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Early application of an intermittent pneumatic compression device is safe and results in proximal arteriovenous fistula enlargement

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Abstract

Introduction: Delays in arteriovenous fistula maturation can cause care delays and increased costs. Increased distention pressure and intermittent wall shear stress may dilate veins based on prior research. Early use of non-invasive devices may help assist clinical arteriovenous fistula dilation.

Methods: This was an Institutional Review Board approved study. After arteriovenous fistula creation, a novel, intermittent pneumatic compression device (Fist Assist®) was applied 15 cm proximal to arteriovenous fistula enabling 60 mmHg of cyclic compression for 6 h daily for 30 days. Among the patients who completed 1 month follow-up, 30 (n = 30) arteriovenous fistula patients were in the study arm to test vein dilation with Fist Assist. Controls (n = 16) used a sham device. Vein size was measured and recorded at baseline and after 30 days by duplex measurement. Clinical results (percentage increase) were recorded and tested for significance.

Results: No patients experienced thrombosis or adverse effects. Patient compliance and satisfaction was high. After 1 month, the mean percentage increase in vein diameter in the Fist Assist treatment group was significantly larger ($p = 0.026$) than controls in the first 5 mm segment of the fistula after the anastomosis. All fistulas treated with Fist Assist are still functional with no reported thrombosis or extravasations.

Conclusions: Early application of an intermittent pneumatic compression device may assist in arteriovenous fistula dilation and are safe. Non-invasive devices like Fist Assist may have clinical utility to help fistulae development and decrease costs as they may eventually assist maturation.

Keywords

Dialysis, arteriovenous fistula, intermittent pneumatic compression device

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Introduction

Renal failure affects about 20 million people in the United States alone and many will progress to end-stage renal disease (ESRD).[1] Patients and healthcare providers prefer arteriovenous fistula (AVF) as the permanent access for hemodialysis (HD) based on its durability, reduced complication rate, and cost effectiveness.[2–7] Availability of suitable veins and its development into a suitable needle access conduit providing necessary blood flows to sustain dialysis need is a major limitation to increase the prevalence of AVF.[3,4,8] Attempts to predict maturation that requires appropriate increase in blood flow with vein and thickened dilation have not been reliable.[8–15] Delay and lack of fistula maturation results in catheter dependence with increased catheter contact time leading to catheter-related complications,

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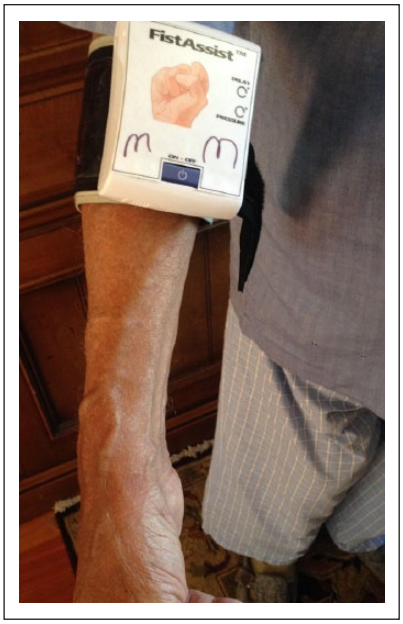

Figure 1. Fist Assist® device. Device worn in forearm location for dilation of radiocephalic fistula.

increased morbidity, mortality, and healthcare expenditure.[16,17]

Attempts to achieve reliable vein dilation following a successful fistula creation have included hand exercises,[18,19] the use of topical agents such as heat and nitric oxide[20] and intermittent tourniquets with hand exercises.[21,22] Intermittent tourniquets, using hand exercises with squeezing devices and arm exercises,[23–25] have shown some benefit in fistula outflow vein dilation following AVF creation. Patient compliance has been a problem with such approaches.

Fist Assist (US Patent 8231558: Figure 1) is a device developed with a specific aim to apply reliable intermittent pneumatic compression to the outflow veins after successful AVF creation. In this article, we describe the outcome of using this device for the first time in patients undergoing successful AVF creation to assess its effect of fistula outflow vein dilation.

Methods

The study was performed with the approval from Institutional Review Board (IRB) in a tertiary medical center/teaching medical college hospital in India. The device was considered a non-significant risk device by the IRB as it was an external application low pressure device. This was a single blinded randomized controlled trial. The trial was coordinated by the Departments of Nephrology and Vascular Surgery with the help of a dedicated research coordinator. All patients identified as having stage 5 renal failure and referred to the vascular access surgeons for fistula placement were evaluated.

Inclusion criteria

1. Stage 5 chronic kidney disease (CKD) on catheter dialysis who is a candidate for upper arm radiocephalic or brachiocephalic AVF.
2. Patient able to understand the study protocol and willing to comply with adequate family support.

