2022

The use of compression to treat phlebolymphedema symptomology: A systematic review

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The use of compression to treat phlebolymphedema symptomology: A systematic review

Presented in Partial Fulfillment of the
Requirements for the Degree of
Doctor of Occupational Therapy

Eastern Kentucky University
College of Health Sciences
Department of Occupational Science and Occupational Therapy

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2022

Executive Summary

Background: There is a lack of clinical practice guidelines regarding treating phlebolymphedema symptomology. To facilitate client centered evidence-based practice, occupational therapists (OTs) who are Certified Lymphedema Therapists (CLTs) need disease specific evidence for treating phlebolymphedema. Finding available evidence regarding the use of complete decongestion therapy (CDT) for this population will support evidence-based practice. For this capstone compression usage is the one component of CDT that will be researched.

Purpose: A systematic review of evidence related to use of static compression for treatment of lower leg phlebolymphedema that is within the scope of a CLT who is not wound care certified.

Methods: Four databases were searched to extensively retrieve potentially eligible studies published between 2012 and 2022: Medline, Cochrane Central Registrar of Controlled Trials, CINAHL Ultimate, and Academic Search Ultimate. Findings were restricted to peer reviewed articles published in academic journals in the English language. Inclusion and exclusion criteria were defined. Eight randomized control trials (RCTs) were identified for inclusion. These articles were assessed for quality and strength of evidence.

Results. All eight articles were assessed to be low quality randomized control trials (RCTs). There was moderate strength of evidence to support use of Velcro wraps as compression garments to treat symptomology of phlebolymphedema, and moderate strength of evidence that the use of bandages is not always the best option during the decongestion phase of CDT for this population. The strength of evidence was low to

support use of multilayer compression or compression with imbedded skin hydration is indicated for some people with phlebolymphedema.

Conclusions: This systematic review highlighted the lack of available practice guidelines, evidence and clinical recommendations for use of compression for treating symptomology of phlebolymphedema. Without RCTs with high methodological quality producing strong evidence, OTs who are CLTs are at risk for providing care that is not evidence based.

Acknowledgements

EKU

Dr. Dana Howell

Dr. Shirley O'Brien

Dr. Anne Fleischer

Dr. Camille Skubik-Peplaski

Karen Gilbert, Librarian Liaison

Jared Hebert, Lieutenant Colonel, USAF (Retired)

Family, colleagues, classmates, and friends.

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CERTIFICATION OF AUTHORSHIP

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Date of Submission: 11/29/2022

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Introduction

Occupational therapists (OT) are client-centered, evidence-based practitioners who strive to "maximize health, well-being, and quality of life…though effective solutions that facilitate participation in everyday living" (American Occupational Therapy Association [AOTA], 2022). Occupational therapists who are Certified Lymphedema Therapists (CLTs) have undergone specialized training for health management and health promotion, as defined by the Occupational Therapy Practice Framework (AOTA, 2020), for clients who are at risk for or are living with lymphedema. This population includes people who have chronic venous insufficiency (CVI) related lymphedema, a condition known as phlebolymphedema. The goal of this systematic review is to support evidence-based practice by OTs who are CLTs, by increasing awareness of current evidence that impacts practice. Awareness, in combination with consultation with the client, creativity, and clinical judgement including consideration of clinical expertise, elevates OT practice towards evidence-based rehabilitation (Law & MacDermid, 2014).

Lymphedema is a chronic condition that results in "an abnormal accumulation of water and proteins, principally in the subcutaneous tissues" (Zuther & Norton, 2018, p. 60). This condition presents with areas of swelling and disfigurement, often in the limbs. Lymphedema that is hereditary or congenital is considered primary lymphedema. Acquired, or secondary lymphedema, can result from damage caused by trauma, surgical removal of lymph nodes, radiation, or system overload (Zuther & Norton, 2018). System overload can be due to contributing factors such as renal or kidney disease, immobility, infections, or other causes (Ajiboye, 2020; Farrow, 2010; Gasparis et al., 2020; Lee, 2020; Lymphedema/ phlebolymphedema, 2012; Patel & Surowiec, 2020; Piller, 2009). When the overload to the lymphatic system is related to chronic venous disease (CVD), it can cause a secondary

lymphedema labeled as phlebolymphedema (Son et al., 2019). Venous disease is the second largest comorbidity associated with lymphedema, after breast cancer (Son et al., 2019).

