Use of a Novel, Intermittent Pneumatic Compression Device to Promote Perforator Vein Dilation in Patients with Chronic Renal Failure: The pFACT Trial

Meghan Burr[1]; Amit Mitra, PhD[2]; Sanjay Desai, MD[3]; Mary Hammes, DO[4]; Dalena Pham[5]; John Lucas III, MD[6]

[1]Biomolecular Engineering Department, Baskin School of Engineering, University of California, Santa Cruz, California; [2]Department of Systems and Technology, Auburn University, Auburn, Alabama; [3]Division of Vascular Surgery, MS Ramaiah Medical Center, Bangalore, India; [4]Department of Medicine, Section of Nephrology, University of Chicago, Illinois; [5]University of California, San Diego, California; [6]Department of Surgery, Greenwood Leflore Hospital, Greenwood, Mississippi

Abstract: Objective. Arteriovenous fistula (AVF) creation is an important procedure for hemodialysis in chronic renal failure (CRF) patients. Recent advancements in vascular access have resulted in endovascular AVF (endoAVF) creations. EndoAVFs are less invasive and less expensive when placed. The dilation of the perforator vein pre-procedure is crucial to consistent, successful endoAVF placement. The Fist Assist Model FA-1 (Fist Assist Devices, LLC) device is an external, intermittent, pneumatic compression device. The objective of this study was to analyze the effects of the device on perforator vein dilation. **Methods.** Three centers enrolled CRF subjects from 2019 to 2021. Baseline Doppler measurements of the perforator in the forearm with and without a blood pressure cuff were recorded. Patients were instructed to use the Fist Assist Model FA-1 on their nondominant arm for up to 4 hours daily for 90 days. The primary endpoint was perforator enlargement compared to baseline measurements, with the secondary endpoint of perforator vein greater than 3.0 mm. **Results.** Nineteen subjects were enrolled and completed the trial with perforator measurements. The data collected reviewed the initial mean perforator vein dilation and the mean perforator vein dilation after 90 days of using the Fist Assist Model FA-1 device. Diameter measurements of the perforator vein showed significant enlargement backed by one-tail, paired-difference t-tests (P<.05). **Conclusions.** The use of the Fist Assist Model FA-1 device was successful in enhancing dilation of the perforator vein in patients with chronic kidney disease. Perforator veins increased by an average of 0.6 mm after 3 months of Fist Assist Model FA-1 application. The Fist Assist Model FA-1 employed intermittent pneumatic compression resulting in perforator vein enlargement, which can assist in successful endoAVF outcomes and cost savings.

VASCULAR DISEASE MANAGEMENT 2021;18(10):E187-E193
Key words: endovascular arteriovenous fistula, perforator vein, pneumatic compression

Introduction

According to the National Kidney Foundation, approximately 10% of the global population has chronic kidney disease (CKD), and in the United States 40 million people have stage 4 CKD.[1] Hemodialysis (HD) patients require reliable vascular access for successful treatment and life-sustaining hemofiltration. Central venous catheters (CVCs), arteriovenous grafts, and arteriovenous fistulas (AVFs) are the current methods for venous access in HD patients.[2] CVCs are the current primary method, with over 80% of HD patients receiving the treatment. However, AVFs are known to be a safer option for receiving hemodialysis treatment because there are fewer complications with catheter infections and hospital admissions.[2]

Patients with chronic renal failure (CRF) are encouraged to have AVF placement in advance of stage 5 CKD to obviate CVC placement. AVF creation has been historically surgical in the forearm or upper arm, with favorable results. Surgical AVFs (sAVFs) have been reported to have high reintervention rates and a mean maturation rate of 4 to 9 months, and require a sutured anastomosis along with a skin incision that increases both the risk of infection and healing time.[3] Recently, endovascular AVF (endoAVF) has been identified as a less-invasive procedure to assist in AVF placement in patients who are not appropriate candidates for sAVF.[3-7] There are currently two endoAVF devices on the market: the Ellipsys Vascular Access System (Medtronic) and the WavelinQ 4F EndoAVF System (BD). Both

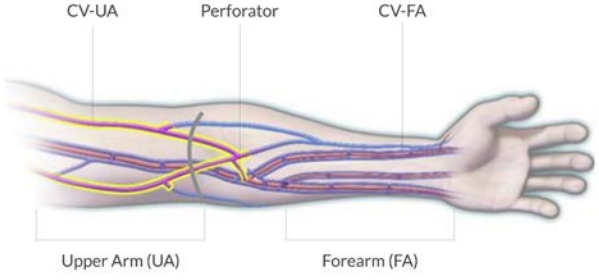


Figure 1. Arm perforator location measurement site (CV = cephalic vein).

