Long Term Results of a Comparative Study of Percutaneous and Surgically Created Proximal Forearm Arteriovenous Fistulae

Robert Shahverdyan [a,*], **Tej I Mehta** [b], **Nicholas Inston** [c], **Klaus Konner** [d], **Shant Vartanian** [e]

[a] Vascular Access Centre, Asklepios Klinik Barmbek, Hamburg, Germany
[b] Department of Radiology, The Johns Hopkins Hospital, Baltimore, MD, USA
[c] Renal Surgery and Transplantation, Queen Elizabeth Hospital Birmingham, Birmingham, UK
[d] Vascular Access Unit, University Hospital of Cologne, Cologne, Germany
[e] Department of Surgery, Division of Vascular and Endovascular Surgery, University of California, San Francisco, CA, USA

WHAT THIS PAPER ADDS

This study is the first comparative effectiveness study between proximal forearm surgical arteriovenous fistula (sAVF) and both available percutaneous arteriovenous fistula (pAVF) devices with long term outcomes. It rigorously compared short and long term results and sheds light on the variances in maturation, follow up procedures, and complications. The findings indicate that although both pAVFs and sAVFs demonstrated high technical success, significantly higher maturation rates for Ellipsys and sAVFs, higher primary patency rates for sAVFs, and lower secondary patency rates for WavelinQ pAVFs were observed, with similar number of re-interventions. The differences in effectiveness and durability among these options underscore the importance of personalised dialysis access choices.

Objective: This retrospective, single centre, comparative effectiveness study aimed to compare the long term outcomes of percutaneous arteriovenous fistula (pAVF) and surgically created arteriovenous fistula (sAVF) created in the proximal forearm for haemodialysis access.

Methods: Data were reviewed from a prospectively maintained database on patients who underwent pAVF or sAVF creation from September 2017 to September 2023. A total of 217 pAVFs (61 WavelinQ and 156 Ellipsys) and 158 sAVFs were analysed. Outcome measures included technical success, maturation, patency, time to first successful use, re-interventions, and complications.

Results: Technical success was 100% for sAVF and Ellipsys, and 93.4% for WavelinQ ($p < .001$). Maturation at four weeks was higher in Ellipsys (78.6%) and sAVF (79.7%) groups than in WavelinQ (64.9%) ($p = .042$). Median time to first cannulation was shortest for Ellipsys (57 days), followed by sAVF (73 days), and longest for WavelinQ (98.6 days) ($p = .048$). Mean follow up was 654 days (interquartile range 164, 1049 days; range 0 − 2061 days). Primary patency was higher in sAVFs than in pAVFs. The Cox proportional hazard ratio (HR) for loss of primary patency was 1.50 for WavelinQ and 1.42 for Ellipsys compared with sAVF ($p = .045$). Secondary patency was statistically significantly lower for WavelinQ (HR 2.76; $p < .001$), but not for Ellipsys (HR 0.74; $p = .33$). Haemodialysis access induced distal ischaemia (HAIDI) was more common in the sAVF group with nine events (5.7%) compared with one for the Ellipsys (0.6%; $p = .008$). Re-intervention rates per patient year were comparable across groups (0.60 *vs.* 0.61 *vs.* 0.69 for sAVF, WavelinQ, and Ellipsys, respectively).

Conclusion: This study indicates that while all access types can provide long term functional haemodialysis access, sAVFs perform better in some outcome domains and pAVFs (particularly Ellipsys) in others, with sAVFs showing higher rates of HAIDI, yet lower rates of juxta-anastomotic stenosis. The findings underscore the importance of personalised vascular access planning, weighing immediate procedural outcomes against long term functionality.

Keywords: Arteriovenous fistula, Dialysis access, Haemodialysis, Long term outcomes, Percutaneous AVF, Surgical AVF
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* Corresponding author. Ruebenkamp 220, D-22307, Hamburg, Germany.
E-mail address: robert.shahverdyan@icloud.com (Robert Shahverdyan).
@robshahverdyan
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INTRODUCTION

Reliable vascular access (VA) is crucial for consistent treatment and improved quality of life in end stage kidney disease (ESKD). While traditional surgical arteriovenous fistulae (sAVFs) have long been used, endovascular/percutaneous AVFs (endoAVF/pAVFs) were introduced in 2018 (WavelinQ, BD and Company, Franklin Lakes, NJ, USA; and Ellipsys, Medtronic Inc., Minneapolis, MN, USA), with most studies focusing on midterm outcomes and non-comparable anatomical sites.[1–4] A major gap in comparative effectiveness research for VA is the long term performance of pAVFs. Other than a single industry sponsored trial, the outcomes for pAVFs reported in other publications have been limited to twenty four months or less.[5–7] Additionally, nearly all studies use a sAVF site that is not anatomically comparable.[1,5,8–10]

The comprehensive VA centre in this study performs all varieties of haemodialysis (HD) access, and both pAVF systems have been incorporated into the VA selection algorithm. To address deficient long term functional outcomes of pAVFs, a single centre experience of more than five years with both systems has been reported and the results were compared with the anatomically closest comparator, the antecubital sAVF (known as Gracz type AVF), which uses the proximal forearm and antecubital arteries and veins with similar outflow veins as the pAVFs.[11,12]

MATERIALS AND METHODS

Between September 2017 and September 2023, 217 pAVFs created with both devices and 158 Gracz sAVFs from 951 VA creations were identified. This study adhered to institutional review board requirements and the Declaration of Helsinki. All procedures were performed at a single VA centre by the same surgeon.

