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## Management of Venous Leg Ulcers

Clinical Practice Guidelines of the Society for Vascular Surgery® and the American Venous Forum





Mosby www.jvascsurg.org

## SVS – AVF Clinical Practice Guidelines Venous Ulcer

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    - Union Internationale de Phlébologie





# SVS – AVF Clinical Practice Guidelines Methodology

- Target audience specialists who treat vascular disease and/or wounds.
- Methodology
  - Subcommittee Structure
    - Clinical Evaluation
    - Wound Care
    - Compression
    - Surgery
    - Ancillary
    - Primary Prevention:
  - Evidence Review
  - Recommendations
  - GRADE strength of recommendation / level of evidence
  - Knowledge and Evaluations Research Unit at the Mayo Clinic, Rochester MN
    - Corroborate proper strength of evidence and quality of evidence for each guideline
    - Commissioned for systematic review: surgery/endovascular and compression



Grade	Description of Recommendation	Benefit vs Risk	Methodological Quality of Supporting Evidence	Implications	
1A	Strong recommendation, high- quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation	
1B	Strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational	Strong recommendation, can apply to most patients in most circumstances without reservation	
1C	Strong recommendation, quality or very low-quality evidence    Comprehensive guideline that encompasses all the details				
2A	Weak recommendation, it quality evidence	comprehensive guideline that encompasses all the details needed for providing care for patients with venous ulcers  - When there are no comparable alternatives to a recommendation, or evidence is lacking  - Case series supplemented by the best opinion of a panel of			
2B		experts		,	
	moderate-quality evidence	WITH TISKS and Durdens	methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	circumstances or patients' or societal values  Very weak recommendations; Other	
2C	Weak recommendation, low- quality or very low-quality evidence	Uncertainty in the estimates of benefits and risk, and burdens; Risk, benefit, and burdens may be closely balanced	Observational studies or case series	alternatives may be reasonable	

## SVS – AVF Clinical Practice Guidelines Definition – Venous Ulcer

• **Guideline 1.1**: Venous Leg Ulcer Definition

We suggest use of a standard definition of venous ulcer as an open skin lesion of the leg or foot that occurs in an area affected by venous hypertension. [BEST PRACTICE]





# SVS – AVF Clinical Practice Guidelines Anatomy - Pathophysiology

Guideline 2.1: Venous Anatomy Nomenclature

We recommend use of the International Consensus Committee on Venous Anatomical Terminology for standardized venous anatomy nomenclature. [BEST PRACTICE]

• **Guideline 2.2**: Venous Leg Ulcer Pathophysiology

We recommend a basic practical knowledge of venous physiology and venous leg ulcer pathophysiology for all practitioners caring for venous leg ulcers. [BEST PRACTICE]





Table II. The International Consensus Committee on Venous Anatomical Terminology for standardized venous anatomy nomenclature of the leg

Su perficial venous system	Deep venous system	Perforating venous system
Superficial inguinal veins External pudendal vein Superficial circumflex iliac vein Superficial epigastric vein Superficial dorsal veins (clitoris/penis) Anterior labial veins Anterior scrotal veins Great saphenous vein Saphenofemoral junction Terminal valve Preterminal valve Preterminal valve Preterminal valve Anterior accessory great saphenous vein Posterior accessory great saphenous vein Superficial accessory great saphenous vein Anterior thigh circumflex vein Small saphenous vein Saphenopophiteal junction Terminal valve Preterminal valve Cranial extension of small saphenous vein Superficial accessory small saphenous vein Intersaphenous veins Lateral venous system Dorsal venous network of the fixet Dorsal venous arch of the foot Dorsal venous arch of the foot Superficial metatarsal veins (dorsal/plantar) Plantar venous subcutaneous network Superficial digital veins (dorsal/plantar) Lateral marginal vein Medial marginal vein	Common femoral vein Femoral vein Deep femoral vein Medial circumflex femoral vein Lateral circumflex femoral vein Deep femoral communicating veins Sciatic vein Pophiteal vein Genicular venous plexus Anterior tibial veins Posterior tibial veins Fibular or peroneal veins Sural veins Soleal veins Gastrochemius veins Medial Lateral Intergemellar Medial plantar veins Lateral plantar veins Deep plantar venous arch Deep metatarsal veins (plantar/dorsal) Deep digital veins (plantar/dorsal) Pedial vein	Glute al perforators Superior gluteal Midglute al Lower gluteal Thigh perforators Medial thigh Femoral canal Inguinal Anterior thigh Posterior thigh Posterior thigh Posteromedial Scianic Posterolateral Pudendal Knee perforators Medial knee Suprapatellar Lateral knee Infrapatellar Popliteal fossa Leg (calf) perforators Medial leg Paratibial Posterior tibial Anterior leg Lateral leg Posterior leg Medial gastrochemiu Lateral gastrochemiu Intergemellar Para-achillean Ankle perforators Medial ankle Anterior ankle Lateral ankle Foot perforators Dorsal foot Medial foot Lateral foot

Modified from Caggiati A, Bergan JJ, Glowczki P, Eklof B, Allegra C, Partich H. Nomenclature of the veins of the lower limb: Extensions, refinements, and clinical application J Vasc Surg 2005;41:719-24.

