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Midterm results of percutaneous arteriovenous fistula creation with the Ellipsys Vascular Access System, technical recommendations, and an algorithm for maintenance

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ABSTRACT

Objective: The aim of this study was to report our midterm results of percutaneous arteriovenous fistula (pAVF) creation using the Ellipsys (Avenu Medical, San Juan Capistrano, Calif) device and to present technical recommendations and our algorithm of pAVF maintenance.

Methods: A single-center comprehensive database of all consecutive predialysis and end-stage renal disease patients who had a pAVF creation with the Ellipsys device was reviewed retrospectively. Study end points included technical success, maturation, functional patency, and required interventions.

Results: Between May 2017 and July 2019, there were 234 patients (mean age, 64 years; 148 male [63%]) who had a pAVF created. Technical success was achieved in 232 individuals (99%), and average duration of the procedure was 15 minutes (7-35 minutes). Average follow-up was 252 days (range, 83-696 days). The 1-year primary, primary assisted, and secondary patency rates were 54%, 85%, and 96%, respectively. Average pAVF flow was 923 mL/min (range, 425-1440 mL/min). There were no significant adverse events related to the procedure. Only three patients (1%) required a later conversion of the pAVF anastomosis to a surgical fistula. Twenty-four (10%) patients required superficialization of deep outflow veins because of difficult cannulation. Average maturation time was 4 weeks (range, 1-12 weeks). Fourteen patients (6%) had early (<2 weeks after creation) cannulation of the pAVF.

Conclusions: The Ellipsys pAVF device allows the rapid and safe creation of a reliable autogenous access. Rates of technical success, patency, and maturation were excellent. For patients unsuited for a distal radiocephalic arteriovenous fistula, it should be considered the next preferred access option. (*J Vasc Surg* 2020;■:1-10.)

Keywords: Percutaneous arteriovenous fistula; pAVF; AVF; Ellipsys; EndoAVF; Hemodialysis

The Ellipsys (Avenu Medical, San Juan Capistrano, Calif) Vascular Access System creates a percutaneous arteriovenous fistula (pAVF) at the proximal forearm between the proximal radial artery (PRA) and the perforating vein of the elbow (PVE). Thermal energy and pressure allow the creation of permanent anastomosis through tissue fusion of the artery and vein walls.¹ The pAVF is an appropriate option when a radiocephalic arteriovenous fistula (AVF) at the wrist is not feasible or unlikely

to mature. The Ellipsys pAVF technique creates an AVF similar to the one described by Drs Gracz, Konner, and Jennings,^{2,3} taking advantage of the proximity of these larger proximal vessels in the cubital fossa while avoiding the risks associated with brachial artery inflow and the common issues with sclerotic forearm superficial veins or atherosclerotic arterial inflow at the wrist. The percutaneous approach and the simplicity of the technique make it an attractive alternative to surgical fistulas, with

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excellent functional patency results and a minimally invasive procedure.^{4,5}

We have previously described our initial experience with excellent technical success and patency rates, incorporating immediate balloon maturation with the primary procedure and avoidance of side branch ligations, creating moderate-flow and low-pressure pAVFs.⁵ Since that report, we have further refined the technique of creation and standardized the monitoring protocol as well as the interventions needed in cases of delayed maturation. In this paper, we report our midterm pAVF results and describe our updated techniques of Ellipsys pAVF creation along with a review of the access maintenance protocol.

METHODS

A retrospective review of our vascular access prospective database was performed for all consecutive patients who underwent a pAVF creation with the Ellipsys Vascular Access System between May 2017 and July 2019.

In addition to physical examination, each patient had duplex ultrasound vessel mapping by the operating surgeon. Patients with vessels at the wrist adequate for a surgical AVF that was expected to mature promptly had a radiocephalic AVF. An Ellipsys pAVF was the second choice when anatomic criteria were met. These included a PRA inner diameter >2 mm, a PVE diameter >2 mm, and a distance between these vessels <1.5 mm. Follow-up examination was 4 to 7 days and then at 4 weeks if maturation could be predicted by physical examination and ultrasound findings, including flow volume >500 mL/min. Patients with lower flows or other evidence predicting delayed maturation were seen again sooner or scheduled for an interventional procedure. Study end points included immediate technical success, maturation, functional patency, complications, and required interventions.

Primary, primary assisted, and secondary patency and maturation rates were evaluated following international society recommendations.^{6,7} An immediate balloon angioplasty of the anastomosis at the time of pAVF creation was considered part of the index procedure; therefore, only subsequent interventions were considered for calculating primary patency. Data were also examined for technical success, procedural or later pAVF-related complications, access flow rates, and need for conversion to surgical AVFs or outflow superficialization.

MedCalc software (Ostend, Belgium) was used for Kaplan-Meier survival analysis of patency rates. This study was approved by the Institutional Review Board (Comité d'Évaluation des Protocoles et d'Aide à la Recherche [Protocol Evaluation and Research Assistance Committee]) and is in accordance with the Declaration of Helsinki. Individual informed consent was obtained from all patients.