The previously published VA planning protocol describes a patient centred, distal to proximal selection algorithm, starting in the anatomical snuffbox and extending to the proximal forearm.[13] Gracz sAVFs were typically created if pAVF creation was deemed unsuitable or failed.

Nearly 60% of the patient population were eligible for pAVFs.[14] The proximal radial artery (PRA) was used for Ellipsys pAVFs, while WavelinQ pAVFs and sAVFs used either the PRA or proximal ulnar artery. Additionally, sAVF inflow included the antecubital brachial artery (BA), with two WavelinQ pAVFs using the proximal interosseous and distal BA. All pAVF patients had a perforator vein diameter of $\geq$ 2 mm after tourniquet application. The sAVF patients had either the perforator vein or proximal forearm cephalic or basilic vein $\geq$ 2 mm.

All procedures were performed as previously described.[1,13] In sAVF, the cephalic and basilic venous outflow branches were routinely left undisturbed, similar to pAVFs. However, for patients with significant forearm arterial atherosclerosis, early cannulation needs with sufficient intra-operative BA flow ($Q_a \geq$ 500 mL/min), or left ventricular insufficiency (ejection fraction $<$ 30%), banding or ligation of the median cubital vein (MCV) was performed to reduce the risk of developing high flow fistula, which could lead to heart failure or haemodialysis access induced distal ischaemia (HAIDI). Additionally, if the expected outflow was primarily through the basilic vein despite the presence of a suitable cephalic vein, and the cubital veins were too deep for cannulation without a secondary basilic vein transposition (BVT), simultaneous MCV banding was performed during sAVF creation.

Clinical and duplex ultrasound (DUS) examinations were performed at the end of every procedure and during follow up examination on days 1 — 2, week 4, and every three to six months thereafter. The DUS protocol included measuring Q_a in the inflow BA, unless patients had a high arterial bifurcation, in which case the Q_a was measured in the axillary artery.[15] Outflow veins were evaluated by physical examination and ultrasound to determine suitability for cannulation. Indications for re-interventions were left to the judgement of the clinical team based on failed maturation, access dysfunction (difficulty with cannulation, access pressures, excessive bleeding), and or significant ($>$ 30%) flow reduction in either the inflow artery or target vein compared with previous studies and an accompanying identifiable stenosis in the DUS.

Outcome measures and definitions

Outcome measures included technical success, maturation, access failure, time to first successful use, patency, and time from AVF creation to tunnelled cuffed dialysis catheter (TDC) removal in patients with ESKD.[16] Technical success was defined as arterialised fistula flow in the outflow vein, confirmed by DUS at the end of each procedure. Maturation was defined as Qa $\geq$ 500 mL/min with an outflow vein diameter $\geq$ 5 mm and target vein flow $\geq$ 300 mL/min.[17] Functional maturation was achieved when the AVF was successfully used for HD with two needles for six consecutive sessions, allowing TDC removal in patients with ESKD. An AVF was declared abandoned if a new VA was created, regardless of whether the outflow vein remained the same as the index procedure.

Primary patency (PP) was defined as the time from AVF creation to unplanned secondary re-intervention for AVF dysfunction, thrombosis, or AVF abandonment.[16] PP was not impacted by planned balloon angioplasty during the index creation procedure of Ellipsys pAVF or coil embolisation of the brachial vein during the WavelinQ pAVF. Assisted primary patency (APP) was defined as the time from AVF creation to unplanned re-intervention for AVF thrombosis or AVF abandonment. Secondary patency (SP) was defined as the time from AVF creation to AVF abandonment. Time to successful clinical use was the time from AVF creation to successful cannulation for treatment to achieve prescribed dialysis. Time to TDC removal was the time from AVF creation to TDC removal after a successful continuous two needle dialysis was achieved. Any unplanned procedure on the AVF (surgical, endovascular, or hybrid) was defined as an intervention. Interventions were reported as the number of interventions per patient year. Planned secondary transposition, elevation, or lipectomy was not assessed as an unplanned re-intervention. The definition of high flow AVF was the measured $Q_a \geq$ 2 000 mL/min in asymptomatic patients or $\geq$ 1 500 mL/min for patients with HAIDI and

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or cardiopulmonary symptoms. HAIDI and its stages were defined as previously described.[18]

Statistical analysis

Study variables were evaluated using descriptive statistics. Frequencies and percentages were calculated for categorical variables, while median and range or mean ± standard deviation were used for continuous variables. Normality of data distribution was tested using the Kolmogorov–Smirnov or Shapiro–Wilk tests. Analysis of variance (ANOVA) determined the initial between group differences for continuous variables; statistically significant differences were further analysed with pairwise *t* tests using the Bonferroni correction. Associations between categorical variables and AVF groups were assessed using Chi squared or Fisher's exact test as appropriate. Patency rates were evaluated using Cox proportional hazard ratios (HRs) and Kaplan–Meier curves, with HR and 95% confidence interval (CI) reported. Multivariable Cox analyses adjusted for AVF type, patient age, HD status, prior ipsilateral AVF, TDC presence, and follow up days were also conducted. Variables with $p < .20$ in univariable Cox regression were included in the multivariable models. Crude patency rates were calculated as total number of patency events divided by total group size for each given patency outcome. Statistical analyses were performed using SAS 9.4 (SAS Institute, Cary, NC, USA) or R4.2.0 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Demographics

During the study period, 951 VAs were created, with 217 pAVFs and 158 Gracz sAVFs. The WavelinQ group included 61 patients, 21% of whom had previous failed ipsilateral permanent VA. In the Ellipsys group of 156 individuals, 22% had previously failed ipsilateral access. Among the 158 sAVF patients, 42% had previous failed ipsilateral access.

