Percutaneous Arteriovenous Fistula Creation with the WavelinQ 4-French EndoAVF System: A Single-Center Retrospective Analysis of 30 Patients

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ABSTRACT

Purpose: To retrospectively assess the safety and efficacy of percutaneous arteriovenous fistula (pAVF) creation with the WavelinQ 4-F EndoAVF System.

Materials and Methods: From February 2018 to June 2020, 30 pAVFs were created in 30 consecutive patients (men; age, 55.3 years ± 13.6). Of the 30 patients, 21 (70%) were already on hemodialysis using a central venous catheter. The primary outcome measures were technical success, complications, and cannulation rate. The secondary outcome measures included the number of secondary procedures needed for cannulation, maintenance time to cannulation, and pAVF survival.

Results: Technical success was 100%. The adverse event rate was 6.7% (2/30), including a pseudoaneurysm of the brachial artery that developed immediately after sheath removal and an aneurysm of the anastomosis 17 days after the procedure, which was treated with a covered stent placed in the arterial side. The mean follow-up was 547 days ± 315.7 (range, 14–1,071 days). The cannulation rate was 86.7% (26/30). The mean time to cannulation was 61.3 days ± 32.5 (range, 15–135 days). The mean follow-up after cannulation was 566.2 days ± 252.7 (range, 35–1,041 days). Four pAVFs were thrombosed after cannulation, with 2 of them successfully declotted. Sixteen interventions were needed to achieve cannulation after the index procedure in 15 patients (overall, 0.53 procedures/patient). Seven maintenance endovascular interventions (following cannulation) were performed during the follow-up period in 6 patients (overall, 0.27 procedures/patient, 0.17 procedures/patient-years). For the pAVFs that were cannulated, patency was 96% at 1 year, and 82% at 2 and 3 years, according to the Kaplan-Meier survival analysis.

Conclusions: This initial experience suggests that pAVF creation is safe and can be successfully performed with high maturation and long-term patency rates. Larger-scale prospective studies are needed to validate the results.

ABBREVIATIONS

AVF = arteriovenous fistula, CVC = central venous catheter, HD = hemodialysis, pAVF = percutaneous arteriovenous fistula, RF = radiofrequency, sAVF = surgical arteriovenous fistula, VA = vascular access

Percutaneous arteriovenous fistula (pAVF) is a newly introduced endovascular technique of anastomosis creation for patients with end-stage kidney disease in need of a vascular access (VA) for hemodialysis (HD). Two devices are currently available: the WavelinQ EndoAVF System (BD, Franklin Lakes, New Jersey) creates an anastomosis between the radial and ulnar vessels (artery and vein), whereas the Ellipsys Vascular Access System (Medtronic, Minneapolis, Minnesota) uses the relationship between the perforating vein and proximal radial artery. Although initial results suggest that pAVFs may offer comparable outcomes with surgical arteriovenous fistulae (sAVFs), evidence remains low (1–6).

The WavelinQ EndoAVF System has evolved from its original design available in 6-F catheters enabling access only from the brachial vessels to a thinner device of 4-F catheters allowing the ability of wrist vessel access.
offering versatility and additional options for the operator to create the anastomosis (7,8). However, data regarding the clinical use of the 4-F system are restricted to 3 published studies: (a) the Endovascular Access System Enhancements study (8), which was the first to explore the use of the 4-F system, (b) the study by Inston et al (1) who prospectively compared the system with the surgical radiocephalic fistulae, and (c) the study by Shahverdyan et al (2) who retrospectively compared the 2 endovascular systems. In all, 97 patients have been evaluated in these studies with the 4-F system.

The current analysis aimed to evaluate the safety and assess the effectiveness of the WavelinQ 4-F EndoAVF System, providing additional real world evidence regarding percutaneous arteriovenous fistula (AVF) creation.

