Comparison of surgical versus percutaneously created arteriovenous hemodialysis fistulas

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ABSTRACT

Objective: The aim of the present study was to compare the results between percutaneous arteriovenous fistulas (p-AVFs) created with the Ellipsys device (Ellipsys Vascular Access System; Avenu Medical, San Juan Capistrano, Calif) and surgical arteriovenous fistulas (s-AVFs).

Methods: A single-center retrospective comparative study of the first 107 patients who had undergone p-AVF creation with the Ellipsys system from May 2017 to May 2018 with an equal number of consecutive patients who had undergone s-AVF creation in our center during the same period. The primary endpoints included the maturation and patency rates. The secondary endpoints were reintervention, risk of infection, and the incidence of steal syndrome and aneurysm formation.

Results: The demographic, hypertension, and diabetes data were similar for both groups. The only difference between the two groups was that more p-AVF patients had already been receiving hemodialysis (61% vs 47%; $P < .05$). The p-AVFs showed superior maturation rates at 6 weeks (65% vs 50%; $P = .01$). The primary patency rates were greater for the s-AVFs at 12 months (86% vs 61%; $P < .01$). However, primary patency was comparable between the two groups at 24 months (52% vs 55%; $P = .48$). No significant difference was found in the secondary patency rates at 12 (90% vs 91%) and 24 (88% vs 91%) months. At the 2-year follow-up point, the rate of percutaneous reintervention was similar; however, the s-AVFs had required more frequent surgical revision (36% vs 17%; $P = .01$). Issues with wound healing and infection were also more frequent with s-AVFs (9% vs 0.9%; $P < .01$).

Conclusions: Fistulas created percutaneously with the Ellipsys system showed superior maturation rates and similar patency with s-AVFs created in an experienced high-volume vascular surgery practice. p-AVFs had a lower risk of wound healing issues, infection, and surgical revision. Larger, prospective, randomized multicenter studies are needed to confirm these findings. (J Vasc Surg 2021;■:1-9.)

Keywords: Arteriovenous fistula; EndoAVF; Ellipsys; Hemodialysis fistula; pAVF; Percutaneous fitsula

The use of native arteriovenous fistulas (AVFs) has been recommended as the first choice for most patients with end-stage renal disease (ESRD) who are not candidates for peritoneal dialysis. A radiocephalic (rc)-AVF at the wrist (w-AVF) has been the most widely accepted option, with brachiocephalic AVFs (bc-AVFs) and brachiobasilic AVFs (bb-AVFs) as second and third choices in the algorithms of most centers. We have previously described our experience with proximal radial and proximal ulnar artery inflow AVFs as our preferred option when a w-AVF is not feasible or appears to have a high risk of nonmaturation. The former both minimize the risk of hemodialysis access-related distal ischemia (HAIDI).[1-5]

Despite the generally accepted superiority of native fistulas compared with catheters, issues with AVFs are not uncommon. The reported risk of primary failure of surgical AVFs (s-AVFs) has varied from 23% to 60%,[6] and the incidence of HAIDI has been reported to be as great as 28% in surgical brachial-based fistulas.[7] The incidence of wound dehiscence and infection can reach 13% in patients with bb-AVFs.[8]

The Ellipsys Vascular Access System (Avenu Medical, San Juan Capistrano, Calif) offers a minimally invasive percutaneous alternative when a rc-AVF at the wrist is not feasible or unlikely to mature. The thermal resistance anastomosis device creates a permanent anastomosis between the proximal radial artery (PRA) and the perforating vein of the elbow (PVE). The reported results for percutaneous AVFs (p-AVFs) created using the Ellipsys have been promising[9-15]; however, no comparative studies have evaluated s-AVFs and p-AVFs. We have

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presented the results from our center using both techniques.

