AJKD

Original Investigation

Endovascular Proximal Forearm Arteriovenous Fistula for Hemodialysis Access: Results of the Prospective, Multicenter Novel Endovascular Access Trial (NEAT)

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Background: Hemodialysis arteriovenous fistulas (AVFs) are suboptimally used primarily due to problems with maturation, early thrombosis, and patient nonacceptance. An endovascular approach to fistula creation without open surgery offers another hemodialysis vascular access option.

Study Design: Prospective, single-arm, multicenter study (Novel Endovascular Access Trial [NEAT]).

Settings & Participants: Consecutive adult non−dialysis-dependent and dialysis-dependent patients referred for vascular access creation at 9 centers in Canada, Australia, and New Zealand.

Intervention: Using catheter-based endovascular technology and radiofrequency energy, an anastomosis was created between target vessels, resulting in an endovascular AVF (endoAVF).

Outcomes: Safety, efficacy, functional usability, and patency end points.

Measurements: Safety as percentage of device-related serious adverse events; efficacy as percentage of endoAVFs physiologically suitable (brachial artery flow ≥ 500 mL/min, vein diameter ≥ 4 mm) for dialysis within 3 months; functional usability of endoAVFs to provide prescribed dialysis via 2-needle cannulation; primary and cumulative endoAVF patencies per standardized definitions.

Results: 80 patients were enrolled (20 roll-in and 60 participants in the full analysis set; the latter are reported). EndoAVFs were created in 98% of participants; 8% had a serious procedure-related adverse event (2% device related). 87% were physiologically suitable for dialysis (eg, mean brachial artery flow, 918 mL/min; endoAVF vein diameter, 5.2 mm [cephalic vein]). EndoAVF functional usability was 64% in participants who received dialysis. 12-month primary and cumulative patencies were 69% and 84%, respectively.

Limitations: Due to the unique anatomy and vessels used to create endoAVFs, this was a single-arm study without a surgical comparator.

Conclusions: An endoAVF can be reliably created using a radiofrequency magnetic catheter-based system, without open surgery and with minimal complications. The endoAVF can be successfully used for hemodialysis and demonstrated high 12-month cumulative patencies. It may be a viable alternative option for achieving AVFs for hemodialysis patients in need of vascular access.

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INDEX WORDS: Arteriovenous fistula (AVF); endovascular; hemodialysis; magnetic; radiofrequency; vascular access; endoAVF; ESRD; endovascular fistula; access creation; fistula maturation; fistula failure; blood flow rate; cannulation; patency; end-stage renal disease (ESRD).

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In 1966, Brescia, Cimino, Appel, and Hurwich[1] detailed a surgical technique that affects millions of people globally: the surgical creation of the arteriovenous fistula (AVF), now deemed the recommended vascular access.[2-5] However, currently only 14% of patients in the United States initiate hemodialysis with an AVF,[2] and prevalent use of AVFs remains low in many regions worldwide.[6] Factors contributing to their underuse include long cumulative wait times for surgical consultation and AVF creation (3-10 weeks[7,8]), inconvenient and time-consuming preoperative visits, patient refusal of surgery, surgical risk, and high early thrombosis of 12% to 26%.[9,10] Following AVF creation, maturation can be challenging, requiring the use of bridging catheters[11-14] and an average of 1.5 to 3.3 procedures to allow fistula usability.[14-16] All these factors together ultimately increase patient reluctance concerning surgical AVF creation, especially for patients with previously failed arteriovenous access.[17]

Creating an AVF using an endovascular approach may reduce vessel trauma, thus lessening the stimulus for intimal hyperplasia linked with fistula maturation failure[18]; may reduce morbidity; and may improve patient acceptance and fistula use. We previously reported proof of concept, developmental work regarding a novel magnet-based endovascular technology to create an AVF (endovascular AVF [endoAVF]).[19] However, this work was limited by the single-center experience in a select population: young patients without significant vascular disease. Thus, the real-world use of this technology in a range of operators and patients with chronic kidney disease (CKD) is untested and unknown. We sought to evaluate the safety and efficacy of this technology with multiple operators and in a broad CKD population via an international prospective clinical study.

METHODS

Study Design

The Novel Endovascular Access Trial (NEAT) is a prospective single-arm multicenter study. It aimed to determine the safety and efficacy of using an endovascular technique (see Treatments section) to create an arteriovenous connection that would develop one or more draining vein(s) into a physiologically suitable AVF for dialysis. We hypothesized that 75% of endoAVFs would be physiologically suitable for dialysis within 3 months of creation.

Patient Population

The study was conducted with strict adherence to Good Clinical Practice guidelines and the Declaration of Helsinki. Study sites received local research ethics board approval (University Health Network REB # 13-6547-B), and all patients provided written informed consent before enrollment. Patients with CKD stage 5 (non−dialysis dependent or dialysis dependent) in need of hemodialysis vascular access were identified by their nephrologists and evaluated according to local practices (eg, in a vascular access clinic, by surgical referral). Patients were consecutively evaluated for study eligibility according to study inclusion and exclusion criterion (Item S1, available as online supplementary material), which followed recent guidelines for vessel criteria for AVF creation.[5,20] Participants were enrolled at 6 sites in Canada and 3 sites in Australia and New Zealand. Participants became either "roll-in participants" or "full-analysis-set cohort participants" (Fig 1). Roll-in participants met all inclusion and no exclusion criteria but were excluded from analysis (see Treatments section). The rest of the full-analysis-set participants constituted the study cohort used for study analysis.

Treatments

Operators were board certified (or country equivalent) interventional radiologists or vascular surgeons. They were trained with demonstration models on the procedure before local study commencement. The study protocol stipulated a priori that an operator without prior experience or who did not directly observe at least 5 procedures with the study device was required to enroll his or her first 2 consecutive patients as roll-in participants to gain clinical technical experience.