MATERIALS AND METHODS

This was a single-center, single-arm, retrospective analysis assessing the safety and efficacy of pAVF creation with the WavelinQ 4-F EndoAVF System. As this was a retrospective analysis, no dedicated consent was needed other than consent for the procedures, and ethics committee approval was waived. All procedures performed were in accordance with the ethical standards of the local institutional research committee and with the 1964 Helsinki Declaration and its later amendments. Operators performing the procedure were interventional radiologists with 10 and 25 years of experience. The inclusion and exclusion criteria of the study are presented in Table 1, and patients’ baseline characteristics are shown in Table 2.

Device Characteristics

The WavelinQ EndoAVF System consists of two 4-F magnetic, rapid-exchange catheters over a 0.014-inch wire; a venous catheter, powered by an electrosurgical unit; and an arterial catheter. The venous catheter contains a radiofrequency (RF) electrode. As RF energy is delivered, the patient is grounded with a grounding pad. The arterial catheter contains a ceramic backstop for receiving the electrode from the venous catheter. Rotational indicators are present in each catheter to secure the accurate position of the catheters. Once catheters are correctly aligned, 60-Watt RF energy is delivered through the electrode for 0.7 seconds for cutting and/or coagulating tissue to create the anastomosis.

Screening, Procedural Characteristics, and Follow-up

Prior to the procedure, the patient was examined with ultrasound to evaluate if the anatomical criteria for vessel diameters were fulfilled, and the operator decide whether a radial (radial artery and vein, medial or lateral) or ulnar (ulnar artery and vein, medial or lateral) pAVF would be created and planned the procedure in terms of which vessels would be accessed. The key elements were the presence of the perforator vein, the identification of the deep vein feeding the perforator, and the superficial vessel to which the perforating vein drained, which was ideally the cephalic vein (Fig 1). Based on these criteria, access at the wrist level was the first choice. This was because the arteries at the level of the wrist were easier to compress at the end of the procedure compared with the brachial artery. Moreover, for the venous part of the procedure, wrist access allowed antegrade venography and traversal of valves with wire and catheter. Additionally, volume flow at the brachial artery was assessed, and Doppler measurements were taken on the ulnar and radial arteries.
at the level of the wrist to verify adequate flow to the hand. Finally, blood pressure measurements and physical examination were performed.

Procedural steps have been described in previous publications (1,8). In the current analysis, all procedures were performed under local anesthesia, which was administered following venous puncture to avoid compromising the venous lumen by mass effect from excessive volume of local anesthetic around the vessel. A crucial part of the procedure was catheter alignment prior to activation. Indicators on both catheters should ideally be square, ensuring that both catheters were perpendicular to the x-ray beam (Fig 2a–d). After activation, catheters were removed, and a fistulogram was performed from the arterial sheath (Fig 3). It was common for some contrast extravasation to be observed immediately after activation since the anastomosis created between the vessels occurred in the tissue space between the catheters, and the passageway could take several seconds to seal. The decision to coil embolize one of the brachial veins to assist the maturation of the superficial system during the index procedure depended on whether these vessels were opacified on the final angiogram. The postintervention volume flow at the level of the brachial artery was measured for future reference.

Follow-up included physical examination and ultrasound assessment by the same physicians performing the procedure. The first visit took place 1 week following the intervention to observe any periprocedural complications and to assess the anatomical and flow characteristics of the circuit. Then, a second follow-up was scheduled at 1 month to assess maturation. At that point, the volume flow of the brachial artery, the ulnar or radial artery before the anastomosis, and the brachial veins was evaluated. If “blood stealing” to the deep venous network of the arm occurred or in the case that some part of the outflow system was stenosed, intervention was recommended to solve the aforementioned issues. A third visit took place at 2 months, unless the pAVF was ready to be cannulated earlier. The criteria for a pAVF to be considered ready for cannulation were a flow volume of ≥500 mL/min in the brachial artery and a ≥5-mm diameter of the vein for cannulation. If the fistula was not yet matured, another follow-up visit took place as per a multidisciplinary meeting’s consensus decision. The initial cannulations were always performed in the dialysis clinic of our tertiary hospital by the superintendent dialysis nurse with 30 years of experience.

