NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of percutaneous endovascular forearm arteriovenous fistula creation for haemodialysis access

Haemodialysis removes waste products and excess fluid from the blood when the kidneys have stopped working properly. An arteriovenous fistula is a connection created to allow haemodialysis by joining a vein to an artery, usually in the forearm. Blood from the artery goes into the vein, which becomes bigger over a few weeks. This makes it possible to put 2 large needles into the vein so that blood can be taken out of the body, sent through the haemodialysis machine, and returned. Usually, the arteriovenous fistula is created surgically as an open procedure. In this procedure, the arteriovenous fistula is created by inserting 2 thin tubes (catheters) through the forearm skin (percutaneous). One tube goes into an artery and the other goes into a vein (endovascular). The tubes are positioned close to each other, sometimes using magnets, to bring the artery and vein together. Radiofrequency energy, or heat and pressure, from the tubes is then used to join the artery and vein together creating the fistula. The aim is to avoid the need for open surgery.

Contents

Abbreviations

Word or phrase	Abbreviation
Arteriovenous fistula	AVF
Arteriovenous graft	AVG
Central venous catheter	CVC
Confidence interval	CI
Distal revascularisation and interval ligation	DRIL
Endovascularly created arteriovenous fistula	EndoAVF
Hazard ratio	HR
Perforating vein of the elbow	PVE
Proximal radial artery	PRA
Standard deviation	SD
Surgically created arteriovenous fistula	SAVF

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in January 2021 and updated in June 2021.

Procedure name

- Percutaneous endovascular forearm arteriovenous fistula creation for haemodialysis access

Professional societies

- British Society of Interventional Radiology
- The Renal Association
- British Renal Society

Description of the procedure

Indications and current treatment

Chronic (long-term) haemodialysis is used to treat advanced chronic kidney disease in many people who have renal replacement therapy.

An AVF is considered the best type of vascular access for haemodialysis. The preferred way of creating such access is to surgically join an artery and vein together in the distal forearm (radiocephalic fistula). However, other anatomical sites may be used. Alternative surgical approaches for vascular access include AVGs and placing tunnelled catheters into a large vein. A minimally invasive, percutaneous, endovascular procedure is another way of creating an AVF.

What the procedure involves

This procedure can be done using different systems, and is usually done in a day-case facility under local anaesthesia, with or without conscious sedation. Using ultrasound or fluoroscopic guidance, 2 small needles are inserted into an artery and a vein in the proximal forearm, that is, the radial, ulnar or brachial artery and adjacent vein. Thin, flexible, specially designed catheters are then advanced and positioned by guidewires in the chosen vessels. The catheters are aligned close to each other (using inbuilt magnets or mechanically, depending on the system). The arterial and venous walls are then fused side to side using heat and pressure, or a small burst of radiofrequency energy released from the catheters. This creates an AVF between the target vessels. The catheters are then removed. High-flow arterial blood passes through the vein and, with time, arterialises. This allows needles to be inserted into the vein to provide vascular access during haemodialysis.

The exact technique may vary slightly depending on the device used.

Efficacy summary

Technical success (successful creation of an AVF)

IP overview: Percutaneous endovascular forearm arteriovenous fistula creation for haemodialysis access

In a systematic review and meta-analysis of 7 studies (with 300 patients) who had endoAVF creation for end-stage renal disease, the pooled overall technical success rate was 98% (95% CI, 95% to 99%; I^2=0%; p=0.487). Subgroup analysis showed that the pooled technical success rate was 99% for the everlinQ system (95% CI, 96% to 100%; I^2=0%; 4 studies) and 95% for the Ellipsys system (95% CI, 91% to 98%; I^2=0%; 3 studies; Yan Wee 2020).

In a prospective registry of 60 patients with endoAVFs, there was technical success in 100% (60/60) of patients (Hull 2020).

In a retrospective case series of 234 patients who had an endoAVF creation for end-stage renal disease and predialysis, there was technical success in 99% (232/234) of patients (Mallios 2020).

In a retrospective case series of 105 patients with endoAVF creation, there was technical success in 100% (105/105) of patients (Beathard 2020).

In a retrospective case series of 100 patients with endoAVF creation, there was technical success in 99% (99/100) of patients (97% [34/35] using the WavelinQ system and 100% [65/65] using the Ellipsys system; p=0.35; Shahverdyan 2020).

In a matched comparative case series of 70 patients (30 with endoAVFs and 40 with SAVFs), there was procedural success in 97% (28/29) of patients in endoAVF group and 93% (35/38) of patients in SAVF group (p=0.6; Inston 2020).

AVF maturation and usability

In the systematic review of 7 studies, the overall pooled 90-day maturation rate was 89% (95% CI, 84% to 94%; I^2=21%; p=0.283). Subgroup analysis showed that the rate was 88% for the everlinQ system (95% CI, 81% to 94%; I^2=0%; 4 studies) and 89% for the Ellipsys system, (95% CI, 84% to 94%; I^2=0%; 3 studies; Yan Wee 2020).

In the prospective registry of 60 patients, at a mean of 32 days, 67% (40/60) of AVFs needed maturation procedures to make them suitable for 2-needle cannulation haemodialysis (defined as a palpable target vein, 500 ml/min flow and 5 mm diameter). There was then 90-day endoAVF maturation (defined as brachial artery flow of 500 ml/min and a target vein of 4 mm) in 97% (58/60) of patients. There was clinical success (defined as 2-needle cannulation with dialysis at the prescribed rate as determined by the dialysis centre during 2 of 3 dialysis sessions) in 87% (47/54) of endoAVFs at a mean of 66 days (Hull 2020).

In the retrospective case series of 100 patients, there was maturation by 4 weeks in 63% (60/95) of patients in whom the procedure had been technically successful (54% [19/35] using the WavelinQ system and 68% [41/60] using Ellipsys device; p=0.17). The median time to cannulation was 68 days overall (range 1 to 180), 60 days for the Ellipsys group (range 1 to 164) and 90 days for the WavelinQ group (range 1 to 180; p=0.36). Successful endoAVF use in dialysis was established in 80% (31/39) of patients using the Ellipsys device and 58% (14/24) of patients using the WavelinQ device (p=0.071; Shahverdyan 2020).

In the retrospective case series of 105 patients, there was a physiologically mature AVF (defined as blood flow of more than 500 ml/min and a target vein internal diameter of more than 4 mm) in 98% (103/105) of patients. There was a clinically functional AVF (defined as supporting 2-needle dialysis according to the patient's prescription) in 95% (100/105) of patients (Beathard 2020).

In the retrospective case series of 234 patients, the average time to maturation (for patients both predialysis and having dialysis) was 4 weeks (range 1 to 12 weeks). There was successful cannulation after less than 2 weeks of the endoAVF creation in 10% (24/234) of patients (Mallios 2020).

In the matched comparative case series of 70 patients, mean time from formation to use (2-needle cannulation) was 130±86 days and 141±118 days respectively (p=0.66; Inston 2020).

In a retrospective comparative case series of 214 patients (107 with endoAVFs and 107 with SAVFs), the maturation rate at 6 weeks was higher for endoAVFs (65% compared with 50%; p=0.02). Subgroup analysis showed that there were no statistically significant differences in maturation rate between endoAVFs and elbow-SAVFs (65% compared with 60%; p=0.48). However, radiocephalic SAVFs reported delayed maturation (43% compared with 65%; p=0.005; Harika 2021).

Secondary procedures and interventions used in maturation and maintenance of an endoAVF

In the registry of 60 patients, 70 maintenance procedures were done in 63% (38/60) of patients at a mean 130±76 days (range, 27 to 333). Procedures included: 63 balloon dilations; 2 stenting; 14 deep embolisations; 5 branch embolisations; 6 percutaneous bandings; 5 thrombectomies; and 1 valvulotomy. In these patients, the mean target vein blood flow volume increased from 238±509 ml/min to 798±356 ml/min (p<0.0001; Hull 2020).

In the case series of 234 patients, there was conversion to a new surgical AVF or AVG in 1% (3/234) of patients. Banding of the pre-anastomotic PRA for flow reduction was needed in 1 patient (with arm swelling because of subclavian vein stent occlusion). Balloon angioplasty of the anastomosis was reported in 35% (94/234) of patients and superficialisation of deep outflow veins because of difficult cannulation was reported in 11% (24/234) of patients (half of them had a basilic vein transposition and the other half had a surgical lipectomy for a deep cephalic vein; Mallios 2020).

In a propensity scored matching cohort study comparing endoAVF with SAVF in 120 patients, patients with both incident and prevalent end-stage kidney disease who had endoAVF needed fewer interventions compared with matched patients who had SAVF. The total event rate was 0.74 per patient-year for incident patients with endoAVF compared with 7.22 per patient-year for matched incident patients with SAVF ($p<0.0001$). Similarly, in matched prevalent patients, the event rate was 0.46 per patient-year for endoAVF compared with 4 per patient-year for SAVF ($p<0.0001$; Arnold 2019).

In the retrospective case series of 100 patients, interventions were done in 28% (33/65 Ellipsys) and 27% (15/35 WavelinQ) of patients, and the number of interventions per patient-years was 0.96 with Ellipsys and 0.46 with WavelinQ (Shahverdyan 2020).

In the retrospective comparative case series of 214 patients, at 12 months, patients who had endoAVFs had higher rates of secondary percutaneous interventions than patients with SAVFs (41% compared with 4%; $p<0.001$). But the need for surgical interventions was lower (12% compared with 33%; $p<0.001$). At 24 months, there were similar rates of percutaneous interventions with SAVFs and endoAVFs (42% compared with 53%; $p=0.1$) but more surgical interventions were needed with SAVFs (36% compared with 17%; $p=0.002$; Harika 2021).

Longevity of an AVF (patency)

In the systematic review of 7 studies, the overall pooled 6-month patency rates were 92% (95% CI, 88 to 95%; $I^2=0\%$; $p=0.780$) and the overall 12-month patency rates were 86% (95% CI, 80 to 91%; $I^2=0\%$; p=not significant). Subgroup analysis showed that. at 6 months, the rate was 93% for the everlinQ system (95% CI, 86 to 97%; $I^2=0\%$; 4 studies) and 91% for the Ellipsys system (95% CI, 85 to 95%; $I^2=0\%$; 3 studies; Yan Wee 2020).

In the prospective registry of 60 patients, the cumulative patency rate was 96% at a mean 375.2±9.7 days and functional patency was 94% at a mean 321.4±7.3 days (Hull 2020).

In the retrospective case series of 234 patients, the 1-year primary patency rates were 54%, the primary-assisted rates were 85% and the secondary rates were 96% (Mallios 2020).

In the retrospective case series of 105 patients, the cumulative patency rate at 6 months was 97%, at 12 months 94%, at 18 months 94% and at 24 months 93% (Beathard 2020).

In the retrospective case series of 100 patients, primary patency rates (that is, time from creation to first intervention) were 33% (with Ellipsys system) and 32% (with WavelinQ system). Secondary patency (that is, time from creation to abandonment) at 12 months was statistically significantly higher among patients who had an Ellipsys procedure (82%) than those who had the WavelinQ procedure (60%). Cox regression analysis showed no statistically significant difference in primary patency (HR: 0.92; 95% CI 0.53 to 1.59) but statistically significantly higher secondary patency was seen with the Ellipsys procedure (HR: 0.42; 95% CI 0.19 to 0.97). Functional patency rate for WavelinQ was 86% and 100% for Ellipsys (p=not significant; Shahverdyan 2020).