Figure 2. The Fist Assist Model FA-1 device.

systems require a standard minimal vessel size according to their instructions for use. Therefore, pre-procedure vein dilation is critical so more patients can be candidates for these less invasive procedures.

EndoAVF is a fistula placement technique using either image-guided ultrasound technology or fluoroscopy to create fistulas.[2,6,7] As a result, endoAVFs have a reported faster initial healing time, making it possible for patients to have the procedure completed in an outpatient setting.[4] The Ellipsys system creates a thermal resistance anastomosis between the perforating cubital vein and the proximal radial artery via a needle inserted at the elbow and guided via ultrasound.[2] The WavelinQ 4F consists of a dual catheter-based system that utilizes magnets and radiofrequency electrodes to create a fistula between deep arteries and veins in the proximal forearm with the use of fluoroscopy.[2,3]

Compared with sAVF, endoAVF is the safer and more cost-effective method of AVF creation.[8-10] It has been shown that around 20% of sAVFs thrombose acutely, which requires re-intervention, resulting in higher total costs within the first year.[4] EndoAVF has shown success rates in clinical studies from 80% to 100%.[11] However, the success rates of both sAVFs and endoAVFs depend largely on vein size and initial blood flow.[12] The perforator vein (**Figure 1**) is the connection between the deep venous system and the superficial venous system and is critical for successful endoAVF placement.[13] Fistulas created with endovascular devices having large perforator veins have significantly higher patency rates and lower thrombosis rates than those that are not, thus making perforator vein size the limiting factor in endoAVF placement.[2,13]

The Fist Assist Model FA-1 device (Fist Assist Devices, LLC) (**Figure 2**) is a noninvasive, intermittent pneumatic external device that uses a pneumatic balloon for intermittent vein compression. The Fist Assist Model FA-1 device is a self-contained, battery-operated, wearable, focal intermittent pneumatic compression device. The small control unit is integrally attached to an inflatable cuff that is held to the upper extremity using a hook-and-loop attachment. Patients can apply and remove the device themselves using only the contralateral hand. All pressure and timing parameters are preset at the factory. The bladder is inflated to a pressure of 60 mm Hg and held for 20 seconds then deflated to 10 mm Hg for 55 seconds before the next inflation. In comparison, when blood pressure is measured as part of routine medical care, pressures of 160 to 180 mm Hg are applied for approximately 45 to 60 seconds, and a lymphedema garment applies unremitting pressure of 40 mm Hg to an arm for 8 to 12 hours at a time.

Table 1. Baseline Patient Characteristics from the Complete FACT Trial.

Characteristic	N = 19
Age, mean (SD)	59.9 ± 12.03
Male gender %	68.4
BMI, mean (SD)	28.91 ± 10.52
Creatinine (mg/dL), mean (SD)	4.86 ± 2.65
eGFR (mL/min), mean (SD)	14.73 ± 5.92
African American %	36.8
Caucasian %	31.6
Other %	31.6
Smokers %	47.4
Comorbid condition	
Hypertension %	84.2
Diabetes %	63.2
Coronary artery disease %	15.8
Peripheral vascular disease %	5.3
Cerebrovascuar accident %	15.8

Abbreviations: BMI, body mass index; SD, standard deviation.

