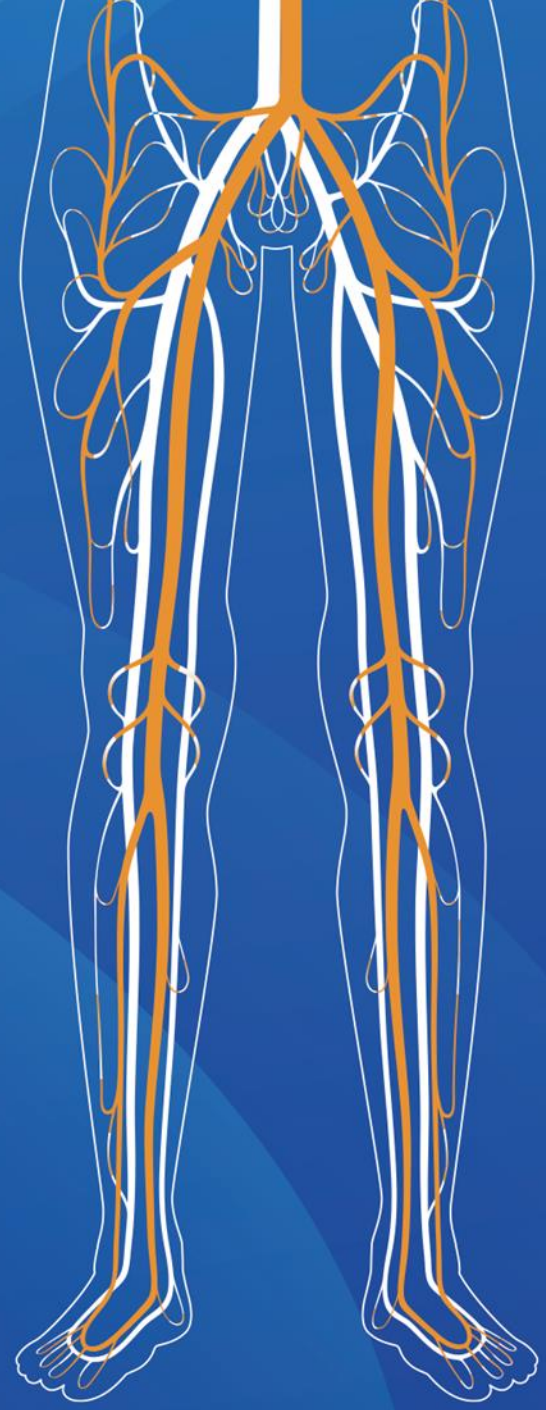
Leg Ulcer & Compression Day:

The “Four Cs” Redefining the Standard of Care



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Faculty

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Faculty Disclosures

- **Heather Barnhart, PT, PhD, CWS, CLT-LANA, CLWT**
  Advisory Board: World Alliance of Wound & Lymphedema Care; Consultant: Urgo Medical
- **Karen Bauer, DNP, CNP-FNP, CWS, FAAWC**
  Advisory Board: Urgo Medical NA; Consultant: Urgo Medical NA; Solventum, Medical Surgical Business; Speakers Bureau: Urgo Medical NA; Solventum, Medical Surgical Business
- **Caroline Fife, MD**
  Nothing to disclose in relation to this activity
- **Loan Lam, DPM, FAWPHc, FAPWCA, CWSP, CHWS, CLWT**
  Advisory Board: Save a Leg, Save a Life Foundation; Consultant: Urgo Medical NA; LifeNet Health; Research: Merakris; Samaritan Biologics; Speakers Bureau: Paratek; Organogenesis Inc.; Hartmann; AOTI

Disclosures

- The faculty have been informed of their responsibility to disclose to the audience if they will be discussing off-label or investigational use(s) of drugs, products, and/or devices (any use not approved by the U.S. Food and Drug Administration).
  - Applicable CME staff have no relationships to disclose relating to the subject matter of this activity
  - This activity has been independently reviewed for balance

Agenda

Start	End	Topic	Faculty
1:20pm	1:25pm	Welcome and Introduction	Karen Bauer, DNP, CWS, FAAWC
1:25pm	1:40pm	Compression Uncovered: Old Wisdom, New Science in VLU	Karen Bauer, DNP, CWS, FAAWC
1:40pm	1:55pm	Why Is It So Hard to Do the Right Thing with VLU Compression?	Caroline Fife, MD
1:55pm	2:10pm	Role of Compression in Lymphedema Management, Prevention of Venous Ulcerations, and Impact on Periwound Skin	Loan Lam, DPM, FAWPHc, FAPWCA, CWSP, CHWS, CLWT
2:10pm	2:25pm	The Fourth “C”	Heather Barnhart, PT, PhD, CWS, CLT-LANA, CLWT
2:25pm	2:35pm	Q&A	
2:35pm	3:20pm	Demonstration and Hands On	Karen Bauer, DNP, CWS, FAAWC

Learning Objectives

- Explain the importance of compression therapy, despite its underutilization, as a standard of care (SOC) in managing venous ulcers and phlebolymphedema
- Demonstrate knowledge of the "Three Cs" of effective compression therapy — consistency, continuity, and comfort — and recognize how advances in materials and application techniques can address these critical factors
- Assess the role of compression in controlling lymphedema and preventing further venous ulcerations, including its impact on peri-ulcer skin health
- Describe the emerging concept of the "Fourth C" (*cutis* — the Latin name for "dermis") and articulate how compression therapy may positively influence skin microcirculation and dermal health beyond ulcer closure

SOC = standard of care.

Compression Uncovered: Old Wisdom, New Science in VLU

Karen Bauer, DNP, CNP-FNP, CWS, FAAWC
Emory Heart & Vascular
Atlanta, GA

Back to Basics

- VLUs = 60%-80% of all leg ulcers
- >40% of venous ulcers persist >6 wks

The Society for Vascular Surgery (SVS) and the American Venous Forum (AVF): “Full-thickness defect of skin, most frequently in the ankle region, that fails to heal spontaneously and is sustained by chronic venous disease, based on venous duplex ultrasound testing”

- **Despite research into VLU, mechanisms are unclear, and healing rates are low**
- **Despite costs to society and patients, there has been slow progression in VLU management**

VLU = venous leg ulcer; SVS = Society for Vascular Surgery; AVF = American Venous Forum.

Etiology

- Complex and affects micro- and macrovasculature
- 70%-80%: Primary venous insufficiency (reflux/varicose vein disease)
- 20%-30%: Post-thrombotic syndrome (PTS)

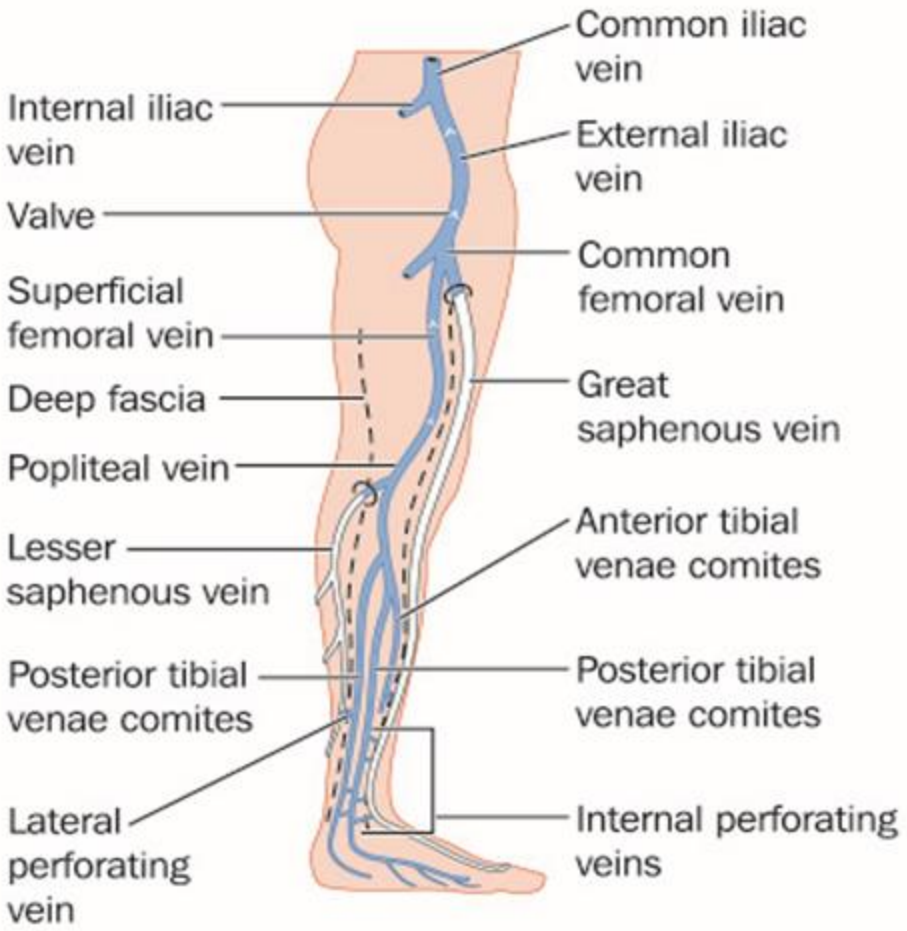
- DVT, surgery, trauma, multiple pregnancies, congenital vein abnormalities
- CMP failure: Paralysis, immobility, chair sleeping with legs dependent, fixed ankle joints

PTS = post-thrombotic syndrome; DVT = deep vein thrombosis; CMP = calf muscle pump.

Darwin E, et al. *J Am Acad Dermatol.* 2021;84(1):76-85. Raffetto JD, et al. *J Clin Med*. 2020;10(1):29.

Venous Physiology

- Superficial to perforators to deep system
- Blood from deep system to inferior vena cava (IVC) with calf muscle contraction
- Valvular incompetence leads to vein distension and valve dysfunction
- Retrograde flow and venous hypertension/ increased ambulatory venous pressure
- Fluid leakage into tissue



IVC = inferior vena cava.

Chronic Venous Disease (CVD) Pathophysiology

Primary, Secondary, Congenital

Hemodynamic, cellular, and biochemical changes

Macro and micro

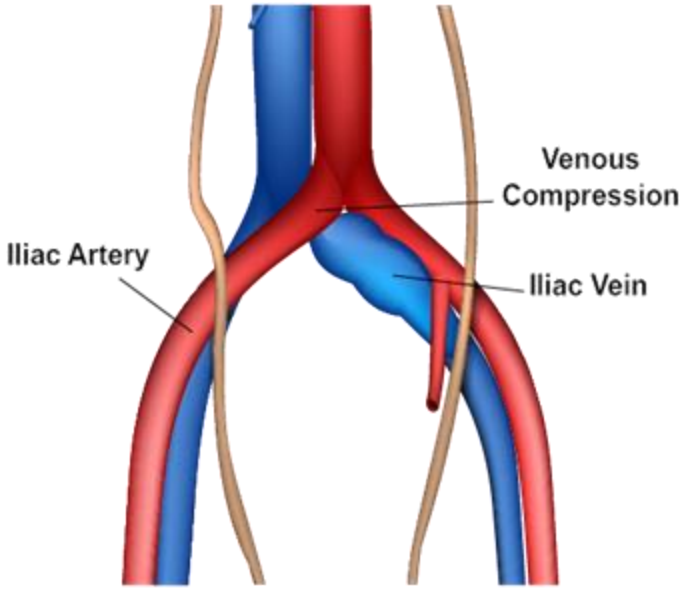
Valve dysfunction, venous obstruction, calf muscle dysfunction

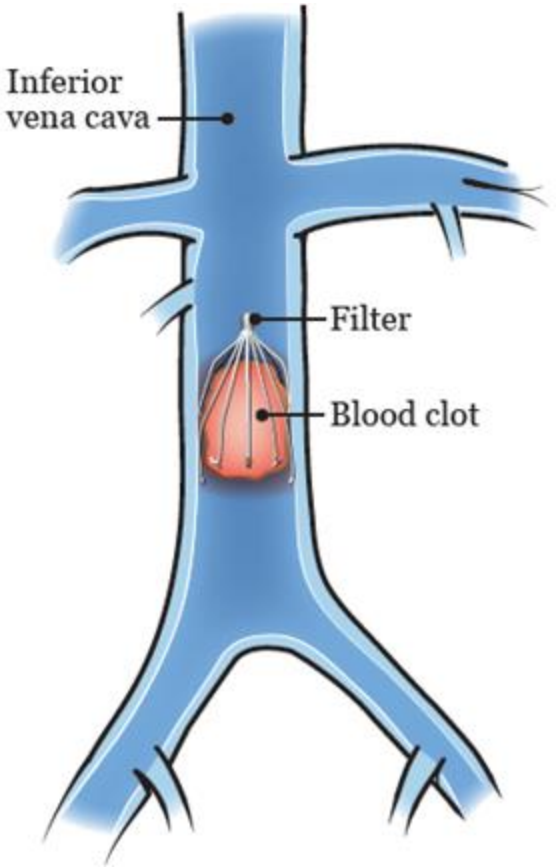
Valve incompetence → pooling of venous blood → increased pressure on vein walls → changes physiological shear stress that maintains blood fluidity and inhibits blood cell attachment

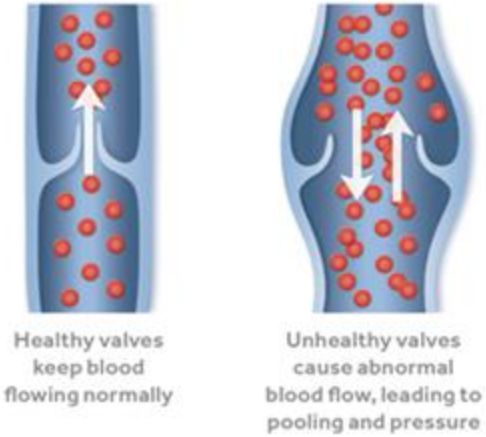
- Damage to the endothelium cells from disrupted protective glycocalyx layer
- Endothelial cell activation → increased permeability
- Adhesion molecules (ICAM-1, VCAM-1, E-selectins) and chemoattractant molecules
- WBC recruitment, attach to vein wall and surrounding tissue

CVD = chronic venous disease.

Chronic Venous Disease (CVD)







Venous Insufficiency Is Common

Unclear why few patients who have chronic venous insufficiency (CVI) develop VLU

(prevalence estimate = 0.5% of adults <65 yrs and 2.2% >65 yrs)

CVI = chronic venous insufficiency.

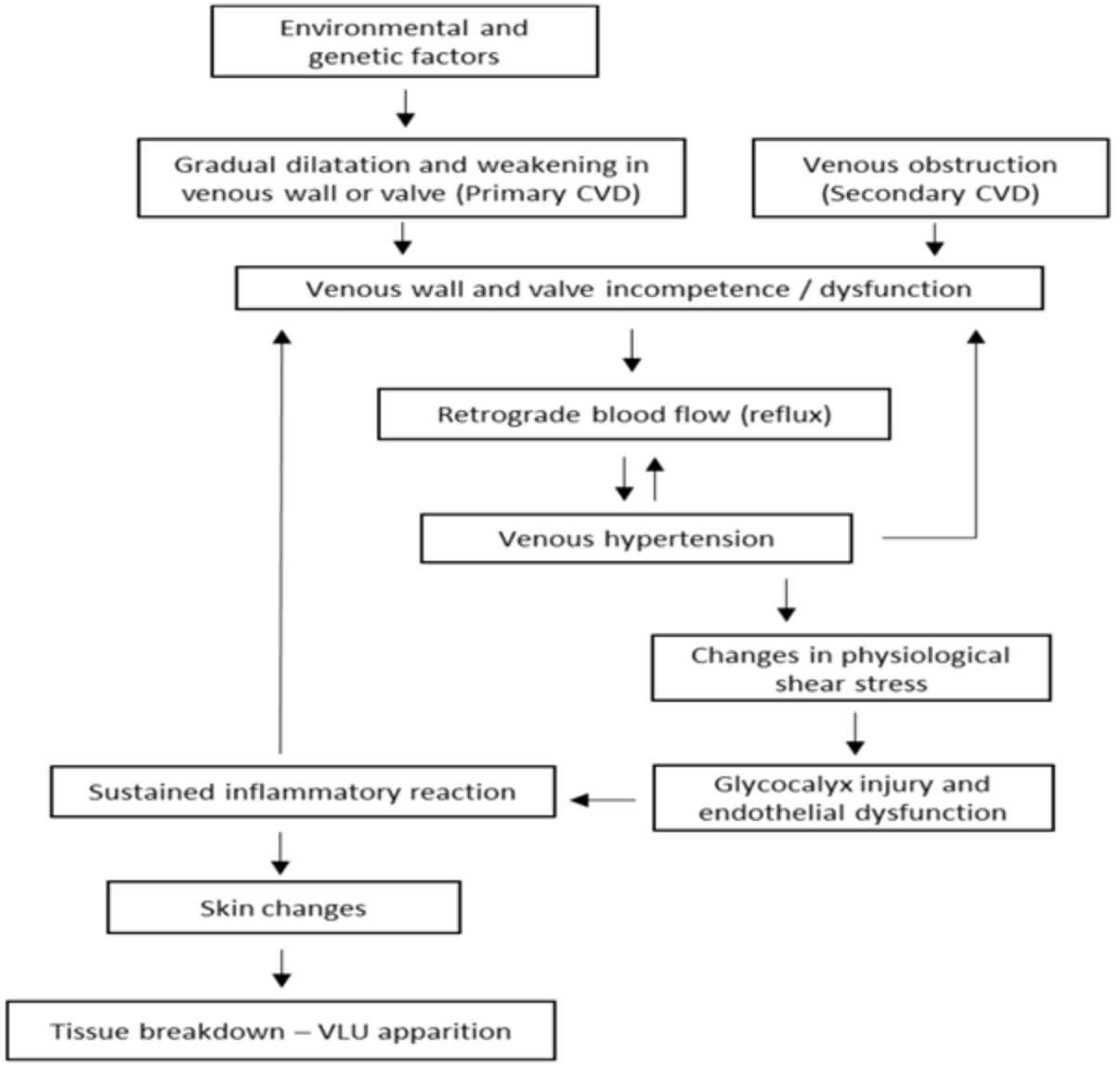


Figure 1. Sequence of events from CVD to VLU apparition.

Coelho GA, et al. *J Clin Med*. 2023;12(17):5605.

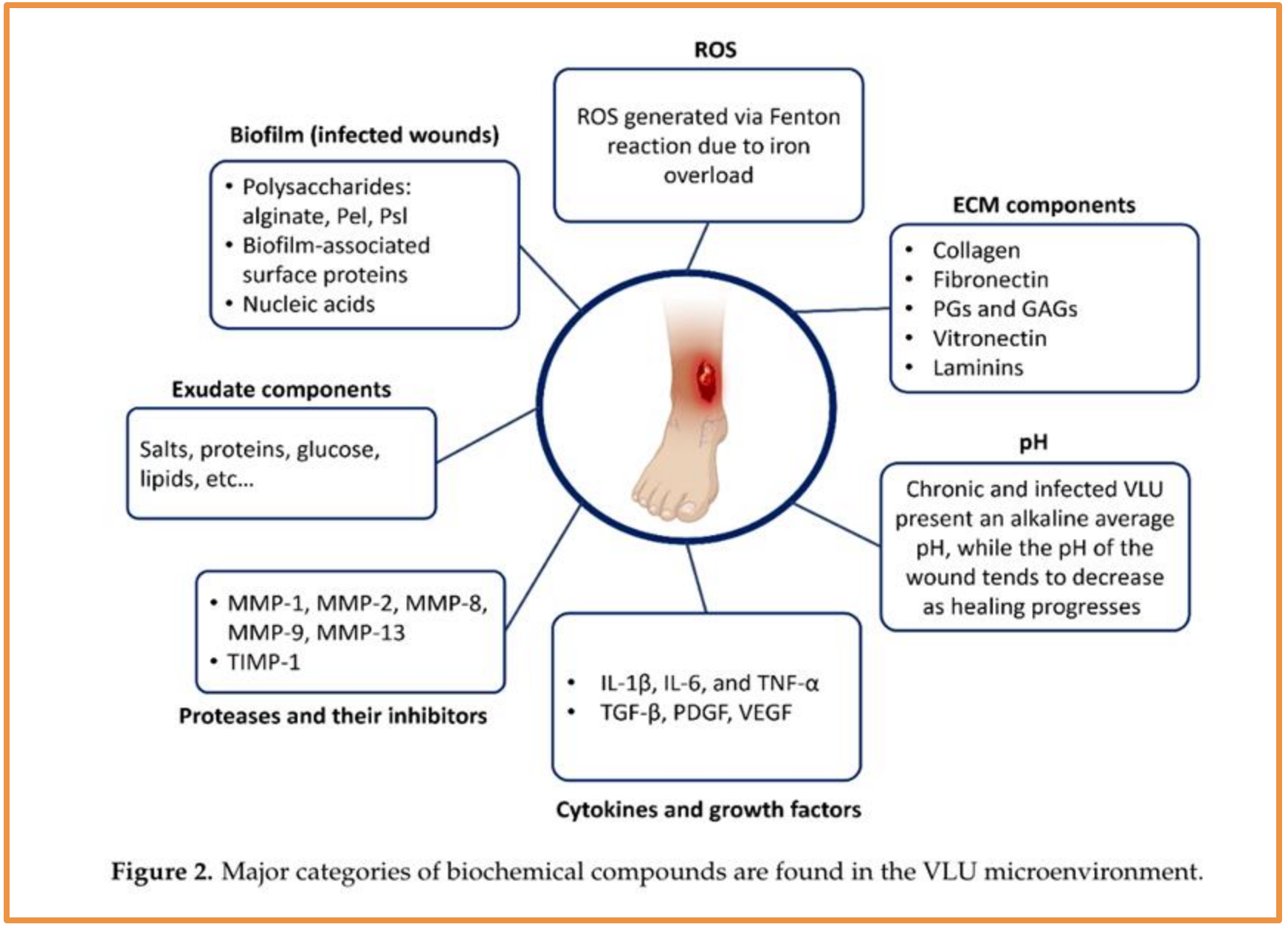
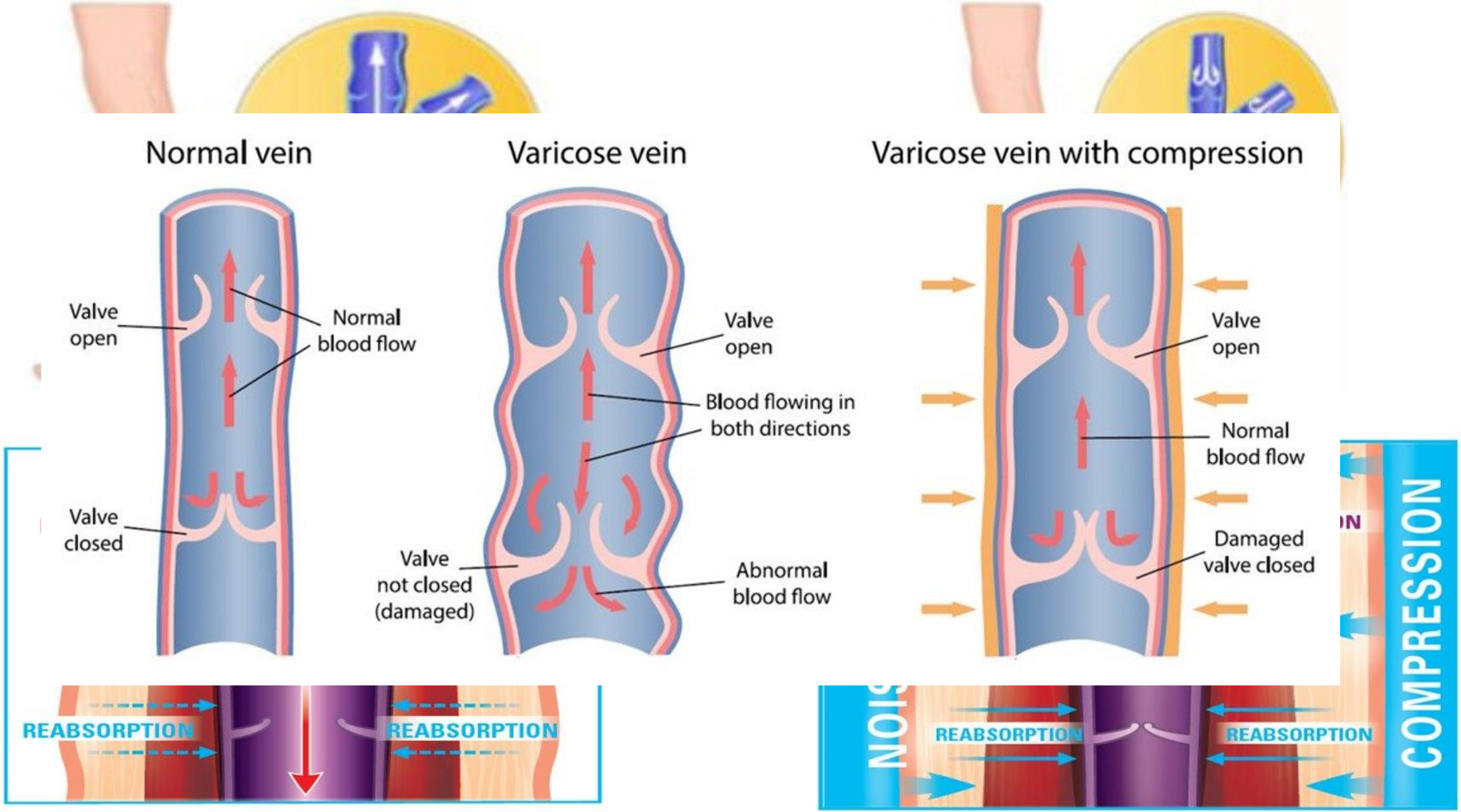


Figure 2. Major categories of biochemical compounds are found in the VLU microenvironment.