Technique update

Creation. Our technique for creation of an Ellipsys pAVF is available online and has been modified slightly

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center, retrospective cohort study
- **Key Findings:** There were 232 patients who had Ellipsys percutaneous arteriovenous fistulas created, with an average follow-up of 252 days. Technical success was 99%; average procedure time was 15 minutes. Primary, primary assisted, and secondary patency rates at 1 year were 54%, 85%, and 96%, respectively. There were no procedure-related adverse events.
- **Take Home Message:** The Ellipsys percutaneous arteriovenous fistula device allows the rapid and safe creation of a reliable autogenous access. Rates of technical success, patency, and maturation were excellent. For patients unsuited for a distal arteriovenous fistula, it should be considered the next preferred access option.

in comparison to our initial publication; however, the device function and tissue fusion remain unchanged.^{5,8} A direct puncture of the median cephalic (or less commonly, median cubital) vein with the micropuncture needle (Cook, Bloomington, Ind) under ultrasound guidance is performed as previously described. In our current approach, however, we advance the needle down the PVE directly without using a guidewire, ensuring that the echogenic needle tip is visualized at all times. This maneuver is accomplished under ultrasound guidance with the probe in a transverse orientation and allows successful needle passage through even more tortuous perforating veins, helping to avoid guidewire contact with the vein wall that may induce vessel spasm. The operator holds the probe with one hand and advances the needle with the opposite hand, a step-by-step repeating process, advancing the ultrasound probe 1 or 2 mm and then advancing the needle 1 or 2 mm, making sure that the echogenic needle tip stays at the center of the vein. This sequenced process is important in avoiding a vein wall puncture with resulting hematoma and contact with the vein wall that will cause spasm. For less experienced operators, when the ultrasound view of the needle tip is lost, changing to the longitudinal ultrasound view helps to relocate the exact position of the needle. When the needle tip is adjacent to the artery, the same small-motion progressive repositioning of the ultrasound probe followed by identifying the tip of the needle is continued until the needle tip can be seen at the center of the radial artery accompanied by a tactile sensation of going through the resistance of the artery wall felt by the operator.⁸ Low-pressure pulsatile flow is normally seen through the needle but may be absent, particularly if the puncture is prolonged, possibly resulting in clot within the needle, inhibiting pulsatile flow.

When the operator is confident that the needle is in the right position, the 0.021-inch wire of a 6F radial artery sheath (6F Slender; Terumo Interventional Systems, Somerset, NJ) should advance easily as seen in the longitudinal ultrasound view, reaching the distal radial artery at the wrist. The sheath is then positioned fully in the radial artery over the wire, and 50 units/kg of heparin is administered intravenously. The creation of the pAVF with Ellipsys as previously described (available online)⁵ is performed, followed by immediate angioplasty of the anastomosis with a 5- × 20-mm monorail balloon (Boston Scientific, Marlborough, Mass). A 4-mm or 6-mm balloon may be chosen less commonly, depending on the size of the artery.

In cases of a small PRA (<2 mm in diameter) or when difficulty is encountered with the needle crossing into the artery, resulting in a hematoma and poor visualization, angioplasty of the first few centimeters of the PRA approached from the wrist with a 3- × 40-mm or 3- × 60-mm balloon, ensuring that the balloon tip extends into the brachial artery, may be used to establish or to restore the appropriate size and visibility of the PRA. The crossing puncture can then be reliably completed. If this technique is to be employed as a salvage technique in case of initial failure with hematoma or spasm hindering clear visualization, the Ellipsys crossing needle should be left in place within the PVE if it is already at the lower part of the vein and adjacent to the artery.

If low flow is detected after creation of the pAVF, immediate angioplasty of the PRA with a 4- × 40-mm balloon through radial artery access from the wrist may be necessary for prompt maturation. Low flow may be identified by brachial artery flow <200 mL/min, absence of a thrill, or duplex ultrasound demonstrating low diastolic flow. This is especially important for patients who may have a small atherosclerotic PRA or when the proximal artery may be compressed as a result of angioplasty of the pAVF anastomosis. In addition, individual patients may benefit who have social issues or other reasons for which follow-up may be difficult. This immediate inflow augmentation rapidly hastens maturation for patients in urgent need of dialysis and without another vascular access available, allowing cannulation in selected patients soon after pAVF creation. On occasion, a "kissing balloon" technique can be performed, with one balloon inserted through the proximal venous sheath and one balloon placed through the distal radial artery sheath (Fig 1).

Maturation procedures. In some patients, secondary procedures are required to improve or to accelerate maturation. The most common problems requiring treatment in Ellipsys pAVFs are stenoses of the PVE at the anastomosis and a preanastomotic narrowing of the PRA that may appear as compression from the angioplasty performed during the anastomosis. In more

rare occasions, seen in patients who have an established pAVF, an anastomotic plug, most likely thrombus or intimal hyperplasia, may occlude the inflow. Fortunately, none of these patients have occlusion of the PVE past the small plug because of the venous flow coming in from the multiple small collateral venous tributaries.

All procedures are performed exclusively under ultrasound guidance, avoiding fluoroscopy and administration of contrast material. Most interventions are completed through distal radial artery access. On occasion, a second sheath is inserted through the proximal pAVF venous outflow for simultaneous access (radial and pAVF outflow access). The two alternatives are reviewed.

