

Innovative new device for fistula maturation in the management of dialysis access

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I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest

Traditional AV Fistulas: Clinical Problems

Primary failure rate ²⁻⁵	20-60%
Mean maturation time ¹	6-9 weeks
Average time to usable AVF ^{3*}	5-12 months
Average interventions for successful AVF ¹	2-3
Thrombosis ^{5,6}	17-25%

* Mean time to useable AV fistula defined as time from referral for vascular access to dialysis

1 Kimball, et al. Efficiency of the kidney disease outcomes quality initiative guidelines for preemptive vascular access in an academic setting. Journal of Vascular Surgery. Vol 54, No 3. 2011

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3 Lee, T. et al. Tunneled Catheters in Hemodialysis Patients: Reasons and Subsequent Outcomes. American Journal of Kidney Diseases, Vol 46, No 3 (September),

4 Biuckians A, Scott EC, Meier GH, et al. The natural history of autologous fistulas as first-time dialysis access in the KDOQI era. J Vasc Surg 2008; 47:415-421

5 Dember LM, Beck GJ, Allon M, et al. Effect of clopidogrel on early failure of arteriovenous fistulas for hemodialysis: a randomized controlled trial. JAMA 2008; 299:2

6 Stolic R. Most Important Chronic Complications of Arteriovenous Fistulas for Hemodialysis. Med Princ Pract. 2012

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164-2171

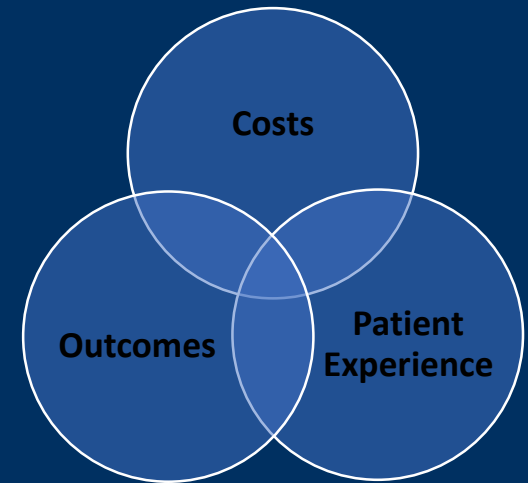
Poor Outcomes, Complications, Significant Costs, and lack of Compliance for End Stage Renal Disease (ESRD) patients & the entire ESRD Community

AV Access-The life line for dialysis patients



AV Fistula

Need to Improve



Upper arm rubber band dilation

- Squeeze Ball technique



Beninson et al: Use of intermittent pneumatic compression in hemodialysis. 1974

Leaf et al: **Exercise increases the size of forearm veins** in patients with chronic renal failure. 2003

Rus et al: Effect of **local physical training** on the forearm arteries and veins in patients with end stage renal disease. 2003

Rus et al: Effect of **intermittent compression of upper arm veins** on forearm vessels in patients with end stage renal disease. 2005

Fist Assist Device: Single Balloon Intermittent Compression



US008231558B2

(12) **United States Patent**
Singh

(10) **Patent No.:** US 8,231,558 B2
(45) **Date of Patent:** Jul. 31, 2012

(54) **HEMODIALYSIS VEIN PREPARATION APPARATUS AND METHODS**

(76) **Inventor:** Tej M. Singh, Los Altos, CA (US)

(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1038 days.

(21) **Appl. No.:** 12/049,651

(72) **Filed:** Mar. 17, 2008

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WO	97/02783		1/1997
WO	2007/024995	A2	3/2007
WO	2007/024995	A3	3/2007

OTHER PUBLICATIONS



1. External Intermittent Pneumatic Compression
2. Focal compression on the fistula
3. **Worn below elbow or shoulder**
4. Easy application and easy monitoring
5. High patient compliance
6. 60 mm Hg for 20 seconds and cyclic