In the matched comparative case series of 70 patients, primary patency was higher in the endoAVF group than the SAVF group at 6 months (66% [9/29] compared with 53% [21/39]; p=0.69) and at 12 months (57% [13/23] compared with 44% [12/27]; p=0.63). Mean primary patency was statistically significantly higher for the endoAVF group (362±240 days) compared with the SAVF group (235±210 days; p=0.018). Secondary patency was higher in the endoAVF group than the SAVF group at 6 months (76% [22/29] compared with 67% [26/39]; p=0.86) and at 12 months (70% [16/23] compared with 58% [15/26]; p=0.81). Mean secondary patency was higher for the endoAVF group (395±249 days) compared with the SAVF group (286.9±219.2 days; p=0.05; Inston 2020).

In the propensity scored matching cohort study, time-to-event analysis showed that, a, 1 year, more incident patients with endoAVF experienced freedom from intervention (defined as period from the AVF creation date until the date of the first intervention) compared with incident patients with SAVF (70% compared with 18%, p<0.0004). Similarly, more prevalent patients with endoAVF experienced freedom from intervention compared with prevalent patients with SAVF (62% compared with 18%, p<0.0001; Arnold 2019).

In the retrospective comparative case series of 214 patients, at 12 months, the primary patency rate was higher in patients who had SAVFs (86% compared with 61%; p<0.01). However, it was comparable between the 2 groups at 24 months (52% compared with 55%; p=0.48). There was no statistically significant difference in secondary patency rates at 12 (90% compared with 91%) or 24 months (88% compared with 91%; Harika 2021).

endoAVF flow

In the prospective registry of 60 patients, target vein flow volume increased after maturation procedures from 188.9±146.4 ml/min to 630.2±437 ml/min ($p<0.0001$). The mean brachial artery flow volume after maturation procedures, increased from 602.7±305 ml/min to 857.8±371.4 ml/min ($p<0.012$; Hull 2020).

In the retrospective case series of 234 patients, the average endoAVF flow measured in the proximal brachial artery, was 923 ml/min (range, 425 ml/min to 1440 ml/min) at latest follow up (Mallios 2020).

AVF access failure

In the prospective registry of 60 patients, primary fistula failure (inability to use a fistula for dialysis despite interventions and classified as immediate [less than 72 hours], early [72 hours to 90 days] or late [90 to180 days]) occurred in 3% (2/60) of patients with 1 early failure because of thrombosis of anastomosis, and 1 late failure because of intractable arm swelling. Two early fistula thromboses, and 1 late thrombosis were reported; 1 was abandoned, and the other 2 were percutaneously declotted. There was 1 thrombosed anastomosis with all other vessels intact at 58 days. A new endoAVF was created at the original location. Mid-AV access thrombosis (4 related to cannulation injury and 1 because of thrombosis) were reported in 5 patients; all these were treated by balloon dilatation and catheter insertion (Hull 2020).

In the retrospective case series of 105 patients, access failure occurred in 8% (8/105) of patients during the study period; 2% (n=2/105) were primary failures and 6% (n=6/105) were late failures occurring at a mean of 317 days (95% CI 120 to 514, range 35 to 603) (Beathard 2020).

In the retrospective case series of 100 patients, endoAVF access failure occurred in 23% (23/100) of patients overall, in 15% (10/65) patients in the Ellipsys group and in 37% (13/35) of patients in the WavelinQ group ($p=0.01$; Shahverdyan 2020).

In the matched comparative case series of 30 patients, fistula failure (defined as a failure to achieve functional dialysis use) was reported in 27% (8/30) of patients in the endoAVF group and 43% (17/40) in the SAVF group (Inston 2020).

Patient satisfaction

In the retrospective case series of 105 patients, there was a high level of satisfaction with the procedure. A lack of pain perceived by the patient was rated as excellent or very good by 95% of patients. The overall satisfaction with the

procedure was rated as excellent or very good by 93% of patients (Beathard 2020).

Safety summary

Procedure-related complications

In the systematic review of 7 studies, the overall pooled procedure-related complication rate was 5% (95% CI 0.3% to 14%; I^2=81%; p=0.000). Subgroup analysis showed that the rate was 9% for the everlinQ system (95% CI 3% to 16%; I^2=29%; 4 studies) and 2% for the Ellipsys system (95% CI, 0 to 16%; I^2=87%). Complications related to endoAVF creation using everlinQ device were mainly associated with brachial artery access, including haematoma (n=2), pseudoaneurysm (n=4), thrombosis of the brachial artery (n=2), iatrogenic AVF between the brachial artery and vein (n=1), thrombosis of endoAVF (n=2), brachial artery dissection (n=1), detached tip of venous catheter (n=1), venous injury (n=1) and closure device embolisation (n=2). Complications related to endoAVF creation using Ellipsys device were mainly thrombosis on endoAVF (n=15), steal syndrome (n=1), venous injury or perforation (n=1), tract fistula (n=1) and infection (n=1; Yan Wee 2020).

In the retrospective case series of 100 patients, serious access-related adverse events were seen in 4 patients overall (3 in the WavelinQ group and 1 in the Ellipsys group, p=0.11). The 3 events in the WavelinQ group were: 1 unsuccessful anastomosis creation with arterial bleeding from the brachial artery (access site), treated using a stent graft; 1 anastomotic pseudoaneurysm that was resected and a SAVF constructed; and 1 peripheral pulmonary migration of both primary and secondary brachial vein coils (patient remained asymptomatic). The single event in the Ellipsys group was an anastomotic site hematoma, needing surgical revision after 2 days. (Shahverdyan 2020).

In the retrospective comparative case series of 214 patients, wound infections were lower for patients who had endoAVFs (1% compared with 9%; p<0.005). Steal syndrome (in 4) and aneurysm formation (in 3) occurred in patients who had SAVFs (Harika 2021).

Mortality

In the registry of 60 patients, 12% (7/60) of patients died during study period. These deaths were unrelated to the access procedure (Hull 2020).

In the retrospective case series of 105 patients, 17% (18/105) of patients died with a functioning AVF during the study period. These deaths were unrelated to the access procedure (Beathard 2020).

Other adverse events

In the registry of 60 patients, intractable arm swelling, steal syndrome abnormal vasculature and venous hypertension central-line thrombosis were each reported in 1 patient. AV access thrombosis (4 related to cannulation injury and 1 because of thrombosis) was reported in 5 patients, and all were treated by balloon dilatation and catheter insertion (Hull 2020).

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, we received no questionnaires.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to percutaneous endovascular forearm AVF creation for haemodialysis access. The following databases were searched, covering the period from their start to 02.06.2021: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The inclusion criteria were applied to the abstracts identified by the literature search. When selection criteria could not be determined from the abstracts the full paper was retrieved.

Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded when no clinical outcomes were reported, or when the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with chronic kidney disease needing haemodialysis access.
Intervention/test	Percutaneous endovascular forearm AVF creation.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 1,203 patients from 1 systematic review (Yan Wee IJ, 2020), 1 prospective registry study (Hull J, 2020), 3 retrospective case series (Mallios A, 2020; Beathard GA, 2020; Shahverdyan R, 2020), 1 propensity scored matching cohort study (Arnold RJG, 2019) and 2 comparative case series (Inston N, 2020; Harika 2021).

Other studies that were considered to be relevant to the procedure but were not included in the main summary of the key evidence are listed in the appendix.

Summary of key evidence on percutaneous endovascular forearm AVF creation for haemodialysis access

Study 1 Yan Wee IJ 2020

Study details

Study type	Systematic review
Country	Singapore
Study period	databases searched: MEDLINE, Embase, and Cochrane Library from inception to February 2018. Reference lists of included studies were also manually searched.
Study number and population	n=7 studies (300 patients with end-stage renal disease who had endovascular AVF-[endoAVF] creation) (4 prospective studies and 3 retrospective cohort studies)
Age and sex	Median age ranged from 45.5 to 64 years; 38% to 97% male
Patient selection criteria	Inclusion criteria: randomised or non-randomised studies that assessed the safety and efficacy of endoAVF systems. Exclusion criteria: non-English studies, case reports and series, animal and laboratory studies, and literature reviews.
Technique	Devices: everlinQ system (in 4 studies: Lok 2017 [NEAT trial], Rajan 2015 [FLEX trial], (Radosa 2017) and Berland 2019 [EASE study]). Site of AVF creation: an ulnar artery-ulnar vein anastomosis coil embolisation of the entry brachial vein was done to redirect flow to the superficial veins. Ellipsys system (in 3 studies: Hull 2017, 2018, Mallios 2018): 2 studies used the older 6F system and 1 used the newer 4F system. Site of AVF creation: anastomosis with the PRA and perforating vein. ultrasound-guided cannulation was done in 1 study (Mallios 2018). Vascular surgeons, an interventional radiologist, and an interventional nephrologist done these procedures.
Follow up	Varied across studies (6 to12 months)
Conflict of interest/source of funding	None

Analysis

Follow-up issues: short-term follow up in studies included in the systematic review.

Study design issues: systematic review was done according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Two reviewers screened and selected studies, extracted data, and any disagreements were resolved by consensus. Studies included were small retrospective or non-randomised studies and are subject to confounding and selection bias. Quality of studies was assessed using the Newcastle Ottawa Scale, and risk of bias was low in all studies (scored 6 of 9 points). Key outcomes were technical success, 90-day maturation, cumulative patency at 6 and 12 months, and procedure-related complications. These were defined by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative clinical practice guidelines and clinical practice recommendations. Meta-analysis was done using random effects model. Mixed-effects meta-regression was done to explore for sources of heterogeneity.

Study population issues: there were no differences between baseline characteristics, comorbidities, and perioperative measures between the included studies. Other issues: authors state that because of the lack of data, fistula function by its ability to be used for dialysis was not analysed.

Key efficacy findings

Number of patients analysed: 300 (7 studies)

Efficacy outcomes

Outcome	Overall (n=300)	everlinQ system	Ellipsys system
Pooled technical success rate % (7 studies)	97.50% (95% CI, 94.98-99.31%; I^2=0%)	99.45% (95% CI, 96.46-100%; I^2=0%)	95.19% (95% CI, 91.07-98.23%; I^2=0%)
Pooled 90-day maturation rate| % (4 studies)	89.27% (95% CI, 84.00-93.66%; I^2=21.29%)	88.17% (95% CI, 80.51-94.24%; I^2=0%)	89.35% (95% CI, 83.53-94.11%; I^2=0%)
6-month patency % (6 studies)	91.99% (95% CI, 87.98-95.35%; I^2=0%)	92.61% (95% CI, 86.47-97.26%; I^2=0%)	91% (95% CI, 85 to 95%; I^2=0%)
12-month patency % (2 studies)	85.71% (95% CI, 79.90-90.71%; I^2=0%)	90.98% (95% CI, 85.45-95.38%; I^2=0%)	

Technical success was defined as angiographic evidence of brisk flow within the AVF and absence of leakage of blood outside the AVF.

Maturation was defined as brachial artery flow rate more than 500 ml/min and vein diameter more than 4 mm.

Cumulative patency (duration of patency) was defined as the time from fistula creation until the last follow-up assessment or until fistula failure.

Meta-regression done on the pooled rates of technical success and complication, showed that age, diabetes, white race, hypertension, on dialysis, and body mass index were not significant sources of heterogeneity.

Rate of secondary procedures

In 1 everlinQ study (Lok 2017) the rate of secondary procedure was 0.46 per patient per year. Common procedures included basilic vein embolisation, transposition, and embolisation of a tributary vein. Another study (Hull 2018) reported that the mean number of procedures per patient per year was 2 with the Ellipsys system.

