Comparison of Outcomes of Percutaneous Arteriovenous Fistulae Creation by Ellipsys and WavelinQ Devices

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ABSTRACT

Purpose: The purpose of this study was to compare the clinical outcomes of Ellipsys with those of WavelinQ-4F percutaneous arteriovenous fistulae (pAVF) devices in a single center by a single operator.

Materials and Methods: A retrospective review was conducted in 100 patients who underwent pAVFs procedures (65 Ellipsys and 35 WavelinQ patients) and created between December 2017 and December 2019. A total of 69% were male and 37% were diabetic. Median age was 64.1 years (range: 28–86), and median body mass index was 27.2 (range: 15–45.1) kg/m^2. A procedure sequence algorithm was followed for selecting all vascular accesses created.

Results: Ellipsys outcomes were compared to WavelinQ outcomes. Technical success was 100% versus 97%, respectively, and median procedure times were 14 versus 63 minutes, respectively ($P < .001$), with 183 (1–487) versus 185 (0–760) days follow-up, respectively. Maturation at 4 weeks was 68.3% versus 54.3%, respectively, and median times to cannulation were 60 (1–164) versus 90 (1–180) days, respectively. Successful pAVF dialysis was established in 31 of 39 patients (79.5%) versus 14 of 24 patients (58%), respectively ($P = .071$), dialysis patients with access-related adverse events observed in 4 individuals (1 Ellipsys versus 3 WavelinQ). Six patients (5 versus 1) with matured outflow from previous AVFs underwent first-day cannulations. Interventions were performed in 27.7% (33 Ellipsys) and 26.5% (15 WavelinQ) patients, and the number of interventions per patient-years was 0.96 versus 0.46, respectively. pAVF failure was seen in 15.4% versus 37.1% patients, respectively ($P = .0137$). Secondary patency at 12 months was significantly higher among patients who had an Ellipsys procedure (82%) than among those who underwent the WavelinQ procedure (60%).

Conclusions: pAVFs were created with high technical success and low complications with both devices. Ellipsys pAVFs demonstrated significantly shorter procedure times without a need for radiation exposure and with superior secondary patency.

ABBREVIATIONS

DCV = deep communicating vein, pAVF = percutaneous arteriovenous fistulae, PRA = proximal radial artery, sAVF = surgically created arteriovenous fistulae

Early results with newly approved devices to create percutaneous arteriovenous fistulae (pAVF) suggest that they may offer improved outcomes compared to open surgical AFV (sAVF) access without compromising conventional surgical sites for future dialysis access creation ([1–6]). Two such devices have been certified by Conformité Européenne and approved by US Food and Drug Administration, the WavelinQ-4F system (Beckton Dickinson, Franklin Lakes,

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Table 1. Anatomic Criteria Used for AVF Creation

All access procedures

- Intact arterial system with the non-AVF-inflow forearm artery adequately supplying the palmar arch (modified Allen's test) with triphasic flow using ultrasound (pulse-wave)
- Unobstructed draining central venous system, intact superficial venous outflow vein (cephalic and/or basilic vein internal diameter >2 mm, using tourniquet)

WavelinQ

- Presence of deep communicating vein (DCV, perforating vein)
- Brachial artery diameter >2 mm, radial or ulnar artery diameter >2 mm at the anastomosis location and access site
- Radial and/or ulnar and/or brachial vein diameter >2 mm at the anastomosis location and access site
- The distance between the proximal radial/ulnar artery and vein (anastomosis site) <1 mm

Ellipsys

- Presence of deep communicating vein (DCV, perforating vein)
- DCV diameter >2 mm
- Proximal radial artery lumen diameter >2 mm at the anastomosis location
- The distance between the perforating vein and the proximal radial artery <1.5 mm

AVF = arteriovenous fistulae; DCV = deep communicating vein.

New Jersey) and the Ellipsys vascular access system (Avenu Medical, San Juan Capistrano, California). Both systems use the deep communicating vein (DCV/perforating vein) in the upper forearm and its relationship to the proximal radial or proximal ulnar arteries and veins. However, the devices differ significantly in technical design and pAVF creation technique (ie, Ellipsys uses thermal energy and ultrasonographic guidance, whereas WavelinQ-4F uses radiofrequency energy and fluoroscopy), as well as location of the pAVF anastomosis.

