2023 MID-ATLANTIC CONFERENCE

11th ANNUAL CURRENT CONCEPTS IN

VASCULAR THERAPIES

2023

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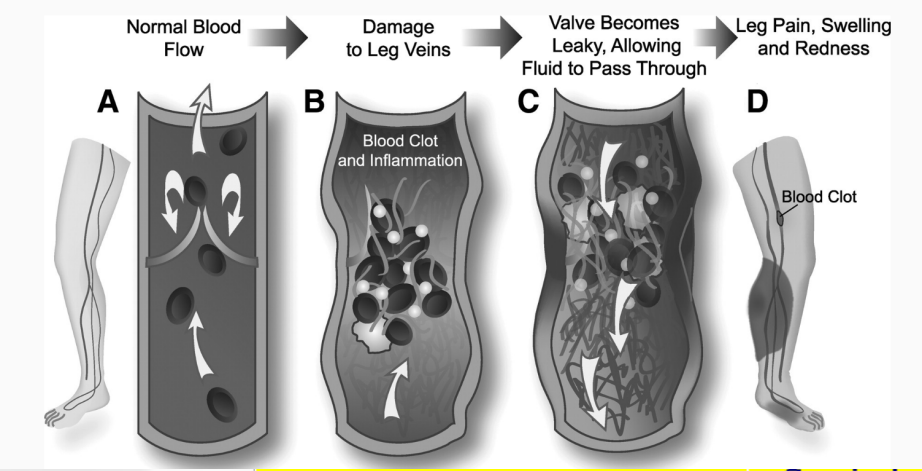
My DVT Was Treated; Years Later I Still Have Pain and Swelling: What to Do With Post Thrombotic Syndrome

David Dexter MD FACS RPVI

Sentara Vascular Specialists

Why treat DVT surgically?

- Early return of vein patency
- Preserve valvular function to limit long term complication
- Prevent pulmonary embolism
- Limit Post-thrombotic syndrome



	Recurrent DVT	Post-thrombotic syndrome	Survival rate
2 years	17%	25%	80%
5 years	24%	30%	74%
8 years	30%	30%	69%

Prandoni 96, Prandoni 98; Prandoni 97

Sara R. Vazquez Susan R. Kahn **Postthrombotic Syndrome**

Circulation 2 Mar 2010. 2010;121:e217–e219

Heparin vs. Thrombolysis Comparison of 13 studies

Outcome	Heparin	Thrombolysis
	N=254	N=337
Complete Lysis	4%	45%
Partial Lysis	14%	18%
No Change/Worse	82%	37%

Comerota A, Aldridge S. *Semin Vasc Surg.* 1992;5(2):76-81.

Greater thrombus removal gives lower PTS rate

Comerota et al. J Vasc Surg. 2012 Mar;55(3):768-73.

Journal of Vascular Surgery®

Postthrombotic morbidity correlates with residual thrombus following catheter-directed thrombolysis for iliofemoral deep vein thrombosis

Anthony J. Comerota, MD,[a] Nina Grewal, MD,[a] Jorge Trabal Martinez, MD,[a] John Tahao Chen, PhD,[b] Robert DiSalle, MD,[a] Linda Andrews, RN,[a] Deb Sepanski, RT(R),[a] and Zakaria Assi, MD,[a] *Toledo and Bowling Green, Ohio*

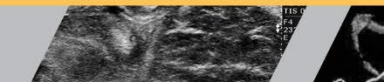
Background: Iliofemoral deep vein thrombosis (DVT) is associated with severe postthrombotic morbidity when treated

correlation of clinical class of CEAP with residual thrombus ($R^2 = .74$; $P = .004$) and a direct linear correlation of Villalta score with residual thrombus ($R^2 = .61$; $P = .0014$).

Conclusion: In patients with iliofemoral DVT treated with catheter-based techniques of thrombus removal, postthrombotic morbidity is related to residual thrombus. When thrombus clearance was complete, the postthrombotic syndrome was avoided. Residual thrombus is associated with an increasing risk of postthrombotic syndrome. (J Vasc Surg 2012;■■:■■■.)

Study to evaluate correlation between residual thrombus and post-thrombotic syndrome (PTS)

- 71 consecutive IFDVT patients treated with CDT
- Blinded comparison of pre- and post-treatment phlebograms and evaluation of CEAP/Villalta scores



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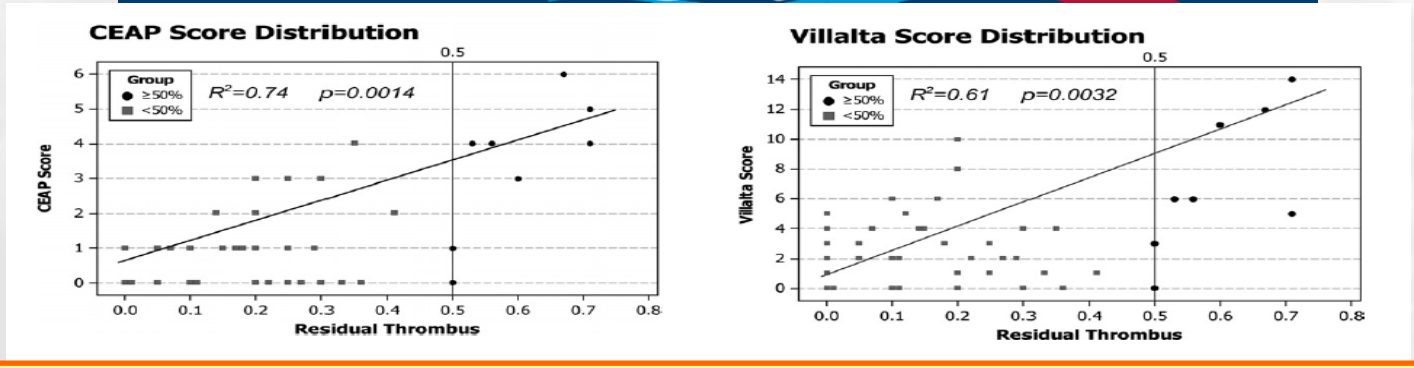
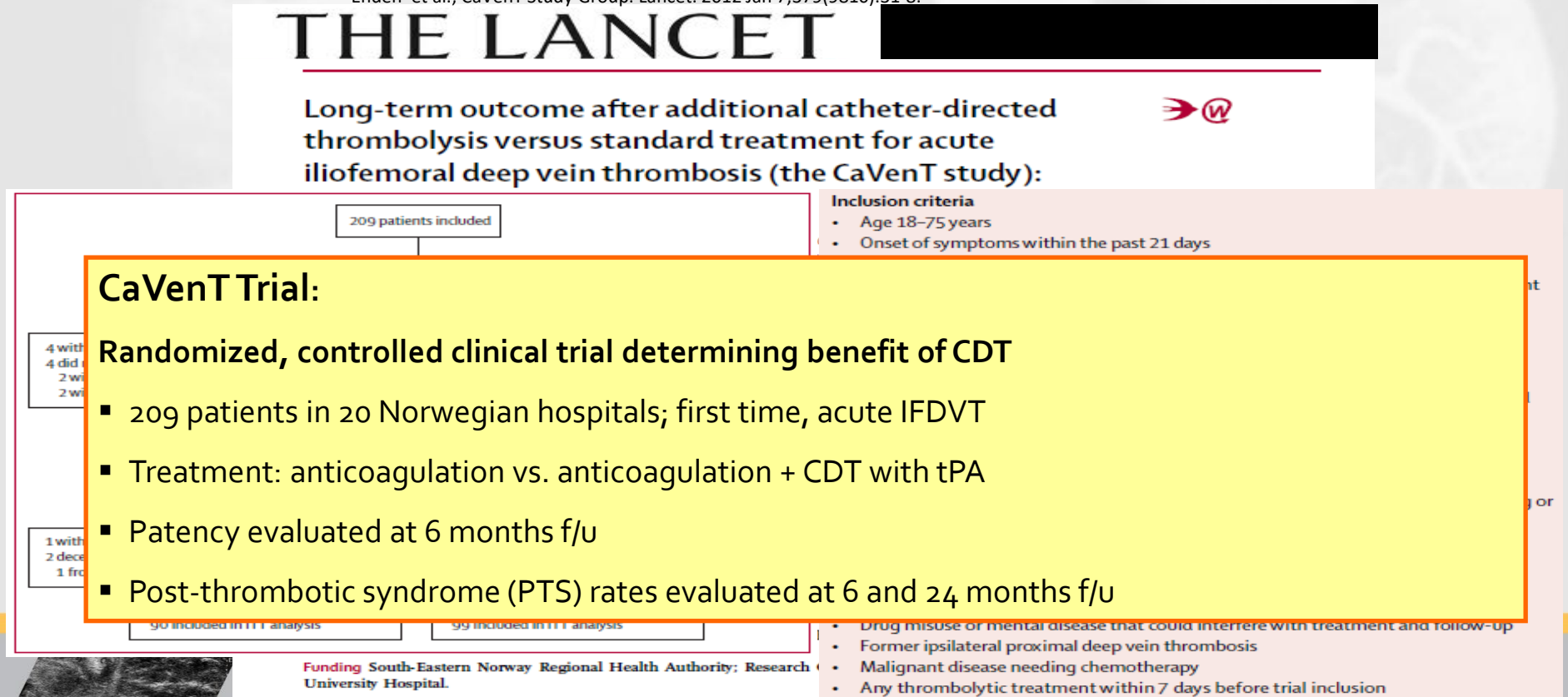


First study to demonstrate:

- **Direct** and **significant** correlation of between PTS scores and thrombus clearance
- Conclusion: when thrombus clearance is complete, PTS can be avoided

CDT improves patency and reduces PTS compared to anticoagulation

Enden et al.; CaVenT Study Group. Lancet. 2012 Jan 7;379(9810):31-8.