The gold standard for treatment of lymphedema, regardless of etiology, is Complete Decongestive Therapy (CDT), provided by a CLT (NLN Medical Advisory Committee, 2011). Certified Lymphedema Therapists are specialists, often physical therapists or OTs, who have completed specialized training to treat lymphedema; some may also be wound care certified. Complete Decongestive Therapy includes skin hygiene, exercise, compression, and manual lymph drainage (MLD). Evidence to support CDT is limited. Much of the available literature focuses on compression, with little research related to skin hygiene, exercise, and MLD. In 2012, Oremus et al. completed a systematic review of conservative treatments for secondary lymphedema. The authors concluded the literature lacked evidence for the most effective treatment for lymphedema. Tan et al. (2020) noted that none of the available clinical practice guidelines (CPGs) for lymphedema were adequate for clinical practice due to deficits in methodology. Lymphedema resources, available CPGs and clinical recommendations for CDT provide limited guidance for modifying treatment specific to phlebolymphedema (Grada & Phillips, 2017; Jackson et al., 2021; Lasinski et al., 2012) and there is a lack of research on phlebolymphedema to guide CLTs (Son et al., 2019). Much of the available research on CVD intervention relates to surgical or medication interventions, or research specific to a marketed device including pneumatic pumps or specific brand of bandage. Treatment information that would be most relevant to CLTs is often immersed in consensus statements, CPGs, and position statements on phlebology and chronic venous disorders. These articles target a variety of providers other than CLTs, including vascular surgeons, vein specialists, and primary care providers and included surgical and medication interventions. In the quest to provide evidence-

based client centered care, an examination of the evidence for OT treatment of phlebolymphedema by CLTs was initiated. The aim of this capstone project was to complete a systematic review of evidence related to one component of CDT, the use of compression, for treatment of phlebolymphedema within the scope of an OT CLT who is not wound care certified. Compression was selected as a focus because it constituted the majority of available evidence.

Background

Chronic Venous Insufficiency

Chronic venous disease is a condition when the venous system is not working effectively to return blood from the legs to the heart (Todd, 2012). This disruption can result from malfunctioning valves, obstruction in the deep veins, or failure in the calf muscle system (Kumar et al., 2022) and results in venous hypertension. Risks for developing CVD are associated with factors that put sustained stress on the veins in the legs (Kumar et al., 2022; Todd, 2012). In addition to trauma and congenital factors, risks include standing for extended periods of time, pregnancy, smoking, obesity, decreased mobility, aging, and a history of a deep vein thrombosis (DVT; Kumar et al., 2022).

Chronic Venous Disease is staged for severity using the Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification system (Lurie et al., 2020).

C0: No visible or palpable signs of venous disease.

C1: Telangiectasis or reticular veins.

C2: Varicose veins.

C3: Edema.

C4: Changes in skin and subcutaneous tissue divided into two subclasses:

C4a Pigmentation or eczema

C4b Lipodermatosclerosis or atrophie blanche.

C4c Corona phlebectatica

C5: Healed venous ulcer.

C6: Active venous ulcer.

Todd (2012) detailed the progression from early stages of CVD to chronic CVD. In the earlier stages of CVD, edema may be intermittent. Patients may experience heavy, tired, aching, or restless legs. Spider veins and varicose veins may be evident, possibly tortuous veins, and the patient may have had or is at risk for blood clots. Decreased sensation in the feet may be present or developing. Todd (2012) described how feet and legs may become itchy and/or flaky and leathery. Any wounds may heal slowly or not at all. Left untreated, symptomology often progresses (Todd, 2012). Where previously edema was intermittent, now it becomes more regular (Todd, 2014). Edema may still lessen when legs are elevated for extended periods of time such as overnight in bed, however the skin on the legs starts to reflect decreased health (Todd, 2014). Skin gets harder, and wounds are more likely to occur and less likely to heal (Todd, 2014). The fluctuation in limb volume can impact mobility, cause pain, and increases risk for skin damage from expanding and contracting (Todd,2012). Continued overload on the lymphatic system leads to lymphatic insufficiency (Todd, 2014). Edema no longer resolves with elevation (Todd, 2012). Both fluid and proteins accumulate in the tissues of the lower leg and skin starts to harden, thicken, develop increased pigmentation, blisters, and bumps (Chatham et al., 2013). There is an increased risk for wounds and fungal infections (Todd, 2015). As symptomology progresses, declines in mobility and sensation result and impacting all aspects of quality of life (Todd, 2012). Untreated, wounds and infections such as cellulitis and sepsis, immobility, and pain are inevitable (Gloviczki et al., 2011). From a quality of life perspective, the impairments

