



Compression for Lower Extremity Venous Disease and Lymphedema (CLEVDAL)

Update of the VLU Algorithm

Catherine R. Ratliff ◆ Stephanie Yates ◆ Laurie McNichol ◆ Mikel Gray

ABSTRACT

The Wound, Ostomy and Continence Nurses (WOCN) Society charged a task force with updating the venous leg ulcer (VLU) algorithm to include the addition of lymphedema with the new title of “Compression for Lower Extremity Venous Disease and Lymphedema (CLEVDAL).” As part of the process, the task force was charged to develop consensus-based statements to serve as clinical guidance related to CLEVDAL. The 3-member task force assisted by a moderator completed a scoping literature review to identify recommendations supported by research to qualify as evidence-based and to identify areas where guidance is needed to provide CLEVDAL. Based on the findings of the scoping review, the WOCN Society convened a panel of experts to develop consensus statements to direct care for those with lower extremity venous disease and lymphedema. These consensus statements underwent a second round of content validation with a different panel of clinicians with expertise in venous disease and lymphedema management. This article reports on the scoping review and subsequent evidence-based statements, along with the generation and validation of consensus-based statements to assist clinical decision-making in the CLEVDAL algorithm.

KEY WORDS: Algorithm, Chronic venous insufficiency (CVI), Compression, Lymphedema, Phlebolymphe­dema, Venous leg ulcer (VLU), Venous ulcer, VLU algorithm, Wound.

INTRODUCTION

Venous leg ulcers (VLUs) include about 70% of all leg ulcers and affect 2.2 million Americans annually, with compression therapy being the standard of care.¹ In 2015, the Wound, Ostomy and Continence Nurses (WOCN) Society appointed a task force to develop an algorithm for VLUs to address the need for clinical guidance on compression therapy for prevention, treatment, and prevention of recurrence of VLUs.² The VLU algorithm was launched in July 2016. Since the release, the VLU algorithm has been accessed by over 20,929 users, with over 32,565 pages viewed from 125 countries. It has been 5 years since the VLU tool was released; it is time to update the algorithm.

In 2021, the WOCN Society appointed a task force to update the VLU algorithm. Since lymphedema shares many

clinical features with VLU, it was agreed to add the topic to the updated algorithm with the new title of “Compression for Lower Extremity Venous Disease and Lymphedema (CLEVDAL).” The target audience of the updated algorithm includes nurses, specialty and advanced practice providers (eg, wound care nurses, WOC nurses, nurse practitioners, clinical nurse specialists, physician assistants), occupational therapists, physical therapists, and physicians. The CLEVDAL algorithm is designed for adult patients in a variety of care settings such as acute care facilities, rehabilitation facilities, long-term/skilled facilities, outpatient clinics, and home care settings. The purpose of this article is to report findings from an updated scoping review with subsequent evidence-based statements, along with the generation and validation of consensus-based statements to assist clinical decision-making related to CLEVDAL.

Lymphedema

Lymphedema affects an estimated 35 million individuals in the United States, with over 140 million people worldwide.³ It may be classified as primary lymphedema (congenital) or secondary lymphedema occurring after surgery, lymphatic trauma, infection, radiation therapy, or chronic venous insufficiency (CVI). Lymphedema caused by both the venous and lymphatic systems is known as phlebolymphe­dema (PLE). Phlebolymphe­dema may be caused by a congenital defect of the venous and lymphatic systems or secondary to CVI. It is the most common cause of secondary lymphedema in the Western hemisphere.⁴ The signs and symptoms of lymphedema may include progressive edema leading to fibrosis, irreversible skin changes, and heaviness in the affected limbs with reduced mobility. Obesity is an independent risk factor for lymphedema (ie, obesity-related PLE). A body mass index

Catherine R. Ratliff, PhD, GNP-BC, CWOCN, CFCN, FAAN, Department of Surgery, UVA Health, Charlottesville, Virginia.

Stephanie Yates, MSN, RN, ANP-BC, CWOCN, Department of Advanced Clinical Practice, Duke University Medical Center, Durham, North Carolina.

Laurie McNichol, MSN, RN, CNS, GNP, CWOCN, CWON-AP, FAAN, Cone Health, Greensboro, North Carolina.

Mikel Gray, PhD, FNP, PNP, CUNP, CCCN, FAANP, FAAN, Department of Urology, University of Virginia, Charlottesville, Virginia.

The WOCN Society thanks Urgo Medical for providing an unrestricted educational grant to support this consensus conference and update of the VLU algorithm.

The authors have no conflicts of interest to declare.

Correspondence: Catherine R. Ratliff, PhD, GNP-BC, CWOCN, CFCN, FAAN, Department of Surgery, UVA Health, PO Box 800679, Charlottesville, VA 22908 (crr9m@virginia.edu).

DOI: 10.1097/WON.0000000000000889

(BMI) of more than 50 kg/m² may lead to the development of lymphedema.^{5,6} When left untreated, lymphedema is associated with a high risk of morbidity including wounds, recurrent episodes of cellulitis, deep vein thrombosis, lymphangiosarcoma, decreased quality of life (QOL), and increased health care costs for frequent clinic visits and recurrent hospitalizations.⁷

The Executive Committee of the International Society of Lymphology (ISL) updated their consensus document⁸ in 2020 on the diagnosis and treatment of peripheral lymphedema. The document emphasizes the importance of meticulous skin care (eg, frequent skin cleansing, using low pH lotions, and emollients). Exercises of the lower extremities (muscle calf pumping exercises) should be performed as part of daily activities (such as walking, using stairs instead of elevators) since they promote external limb compression. Complete decongestive therapy (CDT) or combined physical therapy (CPT) or complex decongestive physiotherapy (CDP) involves a 2-stage treatment program: an active phase I and a maintenance phase II. The first phase consists of skin care, light manual massage (manual lymphatic drainage [MLD]), and sometimes deeper massage techniques for those classified above lymphedema stage I, and also using muscle calf pumping exercises, and compression typically applied with multilayered bandages. In phase II, the individual with lymphedema continues with exercises, compression, and MLD, as needed.⁸

There are multiple devices/garments that provide compression, which may facilitate compliance by offering compression alternatives. A prescription for elastic garments (eg, custom-made garment with specific limb measurements) to maintain lymphedema reduction after CDT is important for long-term care of patients with lymphedema. Generally, the highest compression level tolerated is likely to be the most beneficial. Patient selection, choice, physical ability, and cost need to be taken into consideration when assessing mobility and compliance (including use of alternative compression devices).⁸

After intermittent pneumatic compression (IPC) therapy is applied, preferably by a sequential gradient pump, a low-stretch elastic stocking or sleeve is used to maintain edema reduction. Newer compression pump devices may simulate manual lymphatic massage, and newer pump designs may be easier to use, which may increase patient compliance, particularly for those who cannot complete both phases of CDT (eg, exercise with compression). Combining IPC with manual lymph drainage has been recommended, but currently it has not been sufficiently studied.⁸

Diuretic agents are of limited use during the initial treatment phase of CDT and should be reserved only for patients with specific comorbid conditions such as heart failure. Long-term administration of diuretics is discouraged because it is of little benefit in the treatment of peripheral lymphedema and may cause fluid and electrolyte imbalance. No special diet has proven to be of benefit for patients with peripheral lymphedema. While higher BMI has been consistently associated with an increased risk of developing lymphedema, there is very limited evidence to support that weight loss may reduce lymphedema. However, weight loss will likely contribute to reductions in lymphedema-associated symptoms.⁸

A systematic review of the available clinical practice guidelines (CPGs) for lymphedema was conducted by O'Donnell and others.³ They searched guidelines from the National Guideline Clearinghouse (www.guidelines.gov), BMJ Clinical

Evidence (<http://clinicalevidence.bmj.com>), and the National Institute for Health and Care Excellence (<http://www.nice.org.uk>), as well as from MEDLINE and Google. They identified 13 potential CPGs; 4 satisfied the criteria for lymphedema, with inclusion of diagnosis and treatment of lymphedema. The 4 CPGs are as follows:

- International Lymphoedema Framework. *International Consensus: Best Practice for the Management of Lymphoedema*. London, England: MEP Ltd; 2006.
- The Japan Lymphoedema Study Group. A practice guideline for the management of lymphedema. *J Lymphoedema*. 2011;6:60-71.
- Clinical Resource Efficiency Support Team. Guidelines for the diagnosis, assessment and management of lymphoedema. www.crestni.org.uk. Published 2008.
- Gloviczki P. *Handbook of Venous Disorders: Guidelines of the American Venous Forum*. Boca Raton, FL: CRC Press; 2017.

Only one of the 4 CPGs was based on a systematic review date of 2016, with the remaining ones having older systematic reviews dates. The authors concluded from the systematic review that there is a need for updated CPGs on lower extremity lymphedema.³

METHODS

The WOCN Society appointed a task force to update and review the literature relevant to CLEVDAL. The task force comprised 3 individuals with expertise in lower extremity venous disease (LEVD) and lymphedema (C.R., S.Y., and L.M.). Task force members were responsible for reviewing the literature, generation of draft consensus statements, and authorship of this article. The VLU algorithm was published in 2016.² In 2019, the Guideline for Management of Wounds in Patients With Lower-Extremity Venous Disease was published by the WOCN Society.⁹ The 3 task force members had access to the articles reviewed for the LEVD guideline, avoiding an extensive review of the VLU literature.

Based on the limited evidence regarding compression for lymphedema, the task force completed a scoping review to identify current best practice evidence on the topic of compression for lymphedema, as well as updating the scoping review on VLUs to support decision points and pathways within the CLEVDAL algorithm. A scoping review is a structured technique of examining the literature to identify key concepts, levels of evidence, and gaps in the evidence. The review used the method described by Levac and colleagues¹⁰ and refined by Colquhoun and coworkers.¹¹ The primary aim was to identify current knowledge and clinical evidence and to identify gaps in evidence, which required generation of consensus-based best practice statements. Results of the structured review were also used to generate levels of evidence underlying these statements using a 3-point ordinal scale adapted from the Strength of Recommendation Taxonomy (SORT) statements disseminated by the American Academy of Family Physicians and regularly used by the WOCN Society to generate similar scholarly documents.¹²⁻¹⁶ The methodologic quality of individual studies was ranked using a 3-point scale adapted from the John Hopkins Evidence-based Practice methodology, where A indicates high quality, B indicates good quality, and C indicates low quality (Table 1).¹⁷ In formulating the scope

TABLE 1.
Strength of Evidence^a

Level	Supported by
A	Consistent findings from ≥ 2 RCTs or a systematic review with meta-analysis (pooled data) of multiple clinical trials
B	Consistent findings from 1 RCT or >1 nonrandomized clinical trial or inconsistent (mixed) evidence from ≥ 2 RCTs or systematic reviews with meta-analysis
C	Expert opinion based on consensus among clinical experts, findings from a single nonrandomized clinical trial, case study, or series of clinical case studies

Abbreviation: RCT, randomized controlled trial.