Key safety findings

Complications

Outcome	Overall (n=300)	everlinQ system	Ellipsys system
Procedure-related complication rate %	5.46% (95% CI, 0.310-14.42%; I^2=81.21%, p=0.000)	8.59% (95% CI, 2.96-16.15%; I^2=28.76%)	2.48% (95% CI, 0.00-16.23%; I^2=86.85%)

Procedure-related complication was defined as any unintended medical occurrence arising from the procedure or device from procedure initiation to completion. This may or may not include access site complications, pseudoaneurysm, thrombosis, arterial dissection, closure device embolisation, haematoma, and steal syndrome.

Adverse events	Studies	Device	% (n)
Pseudoaneurysm	Rajan 2015	everlinQ system	6.0 (2/33)
	Lok 2017	everlinQ system	3.3 (2/60)
Hematoma	Rajan 2015	everlinQ system	6.0 (2/33)
	Hull 2017	Ellipsys system	3.8 (1/26)
Detached tip of venous catheter	Rajan 2015	everlinQ system	3.0 (1/33)
Thrombosis of endovascular AVF	Rajan 2015	everlinQ system	3.0 (1/33)
	Berland 2019	everlinQ system	3.1 (1/32)
	Hull 2017	Ellipsys system	11.5 (3/26)
	Hull 2018	Ellipsys system	11.2 (12/107)
Thrombosis of brachial artery	Lok 2017	everlinQ system	3.3 (2/60)
Iatrogenic AVF between brachial artery/vein	Radosa 2017	everlinQ system	12.5 (1/8)
Closure device embolisation	Lok 2017	everlinQ system	3.3 (2/60)
Brachial artery dissection	Lok 2017	everlinQ system	1.6 (1/60)
Steal syndrome	Lok 2017	everlinQ system	1.6 (1/60)
	Hull 2018	Ellipsys system	0.9 (1/107)
Venous injury/perforation	Berland 2019	everlinQ system	3.1 (1/32)
	Hull 2018	Ellipsys system	0.9 (1/107)
Tract fistula	Hull 2017	Ellipsys system	3.8 (1/26)
Infection	Hull 2018	Ellipsys system	0.9 (1/107)

Study 2 Mallios A (2020)

Study details

Study type	Retrospective case series
Country	France
Recruitment period	2017 to 2019
Study population and number	n=234 patients with end-stage renal disease and predialysis who had a percutaneous AVF creation.
Age	mean age, 64 years; 63% (148/234) male.
Patient selection criteria	Patients who had an endovascular percutaneous AVF creation after anatomic criteria were met. These included a PRA inner diameter >2 mm, a PVE diameter >2 mm, and a distance between these vessels <1.5 mm.
Technique	Percutaneous AVF creation using the Ellipsys device Site of AVF creation: at the proximal forearm between the PRA and the PVE. Technique of creation was further modified, monitoring protocol and interventions for delayed maturation were standardised. Under ultrasound guidance a direct puncture of the median cephalic/cubital vein is done, and the needle is advanced down the PVE directly without using a guidewire. Using these veins for cannulation increases the AVF cannulation zone and reduces the need for basilic vein transposition. A wire of a 6F radial artery sheath is advanced, reaching the distal radial artery at the wrist. The sheath is then positioned fully in the radial artery over the wire. Creation of the percutaneous AVF was done followed by immediate angioplasty of the anastomosis and adjacent vessels. Most maturation procedures were done through distal radial artery access only. Sometimes, a double access procedure was used for patients who presented with complete occlusion of the anastomosis with an anastomotic plug on the ultrasound image but no clot extending into the PVE or draining veins. A second sheath is inserted through the proximal percutaneous AVF venous outflow for simultaneous access (distal radial and proximal percutaneous AVF outflow access).
Follow up	Mean 302 days (range, 83-873 days)
Conflict of interest/source of funding	One author received consulting fee and shares by Avenu Medical and is on the speaker's bureau and another has shares in Avenu Medical.

Analysis

Follow-up issues: longer follow up of patients. The paper states that patients were assessed at 4 to 7 days and then at 4 weeks if maturation could be predicted. Patients with lower flows or other evidence predicting delayed maturation were seen again sooner or scheduled for an interventional procedure.

Study design issues: Retrospective, single-centre, observational cohort study. Prospective database was retrospectively reviewed. Outcomes included technical success, maturation, functional patency, and secondary interventions needed. Kaplan–Meier survival analysis of patency rates was done.

Study population issues: 55% patients had diabetes and 35% had obesity or overweight.

Key efficacy findings

- Number of patients analysed: 234

Efficacy outcomes

Technical success (successful creation) % (n)	99% (232/234)
Average procedure duration, minutes	15 minutes (range, 7-35)
Patients having dialysis through percutaneous AVF (and removed tunnelled catheters) % (n)	54% (134/234)
Primary patency at 1 year, %	54%
Primary assisted patency at 1 year, %	85%
Secondary patency rate at 1 year, %	96%
Average time to maturation (for both predialysis and current dialysis patients)	4 weeks (range, 1-12)
Average percutaneous AVF flow (in the proximal brachial artery)	923 ml/min (range, 425-1440)
Early successful cannulation of the percutaneous AVF (in <2 weeks)	10% (24/234)
Cannulation at the elbow crease (with plastic cannulas of the median cephalic or median basilic veins)	20% (55/234)
Secondary procedures used in maturation and maintenance of percutaneous AVF	
Conversion to SAVF/AVG (at PRA with PVE or the proximal cephalic vein of the forearm). 2 had occlusion of the anastomosis, 1 because of perforator rupture because of angioplasty for maturation following painful pseudoaneurysm without any neurological compromise)	1% (3/234)
Superficialisation of deep outflow veins (because of difficult cannulation; half had a basilic vein transposition and the other half had a lipectomy for a deep cephalic vein)	11% (24/234)
Percutaneous balloon angioplasty of the anastomosis	35% (94/234)
Percutaneous AVF banding of the pre-anastomotic PRA for flow reduction (patient had arm swelling because of subclavian vein stent occlusion)	n=1

Key safety findings

Local or systemic complications	0
Procedure-related adverse events	0

Study 3 Beathard GA 2020

Study details

Study type	Retrospective case series
Country	USA
Recruitment period	Not reported
Study population and number	n=105 patients with endovascular AVF (endoAVF) access creation
Age	Mean age 56.2 years; male 73% (77/105).
Patient selection criteria	all patients with an endoAVF created during a period that would allow for a 2-year follow up.
Technique	An endovascular AVF was created using Ellipsys Vascular Access System. Site of AVF creation: the deep communicating vein and into the adjacent PRA.
Follow up	24 months
Conflict of interest/source of funding	The author(s) received no financial support. One author is a patient advocate for Avenu Medical, and another received a consulting fee as stock options.

Analysis

Study design issues: this is a retrospective, large multicentre cohort study. Patient data were obtained from 5 electronic health record databases. Data collection was done 2 years after endovascular creation (730 days). Main outcomes assessed were 2-year cumulative patency rate (determined using Kaplan–Meier life table analysis) and patient satisfaction (measured through questionnaires using a 5 level Likert scale, with 1 being excellent and 5 being poor, or with a yes or no). A patient engagement focus group also contributed to patient satisfaction survey.

Study population issues: most of the patients had moderately obesity. One third of patients had previous dialysis access procedures.

Key efficacy findings

- Number of patients analysed: 105

Efficacy outcomes

Outcomes	% (n)
Technical success (successful creation)	100 (105/105)
Physiologically mature AVF	98 (103/105)
Clinically functional AVF	95 (100/105)
Access failure (loss of access)	7.6 (8/105)
Primary failure	1.9 (2/105)
Late failure (at a mean 317 days)	5.7 (6/105) (95% CI 120–514, range 35–603)
Cumulative patency rate	
6 months	97.1
12 months	93.9
18 months	93.9
24 months	92.7

Physiologically mature AVF was defined as brachial artery blood flow 500 ml/min or more and a target vein internal diameter 4 mm of more.

Clinically functional AVF was defined as an access capable of supporting 2-needle dialysis according to the patient's dialysis prescription.

Patient satisfaction

Patient satisfaction survey response rate	39%
Lack of pain perceived by the patient (excellent or very good)	95%
Perception of technical ease by operator	63%
Overall satisfaction (excellent or very good)	93%
Comparison with previous procedure (excellent and very good)	29%

Patient responses and focus groups indicated a high level of satisfaction with the procedure.

Key safety findings

Adverse events	% (n)
Deaths unrelated to access procedure (and with a functioning AVF at a mean 353 days)	17 (18/105) (95% CI 252–453, range 28–669)
Secondary procedures	
Renal transplant	5.7 (6/105)

For renal transplant, endoAVF was functioning during the transplant procedure at a mean of 201 days (95% CI=75–327, range=79–381).

Study 4 Hull J (2020)

Study details

Study type	Prospective case series (NCT03828253- Ellipsys postmarket registry).
Country	USA
Recruitment period	2018 to 2019
Study population and number	n=60 patients eligible for endoAVF and enrolled in the postmarket registry.
Age	Mean 64±14 years (range 24–90); 57% (34/60) males.
Patient selection criteria	Patients with end-stage renal disease stages 4 and 5 needing immediate or near-term haemodialysis access, and for whom dialysis AVF access creation is suitable according to standard guidelines were included.
Technique	EndoAVF created with Ellipsys device. Site of AVF creation: at the proximal forearm between the PRA and the PVE using multiple venous outflows into the target vein for dialysis (the cephalic vein in 70% [42/60], the basilic vein in 22% [13/60], and the brachial vein in 8% [5/60]). EndoAVF procedures were standardised: including 5-mm balloon dilation of the proximal fistula at the time of fistula creation and preparation for dialysis using maturation procedures at 4 weeks to achieve a palpable pulse in the target vein.
Follow up	mean 282±109 days (range, 103–385 days).
Conflict of interest/source of funding	Avenu Medical, Inc assisted through a grant of Ellipsys devices.

Analysis

Follow-up issues: the paper states that follow-up examinations were done at 1-week, 4-week and 3-month intervals. 2 patients were lost to follow up within 90 days.

Study design issues: postmarket prospective registry from a single centre in the USA with procedures done by experienced surgeons and an interventional radiologist. Registry evaluated patient selection and fistula maturation data. Results were recorded according to reporting standards for the North American Vascular Access Consortium, Society for Vascular Surgery, and Society of Interventional Radiology guidelines.

Key efficacy findings

- Number of patients analysed: 60

endoAVF maturation outcomes

Technical success (successful endoAVF access creation) %	100% (60/60)
Procedure time, minutes	19.5±11.3 (range, 7–70)
EndoAVF Maturation procedures at a mean 32.1±14.6 days (in AVFs not suitable for 2-needle cannulation: with a target vein volume of 500 ml/min and 5 mm diameter)	**67% (40/60)**
Balloon dilation	62% (37/60)
Brachial vein embolisation	32% (19/60)
Cubital vein banding	30% (18/60)
Valvulotomy	3.3% (2/60)
Uncovered stent placement in diseased PRA	n=1
Target vein flow volume, ml/min (mean±SD)	
Before maturation procedures	188.9±146.4
After maturation procedures	630.2±437 (p<0.0001)
Mean brachial artery flow volume, ml/min (mean±SD)	
Before maturation procedures	602.7±305
After maturation procedures	857.8±371.4 (p<0.012)
Transposition (in 8 basilic vein fistulas, 5 brachial vein fistulas, and 5 cephalic vein fistulas) at a mean 61.9±20.8 days	33% (20/60)
Pretransposition (mean±SD)	
Mean target vein flow, ml/min	831±296 (range, 516–1,602)
Mean diameter, mm	5.9±1.0 (range, 4.0–8.4)
Mean depth, mm	10.9±4.5 (range, 6.0–23)
Posttransposition (mean±SD)	
Mean target vein flow, ml/min	751±458.1 (range, 312–1,638)
Mean diameter, mm	6.0±1.0 (range, 4.5–8.2)
Mean depth, mm	3.5±1.5 (range, 1.6–5.4) (p<0.0001)

Maturation procedures were secondary procedures done before there was physiological maturation of the target vein or before they were used for haemodialysis, as recommended by American Society of Nephrology Kidney Health Initiative.