from CVD negatively impact an individual's ability to engage in meaningful activities which can lead to occupational deprivation (Shier, 2014). Occupational deprivation "consists of conditions when there is prolonged exclusion from engagement of occupations that are necessary or meaningful" (Christiansen, 2011, p. 22).

In 2022, a panel of experts produced a consensus statement regarding the diagnosing and treating lymphedema (Lurie et al., 2022). Findings relevant to this capstone project include the consensus that was achieved:

- 96% "Chronic venous insufficiency is a common risk factor for lymphedema" (p. 254)
- 72% "All patients with CVI (C3-C6) should be considered as lymphedema patients" (p. 256)
- 89% "Regular use of compression garments reduces progression of lymphedema" (p. 257)
- 90% "The choice of circular versus flat knit elastic compression is dependent upon the severity of lymphedema and limb shape" (p. 258)

The 2022 panel of experts reported limitations in developing consensus among treatment practices. Lurie et al. (2022) noted that despite the intent to identify the evidence that experts were using to guide treatment, the experts primarily relied on their clinical experience and "selectively referenced studies that…aligned with their clinical experience" (p. 263). Additionally, the areas of majority expert disagreement reflected different practice patterns based on weak evidence from randomized controlled trials (RCT) and systematic reviews that found insufficient evidence (Lurie et al., 2022). Likewise, Das et al. (2022) review of evidence for compression included the following limitations (p. 1250):

> "Elastic stockings is effective for symptoms of and signs of CVD…Ib" indicating the evidence or general agreement is that the intervention is beneficial is derived from one RCT or large non randomized trial.

> "Temporary use of elastic stockings may be considered in patients with CVD awaiting further investigations and as a definite treatment in patients who are not managed by invasive methods... IIbC" indicating the efficacy is less well established by evidence or opinion and is derived from consensus options of experts, and/or small or retrospective studies, or registries.

An additional area of expert disagreement is terminology. In the literature some authors labeled CEAP stages C4-C6 Chronic Venous Insufficiency (CVI; Kumar et al., 2022) while others discussed CVI as including stages C3 to C6 (Pannier & Rabe, 2012). In some of the literature CVD and CVI were used interchangeably. Other terms used to distinguish when the lymphatic system is overloaded due to chronic venous hypertension included lymphovenous disease (Todd, 2012) and phlebolymphedema. For this article, CVD will refer CEAP classification C1-C6, and CVI will refer to C3-C6, when edema is present and is also termed phlebolymphedema.

The lack of quality high grade studies was reflected in a study published in 2020 examining CPGs for lymphedema (Tan et al., 2020). The authors used the Appraisal of Guidelines for Research and Evaluation (AGREE) criteria. The AGREE instrument is a tool to assess the methodological quality of CPGs (Brouwers et al., 2010). Tan et al. (2020) concluded that none of the current guidelines were adequate for clinical practice based on their

methodological aspects. Son et al. (2019) discussed that the gap in disease specific lymphedema CPGs impacted the methodological quality of the CPGs. The authors identified a treatment gap between people with cancer related lymphedema and people with phlebolymphedema (Son et al., 2019). For example, one of the standard textbooks (Zuther & Norton, 2018) has only six pages of a 550 plus page book dedicated to lymphedema associated with CVD. There are also a limited percentage of questions related to phlebolymphedema on the North American Lymphedema Association's (LANA, n.d.) certification exam. Of note, 53 pages in the Zuther and Norton (2018) book address wounds and wound care including venous ulcerations. The emphasis on venous wounds was also evident when searching for peer reviewed literature on CVI for this capstone project. Once the search parameters excluded wounds or ulcers, searches for venous disorders and compression therapy produced very limited results.

