

The First Wearable for Vascular Access Dilation: The Fist Assist Device

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Innovations Session

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Disclosures

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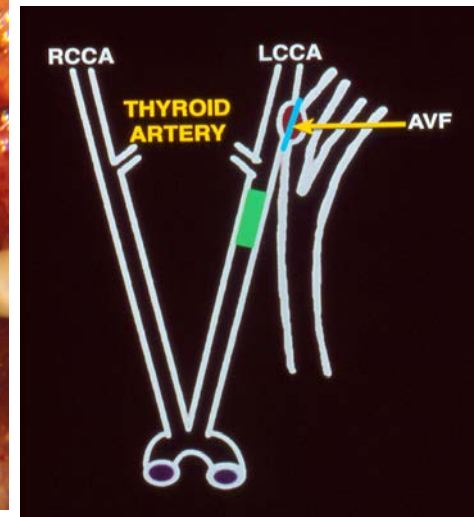
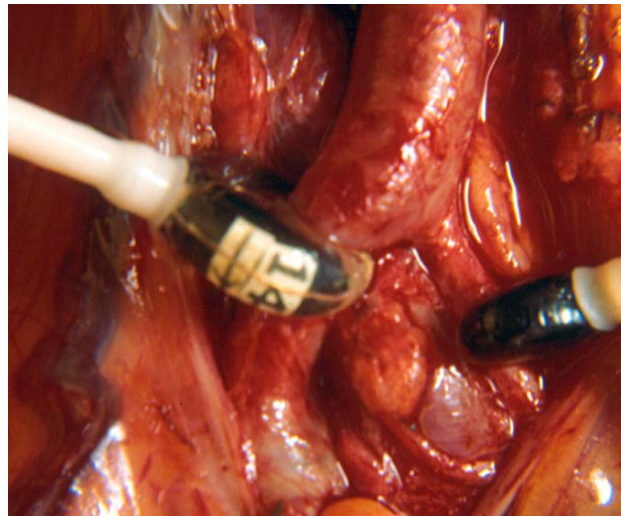
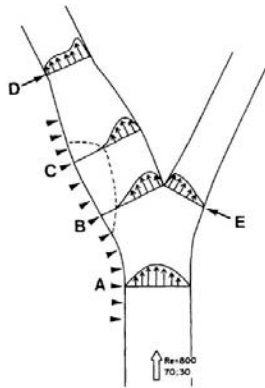
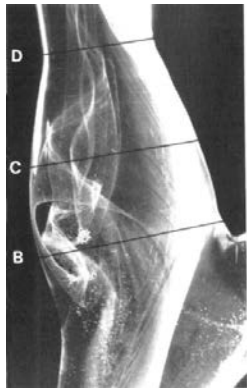
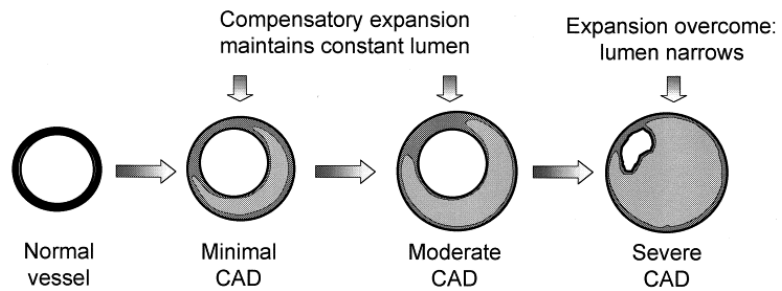
CEO, Founder of Fist Assist Devices, LLC

