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## Long-Term Results Of The SAVVE Trial: A Bioprosthetic Valve



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Disclosures






### Chronic Venous Insufficiency (CVI)

~2.5M Total Available Market	~\$30k Spent on wound care per patient per year <sup>2</sup>	20-40% 1-year ulcer recurrence <sup>1</sup>
~\$3B Direct medical costs <sup>2</sup>	~40% More workdays missed <sup>1</sup>	


1. Yoon, Minky, The Sage Group, Chronic Venous Disease, Epidemiology, Costs, and Consequences, 2018  
2. Satchley, Uky, et al. Suppressed Benefits of Inflammatory Modulators Characterize Chronic Venous Insufficiency. Journal of Vascular Surgery: Venous and Lymphatic Disorders, May 2018  
3. Kwon, B. Healthcare Burden of Chronic Leg Ulcers in the United States. Journal of Medical Economics, Volume 37, 2018

### VenoValve: Unique Bioprosthesis

**Monocusp Valve**

- Rigid stainless-steel frame
- Porcine aortic valve noncoronary leaflets




**FDA Breakthrough Device Designation**

FIH Pilot study demonstrated sustained benefit in patients up to 3 years

Ulloa & Gilchrist. Vascular and Endovascular Surgery 2023; 10(1): 1602-167-169

### U.S Pivotal Trial SAVVE

75 Patients  
21 Clinical Sites

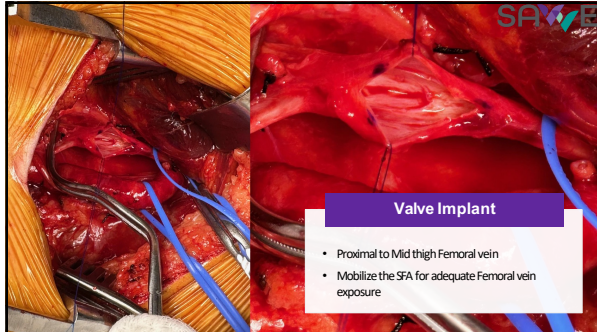


**Inclusion**

- Failure of at Least 3 Months Standard Care
- AXIAL Reflux > 1 Second
- CEAP Scores: C4b, C4c, C5, C6
- Ability to Ambulate Without Assistance
- ABI > .61
- BMI < 40

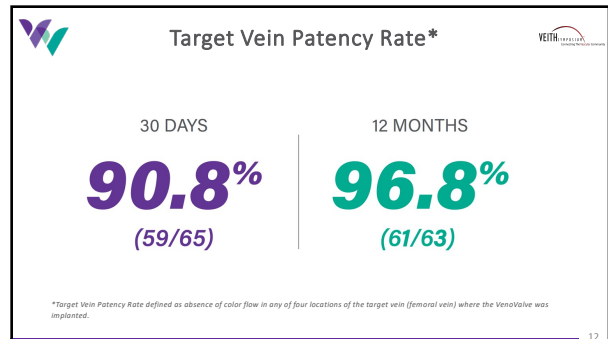
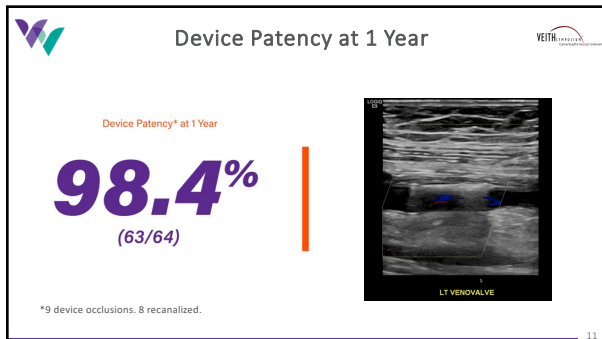
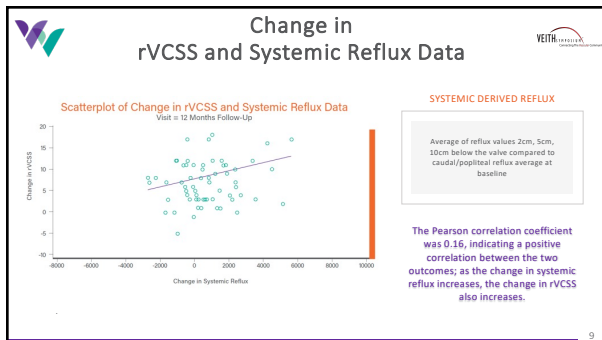
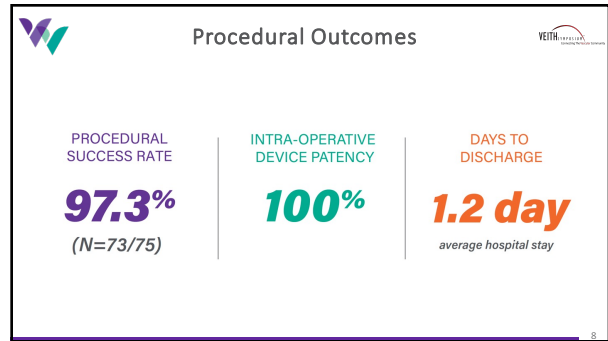
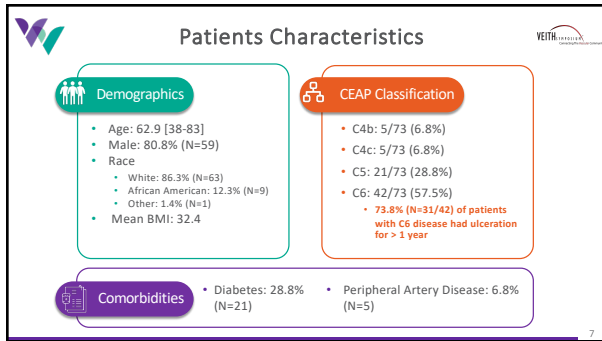
**Exclusion**