CaVenT Trial:

Randomized, controlled clinical trial determining benefit of CDT

- 209 patients in 20 Norwegian hospitals; first time, acute IFDVT
- Treatment: anticoagulation vs. anticoagulation + CDT with tPA
- Patency evaluated at 6 months f/u
- Post-thrombotic syndrome (PTS) rates evaluated at 6 and 24 months f/u

CDT improves patency and reduces PTS compared to anticoagulation

Enden et al.; CaVenT Study Group. Lancet. 2012 Jan 7;379(9810):31-8.

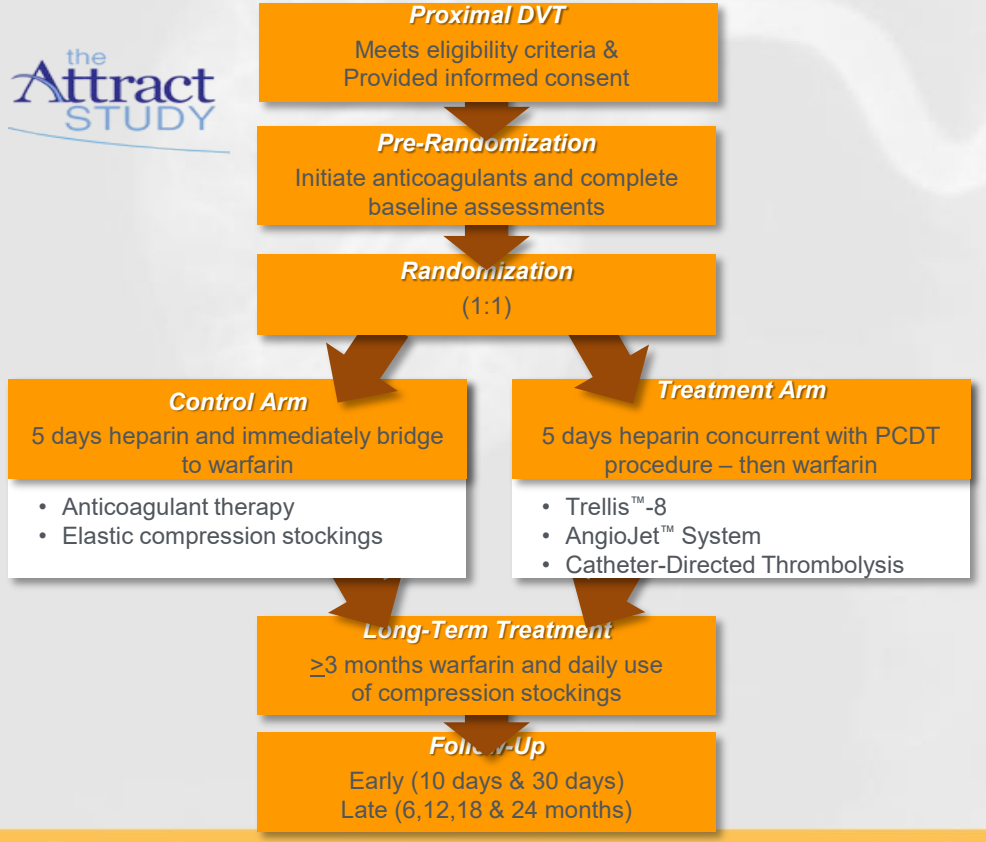
THE LANCET [redacted]

Long-term outcome after additional catheter-directed thrombolysis versus standard treatment for acute iliofemoral deep vein thrombosis (the CaVenT study): a randomised controlled trial

	Additional catheter-directed thrombolysis (n=90)		Standard treatment only (n=99)		p value*
	n	% (95% CI)	n	% (95% CI)	

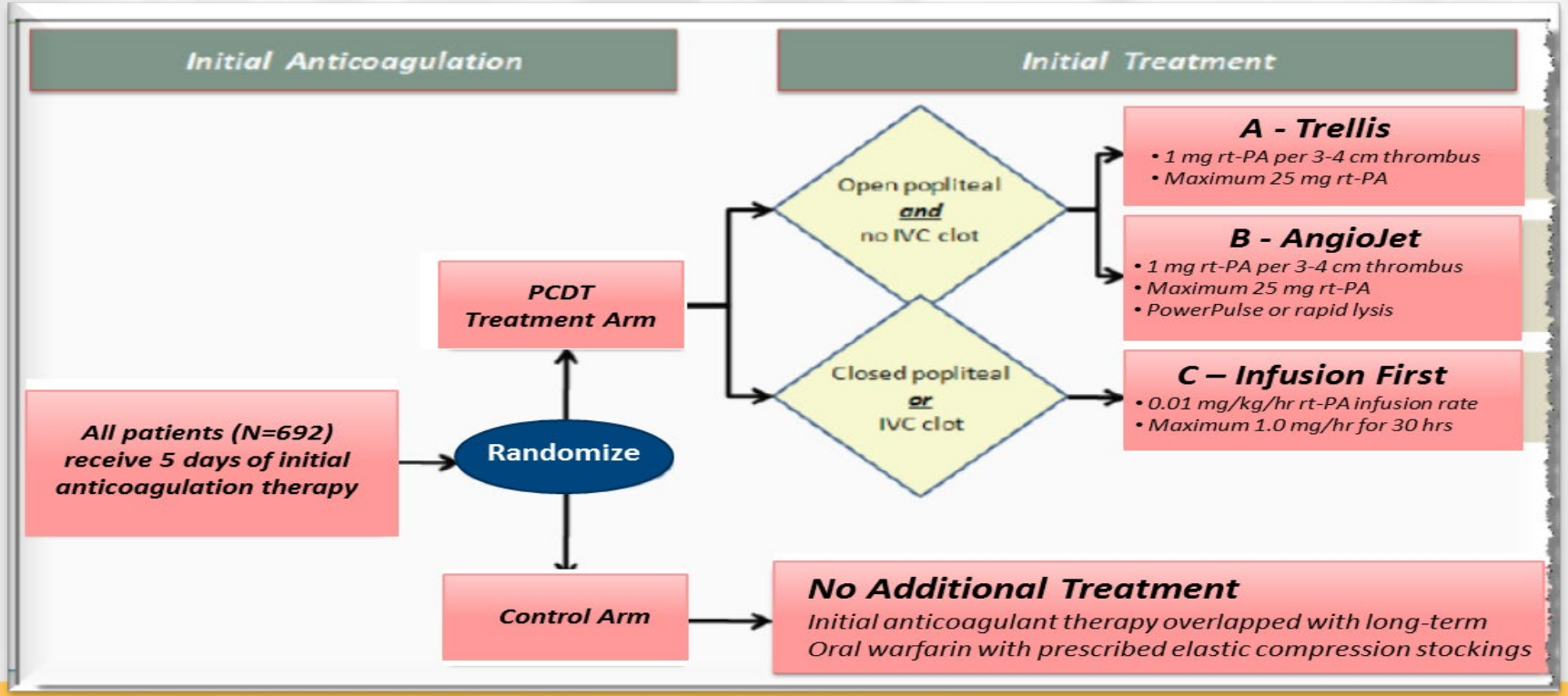
- CDT group achieved:
  - Higher patency at 6 months f/u
  - Lower rate of PTS at 24 months f/u
- Further improvement in PTS rates likely if **more adjunctive procedures had been performed following CDT**
- 20 Bleeding Events 3 Major and 5 Clinically Relevant

the Attract STUDY



- NIH-funded, Phase III, multicenter, randomized, open-label, assessor-blind, parallel two-arm, controlled clinical trial
- 692 patients at 30-60 centers
- Determining if the use of Pharmamechanical CDT (e.g. AngioJet) in acute DVT reduces occurrence of post thrombotic syndrome (PTS) over 24 months
- Includes both clinical and economic outcomes

ATTRACT Trial Overview



ATTRACT[a]: Long-Term Effects of PCDT

Outcome (24 months)	PCDT n=336	No PCDT n=355	P Value
Any PTS	46.7%	48.2%	.56
Recurrent VTE	12.5%	8.5%	.09
Generic QOL (SF-36 PCS)	11.8	10.1	.37
Venous QOL (VEINES)	27.7	23.5	.08
Moderate or Severe PTS	17.9%	23.7%	.035
MS-PTS IFDVT	18.4%	28.2%	-
MS-PTS FPDVT	17.1%	18.1%	-

PCDT likely to benefit patients with iliofemoral DVT

PCDT less effective in patients ≥65 years old (p= .038)

Where does this put us?

- 1. Medical Therapy (anticoagulation) has a low rate of clearing clot
- 2. There appears to be a relationship between failure to remove DVT and PTS
- 3. Even in the setting of DVT treatment there is a high risk of progression of symptoms

Sequelae of DVT

- Post-thrombotic syndrome may result in:
  - Chronic pain
  - Swelling
  - Skin ulceration secondary to post-phlebitic syndrome
- Chronic condition in 30-75% of DVT patients within 2 years
  - 90% unable to work due to leg symptoms 10 years after iliofemoral DVT
- Irreversible damage to veins & valves
  - **Impact on quality of life**

1. Geerts et al. Chest. 2004; 126(suppl):338S-400S
2. Parikh et al. AJR 2008 19; 521-528
3. Kahn SR, Ginsberg JS. "Relationship Between Deep Venous Thrombosis and the Post-thrombotic Syndrome". Arch Intern Med 2004; 164:17–26.

CEAP Score

- The CEAP score was designed to score all **chronic venous disease**, categorizing patients' disease according to
- **C**linical signs
- **E**tiology
- **A**natomic distribution
- **P**athophysiologic condition

Clinical classification (C)[a]	
C_0	No visible sign of venous disease
C_1	Telangiectases or reticular veins
C_2	Varicose veins
C_3	Edema
C_4	Changes in skin and subcutaneous tissue[b]
	(A) Pigmentation or eczema
	(B) Lipodermatosclerosis or atrophie blanche
C_5	Healed ulcer
C_6	Active ulcer
Etiologic classification (E)	
E_c	Congenital (e.g., Klippel-Trenaunay syndrome)
E_p	Primary
E_s	Secondary (e.g., postthrombotic syndrome, trauma)
E_n	No venous cause identified

Anatomic classification (A)	
A_s	Superficial
A_d	Deep
A_p	Perforator
A_n	No venous location identified
Pathophysiologic classification (P)	
P_r	Reflux
P_o	Obstruction, thrombosis
$P_{r,o}$	Reflux and obstruction
P_n	No venous pathophysiology identified

CEAP, clinical, etiologic, anatomic, pathophysiological.