Inventor and owner of the Intellectual Property for Fist Assist Device

Silicon Valley, CA USA

The 30 Year Fist Assist Story: Chicago to Stanford to Japan

Progression 

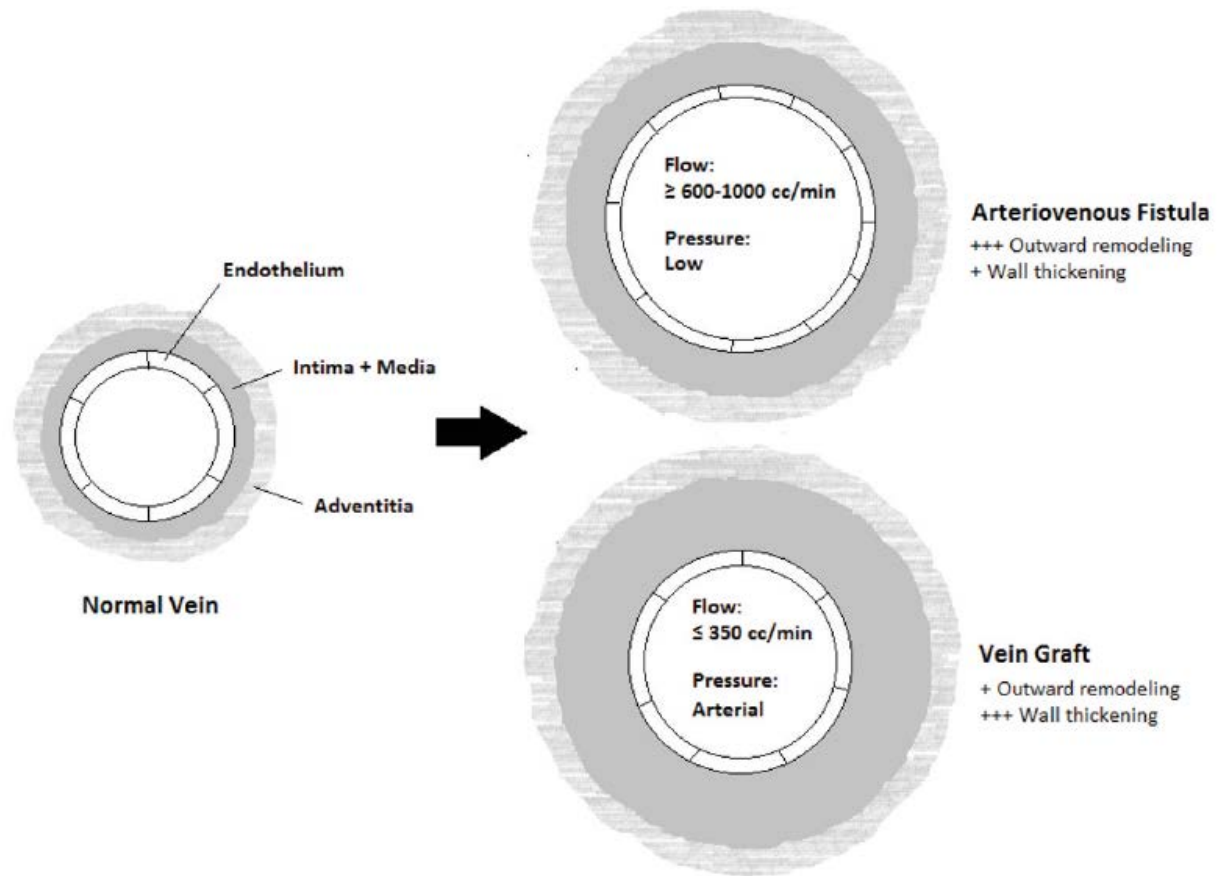


Research in vein dilation started in 1988
Using animal AVF models



Vein Adaptation to Hemodynamic Forces

**Fistula is now
adapting!**



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

Clinical Research 2000s

- Beninson et al: Use of intermittent pneumatic compression in hemodialysis. 1974
- Chleboun et al: Intermittent pneumatic compression effects on eccentric exercise induced swelling, stiffness, and strength loss. 1995
- 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

AV Fistula

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



Advantages	Challenges
Best overall performance.	May not be possible for all patients due to poor vein quality or other medical conditions.
Typically lasts longer than other types of accesses and has fewer problems once matured.	Takes longer to heal and mature than other types of accesses.
Created with your own vessels so no artificial materials are used.	If not placed early or problems develop, it may require a temporary access (catheter).
Better blood flow which increases the quality of dialysis treatments.	May be visible under the skin. Pressure must be applied after treatment to stop bleeding from needle sites.
Can use the buttonhole technique for needle placement (less painful and helps preserve your access).	Fistulas require special exercises (squeezing a soft foam ball) to develop and mature. Some fistulas fail to mature.



Technology & IP status

		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	6,960,159 B2 11/2005 Chung et al.		
	7,063,676 B2 6/2006 Barak et al.		
(76) Inventor: Tej M. Singh , Los Altos, CA (US)	2005/0080366 A1 4/2005 Cushman		
	2005/0107725 A1 5/2005 Wild et al.		
(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1038 days.	FOREIGN PATENT DOCUMENTS		
	EP 1 382 306 A2 1/2004		
	EP 1382306 A3 6/2004		
	WO 97/02783 1/1997		
	WO 2007/024995 A2 3/2007		
	WO 2007/024995 A3 3/2007		
(21) Appl. No.: 12/049,651	OTHER PUBLICATIONS		
(22) Filed: Mar. 17, 2008	Notification Concerning Transmittal of IPRP(1 pg) & the international Preliminary Report on Patentability for PCT Application No. PCT/US2008/017417 mailed Nov. 18, 2010 (60 pages)		
(65) Prior Publication Data			

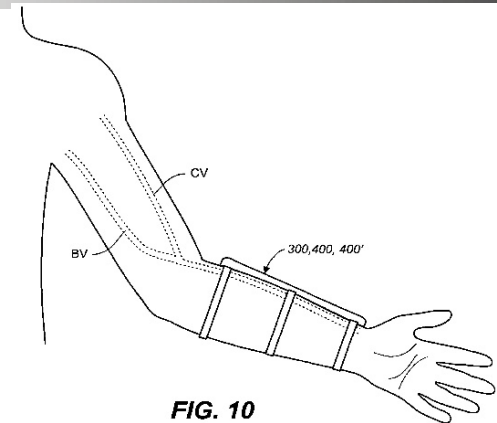


FIG. 10



- Patented Technology Includes:
 - **External arm fistula dilation**
 - **External pneumatic compression**
 - **Technological and method patent**
- Fist Assist takes a fistula and exposes it to intermittent arterial pressure surges
- Leads to intermittent changes in Wall Shear Stress, Wall Tensile stress and Nitric oxide release

The Problem

Significant Health Care Costs for Fistula Maturation and Delay Leads to Further Clinical Issues

- Balloon maturation/interventional costs rising with increased complications
- Prolonged catheter usage in the veins result in infections, readmissions, and central stenosis: quality issues
- Third party payers monitoring results and quality: survival, hospitalization, infection, transplants, vascular access
- Placement new access cost \$34 million per year: yearly maintenance and care of access may exceed \$2.5 billion per year

Need to Develop a Non-invasive, Cost-effective Way to Help Fistulae Mature

The crux of renal failure patients/costs worldwide

Traditional AV Fistulas: Clinical Problems

The Disappointing Results: Need to Change!