Table 1. Pre-operative demographics and procedural details for patients ($n = 217$) who underwent percutaneous arteriovenous fistula (pAVF) or surgical arteriovenous fistula (sAVF) creation.

Characteristic	sAVF ($n = 158$)	WavelinQ pAVF ($n = 61$)	Ellipsys pAVF ($n = 156$)	*p* value
Age – y	66.1 (19–90)	67.2 (28–92)	65.2 (28–86)	.63
Sex				.006
Female	72 (45.6)	16 (26.2)	49 (31.4)	
Male	86 (54.4)	45 (73.8)	107 (68.6)	
BMI – kg/m^2	28.3 ± 5.96	26 ± 6.54	27.3 ± 6.16	.052
Diabetes	76 (48.1)	28 (45.9)	69 (44.2)	.89
Indication for VA[*]				.24
Dialysis (ESKD)	106 (67.1)	32 (52.5)	92 (59.0)	
Pre-emptive (CKD 5)	41 (25.9)	24 (39.3)	48 (30.1)	
Pre-emptive (CKD 4)	7 (4.4)	5 (8.2)	14 (9.0)	
Apheresis	4 (2.5)	0	3 (1.9)	
Previous kidney transplant	2 (1.26)	3 (4.9)	2 (1.3)	.16
Previous ipsilateral VA	68 (43.0)	13 (21.3)	35 (22.4)	.001
Dialysis modality at time of AVF creation				.10
Haemodialysis	106 (67.1)	32 (52.5)	92 (59.0)	
Peritoneal dialysis	3 (1.9)	0	0	
Pre-dialysis	49 (31.0)	29 (47.5)	64 (41.0)	
TDC at time of AVF creation	86 (54.4)	28 (45.9)	73 (46.8)	.32
Technical success	158 (100)	57 (93.4)	156 (100)	<.001
Procedure time – min	69.7 (34–147)	62.4 (28–150)	14.1 (8–31)	<.001
Inflow artery[†]				<.001
Brachial	71 (44.9)	1 (1.7)	0 (0)	
Radial	64 (40.5)	28 (49.1)	156 (100)	
Ulnar	23 (14.6)	27 (47.4)	0 (0)	
Interosseous	0 (0)	1 (1.7)	0 (0)	
Outflow vein[*,†]				<.001
Cephalic	68 (43.0)	20 (35.1)	43 (27.6)	
Basilic	37 (23.4)	10 (17.5)	14 (9.0)	
Split (cephalic and basilic)	38 (24.1)	16 (28.1)	67 (42.9)	
Split (cephalic dominant)	14 (8.9)	3 (5.3)	26 (16.7)	
Split (basilic dominant)	1 (0.6)	0 (0)	6 (3.8)	
Brachial	0 (0)	8 (14.0)	0 (0)	
Brachial vein coil embolisation	0 (0)	43 (70.5)	0 (0)	<.001

Data are presented as median (minimum–maximum), *n* (%), or mean ± standard deviation. sAVF = surgical arteriovenous fistula; pAVF = percutaneous arteriovenous fistula; BMI = body mass index; VA = vascular access; ESKD = end stage kidney disease; CKD = chronic kidney disease; TDC = tunnelled cuffed dialysis catheter.

[*] Fisher–Freeman–Halton test.

[†] Inflow artery and outflow vein details for WavelinQ calculated for technically successful cases (57/61).

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Patient demographics are shown in Table 1. A statistically significant difference in sex distribution was observed, with females representing 45.6% in the sAVF group, 31.4% in the Ellipsys group, and 26.2% in the WavelinQ group ($p = .006$).

The PRA was the arterial inflow in all Ellipsys pAVFs (Table 1). The sAVF group had 71 cases using the BA, as well as one WavelinQ pAVF. The proximal ulnar artery was used in 23 sAVFs and 27 WavelinQ pAVFs. Statistically significantly more sAVFs used the cephalic vein for venous outflow than in the Ellipsys group. The Ellipsys group more frequently used split superficial outflow, and the WavelinQ group more often used brachial vein outflow ($p < .001$).

Peri-operative outcomes

Technical success was achieved in 100% of sAVFs and Ellipsys pAVFs, and 93.4% of WavelinQ pAVFs ($p < .001$). In four WavelinQ pAVFs, the arteriovenous anastomosis could not be created despite proper introduction, alignment, and activation of both catheters, so the remaining 57 patients were analysed for post-procedural outcomes. Mean procedure time varied statistically significantly, with sAVFs taking the longest (mean 69.7 ± 15.5 minutes) and Ellipsys the shortest (mean 14.1 ± 4.4 minutes) ($p < .001$). During WavelinQ pAVF creation, per protocol brachial vein coil embolisation was performed in 70.5% of cases. Additionally, four patients (2.6%) in the Ellipsys group underwent simultaneous transradial angioplasty of the PRA and cubital veins due to spasm. One (1.6%) WavelinQ pAVF had peri-operative angioplasty of both the PRA and vein. Nineteen sAVFs (12.0%) underwent simultaneous banding ($n = 14$) or ligation ($n = 5$) of the MCV in dual outflow anatomies.

