Early results of percutaneous arteriovenous fistula creation with the Ellipsys Vascular Access System

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ABSTRACT

Objective: We reviewed our initial experience creating a percutaneous arteriovenous fistula (pAVF) using a thermal resistance anastomosis device with proximal radial artery inflow.

Methods: A retrospective review was conducted of all patients who underwent a pAVF creation procedure between May 2017 and October 2017. Primary end points of the study were technical success, patency by Doppler ultrasound examination or angiography, flow levels achieved, time to first use, and pAVF-related complications.

Results: A pAVF was attempted in 34 patients with technical success in 33 individuals (97%). Patency of the pAVF was 94%. Mean access flow was 946 mL/min (brachial artery measurement) at the latest follow-up visit (53-229 days; average, 141 days). At 6 weeks, all fistulas have been used or were ready for dialysis by clinical examination or ultrasound examination. Only one patient required superficialization of the upper arm cephalic vein by lipectomy. There were no adverse events related to the pAVF creation or use, nor was there need for further interventions.

Conclusions: Successful pAVFs with proximal radial artery inflow were created with excellent initial results regarding technical success, patency, and safety. Advantages include avoidance of a surgical incision, short procedure times, good acceptance by patients, prompt access maturation, moderate flow, and low-pressure access, with possible reduction of risk for ischemic complications. Avoidance of vessel manipulation and side branch ligation might reduce risk of thrombosis and improve long-term patency and reduce need for further interventions. These early findings need to be confirmed in larger and longer follow-up studies. (J Vasc Surg 2018;■:1-7.)

Keywords: Arteriovenous fistula creation; Percutaneous; Proximal radial artery; Ultrasound

Arteriovenous fistulas (AVFs) provide the best vascular access for hemodialysis in patients with end-stage renal disease, offering higher patency rates, fewer complications and hospitalizations, and lower costs compared with grafts and catheters.1,2 Since the conception of surgical AVF creation by Brescia and Cimino,3 the number of AVF options has increased substantially. This has been paralleled by the ability to intervene and salvage dysfunctional fistulas along with a greater understanding of the mechanisms of access failure. Still, it appears that the success of a surgical AVF is largely dependent on reliable preoperative vessel mapping in addition to surgical skill, experience, and a working knowledge of the wide range of autogenous access options.2,4 In contrast to the evolution of techniques and options for AVF configuration, the surgical method of creating the arteriovenous anastomosis has remained the same until very recently. Two new devices have been described for creating a percutaneous AVF (pAVF) using different mechanisms and techniques.5-9 We describe our experience with one of these devices, using pressure and thermal resistance energy (thermal resistance anastomosis device [TRAD]) to create an arteriovenous anastomosis with fusion of the arterial and venous walls between the proximal radial artery (PRA) and the deep communicating vein (DCV) in the proximal part of the forearm.

METHODS

A retrospective review of data from May to October 2017 at a single tertiary medical center was performed for all patients scheduled for a pAVF creation with the Ellipsys Vascular Access System (Avenu Medical, San Juan Capistrano, Calif). Each individual was included in a prospective registry. The primary end points of the study were technical success, postoperative patency by Doppler ultrasound examination or angiography, access flow rate, time to first use, and pAVF-related complications. One week after pAVF creation, the first 14 patients had a planned percutaneous transluminal angioplasty (PTA) of the anastomosis through distal radial artery access as done in previous studies of this device.9 For the rest of this series, the PTA of the anastomosis was performed at the time of creation, thus avoiding the 1-week postoperative procedure. All patients had regular follow-up visits 1 week after each procedure and monthly
for the rest of the follow-up period. In addition, all patients had ultrasound flow measurements immediately after access creation and for every follow-up examination using the brachial artery as a surrogate for total access flow. Flow volumes in individual outflow branches were often helpful in determining readiness for cannulation or evaluating maturation issues.

The study was approved by the Institutional Review Board, and all patients signed an informed consent. Primary patency was the time in months of uninterrupted patency without intervention. Primary assisted patency was the time of uninterrupted patency to any interventional procedure that was necessary to maintain patency. Secondary patency was the time from AVF creation until abandonment of the access or until completion of the study period, including any procedure to re-establish patency. Patency in this report refers to a functional access.