Primary failure rate ²⁻⁵	20-60%
Mean maturation time ¹	4-9 months
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

2 Peterson W., et al. Disparities in Fistula Maturation Persist Despite Preoperative Vascular Mapping. Clin J Am Soc Nephrol. 2008 March; 3(2):437-441. 2005; pp. 501-508

3 Lee, T. et al. Tunneled Catheters in Hemodialysis Patients: Reasons and Subsequent Outcomes. American Journal of Kidney Diseases, Vol 46, No 3 (September), 1995; pp. 411-416

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

Non Invasive Competitors for Fistula Maturation

Upper arm rubber band dilation

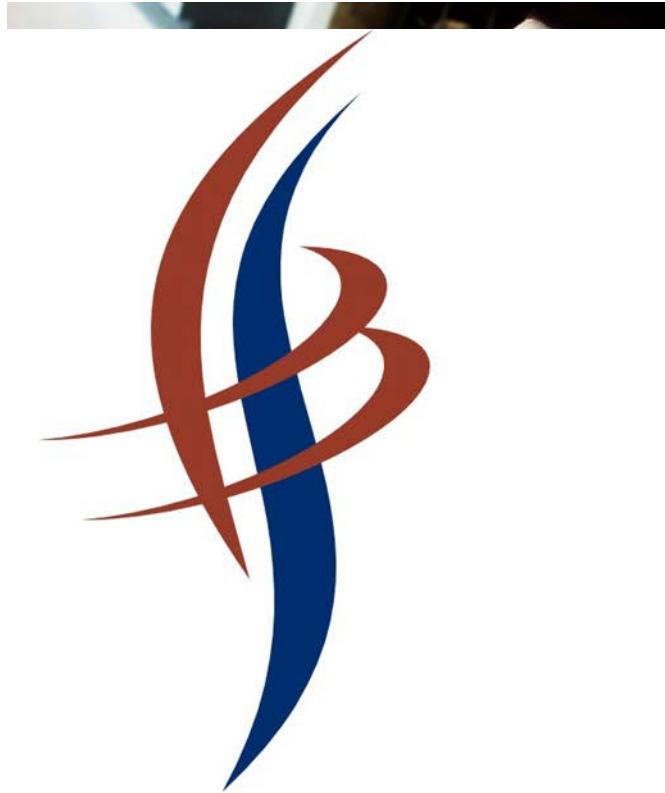


Squeeze Ball technique



Fist Assist is the Ideal device for Pre - Dialysis education and preparation

Exercise has GLOBAL benefits



Fist Assist™

Hammer Curl

Background and Mission



● Background of Device

- Supported by a team with over 80 plus years of Med Device experience: Innovation, Technology, Marketing, Legal and Sales
- *Introduced Globally 2015-2017*



● Mission

- Develop a novel, non-invasive, low cost device to
 - assist with Fistula Dilation
 - assist with Venous Pre-surgery preparation
 - decrease total catheter contact time and fistula development time
- Significantly reduce costs in treating Stage 4 and ESRD markets
- Develop robust clinical data to highlight Fist Assist increasing patient compliance