ARTICLE HIGHLIGHTS

- **Type of Research:** A single-center, retrospective comparative study
- **Key Findings:** In the present study, the first 107 patients who had had Ellipsys (Ellipsys Vascular Access System; Avenu Medical, San Juan Capistrano, Calif) percutaneous arteriovenous fistulas (p-AVFs) created from May 2017 to May 2018 were compared with 107 patients who had undergone surgical AVF (s-AVF) creation during the same period in our center. The p-AVFs had shown superior maturation rates, similar patency, and a lower risk of infection, steal syndrome, and aneurysm formation.
- **Take Home Message:** The present study is the first direct comparison between surgical and percutaneous fistulas created using the Ellipsys p-AVF system. These data support the conclusion that p-AVFs, although minimally invasive, have results comparable, and in some respects superior, to those s-AVFs.

METHODS

We retrospectively identified all patients who had undergone p-AVF and s-AVF creation from May 2017 to May 2018. All procedures were completed at a not-for-profit teaching hospital and outpatient setting. All the patients had undergone preoperative venous and arterial ultrasound mapping. In accordance with the guidelines, we aimed for the creation of an AVF in the most distant possible location on the nondominant arm of the patient. If a wrist and/or mid- or distal forearm AVF were not possible (eg, vein and/or artery <2 mm, poor vessel quality, diabetes mellitus) or the AVF had a high risk of nonmaturation in the surgeon's judgment, we will create an AVF between the PRA (or, less often, the proximal ulnar artery) and the PVE. Since May 2017, another option has been a surgical or percutaneous PRA AVF according to surgeon preference and if the ultrasound evaluation has indicated that puncture is possible for p-AVF creation. In the absence of the possibility for a proximal radial or ulnar artery AVF, a bc-AVF or bb-AVF will be created, with brachiocephalic having priority because it does not require superficialization in nonobese patients.

Patients who had grafts or lower extremity fistulas were excluded. A total of 107 p-AVFs were included and were compared with the first 107 s-AVFs created during the same period. A single surgeon (A.M.) had created all the p-AVFs, and the entire team of four experienced access surgeons (A.M., B.B., A.C., R.d.B.) had participated in the creation of the s-AVFs. The baseline patient information was extracted from the medical records and included age, body mass index, gender, selected medical conditions (eg, hypertension, diabetes, dialysis status), and type of s-AVF. Access outcomes, including maturation, complications encountered, and additional procedures required, were determined by a direct examination of the patient and the patient's medical records and/or interviews with the nephrologist and dialysis unit nursing staff.

The primary outcomes were maturation and the primary and secondary patency rates. Maturation was considered present by AVF usage for patients already receiving hemodialysis (50% and 60% for the s-AVF and p-AVF groups, respectively) and the clinical examination findings and meeting of ultrasound criteria (>4 mm diameter and >500 mL/L of flow) for patients not yet receiving hemodialysis.[16] Primary patency was defined as the interval between AVF creation and any open or percutaneous intervention to maintain or reestablish patency access (excluding routine procedural balloon dilatation of each p-AVF at creation). Secondary patency was defined as the interval from access placement to access abandonment. The secondary outcomes were the number and type of additional interventions (ie, percutaneous or surgical revision, which mainly included planned and staged superficialization for both groups) required for assisted maturation and/or AVF dysfunction and rate of complications, including wound healing issues, infection, and steal syndrome. Comparisons were performed between the p-AVF and s-AVF groups. A subgroup analysis was also performed of w-AVFs and elbow s-AVFs (e-AVF). In addition, p-AVFs created early and late in the present series' experience were compared to evaluate for any potential learning curve effects.

The baseline information, medical history, and procedure outcomes were compared using the Student *t* test for continuous variables and a χ^2 test for categorical variables. MedCalc software (MedCalc Software Ltd, Ostend, Belgium) was used for the Kaplan-Meier patency rate analysis. The institutional review board (Comité d'Evaluation des Protocoles et d'Aide à la Recherche Protocol Evaluation and Research Assistance Committee) approved the present study, which was performed in accordance with the Declaration of Helsinki. All included patients provided written informed consent.