Table III. The International Consensus Committee on Venous Anatomical Terminology for standardized venous anatomy nomendature of the pelvis

Main collector	Draining reins	Hexus and peripheral veins
Inferior vena	Ovarian/testicular weins	Pampiniform plexus
Common iliac vein	Me dian sacral vein Iliohambar vein Internal iliac (hypogastric) External iliac	Sacral venous plexus
Inferior mesen teric ve in	Superior rectal vein Middle rectal vein Inferior rectal vein Superior gluteal vein Inferior gluteal vein Lat eral sacral vein	External rectal plexus Internal rectal plexus
Internal iliac we'm	Internal pudendal vein Obturator veins Vesical veins Uterine veins Vaginal veins	Deep perineal veins Superficial perineal veins Deep dorsal veins of clinoris/penis Deep veins of clinoris/ penis Urethral bulb veins Pudendal plexus Vesical/prostatic plexus Uterine plexus Vein of the broad ligament Vaginal plexus
External diac vein	Pubic veins (accessory obturator veins) Sovrapubic veins Inferior epigastric vein Deep circumflex iliac vein	

Modified from Caggiari A, Bergan JJ, Gloviczki P, Eklof B, Allegra C, Partsch H. Nomenclature of the veins of the lower limb: Extensions, refinements, and clinical application J Vasc Surg 2005;41:719:24.

## SVS – AVF Clinical Practice Guidelines Clinical Evaluation

## • **Guideline 3.1**: Clinical Evaluation

We recommend that for all patients with suspected leg ulcers fitting the definition of venous leg ulcer, clinical evaluation for evidence of chronic venous disease be performed. [BEST PRACTICE]





## SVS – AVF Clinical Practice Guidelines Clinical Evaluation

Guideline 3.2: Nonvenous Causes Leg Ulcers

We recommend identification of medical conditions that affect ulcer healing and other non-venous causes of ulcers. [BEST PRACTICE]





#### Table IV. Differential diagnosis for leg ulcers

#### Vascular disease

- Venous: post-thrombotic syndrome, varicose veins, chronic venous reflux
- Arterial: peripheral arterial occlusive disease, hypertension, arteriovenous fistulas, arterial thrombosis, embolism, dysplasia, thromboanguitis obliterans, aneurysm
- Lymphatic: lymphedema
- Microangiopathy: diabetes mellitus, livedoid vasculopathy
- Vasculitis
- Hypertensive arteriologathy

#### Neuropathic

- Peripheral neuropathy; diabetes mellitus, alcohol, medication, hereditary
- Central neuropathy: tabes dorsalis, myelodysplasia, syringomyelia, spina bifida, poliomyelitis, multiple sclerosis.

#### Metabolic

- Diabetes mellitus, gout, prolidase deficiency, Gaucher disease, amyloidosis, calciphylaxis, porphyria, hyperhomocysteinemia

#### Hematologic

Sickle cell anemia, thalassemia, polycythemia vera, leukemia, thrombocythemia, lymphoma, myeloplastic disorders, disorders of coagulation factors (factors I-XIII), coagulation inhibitors (antithrombin III, activated protein C resistance, protein C and S), or fibrinolysis factors (tissue plasminogen activator, plasminogen activator inhibitor, plasmin)

#### Autoimmune

Rheumatoid arthritis, leukocytoclastic vasculitis, polyanteritis nodosa, Wegener granulomatosis, Churg-Strauss syndrome, systemic lupus erythematosus, Siögren syndrome, scleroderma, Behoet disease, cryoglobulinemia

#### Exogenous

- Heat, cold, pressure, ionizing radiation, chemical, allergers, trauma

#### Neoplasia

Basal cell carcinoma, squamous cell carcinoma (Marjolin ulcer), malignant melanoma, angiosarcoma, cutaneous lymphoma, papillomatosis cutis carcinoides, kerato acanthoma

#### Indection

- Bacterial: furuncles, ecthyma, mycobacterioses, syphilis, erysipelas, anthrax, diphtheria, chronic vegetative pyodermia, tropical ulcer
- Viral: herpes, variola virus, cytomegaly
- Fungal; sporotrichosis, histoplasmosis, blastomycosis, coccidioidomycosis
- Protozoal: leishmaniasis

#### Medication

- Hydroxyurea, leftunomide, methorrexate, halogens, coumarin, vaccinations, ergotamine, infiltration cytostatic agents.
   Genetic defect
- Kline felter syndrome, Felty syndrome, TAP1 mutation, leukocyte adhesion deficiency, inherited hypercoagulable factors.
   Skin disorder
- Pyoderma gangrenosum, necrobiosis lipoidica, sarcoidosis, perforating dermatosis, Langerhans cell histiocytosis, papulosis maligna atrophicans, bullous skin diseases

Modified from Dissemond J, Korber A, Grabbe S. Differential diagnosis of leg ulcers. J Disch Dermatol Ges 2006;4:627-34.