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



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



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



VASA Abstract 2015: Chicago

Adverse effects

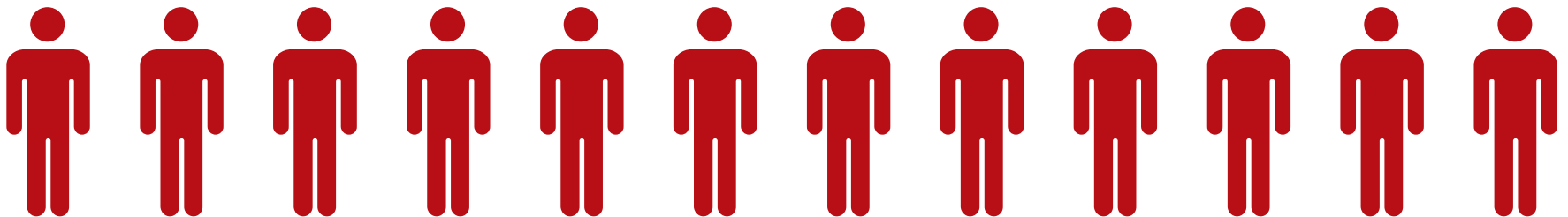
Thrombosis rate

Device failure

= 0



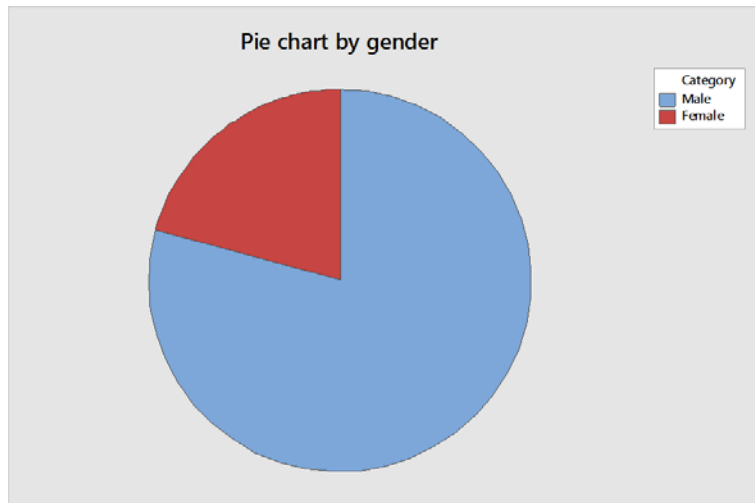
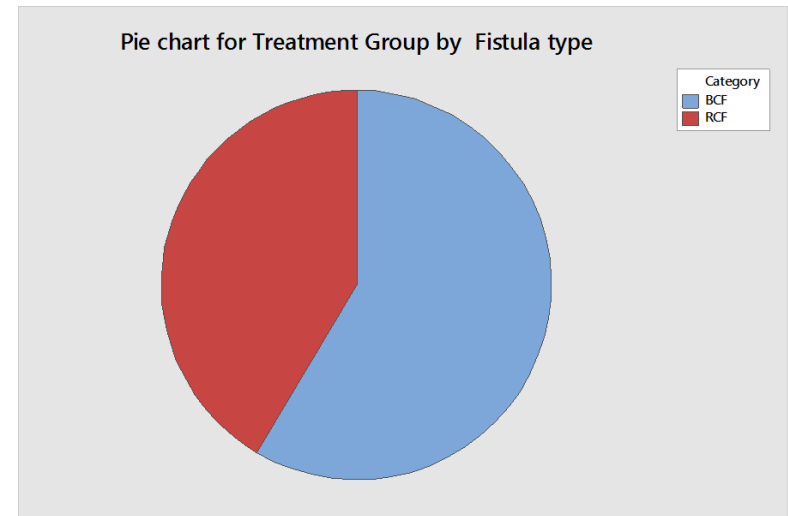
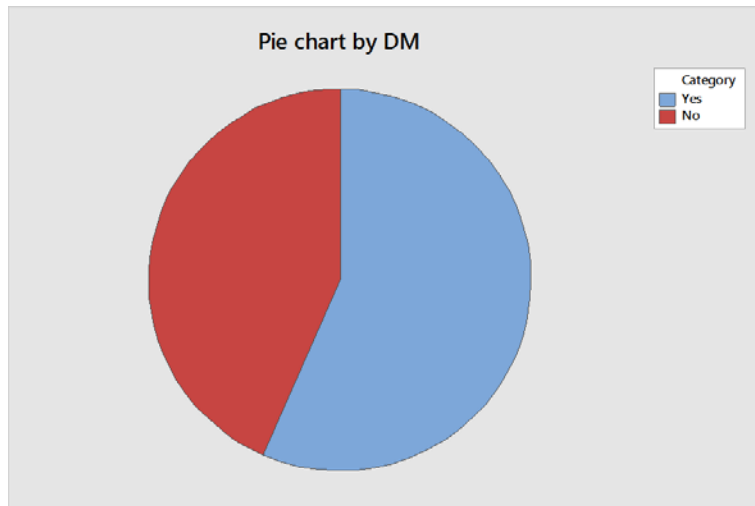
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- Vein diameter measurements at baseline, 1 month and 3 months
 - Patient satisfaction with device, compliance and comfort