RESULTS

From May 2017 to May 2018, 107 patients had undergone p-AVF creation. The same number of consecutive patients with s-AVF creation during the same period was selected. Of the 107 s-AVFs, 59 (55%) were w-AVFs and 48 (45%) were e-AVFs (12 proximal rc-AVF, 16 bc-AVFs, and 20 bb-AVF). Of the 107 patients in the s-AVF group, 65 (60.8%) were men, and their mean age was 63.5 years. Of the 107 patients in the p-AVF group, 66 (61.7%) were men, and their mean age was 63.6 years. Although age, gender, presence of diabetes, body mass

Table I. Baseline characteristics for s-AVF and p-AVF groups

Variable	s-AVF (n = 107)	p-AVF (n = 107)	*P* value
Demographic			
Age, years	63.5 ± 15.69	63.6 ± 15.41	.48
BMI, kg/m^2	26.8 ± 5.95	27.2 ± 5.78	.47
Gender			.88
Female	42 (39.2)	41 (38.3)	
Male	65 (60.8)	66 (61.7)	
Medical history			
Hypertension	102 (95.3)	99 (92.5)	.39
Diabetes	52 (48.6)	66 (61.7)	.07
Hemodialysis	50 (46.7)	65 (60.7)	<.05
Procedure side			.76
Right	27 (25.2)	29 (27.1)	
Left	80 (74.8)	78 (72.9)	
Location			
Wrist	59 (55.1)	0 (0)	
Elbow	48 (44.9)	107 (100)	

BMI, Body mass index; *p-AVF,* percutaneous arteriovenous fistula; *s-AVF,* surgical arteriovenous fistula.
Data presented as mean ± standard deviation or no. (%).

index, and access side were comparable, the patients who had undergone p-AVF creation were more likely to have been receiving hemodialysis (61% vs 47%; $P < .05$). This difference was mainly seen between the p-AVF and w-AVF groups (61% vs 40%; $P = .01$). The baseline characteristics and results of the comparisons between p-AVF and s-AVF, w-AVF, and e-AVF are presented in Tables I to III.

The maturation rate at 6 weeks was higher for the p-AVFs (65% vs 50%; $P = .01$). No significant differences were found between the p-AVFs and e-AVFs (65% vs 60%; $P = .48$). However, the w-AVFs more frequently had had delayed maturation (43% vs 65%; $P = .01$). The Kaplan-Meier analysis revealed that the primary patency rate was greater for the s-AVF group than for the p-AVF group at 12 months (86% vs 61%; $P < .01$). However, the primary patency rate was comparable between the two groups at 24 months (52% vs 55%; $P = .48$; Table IV; Fig 1). No significant differences were found in the secondary patency rates at 12 (90% vs 91%) and 24 (88% vs 91%) months.

At 12 months, the patients with a p-AVF had required more secondary percutaneous interventions than had patients with an s-AVF (41% vs 4%; $P < .001$) but fewer open surgical interventions (12 vs 33; $P < .001$). At 24 months, the s-AVF and p-AVF groups had undergone a similar proportion of percutaneous interventions (42% vs 53%; $P = .1$). However, the s-AVF group had maintained the more frequent requirement for operative interventions (36% vs 17%; $P = .01$). A comparison of p-AVFs and e-AVFs showed notable differences at 6 months in the requirement for percutaneous (41% vs 4%; $P < .001$) and surgical (12% vs 40%; $P < .001$) interventions (including superficialization). At 24 months, the e-AVFs had continued to require a greater rate of surgical revision (49% vs 18%; $P < .001$). Wound healing issues and infections were higher for the s-AVF group (9% vs 0.9%; $P < .01$; one patient with a p-AVF had experienced wound separation after superficialization). In the s-AVF group, three patients had developed high-flow AVFs and three had experienced aneurysmal degeneration. These complications did not occur in the p-AVF group. However, the cohorts were small, and, therefore, the difference was not statistically significant. All outcomes and comparisons between the different groups are presented in Tables IV to VI and Figs 1 and 2. A comparison of primary patency between the first and last 50 patients with creation of a p-AVF with the Ellipsys system showed very similar Kaplan-Meier curves, suggesting little effects from a learning curve (Fig 3).