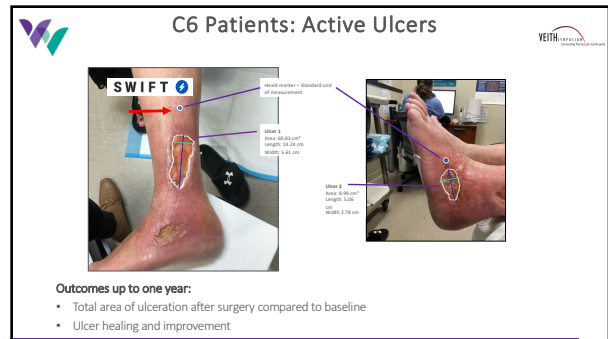
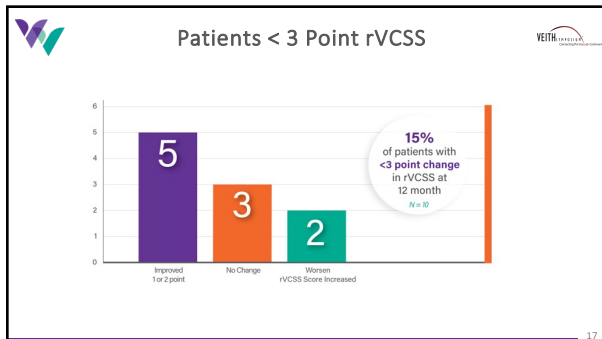
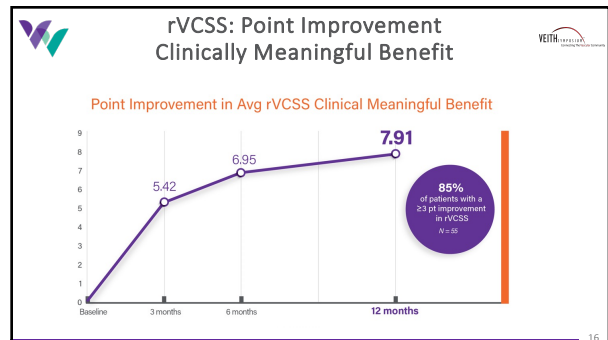
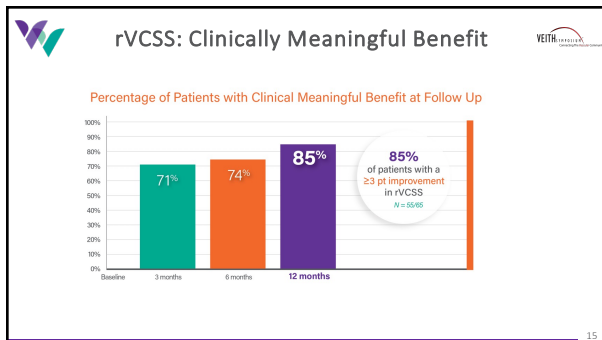
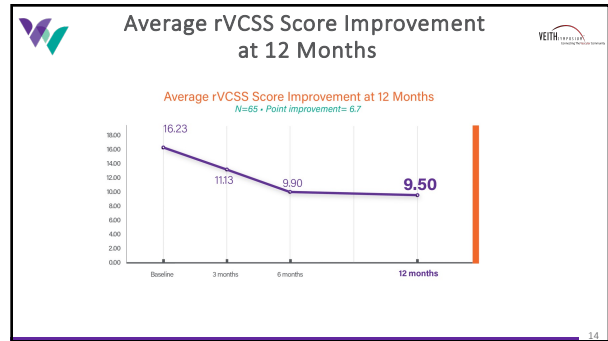
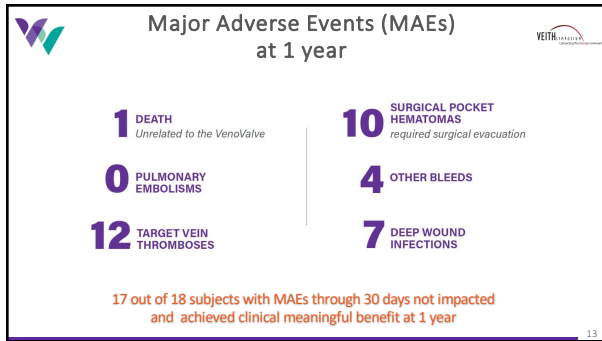
- Hypercoagulable Condition
- Acute Deep Venous Thrombosis or Pulmonary Embolism
- Lymphedema
- Superficial Reflux
- Iliac/IVC Obstruction or Poor Central Venous Flow
- Uncontrolled Diabetes Mellitus
- Sepsis