Eligible participants did not require multiple preoperative patient assessments (eg, preadmission consults) beyond routine vessel mapping. All procedures were performed as an outpatient procedure with the participant under conscious sedation and with sterile technique. The endoAVF creation procedure, using the everlinQ endoAVF System, TVA Medical (Fig 2),[21] was conducted under fluoroscopic guidance. Briefly, one magnetic catheter was inserted into the ulnar artery via the brachial artery and one magnetic catheter was inserted into the ulnar vein via the brachial vein. When the catheters were aligned with one another, the magnets within each catheter were attracted to one another, holding the artery and vein together while simultaneously aligning a radiofrequency electrode in the venous catheter and a ceramic backstop in the arterial catheter. The radiofrequency electrode was released from the venous catheter and energized for approximately 2 seconds. This created a 5 mm × 1 mm channel (anastomosis) between the ulnar vessels, resulting in a side-to-side ulnar vein fistula in the forearm (endoAVF). Next, if the patient had more than one brachial vein, the entry brachial vein was coil embolized to redirect flow to the superficial veins. A final fistulogram was obtained via the brachial artery sheath (Fig 3A-E).

After endoAVF creation, participants had study assessments within 1 week, at 6 weeks, and monthly for 12 months. A duplex ultrasound was obtained at baseline before endoAVF creation and after endoAVF creation in the first week (days 1-7) and at 1, 3, 6, and 12 months.

Study Definitions and Measures

Technical success or successful creation of an endoAVF was defined as visualizing blood flow through the AVF via a fistulogram before the participant left the procedure room. The primary efficacy end point was the percentage of endoAVFs physiologically suitable for hemodialysis within 3 months of creation. This was defined as freedom from fistula stenosis and thrombosis and brachial artery flow ≥ 500 mL/min and vein diameter ≥ 4 mm measured by duplex ultrasonography[22,23] or successful hemodialysis delivery using 2 needles. Physiologic suitability of the endoAVF was defined by the brachial artery flow and vein diameter criterion, an accepted measure that allows endoAVF evaluation in non−dialysis-dependent patients with CKD who may not have needed to initiate hemodialysis within the 3-month postcreation time frame.[24-28] Brachial artery and arterialized vein flow rates and diameters were determined by qualified vascular ultrasonographers who were unaware of the study primary end point.

For patients who were already on dialysis or who were non−dialysis dependent and initiated dialysis during the course of the study, we also report functional endoAVF usability (cannulation) within 12 months of endoAVF creation. Because this was the first exposure of the endoAVF to clinicians and nurses in the study,

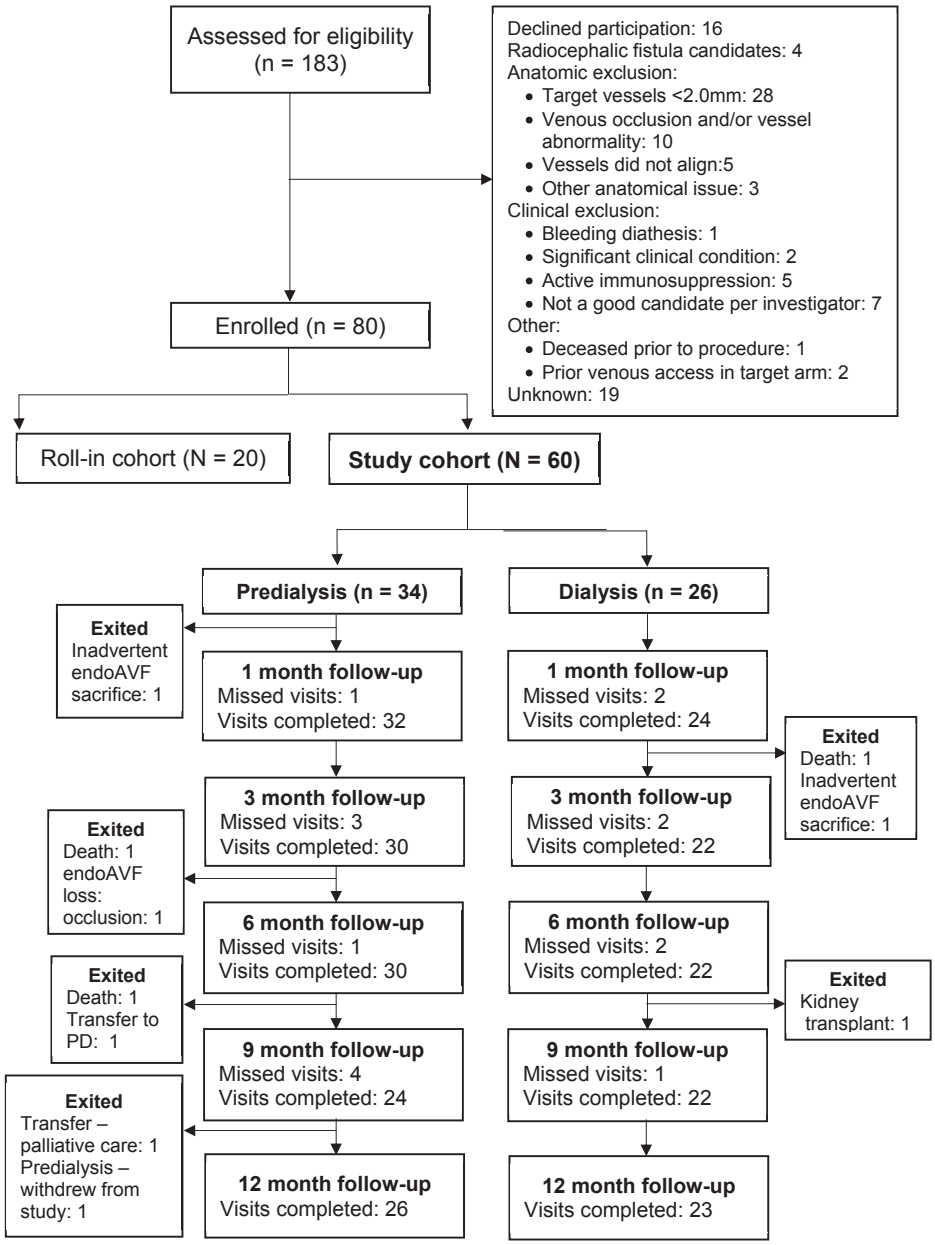


Figure 1. CONSORT participant flow. Note: Because the endovascular arteriovenous fistula (endoAVF) creation procedure used in the Novel Endovascular Access Trial (NEAT) was entirely novel, "roll-in" cases (2 cases/operator) were deemed necessary by operators who created the endoAVF and physicians who subsequently managed them, to gain technical and clinical experience.