Exclusion criteria

1. Active infection, skin disorders or previous failed arteriovenous graft (AVG) in the ipsilateral arm.
2. Restless arm or low systemic blood pressure (>70 mmHg during dialysis).
3. Poor pain tolerance.
4. Poor understanding of AV access, study protocol, and poor family support.

Study design

Patients eligible for the study were provided with necessary education and information related to AVF surgery, device, and the trial protocol and provided informed consent to the study coordinator. Details of demographics, history, and vascular access focused physical examination and planned access site were recorded. Procedural success was confirmed by clinical exam and Doppler duplex US evaluation, a week following the fistula creation surgery. Following this, the study coordinators randomized consented patients with functioning fistulae to study or control group. The study group received a regular device while the control group received a sham device. Figure 2 provides the flow chart of the study design.

Fistula outflow vein measurements were performed prior to and following fistula creation surgery. The vein size was also measured during enrollment (day 7) and at day 30 (1 month). All measurements were performed using a duplex Doppler US (Mindray Model—M7; Linear probe 8–12 MHz). Attempts were made to standardize parameters such as room temperature and measurement timing to ensure reliable vein measurements. All vein diameters were performed in three locations, that is, 5, 10, and 15 cm proximal from arteriovenous anastomotic site. They were recorded after confirmation of the accuracy.

Surgical procedures were performed by experienced surgeons well trained in AV access surgery using standard, globally accepted techniques. The site selection was patient preference. They were either radiocephalic or brachiocephalic. Access patency was evaluated at day 7 following which the patients were randomized. All patients were to wear the device for 6 h every day for 4 weeks. To ensure compliance with the protocol, a family member was instructed to confirm and record the daily usage time. All access and device-related complications and thrombotic events were recorded.

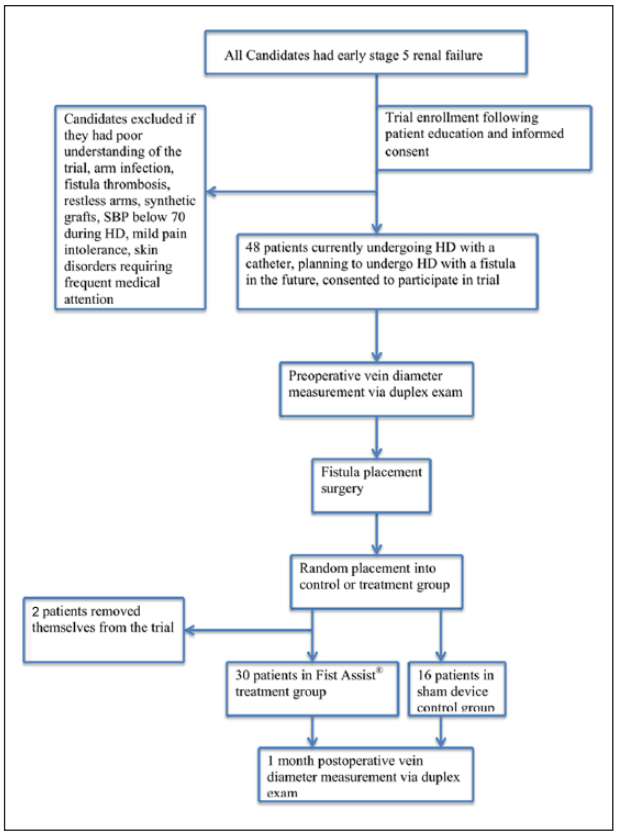

Figure 2. Patient selection and enrollment diagram.

Table 1. Patient demographics for control and treatment groups.

Attribute	Control	Treatment	p-value
Sample size	16	30	
DM (%)	75.00	53.33	0.126
HTN (%)	93.75	86.67	0.414
Gender: males (%)	68.75	76.67	0.570

DM: diabetes mellitus; HTN: hypertension.

Device description. Fist Assist® is a miniaturized control unit attached to a wearable pneumatic cuff that can be set to provide intermittent pneumatic inflation. A hook and loop attachment provide the patient an opportunity for easy wear and removal using the contralateral extremity. This battery-operated unit with a single on-off switch has factory preset time and pressure parameters. The bladder in the cuff inflates to a pressure of 60 mmHg held for 20 s that deflates to 10 mmHg for 55 s before the cycle repeats.

Sham units used in the study had a similar looking device which was set for the bladder in the cuff to inflate to 10 mmHg and deflate to 0 mmHg.