An additional challenge to accessing relevant evidence is the inclusion of decades old research in current CPGs, expert consensus statements, and position papers (Gianesini et al., 2019; Gloviczki et al., 2011; Kumar et al., 2022; Lurie et al., 2022; Maeseneer et al., 2022; Orhurhu et al., 2021). For example, Armsrong and Meyr (2021) compiled findings for *"Compression Therapy for the Treatment of Chronic Venous Insufficiency"* (Armstrong & Meyr, 2021) included 78 references. Four studies were from the 1970's. In total 27 studies were from prior to 2000, 25 were from between 2000 and 2011, and only 26 of the studies referenced were published between 2012 and 2022.

CVI and Compression

Although CDT includes skin care, compression, exercise, and manual lymph drainage (Zuther & Norton, 2018), initial literature searches produced studies that addressed compression, while exercise, skin care and MLD were more sparce. For example, despite multiple searches

resulting in thousands of articles, less than five articles were published within the last 10 years addressing exercises targeting people with CVI. There were numerous articles located that looked at pneumatic compression pump impact on edema and wounds related to CVI, however they were sponsored by specific product manufactures, which may indicate bias. The compression studies examined materials, assessing the amount of pressure from the compression products, compliance, impact on venous reflux and return, and compared different types of products from both clinical results and patient responses and preferences, hence the focus on this study on compression options for below knee compression when working with this population.

The 2022 CPG from the European Society for Vascular Surgery (Maeseneer et al., 2022) presented the following statements regarding the use of elastic compression stockings, adjustable compression garments and inelastic bandages as part of conservative management of CVD:

> "For patients with symptomatic chronic venous disease, elastic compression stockings exerting a pressure of at least 15 mmHg at the ankles are recommended to reduce venous symptoms" (p. 203)
>
> "For patients with chronic venous disease and oedema (CEAP clinical class C3) compression treatment using below knee elastic compression stockings, inelastic bandages, or adjustable compression garments exerting a pressure of 20-40mmHg at the ankle is recommended to reduce oedema" (p. 203)
>
> "For patients with chronic venous disease and lipdermatosclerosis and/or atrophe blanche (CEAP clinical class C4b) using below knee elastic compression stocking, exerting a pressure of 20-40mmHg at the ankle, is recommended to reduce skin induration" (p. 203)

The recommendations of Rabe et al. (2020) for contraindications to using compression were also included in this 2022 CPG for CVD (Maeseneer et al., 2022). These included not using compression in the following circumstances: if the individual's ankle brachial index was less than 0.6, in the presence of severe heart failure, allergy to the material that was to be used, severe diabetic neuropathy with sensory loss, or microangiopathy with a risk for skin necrosis. Additional recommendations offered by Rabe et al. (2020) addressed the length of the compression hosiery, presence of deep or superficial vein thrombosis, considerations for adding antibacterial treatment or in the presence of wounds or inflammatory diseases, cardiac insufficiency, risk for nerve damage, and other risks and contraindications. The authors concluded that when compression is used correctly, and contraindications are considered, adverse events associated with the use of compression are rare.

Compression garments do not reduce volume; their goal is to sustain the lowest volume (Lurie et al., 2022). Baish et al. (2022) presented a comprehensive model of how gravity affects fluid in the limb, and how compression works to decrease backflow by improving the one-way valves in the veins and how it "deforms and confines the interstitium" (p. 11) thus preventing fluid to pool in the areas under compression. The authors' model demonstrated how the use of compression can break the cycle of the gravitational effects on fluid pooling in the low legs, however they did note that with chronic pooled fluid, fibrosis occurs, and tissues become stiffer and less resistant to the mobilization of fluid (Baish et al., 2022).