ROS = reactive oxygen species; MMP = matrix metalloproteinase; TIMP = tissue inhibitor of metalloproteinase; PG = proteoglycans; GAG = glycosaminoglycans.

Coelho GA, et al. *J Clin Med*. 2023;12(17):5605.


Normal vein
Varicose vein
Varicose vein with compression
Valve open
Normal blood flow
Valve closed
Valve open
Blood flowing in both directions
Valve not closed (damaged)
Abnormal blood flow
Valve open
Normal blood flow
Damaged valve closed
REABSORPTION
REABSORPTION
REABSORPTION
REABSORPTION
COMPRESSION

Obesity

- Accompanied by reduced mobility
- Reduced CMP function
- Increased abdominal pressure
- Increased adipose tissue mass
- Hemodynamic changes

Early recognition of CVI symptoms in overweight patients is crucial in efforts to prevent VLU

Meulendijks AM, et al. *J Tissue Viability*. 2020;29(3):190-196.

Venous pathology may include:

A. Large, tortuous veins

B. Compression or obstruction of the IVC or iliac veins

C. Large or refluxing varicose veins

D. All of the above

Post-Thrombotic Syndrome

- 2023: Single-center study
- 67 patients (79 legs) with CEAP: C5/C6 prevalence of 31.6% combine iliocaval venous obstruction (ICVO)/superficial venous reflux (SVR)
- Independent predictors of >50% ICVO in patients with CVD and SVR
  1. History of DVT in the affected leg
  2. VLU in the left leg
  3. Recurrent VLU

Investigation for ICVO and SVR should be considered for patients with CVD

CEAP = clinical manifestations, etiology, anatomic distributions, pathophysiology; ICVO = iliocaval venous obstruction; SVR = superficial venous reflux.
Chinchalongporn W, et al. *J Vasc Surg Venous Lymphat Disord*. 2023;11(3):502-509.

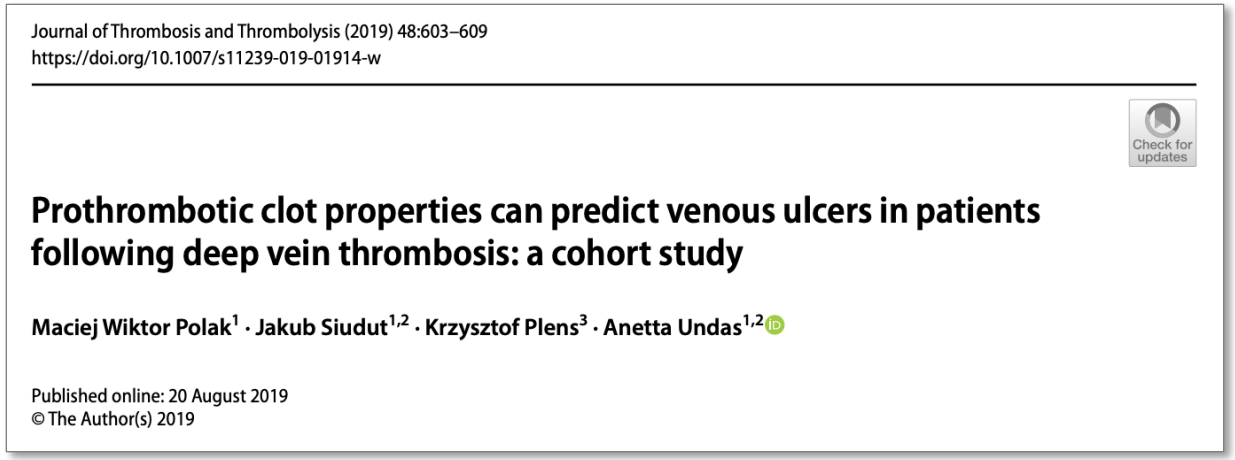
Post-Thrombotic Syndrome

- Up to ½ of patients with diagnosis of DVT will develop post-thrombotic syndrome (PTS)
- 2023: 11 patients with 15 VLUs, 14 limbs
- Mean age was 59.7; 36.4% female
- Median VLU duration 11.0 months
- 2 patients had VLUs secondary to DVT >40 yrs prior
- Technical success achieved in 100% of the 14 limbs

- Stents in 10 limbs (71.4%)
- VLU *time to close* improvement
- Severity scale improvement
- Size reduction

Mouawad NJ. *J Vasc Surg Venous Lymphat Disord*. 2023;11(5):964-971.e1.

Personalized Medicine?



Journal of Thrombosis and Thrombolysis (2019) 48:603–609
https://doi.org/10.1007/s11239-019-01914-w

Check for updates

Prothrombotic clot properties can predict venous ulcers in patients following deep vein thrombosis: a cohort study

Maciej Wiktor Polak[1] · Jakub Siudut[1,2] · Krzysztof Plens[3] · Anetta Undas[1,2]

Published online: 20 August 2019

- 186 patients
- Median follow-up 53 months,
  PTS diagnosed in 57 (30.6%)
- Venous ulcers occurred in 12 (6.45%)
- Denser fibrin clot formation and reduced susceptibility to lysis increases PTS VLU risk
- Anticoagulant therapy and the use of compression stockings did not reduce the risk of venous ulceration
- Elevated CRP not related to the risk of leg ulceration
- Clot permeability and CLT — role in prediction of PTS VLU?
- Research needed!

Polak MW, et al. *J Thromb Thrombolysis.* 2019;48(4):603-609.

Classification of Venous Leg Ulcers: CEAP

Clinical Classification

C0: No visible or palpable signs of venous disease
C1: Telangiectasias or reticular veins
C2: Varicose veins – distinguishable from reticular veins by a diameter of 3mm or more
C3: Edema
C4: Changes in the skin and subcutaneous tissue secondary to CVD are divided into 2 subclasses to better define the differing severity of venous disease
C4a: Pigmentation and/or eczema
C4b: Lipodematosclerosis and/or atrophie blanche
C5: Healed venous ulcer
C6: Active venous ulcer

S = symptomatic; A = absence of symptoms, asymptomatic

Etiological Classification

Ec: Congenital
Ep: Primary
Es: Secondary (post-thrombotic)
En: No venous etiology identified

Pathophysiological Classification

Pr: Reflux
Po: Obstruction
Pro: Reflux and obstruction
Pn: No venous pathophysiology identifiable

Anatomical Classification

Superficial veins:
1. Telangiectasias/reticular veins
2. Great saphenous vein (GSV) above knee
3. GSV below knee
4. Small saphenous vein
5. Nonsaphenous veins

2020 Updates

- Corona phlebectatica (C4c) added
- Modifier “r” for recurrent varicose veins and VLU
- Common abbreviations for venous segments

GSV = great saphenous vein.
Lurie F, et al. *J Vasc Surg Venous Lymphat Disord*. 2020;8(3):342-352. Erratum in: *J Vasc Surg Venous Lymphat Disord*. 2021;9(1):288.

Classification of Venous Leg Ulcers: Venous Clinical Severity Score (VCSS)

Attribute	Absent = 0	Mild = 1	Moderate = 2	Severe = 3
Pain	None	Occasional, not restricting activity *or* requiring analgesics	Daily, moderate activity limitation, occasional analgesics	Daily, severe limiting activities *or* requiring regular use of analgesics
Varicose veins*	None	Few, scattered: branch VV's	Multiple: GS varicose veins confined to calf or thigh	Extensive: thigh *and* calf *or* GS *and* SS distribution
Venous edema†	None	Evening ankle edema only	Afternoon edema, above ankle	Morning edema above ankle *and* requiring activity change, elevation
Skin pigmentation‡	None *or* focal, low intensity (tan)	Diffuse, *but* limited in area, *and* old (brown)	Diffuse over most of gaiter distribution (lower 1/3) *or* recent pigmentation (purple)	Wider distribution (above lower 1/3) *and* recent pigmentation
Inflammation	None	Mild cellulitis, limited to marginal area around ulcer	Moderate cellulitis, involves most of gaiter area (lower 1/3)	Severe cellulitis (lower 1/3 and above) *or* significant venous eczema
Induration	None	Focal, circummalleolar (< 5 cm)	Medial *or* lateral, less than lower third of leg	Entire lower third of leg *or* more
No. of active ulcers	0	1	2	> 2
Active ulceration, duration	None	< 3 mo	> 3 mo < 1 y	Not healed > 1 y
Active ulcer, size§	None	< 2-cm diameter	2- to 6-cm diameter	> 6-cm diameter
Compressive therapy‖	Not used *or* not compliant	Intermittent use of stockings	Wears elastic stockings most days	Full compliance: stockings + elevation

Evaluative and longitudinal

Vasquez MA, et al. *J Vasc Surg*. 2010;52(5):1387-1396.

Prevention

- **Venous surgery**
- Compression stockings
- Statin medications
- **Early identification of varicose veins (VV)/skin changes**
- Pain medications

- Venous surgery appeared to offer the greatest reduction in first venous leg ulcer (fVLU)
- Studies suggest venous surgery improves healing and prevents ulcer recurrence

Early, frequent clinician engagement provides opportunities to support health promotion activities.

VV = varicose veins; fVLU = first venous leg ulcer.

Darwin E, et al. *J Am Acad Dermatol.* 2021;84(1):76-85. Gethin G, et al. *J Tissue Viability.* 2021;30(1):78-88.

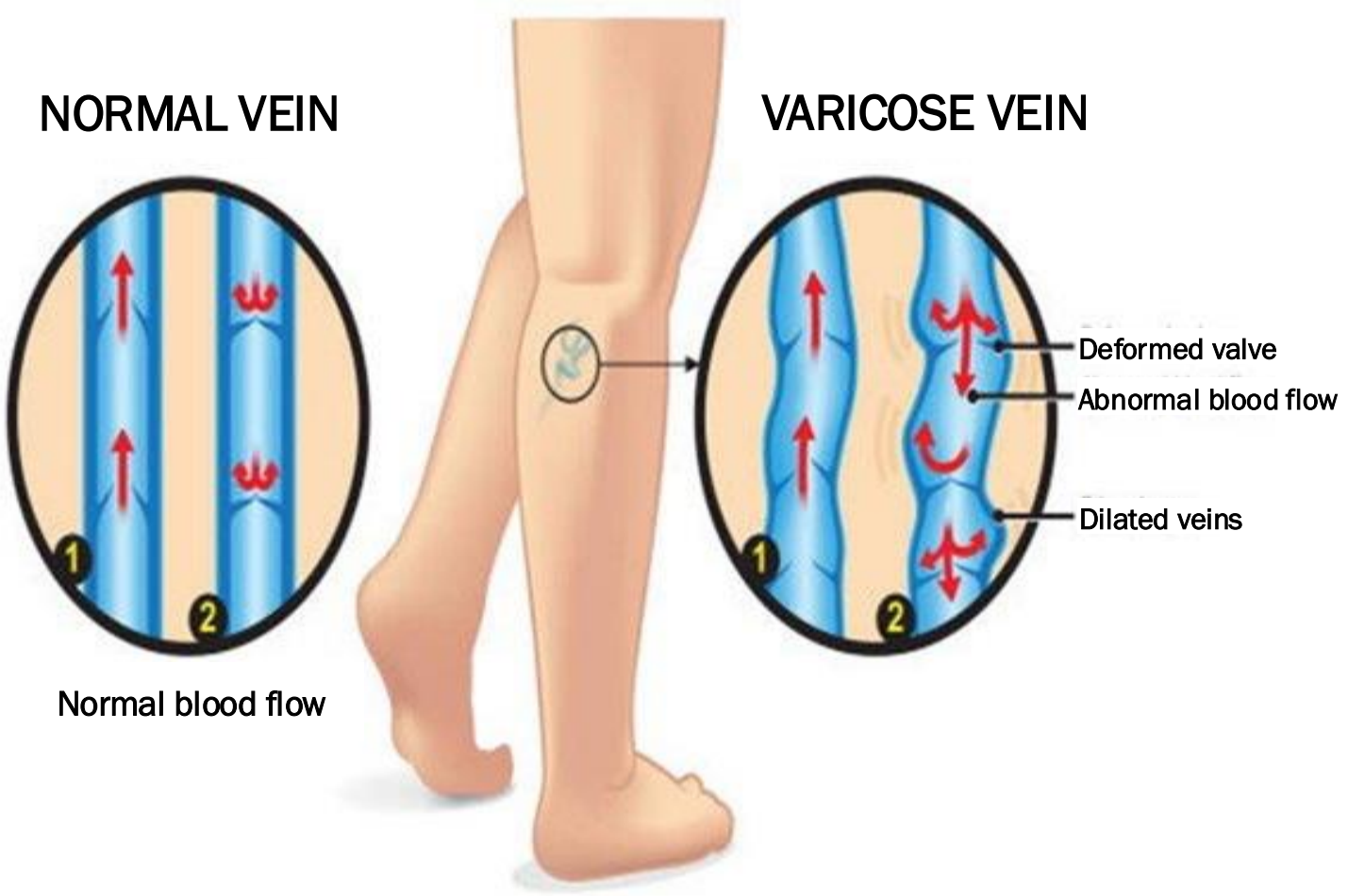
Risk of Recurrence

- Highest 3 mos after healing
- Majority recur within 12 mos
- 28% of patients experience >10 episodes of VLU in their lifetime
- Living alone, decreased activity, limited leg elevation, compression therapy, and non-use are markers for recurrence within 12 mos

Finlayson KJ, et al. *Int Wound J.* 2018;15(5):686-694.

Big Picture Purpose of Compression

- Reduced vein diameter
- Increased venous flow
- Reduced venous reflux
- Less cellular leakage into the interstitial space
- Reduced edema
- Decreased inflammation
- Improved capillary perfusion



Adequate compression in a patient with a VLU may consist of:

A. Open-weave crinkled gauze and elastic bandage
B. Elastic bandage alone
C. Compression stockings
D. Multi-component (multi-textile) wraps

Beyond Dosage: Stiffness Matters

- Stiffness provides insight into performance during posture changes and movement and impacts edema prevention and hemodynamics

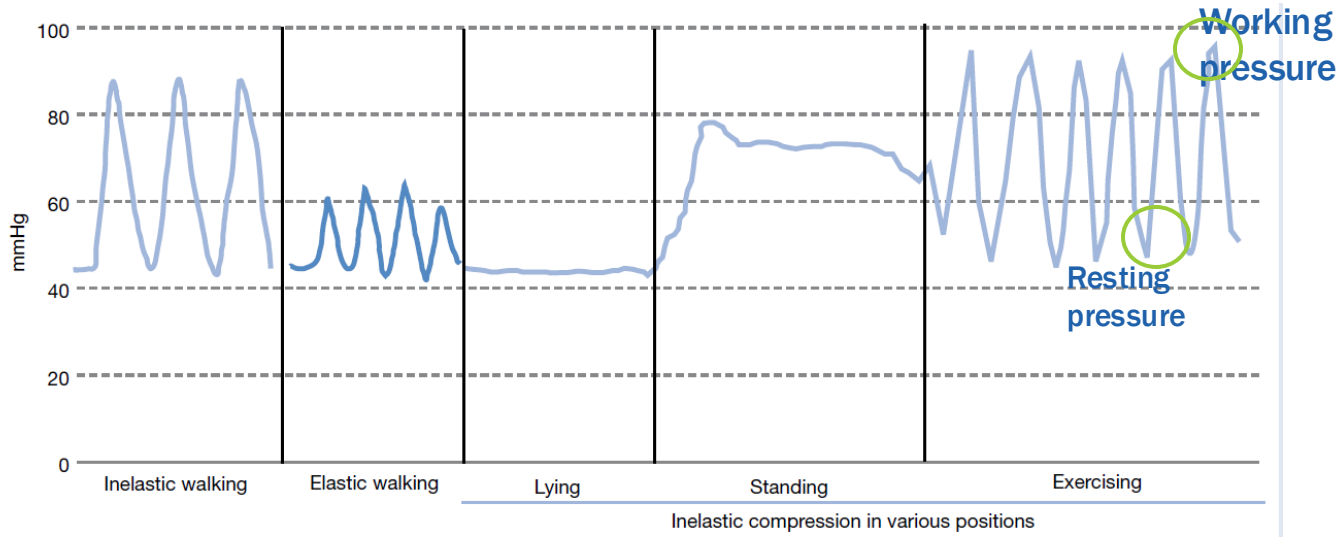


Fig 6. Graphic tracing of interface pressure measurements under inelastic and elastic compression with movement.

Static Stiffness Index (SSI) = Working Pressure – Resting Pressure

- ✓ **Dosage (mm Hg) is the inward pressure from a compression application's elastic recoil**
- ✓ **Stiffness is a compression application's resistance to stretching from swelling or muscle expansion**

Bjork R, Ehmann S. *J Wound Care*. 2019;28(6a):1-44. Hirai M, et al. *Phlebology*. 2010;25(4):196-200. Hirai M, et al. Vascular. 2008;16(2):95-100. van der Wegen-Franken K, et al. Dermatol Surg. 2008;34(11):1477-1485. Partsch H. Dermatol Surg. 2005;31(6):625-630.

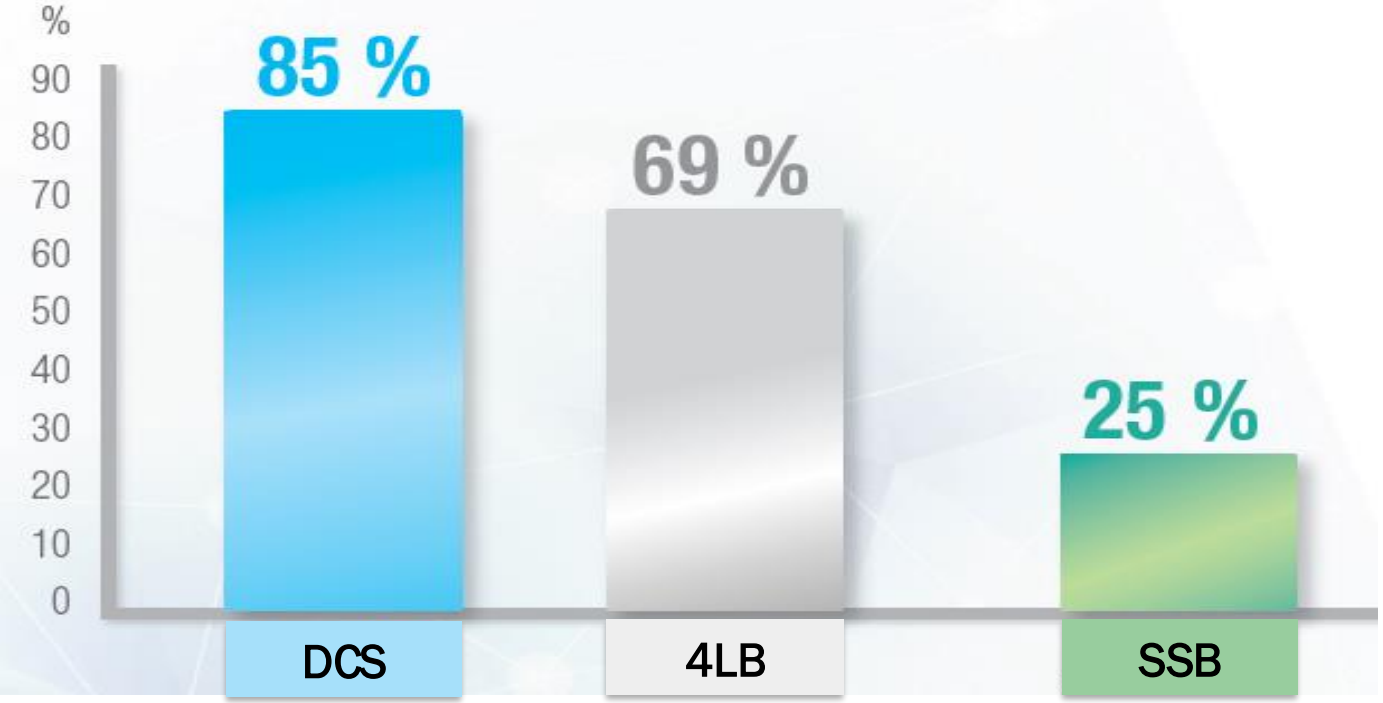
Three Principles for Good Compression: Continuous, Consistent, Comfortable

The 3 Cs of good compression and the results with DCS

- Continuous pressure, 24/7
  - Interface pressure remained the same for DCS up to 7 days and at different levels of activity
- Consistent pressure and application
  - 87% of nurses achieved therapeutic pressure at first application
- Comfortable compression that patients will wear
  - 95.7% patient compliance in winter months
  - 92.2% patient compliance in summer months

Hanna R, et al. *Br J Nurs*. 2008;17(20):S16-S24. Jünger M, et al. *J Wound Care.* 2009;18(11):474, 476-480. Pilati L. Do the findings in winter of a dual compression system compression bandage's wear compliance with patients replicate if the study is repeated in the summer months? Presented at Symposium on Advanced Wound Care Fall 2021.

Percentage of nurses achieving 30-50 mm Hg on 1st application



- 85% of nurses (n=32) achieve therapeutic pressure on first application with dual compression system (DCS), with no prior experience
- SSB results in sub-therapeutic pressures
- 4LB delivers high pressure, which can be uncomfortable and lead to skin damage

DCS = dual compression system.

Hanna R, et al. *Br J Nurs*. 2008;17(20):S16-S24.