In research published in 2018, the Fist Assist Model FA-1 device was applied for 6 hours a day for 30 days to 43 patients with new radiocephalic and brachiocephalic AVFs starting 1 week after surgery. Acceptance of the device was excellent, and no patient suffered fistula thrombosis or reported pain, skin reactions, or bleeding from the AVF cannulation sites.[14] In this initial study, significant dilation of AVF outflow veins was demonstrated in patients using the Fist Assist Model FA-1 device compared with control patients using a sham device ($P<.05$).[14-15]

There is an urgent need to find more effective methods to promote perforator vein dilation and develop cost-effective, noninvasive devices to help AVF mature for cannulation. In this study, proper use of the Fist Assist Model FA-1 device was tested to understand its role on the perforator vein. This novel study is the first to document pneumatic compression causing potential changes to the perforator vein size.

Study procedures	Enrollment	3 Months
Medical history/exam	X	
Informed consent	X	
Demographics	X	
Doppler measurements	X	X
Device education	X	
Device compliance		X
Adverse events		X
Secondary endpoints		X

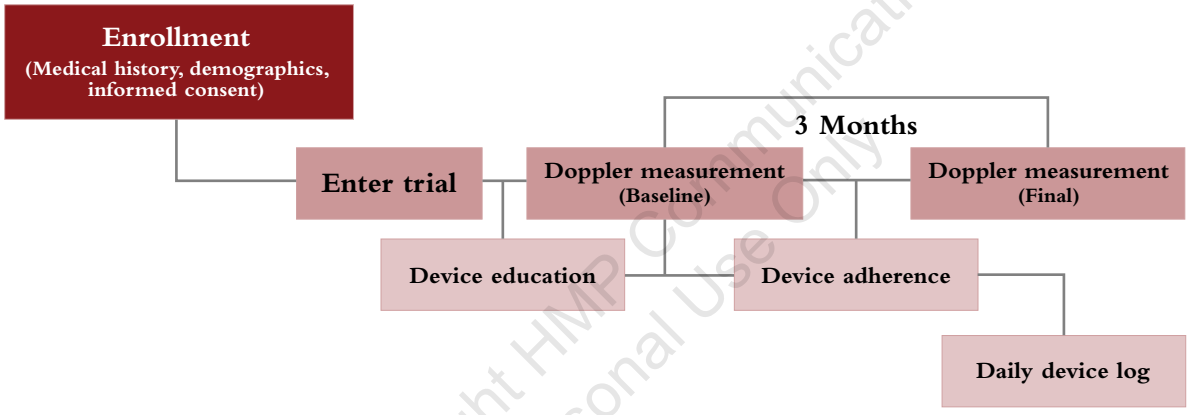


Figure 3. pFACT patient flow.

Table 2. Patient Characteristics.

Variable	N	Mean	SE Mean	SD	Minimum	Q1	Median	Q3	Maximum
Age	19	59.95	2.76	12.03	29.00	51.00	52.00	70.00	79.00
BMI	19	28.91	2.41	10.52	14.20	21.30	26.50	33.60	54.70
Cr	19	4.863	0.467	2.034	2.650	3.100	4.300	5.960	10.070
GFR	19	14.73	1.36	5.92	5.59	8.00	17.00	20.00	23.00

Abbreviations: BMI, body mass index; Cr, creatinine; GFR, glomerular filtration rate; SD, standard deviation; SE, standard error.

Methods

The pFACT is a sub-study of the Intermittent Pneumatic Compression Device for Vein Dilation in Kidney Disease Patients to Enable AVF Creation (FACT) trial, which began in June 2019 and concluded in June 2021. The FACT trial was conducted in multiple centers and was approved by the University of Chicago Institutional Review Board (IRB) in March 2019 (IRB19-0306), the Greenwood, Mississippi site in June 2020 (20-02-114-738) by the Biomedical Research Alliance of New York, and the Bangalore site by the MS Ramaiah IRB in October 2020. It was registered at ClinicalTrials.gov (NCT 04063787) on August 21, 2019.

Protocol

This study included patients with advanced renal failure, defined as CKD stages 4 or 5, predicted to need an AVF placed for dialysis. Patients were consented to enroll if they had stage 4 or 5 CKD (eGFR less than 29 mL/min) and expected to require renal replacement therapy, specifically HD. All patients were assigned treatment with the Fist Assist Model FA-1 device. Patients were excluded from the study if they refused, had limited cognitive ability, or were unable to give informed consent; were unable to comply with trial requirements; had arm infections; or had skin disorders that require frequent medical attention. We also excluded patients

Table 3. Perforator Results.

