Intermittent Pneumatic Compression Device for Vein Dilation in Kidney Disease Patients to Enable AVF Creation (FACT)

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Use of an Intermittent Pneumatic Compression Device to Promote Vein Dilation in Patients with Kidney Disease to Enable Creation of Arteriovenous Fistulas

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BACKGROUND

More than 100,000 Americans initiate hemodialysis (HD) each year. More than 80% of patients use central venous catheters (CVC) as their initial vascular access, with only a quarter of such patients having a concurrent AVF (composed of native vessels) or AVG (with use of prosthetic vascular graft material) which might mature into use.[1] AVF promotion has been part of the government's Healthy People 2010 and 2020 objectives, and numerous local and national initiatives, with only incremental improvements.[1] The proportion of AVF use in new HD patients has remained below 20% over the past decade (Figure 1.)

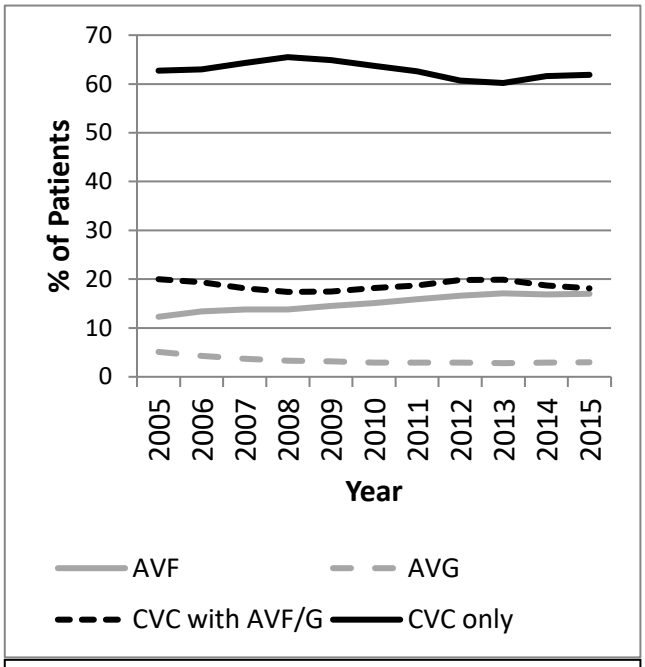

Figure 1: Vascular Access used at 1st HD in the US (Data from 2017 US Renal Data System Annual

CVC use for HD imposes many disadvantages upon patients, some lethal. CVC perform less reliably than AVF or AVG, resulting in reduced treatment efficiency. CVC are large devices that damage the veins in which they dwell, increasing the risks of thromboembolic events, as well as stenosis, occlusion, and superior vena cava syndrome.[2] CVC are long-term intravascular devices that may also result in central line associated bacteremias (CLABSI), which may be complicated by secondary infections such as infectious endocarditis and vertebral osteomyelitis.[3] The prevalence of each of these complications increases with the duration of CVC use.[4]

The net effects of all of these disadvantages is markedly decreased survival among HD patients using CVC, with increased hospitalization, costs, and suffering. Over the first two years of HD, CVC use falls, to approximately 12%. Unfortunately, this apparent 'improvement' is due not just to conversion from CVC to AVF/G, but also due to excess mortality among patients with CVC (Figure 2). Therefore, strategies that avert the need for CVC placement and reduce the duration of catheter use would both be expected to improve the health and survival of people receiving hemodialysis.

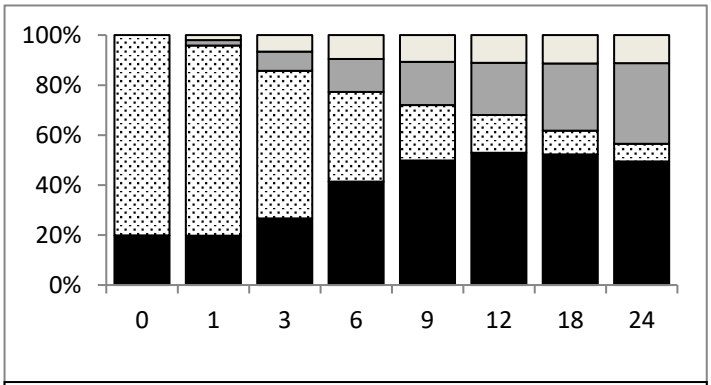

Figure 2: Vascular Access and Mortality over the first two years of hemodialysis, in the US [1]

Arteriovenous fistulas (AVF) are universally acknowledged to be the safest way to access the bloodstream for hemodialysis[5-10]. Successful AVF require the preservation of native veins, which must dilate after surgery. Guidelines suggest that all suitable forearm and upper-arm veins should be

preserved in patients with chronic kidney disease (CKD) and estimated glomerular filtration rates (eGFR) of less than 30 mL/min/1.73 m^2, avoiding both peripheral and subclavian venipuncture for any reason[11].