The Zuther and Norton (2018) textbook on lymphedema detailed types of compression used by CLTs. Compression can be achieved thru either static or dynamic application. Static compression is achieved thru use of compression hosiery and bandages (Zuther & Norton, 2018). Dynamic compression is intermittent, such as using pneumatic compression pumps. Different

materials are used to achieve static compression. Short stretch bandages exert a high working pressure and a lower resting pressure, thus improving the venous and lymphatic return, and are often used in the decongestion phase of CDT by CLTs (Zuther & Norton, 2018). The amount of pressure applied by application can vary greatly between therapists and techniques used during bandaging (Hara et al., 2018; Suehiro et al., 2013)

Other compression options include ready to wear compression, made of circular or flat knit. Circular knit material is generally seamless and produced in a tube shape which can be modified for different shapes and compression levels based on the knit and ratio of different materials used (Zuther & Norton, 2018). The amount of containment can be varied as they can allow some stretch and expansion. (Lurie et al., 2022). Flat knit material used for compression is produced in sheets which are sewn together (Zuther & Norton, 2018). The aim of these garments typically is to provide more resistance to expansion due to less elasticity, thus provide more containment (Zuther & Norton, 2018). Flat knit tends to be heavier than circular knit and allows for customization to accommodate specific limb shapes and presentations (Zuther & Norton, 2018).

Circular knit and flat knit static compression can both be ready made or custom made. Zuther and Norton (2018) presented the different ranges for compression used in the United States. Circular knit compression is generally staged from level I, 20-30mmHg, level II, 30-40mmHg, and level II, 40-50mmHg. Flat knit compression is more in alignment with international classification. Level I is 18-21mmHg, level II is 23-32mmHg, level III is 34-46mmHg, and level IV is greater than 50mmHg (Zuther & Norton, 2018). The interface pressure (IP) is the amount of compression between the compression material and the skin surface, measured in millimeters of mercury (mmHg). A PicoPress (Microlab Elettronica, n.d.) tool can

be used to measure IP. Studies indicated that similar to bandaging, both flat and circular knit ready to wear compression stockings are inconsistent with that amount of compression produced (Lurie & Kistner, 2012).

Velcro wraps are short stretch static compression that offer an alternative to bandages and compression stockings for people with CVI (Balet et al., 2021). Velcro garments allow for adjustments and modifications, can accommodate various shaped legs, can accommodate fluctuation in volume, require training for gauging amount of compression and application, and different products offer different features to address application challenges and adjusting compression levels (Caprini, 2017; Kroeger & Dissemond, 2019). Some clients have challenges to donning and doffing Velcro compression garments that impacts compliance (Balet et al., 2021).

Compliance with use of compression has been addressed by various researchers. Difficulty in application and removal of devices is a barrier to compliance (Caprini, 2017; Kroeger & Dissemond, 2019; Shepherd, 2016). Balcombe et al. (2017) published a literature review on studies on donning and doffing compression and concluded that four approaches increased the ease of application of compression. These approaches were to train using a device to don and doff compression, alter the compression garment design, use of adjustable compression garments, and education.

Additional considerations for static compression are whether progressive or graduated compression is indicated for treating symptomology of CVD (Mosti, 2014; Mosti & Partsch, 2012; Shepherd, 2016). Graduated compression, where the pressure exerted is greater at the ankle than the calf, has traditionally been accepted as the standard of care for compression for venous insufficiency (Mosti, 2014). In recent years, progressive compression, where there is

greater compression at the calf than the ankle, has been studied (Mosti, 2014; Mosti & Partsch, 2012; Shepherd, 2016). This author was unable to locate recommendations regarding use of progressive compression in CPGs or consensus statements during the literature review for this capstone project.

One challenge to reviewing the evidence for use of compression is product sponsored studies (Fabbri et al., 2018; Jefferson, 2020). For this project, it was crucial to search each article closely for funding and sponsorship sources, authors' employment and associations, and the products discussed. For example, a Lurie et al. (2022) peer reviewed article is titled as an "Expert option consensus on lymphedema diagnosis and treatment." Five of the thirteen authors were employees of Tactile Medical, the makers of a specific brand of home compression pump. As discussed in the next section, an attempt was made to limit the studies reviewed for this study to non-sponsored research.

Methods

This study aimed to complete a systematic review of evidence related to use of static compression for treatment of lower leg phlebolymphedema that is within the scope of a CLT who is not wound care certified. The results of this systematic review will summarize clinical evidence for OTs who are CLTs, which will lead to improved treatment options and quality of life for individuals with CVI.