Other countries, such as France, show **3x** higher usage of compression for VLU (based on population)

	Estimation USA	Estimation FR
Population	333,229,000	64,889,000
% Prevalence VLU	1.08% (1)	1.08% (1)
Existing VLUs	3,598,873	700,801
Units needed per VLU(2)	18	18
Units needed for all VLUs	64,779,718	12,614,422
Total Compression Kits units (3)	8,970,874	5,261,513
% estimation of VLUs receiving compression treatment	**13.8%**	**41.7%**

3x higher rate of compression

1. Probst S, et al. *Int Wound J.* 2023;20(9):3906-3921. 2. Estimated as 12 wks to heal at 1.5 compression kits per wk. 3. Source: Clarivate Market Data. Including MLB compression kits and Unna Boot for 2024.

Compression therapy is THE etiological treatment for VLUs

Clinical Pearls

- VLUs are complex and require thorough history taking and physical examination — we can outsmart them!
- Diagnostic imaging/evaluation should be completed prior to employing advanced and o
- H
in
- Talk with your patient! Using simple analogies can help them understand the WHY and lead to better adherence to care plans — and fun!
- Emerging research will hopefully elucidate the role of interventional, topical, and compression-related modalities

Compression addresses both macro and microvascular components and decreases inflammation

Innovation in VLU etiology emphasizes the complex interplay of factors contributing to chronic inflammation. Focus on understanding these mechanisms, identifying key biomarkers, and developing novel therapies to effectively target inflammation and improve healing outcomes is crucial.

Why Is It So Hard To Do the Right Thing with VLU Compression?

Caroline E. Fife, MD
Chief Medical Officer, Intellicure LLC
The Woodlands, TX

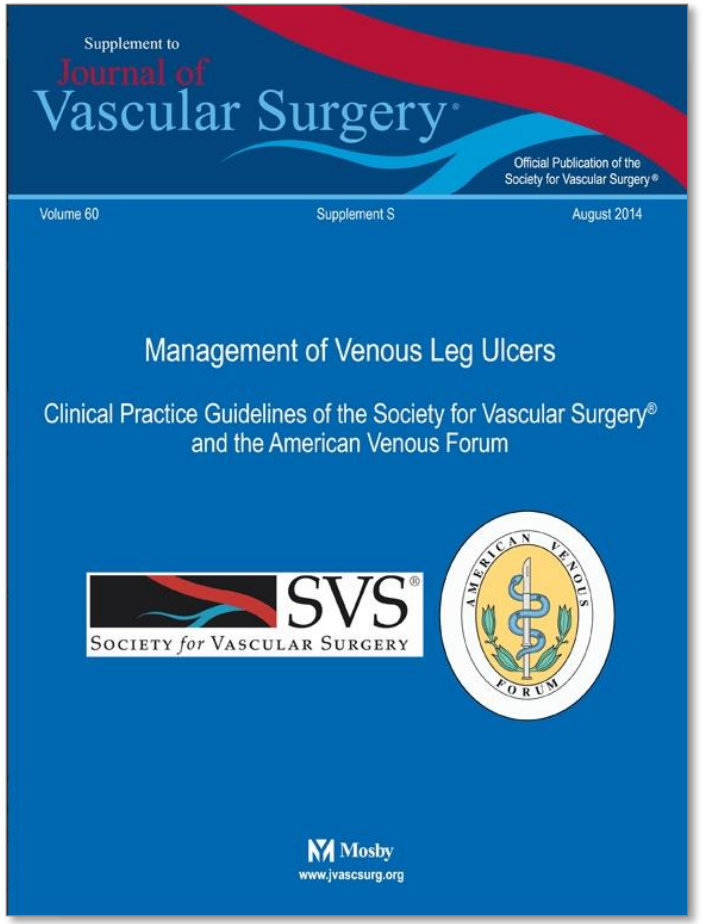
We Have Known about Compression for a Long Time

- 1999
  - 72y Female
  - Diabetes
  - Rheumatoid arthritis
  - Healed with compression and wound care

These photos are a little blurry because they were originally taken with a Polaroid camera.

Compression: The Cornerstone of VLU Care for 40+ Years

- Ancient
  - 5th Century BCE: Hippocrates recommends bandaging swollen legs
  - 17th–19th Centuries: Use of compression bandages and stockings common in European medicine for treating varicose veins, leg ulcers
- Wound Healing Society (WHS); 1999, updated 2006
- Society for Vascular Surgery (SVS) & American Venous Forum (AVF) Clinical Practice Guidelines; 2014
- SIGN Guideline No. 120 (Scotland) – Management of Chronic Venous Leg Ulcers; 2010
- EWMA/Wounds International Consensus Document; 2007/2009
- NICE (UK); 2013, 2022



Compression improves healing, reduces recurrence of VLUs.

Yet, 40%-70% of VLU patients do NOT receive adequate compression.

Wounds International. Published May 7, 2015. Accessed Aug 1, 2025. https://woundsinternational.com/consensus-documents/simplifying-venous-leg-ulcer-management-consensus-recommendations/

Is There Any Excuse for This?

- 54y Male with 10-yr history of non-healing, bilateral, circumferential LE ulcerations
- Has never been provided with compression or venous assessment
- Hypercoagulable state confirmed with blood tests; near complete occlusion of his deep venous system, not a candidate for any venous intervention
- Near complete healing over 10 months with compression bandaging – wife trained

Key Findings from Literature

- O'Meara, et al. (2009): Cochrane review shows strong evidence, poor implementation
- Fife, et al. (2010): 17% of VLU visits included adequate compression
  - Cost doubles when evidence-based care is not performed
- Moffatt, et al. (2011): Only 31% of patients received high compression (UK)

Editors left this quote in the 2010 manuscript:
"For I have the desire to do what is good, but I cannot carry it out. For what I do is not the good I want to do." (Romans 7:14 NIV)

Why is it so hard to do the right thing about compression?

Wound Repair and Regeneration

Why is it so hard to do the right thing in wound care?

Caroline E. Fife, MD[1]; Marissa J. Carter, PhD, MA[2]; David Walker, CHT[3]

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ABSTRACT

"Doing the right thing" in wound care is not an easy task. Studies suggest that 3 factors determine compliance with performing basic wound care from an evidence-based medicine perspective: complexity, cognitive effort, and the compensation system. Two models were explored to investigate compliance with basic wound care at hospital based wound centers: offloading of diabetic foot ulcers (DFUs) and compression bandaging for venous leg ulcers. Using a very large wound-care registry it was determined that only 6% of DFU patients received the gold standard of care for offloading, i.e., total contact casting (TCC), but among those patients who received it, the average cost of treatment was half the cost of those who did not. Although inexpensive to administer, TCC is a relatively time-consuming procedure which is poorly reimbursed. Other DFU treatments such as bilaminate skin, are more costly but are reimbursed much more generously. Thus, the reimbursement system favors the use of more expensive therapies over more economical ones. In the case of venous leg ulcers (VLUs), only 17% of patients received adequate compression. Provision of adequate compression among VLU patients has been similarly hindered by inadequate reimbursement policy. Lack of familiarity with clinical practice guidelines increases the cognitive effort for clinicians. Improving the economic model to favor the provision of effective basic care, creating easier-to-use products, and making clinical practice guidelines available at the point of service may make it easier to "do the right thing(s)" in wound care.

The United States has a US$2.1 trillion health care industry.[1] Medicare expenditures alone are up from US$219 billion in 2000 to a projected US$486 billion in 2009, and the Medicare Trust Fund is projected to be depleted by 2016.[2] Overall, we spend twice as much per capita as Sweden, the Netherlands, and the United Kingdom, but these countries achieve better overall health outcomes.[3–5] This disparity between expenditure and quality is the focus of much national debate and important recent legislation.

On December 20, 2006, President Bush signed the Tax Relief and Health Care Act of 2006 (TRHCA), which authorized the establishment of a pay-for-performance program known as the Physician Quality Reporting Initiative (PQRI). In this initiative, payment is linked to whether the clinician performs certain tasks in a given time frame for specific patients. The Medicare Improvements for Patients and Providers Act (MIPAA) of 2008 authorized a 2% bonus for those who successfully report quality measures.

In 2009, there were 153 measures from which to choose, only one of which relates directly to wound care. The one wound-related measure is the percentage of patients over age 18 with a diagnosis of venous ulcer who were prescribed compression therapy one time in the previous 12 months. No distinction is made as to whether the compression provided would be considered adequate by randomized clinical trial (RCT)-based criteria. There is also a PQRI measure relating to diabetic "foot care"—specifically, performing peripheral neuropathy evaluation, and prescribing appropriate footwear. However, offloading of existing diabetic foot ulcers (DFU) is not a PQRI measure. Clearly, much work is needed before PQRI measures can significantly impact the wound care industry.

DOING THE RIGHT THING: BASIC WOUND CARE

Despite its obvious limitations, the impetus behind PQRI is the benefit resulting from performing basic care, which has been shown through evidence-based medicine (EBM) to be highly effective. We term this "doing the right thing." But, doing the right thing when it comes to treating patients in medical practice is not an easy task. Even activities as basic and presumably instinctive as hand washing are apparently poorly observed. Studies suggest that physicians wash their hands only approximately 50% of the time that they conduct a patient encounter.[6] This poor adherence to a basic tenet of patient safety is directly related to the significant incidence of hospital-acquired infections. Yet, hand washing frequency can be easily improved by making washing stations and antiseptic dispensers more readily available.[7] In other words, compliance with care protocols is related to the difficulty or *complexity* of performing the task. The more difficult it is to comply, the less likely a clinician will do it. Another factor affecting performance is the *cognitive effort* involved. Physicians simply

Wound Rep Reg (2010) 18 154–158 © 2010 by the Wound Healing Society

O'Meara S, et al. Cochrane Database of Systematic Reviews. Published 2012. Accessed Aug. 2, 2025. https://doi.org/10.1002/14651858.CD000265.pub3. Fife CE, et al. *Wound Repair Regen*. 2010;18(2):154-158. Moffatt C, et al. *Int Wound J*. 2011;8(5):469-483.

Factors Affecting “Concordance” with Compression

- Physical factors
- Lack of patient education about their condition and treatment prescribed
- Aesthetic and cosmetic factors
- Cost of therapy
  - Compression products for continued edema control are not covered by most payers
- Clinician issues

Moffatt C, et al. *Int Wound J*. 2011;8(5):469-483. O’Meara S, et al. Cochrane Database of Systematic Reviews. Published 2012. Accessed Aug. 2, 2025. https://doi.org/10.1002/14651858.CD000265.pub3.

The Patients Are Challenging

- 80y Male; O_2 saturation at 84%
- Medical problems
  - Obesity
  - T2DM
  - CKD
  - COPD
  - CHF
  - A-fib
  - Sleep apnea

T2DM = type 2 diabetes mellitus; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; CHF = congestive heart failure.

Chronic Ulcer Patients Are Complicated

DFUs

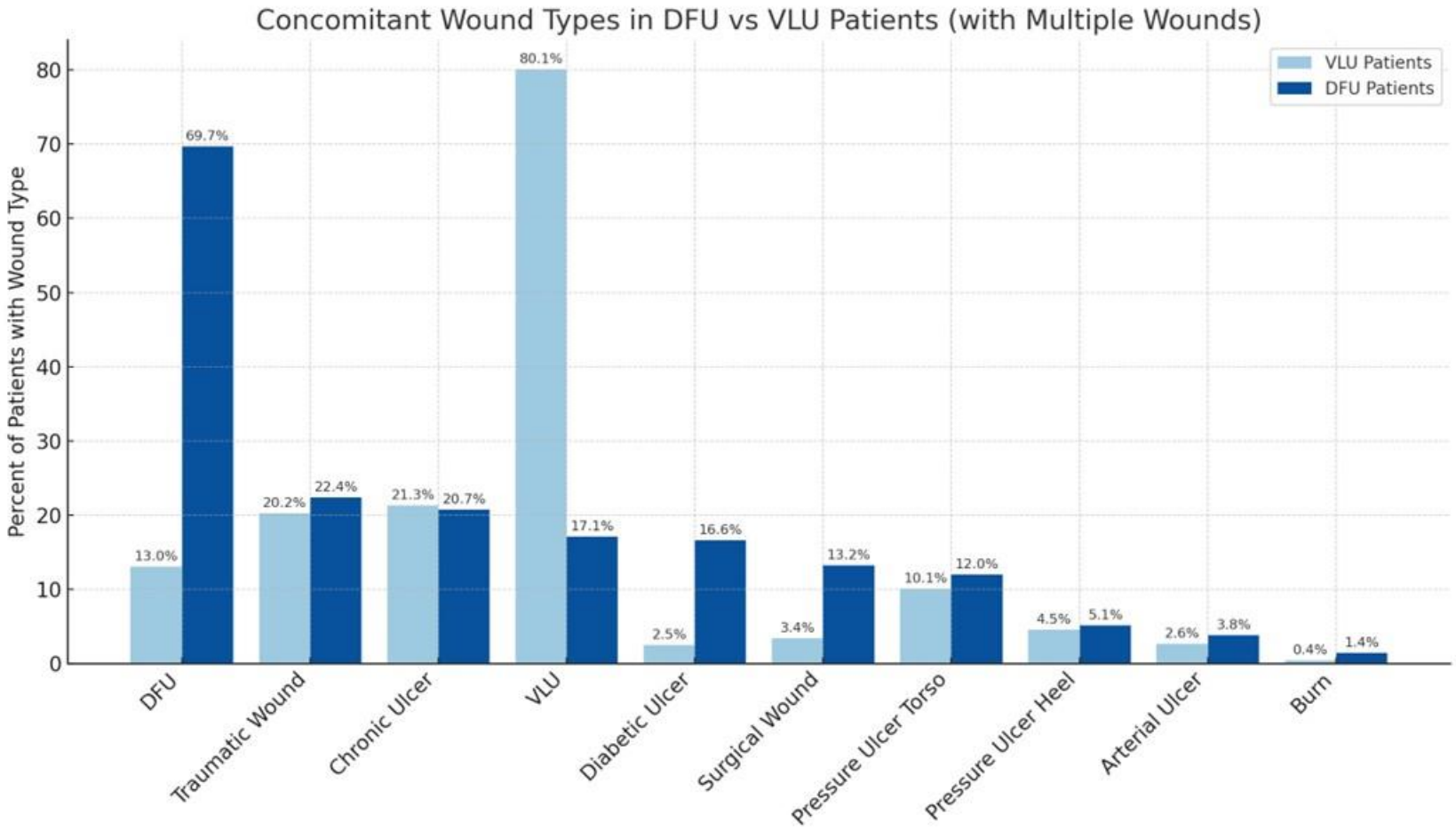
- **Patients: 10,966; DFUs: 26,042**
- Median age: 63.5 yrs
- Male: 70%
- Concomitant DFUs:
  - 1.7 mean; 1 median
- Concomitant wounds/ulcers (any type)
  - 2.7 mean; 2.0 median
- **41% developed a new DFU while in treatment for the initial DFU**

VLUs

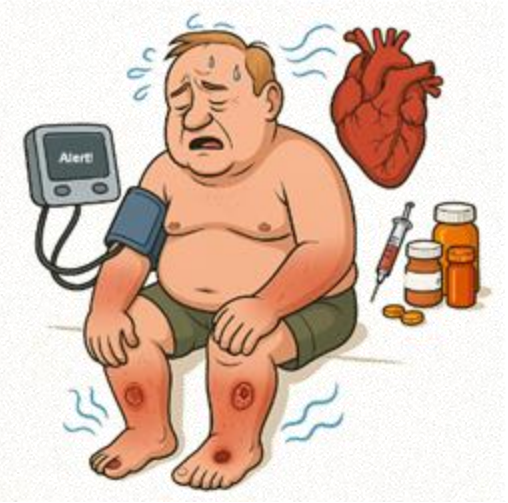
- **Patients: 11,197; VLUs: 30,790**
- Median age: 71.2 yrs
- Male: 54%
- Concomitant VLUs:
  - 1.8 mean; 1 median
- Concomitant wounds/ulcers (any type)
  - 2.5 mean; 2.0 median
- **41.3% developed a new VLU while in treatment for the initial VLU**

"Natural History Project": Wound Care Collaborative Community 2025, manuscript in progress

Comorbid Diseases in Real-World Patients



- 43% of patients with VLUs have diabetes
- Among those with diabetes, 41.6% had a venous ulcer
- Autoimmune disease is present in 13.7% of patients with VLUs
- 13% of patients with a DFU have a VLU
- 17% of patients with a VLU have a DFU



"Natural History Project": Wound Care Collaborative Community 2025, manuscript in progress

Patient Education about the Importance of Compression

- Time consuming
- Challenging in some patients (eg, dementia)
- Surprisingly effective at improving adherence

Why the Compression Gap Exists: Barriers

- Patient non-adherence (comfort, usability)
  - Often due to a lack of communication on our part
- Availability/cost of supplies
  - Compression bandage kits = >80% of all dressing costs for clinics
- Lack of provider training
- Fear of (undiagnosed) arterial disease
  - You are not a “wound clinic” if you can’t do arterial assessment in the clinic/office
  - ABI in office
    - 0.5 or less: Severe arterial disease
    - 0.6–0.7: Arterial insufficiency
    - 0.8–1.3: Normal
    - 1.3 or higher: Calcified vessels
  - You need a standard protocol for all patients that includes arterial assessment in the office/clinic on all patients (at the first visit!)

Adequate Compression and Arterial Assessment Quality Measures Endorsed by Medicare

U.S. Wound Registry | U.S. Podiatry Registry

ABOUT RESOURCES CONTACT US

QUALITY MEASURES: PROVIDED BY THE US WOUND & PODIATRY REGISTRIES, DEVELOPED WITH CLINICAL ASSOCIATIONS.

The Quality measure listed below were developed in conjunction with various specialty organizations. Those specialty organizations include the Alliance of Wound Care Stakeholders, the Undersea and Hyperbaric Medical Society (UHMS), and the American Podiatric Medical Association (APMA).
Click here to see the latest CMS Quality Reporting Requirements.

2025 Wound Care Quality Measures | 2024 Wound Care Quality Measures | 2023 Wound Care Quality Measures

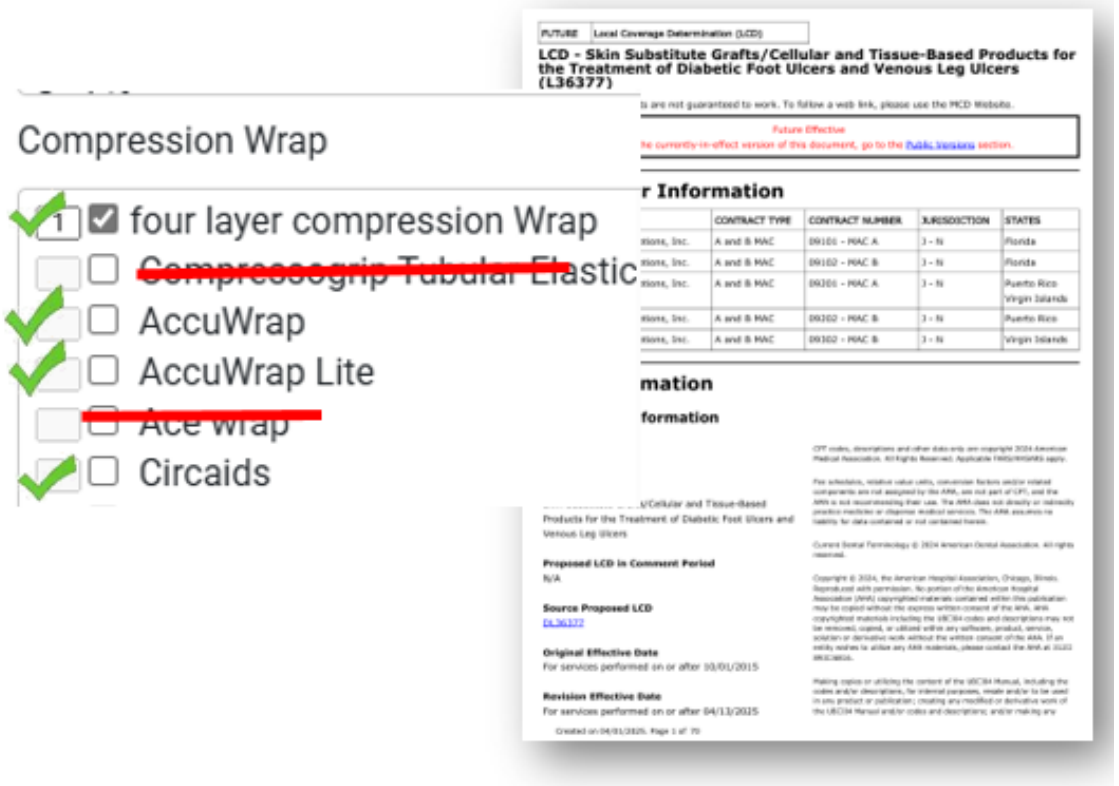
2025 WOUND-RELEVANT QUALITY MEASURES FROM THE US WOUND REGISTRY, APPROVED BY CMS

Measure Number	Title	Specification
USWR22	Nutritional Assessment and Intervention Plan in Patients with Wounds and Ulcers	
USWR30	Non-Invasive Arterial Assessment of patients with lower extremity wounds or ulcers for determination of healing potential	
USWR32	Adequate Compression at each visit for Patients with Venous Leg Ulcers (VLUs) appropriate to arterial supply	
USWR33	Diabetic Foot Ulcer (DFU) Healing or Closure	
USWR34	Venous Leg Ulcer (VLU) Healing or Closure	
USWR35	Adequate Off-loading of Diabetic Foot Ulcers performed at each visit, appropriate to location of ulcer	
USWR36	Pressure Ulcer* (PU) Healing or Closure (ulcerations not on the lower extremity)	

U.S. Wound Registry. Accessed Aug. 2, 2025. https://uswoundregistry.com/quality-measures/

Adequate Compression of VLUs is Required by Medicare

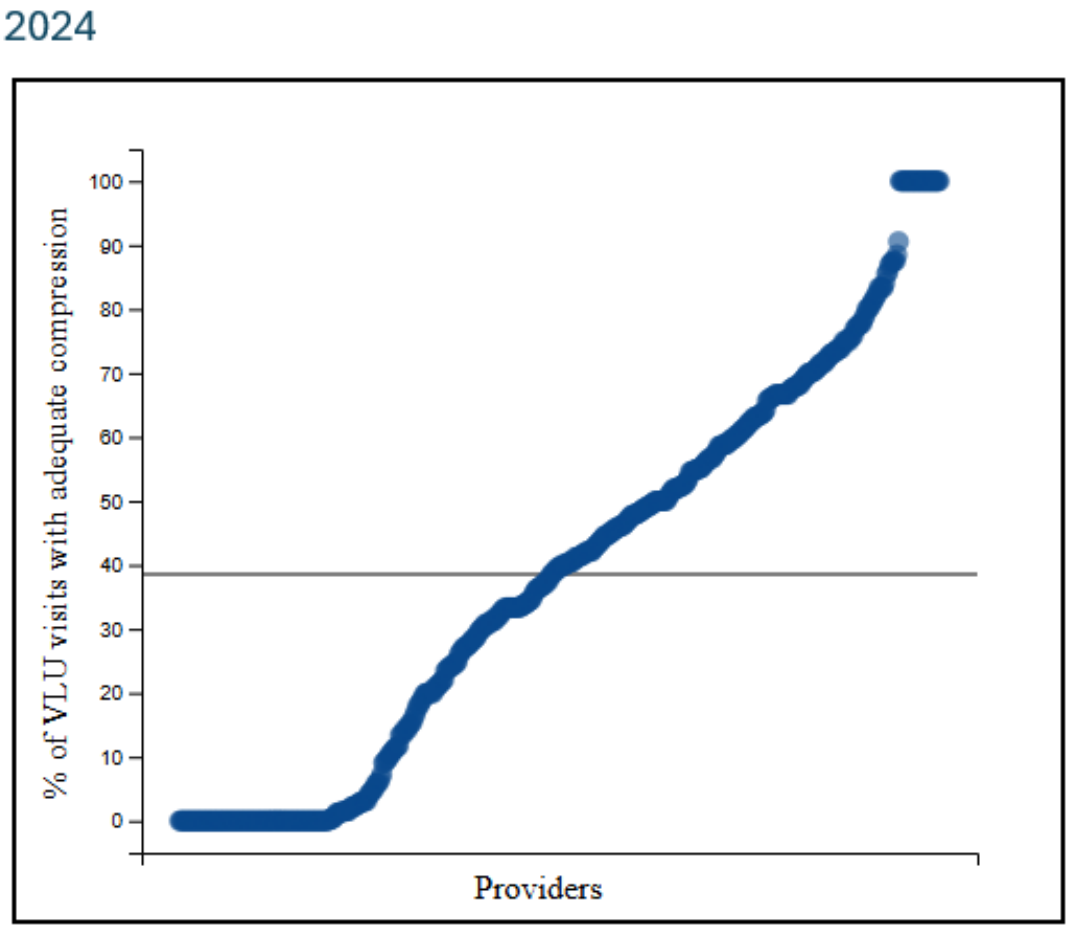
- CTPs/CAMPs are reserved for DFUs and VLUs that do not heal with properly implemented standard of care (SOC)
- Medicare Administrative Contractors (MACs) have issued LCDs requiring “firm compression (>20 mm Hg)” at each VLU-DFU visit if CTPs/CAMPs are to be reimbursed
- Even though the most recent LCD is on hold, auditors are clawing back Medicare payments for skin substitutes applied to VLUs if adequate compression is not documented



CMS.gov. Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers. Accessed August 28, 2025. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=36377

Real-World Data from U.S. Wound Registry

- 30,612 patients, 55,402 VLUs, 151,192 visits
- Only 20% of VLU visits get adequate compression
- Among the *in*adequate compression choices
  - ≈50% physician recommendation to “elevate legs”
  - ≈30% get tubular bandage or elastic bandage
  - ≈10% get a single layer of high-stretch cohesive bandages
  - ≈20% get non-prescription “socks”
- Data on >500 practitioners
  - Adequate compression use may increase with point-of-care reminders
  - “Mobile” practitioners are slightly less likely to provide adequate compression



U.S. Wound Registry. Manuscript in progress.