General consensus recommends creating an initial access at the wrist and then progressing proximally in the forearm and into the upper arm as additional access points are required (7–9). Proximal forearm sAVF such as the proximal radial artery (PRA)-AVF offers less risk of clinically relevant stealing of blood and should be the next alternative before proceeding to brachial AVFs. The concept of proximal forearm AVF is reproduced by the new pAVF procedures by leveraging the medial cubital venous anatomy to route AVF flow from the pAVF anastomosis superficially through the DCV into the cephalic and/or basilic veins in the arm. This paper reviews and reports outcomes of the 2 approved pAVF devices incorporated into a single-center, single-operator vascular access practice.

METHODS
Study Type
This was a retrospective review of deidentified, prospectively collected data at a single vascular access center. Between December 2017 and December 2019, all patients

undergoing the creation of a dialysis access were included in a database with the current study analysis focused on pAVF outcomes. This study complied with Ethics Committee and Institutional Review Board requirements and was conducted in accordance with the Declaration of Helsinki.

Inclusion and Exclusion Criteria
A standardized protocol was used in access planning for each patient based on evaluation of the patient's vascular anatomy. This included an assessment of the arterial system to evaluate peripheral pulses, differential blood pressure measurements, modified Allen tests, and ultrasonographic vessel mapping. Eligibility for pAVF creation required an intact arterial system with the non-AVF inflow artery adequately supplying the palmar arch. Vessel size requirements for pAVF eligibility were followed as recommended for each of the 2 devices according to the manufacturer's instructions for use (Table 1) (1–3). If the cephalic vein outflow was not adequate, a basilic or brachial vein transposition was anticipated.

Selection Protocol
The algorithm (Fig 1) used for the selection of location and procedure for access creation started distally and was divided into 4 zones. The first choice for access placement was a radial-cephalic sAVF at the wrist (zone 1), including a snuffbox-AVF. Ulnar-basilic sAVFs were also considered. The next consideration was proximal forearm radial and ulnar inflow AVF, starting with a pAVF option (zone 2). If anatomic criteria were met, a pAVF was created because an sAVF could still be an option after either a failed WavelinQ or Ellipsys procedure. If both WavelinQ and Ellipsys procedures were possible with an equal expectation of success, WavelinQ was used first as an Ellipsys pAVF could potentially be created even if a WavelinQ anastomosis failed due to its location, incorporating the radial or ulnar vein and adjacent artery, leaving the DCV undisturbed. The third choice in the access sequence plan was a proximal radial or ulnar or distal brachial sAVF using either the classic Gracz-sAVF technique (10,11) or a similar procedure (zone 3). Patients were evaluated for an upper arm sAVF with brachial artery inflow (zone 4) if forearm vascular anatomy was not suitable. An arteriovenous graft (AVG) was generally placed only when there was no opportunity for the creation of a successful autogenous access, although an individual approach was taken based on the patient's life plan. The presence of a dialysis catheter was not a critical influence in the decision for access site selection (12).

Although this analysis focused on pAVF outcomes, the algorithm used for the selection of a site and procedure resulted in 337 dialysis vascular access techniques (227 surgical and 100 percutaneous) created during the study period. These techniques included 143 distal radial-cephalic (49 of which were snuffbox-sAVFs), 100 pAVFs, 55 Gracz-sAVF, 3 brachial-cephalic, 22 brachial-basilic, 2 brachial-brachial sAVFs, and 12 AVGs (3.6%).
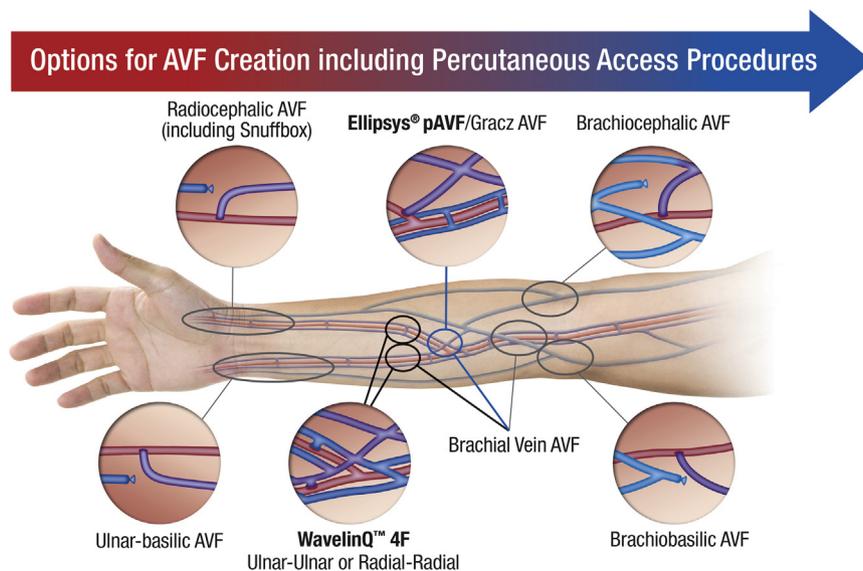
Figure 1. Sequence of access site and procedure selection.

