VEITH SYMPOSIUM 51st
Connecting The Vascular Community

Deep Vein Valve Devices: What Outcome Measures Should Be Used?

JOBST VASCULAR INSTITUTE
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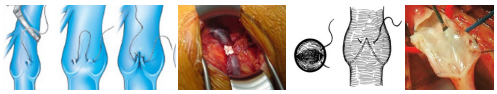
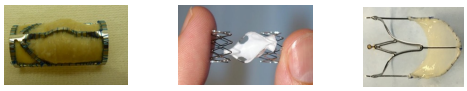
New solutions, old questions

1968 - 1990



21st Century

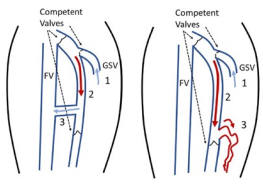


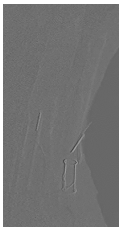
New solutions, old questions

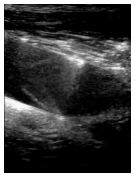
- Does the new valve work (and how long)?
- How does it change venous flow dynamics in the treated limb?
- What are clinical outcomes causally related to:
  - Changes in focal reflux
  - Changes in limb flow dynamics

Does the new valve work (and how long)?

Reflux vs. valve incompetence

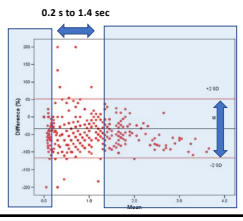






Lurie F. Cardiol Ther. 2020 Dec;9(2):215-218.

Does the new valve decrease or eliminate the reflux?



± 70%

INVEST Study (INvestigating Venous disease Evaluation and Standardization of Testing)

Example:
1st test: RT= 1 sec

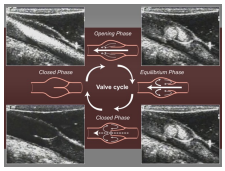
2nd test: RT= 0.3 sec

J Vasc Surg. 2012 Feb;55(2):437-45.

Does the new valve work (and how long)?

Outcome measure – direct visualization + Time of the opening and close phases of the valve cycle

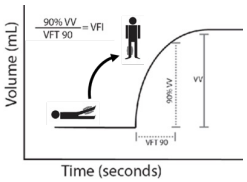
Opening phase ≈ 0.25 sec
Closing phase 0.3 – 0.4 sec



J Vasc Surg. 2003 Nov;38(5):955-61.

How does it change venous flow dynamics in the treated limb?

The only existing test for severity of global reflux: Plethysmography



- Requires expertise in testing and interpretation
- Patient-dependent
- Close to extinction in the USA

What are clinical outcomes causally related to changes in focal reflux or limb flow dynamics

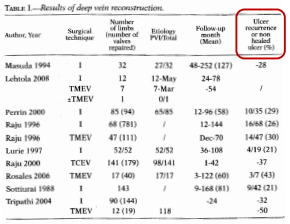


Table I.—Results of deep vein reconstruction.

Author, Year	Surgical technique	Number of limbs (number of valves repaired)	Etiology PVT/Total	Follow-up month (Mean)	Ulcer recurrence or non healed ulcer (%)
Masuda 1994	I	32	27/32	48-252 (127)	-28
Lehtola 2008	I	12	12-May	24-78	
	TMEV	7	7-Mar	-54	/
	±TMEV	1	0/1		
Perrin 2000	I	85 (94)	65/85	12-96 (58)	10/35 (29)
Raju 1996	I	68 (781)	/	12-144	16/68 (26)
Raju 1996	TMEV	47 (111)	/	Dec-70	14/47 (30)
Lurie 1997	I	52/52	52/52	36-108	4/19 (21)
Raju 2000	TCEV	141 (179)	98/141	1-42	-37
Rosales 2006	TMEV	17 (40)	17/17	3-122 (60)	3/7 (43)
Sottiurai 1988	I	143	/	9-168 (81)	9/42 (21)
Tripathi 2004	I	90 (144)		-24	-32
	TMEV	12 (19)	118		-50

Almost all series started before VCSS was published

Int Angiol. 2010 Jun;29(3):199-204.

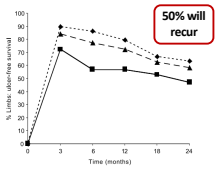
What are clinical outcomes causally related to changes in focal reflux or limb flow dynamics

Attribute	Absent [0]	Mild [1]	Moderate [2]	Severe [3]
Pain	None	Occasional		
Varicose veins (>4 mm in diameter)	None	Few,		
Venous edema	None	Limited ankle		
Skin pigmentation	None	Limited area		
Inflammation	None	Limited area		
Induration	None	Limited area		
Number of active ulcers	0	1		
Longest active ulcer duration	N/A	<3 mo		
Largest active ulcer size (cm)	N/A	Diame		
Ulcer duration	None	<3 mo		
Compression therapy stockings	None	Intermitte		

VCSS: Which of these attributes casually relates to changes in reflux?

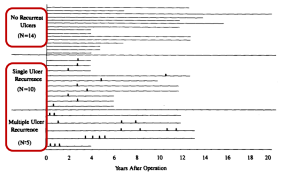
What are clinical outcomes causally related to changes in focal reflux or limb flow dynamics

Ulcer healing



50% will recur

Ulcer-free time



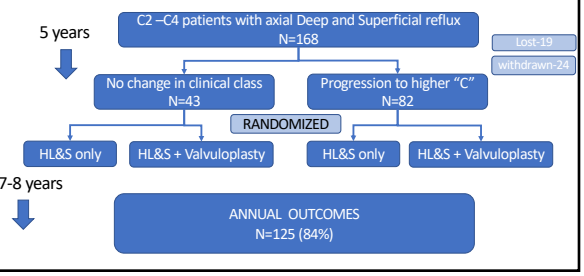
R. Tripathi et al. ANZ J Surg. 2004 Jan-Feb;74(1-2):34-9.

E. Masuda, R Kistner. J Vasc Surg. 1994 Mar;19(3):391-403.

Does surgical correction of the superficial femoral vein valve change the course of varicose disease?

J Vasc Surg 2001;33:361-8

Nina Petrovna Makarova, MD, PhD,[a] Fedor Lurie, MD, PhD,[b] and Semen Markovich Hinchniker, MD, PhD,[b] *Ekaterinburg, Russia*

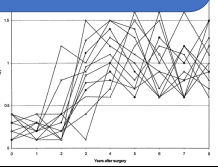


Does surgical correction of the superficial femoral vein valve change the course of varicose disease?

J Vasc Surg 2001;33:361-8

- Benefits of valve reconstruction only in progressive disease
- No relationship between clinical outcomes and reflux time (because of variability in RT)

	Stable			Progressive		
	HL&S+ Valvuloplasty	HL&S only	P	HL&S+ Valvuloplasty	HL&S only	P
Improvement	95%	90%	NS	80%	51%	<0.01
No improvement or worsening	5%	5%	NS	34%	15%	<0.01



CONCLUSIONS

- Does the new valve work (and how long)? –direct visualization + time of the opening and closing phases
- How does it change venous flow dynamics in the treated limb? – APG (with all negative features)
- What are clinical outcomes causally related to valve reconstruction? – natural history change:
  - C5-C6 Frequency of ulceration (ulcer-free time)
  - C2-C4 Progression to C6