^aStrength of evidence was ranked using a 3-point ordinal scale adapted from the Level of Evidence Rating found in the WOCN Clinical Practice Guideline for Management of Wounds in Patients With Lower-Extremity Venous Disease and the Strength of Recommendations Taxonomy (SORT) statements from the American Academy of Family Physicians.

for the reviews, search terms were devised using the PICO (participants, interventions, comparisons, outcomes)¹⁸ to help compare and summarize any systematic reviews that addressed lymphedema (Box).

Initial review by the professional librarian used the following sources: MEDLINE, CINAHL, and Cochrane Library of Systematic Reviews. These databases were selected for their robust, international scope of searchable literature. Medical subject headings (MeSH) terms were practice guidelines, venous insufficiency, varicose veins, varicose ulcers, compression bandages, compression stockings, intermittent pneumatic compression devices, and lower extremity lymphedema. Key terms were compression, clinical practice guidelines, chronic venous insufficiency, compression therapy, venous ulcers, venous leg ulcers, lipedema, lymphedema, lymphoedema, diabetic lymphedema, phlebolymphe-
dema, and pneumatic compression devices.

Inclusion criteria were articles published on lymphedema from 2009 to 2021, based on the ISL Consensus Document for the evaluation and management of peripheral lymphedema,¹⁹ and articles that reviewed compression in LEVD published from 2016 to 2021. Articles published in the English language, full-text articles, original research reports, randomized controlled trials (RCTs), nonrandomized comparison cohort studies, systematic reviews with meta-analysis, integrative and scoping review articles, and expert opinion (consensus statements or position statements) were also included. Exclusion criteria were articles published in a language other than English, articles with subjects younger than 18 years, studies of lymphedema involving both upper and lower extremities, and

studies comparing compression products not currently available in the United States.

Selection of Articles

The initial search returned 340 articles, 30 bibliographic reviews, and 10 duplicates. A total of 360 abstracts were reviewed by the 3 task force members (C.R., S.Y., and L.M.), with 310 of these abstracts excluded. Fifty full-text articles were reviewed by the 3 task force members. Methodologic quality was judged for each study by all 3 task force members. Disagreements concerning study inclusion and methodologic quality were resolved by discussion. Thirty articles were included, with 20 articles excluded as shown in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram (Figure).

RESULTS OF SCOPING REVIEW OF CLEVDAL

Adjustable compression wraps (ACWs) are devices that are made with short-stretch material secured with Velcro and are used for treating lower-leg edema in CVI and lymphedema. There are currently multiple brands of compression devices available on the market. Balet and colleagues in 2021²⁰ conducted a prospective cohort study to determine factors that may prevent self-application of the adjustable compression device (Circaid Juxtalite) to the lower limb by comparing the interface pressures recorded below the wrap. The study included 30 subjects older than 65 years with a Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P) (CEAP) classification of C0-C3. Only 30% (N = 8) of the subjects were able to apply the wrap with a pressure of more than 30 mm Hg. Obesity (BMI > 30 kg/m²), gripping difficulties, cognitive impairment, and low social status were the factors limiting the self-management of an ACW in subjects older than 65 years. The role of age (<75 years vs >75 years) was not significant.²⁰

Compression is an important component of CDT. Borman and others²¹ in 2021 conducted a prospective, randomized, single-blind study to evaluate the comparative efficacy of conventional multilayer short-stretch bandaging, and a Velcro ACW assessing volume reduction, ultrasonographic measurements, functional status, and QOL in the active CDT period of individuals with lower-limb lymphedema. The clinical diagnosis of lower-limb lymphedema was defined as an inter-limb difference of more than 10% in volume or excess volume ratio between the affected and unaffected lower limbs. All individuals received skin care education, MLD, and supervised lymphedema exercises. Participants were randomly assigned either to group 1 (multilayer short-stretch bandaging Rosidal-K) or to group 2 (adjustable compression Velcro wrap Circaid Reduction kit) for 3 weeks. A total of 36 individuals (10 males, 26 females) were enrolled in the study, with a mean age of 51.6 years. Significant improvements in limb-volume reductions and ultrasonographic measurements were observed in both groups at the end of treatment. The authors concluded that an adjustable compression hook and loop or Velcro wrap is an alternative to conventional multilayer compression wraps in the active treatment phase of lymphedema.²¹

Compression stockings are usually knitted with a graduated pressure profile, with the highest interface pressure exerted over the supramalleolar area decreasing toward the knee to counteract the increased venous hypertension caused by gravity when standing. The circumference of the heel is 1.5 times

BOX.

Literature Review Search Terms

PICO Terms for Lymphedema

Population: Adults

Intervention: Compression and lower extremity edema

Comparison: Compression versus complete decongestive therapy (CDT), which includes manual lymphatic drainage (MLD), lymphedema exercises, skin care, kinesiology taping in lymphedema, pneumatic compression devices, compression wraps

Outcomes: Reduction in limb volume, improvement in lymphatic skin fibrosis, quality-of-life component, therapeutic role of compression

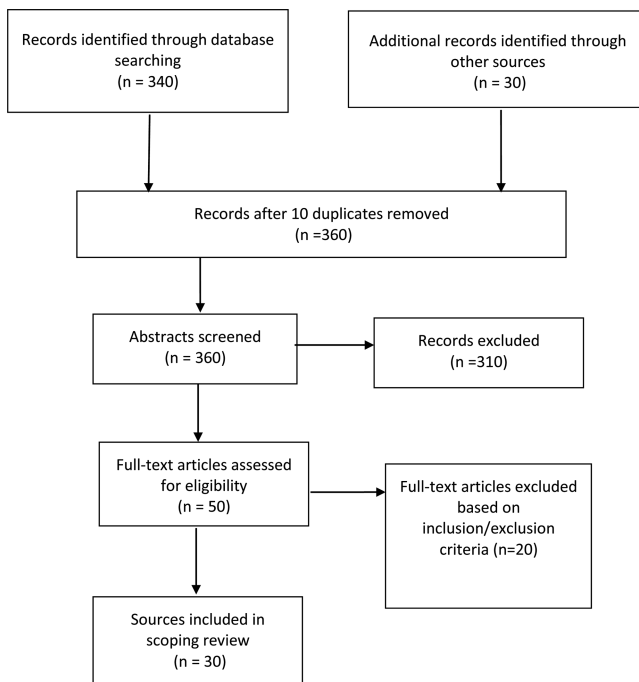


Figure. PRISMA flow diagram.

larger than the circumference of the supramalleolar area, so when donning or doffing a compression stocking, overcoming the heel requires the most effort.²² Buset and others²² in 2021 conducted an open-label RCT to determine whether a 2-layer stocking exerting 27 to 29 mm Hg pressure at the medial supramalleolar level without compression in the foot, including the heel, is easier to put on (donning) and take off (doffing) than a standard stocking of the same compression class (23–32 mm Hg). Participants ($N = 47$) were at least 65 years of age and had CVI with a CEAP classification of C3–C6 in one leg. All patients evaluated both stockings for ease of donning and doffing in the manner of a crossover study, testing the stocking from their assigned study group first (investigational or standard). Patients then wore the stocking from their assigned group for a whole day. All patients could don the investigational stocking ($N = 47/100\%$) versus the success rate with the standard stocking, which was 75% ($N = 35$; $P = .001$). All patients were able to doff the investigational stocking ($N = 47$; 100%) compared to a 66% success rate with the standard stocking ($N = 31$; $P = .001$). There was no significant difference in leg-volume reduction between the study groups after wearing the stocking for 1 day. The investigational stocking was also rated as being more comfortable than the standard stocking ($P = .001$). The authors concluded that compression stockings that do not compress the foot and heel area may improve treatment adherence since they are significantly easier to put on (don) and take off (doff) than standard stockings, while providing the same degree of edema prevention.²²

Damstra and Partsch²³ in 2013 conducted a prospective RCT to assess the effectiveness of an ACW in the treatment of lower extremity lymphedema by comparing the traditional treatment with inelastic multicomponent compression (IMC) bandages. Thirty hospitalized individuals were admitted with moderate to severe unilateral lymphedema (stages II–III) of the leg. Participants were randomized into 2 groups

of 15 patients: group A received ACW and group B received IMC bandages. After 2 hours, the clinicians replaced IMC bandages and the individuals applied ACW. Compression was removed after 24 hours. Classic water displacement volumetry was performed before compression, after 2 hours, and after 24 hours of compression. The interface pressure was measured immediately after application of compression, 2 hours after compression, before and after compression removal, and after 24 hours. The initial pressures of the ACW and IMC bandages did not differ significantly after the first application or after the second application 2 hours later. Pressure loss within 2 hours was significant for both types of bandages ($P = .001$). The reduction in median volume after 2 hours was 109 mL (interquartile range [IQR], 64–271 mL; -3.1%) in the ACW group and 75 mL (IQR, 41–135; -2.4%) in the IMC group (not significant). After 24 hours, the reduction in median volume was 339 mL (IQR, 231–493 mL; -10.3%) in the ACW group and 190 mL (IQR, 113–296 mL; -5.9%) in the IMC group ($P < .05$). Adjustable compression wrap achieved significant reduction in volume ($P = .05$) after 24 hours when compared to the IMC bandages. Individuals were able to apply and adjust the ACW, which may encourage better adherence.²³

A meta-analysis²⁴ was conducted to compare the effectiveness of 4-layer compression versus short-stretch bandages for venous ulcer healing. The studies included 1437 patients, average age 70 (range, 23–97) years, with 1446 VLU. Five studies were classified as being at low risk of bias. At 12 and 16 weeks, 259 ulcers (51.08%) healed completely in the 4-layer compression group and 234 (46.34%) in the short-stretch bandage group, respectively ($P = .41$). At 24 weeks, 268 ulcers (69.07%) healed in the 4-layer compression group and 257 (62.23%) in the short-stretch bandage group, respectively ($P = .16$). The 2 bandage systems evaluated were similar in achieving complete healing. The average time for healing was 73.6 ± 14.64 days in the 4-layer compression group and 83.8 ± 24.89 days in the short-stretch bandage group. The authors concluded that the choice of compression system should be based on evidence of effectiveness, patient tolerability, and patient preference.²⁴

A multicenter RCT was conducted to evaluate the efficacy, safety, and acceptability of a 2-component versus 4-component compression system in the management of VLUs. The primary endpoint was complete healing at 16 weeks. Ninety-two patients were randomized to either the 2-component BIFLEX Kit group ($N = 49/53.2\%$) or the 4-component PROFORE group ($N = 43$). In the analysis ($N = 88/95.6\%$), a complete healing rate of 48.9% and 24.4% was reported in the BIFLEX Kit versus PROFORE groups, respectively (ie, a superiority of 24.5%; $P = 0.02$). The authors concluded that the BIFLEX Kit represents a reasonable alternative therapy in the management of VLUs.²⁵