Despite this, construction of a viable AVF is often complicated or prevented by veins of insufficient diameter or quality.[6,7,12] An AVF must 'mature' after creation, which means that the vessel must dilate sufficiently to carry a high blood flow, and the walls of the outflow vein must thicken and become strong enough to endure repetitive needle cannulation and vein dilation in order to remain patent and accommodate repetitive needle cannulation.[9-16] Vein dilation is one of the key requirements for AVF maturation, although blood flow rates, vessel depth, and the length of the accessible segment of vein are also important. Most surgeons require that the target vein for an AV fistula have a diameter of at least 2.5-3.0 mm in either the upper or lower arm. Unfortunately, many arm veins fail to dilate and enlarge sufficiently after AVF creation, which exposes the constricted vein to arterial flow and associated high wall shear stress. When AVF fail to mature, patients are exposed to the risks of CVC for longer periods, and are subjected to additional surgery and invasive percutaneous procedures, resulting in hospital readmissions, delayed care, and increased costs.[17-21] In a carefully performed multicenter study, the 49% of AVF matured, and another 22% required additional procedures; 28% failed outright.[22] Many studies have concluded that it is hard to predict which veins will enlarge to the appropriate size for dialysis use even after preoperative vein mapping studies.[11,22-25] Clinicians try to refer patients for AVF 6 months prior to the need for HD, to allow for these uncertainties, but this is may not be a realistic approach for all patients.

Another popular approach is to encourage patients to develop their veins by exercising their arms before and after AVF surgery, with the expectation that exercise will increase blood flow to the limb and that this will dilate veins. Patients have traditionally been instructed to apply intermittent compression to the upper arm with elastic bands, to perform hand exercises (e.g. squeezing a soft rubber device) and isometric exercises of the entire arm.[26-27] Studies have shown some benefits of exercise in promoting vein dilation and possible fistula maturation.[28-29] The data are more extensive for beneficial effects of intermittent compression, handgrip training, external heat application, and topical agents like nitric oxide on vessel dilation.[25-33] Effects of pneumatic compression on venous flow have been widely studied, and are standard of care for the management of lymphedema, prevention of perioperative deep venous thrombosis, and therapy for venous stasis ulcerations.[34-38]

There is an urgent need to find more effective methods to promote vein dilation and develop cost effective, non-invasive devices to help mature fistulae clinically, and help AVF mature. The Fist Assist® device (US Patent 8231558) is an external medical intermittent pneumatic compression device that can apply intermittent pressure to the arm. Aside from the direct hemodynamic effects of pneumatic compression, there is evidence for effects on wall shear stress and wall

tensile stress for both arteries and veins, which may stimulate the endothelium to produce nitric oxide that enhances venous dilation.[39-41] **This research will evaluate the effects of using the Fist Assist® device to develop veins prior to AVF surgery.**

Device:

The Fist Assist® [**Figure 1**] is a self-contained, miniaturized, wearable 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 are able to apply and remove the device themselves using only the contralateral hand. It is battery operated and has a single control to turn it on or off. All pressure and timing parameters are preset at the factory. The bladder is inflated to a pressure of 60 mmHg and held for 20 seconds then deflated to 10 mm Hg pressure for 55 seconds before the next inflation.

The Fist Assist® device applies 60 mmHg of compression to the limb, which shuts off after 20 seconds; the device cycles every 75 seconds. In comparison, when a blood pressure is measured as part of routine medical care, pressures of 160-180 mmHg are applied for approximately 45-60 seconds, and a lymphedema garment applies unremitting pressure of 40 mm Hg to an arm for 8-12 hours at a time.

In recently published research, The Fist Assist® device was applied for six hours a day for 30 days to 43 patients with new radiocephalic and brachiocephalic AVF, starting one 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.[42] In this initial pilot study, significant dilation of AVF outflow veins was demonstrated in patients using the Fist Assist® device, compared to control patients using a sham device (P <0.05).[42-43]

This first proposal of presurgery vein dilation outlines important research that will help to determine optimal roles of the Fist Assist® device in improving vascular access outcomes in patients receiving HD, by investigating the effects of the device used both before and after AVF surgery. Early use of this device could potentially allow for vein dilation in patients with advanced chronic kidney disease, preparing veins for AVF creation and improving primary AVF outcomes. Post-surgical use of the device may promote further vein dilation and AVF maturation and reduce the need for secondary procedures to assist maturation. Investigation with this device may uncover a safe and noninvasive way to improve outcomes for ESRD patients, and provide important insights into the biology of successful AVF maturation.