the protocol was designed to err on the side of caution. Thus, the protocol did not permit evaluation for cannulation until after 6 weeks postcreation. The NEAT cannulation protocol was a modification of the cannulation guidance provided by the Fistula First Initiative in order to allow for a more gradual increase in dialysis blood pump speeds and needle sizes to achieve a blood pump speed of 350 to 450 mL/min using 14- or 15-gauge needles (see Item S2 for study cannulation protocol). Functional usability was defined as 2-needle cannulation of the endoAVF for prescribed dialysis in two-thirds or more of dialysis sessions over a 4-consecutive-week period within 12 months of endoAVF creation. Primary and cumulative patencies followed published standardized definitions.[29]

Safety was assessed via percentage of serious device-related adverse events. Procedure-related serious adverse events were defined as complications arising from the procedure from time of initiation to completion as adjudicated by an independent clinical events committee. Secondary outcomes included more detailed imaging and clinical end points, such as endoAVF primary and cumulative patencies.

Study Oversight

The trial was sponsored by TVA Medical with appropriate regulatory approvals (eg, Health Canada). Each investigator was trained in Good Clinical Practice, the study protocol, and the endoAVF technique prior to study commencement. Investigators and their research staff collected the data at each site. On-site monitoring visits were performed to assess protocol compliance and perform data verification. An independent statistician analyzed the data according to a prespecified statistical analysis plan. An independent data and safety monitoring board regularly reviewed

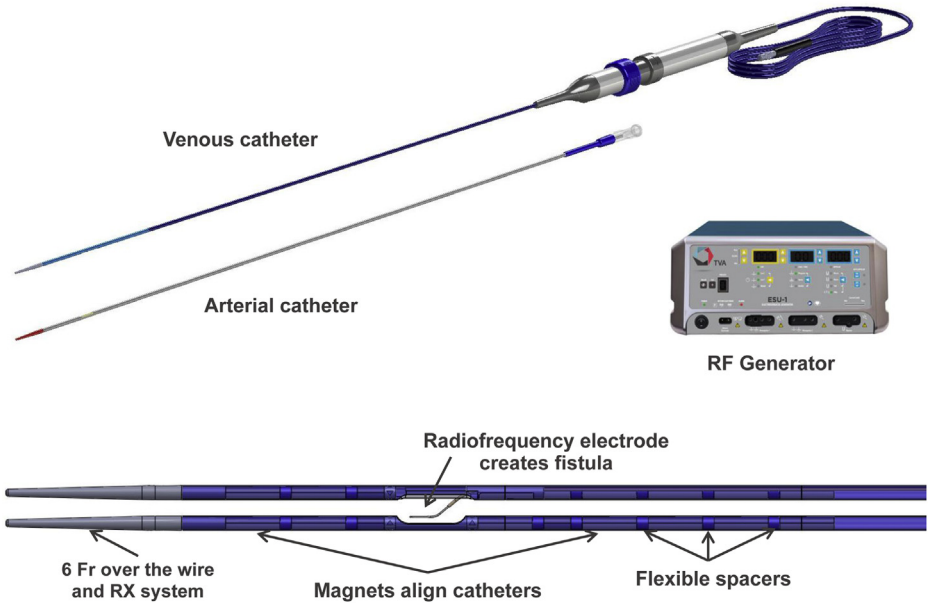


Figure 2. The everlinQ endoAVF System. Abbreviation: RF, radiofrequency.

study data reports, participant safety, and study progress. An independent Clinical Events Committee adjudicated all adverse events for severity and relatedness to the study device or procedure.

Statistical Analysis

It was hypothesized that at least 75% of endoAVFs would be suitable for dialysis within 3 months compared to a fistula suitability benchmark of 57.5%. Sixty participants would provide at least 80% power with α of 0.05 for comparison of the endoAVF with the benchmark. The fistula suitability benchmark was derived from contemporary published studies of surgical hemodialysis fistulas and their outcomes.[9,30-34] The primary outcome was evaluated using an exact binomial 95% confidence interval (CI) with the lower-bound interval compared to the 57.5% benchmark. Continuous variables were reported as mean values ± standard deviations, and categorical variables, as frequencies and percentages. Changes in vessel flow rates and vein diameters were assessed by paired *t* tests, and time to events, by survival analyses (Kaplan-Meier estimator).

Analyses were performed on 60 participants who constituted the full-analysis-set cohort, in which all 60 participants who received the treatment were analyzed, akin to the intention-to-treat principle in randomized controlled trials. A separate analysis of an evaluable cohort was conducted that considered only participants for whom the primary efficacy end point could be determined (ie, participants who died or had other valid censoring events before primary end point evaluation could occur were excluded); this is akin to the per-protocol analysis in randomized controlled trials.[35] All analyses were performed using SAS, version 9.4 (SAS Institute Inc).

RESULTS

Participants

Eighty patients were enrolled from 9 sites in Canada, Australia, and New Zealand in January 2014 to August 2015. The last participant completed the 12-month study follow-up in August 2016. At baseline, participants of the 60 full-analysis-set cohort (Table 1) had a mean age of 59.9 years, 65% were men, 57% had non−dialysis-dependent CKD, and 42% had a central venous catheter in situ. See Fig 1 for follow-up details. Before primary end point evaluation could occur, 1 participant died of cardiac causes unrelated to the procedure, and 2 participants had inadvertent endoAVF sacrifice related to brachial artery complications. One of these was associated with emergent management of a pseudoaneurysm, and the other was due to an arterial closure device. Thus, evaluable data were available for 57 participants and used for evaluable cohort analysis.