Compression Works: Let's Do the Right Thing

- 45y Male who developed lymphedema after a venous procedure for VLU

Clinical Pearls

- Practice your *spiel* (quick, illustrative explanation of how VLUs form and why the patient needs compression)
- Commit to arterial assessment in your office/clinic in every patient (annually) – unless there is a specific reason you can't – and order studies on the rest
- "Normalize" compression
- Get patients treatment for sleep apnea
- Train family members
- Adopt a "no excuses" approach with staff/colleagues

You are evaluating a new VLU patient. Which statements are likely true?

A. They are likely obese (>60%)

B. They may have diabetes (~40%)

C. They may have arterial (undiagnosed) arterial disease (~25%)

D. The reasons for compression have never been discussed with them

E. All of the above

Patient presents with VLU and ABI 0.7

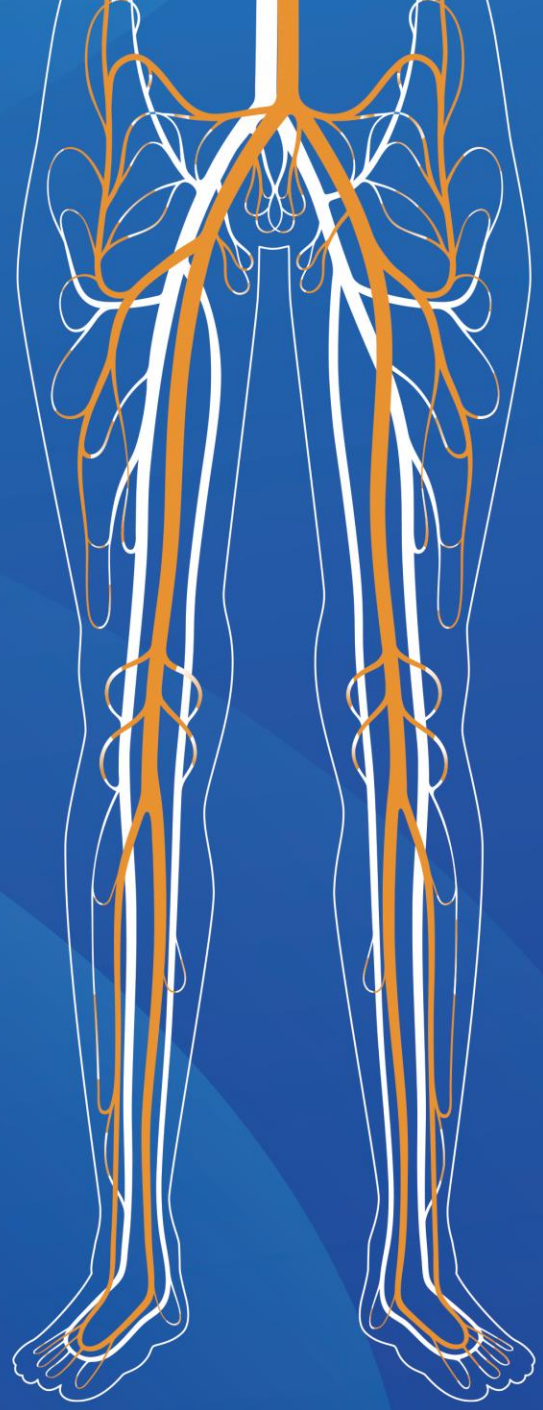
A. Proceed with compression wrap 35-45 mm Hg
B. Proceed with compression 20-25 mm Hg
C. Proceed with very light compression 10-15 mm Hg
D. Compression is contraindicated; refer to vascular specialist

Patient with mixed venous disease, peripheral edema, and PAD. Patient has T2DM. A1c is 7.5, BP is 160/80, and ABI is 0.5. What would you do?

A. Proceed with compression wrap 35-45 mm Hg
B. Proceed with compression 20-25 mm Hg
C. Proceed with very light compression 10-15 mm Hg
D. Compression is contraindicated; refer to vascular specialist

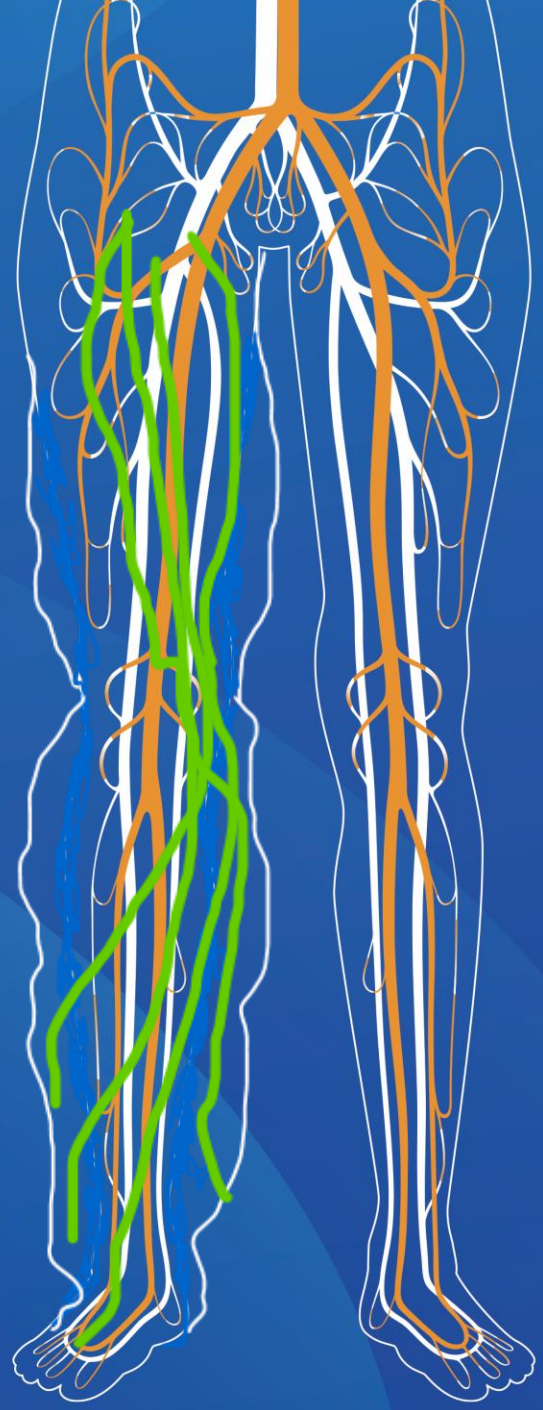
Role of Compression in Lymphedema Management, Prevention of Venous Ulcerations, and Impact on Periwound Skin

Loan Lam, DPM, FAWPHc, FAPWCA, CWSP, CHWS, CLWT
Medical Director of Wound Services,
United Vein and Vascular Centers
Tampa, FL



Lymphedema

- Role of Lymphatics
- Characteristics



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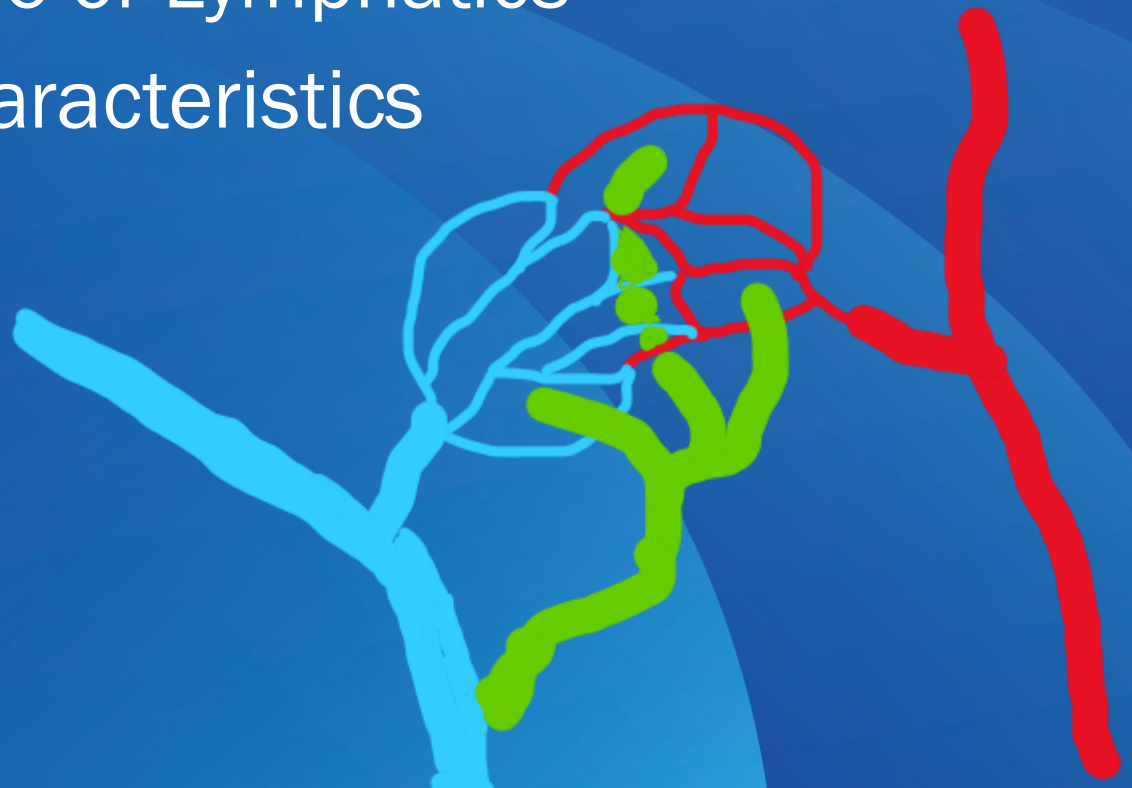
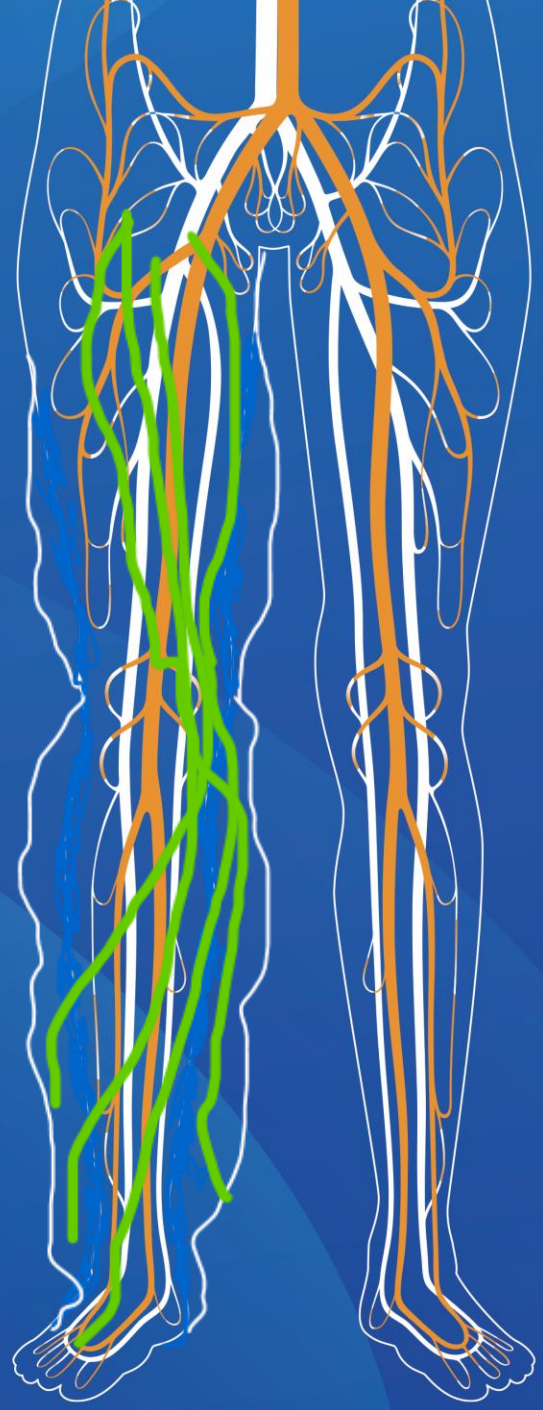
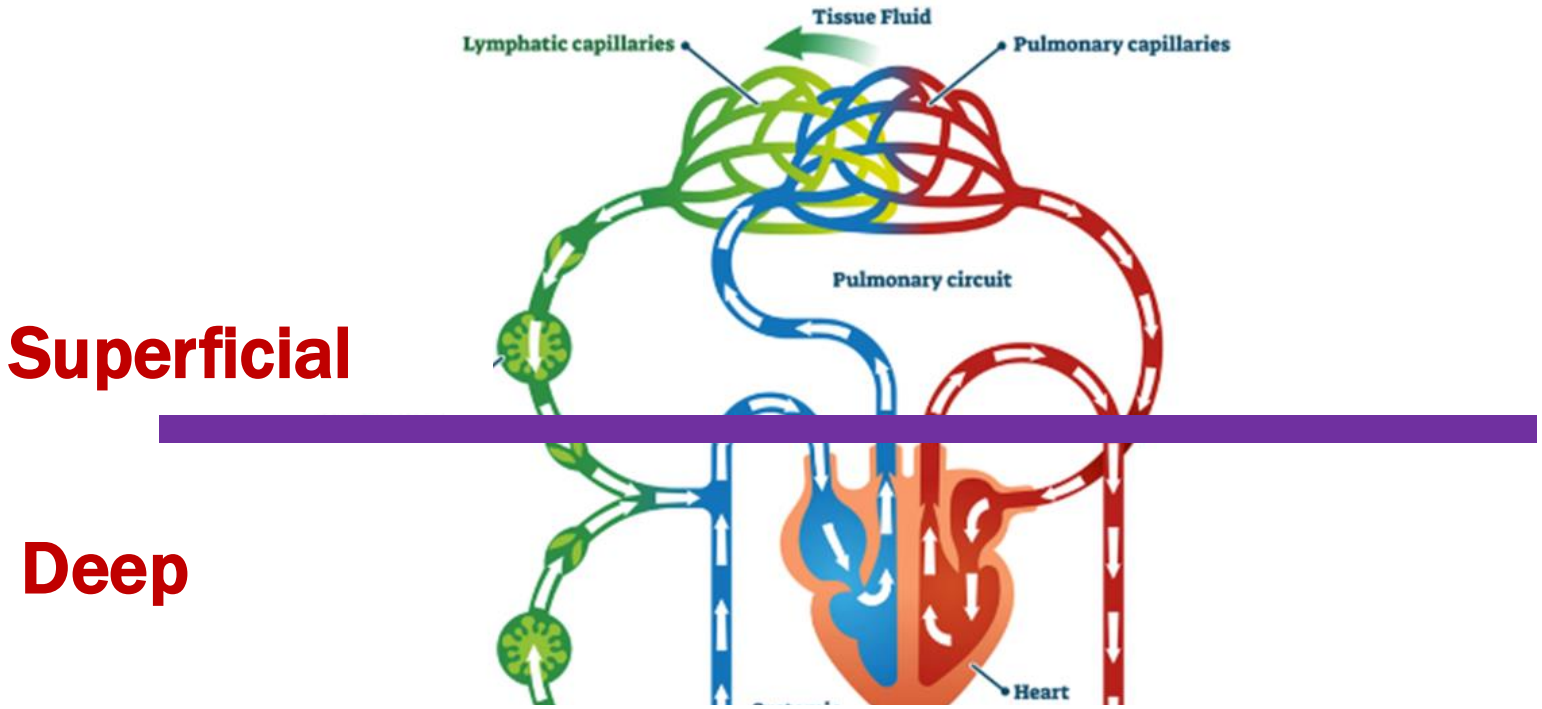




Lymphedema

- Role of the Lymphatic System
  - Removing lymph back into the circulatory system



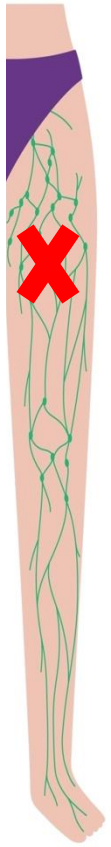
Superficial

Deep

Moore JE Jr, Bertram CD. *Annu Rev Fluid Mech*. 2018;50:459-482.

Lymphedema

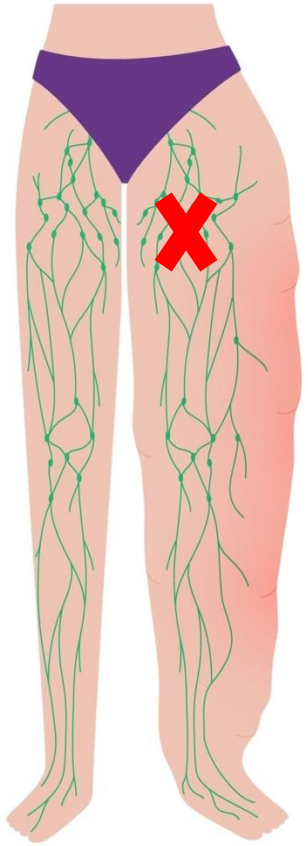
- Role of the Lymphatic System
  - Removing lymph back into the circulatory system
  - Maintaining fluid balance



Moore JE Jr, Bertram CD. *Annu Rev Fluid Mech*. 2018;50:459-482.

Lymphedema

- Role of the Lymphatic System
  - Removing lymph back into the circulatory system
  - Maintaining fluid balance
  - Immune function



Moore JE Jr, Bertram CD. *Annu Rev Fluid Mech*. 2018;50:459-482.

Lymphedema Stages

- **Stage 0 (Latency)**
  - Subclinical changes

National Lymphedema Network. Published Oct 2017. Accessed Sept 21, 2024. https://lymphnet.org/stages-of-lymphedema

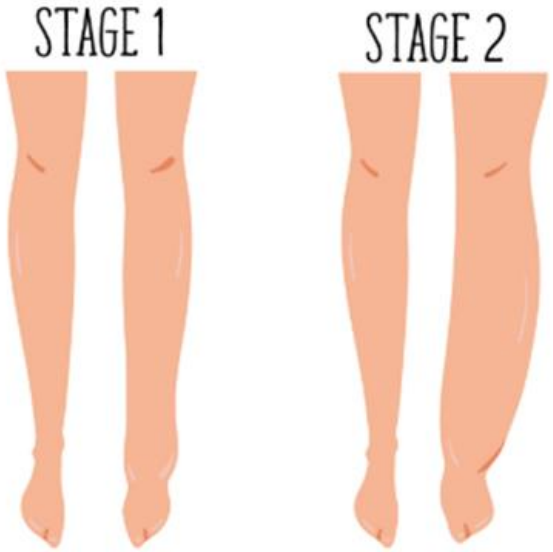
Lymphedema Stages

- **Stage 0 (Latency)**
  - Subclinical changes
- **Stage 1 (Spontaneously Reversible)**
  - Pitting edema, intermittent swelling

National Lymphedema Network. Published Oct 2017. Accessed Sept 21, 2024. https://lymphnet.org/stages-of-lymphedema

Lymphedema Stages

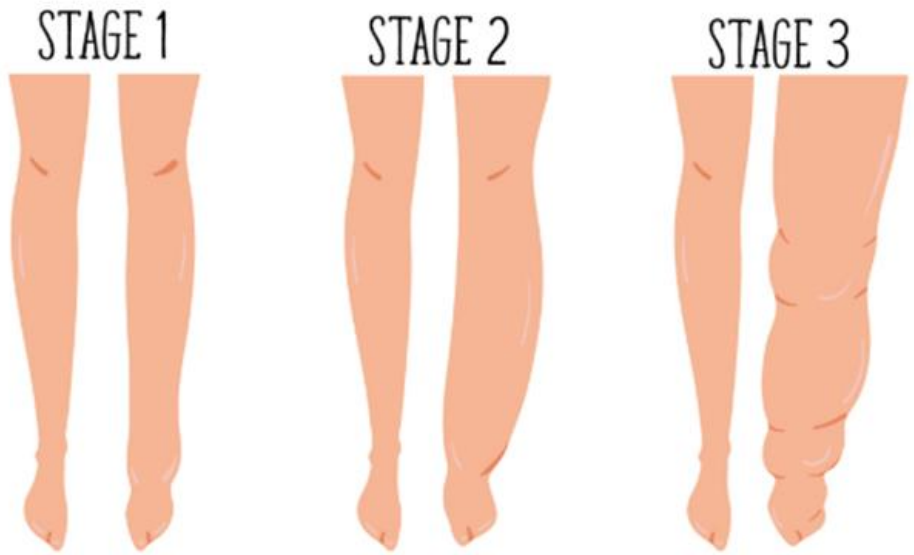
- **Stage 0 (Latency)**
  - Subclinical changes
- **Stage 1 (Spontaneously Reversible)**
  - Pitting edema, intermittent swelling
- **Stage 2 (Spontaneously Irreversible)**
  - Edema not resolving, fibrosis



National Lymphedema Network. Published Oct 2017. Accessed Sept 21, 2024. https://lymphnet.org/stages-of-lymphedema

Lymphedema Stages

- **Stage 0 (Latency)**
  - Subclinical changes
- **Stage 1 (Spontaneously Reversible)**
  - Pitting edema, intermittent swelling
- **Stage 2 (Spontaneously Irreversible)**
  - Edema not resolving, fibrosis
- **Stage 3 (Lymphostatic Elephantiasis)**
  - Fibrotic tissue, skin changes, infections, skin breakdown



National Lymphedema Network. Published Oct 2017. Accessed Sept 21, 2024. https://lymphnet.org/stages-of-lymphedema

Lymphedema

- Swelling
  - Asymmetrical
  - Pitting vs non-pitting
- Skin changes
  - Fibrosis
  - Hyperkeratosis
  - Papilloma
- Lymphorrhea
- Recurrent infections
- Extremity heaviness or tightness
- Limb shape changes
- Stemmer's sign?