Variable	N	Mean	SE Mean	SD	Minimum	Q1	Median	Q3	Maximum
Descriptive statistics on vein perforator diameters at beginning of trials, without cuff									
PERAP-MM	24	2.008	0.175	0.858	0.900	1.125	1.950	2.925	3.400
PERTR-MM	23	2.287	0.274	1.315	0.900	1.200	2.000	3.000	5.200
Descriptive statistics on perforator vein diameters at beginning of trials, with cuff									
CPERAP-MM	24	2.392	0.199	0.977	1.000	1.450	2.500	3.275	4.300
CPERTR-MM	24	2.750	0.289	1.418	1.000	1.425	2.550	3.600	5.200
Descriptive statistics on perforator vein diameters at 3 months, without cuff									
3PERAP-MM	19	2.326	0.240	1.044	1.100	1.500	2.000	3.200	4.700
3PERTR-MM	19	2.589	0.293	1.277	1.100	1.600	2.106	3.600	5.400
Descriptive statistics on perforator vein diameters at 3 months, with cuff									
3CPERAP-MM	19	2.947	0.318	1.386	1.200	1.500	3.00	4.100	5.600
3CPERTR-MM	19	3.268	0.375	1.633	1.100	1.700	2.900	4.700	6.200

Abbreviations: CPERAP-MM, perforator anteroposterior (AP) measurement with cuff; CPERTR-MM, perforator transverse (TR) measurement with cuff; PERAP-MM, perforator AP measurement without cuff; PERTR-MM, perforator TR measurement without cuff; SD, standard deviation; SE, standard error; 3CPERAP-MM, 3 months perforator AP measurement with cuff; 3CPERTR-MM, 3 months perforator TR measurement with cuff; 3PERAP-MM, 3 months perforator AP measurement without cuff; 3PERTR-MM, 3 months perorator TR measurement without cuff.

with obvious scarring from I.V. drug use, previous phlebitis, occluded arteriovenous grafts or fistulae, arterial aneurysms, arm deep vein thrombosis, or any previous vascular surgery on their nondominant arm. In addition, patients were excluded if they had any motor or sensory deficits in their upper arms (**Figure 3**).

Medical records of enrolled patients were reviewed to collect gender, date of birth, height, weight, ethnicity, and medical history related to factors that may affect vascular health, including, but not limited to, dialysis history, diabetes, hypertension, coronary artery disease, peripheral vascular disease, medication history, and any other factors that contribute to vascular health (**Table 1** and **Table 2**). All patients had renal function measured by serum creatinine and calculated eGFR.

The Fist Assist Model FA-1 device was assigned to each enrolled subject with a detailed education session. All subjects were asked to use their assigned device twice daily for two 2-hour sessions, once in the morning and once in the evening. Patients applied the device to the nondominant arm above the level of the elbow and kept a written log to record use, complications, and any problems.

A Doppler ultrasound exam was done using a portable device at baseline and at 3 months. Patients were seated with arms supported at the level of the heart on an exam table in a room with a temperature of at least 20° C. The diameter of the perforator vein was measured using a B-mode image acquired with a vascular probe going from the outer walls per protocol. Measurements were done with and without a blood pressure cuff (60 mm Hg) with both anteroposterior (AP) and transverse (TR) measurements recorded. Arm locations are described in **Figure 1.**

Table 4. Perforator Results Comparison.

