2021 VASCULAR ANNUAL MEETING®

Fundación Santa Fe de Bogotá

Two Year Results Of A Bioprosthetic Valve, The VenoValve ®, Surgically Implanted In Patients For Severe Chronic Venous Insufficiency, C5-C6 Disease

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Disclosure

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HANCOCK JAFFE
LABORATORIES INC
Restoring Cardiac and Vascular Health

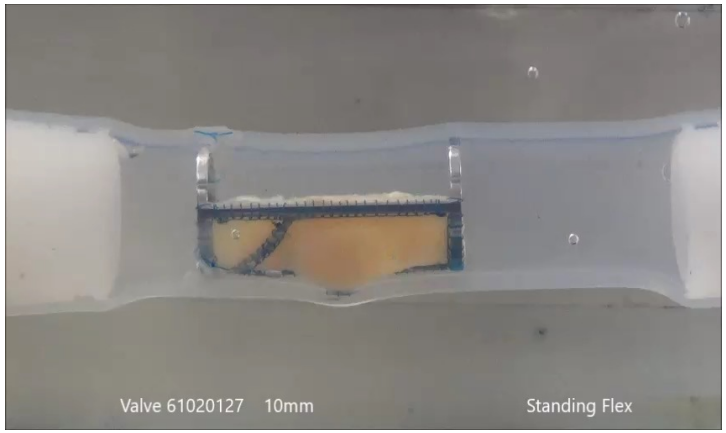
VenoValve® System

Model #	Outer Diameter (Nominal)	Length
HJL-060-10	10 mm	21mm

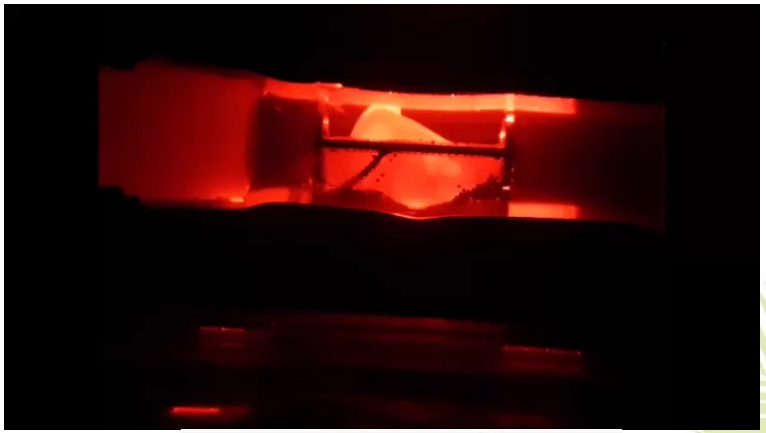
VenoValve® System: crosslinked monocusp porcine aortic valve with a section of aorta and a porcine mitral valve in a rigid stainless steel 316 LVM frame.

VenoValve® Flow Visualization

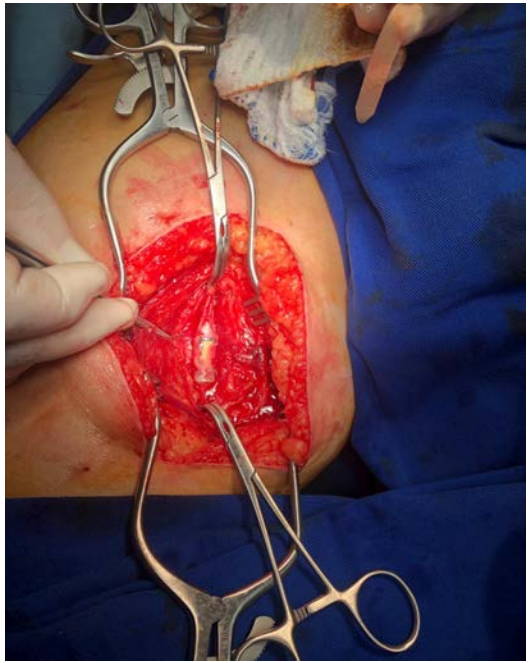
Dye injection test: the dye is washed out completely with no zones of stagnation.