Lymphedema:

- A progressive disease leading to a decrease QoL
- Can be manageable
- Delays healing cascade
- Protein rich fluid
- Approx 15 years to be dx

Asymmetrical leg swelling

- Gold standard tx = Complete Decongestive Therapy

Bandaging is a SKILL

Lymphedema Characteristics

- Swelling
  - Asymmetrical
  - Pitting vs non-pitting

Lymphedema Characteristic Skin Changes

- Skin changes
  - Fibrosis
  - Hyperkeratosis
  - Papilloma
  - Lymphorrhea
  - Elephantiasis nostra

Noninvasive Objective Skin Assessment in Lymphedema

- **Skin elasticity.** The skin's resistance to negative pressure (firmness) and its ability to return to its original position (elasticity) measured in real time
- **Skin stiffness.** Measured through sensing the force (Newton, N) against the indurated tissue and can be applied to evaluate the degree of fibrosis of the affected limb
- **Tissue dielectric constant.** The percentage water content of human skin measured at a frequency of 300MHz is directly proportional to skin water content
- **Transepidermal water loss (TEWL).** TEWL [measures as g/(m^2xh)] is a physiological characteristic reflecting epidermal permeability barrier function

TEWL = transepidermal water loss.

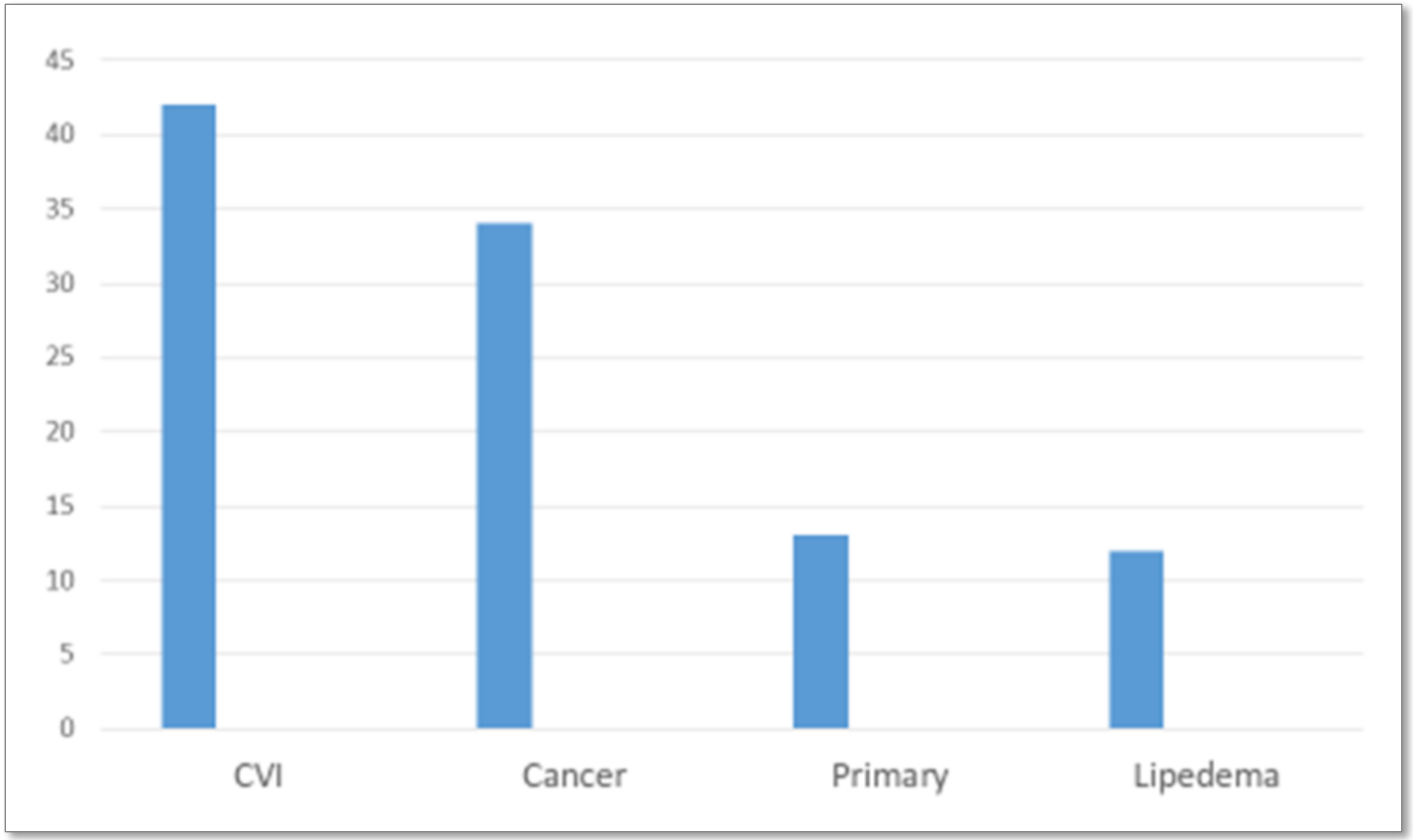
Fujimoto Y, et al. Skin Res Technol. 2024;30(8):e13861. Yu, Ziyou, et al. *Lymph Res Biol.* 18.3 2020;212-218.

Transepidermal Water Loss in Lymphedema

- TEWL is the most widely used objective measurement for assessing the barrier function of skin in healthy individuals and in patients with skin diseases that are associated with skin barrier dysfunction
- TEWL refers to the quantity of condensed water that diffuses across a fixed area of stratum corneum to the skin surface per unit of time
- TEWL values increase significantly in lymphedematous skin, which indicates an impaired skin barrier system due to long-term lymph stasis
  - The compromised skin barrier function may result in increased risks of skin irritation, sensitization, or infection in the affected limb
  - The TEWL ratio tends to increase with disease severity

Alexander H, et al. *J Invest Dermatol.* 2018;138(11):2295-2300.e1. Yu Z, et al. *Lymphat Res Biol.* 2020;18(3):212-218.

Phlebolymphedema: Lymphedema of Venous Etiology



Dean SM, et al. *J Vasc Surg Venous Lymphat Disord*. 2020;8(5):851-859.

The Evidence for Compression Varies by Type

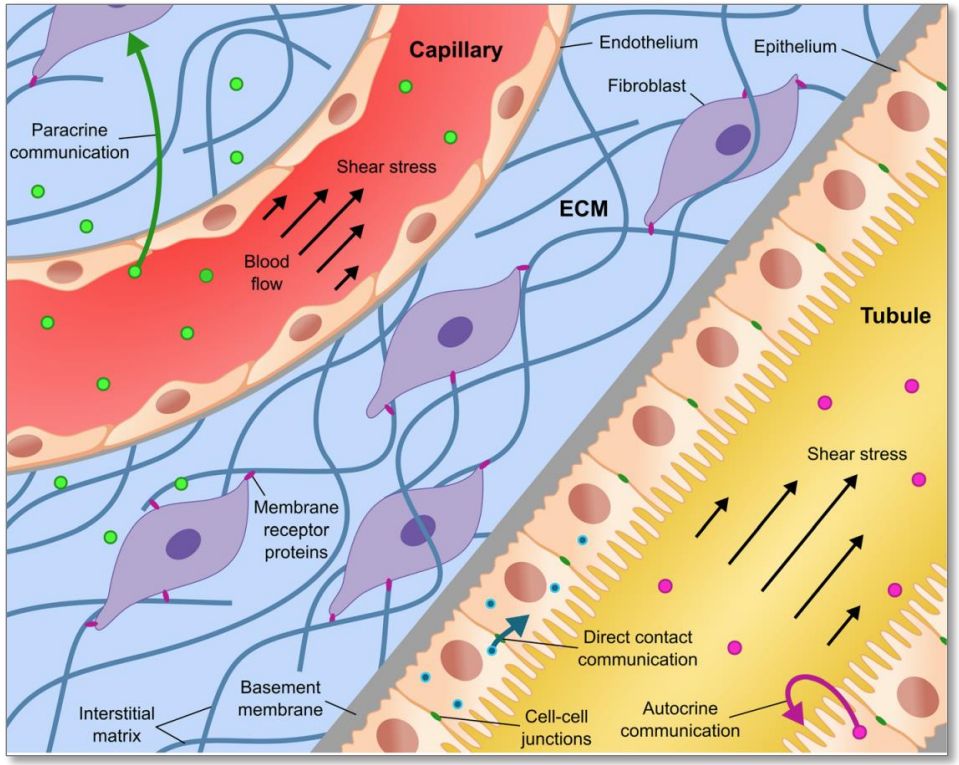
- Some compression is better than none
- Inelastic compression has a significant effect on deep venous hemodynamics compared with elastic compression applications
- Multi-layer compression bandage is more effective than low-compression, single-layer
  - Interface pressure (IP)/dosage (mm Hg) and stiffness are changeable according to combination of materials in a bandage set
  - Inclusion of a cohesive component has been shown to maintain IP longer
  - Inclusion of an elastic component has been shown to have higher IP maintained over a longer period of time
- Compression garment (self-gripping wrap/stockings) stiffness varies *independent* of dosage

IP = interface pressure.

Benigni JP, et al. *Int Angiol.* 2023;42(3):247-253. Ehmann S, et al. *Wound Manag Prev*. 2023:69(2):14-25. Shi C, et al. *Cochrane Database Sys Rev*. 2021;7(7). Vowden KA, Mosti G. *Wounds Int*. 2020. Rabe E, et al. *Phlebology*. 2020;35(7):447-446. Lantis JC, et al. *J Wound Care*. 2020;29(S9):S29-S37. Liu R, et al. *Text Res J*. 2017; 87(9):1121-1141. Franks PJ, et al. *J Wound Care*. 2016;25(Suppl6):S1-S67. Junger M, et al. *J Wound Care*. 2009;18(11):474-480. van der Wegen-Franken CP, et al. *Phlebology*. 2008;23(2):77-84.

Compression Effects

- Vascular
  - Enhances venous, lymphatic, and arterial flow
- Cellular
  - Compression forces mechanically deform tissue
    - Internal – within the vessels – shear forces
    - External – within extracellular matrix (ECM) – shear forces
  - "Outside-in signaling" triggers a change in biochemistry and gene expression impacting cellular processes, such as cellular migration, growth, and differentiation



ECM = extracellular matrix.

Godoy MFG, et al. *Med Sci.* 2021;25(113):1578-1582. Geng X, et al. *Cell Mol Life Sci.* 2021;78(16):5903-5923. Berszakiewicz A, et al. *Postepy Dermatol Alergol.* 2020;37(6):842-847. Raffetto JD, et al. *J Clin Med.* 2020;10(1):1-34. Yeste J, et al. *J Biol Eng.* 2018;12(1)1-18. Nicolaides A, et al. *Int Angiol.* 2018;37(3):181-254. Mosti G, Partsch H. *Eur J Vasc Endovasc Surg.* 2014;47(5):545-549. Liu R, et al. *Adv Ther.* 2008;25(5):465-478. Mayrovitz HN, Larsen PB. *Clin Physiol.* 1997;17(1):105-117.

Compression: More than a Bandage

- Compression bandage applications
  - Reusable
  - Disposable
    - 2-/3-/4-layer sets
    - Impregnated sets
- Compression garments
  - Adjustable self-gripping wraps
  - “Stockings”

Match the patient’s presentation:

- Treatment vs maintenance
- Tissue texture
- Coexisting comorbidities
- Patient’s ability

Textile Composition Matters

- # layer of layers *does not* define a bandage system
- Study found significant differences in 2-layer compression bandage set at the time of application
  - IP or dosage (mm Hg)
  - SSI

There is *no way to know* how much IP or static stiffness index (SSI) is applied with a homemade bandage system

Table 6. Post hoc analysis of the in vivo IP measured at B1 (supine) (20 observations for each wrap)

IP B1—Supine			Bonferroni Grouping
Wrap	Average	SD	
1	73.70	13.44	A
7	66.40	6.06	B
5	61.70	10.55	C
4	58.40	8.68	D
3	52.75	7.59	E
6	51.65	7.11	
2	50.10	5.33	

Table 8. In vivo SSI at B1 (20 observations for each wrap)

SSI Measured at B1				Bonferroni Grouping
Wrap	Average	SD	Observations	
1	11.95	5.36	19	A
4	11.45	5.44	20	
7	9.00	4.55	19	B
3	8.30	4.55	20	
6	7.45	4.15	20	C
2	7.00	3.63	20	
5	6.65	4.36	20	

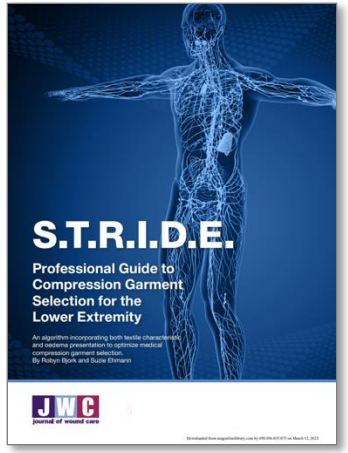
SSI = static stiffness index.

Ehmann S, et al. *Wound Manage Prev*. 2023;69(2):14-25.

What are the best compression garments recommended for lymphedema patients?

A. Stiff circular knit
B. Flat knit
C. Multi-layer
D. Night
E. Decongestative
F. All of the above

Lower Extremity Compression Garment Options

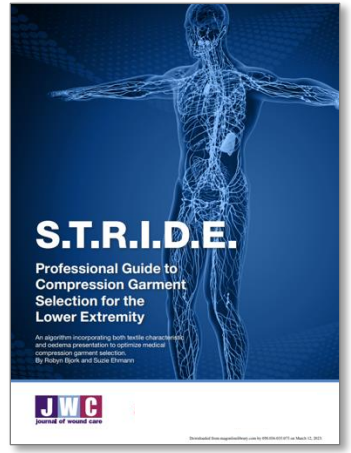


Garment Categories

- Circular knit
- Stiffer circular knit
- Flat knit
- Wraps
- Night
- Decongestive

Bjork R, Ehmann S. *J Wound Care.* 2019;28(S6a):1-44.

Compression Garments: More than Dosage



Maintenance Phase
or
STABLE Volume

Decongestive and/or UNSTABLE Volume

Decongestive UNSTABLE Volume

Garment categories

Circular knit	Stiffer circular knit	Flat knit	Adjustable wraps	Night	Decongestive
Light	Light	L = Light	Light	Light	Light
Regular	Regular	R = Regular	Regular	Regular	Regular
Firm	Firm	Firm	Firm	Firm	Firm

Mild Edema
No/Mild Skin Changes
Normal Tissue Composition

Limb Reduced
Moderate to Significant
Skin Changes

Wound
Fragile Skin
Difficulty Donning Garment

Lower → Higher

Stiffness

Bjork R, Ehmann S. *J Wound Care.* 2019;28(S6a):1-44.

Clinical Skin Improvement with Appropriate Compression

- 55y Hispanic male, NIDDM, with painful, itching, recurrent stasis dermatitis and lymphorrhea x5 yrs

Wk 1 Wk 4

Wk 1 Wk 4

NIDDM = non-insulin-dependent diabetes mellitus.

Clinical Skin Improvement with Appropriate Compression

- 78y White female, NIDDM, lymphedema, recurrent venous stasis wound x3 yrs

Wk 1

Wk 3

Clinical Pearls

- Every venous ulcer patient has some level of secondary lymphedema – for optimal healing and prevention of recurrence, both underlying diseases need to be addressed
- There is a fallacy that damaged, hyperkeratotic skin is “too hard” to respond to compression therapy when, in fact, compression helps with re-texturing skin
- Think of prescribing compression as prescribing a medication – textile type, dosage, and timing matter
- Custom compression is available; meet the patient’s compression needs at each stage of their journey

The Fourth “C”

Heather Barnhart, PT, PhD, CWS, CLT-LANA, CLWT
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Learning Objective

To understand how compression can influence microcirculation and integumentary health, let's set the stage by discussing the concept of lymphostatic dermopathy and the interconnection of the VAIL systems.

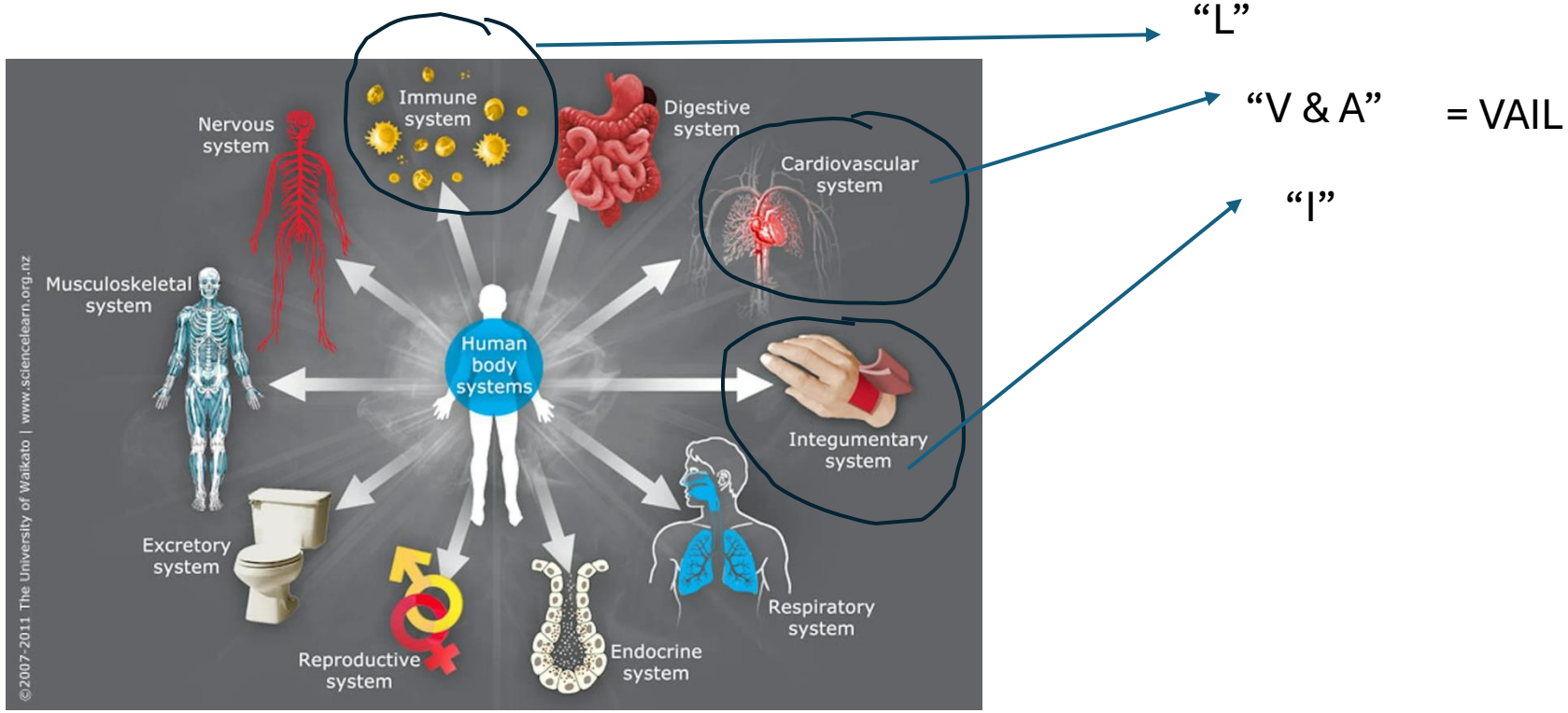


Image: https://www.sciencelearn.org.nz/resources/1885-body-systems

Key: Lymphatic System (LS) Helps Keep Edema from Forming

Dynamic insufficiency

Mechanical insufficiency

Continuum

Edema → *symptom*

System is overwhelmed but not damaged

Disruption in the EGL

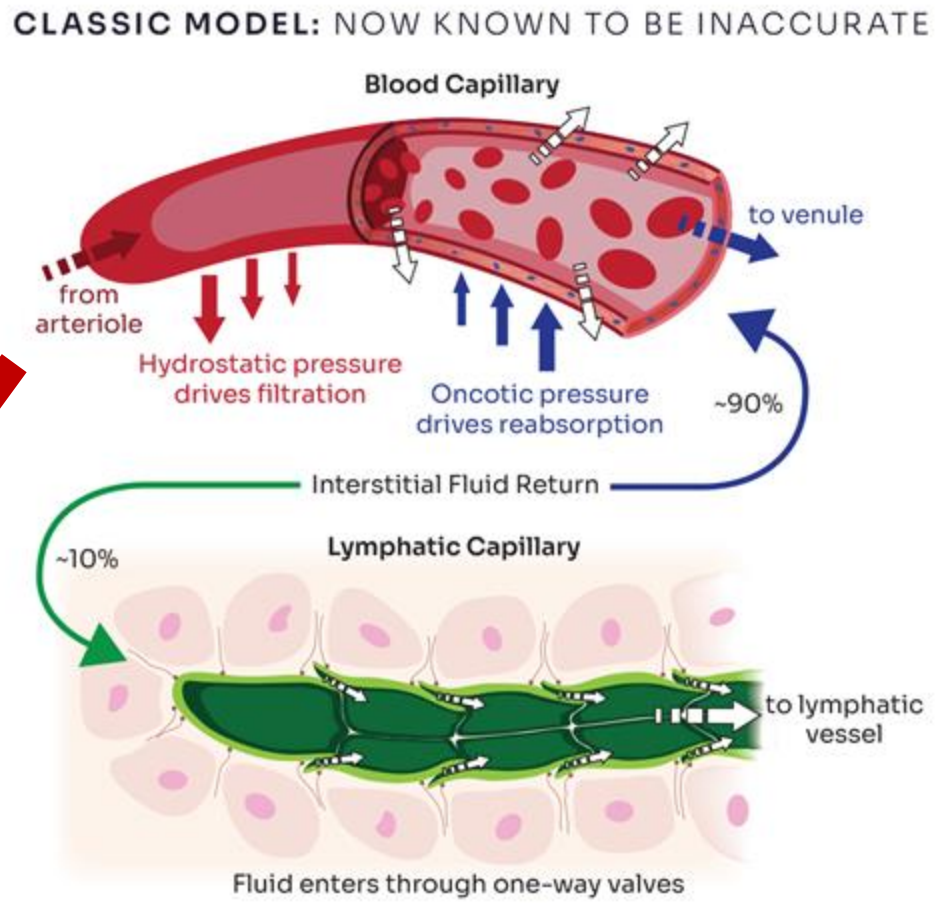
Lymphedema → *disease*

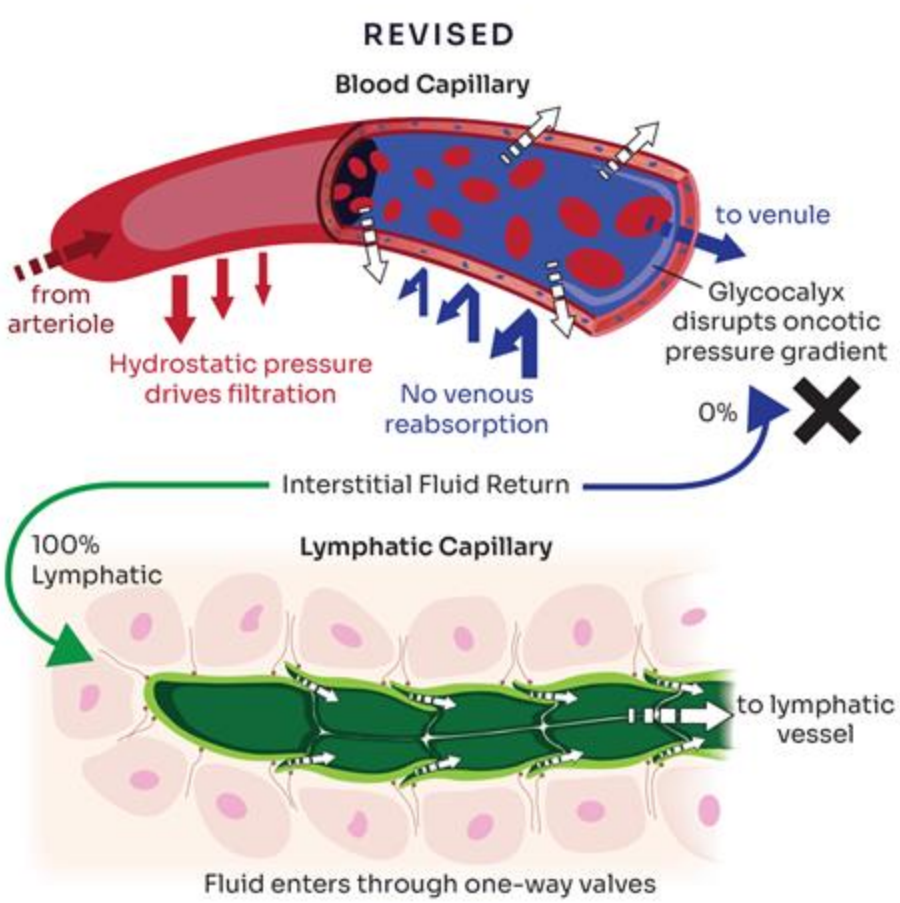
System is damaged or diseased
Currently no cure

