**Novel Intermittent Pneumatic Compression Is The Future of Cost Effective Fistula Maturation**

**The Fist Assist Device**

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**Disclosures**

Tej M. Singh, MD, MBA

CEO, Founder of Fist Assist Devices, LLC

Inventor and owner of the Intellectual Property for Fist Assist Device

Silicon Valley, CA USA

The Journey: Chicago to Stanford to Japan to VEITH

Veith Innovation Sessions

2015

2016

2017

AV Fistula

Fistulae are preferred for hemodialysis: **Fistula First** initiative

**Tradition AV Fistulas: Clinical Problems**

The Disappointing Results: Need to Change!

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<tr>
<td>Primary failure rate</td>
<td>20-30%</td>
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<tr>
<td>Mean maturation time</td>
<td>4-9 months</td>
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<tr>
<td>Average time to usable AVF</td>
<td>5-12 months</td>
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<tr>
<td>Average interventions for successful AVF</td>
<td>2-3</td>
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<tr>
<td>Thrombosis</td>
<td>17-25%</td>
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**Non Invasive Competitors for Fistula Maturation**

Upper arm rubber band dilation

Squeeze Ball technique

Assessment of effects of upper extremity exercise with anti-thrombotic therapy on maturation of arteriovenous fistulae in hemodialysis patients

Seo HS, Song JH, Park JS, et al. Randomized, pilot, double-blind, placebo-controlled, phase 1b study: exercise and non-steroidal anti-inflammatory drugs may improve maturation of autologous arteriovenous fistulas in hemodialysis patients.
Blood Flow Restriction and Vein Dilation

Exercise Science
Blood flow restriction exercise and training
Enlarged arms vein with exercise and continuous compression

Vein Adaptation to Hemodynamic Forces
Fistula is now adapting!
The Key: Wall Shear Stress, Wall Tensile Stress and Nitric Oxide

Technology & IP status: Cephalic Vein Device
- Patented Technology Includes:
  - External arm vein/fistula dilation
  - External pneumatic compression
  - Technological and method patent
  - Isolated pneumatic compression of the cephalic vein for identification, flow restriction and eventual dilation

Fist Assist Device: Single Balloon Intermittent Compression on Fistula
1. External Intermittent Pneumatic Compression
2. Worn below elbow or shoulder
3. Easy application and easy monitoring
4. High patient compliance
5. 60 mm Hg for 20 seconds and cyclic

Study Site:
- MS Ramaiah Medical College Hospitals and Research Center, Bangalore, India
- Data collection and discussion biweekly
- Complete IRB approved study
- Large Dialysis Center with small Indian veins and AVF

Bangalore Clinical Efficacy Study: 2017
- 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 to be recorded
  - Fistula start date recorded
  - Fistula complications after dialysis start (extravasation and thrombosis) monitored
First 5 cm of vein confirmed to dilate.

Box Plot of 1 Month Data and Vein Segment all Fistulas

Fist Assist will help dilate forearm veins 1 and 3 Months!

Fist Assist Trial Patients Assessed Fistulas Faster

Observations

- Patient and family compliance at home good/daily log
- No device/patient complications or failures
- Time to fistula use: 35±13 days, in trial 10% faster fistula access with needle
- Total Catheter contact time: 46±28 days
- Veins enlarged significantly compared to controls at 1 month
- No intervention or dialysis complications on the fistula after HD started at 3 months
- RCF dilation better than BCF on initial analysis

Cost Effective Fistula Dilation and Maturation!

Enrolling January 2019: FACT@UChicago

Fist Assist Clinical Trial at UChicago

IMPROVING YOUR PATIENTS JOURNEY

- Less total catheter contact time (TCCT)
- Less central venous access (CVA) related complications
- Less infections and admissions
- Longer fistula durability
- Lower complications
- Longer interval between surgeries

- Preparation for fistula
- Insures best vein used for surgery
- Develop wrist fistula

Note: above claims have already been studied or are expected outcomes of future studies
Fist Assist Global Awareness and International Acceptance

Fist Assist Global Partners 2019

Global Regulatory Pathways Set

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, vein dilation and fistula maturation
- Patient compliance very favorable in ESRD
- Will insure patient education
  - Pre-dialysis vein enlargement
- Global Vein and Fistula Dilation Device
- Global Product release in March 2019
  - India
  - Europe
  - USA

Fist Assist ™
Changing the Standard of Care in Vein Dilation
www.fistassistdevices.com