Patency and cumulative probability of success (with Kaplan–Meier analysis)

Outcome	Mean days	Rate of events % (n)	Cumulative probability of success %
Physiological fistula maturation	40.4±4.3	90 (54/60)	90

(target vein flow 500 ml/min and diameter 5 mm or used for dialysis)			
90-day EndoAVF maturation (brachial artery flow of 500 ml/min and a target vein of 4 mm)	11.4±1.3	97 (58/60)	97
Patients released for dialysis	59.6±6.5	87 (47/54)	87
2-needle cannulation or clinical success (defined as 2-needle cannulation with dialysis at prescribed rate)	65.6±45.7	87 (47/54)	87
Fistula success	87.7±8.8	87 (47/54)	87
Tunnelled catheter removal	113.4±62	82.9 (39/47)	83
			Kaplan–Meier survival (%) at 180 days
Primary patency	52.9±8.4	83.3 (50/60)	7
Primary assisted patency	374.7±9.9	6.6 (4/60)	97
Cumulative patency	375.2±9.7	6.6 (4/60)	96
Functional patency	321.4±7.3	4.2 (2/47)	94

endoAVF maintenance procedures (secondary procedures in patients on 2-needle cannulation dialysis)

Maintenance procedures were done in 63% (38/60) of patients and included 70 procedures at a mean 130±75.6 days (range, 27–333 days). These were: 11 with low inflow, 35 with low flow in cannulation segment, 11 with low outflow, 8 with collateral flow, 3 with thromboses, and 2 with arm swelling. Procedures included 63 balloon dilations; 2 stenting; 14 deep embolisations; 5 branch embolisations; 6 percutaneous banding; 5 thrombectomy; and 1 valvulotomy. In these patients mean target vein blood flow volume increased from 238±509 ml/min to 798±356 ml/min; p<0.0001).

Key safety findings

Adverse events

Inability to use a fistula for dialysis despite interventions and was classified as immediate (under 72 hours), early (72 hours to 90 days), or late (90 days to180 days).

Adverse events	**n**
Haematoma (related to cannulation injury, treated by balloon dilatation and catheter insertion)	5
Haematoma post AVF creation (at puncture site, resolved under pressure)	1
Stenosis with intimal hyperplasia (treated by balloon dilation)	4
Mid-AV access stenosis (treated by balloon dilation)	3
Mid-AV access cannulation injury (treated by balloon dilatation and catheter insertion)	4

Mid-AV access thrombosis (4 related to cannulation injury and 1 because of thrombosis; treated by balloon dilatation and catheter insertion)	5
Stenosis postsurgical elevation	1
Fistula access thromboses (2 within and 1 after 30 days, 1 abandoned, and 2 were percutaneously declotted)	3
Thrombosed anastomosis (at 58 days, a new EndoAVF was created in same location)	1
Primary fistula failure (1 early failure because of thrombosis of anastomosis, and 1 late failure because of intractable arm swelling)	3% (2/60)
Intractable arm swelling (fistulae ligated)	1
Steal syndrome abnormal vasculature (fistula ligated)	1
Venus hypertension central-line thrombosis (fistula ligated)	1
Deaths unrelated to fistula procedure (4 within 30 days and 3 between 90 to 180 days)	11.6 (7/60)

Study 5 Arnold RJG (2019)

Study details

Study type	Propensity score matching cohort study
Country	USA
Recruitment period	2010-2013
Study population and number	n=120 patients with incident and prevalent end-stage kidney disease • 27 incident patients with an endoAVF versus 27 matched incident patients with SAVF. • 33 prevalent patients with endoAVF versus 33 matched prevalent patients with SAVF
Age	Median 66 years (range 30 to 88)
Patient selection criteria	SAVF cohort: patients 18 years of age in the United States Renal Data System national registry with SAVF created during 2011–2013, and enrolled in Medicare Parts A and B, 6 months before and 6-months after AVF creation. Endo AVF Cohort all Novel Endovascular Access Trial (NEAT study, Lok 2017) patients with incident and prevalent endoAVF (n=60) with deidentified demographic and clinical data collected during the study (including the type, frequency, and complications associated with procedures).
Technique	EndoAVF: endovascular fistula created with everlinQ endoAVF System Site of AVF creation: ulnar artery-vein anastomosis SAVF: traditional surgical haemodialysis AVF created.
Follow up	1 year
Conflict of interest/source of funding	Funding for this study was provided by TVA Medical.

Analysis

Study design issues: Retrospective cohort study comparing prospective study data to historical registry data. Data on incident and prevalent patients who had SAVFs from the United States Renal Data System (national registry) and comparative data from patients with incident and prevalent endoAVF from the prospective Novel Endovascular Access Trial (NEAT study, Lok 2017) were obtained. Propensity scoring was used to match SAVF and endoAVF incident and prevalent patients on a 1:1 ratio. Event rates, intervention-free survival (using Kaplan–Meier survival curves), and costs were compared between endoAVF and SAVF cohorts. Data on interventions in the SAVF cohort were identified from Medicare claims, so they might be procedure code errors. The United States Renal Data System database does not distinguish between types of SAVFs placed.

Study population issues: Baseline characteristics among incident and prevalent endoAVF patients and their corresponding 1:1 matched SAVF cohorts were similar indicating an accurate comparison of matched populations. However, authors state that populations in the NEAT study may differ from the US comparison

cohort in unmeasured ways that propensity score matching does not address (for example, process of care issues).

Other issues: data on associated healthcare costs were not extracted as it is out of the remit of this overview. endoAVF data from the prospective Novel Endovascular Access Trial (NEAT study, Lok 2017) is included in study 1, therefore there is some overlap in data between these studies.

Key efficacy findings

- Number of patients analysed: 27 incident EndoAVF versus 27 matched incident SAVF; 33 prevalent endoAVF versus 33 matched SAVF.

AVF intervention (maintenance) rates for incident patients

In the United States Renal Data System, SAVF patients were considered as incident patients if they were not on haemodialysis or peritoneal dialysis at the time of AVF creation; all patients who had incidents had dialysis.
endoAVF patients were considered to be incident patients if they were not on haemodialysis or peritoneal dialysis at the time of endoAVF creation, even if they did not start dialysis by the end of the study.

Outcomes	**Event rate per patient-year**		
	endoAVF cohort (n=27) %	**matched SAVF cohort (n=27) %**	**Difference**
Inpatient vascular access-related infection	0.000	0.461	0.461
Outpatient vascular access-related infection	0.000	0.384	0.384
Thrombectomy	0.083	0.077	-0.006
Revision	0.041	0.461	0.419
DRIL for steal syndrome	0.041	0.001	-0.041
Angioplasty	0.041	0.844	0.803
Catheter placement	0.124	3.070	2.947
AVG creation	0.041	0.384	0.342
New AVF or transposition	0.083	1.382	1.299
Thrombin injection	0.083	0.000	-0.083
Embolisation/ligation	0.207	0.077	-0.130
Thrombolysis	0.000	0.000	0.000
Stent placement	0.000	0.077	0.077
Total event rate	**0.744**	**7.216**	**6.472** ($p<0.0001$).

AVF intervention (maintenance) rates for prevalent patients

Outcomes	Event rate per patient-year		
	endoAVF cohort (n=33) %	matched SAVF cohort (n=33) %	Difference
Inpatient vascular access-related infection	0.035	0.064	0.029
Outpatient vascular access-related infection	0.000	0.064	0.064
Thrombectomy	0.000	0.384	0.384
Revision	0.035	0.192	0.157
DRIL for steal syndrome	0.000	0.000	0.000
Angioplasty	0.035	1.217	1.181
Catheter placement	0.106	0.512	0.406
AVG creation	0.000	0.640	0.640
New AVF or transposition	0.141	0.640	0.499
Thrombin injection	0.000	0.000	0.000
Embolisation/ligation	0.071	0.192	0.121
Thrombolysis	0.035	0.000	-0.035
Stent placement	0.000	0.192	0.192
Total event rate	**0.459**	**4.098**	**3.639** ($p<0.0001$).

Intervention-free survival (assessed using Kaplan–Meier survival curves)

(defined as the period from the AVF creation date until the date of the first intervention)

At 1 year, time-to-event analysis showed that 70% of incident endoAVF patients and 18% of incident SAVF patients experienced freedom from intervention ($p=0.0004$); 62% and 18% of prevalent endoAVF and SAVF patients experienced freedom from intervention respectively ($p<0.0001$).

Study 6 Inston N (2020)

Study details

Study type	Comparative case series (matched cohort study)
Country	UK
Recruitment period	2016 to 2019
Study population and number	n=70 30 patients with endoAVFs versus 40 patients with SAVFs
Age and sex	Mean age: endoAVF group 57 ±15 years and SAVF group 54±17 years Sex: endoAVF group 83% (25/30) male and SAVF group 73% (29/40) male
Patient selection criteria	Data of both surgical and endoAVFs created between 2016 and 2019, comparatively matched with same inclusion and exclusion criteria were included. Patients referred from peripheral centres who would have had their follow up and cannulation elsewhere were excluded because of data linkage and logistic constraints.
Technique	endoAVF created using WavelinQ endoAVF system Site of AVF creation: ulnar in 27 (90%), radial in 2 (7%) and interosseous in 1 (3%). Access used: upper arm parallel access in 14 (47%), wrist in 2 (6%) and antiparallel upper arm and wrist in 14 (47%). SAVF procedures were done in a specialist tertiary referral centre. All procedures were done by an experienced surgeon and an interventional radiologist.
Follow up	Mean: endoAVF group 497 ±187 days; SAVF group 468±148 days (p=0.7).
Conflict of interest/source of funding	Authors have received honoraria for training and teaching from BD Bard and formerly TVA medical.

Analysis

Study design issues: small single-centre matched cohort study, data from a prospectively collected database of both surgical and endoAVFs was used. Comparative matching was done for demographics.

Study population issues: Patients in endoAVF group either did not have an SAVF option or had a primarily failed SAVF.