Maturation

At four weeks, maturation rates were 78.6% for Ellipsys, 79.7% for sAVFs, and 64.9% for WavelinQ. Statistically significantly more AVFs matured in the Ellipsys and sAVF groups than in WavelinQ ($p = .042$ and $p = .033$, respectively). No statistically significant difference was found between Ellipsys and sAVFs. Maturation at study completion was 90.3%, 89.7%, and 77.2% for Ellipsys, sAVFs, and WavelinQ, respectively, with statistically significantly higher rates in Ellipsys and sAVFs ($p = .021$ and $p = .011$, respectively). Unassisted maturation was 74.7% for Ellipsys, 81.3% for sAVFs, and 66.7% for WavelinQ, with sAVFs showing a statistically significant advantage over WavelinQ ($p = .021$). Functional maturation for patients with ESKD was 91.4%, 84.7%, and 78.3% for Ellipsys, sAVFs, and WavelinQ, respectively, with statistically significantly more Ellipsys than WavelinQ ($p < .001$) AVFs cannulated. Functional maturation relative to sAVFs was not statistically significantly different for either WavelinQ (HR 0.67; $p = .13$) or Ellipsys (HR 1.29; $p = .12$) (Table 2; Supplementary Table S1; Fig. 1). Crude functional maturation rates were 100% for both Ellipsys and sAVFs, and 94.4% for WavelinQ. The log rank Chi squared test statistic was 23.2 ($p < .001$). Presence of a TDC was associated with decreased hazard of functional maturation (HR 0.27, 95% CI 0.19 − 0.39; $p < .001$). In multivariable analysis, WavelinQ pAVFs had a statistically significantly lower maturation rate (HR 0.52, 95% CI 0.29 − 0.95; $p = .031$). The HD patients had statistically significantly higher maturation rates (HR 2.50, 95% CI 1.16 − 5.34; $p = .002$), while those with a TDC at surgery had a statistically significantly lower hazard (HR 0.22, 95% CI 0.15 − 0.32; $p < .001$).

Mean days to cannulation from AVF creation were 72.6 ± 71.7 for sAVFs, 98.61 ± 65.5 for WavelinQ, and 56.7 ± 52.5 for Ellipsys. Statistically significant differences in cannulation times were observed between sAVF and WavelinQ ($p = .048$) and between Ellipsys and WavelinQ ($p = .003$), but not between sAVF and Ellipsys ($p = .12$).

Re-interventions

In total, 212 patients underwent re-interventions. Numerically, secondary procedures were more frequent in the Ellipsys group, with an mean total number of procedures of 1.36 compared with 1 in sAVF and 0.9 in WavelinQ groups, although there were no statistically significant differences in the mean number of secondary procedures between groups ($p = .62$). Per patient year, there were mean re-interventions of 0.60 ± 2.54, 0.61 ± 2.20, and 0.69 ± 2.48 for sAVFs, WavelinQ, and Ellipsys groups, respectively ($p = .98$).

The rate of juxta-anastomotic stenosis (JAS) among the sAVF, WavelinQ, and Ellipsys groups was 30.1%, 54.4%, and 51.3%, respectively, with statistically significantly more JAS seen in both pAVF groups ($p < .001$). These were treated by balloon angioplasty, but eight patients (seven Ellipsys and one WavelinQ) required a stent graft to treat the residual stenosis and simultaneously cover the deep venous outflow.

The rate of cephalic arch stenosis (CAS) was 3.5%, 8.5%, and 0% for Ellipsys, sAVF, and WavelinQ groups, respectively ($p = .083$). All CAS were treated percutaneously. Of those, one Ellipsys pAVF patient had high flow AVF. Eight of ten sAVF and five of five Ellipsys pAVF patients had previous treatment of JAS.

Secondary procedures included MCV banding, brachial vein ligation, BVT, and cephalic vein transposition or elevation. Eighteen (11.4%), four (7.0%), and 25 (16.0%) individuals in the sAVF, WavelinQ, and Ellipsys groups underwent MCV banding ($p = .18$). Statistically significantly more individuals in the WavelinQ and Ellipsys groups ($p < .001$) underwent brachial vein ligation. Also, statistically significantly more patients in the sAVF group underwent BVT ($p = .002$).