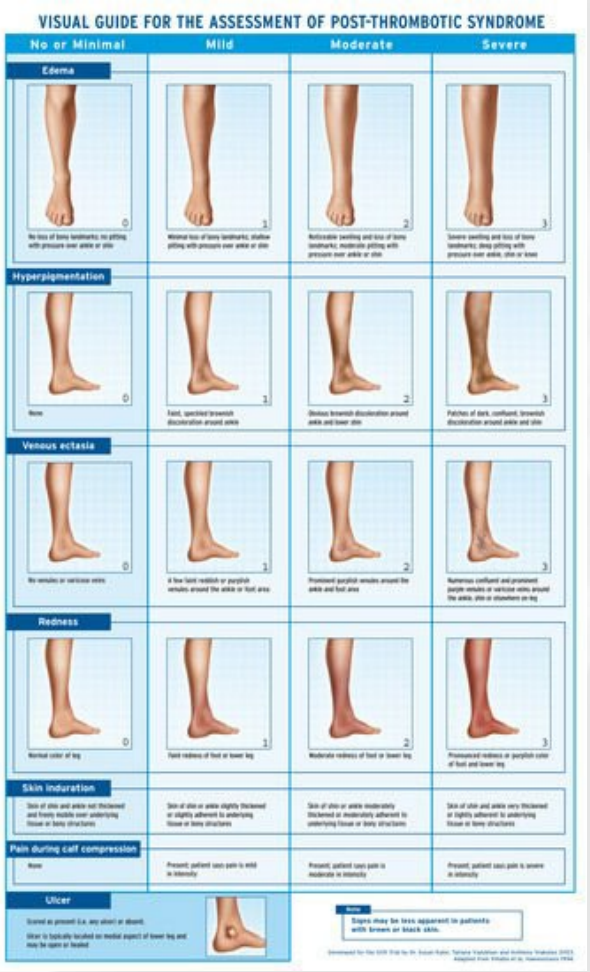
[a]The descriptor A (asymptomatic) or S (symptomatic) is placed after the C clinical class.

[b]C4 is subdivided into A and B, with B indicating higher severity of disease and having a higher risk for ulcer development.

Villalta

- The Villalta score is a disease score specific for PTS It can be used to both diagnose and categorize the severity of the condition.

Symptoms/clinical signs	*None*	*Mild*	*Moderate*	*Severe*
Symptoms				
Pain	0 points	1 point	2 points	3 points
Cramps	0 points	1 point	2 points	3 points
Heaviness	0 points	1 point	2 points	3 points
Paresthesia	0 points	1 point	2 points	3 points
Pruritus	0 points	1 point	2 points	3 points
Clinical signs				
Pretibial edema	0 points	1 point	2 points	3 points
Skin induration	0 points	1 point	2 points	3 points
Hyperpigmentation	0 points	1 point	2 points	3 points
Redness	0 points	1 point	2 points	3 points
Venous ectasia	0 points	1 point	2 points	3 points
Pain on calf compression	0 points	1 point	2 points	3 points
Venous ulcer	Absent			Present



Venous Clinical Severity Score (VCSS).

- The VCSS includes 9 hallmarks of venous disease, each scored on a severity scale from 0 to 3.
- In order to generate a dynamic score, VCSS categories are scored individually, which adds emphasis to the most severe sequelae of venous disease that are likely to show the greatest response to therapy.
- These include skin changes and pigmentation, inflammation and induration, and ulcers (including number, size, and duration). The current version of the VCSS contains a category for compression, with higher scores representing greater compliance.
- The VCSS has been discussed extensively in research

Clinical descriptor	Absent (0)	Mild (1)	Moderate (2)	Severe (3)
Pain	None	Occasional	Daily not limiting	Daily limiting
Varicose veins	None	Few	Calf or thigh	Calf and thigh
Venous oedema	None	Foot and ankle	Below knee	Knee and above
Skin pigmentation	None	Limited perimalleolar	Diffuse lower 1/3 calf	Wider above lower 1/3 calf
Inflammation	None	Limited perimalleolar	Diffuse lower 1/3 calf	Wider above lower 1/3 calf
Induration	None	Limited perimalleolar	Diffuse lower 1/3 calf	Wider above lower 1/3 calf
Number of active ulcers	None	1	2	≥ 3
Ulcer duration	None	< 3 month	3-12 month	> 1 year
Active ulcer size	None	< 2 cm	2-6 cm	> 6 cm
Compression therapy	None	Intermittent	Most days	Fully comply

Chronic Venous Insufficiency Questionnaire (CIVIQ)

- The CIVIQ comprises 20 questions in four quality-of-life domains: physical, psychological, social, and pain.
- The first version of the CIVIQ instrument, the CIVIQ 1, was validated in a sample of 2001 patients, 50% of whom had been diagnosed with venous insufficiency and the remainder of whom presented to a general practitioner for other reasons
- CIVIQ-20 showed good internal consistency and reliability (above 0.80) through test-retest correlations in 3956 patients,.
- Both versions of the CIVIQ have been used in studies and proven to be valid quality-of-life measurements.

Post-Thrombotic Syndrome

- PTS develops in 29% to 74% of patients following DVT
- Affects 5% of US population
- 400,000 to 500,000 individuals have venous stasis ulcers
- Annual direct cost of PTS in the US of $200 million
- 2 million workdays lost annually in the US

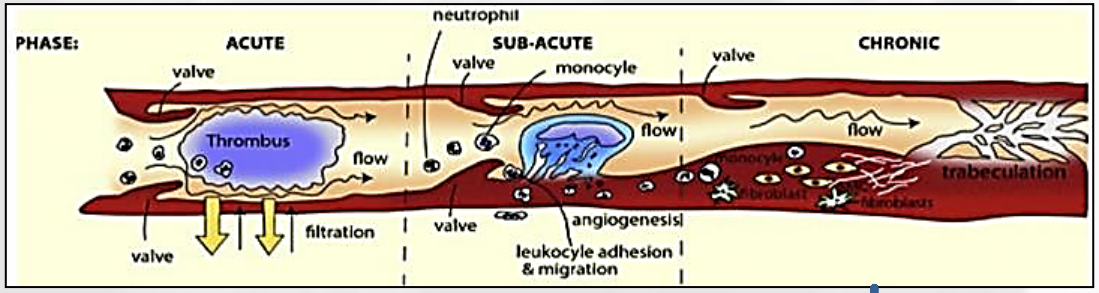
Heit, *J Vasc Surg* 2001
Phillips, *J Amer Acad Derm* 1994

Post-Thrombotic Syndrome (PTS):Valve Destruction & Obstruction

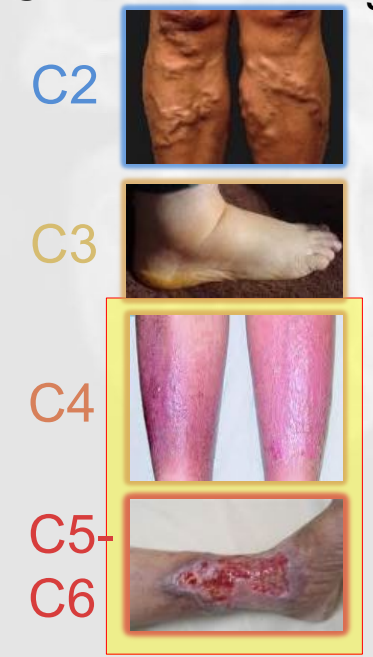
The post thrombotic syndrome: Ignore it and it will come back to bite you

Arina J. ten Cate-Hoek [a,*], Peter K. Henke [b], Thomas W. Wakefield [b]

[a] Cardiovascular Center and Laboratory for Clinical Thrombosis and Hemostasis, Maastricht University Medical Center, Maastricht, the Netherlands
[b] Section of Vascular Surgery and the John Vascular Research Laboratory, Department of Surgery, University of Michigan School of Medicine, Ann Arbor, MI, USA



CVI CEAP Score Progression



Collagen scarring, trabeculae damage valves and cause obstruction

Correlation of AVP (Column Pressure) and Ulceration is Well Established, DVR Prevents Normal Pressure Drop via Calf Pump

Reflux (& Outflow Obstruction) worsen impact by *preventing* normal pressure drop via calf pump function

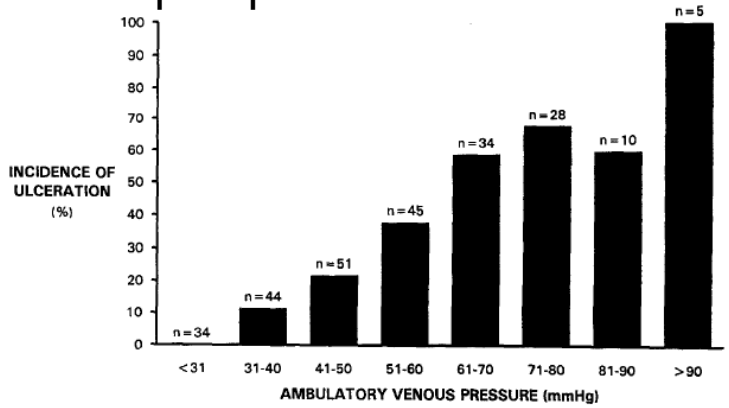


Fig. 1. Incidence of ulceration in relation to AVP.

The relation of venous ulceration with ambulatory venous pressure measurements

A.N. Nicolaides MS, FRCS, M.K. Hussein, MD, FRCS, G. Szendro, MD, D. Christopoulos, MD, PhD, S. Vasdekis, MD, and H. Clarke, PhD,
London, United Kingdom

(J Vasc Surg 1993;17:414-9.)