DISCUSSION

AVFs for dialysis have been recommended for ESRD patients who require chronic hemodialysis.[1,2] Nonetheless, the reported results have varied greatly and have often been disappointing. Al-Jaishi et al,[17] in a recent meta-analysis, reported a primary failure rate of 23% and secondary patency rate of 64% at 2 years, with the results actually becoming worse in the most recent years. A well-conducted national study by Stoumpos et al[18] reported similar findings. Of a total of 582 access sites created in 537 patients, only 55.3% were in use at the end of follow-up. The 1-year primary and secondary patency rate was 48% and 69%, respectively.[18]

Table II. Baseline characteristics for e-AVF and p-AVF groups

Variable	e-AVF (n = 47)	p-AVF (n = 107)	*P* value
Demographic			
Age, years	63.9 ± 14.74	63.6 ± 15.41	.44
BMI, kg/m^2	26.45 ± 5.4	27.2 ± 5.78	.28
Gender			.62
Female	20 (42.6)	41 (38.3)	
Male	27 (57.4)	66 (61.7)	
Medical history			
Hypertension	45 (95.7)	99 (92.5)	.45
Diabetes	23 (48.9)	66 (61.7)	.14
Hemodialysis	26 (55.3)	65 (60.7)	.52
Procedure side			.29
Right	9 (19.1)	29 (27.1)	
Left	38 (80.9)	78 (72.9)	

BMI, Body mass index; *e-AVF*, elbow surgical arteriovenous fistula; *p-AVF*, percutaneous arteriovenous fistula.
Data presented as mean ± standard deviation or no. (%).

Table III. Baseline characteristics for w-AVF and p-AVF groups

Variable	w-AVF (n = 60)	p-AVF (n = 107)	*P* value
Demographic			
Age, years	63.2 ± 16.65	63.6 ± 15.41	.46
BMI, kg/m^2	27.07 ± 5.56	27.2 ± 5.78	.35
Gender			.83
Female	22 (36.7)	41 (38.3)	
Male	38 (63.3)	66 (61.7)	
Medical history			
Hypertension	57 (95.0)	99 (92.5)	.54
Diabetes	29 (48.3)	66 (61.7)	.94
Hemodialysis	24 (40.0)	65 (60.7)	.01
Procedure side			.67
Right	18 (30.0)	29 (27.1)	
Left	42 (70.0)	78 (72.9)	

BMI, Body mass index; *p-AVF*, percutaneous arteriovenous fistula; *w-AVF*, wrist surgical arteriovenous fistula.
Data presented as mean ± standard deviation or no. (%).

The percutaneous Ellipsys Vascular Access System (Avenu Medical) creates an AVF between the PRA and PVE in the proximal forearm, similar to that described by Palmes et al,[19] Jennings et al,[4] and Hull et al.[9] The results from the Ellipsys p-AVF pivotal trial and our retrospective studies have been very promising.[10-14] A systematic review by Yan Wee et al[15] confirmed the efficacy and safety but accurately concluded that given the lack of head-to-head comparisons, superiority could not be established. Inston et al[20] compared p-AVFs created using the WavelinQ (BD Medical, Franklin Lakes, NJ) and surgical rc-AVFs. They reported that the p-AVFs were superior in terms of primary and secondary patency. However, the cohorts were small, with suboptimal secondary patency rates for both groups in the range of 60% to 70%. In addition, the two p-AVF systems have considerable differences. The WavelinQ system uses two catheters (arterial and venous puncture) and fluoroscopy to create a communication between an ulnar or a radial artery and the deep adjacent vein. The Ellipsys system uses a single venous catheter puncture with ultrasound guidance only, creating a permanent fused anastomosis between the PRA and PVE.[21]