Distal radial artery access only. A standard 5F sheath is placed in the distal radial artery and a J-configured hydrophilic guidewire is introduced, ensuring that the J is oriented toward the anastomosis while it is being inserted into the sheath (Fig 2, A). In patients with a patent anastomosis and a relatively straight PVE, the wire will invariably cross into the pAVF and then into the cephalic or basilic vein. A 6- × 40-mm compliant balloon is then used to dilate the anastomosis and PVE, maintaining the distal part of the balloon in the artery. The compliance of the balloon will allow a tapering of the balloon toward the PVE and avoid overdilation of the artery. The balloon is then removed; flow is evaluated clinically (strength of thrill), and ultrasound flow is measured in the brachial artery proximal to the anastomosis. If the result is not satisfactory and the preanastomotic PRA appears narrowed with limited inflow, a 4- × 40-mm balloon can be used as previously mentioned (Fig 1, C), resulting in a dramatic improvement of the flow in most patients.

Double access (distal radial and proximal pAVF outflow). This technique (Fig 2, B) is recommended for patients with complete occlusion of the anastomosis or when anatomic configuration indicates that cannulation through the distal radial artery sheath will be technically challenging. A puncture of the pAVF outflow is performed exactly as for the pAVF creation procedure, and following the same initial steps, the micropuncture needle is guided through the PVE into the PRA. When a complete occlusion of the anastomosis is noted with ultrasound imaging in most patients, a small plug is noted but without thrombus in the PVE. In these cases, the needle traverses the anastomosis easily with little or no resistance, and there is a clear tactile difference compared with going through a vessel (vein or artery) wall. Crossing into the artery is usually easier as it has been previously dilated. Once it is in the artery, the 6F Slender sheath is introduced fully into the artery. The distal radial artery is then cannulated with a 5F sheath, and a 0.035-inch hydrophilic wire is advanced into the proximal 6F sheath (the wire will pass easily into the proximal sheath as it occupies