A prospective, open, randomized, monocentric study was conducted on 19 patients (6 men [31.5%] and 13 women [68.4%]), with an average age of 73.7 years ($SD = 5.2$), who received both knee-length compression stockings with an interface pressure of 18 to 21 mm Hg (stocking type 1) and 23 to 32 mm Hg (stocking type 2) for lower-leg edema. The primary outcome was comfort of both knee-length compression stockings. Secondary outcomes included the influence of foot deformities, rheumatism, and arthritis on stocking comfort. On 2 consecutive days, each of the 2 compression stocking types

was worn at least 8 hours. A significant ($P = .001$) subjective reduction in the symptoms and leg edema was reported with both knee-length compression stockings. Stocking type 1 recorded a significant ($P = .045$) better wearing comfort. Stocking type 2 was significantly too large in the forefoot for the women ($P = .044$). The most common side effects from the stockings were constriction on the proximal lower leg (stocking type 1 = 73.7% [14/19]; stocking type 2 = 78.9% [15/19]). Subjects with arthritis ($P = .006$), hallux valgus ($P = .034$), and/or digitus flexus ($P = .021$) found stocking type 1 significantly more comfortable. The authors concluded that to achieve compliance, prescribe knee-length compression stockings with an interface pressure of 18 to 21 mm Hg if the following criteria are met: age 65 years or more, female, arthritic, and presence of digitus flexus (claw toe) or hallux valgus.²⁶

Goka and others²⁷ in 2020 conducted a systematic review of MEDLINE, EMBASE, CINAHL, Cochrane Library, National Health Service (NHS) Economic Evaluation, and EconLit databases to evaluate the effectiveness of a 2-layer compression system (2LBa; 3M Coban) compared with other 2-layer compression systems (2LBc; UrgoK2, Rosidal-K) and 4-layer (4LBb) compression system (PROFORE and a modified Unna boot) in patients with noninfected VLU. Five studies ($n = 1509$ patients) of mixed methodologic quality were included. At 6 months, 2LBa achieved better ulcer healing in comparison with 2LBc (odds ratio [OR] = 1.57; 95% confidence interval [CI], 1.10-2.24; $P = .03$) and 4LBa (OR = 1.93; 95% CI, 1.26-2.97; $P = .05$) in patients with newly diagnosed VLUs only. For a combined population with newly diagnosed and existing VLUs, healing outcomes were OR = 2.87; 95% CI, 1.06-7.77; $P = .04$; and OR = 16.51; 95% CI, 2.08-131.37; $P = .008$, for 2LBc and 4LBb, respectively. The authors concluded that 2LBa may result in lower treatment costs and better ulcer healing and QOL compared with other multicomponent therapies, especially in patients with newly diagnosed VLUs.²⁷

Knight and colleagues²⁸ conducted a 2021 update of a 2011 Cochrane review²⁹ that assessed the effectiveness of compression stockings for initial treatment of varicose veins in people without venous ulcers. The authors in the update included 13 studies with 1021 participants with varicose veins without healed or active VLUs. The stockings used in the studies exerted different levels of pressure, ranging from 10 to 50 mm Hg. Five studies assessed compression stockings versus no compression stockings or placebo stockings. Three of these studies used knee-length stockings, one used full-length stockings, and one used tights. Eight studies compared different types or pressures of knee-length stockings. The risk of bias of many of the included trials was unclear, mainly because of inadequate reporting. The authors of the Cochrane review were unable to pool studies, as the studies did not report the same outcomes or used different ways to assess them. Many studies were small, and there were differences in the populations studied. The certainty of the evidence was low to very low. They concluded that there is insufficient high-certainty evidence to determine whether or not compression stockings are effective as the only and initial treatment of varicose veins in people without healed or active VLUs or whether any type of stocking is superior to any other type.²⁸

Lazareth and others³⁰ in 2012 conducted an RCT in 37 centers in Europe to evaluate the efficacy, tolerance, and acceptability of a 2-layer system (UrgoK2) versus a 4-layer bandage system (PROFORE) in the management of VLUs. Participants were nonimmunosuppressed adults who presented with noninfected, nonmalignant leg ulcers, predominantly of venous origin (ankle brachial index [ABI] > 0.8), with a surface area of 2 to 50 cm² and duration 1 of 24 months. In total, 187 patients were randomized to either the 2-layer bandage system (2LB; $n = 94$) or the 4-layer bandage system (4LB; $n = 93$). Patients were followed every 2 weeks for a period of 12 weeks, or until closure. By week 12, 44% ($N = 41$) of VLUs in the 2LB group and 39% ($N = 36$) in the 4LB group had healed. The analysis further showed that complete wound closure was obtained in 48% and 38% of the 2LB and 4LB groups, respectively. The 2LB compression system was considered significantly easier to apply than the 4LB system ($P = .038$).³⁰

An open, prospective, randomized, single-center study with a 5-year follow-up was conducted to establish the efficacy of 2 different strengths of knee-high compression hosiery (class 2, class 3) in the prevention of VLU recurrences. Patients were randomized into 2 groups: group A, 186 patients who wore a heel-less, open-toed elastic class 3 compression device knitted in tubular form, and group B, 175 patients who wore a class 2 elastic stocking. All patients were instructed to wear compression stockings continuously for the first 2 years of follow-up (both during the day and at night). In the third, fourth, and fifth years of follow-up, patients were instructed to wear elastic stockings during the day only. The main outcome measures were recurrence of leg ulceration and compliance with the treatment. There were 147 ulcers that recurred: 51 (28.98%) in the class 3 group and 96 (60%) in the class 2 group ($P = .001$, log-rank test). Patients in the compression class 3 group experienced significantly longer absolute (46 vs 40 months; $P = .001$, Mann-Whitney U test) and proportional (77% vs 67%; $P = .001$, Mann-Whitney U test) ulcer-free time after 5 years than those in the compression class 2 group. Rates of noncompliance after 5 years were 10.23% for the compression class 3 group and 6.25% for the compression class 2 group ($P = .188$, χ^2 test).³¹

Mosti and colleagues³² in 2015 compared the efficacy and comfort of inelastic bandages (IBs) and adjustable Velcro compression devices (AVCDs) in reducing venous leg edema. Forty legs from 36 patients with CEAP C3 (17 men, 19 women; age mean $\pm$ SD = 71.4 $\pm$ 10.2 years; range, 52-85 years) affected by CVI were randomized to receive 2 different compression systems to be applied for 1 week. Group A received IBs and group B received AVCDs. At T_1 , the median percent volume reduction was 13% for the IB group versus 19% for the AVCD group; at T_2 , it was 19% versus 26%, respectively ($P = .001$). The pressure of the IBs was significantly higher compared with the AVCDs at T_0 (63 vs 43 mm Hg) but dropped by more than 50% over time, while it remained unchanged with AVCDs probably due to the periodic readjustment by the patient. Comfort was reported to be similar with the 2 compression devices. Readjustable AVCDs with a resting pressure of 40 mm Hg were more effective in reducing chronic venous edema than IBs, with a resting pressure of 60 mm Hg. Adjustable Velcro compression devices were effective and well tolerated, not only during maintenance therapy but also in the initial decongestive treatment phase of patients with venous leg edema. The authors concluded that AVCDs may be more effective than IBs in exerting a very stronger pressure in the initial treatment phase and are at least equally well-tolerated as IBs.³²

Bakar and others³³ in 2010 used a convenience sample of 62 individuals aged 59 to 68 years who were treated for CVI with CDT (ie, MLD, skin care, compression, exercise). The treatment consisted of 1 MLD session per day, 5 days a week for 4 weeks plus the maintenance phase. A pH-balanced moisturizer was applied to the limb before the compression. Next, short-stretch bandages were applied to the limb. Compression was worn 24 hours per day during the treatment phase. After compression was applied, exercises with the foot using dorsiflexion and plantar flexion, and ankle circular exercises, were done 3 times a day, with recommended 10 repetitions for each exercise. Mean age of the 62 individuals was 64.95 ± 2.54 years, and the mean duration of CVI symptoms was 6.33 ± 1.85 years. All had edema in their legs (CEAP C3), and 23 of them had color changes in their foot and/or skin (CEAP C4). Limb volume, pain intensity, pain-free walking distance, and activities of daily living improved significantly following the treatment ($P = .01$). These results suggest that CDT may be used as adjunct to compression therapy in individuals with venous disease, CEAP 3-4.³³

A multicenter, single-arm, observational, clinical trial conducted in the Veterans Affairs Healthcare System evaluated patients with a diagnosis of primary or secondary edema of unilateral or bilateral lower extremities being treated with the Flexitouch Advanced Pneumatic Compression Device (APCD) (Tactile Medical). Patients were assessed at baseline and 12, 24, and 52 weeks with limb circumference, QOL assessments (Short Form-36 [SF-36] and Lymphedema Quality of Life), device compliance, cellulitis episodes, and lymphedema-related health care use since the previous visit. The primary endpoints were the QOL at baseline compared at 12 weeks, unscheduled lymphedema-related clinic visits, and hospital admissions at 52 weeks. The secondary endpoints included the change in limb girth and QOL at 52 weeks compared with baseline. A total of 178 patients with lower extremity lymphedema were prospectively enrolled. The present study reported the interim data for the first 74 subjects to complete 52 weeks of APCD treatment. The cohort was male (94.6%), elderly (mean age = 67 years), obese (median BMI = 32 kg/m^2), and the most common diagnosis was PLE (71.6%) with bilateral lower extremity involvement (91.9%). No significant difference was seen in QOL at 12 weeks. However, at 52 weeks, the Lymphedema Quality of Life scores had significantly improved from baseline (6.3 vs 7.4 ; $P = .001$) and the SF-36 demonstrated significant improvement from baseline in the physical component (38.6 vs 40.8 ; $P = .035$), with an effect toward overall improvement in the mental component (49.9 vs 51.3 ; $P = .549$). The limb circumference had decreased significantly at 12 weeks compared with baseline (28.5 cm vs 27.7 cm ; $P = .0005$) in the most affected lower extremity, with this reduction stable for the study duration. Advanced pneumatic compression device treatment was associated with a significant reduction in cellulitis episodes (24.3% vs 8.1% ; $P = .005$), lymphedema-related clinic visits (2.2 vs 0.7 ; $P = .02$), urgent care visits (1.2 vs 0.3 ; $P = .004$), and hospital admissions (0.5 vs 0.1 ; $P = .047$) per patient. The Flexitouch APCD resulted in initial significant limb girth reduction as early as 12 weeks and a sustained improvement in QOL for 1 year or less.⁷

In 2020, Alvarez and colleagues³⁴ conducted a prospective RCT of 52 subjects with CVI with prolonged healing of VLU who were treated with either IPC ($n = 27$) with standard

compression therapy (treatment group) or compression therapy alone (control group). Compression therapy consisted of a nonadherent primary wound dressing plus a 4-layer compression bandage ($N = 25$). Intermittent pneumatic compression was performed using a 4-chamber pneumatic leg sleeve and a gradient, sequential pump. Pumps were calibrated to a pressure setting of 50 mm Hg, and treatments were for 1 hour twice a day. Assessments were performed weekly to measure edema, pain, granulation tissue, and wound healing. Median time to wound closure at 9 months was 141 days for the IPC-treated group and 211 days for the control group ($P = .031$). The rate of healing was $0.8 \pm 0.4 \text{ mm/d}$ for the control group and $2.1 \pm 0.8 \text{ mm/d}$ for the group treated with IPC ($P = .05$). At weeks 1, 2, and 3, visual analog pain scores were significantly lower for the IPC-treated group ($P = .05$). The authors concluded that IPC may be used as adjunct to 4-layer compression therapy in individuals with VLUs, PLE, and lower extremity lymphedema.³⁴