**Outcome Measures**

Technical success was defined as the creation of an anastomosis evident on the final angiogram. The adverse event rate was defined as per the Society of Interventional Radiology Clinical Practice Guidelines (9). The primary outcome measure of efficacy was cannulation rate, defined as the ability to perform at least 1 successful dialysis with the pAVF. The secondary outcome measures were the time to cannulation, defined as the time between the initial procedure and the time that the patient received a complete session of HD with 2 needles; the number of reinterventions needed for cannulation, defined as the interventions needed following the index procedure for the patient to perform at least 1 session of successful HD; the number of maintenance interventions, defined as the number of interventions needed for circuit maintenance following cannulation; and patency rate, defined as the time between initial cannulation and an event of thrombosis, surgical intervention, or abandonment of the VA.

### Table 2. Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number</th>
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<tbody>
<tr>
<td>Patients</td>
<td>30</td>
<td>100%</td>
</tr>
<tr>
<td>Male</td>
<td>30/30</td>
<td>100%</td>
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<tr>
<td>Age (y)</td>
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<tr>
<td>Hypertension</td>
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<tr>
<td>Diabetic</td>
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<tr>
<td>Smokers (current or former)</td>
<td>21/30</td>
<td>70%</td>
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<tr>
<td>Hyperlipidemia</td>
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<td>56.7%</td>
</tr>
<tr>
<td>On dialysis</td>
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<td>70%</td>
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<tr>
<td>Predialysis</td>
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<td>30%</td>
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<tr>
<td>Years on dialysis</td>
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<tr>
<td>Previous access on target arm</td>
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<tr>
<td>Access characteristics</td>
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<tr>
<td>Left side</td>
<td>22/30</td>
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</tr>
<tr>
<td>Right side</td>
<td>8/30</td>
<td>26.7%</td>
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<tr>
<td>Venous wrist access*</td>
<td>19/30</td>
<td>63.3%</td>
</tr>
<tr>
<td>Radial</td>
<td>17/30</td>
<td>56.6%</td>
</tr>
<tr>
<td>Ulnar</td>
<td>2/30</td>
<td>6.6%</td>
</tr>
<tr>
<td>Venous upper arm access*</td>
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<tr>
<td>Brachial</td>
<td>8/30</td>
<td>26.7%</td>
</tr>
<tr>
<td>Cephalic</td>
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<td>6.6%</td>
</tr>
<tr>
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<td>3.3%</td>
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<tr>
<td>Arterial access</td>
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<tr>
<td>Radial</td>
<td>21/30</td>
<td>70%</td>
</tr>
<tr>
<td>Brachial</td>
<td>6/30</td>
<td>20%</td>
</tr>
<tr>
<td>Ulnar</td>
<td>3/30</td>
<td>10%</td>
</tr>
</tbody>
</table>

*Venous access sites presented are the ones finally used. In 1 case, a radial vein approach was changed to cephalic vein access due to extensive spasm of the vessel.

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**Figure 1.** Ultrasound image showing the anatomy between the perforator vein, cephalic vein, and deep vein. The arrows show the direction of blood flow.
Statistics
Discrete variables are presented as counts and percentages, whereas continuous variables are presented as means ± standard deviation if originating from normal distributions (Kolmogorov-Smirnov test). The Kaplan-Meier survival analysis was applied to demonstrate the incidence of VA loss over time. Statistical analysis was performed using GraphPad Prism version 8.0.2. The points of censoring for the patency analysis of the access circuit were thrombosis, surgical intervention, or abandonment.