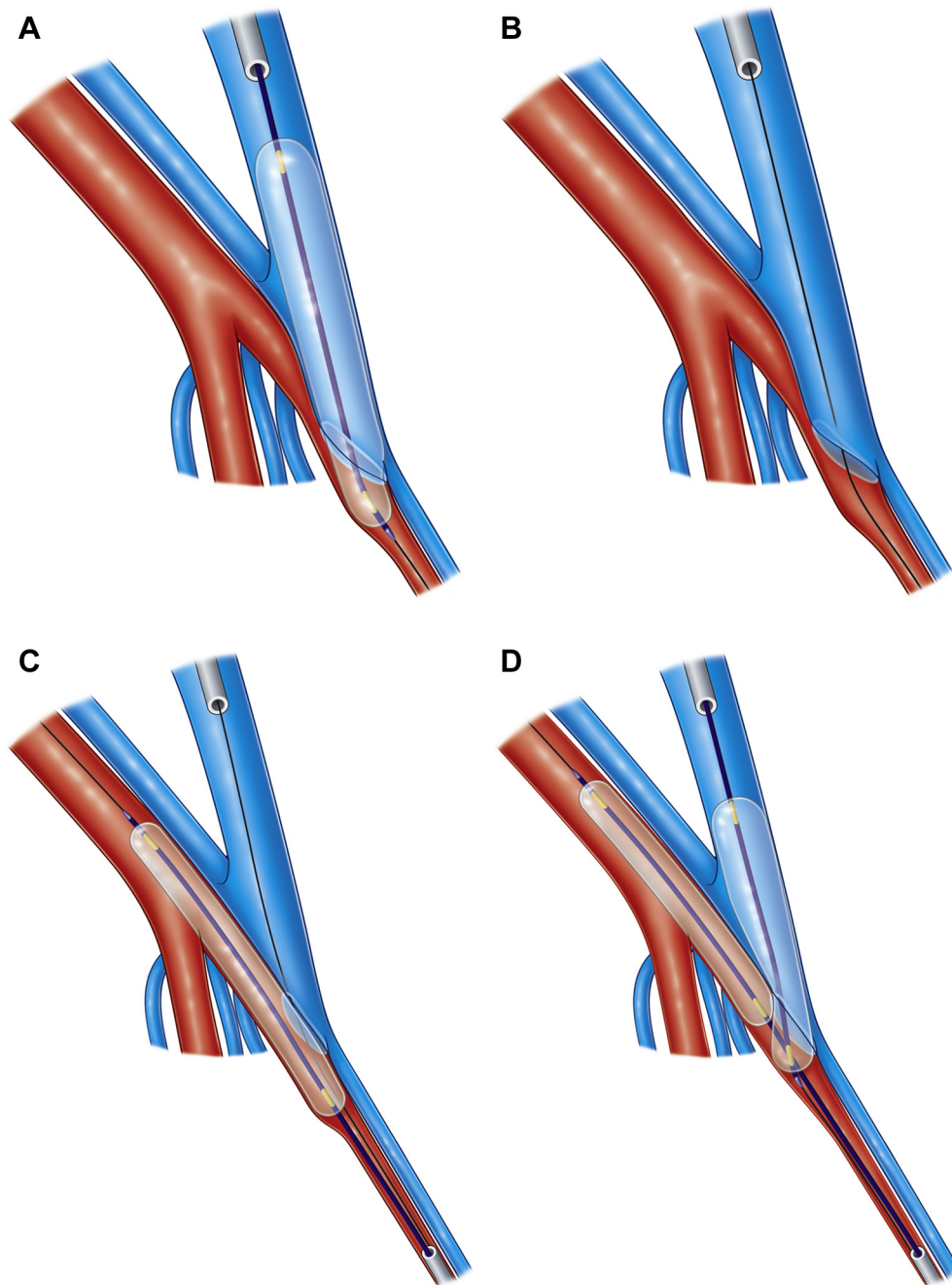


Fig 1. **A**, Balloon dilation of the anastomosis and deep communicating vein. Note that the 6- × 40-mm compliant balloon allows tapering of the balloon from the artery to the vein, avoiding overdilation of the artery wall. **B**, In some patients, the preanastomotic radial artery may be compressed from the previously described dilation, and this may lead to reduced inflow. **C**, When needed for this phenomenon (see Fig 3), the preanastomotic radial artery can be dilated with a 4- × 40-mm compliant balloon. **D**, Kissing balloon technique can be applied in patients for whom all of these steps are not sufficient to provide enough flow through the fistula.

the entire radial artery lumen in the mid forearm) until it hits the external valve in the proximal sheath. The 6 F sheath is then removed, and the 0.035-inch wire is then identified outside the skin at the pAVF puncture location (establishing through-and-through access); the wire is then carefully retracted into the cephalic vein

and readvanced within the vein toward the shoulder to have a safe wire purchase to complete the angioplasty procedure following the same steps for balloon angioplasty of the PVE and PRA as described in the previous section. Our algorithm for dysfunctional pAVF is illustrated in Fig 3.

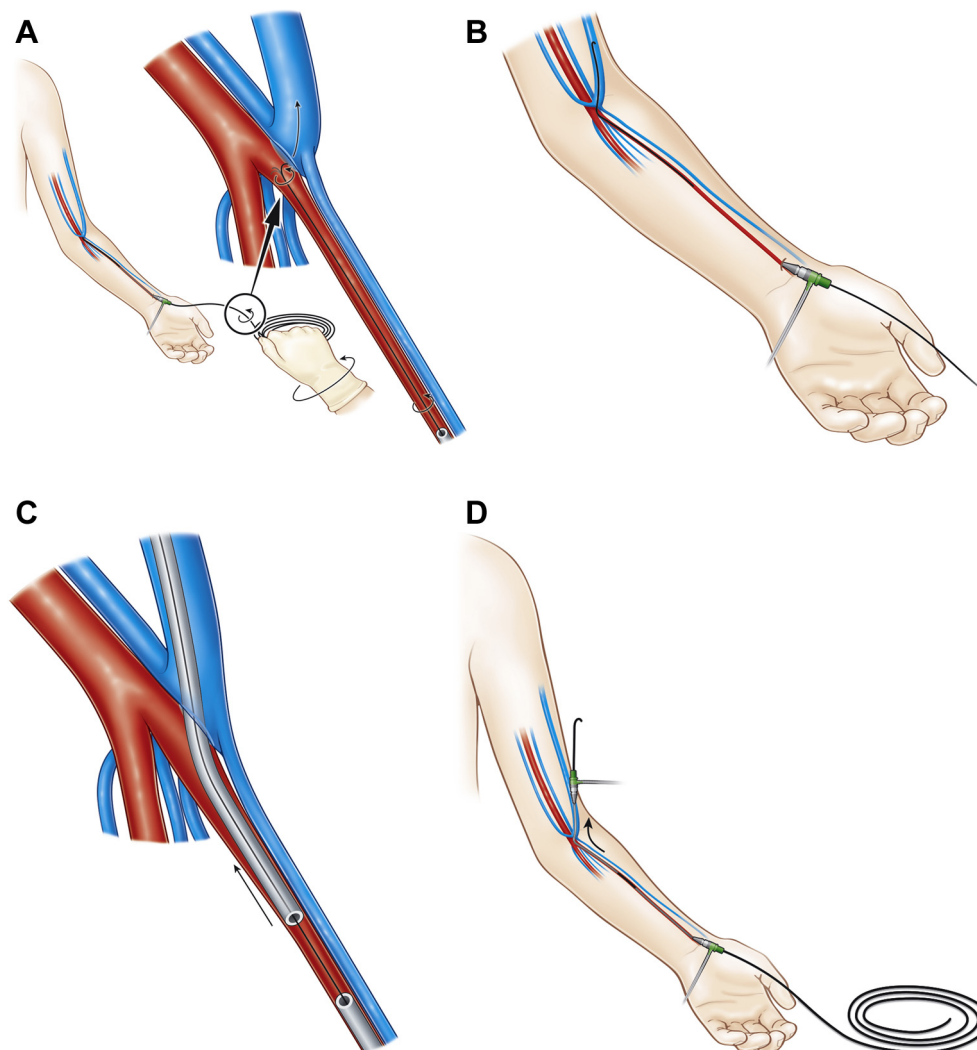


Fig 2. **A**, Most procedures can be performed through distal radial artery access only. Appropriate orientation of the J wire when it is being introduced through the sheath is enough to get the wire in the fistula under ultrasound guidance. **B**, After successful passage of the wire into the fistula and placement in the targeted vein for assisting maturation. The cephalic vein is illustrated here. **C**, Double puncture technique. When the anastomosis is occluded or anatomy is such that catheterizing the fistula is anticipated to be challenging, a sheath can be brought in the proximal radial artery (PRA) exactly as is being done for the creation procedure. This sheath is then easily catheterized with the wire coming up from the distal radial artery sheath. **D**, The wire will be advanced until it hits the valve of the sheath or completely exits. Removal of the sheath will provide a through-and-through access.