## SVS – AVF Clinical Practice Guidelines Clinical Evaluation - Wound

### • **Guideline 3.3: Wound Documentation**

We recommend serial venous leg ulcer wound measurement and documentation. [BEST PRACTICE]

### Guideline 3.4: Wound Culture

We suggest against routine culture of venous leg ulcers and to only obtain wound cultures when clinical evidence of infection is present. [GRADE - 2; LEVEL OF EVIDENCE - C]

### • Guideline 3.5: Wound Biopsy

We recommend wound biopsy for venous leg ulcers that do not improve with standard wound and compression therapy after 4-6 weeks of treatment and for all ulcers with atypical features. [GRADE -1; LEVEL OF EVIDENCE - C]



## SVS – AVF Clinical Practice Guidelines Clinical Evaluation - Arterial

### Guideline 3.7: Arterial Testing

We recommend arterial pulse examination and measurement of ankle brachial index (ABI) on all patients with venous leg ulcer. [GRADE -1; LEVEL OF EVIDENCE -B]

### • **Guideline 3.8**: **Microcirculation Assessment**

We suggest against routine microcirculation assessment of venous leg ulcers, but suggest selective consideration as an adjunctive assessment for monitoring of advanced wound therapy. [GRADE -2; LEVEL OF EVIDENCE -C]





# SVS – AVF Clinical Practice Guidelines Clinical Evaluation – Venous Imaging

### Guideline 3.9: Venous Duplex Ultrasound

We recommend comprehensive venous duplex ultrasound examination of the lower extremity in all patients with suspected venous leg ulcer. [GRADE -1; LEVEL OF EVIDENCE -B]

### • **Guideline 3.10**: **Venous Plethysmography**

We suggest selective use of venous plethysmography in the evaluation of patients with suspected venous leg ulcer if venous duplex ultrasound does not provided definitive diagnostic information. [GRADE -2; LEVEL OF EVIDENCE -B]





# SVS – AVF Clinical Practice Guidelines Clinical Evaluation – Venous Imaging

### Guideline 3.11: Venous Imaging

We suggest selective computed tomography venography, magnetic resonance venography, contrast venography, and/or intravascular ultrasound in patients with suspected venous leg ulceration if additional advanced venous diagnosis is required for thrombotic or non-thrombotic iliac vein obstruction, or for operative planning prior to open or endovenous venous interventions. [GRADE -2; LEVEL OF EVIDENCE - C]





## SVS – AVF Clinical Practice Guidelines Clinical Evaluation – Classification

### • **Guideline 3.12**: **Venous Disease Classification**

We recommend that all patients with venous leg ulcer should be classified based on venous disease classification assessment including clinical CEAP, revised venous clinical severity scoring (VCSS), and venous disease specific quality of life (QOL) assessment. [BEST PRACTICE]





#### Table V. Basic CEAP classification system

Clinical classification.

C0 No visible or palpable signs of venous disease

C1 Telangiectases or reticular veins

C2 Varioose veins

C3 Edema

C4a Pigmentation and/or eczema

C4b Lipodermatosclerosis and/or atrophic blanche

C5 Healed venous ulcer

C6 Active venous ulcer

CS Symptoms, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction

CA Asymptomatic

Etiologic classification

Ec Congenital

Ep Primary

Es Secondary (post-thrombotic)

En No venous enology identified

Anatomic classification

As Superficial veins

Ap Perforator veins

Ad Deep veins

An No venous location identified

Pathophysiologic classification

Pr Reflux

Po Obstruction

Pr.o Reflux and obstruction

Pn No venous pathophysiology identifiable

Modified from Eklöf B, Rutherford RB, Bergan JJ, Carpentier PH, Gloviczki P, Kistner RL, et al. Revision of the CEAP classification for chronic venous disorders: Corsensus statement, J Vasc Surg 2004;40:1248-52.

	None: 0	Mild: 1	Moderate: 2	Sepere: 3
Pain or other discomfort (ie, aching, heaviness, fatigue, soreness, burning)	8	Occasional pain or other discomfort (ie, not restricting regular daily activities)	Daily pain or other discomfort (ie, interfering with but not preventing regular daily activities)	
Presumes venous origin			- F-91-04 - ANNE B-CS-1	
Varicose veins				
*Varicose* veins must be ≥3 mm in diameter to qualify in the standing position		Few: scattered (ie, isolated branch varicosities or clusters) Also includes corona phle bectatica (ankle flare)	Confined to calf or thigh	Involves calf and thigh
Venous edema		The state of the s		
Presumes venous origin		Limited to foot and ankle area	Extends above ankle but below knee	Extends to knee and above
Skin pigmentation				
Presumes venous origin	None or focal	Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of calf
Does not include focal pigmentation over varicose veins or pigmentation due to				
other chronic diseases				
Inflammation				
More than just recent pigmentation (ic, crythema, cellulitis,		Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of calf
venous eczena, demutitis)				
Induration				
Presumes venous origin of secondary skin and subcutaneous changes (ie, chronic edema with fibrosis, hypodermitis). Includes white atrophy and lipodermatoselerosis		Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of calf
Active ulcer number	0	1	2	≥3
Active ulcer duration (longest active)	N/A	<3 mo	>3 mo but <1 y	Not healed for >1 y
Active ulcer size (largest active)	N/A	Diameter <2 cm	Diameter 2-6 cm	Diameter >6 cm
Use of compression therapy	0	1	2	3
	Not used	Intermittent use of stockings	Wears stockings most days	Full compliance: stockings

Modified from Vasquez MA, Rabe E, McLafferty RB, Shortell CK, Maston WA, Gillespie D, et al. Revision of the venous dinical severity score. Venous outcomes consensus statement: Special communication of the American Venous Forum Ad Hoc Outcomes Working Group. J Vasc Surg. 2010;52:1387-96.