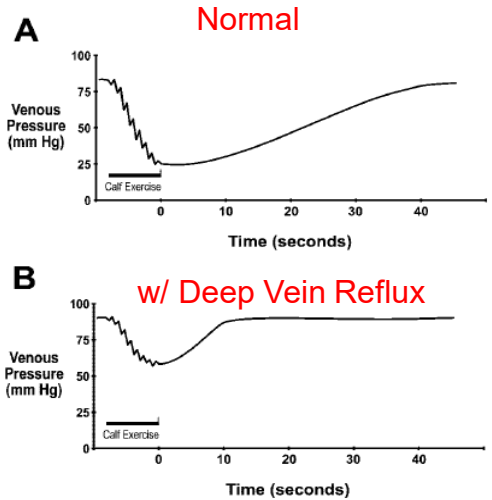


Figure 1. Illustrative ambulatory venous pressure measurements. (A) Normal venous pressure. The resting standing venous pressure is ≈80 to 90 mm Hg. The pressure drops with calf exercise to ≈20 to 30 mm Hg, or a >50% decrease. The return in pressure is more gradual, with refill taking >20 s. (B) Abnormal venous pressure with deep venous reflux. The drop in pressure with exercise is blunted (<50% decrease). The return in venous pressure to the resting level is rapid because of a short refill time (<20 s).

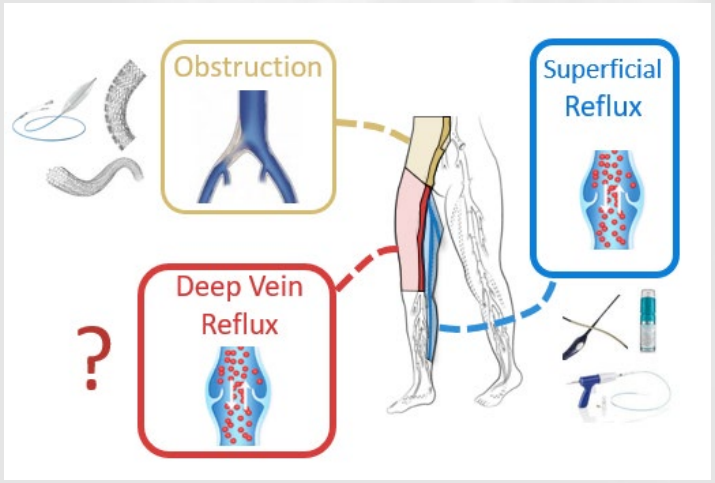
Contemporary Reviews in Cardiovascular Medicine

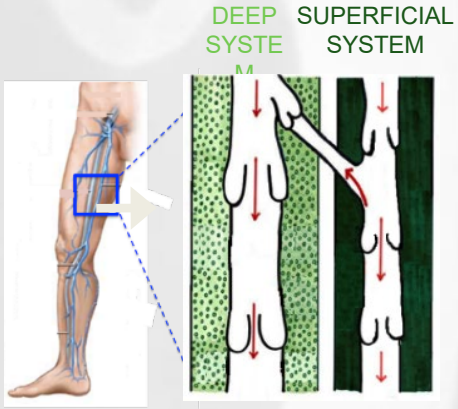
Chronic Venous Insufficiency

Robert T. Eberhardt, MD; Joseph D. Raffetto, MD

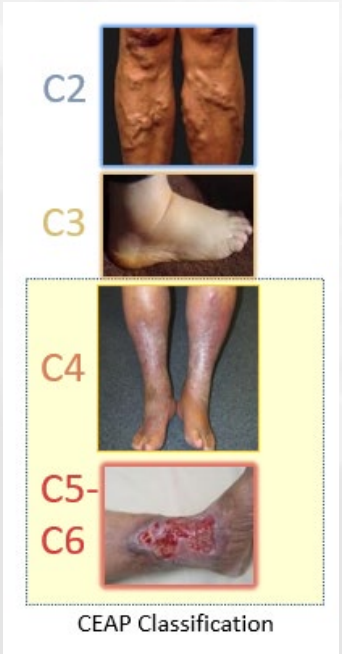
(Circulation. 2005;111:2398-2409.)

Three Major Underlying Causes of *Symptoms of Post-Thrombic Syndrome*





Diseased Refluxing Veins

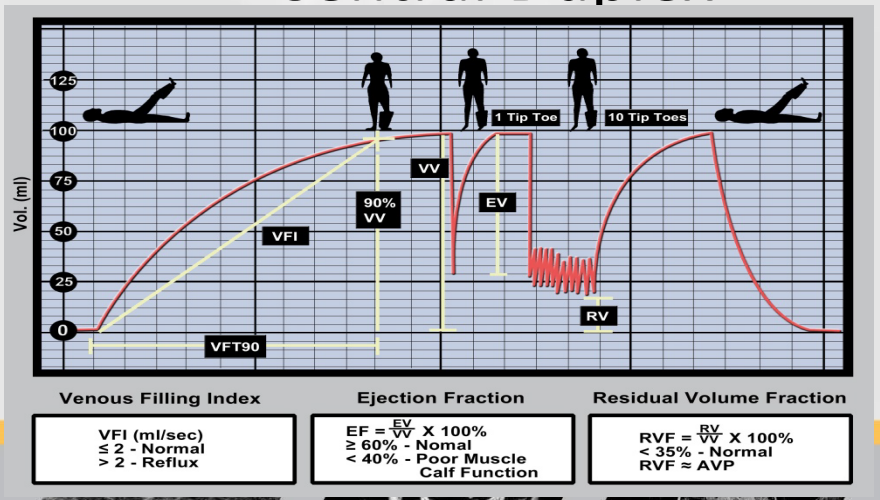


CEAP Classification

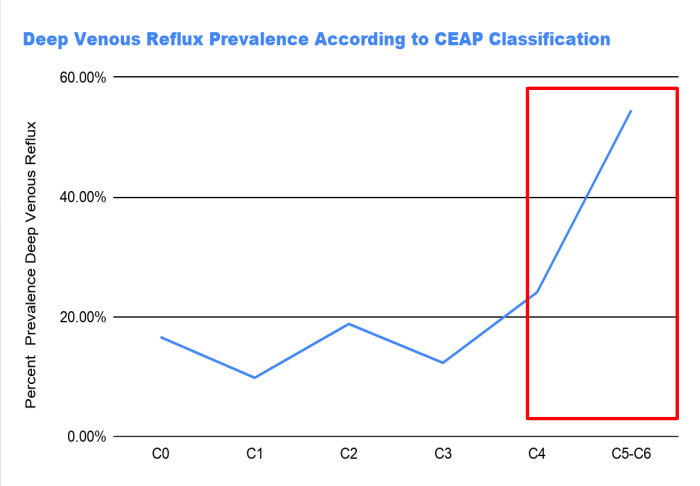
'CVI' refers to *severe* Venous Disease (CEAP 4-6), where mixed etiologies are common including Deep Vein Reflux (DVR), Superficial Reflux, and Venous Obstruction. The most prevalent and progressive is *postthrombotic* after DVT

Imaging Support

- Non-Invasive Vascular Lab
  - Reflux Study
  - Central Duplex



High Prevalence of Deep Venous Reflux (DVR), PTS, Obstruction among *Severe* CVI patients, DVR common with non-healing Ulcers



Distribution and prevalence of reflux in the superficial and deep venous system in the general population – results from the Bonn Vein Study, Germany

Uldis Maurins, MD[a] Barbara H. Hoffmann, MD, MPH,[b] Christian Lösch, Dipl Math,[b] Karl-Heinz Jöckel, Prof Dr,[b] Eberhard Rabe, Prof Dr,[c] and Felicitas Pannier, Dr,[c]
Riga, Latvia; and Essn and Bonn, Germany

. J. Vasc Surg. 2008;48:680-87.

Table II. Patients' ulcer characteristics

	Healed cohort (n = 46), % (No.)	Unhealed cohort (n = 19), % (No.)	*P*
Primary etiology	78 (36)	32 (6)	**<.001**
Secondary etiology	22 (10)	63 (12)	**.001**
Congenital etiology	0 (0)	5 (1)	.13
Duplex ultrasound-documented post-thrombotic	11 (5)	63 (12)	**<.0001**
Superficial venous reflux	83 (38)	63 (12)	.09
Overall deep venous disease	48 (22)	84 (16)	**.006**
Deep venous reflux	48 (22)	79 (15)	**.02**
Deep venous obstruction	15 (7)	42 (8)	**.02**
Incompetent perforator around ulcer	24 (11)	5 (1)	.08

Boldface values indicate statistical significance.