RESULTS

Between May 2017 and July 2019, there were 234 patients who had a pAVF created. Mean age was 64 years (25-92 years), and 148 were male (63%); 140 patients (55%) were diabetic, and 88 were obese or overweight (35%).

Technical success was achieved in 232 patients (99%), and average duration of the procedure was 15 minutes (range, 7-35 minutes). Average follow-up was 302 days (range, 83-873 days). There were 137 patients (54%) who were receiving dialysis, and their tunneled catheters were successfully removed after dialysis was initiated through the pAVF. At 1 year, primary, primary assisted,

and secondary patency rates were 54%, 85%, and 96%, respectively. Kaplan-Meier survival analysis of patency rates can be seen in Fig 4. The most frequent intervention required (94 patients [35%]) was angioplasty of the anastomosis and perforator vein performed with distal radial artery access and a 6- × 40-mm balloon. In the most recent patients, this angioplasty was often completed with a dilation of the preanastomotic PRA with a 4- × 40-mm balloon. Only two patients (<1%) required angioplasty of the cannulation segments, whereas none of the patients in this series developed a proximal draining vein stenosis, such as the cephalic arch or central

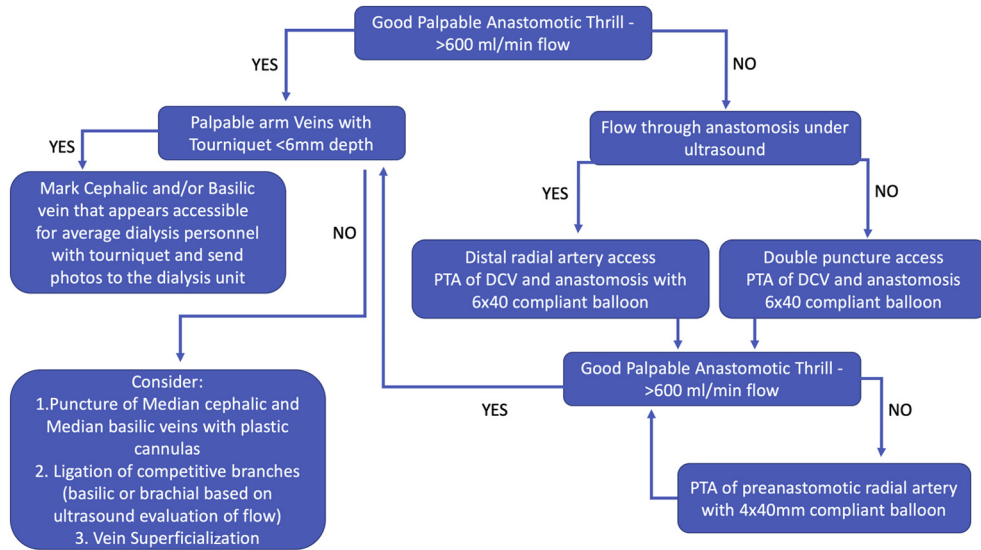


Fig 3. Algorithm of percutaneous arteriovenous fistula (pAVF) maintenance. DCV, Deep communicating vein; PTA, percutaneous transluminal angioplasty.

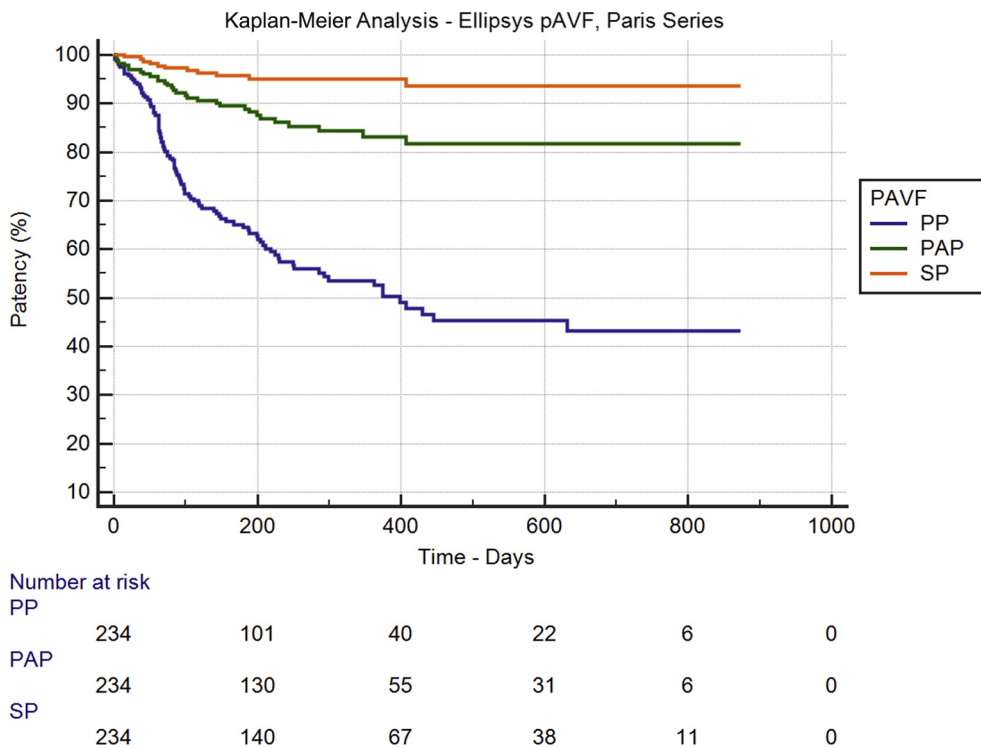


Fig 4. Kaplan-Meier analysis for patency rates. pAVF, Percutaneous arteriovenous fistula; PAP, primary assisted patency; PP, primary patency; SP, secondary patency.