A systematic review published in by Oremus et al. in 2012 concluded that "the literature contains no evidence to suggest the most effective treatment for secondary lymphedema," thus this capstone focused on literature published from 2012 to the current year. Four databases were searched to extensively retrieve potentially eligible studies published between 2012 and 2022: Medline, Cochrane Central Registrar of Controlled Trials, CINAHL Ultimate, and Academic

Search Ultimate. Findings were restricted to peer reviewed articles published in academic journals in the English language. Search terms were:

> "Venous AND (bandages or bandaging or compression or Velcro or bandages) AND (edema or oedema or lymphedema or phlebolymphedema) NOT (pregnancy or pregnant or prenatal or antenatal or perinatal or maternal) NOT (ulcer or wound)"

References of all eligible papers were scanned to identify additional eligible publications. In addition, references from relevant CPGs, expert consensus or position statements were also scanned to identify eligible studies.

Inclusion and Exclusion Criteria

Inclusion criteria included the following:

Adult population, static compression interventions for venous disease, varicose veins, venous insufficiency, lymphovenous, phlebolymphedema. All treatment settings were included.

Exclusion criteria included the following:

Not sponsored by a product/ company, not dynamic compression, not focusing on the impact on wounds/venous ulcers or impact of compression after surgical procedures for CVD, or impact on treating or preventing thromboembolisms. Not included were interventions that were outside the scope of a CLT who is not wound care certified.

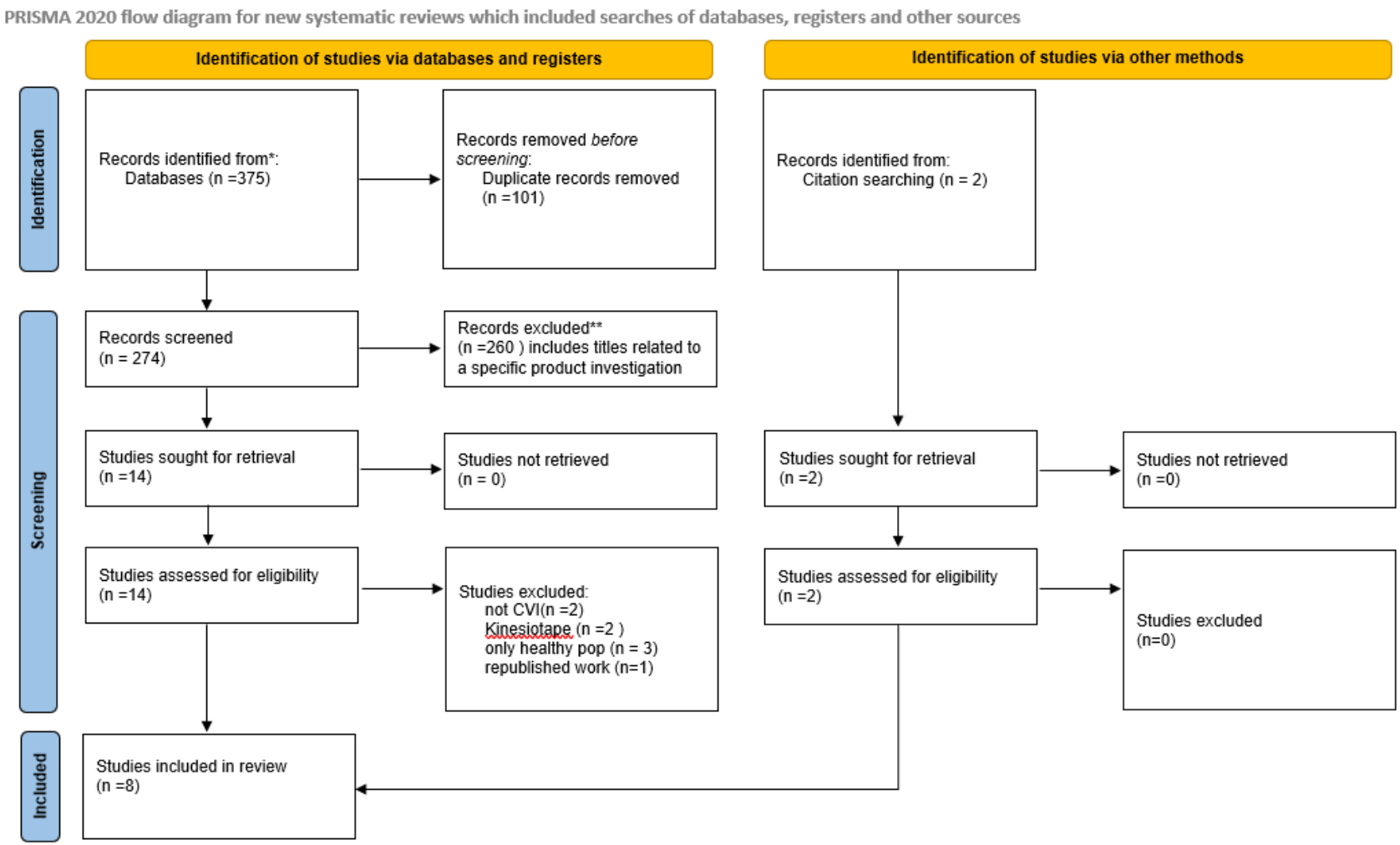
Outcomes that were included were: Quality of life, volume of pooled fluid, skin moisture, skin roughness, skin integrity excluding wounds, and wearing comfort and ease of donning. An additional outcome in many studies was interface pressure (IP). IP reflects the amount of amount of pressure between the compression layer and the skin, measured in mmHg. A PicoPress (Microlab Elettronica, n.d.) was used in most studies to measure actual compression interface pressure.