From the American Venous Forum

Risk factors associated with the venous leg ulcer that fails to heal after 1 year of treatment

Raffi Melikian, BS,[a] Thomas F. O'Donnell Jr, MD,[a,b] Luis Suarez, MD,[a,b] and Mark D. Iafrati, MD,[a,b] *Boston, Mass*

[redacted]j.jvsv.2018.07.014

DVR (and PTS) results in the Most Severe Symptoms including Non-Healing Ulcers despite use of Current SVS Std of Care Tx

- Despite rigorous use of SVS Practice Guidelines at Venous Center of Excellence many ulcers could not be healed

- Deep venous disease, prior Hx of DVT and Depression were all shown to be significant
  risk factors for nonhealing

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/j.jvsv.2018.07.014

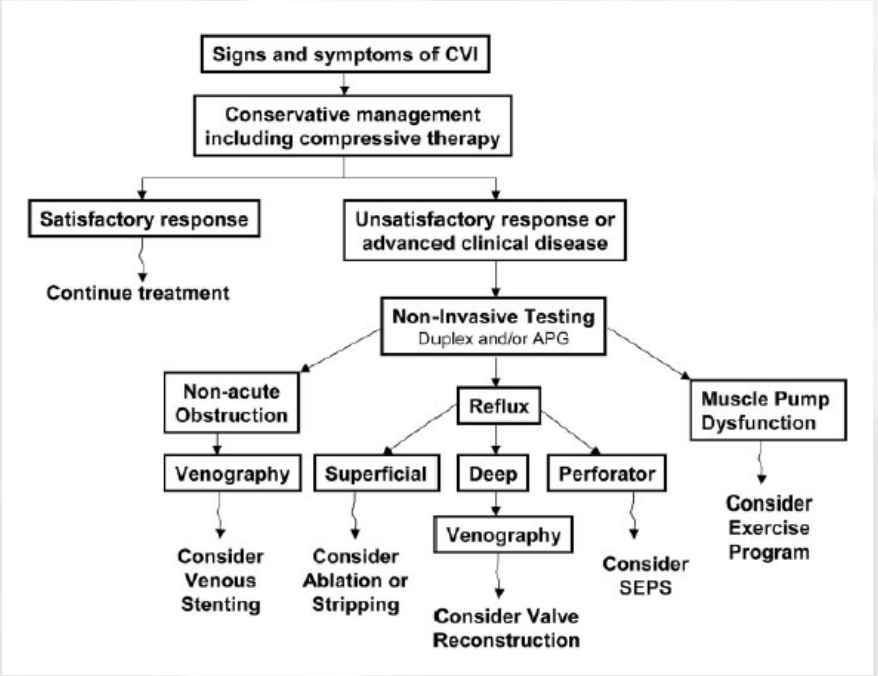
Today DVR Tx Options are Limited to Compression & Wound Care

Contemporary Reviews in Cardiovascular Medicine

Chronic Venous Insufficiency

Robert T. Eberhardt, MD; Joseph D. Raffetto, MD

(Circulation. 2005;111:2398-2409.)



Treatment for Post Thrombotic Syndrome

- Recommendations for Compression to Prevent PTS
- The effectiveness of ECS for PTS prevention is uncertain, but application of ECS is reasonable to reduce symptomatic swelling in patients with a diagnosis of proximal DVT *(Class IIb; Level of Evidence A*).
- Recommendations for the Use of Graduated ECS and Intermittent Compression to Treat PTS
- A trial of ECS may be considered in patients with PTS who have no contraindications (eg, arterial insufficiency) *(Class IIb; Level of Evidence C*).
- For patients with moderate or severe PTS and significant edema, a trial of an intermittent compression device is reasonable *(Class IIb; Level of Evidence C*).

Table 7. RCTs of Graduated Compression Stockings to Prevent PTS

Study, Year	Sample Size, n	Blinding	Time of Intervention After DVT	Type of Stocking	Duration of Follow-Up, y	Primary Outcome
Brandjes et al,[38] 1997	96 Stockings, 98 no stockings	No	2–3 wk	30 mm Hg at ankle; knee high	Up to 5	PTS by modified Villalta
Ginsberg et al,[9] 2001	24 Active stockings, 23 placebo stockings	Double-blinded	1 y	20–30 mm Hg knee-high	Up to 9	Daily pain and swelling
Prandoni et al,[51] 2004	90 Stockings, 90 no stockings	No	5–10 d	30–40 mm Hg	Up to 5	PTS by Villalta scale
Aschwanden et al,[12] 2008	84 Stockings, 85 no stockings	No	6 mo	26–36 mm Hg knee-high	Up to 7	Skin changes (CEAP ≥4)
Partsch et al,[88] 2004	18 Stockings plus walking, 18 Unna boot plus walking, 17 bed rest	No	At admission	30 mm Hg thigh-length	2	PTS by Villalta scale
Kahn et al,[53] 2014	410 Active stockings, 396 placebo stockings	Double-blinded	5–6 d	30–40 mm Hg knee-high	Up to 2	Daily pain and swelling

CEAP indicates clinical, etiological, anatomic, pathophysiological; DVT, deep venous thrombosis; PTS, postthrombotic syndrome; and RCT, randomized, controlled trial.

Treatment for Post Thrombotic Syndrome

- Recommendations for Pharmacotherapy to Treat PTS
- The effectiveness and safety of rutosides, hidrosmin, and defibrotide to treat PTS are uncertain *(Class IIb; Level of Evidence B*).

Table 9. Pharmacotherapy for the Treatment of PTS

Study, Year	Design	Population	Intervention	Control	Follow-Up	Results
de Jongste et al,[111] 1989	Parallel-group RCT	83 Patients with PTS of ≥6-mo duration; minimum 10-mm difference in calf/ankle circumference between PTS leg and other leg	HR 1200 mg daily (4 equal doses) for 8 wk	Placebo 4 times daily; use of GCS not allowed	8 wk (4- and 8-wk follow-up visits)	Greater improvement of symptoms* seen in HR group at 4 and 8 wk (only tiredness was statistically significant, P=0.02).Greater reduction in mean calf (−6.7 mm) and ankle (−3.4 mm) circumference at 8 wk in HR group.
Monreal et al,[113] 1994	Crossover RCT	29 Patients with PTS of ≥12-mo duration; minimum 20-mm difference in calf/ankle circumference between PTS leg and other leg	Hidrosmin 600 mg daily (3 equal doses) for 6 mo; HR 900 mg daily (3 equal doses) for 6 mo	All subjects took both study drugs; all were encouraged to use GCS	18 mo; study period of 6 mo and then follow-up every 3 mo	Improvement of symptoms† with both drugs.Small reduction in calf/ankle circumference with hidrosmin.Ulcer healing with both drugs.
Coccheri et al,[112] 2004	Parallel-group RCT	288 Patients with CEAP class C2-C4 venous disease; only 64% had history of DVT	Defibrotide, 800 mg daily (2 equal doses) for 12 mo	Placebo twice a day; GCS used by both groups	12 mo (follow-up visits every 2 mo)	Improvement in symptoms,‡ statistically significant for pain (*P*=0.01) and edema (*P*=0.03).Decreased mean ankle circumference over 12 mo in treatment group (*P*=0.0013)
Frulla et al,[49] 2005	Parallel-group RCT (3 arms)	120 Patients with PTS (defined by Villalta scale) and previous proximal DVT	HR 1,000 mg twice daily (soluble powder) alone or combined with GCS (30-40 mm Hg) for 12 mo	GCS (30-40 mm) for 12 mo	12 mo (follow-up visits at 3,6,12 mo)	1) PTS improvement§: 26/40 HR, 25/40 CGS + HR, 28/40 GCS alone2) PTS worsening: 9/40 HR, 9/40 GCS + HR, 6/40 GCS alone

Treatment for Post Thrombotic Syndrome

- Recommendations for Exercise Training to Treat PTS
- In patients with PTS, a supervised exercise training program consisting of leg strength training and aerobic activity for at least 6 months is reasonable for patients who are able to tolerate it *(Class IIa; Level of Evidence B*).

Treatment for Post Thrombotic Syndrome

- Recommendations for Venous Ulcer Management

- Compression should be used to treat venous ulcers in preference to primary dressing alone, noncompression bandage, or no compression (*Class I; Level of Evidence A*).

Treatment for Post Thrombotic Syndrome

- Recommendations for Endovascular and Surgical Treatment of PTS
- For the severely symptomatic patient with iliac vein or vena cava occlusion, surgery (eg, femoro-femoral or femoro-caval bypass) (*Class IIb; Level of Evidence C*) or percutaneous endovenous recanalization (eg, stent, balloon angioplasty) *(Class IIb; Level of Evidence B*) may be considered.
- For severely symptomatic patients with postthrombotic occlusion of their common femoral vein, iliac vein, and vena cava, combined operative and endovenous disobliteration may be considered (*Class IIb; Level of Evidence C*).
- For severely symptomatic patients with PTS, segmental vein valve transfer or venous transposition may be considered (*Class IIb; Level of Evidence C*).

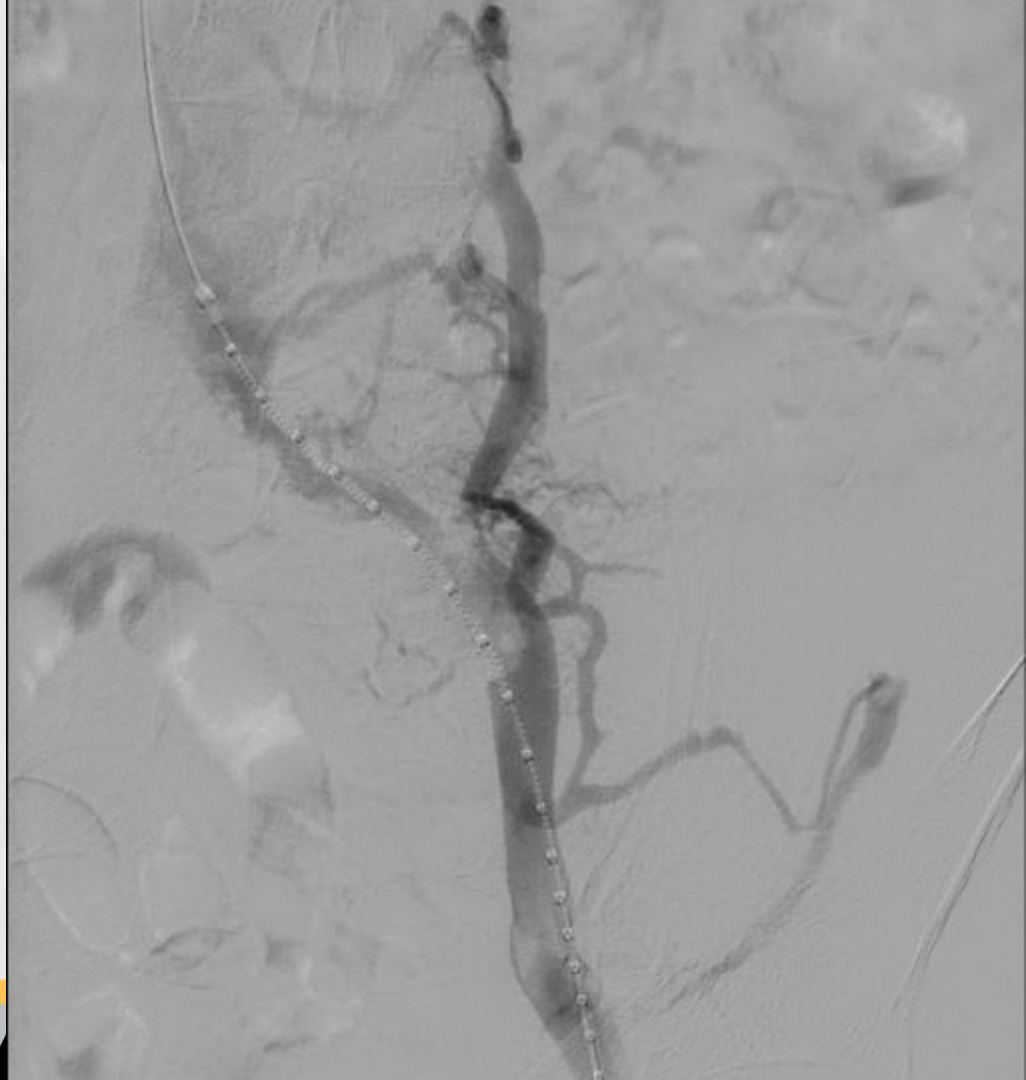
So. What do we do?