Statistical methods. The study evaluated the growth in the fistula outflow vein. The data are presented as percentage increase in the size of the vein using the device or using the sham unit at each location (5, 10, and 15 cm) examined. Thus, each vein acted as its own control and eliminated the vein size variability between individual patients. We compared the mean percentage vein increase in all vein at different locations in patients using the device (study group) compared to patients using the sham units (controls group). Hypothesis tests on the mean percentage increase in vein size dilation are conducted for the control and treatment groups. A one-sided, two-sample t-test is performed to determine whether the mean percentage increase in vein size dilation for the treatment group exceeds that for the control group. At a proximal distance of 5 cm, the results were significant ($t=-2.00$, $p=0.026$).

Results

The study was conducted from May 2016 to February 2017. A total of 46 patients (76% male) were included in the study. There were 30 patients in the treatment group and a total of 16 patients in the control group. Only two patients removed themselves from the trial: one in each arm due to noncompliance with the study only, not medical or device issues. Patient risk factors were similar to the global renal failure epidemic with diabetes and hypertension (HTN) being very common in the enrolled patients. Table 1 shows the patient demographics (in %) by presence of diabetes mellitus (DM), presence of HTN, and gender (percentage of males) for the control and treatment groups. The proportion of patients with DM were compared between the control and treatment groups and no significant difference was found ($p=0.126$). Similarly, no significant difference was found in the proportion of patients with HTN ($p=0.414$), and gender as represented by proportion of males ($p=0.570$), between the control and treatment groups, respectively. Patient risk factors and comorbidities for renal failure in the study were similar to patients in the Western world.

Percentage increase in vein dilation

Results are shown for percentage increase in vein dilation after 1 month, for the treatment and control groups, at distances of 5, 10, and 15 cm from the anastomosis, respectively, in Table 2. It is important to note that mean increases in vein size dilation for the treatment group outperform that for the control group at the distances of 5 and 10 cm (45.24 vs 25.08; 49.31 vs 42.07, respectively). In order to obtain a better idea of the distribution of percentage increase in vein size dilation, for the treatment and control groups, Figure 3 shows side-by-side box plots for the percentage increase in vein size dilation, for the control and treatment groups at the three proximal distances of 5, 10, and 15 cm, respectively. As can be observed, the medians for the treatment group are higher than that of the control

Table 2. Percentage increase in vein dilation at distances of 5, 10, and 15 cm from the fistula.

Group	Sample size	Mean	Standard deviation	Standard error	Median
Distance: 5 cm					
Control	16	25.08	24.50	6.12	23.76
Treatment	30	45.24	43.83	8.00	24.57
p-value = 0.026					
Distance: 10 cm					
Control	16	42.07	25.58	6.39	34.48
Treatment	30	49.31	43.99	8.03	44.64
p-value = 0.242					
Distance: 15 cm					
Control	16	41.52	39.05	9.76	32.96
Treatment	30	38.76	42.76	7.81	29.26
p-value = 0.587					

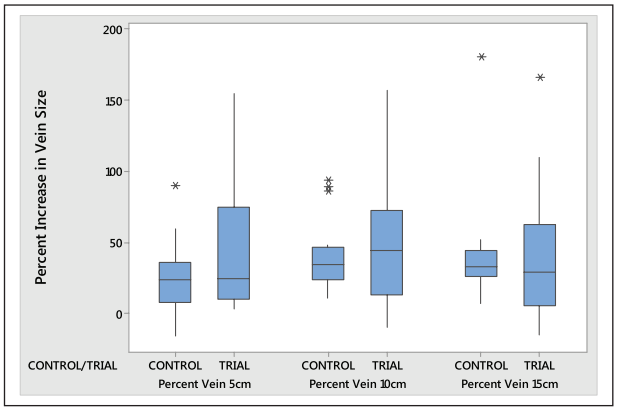

Figure 3. Box plots of percent increase in vein size for control and treatment groups at each proximal location.
*In a box plot, the whiskers are 1.5 (IQR) from the edges of the box, which are the 25th and 75th percentiles, respectively. IQR stands for the inter-quartile range, which is the distance between the 25th percentile and the 75th percentile. Data points beyond the whiskers are considered as outliers.

group at 5 and 10 cm. The variation in the percentage increase in vein size, as indicated by the width of the box, is higher for the treatment group at each of the three distances. Table 3 shows the percentage increase in vein size dilation for the treatment fistulas at the measured locations by type of fistula.

Discussion

It is well known that AVF creation followed by dilation and maturation is important to insure HD for renal failure patients.[26] AVF dilation and maturation have been studied from many angles including basic science studies[27] and clinical evaluations.[28–30] Anecdotal studies and reports have also demonstrated the importance of hand exercise[19,24,31] and possible rubber band tourniquets[18] to help dilate veins before and after AVF surgery. The mechanisms based on earlier basic science studies[32,33] and evaluations may involve changes in wall shear stress and wall tensile stress for both arteries and veins.[34,35] There is extensive research on the topic of the importance of hemodynamics in AV fistula maturation.[33]

There has been a motivation to further understand external compression on venous hemodynamics and fistula maturation.[36] Our intermittent pneumatic device placed proximal and directly on the fistula may be the first device of its type to help patients with early fistula enlargement. This article attempts to demonstrate the early benefit of pneumatic compression on AVF vein dilation as early as 1 month after surgery with a safety focus in a patient population with risk factors similar to global trends on renal failure development.