Blumberg and others³⁵ in 2016 conducted a prospective observational study of 100 individuals treated for lower extremity lymphedema at a single institution with pneumatic compression (PC) pumps for at least 3 months. All participants underwent pre- and post-PC assessments of episodes of cellulitis, number of ulcers, and venous insufficiency. Seventy percent were females, with a mean age of 57.5 years. Mean length of PC use was 12.7 months, with a mean of 5.3 treatments per week. Ankle and calf limb girth decreased after PC use (28.3 cm vs 27.5 cm ; $P = .01$; and 44.7 cm vs 43.8 cm ; $P = .018$, respectively). In the year before PC, 15% of the individuals reported 26 episodes of cellulitis, which decreased to 5 episodes after initiation of PC ($P = .002$) in median follow-up of 12.7 months. Eight percent of individuals reported ulcers on the affected lower extremity in the year before PC treatment. The number of lower extremity ulcers pre- and post-PC also decreased significantly from 7 to 2 ($P = .007$). Fourteen percent had CVI, and all of them underwent venous ablation. Overall, 100% of patients reported symptomatic improvement post-PC, with 54% greatly improved, 35% moderately improved, and 11% mildly improved. Pneumatic compression was well tolerated, and the authors concluded that it could be an adjunct to standard lymphedema therapy with concurrent venous disease.³⁵

A prospective cohort of 18 patients with unilateral leg lymphedema stage II to IV was treated for 3 years with an IPC device using an 8-chamber sleeve with sequential inflation of chambers to 100 to 120 mm Hg for 50 seconds (total 400 seconds). Limb circumference and tissue tonicity were measured monthly. Correlation between decrease in calf and thigh circumference and increase in elasticity was obtained. Intermittent pneumatic compression was applied on each patient daily for 45 minutes for 24 to 36 months. Results of 3 years of treatment of lower-limb lymphedema by daily IPC demonstrated a decrease in limb circumference and increased elasticity of tissues.³⁶

In 2020, Desai and Shao³⁷ conducted a study to review clinical outcomes, QOL metrics, functional status, and cost of care analysis for patients who underwent PC therapy for lymphedema. A total of 117 individuals were enrolled for a period of 3 years for a total of 232 extremities treated for secondary lymphedema. Two patients had a single extremity treated for lymphedema. The average age was 55.2 ± 12.0 years, and 60.7% of the patients were women. Pneumatic compression

therapy was utilized for all individuals, leading to a 28% decrease in absolute limb volume ($P = .001$), decrease in BMI ($P = .001$), significant improvement in SF-36 QOL in 7 of 8 domains ($P = .001$), and a significant improvement in leg lymphedema complexity score (LLCS) ($P = .001$) at 1 year. A subsequent decrease in hospitalization for lymphedema-associated complications saved over \$3200 per patient per year.³⁷

A prospective RCT compared the effects of Kinesio taping and compression stockings on pain, edema, functional capacity, and QOL in patients with chronic venous disease (CVD). The experimental group ($N = 29/50\%$) received Kinesio taping intervention once a week for 4 weeks, while the control group ($N = 29/50\%$) received compression stockings for 4 weeks. All patients also took an exercise training program including calf muscle pump exercises, flexibility exercises, and diaphragmatic breathing. Visual analog scale, lower-limb circumference measurements, 6-minute walk test, and SF-36 questionnaire were applied before and after 4 weeks. The control group showed statistically significant reductions in pain ($P = .001$), ankle circumferences (right ankle, $P = .002$; left ankle, $P = .037$), calf circumferences (right calf, $P = .020$; left calf, $P = .022$), knee circumference (left knee, $P = .039$), and thigh circumference (right thigh, $P = .029$; left thigh, $P = .002$) compared with the experimental group. There were no significant differences between groups regarding functional capacity and QOL ($P > .05$). Both groups significantly improved 6-minute walk distance ($P = .001$) and SF-36 physical component summary (experimental group, $P = .002$; control group, $P = .006$). This study demonstrated that Kinesio taping and compression stockings generated similar improvements in functional capacity and QOL with CVD patients. Within 4 weeks, the compression stockings decreased pain and edema more effectively than the Kinesio taping intervention in patients with CVD.³⁸

In 2018, Klonizakis and colleagues³⁹ assessed the feasibility of a 12-week supervised exercise program as adjunctive therapy to compression in 39 patients with VLUs. This was a 2-center, 2-arm, parallel-group, randomized feasibility trial. Thirty-nine patients (24 men/61.5%; 15 women/38.4%) with VLUs were randomized 1:1 either to exercise (3 sessions weekly) plus compression therapy or compression alone. Baseline assessments were repeated at 12 weeks, 6 months, and 1 year, with healing rate and time, ulcer recurrence, and infection rates documented. Eighteen participants were allocated to exercise and 21 to compression alone. Of the 18 exercise participants, 13 (72%) completed all sessions. Median ulcer size was similar between both groups at 12 months, but the healing rate was higher in the intervention group (83% vs 60%), with shorter median (range) ulcer healing time: 13 (39–52) versus 347 (43–52) weeks. No serious adverse events and only 2 exercise-related adverse events were reported (2 patients had increased VLU drainage). The authors concluded that the findings support the feasibility and acceptability of supervised exercise program in conjunction with compression therapy.³⁹

Jull and others⁴⁰ conducted a 2018 systematic review and meta-analysis to summarize the association of different exercise interventions with healing of VLUs when used with compression. Six RCTs were identified, and 5 (190 participants) met inclusion criteria for meta-analysis. The exercise interventions were progressive resistance exercise alone (2 RCTs, 53 participants) or combined with prescribed physical activity (2 RCTs, 102 participants), walking only (1 RCT, 35 participants), or

ankle exercises (1 RCT, 40 participants). Overall, exercise was associated with increased VLU healing at 12 weeks, although the effect was imprecise (additional 14 cases healed per 100 patients; 95% CI, 1–27 cases per 100; $P = .04$). The combination of progressive resistance exercise plus prescribed physical activity appeared to be the most effective, again with imprecision (additional 27 cases healed per 100 patients; 95% CI, 9–45 cases per 100; $P = .004$). Clinicians may consider recommending simple progressive resistance and aerobic exercises for patients with VLUs. Prescribing exercise for treating VLUs may have an added beneficial effect when used in addition to compression, and it appears that the combination of progressive resistance exercises (such as heel raises) and aerobic activity (such as walking for 30 minutes at least 3 times per week) may be the most effective exercise regimen. However, the evidence remains limited in terms of the number of participants randomized and definitive trials are still needed.⁴⁰

A prospective, multicenter, observational study with a multicomponent 2-bandage compression system (UrgoK2) was conducted in 103 centers in Germany. Main outcomes included wound healing rate, wound healing progression, assessment of edema and ankle mobility, local tolerability, and acceptance of the compression therapy. A total of 702 patients with VLUs and/or with lower-limb edema due to CVI were treated with the multicomponent 2-bandage compression system for a mean $\pm$ SD duration of 27 ± 17 days. For patients who presented with a VLU at the initial visit ($N = 414/58.9\%$), wound closure in 30.9% ($n = 128$) of patients and improvement in wound healing in 61.8% ($N = 256$) of patients at the final assessment visit were reported. Limb edema was resolved in 66.7% of patients, and an improvement in ankle mobility was reported in 44.2% of patients. The skin condition under the compression therapy was also considered improved in 73.9% of patients and a substantial reduction in pain was achieved, both in the number of patients reporting pain and in pain intensity. The study supports the use of this multicomponent compression system as one type of first-line intervention in patients with symptoms caused by CVI.⁴¹

The role MLD, a component of CDT, has in VLU healing is lacking. Szolnoky and others⁴² conducted a 2018 prospective, randomized, comparative study to see if CDT plays a role in healing of VLUs when compared to CDT with multilayered compression short-stretch bandages. Seventeen patients with VLUs were treated with CDT, while the control group of 9 patients received only multilayer compression. Eight patients (mean age: 64.8 years; mean ulcer area: 23.07 cm^2 ; duration of ulcers: 25.37 months) were treated with 5 days of CDT, and 9 patients (mean age: 70.77 years; mean ulcer area: 21.47 cm^2 ; duration of ulcers: 15.8 months) were included in 10 days of CDT. The control group consisted of 9 patients (mean age: 56.33 years; mean ulcer area: 13.87 cm^2 ; duration of ulcers: 6.11 months) receiving multilayered compression. Wound surface measurement was carried out on days 5 and 10. The VLU area reduction rate was calculated as $\text{area (initial)} - \text{area (final)}/\text{time unit}$. There was no statistical difference between the 5-day course of CDP and multilayered compression of the same duration regarding ulcer healing ($t = -1.62$, $df = 15$, $P = .125$). A 10-day course of CDP significantly increased VLU healing compared to multilayered compression of the same duration ($t = -2.42$, $df = 16$, $P = .039$). The authors concluded that the results suggested that MLD as a part of CDT supports healing of VLUs.⁴²

Individuals affected by loss of mobility often experience lower-limb edema. Those who are incapacitated or wheelchair bound for long periods of time with legs dependent may develop impairment of the venous and lymphatic return. A pilot, 2-arm RCT was conducted on 50 individuals who were randomly allocated to the IPC group ($N = 29$) versus a control group ($N = 21$). Leg edema was assessed by measuring subcutaneous thickness (high-resolution ultrasound) and circumferences, both assessed at different levels of the lower limbs, and volume (water plethysmography). Ankle range of motion (ROM, goniometer) and QOL were assessed by the 36-Item Short Form Health Survey. Nine patients (31.0%) in the IPC group and 7 (33.3%) in the control group were affected by edema with CVI. Twenty patients (68.9%) in the IPC group and 14 (66.6%) in the control group were affected only by lymphedema. Edema significantly decreased in the IPC group (for all outcome measures, $P = .0001$), whereas it significantly increased in the control group ($P = .0001$). Ankle ROM was significantly enhanced in the IPC group (dorsiflexion, $P = .0001$; plantar flexion, $P = .002$) and remained stable in the control group. Quality of life showed an improvement in the IPC group, particularly significant for the General Health subscale ($P = .004$), whereas no changes were highlighted in the control group. For individuals with reduced mobility with leg edema, IPC treatment was effective in reducing the edema, improving the ankle ROM, and determining a positive impact on QOL together.⁴³

A Cochrane review of interventions to prevent cellulitis identified 6 studies investigating prophylactic antibiotics. However, no studies looking at additional treatment modalities such as edema management were identified.⁴⁴ Webb and others⁴⁵ conducted a 2020 single-center, randomized, nonblinded trial to study the role of compression therapy to prevent recurrent cellulitis of the leg. Participants were randomly assigned in a 1:1 ratio to receive either compression therapy plus education on cellulitis prevention (compression group) or cellulitis prevention education alone (control group). Randomization was stratified according to prophylactic antibiotic use (yes or no), with follow-up every 6 months up to 3 years. Participants in the control group crossed over to the compression group when they had an episode of cellulitis. A total of 84 patients were enrolled; 41 (48.8%) participants were assigned to the compression group and 43 (51.1%) to the control group. At the time of the interim analysis, 23 episodes of cellulitis had occurred, 6 participants (15%) in the compression group and 17 (40%) in the control group had had an episode of cellulitis (hazard ratio = 0.23; 95% CI, 0.09-0.59; $P = .002$; relative risk [post hoc analysis] = 0.37; 95% CI, 0.16-0.84; $P = .02$), and the trial was stopped for efficacy highlighting the role that compression may play in preventing recurrent cellulitis.⁴⁵