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

Trial Demographics

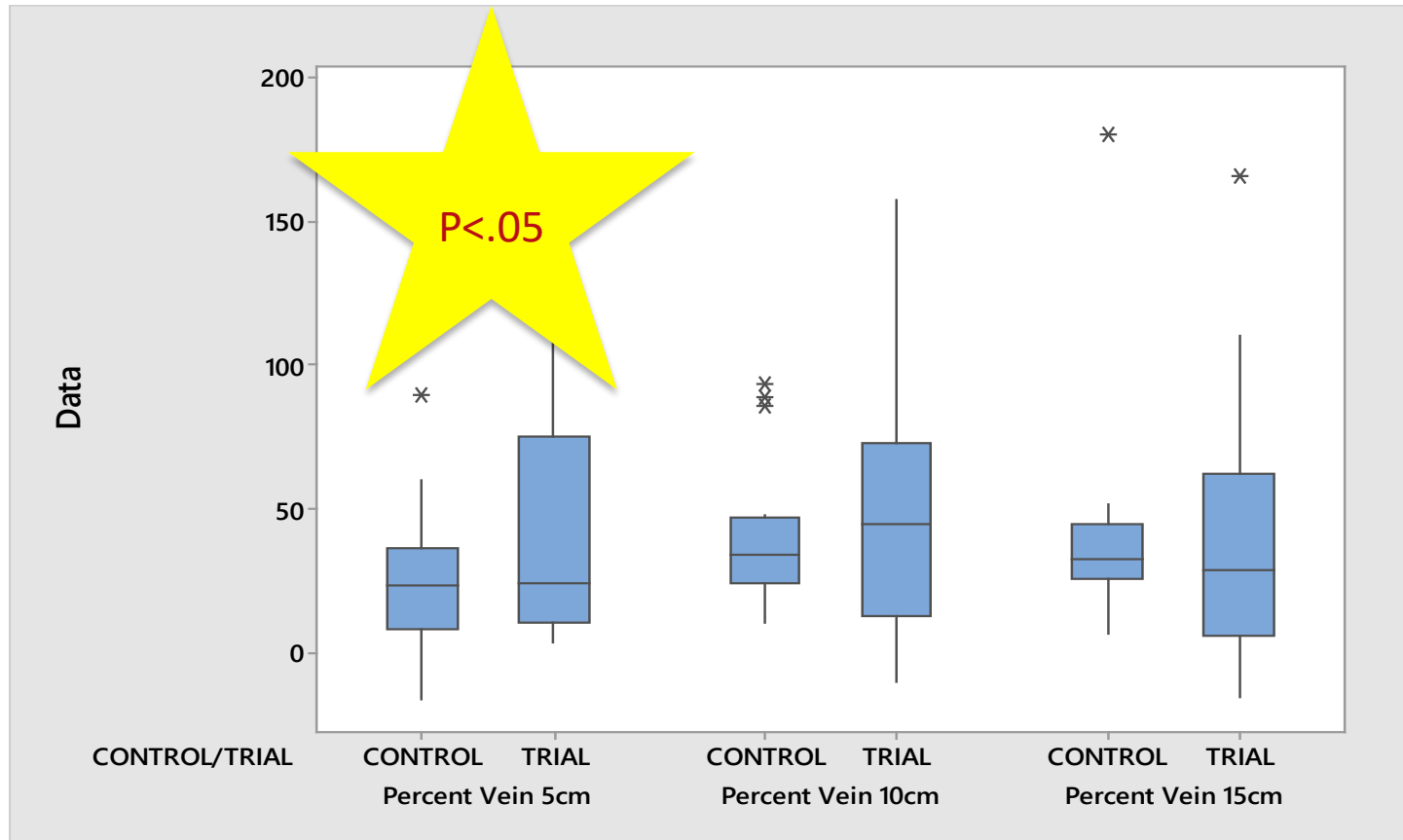


Mean BMI 24.6 (SD 3.365)
African American BMI 30.0 (SD 5.7)
 $P < .05$

Vein size forearm cephalic vein:
US population .5 mm smaller
than Indian measurement: Not
significant

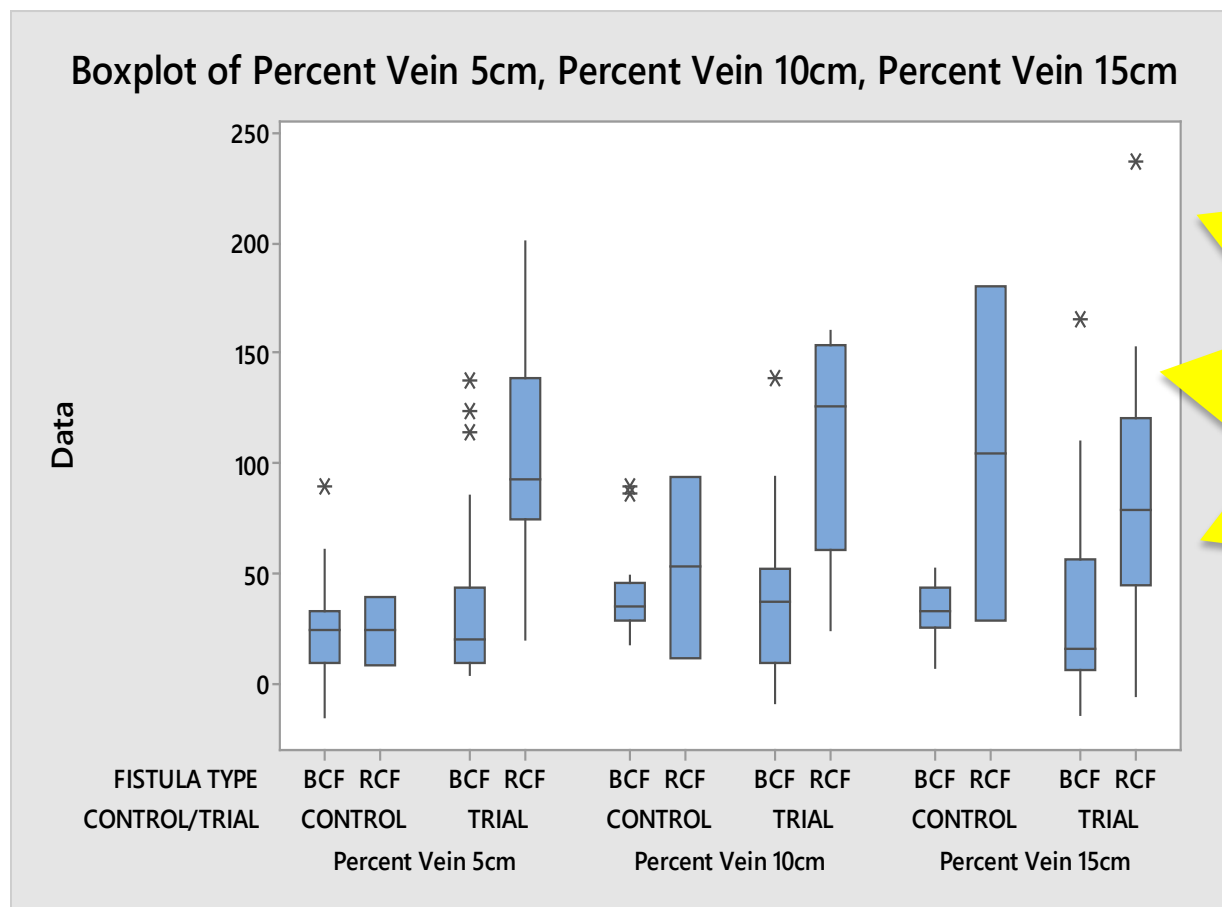
Box Plot of 1 Month Data and Vein Segment all Fistulas