Table VII. Villalta scoring for post-thrombotic syndrome

Symptoms and clinical signs	None	Mild	Moderate	Severe
Symptoms	607	2477	7250	101
Pain	0	1	2	3
Cramps	0	1	2	3
Heaviness	0	1	2	3
Paresthesia	0	1	2	3
Pruntus	0	1	2	3
Clinical signs				9.9
Pretibial edema	0	1	2	3
Skin induration	0	1	2	3
Hyperpigmentation	0	1	2	3
Redness	0	1	2	3
Venous ectavia	0	1	2	3
Pain on calf compression	0	1	2	3
Venous uker	Absent			Present

Villalta score ≥5 or if venous ulcer present: Villalta score of 5-9 mild., 10-14 moderate, and ≥15 severe.

Modified from Villalta S, Bagarella P, Piccioli A, Lensing AW, Prins MH, Prandoni P. Assessment of validity and reproducibility of a directl scale for the postthrombotic syndrome [abstract]. Haemostasis 1994;24:158a.

## SVS – AVF Clinical Practice Guidelines Clinical Evaluation – Venous Outcomes

• Guideline 3.13: Venous Procedural Outcome Assessment

We recommend venous procedural outcome assessment including reporting of anatomic success, venous hemodyamic success, procedure-related minor and major complications, and impact on venous leg ulcer healing. [BEST PRACTICE]





# SVS – AVF Clinical Practice Guidelines Wound Care - Categories

#### Wound bed preparation

- Wound cleansers
- Debridement
- Surgical debridement
- Anesthesia for debridement
- Hydrosurgical debridement
- Ultrasonic debridement
- Enzymatic debridement
- Biologic debridement
- Nutritional assessment and management
- Measurement of wound progress

#### **Wound infection and bacterial control**

- Wound culture
- Indications for culture
- Method of wound culture
- Management of limb cellulitis
- Wound colonization and bacterial biofilms
- Treatment of wound infection
- Topical antibiotics
- Systemic antibiotics

#### **Primary wound dressings**

- Topical dressing selection
- Antimicrobials in topical dressings
- Peri-ulcer skin management
- Anti-inflammatory dressings

#### **Adjunctive wound therapies**

- Indications for adjunctive therapies
- Split-thickness skin grafting
- Cellular Therapy
- Use of cellular therapy
- Preparation for cellular therapy
- Frequency of cellular therapy application
- Negative pressure therapy
- Electrical stimulation
- Ultrasound therapy





## SVS – AVF Clinical Practice Guidelines Wound Care - Cleansers

## • **Guideline 4.1: Wound Cleansers**

We suggest that venous leg ulcers be cleansed initially and at each dressing change using a neutral, nonirritating, nontoxic solution, performed with a minimum of chemical or mechanical trauma. [GRADE -2; LEVEL OF EVIDENCE -C]





## • **Guideline 4.2: Debridement**

We recommend that venous leg ulcers receive thorough debridement at their initial evaluation to remove obvious necrotic tissue, excessive bacterial burden, and cellular burden of dead and senescent cells. [GRADE -1; LEVEL OF EVIDENCE -B] We suggest additional maintenance debridement be performed to maintain the appearance and readiness of the wound bed for healing. [GRADE -2; LEVEL OF EVIDENCE -B] We suggest that the health care provider choose from a number of debridement methods including sharp, enzymatic, mechanical, biological, or autolytic. More than one debridement method may be appropriate. [GRADE -2; LEVEL OF EVIDENCE -B]





• **Guideline 4.3: Anesthesia for Surgical Debridement** 

We recommend that local anesthesia (topical or local injection) be administered to minimize discomfort associated with surgical venous leg ulcer debridement. In selected cases, regional block or general anesthesia may be required. [GRADE -1; LEVEL OF EVIDENCE -B]





### Guideline 4.4: Surgical Debridement

We recommend that surgical debridement be performed for venous leg ulcers with slough, non-viable tissue or eschar. Serial wound assessment is important in determining the need for repeat debridement(s). [GRADE -1; LEVEL OF EVIDENCE -B]





### Guideline 4.5 Hydrosurgical Debridement

We suggest hydrosurgical debridement as an alternative to standard surgical debridement of venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -B]

## • **Guideline 4.6: Ultrasonic Debridement**

We suggest against ultrasonic debridement over surgical debridement in the treatment of venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -C]





### Guideline 4.7: Enzymatic Debridement

We suggest enzymatic debridement of venous leg ulcers when no clinician trained in surgical debridement is available to debride the wound. [GRADE - 2; LEVEL OF EVIDENCE -C] We do not suggest enzymatic debridement over surgical debridement. [GRADE -2; LEVEL OF EVIDENCE -C]

### • **Guideline 4.8: Biologic Debridement**

We suggest larval therapy for venous leg ulcers can be used as an alternative to surgical debridement. [GRADE -2; LEVEL OF EVIDENCE -B]





## SVS – AVF Clinical Practice Guidelines Wound - Infection

Guideline 4.9: Management of Limb Cellulitis

We recommend that cellulitis (inflammation and infection of the skin and subcutaneous tissue) surrounding the venous leg ulcer be treated with systemic gram-positive antibiotics. [GRADE -1; LEVEL OF EVIDENCE -B]

Guideline 4.10: Wound Colonization and Bacterial Biofilms

We suggest against systemic antimicrobial treatment of venous leg ulcer colonization or biofilm without clinical evidence of infection. [GRADE -2; LEVEL OF EVIDENCE -C]