Comparison	Sample Size	Mean Difference (mm)	SD (mm)	*t*-statistic	*P*-value
3CPERAP-MM vs. CPERAP-MM	19	0.605	0.795	3.31	0.002
3CPERTR-MM vs. CPERTR-MM	19	0.553	0.905	2.66	0.008

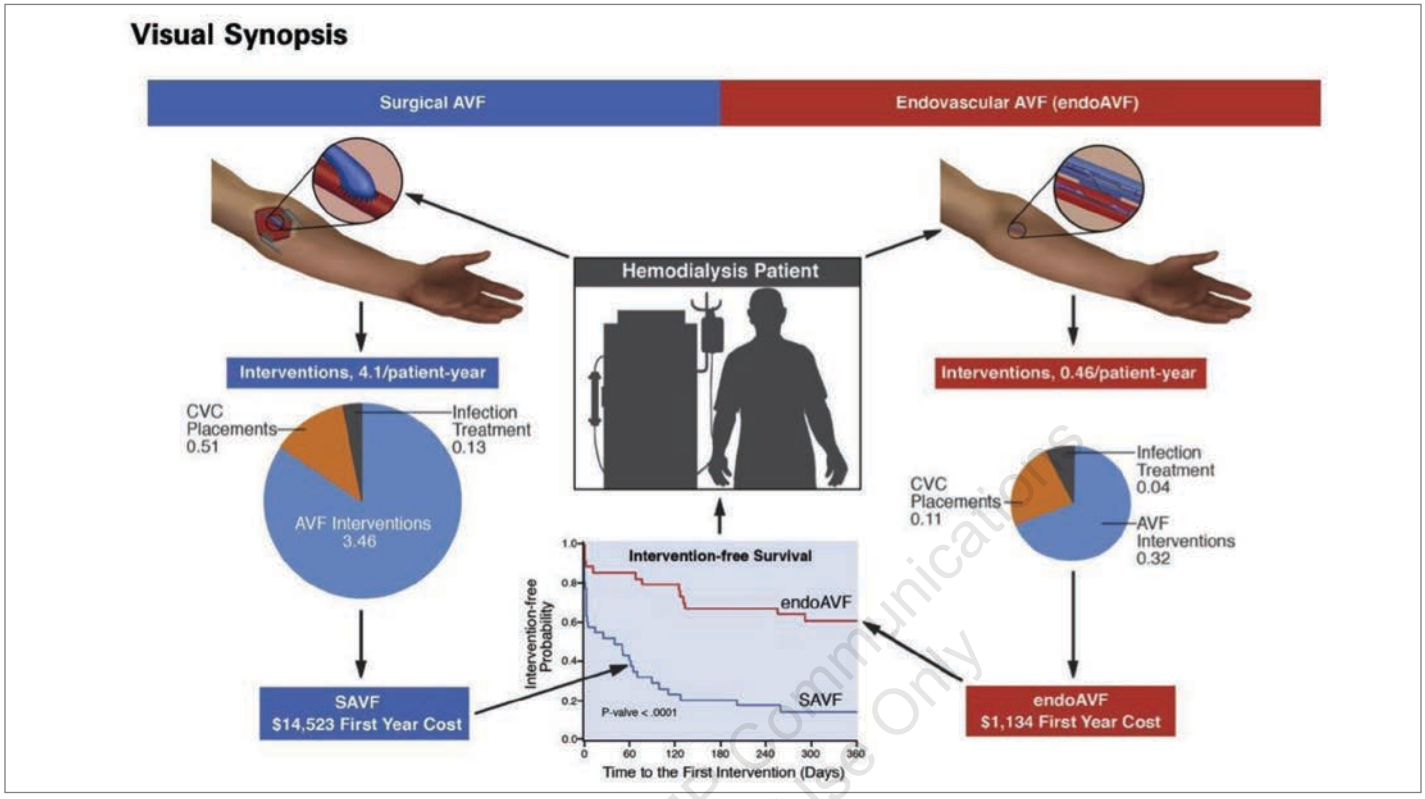
Abbreviations: CPERAP-MM, perforator anteroposterior (AP) measurement with cuff; CPERTR-MM, perforator transverse (TR) measurement with cuff; SD, standard deviation; CPERAP-MM, 3 months perforator AP measurement with cuff; 3CPERTR-MM, 3 months perforator TR measurement with cuff.

Statistics

The primary outcome was the statistical measurement of the difference in perforator vein diameter with and without a tourniquet before and after use of the Fist Assist Model FA-1 device.

