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

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<table>
<thead>
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<tbody>
<tr>
<td><strong>Primary failure rate</strong></td>
<td>20-60%</td>
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<tr>
<td><strong>Mean maturation time</strong></td>
<td>6-9 weeks</td>
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<tr>
<td><em><em>Average time to usable AVF&lt;sup&gt;3</em>&lt;/sup&gt;</em>*</td>
<td>5-12 months</td>
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<td><strong>Average interventions for successful AVF&lt;sup&gt;1&lt;/sup&gt;</strong></td>
<td>2-3</td>
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<td><strong>Thrombosis</strong>&lt;sup&gt;5,6&lt;/sup&gt;</td>
<td>17-25%</td>
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<sup>1</sup> Mean time to usable AV fistula defined as time from referral for vascular access to dialysis


* Courtesy Dr. Lok/VASA
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

Need to Improve

AV Fistula
Fistula Dilation Assisting Devices

Upper arm rubber band dilation

• Squeeze Ball technique

Photos courtesy of Dr. John Lucas
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

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
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
Bangalore Clinical Studies: Safety & Efficacy

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

Data

CONTROL/TRIAL

CONTROL   TRIAL
Percent Vein 5cm  Percent Vein 10cm

P<.05

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

Sanjay Desai1, Amit Mitra2, Ed Arkans3 and Tej M Singh4
Fist Assist will help dilate forearm veins 1 and 3 Months!

Boxplot of Percent Vein 5cm, Percent Vein 10cm, Percent Vein 15cm

*p<.05*

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*Early application of an intermittent pneumatic compression device assists dilation of radiocephalic fistulas*

Breanna Sullivan, Sanjay Desai, Tej M Singh and Amit Mitra

*Original research article from The Journal of Vascular Access*
A Solution for The Global ESRD Community

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

Treatment Stage
- Planning for End-stage renal failure
- Invasive Intervention
- Intervention Follow-up

Invasive Procedure
- Durable Fistula Creation

Fist Assist Wearable Application
- Education
- Enhancement
- Maturation & Development
- Cannulation
- Maintenance

Fist Assist Benefit Application
- Patients surgery preparation and awareness
- Pre-surgery vein dilation
- Less catheters
- Less interventions
- Vein dilation occurs
- Functional fistula: 5 mm
- Thicker vein wall
- Less extravasations
- Changes in shear and wall tensile stress
- Stimulate vein to keep system flushed

Cost Savings
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

The Following Countries have quick approval Follow CE Mark

Australia  Canada  Malaysia  Singapore  Central & South America

Is the current consultant supporting all regulatory submissions for approval
THANK YOU FOR YOUR INTEREST IN THE CARE OF DIALYSIS PATIENTS

Changing the Standard of Care in Vein Dilation

www.fistassistdevices.com
www.fistassisteurope.com
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