Key efficacy findings

- Number of patients analysed: 70 (30 endoAVF versus 40 SAVF)

Efficacy outcomes

Outcome	endoAVF n=30	Surgical radiocephalic AVF, n=40	P value
Predialysis versus dialysis, ratio	19:11 (1.7:1)	31:9 (3.4:1)	0.28
Mean time from assessment to fistula formation, (Mean±SD), days	33±21	86±58 days	0.0001
Technical or procedural success % (n)	96.7% (28/29)	92.6% (35/38)	0.6
Mean time from formation to use (2-needle cannulation), (Mean±SD), days	130±86	141±118	0.66
Starting on fistula versus start on a CVC (predialysis patients), ratio	11:4 (2.75:1)	13:6 (2.17:1)	1.0
Overall CVC use (days from formation to last CVC use; total for group), days	2,322	2,630	
CVC days per overall patient follow-up days (=total CVC use/follow-up days)	0.15 (2322/14,910)	0.14 (2630/18,713)	
Mean CVC duration of use, days	155±177	157±90	NS
Interventions	16	14	
Intervention rate per patient-year	0.402 (16/39.78)	0.273 (17/51.28)	0.14
Primary patency % (n)			
6 months	65.5% (9/29)	53.4% (21/39)	0.69
12 months	56.5% (13/23)	44% (12/27)	0.63
Mean primary patency (mean±SD), days	362±240	235±210	0.018
Secondary patency % (n)			
6 months	75.8% (22/29)	66.7% (26/39)	0.84
12 months	69.5% (16/23)	57.6% (15/26)	0.81
Mean secondary patency (Mean±SD), days	395±249	286.9±219.2	0.05

Interventions included angiovenoplasty, stenting, coil embolisation, transposition or revision, balloon assisted maturation, thrombolysis.

Technical success of an endoAVF was defined as visualising AV shunt blood flow through the created endoAVF using angiography at completion of the index procedure. For surgical fistulas, the presence of a thrill reported by the operating surgeon at the end of the procedure was classed as technical success.

Primary patency was defined as time from creation to intervention or abandonment and secondary patency as time from the creation date to the last needling date before the AVF was abandoned for a new form of access formation.

Key safety findings

Complications

Adverse event	endovascular AVF n=30	Surgical radiocephalic AVF, n=40	P value
Deaths	0	1	1.0
Fistula failure (failure to achieve functional dialysis use).	26.6% (8/30)	42.5% (17/40)	0.21

Study 7 Harika G (2021)

Study details

Study type	Retrospective comparative case series
Country	France (single centre)
Recruitment period	2017 to 2018
Study population and number	n=214 107 patients with endoAVFs versus 107 patients with SAVFs
Age and sex	Mean age: endoAVF group 63.6 years and SAVF group 63.5 years Sex: endoAVF group 62% (66/107) male and SAVF group 61% (65/107) male
Patient selection criteria	Patients may get a surgical or percutaneous PRA AVF according to surgeons' preference and if ultrasound evaluation indicates that the puncture is possible for an endoAVF creation. In the absence of a possibility for a proximal radial or ulnar artery AVF, a brachiocephalic or brachiobasilic AVF is created. Patients who had grafts or lower extremity fistulae were excluded.
Technique	endoAVF procedures were created using Ellipsys endoAVF system by a single surgeon. Site of AVF creation: AVF between the PRA and perforating vein in the elbow Access used: SAVF procedures were done in the same centre by 4 experienced access surgeons. Access and site of creation: 55% (59/107) were radiocephalic fistula at the wrist (w-AVF) and 45% (48/107) were elbow fistulae (12 proximal radiocephalic AVF, 16 brachiocephalic (bc-AVF) and 20 brachiobasilic (bb-AVF) fistulae).
Follow up	2 years
Conflict of interest/source of funding	Not reported.

Analysis

Study design issues: a single centre retrospective comparative study, data from a high volume vascular access medical centre on both SAVFs and endoAVFs done during the same period were collected from medical or patient records and examining patients or contacting dialysis unit staff. Primary endpoints included maturation and primary and secondary patency rates. Secondary endpoints were reinterventions, risk of infection, steal syndrome and aneurysm formation. Comparisons were made between endoAVF and SAVF groups and for subgroup analysis of radiocephalic fistula at the wrist (w-AVF) and elbow surgical fistulae (e-AVF). EndoAVFs created early and late in the study were compared to evaluate learning curve effect.

Study population issues: patients' groups were not matched but demographics and medical conditions were similar between groups. More patients who had an endoAVF were having haemodialysis (61% versus 47%;

p<0.05). this difference was mainly seen between endoAVF and radiocephalic wrist AVF patient groups (61% versus 40%, p=0.01).

Other issues: study compared the entire upper extremity SAVFs (in different anatomical locations) with PRA endoAVFs.

Key efficacy findings

- Number of patients analysed: 214 (107 endoAVF versus 107 SAVF)

Efficacy outcomes

Outcome	endoAVF % (n=107)	SAVF n=107	p value
Maturation at 6 weeks	65%	50%	0.02
Reinterventions at 12 months	17%	36%	0.013
Percutaneous intervention	41%	4%	<0.001
Surgical intervention	12%	33%	<0.001
Reinterventions at 24 months	53%	36%	0.21
Percutaneous intervention	53%	42%	0.10
Surgical intervention	17%	36%	0.002
Primary patency (Kaplan–Meier analysis)			
12 months	61%	86%	<0.01
24 months	55%	52%	0.48
Secondary patency (Kaplan-Meier analysis)			
12 months	91%	90%	Not significant
24 months	91%	88%	Not significant

Maturation: AVF use in patients already having haemodialysis and with ultrasonography criteria (over 4 mm diameter and over 500 ml/litre flow).

Reinterventions: additional interventions (percutaneous or surgical revisions, including superficialisations) needed for assisted maturation and AVF dysfunction.

Primary patency was defined as the interval between fistula creation and any open or percutaneous intervention to maintain or re-establish patency access (excluding routine procedural balloon dilatation of each p-AVF at the time of creation).

Secondary patency was defined as the interval from the time of access placement until access abandonment.

Comparison of elbow-AVF and radiocephalic AVFs [w-AVFs] versus endoAVFs

Maturation rates

There were no statistically significant differences between endoAVFs and elbow AVFs (65% versus 60%; p=0.48). However, radiocephalic AVFs (w-AVFs) demonstrated more delayed maturation (43% [26/60] versus 65% [70/107]; p=0.005).

Reintervention rates

Comparison of endoAVF with elbow-AVF showed statistically significant differences at 12 months for percutaneous interventions (41% versus 4%; p<0.001) and surgical (12% versus 40%; p<0.001) interventions (including superficialisations). At 24 months, endoAVFs had lower surgical revisions compared with elbow AVFs (17% versus 49%; p<0.001).

Comparison of endoAVF with radiocephalic AVF (w-AVF) showed statistically significant differences at 12 months for percutaneous interventions (44% versus 3%; p=0.02) and surgical (12% versus 27%; p<0.001) interventions. At 24 months, endoAVFs had lower surgical revisions compared with elbow AVFs (17% versus 25%; p=0.02).

Comparison of primary patency between early versus late endoAVFs

The first and last 50 patients that had creation of endoAVFs showed very similar Kaplan–Meier curves, suggesting little impact of a learning curve.

Key safety findings

Complications

Adverse event	EndoAVF n=107	SAVF n=107	P value
Wound infection	0.9%	9%	0.005
High-flow/steal syndrome	0	4	Not statistically significant
Aneurysm formation	0	3	Not statistically significant

Study 8 Shahverdyan R (2020)

Study details

Study type	Retrospective case series
Country	Germany
Recruitment period	2017-2019
Study population and number	n=100 patients who had endovascular AVF (endoAVF) procedures (65 with Ellipsys and 35 with WavelinQ devices).
Age	Median age was 64.1 years (range: 28–86), 69% (69/100) were male median body mass index was 27.2 (range: 15–45.1) kg/m^2
Patient selection criteria	All patients having the creation of a dialysis access and included in a database with focus on endoAVF outcomes were included. Patients were judged to be eligible for a particular procedure according to manufacturer's instructions for use. A standardised protocol was used in access planning based on evaluation of the patient's vascular anatomy. This included an assessment of the arterial system to evaluate peripheral pulses, differential blood pressure measurements, modified Allen tests, and ultrasonographic vessel mapping. Eligibility for endoAVF creation needed an intact arterial system with the non-AVF inflow artery adequately supplying the palmar arch. If the cephalic vein outflow was not adequate, a basilic or brachial vein transposition was anticipated. A procedure sequence algorithm was followed for the selection of a site and procedure.
Technique	Percutaneous endoAVF were created using Ellipsys (n=65) and WavelinQ-4F (n=35) devices. Anaesthesia was mainly by regional block. All procedures were done by a single operator. Site of AVF creation: WavelinQ: anastomosis with the PRA artery (n=22) ulnar (n=11), and brachial artery (n=1). Venous catheter placements were radial (57.1%), ulnar (11.4%), brachial (25.7%), and cephalic and basilic veins in 1 case each. Ellipsys: at the proximal forearm between the PRA and the deep communicating vein (PVE) using multiple venous outflows into the target vein (cephalic, basil, brachial veins). anastomoses with the PRA (in 64) and 1 patient had a distal brachial anastomosis. endoAVF creation technique: Ellipsys uses thermal energy and ultrasonographic guidance, whereas WavelinQ-4F uses radiofrequency energy and fluoroscopy. primary embolisation coiling of the outflow brachial vein was done in 26 WavelinQ patients and angioplasty was done when the Ellipsys device was used.
Follow up	Median follow up: overall 186.5 (0 to 760) days Ellipsys device 183 (1 to 487) versus WavelinQ-4F device 185 (0 to 760) days
Conflict of interest/source of funding	One author is a paid speaker for Avenu Medical, Inc and Becton Dickinson Company/BARD. One received personal fees and 1 owns stock in Avenu Medical, Inc

Analysis

Follow-up issues: The paper states that follow-up evaluations were done at 24 to48 hours, week 4, and at 3, 6, 9, and 12 months.

Study design issues: Retrospective review of prospectively collected data from a single vascular access centre. The 2 devices differ significantly in technical design and endoAVF creation technique, vessels involved, location of the endoAVF anastomosis and outcomes. Primary endpoints were technical success, time to maturation, functional patency, and time to first clinical use.

Study population issues: 37% patients had diabetes. there were no statistically significant differences between patients who had endoAVFs with WavelinQ and Ellipsys devices in terms of age, presence of diabetes, body mass index, chronic kidney disease status at the time of access creation, history of a previous ipsilateral endoAVF, or the percentage of patients with a CVC. Both groups had 25% patients with previously failed ipsilateral access.

Other issues: authors state that there is a “learning curve” for both devices, ultrasonography experience for evaluating vascular anatomy and skill in clinical techniques are key before doing endoAVF procedures. They also state that it is important to consider patient eligibility.

Key efficacy findings

- Number of patients analysed: 100

Clinical outcomes

Clinical outcomes	Overall n=100	endoAVF with Ellipsys device, n=65	endoAVF with WavelinQ, n=35	P value
Technical success % (n)	99 (99/100)	100 (65/65)	97 (34/35)	0.35
Median procedure times, minutes	18 (9-150)	14 (9-31)	63 (28-150)	<0.001
AVF blood flow, ml/min				
Post procedure (day 1)	450 (85-1,400) n=99	460 (150-1,400) n=65	450 (85-1,300) n=34	0.62
6 months	790 (70-1,600) n=35	750 (70-1,000) n=22	1,000 (480-1600) n=13	0.11
Maturation at 4 weeks, %	63.1 (60/95)	68.3 (41/60)	54.2 (19/35)	0.17
Suitability for cannulation, %		83.3	71.4	
Median time to cannulation/first use, days	68 (1-180) n=44	60 (1–164) n=31	90 (1–180) n=13	0.36
endoAVF used in dialysis patients, % (n)	71 (45/63)	79.5 (31/39)	58 (14/24)	0.071
Interventions done		27.7 (33/65)	26.5 (15/35)	

Number of interventions per patient-years		0.96	0.46	
Primary patency rate, %		32	33	(HR: 0.92; 95% CI: 0.53–1.59).
Secondary patency at 12 months, %		82%	60%	(HR: 0.42; 95% CI: 0.19–0.97).
Functional patency rate %		100	85.7	NS

Technical success was defined as a patent anastomosis and fistula flow in the deep communicating vein and outflow veins.