Fist Assist Safety Features: The device has many safety features to prevent patient complications. These include:

1. Patient being able to remove it with ease as its velco and can be easily taken off

2. The device having incorporated firmware to monitor the pressure to ensure it never goes over 60 mm Hg with auto-inflate and auto-vent features. This will ensure steady pressure at 60 mm Hg.

3. A battery monitoring system that ensures there is enough battery power to vent the balloon and turn off the device as the battery decreases to a low level. As the battery deceases to low levels, the device will save enough power to ensure total balloon venting and shut down.**OBJECTIVE:** To determine whether use of the Fist Assist® device facilitates vein dilation before AVF creation.

Hypotheses:

Use of the Fist Assist® before AVF creation will enhance superficial vein dilation, resulting in increased absolute vein diameters at three months when compared to baseline values.

SPECIFIC AIM:

To determine whether the use of the Fist Assist® device for 360 hours over 90 days by patients with advanced CKD prior to AVF surgery results in significant increases in cephalic vein diameters prior to AVF surgery.

SUBJECTS:

Population:
Inclusion criteria: Patients followed in the Nephrology Clinic who are expected to initiate HD will be approached for participation in the study. We will consider all patients with eGFR<30 mL/min.1.73m^2.[39] Patients will be assigned to treatment with the Fist Assist®.

Exclusion criteria: Refusal/inability to give informed consent, inability to comply with trial requirements, arm infections, and skin disorders that require frequent medical attention. In addition, we will exclude patients with obvious scarring from IV drug use or previous phlebitis. Patients will be excluded if they have previous occluded arteriovenous grafts or fistulae, arterial aneurysms, or arm deep vein thrombosis or any previous vascular surgery on their non-dominant arm. Patients will be excluded they have limited cognitive ability. Patients will be excluded if they have any motor or sensory deficits in their upper arms.

Patients will have a preliminary evaluation of their cephalic vein, measured 5 cm proximal to the styloid process of the radius, and also at the antecubital fossa. Patients will be excluded if there are no detectable superficial veins of at least 1.0 mm diameter, and also if a superficial vein of more than 3.0 mm is present in this lower arm location.

LOCATION: The study will be conducted in the Ambulatory Care facilities at the University of Chicago Medical Center (UCMC).

METHODOLOGY:

Medical History: Medical records of enrolled patients will be reviewed to collect: date of birth, height, weight, ethnicity, and medical history related to factors which may affect vascular health, including but not limited to: dialysis history, diabetes, hypertension, systemic lupus erythromatosis, coronary artery disease, peripheral vascular disease, medication history, and any other factors that contribute to vascular health.

Intervention: The Fist Assist® device will be assigned to each enrolled subject by randomization code. All subjects will be asked to use their assigned device twice daily, for two 2-hour sessions, once in the morning and once in the evening. Patients will apply the device to the non-dominant arm above the level of the elbow, and to keep a written log to record use, complications and any problems.

Blood Draws: 10 mL of blood will be obtained from patients being enrolled at the time of their next routine standard of care phlebotomy.These samples will be frozen for future assays of endothelial biomarkers of nitric oxide production and venous dilation, such as asymmetric dimethyl arginine (ADMA) and its metabolites.

Doppler: Patients will undergo examination of their cephalic veins in the Nephrology Clinic, using a portable vascular ultrasound device operated by a co-investigator trained by the UCMC Vascular Lab in this technique. The cephalic vein, a superficial vein originating in the wrist, is the most common vein used for AVF creation. In order to standardize these measurements, the diameter of the cephalic vein and vein wall thickness will be measured in both arms at: (a) 5 cm proximal to the styloid process of the radius, and (b) at the antecubital fossa. The diameter and thickness of the vein will be measured using a B-mode image acquired using a standard ultrasound machine with vascular probe going from outer walls per protocol. Patients will be seated with arms supported at the level of the heart on an exam table with in a room with a temperature of at least 20 degrees Celsius. A layer of at least 1 cm of gel will be applied locally to optimize the ultrasound image quality. Vascular Doppler measurements will be obtained on both arms at the time of consent (baseline), and at the conclusion of therapy. Measurements will be recorded.

Follow Up: Those who are subsequently able to undergo successful AVF creation will be followed clinically for up to 12 months.

Protocol: **I**nformed consent will be obtained by the co-investigators using a written consent form approved by the Institutional Review Board. After informed consent is obtained, patients will receive: physical examination of both forearms; and a vascular Doppler to determine cephalic vein diameters of the nondominant arm.. A 10 mL blood sample will be drawn at the next routine phlebotomy.

Patients will be asked to apply the Fist Assist® to the upper half of the non-dominant arm. Patients will be asked to use the device twice daily for two 2-hour periods, and report any complications or problems, using a log (see log attached at end of References). Patients will have follow up examinations with measurement of cephalic vein diameter at three months after enrollment.