Fluid imbalance = Edema =
Accumulation of lymph fluid in tissues

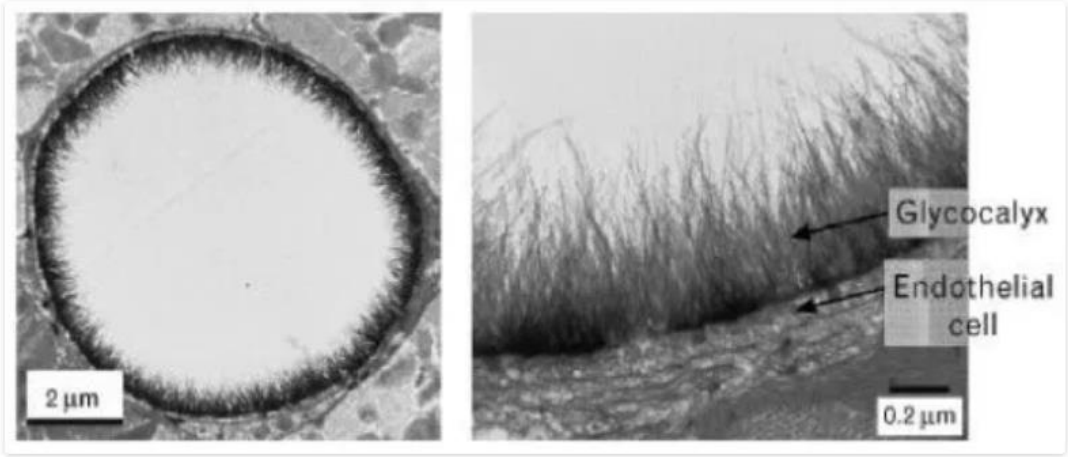
Lymph and the Microcirculation

Lymph is formed when blood plasma passes through capillary walls at the arteriole end





Starlings' Law Redefined



Reprinted with permission from Biddle, C., 2013. Like a slippery fish, a little slime is a good thing: the glycocalyx revealed. *AANA journal*, *81*(6).

Endothelial Glycocalyx Layer (EGL): gel-like matrix with hair-like projections extending into the lumen of blood vessels; acts as a molecular sieve regulating fluid and macromolecule movement

There is only a diminishing net filtration across the capillary bed

Blood flow shear forces act on the endothelial cells (mechanotransduction), which respond to the mechanical signals, producing and releasing nitric oxide, which dilates the vessel

What Constitutes Lymph?

The fluid that causes edema is lymph. When the LS picks up lymph, it is called a lymphatic load. The LS transports the load to regional lymph nodes, where adaptive immunity is initiated and where the fluid is cleansed.

Lymph is made up of

- ✓ All fluid
- ✓ 50%+ of blood plasma proteins
- ✓ Lipids
- ✓ Byproducts of tissue/wound healing
- ✓ Dead and senescent cells
- ✓ Cancer cells
- ✓ Enzymes/MMPs
- ✓ Bacteria
- ✓ Endotoxins
- ✓ Perfumes, dyes
- ✓ Pollutants

Lymph can be caustic to the skin; lymphorrhea (lymphatic drainage through the skin) can lead to denudement/chemical-like burn of the skin. It can occur with fluid stagnation or lymphostasis when the system is impaired.

Imagine what happens when this does not get properly filtered and cleansed

Lymphatic System

A healthy, functional lymphatic system is like a clean, flowing river

(no stagnation)

Lymphatic System

However,

Disease Progression…the Lymphedema Continuum

All the substances that make up lymph
become stagnant and congested when the system is disrupted

Edema vs Lymphedema
All Edema Is Lymphatic Fluid = Lymphedema Continuum

- **Edema** is the abnormal, excess accumulation of serous fluid in connective tissue that temporarily overwhelms the lymphatic system (lymphatic insufficiency) but does not cause permanent damage
- **Lymphedema** is an accumulation of protein-rich fluid in an extremity or body part as a result of damage or loss (lymphatic impairment) to part of the lymphatic vessel system

Low-protein edema = transient
Watery consistency

Protein-rich edema = progressive/permanent
Viscous (like honey in a plastic bag)

Another Way to Look at It

Lymphatics temporarily overwhelmed

Lymphatic transport capacity

Injuries
Post-op edema
CHF

Overwhelmed … most edemas
(30+ medical causes of edema)
temporary lymphedema

Lymphatics permanently impaired or damaged

Permanently damaged …
the **disease** of lymphedema

If It's Just Swelling, Why Does This Happen to the Skin? Let's Discuss the VAIL...

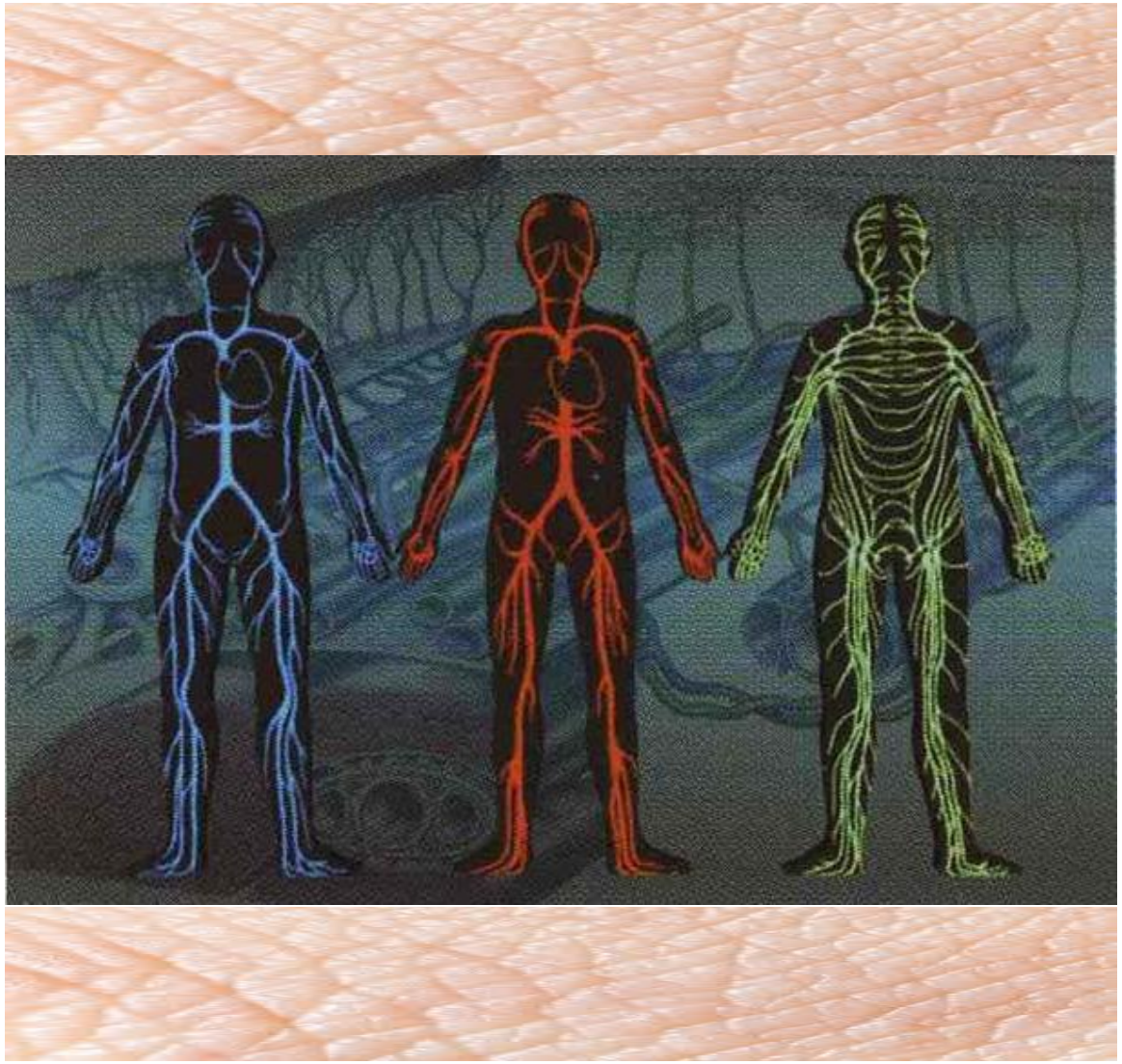
Origin of the VAIL Concept

The venous, arterial, integumentary, and lymphatic systems (think VAIL) are interrelated.

Anatomically, physiologically, and biochemically, these systems work in unison to maintain homeostasis.

Dysfunction in one system will lead to dysfunction in the other systems, and this may manifest sub-clinically or be overt.

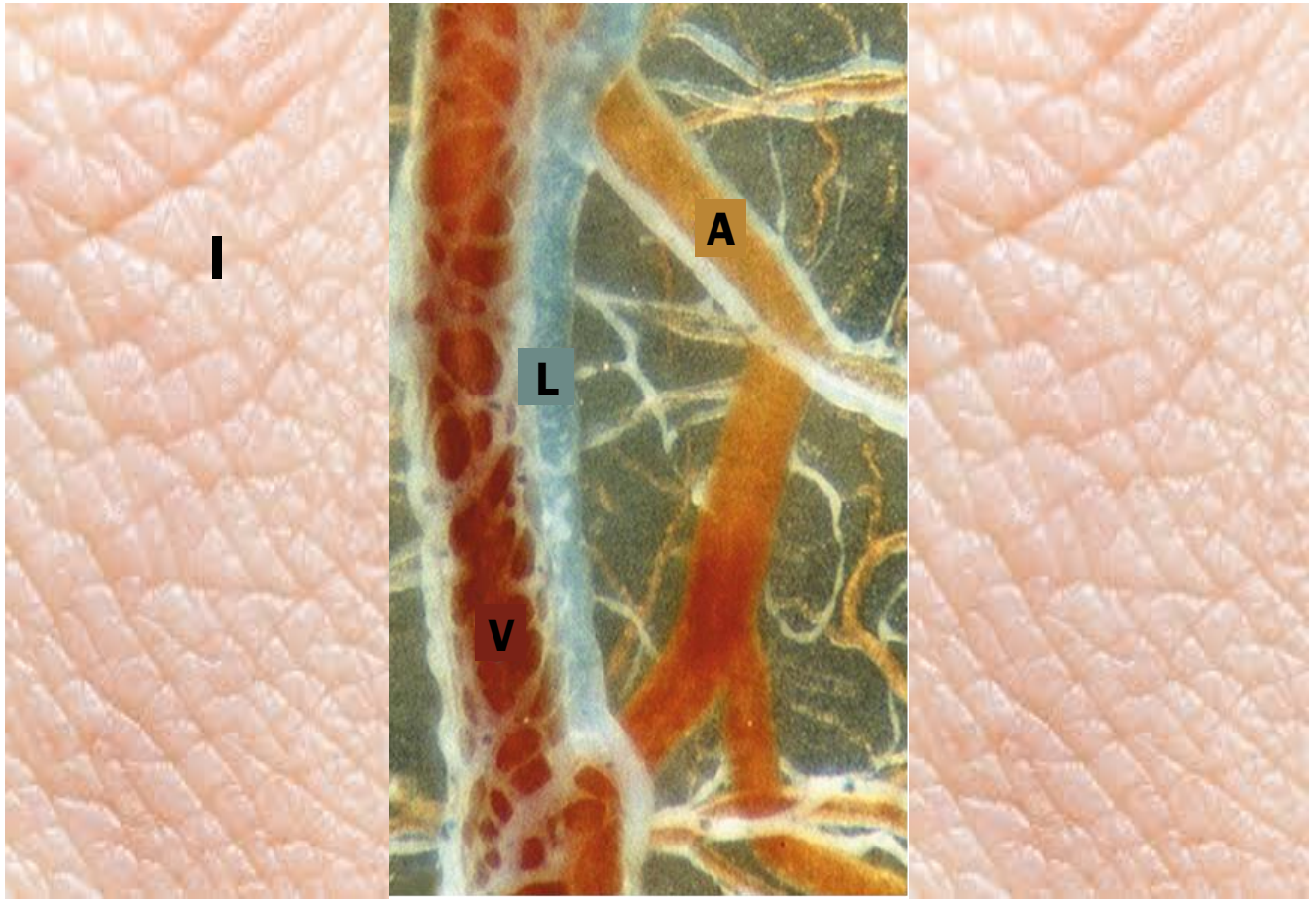
-Dr. Heather Barnhart



VAIL = venous, arterial, integumentary, and lymphatic.

VAIL Interrelationship

V = vein
A = artery
I = integument
L = lymph vessels



VAIL: Interconnected Systems

- ***Decongesting and maintaining interstitial fluid mitigates and prevents deleterious effects of stagnant fluid on tissue and skin***
- ***Chronic lymph stasis (lymphostasis) has numerous consequences***, including inflammation, lipogenesis, fibrosis, and immunosuppression
- Lymphostasis leads to the accumulation of antigens, foreign material, and immune complexes in the interstitial space, which leads to ***chronic localized inflammation***
- This can ***manifest on the skin*** as disruption of immune cell trafficking leading to localized immune suppression, predisposing the area affected to chronic inflammation, connective tissue proliferation, infection, and malignancy
- In essence, it ***disrupts the skin's barrier function***

Carlson JA. *Clin Dermatol*. 2014;32(5):599-615. Finegold DN, et al. *Lymphat Res Biol*. 2008;6(2):65-68.

VAIL: Interconnected Systems

- The venous and lymphatic systems are mutually interdependent; when dysfunctional, the result is a ***dual outflow system failure*** → tri-system failure with integumentary impairments (VLUs, dermatitis, etc.)
- ***Disorders of the lymph system*** – whether systemic (macro-lymphedema) or localized (micro-lymphedema) – ***produce cutaneous regions susceptible to infection, inflammation, and carcinogenesis*** (lymphostatic dermopathy = skin barrier failure; tri-system failure)
- The ***pathophysiology of lymphedema explains the propensity for infections*** (cellulitis) and ***hypersensitivity*** reactions in ***patients with CVI*** (lymphostatic dermopathy)
- A functional lymphatic system is essential to an organism's overall health given its role in fluid homeostasis, removal of cellular debris, and mediating immunity and inflammation
- ***Lymph stasis (lymphostasis) is problematic → it induces a chronic inflammatory state***

Carlson JA. *Clin Dermatol*. 2014;32(5):599-615. Finegold DN, et al. *Lymphat Res Biol*. 2008;6(2):65-68.

Lymph Stasis = Chronic Inflammatory State

...stagnating lymphatic load/lymph results in a pathohistological state of chronic inflammation resulting in fibrotic changes, thickening, and connective tissue proliferation...

"Oxidation and degradation of interstitial proteins attract monocytes that change into macrophages. Macrophages ingest the proteins and activate fibroblasts that, in turn, form collagen, resulting in connective tissue proliferation." Also triggers adipocytes, leading to fatty tissue proliferation.

Skin changes = visual biomarker of lymphostasis

The body's plumbing and recycling are backed up; this affects the skin's barrier function negatively

VAIL: Interconnected Systems

- Clinically, fibrosis, papillomatosis, stasis dermatitis, and classic venous and lymphatic skin changes are seen
- ***Chronic inflammation*** also attenuates (reduces) lymphatic contraction, ***hindering lymphatic flow*** to the lymph node
- Hemosiderin, classic with CVI, also suppresses lymphatic contractility

- To trigger an effective immune response, antigen and antigen-presenting cells must travel to the lymph node; thus, lymphostasis disrupts cell-mediated (adaptive) immunity by decreasing or obstructing immune trafficking by antigen, lymphocytes, macrophages, and dendritic/antigen-presenting cells to the lymph node, creating a ***cutaneous region of immunosuppression***
- All of these abnormalities lead to a condition termed ***lymphostatic dermopathy***, which is ***failure of the skin as an immune organ***

Carlson JA. *Clin Dermatol*. 2014;32(5):599-615. Finegold DN, et al. *Lymphat Res Biol*. 2008;6(2):65-68. Wandolo G, et al. *J Vasc Res*. 1992;29(3):248-255.

Lymphostatic dermopathy leads to:

A. Failure of the skin as an immune organ
B. The disease of lymphedema
C. Dystrophic nails
D. Rapid skin aging

VAIL: Interconnected Systems

- Lymphostatic dermopathy, in part, explains the propensity of skin infections and VLUs in people with CVI
- Therefore, it is imperative to reduce and manage the fluid burden to optimize venous and lymphatic function while simultaneously facilitating wound resolution and tissue remodeling
  - Reducing the fluid burden and diffusion distance also supports better perfusion by optimizing arterial inflow
  - Compression over time restores the skin barrier function and reverses the effects of lymphostatic dermopathy
  - ***Compression is the cornerstone intervention for all forms of edema and is essential for managing venous/lymphatic impairment***
    - ***It also helps with remodeling the skin***

Think: Drain and Maintain!

Compression Is Cornerstone: Drain and Maintain

- It has been well established that externally applied compression aids in providing support to the venous system by approximating the valves to reduce venous backflow and promote blood flow toward the heart
- Additionally, compression provides necessary containment of interstitial fluid to prevent and reduce edema formation resulting from an overburdened superficial lymphatic system
- **When compression is properly applied, it has been shown to reduce edema, normalize venous function, optimize healing of VLUs, improve lymphatic function, enhance arterial pulse width, diminish episodes of recurrent cellulitis, promote resolution of trophic changes, decrease the presence of inflammatory mediators and symptoms, and reduce pain**

Stout N, et al. *Int Angiol*. 2012;31(4):316-329. Gianesini S, et al. *Phlebology*. 2019;34(1 Suppl):4-66. Shi C, et al. *Cochrane Database Syst Rev*. 2021;7(7):Cd013397. Dissemond J, et al. *J Dtsch Dermatol Ges*. 2016;14(11):1072-1087. Kitayama S, et al. *Lymphat Res Biol*. 2017;15(1):77-86. Mukherjee A, et al. *J Physiol*. 2021;599(10):2699-2721. Negrini D, Moriondo A. *J Physiol*. 2011;589(Pt 12):2927-2934. Schmid-Schönbein GW. *Lymphat Res Biol*. 2003;1(1):25-29. McGeown JG, et al. *J Physiol*. 1987;387:83-93. Mosti G, Cavezzi A. *Phlebology*. 2019;34(8):515-522. Mosti G. *Phlebology*. 2014;29(1 suppl):13-17. Mayrovitz HN, Macdonald JM. *Int Angiol*. 2010;29(5):436-441. Mayrovitz HN, Larsen PB. *Clin Physiol*. 1997;17(1):105-117. O'Meara S, et al. *Cochrane Database Syst Rev*. 2012;11(11):CD000265. Partsch H. *J Wound Care*. 2019;28(7):427. White-Chu EF, Conner-Kerr TA. *J Multidiscip Healthc*. 2014;7:111-117. Beidler SK, et al. *J Vasc Surg*. 2009;49(4):1013-1020. Beidler SK, et al. *Wound Repair Regen*. 2008;16(5):642-648. Bojesen S, et al. *Eur J Dermatol*. 2019;29(4):396-400. Travis TE, et al. *Eplasty*. 2018;18:e1. Webb E, et al. *N Engl J Med*. 2020;383(7):630-639. Ebell MH. *Am Fam Physician*. 2021;103(4):247. Lerman M, et al. *J Vasc Surg*. 2019;69(2):571-580. Rabe E, et al. *Phlebology*. 2020;35(7):447-460. Kerr A, et al. *Wounds International*. 2020;10:4-32.

Compression Is Cornerstone

- **Compression increases ulcer healing** rates compared with no compression
- **Multi-component systems are more effective** than single-component systems
- Multi-component **systems containing an elastic bandage appear to be more effective** than those composed mainly of inelastic constituents
- 2-component bandage systems appear to perform as well as 4-layer bandage (4LB)
- Patients receiving the 4LB heal faster than those allocated the short stretch bandage (SSB)

SVS | Society for Vascular Surgery

THE GOLD STANDARD

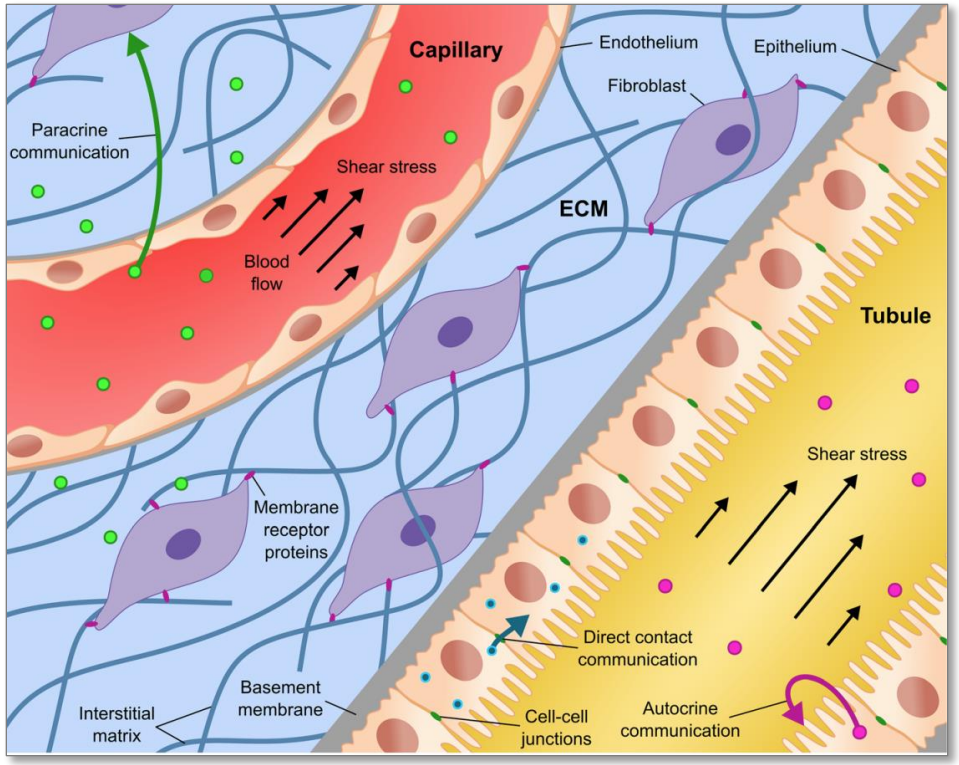
Cochrane

SSB = short stretch bandage.