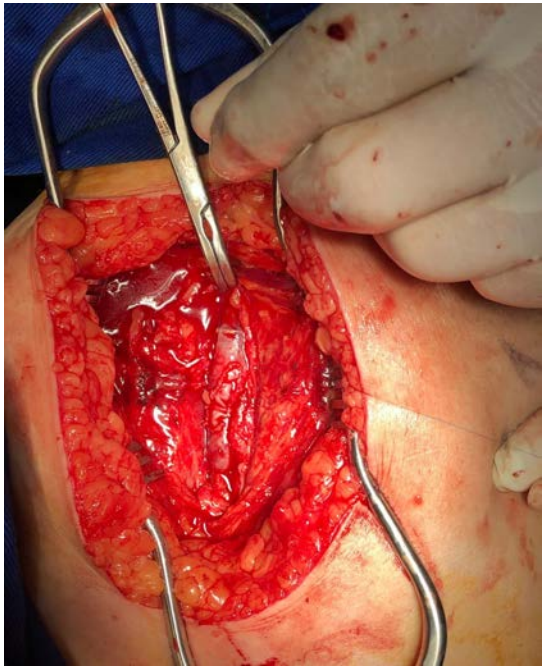


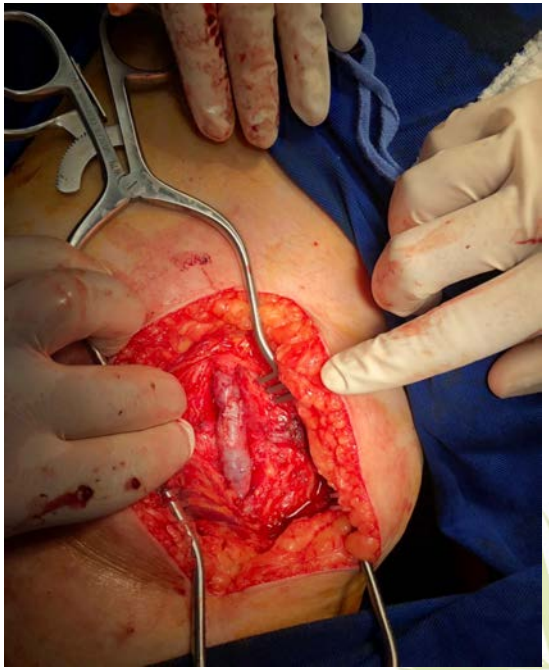
Particle Image Velocimetry (PIV): the flow streams are undisturbed, parallel with maximum peak velocity of 1.4 m/s



VenoValve®: Surgical Implantation

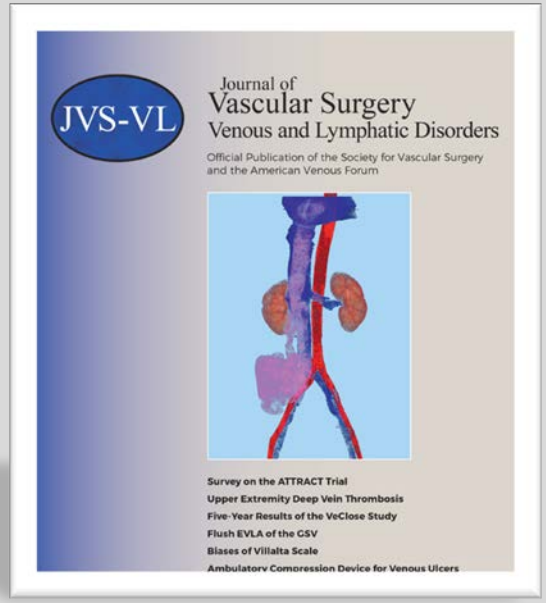






Trial Results Reports

6 Months



12 Months

International Symposium
CHARING CROSS

24 Months

SVS
75 YEARS
2021
VASCULAR
ANNUAL MEETING
SAN DIEGO

VenoValve® Trial Patient Demographics

	FIH Study – 1Yr.	2 Yr. Follow-up
Number of Patients	11	8
Average Age	70.8	67.6
Men/Women	5/6	5/3
C5/C6	5/6	4/4

Patient Criteria

Inclusion Criteria
Axial Reflux > 1 sec.
Valvular Incompetence (primary or secondary)
CEAP: C5 - C6
Ability to Walk Unassisted
ABI > .61
BMI < 35