Patency

The pAVFs created with both systems had higher hazard of PP loss than sAVFs (Fig. 2). The HR for PP loss among pAVFs created with WavelinQ relative to sAVFs was 1.50 (95% CI 1.04 − 2.16; $p = .033$). The HR for loss of PP among pAVFs created with Ellipsys relative to sAVFs was 1.40 (95% CI 1.07 − 1.88; $p = .004$). The median days to PP loss were 333, 178, and 154 for sAVFs, Ellipsys, and WavelinQ, respectively. Crude PP rates were 43.0%, 30.1%, and 26.3% for sAVFs, Ellipsys, and WavelinQ, respectively, with crude median times to PP loss of 199, 145, and 98 days, respectively. Prior ipsilateral AVF was associated with an increased

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Table 2. Post-procedural details for patients (n = 217) who underwent percutaneous arteriovenous fistula (pAVF) or surgical arteriovenous fistula (sAVF) creation.

	sAVF (n = 158)	WavelinQ pAVF (n = 57)	Ellipsys pAVF (n = 156)	p value		
				Ellipsys/ WavelinQ	sAVF/ WavelinQ	Ellipsys/ sAVF
Maturation at four weeks	110 (79.7)	37 (64.9)	121 (78.6)	.042	.033	.81
Patients with missing information	20	4	2			
Matured vascular access in total	139 (89.7)	44 (77.2)	139 (90.3)	.021	.011	.87
Patients with missing information	3	0	2			
Unassisted maturation	126 (81.3)	38 (66.7)	115 (74.7)	.67	.020	.16
Patients with missing information	3	4	2			
Functional maturation[*]	116 (84.7)	36 (78.3)	117 (91.4)	<.001	.089	.51
Patients with missing information	4	0	7			
Patients not requiring HD at time of study termination	17	11	21			
Days to AVF cannulation	72.6 ± 71.7	98.61 ± 65.5	56.7 ± 52.6	.003	.048	.12
High flow AVF, ≥2 L/min	15 (10.3)	8 (14.0)	10 (6.4)	.077	.34	.31
HAIDI[†]	9 (5.7)	0	1 (0.6)	N/A	N/A	**.022**
Secondary procedures to maintain patency						
Total	162	55	212	.096	.77	.052
Mean	1	0.9	1.36			
Min	0	0	0			
Max	5	5	10			
Interventions per patient year	0.60	0.61	0.69	.98		
Surgical re-intervention	60 (38.0)	15 (26.3)	67 (430.0)	.047	.16	.43
Endovascular re-intervention	54 (34.2)	24 (42.1)	88 (56.4)	.091	.37	<.001
Juxta-anastomotic stenosis − %	30.1	54.4	51.3	.78	.003	<.001
Cephalic arch stenosis[‡] − %	8.47	0.0	3.47	.52	.13	.15
Access abandonment	24 (15.2)	23 (40.4)	19 (12.2)	<.001	<.001	.44

Data are presented as n (%), mean ± standard deviation, or n, unless otherwise stated. sAVF = surgical arteriovenous fistula; pAVF = percutaneous arteriovenous fistula; HD = haemodialysis; HAIDI = haemodialysis access indued distal ischaemia; N/A = not applicable; min = minimum; max = maximum.

* Only for patients who reached HD or apheresis.

† Fisher exact test.

‡ Only for patients with cephalic or split venous outflow.

risk of PP loss (HR 1.48, 95% CI 1.08 − 2.03; p = .011). The log rank test Chi squared statistic was 11.91 (p = .062). In multivariable Cox regression, no individual variables statistically significantly affected the model.

For APP (Fig. 3), there was no statistically significant difference between sAVFs and WavelinQ (HR 1.30, 95% CI 0.79 − 2.13; p = .31), with median time to event of 1 359 days for WavelinQ and 1 749 days for sAVFs. Similarly, no

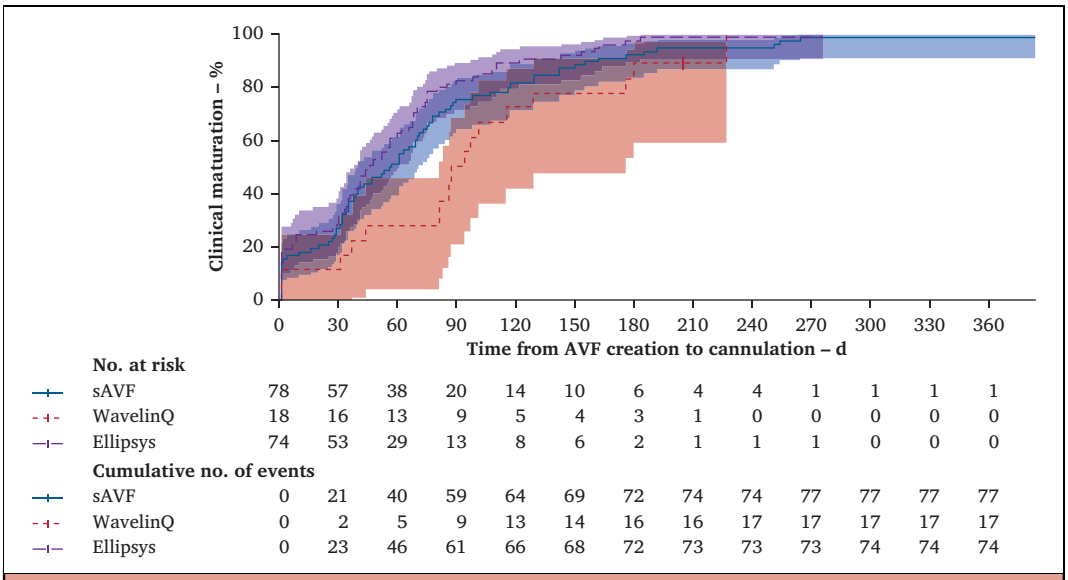

Figure 1. Cumulative Kaplan–Meier estimate of arteriovenous fistula (AVF) clinical maturation rates. Log rank test statistic = 23.2, p < .001. Shaded areas represent 95% confidence intervals. sAVF = surgically created AVF.