Results

In the total FACT trial, 37 subjects completed the trial and were included in the analysis. Nine subjects were excluded due to death during trial, failure to follow up, or unusable Doppler reading. Of the 3 deaths during the trial, 2 were caused by COVID-19 and 1 was due to sepsis, all being unrelated to this trial and the Fist Assist Model FA-1 device. Of the patients who completed the trial and were included in the analysis, the average age was 59.95 ± 12.03 years, with a body mass index of 28.9 ± 10.5, creatinine 4.9 ± 2.03 mg/dL, and eGFR 14.73 mL/min ± 5.92. Perforator vein dilation measurements were taken from 19 of the 37 subjects during the study.



Source: Arnold RJG, Han Y, Balakrishnan R, et al. Comparison between surgical and endovascular hemodialysis arteriovenous fistula interventions and associated costs. *J Vasc Interv Radiol*. 2018;29:1558-1566. Reprinted with permission.

Figure 4. Visual synopsis of surgical arteriovenous fistula (AVF) vs endovascular AVF costs and outcomes.

AP and TR diameter measurements were taken on the perforator vein below the elbow with and without the 60 mm Hg cuff. One-tailed t-tests were conducted to determine paired differences for increases in perforator vein diameter. The data without the cuff were labeled as PERAP-MM and PERTR-MM for both the AP and TR measurements, respectively (**Table 3**). The data with the cuff compared the difference in perforator vein diameter in the area below the elbow at 3 months versus the start of the trials for AP measurements shown as 3CPERAP-MM vs CPERAP-MM, and the trials for TR measurements shown as 3CPERTR-MM vs CPERTR-MM (**Table 4**). The chosen level of significance was .05.

The AP measurements of the perforator vein (3CPERAP-MM vs. CPERAP-MM) increased from an average of 2.342 mm ± 0.966 mm at baseline to 2.947 mm ± 1.386 mm and produced a t-statistic of t = 3.32, *P*-value = .002. This was found to be highly significant when compared with the chosen level of significance. The TR measurements of the perforator vein (3CPERTR-MM vs CPERTR-MM) similarly increased from an average of 2.716 mm ± 1.481 mm to 3.268 mm ± 1.633 and produced a t-statistic of t = 2.66, *P*-value = .008. This was also found to be highly significant when compared with the chosen level of significance.

Secondary endpoint: Without cuff measurements: Perforator veins greater or equal to the threshold vein size of 3.0 mm were 40%. With a cuff: Perforator veins reaching 3.0 mm or greater were 90%.

Discussion

The FACT trial was a large, 3-center trial designed to understand the role of a novel pneumatic device to help enlarge superficial arm veins in CRF patients. A subset of the study was perforator vein measurements done on 19 patients. In addition to sAVF, endoAVF is now an acceptable form of fistula creation, with 2 devices on the market globally. EndoAVF adoption and use creation is limited by many factors, including inadequate veins.[12] An enlarged perforator vein is the key to consistent, successful endoAVF placement, which is the focus of this study. This trial is the first time the perforator vein has been proven to dilate using a novel intermittent pneumatic compression device.

There were no safety concerns in the study, and perforator vein measurements were done without any difficulty. After 360 hours of use, the Fist Assist Model FA-1 device was able to significantly dilate the perforator vein below the elbow in the antecubital space. Similar results have never been seen by any device on the market before the Fist Assist Model FA-1 device.

Increasing the perforator vein allows for more endoAVF placement and success. In addition to other limiting factors such as difficult access to the mid-forearm AVF site, having a

sufficient flow rate from an adequately sized vein is critical.[5,12,16] Preoperative selection of appropriate vessels not only leads to endoAVF success but also successful overall hemodialysis treatment.[16] It is common for a patient to be unable to receive endoAVF due to inaccessible veins. Having an enlarged perforator vein ensures better endoAVF placement and a better chance of successful maturation and cannulation of these new AVFs.

It has been shown that endoAVFs are significantly safer compared with sAVFs. The minimally invasive techniques that the endoAVF employs lead to lower rates of infection, lower rates of reintervention, and increased patency rates. EndoAVF also eliminates the need for general anesthesia.