**Patients.** All patients referred to our institution for AVF creation underwent a Doppler ultrasound arterial and venous upper extremity examination (SonoSite M-Turbo linear 5-13 MHz linear transducer; SonoSite, Bothell, Wash). Patients with questionable anatomy for a distal radiocephalic AVF (calcified or small radial artery and small or diseased forearm veins) and an adequate PRA >2 mm and DCV >3 mm were considered candidates for a pAVF creation. Patients with extremely tortuous DCV or other anatomic variations that made venous or arterial puncture unsuitable for the pAVF technique were offered a surgical AVF. The same recommendation applied for patients in whom the distance between the PRA and the DCV was >1.5 mm. Characteristics and comorbidities of the patients can be seen in Table I.

**Procedure.** The Ellipsys TRAD catheter has been previously described and uses direct heat and pressure to fuse the arterial and venous wall, creating an anastomosis between the DCV and the PRA within the fossa where the two anatomic elements are adjacent to each other.9

Per our hospital protocol for all AVF interventions, each patient had an ultrasound-guided axillary nerve block with conscious sedation. The entire pAVF procedure was performed under continuous ultrasound visualization. Initial access was gained with direct puncture of the median basilic or median cephalic vein using a micropuncture needle (Cook Medical, Bloomington, Ind). Under ultrasound guidance, the 0.021-inch wire of a 6F radial artery sheath (6F Slender; Terumo Interventional Systems, Somerset, NJ) was advanced into the DCV to the position where the PRA appeared to be adjacent. Subsequently, the micropuncture needle was advanced over the wire into the same position within the vein. Under continuous ultrasound visualization of the needle tip, a puncture of the PRA was performed that created a connection between the DCV and the PRA (Fig 1). The wire was advanced into the radial artery, and the position was verified under ultrasound guidance. The sheath was subsequently positioned into the artery, and the first guidewire was exchanged for a 0.014-inch wire (Nitrex; ev3, Plymouth, Minn). The Ellipsys catheter was then advanced over the guidewire into the sheath in an “open” position until the tip of the device was positioned in the artery and the base of the device remained in the vein (Fig 2, A). The sheath was retracted to the more superficial part of the DCV, and gentle traction was applied to the Ellipsys catheter until the tip of the device engaged the anterior wall of the PRA, providing tactile resistance to further traction (Fig 2, B). The catheter was closed, capturing the arterial and venous walls between the tip and base. Proper positioning of the device was confirmed by verifying the correct tissue capture through a display on the power controller. The power controller was subsequently activated, and within a few seconds, the anastomosis was created (Figs 3 and 4). The catheter was then removed, keeping the guidewire in position, and balloon angioplasty of the anastomosis was performed. For the first 14 patients, gentle inflation of a 4 × 20-mm or 5 × 20-mm monorail balloon was selected (Boston Scientific, Marlborough, Mass). For the rest of the series, PTA was performed with a 5 × 20-mm balloon and inflation at nominal pressure. These balloon dilations included the anastomosis and the DCV but did not extend into the artery. PTA inflation was guided with direct ultrasound observation. The Ellipsys pAVF device creates an elliptical anastomosis that is roughly 4 × 2 mm. Assuming some recoil after the 5-mm PTA, we anticipated a 4- to 5-mm anastomosis. Successful fistula creation and flow were confirmed by ultrasound, and the wire and sheath were removed. Gentle pressure for a few minutes was sufficient to achieve hemostasis. As in previous reports of the Ellipsys device, the first 14 patients had a PTA of the anastomosis with a 6-mm compliant balloon 1 week after creation through distal radial artery access. This was unnecessary after the implementation of the 5-mm PTA with
RESULTS

Thirty-four patients had a pAVF creation during the study period. Technical success (patent AVF) was achieved in 33 patients (97%). One of the first patients had failed needle access and underwent construction of a successful surgical PRA AVF at the same site without any negative impact of the previous unsuccessful attempt on surgical AVF technique or patency. Primary patency (no further interventions after the planned 1-week maturation PTA) was 82%, whereas primary assisted patency and secondary patency were both 94% (31 patients; Table II). Six patients (18%) required a second PTA to improve access flow. Three of these patients (9%) presented after the first PTA with no flow through the anastomosis but a patent outflow vein. Recanalization of the anastomosis with PTA was sufficient to re-establish AVF flow. The fourth patient (3%) had a coil placed in a brachial vein because of significant collateral flow. This was performed during his second PTA for access flow improvement. The same patient was the only patient who required a superficialization procedure (lipectomy) to facilitate the second needle placement in the upper arm cephalic vein as it was deeply situated. The two remaining patients early in the series presented with a similar focal stenotic or occlusive phenomenon 1 week after the pAVF creation with no thrombus present. In both patients, the anastomosis was easily cannulated with a guidewire through distal radial access with PTA to re-establish a successful access. After implementation of the immediate 5-mm PTA at the time of pAVF creation, this phenomenon was not observed again.