veins. Similarly, none of these patients required an extensive declotting procedure, and none of the patients required interventions for aneurysms or other degenerative problems. A double access procedure (see earlier) was used for patients who presented with complete occlusion of the anastomosis with an anastomotic plug on

the ultrasound image but no clot extending into the PVE or draining veins.

The average pAVF flow (latest follow-up for every patient), measured in the proximal brachial artery, was 923 mL/min (range, 425-1440 mL/min). There was only one intervention for flow reduction in a patient with

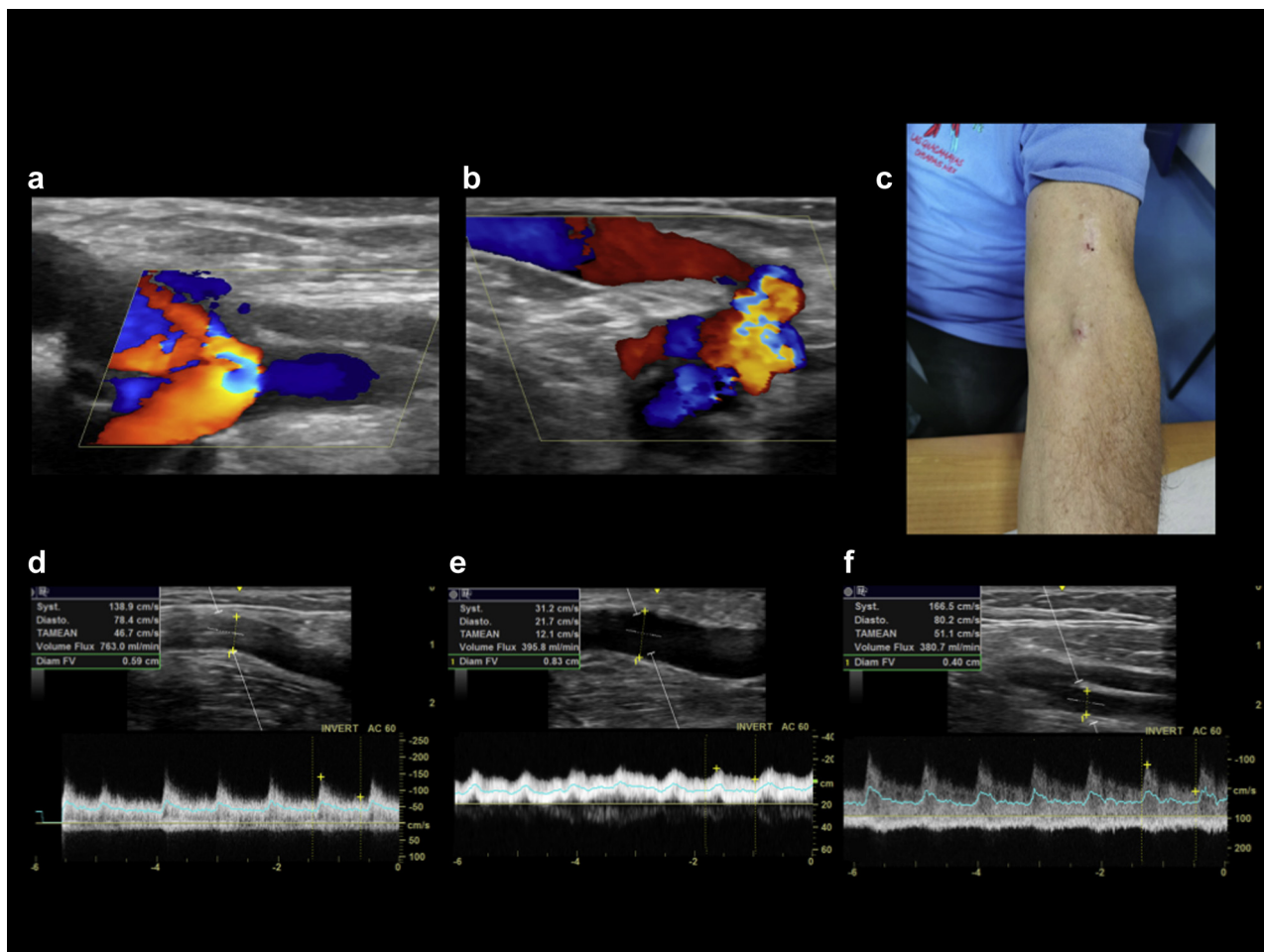


Fig 5. Illustration of patient who has been on dialysis for 1 year without puncture problems and excellent quality of dialysis. **a**, Anastomosis. **b**, Outflow divided between superficial and deep venous system. **c**, Patient's arm with puncture sites showing no signs of degeneration or complication. **d**, Flow measurement in brachial artery shows overall flow 763 mL/min. **e**, Flow measurement in the well-developed cephalic vein of 395 mL/min. **f**, Flow measured in the brachial vein, 380 mL/min. This flow division allows a lower pressure and lower velocities in the cephalic vein, whereas inflow through the anastomosis is adequate for dialysis. During sessions, negative pressures are applied by the arterial needle that is aspirating blood, and therefore the flow in the cephalic vein would be higher compared with these measurements.