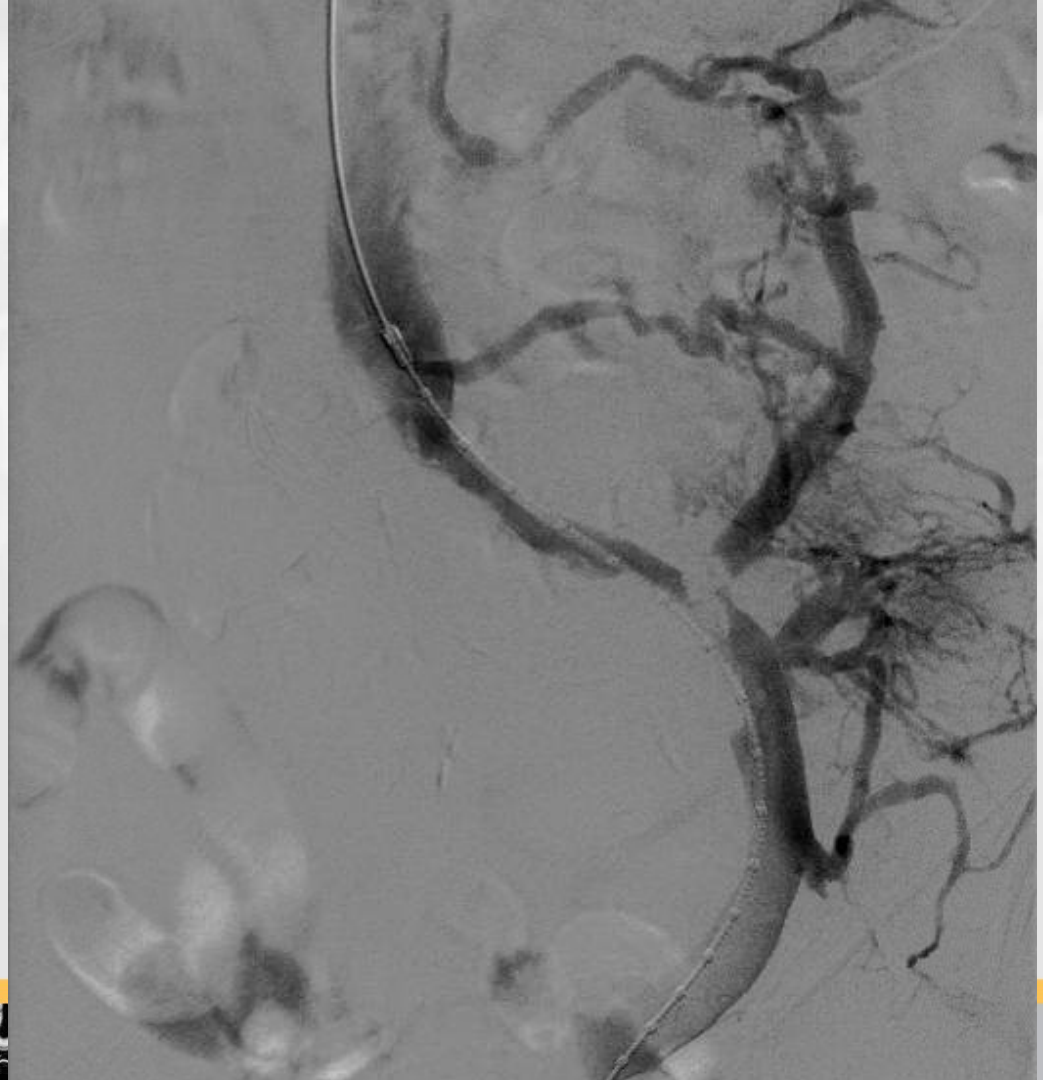
- Chronic DVT Treatment with Post Thrombotic Syndrome or Venous Ulcers
  - A-B-C
    - Activity
    - Blood Thinners
    - Compression

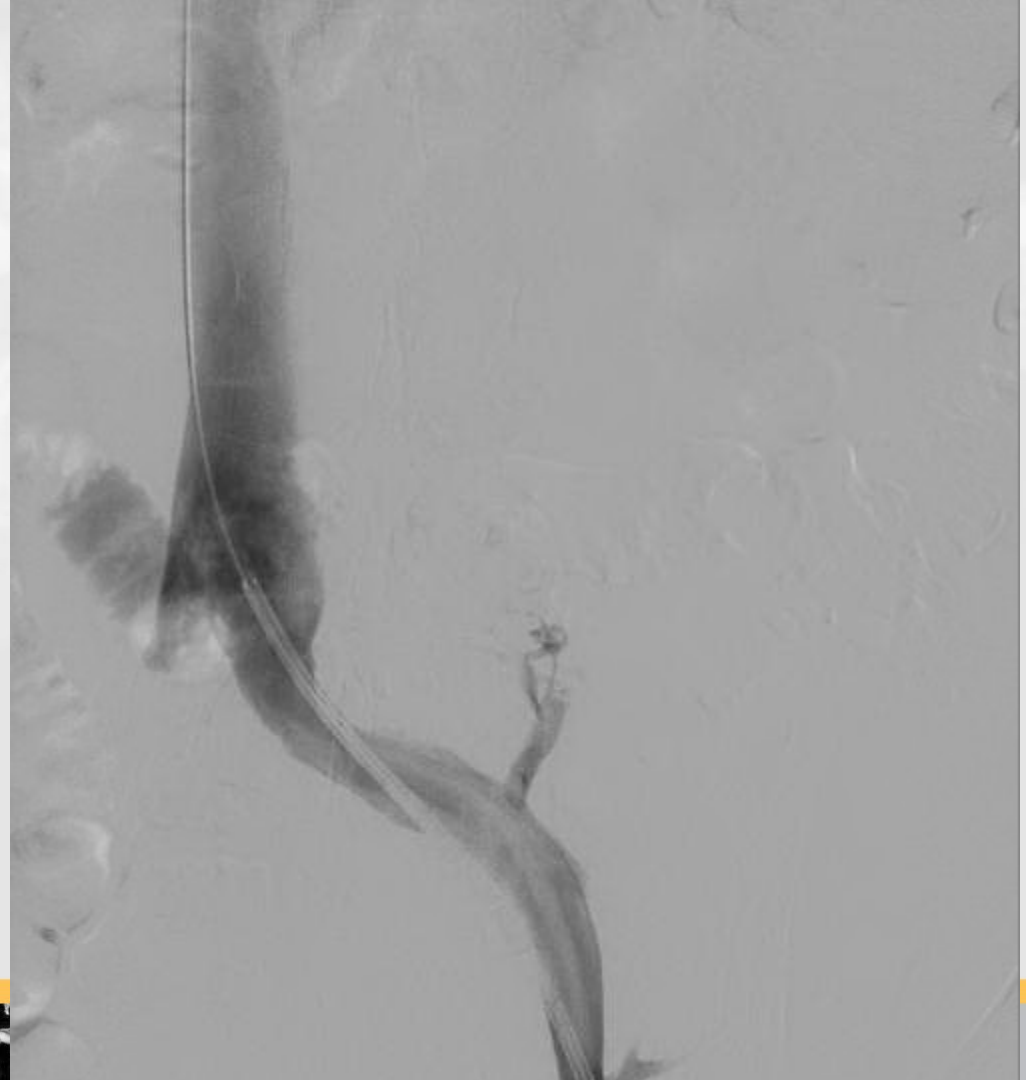
Interventional Management of Chronic Obstruction

Popliteal Approach
Supine (prone is an option)
Femoral Vein was normal.
Occlusion identified at the
Common Iliac Vein

- Key Steps
- Identify a central obstruction
- Multiple views and imaging modalities