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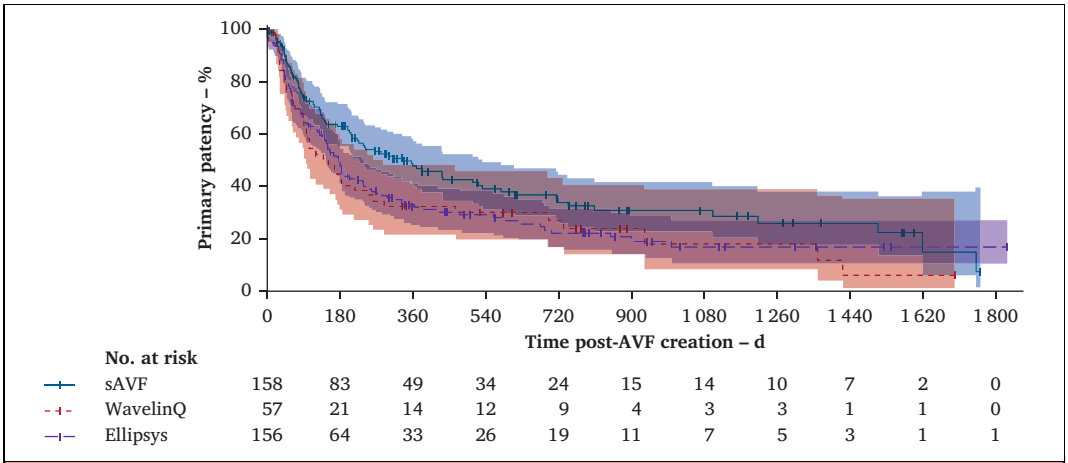

Figure 2. Cumulative Kaplan–Meier estimate of arteriovenous fistula (AVF) primary patency rates. Log rank test statistic = 7.60, $p = .020$. Both WavelinQ and Ellipsys percutaneous AVFs had statistically significantly higher hazard ratios of primary patency loss than surgically created arteriovenous fistulae (sAVFs). Shaded areas represent 95% confidence intervals.

difference was observed between sAVFs and Ellipsys (HR 0.995, 95% CI 0.47 — 1.11; $p = .14$). Median time to event was not reached for Ellipsys. Crude APP rates were 69.0%, 76.3%, and 59.6% for sAVFs, Ellipsys, and WavelinQ, with crude median times to APP loss of 377.5, 478.5, and 334 days, respectively. The log rank test Chi squared statistic was 10.99 ($p = .091$). In multivariable Cox regression, no individual variables statistically significantly affected the model.

For SP loss, WavelinQ had higher hazard than sAVFs (HR 2.76, 95% CI 1.56 — 4.90; $p < .001$), with median time to event of 1 359 days (Fig. 4). There was no statistically significant difference between sAVFs and Ellipsys (HR 0.74, 95% CI 0.41 — 1.36; $p = .33$). Median time to event was not reached for either sAVF or Ellipsys groups. The VA abandonment rates statistically significantly differed, with the highest rate in WavelinQ at 40.4% ($p < .001$) (Table 2). Crude SP rates were 84.8%, 87.8%, and 59.6% for sAVFs, Ellipsys, and WavelinQ, respectively, with crude median times to SP loss of 425, 669, and 334 days, respectively. The log rank test Chi squared statistic was 21.8 ($p < .001$). In multivariable Cox regression, WavelinQ was associated with a statistically significantly greater hazard of SP loss (HR 3.62, 95% CI 1.64 — 8.01; $p < .001$) (Supplementary Tables S2 — S4).

Dialysis catheter dwell time

There were 86 sAVF (54.4%), 28 WavelinQ (45.9%), and 73 (46.8%) Ellipsys patients who underwent their AVF creation with prior TDC in place. Mean TDC dwell time was 147.07 ± 107.84, 220.53 ± 178.46, and 148.36 ± 101.03 days for sAVF, WavelinQ, and Ellipsys, respectively (Fig. 5). History of ESKD was associated with increased hazard of TDC dwell time in univariable (HR 8.37, 95% CI 1.10 — 63.70; $p = .042$) but not multivariable analysis (Supplementary Table S5).

Long term complications

The mean follow up was 654 days (interquartile range 164, 1 049 days; range 0 — 2 061 days). HAIDI occurred more frequently in the sAVF group, with nine events (5.7%)