Maturation was defined as a brachial artery blood flow of 500 ml/min with an AVF diameter 5 mm.

Functional patency defined as the time from successful 2-needle cannulation of endoAVF until its abandonment.

Primary patency was the time from creation to first intervention.

Secondary patency was the time from creation to abandonment.

Six patients (5 compared with 1) with matured outflow from previous AVFs had first-day cannulations because of prematured veins after previous AVFs that had failed.

Key safety findings

Adverse events

	Overall % (n=100)	**endoAVF with Ellipsys device, % (n=65)**	**endoAVF with WavelinQ, % (n=35)**	**P value**
access-related serious adverse events		1.5 (1/65)*	8.5 (3/35)	0.11
endoAVF access failure^	23 (23/100)	15.4 (10/65)	37.1 (13/35)	0.01

Access failure was defined as abandonment of the endoAVF when salvage of the occluded or dysfunctional endoAVF (that is, keeping the endoanastomosis and endoAVF outflow) was either technically impossible or the patient decided to convert to a new percutaneous or SAVF/AVG. failed endoAVFs occurred because of the localisation of the occlusion or untreatable stenosis at the anastomosis or juxta-anastomotic outflow veins.

For endoAVF with Ellipsys device, 1 anastomotic site haematoma needed surgical revision after 2 days.

For endoAVF with WavelinQ, 1 unsuccessful anastomosis creation with arterial bleeding from the brachial artery (access site), treated using a stent graft, 1 anastomotic pseudoaneurysm that was resected, and a SAVF constructed and 1 peripheral pulmonary migration of both primary and secondary brachial vein coils but patient remained asymptomatic.

Validity and generalisability of the studies

- There are no randomised controlled trials comparing the effect of percutaneous endoAVF creation with SAVF creation for haemodialysis access in patients with end-stage kidney disease. Evidence included in the systematic review was mainly from small prospective and retrospective studies (Yan Wee 2020).
- 3 studies compared endoAVF procedures with SAVFs (1 propensity scored matched study based on endoAVF published results and SAVF historical controls from registry data, Arnold 2019; 1 matched cohort study, Inston 2020 and 1 retrospective comparative study, Harika 2021).
- There are 2 endoAVF devices (Ellipsys and WavelinQ [previously everlinQ]) with differences in terms of technical design, endoAVF creation technique, vessels involved, and location of the endoAVF anastomosis and mechanism of creation of the AVF. These techniques have evolved with time.
- Subgroup analyses for the 2 devices are presented in the systematic review (Yan Wee 2020) and a retrospective case series compared outcomes of endoAVF creation by Ellipsys and WavelinQ devices (Shahverdyan 2020).
- Follow-up periods varied across studies and was 6 to 12 months in many studies. Only 1 study had a 2-year follow up. There is a lack of long-term follow-up data.
- None of these studies reported data on quality of life.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

NICE guidelines

- Renal replacement therapy and conservative management. NICE guideline 107 (2018). Available from http://www.nice.org.uk/guidance/NG107

Additional information considered by IPAC

Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, when comments are considered voluminous, or publication would be unlawful or inappropriate. No professional expert questionnaires for percutaneous endovascular forearm AVF creation for haemodialysis access were submitted.

Patient commentators' opinions

NICE's Public Involvement Programme sent questionnaires to NHS trusts for distribution to patients who had the procedure (or their carers). NICE received 16 completed questionnaires and 1 patient organisation submission representing patients who have had this procedure. The patient commentators' views on the procedure were consistent with the published evidence and the opinions of the professional experts. See the patient commentary summary for more information.

Company engagement

A structured information request was sent to 2 companies who manufacture a potentially relevant device for use in this procedure. NICE received 2 completed submissions. These were considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

- NCT04404985: Endovascular compared with surgical AVF outcomes (ESAVFO); randomised controlled trial, n=80 participants who started dialysis with a catheter or have advanced chronic kidney disease, **Ellipsys** device is

used for endovascular procedures; primary outcome: physiological fistula maturity; location: USA; study completion date: September 2025. Study status: active, not recruiting.

- NCT04197544: Evaluation of the implantation of the end-vascular creation of the AVFs in patients in the university hospital of araba. Pilot study, non-randomised study, n=14 patients having chronic dialysis or waiting to start the chronic dialysis in the next 6 months; primary outcome: percentage of endoAVFs physiologically appropriate for dialysis during 3 months to the creation; location: Spain, completion date: January 2022; study status: not yet recruiting.
- NCT03454113; **Ellipsys** Vascular Access System Registry; prospective cohort study, n=17 patients with end-stage renal disease currently needing dialysis or it is anticipated will need dialysis within 6 months of enrolment; primary outcome: number of patients with a vascular access site that achieves a venous diameter of greater than or equal to 4 mm and blood flow greater than or equal to 500 ml/min in the brachial artery; follow up of 1 year, location: Germany; completion date: July 2020; study status: recruitment completed.
- NCT04484220: **Ellipsys** Vascular Access System Post Market Surveillance (PS) Study PS200001 Reference DEN170004; single-group assignment n=134; primary outcomes: secondary patency at 6 months and 12 months, occlusion rate at 7 days and 12 months; completion date: January 2023; status: not yet recruiting.
- NCT03828253: **Ellipsys** Percutaneous Arteriovenous Fistula for Hemodialysis Access; observational study, n=100 patients having percutaneous PRA fistula creation; primary outcomes: blood flow volume; location: USA; completion date: August 2021; status: recruiting.
- NCT04626427: The **WavelinQ** Arterio-Venous Endovascular Fistula: A Global, Multi-Center, Prospective, Post-Market, Confirmatory, Interventional, Investigation; non-randomised single-arm study; n=150 patients who need a

vascular access for haemodialysis; primary outcomes: proportion of patients with freedom from device- and procedure-related adverse events, number of interventions to help or maintain AVF use; location: Greece; study completion date: February 2024, study status: recruiting.

- NCT04634916: Post-market Surveillance Study of the BD **WavelinQ** EndoAVF System (CONNECT-AV); A Prospective, Multi-Center Clinical Study of the BD WavelinQ EndoAVF System for the Creation of Arteriovenous (AV) Fistula in Patients Requiring Dialysis; single-group assignment; n=280; primary outcomes: functional cannulation success, primary patency, device, and procedure-related serious adverse events; location: USA, study completion date: July 2024; study status: not yet recruiting.
- NCT04633304: A single-arm study to evaluate the effectiveness of EndoAVF in a predialysis population (STEP Study), this postmarketing study will evaluate use of the **WavelinQ** system; single-group assignment; n=30; primary outcome: procedure success (successful endoAVF creation); location: USA; study completion date: December 2021; study status: not yet recruiting.

References

1. Yan Wee IJ, Yap HY, Tang TY et al. (2020) A systematic review, meta-analysis, and meta-regression of the efficacy and safety of endovascular arteriovenous fistula creation. Journal of Vascular Surgery 71: 309–17.e5
2. Mallios A, Bourquelot P, Franco G, et al. (2020) Mid-term results of percutaneous arteriovenous fistula creation with the Ellipsys vascular access system, technical recommendations and an algorithm for maintenance. Journal of Vascular Surgery S0741–5214(20): 30476–6
3. Beathard GA, Litchfield T, Jennings WC (2020) Two-year cumulative patency of endovascular arteriovenous fistula. The Journal of Vascular Access 21(3): 350–6
4. Hull J, Deitrick J, Groome K et al. (2020) Maturation for hemodialysis in the Ellipsys post-market registry. Journal of Vascular and Interventional Radiology 31: 1373–81
5. Arnold RJG, Han Y, Balakrishnan R et al. (2018) Comparison between surgical and endovascular hemodialysis arteriovenous fistula interventions and associated costs. Journal of Vascular and Interventional Radiology 29: 1558–66
6. Inston N, Aurangzaib K, Tullet K et al. (2010) WavelinQ created arteriovenous fistulas versus surgical radiocephalic arteriovenous fistulas? A single-centre observational study. The Journal of Vascular Access 21(5): 646–51
7. Harika G, Mallios A, Allouache M et al. (2021) Comparison of surgical versus percutaneously created arteriovenous hemodialysis fistulas. Journal of Vascular Surgery 74 (1): 209–16. doi: https://doi.org/10.1016/j.jvs.2020.12.086
8. Shahverdyan R, Beathard G, Mushtaq N et al. (2020) Comparison of outcomes of percutaneous arteriovenous fistulae creation by Ellipsys and WavelinQ devices. Journal of Vascular and Interventional Radiology 31: 1365–72

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	02/06/2021	Issue 6 of 12, June 2021
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	02/06/2021	Issue 6 of 12, June 2021
International HTA database (INAHTA)	02/06/2021	-
MEDLINE (Ovid)	02/06/2021	1946 to June 01, 2021
MEDLINE In-Process (Ovid)	02/06/2021	1946 to June 01, 2021
MEDLINE Epubs ahead of print (Ovid)	02/06/2021	June 01, 2021
EMBASE (Ovid)	02/06/2021	1974 to 2021 June 01

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1 (Arteriovenous Fistula/ or Arteriovenous Shunt, Surgical/) and (Endovascular Procedures/ or Vascular Access Devices/)
2 ((Percutan* or endovascular* or elbow* or forearm* fore-arm* or "fore arm*" or side-to-side or "side to side") adj3 (arteriovenous or AVF or A-V) adj2 fistula*).tw.
3 ((percutan* or endovascular* or forearm* or elbow*) adj3 (renal or haemodialys* or hemodialys* or dialys* or venous or vascular*) adj2 (access* or anastomos*)).tw.
4 or/1-3
5 Renal Dialysis/ or Dialysis/
6 (haemodialys* or hemodialys* or dialys*).tw.
7 5 or 6
8 4 and 7
9 (Everlin or Ellipsys or WavelinQ or endoAVF).tw.
10 8 or 9
11 animals/ not humans/
12 10 not 11
13 limit 12 to ed=20210112-20210630

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the summary of the key evidence. It is by no means an exhaustive list of potentially relevant studies.