RESULTS
Technical success was 100% (30/30). In 24 of 30 (80%) cases, the anastomosis was created between the radial artery and vein. Twenty-five of 30 (83.3%) procedures were performed with the catheters aligned parallel to each other (wrist or brachial access). The mean venous diameter at the side for wrist access (ulnar and radial veins) was 2.1 mm ± 0.2, whereas that in the upper arm (brachial, cephalic, and basilic veins) was 4.7 mm ± 0.8. The mean arterial diameter for wrist access (ulnar and radial arteries) was 2.6 mm ± 0.6, and that for brachial artery access was 3.8 mm ± 1. At the creation site, the mean venous diameter was 2.5 mm ± 0.6, and the mean arterial diameter was 2.7 mm ± 0.5. The mean diameter of the perforator vein was 3.7 mm ± 0.9. The mean amount of contrast used was 21 mL ± 12.  

Coil embolization of a brachial vein at the index procedure was performed in 16 of 30 (53%) cases. In 1 case, the initial plan to access the radial vein changed to cephalic vein access due to vessel spasm. In 2 cases, 2 activations of the device were required, and in another case, 3 activations were required, due to extensive calcification of the artery. In these cases, the catheters were removed after each activation, an angiogram was performed, and then the catheters were reinserted for the subsequent activation.  

The adverse event rate was 6.7% (2/30). In 1 case, a brachial artery pseudoaneurysm developed after sheath removal and was treated with manual compression and thrombin injection, whereas in another case, 17 days after the procedure, an aneurysm was diagnosed at the site of the
anastomosis. A covered stent (4.80 × 16 mm, Graft-Master GRX Coronary Stent Graft System; Abbott Vascular, Minnesota) was introduced at the arterial side of the anastomosis to exclude the aneurysm while sacrificing the pA VF.

The mean follow-up was 547 days ± 315 (range, 14–1,071 days). Twenty-six of 30 (87%) pAVFs achieved cannulation. Sixteen endovascular procedures were needed in 15 patients for the pAVFs to achieve maturation for cannulation (16/30, 0.53 procedures/patient), with 15 of them being coil embolization, angioplasty, or a combination of both. No surgical procedures were performed.

The mean follow-up after cannulation was 566 days ± 253 (range, 135–1,041). The cannulated veins were the cephalic in 20 of 30 (67%) cases or the cephalic and mid-cubital/basilic in 10 of 30 (33%) cases. Seven maintenance procedures were performed in 6 of the 26 matured pAVFs (0.27 procedures/patient, 0.17 procedures/patient-years), with 5 of them being angioembolization of the deep venous part of the circuit and/or the perforator vein. Once matured (26/30 pAVFs), patency was 96% at 1 year and 82% at 2 and 3 years based on the Kaplan-Meier analysis (Fig 4). Four fistulae were thrombosed during the cannulation follow-up period (at 183, 278, 390, and 450 days, respectively), with 2 of them successfully declotted and functional. From the time of creation to the end of the follow-up period, 22 of 30 (73%) pAVFs were nonthrombosed and cannulated (Fig 5). A detailed analysis of the results is shown in Table 3.

**DISCUSSION**

The 2019 National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines moved from the “fistula first” to the “right access for the right patient, at the right time” approach, which significantly influences and alters the decision for access selection (10). Additionally, it implies that the term “best AVF” does not independently exist even when the discussion focuses on the AVF type. A patient requiring HD would have a radiocephalic AVF created before moving to a brachiocephalic AVF, although the latter may provide better patency rates, provided that eligibility criteria stand for both options, and the first will not compromise the creation of the latter (11,12). Based on the patient’s life plan, an AVF that does not compromise future options should be considered first. In this case, pAVFs using the deep venous network, avoiding surgical manipulations of the vessels, preserving their microenvironment, and not compromising future sAVF creation could possibly be the most suitable for VA creation.