The research supports that compression therapy is effective in reducing lower-leg edema with CVI. However, it is not known which interventions improve adherence to compression therapy. An updated 2016 Cochrane review⁴⁶ searched for research studies that addressed interventions for assisting people adhere to compression therapy for VLUs. They looked at interventions to assist those with VLUs adhere to compression therapy compared with usual care, or no intervention, or another intervention. The main outcomes were ulcer healing, ulcer recurrence, QOL, pain, adherence to compression therapy, and the number of people with adverse events. They found that it is unclear whether community-based clinics promote

adherence to compression therapy or improve ulcer healing or recurrence. The available evidence from the studies was low quality due to the risk of bias in the studies and their small sample sizes, which lead to uncertainty and imprecision. There is a lack of trials of interventions that promote adherence to compression therapy for venous ulcers.⁴⁶

Rother and others⁴⁷ in 2020 conducted a prospective analysis of 94 consecutive patients undergoing compression therapy (44 with diabetes mellitus [DM], 45 with peripheral arterial disease [PAD], and 5 healthy controls) to assess the effect of compression therapy on microperfusion and its safety in patients with DM or PAD. Microperfusion was assessed by white light tissue spectrometry and laser Doppler flowmetry under medical compression therapy (classes I and II) in different body positions (supine, sitting, standing, and elevated leg positions) and at different locations on the body (great toe, lateral ankle, and calf). Evaluation of microcirculation parameters (oxygen saturation of hemoglobin and flow) at different locations and sitting and standing positions of patients with DM and PAD wearing compression garments classes I and II revealed no tendency for reduced microperfusion in either group. In contrast, in the elevated leg position, all mean perfusion values decreased in the DM and PAD groups, with the same effect seen in the healthy subgroup. The authors concluded that the use of compression stockings is safe in patients with DM or PAD.⁴⁷

Clinical practice guidelines for VLU management recommend below-knee compression to improve healing outcomes after calculating the ABI to rule out significant arterial disease. This systematic scoping review⁴⁸ aimed to complete a qualitative and quantitative content analysis of international CPGs for VLU management to determine if consensus existed in relation to recommendations for compression application based on an ABI and clinical assessment. The authors review showed that there was a lack of consensus across 13 VLU CPGs and a lack of clear guidance in relation to the specific ABI range of compression therapy that can be safely applied. Disagreement existed in relation to an ABI between 0.6 and 0.8, with some guidelines advocating that compression is contraindicated and others indicating that there should be reduced compression. The authors stated with a high level of confidence that compression therapy is contraindicated if the ABI is 0.5 or less.⁴⁸

Generation of Consensus and Evidence-Based Statements

Consensus statements were developed from the articles in the scoping review to generate statements that would drive clinical decision points and various pathways for the CLEVDAL algorithm. Strength of Evidence was ranked using a 3-point ordinal scale adapted from the Level of Evidence Rating found in the WOCN Clinical Practice Guideline for Management of Wounds in Patients With Lower-Extremity Venous Disease⁹ and the SORT statements from the American Academy of Family Physicians.¹² Level A evidence-based statements were consistent findings from 2 or more RCTs or a systematic review with meta-analysis (pooled data) of multiple clinical trials. Level B evidence-based statements were consistent findings from 1 RCT or more than 1 nonrandomized clinical trial or inconsistent (mixed) evidence from 2 or more RCTs or systematic reviews with meta-analysis. Level C evidence-based statements were an expert opinion based on consensus among

clinical experts, findings from a single nonrandomized clinical trial, case study, or series of clinical case studies (Table 1). The rating refers to the strength of the evidence for a recommendation and does not relate to the importance of the recommendation.

In the VLU algorithm, there were 27 evidence-based statements generated from the findings of the scoping review that looked at primary prevention, treatment, and prevention of recurrence in VLUs.² The evidence-based statement: IPC may be used when other compression options are not available, cannot be used (immobile, extremely large legs, intolerant of stockings or wraps), have failed to aid in VLU healing after prolonged compression therapy, or when higher levels of compression are needed than that can be provided by stockings or wraps, was a level B evidence in the VLU algorithm,² but with the current scoping review, it was raised to level A (Table 2). With CLEVDAL, 14 level A or B evidence-based statements were generated from the findings of the scoping literature review (Table 3) that addressed CLEVDAL. Twenty-four level C evidence-based statements were drafted from the findings of the scoping literature review and the 2020 Consensus Document of the ISL.⁸

Consensus Statements Development

A structured process for establishing a synthesis of best practice when evidence is insufficient to inform clinical decision-making is designed to make best use of available information and often serves as impetus for criticism and additional research or policy development. Advantages of the formal consensus process are that it engages multiple key opinion leaders; replaces individual expert opinion with collective

TABLE 2.
Updated Evidence Statement

Revised Evidence-Based Statement	Level of Evidence
(2016 Statement): Intermittent pneumatic compression may be used when other compression options are not available, cannot be used (immobile, extremely large legs, intolerant of stockings or wraps), have failed to aid in VLU healing after prolonged compression therapy, or when higher levels of compression are needed than can be provided by stockings or wraps. ⁵⁵	B
(2021 Revised): Intermittent pneumatic compression may be used as an adjunct to 4-layer compression for patients with venous disease, phlebolymphe- dema, and lower extremity lymphedema. ^{7,34,36,37,43}	A

Abbreviation: VLU, venous leg ulcer.

group opinion; and allows generation of statements based on a wider source of collective knowledge while avoiding undue influence from a single person or a group of individuals within a larger group.⁴⁹ Rather than rely on agreement from the 3-member core group, the task force sought formal input from a representative group of clinical experts who provide care for these patients.

A consensus conference was held virtually on October 9, 2021, to develop consensus-based CLEVDAL statements to serve as guidance for the updated algorithm. The main task of the consensus panel was to reach formal consensus on statements guiding decision points and pathways of the algorithm that were not supported by level A or B evidence. A 20-member panel of clinicians with expertise in CLEVDAL from a variety

TABLE 3.
New Evidence-based Statements

	Level of Evidence
Complete decongestive therapy (CDT) may be used as an adjunct to compression in patients with venous disease CEAP 3 and 4. ³³	B
Age is not a barrier to adherence when using adjustable compression wraps for self-management of CVI CEAP 0-3. Limited evidence suggests that obesity, gripping difficulties, and cognitive impairment are barriers to self-management. ²⁰	B
Compression garments that do not cover the foot and heel are not inferior to standard compression stockings that include the foot and heel in patients with venous disease CEAP 3-6. ²²	B
Compression garments that do not cover the foot and heel are easier to don and doff unaided than garments that cover the foot and heel and may improve adherence in patients with venous disease CEAP 3-6. ²²	B
Simple progressive resistance and aerobic exercises are recommended to supplement compression therapy in the treatment of venous disease CEAP 6. ^{39,40}	A
Adjustable hook-and-loop compression devices are more effective than multilayer bandages in patients with venous disease CEAP 3. ³²	B
Compression stockings class 1 or 2 have not been shown to impair microcirculation in patients with peripheral arterial disease or diabetes mellitus. ⁴⁷	B
Patients using class 3 compression stockings have a significantly longer time to venous leg ulcer recurrence than class 2. ³¹	B
Manual lymphatic drainage (MLD) may be used as an adjunct to compression therapy in patients with venous disease CEAP 5-6. ⁴²	B
Evidence is lacking concerning which interventions designed to improve adherence are effective to promote healing or prevent recurrence in venous disease CEAP 5-6. ⁴⁶	B
Complete decongestive therapy (CDT) is a bundled intervention that is more effective than its individual components in the acute intensive phase of treatment of LE lymphedema. ^{8,27}	B
Pneumatic compression is a first-line therapy for lymphedema with and without concurrent venous disease. ³⁵	B
An adjustable hook-and-loop compression wrap is an alternative to conventional multilayer compression wraps in the active treatment phase of lymphedema. ^{21,23}	A
Use of compression stockings (class 2 or higher) has been shown to reduce recurrence of cellulitis in patients with lymphedema and CVI. ⁴⁵	B

Abbreviations: CEAP, Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P) classification; CVI, chronic venous insufficiency; LE, lower extremity.

TABLE 4.
Consensus Panel Members

Participant	Practice Setting/Affiliation
Tara Beuscher, DNP, RN, ANP-BC, GCNS-BC, CWOCN, CFCN, NEA-BC, NPD-BC	Outpatient Care/Clinic, Duke Health, Durham, North Carolina
Phyllis Bonham, PhD, MSN, RN, CWOCN, DPNA, FAAN	Retired, Medical University of South Carolina, College of Nursing, Charleston, South Carolina
Teresa Brown, PT, CLT	Outpatient Care/Clinic, Cone Health, Greensboro, North Carolina
Renee Cordrey, PhD(c), MSPT, MPH, PT, CWS, FAAWC	Home Healthcare (includes Hospice), Encompass Home Health and Hospice, Williamsburg, Virginia
Lea Crestodina, APRN, CWOCN-AP, CDCES	Acute Care, Joe DiMaggio Children's Hospital, Coral Springs, Florida
Dorothy Doughty, MN, RN, CWOCN, CFCN, FAAN	Research/Academia, Emory University Hospital and Emory University WOC Nursing Education Center, Atlanta, Georgia
Linda Droste, MSN, RN, CWOCN, CBIS	Acute Care, Central Virginia VA Health Care System: McGuire VA Medical Center, Richmond, Virginia
Kevin Emmons, DrNP, APN, RN, AGPCNP-BC, CWCN, CFCN	Research/Academia, Rutgers School of Nursing-Camden, Camden, New Jersey
Patty Flanagan, MSN, RN, CV-BC	Acute Care, Albany Medical Center, Albany, New York
Margaret Goldberg, MSN, RN, CWON	Outpatient Care/Clinic, Delray Wound Treatment Center, Delray Beach, Florida
Arturo Gonzalez, DNP, APRN, ANP-BC, CWCN-AP	Private Practice, MedSource Consultants, Miami, Florida
Laura Kenney, DNP, CNP, CWOCN, CFNC, CLT	Outpatient Care/Clinic, M Health Fairview, Maplewood, Minnesota
Dianne Mackey, MSN, RN, CWOCN	Home Healthcare (includes Hospice), Kaiser Permanente, San Diego, California
Laurie McNichol, MSN, RN, CNS, GNP, CWOCN, CWOC-AP, FAAN	Acute Care, Cone Health, Greensboro, North Carolina
Barbara Pieper, PhD, RN, BC-ACNS, CWOCN, FAAN	Retired, Wayne State University, College of Nursing, Detroit, Michigan
Janet Ramundo, MSN, RN, APRN, CWOCN	Research/Academia, Emory University Wound Ostomy Continence Nursing Education Center, Decatur, Georgia
Catherine Ratliff, PhD, GNP-BC, CWOCN, CFCN, FAAN	Outpatient Care/Clinic, UVA Health, Charlottesville, VA
Lee Ruotsi, MD, CWS-P, ABWMS, UHM	Outpatient Care/Clinic, Saratoga Hospital Medical Group, Saratoga Springs, New York
Jody Scardillo, DNP, RN, ANP-BC, CWOCN (alternate)	Outpatient Care/Clinic, Albany Medical Center/Russell Sage College, Albany, New York
Mary Sieggreen, MSN, CNS, NP, CVN	Retired, Detroit Medical Center, Vascular Surgery and Nursing, Detroit, Michigan
Stephanie Yates, MSN, RN, ANP-BC, CWOCN	Outpatient Care/Clinic, Duke University Medical Center, Durham, North Carolina

of clinical settings was convened; invitations were based on practice settings, years of clinical experience, and educational backgrounds (Table 4). This conference was facilitated by Dr Mikel Gray, who has extensive experience in the conduct of consensus-based practice development proceedings. Prior to the conference, the 3-member task force generated 24 draft statements for consideration by the panel based on the scoping review. During the conference, each statement was read by the moderator (M.G.), and an initial vote from each panel member was taken to determine the level of agreement with the consensus statement. Votes were cast using an anonymous voting system, with a required quota for approval of 80%. If an individual statement did not reach 80% agreement among panelists after its introduction, up to 3 rounds of moderated discussion was held to determine if the statement could be clarified or altered to gain consensus. No statements were discarded for failure to obtain consensus after 3 rounds.