All s-AVFs were created by experienced vascular access surgeons aiming for the best possible AVF for each patient, as determined by the preoperative mapping findings and the patient's overall health status and life expectancy. Our outcomes compare favorably

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Table IV. Outcomes for s-AVF and p-AVF groups

Outcome	s-AVF (n = 107)	p-AVF (n = 107)	*P* value
Maturation at 6 weeks	50	65	.02
At 12 months			
Primary patency	86	61	.01
Secondary patency	90	91	NS
Wound infection	9	0.9	.005
Intervention	36	53	.013
Percutaneous	4	41	<.001
Surgical	33	12	<.001
At 24 months			
Primary patency	52	55	NS
Secondary patency	88	91	NS
High flow/steal syndrome	3.7	0	NS
Aneurysm	2.8	0	NS
Intervention	78	70	.21
Percutaneous	42	53	.10
Surgical	36	17	.002

NS, Not significant; *p-AVF,* percutaneous arteriovenous fistula; *s-AVF,* surgical arteriovenous fistula.
Data presented as percentages.

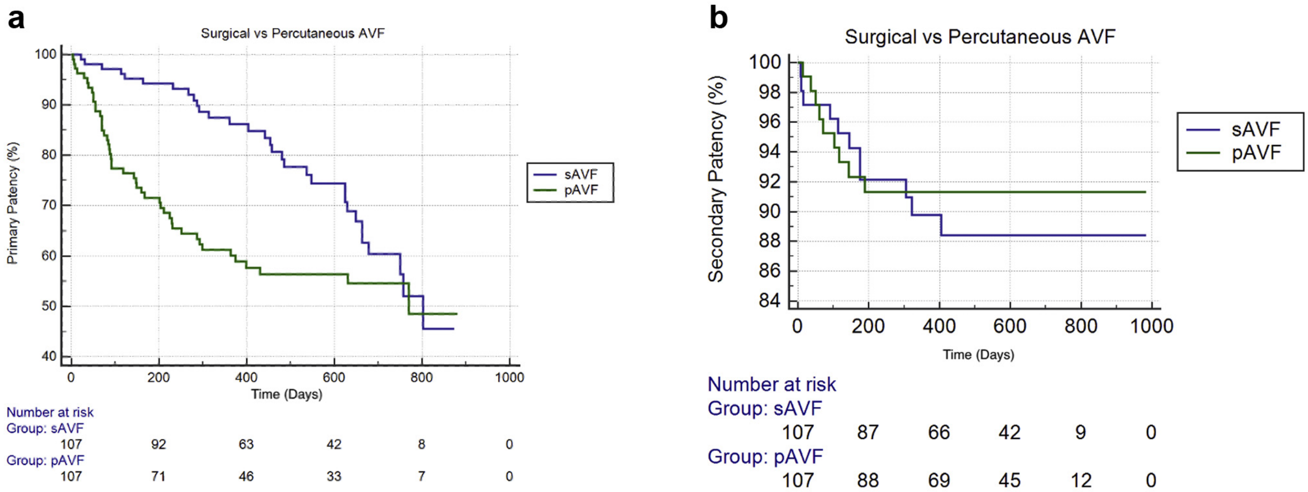

Fig 1. Comparison of patency rates for surgical arteriovenous fistulas *(s-AVFs)* and percutaneous arteriovenous fistulas *(p-AVFs).* **a,** Primary patency. **b,** Secondary patency. *pAVF,* Percutaneous arteriovenous fistula; *sAVF,* Surgical arteriovenous fistula.