arm swelling due to previously placed subclavian vein stent occlusion. This patient had a distal radiocephalic AVF in the past that was thrombosed, resulting in dilated brachial and radial arteries, and had ipsilateral hemiplegia from previous stroke. The flow was reduced from 1400 mL/min to 600 mL/min with banding of the preanastomotic PRA, and the cephalic vein was superficialized during the same procedure. The pAVF was subsequently used without other problems or need for interventions and with improvement of swelling. No patients developed access-related hand ischemia.

No significant adverse events related to the procedures were recorded. None of the patients had local or systemic complications, and only three patients (1%) required a later conversion of the anastomosis to a surgical fistula. Two of these three patients had occlusion of

the anastomosis that could not be recanalized endovascularly (the radial artery distal to the anastomosis was occluded and double access could not be established). One patient had a conversion to a surgical AVF because of rupture of the perforator as a result of an angioplasty procedure for assisted maturation and a subsequent pseudoaneurysm that was painful but without any neurologic compromise. Each of these three patients had successful conversion to a surgical fistula at the level of the PRA with the PVE or the proximal cephalic vein of the forearm without further consequences or need for other interventions.

Twenty-four (11%) patients required superficialization for deep veins and difficult cannulation. Half of these patients had a basilic vein transposition and half had a surgical lipectomy for a deep cephalic vein. Fifty-five

patients (20%) had cannulation at the elbow crease with plastic cannulas of the median cephalic or median basilic veins. Average maturation time by clinical or ultrasound criteria was 4 weeks and was similar for predialysis and current dialysis patients (range, 1-12 weeks). Successful cannulation was established in <2 weeks in 24 patients (10%). In nine of these patients (4%), ultrasound-guided puncture with plastic cannulas allowed removal of an infected catheter while avoiding placement of a new tunneled catheter.

DISCUSSION

An autologous AVF provides the best option for hemodialysis access compared with catheters and grafts. However, primary failure rates for surgical distal AVFs as high as 23% and 2-year secondary patency rates as low as 64% indicate that a significant problem remains in providing vascular access, with clear need for improvement.⁹ Whereas these disappointing numbers do not necessarily reflect the result of more experienced centers, the challenging nature of vascular access surgery combined with increased prevalence of diabetes, obesity, and vascular disease suggests that an easier and more reproducible technique is required for improved results and patient care.¹⁰⁻¹²

The 2-year Ellipsys pivotal trial results were recently published by Beathard et al.^{4,13} The authors independently obtained data from each program's electronic health record system completed at 2 years after the procedure to calculate outcomes and cumulative patency. For the 105 patients, a physiologically mature AVF was achieved in 98%, and a clinically functional elbow AVF was established in 95%. Cumulative patency was 97.2% at 2 years.

Yan Wee et al¹⁴ completed the first systematic review and meta-analysis regarding efficacy and safety of endovascular AVF creation, reporting seven studies totaling 300 patients, four for the WavelinQ system (former EverlinQ by TVA Medical, Becton Dickinson, Franklin Lakes, NJ) and three for Ellipsys. The authors concluded that both systems appear to be effective and safe; nonetheless, given the lack of a head-to-head analysis, superiority to a surgically created access could not be established. Interestingly, data for both systems are reported together despite the significant differences of the two systems in terms of anatomic location and mechanism of creation of the arteriovenous communication. In a subset analysis, however, we noted that all studies of the WavelinQ mention need for coil embolization of the brachial vein and 8.6% procedure-related complications, in contrast to Ellipsys, for which need for coil embolization was exceptional and procedure-related complication was 2.5%. Of note, most complications for Ellipsys appeared to be related to the first publication of Hull et al¹ rather than to the pivotal trial or our initial results series, in which no complication was observed.

Berland et al¹⁵ published the most recent study for WavelinQ and the only one using the 4F system. Thirty-two patients were operated on by four independent operators in a hospital in Latin America. Technical success was reported at 100%, although in one patient (3%), a vein perforation and extravasation required placement of a stent graft over the AVF, and it is unclear whether this patient eventually developed a successful pAVF. Only 25 patients had 1-month follow-up completed, whereas only 22 patients had a full 6-month follow-up, making it difficult to draw conclusions. Nonetheless, the authors reported 78% successful two-needle cannulation at 3 months for 27 patients.

Stoumpos et al¹⁶ from the United Kingdom in a large and contemporary study concluded that surgical AVF success rates have not improved over time, with only 55.3% of AVFs being used at the end of a mean 11.8-month period and a primary failure rate of 29%. Clearly, this problem calls for solutions, and although vessel status and diameter, patient comorbidities, use of locally applied drugs, and technical or anesthesiology considerations have been implicated or tested with variable results,¹⁷⁻²² none have established a dramatic answer. All these variables have been shown to have some predictive value or promise toward establishing prolonged functional patency, but creating a reliable and durable autogenous access that is successfully replicated in most centers remains a challenge.