Technique

The pAVF devices and procedures have been previously described (1–3,6,13) and use quite different concepts, technologies, imaging strategies, and techniques. Manufacturers' recommended patient eligibility criteria (1–3) were followed for each device (Table 1).

The WavelinQ-4F device is a 2-catheter system with the arterial catheter introduced through the artery (US approval was given for brachial artery only; brachial, radial, or ulnar artery insertion was approved in Europe) and a venous catheter (with an electrode) placed through the brachial, radial, or ulnar vein. Fluoroscopic guidance with contrast imaging is used to position and align the catheters while magnets hold the artery and vein together as a radiofrequency electrode incises a channel between proximal forearm vessels, resulting in AVF flow. Coil embolization of the brachial vein increases superficial pAVF flow through the DCV and completes the procedure.

The Ellipsys device is inserted over a single superficial venous guidewire, advanced through the DCV, and introduced through the vein wall into the PRA. The entire procedure is performed with duplex ultrasonographic guidance; no fluoroscopy or contrast is used. The device is advanced over the wire, capturing both arterial and venous walls and, when closed and activated, generates a secure anastomosis through thermal resistance and pressure. A balloon dilation of the anastomosis completes the procedure, removing any spasm and establishes outflow through the DCV to the superficial venous system.

All procedures were performed at the Vascular Access Center of a nonprofit teaching hospital. Anesthesia was administered by regional block in 96 patients. One WavelinQ patient had general and 3 Ellipsys had local anesthesia (patients' preferences). Heparin, 2000 units, was administered during creation with both devices. Prophylactic antibiotics were not used. During WavelinQ procedures, intra-arterial nitroglycerin was administered to reduce arterial spasm, and coiling of the outflow brachial vein was performed depending on the procedural completion venogram.

Demographics

Characteristics of the study groups are presented in Table 2. The total cohort included 69% males. Median age was 64.1 years of age (range: 28–86 years old), and 37% patients were diabetic. Body mass index was 27.2 (range: 15–45.1) kg/m^2. The WavelinQ group had higher proportion of males compared to Ellipsys. However, there were no significant differences between WavelinQ and Ellipsys patients in age, presence of diabetes, body mass index, chronic kidney disease status at the time of access creation, history of a previous ipsilateral AVF, or the percentage of patients with a central venous catheter.

Among the WavelinQ patients, 9 of 35 patients (25.7%) had previous ipsilateral access that had failed, including 2 AVGs and 2 Ellipsys pAVF. The Ellipsys group had 16 of 85 patients (24.6%) with previously failed ipsilateral access, including one 40-year-old Scribner-Shunt and 3 WavelinQ pAVFs.

Endpoints, Definitions, Follow-up

Primary endpoints were technical success, time to maturation, functional patency, and time to first clinical use. Technical success was determined by post-procedure examination using Doppler ultrasonography demonstrating a patent anastomosis and fistula flow in the DCV and outflow veins. Maturation was defined as a brachial artery blood flow of $\geq$500 mL/min with an AVF diameter $\geq$5 mm (15). Functional patency was the time from successful 2-needle cannulation of pAVF until its abandonment. Failure was defined as abandonment of the pAVF when salvage of

Table 2. Patient Characteristics by Percutaneous AVF Type

Variable	Overall n (%)	WavelinQ (n = 35) n (%)	Ellipsys (n = 65) n (%)	P Value*
Sex				.0809
Males	69 (69)	28 (80)	41 (63)	
Females	31 (31)	7 (20)	24 (37)	
Mean ± SD age, y	64.18 ± 14.18	65.01 ± 12.98	63.72 ± 14.86	.6664
Mean ± SD BMI, kg/m²	27.21 ± 6.70	25.81 ± 6.37	27.95 ± 6.80	.1284
Diabetes				.3734
Yes	37 (37)	15 (43)	22 (34)	
No	63 (63)	20 (57)	43 (66)	
CKD status				.9674
Apheresis	1 (1)	0 (0)	1 (2)	
Stage IV	9 (9)	3 (9)	6 (9)	
Stage V	36 (36)	12 (34)	24 (37)	
ESRD	54 (54)	20 (57)	34 (52)	
Previous ipsilateral AVF				.9037
Yes	25 (25)	9 (26)	16 (25)	
No	75 (75)	26 (74)	49 (75)	
Dialysis with a central catheter at time of index procedure				.5425
Yes	53 (53)	20 (57)	33 (51)	
No	47 (47)	15 (43)	32 (49)	