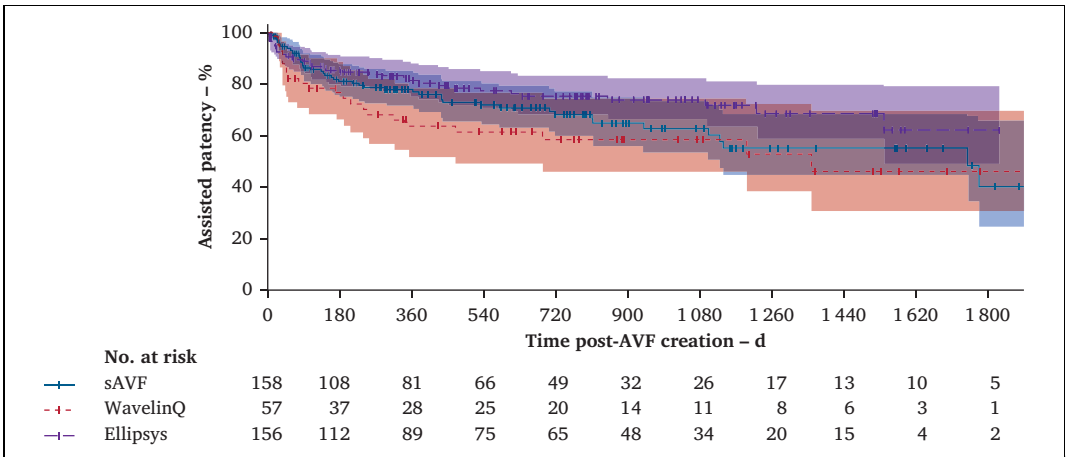

Figure 3. Cumulative Kaplan–Meier estimate of arteriovenous fistula (AVF) assisted primary patency rates. Log rank test statistic = 5.20, $p = .072$. No statistically significant differences were noted between any AVF types. Shaded areas represent 95% confidence intervals. sAVF = surgically created AVF.

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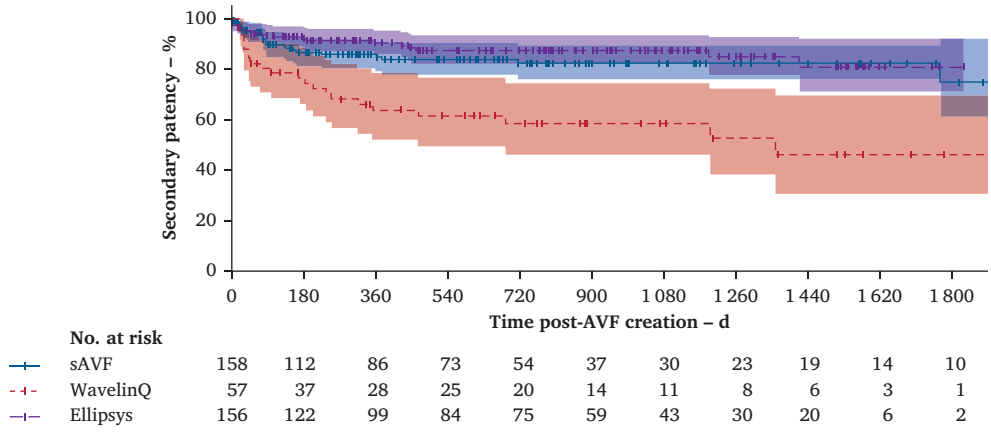

Figure 4. Cumulative Kaplan–Meier estimate of arteriovenous fistula (AVF) secondary patency rates. Log rank test statistic = 23.2, $p < .001$. WavelinQ percutaneous arteriovenous fistulae (pAVFs) had a higher hazard ratio of secondary patency loss than surgically created arteriovenous fistulae (sAVFs). There was no statistically significant difference between Ellipsys pAVFs and sAVFs. Shaded areas represent 95% confidence intervals.

compared with none in WavelinQ and one in Ellipsys (0.6%; $p = .008$). Among the nine sAVF patients with HAIDI, three had stage 1 – 2a and remained under surveillance, two underwent proximalisation of arterial inflow, two had banding for flow reduction, and two refused intervention, being lost to follow up after 89 and 793 days. Three of these patients had high flow AVF.

There were no statistically significant differences in the prevalence of high flow AVFs: 15 (10.3%) in sAVF, ten (6.4%) in Ellipsys, and eight (14%) in WavelinQ groups ($p = .19$). Banding was performed in nine of 15 patients, one patient is scheduled for intervention, one refused, and four remain under surveillance. In pAVFs, banding typically redirects the flow into the deep veins. Among Ellipsys patients, six of ten were treated, one is scheduled for a procedure, and three remain under surveillance. Four MCV bandings were performed to reduce basilic vein flow in dual outflow patients, and two aneurysmorrhaphies of the cubital vein were conducted. For WavelinQ, flow reduction was achieved through deep vein ligation or coiling in four patients and MCV banding in one, which was later abandoned after a transbrachial vein placement of a covered stent into the juxta-anastomotic ulnar vein five years later, closing the ulnar–ulnar pAVF anastomosis.[19] Of the remaining three patients, one died and three remain under surveillance.

DISCUSSION

These findings indicate that all three access types, sAVFs, Ellipsys pAVFs, and WavelinQ pAVFs, can provide reliable long term access for HD, although there are differences in