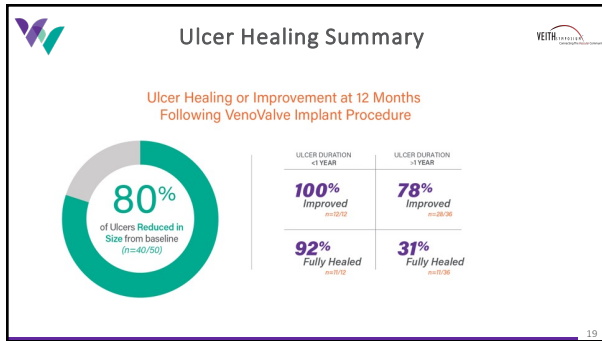


**Valve Implant**

- Proximal to Mid thigh Femoral vein
- Mobilize the SFA for adequate Femoral vein exposure

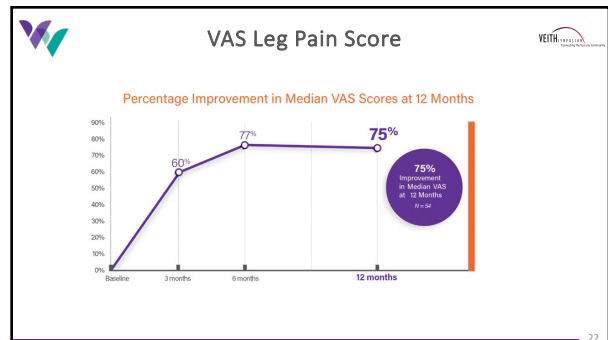
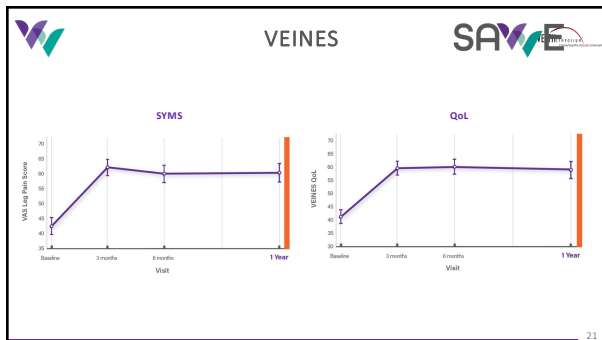






### Quality Of Life Indicators

Patient Reported Outcomes				
Endpoint	Baseline	12 Months	Change from Baseline <small>A negative value is indicative of an improvement</small>	% Change
VEINES Symptoms Score (Mean ± SD)	44.1 ± 24.36	60.3 ± 24.60	-16.3 ± 21.40 (p<0.0001)	91.9%
VEINES QoL Score (Mean ± SD)	43.2 ± 22.67	58.9 ± 25.59	-15.7 ± 21.51 (p<0.0001)	57.8%
EQ-5D-5L Index Score (Mean ± SD)	0.7 ± 0.18	0.8 ± 0.16	-0.1 ± 0.18 (p=0.0004)	37.2%



### Conclusion

The Venovascular Implants is a safe and effective treatment for patients with chronic venous insufficiency (CVI) due to deep valvular incompetency.

Benefits include improvement in QoL, reduction in pain, improvement in clinical outcome, and ulcer healing.