AVF = arteriovenous fistulae; BMI = body mass index; CKD = chronic kidney disease; ESRD = end-stage renal disease; SD = standard deviation.

*Fisher exact test was used for CKD status, whereas for all other categorical variables, chi-squared test of independence was used. Student t-test was used for age and BMI.

the occluded or dysfunctional pAVF (ie, keeping the endoanastomosis and pAVF outflow) was either technically impossible or the patient decided to convert to a sAVF/AVG. Standard definitions for patency and maturation were used (14,15). Primary patency was the time from creation to first intervention. Secondary patency was the time from creation to abandonment. Flow values were determined by the operator by measuring flow rate (Qa) in the distal brachial artery, using duplex ultrasonography postoperatively and at follow-up evaluations at 24–48 hours, week 4, and at 3, 6, 9, and 12 months. All venous outflow branches were evaluated at each follow-up visit by using ultrasonographic imaging to determine progress toward maturation.

Statistics

Exploratory analysis of all study variables was performed to obtain descriptive statistics. Frequencies and percentages were calculated for categorical variables, whereas median and ranges were calculated for continuous variables. Distribution of the data for continuous variables was tested for normality using the Shapiro-Wilk test and Kolmogorov-Smirnov test. Tests for normality indicated that the data

for continuous variables including age, procedure time, contrast, AVF blood flow, and follow-up days, and days until first use were not normally distributed, therefore, the Mann-Whitney U test was used to determine differences between 2 pAVF device groups for baseline patient characteristics and procedure-related variables. Association between categorical variables and the intervention groups were assessed by chi-squared test of independence or Fisher exact test, as appropriate. Life table analysis was used to obtain Kaplan-Meier plots and evaluate patency rates at different time points for each intervention group. Associations of primary and secondary patency with the intervention groups were examined by Cox proportional hazard models. Hazard ratios (HR) and 95% confidence intervals (95% CI) were reported. All statistical analyses were performed using SAS version 9.4 software (SAS Institute, Cary, North Carolina).

RESULTS

pAVFs were created in 100 patients (29.7% of all vascular access creation procedures during the study period). Overall technical success was 99%, 34 of 35 (97%) using the WavelinQ system and 65 of 65 (100%) using the Ellipsys system. Procedural details are shown in Table 3. The median time required to complete the procedure using the Ellipsys device (14 minutes) was significantly less (P < .001) than that with WavelinQ (63 minutes) device.

WavelinQ pAVFs were created using the PRA in 63% and the proximal ulnar artery in 31%. The arterial catheter placement site was radial (65.7%), ulnar (28.6%), and brachial (5.7%). Venous catheter placements were radial (57.1%), ulnar (11.4%), brachial (25.7%), and cephalic and basilic veins in 1 case each. The Ellipsys anastomoses were made with the PRA in 64 patients. One patient had a distal brachial anastomosis for brachial vein outflow and transposition. Primary coiling of a brachial vein was required in 74.3% of WavelinQ procedures and was not performed in 6 patients when brachial vein outflow was the intended target and was avoided in 2 patients with cephalic/basilic vein outflow due to the dominant contrast outflow through the superficial veins in the post-procedure venogram. A completion balloon angioplasty of each Ellipsys pAVF was an integral primary component of the procedure and was routinely performed using 4- × 20-mm balloon in 3 and 5- × 20-mm balloon in 62 patients.

The WavelinQ pAVFs outflow veins were either the cephalic (22.9%), basilic (25.7%), cephalic and basilic (31.4%), or brachial veins (20%). For Ellipsys pAVFs were the cephalic (21.5%), basilic (13.9%), cephalic and basilic (63.1%), or brachial veins (1.5%).