The goal is to reach consensus rather than perfect agreement. Respect for divergent opinions of others is essential. The facilitator will designate who may speak at a given moment while moving group efficiently toward the ultimate goal, which is reaching consensus around multiple statements. When consensus is not reached, the facilitator will address comments toward which aspect of the statement consensus panel members disagree with and how they would suggest altering the statement so the group can reach consensus. When voting and providing input to alter statements so that consensus may be

reached, the facilitator will ask whether this statement conveys the essential information needed to influence practice while noting that few if any statements can conform to every possible case scenario.

An electronic system was selected because it allowed feedback concerning progress toward consensus within a matter of seconds and because it enabled anonymous voting by participants, thus reducing the risk of bias associated with public voting.

RESULTS

The consensus statement development process led to the generation of 24 statements, which were used to support decision points and supplemental materials within the updated CLEVDAL algorithm. They are listed as follows:

Consensus Statement 1:

Essential components of evaluation of CVI or lower extremity lymphedema include:

- Health history;
- Risk and contributing factors (past medical, family, and social history, occupational history, thrombophilia, deep vein thrombosis, abdominal or lower extremity surgery, obesity, female sex, sedentary lifestyle, pelvic lymph node dissection, radiation to pelvis or abdomen, injection drug use especially in lower extremities, PAD, full-thickness burn, cellulitis, pregnancy, prior trauma, etc); and

- Triggers or exacerbating factors (recent trauma, cellulitis, contact dermatitis, lower extremity constriction, insect bite, etc).

Consensus Statement 2

Essential components of evaluation of CVI or lower extremity lymphedema include:

- Physical assessment; and
- Examine both lower extremities noting appearance and texture of the skin, lower extremity ROM and muscle strength, functional mobility, assessment of edema (location, circumference of lower extremity, pitting vs nonpitting), superficial vascular changes (hemosiderin staining, varicosities, hair growth distribution of lower extremity), palpation of lymph nodes, presence of any wounds or scar tissue, lower extremity pulse assessment (ideally with a handheld Doppler probe), and Stemmer sign.

Consensus Statement 3

Comprehensive management of lower extremity lymphedema should be based on the ISL stages of lymphedema (stages 0-III).

Consensus Statement 4

If assessment suggests stage 0 lymphedema (no visible edema), but the patient has symptoms of numbness, tingling, heaviness, consider alternative causes (such as CVI, peripheral neuropathy, spinal pathology, undiagnosed malignancy).

Consensus Statement 5

For stage 0-I lymphedema, educate the patient and family about lifestyle factors that promote lower extremity health and improve lymphatic function including:

- Avoid triggers for lymphedema (trauma, cellulitis, contact dermatitis, lower extremity constriction, insect bite, etc).
- Apply topical moisturizers after bathing to prevent dry cracking skin.
- Follow healthy nutrition practices, for example, limit sodium intake to Recommended Daily Allowance (RDA), and maintain hydration.
- Maintain a healthy weight.
- Avoid crossing lower extremities, prolonged sitting or standing.
- Exercise and participate in physical activity regularly.
- Keep feet meticulously clean and toenails trimmed.

Consensus Statement 6

If assessment suggests stage I lymphedema (reversible edema), consider additional etiologies (eg, venous disease CEAP C3 is characterized by pitting edema plus reticular veins, telangiectasias, etc).

Consensus Statement 7

In stage I lymphedema, educate the patient and family about lifestyle factors that promote lower extremity health and improve lymphatic function including:

- Avoid triggers for lymphedema (trauma, cellulitis, contact dermatitis, lower extremity constriction, insect bite, etc).
- Apply topical moisturizers after bathing to prevent dry cracking skin.
- Follow healthy nutrition practices, for example, limit sodium intake to RDA, and maintain hydration.
- Maintain a healthy weight.

- Avoid crossing lower extremities, prolonged sitting or standing.
- Exercise and participate in physical activity regularly.
- Keep feet meticulously clean and toenails trimmed.

Consensus Statement 8

In stage I lymphedema, recommend compression, such as knee-high stockings, hook-and-loop garments, or short-stretch wraps/bandages at a level of 20 to 30 mm Hg, during waking hours and during 2 hours or more of air or vehicle travel to control edema. In addition, recommend frequent calf muscle exercises and elevation of lower extremity above the level of the heart.

Consensus Statement 9

If assessment indicates stage II lymphedema (irreversible edema), obtain a history of prior treatment and response including CDT, which comprises MLD, compression therapy, skin and nail care, and exercise.

Consensus Statement 10

In stage II lymphedema, educate the patient and family about lifestyle factors that promote lower extremity health and improve lymphatic function:

- Cleanse skin daily using antibacterial and fragrance-free skin pH-balanced soap or body wash, followed by application of a skin pH-balanced fragrance-free moisturizer.
- Avoid foot soaking.
- Apply sun block (SPF 30 or greater) to prevent sunburn.
- Avoid excessive heat to the extremity (sauna, hot tub, hot compresses, etc).
- Follow healthy nutrition practices, for example, limit sodium intake to RDA, maintain hydration, and manage weight.
- Increase physical activity gradually while wearing compression garments.
- Participate in swimming and water therapy (do not wear compression garments in the water).
- Avoid injury to affected lower extremity; use caution when shaving lower extremities and trimming nails.

Consensus Statement 11

Educate colleagues regarding the potential adverse effects of the use of diuretics for lower extremity edema associated with CVI and/or lymphedema, due to the risk of worsening fibrosis, volume depletion, renal insufficiency, and hypotension.

Consensus Statement 12

In stage II lymphedema, refer the patient to a certified lymphedema therapist (CLT) as indicated for CDT, which includes MLD, compression therapy, skin and nail care, and exercise.

Consensus Statement 13

In stage II lymphedema, initiate and coordinate topical wound care for patients with lower extremity wounds.

Consensus Statement 14

In stage II lymphedema, encourage consultation with a CLT or other provider regarding initiation of pneumatic compression pump and accessories.

Consensus Statement 15

In patients with stage II lymphedema, regular follow-up with a health care provider is needed, with frequency based on individual and clinical circumstances, to evaluate response to treatment and ensure effectiveness of compression garments or devices and treatments.

Consensus Statement 16

If assessment indicates stage III lymphedema (elephantiasis), obtain a history of prior treatment and response including CDT, which comprises MLD, compression therapy, skin and nail care, and exercise.

Consensus Statement 17

In stage III lymphedema, refer the patient to a CLT for CDT, MLD, compression therapy, skin and nail care, and exercise, as indicated.

Consensus Statement 18

In stage III lymphedema, initiate and coordinate topical wound care for patients with lower extremity wounds.

Consensus Statement 19

In patients with stage III lymphedema, regular follow-up with a health care provider is needed, with frequency based on individual and clinical circumstances, to evaluate response to treatment and ensure effectiveness of compression garments or devices, and treatments.

Consensus Statement 20

In patients with persistent or refractory stage III lymphedema despite previous CDT, consider referral to a surgeon for lymphatic system reconstruction or lower extremity reduction procedures.

Consensus Statement 21

In stage III lymphedema, evaluate skin of the affected lower extremity for lymphorrhea and consider absorbent products with application of multilayer compression wraps/bandages.

Consensus Statement 22

In patients with lymphedema, evaluate skin of the lower extremity for cellulitis and initiate or refer to a provider for antimicrobial treatment.

Consensus Statement 23

In patients with lymphedema, initiate and coordinate topical wound care for patients with lower extremity wounds.

Consensus Statement 24

In patients with lymphedema, initial and ongoing assessment should include the patient's social determinants of health, self-care abilities, the presence of a caregiver who is able, willing, and available, and adherence to the plan of care.

CONTENT VALIDATION

After the consensus conference in which a structured method to generate nonbiased consensus statements was completed, content validation was undertaken using methods modified by Grant and Davis,⁵⁰ from procedures originally proposed by Lynn,⁵¹ and Waltz and Bausell⁵² by the content validation panel to strengthen the validity of these best practice recommendations. An independent panel of 20 clinicians with content expertise in CLEVDAL from a variety of clinical settings was employed to rate content validity of the 24 consensus statements (Table 5).

Each of the 24 consensus statements was rated by each of the panel members for relevance on a scale, where 1 indicating no relevance or statement is not appropriate, 2 indicating that

TABLE 5.
Content Validation Panel Members

Participant	Practice Setting/Affiliation
Derik Alexander, FNP-BC, CWOCN, CFCN	Outpatient Care/Clinic, St Joseph's Hospital & Medical Center, Phoenix, Arizona
John F. Angle, MD	Interventional Radiology/Vein Clinic, UVA Health, Charlottesville, Virginia
Michelle Y. Browne, PT, CLT, CWS	Acute Care, MedStar Washington Hospital, Washington, District of Columbia
Glenda Brunette, MSN, RN, CWON	Acute Care, Medical University of South Carolina, Charleston, South Carolina
Barbara Ann Dale, BSN, RN, CWOCN, CHHN	Home Healthcare (includes Hospice), Quality Home Health & Hospice, Hilham, Tennessee
Suzie Ehmann, DPT, CWS, CWLT, CLT-LANA, DN-Cert	Outpatient Care/Clinic, Atrium Health Stanly, Albemarle, North Carolina
Catherine Healy, DPT, CLT	Outpatient Care/Clinic, Wake Med, Cary, North Carolina
Heather Hettrick, PT, PhD, CWS, AWCC, CLT-LANA, CLWT, CORE	Research/Academia, Nova Southeastern University, Fort Lauderdale, Florida
Sandy Hughes, MSN, RN, CWOCN	Acute Care, Boston Medical Center, Needham, Massachusetts
Kelly Jaszarowski, MSN, RN, CNS, ANP, CWOCN	Research/Academia, Cleveland Clinic Foundation, Cleveland, Ohio
Teresa Kelechi, PhD, RN, GCNS, CWCN	Research/Academia, Medical University of South Carolina, Charleston, South Carolina
Mary Arnold Long, DNP, APRN, CRRN, CWOCN-AP, ACNS-BC	Private Practice, Relias, Johnson City, Tennessee
Rose W. Murphree, DNP, RN, CWOCN, CFCN, FAAN	Research/Academia, Emory University School of Nursing, Alpharetta, Georgia
Kendra Nicholson, OTR/L CLT-LANA	Outpatient Care/Clinic, UVA Health, Charlottesville, Virginia
Christine Owen, MS, ACNP, RNFA	Acute Care/Interventional Radiology, MedStar Washington Hospital Center, Washington, District of Columbia/Past President, Society of Vascular Nursing
Gail A. Parry, MSN, APRN-CNS, CWON	Acute Care, Ochsner Medical Center Westbank, Gretna, Louisiana
Charleen Singh, PhD, MBA, MSN/ED, FNP-BC, CWOCN, RN	Acute Care, San Jose State University School of Nursing, Granite Bay, California
Nancy Tomaselli, MSN, RN, CNS, FNP, CWCN, LNC	Private Practice, Premier Health Solutions, LLC, Ocean View, Delaware
Dot Weir, RN, CWON, CWS	Outpatient Care/Clinic, Saratoga Hospital Center for Wound Healing and Hyperbaric Medicine, Gansevoort, New York
Sunniva Zaratkiewicz, PhD, RN, CWCN	Acute Care, Harborview Medical Center, Seattle, Washington