Additional papers identified

Article	Number of patients/follow up	Direction of conclusions	Reasons for non-inclusion in summary of key evidence section
Berland T, Westin G, Clement J et al. (2019) Endovascular creation of an arteriovenous fistula with a next generation 4 Fr device design for hemodialysis access: clinical experience from the EASE study. Ann Vasc Surg; 60: 182–192.	Prospective case series N=32 patients on haemodialysis who had the endoAVF procedure in the forearm- radial artery-vein AV in 37.5% and ulnar artery and vein AV in 62.5% (everlinQ). Follow up: 6 months	Technical success rate100% (32/32). The device- or procedure-related serious adverse event rate was 3% (1/32); 1 venous guidewire perforation successfully managed with a stent graft. Primary and cumulative patency rates through 6 months were 83% and 87%, respectively, with an intervention rate of 0.21 per patient-year. There was physiological suitability in 91% (29/32) of patients by 90 days. There was successful 2-needle cannulation in 78% (21/27) by 90 days, with mean time to cannulation of 43±14 days. There was functional cannulation in 95% (20/21) of the patients who were successfully cannulated for an overall rate of 74% (20/27). All patients who had functional cannulation had their CVCs removed before the 90-day follow up for a CVC removal rate of 74% (20/27).	Included in systematic review added to table 2.
Choinski KN, Sundick SA, Rao AG et al. (2020) The current role of the	Review	This paper describes the current use, differences and results with the devices (the Ellipsys Vascular Access System and the WavelinQ EndoAVF	Review

percutaneous arteriovenous fistula for hemodialysis access. Surgical Technology International 37, 1-8		System) and investigates the advantages, disadvantages, and selection criteria for creation of percutaneous AVFs for haemodialysis access.	
Dawoud D, Lok CE, and Waheed U. (2020) Recent Advances in Arteriovenous Access Creation for Hemodialysis: New Horizons in Dialysis Vascular Access. Advances in chronic kidney disease, 27 (3), 191-198.	Review	This review discusses novel methods for creating an anastomosis for AVF and new materials for prosthetic AV grafts. Two technologies for endovascular AVF creation, the Ellipsys and WavelinQ endovascular systems, are discussed. Devices designed to optimise blood flow to reduce maturation failure and improve AV fistula outcomes are explored.	Review
DeVita MV, Khine SK and Shivarov H. (2020) Novel approaches to arteriovenous access creation, maturation, suitability, and durability for dialysis. Kidney Int Rep 5, 769–778.	Review	This review discusses novel approaches to AVF creation and devices to enhance maturation, advances in AVG materials, and devices to safely prolong the use of tunnelled dialysis catheters. Haemodialysis access remains a problem and these innovations may optimise care and the quality of life.	Review
Franco G, Mallios A, Bourquelot P et al. (2020) Ultrasound evaluation of percutaneously created arteriovenous fistulae between radial artery and perforating vein at the elbow. The	Retrospective comparative case series N=31 endoAVF created PRA to perforating vein (with Ellipsys Vascular Access System) compared with 32 control patients with clinically	Mean access flow and distribution range were similar in the 2 study groups, there was no statistically significant difference in the mean radial artery diameter (4 mm versus 4.3 mm, p=0.2). Statistically significant trends were seen for resistive index (0.57 pAVF versus 0.52 (0.07) and brachial vein cross-sectional area (13 pAVF versus 33 mm2, p=0.06).	Haemodynamic profile assessed. Outcomes already reported in larger studies added to table 2.

Journal of Vascular Access, Vol. 21(5) 694–700	well-functioning surgical wrist radiocephalic AVFs. Mean follow up of 254 days.	The arteriovenous anastomosis area was statistically significantly smaller with percutaneous AVFs (13 versus 43 mm2, p=0.002) and the pressure difference between extremities was less for the pAVF group versus surgical wrist radiocephalic AVFs (19 versus 27 mmHg, respectively, p=0.03). Existence of single cephalic or basilic versus cephalic and basilic outflow did not affect vein maturation or overall flow.	
Franco G, Mallios A, Bourquelot P et al. (2020) Feasibility for arteriovenous fistula creation with Ellipsys®. The Journal of Vascular Access, Vol. 21(5) 701–704.	Prospective study N=100 patients assessed for feasibility of endoAVF access creation and a distal radiocephalic fistula.	63% (63/100) were found to be eligible for an endoAVF creation with Ellipsys. 37% of patients were ineligible because of the absence of both median cephalic and median cubital veins (15%), absence or inadequate elbow perforating vein and/ or smaller than 2 mm PRA (14%), and/or distance greater than 1.5 mm (8%). Suitable vessels were found for a surgical distal fistula creation in 91 extremities (45%), but this dropped to 17% in patients over 70 years old. Among the 100 limbs eligible for percutaneous AVF, only 30 (30%) were eligible for radiocephalic AVF.	Ultrasound mapping assessing feasibility of endoAVF.
Hebibi H, Achiche J, Franco G et al.(2019) Clinical hemodialysis experience with percutaneous arteriovenous fistulas created using the Ellipsys® vascular access system.	Retrospective case series N=34 permanent pAVF created with an Ellipsys device (anastomosis between the PRA and the deep vein in the proximal forearm)	Technical success 97% (33/34). 82% (28/34) patients had successful 2-needle cannulation within 10 days to 6 weeks after pAVF creation. 35% (12/34) needed an additional procedure to assist maturation of the pAVF. 44% (15/34) needed no further access intervention. 4 patients died from unrelated causes; 2 patients needed revision to a surgical AVF. None	Larger studies included in table 2.

Hemodialysis International; 23:167–172.	1 year follow up.	developed aneurysmal degeneration steal syndrome, or high access flow related issues.	
Hull JE, Elizondo-Riojas G, Bishop W et al. (2017) Thermal resistance anastomosis device for the percutaneous creation of arteriovenous fistulae for hemodialysis. J Vasc Interv Radiol; 28:380-7	Prospective case series N=26 patients in whom dialysis was suitable had ultrasound-guided AVF creation with a thermal resistance anastomosis device (Ellipsys) PRA-perforating vein AV anastomosis Follow up: 12 months	Technical success rate of fistula creation was 88% (23/26). 96% (22/26) of anastomoses were fused. At 6 weeks, 87% (20/23) of AVFs were patent, 1 patient was having dialysis, 2 fistulae had thrombosed, and 1 patient had died unrelated to the procedure. 80% (16/20), 70% (14/20), and 60% (12/20) of patients were having dialysis at 3, 6, and 12 months; 4 patients died, 3 fistulae failed, and 1 patient was lost to follow up. Overall, 87% (20/23) of AVFs had an additional procedure at a mean of 56 days, including balloon dilation in 10, brachial vein embolisation in 6, basilic vein ligation in 4, venous transposition in 7, and valvulotomy in 1.	Included in systematic review added to table 2.
Hull JE, Jennings WC, Cooper RI et al. (2018) The pivotal multicenter trial of ultrasound-guided percutaneous arteriovenous fistula creation for hemodialysis access. J Vasc Interv Radiol; 29:149-58.e5	Prospective case series N=107 patients in whom dialysis was suitable had ultrasound-guided AVF creation with a thermal resistance anastomosis device (Ellipsys vascular access system) PRA-perforating vein AV anastomosis Follow up: 12 months	AVFs with fused anastomoses were created in 95% (102/107) of patients. Maturation procedures included anastomotic balloon dilation in 72% (77/107), brachial vein embolisation in 32% (34/107), cubital vein ligation in 31% (33/107), and surgical transposition in 26% (28/107) of patients. The primary flow and diameter endpoints were met in 86.0% (92/107) of patients, exceeding performance goal of 49% ($p<0.0001$). No major adverse events were attributed to the device. Cumulative patency was 91.6%, 89.3%, and 86.7% at 90 days, 180 days, and 360 days. Target dialysis veins were cephalic, basilic, and	Included in systematic review added to table 2.

		brachial veins in 74% (73/99), 24% (24/ 99), and 2% (2/99) of patients. There was 2-needle dialysis in 88% (71/81) of patients on haemodialysis at a mean 114.3 days ±66.2. Functional patency was 98.4%, 98.4%, and 92.3% at 90 days, 180 days, and 360 days.	
Inston NG. (2019) Clinical Utility of the WavelinQ™ EndoAVF System. New technologies put the thrill back in dialysis access. Supplement to Endovascular Today, Fall. 8-11.	Review considered future options and analysed current application in predialysis patients, basilic and brachial vein fistulas, and conditioning poor veins.	The evidence to date supports endoAVFs created using the WavelinQ EndoAVF System in terms of technical success, patency, and reduced interventions. Further benefits may be realised from this approach across various aspects of the patient pathway, from predialysis use to tertiary access options.	Review
Jones RG, Khawaja A, Tullett K et al. (2020) Early experience and observations in endovascular dialysis fistula reintervention. The Journal of Vascular Access, Vol. 21(6) 818–825	Review on WavelinQ endoAVF.	Evidence to date on endovascular creation of dialysis fistulas in the proximal forearm has demonstrated high rates of technical success in fistula creation, high rates of dialysis functionality, and low rates of reintervention using 2 systems. Experience of endovascular reintervention in endoAVF created with the WavelinQ system reviewed.	Review
Jones RG and Morgan RA. (2019) A review of the current status of percutaneous endovascular arteriovenous fistula creation for haemodialysis access. Cardiovasc	Review	Initial studies on endovascular creation of fistulas demonstrated high technical success rates, low reintervention, failure rates and good usability for haemodialysis. Two device systems are currently available, an overview of the current global status of endoAVF, patient selection criteria, trial results, technical aspects,	Review

Intervent Radiol, 42:1–9		reinterventions, and outlook for the future are presented.	
Koo KSH, Monroe EJ, Reis J et al. (2021) Initial experience with the Ellipsys Vascular Access System for percutaneous arteriovenous fistula creation in adolescents: A case report. Radiology Case Reports, 16 (3), pages 441-447.	Case report describes the use of the Ellipsys Vascular Access System for percutaneous AVF creation in adolescents.	pAVF creation was successful in both patients and there was physiological maturation of the fistula within 8 weeks of creation with subsequent 2-needle cannulation. No complications or adverse events were encountered.	Larger studies included in table 2.
Lobato M, Vaquero JAH, and Fonseca JL. (2020) Percutaneous endovascular arteriovenous fistula creation for hemodialysis access using “off-the-shelf” conventional devices. J Vasc Surg Cases and Innovative Techniques; 6 (4): 664-5.	Case report Percutaneous AVF (in the upper limb basilic vein and radial artery) of an 82-year-old patient with end-stage renal failure for haemodialysis with an off shelf conventional device.	Adequate venous runoff with no leakage was seen at the level of the anastomosis and an excellent drainage of the AVF through both the cephalic and basilic veins was seen. The fistula was first used 4 weeks after its creation with access flow at the brachial artery of 645 ml/min and no further interventions have been needed to date.	Larger studies included in table 2.
Lok C, Rajan DK, Buldo G et al. (2017) Endovascular proximal forearm arteriovenous fistula for hemodialysis access: results of the prospective, multicenter Novel	Prospective case series N=60 non-dialysis/dialysis-dependent patients needing haemodialysis vascular access had endovascular	EndoAVFs were created in 98% of patients; 8% had a serious procedure-related adverse event (2% device related). 87% were physiologically suitable for dialysis. EndoAVF functional usability was 64% in patients who had dialysis. 12-month primary and cumulative	Included in systematic review added to table 2.