Patients older than 75 years who can tolerate surgery are better served with pre-emptive AVF creation or conversion of a tunneled catheter to an AVF when life expectancy is >4 months, according to a recent publication.²³ Creating a pAVF is minimally invasive, and our results indicate a low risk of complications that suggests this technology may be particularly beneficial in older patients. Importantly, PRA inflow and the creation of a small anastomosis with moderate pAVF flow lower the risk of vascular access steal syndrome and high-flow cardiac issues that are much more common in patients with brachial artery inflow AVFs.^{24,25}

Creating an AVF as distal as possible in the nondominant arm to preserve veins more proximally for the future has been the standard of care for many years and was recently reiterated in the European vascular access guidelines.⁷ However, following this recommendation as a rule without taking into consideration potential maturation problems in patients with inadequate inflow or outflow vessels, significant comorbidities, and poor forearm skin and soft tissue condition for cannulation loses sight of the overarching goal of prompt catheter removal.^{26,27} In our practice, we tend to choose the best AVF location based on the patient's anatomy and health status that will lead to the access with the fewest interventions and fastest possible maturation. A radiocephalic AVF remains our preferred access when physical and ultrasound findings suggest a successful AVF and

prompt maturation. In our reported series, 54% of patients were already on dialysis with a tunneled catheter and the creation of a pAVF did not significantly prolong the time to catheter removal, whereas maturation time was similar for both predialysis and current dialysis patients. Arm side dominance is taken into consideration in patients who have similar anatomy and likelihood for successful AVF creation on both sides. Existence of an ipsilateral catheter is not a contraindication to creation of a pAVF, and this has recently been validated by Kim et al,²⁸ showing no effect on maturation rates and early failure of AVFs in patients with tunneled catheters on the same side as the access.²⁹

Need for repeated interventions either for maturation problems or for access maintenance remains a major problem for AVF patients, with significant cost and quality of life implications.³⁰ Our results demonstrate that pAVFs have less need for reinterventions through the outflow draining veins and cannulation sites, whereas maturation rates were excellent. Avoidance of ligation of vein tributaries at the lower level of the PVE (that is normally done during the creation of a surgical PRA-AVF) allows the maintenance of venous flow in case of occlusion of the anastomosis and permits a simple sharp needle recanalization of the anastomosis with salvage of a patent pAVF using only a simple balloon dilation.³¹ The moderate-flow Ellipsys pAVF established with the PRA and the shared venous drainage provide a low-pressure pAVF that has adequate inflow for dialysis with lower turbulence and pressure in the outflow veins (Fig 5). These qualities seem to be similar to the “gold standard” distal surgical radiocephalic AVF (radial artery inflow and multiple vein outflow through the PVE and cephalic and basilic systems).

Maturation problems and failed AVFs explain the continued high use of grafts, especially in certain centers of the United States and in Europe.³²⁻³⁵ Although it is reasonable to suggest that a well-functioning graft is better than a dysfunctional AVF, in our opinion, a problematic AVF is often the result of poor initial site selection for the new access, such as using small or diseased vessels to create a distal wrist fistula that is destined to fail. Both physical and ultrasound evaluations by the operating surgeon are important elements for success. Using the PRA as inflow site and PVE as outflow can be the solution for the group of patients for whom preoperative mapping indicates poor venous or arterial anatomy in the distal forearm with a high likelihood for failure or failure to mature at the wrist. A pAVF at this location offers a greater likelihood of success in such patients while avoiding the risks of brachial artery inflow and grafts.^{3,5,36,37}

Two of us (W.C.J., A.M.) have previously described our experience of banding of high-flow AVF in patients with a successful kidney transplant to maintain the AVF. In many countries, access ligation is suggested 1 year after kidney transplantation, although no solid

scientific evidence supports this practice. Gkotsis et al³⁸ found that access ligation after kidney transplantation has minimal systemic benefits and needs to be reserved for patients with access-related issues or complications. Our experience with the pAVF created with Ellipsys indicates a high safety profile with low risk for high flow or steal syndrome and a much more acceptable aesthetic result, which makes it more likely for patients to be willing to maintain the fistula after kidney transplantation.

CONCLUSIONS

The Ellipsys pAVF Vascular Access System allows the rapid and safe creation of a reliable autogenous access. Rates of technical success, patency, and maturation are excellent. For patients unsuited for a distal AVF, it should be considered the next preferred access option. Despite the larger numbers and longer follow-up of pAVF patients, this study has the limitations associated with all single-center, retrospective reports. Large-scale randomized studies are needed to confirm our findings.

AUTHOR CONTRIBUTIONS

Conception and design: AM

Analysis and interpretation: AM

Data collection: AM, PB, GF, HH, HF, MA, AC, RB, GH, BB, WJ

Writing the article: AM

Critical revision of the article: AM, PB, GF, HH, HF, MA, AC, RB, GH, BB, WJ

Final approval of the article: AM, PB, GF, HH, HF, MA, AC, RB, GH, BB, WJ

Statistical analysis: AM

Obtained funding: Not applicable

Overall responsibility: AM

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