TABLE 6.
Consensus Statements

#		I-CVI
1	Essential components of evaluation of chronic venous insufficiency or lower extremity lymphedema include: • Health history ○ Risk and contributing factors (past medical, family, and social history, occupational history, thrombophilia, deep vein thrombosis, abdominal or lower extremity surgery, obesity, female sex, sedentary lifestyle, pelvic lymph node dissection, radiation to pelvis or abdomen, injection drug use, especially in lower extremities, peripheral arterial disease, full-thickness burn, cellulitis, pregnancy, prior trauma, etc) ○ Triggers or exacerbating factors (recent trauma, cellulitis, contact dermatitis, lower extremity constriction, insect bite, etc)	1.0
2	Essential components of evaluation of chronic venous insufficiency or lower extremity lymphedema include: • Physical assessment ○ Examine both lower extremities, noting appearance and texture of the skin, lower extremity range of motion and muscle strength, functional mobility, assessment of edema (location, circumference of lower extremity, pitting vs nonpitting), superficial vascular changes (hemosiderin staining, varicosities, hair growth distribution of lower extremity), palpation of lymph nodes, presence of any wounds or scar tissue, lower extremity pulse assessment (ideally with a handheld Doppler probe), and Stemmer sign.^a 	1.0
3	Comprehensive management of lower extremity lymphedema should be based on the International Society of Lymphology stages of lymphedema (stages 0-III).	1.0
4	If assessment suggests stage 0 lymphedema (no visible edema) but the patient has symptoms of numbness, tingling, heaviness; consider alternative causes (such as chronic venous insufficiency, peripheral neuropathy, spinal pathology, undiagnosed malignancy).	1.0
5	For stage 0-I lymphedema, educate the patient and family about lifestyle factors that promote lower extremity health and improve lymphatic function including: • Avoid triggers for lymphedema (trauma, cellulitis, contact dermatitis, lower extremity constriction, insect bite, etc) • Apply topical moisturizers after bathing to prevent dry cracking skin • Follow healthy nutrition practices for example limit sodium intake to RDA and maintain hydration • Maintain a healthy weight • Avoid crossing lower extremities, prolonged sitting or standing • Exercise and participate in physical activity regularly • Keep feet meticulously clean and toenails trimmed	1.0
6	If assessment suggests stage I lymphedema (reversible edema), consider additional etiologies (eg, venous disease CEAP C3 is characterized by pitting edema plus reticular veins, telangiectasias, etc).	0.9
7	In stage I lymphedema, educate the patient and family about lifestyle factors that promote lower extremity health and improve lymphatic function including: • Avoid triggers for lymphedema (trauma, cellulitis, contact dermatitis, lower extremity constriction, insect bite, etc) • Apply topical moisturizers after bathing to prevent dry cracking skin • Follow healthy nutrition practices for example limit sodium intake to RDA and maintain hydration • Maintain a healthy weight • Avoid crossing lower extremities, prolonged sitting or standing • Exercise and participate in physical activity regularly • Keep feet meticulously clean and toenails trimmed	1.0
8	In stage I lymphedema, recommend compression, such as knee-high stockings, hook-and-loop garments, or short-stretch wraps/bandages at a level of 20-30 mm Hg, during waking hours and during 2 h or more of air or vehicle travel, to control edema. In addition, recommend frequent calf muscle exercises and elevation of lower extremity above the level of the heart.	0.9
9	If assessment indicates stage II lymphedema (irreversible edema), obtain a history of prior treatment and response including CDT, which comprises MLD, compression therapy, skin and nail care, and exercise.	1.0
10	In stage II lymphedema, educate the patient and family about lifestyle factors that promote lower extremity health and improve lymphatic function: • Cleanse skin daily using nonantibacterial and fragrance-free skin pH-balanced soap or body wash, followed by application of a skin pH-balanced fragrance-free moisturizer • Avoid foot soaking • Apply sun block (SPF 30 or greater) to prevent sunburn • Avoid excessive heat to the extremity (sauna, hot tub, hot compresses, etc) • Follow healthy nutrition practices, eg, limit sodium intake to RDA, maintain hydration, and manage weight • Increase physical activity gradually while wearing compression garments • Participate in swimming and water therapy (do not wear compression garments in the water) • Avoid injury to affected lower extremity; use caution when shaving lower extremities and trimming nails	0.9

(continues)

TABLE 6.
Consensus Statements (Continued)

#		I-CVI
11	Educate colleagues regarding the potential adverse effects of the use of diuretics for lower extremity edema associated with chronic venous insufficiency and/or lymphedema, due to the risk of worsening fibrosis, volume depletion, renal insufficiency, and hypotension.	0.9
12	In stage II lymphedema, refer the patient to a CLT as indicated for CDT, which includes MLD, compression therapy, skin and nail care, and exercise.	1.0
13	In stage II lymphedema, initiate and coordinate topical wound care for patients with lower extremity wounds.	1.0
14	In stage II lymphedema, encourage consultation with a CLT or other provider regarding initiation of pneumatic compression pump and accessories.	1.0
15	In patients with stage II lymphedema, regular follow-up with a health care provider is needed, with frequency based on individual and clinical circumstances, to evaluate response to treatment and ensure effectiveness of compression garments or devices and treatments.	1.0
16	If assessment indicates stage III lymphedema (elephantiasis), obtain a history of prior treatment and response including CDT, which comprises MLD, compression therapy, skin and nail care, and exercise.	0.9
17	In stage III lymphedema, refer the patient to a CLT for CDT, MLD, compression therapy, skin and nail care, and exercise, as indicated.	1.0
18	In stage III lymphedema, initiate and coordinate topical wound care for patients with lower extremity wounds.	0.9
19	In patients with stage III lymphedema, regular follow-up with a health care provider is needed, with frequency based on individual and clinical circumstances, to evaluate response to treatment and ensure effectiveness of compression garments or devices, and treatments.	1.0
20	In patients with persistent or refractory stage III lymphedema despite previous CDT, consider referral to a surgeon for lymphatic system reconstruction or lower extremity reduction procedures.	0.9
21	In stage III lymphedema, evaluate skin of affected lower extremity for lymphorrhea and consider absorbent products with application of multilayer compression wraps/bandages.	1.0
22	In patients with lymphedema, evaluate skin of lower extremity for cellulitis and initiate or refer to a provider for antimicrobial treatment.	1.0
23	In patients with lymphedema, initiate and coordinate topical wound care for patients with lower extremity wounds.	0.9
24	In patients with lymphedema, initial and ongoing assessment should include the patient's social determinants of health, self-care abilities, the presence of a caregiver who is able, willing and available, and adherence to the plan of care.	1.0

Abbreviations: CDT, complete decongestive therapy; CEAP, Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P) classification; CLT, certified lymphedema therapist; I-CVI, content validity index; MLD, manual lymphatic drainage; RDA, Recommended Daily Allowance.

*Stemmer sign is the inability to pinch the skin proximal to the phalanx of the second or third toe in patients with lymphedema.

the panel member was unable to assess the relevance of the statement without revision, 3 indicating that the statement is relevant but needs some modification, and 4 indicating high relevance and appropriateness of a statement. Following recommendations by Polit and Beck,⁵³ ratings of 3 or 4 for a given statement are considered relevant. For each of the statements, a content validity index (I-CVI) was calculated; a scale-level content validity index (S-CVI/Ave) was obtained by averaging across all item-level I-CVI. Data were analyzed using SAS for Windows (version 9.4; SAS Institute, Inc, Cary, North Carolina).

Table 6 summarizes the content validation indices for the 24 consensus statements across the 20 content validation panel members. Sixteen of 24 statements were considered relevant by all 20 panel members with I-CVIs of 1.0; the remaining 8 statements received uniformly I-CVIs of 0.9, indicating that all consensus statements were rated as “very relevant and appropriate” or “relevant and needed only minor alteration” and met the cutoff of 0.78 recommended by Lynn.⁵¹ The S-CVI/Ave of 0.93 indicated acceptable congruency when using the cutoff criterion of 0.9 as suggested by Waltz and others⁵⁴ for the equivalent index average congruency percentage (ACP).

DISCUSSION

The results of our scoping review of 30 articles reviewed by 3 core members appointed by the WOCN Society formed the basis for the development of 24 consensus statements by a 20-member expert panel at the CLEVDAL Conference, which was subsequently validated by a 20-member panel of content experts. The validated consensus statements will be used in the

CLEVDAL algorithm to assist clinicians in providing care for these patients.

CONCLUSIONS

The 24 consensus-based statements provided guidance for the care of individuals with LEVD and lymphedema and will be incorporated in the CLEVDAL algorithm. Similar to all WOCN Society guidelines and consensus conferences, the CLEVDAL algorithm will be regularly updated and revised as evidence is published.