Application of the Fist Assist device was very simple and tolerated by patients. Patient enrollment and cooperation were excellent. Once again, there were no adverse complications or thrombosis of AVF which were exposed to the intermittent compression of the Fist Assist device. The Fist Assist device was found to be safe and of no significant risk or danger to our patient population which had the usual systemic risk factors for universal renal failure and surgical complications after surgery and Fist Assist device application. Initially, concern was directed that the device could lead to vein and arterial thrombosis, increased pain, skin reactions, or bleeding from the site. No complications or safety events occurred with the Fist Assist device and the device held up to its non-significant risk indications. The device which had a maximum inflation pressure of 60 mmHg, based on the well-studied hemodynamics of acute AVFs,[37] posed no risk for arterial occlusion since we had exclusion criteria of at least 70 mmHg systolic blood pressure for the trial and was suitable for venous occlusion. Our initial pilot studies demonstrated the device was not harmful to patients, their fistulas, or their health.

Review of the data endpoints demonstrates that the Fist Assist device did lead to significant early vein dilation in the first 5 cm vein portion of the fistula compared to the sham controls. After early use of the Fist Assist device, the vein did show signs of dilation and this is a promising

Table 3. Percentage increase in vein dilation by type of fistula and at measured locations for treatment patients.

Fistula type	Sample size	Mean	Standard deviation	Standard error	Median
Distance: 5 cm					
BCF	14	25.32	25.57	6.83	23.76
RCF	2	23.4	22.20	15.70	23.4
Distance: 10 cm					
BCF	14	40.59	21.76	5.81	34.48
RCF	2	52.4	58.40	41.30	52.40
Distance: 15 cm					
BCF	14	32.60	13.57	3.63	32.96
RCF	2	104.00	107.50	76.00	104.00

BCF: brachiocephalic fistula; RCF: radiocephalic fistula.

result for the early device use. The patients experienced no complications or reactions to the device. Many found it comfortable and better tolerated than a squeezing ball, rubber band occlusion devices, or waiting. We also demonstrated early dilation in the vein segment 10 cm from the fistula which was not significant in this early 1 month study. It is possible that the small sample size or the large variability in the percentage increase in vein size in the treatment group may have been a reason. It was expected that the vein 15 cm from the fistula (closer to the heart) would not dilate in this study as this was the vein segment that was compressed by the device. It is hoped that longer time point trials, timing adjustments, and considering the device placement in a standard location in the upper arm (below the shoulder) of all patients may assist in allowing all forearm and upper arm veins to dilate.

Most of the fistulas in our study were brachiocephalic fistula in the upper arms. Our device dilated these veins well, but more radiocephalic fistula should be enrolled in the next phase of the study to see whether there is any benefit to forearm vein dilation as this would be a very important vein for enlargement and future upper arm preconditioning.[38–40] The standard practices of fistula creation and surgical steps were followed by all surgeons in the study. Radiocephalic and brachiocephalic fistula creation was done per standard accepted surgical techniques as developed and followed by vascular access surgeons.[40]

Long-term studies are planned that will help us understand the device's role as a possible adjunct to fistula maturation and eventual primary patency. We are planning larger studies up to 12 weeks of follow-up that may address the potential benefits of this easy to use portable device.

Limitations

The study was conducted in a very active vascular access center at a tertiary hospital. Surgeons were very well trained in vascular access surgery and clinical outcomes were very good with either upper arm or forearm fistula placement. For this study, most of the fistulas were upper arm by surgeon choice. Patient enrollment and participation (application, compliance, and data recording) were all favorable. Potential limitations that include compliance with the device application, technical issues with device fastening straps and battery failure were addressed at times. Unfortunately, weights and eventual body mass index were not recorded for this study. This limitation will be addressed in future studies. A small number of patients in the study may also be a limitation, which will be addressed in future studies.

Conclusion

This study is the first to demonstrate that an external pneumatic device worn by patients after fistula creation can show early vein dilation compared to controls. The Fist Assist device adds another tool the patient can use to help assist in vein enlargement and eventual maturation with less dependency on catheters and multiple endovascular interventions. Future trials and clinical evaluation are ongoing to assist in fistula dilation with this novel medical wearable.

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Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr Tej M. Singh is the President, CEO of Fist Assist® Devices, LLC, which owns the device used in the study. Dr Singh owns the intellectual property associated with the Fist Assist device.

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