Percutaneous AVF creation with the WavelinQ EndoAVF System has been assessed in 3 company-sponsored studies with published data and 3 investigator-initiated studies. In the FLEX study, Rajan et al (13) reported the first study on the WavelinQ 6-F System. This was a proof-of-concept study with 33 patients divided into groups based on the evolution of the procedure. Technical success was 97%, with 1 serious adverse event being a pseudoaneurysm of the brachial artery treated successfully with thrombin injection. In the Novel Endovascular Access Trial, Lok et al (7) studied the same device in a larger sample size of 60 patients. Procedural success was 98%, and the device-related serious adverse event rate was 2%. All pAVFs created in the aforementioned studies were ulnar. The Endovascular Access System Enhancements study was the first study using the 4-F system (8). Technical success was 100%, and no serious adverse events were recorded in the 32 patients participating in the study. Both ulnar and radial AVFs were created. Zemela et al (14) and Radosa et al (15) published their initial experience with the 6-F system (35 and 8 patients, respectively). In both retrospective studies (14,15), the technical success was 100%, and a pseudoaneurysm, which is considered a serious adverse event, was observed in the study by Zemela et al.
In their article, Inston et al (1) shared their experience on the use of both generations of devices. In their study, pAVFs (30 patients) were prospectively compared with radiocephalic AVFs (40 patients). Technical success and primary and secondary patency endpoints were comparable between the 2 groups. Shahverdyan et al (16) in their retrospective study compared the WavelinQ with the Ellipsys device, with no significant differences observed in the primary outcome measures. Interesting findings regarding the WavelinQ device was the amount of contrast used (mean, 8 mL) and the time to first use, one of the longest in the literature, being 90 days. However, in their study, 8 of 35 (23%) cases needed superficialization of their brachial or basilic vein, a secondary procedure that highly influences and prolongs the time to cannulation.

The European/Canadian study was a multicenter, multinational prospective study utilizing both generations of devices (17). An important finding in this study, where 100 patients were recruited, was that coil embolization at the index procedure reduced the number of reinterventions (maturation and maintenance) by 52% compared with cases without embolization performed. All aforementioned studies provided follow-ups of up to 6 months. The current study reports similar technical success and safety rates to these studies. Additionally, with a mean follow-up of 547 days ± 316 (range, 14–1,071 days), a mid-term dataset is provided on the commercially available 4-F system. Contrast medium used (mean 21 mL) was higher than that in the study by Shahverdyan et al (16) (mean 8 mL); however, its quantity remained adequately low.

Six of 9 predialysis patients required a long-term central venous catheter (CVC) placed prior to using their pAVF for dialysis. Although the avoidance of CVCs is an important element in the life of a patient with HD, it is dependent on not only the time an AVF needs to mature but also the lead time when a patient is referred to undergo the AVF creation. In the current study, 1 patient had a CVC inserted the day the pAVF was created. The Kidney Disease Outcomes Quality Initiative guidelines suggest the “intervention goal” of 1-2-3, translated as 1 VA may undergo ≤2 interventions to facilitate VA use (maturation) and ≤3 interventions to maintain VA use per year (10). In the current analysis, 0.53 interventions/patient were performed for maturation purposes, whereas 0.17 procedures/patient-years were needed to maintain VA, values well below the suggested thresholds.

This study suffers the inherent limitations of a retrospective, single-arm study lacking a comparator. The study sample is small, forbidding any valid further exploratory analysis of the results. It is also biased by patient selection, by both the referring physicians and the operators, and a strict adherence to eligibility criteria in the frame that patients not fully eligible to have a pAVF could alternatively have an sAVF. This is reflected by the fact that in the current analysis, all subjects were men. The percentage of patients eligible to undergo a pAVF creation was also not recorded. Additionally, it includes the operators’ learning curve, particularly their familiarity with the ultrasonographic and the angiographic anatomy of the forearm, and contrast use. Volume flow data were not available for all patients and were excluded from the analysis. Procedural times were not recorded as most of the cases were performed in the frame of educational workshops or live broadcasts.

To conclude, in our early experience, pAVF creation with the WavelinQ 4-F EndoAVF System was safe, with high technical success rates. Mid-term follow-up showed...
high maturation and survival rates with a low number of reinterventions. Larger prospective studies are needed to validate the results.

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