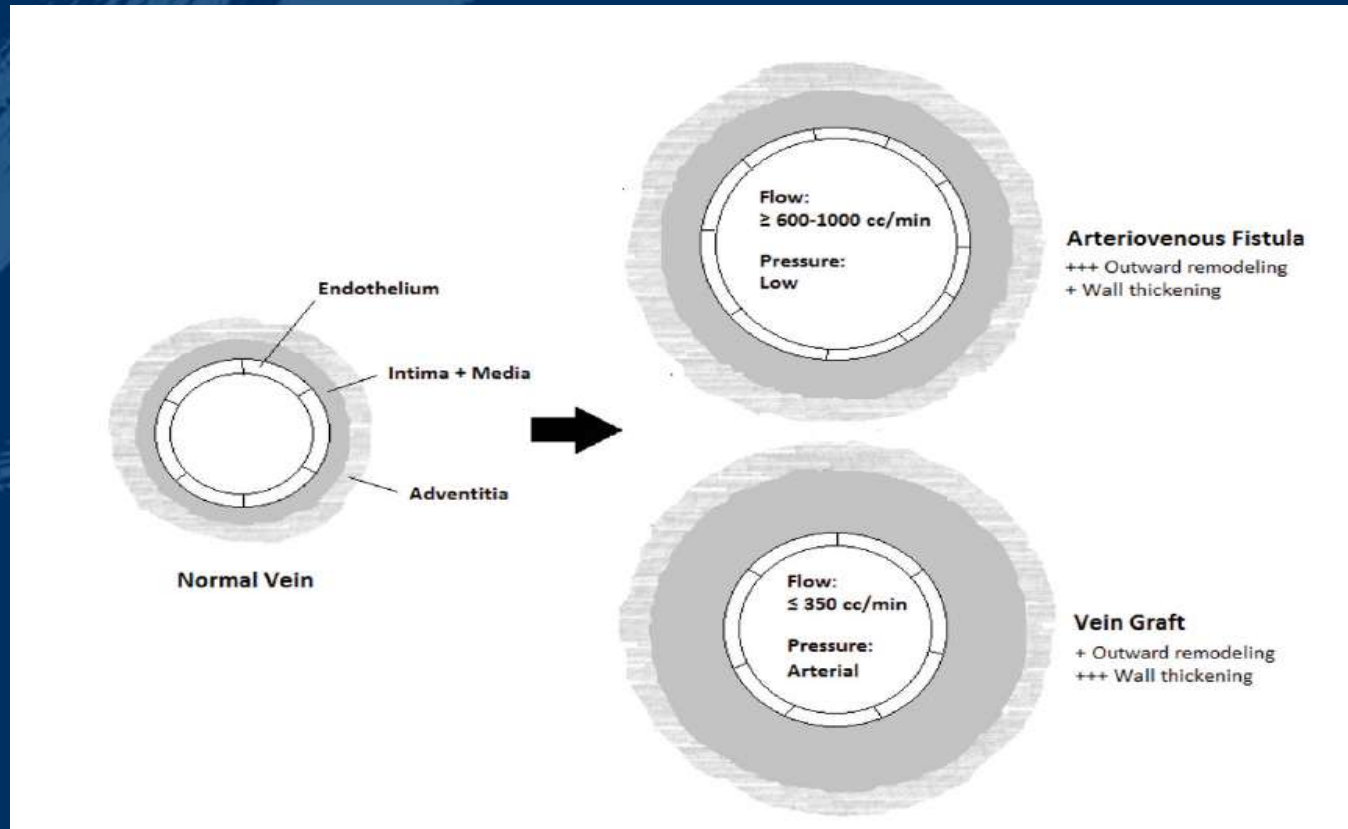


Fist Assist™

DR TEJ SINGH

LINC Vein Adaptation to Hemodynamic Forces

Fistula is now adapting!



The Key: Wall Shear Stress, Wall Tensile Stress and Nitric Oxide

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

International Study Site

Data collection and discussion research team

Complete IRB approved study

Large Dialysis Center with small veins and high AVF



56 Patient Fist Assist study

40 with Fist Assist and 16 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 recorded

Fistula start date recorded

Fistula complications after dialysis start (extravasation and thrombosis) monitored