O'Meara S, et al. *Cochrane Database Syst Rev*. 2012;11(11):CD000265.

Compression Effects

- Vascular
  - Enhances venous, lymphatic, and arterial flow
- Cellular
  - Compression forces mechanically deform tissue
    - Internal – within the vessels – shear forces
    - External – within extracellular matrix (ECM) – shear forces
  - "Outside-in signaling" triggers a change in biochemistry and gene expression impacting cellular processes, such as cellular migration, growth, and differentiation



Let's look at some visual examples of compression effects

ECM = extracellular matrix.

Godoy MFG, et al. *Med Sci.* 2021;25(113):1578-1582. Geng X, et al. *Cell Mol Life Sci.* 2021;78(16):5903-5923. Berszakiewicz A, et al. *Postepy Dermatol Alergol.* 2020;37(6):842-847. Raffetto JD, et al. *J Clin Med.* 2020;10(1):1-34. Yeste J, et al. *J Biol Eng.* 2018;12(1)1-18. Nicolaides A, et al. *Int Angiol.* 2018;37(3):181-254. Mosti G, Partsch H. *Eur J Vasc Endovasc Surg.* 2014;47(5):545-549. Liu R, et al. *Adv Ther.* 2008;25(5):465-478. Mayrovitz HN, Larsen PB. *Clin Physiol.* 1997;17(1):105-117.

Dual Compression Therapy Case Examples

- Before and after 8 wks of dual compression – focus on venous dermatitis

Yvette Mier BSN, RN, CWON, Marietta GA. Poster: Rapid Resolution of Venous Dermatitis Using Dual Compression Therapy: A Case Series.

Dual Compression Therapy Case Examples

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Dual Compression Therapy Case Examples

- Before and after 8 wks of dual compression – focus on venous dermatitis

Yvette Mier BSN, RN, CWON, Marietta GA. Poster: Rapid Resolution of Venous Dermatitis Using Dual Compression Therapy: A Case Series

Foundational Data: The 3 Cs

Comfortable

journal of wound care JWC

VOLUME 16. NUMBER 9. OCTOBER 2007

Efficacy, safety and acceptability of a new two-layer bandage system for venous leg ulcers

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THIS ARTICLE IS REPRINTED FROM JOURNAL OF WOUND CARE VOL 16, NO 9, OCTOBER 2007

Consistent

A comparison of interface pressures of three compression bandage systems

Richard Hanna, Serge Bohbot, Nicki Connolly

Abstract

Objective: To measure and compare the interface pressures achieved with two compression bandage systems – a four-layer system (4LB) and a two-layer short-stretch system (SSB) – with a new two-layer system (2LB), which uses an etalonnage (performance indicator) to help achieve the correct therapeutic pressure for healing venous leg ulcers – recommended as 40 mmHg. *Method:* 32 nurses with experience of using compression bandages applied each of the three systems to a healthy female volunteer in a sitting position. The interface pressures and time taken to apply the systems were measured. A questionnaire regarding the concept of the new system and its application in comparison to the existing two systems was then completed by the nurses. *Results:* The interface pressures achieved show that many nurses applied very high pressures with the 4LB (25% achieving pressures >50 mmHg) whereas the majority of the nurses (75%) achieved a pressure of <30 mmHg when using the SSB. A pressure of 30–50 mmHg was achieved with the new 2LB. The SSB took the least time to be applied (mean: 1 minute 30 seconds) with the 4LB the slowest (mean: 3 minutes 46 seconds). A mean time of 2 minutes 35 seconds was taken to apply the 2LB. Over 63% of the nurses felt the 2LB was very easy to apply. *Conclusion:* These results suggest that the 2LB achieves the required therapeutic pressure necessary for the management of venous leg ulcers, is easy to apply and may provide a suitable alternative to other multi-layer bandage systems.

Key words: Bandage • Compression • Interface pressure • Tissue viability • Venous leg ulcer

Continuous

research

Comparison of interface pressures of three compression bandaging systems used on healthy volunteers

- **Objective:** To compare changes in interface pressures of three compression systems (four layer, two layer and short stretch) recorded over seven days in healthy volunteers in different positions: supine, sitting, active standing and working pressure during exercise.
- **Method:** Twenty-four volunteers were bandaged with one of the three compression systems on both legs. Interface pressures were measured at inclusion (day 0) and on days 1, 3 and 7 using an air sensor system, with the sensor placed in the medial B1 position above the inner ankle. In addition, the volume of the lower legs were also measured on days 0 and 7 using a three-dimensional imaging system. Comfort and tolerability were also assessed.
- **Results:** The performance, based on the loss of interface pressure compared with baseline, of the two-layer system was partially better than that of the short-stretch system for maximal working pressure and loss of volume. The two-layer system and short-stretch system had similar results for the supine, sitting and active standing positions. No difference was observed between the two-layer system and the four-layer system for the maximal working pressure. However, the two-layer system compared better than the two other systems for comfort and tolerability: 25% of the patients treated with the four-layer system discontinued the treatment after three days because of pain.
- **Conclusion:** The two-layer bandage system maintained, over one week, a similar level of sub-bandage pressure similar to a four-layer system and was partially better than short-stretch bandaging. However, the volunteers found the two-layer system more comfortable and tolerable than the other two systems.
- **Declaration of interest:** The investigators received an education grant from Urgo for the study. However, Urgo had no influence on the data analysis or interpretation.

compression therapy; two-layer bandaging system; comfort; tolerance

Efficacy

journal of wound care JWC

VOLUME 21. NUMBER 11. NOVEMBER 2012

Efficacy of two compression systems in the management of VLUs: results of a European RCT

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THIS ARTICLE IS REPRINTED FROM THE JOURNAL OF WOUND CARE VOL 21, NO 11, NOVEMBER 2012

Begnini

- 95% of patients prefer 2LB in the day
- 92% of patients prefer 2LB at night

Hanna

- 85% of nurses applied 2LB in therapeutic range in their first application

Junger

- 2LB maintained therapeutic compression for 7 days in supine, sitting, and working positions

Odyssey

- 186 patient RCT proving 2LB is non-inferior to 4LB

HANNA STUDY: Evaluation of the level of interface pressure applied by compression systems

HANNA STUDY

Objective

Evaluation of the level of interface pressure applied by compression systems on a lower limb by a group of healthcare professionals

- Two-layer bandage compression system (**2LB**)
- Four-layer compression bandage system (**4LB**)
- Two-layer short-stretch compression bandage system (**SSB**)

Design

32 nurses from 4 different areas in England with regular experience in leg ulcer compression bandage systems

Each nurse applied the 3 systems to the same healthy female volunteer in a sitting position

Endpoints

- Evaluation of the level of interface pressure applied by the 3 compression systems
- Measure of the time taken to apply the bandages
- Assess the acceptability of the 3 systems

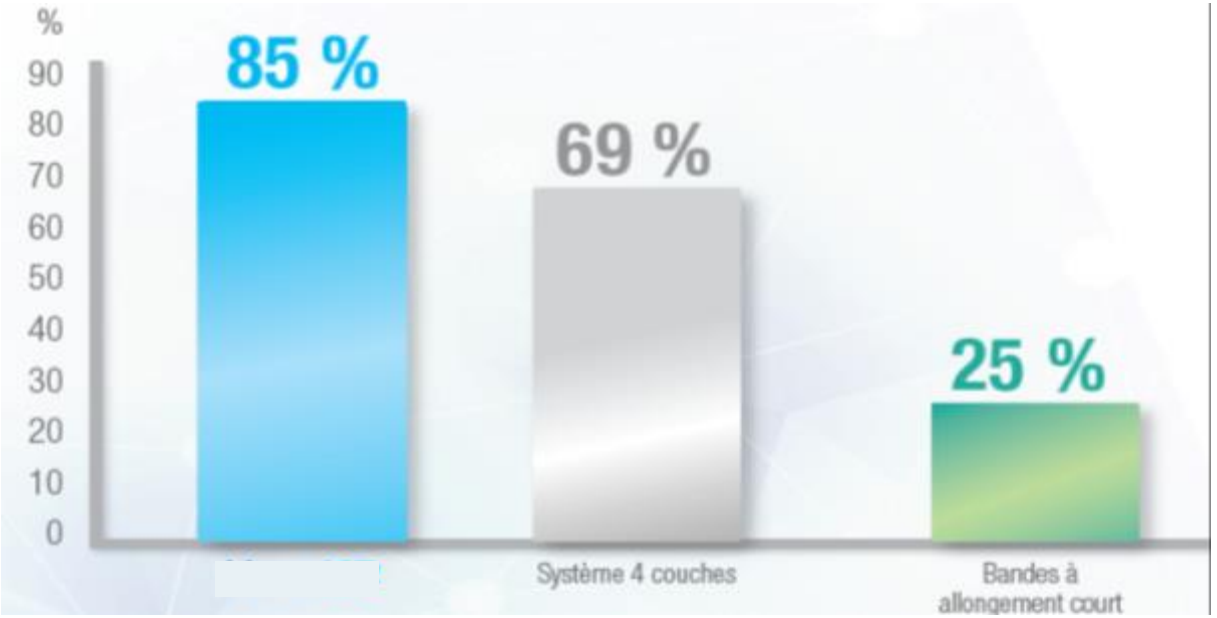
Hanna R, et al. *Br J Nurs.* 2008;17(20):Tissue Viability Suppl.

HANNA STUDY: With 2LB, nurses achieve the gold standard pressure (~40 mm Hg) from the 1st application

HANNA STUDY

- Product evaluation
- 32 nurses
- 3 compression systems
- Evaluation of
  - Level of pressure
  - Time to apply
  - Acceptability

% of nurses achieving recommended therapeutic pressure (30-50 mm Hg)



- 85% of nurses achieve therapeutic pressure from the first application with 2LB with no prior experience
- SSB achieves sub-therapeutic pressures
- 4LB delivers high pressure, which can be uncomfortable and lead to skin damage

HANNA STUDY: 2LB is easier to use and more comfortable

HANNA STUDY

	2LB	4LB	SSB
Ease of use	63%	47%	22%
Lower bulk	72%	3%	47%
Comfort	69%	13%	31%
Best compliance expected	63%	13%	31%
Best holding position expected	56%	56%	25%
Average time of application	2.30 min	3.46 min	1.50 min

- 88% of the nurses judged 2LB to be overall better than the 4LB and SSB systems
- On a scale of 1-10, 2LB scored best for its ease of application, low bulk, comfort, and anticipated patient concordance
- 97% of the nurses found the pressure spot indicators system useful or very useful

JUNGER STUDY: Comparison of the interface pressures and acceptability of 3 compression systems over a period of 7 days

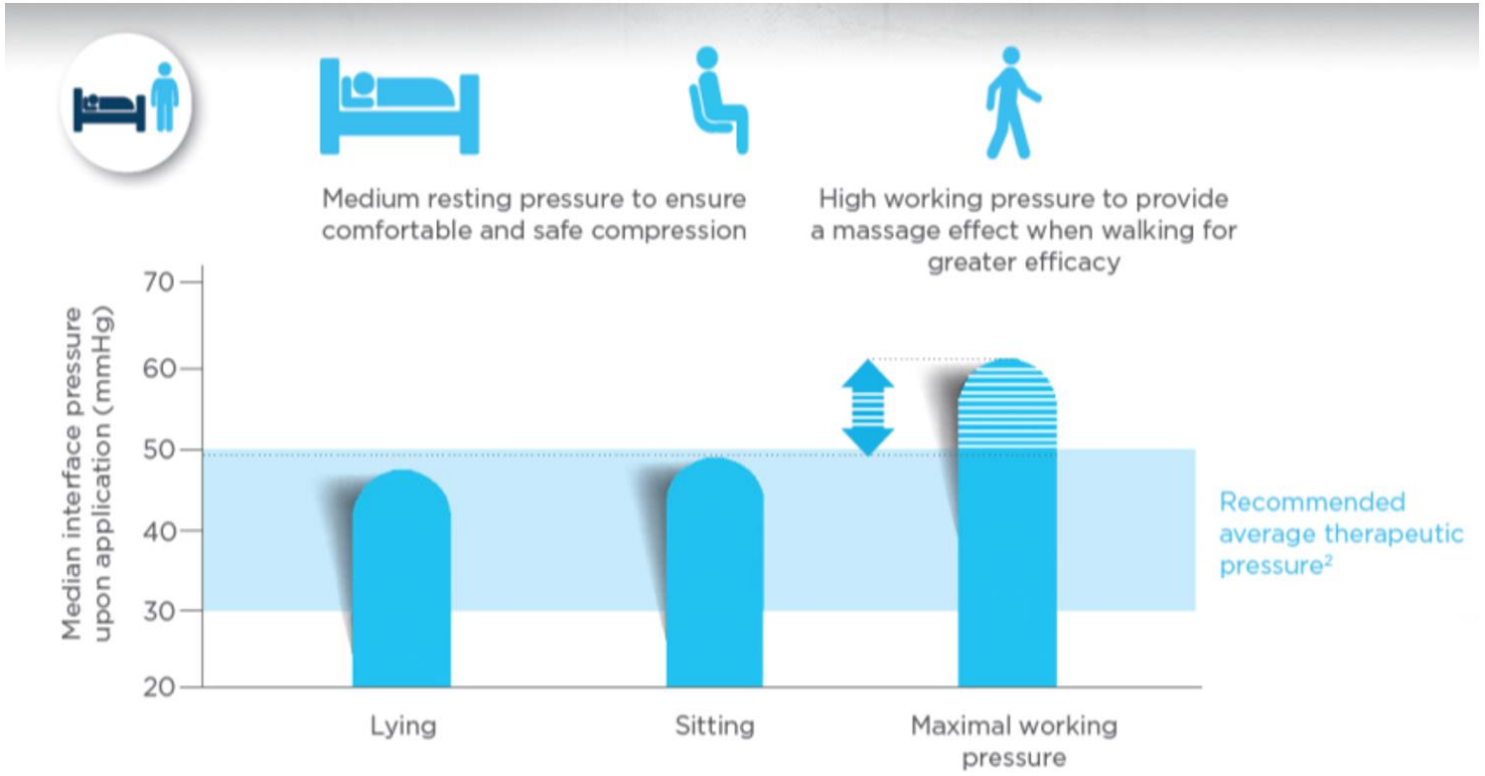
JUNGER STUDY

Objective	Comparison of the interface pressures and acceptability of 3 compression systems over a period of 7 days
Design	Randomized, open, controlled, single-center
Treatment arms	24 patients: 2LB, 4LB, and SSB
Indication	Healthy volunteers with intact skin
Primary endpoint	Interface pressure measurement at D1, D3, and D7, in supine, sitting, and active standing position

2LB stays in place up to 7 days, maintaining therapeutic pressure (~40 mm Hg) regardless of patient's position, with pressure peaks when walking

JUNGER STUDY

- Product evaluation
- 24 patients
- 3 compression systems
- Interface pressure at D1, D3, and D7, in different positions



- After 7 days, 2LB maintained an effective therapeutic pressure (~40 mm Hg), in supine, sitting, and standing position
- On Day 3, 2LB achieved a significantly smaller reduction in maximal working pressure than did the SSB (-30%)

2LB stays in place up to 7 days, maintaining therapeutic pressure (~40 mm Hg) regardless of patient's position, with pressure peaks when walking

JUNGER STUDY

Position	Two layers	Short stretch	Four layers
Supine	47.81	48.47	51.54
Sitting	49.44	47.97	54.02
Active standing	55.81	64.72	62.08
Maximal working pressure	61.62	71.46	78.97

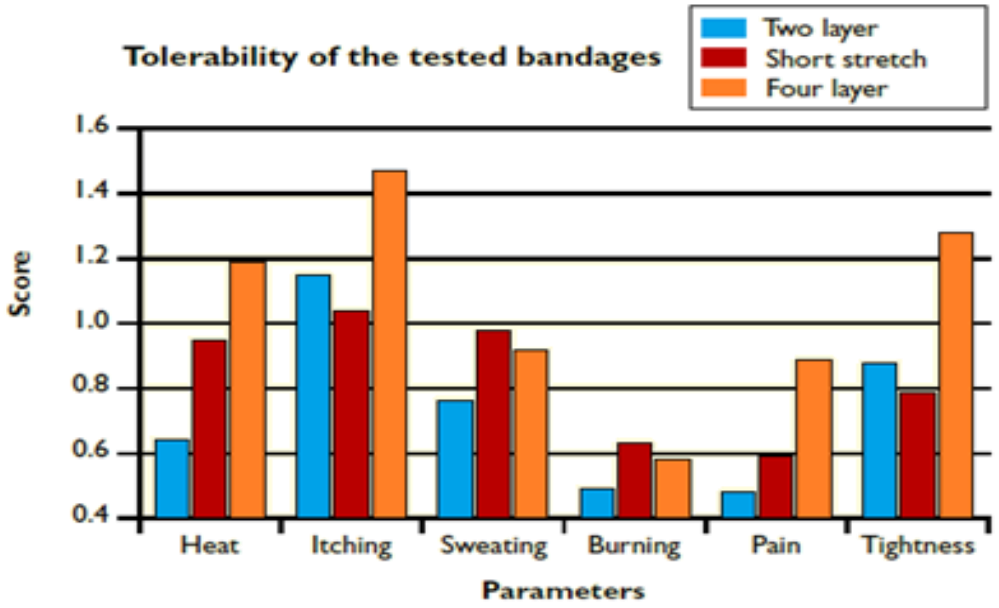
Maximal working pressure (mmHg)	After application	D3	D7
2LB	61.62	53.6	46.8
4LB	78.97	75.0	69.5
SSB	71.46	54.35	50.0

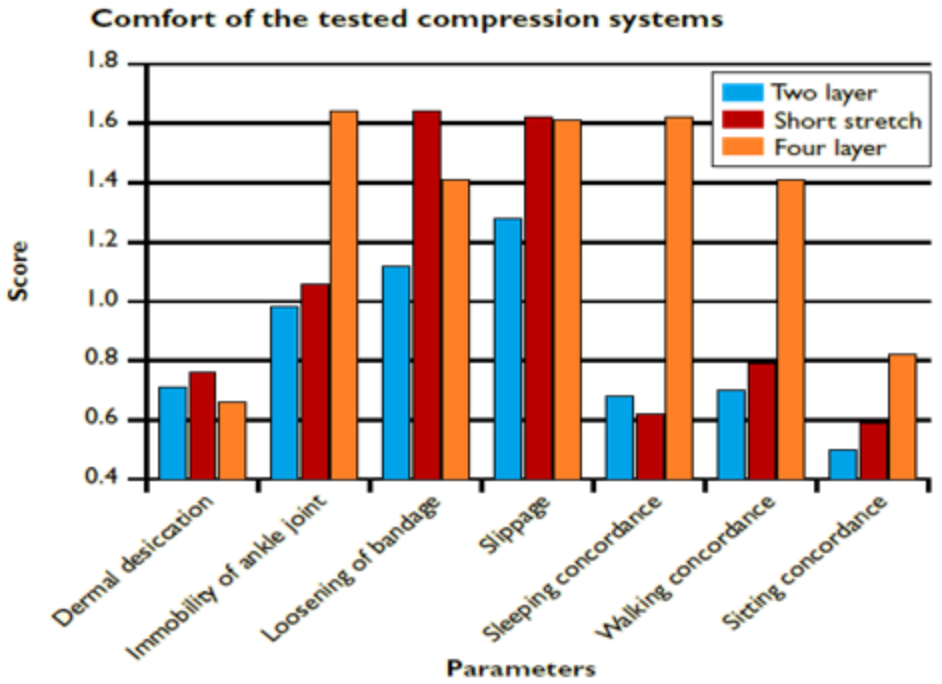
Median baseline interface pressure values (mm Hg)

- 2LB maintains up to 7 days an effective therapeutic pressure (~ 40 mm Hg), regardless of the position of the subject
- The SSB shows, over 7 days, a progressive and significant loss of pressure (30% at D3)

2LB is better tolerated and more comfortable

JUNGER STUDY





- Regarding safety and comfort, all the evaluated criteria show a greater acceptability of the system 2LB, resulting in **better day and night compliance**
- **25% of volunteers wearing the 4LB stopped the test** on the third day, which could be explained by a high pressure in all position

BENIGNI STUDY: Assessment of the reduction of efficacy, safety, and acceptability of 2LB for venous leg ulcers

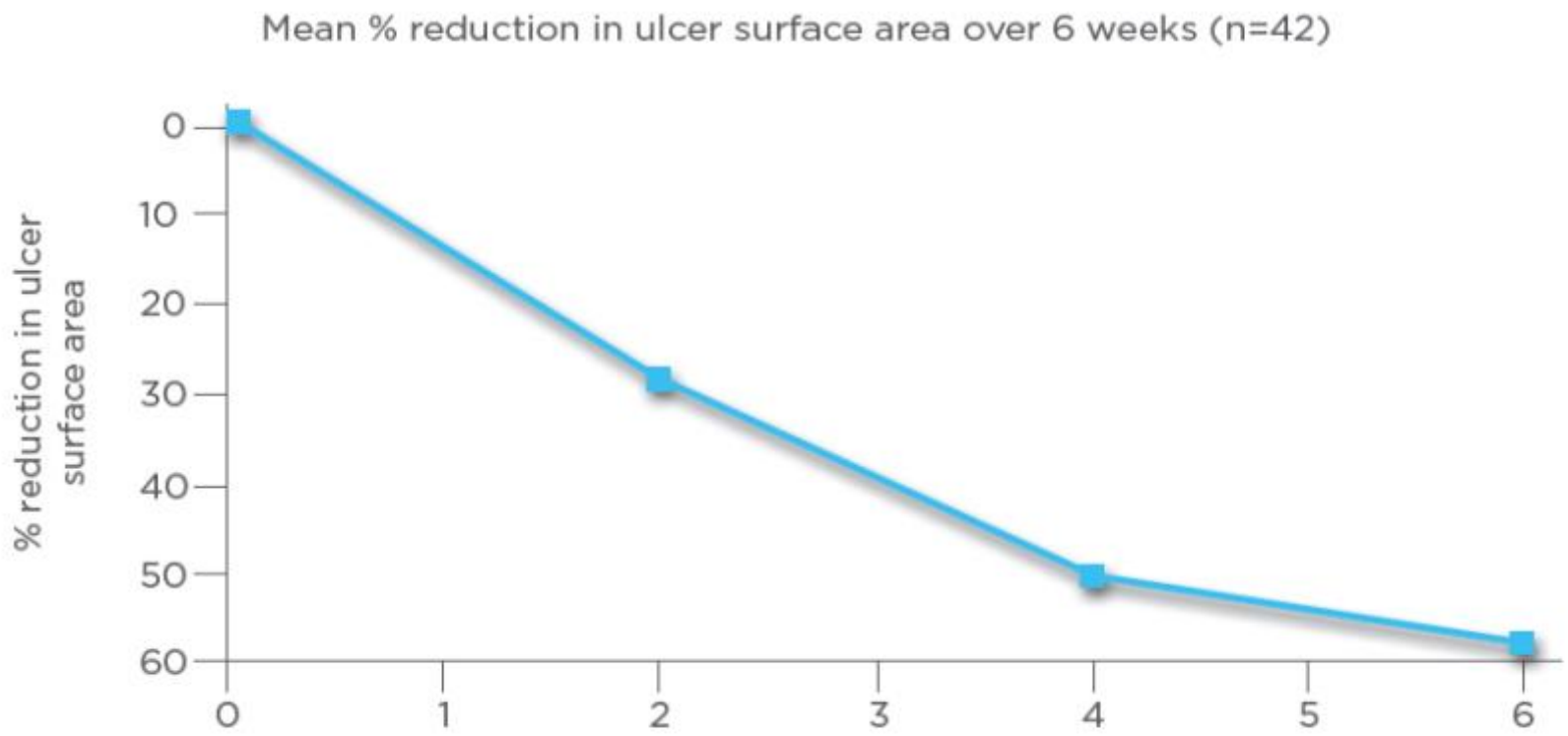
BENIGNI STUDY

Objective	Assessment of the reduction of efficacy, safety, and acceptability of 2LB for venous leg ulcers
Design	Open-label, non-comparative, multicenter
Treatment arms	42 patients, 6-wk follow-up
Indication	Venous leg ulcer patients (ABPI = 1.0 + 0.1), already treated by multi-components without clinical improvement
Primary endpoint	Reduction in wound surface area
Secondary endpoint	Measure the lower limb edema evolution