Outcomes: The primary outcome will be the difference in vein diameter before and after Fist Assist® use. Secondary outcomes include: whether or not an AVF was created (versus a synthetic graft or use of a central venous catheter), whether the

resultant vascular access matured sufficiently to be used for HD, and the subsequent exposure of patients to central venous catheters during their first year of HD.

DURATION OF STUDY: All subjects will be enrolled and treated for three months. The duration of the study including data analysis and statistical analysis is expected to be 6-9 months.

Table 1. Timeline for Study		
Measurement	Baseline	Post-Rx
H & P	X	
Clinical examinations	X	X
Blood sample	X	X
Doppler	X	X

DATA MANAGEMENT: Study data will be collected and managed using REDCap electronic data capture tools hosted at The University of Chicago.

STATISTICAL ANALYSES: The primary outcome of interest will be the difference in the diameter of the cephalic vein between baseline (Pre) and 3 months (Post) in patients treated with the Fist Assist® device. Based on prior work, mean vein diameters at baseline are anticipated to be approximately 1.8 mm with a standard deviation of 0.5 mm,[44] and we anticipate that the standard deviation of the change in diameter is likely to be approximately 0.75 mm.

$$\textbf{Effect} = [(D_s\text{Post}) - (D_s\text{Pre})]$$

We would consider calculated effect sizes of 0.25-1.0 mm to be clinically meaningful changes that would increase the numbers of patients with vein diameters that meet commonly accepted thresholds for surgical suitability (normally 2.5-3.0 mm). Sample size calculations for a variety of effects are presented in table 1 (below), based on paired t-tests with alpha error of 0.05, standard deviation of the effect size of 0.75 mm, for power of 80% and 90%.

Table 2. Sample size required to compare vein size before and after treatment		
Effect size mm)	80% power	90% power
0.25	73	97
0.50	21	27
0.75	11	14
1.00	8	9
1.25	6	7
1.50	5	6

A secondary aim will be to compare the proportions of treated patients who achieve 3-month vein diameters of 2.5 mm and 3.0 mm, to proportions achieved among controls. Given a normal distribution around a mean vein diameter of 1.8 mm with a standard deviation of 0.5 mm, the probability of an untreated wrist vein exceeding 2.5 mm (or 3.0 mm) would be 8.1% and 0.8%, respectively. Given that the standard deviation of

the diameter of treated veins is at least 0.75, then the observed probabilities of a treated vein exceeding either 2.5 mm or 3.0 mm can be calculated, and is shown in the table below, any of which could be shown to be a significantly different proportion from the baseline state. The sample sizes required to demonstrate a difference in proportions were calculated using a McNemar test of paired proportions, with the very conservative assumption that 10% of veins that are adequate on preliminary measurement may fall below the cut-off value, due to variation in measurements.

Table 3. Sample sizes required to demonstrated increased proportions of surgically adequate veins

Effect size	% veins >2.5 mm	Required sample		%veins >3.0 mm	Required sample	
		80% power	90% power		80% power	90% power
0.25	27.4	42	55	10.2	83	110
0.50	39.6	24	31	17.6	45	59
0.75	47.5	19	24	27.4	28	36
1.00	68.8	11	14	39.6	18	23
1.25	77.9	9	11	47.5	15	18
1.50	85.3	8	9	68.8	9	11

We intend to study 90 patients, and anticipate effects which should be more than adequate for these purposes.

POTENTIAL RISKS AND BENEFITS TO SUBJECTS: The benefit to the subjects will be that this research could identify interventions that are more likely to result in vascular access patency. The primary risk is that patients may find the device irritating or annoying to wear. The patients will be given a 90 day log with check boxes to determine if any complications occur (see attached log at end of references). All patients enrolled will give informed consent about the study and device to ensure their full understanding and participation.

PAYMENT TO THE SUBJECT: The subject will not incur any cost as a result of participating in the study. The subject will not receive payment for participation in the study. No advertisement will be used to recruit subjects.

PROCESS OF CONSENT: The patient will give informed written consent approved by the IRB prior to participation.

CONFIDENTIALITY: All records will be kept confidential. The subjects will be assigned an identification number prior to entering any information into the computer database. Only study personnel will have access to the database. All forms will be stored and locked in the primary investigator's office immediately. Data will not be shared outside of the University of Chicago.

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Fist Assist® Trial Log

Patient Name: _____ Date:_____

AM Session	**PM Session**
Time On: _____	**Time On: _____**
Time Off: _____	**Time Off: _____**

Complications (check all that apply):

- ☐ **Arm pain**
- ☐ **Arm swelling**
- ☐ **Arm numbness**
- ☐ **Arm weakness**
- ☐ **Skin irritation**
- ☐ **Skin rash**

Other Complications/Comments:

_____

_____