## SVS – AVF Clinical Practice Guidelines Wound - Infection

### • Guideline 4.11: Treatment of Wound Infection:

We suggest that venous leg ulcers with >1x10<sup>6</sup> CFU/g of tissue and clinical evidence of infection should be treated with antimicrobial therapy. [GRADE -2; LEVEL OF EVIDENCE – C] We suggest antimicrobial therapy for virulent or difficult to eradicate bacteria (such as beta hemolytic streptococci, pseudomonas, and resistant staphylococal species) at lower levels of CFU/g of tissue. [GRADE -2; LEVEL OF EVIDENCE – C] We suggest a combination of mechanical disruption and antibiotic therapy as most likely to be successful in eradicating venous leg ulcer infection. [GRADE -2; LEVEL OF EVIDENCE – C]





## SVS – AVF Clinical Practice Guidelines Wound Care - Infection

### • **Guideline 4.12: Systemic Antibiotics**

We recommend that venous leg ulcers with clinical evidence of infection be treated with systemic antibiotics guided by sensitivities performed on wound culture. [GRADE -1; LEVEL OF EVIDENCE -C] Oral antibiotics are preferred initially and the duration of antibiotic therapy should be limited to 2 weeks unless persistent evidence of wound infection is present. [GRADE -1; LEVEL OF EVIDENCE -C]

### • **Guideline 4.13: Topical Antibiotics for Infected Wounds**

We suggest against using topical antimicrobials agents for the treatment of infected venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE – C]





### • **Guideline 4.14: Topical Dressing Selection**

We suggest applying a topical dressing that will manage venous leg ulcer exudate and maintain a moist warm wound bed. [GRADE -2; LEVEL OF EVIDENCE -C] We suggest selection of a primary wound dressing that will absorb wound exudate produced by the ulcer (alginates, foams) and protect the peri-ulcer skin. [GRADE -2; LEVEL OF EVIDENCE -B]





• <u>Guideline 4.15</u>: <u>Topical Dressings Containing Antimicrobials</u>
We recommend against the routine use of topical antimicrobial containing dressings in the treatment of non-infected venous leg ulcers. [GRADE -2;

LEVEL OF EVIDENCE -A]

Guideline 4.16: Peri-Ulcer Skin Management

We suggest application of skin lubricants underneath compression in order to reduce dermatitis that commonly affects peri-ulcer skin. [GRADE -2; LEVEL OF EVIDENCE -C] In severe cases of dermatitis associated with venous leg ulcers, we suggest topical steroids to reduce the development of secondary ulcerations and to reduce the symptoms of dermatitis. [GRADE -2; LEVEL OF EVIDENCE -C]



# SVS – AVF Clinical Practice Guidelines Wound Care – Anti-inflammatory

• **Guideline 4.17: Anti-Inflammatory Therapies** 

We suggest against using anti-inflammatory therapies for the treatment of venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -C]





# SVS – AVF Clinical Practice Guidelines Wound Care – Adjuvant Therapy

• **Guideline 4.18: Indications for Adjuvant Therapies** 

We recommend adjuvant wound therapy options for venous leg ulcers that fail to demonstrate improvement after a minimum of 4-6 weeks standard wound therapy. [GRADE -1; LEVEL OF EVIDENCE -B]





## SVS – AVF Clinical Practice Guidelines Wound Care – Skin Graft

Guideline 4.19: Split Thickness Skin Grafting

We suggest against split thickness skin grafting as primary therapy in treatment of venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -B] We suggest split thickness skin grafting with continued compression for selected large venous leg ulcers that have failed to show signs of healing with standard care for 4-6 weeks. [GRADE -2; LEVEL OF EVIDENCE -B]





# SVS – AVF Clinical Practice Guidelines Wound Care – Cellular Therapy

### • Guideline 4.20: Cellular Therapy

We suggest the use of cultured allogeneic bilayer skin replacements (with both epidermal and dermal layers) to increase the chances for healing patients in patients with difficult to heal venous leg ulcers in addition to compression therapy in patients that have failed to show signs of healing after standard therapy for 4-6 weeks. [GRADE -2; LEVEL OF EVIDENCE -A]





#### SVS – AVF Clinical Practice Guidelines Wound Care – Cellular Therapy

• **Guideline 4.21:** Preparation for Cellular Therapy

We suggest a therapeutic trial of appropriate compression and wound bed moisture control prior to application of cellular therapy. [GRADE -2; LEVEL OF EVIDENCE -C] We recommend that prior to the application of a bilayered cellular graft that adequate wound bed preparation be completed including complete removal of slough, debris and any necrotic tissue. [GRADE -1; LEVEL OF EVIDENCE -C] We recommend additional evaluation and management of increased bio-burden levels prior to the application of cellular therapy. [GRADE -1; LEVEL OF EVIDENCE -C]





#### **SVS – AVF Clinical Practice Guidelines**

Guideline 4.22: Frequency of Cellular Therapy Application

We suggest re-application of cellular therapy as long as the venous leg ulcer continues to respond based on wound documentation. [GRADE -2; LEVEL OF EVIDENCE -C]





#### SVS – AVF Clinical Practice Guidelines Wound Care – Tissue Substitutes

• <u>Guideline 4.23: Tissue Matrices, Human Tissues or Other Skin Substitutes</u>
We suggest the use of a porcine small intestinal submucosal tissue construct in addition to compression therapy for the treatment of venous leg ulcers that have failed failed to show signs of healing after standard therapy for 4-

6 weeks. . [Grade 2; Level of Evidence – B]





#### SVS – AVF Clinical Practice Guidelines Wound Care – Additional Therapy

Guideline 4.24: Negative Pressure Therapy

We suggest against routine primary use of negative pressure wound therapy for venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -C]

Guideline 4.25: Electrical Stimulation

We suggest against electrical stimulation therapy for venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -C]

Guideline 4.26: Ultrasound Therapy

We suggest against routine ultrasound therapy for venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -B]





## SVS – AVF Clinical Practice Guidelines Compression – Healing/Recurrence

• **Guideline 5.1: Compression – Ulcer Healing** 

In a patient with a venous leg ulcer, we recommend compression therapy over no compression therapy to increase venous leg ulcer healing rate.