EndoAVF Outcomes

EndoAVF creation was successful in 59 of 60 (98%) cases (Table 2). In the 1 unsuccessful case, the investigator used a braided vascular sheath that acted as an energy sink, which prevented adequate radiofrequency energy delivery to create the anastomosis.

The primary efficacy end point, physiologic suitability of the endoAVF for dialysis, was 52 of 60 (87%; 95% CI, 75%-94%) in the full-analysis-set cohort and 52 of 57 (91%; 95% CI, 81%-97%) in the evaluable cohort. Of the 8 participants with an endoAVF nonsuitable for dialysis within 3 months, 1 endoAVF was not created as already noted, 3 endoAVFs failed to mature (ie, inadequate brachial artery flow < 500 mL/min), 1 had an intraprocedural thrombosis that resulted in endoAVF closure, and, as previously mentioned 2 were inadvertently sacrificed and 1 patient died. Mean brachial artery flow increased from 82 mL/min at baseline to 918 mL/min

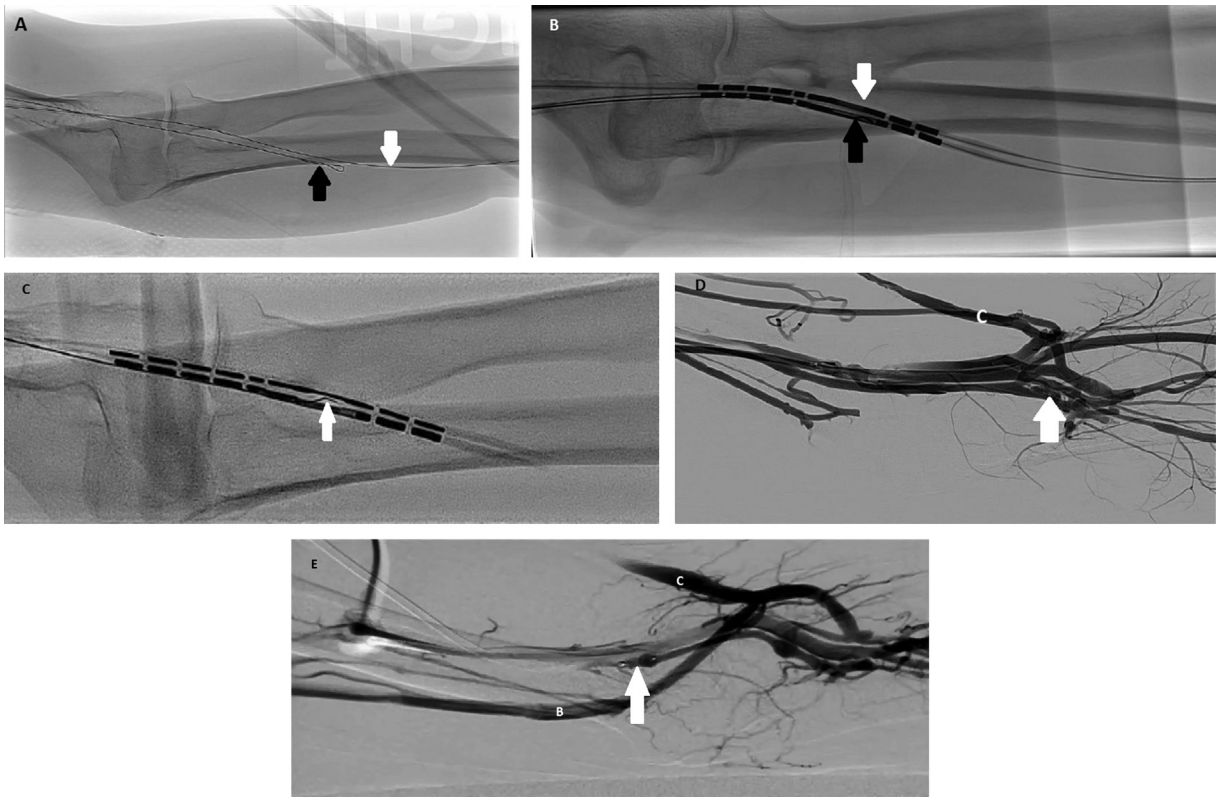


Figure 3. Endovascular arteriovenous fistula (endoAVF) procedure steps. (A) After entering the brachial vein with a 21-gauge needle, a 0.018-inch guidewire is advanced through the needle to the ulnar vein (black arrow) under fluoroscopy, and a 7Fr sheath is inserted. White arrow indicates wire in the ulnar artery. (B) Next, access to the brachial artery is similarly achieved; a guidewire is advanced to the ulnar artery, and a 6Fr sheath is inserted. The everlinQ venous catheter is advanced to the ulnar vein (black arrow), and arterial catheter, to the ulnar artery (white arrow) under fluoroscopy. (C) Magnetic catheters align and then the radiofrequency electrode is deployed (white arrow). (D) After removing catheters, the endoAVF (white arrow) is confirmed with brachial artery contrast injection. (E) One brachial vein is embolized to divert flow to superficial veins (arrow; Amplatzer plug in embolized brachial vein). Last, the arterial sheath is removed and hemostasis attained per institutional practice. Abbreviations: B, basilic vein; C, cephalic vein. Note: If the operator did not use a vascular closure device during the procedure to attain hemostasis, participants had manual compression over the puncture sites for 15 to 20 minutes and then they were covered with a simple adhesive bandage. Additional adhesive dressings, bandages, and supportive wrappings were discouraged.

at 3 months ($P < 0.001$). All draining veins significantly increased from baseline to 3 months (all $P < 0.001$). Mean change in vein diameter and mean vein diameters at 3 months (in parenthesis) were as follows: median cubital vein: 1.7 (5.9) mm; cephalic vein: 2.0 (5.2) mm, and basilic vein: 1.8 (6.0) mm.