Types of research included in this review were RCTs, both blind and open. Pilot RCTs were included. Systematic reviews of RCTs and quasi-experimental studies were scanned to obtain the RCTs reviewed. Only RCTs accessible for review by the author were included in this study. After removing duplicates, published articles from the search were scanned by title for relevant to the search query. Full abstracts and papers were read and assessed based on the inclusion/exclusion criteria. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis 2020 (PRISMA 2020) flowchart in Figure 1 reflects the search results completed for this capstone project. PRISMA 2020 is a reporting system designed to help authors present systematic review findings in a transparent and complete manner (Page et al., 2021).

Quality Assessment

Each article was assessed for quality using the Critical Appraisal Skills Programme (CASP) checklist for RCTs (CASP, 2020). This tool incorporates aspects of the Consolidated Standards of Reporting Trials (CONSORT) guidelines as well as a series on critical appraisal by JAMA (CASP, 2020). AOTA (2020) guidelines for systematic reviews were used to determine the level and strength of the evidence.

Figure 1. PRISMA Flowchart



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).
**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/

Results

Eight studies were included in the review. Table 1 below provides a snapshot of the articles reviewed. Expanded reviews are presented in the appendix.

Table 1. Summary of Studies

Study Citation	Participants	Interventions	Time Frame	Outcomes Measured	Findings	Study Protocol Concerns	Practice Implications
Benigni, Uhl, Balet, & Chahim, 2018	30 poorly mobile nursing home residents with CEAP C3-C5	Velcro compression wraps for 30 days compared to Velcro wraps for 15 days followed by 15 days of 15-20 mmHg compression hose	Day 0, 15 and day 30	Circumference volume	Days 1-15 volume decreased in both groups, no significant difference. Day 30 no statistically significant difference, though Velcro wrapped continued to decrease in volume and compression hosed increased slightly	On day 15 one group transitioned to 15-20mmHg while people who had Velcro wrapping remained at 40mmHg. Does not present as comparable.	Velcro compression wraps are effective for decongestion of poorly mobile people with CEAP C3 to C5.
Benigni, Uhl, Balet, Filori, et al., 2018	38 poorly mobile nursing home residents with CEAP C3-C5	IB vs IB + Veinoplus (8) Velcro wrap vs Velcro wrap + Veinoplus (8) Nothing vs Veinoplus (8) IB vs Velcro wrap (14)	Baseline each leg compared to 2 hours of treatment, each leg receiving one of the treatments in their designated group.	Circumference volume, IP***	Veinoplus device had no impact on results in any group. The Velcro wrap resulted in more volume reduction than the IB.	No details on Veinoplus protocol provided. No details on why different group size for the IB vs the Velcro wrap. Authors conclusions reflect application ease and staff training despite no indication	Velcro wraps are useful during decongestion of poorly mobile people with CVD. Based on authors discussion findings, it is unclear how their study supported conclusion