Box Plot of 1 Month Data and Vein Segment all Fistulas

First 5 cm of vein confirmed to dilate

$P < .05$

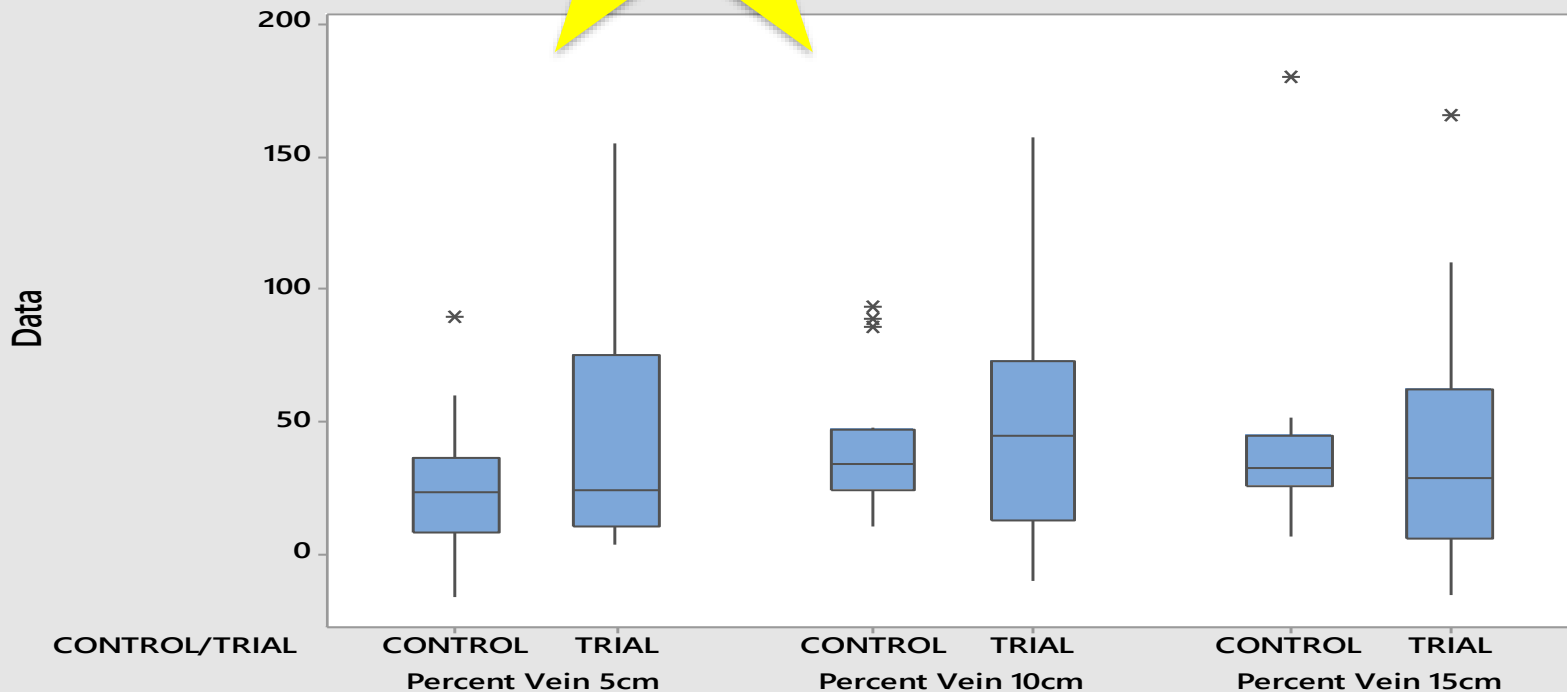
Original research article

JVA The Journal of
Vascular Access

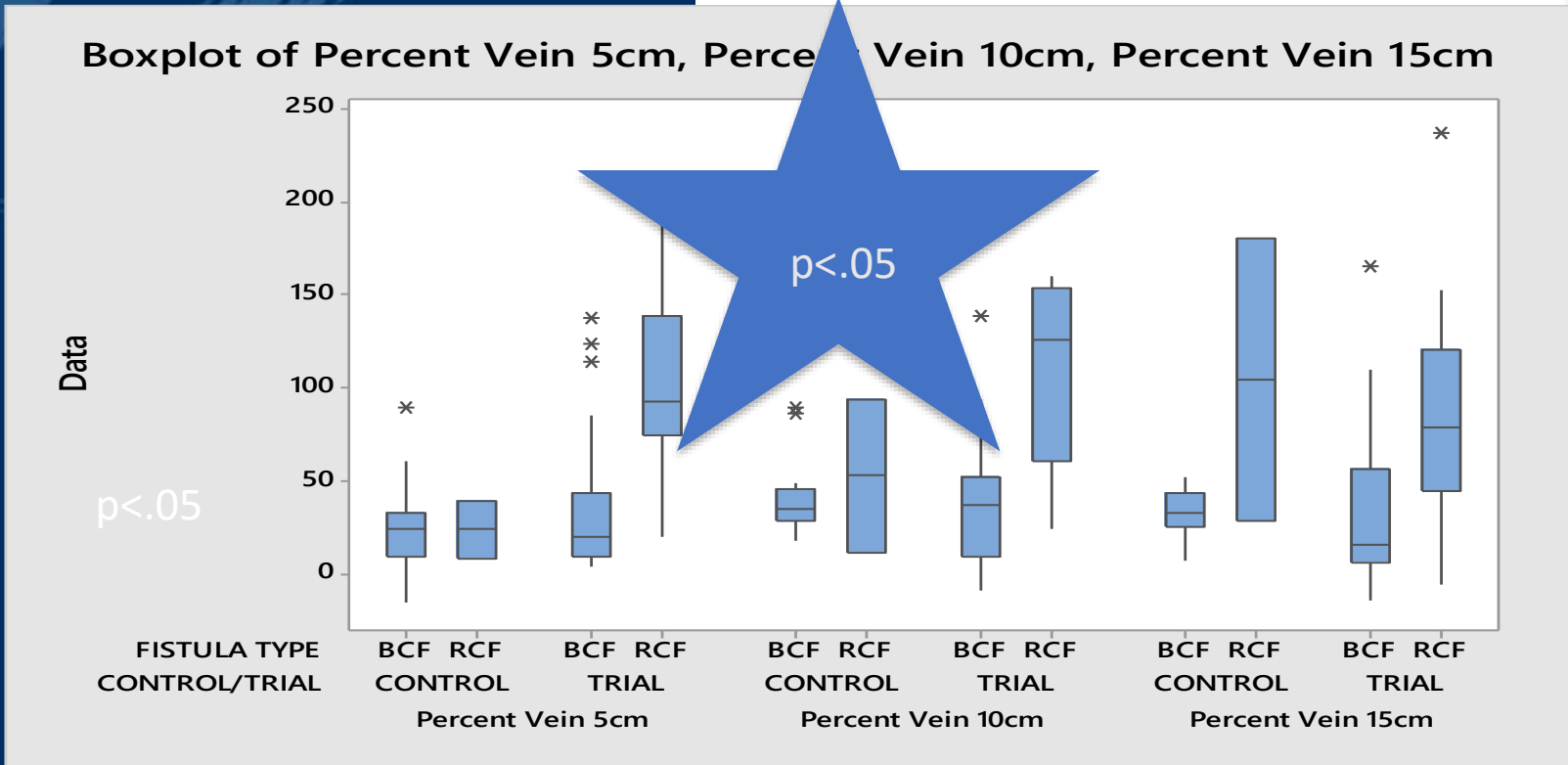
**Early application of an intermittent
pneumatic compression device is safe
and results in proximal arteriovenous
fistula enlargement**

The Journal of Vascular Access
1-7
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Fist Assist will help dilate forearm veins 1 and 3 Months!