Initiation of 2-needle cannulation followed the study protocol; thus, endoAVFs were not assessed for cannulation readiness until the 2-month follow-up visit. Nurses assessed the endoAVF for cannulation as they would a traditional surgical AVF (look, listen, and feel). Because each endoAVF is unique, the nurses were able to use their clinical judgment regarding placement of cannulation needles. For example, if there was a long segment, they had the option of proximal and distal placement of needles in the same vein; if 2 separate veins matured (eg, median cubital and cephalic), they could place the arterial and venous needles in each vein; this had the benefit of allowing greater needle rotation (avoiding "one-siteitis") and eliminating concerns of recirculation (Fig 4). The average vein length available for cannulation was 10.8 cm. Of the full-analysis-set cohort, 44 participants could be evaluated for functional usability (Table 3). In the evaluable-cohort analysis, the 2 inadvertent losses previously noted were excluded from analysis. Functional endoAVF usability with 2-needle cannulation was 28 of 44 (64%) in the full-analysis-set cohort and 28 of 42 (67%) in the evaluable cohort (Table 3). Mean time to 2-needle cannulation was 111.8 days in baseline dialysis participants and 32.4 days in baseline non−dialysis-dependent participants after they initiated dialysis. Seventy-five percent of baseline non−dialysis-dependent participants initiated dialysis using 2-needle cannulation of the endoAVF. Reasons for not cannulating are detailed in Table 4. At 12 months, endoAVF primary patency was 69% (95% CI, 54%-79%), whereas cumulative patency was 84% (95% CI, 71%-91%; Fig 5).

Table 1. Baseline Participant Characteristics

Characteristic	All (N = 80)	Full-Set-Analysis Participants (n = 60)	Roll-In Participants (n = 20)
Male sex	54 (68%)	39 (65%)	15 (75%)
Age, y	60.1 ± 13.1 61.0 [28.0-85.0]	59.9 ± 13.6 61.0 [28.0-85.0]	60.7 ± 11.6 61.0 [40.0-82.0]
Race			
White	49 (61%)	36 (60%)	13 (65%)
Black	3 (4%)	0 (0%)	3 (15%)
Asian	21 (26%)	19 (32%)	2 (10%)
Native Hawaiian/Pacific Islander	2 (3%)	1 (2%)	1 (5%)
Other	5 (6%)	4 (7%)	1 (5%)
Cause of ESKD			
Diabetes	40 (50%)	30 (50%)	10 (50%)
Glomerular-based disease	9 (11%)	8 (13%)	1 (5%)
Hypertension	10 (13%)	9 (15%)	1 (5%)
Interstitial nephritis	1 (1%)	1 (2%)	0 (0%)
Polycystic kidney disease	5 (6%)	4 (7%)	1 (5%)
Other/unknown	13 (16%)/2 (3%)	7 (12%)/1 (2%)	6 (30%)/1 (5%)
BMI, kg/m^2	28.1 ± 6.1	27.9 ± 6.1	28.3 ± 6.1
BMI > 25 kg/m^2	51/79 (65%)	38/60 (63%)	13/20 (65%)
Comorbid conditions			
Diabetes	49 (61%)	39 (65%)	10 (50%)
Congestive heart failure	10 (13%)	7 (12%)	3 (15%)
Coronary artery disease	17 (21%)	13 (22%)	4 (20%)
Hypertension	73 (91%)	55 (92%)	18 (90%)
Cerebrovascular disease	11 (14%)	9 (15%)	2 (10%)
Peripheral vascular disease	5 (6%)	3 (5%)	2 (10%)
Prior PD	23 (29%)	18 (30%)	5 (25%)
Prior kidney transplant	9 (11%)	8 (13%)	1 (5%)
Previous AVF[a]	22 (28%)	19 (32%)	3 (15%)
CVC use at screening	39 (49%)	25 (42%)	14 (70%)
On hemodialysis at screening	40 (50%)	26 (43%)	14 (70%)

Note: Unless otherwise indicated, values for categorical variables are given as number (percentage); values for continuous variables, as mean ± standard deviation or median [interquartile range].

Abbreviations: AVF, arteriovenous fistula; BMI, body mass index; CVC, central venous catheter; ESKD, end-stage kidney disease; PD, peritoneal dialysis.

[a]Prior to study.