[GRADE -1; LEVEL OF EVIDENCE -A]

Guideline 5.2: Compression – Ulcer Recurrence

In a patient with a healed venous leg ulcer, we suggest compression therapy to decrease the risk of ulcer recurrence.

[GRADE -2; LEVEL OF EVIDENCE -B]





### SVS – AVF Clinical Practice Guidelines Compression – Multi-Component

• Guideline 5.3: Multi-Component Compression Bandage

We suggest the use of multi-component compression bandage over single component bandages for the treatment of venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE -B]





## SVS – AVF Clinical Practice Guidelines Compression – Arterial Insufficiency

• Guideline 5.4: Compression – Arterial Insufficiency

In a patient with a venous leg ulcer and underlying arterial disease, we do not suggest compression bandages or stockings if ABI is 0.5 or less or if absolute ankle pressure is less than 60mmHg. [GRADE -2; LEVEL OF EVIDENCE -C]





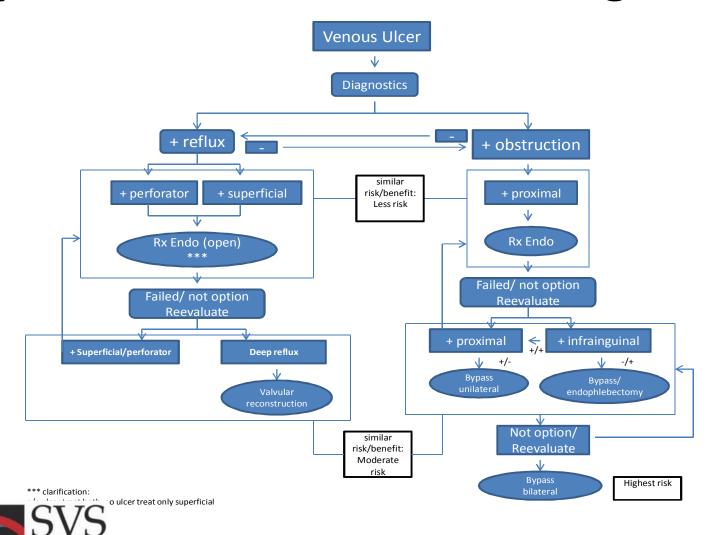
# **SVS – AVF Clinical Practice Guidelines Compression – Intermittent Pneumatic**

• **Guideline 5.5**: **Intermittent Pneumatic Compression** 

We suggest using intermittent pneumatic compression (IPC) when other compression options are not available, cannot be used, or have failed to aid in venous leg ulcer healing after prolonged compression therapy. [GRADE - 2; LEVEL OF EVIDENCE -C]







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• <u>Guideline 6.1 Superficial Venous Reflux and Active Venous Leg Ulcer – Ulcer Healing</u>

In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, we suggest ablation of the incompetent veins in addition to standard compressive therapy to improve ulcer healing. [GRADE -2; LEVEL OF EVIDENCE -C]

• <u>Guideline 6.2 Superficial Venous Reflux and Active Venous Leg Ulcer – Prevent Recurrence</u>

In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, we recommend ablation of the incompetent veins in addition to standard compressive therapy to prevent recurrence. [GRADE -1; LEVEL OF EVIDENCE-B]



- <u>Guideline 6.3 Superficial Venous Reflux and Healed Venous Leg Ulcer</u> In a patient with a healed venous leg ulcer (C5) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, we recommend ablation of the incompetent veins in addition to standard compressive therapy to prevent recurrence. [GRADE -1; LEVEL OF EVIDENCE -C]
- Guideline 6.4: Superficial Venous Reflux with Skin Changes at Risk for Venous Leg Ulcer (C4b):

In a patient with skin changes at risk for venous leg ulcer (C4b) and incompetent superficial veins that have axial reflux directed to the bed of the affected skin, we suggest ablation of the incompetent superficial veins in addition to standard compressive therapy to prevent ulceration. [GRADE]

-2; LEVEL OF EVIDENCE -C]



• <u>Guideline 6.5: Combined Superficial / Perforator Venous Reflux With or Without Deep Venous Reflux and Active Venous Leg Ulcer.</u>

In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have reflux to the ulcer bed in addition to pathologic perforating veins (outward flow of >500 msec duration, with a diameter of >3.5mm) located beneath or associated with the ulcer bed, we suggest ablation of both the incompetent superficial veins and perforator veins in addition to standard compressive therapy to aid in ulcer healing and prevent recurrence.