Five patients (15%) had ultrasound-guided AVF puncture to facilitate the first cannulation and to avoid the need for superficialization. Three patients (9%) were punctured with the buttonhole technique.

Not all patients had started dialysis during the study period. However, within 4 to 6 weeks after pAVF creation, all predialysis patients (created May-August) met the ultrasound criteria for clinical success (diameter >6 mm for 10 cm, flow >600 mL/min). All pAVFs for patients on catheter access dialysis (23 patients [69%]) were successfully cannulated for two-needle dialysis, and the catheters were removed with the exception of one individual, who expressed fear of needles and refused further AVF use after initial successful cannulation and dialysis. Early pAVF use would have been possible if needed in predialysis patients (10 patients [30%]) on the basis of clinical and ultrasound criteria with the identification of well-developed and mature pAVF outflow veins. In one patient, the pAVF was cannulated successfully 1 week after creation with two-needle cannulation (Fig 5).

No vessels were occluded to promote flow to one outflow path in favor of another. In four patients (12%), both cephalic and median basilic veins were used with the prescribed dialysis flow and low recirculation rates. In 12 patients (36%), cannulation of both veins would have been possible on the basis of ultrasound criteria, if required. In eight patients (24%), based on anatomic criteria, a surgical basilic vein transposition would have been necessary; however, this was avoided while maintaining the advantages of upper radial artery-based AVF. Access flow (measured by ultrasound at the brachial artery) averaged 669 mL/min immediately after creation and 946 mL/min (range, 645-1486 mL/min) at the latest follow-up visit (range, 53-229 days; average, 141 days). Dressings were removed on day 1, and no patient required additional medical or nursing attention for wound issues or pain management. All fistulas have been used or are ready for dialysis by clinical examination or ultrasound examination within 6 weeks of pAVF creation. There were no adverse events related to the pAVF creation, PTAs, or use and no need for further interventions. During the study period, 138 total AVFs were constructed, including 33 pAVFs and 105 surgical AVFs.

Table I. Characteristics and comorbidities of the patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Age, years (range)</td>
<td>64 (22-89)</td>
</tr>
<tr>
<td>Sex, M/F</td>
<td>22/11</td>
</tr>
<tr>
<td>African ancestry</td>
<td>8 (24)</td>
</tr>
<tr>
<td>White</td>
<td>25 (75)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>21 (63)</td>
</tr>
<tr>
<td>Obesity (BMI &gt;30)</td>
<td>13 (39)</td>
</tr>
<tr>
<td>Previous AVF</td>
<td>10 (30)</td>
</tr>
<tr>
<td>Dialyzed on catheter</td>
<td>23 (69)</td>
</tr>
</tbody>
</table>

AVF, Arteriovenous fistula. BMI, body mass index.
Values are presented as absolute numbers (percentages). Average value is given where applicable.
DISCUSSION

We have previously reviewed our experience with open surgery PRA inflow AVFs at the same anatomic level as the Ellipsys device pAVFs in this study, reporting excellent functional patency in addition to maturation rates superior to distal fistulas.\textsuperscript{10,11} We and other authors found a low risk of PRA access-related steal syndrome and noted more moderate AVF flow volume compared with AVFs based on the brachial artery.\textsuperscript{10,11} Bourquelot

**Fig 2.** A. The Ellipsys catheter is advanced into the artery in an "open" position with the tip of the device in the artery and the base of the device remaining in the vein. B. Gentle traction is applied to the device to make sure that the device has captured the arterial wall—the operator can feel the resistance while the artery is seen secured adjacent to the vein.

**Fig 3.** The device is closed and activated. Thermal energy and pressure will cut and fuse the anastomosis between the proximal radial artery (PRA) and the deep communicating vein (DCV).