The study was small compared with the FACT trial but showed a statistically significant dilation of the perforator vein with the use of a cuff after 3 months. The vein dilation of the perforator showed that the Fist Assist Model FA-1 device worn below the shoulder location truly has local effects on the perforator vein, including distensibility. We feel these changes will once again be regulated by changes in wall shear stress and wall tensile stress.

Given the perforator dilation described in the trial, there are significant cost benefits for patients who consider the endoAVF procedure and for the entire healthcare system overall. It is well documented that CKD causes a financial strain on healthcare systems. In 2018, Medicare records indicated that treating CKD cost over $81.1 billion, and treating end-stage renal disease (ESRD) cost an additional $36.6 billion, which equates to $80,000 per person annually or 7% of all Medicare annual claim costs.[17] It is possible that dilating superficial arm veins, especially the perforator, and enabling more patients to be candidates for endoAVF procedures could significantly reduce costs associated with ESRD compared with traditional surgical options. In a European study by Rognoni et al, a budget impact analysis on hemodialysis patients from the National Healthcare Service found that endoAVF procedures vs sAVF resulted in considerable savings by "considering the standard DRG tariff for both WavelinQ and sAVF procedures, the total savings on a time horizon of 5 years would be about 30 million Euro. This demonstrated a great difference in costs for AVF creation and management."[18] Likewise, in a similar study by Arnold et al[19] comparing surgical and endovascular hemodialysis arteriovenous fistula interventions and associated costs **(Figure 4)**, endoAVFs had lower catheter placements, lower infection rates, and lower fistula interventions, all leading to a $13,389 cost reduction per year per patient.

In 2020, Franco et al found that more than 60% of patients were eligible for the Ellipsys Vascular Access System.[20] However, the absence of acceptable veins at the elbow and the large distance between vessels were the most common limiting factors for endoAVF.[20] Based on the results of this trial and the great success rate in dilating the perforator, there is a possible significant increase in candidates for the endoAVF procedure based on size criteria, which directly correlates to a significant savings per patient per year and the entire healthcare system.

This paper is the first of its kind highlighting the benefits of pneumatic compression and perforator vein dilation. There is a dearth of literature showcasing methods to enlarge the perforator vein. This dataset and trial indicate that perforator dilation can be achieved with external devices and can help prepare the patient with a possible successful conduit for endoAVF placement.

If the trial was reconducted, a larger sample size would be favorable. This would offset the effect on the data of subjects who were unable to complete the trial, which was expected due to the mortality rate of patients with renal failure who are also at risk during the COVID-19 pandemic.

Having found that the perforator vein reacted favorably to the novel Fist Assist Model FA-1 device that employs intermittent focal vein compression, our expectation and hope is that the results of this study will lead to more successful endoAVF placements with faster maturation rates and a lower risk of infection, overall cost reduction, and decreased morbidity rate in ESRD patients.

Conclusions

The results from the pFACT cohort data support the claim that the Fist Assist Model FA-1 device significantly dilates the perforator vein, which helps endoAVF placement and results in the increased success rate of both endoAVF patency and hemodialysis. EndoAVFs have been shown to be a safe option for hemodialysis, and a potential challenge in endoAVF placement is a small perforator vein size. The Fist Assist Model FA-1 device provided an effective, safe, simple, and cost-effective solution that is expected to greatly increase the use of endoAVFs in the future, with potential cost-saving benefits globally for CKD. ■

Acknowledgments. *The authors would like to sincerely thank all the patients and support staff who gave their time to support this trial. We also thank the Vascular Lab at the University of Chicago (Ms. Laurie Lozanski and Dr. Christopher Skelly) for assisting with the development of the vascular lab protocol used at all sites. We are grateful for the donation of the Fist Assist Model FA-1 devices, which made this trial possible. We thank Mr. Ed Arkans and ACI Medical for their expertise and skill in making the research devices for the FACT trial.*

Disclosure: *The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors report no conflicts of interest regarding the content herein.*

Manuscript accepted August 27, 2021.