with those from other AVF reports. Although an anatomically valid comparison might be performed between surgical PRA-AVFs and p-AVFs created with the Ellipsys system, we believed that comparing the entire upper extremity s-AVF group with the p-AVF group would have value as a “real-world” study evaluating the changing vascular access practice patterns. In the future, the overall results of experienced vascular surgeons creating the best surgical AVFs individualized for each patient will be compared with other groups of vascular surgeons, interventional nephrologists, and/or radiologists creating p-AVFs when feasible, with many of these physicians not having access to open surgery options. In addition, we performed separate comparisons of p-AVFs and distal and elbow s-AVFs and compared the early p-AVF cases with the later p-AVF cases to assess the effect of a learning curve for p-AVFs. Furthermore, even in the best-case scenario of comparing surgical PRA-AVFs and p-AVFs, significant hemodynamic differences still exist because p-AVF creation does not involve any vein branch ligation, which is not the case for PRA-based s-AVFs.

Table V. Outcomes for e-AVF and p-AVF groups

Outcome	e-AVF (n = 47; 100%)	p-AVF (n = 107; 100%)	*P* value
Maturation at 6 weeks, No. (%)	28 (59.6)	70 (65.4)	.48
At 12 months			
Primary patency, %	85	61	.02
Secondary patency, %	86	91	NS
Wound infection, no. (%)	8 (17)	1 (0.93)	.0001
Intervention, no. (%)	21 (44.7)	57 (53.3)	.32
Percutaneous	2 (4.3)	44 (41.1)	<.001
Surgical	19 (40.4)	13 (12.1)	<.001
At 24 months			
Primary patency, %	65	55	NS
Secondary patency, %	83	91	NS
High flow/steal syndrome, No. (%)	3 (3.6)	0 (0)	NS
Aneurysm, No. (%)	2 (4.3)	0 (0)	NS
Intervention, No. (%)	43 (91.5)	75 (70)	.04
Percutaneous	20 (42.6)	57 (53.3)	.22
Surgical	23 (48.9)	18 (16.8)	<.001

e-AVF, Elbow surgical arteriovenous fistula; *p-AVF,* percutaneous arteriovenous fistula.

Table VI. Outcomes for w-AVF and p-AVF groups

Outcomes	w-AVF (n = 60)	p-AVF (n = 107)	*P* value
Maturation at 6 weeks, No. (%)	26 (43.3)	70 (65.4)	.005
At 12 months			
Primary patency, %	86	61	.05
Secondary patency, %	93	91	NS
Wound infection, no. (%)	6 (9.3)	1 (0.93)	.005
Intervention, no. (%)	18 (30)	57 (53.3)	.004
Percutaneous	2 (3.3)	44 (41.1)	.02
Surgical	16 (26.7)	13 (12.1)	<.001
At 24 months			
Primary patency, %	35	55	NS
Secondary patency, %	93	91	NS
High flow/steal syndrome, No. (%)	1 (3.6)	0 (0)	NS
Aneurysm, No. (%)	1 (1.6)	0 (0)	NS
Intervention, No. (%)	40 (66.7)	75 (70)	.64
Percutaneous	25 (41.7)	57 (53.3)	.31
Surgical	15 (25)	18 (16.8)	.2

p-AVF, Percutaneous arteriovenous fistula; *w-AVF,* wrist surgical arteriovenous fistula.

The smaller size anastomosis (4-5 mm) created using the Ellipsys system might explain the more frequent need for percutaneous transluminal angioplasty after p-AVF creation, resulting in higher primary patency rates for s-AVFs. We found a trend toward higher p-AVF secondary patency rates compared with that for e-AVFs, with a flattening of the Kaplan-Meier curve after 1 year for both p-AVFs and w-AVFs, demonstrating that, once established, these AVFs remain stable. We have previously reported that p-AVFs and w-AVFs share common hemodynamic characteristics, including radial artery-based modest flow volume and multiple venous outflow channels.[22] We believe these shared characteristics are key for the creation of stable and safe AVFs in the long term compared with brachial artery-based AVFs, which too often result in a sequence of increasing flow with outflow stenosis, aneurysm formation, and HAIDI, in addition to a greater risk of cardiopulmonary compromise.[23]

