per patient-year associated with post-creation procedures was $11,240 lower for endoAVF than surgical AVF [21].

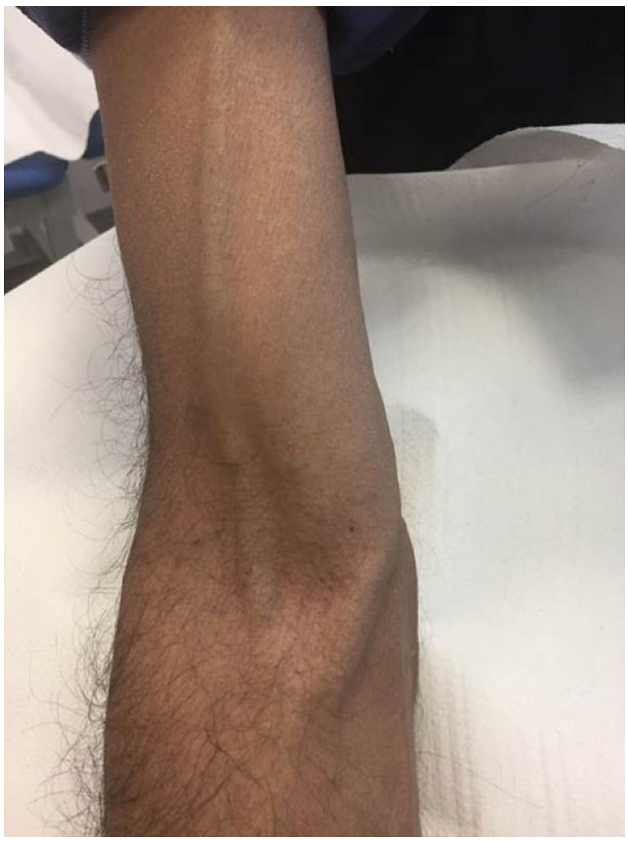

Fig. 10 Image of an endoAVF 6-week post-creation in the right arm using the EverlinQ device. Note dilatation of both cephalic and basilic veins from shared flow

There are several features of the endoAVF that are likely to add value to hemodialysis care. These minimally invasive procedures can be performed as day-case procedures or in outpatient vascular facilities, so that they do not require anesthesia or the use of the operating theatre. EndoAVF procedures have been performed successfully by all three of the specialities involved in care of the dialysis patients: interventional radiologists, surgeons, and interventional nephrologists [14].

One of the perceived limitations of the currently available data on endoAVF cohorts has been the mean age of patients who were included. FLEX was 51 years, NEAT

59 years, TRAD 45 years, and PIVOTAL was 56 [10–12, 14]. For example, this is lower than the average age of patients who commence haemodialysis in the UK of 67 years (www.renalreg.org/reports/2014-seventeenth-annual-report). Therefore, the question remains: "Are the endoAVF results reproducible in an older 'real-world' population?" Another real-world consideration is: "Are the trial results reproducible in centres, which are not AV access focussed as in the reported trials"?

To date, there are very few reports of endoAVF patients requiring secondary surgical intervention, but their complex anatomy akin to a post-traumatic AVF could potentially make them challenging to ligate or modify should this be required (either surgically or with embolization).

Conclusion

Despite these unanswered questions and controversies, the data available so far present endoAVF as the most encouraging and exciting development in AV access in 50 years. EndoAVF has the potential to provide an extended lifeline requiring much lower maintenance and morbidity than the traditional AV access in end-stage renal failure patients, but the effect of the endoAVF on current vascular access paradigms will depend on the continued success and development of this technology. Local expertise will probably determine who will be the main operators in endoAVF creation, but a multidisciplinary approach is mandatory in providing access patients with the best care possible and this approach should remain the gold standard.

Compliance with Ethical Standards

Conflict of interest Robert G Jones: Speaker/Consultancy for TVA. Robert A Morgan: Speaker for TVA, Penumbra, and Medtronic.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study. Additional informed consent was obtained from all individual participants for whom identifying information is included in this article: Does not apply.

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