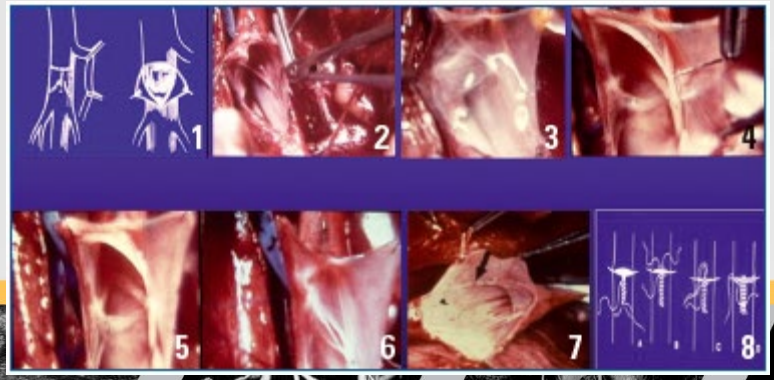


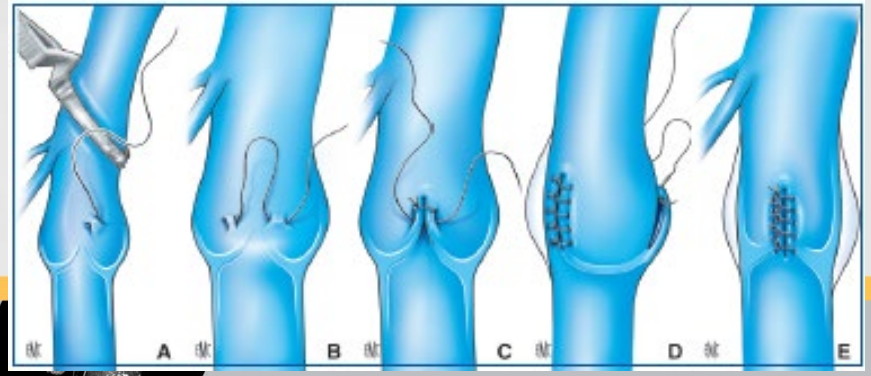



Interventional Management of Deep Reflux

Valvulplasty

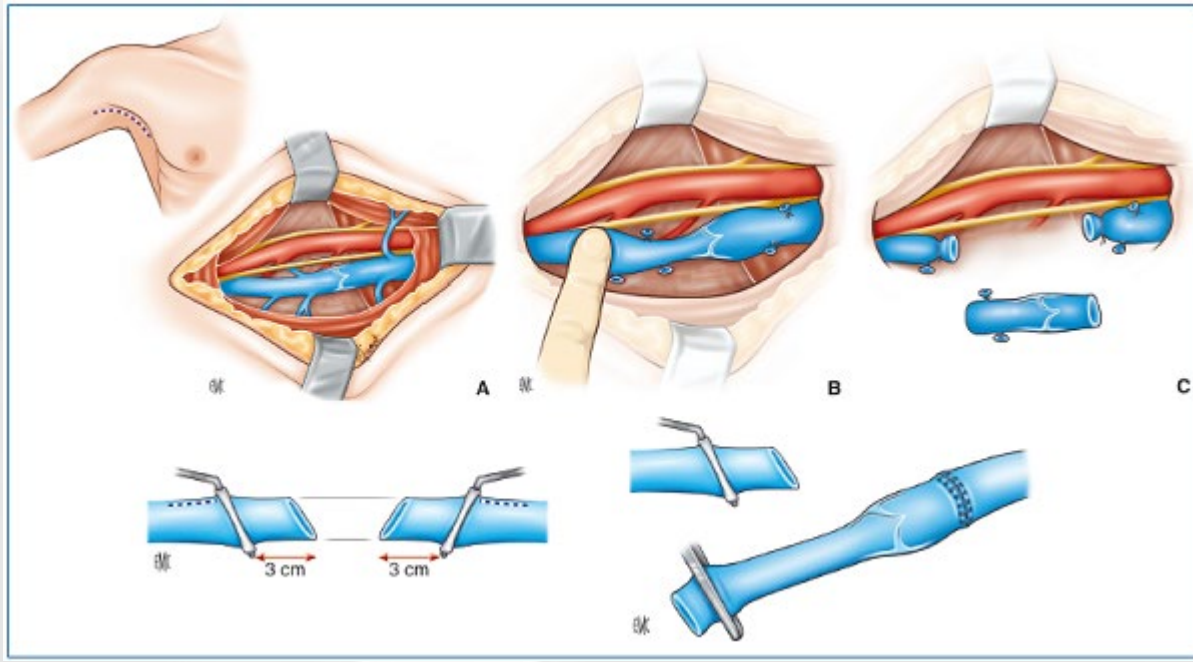
- The valve can be primarily repaired
- Kistner 1968 performed the first valvuloplasty
- In internal valvuloplasty, the vein is opened and the valve is identified under direct visual control
- In external valvuloplasty, the vein is repaired without opening



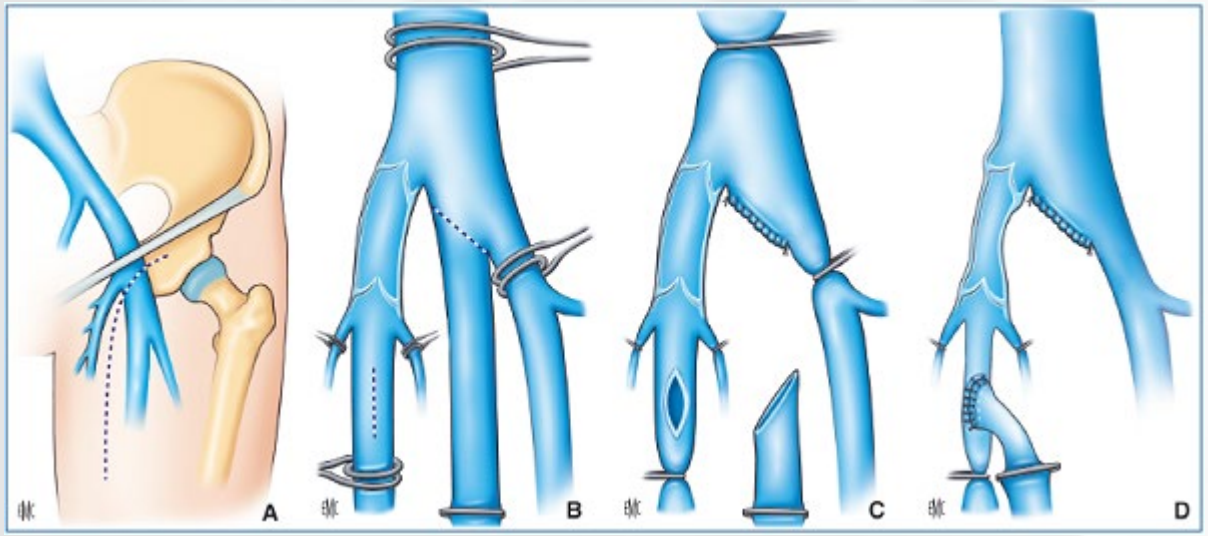


Venous Valvular Transplantation

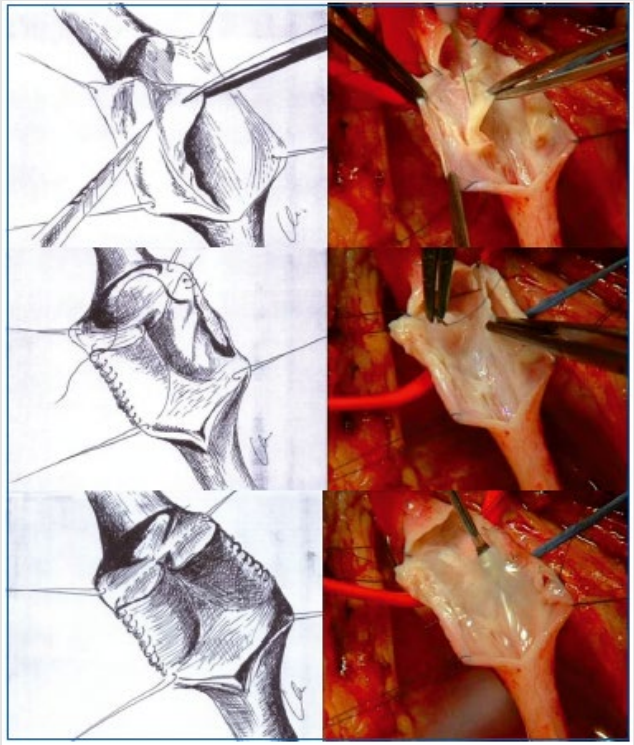
- Transplantation of a venous valvular segment. In 1982, Taheri (USA) and Raju (USA) proposed using the humeral and axillary veins which have a functional valve and can be collected undamaged and transplanted into the lower limb

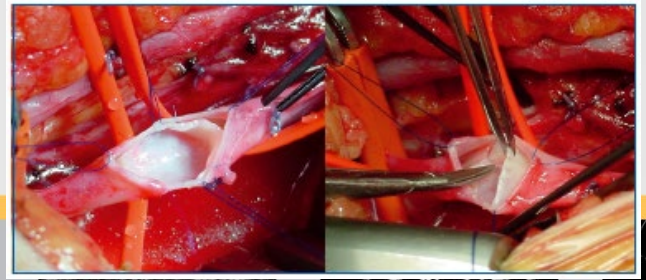


Venous Valve Transposition



- Transposition consists of transposing the vein that is the site of reflux onto another lower limb vein, below its competent valve). R. Kistner (USA) invented this technique in 1982.

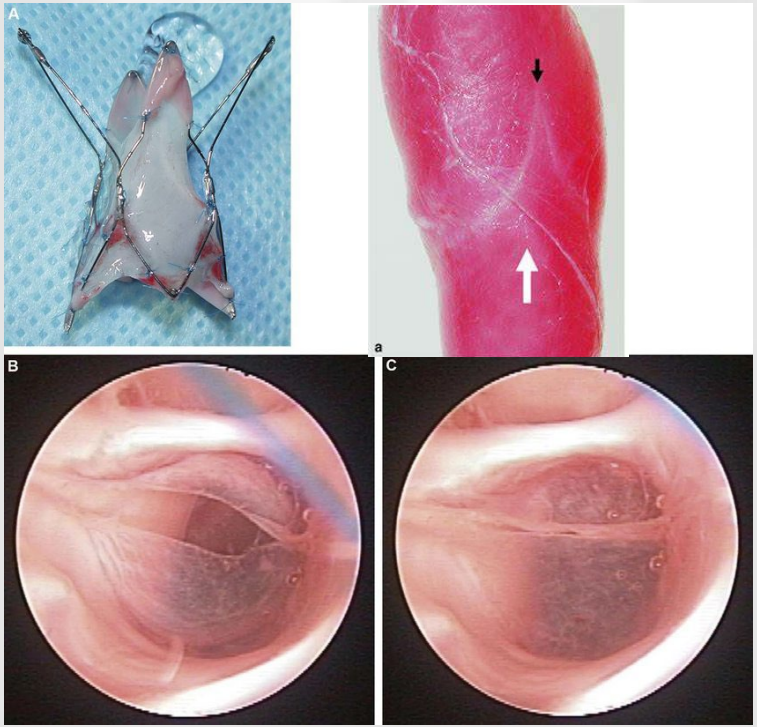




Neo-Valve Creation

- The creation of a neovalve using venous tissue from the patient was proposed by P. Plagnol (France) in 1999 and by O. Maleti
  – After opening the vein a few centimeters along its axis, the operator divides its wall on one side into two layers.
  – This detachment stopped in the middle allows construction of a sac which corresponds to a valve in a normal subject.
  -The same technique is performed on the other side thus creating a valve with 2 valvular cusps.(Italy) in 2002.