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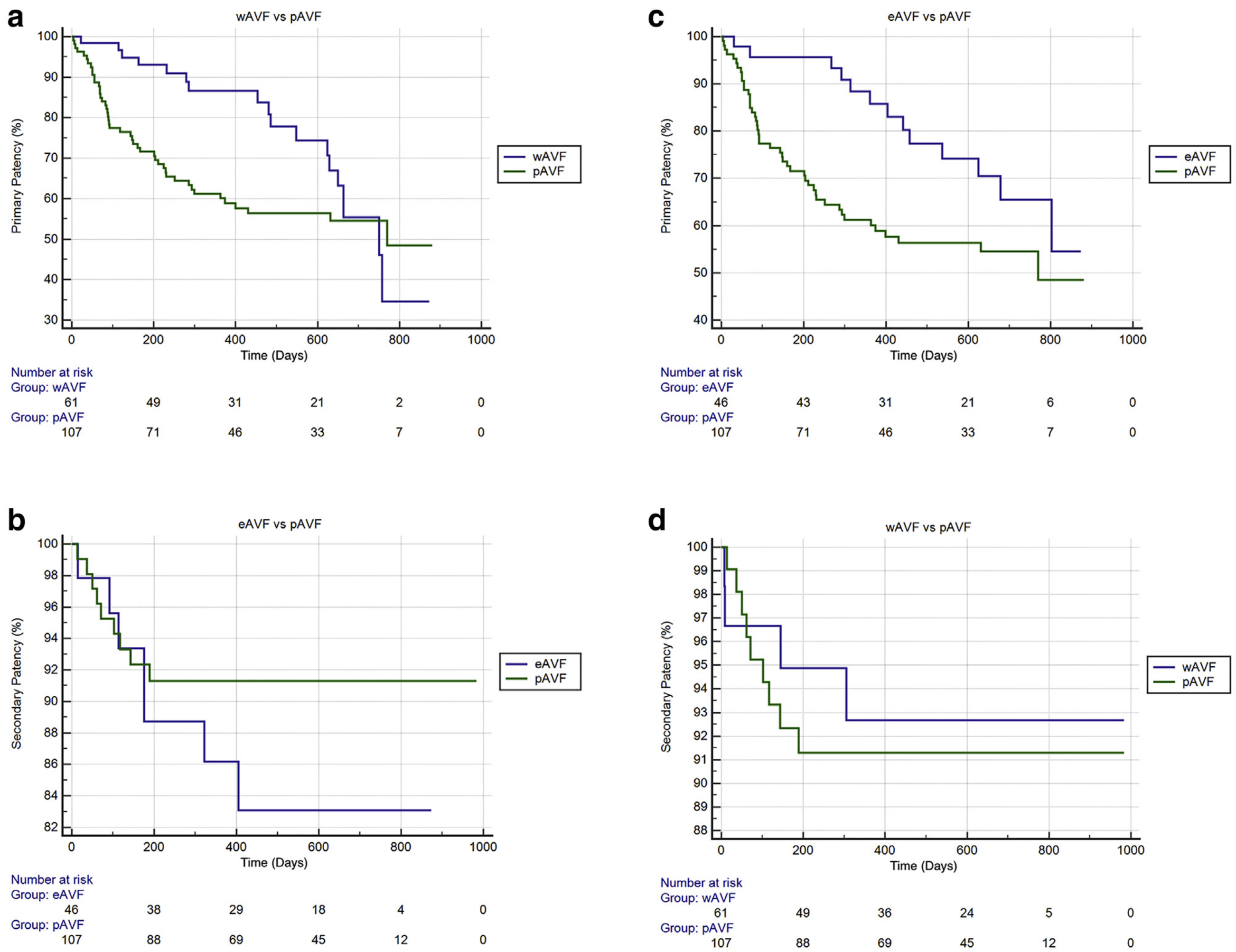