Adverse Events and Interventions

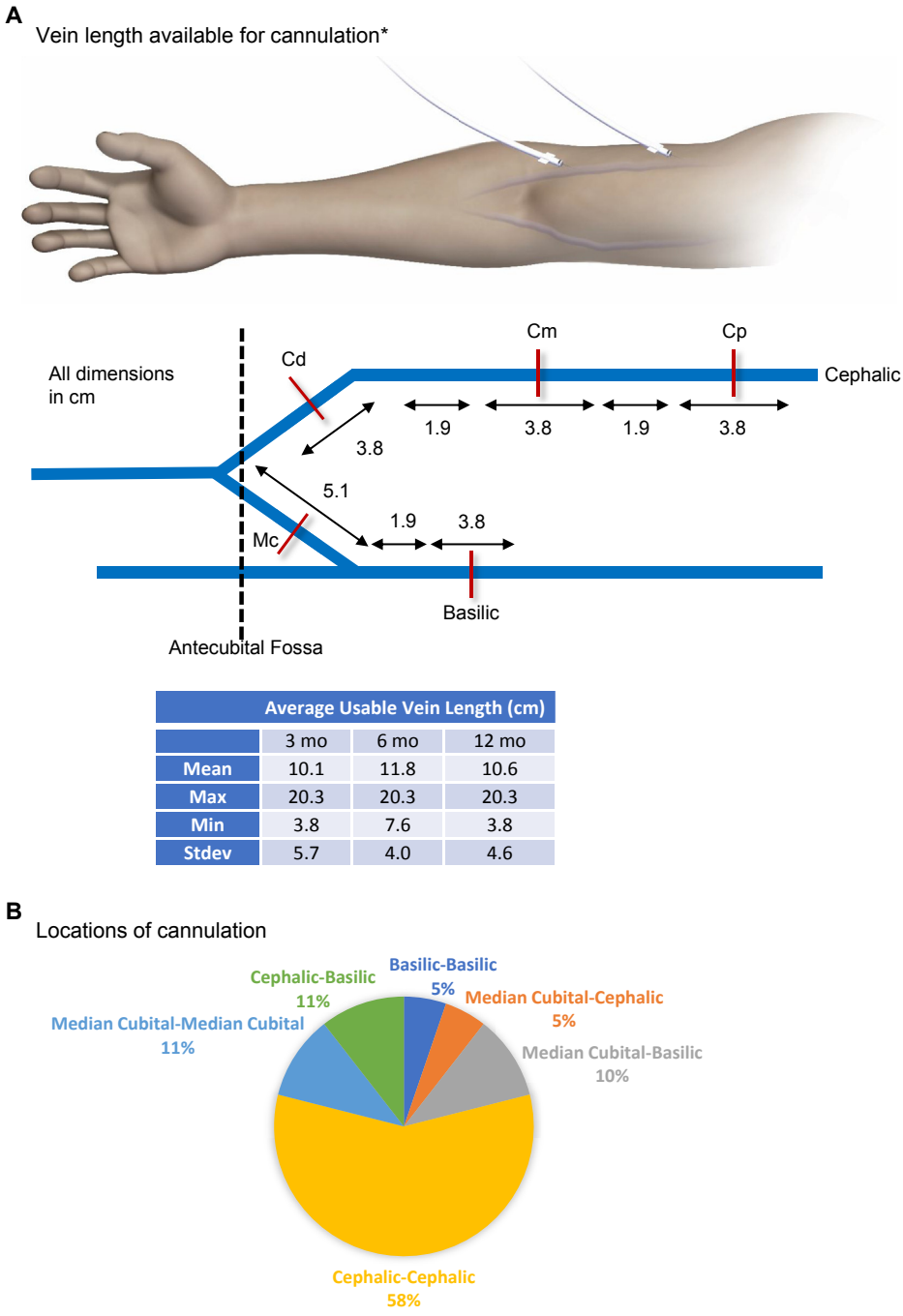
Eight serious procedure-related adverse events occurred in 5 (8%) participants (Table 5), most commonly due to access-site management and hemostasis. One of the 8 events was adjudicated as related to the study device: a pseudoaneurysm at the endoAVF site caused by a second delivery of radiofrequency energy (after the initial energy delivery was unsuccessful at creating an anastomosis); it was surgically repaired. In total, there were 2 pseudoaneurysms, which occurred at different locations: (1) at the endoAVF site as mentioned, and (2) at the brachial artery access (ie, entry) site (Table 5).

Table 2. Primary EndoAVF Events: Efficacy

	All (N = 80)	Study Cohort (n = 60)	Roll-in Cohort (n = 20)
EndoAVF created			
Full-analysis-set and evaluable cohorts	79/80 (99%; 93%-100%)	59/60 (98%; 91%-100%)	20/20 (100%; 83%-100%)
EndoAVF physiologically suitable for dialysis within 3 mo			
Full-analysis-set cohort	64/80 (80%; 70%-88%)	52/60 (87%; 75%-94%)	12/19 (63%; 38%-84%)
Evaluable cohort		52/57 (91%; 81%-97%)	

Note: Values are given as n/N (percentage; 95% confidence interval).

Abbreviation: AVF, arteriovenous fistula; endoAVF, endovascular AVF.



	Average Usable Vein Length (cm)		
	3 mo	6 mo	12 mo
Mean	10.1	11.8	10.6
Max	20.3	20.3	20.3
Min	3.8	7.6	3.8
Stdev	5.7	4.0	4.6

Figure 4. Available veins for cannulation and locations. (A) Vein length available for cannulation. *Based on duplex ultrasound, vein segment was considered available for cannulation if the vein diameter was >4 mm, venous flow rate was >500 mL/min, and vein depth was <6 mm from the skin surface. (B) Locations of cannulation. Abbreviations: Cd, cephalic distal; Cm, cephalic medial; Cp, cephalic proximal; MC, median cubital.

Twenty-four secondary interventions were performed in 19 participants (0.46/patient-year), including 5 basilic vein transpositions, 5 coil embolizations of a tributary vein, 3 endoAVF ligations, 2 thrombin injections, 2 angioplasties, 1 thrombolysis, 2 thrombectomies, 2 surgical artery repairs, and 2 new AVFs or arteriovenous grafts.

DISCUSSION

Our study of non−dialysis-dependent and dialysis-dependent patients requiring vascular access found that an upper-extremity AVF can be reliably and safely created using a minimally invasive radiofrequency magnetic catheter−based system. Ninety-eight percent

Table 3. EndoAVF Functional Usability

Cohort	Unassisted Functional Usability	Assisted Functional Usability	Total Functional Usability
Full analysis set			
NDD at baseline	11/20 (55%; 32%-77%)	1/20 (5%; 0%-25%)	12/20 (60%; 36%-81%)
On dialysis at baseline	12/24 (50%; 29%-71%)	4/24 (17%; 5%-37%)	16/24 (67%; 45%-84%)
Total	23/44 (52%; 37%-68%)	5/44 (11%; 4%-25%)	28/44 (64%; 48%-78%)
Evaluable			
NDD at baseline	11/19 (58%; 34%-80%)	1/19 (5%; 0%-26%)	12/19 (63%; 38%-84%)
On dialysis at baseline	12/23 (52%; 31%-73%)	4/23 (17%; 5%-39%)	16/23 (70%; 47%-87%)
Total	23/42 (55%; 39%-70%)	5/42 (12%; 4%-26%)	28/42 (67%; 51%-80%)

Note: Values are given as n/N (percentage; 95% confidence interval). Functional usability indicates 2-needle cannulation for two-thirds of dialysis sessions over a 4-week period. Reasons for exclusion from functional usability analysis: 13 NDD at enrollment and completed the study without needing dialysis, 1 participant who received a kidney transplant, and 2 who died before evaluable period (1 death noted previously and 1 patient who successfully cannulated and dialyzed with the endoAVF using 2 needles but died a week later of study-unrelated causes).

Abbreviations: AVF, arteriovenous fistula; endoAVF, endovascular AVF; NDD, non−dialysis-dependent.

of endoAVFs were successfully created, 87% were deemed physiologically suitable for dialysis (within 3 months), and 64% were functionally used for dialysis (within 12 months).