**Fig 4.** The anastomosis between the proximal radial artery (PRA) and the deep communicating vein (DCV) is completed.
Table II. Results

<table>
<thead>
<tr>
<th>Result</th>
<th>Value</th>
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<tbody>
<tr>
<td>Technical success, %</td>
<td>96</td>
</tr>
<tr>
<td>AVF cumulative patency at latest follow-up visit, %</td>
<td>92</td>
</tr>
<tr>
<td>Average flow after creation, mL/min (range)</td>
<td>669 (298-1104)</td>
</tr>
<tr>
<td>Average flow at the latest follow-up visit, mL/min (range)</td>
<td>946 (645-1486)</td>
</tr>
<tr>
<td>Follow-up, days, mean (range)</td>
<td>91 (6-182)</td>
</tr>
</tbody>
</table>

*AVF, Arteriovenous fistula.*

and Pirozzi12 have described in detail how small-caliber vessel issues can be managed using microsurgery techniques, and we remain in favor of constructing distal radiocephalic AVFs when adequate vessels are present and in appropriate patients.

The Ellipsys Vascular Access System uses thermal energy and pressure to achieve fusion of the arterial and venous wall between the PRA and DCV, taking advantage of the proximity of the two vessels at the level of the antecubital fossa. Hull et al.9 created 23 pAVFs in 26 patients with high technical and device success rates. There were no serious adverse events. Patency at 6 weeks was 87%, whereas 80% of patients were receiving dialysis on their pAVF 3 months after creation.

This is the first report of pAVF with the Ellipsys system in Europe. Patency rates were excellent during the follow-up period, and the procedure had a high safety profile with no serious adverse events in this series of patients. In the few patients with focal stenosis or occlusion at the anastomosis, we noted that the access remained patent without thrombosis, and a percutaneous angioplasty was easily sufficient to re-establish AVF flow and function. The preservation of venous side branches at the level of the DCV was likely to be responsible for this phenomenon; however, important shunting of access flow toward the deep system occurred in only one patient and was easily corrected by coil occlusion of a brachial vein.

In patients with both median cephalic and median basilic veins patent, we elected not to ligate either branch, contrary to traditional teaching that one of the two draining veins should be ligated to prioritize the other or to prevent future high blood flow. When feasible, both median superficial veins were left intact, resulting in a Y-shaped AVF with more length for puncture and more options in the long term. In creating surgical AVFs at the same PRA site, we may ligate the median basilic vein when the cephalic is clearly the best outflow target; however, we leave both branches open when uncertain about the cephalic vein. During maturation follow-up, ultrasound flow evaluation with digital compression of the median basilic and, alternatively, the cephalic vein usually clarifies the issue and may lead to a simple office procedure for median basilic ligation if necessary. In most patients, both outflow branches may be left open for cannulation and backup access options should one later fail. In occasional patients, simple flow restriction of the median basilic vein is appropriate. If the cephalic vein is clearly adequate, an occlusion coil could be placed in the median basilic vein during the pAVF creation procedure. We have not yet found this to be necessary. Similar to bidirectional AVFs, outflow into both branches may lead to lower flow rate and lower pressure in each with fewer complications, such as aneurysm formation and less need for reintervention. This type of cannulation using both veins was possible in 12 (36%) of the study patients. The localization of the anastomosis in the PRA allows use of both the median basilic vein draining into the basilic at the lower part of the arm and the cephalic vein. The lack of a surgical scar and associated inflammation allowed adequate cannulation length to avoid superficialization of the basilic vein in patients in whom a brachiobasilic surgical transposition AVF would have otherwise been necessary. A basilic vein transposition was avoided in eight (24%) of these patients.

The procedure time is short and will probably be safely reduced with increasing experience, as the procedure is fairly simple with few steps. As the size of the anastomosis is relatively small, essentially defined by the size of the catheter, almost all these pAVFs require balloon dilation to ensure prompt maturation and to improve flows. Our decision to incorporate this PTA as part of the primary pAVF procedure was safe and effective, avoiding a return in 1 week for a secondary intervention.

All AVFs were used or usable by ultrasound criteria at 4 to 6 weeks after creation, and this appears to be equivalent or superior to reported series of surgical fistulas. In five patients, ultrasound-assisted puncture of the matured AVF was performed initially to assist two-needle cannulation. We find that marking the outflow veinpaths before initial cannulation with clinical and ultrasound examinations is an important aide for the dialysis and cannulation staff. On occasion, deep veins may benefit from ultrasound-guided first cannulation or the buttonhole technique.