Fig 2. Comparison of patency rates between elbow surgical arteriovenous fistulas (*e-AVFs*) and wrist surgical AVF (*w-AVFs*) vs percutaneous AVF *(p-AVF).* **a,** Primary patency between w-AVFs and p-AVFs. **b,** Secondary patency between w-AVFs and p-AVFs. **c,** Primary patency between e-AVFs and p-AVFs. **d,** Secondary patency between e-AVF and p-AVF. *eAVF,* Elbow surgical arteriovenous fistula; *pAVF,* percutaneous arteriovenous fistula; *wAVF,* wrist surgical arteriovenous fistula.

p-AVFs fared better than s-AVFs in the secondary outcomes, such as wound infection, steal syndrome, and aneurysm formation. Another potential advantage is the relatively short learning curve, teachability, and reproducibility of the Ellipsys technique. Isaac et al[24] described the first completely tele-proctored p-AVF case, which was completed in Switzerland and guided remotely by a proctor in Paris (A.M.) owing to the coronavirus disease 2019 pandemic, without any previous hands-on experience for the operators in Switzerland.

The creation of p-AVFs with Ellipsys was feasible for >60% of patients. In addition, the increasing age of ESRD patients has made w-AVFs less frequently possible or with a greater risk of nonmaturation.[25,26] These factors, combined with the shortage of vascular access surgeons and the long waiting times for scheduling surgical AVF creation, indicate that the Ellipsys system will play an important role in vascular access in the future. The better esthetic results and lack of scarring results in higher patient satisfaction. In addition, the technique offers short procedure times and reliable outcomes and is easy and appropriate to perform in an outpatient office procedure center.

Our study had several limitations, including its retrospective design and unmatched patient groups. Selecting an appropriate s-AVF group for comparison with a p-AVF group was challenging because p-AVFs are not identical to any s-AVF.

CONCLUSION

AVFs created percutaneously with the Ellipsys system had better maturation and patency rates similar to those of s-AVFs constructed by an experienced vascular surgery group with excellent surgical outcomes. The Ellipsys-created p-AVFs had a lower risk of infection, HAIDI, and aneurysm formation. Larger, prospective, randomized

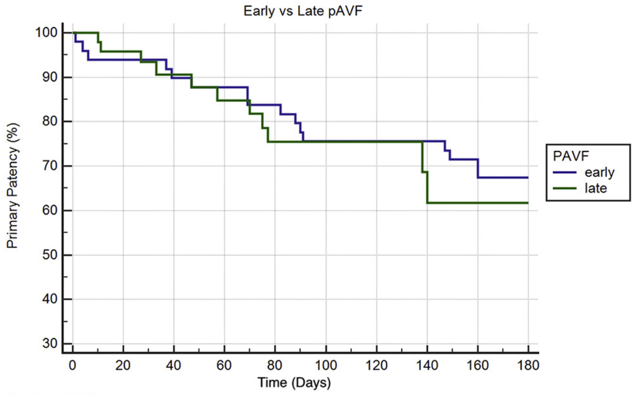

Fig 3. Comparison of primary patency rates between early and late percutaneous arteriovenous fistulas (*p-AVFs*) to assess for potential learning curve effects. *pAVF,* Percutaneous arteriovenous fistula.

multicenter studies are required to confirm these findings.

AUTHOR CONTRIBUTIONS

Conception and design: AM
Analysis and interpretation: AM
Data collection: GH, AM, MA, AC, RDB, BB, WJ
Writing the article: GH, AM
Critical revision of the article: GH, AM, MA, AC, RDB, BB, WJ
Final approval of the article: GH, AM, MA, AC, RDB, BB, WJ
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GH and AM contributed equally to this article and share co-first authorship.
AM and WJ contributed equally to this article and share co-senior authorship.

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