Address for correspondence: John Lucas III, MD, Department of Surgery, Greenwood Leflore Hospital, 1401 River Rd., Greenwood, MS 38930. Email: jflucas@glh.org

REFERENCES

1. United States Renal Data System. *2020 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States.* Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2020.
2. Harika G, Mallios A, Allouache M, et al. Comparison of surgical versus percutaneously created arteriovenous hemodialysis fistulas. *J Vasc Surg.* 2021;74:209-216.
3. Popli K, Dittman J, Amendola M, Plum J, Newton D. Anatomic suitability for commercially available percutaneous arteriovenous fistula creation systems. *Clin Res Study Vasc Access.* 2021;73:999-1004.
4. Jones RG, Morgan RA. A review of the current status of percutaneous endovascular arteriovenous fistula creation for haemodialysis access. *Cardiovasc Intervent Radiol.* 2019;42:1-9.
5. Vachharajani T, Taliercio J, Anvari E. New devices and technologies for hemodialysis vascular access: a review. *Am J Kidney Dis.* 2021;78:116-124.
6. Berland T, Clement J, Griffin J, Westin G, Ebner A. Endovascular creation of arteriovenous fistulae for hemodialysis access with a 4 FR device: clinical experience from the EASE study. *Ann Vasc Surg.* 2019;60:182-192.
7. Lok CE, Rajan DK, Clement J, et al. Endovascular proximal forearm arteriovenous fistula for hemodialysis access: results of the prospective, multicenter novel endovascular access trial (NEAT). *Am J Kidney Dis.* 2017;70:486-497.
8. Yang S, Lok C, Arnold R, Rajan D, Glickman M. Comparison of post-creation procedures and costs between surgical and an endovascular approach to arteriovenous fistula creation. *J Vasc Access.* 2017;18:S8-S14.
9. Jones R, Khawaja A, Tullet K, Inston N. Early experience and observations in endovascular dialysis fistula re-intervention. *J Vasc Access.* 2019;21 818-825.
10. Arnold R, Han Y, Balakrishnan R, et al. Comparison between surgical and endovascular hemodialysis arteriovenous fistula interventions and associated costs. *J Vasc Intervent Radiol.* 2018;29:1558-1566.
11. Radosa CG, Radosa JC, Weiss N, et al. Endovascular creation of an arteriovenous fistula (endoAVF) for hemodialysis access: first results. *Cardiovasc Intervent Radiol.* 2017;40:1545-1551.
12. Lauva LS, Ihnat DM, Goshima KR, et al. Vein diameter is the major predictor of fistula maturation. *J Vasc Surg.* 2009;49:1499-1504.
13. Palmes D, Kebschull L, Schaefer R, Pelster F, Konner K. Perforating vein fistula is superior to forearm fistula in elderly haemodialysis patients with diabetes and arterial hypertension. *Nephrol Dialysis Transplant.* 2011;26:3309-3314.
14. Desai S, Mitra A, Arkans E, et al. Early application of an intermittent pneumatic compression device is safe and results in proximal arteriovenous fistula enlargement. *J Vasc Access.* 2018;20:24-30.
15. Sullivan B, Desai S, Singh TM, et al. Early application of an intermittent pneumatic compression device assists dilation of radiocephalic fistulas. *J Vasc Access.* 2018;20:146-152.
16. Khawaja A, Tullet K, Jones R, Inston N. Preoperative assessment for percutaneous and open surgical arteriovenous fistula creation in patients for haemodialysis. *Clin Kidney J.* 2021;14:408-417.
17. Centers for Disease Control and Prevention. Chronic kidney disease initiative. 2020. www.cdc.gov/kidneydisease/about-the-ckd-initiative.html.
18. Rognoni C, Tozzi M, Tarricone R. Endovascular versus surgical creation of arteriovenous fistula in hemodialysis patients: cost-effectiveness and budget impact analyses. *J Vasc Access.* 2021;21(1):48-57.
19. Arnold RJG, Han Y, Balakrishnan R, et al. Comparison between surgical and endovascular hemodialysis arteriovenous fistula interventions and associated costs. *J Intervention Radiol.* 2018;29:1558-1566.
20. Franco G, Mallios A, Bourquelot P, Hebibi H, Jennings W, Boura B. Feasibility for arteriovenous fistula creation with Ellipsys®. *J Vasc Access.* 2020;21:701-704.