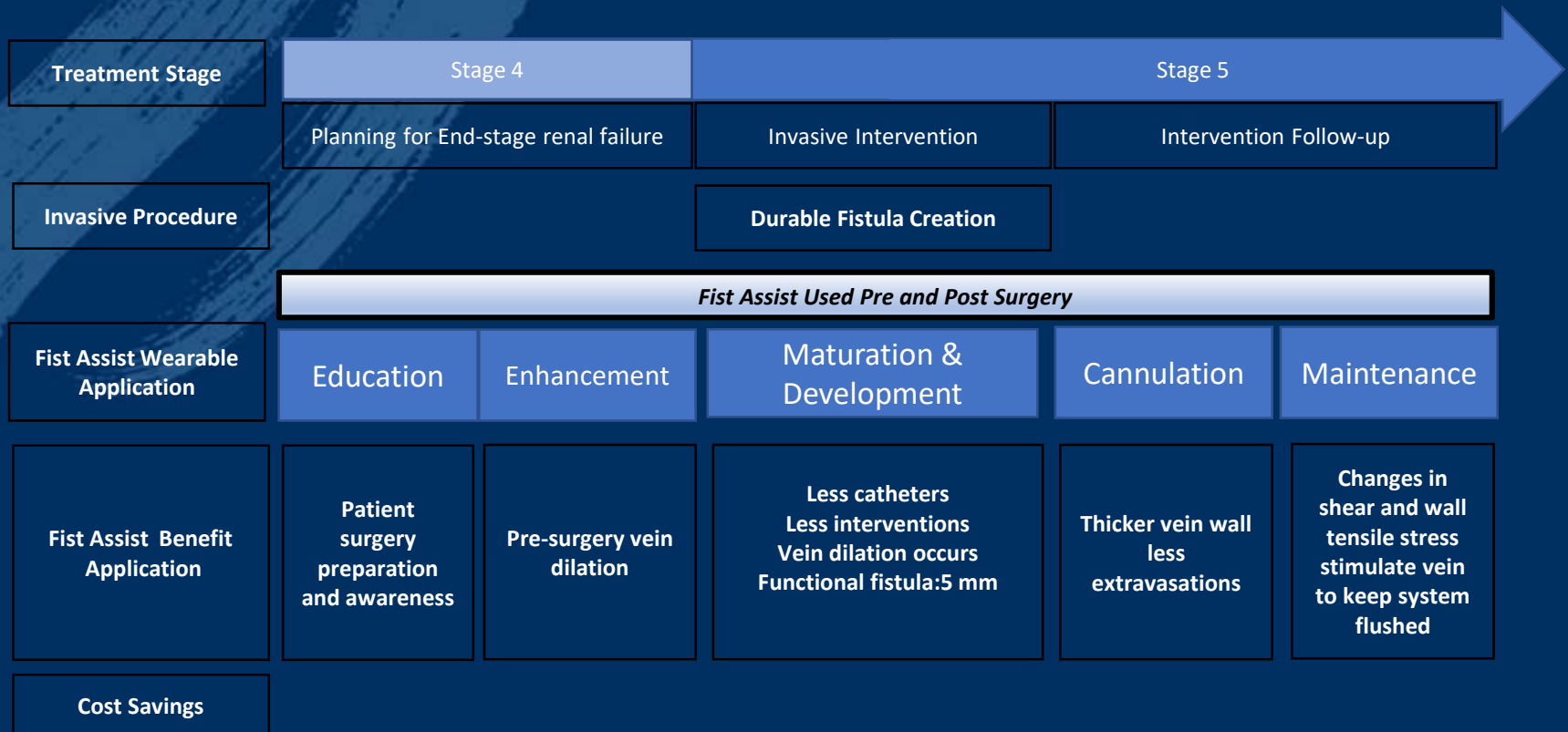
Fist Assist:

Reduces costs by enhancing veins, maturing fistulas, and improving fistula maintenance

Improves compliance, simplifies and enhances the *patient journey* through ESRD

Is the *only device* that provides a substantial benefit to all the components of the *ESRD Global community*

Fist Assist: The Complete Solution



The LINC logo features a stylized, abstract shape in red and blue, resembling a flame or a ribbon, with the letters "LINC" in white to its right.

LINC

FACT

- Fist Assist Clinical (Chicago) Trial

First US Trial: Dr. Mary Hammes

Stage 4 Renal Failure patients

Using Fist Assist for Pre-surgery Vein Dilation

FDA: Non significant risk device/DeNOVO Submission

IRB APPROVED AND ENROLLING

3 month follow up

Endpoints: vein dilation and vein wall thickness

Expect preliminary results 2020



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

Patient compliance very favorable

Will insure patient education

Pre-dialysis vein studies

FACT Trial Enrolling NOW for Stage 4



Global Regulatory Pathways



Regulatory Status

- Class I Device
- Status: Approved

Commercialization

- Distributor: Medifocus
- Launched 2019



Regulatory Status

- Class I
- Pending Approval

Commercialization

- Distributors Announced
- **Expected launch 2020**



Regulatory Status

- Class II / DeNovo Device
- Pre-Submission Phase
- Pending Approval

Commercialization

- Direct & via ecommerce
- **Expected launch Q1 2020**



Regulatory Status

- Class II Device
- Pending Approval

Commercialization

- Distributors
- **Expected launch Q2 2020**



The Following Countries have quick approval Follow CE Mark

Australia

Canada

Malaysia

Singapore

Central & South America


EMERGO *Is the current consultant supporting all regulatory submissions for approval*

LINC

THANK YOU FOR YOUR INTEREST IN THE CARE OF DIALYSIS PATIENTS



Fist Assist®




Fist Assist®
FIST ASSIST DEVICES, LLC

VEIN IDENTIFICATION
VEIN ENHANCEMENT
FOR THE ARM VEINS

CLINICAL ADVANTAGES

- PHLEBOLOGY PROCEDURES
- VEIN ACCESS
- VEIN ENLARGEMENT
- EASIER VEIN PROCEDURES



INTERMITTENT PNEUMATIC COMPRESSION
VENOUS FLOW RESTRICTION DEVICE

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Changing the Standard of Care in Vein Dilation

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