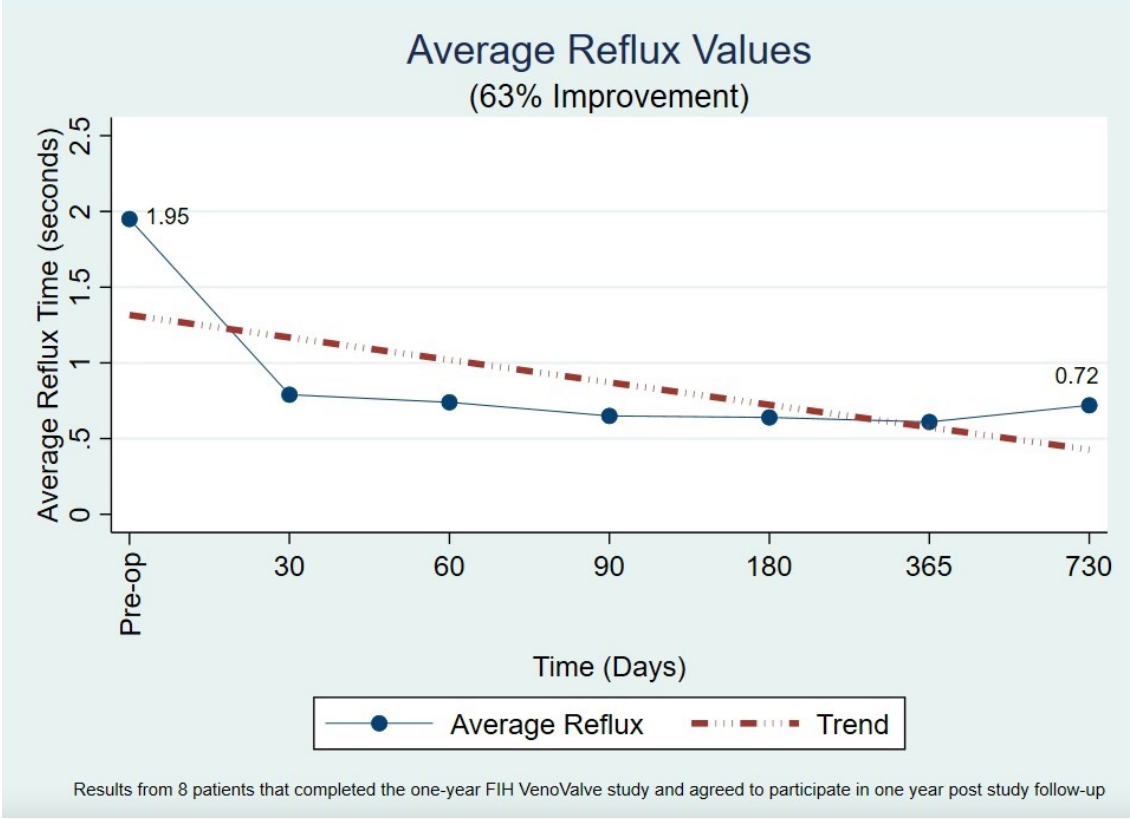
Exclusion Criteria
Hypercoagulable Condition
Acute DVT or PE
Lymphedema
Superficial Reflux
Iliac /IVC Obstruction/poor venous flows
Uncontrolled Diabetis Mellitus, Thyroidism Sepsis, Acute Respiratory Disease

Safety

NO DEVICE RELATED ISSUES

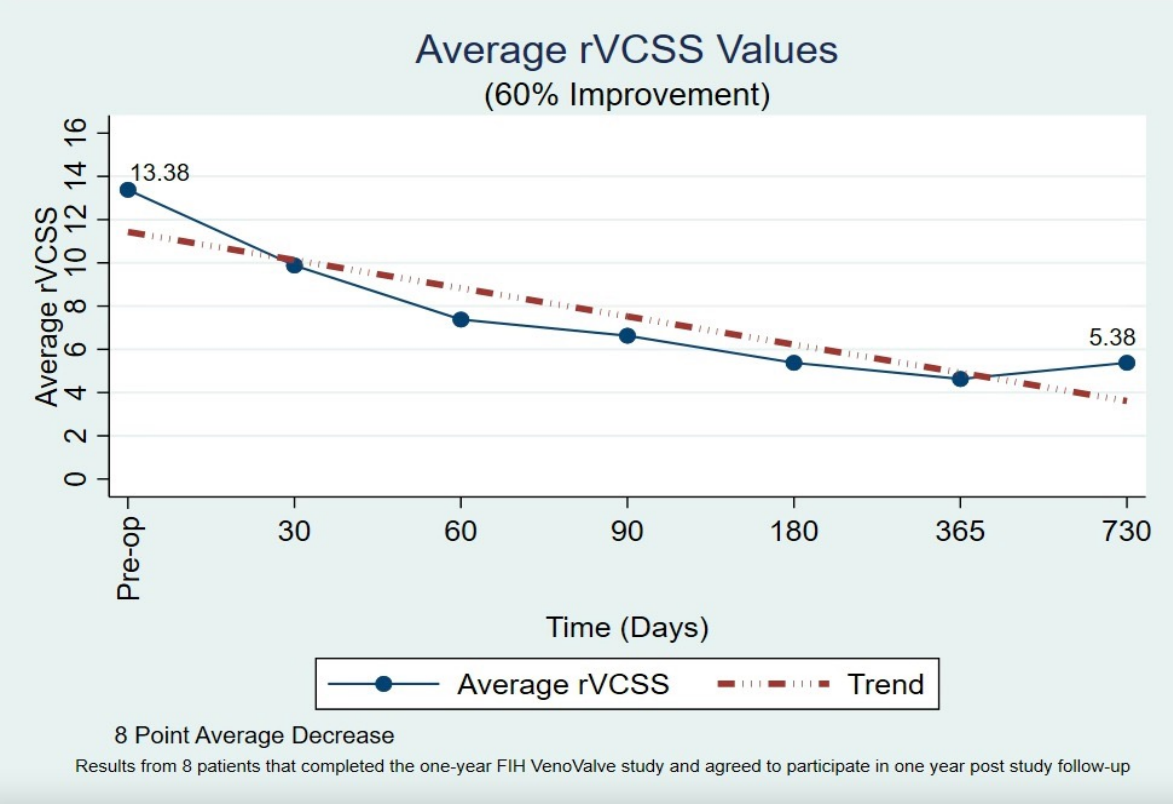
- No post-FIH adverse events.
- One case of contralateral ulcer development.
- No hospitalizations.
- No recurrence or new ipsilateral ulcers (wound healing).