Four serious adverse events were observed in the total series, including 3 of 35 (8.5%) WavelinQ patients and 1 of 65 (1.5%) Ellipsys patients (P = .11). One WavelinQ patient had an unsuccessful anastomosis creation and experienced arterial bleeding from the brachial artery (access site), which was treated using a stent graft. A second WavelinQ patient

Table 3. Procedure Details by Percutaneous AVF Type

Variable	Overall n (%)	WavelinQ n (%)	Ellipsys n (%)	P Value[†]
Technical success				.3500
Yes	99 (99)	34 (97)	65 (100)	
No	1 (1)	1 (2.9)	0 (0)	
Anastomosis				<.0001
Proximal radial artery	86 (87)	22 (65)	64 (98)	
Proximal ulnar artery	11 (11)	11 (32)	0 (0)	
Brachial	2 (2)	1 (3)	1 (2)	
Outflow vein				.0012
Cephalic vein	22 (22)	8 (23)	14 (22)	
Basil vein	18 (18)	9 (26)	9 (14)	
Cephalic and basilic vein	52 (52)	11 (31)	41 (63)	
Brachial vein	8 (8)	7 (20)	1 (2)	
Procedure time, min*	18 (9-150)	63 (28-150)	14 (9-31)	<.0001
Contrast (n = 35), mL*	8 (2-22)	8 (2-22)	—	—
Ancillary procedure, primary embolization coil				<.0001
Yes	26 (26)	26 (74)	0 (0)	
No	74 (74)	9 (26)	65 (100)	
Primary angioplasty				
Yes	65 (65)	0 (0)	65 (65)	
No	35 (35)	35 (35)	0 (0)	
Follow-up, days*	186.5 (0-760)	188 (0-760)	183 (1-487)	.2980
AVF blood flow, mL/min *,‡				
Day 1 (n WavelinQ = 34; n Ellipsys = 65)	450 (85-1400)	450 (85-1300)	460 (150-1400)	.6240
Day 2 (n WavelinQ = 28; n Ellipsys = 57)	640 (180-1450)	640 (200-1450)	640 (180-1300)	.7646
Week 4 (n WavelinQ = 24; n Ellipsys = 47)	780 (150-2600)	775 (150-2600)	780 (290-1300)	.8267
Months 2-3 (n WavelinQ = 19; n Ellipsys = 35)	822.5 (280-1700)	840 (365-1700)	800 (280-1500)	.2142
Month 6 (n WavelinQ = 13; n Ellipsys = 22)	790 (70-1600)	1000 (480-1600)	750 (70-1000)	.1156
Access failure				.0137
Yes	23 (23)	13 (37)	10 (15)	
No	77 (77)	22 (63)	55 (85)	
Maturation at 4 weeks				.1709
Yes[§]	60 (63)	19 (54)	41 (68)	
No	35 (37)	16 (46)	19 (32)	
AVF use in dialysis patients				.0711
Yes	45 (71)	14 (58)	31 (79)	
No	18 (29)	10 (42)	8 (21)	
Days to 1st use* (n WavelinQ = 13; n Ellipsys = 31)	68 (1-180)	90 (1-180)	60 (1-164)	.3676

pAVF = percutaneous arteriovenous fistulae.
*For procedure time, time to first cannulation, contrast, follow-up days, and AVF blood flow, median (min, max) are reported as descriptive statistics.
[†]Chi-squared test of independence was used for failure, physiological maturation at 4 weeks, and AVF use in dialysis patients, whereas Fisher exact test was used for all categorical variables. Mann-Whitney *U* test was used for continuous variables.
[‡]AVF blood flow information was not available from all the study participants. Sample size (n) for procedure type is reported in parenthesis.
[§]Five patients had undergone a pAVF <4 weeks previously and were not included in the maturation analysis.

developed a 2.3-cm anastomotic pseudoaneurysm that was resected, and a Gracz-sAVF was constructed. A third WavelinQ patient experienced peripheral pulmonary migration of both primary and secondary 8-mm brachial vein coils and remained asymptomatic. One Ellipsys patient developed an anastomotic site hematoma, which required surgical revision 2 days later.