Lack of dissection and vessel manipulation suggests that a different physiologic milieu may be present that contrasts with surgical AVFs.13 With no direct manipulation of the vessels and no disturbance of their anatomic course, the vasa vasorum and vasa nervorum remain intact. For this reason, we believe that the pAVF approach may also lead to improved patency and fewer interventions. After pAVF creation, the patient maintains an arm with anatomy identical to that before AVF creation with only physiologic changes. This is perceived much better emotionally by the patient. Finally, if a later surgical AVF creation is needed, it will involve undistorted anatomy and will not be within or through a previous surgical field. As with any secondary access, vessels of larger diameter may develop because of the prior...
existence of the pAVF. The pAVF may not preclude a later distal radiocephalic AVF if forearm vein size increases because of pAVF collateral flow.

Hull et al\textsuperscript{14} described a computational model whereby a side-to-side anastomosis has an optimized hemodynamic profile with shear stress reduction. Ellipsys pAVF is, in essence, a side-to-side configuration, and this factor, in combination with no ligation of small side branches at the level of the DCV and lack of inflammatory postsurgical processes, may lead to increased cumulative patency. No venous thrombosis was detected, and simple balloon angioplasty was sufficient to re-establish AVF flow in those few early patients with a focal anastomotic stenosis.

Good ultrasound skills are of paramount importance for this technique as all steps are performed under continuous ultrasound visualization, avoiding radiation exposure for both patient and physician. Interventional nephrologists, radiologists, and vascular surgeons with contemporary training should have the skills required. Vascular access surgery depends on ultrasound guidance for surgical procedures, preoperative planning, and postoperative follow-up.\textsuperscript{15,16}

During the study period, approximately 25% of the new AVFs created were pAVFs. This percentage is likely to rise with increasing experience. If patients were suitable for a distal surgical AVF, then we offered them a distal radiocephalic AVF; if not, then a PRA AVF was considered, and if anatomically feasible, a pAVF was offered (none declined). Overall, we believe that approximately 50% of patients might be eligible to have a pAVF created as our experience increases. This initial experience reflects

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{Fig5.png}
\caption{Clinical photographs of patients. \textbf{A}, At 4 days after percutaneous arteriovenous fistula (pAVF) creation, no trace of the left arm pAVF site is visible. \textbf{B}, At 4 days after pAVF creation, the cephalic vein is already well developed. This pAVF was used with two needles 1 week after creation. \textbf{C}, The image shows a patient in whom both cephalic and basilic veins can be used for cannulation of the Y-shaped pAVF, taking advantage of both veins, offering more length and lower outflow pressures. \textbf{D}, The first patient of the series with two-needle cannulations "en Y," having dialysis 1 month after creation.}
\end{figure}
our conservative approach to a new technology and the process of expanding the procedure to additional surgeons on our team.

Hull et al reported 87.9% anatomic suitability for pAVF creation at the level of the PRA in a study based on vein and arterial mapping data. We observed that most patients appear to have a DCV close to the PRA that allows concomitant puncture and creation of an anastomosis with TRAD. In our opinion, especially for the first few patients for physicians with less experience, tortuous or short veins should be avoided or referred for a surgical PRA AVF creation. We found that 18% of our patients required a PTA during follow-up and think that this is also likely to be related to a learning curve. For our recent patients, we have added immediate 4- to 5-mm PTA at the conclusion of the pAVF creation. With this modification, we note far fewer maturation problems with no related complications.

CONCLUSIONS

The pAVF with a TRAD device at the level of the PRA appears to be a safe and efficacious vascular access option. Dialysis patients not suitable for a distal fistula and with the anatomic criteria favorable for a pAVF should be considered. Advantages include avoidance of a surgical incision, prompt access maturation, short procedure times, and good acceptance by patients in addition to the benefits seen with PRA inflow, such as a moderate flow access and reduction of risk for ischemic complications. Avoidance of vessel manipulation and side branch ligation may reduce the risk of thrombosis, improve long-term patency, and limit need for further interventions. These early findings need to be confirmed in larger and longer follow-up studies.

AUTHOR CONTRIBUTIONS
Conception and design: AM  
Analysis and interpretation: AM, WJ, BB, AC, PB, MC  
Data collection: AM  
Writing the article: AM  
Critical revision of the article: AM, WJ, BB, AC, PB, MC  
Final approval of the article: AM, WJ, BB, AC, PB, MC  
Statistical analysis: Not applicable  
Obtained funding: Not applicable  
Overall responsibility: AM

REFERENCES