 Guideline 6.6: Combined Superficial and Perforator Venous Reflux With or Without Deep Venous Disease and Skin Changes at Risk for Venous Leg Ulcer (C4b) or Healed Venous Ulcer (C5)

In a patient with skin changes at risk for venous leg ulcer (C4b) or healed venous ulcer (C5) and incompetent superficial veins that have reflux to the ulcer bed in addition to pathologic perforating veins (outward flow of >500 msec duration, with a diameter of >3.5mm) located beneath or associated with the healed ulcer bed, we suggest ablation of the incompetent superficial veins to prevent the development or recurrence of a venous leg ulcer. [GRADE -2; LEVEL OF EVIDENCE -C] Treatment of the incompetent perforating veins can be performed simultaneously with correction of axial reflux or can be staged with re-evaluation of perforator veins for persistent incompetence after correction of axial reflux. [GRADE -2; LEVEL OF EVIDENCE -C]



<u>Guideline 6.7: Pathologic Perforator Venous Reflux in the Absence of Superficial Venous Disease, With or Without Deep Venous Reflux, and a Healed or Active Venous Ulcer:</u>

In a patient with isolated pathologic perforator veins (outward flow of >500 msec duration, with a diameter of >3.5mm) located beneath or associated with the healed (C5) or active ulcer (C6) bed regardless of the status of the deep veins, we suggest ablation of the "pathologic" perforating veins in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [GRADE -2; LEVEL OF EVIDENCE -C]





• <u>Guideline 6.8: Treatment Alternatives for Pathologic Perforator Veins</u>
For those patients who would benefit from pathologic perforator vein ablation, we recommend treatment by percutaneous techniques that include ultrasound guided sclerotherapy or endovenous thermal ablation (radiofrequency or laser) over open venous perforator surgery to eliminate the need for incisions in areas of compromised skin. [GRADE -1; LEVEL OF EVIDENCE -C]





Guideline 6.9: Infrainguinal Deep Venous Obstruction and Skin Changes
 at Risk for Venous Leg Ulcer (C4b), Healed (C5) or Active (C6) Venous Leg
 Ulcer

In a patient with infrainguinal deep venous obstruction and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we suggest autogenous venous bypass or endophlebectomy in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [GRADE -2; LEVEL OF EVIDENCE -C]





Guideline 6.10: <u>Deep Vein Reflux with Skin Changes at Risk for Venous Leg Ulcer (C4b)</u>, <u>Healed (C5) or Active (C6) Venous Leg Ulcer – Ligation</u>

In a patient with infrainguinal deep venous reflux and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we suggest against deep vein ligation of the femoral or popliteal veins as a routine treatment. [GRADE -2; LEVEL OF EVIDENCE -C]





Guideline 6.11: <u>Deep Venous Reflux with Skin Changes at Risk for Venous Leg Ulcer (C4b)</u>, <u>Healed (C5)</u>, <u>or Active (C6) Venous Leg Ulcer – Primary Valve Repair</u>

In a patient with infrainguinal deep venous reflux and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we suggest individual valve repair for those who have axial reflux with structurally preserved deep venous valves in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [GRADE -2; LEVEL OF EVIDENCE -C]





Guideline 6.12: <u>Deep Vein Reflux with Skin Changes at Risk for Venous Leg Ulcer (C4b)</u>, <u>Healed (C5) or Active (C6) Venous Leg Ulcer - Valve Transposition or Transplantation</u>

In a patient with infrainguinal deep venous reflux and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we suggest valve transposition or transplantation for those with absence of structurally preserved axial deep venous valve(s) when competent outflow venous pathways are anatomically appropriate for surgical anastomosis in addition to standard compression therapy to aid in venous leg ulcer healing and to prevent recurrence. [GRADE -2; LEVEL OF EVIDENCE -C]





 Guideline 6.13: Deep Vein Reflux with Skin Changes at Risk for Venous Leg Ulcer (C4b), Healed (C5), or Active (C6) Venous Leg Ulcer – Autogenous Valve Substitute

In a patient with infrainguinal deep venous reflux and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we suggest consideration of autogenous valve substitutes by surgeons experienced in these techniques to facilitate ulcer healing and to prevent recurrence in those with no other option available in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [GRADE -2; LEVEL OF EVIDENCE -C]





#### SVS – AVF Clinical Practice Guidelines Operative / Endovascular – Occlusion

Guideline 6.14: Proximal Chronic Total Venous Occlusion / Severe
 Stenosis with Skin Changes at Risk for Venous Leg Ulcer (C4b), Healed
 (C5) or Active (C6) Venous Leg Ulcer - Endovascular Repair

In a patient with inferior vena cava and/or iliac vein chronic total occlusion or severe stenosis, with or without lower extremity deep venous reflux disease, which is associated with skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we recommend venous angioplasty and stent recanalization in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [GRADE -1; LEVEL OF EVIDENCE -C]





#### **SVS – AVF Clinical Practice Guidelines** Operative / Endovascular – Occlusion

**Guideline 6.15: Proximal Chronic Venous Occlusion / Severe Stenosis** (Bilateral) with Recalcitrant Venous Ulcer - Open Repair

In a patient with inferior vena cava and/or iliac vein chronic occlusion or severe stenosis, with or without lower extremity deep venous reflux disease, which is associated with a recalcitrant venous leg ulcer and who have failed endovascular treatment, we suggest open surgical bypass using an externally supported ePTFE graft in addition to standard compression therapy to aid in venous leg ulcer healing and to prevent recurrence.