REFERENCES

- Alavi A, Sibbald RG, Phillips TJ, et al. What's new: management of venous leg ulcers: treating venous leg ulcers. *J Am Acad Dermatol*. 2016;74(4):643-666.
- Ratliff CR, Yates S, McNichol L, Gray M. Compression for primary prevention, treatment, and prevention of recurrence of venous leg ulcers: an evidence-and consensus-based algorithm for care across the continuum. *J Wound Ostomy Continence Nurs*. 2016;43(4):347-364.
- O'Donnell TF Jr, Allison GM, lafrati MD. A systematic review of guidelines for lymphedema and the need for contemporary intersocietal guidelines for the management of lymphedema. *J Vasc Surg Venous Lymphat Disord*. 2020;8(4):676-684.
- Farrow W. Phlebolympedema—a common underdiagnosed and undertreated problem in the wound care clinic. *J Am Col Certif Wound Spec*. 2010;2(1):14-23.
- Greene AK, Grant FD, Slavin SA. Lower-extremity lymphedema and elevated body-mass index. *N Engl J Med*. 2012;366(22):2136-2137.
- Mehrara BJ, Greene AK. Lymphedema and obesity: is there a link? *Plast Reconstr Surg*. 2014;134(1):154e-160e.
- Maldonado TS, Rokosh RS, Padberg F, et al. Assessment of quality of life changes in patients with lower extremity lymphedema using an

- advanced pneumatic compression device at home. *J Vasc Surg Venous Lymphat Disord.* 2021;9(3):745-752.
8. Executive Committee of the International Society of Lymphology. The diagnosis and treatment of peripheral lymphedema: 2020 consensus document of the International Society of Lymphology. *Lymphology.* 2020;53(1):3-19.
 9. Wound, Ostomy and Continence Nurses Society. *Guideline for Management of Wounds in Patients With Lower-Extremity Venous Disease.* Mt Laurel, NJ: WOCN Society; 2019.
 10. Levac D, Colquhoun HL, O'Brien KK. Scoping studies: advancing the methodology. *Implement Sci.* 2010;5:69.
 11. Colquhoun HL, Levac D, O'Brien KK, et al. Scoping reviews: time for clarity in definition, methods, and reporting. *J Clin Epidemiol.* 2014;67(12):1291-1294.
 12. Ebell MH, Siwek J, Weiss BD, et al. Strength of Recommendation Taxonomy (SORT): a patient-centered approach to grading evidence in the medical literature. *Am Fam Physician.* 2004;69(3):548-556.
 13. Gray M, Beeson T, Kent D, et al. Interventions post catheter removal (IPCaRe) in the acute care setting: an evidence- and consensus-based algorithm. *J Wound Ostomy Continence Nurs.* 2020;47(6):601-618.
 14. Gray M, Kent D, Ermer-Seltun J, McNichol L. Assessment, selection, use, and evaluation of body-worn absorbent products for adults with incontinence: a WOCN Society consensus conference. *J Wound Ostomy Continence Nurs.* 2018;45(3):243-264.
 15. McNichol L, Watts C, Beitz J, Gray M. Identifying the right support surface at the tight time: generation and validation of an algorithm for support surface selection. *J Wound Ostomy Continence Nurs.* 2015;42(1):19-37.
 16. Ratliff CR, Goldberg M, Jaszarowski K, McNichol L, Pittman J, Gray M. Peristomal skin health: a WOCN Society consensus conference. *J Wound Ostomy Continence Nurs.* 2021;48(3):219-231.
 17. Dearhild SL, Dang D. *Johns Hopkins Nursing Evidence-Based Practice: Model and Guidelines.* 2nd ed. Indianapolis, IN: Sigma Theta Tau International; 2012.
 18. Smith V, Devane D, Begley CM, Clarke M. Methodology in conducting a systematic review of systematic reviews of healthcare interventions. *BMC Med Res Methodol.* 2011;11(1):15.
 19. International Society of Lymphology. The diagnosis and treatment of peripheral lymphedema. 2009 consensus document of the International Society of Lymphology. *Lymphology.* 2009;42(2):51-60.
 20. Balet F, Benigni JP, Uhl JF, Chahim M, Filori P. Limitations to self-management of adjustable compression wraps in the elderly: results of a prospective cohort study. *Int Angiol.* 2021;40(3):261-266.
 21. Borman P, Koyuncu EG, Yaman A, et al. The comparative efficacy of conventional short-stretch multilayer bandages and Velcro adjustable compression wraps in active treatment phase of patients with lower limb lymphedema. *Lymphat Res Biol.* 2021;19(3):286-294.
 22. Buset CS, Fleischer J, Kluge R, et al. Compression stocking with 100% donning and doffing success: an open label randomised controlled trial. *Eur J Vasc Endovasc Surg.* 2021;61(1):137-144.
 23. Damstra RJ, Partsch H. Prospective, randomized, controlled trial comparing the effectiveness of adjustable compression Velcro wraps versus inelastic multicomponent compression bandages in the initial treatment of leg lymphedema. *J Vasc Surg Venous Lymphat Disord.* 2013;1(1):13-19.
 24. DeCarvalho MR, Peixoto BU, Silveira IA, Oliveria BGRB. A meta-analysis to compare four-layer to short-stretch compression bandaging for venous leg ulcer healing. *Ostomy Wound Manage.* 2018;64(5):30-37.
 25. Gillet JL, Guex JJ, Allaert FA, et al. Clinical superiority of an innovative two-component compression system versus four-component compression system in treatment of active venous leg ulcers: a randomized trial. *Phlebology.* 2019;34(9):611-620.
 26. Goetz J, Kaisermayer E, Haase H, Jünger M, Riebe H. Better wearing comfort of knee-length elastic compression stockings with an interface pressure of 18-21 mmHg compared to 23-32 mmHg in elderly people after a one-day trial—influence on foot deformities, rheumatism and arthritis. *Clin Hemorheol Microcirc.* 2019;73(1):145-156.
 27. Goka EA, Poku E, Thokala P, Sutton A. Clinical and economic impact of a two-layer compression system for the treatment of venous leg ulcers: a systematic review. *Wounds.* 2020;32(1):11-21.
 28. Knight Nee Shingler SL, Robertson L, Stewart M. Graduated compression stockings for the initial treatment of varicose veins in people without venous ulceration. *Cochrane Database Syst Rev.* 2021;7(7):CD008819.
 29. Shingler S, Robertson L, Boghossian S, Stewart M. Compression stockings for the initial treatment of varicose veins in patients without venous ulceration. *Cochrane Database Syst Rev.* 2011;11(11):CD008819.
 30. Lazareth I, Moffatt C, Dissemmond J, et al. Efficacy of two compression systems in the management of VLU: results of a European RCT. *J Wound Care.* 2012;21(11):553-554, 556, 558 passim.
 31. Milic DJ, Zivic SS, Bogdanovic DC, Golubovic MD, Lazarevic MV, Lazarevic KK. A randomized trial of class 2 and class 3 elastic compression in the prevention of recurrence of venous ulceration. *J Vasc Surg Venous Lymphat Disord.* 2018;6(6):717-723.
 32. Mosti G, Cavezzi A, Partsch H, Urso S, Campana F. Adjustable Velcro compression devices are more effective than inelastic bandages in reducing venous edema in the initial treatment phase: a randomized controlled trial. *Eur J Vasc Endovasc Surg.* 2015;50(3):368-374.
 33. Bakar Y, Öztürk A, Calisal MA, Ertürk K, Daglar B. Complete decongestive physiotherapy for older people with chronic venous insufficiency. *Top Geriatr Rehabil.* 2010;26(2):164-170.
 34. Alvarez OM, Markowitz L, Parker R, Wendelken ME. Faster healing and a lower rate of recurrence of venous ulcers treated with intermittent pneumatic compression: results of a randomized controlled trial. *ePlasty.* 2020;20:e6.
 35. Blumberg SN, Berland T, Rockman C, et al. Pneumatic compression improves quality of life in patients with lower-extremity lymphedema. *Ann Vasc Surg.* 2016;30:40-44.
 36. Zaleska M, Olszewski WL, Durlak M. The effectiveness of intermittent pneumatic compression in long-term therapy of lymphedema of lower limbs. *Lymphat Res Biol.* 2014;12(2):103-109.
 37. Desai SS, Shao M. Vascular outcomes collaborative. Superior clinical, quality of life, functional, and health economic outcomes with pneumatic compression therapy for lymphedema. *Ann Vasc Surg.* 2020;63:298-306.
 38. Naci B, Ozyilmaz S, Aygutalp N, Demir R, Baltaci G, Yigit Z. Effects of Kinesio taping and compression stockings on pain, edema, functional capacity and quality of life in patients with chronic venous disease: a randomized controlled trial. *Clin Rehabil.* 2020;34(6):783-793.
 39. Klonizakis M, Tew GA, Gumber A, et al. Supervised exercise training as an adjunct therapy for venous leg ulcers: a randomized controlled feasibility trial. *Br J Dermatol.* 2018;178(5):1072-1082.
 40. Jull A, Slark J, Parsons J. Prescribed exercise with compression vs compression alone in treating patients with venous leg ulcers: a systematic review and meta-analysis. *JAMA Dermatol.* 2018;154(11):1304-1311.
 41. Stücker M, Münter KC, Erfurt-Berge C, et al. Multicomponent compression system use in patients with chronic venous insufficiency: a real-life prospective study. *J Wound Care.* 2021;30(5):400-412.
 42. Szolnoky G, Tuczai M, Macdonald JM, et al. Adjunctive role of manual lymph drainage in the healing of venous ulcers: a comparative pilot study. *Lymphology.* 2018;51(4):148-159.
 43. Tessari M, Tisato V, Rimondi E, Zamboni P, Malagoni AM. Effects of intermittent pneumatic compression treatment on clinical outcomes and biochemical markers in patients at low mobility with lower limb edema. *J Vasc Surg Venous Lymphat Disord.* 2018;6(4):500-510.
 44. Dalal A, Eskin-Schwartz M, Mimouni D, et al. Interventions for the prevention of recurrent erysipelas and cellulitis. *Cochrane Database Syst Rev.* 2017;6(6):CD009758.
 45. Webb E, Neeman T, Bowden FJ, Gaida J, Mumford V, Bissett B. Compression therapy to prevent recurrent cellulitis of the leg. *N Engl J Med.* 2020;383(7):630-639.
 46. Weller CD, Buchbinder R, Johnston RV. Interventions for helping people adhere to compression treatments for venous leg ulceration. *Cochrane Database Syst Rev.* 2016;3(3):CD008378.
 47. Rother U, Grüssler A, Griesbach C, Almasi-Sperling V, Lang W, Meyer A. Safety of medical compression stockings in patients with diabetes mellitus or peripheral arterial disease. *BMJ Open Diabetes Res Care.* 2020;8(1):e001316.
 48. Weller CD, Team V, Ivory JD, Crawford K, Gethin G. ABPI reporting and compression recommendations in global clinical practice guidelines on venous leg ulcer management: a scoping review. *Int Wound J.* 2019;16(2):406-419.

49. Murphy MK, Black NA, Lamping DL, et al. Consensus development methods, and their use in clinical guideline development. *Health Technol Assess*. 1998;2(3):i-iv, 1-88.
50. Grant JS, Davis LL. Selection and use of content experts for instrument development. *Res Nurs Health*. 1997;20(3):269-274.
51. Lynn MR. Determination and quantification of content validity. *Nurs Res*. 1986;35(6):382-385.
52. Waltz CF, Bausell RB. *Nursing Research: Design, Statistics, and Computer Analysis*. Philadelphia, PA: FA Davis Company; 1981.
53. Polit DF, Beck CT. The content validity index: are you sure you know what's being reported? Critique and recommendations. *Res Nurs Health*. 2006;29(5):489-497.
54. Waltz CF, Strickland OL, Lenz ER. *Measurement in Nursing and Health Research*. 3rd ed. New York, NY: Springer Publishing Co; 2005.
55. O'Donnell TF, Passman MA, Marston WA, et al. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery® and the American Venous Forum. *J Vasc Surg*. 2014;60(2)(suppl):3S-59S.