Follow-up

Median follow-up was 186.5 days (range: 0–760 days), 187 (range: 0–736) days for WavelinQ and 183 (1–487) days for Ellipsys. Access blood flow for WavelinQ and Ellipsys groups postprocedural and at 6 months had mean values of 450 versus 460 mL/min and 1,000 versus 750 mL/min, respectively. All access flow values for multiple time
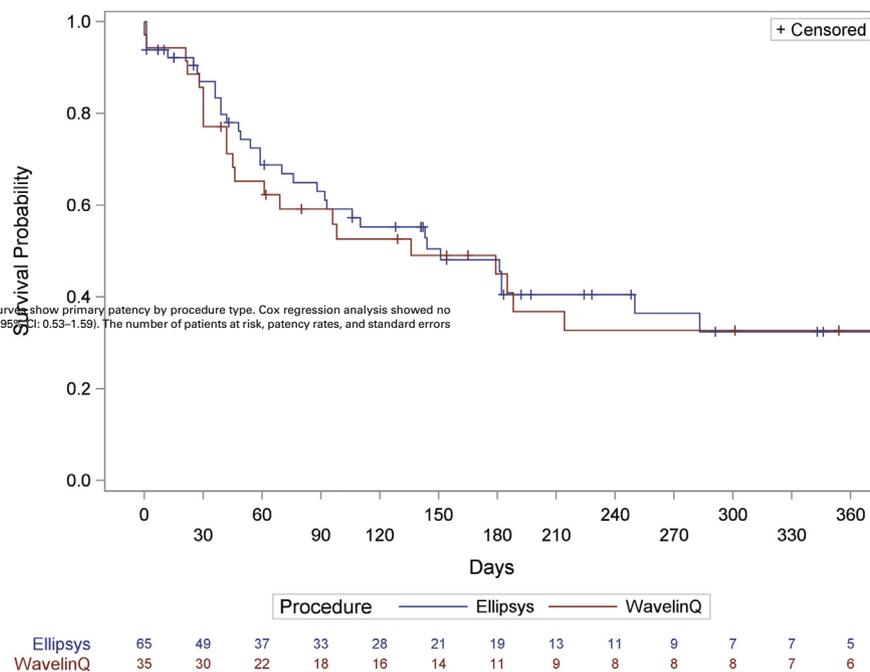
Figure 2. Kaplan-Meier vascular access patency curves show primary patency by procedure type. Cox regression analysis showed no significant differences in primary patency (HR: 0.92; 95% CI: 0.53–1.59). The number of patients at risk, patency rates, and standard errors are shown.

segments are shown in **Table 3**. None of these differences was statistically significant.

Maturation and suitability for cannulation was achieved in 54.3% and 68.3% by 4 weeks and in 71.4% and 83.3%, respectively, of WavelinQ and Ellipsys pAVFs by the end of the study period. A total of 32% of all patients with a pAVF created at chronic kidney disease stages IV and V had not required dialysis by the completion of the study. Among individuals receiving dialysis, pAVF provided access in 60.9% of WavelinQ and 79.5% of Ellipsys patients. The mean time from pAVF creation to first cannulation was 90 (1–180) days for WavelinQ and 60 (1–164) days for Ellipsys. Six patients (1 WavelinQ and 5 Ellipsys patients) underwent cannulations from the first postoperative day due to pre-matured veins after previous AVFs that had failed. Successful early cannulation (<30 days) was attempted in 2 additional Ellipsys pAVFs (days 7 and 25) to avoid a catheter placement.

Patency and Failure
Primary patency rates were 33% and 32%, respectively, and secondary patency was 60% and 82%, respectively, at 12 months for WavelinQ and for Ellipsys pAVFs. Patency rates are shown by Kaplan-Meier analysis in **Figures 2** and **3**. Results of Cox regression analysis showed no significant difference in primary patency (HR: 0.92; 95% CI: 0.53–1.59). However, significantly higher secondary patency was observed among patients who had an Ellipsys procedure (HR: 0.42; 95% CI: 0.19–0.97). Functional patency for WavelinQ was 85.7% and 100% for Ellipsys (P = non significant).

Within the WavelinQ group, access failure occurred in 37.1% of the patients during the study period, requiring a new percutaneous or surgical AV access. The distribution for new AVFs was distal radial-cephalic (n = 1), Ellipsys (n = 3), Gracz-sAVF (n = 5), brachial-basilic (n = 2), and brachial-brachial (n = 1). Transposition of either basilic (n = 4) or brachial (n = 4) vein was performed in 23.5% of WavelinQ cases within 8 weeks. Angioplasty (26.5% of patients) was successfully performed in 9 of 34 WavelinQ pAVFs for proximal juxta-anastomotic radial vein stenosis (n = 4), outflow vein stenosis (n = 4), central venous obstruction (n = 2), and was unsuccessful for proximal ulnar vein stenosis in 1 individual, resulting in conversion to a Gracz-sAVF. One WavelinQ pAVF was abandoned after basilic vein transposition because of a stenotic outflow lesion, and the patient declined interventions. Two patients required secondary coiling of a brachial vein. Of the 22 radial/radial pAVFs created, 8 (36.3%) failed to mature, and 9 (41%) failed, whereas of 11 ulnar/ulnar pAVFs, 2 (18%) failed to mature, and 3 (27.3%) failed.