Currently, a majority of North American patients initiate hemodialysis with a catheter,[36] stimulating national efforts to reduce catheter use.[37,38] The ability to cannulate a fistula at or early after dialysis initiation may assist in reducing catheter use. In our study, 75% of non−dialysis-dependent patients initiated dialysis with their endoAVFs, thus sparing catheter use. Furthermore, the average time to 2-needle cannulation after initiating dialysis was 32 days for baseline non−dialysis-dependent patients and 112 days for baseline dialysis-dependent patients. This is shorter than or comparable to that reported for surgical AVFs, with an average time to first cannulation of 98 to 112 days.[6,39] In the United States, it has been estimated that >70% of patients first cannulate their fistula 3 to 4 months after fistula creation.[6] In NEAT, 64% of endoAVFs were functional. This is similar to data from the US Renal Data System (64.9%)[40] and the Hemodialysis Fistula Maturation (HFM) study (66%).[28] However, in NEAT, 52% of endoAVFs were functional without requiring an intervention compared to 44% in the HFM study[28] (Table 3). The rate of interventions for endoAVFs was 0.46/patient-year and lower than that of surgical AVFs.[41] Surgical AVFs often require 2 to 3 interventions to facilitate maturation.[15,42] The ability to achieve functional usability equivalent to surgical AVFs with fewer interventions and fewer days of catheter exposure is a substantial clinical benefit for patients.

During follow-up ultrasonography, we found an absence of early stenosis in endoAVFs, which may be due to the endovascular approach that spares soft tissue incision, manipulation, and exposure or retained sutures. It has been speculated that aspects of

Table 4. Reasons for Not Cannulating EndoAVF With 2 Needles for ≥2/3 Dialysis Sessions Over 4 Weeks

Reason	Study Cohort (n = 44)
Thrombosed/occluded	4 (9%)
Failure to mature (blood flow < 500 mL/min)	3 (7%)
EndoAVF sacrificed due to procedure complications	2 (5%)
Procedure failure: no endoAVF created	1 (2%)
Vein too deep, not superficialized or transposed	1 (2%)
Ligated due to steal syndrome	1 (2%)
Cannulation needle pain	1 (2%)
Vein too deep, transposed but did not reach 2-needles before 12 mo	1 (2%)
Fear of needles	1 (2%)
Moved to nonstudy dialysis center	1 (2%)
Total	16 (36%)

Note: Values are given as number (percentage).

Abbreviation: AVF, arteriovenous fistula; endoAVF, endovascular AVF.

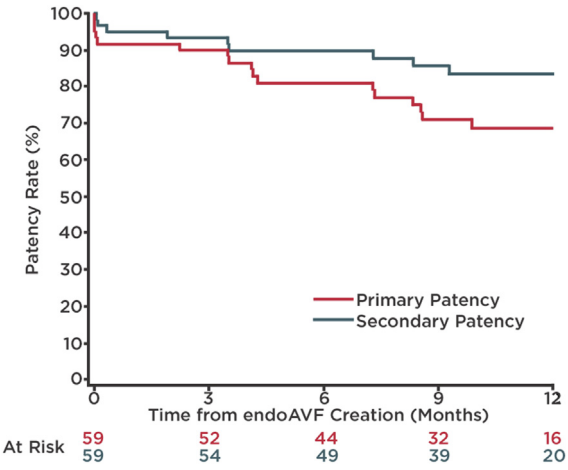


Figure 5. Endovascular arteriovenous fistula (endoAVF) primary and cumulative patencies at 12 months.

Table 5. Safety: Procedure- and Device-Related Serious Adverse Events

Event	All (N = 80)		Full Analysis Set (n = 60)		Roll-in Patients (n = 20)	
	No. of Events	n/N (%; 95% CI)	No. of Events	n/N (%; 95% CI)	No. of Events	n/N (%; 95% CI)
Closure device embolization	2	2/80 (3%; 0%-9%)	2	2/60 (3%; 0%-12%)	0	0/20 (0%; 0%-17%)
Dissection of brachial artery	1	1/80 (1%; 0%-7%)	1	1/60 (2%; 0%-9%)	0	0/20 (0%; 0%-17%)
Pseudoaneurysm near endoAVF[a]	2	2/80 (3%; 0%-9%)	1	1/60 (2%; 0%-9%)	1	1/20 (5%; 0%-25%)
Pseudoaneurysm, access site[b]	1	1/80 (1%; 0%-7%)	1	1/60 (2%; 0%-9%)	0	0/20 (0%; 0%-17%)
Steal syndrome	1	1/80 (1%; 0%-7%)	1	1/60 (2%; 0%-9%)	0	0/20 (0%; 0%-17%)
Intraprocedural thrombus, brachial artery	2	2/80 (3%; 0%-9%)	2	2/60 (3%; 0%-12%)	0	0/20 (0%; 0%-17%)
Intraprocedural thrombus, endoAVF	1	1/80 (1%; 0%-7%)	0	0/60 (0%; 0%-6%)	1	1/20 (5%; 0%-25%)
Swelling, irritation, or pain	1	1/80 (1%; 0%-7%)	0	0/60 (0%; 0%-6%)	1	1/20 (5%; 0%-25%)
Total	11	8/80 (10%)	8	5/60 (8%)[c]	3	3/20 (15%)

Note: In n/N (%; 95% CI) columns, % refers to percentage of patients.

Abbreviations: AVF, arteriovenous fistula; CI, confidence interval; endoAVF, endovascular AVF.

[a]This event was also related to the device.

[b]This type of pseudoaneurysm is typically managed by thrombin injection. However, in this case, it was surgically corrected due to an additional complicating event. A clinical decision was made to use a closure device, but unfortunately, it was improperly deployed, which led to a closure device embolization. Although this did not lead to endoAVF abandonment, it required intervention to retrieve the closure device. Thus, at that time, the pseudoaneurysm was simultaneously corrected.

