

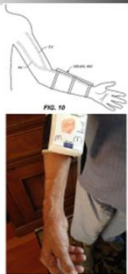
Novel Pneumatic Compression Device May Dilate Veins for Home Hemodialysis

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Introduction

Technology & IP status



- Patented Technology Includes:
 - External arm fistula dilation
 - External pneumatic compression
 - Trackball compression
 - Technological and method patent
- IP protected through July 2032
- Clinical data ongoing

Methods

Clinical Efficacy Study: 2017

- 53 Patient Fist Assist study
- 41 with Fist Assist and 12 as sham controls
 - 1 and 3 month follow-up initially
 - 6 hour application daily by patient at 60 mm Hg for 20 seconds and recycles
 - Complications, patient compliance and vein measurement to be recorded
 - Fistula start date recorded
 - Fistula type noted and monitored

Conclusions

Fist Assist preferentially helps dilate forearm veins at 3 Months! *Journal of Vascular Access*

Boxplot of 3 month data



The mean percentage increase in vein diameter in the Fist Assist treatment group with RCF was significantly larger than those with BCF at proximal locations of 5 cm, 10 cm, and 15 cm from the anastomosis (p=0.000, 0.000, and 0.017, respectively).

AV Fistula

Fistulae are the preferred type of vascular access for hemodialysis: **Fistula First Initiative**

Advantages	Challenges
<ul style="list-style-type: none"> Most durable long-term Technically easier to create Created with your own blood Reduce infection risk Can use the fistula for other treatments 	<ul style="list-style-type: none"> May not be possible for all patients May require surgery May require longer to heal and mature May require special care May require special care May require special care

Non Invasive Competitors for Fistula Maturation



Forms of exercise for fistula maturation include use of hand grips, stress balls, resistance bands, weighted wrist flexions, weights, clothes pins etc, and involve a series of repetitive movements aimed at increasing the blood flow and pressure experienced by the fistula. Based on *Fistula First Data* from the 1980s: Rubber bands were best for dilation.

Study Site: Bangalore India

MS Ramaiah Medical College Hospitals and Research Center, Bangalore, India

- Data collection and discussion biweekly
- Complete IRB approved study
- Large Dialysis Center with high AVF rate

Conclusions

- Early application of external intermittent pneumatic compression: assists in **AVF fistula dilation**
 - **Feasibility and Efficacy Done!**
- External devices may have important role in cost effective education, fistula maturation and clinical outcomes
 - Help in vascular access selection
- Will insure patient education
 - Pre-dialysis vein studies
- Global Fistula Dilation Device
- Excellent results with wrist fistulas

FIST ASSIST[®] THE FIRST RENAL CARE WEARABLE

THE PROBLEM

- Over 400K patients in the US receive hemodialysis for end-stage renal disease (ESRD). 15K-20K new patients start hemodialysis yearly.
- Hemodialysis costs an average of \$80,000 per patient annually in the US. A total annual cost of \$42 billion (significant portion is insurance and out-of-pocket).
- AV fistulas are the preferred method of vascular access for hemodialysis.
- 70% of fistulae thrombose or require corrective procedures to maintain or restore blood flow within 1 year of maturation.
- Real science and clinical studies demonstrate the importance of vein enlargement.

THE SOLUTION

- The **Fist Assist** device:
 - Safe
 - Effective
 - Simple to use
 - Easy to apply
 - Proven to increase venous pressure and vein diameter.
- The **Fist Assist** device helps ensure fistula dilation and maturation.
 - In 10-15 min settings.

“CHANGING THE STANDARD OF CARE IN VEIN DILATION”

INTERNATIONAL INTELLECTUAL PROPERTY

United States Patent: US 8,235,038 B2

CONCLUSIONS

- Early application of external intermittent pneumatic compression: assists in AVF fistula dilation
- External devices may have important role in cost effective education, vein dilation and fistula maturation
- Patient compliance very high even in ESRD
- Will insure patient education
- Global vein and fistula dilation device
- Global product release in 2015

OBSERVATIONS IN INDIA TRIAL

- No device patient complications or failures
- Time to fistula use faster
- Vein diameter significantly compared to controls at 1 month
- No intervention or dialysis complications on the fistula after 100 sessions at 3 months
- RCT started before than RCT on initial analysis

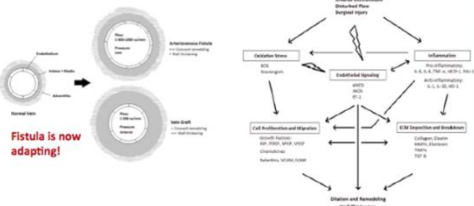
www.fistassistdevices.com

ESRD “Fist Assist” Home Wearable Protocol

Stage 4	Stage 5
Severe GFR ↓	Kidney Failure
New Protocol - Fist Assist Used Pre and Post Fistula Surgery	
Wear Fist Assist Pre Fistula Creation	Wear Fist Assist Post Fistula Creation
Benefits of Fist Assist (Cost Savings and Efficacy) <ul style="list-style-type: none"> Enlarges and Conditions veins Insures best vein used for surgery Develop Wrist Fistula Improves Compliance 	<ul style="list-style-type: none"> Better dilation leads to less interventions Faster Maturation leads to less infections, lower total catheter contact time, longer fistula durability

Fist Assist Medical Device Home Wearable will remove significant costs

Vein Adaptation to Hemodynamic Forces



Fist Assist takes a fistula and exposes it to intermittent arterial pressure surges. This leads to intermittent changes in wall shear stress, wall tensile stress and nitric oxide release

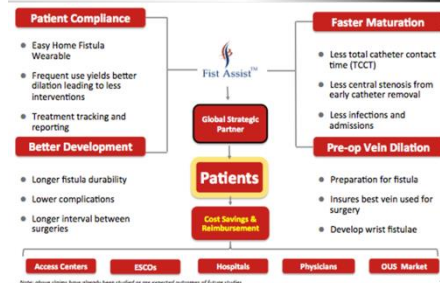
Fist Assist Device

Fist Assist Device: Single Balloon Intermittent Compression on Fistula (2013)

- External Intermittent Pneumatic Compression
- Focal compression on the fistula
- Worn below elbow or shoulder
- Easy application and easy monitoring
- High patient compliance
- 60 mm Hg for 20 seconds and cyclic



IMPROVING THE PATIENTS JOURNEY THROUGH ESRD



CHANGING THE STANDARD OF VEIN DILATION

Fist Assist is a novel, non-invasive, external device which uses a pneumatic balloon for intermittent vein compression. Vein dilation can assist in hemodialysis fistula development and phlebectomy procedures.

Patients can buy Fist Assist directly without a prescription or medical professional order!

RENAL DISEASE DEVICE ARM VEIN ENHANCEMENT

CLINICAL ADVANTAGES

- Assist in Cephalic Vein Dilation
- Cephalic Vein Enlargement
- Vein Preparation
- Stage 4 Vein Care
- Stage 5 Fistula Care

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