Ellipsys patients experienced a 15.4% failure rate. Among these, 1 patient died (unrelated to the access), and 2 declined another surgery. The remaining patients had an AVF created including a Gracz-sAVF (n = 3) and brachial-basilic (n = 2), and 1 patient underwent a successful ipsilateral radial/radial WavelinQ procedure. Two patients within the Ellipsys group required basilic vein transposition and 1 a cephalic vein transposition. Four individuals had a successful ultrasonography-guided angioplasty due to a local plug at the anastomosis site, noted within 7 days after creation. Angioplasty was performed in 18 of 65 patients (27.7%) to
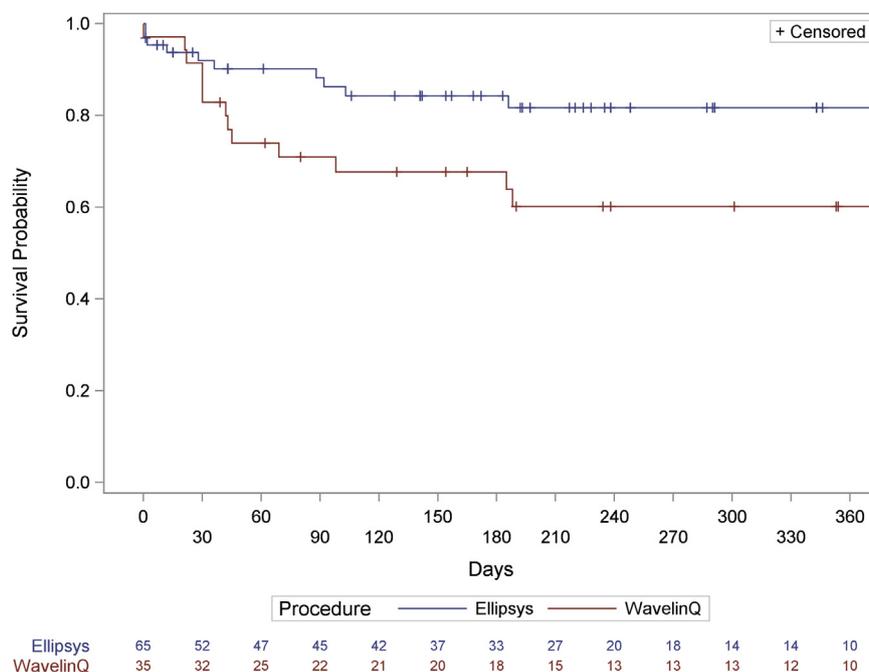
Figure 3. Kaplan-Meier vascular access patency curves show cumulative patency by procedure type. Higher cumulative patency was observed among patients who had an Ellipsys procedure than in the WavelinQ group (HR: 0.42; 95% CI: 0.19–0.97). The number of patients at risk, patency rates, and standard errors are shown.

treat 3 DCV local occlusions (ultrasound-guidance only), adjacent stenosis (n = 9), venous outflow stenoses (n = 5) and central venous stenosis (n = 1). Four patients needed secondary brachial vein coil occlusion/ligation and 1 banding of the median cubital vein during angioplasty to direct more flow to the cephalic vein. The number of interventions per patient-years was 0.96 for Ellipsys and 0.46 for WavelinQ pAVF.

DISCUSSION

Conventionally, the order of dialysis access preference includes the distal radial-cephalic fistula, a brachial-cephalic fistula, and a transposed brachial-basilic fistula, or for some, an AVG (7,9). The creation of an AVF based on the proximal radial and ulnar arteries is a valuable addition (10). Incorporating the pAVFs into access site planning adds 2 additional alternatives and conserves more proximal vessels.