First 5 cm of vein confirmed to dilate



Journal of Vascular Access May 2018

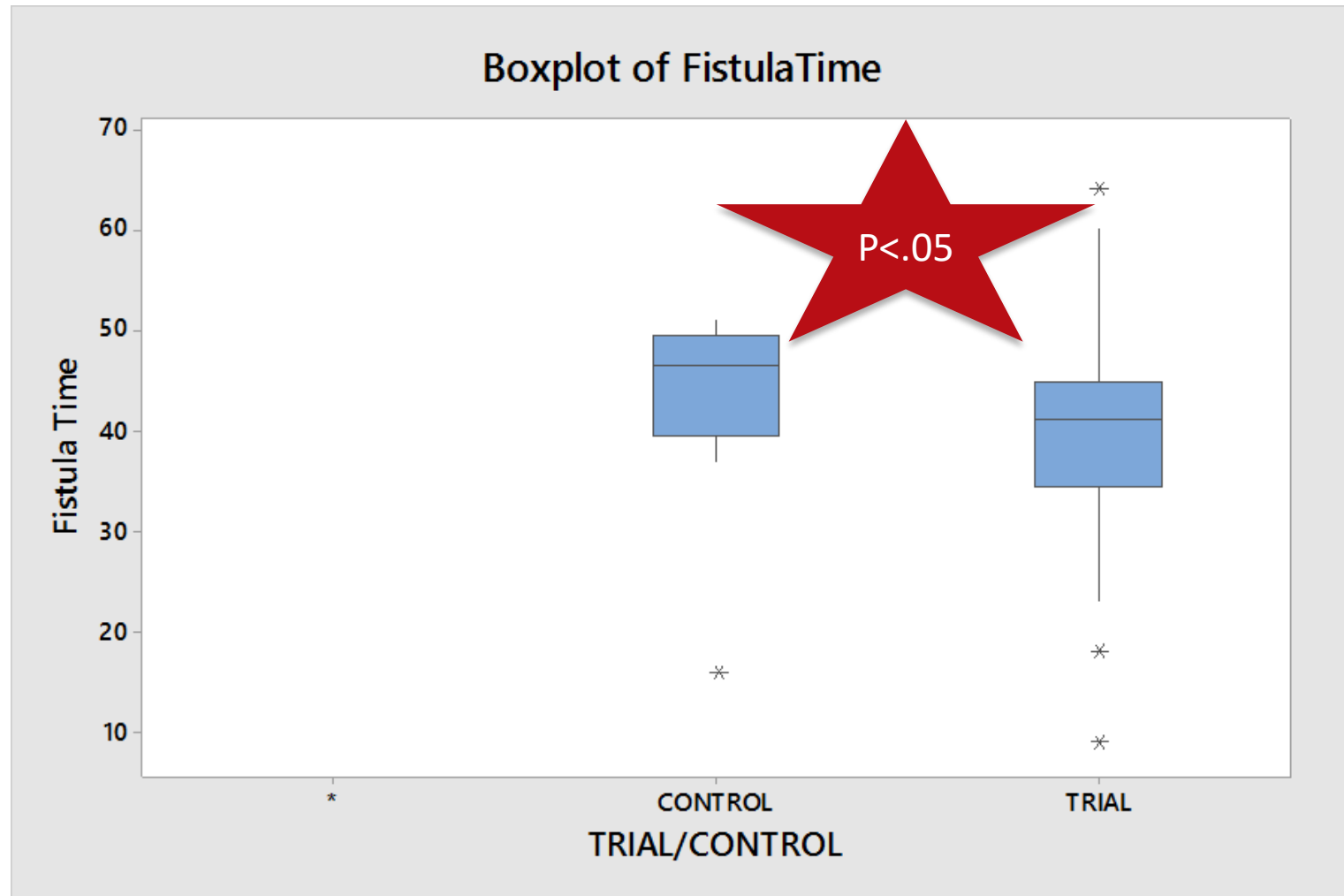
Fist Assist will help dilate forearm veins 1 and 3 Months!



$p < .05$ all
vein
segments

Accepted Journal of Vascular Access

Fist Assist Trial Patients Assessed Fistulas Faster



Fist Assist led to 10% faster fistula needle placement

Pneumatic Dilation Potential: Fist Assist has it!