Percutaneous Autologous Valve Transplant



- Percutaneous autologous venous valve transplantation. (A) The harvested autologous venous valve attached to a stent valve template. (B) Venoscopy of the transplanted valve specimen at 3 months. Bicuspid valve inside a flow model demonstrates thin leaflets in the open position and (C) closed position.

Historical Surgeries and Complex, Invasive and have varied Results with Ulcer Healing & Recurrence

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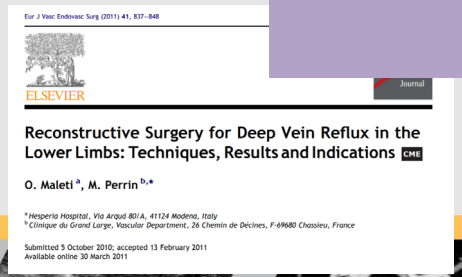
Results of the Varied Techniques have Been Difficult to Replicate (no Multi-Center Evidence) and with *Very* Rare Exceptions, (ie; Modena, Italy), these Surgeries are No Longer Performed

Table 1 Deep vein reconstruction results.

Author, Year	Surgical Technique	Valvuloplasty results: Number of limbs	Aetiology PDVI/Total	Follow-up month (m)	Ulcer recurrence or non healed ulcer (%)	Haemodynamic results: Competent Valves (%)	AVP — VRT
Plagnol, 1999	Bicuspid neovalve	44	44/44	6—47 (17)	3/32 (17)	38/44 (86)	
Maleti-Lugli, 2009	Monocuspid or bicuspid neovalve	19 + 21 = 40	36/40	2—78 (28.5	7/40 (17)	13/19 (68) 21/21 (100)	75 VRT improved
Opie, 2008	Monocuspid neovalve	14	/	(48)	0/6	13/14 (92)	

PTS: post-thrombotic syndrome; AVP: ambulatory venous pressure; VRT: venous return time; m: mean.


Eur J Vasc Endovasc Surg (2011) 41, 837–848

ELSEVIER

Reconstructive Surgery for Deep Vein Reflux in the Lower Limbs: Techniques, Results and Indications CME

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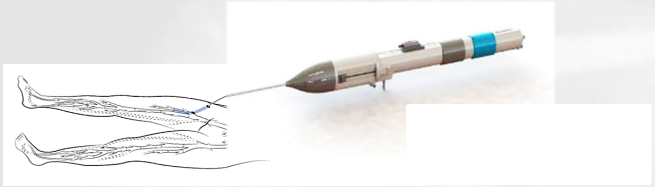
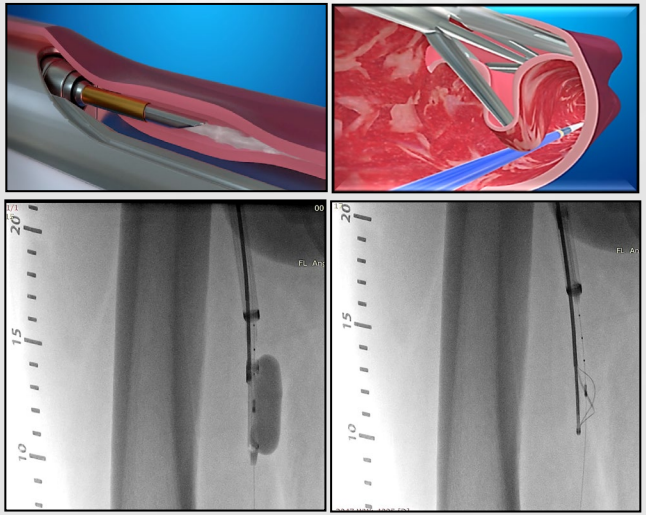
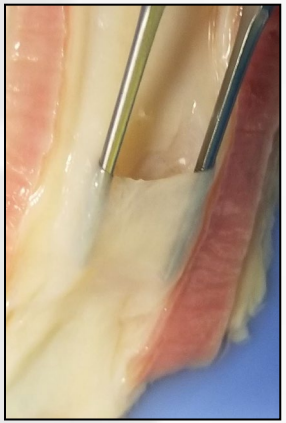
Overview of BlueLeaf and EVF (Endovenous Valve Formation)

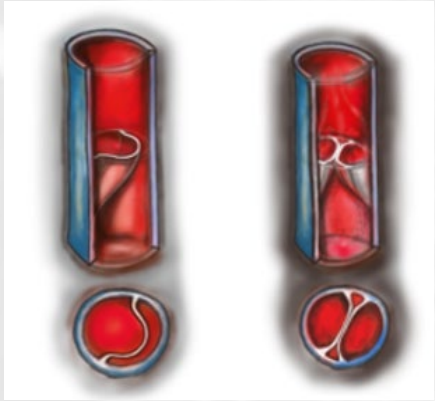


16 Fr Retrograde access,1-3 autogenous valve pockets/stations with no implant in fem & pop vein

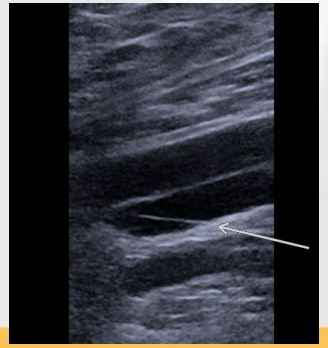


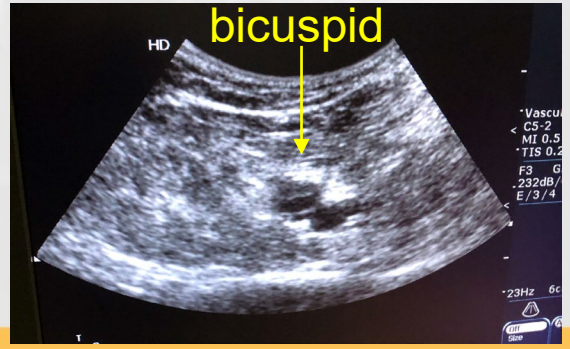


Cadaveric Monocuspid



Monocuspid & Bicuspid EVF Valves

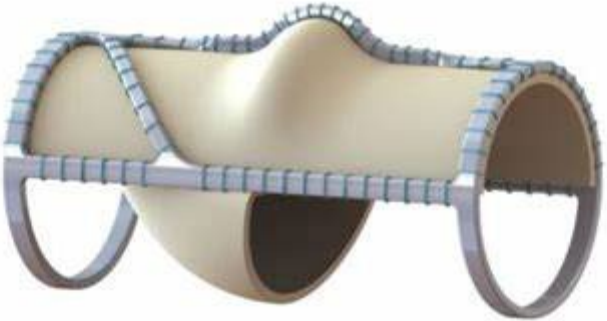




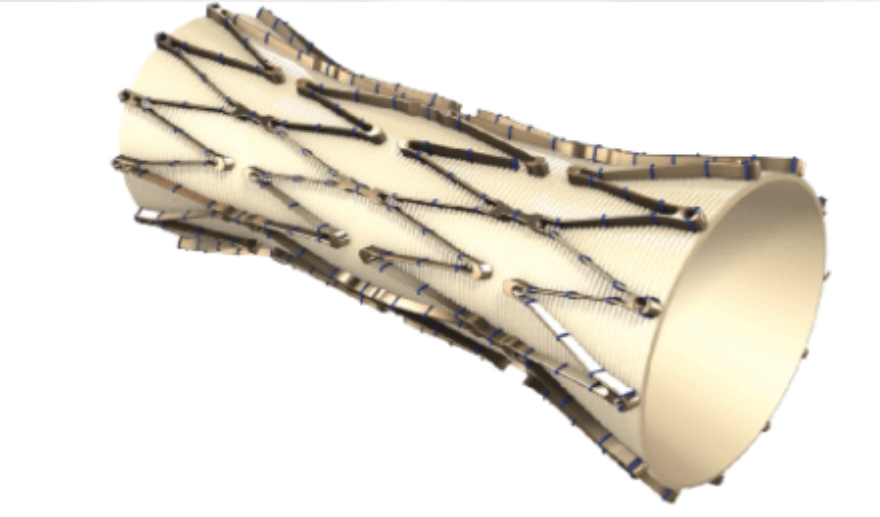
W. Marston, UNC Chapel Hill, NC R. Varcoe, Sydney, Australia (Tbilisi, RoG)

enVVeno

- Venous Valve Implantation
- FDA granted IDE approval to assess the safety and efficacy of the VenoValve for the treatment of patients with deep venous valvular insufficiency
- Prospective, non-blinded, single-arm, multi-center study
- 20 U.S. investigational sites
- 75 patient study
- CEAP Score: C4b – C6 patients



Future Technology



Summary

- Post Thrombotic Syndrome can be caused by multiple etiologies including reflux in the deep system as well as by obstruction
- Deep Venous Insufficiency therapy is currently limited to wound care and compression
- Continued work on surgical repair, implantation and creation of valves will contribute to the treatment of this disease

2023 MID-ATLANTIC CONFERENCE

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VASCULAR THERAPIES

2023

Thank You!