BENIGNI STUDY: Proven Efficacy

BENIGNI STUDY

- Non-comparative, multi-center
- 42 patients, 6 wks
- Reduction in wound surface area

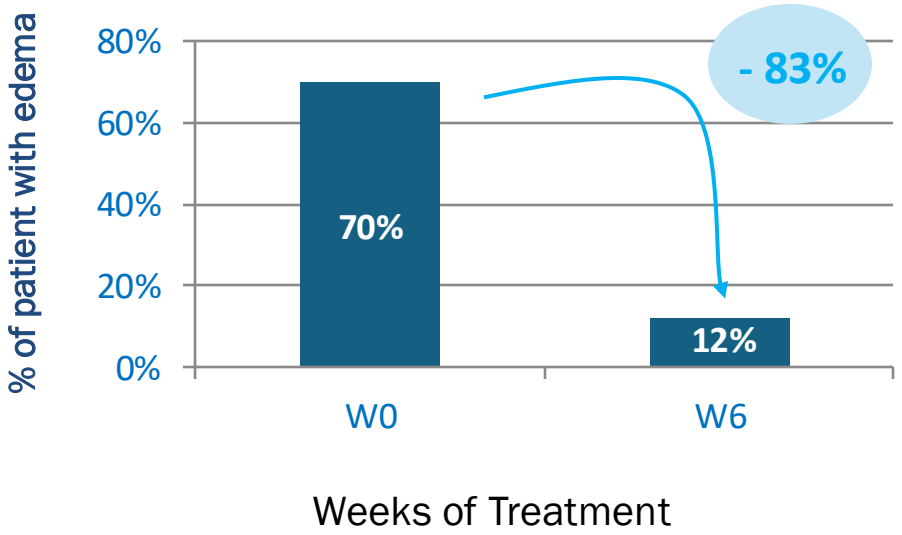


2LB achieves a mean surface area reduction of 58.51% after 6 wks

BENIGNI STUDY: 2LB also decreases edema

BENIGNI STUDY

- Non-comparative, multi-center
- 42 patients, 6 wks
- Reduction in wound surface area

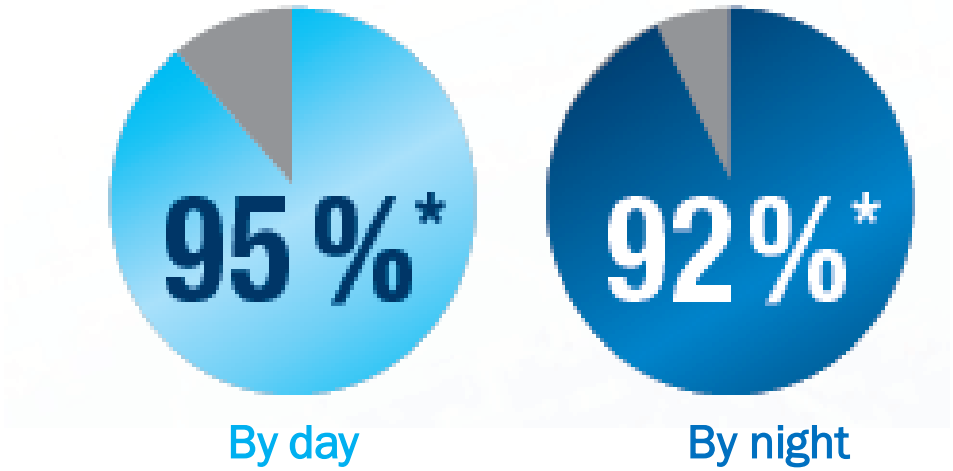


BENIGNI STUDY: 2LB shows high levels of comfort by day and by night

BENIGNI STUDY

- Non-comparative, multi-center
- 42 patients, 6 wks
- Reduction in wound surface area

% of patients who find comfort “good” or “very good” with 2LB



2LB comfort is approved by the patients with high comfort levels day and night, enabling continuous wear to promote adherence

ODYSSEY STUDY: Evaluation of the efficacy, tolerance, and acceptability of 2-layer compression systems in the etiological treatment of venous leg ulcer

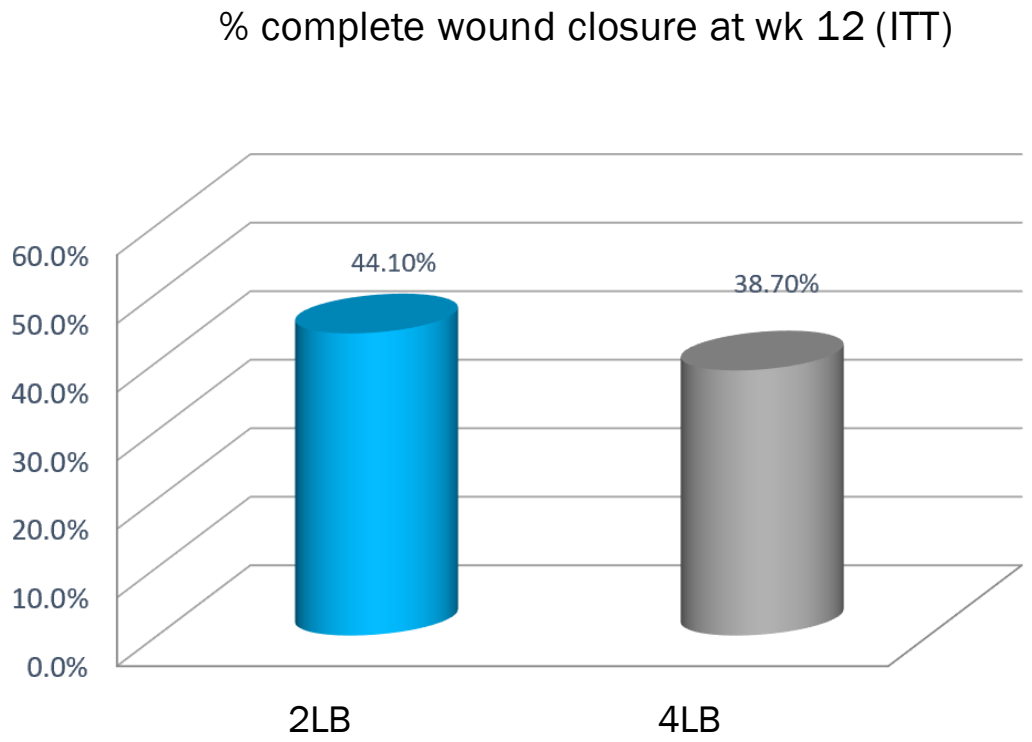
ODYSSEY STUDY

Objective	To assess the efficacy, tolerance, and acceptability of 2-layer compression systems in the etiological treatment of venous leg ulcer
Design	Randomized, open-labeled, controlled non-inferiority in 2 parallel groups
Treatment arms	187 patients: 2LB (n=94); 4LB (n=93)
Indication	Venous leg ulcer (ABPI>0.8)
Primary endpoint	Complete wound closure at the end of the 12-wk follow-up period
Investigation center	37 centers in France, United Kingdom, and Germany
Duration	12 wks

ODYSSEY STUDY: 2LB is as effective as the standard of care, 4 layer compression system

ODYSSEY STUDY

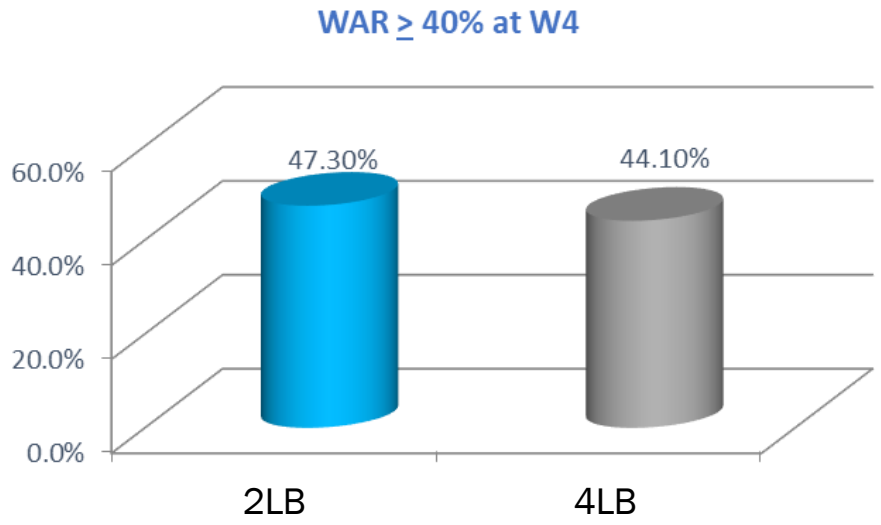
- RCT
- 187 patients, 37 centers
- Non-inferiority vs 4LB
- Complete closure at wk 12



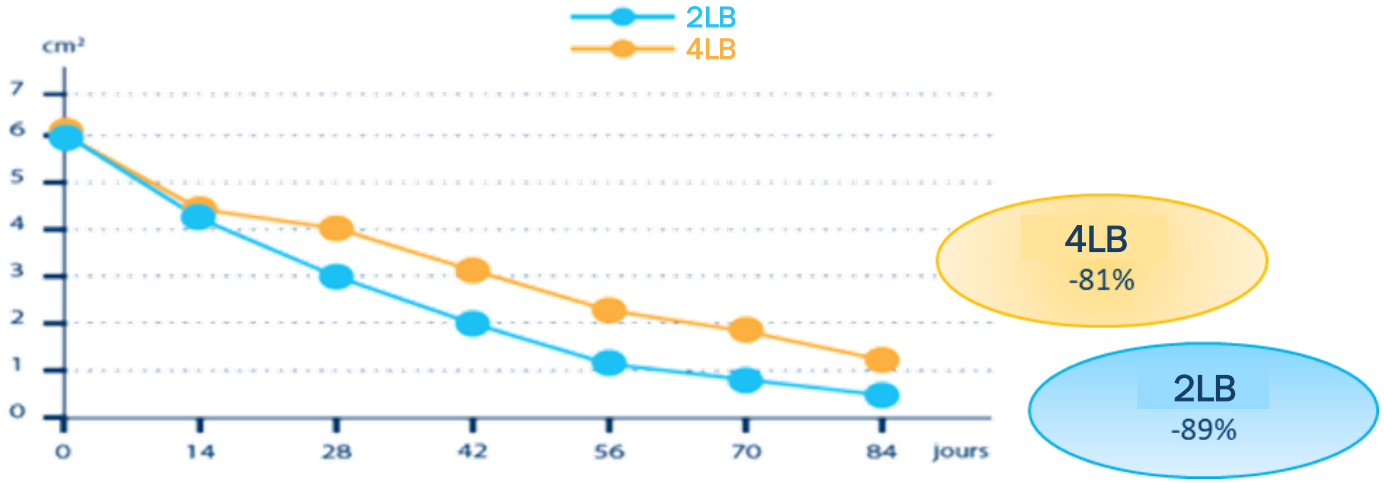
No significant difference in complete wound closure % →Equivalence with 4LB validated

ODYSSEY STUDY: 2LB is as effective as the standard of care 4LB

ODYSSEY STUDY

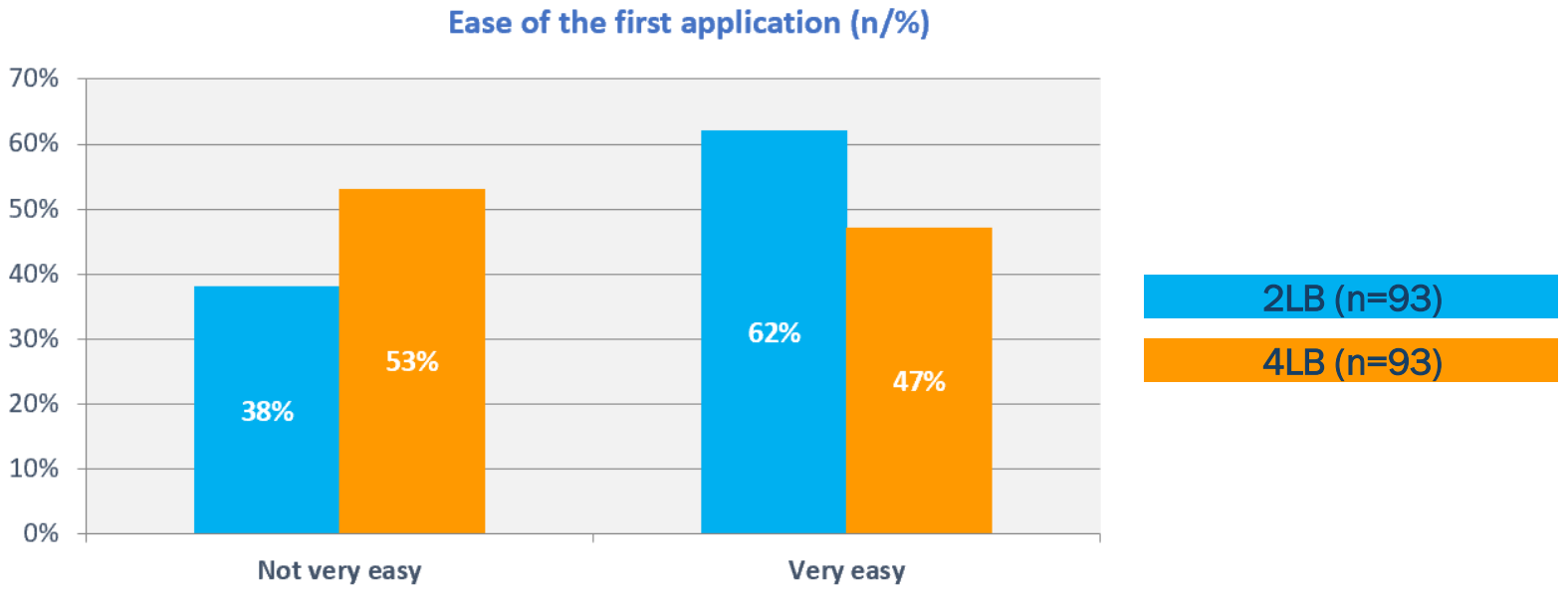


Similar WAR in absolute value (cm^2)



ODYSSEY STUDY: 2LB is easier to apply from the first application

ODYSSEY STUDY



Acceptability – ease of application:

2LB is easier to apply from the first application compared to 4LB

Significant difference between the two groups: *p*=0,035

ODYSSEY STUDY: 2LB is as effective as the standard of care 4LB, easier to apply, and more comfortable

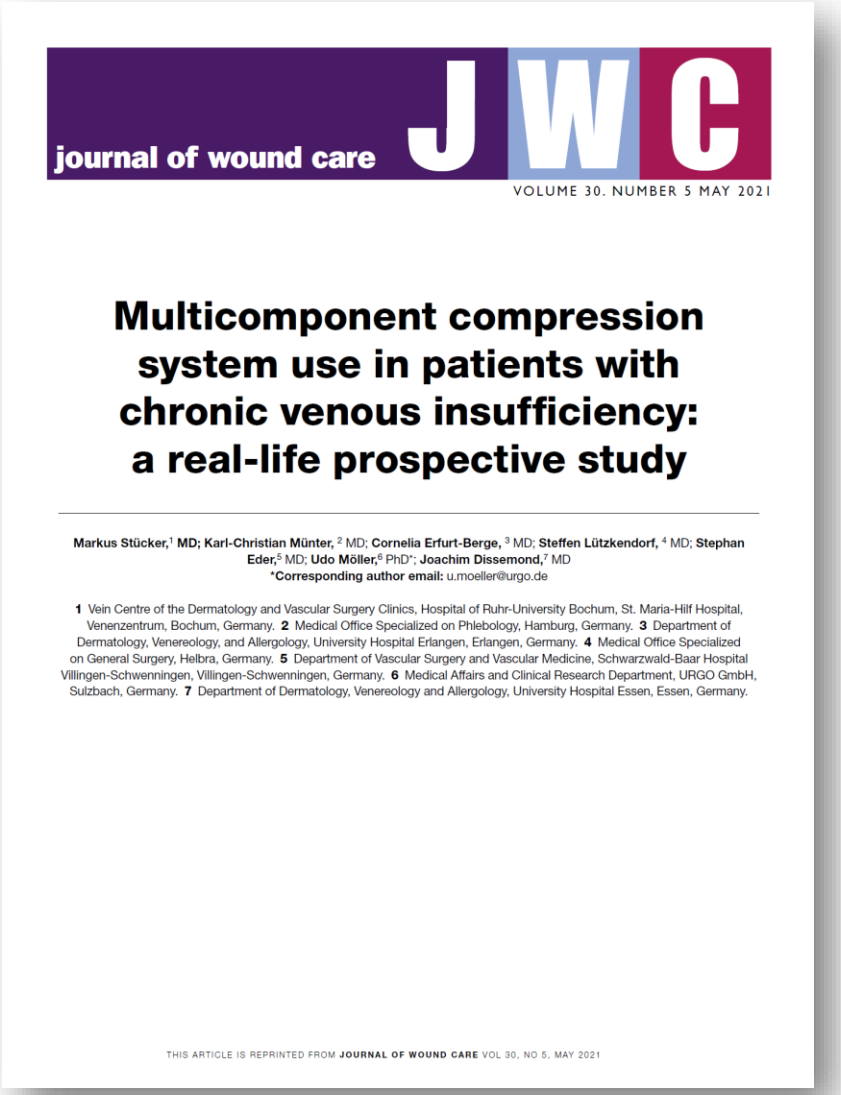
ODYSSEY STUDY

On 2 similar groups in terms of patient profile and condition

- ✓ 2LB is as effective as 4LB in healing leg ulcer
- ✓ However, 2LB is considered
  - Easier to apply
  - Comfortable during day and night

Large Observational, Real-Life Prospective Study Published in *JWC* May 2021

- Real life large prospective, multi-center observational study with 702 total venous leg ulcer and/or peripheral edema patients
- Outcomes analyzed included wound healing rate, wound healing progression, assessment of edema and ankle mobility, local tolerability, and acceptance
- Post-publication analysis was completed on 492 non-diabetic patients, 185 diabetic patients to determine efficacy and safety of 2LB comparatively on the 2 patient groups



Stücker M, et al. *J Wound Care*. 2021;30(5):400-412. doi: 10.12968/jowc.2021.30.5.400. https:// pubmed.ncbi.nlm.nih.gov/33979221/

Compression Evidence

- Some compression is better than none
- Inelastic compression has a significant effect on deep venous hemodynamics compared with elastic compression applications
- Multi-layer compression bandage is more effective than low-compression, single-layer
  - Interface pressure (IP)/dosage (mm Hg) and stiffness are changeable according to combination of materials in a bandage set
  - Inclusion of a cohesive component has been shown to maintain IP longer
  - Inclusion of an elastic component has been shown to have higher IP maintained over a longer period of time
- Compression garment (self-gripping wrap/stockings) stiffness varies *independent* of dosage

IP = interface pressure.

Benigni JP, et al. *Int Angiol.* 2023;42(3):247-253. Ehmann S, et al. *Wound Manag Prev*. 2023:69(2):14-25. Shi C, et al. *Cochrane Database Sys Rev*. 2021;7(7). Vowden KA, Mosti G. *Wounds Int*. 2020. Rabe E, et al. *Phlebology*. 2020;35(7):447-446. Lantis JC, et al. *J Wound Care*. 2020;29(S9):S29-S37. Liu R, et al. *Text Res J*. 2017; 87(9):1121-1141. Franks PJ, et al. *J Wound Care*. 2016;25(Suppl6):S1-S67. Junger M, et al. *J Wound Care*. 2009;18(11):474-480. van der Wegen-Franken CP, et al. *Phlebology*. 2008;23(2):77-84.

Compression Evidence

- Compression results in an increase in leg pulsatile blood flow likely due to arteriolar vasodilation due to a myogenic arteriolar response and a shear dependent venous effect
  - The myogenic mechanism is the intrinsic ability of vascular smooth muscle to contract in response to an increase in intraluminal pressure and dilate due to a decrease in pressure
    - Compression can directly impact this process by its effects on IP
  - The venous effect elicits a release of vasodilatory substances which directly impact arteriolar vasculature
    - This synergistic effect improves VLU resolution likely related to a decrease in leukocyte effects in the distal microvasculature
    - Also helps to explain how compression can impact the VAIL

Mayrovitz H, Macdonald J. Medical compression: effects on pulsatile leg blood flow. *Int Angio*. 2010;29(5):436-441.

When compression is properly used, it has been shown to:

A. Reduce edema

B. Optimize healing of VLUs

C. Promote resolution of trophic changes

D. All the above

Clinical Pearls

- Tear down the silos, practice VAIL clinically
- Integument health is VAIL dependent; healing the wound/skin requires improving the function of all vascular players
- Lymphatic dysfunction ←→ chronic edema; lymph stasis triggers an inflammatory response due to accumulation antigens, foreign material, and immune complexes… Stagnant lymph attenuates lymphatic contraction… Cytokines induce fibroblasts to proliferate increasing connective tissue formation
- Pathologic tissue changes include epidermal thickening, fibrosclerosis, and adipocyte proliferation
- Compression and compression textiles matter and can augment wound resolution and tissue restoration

Clinical Pearls

- Wound healing requires adequate macro and micro circulation; impaired wound healing occurs when growth factors, key peptides, and matrix proteins become trapped (not being mobilized by the lymphatic system = lymph stasis)
  - Improved by reducing the congestion… drain and maintain → maintain with compression!
- Tissue perfusion may be impaired by arterial occlusion or vasoconstriction, hypotension, hypothermia, peripheral venous congestion, increased diffusion distance (edema and adipose)
  - Improved by reducing the congestion… drain and maintain → maintain with compression!
- Compression assists with integument restoration by acting on the VAIL; mechanical deformation, mechanotransduction
- "We hypothesize that the application of mechanical force to wounds induces tissue deformation at the level of individual cells, leading to cell stretch, thereby providing a powerful mechanism for inducing cell proliferation and angiogenesis and hence promoting wound healing"
- Compression textiles matter and can augment tissue restoration

Saxena V, et al. *Plast Reconstr Surg*. 2004;114(5):1086-1096.

Questions?

Thank You