Hierarchical regression modeling

Response variables of interest:

Vein enlargement – Measured by % increase in vein size diameter

Fistula maturation – Measured by mean needle placement time

- Hierarchical regression modeling technique
- Independent variables of interest entered into the model in a hierarchical order:

Patient group : Treatment/Control

Fistula type : BCF/RCF

Patient group * Fistula type : Interaction effect
between the two

Age

DM

HTN

Abstract for Kidney Week 2018

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**
 - In USA: over 4 months.
- 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**
- 3 month data confirms RCF over BCF

Regulatory Pathway

FDA Classification



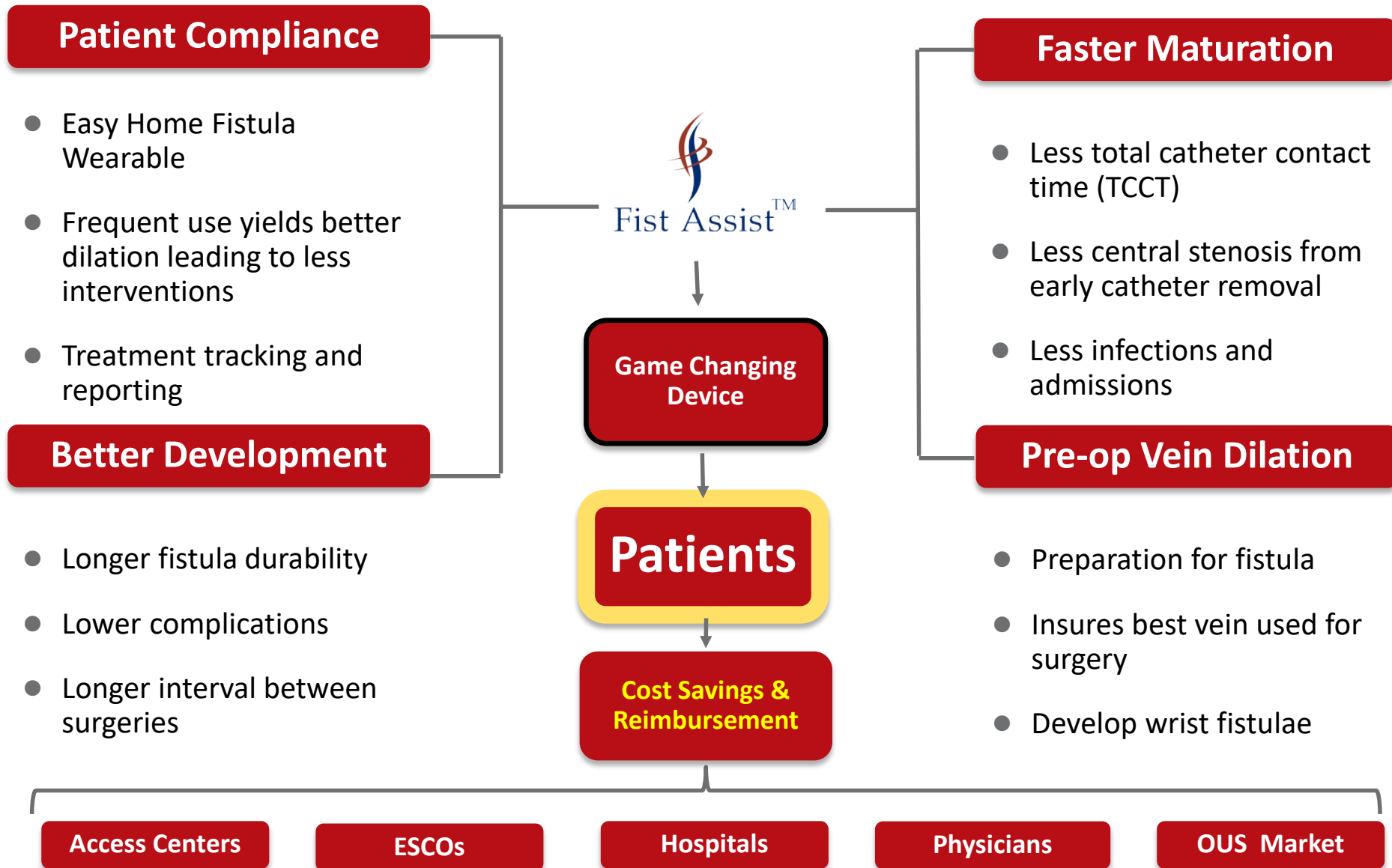
**No Predicate
Device (pre-sub)**



**De Novo
submission in
August 2018**



IMPROVING THE PATIENTS JOURNEY THROUGH ESRD



Note: above claims have already been studied or are expected outcomes of future studies

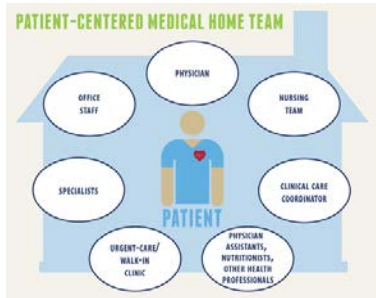
Fist Assist Global Awareness and International Acceptance



ADC Orlando 2018 – Fist Assist International Society for Hemodialysis Award Winner for New Innovation