[GRADE -2; LEVEL OF EVIDENCE -C]





#### SVS – AVF Clinical Practice Guidelines Operative / Endovascular – Occlusion

Guideline 6.16: <u>Unilateral Iliofemoral Venous Occlusion / Severe Stenosis</u>
 With Recalcitrant Venous Ulcer – Open Repair:

In a patient with unilateral iliofemoral venous occlusion/severe stenosis with recalcitrant venous leg ulcer who failed attempts at endovascular reconstruction, we suggest open surgical bypass using saphenous vein as a crosspubic bypass (Palma procedure) to aid in venous ulcer healing and to prevent recurrence. A synthetic graft is an alternative in the absence of autogenous tissue. [GRADE -2; LEVEL OF EVIDENCE -C]





### SVS – AVF Clinical Practice Guidelines Operative / Endovascular – Occlusion

<u>Guideline 6.17: Proximal Chronic Total Venous Occlusion / Severe Stenosis (Bilateral or Unilateral) With Recalcitrant Venous Ulcer – Adjunctive arteriovenous fistula:</u>

For those patients who would benefit from an open venous bypass, we suggest the addition of an adjunctive arteriovenous fistula (4 to 6 mm in size) as an adjunct to improve inflow into autologous or prosthetic cross over bypasses when the inflow is judged to be poor to aid in venous leg ulcer healing and to prevent recurrence. [GRADE -2; LEVEL OF EVIDENCE -C]





#### SVS – AVF Clinical Practice Guidelines Ancillary Measures - Nutrition

Guideline 7.1: Nutrition Assessment and Management:

We recommend that nutrition assessment be performed in any patient with a venous leg ulcer who has evidence of malnutrition and that nutritional supplementation be provided if malnutrition identified. [BEST PRACTICE]





## SVS – AVF Clinical Practice Guidelines Ancillary Measures - Medications

• **Guideline 7.2: Systemic Drug Therapy** 

For long-standing or large venous leg ulcer we recommend treatment with either pentoxifylline or micronized purified flavonoid fraction used in combination with compression therapy. [GRADE -1; LEVEL OF EVIDENCE – B]





### SVS – AVF Clinical Practice Guidelines Ancillary Measures - Physiotherapy

• **Guideline 7.3**: **Physiotherapy** 

We suggest supervised active exercise to improve muscle pump function and reduce pain and edema in patients with venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE - B]





#### SVS – AVF Clinical Practice Guidelines Ancillary Measures – Lymphatic

• **Guideline 7.4**: **Manual Lymphatic Drainage** 

We suggest against adjunctive lymphatic drainage for healing of the chronic venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE - C]





# SVS – AVF Clinical Practice Guidelines Ancillary Measures - Balneotherapy

• **Guideline 7.5**: Balneotherapy

We suggest balneotherapy to improve skin trophic changes and quality of life in patients with advance venous disease. [GRADE -2; LEVEL OF EVIDENCE - B]





#### SVS – AVF Clinical Practice Guidelines Ancillary Measures - Ultraviolet

Guideline 7.6: Ultraviolet light

We suggest against using ultraviolet light for the treatment of venous leg ulcers. [GRADE -2; LEVEL OF EVIDENCE - C]





# **SVS – AVF Clinical Practice Guidelines Primary Prevention – Primary Reflux**

• <u>Guideline 8.1: Primary Prevention - Clinical CEAP C3-4 Primary Venous Disease</u>

In patients with Clinical CEAP C 3-4 disease due to primary valvular reflux, we recommend 20-30 mmHg compression, knee or thigh high. [GRADE -2; LEVEL OF EVIDENCE - C]





# **SVS – AVF Clinical Practice Guidelines Primary Prevention – Post-Thrombotic**

• <u>Guideline 8.2: Primary Prevention - Clinical CEAP C1-4 Post-Thrombotic Venous Disease</u>

In patients with Clinical CEAP C1-4 disease related to prior DVT, we recommend compression, 30 - 40 mmHg, knee or thigh high. [GRADE -1; LEVEL OF EVIDENCE - B]





#### SVS – AVF Clinical Practice Guidelines Primary Prevention – Acute DVT

Guideline 8.3. Primary Prevention – Acute DVT Treatment

As post thrombotic syndrome (PTS) is a common preceding event for venous leg ulcers, we recommend current evidence based therapies for acute DVT treatment. [GRADE -1; LEVEL OF EVIDENCE - B] We suggest use of low molecular weight heparin (LMWH) over vitamin k antagonist therapy of 3 month duration to decrease PTS [GRADE -2; LEVEL OF EVIDENCE - B] We suggest catheter directed thrombolysis in low bleeding risk patients with iliofemoral DVT of duration <14 days [GRADE -2; LEVEL OF EVIDENCE - B]





#### SVS – AVF Clinical Practice Guidelines Primary Prevention - Education

• <u>Guideline 8.4: Primary Prevention – Education Measures</u> In patients with C1-4 disease, we suggest patient and family education, regular exercise, leg elevation when at rest, careful skin care, weight control and appropriately fitting foot wear. [BEST PRACTICE]





#### SVS – AVF Clinical Practice Guidelines Primary Prevention - Operative

• <u>Guideline 8.5:</u> <u>Primary Prevention – Operative Therapy</u>
In patients with asymptomatic C1-2 disease from either primary or secondary causes, we suggest against prophylactic interventional therapies to prevent venous leg ulcer. [GRADE -2; LEVEL OF EVIDENCE - C]







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