The pAVF is anatomically comparable to a surgically created PRA-AVF, which has many advantages compared to a brachial artery inflow access, such as lower risk of blood stealing syndrome and arm edema, while avoiding the uncommon risk of ischemic monomelic neuropathy (10,16,17). The pAVF also offers the benefits of avoiding a surgical procedure with vessel dissection and manipulation, associated inflammation, and a sutured anastomosis, all of which can result in complications and may contribute to failure of AVF maturation (18). The site of the pAVF anastomosis in the distal cubital fossa and the absence of a surgical incision extends the cannulation zone and may present multiple outflow veins for use, including the medial cubital and cephalic veins. A total of 79% of all pAVFs in

this study resulted in a successful access, and these results are expected to improve with increasing procedural and interventional experience (19).

Although both devices can create a functional autogenous access, there are definite differences in techniques required for access creation, including the device technology, vessels involved, and outcomes. There is a "learning curve" for both devices (5–10 procedures/device). In addition, ultrasonography experience for evaluating vascular anatomy and skill in clinical techniques are key prior to performing pAVF-procedures.

Even though some patients had a prior access operation, it was possible to create 72% of all AVFs in the forearm with 143 distal radial-cephalic sAVFs and 100 pAVFs. A failed WavelinQ pAVF does not preclude the possibility of a subsequent successful use of the Ellipsys device, and a pAVF failure following either device did not preclude the ability to establish a subsequent access using an adjacent or more proximal vessel. All of the failed (and therefore abandoned) pAVFs occurred due to the localization of the occlusion or untreatable stenosis at the anastomosis or juxta-anastomotic outflow veins. Importantly, due to the location of the anastomosis, salvaging an occluded Ellipsys pAVF (as reported in 4 anastomotic and 3 DCV occlusions) using ultrasonography-guided angioplasty was easily performed because of its focal or limited occlusion, compared to occlusions of the juxta-anastomotic radial/ulnar veins in WavelinQ pAVFs.

Because of differences in practice patterns and/or limitations with resource use, it is likely that many practitioners who create pAVFs will be limited to 1 of the 2 devices. It is important to consider patient eligibility (potential procedural

feasibility). During preoperative evaluations of the patients, 69% of patients had anatomy suitable for a pAVF procedure (170 patients were screened); however, only 27% of patients evaluated were judged to be eligible for WavelinQ, and 65% were suitable for the Ellipsys procedure according to instructions for use. These percentages may vary. In a prior report which evaluated anatomical eligibility for possible Ellipsys pAVF creation based on the existence of an adequate DCV, 88% met the requirement (20). The WavelinQ NEAT (Novel Endovascular Access Trial) study reported 75% of eligible patients met the anatomic criteria for inclusion.[1] If both devices are available, then it is important to recognize that a patient not anatomically eligible for 1 device may be an acceptable candidate for the other.

Published pAVF investigations have been conducted in Europe, Canada, and other countries (1,2,4–6). The pivotal WavelinQ trial included 9 centers in Canada, Australia, and New Zealand. The pivotal Ellipsys trial was conducted in 5 centers in the United States and has been recently updated to include important 2-year "real world" follow-up studies (21). In this study, 95% of the patients developed a clinically functional pAVF with cumulative patency of 92.7% at 2 years. A second mid-term follow-up study of the Ellipsys device conducted in Europe included 232 patients and found a secondary patency of 96% with mean follow-up of 252 days (22). A WavelinQ report for the 4F device with 12 months of follow-up in 30 patients found secondary patency of 69.5%, and a longer-term follow-up study of the WavelinQ-4F device is pending (23,24).

As a single-center experience reflecting the practice of a single-access surgeon, significant selection bias may exist, although this was minimized by application of the vascular access procedure algorithm. In addition, the study has the recognized limitations of any retrospective analysis of nonrandomized data. This review was not designed as a comparison with a contemporary sAVF cohort as the surgical access procedures varied widely in location and complexity and are not equivalent options. Familiarity with pAVF is evolving, and access can be initially challenging for the unexperienced dialysis center. The addition of ultrasonography guidance (where available) for initial cannulations in selected cases may reduce the risk of cannulation-associated complications or failures.

This study reviews clinical experience with the 2 approved pAVF devices incorporated into a single-center vascular access plan based upon an individualized evaluation of each patient's vascular anatomy. Differences between the devices, patient eligibility, techniques, and outcomes with both pAVF systems are reviewed. Both of the devices had high technical success rates and adequate flow volumes. Cumulative patency at 12 months was higher among patients who had an Ellipsys procedure (82%) than among those in the WavelinQ group (60%). When a radiocephalic AVF at the wrist is not feasible, a pAVF offers an appropriate and logical strategy for establishing a safe and functional access.

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