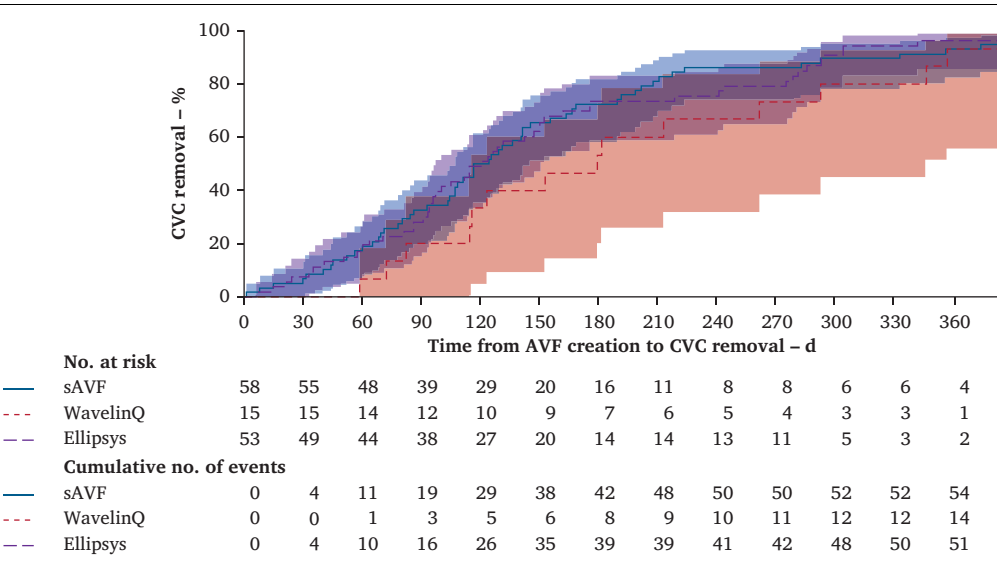

Figure 5. Cumulative Kaplan–Meier estimate of time to dialysis catheter removal. Log rank test statistic = 23.2, $p < .001$. Shaded areas represent 95% confidence intervals. sAVF = surgically created arteriovenous fistula; CVC = central venous catheter.

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re-interventions, maturation time, and management of complications. These results can guide personalised dialysis access decisions. Technical success was high across all methods, but procedure duration for Ellipsys pAVF was statistically significantly shorter (mean 14.1 minutes) than WavelinQ pAVF (62.4 minutes) and sAVF (69.7 minutes). There was a higher proportion of female patients in the sAVF group (45.6%) *vs*. either pAVF device, which was probably due to generally smaller vessel size of radial and or ulnar vessels, hence excluding them from pAVF eligibility.

Maturation rates were generally high, with the sAVFs (89.7%) and Ellipsys (90.3%) outperforming WavelinQ (77.2%). Early re-interventions were more common with WavelinQ, indicating possible access issues that could impact patient quality of life. Unassisted maturation was higher in sAVFs than WavelinQ (81.3% *vs*. 66.7%; $p = .020$), with no statistically significant differences between sAVF and Ellipsys or Ellipsys and WavelinQ. The mean time to cannulation was shorter for sAVFs (73 days) and Ellipsys (57 days) compared with WavelinQ (98 days), although TDC dwell time was similar across groups. The challenges in pAVF cannulation probably require additional procedures. Advantages of multiple outflow pAVFs, such as reduced pressurisation and fewer aneurysms, are offset by cannulation challenges.

Re-interventions were common across groups, with 0.60 − 0.69 interventions per patient year. JAS was observed in roughly 30% of the sAVF population, consistent with previous studies, but was more frequent in both pAVFs (51% and 54%; $p < .001$).[20,21] This might be due to additional inflammation from thermal or radiofrequency devices, barotrauma from procedural angioplasty, and the flow dynamics at the anastomosis.[22] CAS was more prevalent in sAVFs (6.3%), but not statistically significantly compared with WavelinQ (0%) and Ellipsys (3.2%). HAIDI was more common in sAVFs (5.7%) due to larger inflow arteries and high flow AVFs.

Managing high flow pAVFs presents challenges, as banding may redirect flow into the deep system rather than reduce flow. Banding the basilic vein was aimed to redirect flow to the higher resistance cephalic vein. In some cases, stent grafts placed through the arteriovenous anastomosis effectively managed flow without complications. Long term durability was similar for sAVFs and Ellipsys pAVFs, with WavelinQ showing higher access abandonment, probably due to juxta-anastomotic lesions, aligning with recent trial results.

There were several limitations inherent to the study design, including selection bias as the included patients may not have been representative of the broader population. Retrospective analyses can introduce information bias due to incomplete or inaccurate data. Additionally, this study was from a single high volume centre of excellence in VA surgery and the findings might have been influenced by the centre's and surgeon's specific experience, which limits generalisability to other populations. Furthermore, having a higher number of previously failed ipsilateral VAs in the sAVF group (by being the most proximal access type), a higher frequency of failures could be expected. Also, the differences in costs for index procedure need to be considered and vary based on country of practice. Finally, the lack of randomisation in such studies makes it challenging to establish causality for specific outcomes.

Conclusions

This study indicates that while both sAVF and pAVF types can provide long term functional access, sAVFs perform better in some, and pAVFs (particularly Ellipsys) in other outcome domains, with sAVFs showing higher HAIDI rates yet lower rates of JAS. The findings underscore the importance of personalised VA planning, weighing immediate procedural outcomes against long term functionality.

CONFLICTS OF INTEREST

Within the past two years, R.S. is or was a consultant for Becton, Dickinson and Company/Bard, Laminate Medical, Medtronic, Bluegrass Vascular, VentureMed, and Xeltis BV, and serves as Scientific Advisory Board member including stock options for Venova Medical and reports speaker fees from W. L. Gore & Associates, BrosMed Medical, Becton, Dickinson and Company, and Medtronic and support for attending meetings and or travel from Becton, Dickinson and Company, Medtronic and VentureMed. N.I. reports speaker fees and support for attending meetings and or travel from Becton, Dickinson and Company/Bard. S.V. is or was a consultant for Boston Scientific and reports stock options and patents for Venova Medical. The other authors have not identified a conflict of interest.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2025.01.020.

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