[c]Two patients had multiple serious adverse events: 1 patient had a closure device embolization that resulted in an access site pseudoaneurysm and 1 patient had a closure device maldeployment resulting in brachial artery dissection with arterial thrombosis and an eventual onset of steal syndrome 7 days after endoAVF creation.

the surgical technique contribute to the development of neointimal hyperplasia, the pathophysiologic hallmark of access stenosis that leads to fistula maturation failure.[43] The absence of early stenosis may have contributed to the high physiologic maturation (87%) and 12-month primary patency (69%) of endoAVFs. The primary (69%) and cumulative (84%) patencies of endoAVFs are higher than those reported for surgical AVFs: 60% (95% CI, 56%-64%) and 71% (95% CI, 64%-78%),[11] respectively.

Similar to results in studies of surgical AVFs,[10,22,44] functional usability was not as high as physiologic suitability. Physiologic maturation was determined by ultrasonography, and although vessel flow and vessel diameter measurement is the gold-standard surrogate marker for fistula maturation, it is only a surrogate marker. Beyond ultrasound parameters, clinical factors play a role in whether a fistula is cannulated. For example, in our study, we had 9 endoAVFs that met physiologic maturation criteria but did not achieve 2-needle cannulation (late thrombosis, 3; vein too deep, 2; needle pain/fear of needles, 2; steal, 1; and patient transfer to non-study dialysis units unfamiliar with the endoAVF, 1). Due to the high percentage of baseline non−dialysis-dependent patients, many met physiologic suitability but exited the study without needing dialysis; thus, the difference between physiologic and functional usability may be artificially increased.

Compared to the pilot FLEX study, endoAVF creation success was equally high (98% in NEAT and 97% in the FLEX study). However, endoAVF functional usability was lower (64% in NEAT and 96% in the FLEX study),[21] likely reflecting the real-world experience of NEAT using this technology in patients of varying ages, comorbid conditions, and vascular access histories. NEAT included more non−dialysis-dependent patients (57% in NEAT vs 6% in the FLEX study); many exited the study without initiating dialysis and limited the ability to determine the "true" functional usability of endoAVFs in NEAT. Last, NEAT had multiple operators from different disciplines with varying technical skill and experience, which may affect endoAVF maturation. This is suggested by a higher percentage of endoAVFs that attained physiologic maturation in the full-analysis-set study cohort (87%) compared with roll-in participants (63%; Table 2). This learning curve effect is known with surgical AVF creation; surgeons who place fewer fistulas have more fistula failures and lower patencies compared with more experienced surgeons who create more fistulas.[45,46]

In terms of safety, there was one device-related event and most procedural adverse events were related to brachial artery access/exit (Table 5). Although use of arterial closure devices was not part of the study protocol, a number of adverse events were related to their use. Consequently, post-procedural manual compression of the brachial artery quickly replaced closure device use.

Regarding complications after fistula creation, 2% of endoAVFs in the full-analysis-set cohort had thrombosis within 3 months, and 11%, within 12 months (0.11/patient-year). Recent studies of surgical

AVFs reported that 14% to 26% had thrombosis within 12 months (0.14-0.26/patient-year).[10,47-49] Pseudoaneurysms occurred in 3% of patients (including roll-ins) at the fistula site compared to 4.5% to 6.7%[50] in surgical AVFs. These endoAVF complication rates are lower than those reported for contemporary surgical AVFs.[51]

In terms of the clinical implications of this new technology and endoAVF creation, we anticipate based on NEAT that in real-world practice, the endoAVF will provide an alternate proximal forearm site, particularly for patients who have had a failed or a failing radiocephalic fistula, are not candidates for a radiocephalic or more distal snuff-box fistula, as the next progression prior to a more proximal brachiocephalic or brachiobasilic fistula (it does not prohibit the future creation of upper-arm fistulas), and/or for patients who refuse to undergo surgery. Many patients have "surgical fatigue."[17] The endoAVF offers a minimally invasive endovascular approach to AVF creation without needing general anesthesia and the associated preoperative assessments that may be required with such anesthesia. Furthermore, the endoAVF has a role in providing an alternative option for non−dialysis-dependent patients who may need to initiate dialysis soon and want to avoid catheter use.

The strength of our study is its prospective multicenter design conducted in a real-world setting. The endoAVF was consistently and reliably created in vessels as small as 2 mm and in participants with a body mass index up to 44 kg/m^2 and as old as 85 years; thus, the endoAVF may be applicable to a range of patients who need hemodialysis vascular access. We also demonstrated several beneficial clinical applications, including the possibility of cannulating more than one developed vein (cephalic, median cubital, and basilic), avoiding the problem of access recirculation, and helping to preserve vessel integrity.

There are several study limitations. First, many patients were ineligible for the study due to small vessel size (<2 mm) because adequate diameter is required to fit the catheters. However, vessels < 2 mm are also deemed inadequate for surgical fistulas, including radiocephalic fistulas.[52] Second, although this study was conducted in a multiethnic patient population, there were fewer blacks than in other areas of North America; the impact of ethnicity on creation of the endoAVF is unknown. Third, the cannulation protocol was conservative because investigators, nurses, and patients were learning about the "hands on" clinical use of the endoAVF. We now understand that the endoAVF behaves similarly to surgically created AVFs and such a long waiting period to cannulate or the prolonged ramp-up to 2-needle functional cannulation was unnecessary. Fourth, this was a single-arm prospective study without a surgical comparator. Such a comparator would be difficult due to the unique location and different vessels used to create the endoAVF. Last, the longer-term durability of endoAVF creation beyond 12 months is unknown. Further observation with the endoAVF will elucidate long-term outcomes.

Endovascular autogenous fistula creation using a radiofrequency magnetic catheter−based system reliably produces fistulas that are physiologically mature and functionally usable for hemodialysis. Functional usability was achieved with few complications, offering patients and clinicians a minimally invasive option for AVF creation.

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SUPPLEMENTARY MATERIAL

Item S1: NEAT inclusion/exclusion criteria.
Item S2: Cannulation protocol.
Note: The supplementary material accompanying this article (http://dx.doi.org/10.1053/j.ajkd.2017.03.026) is available at www.ajkd.org

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