Endovascular Access Trial (NEAT). Am J Kidney Dis;70:486-97	AVF (with everlinQ) Ulnar artery-vein anastomosis Follow up: 12 months	patencies were 69% and 84%, respectively.	
Mallios A, Jennings WC, Boura B et al. (2018) Early results of percutaneous arteriovenous fistula creation with the Ellipsys Vascular Access System. J Vasc Surg; 68:1150-6	Retrospective case series N=34 patients in whom dialysis was suitable had ultrasound-guided AVF creation with a thermal resistance anastomosis device (Ellipsys vascular access system) PRA-perforating vein AV anastomosis Follow up: 12 months	There was technical success in 97% (33/34) patients. 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. Only 1 patient needed superficialisation 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.	Included in systematic review added to table 2.
Mallios A, Fonkoua H, Allouache M et al. (2020) Percutaneous arteriovenous dialysis fistula. J Vasc Surg; 71:1395.	Case report A woman with end-stage kidney disease had a percutaneous AVF created between the PRA and vein (with Ellipsys vascular access system)	After 19 months no additional interventions have been needed, but 2-needle cannulation and dialysis treatments were done without problems. No statistically significant flow is detected on imaging in deep veins of this patient.	Larger studies included in table 2.
Mallios A, Beathard GA, and Jennings WC. (2020) Early cannulation of percutaneously created arteriovenous	Retrospective case series N=14 percutaneous arteriovenous fistula (pAVF) using Ellipsys	Early cannulation (<14 days post creation) was successful in all except for 1 complication. Dialysis treatments were uncomplicated. Primary patency at 3, 6, and 12 months was 76%, 76%, and 66%, respectively. Assisted primary	Larger studies included in table 2.

hemodialysis fistulae. The Journal of Vascular Access, 21(6) 997–1002	device for haemodialysis. Follow up: 12 months.	patency for the same intervals was 100%, 100%, and 91%, respectively. Cumulative patency was 100% at all intervals.	
Osofsky R, Byrd D, Reagor J et al. (2021) Initial Outcomes Following Introduction of Percutaneous Arteriovenous Fistula Program with Comparison to Historical Surgically Created Fistulas. Annals of Vascular Surgery; 2021	Retrospective review n=88 patients 62 had surgically created brachiocephalic (BC)-AVF, sAVF group and 24 had Ellipsys-created percutaneous AVF group Follow up: 1 year	Both the pAVF and sAVF groups had comparable mean operating times (60+/-40 compared with 56+/-25 min, p=0.67) and frequency of procedural technical success (23 [96%] compared with 62 [100%], p=0.28) respectively. The pAVF group had a lower clinical maturation rate (12 [52%] compared with 54 [87%], p=0.003) and a higher primary failure rate (9 [39%] compared with 6 [10%], p=0.003) when compared with the sAVF group. The pAVF group had an increased overall rate of having a postoperative intervention (18 [78%] compared with 13 [21%], p<0.001), as well as an increased number of total postoperative interventions (1.1+/-0.9 compared with 0.3+/-0.6 interventions, p<0.001) compared with the sAVF group. Percutaneous transluminal angioplasty of the juxta anastomotic segment was the most prevalent postoperative intervention performed in the pAVF group and occurred at a statistically significantly increased frequency when compared with the sAVF group rate (13 [57%] compared with 5 [8%], p<0.001).	Similar studies included in the summary of evidence in the overview.
Patel J, Chang S, Manawar S et al. (2021) Effectiveness and safety of repeated	Retrospective study Repeated percutaneous	The mean overall patency for all limbs was 50.86 months. AVFs had a statistically significantly longer patency than AVGs (51.65 compared with 42.09	More relevant studies added to summary of evidence in the overview.

percutaneous intervention in an office-based endovascular center in maintaining hemodialysis access. Vascular; 2021	dialysis access intervention in upper extremity access site. n=259 (298 limbs: 913 procedures) 190 AVFs, 108 AV grafts brachiocephalic fistula (n=74, 39%) and radio cephalic fistula (n=69, 36%).	months; p=0.01). In addition, patients with 2 or more percutaneous dialysis access intervention in their AVF had statistically significantly greater patency than those with only 1 percutaneous dialysis access intervention (58.5 compared with 7.6 months; HR 0.41; p=0.0008). This was not true for the AVG group. Women represented 49% of the patient group. Overall, fistulas have longer patency than grafts and women have poorer outcomes when compared with men (39.8 compared with 60 months; p=0.0007).	
Popli K, Dittman JM, Amendola MF et al. (2020) Anatomic suitability for commercially available percutaneous arteriovenous fistula creation systems. Journal of Vascular Surgery, 1-6 (article in press).	Retrospective case series N=58 patients having a first-time arteriovenous access consultation (116 upper extremities).	Anatomic suitability was greater for WavelinQ than for Ellipsys. Once the full requirements for pAVF creation were considered, we found no statistically significant differences in usability between the 2 systems. The potential applicability for each system was 32% and 23%, respectively, for all limbs using a clinical algorithm that considered radiocephalic fistula creation as the first choice, when feasible. Anatomic analysis showed that pAVF creation can constitute a substantial part of a haemodialysis access practice.	More relevant studies added to table 2.
Radosa CG, Radosa JC, Weiss N et al. (2017) Endovascular creation of an arteriovenous fistula (endoAVF) for hemodialysis access: first	Retrospective case series N=8 patients needing haemodialysis access had had AVF creation (ulnar artery-vein anastomosis with	Creation of endoAVF was successful in all. One minor intraprocedural complication and no postoperative complications reported. Median time to endoAVF maturation was 63 days (range 26 to 137 days). Patency after 6 months was 100%.	Included in systematic review added to table 2.

results. Cardiovasc Intervent Radiol; 40:1545-51.	everlinQ endoAVF system) Follow up: 6 months		
Rajan DK, Ebner A, Desai SB et al. (2015) Percutaneous creation of an arteriovenous fistula for hemodialysis access. J Vasc Interv Radiol; 26:484-90	Retrospective case series N=33 patients needing haemodialysis access had endovascular AVF creation (ulnar artery-vein anastomosis with everlinQ endoAVF system)	Successfully created AVF in 97% (32/33) patients. 24 had successful dialysis by their pAVF at 6 months. One spontaneous pAVF thrombosis occurred. Cumulative pAVF patency at 6 months was 96.2% (26/27). Mean time to pAVF maturation was 58 days. There was 1 serious and 5 minor procedure-related adverse events. Four patients died during follow up from causes unrelated to the procedure.	Included in systematic review added to table 2.
Rognoni C, Tozzi M and Tarricone R. (2020) Endovascular versus surgical creation of arteriovenous fistula in hemodialysis patients: Cost-effectiveness and budget impact analyses. The Journal of Vascular Access 1–10 March 2020.	Cost-effectiveness and budget impact analyses comparing endovascular AVF creation to surgical AVF creation in haemodialysis patients from the National Healthcare Service (NHS) perspective in Italy.	For both incident and prevalent haemodialysis patients, endovascular AVF creation, done with WavelinQ, was the dominant strategy over surgical AVF approach, showing less cost and better patients' quality of life. Compared with the current scenario, progressively increasing utilisation rates of WavelinQ over surgical AVF creation in the next 5 years in incident haemodialysis patients are expected to save globally 30–36 million euros to the NHS.	cost-effectiveness and budget impact analyses.
Sandhu B, Hill C, Hossain MA et al. (2021) Endovascular arteriovenous fistulas- are they the answer we haven't been looking for?. Expert review of	Review describes the limitations of surgical AVFs and the endovascular devices currently available and studies assessing their use.	Early results achieved with endovascular fistula formation are encouraging. Current limitations of this technology include anatomic suitability and a high rate of re-interventions needed to establish maturity. Greater uptake of the technology will also need a	Review

medical devices; 18 (3); 273-280.		review of long-term outcomes in larger patient cohorts.	
Shahverdyan R, Konner K and Matoussevitch V. (2020) The past and the future of vascular access surgery: Creation of percutaneous arteriovenous fistula using Ellipsys vascular access system in a patient with previous ipsilateral Scribner-shunt. The Journal of Vascular Access 1–4 October 2020.	Case report A 72-year old woman with chronic kidney disease and previous right-sided Scribner-shunt and kidney transplant, had a successful creation of right-sided Ellipsys-pAVF.	The procedure time was 12 min with intraoperative brachial artery volume flow of 720ml/min. At 39 days, an ultrasound-guided balloon angioplasty of the outflow cephalic vein stenosis was done. Cannulations were started 41days after the creation of pAVF. No additional interventions were needed during the follow up of 258 days with last follow-up volume flow of 1400ml/min.	Larger studies added to table 2.
Shahverdyan R, Beathard G, Mushtaq N et al. (2021) Comparison of Ellipsys Percutaneous and Proximal Forearm Gracz-Type Surgical Arteriovenous Fistulas. American journal of kidney diseases: the official journal of the National Kidney Foundation; 2021	Retrospective study n=158 AVF placements 89 pAVFs and 69 sAVFs. Follow up: 12 months.	Technical success was 100% for both groups. Average procedure times were 14 minutes for pAVFs and 74 minutes for sAVFs (p<0.001). PRA was used in all pAVF cases. Inflow for sAVFs included radial (30%), ulnar (12%), and brachial (58%) arteries. Outflow veins for both groups were the cephalic and/or basilic veins. Access flow volumes, times to maturation, and overall numbers of interventions/patient-year were not statistically significantly different. Cumulative incidence of primary patency failure at 12 months was lower for sAVF (47% compared with 64%, p=0.1030), but secondary patency failure was not different between groups (20% compared with 12%, p=0.3323). PRA-sAVFs had similar primary	Similar studies included in the summary of evidence in the overview.

		patency (65% compared with 64%, p=0.7858), but higher secondary patency failure rates than pAVFs at 12 months (34% compared with 12%, p=0.0435). Conclusions: Both pAVF and sAVF showed high rates of technical success and secondary patency. pAVFs needed shorter procedure times. The rate of intervention was similar. When a distal radial artery AVF is not feasible, pAVF might offer an appropriate procedure for creating a safe and functional access, maintaining further proximal forearm sAVF creation options.	
Sultan S, Langsfeld M, Chavez L et al. (2020) Initial 6-month quality review of a percutaneous endovascular arteriovenous fistula program. The Journal of Vascular Access 1–7.	Retrospective case series N=18 percutaneous AVF placements using Ellipsys. Follow up: 6 months	Technical success was 94%. AVFs were used or met maturation characteristics in 47% (7/15) at 6 months. Poor postsurgical maturation or need for additional maturation procedures (55.6%) were the predominate reasons for non-use.	Larger studies included in table 2.
Wasse H, Alvarez AC, Brouwer-Maier D et al. (2020) Patient selection, education, and cannulation of percutaneous arteriovenous fistulae: An ASDIN White Paper. The Journal of Vascular Access,	Review by the American Society of Diagnostic and Interventional Nephrology.	Experts in interventional nephrology, surgery, and interventional radiology convened and provide recommendations on the elements that are fundamental to a functional percutaneous AVF.	Review

Vol. 21(6) 810–817.			
Yang S, Lok C, Arnold R et al. (2017) Comparison of post-creation procedures and costs between surgical and an endovascular approach to arteriovenous fistula creation. J Vasc Access; 18(Suppl 2):S8-14.	Propensity score matching study 60 patients with SAVF (from Medicare Standard Analytical Files) were matched to 60 patients with an endoAVF created using everlinQ system (from NEAT study, Lok 2017).	The total postcreation procedural event rate within 1 year was lower for endoAVF patients (0.59 per patient-year) compared with the matched SAVF cohort (3.43 per patient-year; p<0.05). In the endoAVF cohort, event rates of angioplasty, thrombectomy, revision, catheter placement, subsequent AVG, new SAVF, and vascular access-related infection were all statistically significantly lower than in the SAVF cohort. The average first year cost per patient-year associated with postcreation procedures was estimated at US$11,240 lower for endoAVF than for SAVF.	Similar study (Arnold 2019) included in table 2.
Zemela MS, Hataka R. Minami HR, Alvarez AC et al. (2021) Real-World Usage of the WavelinQ EndoAVF System. Ann Vasc Surg; 70: 116–122.	N=35 patients had placement of the WavelinQ AVF. Average follow up: 73 days	Fistula creation success rate was 100%. 25% (8/32) patients had perioperative complications. 41% (13/32) patients had subsequent endovascular interventions to assist with maturation. 13% (4/32) patients needed subsequent surgical interventions. % (30/32) were ulnar-ulnar fistulas and overall patency at average follow up of 73 days was 88% (28/32) with average brachial artery inflow volume of 1,078 cc/min and average cephalic vein (18/32) outflow volume of 447 cc/min. 48% (11/23) patients on dialysis were successfully using the EndoAVF at follow up.	Larger studies with longer follow up included in table 2.