Global Demand verified & Fist Assist supported by Global KOLS

ESRD “Fist Assist” Home Wearable Protocol



	Stage 4	Stage 5
	Severe GFR ↓	Kidney Failure
	<i>“New” Protocol – Fist Assist Used Pre and Post Fistula Surgery</i>	
	<i>Wear Fist Assist Pre Fistula Creation</i>	<i>Wear Fist Assist Post Fistula Creation</i>
	• Enlarges and Conditions veins • Insures best vein used for surgery • Develop Wrist Fistula • Improves Compliance	• Better dilation leads to less interventions • Faster Maturation leads to less infections, lower total catheter contact time, • Longer fistula durability
Benefits of Fist Assist (Cost Savings and Efficacy)		

Fist Assist Medical Device Home Wearable will remove significant costs

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
 - Catheter removal and fistula quality better
- Will insure patient education
 - Pre-dialysis vein studies
- Global Fistula Dilation Device
- Excellent results with wrist fistulas



FIST ASSIST: The ideal GLOBAL wearable



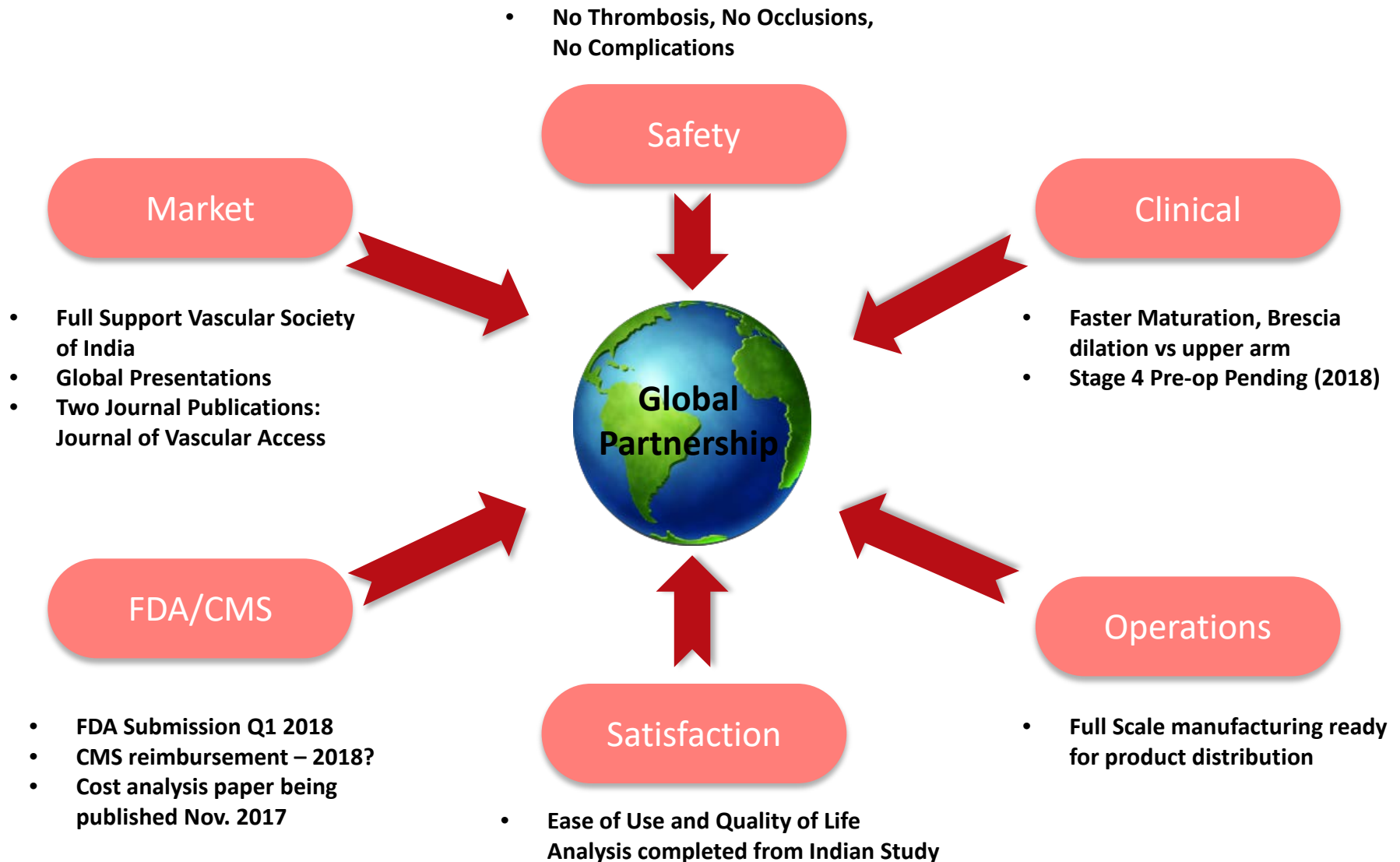


Fist AssistTM

Changing the Standard of Care in Vein Dilation

www.fistassistdevices.com

Global Partnership for Patient Access



Global PARTNERSHIPS in 2018

The Next Steps

- 1 Further device development and refinement for FDA!
- 2 Clinical trials in USA planned
- 3 Validate the fistula (vein) maturation in trials
- 4 Demonstrate clinical and cost benefits
- 5 Provide to patients as part of renal failure coverage and CMS renal care programs as DME