2-year Follow-Up – Results - REFLUX

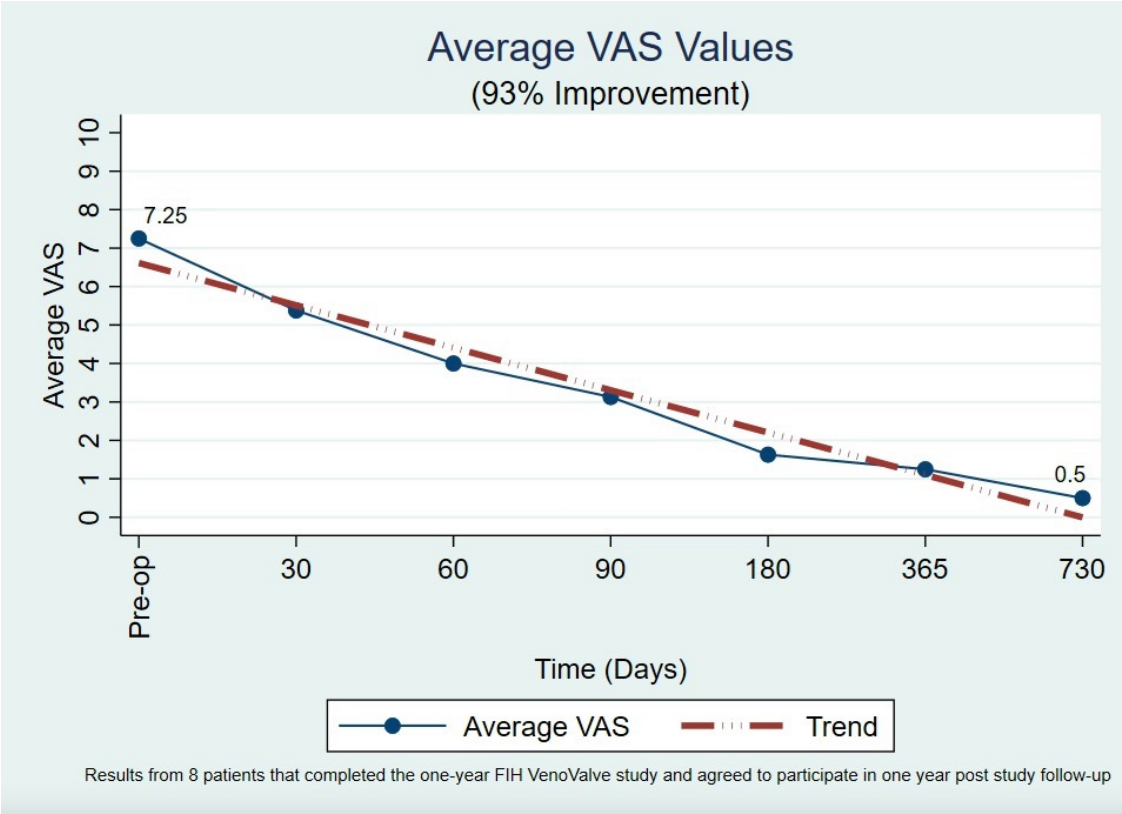


Results from 8 patients that completed the one-year FIH VenoValve study and agreed to participate in one year post study follow-up

2-year Follow-Up – Results - VCSS



2-year Follow-Up – Results - VAS



Results from 8 patients that completed the one-year FIH VenoValve study and agreed to participate in one year post study follow-up

VenoValve® U.S. Pivotal Trial (SAVVE)

- 75 patients in up to 20 sites.
- C4b – C6 patients.
- FDA IDE Approval (April 2021 – 28 days).
- FDA Breakthrough Device Designation (August 2021 – 29 days).
- First patient in the next 60 days.
- www.VenoValve.com

Conclusions

- The VenoValve appears to be safe.
- 63% average improvement reflux.
- 60% average improvement rVCSS (8 points).
- 93% improvement in VAS.
- Continued significant improvement for 2 years without adverse events.
- No ulcer recurrence in the ipsilateral side.

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THANK YOU

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