						that was measured in the study.	regarding ease of training staff to apply Velcro wraps.
Holmes et al., 2014	31 people with Post Thrombotic Syndrome (PTS)	CLT at discretion of treating therapists compared to compression 30-40mmHg hose.	Baseline, 1 month, and 3 months	Quality of Life (QOL) using Villalta QOL and disease specific VEINES-QOL	No difference between groups. People with most severe symptomology at baseline benefited the most in both groups.	15 participants dropped out of study. No standardization of CLT treatment provided.	Isolated use of compression without CLT may still benefit people with symptomatic PTS
Mosti et al., 2015	40 legs of 36 people with CEAP C3	Multilayer IB* compared to Velcro Wrap	Baseline, day 1 and day 7.	Circumference volume, comfort, and IP***.	While both groups decreased in volume, Velcro wraps resulted in significantly more volume reduction.	The Velcro wraps were self-adjusted throughout the 7 days, while the IB was not readjusted.	Velcro wraps are an effective option during the decongestive phase.
Mosti & Partsch, 2013	40 legs of 28 people with CEAP C3	Multilayer IB 2 weeks then 23-32mmHg hose compared to EK liner** 20mmHg 1 week than 3 weeks with 2nd layer on.	Days 0, 1, 7, 14, and day 28.	Circumference volume, water displacement volume, IP***, comfort	At day 14 statistically same. Once IB was changed to 23-32mmHg, although not significantly different, not as effective as the EK.	For days 14-28, IB changed to 23-32mmHg, the EK stayed at 40mmHg.	For people with C3 CVD, Using an EK during initial decongestion phase may be an alternative that decreases frequency and duration of each CLT session
Mosti et.al, 2012	42 legs of 30 people with CEAP stage C3	Multilayer IB compared to 23-32 mmHg elastic hose	Days 0, day 2 and day 7.	Circumference volume, water displacement volume, IP***,	At day 7, no statistically significant difference	Focus of findings on volume decrease. Limited	For people with C3 CVD, use of 23-32 mmHg over the

				comfort, skin thickness		discussion of impact on skin thickness	counter hose may be effective for decongestion
Riebe et al., 2015	32 healthy people and 32 people with CEAP C3-C4.	Graduated Elastic compression stockings (GEC) compared to Progressive Elastic Stockings (PEC)	Day 1 and 7, and day 14 and 21.	Leg volume using 3D imaging system and water displacement, IP***, QOL & wearing comfort.	Both PEC and GEC reduced volume, no statistical difference between products, however differences in where volume was reduced, comfort and donning were identified.	The healthy participants were not comparable in age or gender. Strong study design. Authors re-wrote findings and re-published in 2016 under different title.	No impact on practice. Evidence not available for PEC usage for people with CVD. Findings did not reflect PEC is effective or comparable to GEC in effectiveness.
Westphal et al., 2019	50 people with CVD CEAP C1 to C3	23-32mmHg compression hose with integrated skin care compared to 23-32 mmHg hose without integrated skin care	Baseline, day 1 and day 28.	Skin hydration, water loss, IP***, skin roughness, QOL, and leg volume scanner	No statistical significance between groups for most measures. Some subgroups benefitted from the integrated skin care more than others.	Did not allow people wearing hose without integrated skin care to apply lotion. CLTs train people to apply lotion.	Compression hose with integrated skin care may be a useful product for some people.

Note: * Multilayer IB is inelastic short stretch bandage over padded layer and adhesive wrap. ** EK is elastic kit comprised of 1 layer of 20mmHg liner and 1 layer of 20mmHg elastic hose. *** IP is interface pressure and measured by a Picopress (Microlab Elettronica, n.d.) device.

Table 2 presents the findings from the CASP RCT standard checklist (2020).

Table 2. CASP Checklist for Quality Assessment of Randomized Controlled Trials

	Benigni, Uhl, Balet, &	Benigni, Uhl, Balet,	Holmes et al., 2014	Mosti et al., 2015	Mosti & Partsch, 2013	Mosti et al., 2012	Riebe et al., 2015	Westphal et al., 2019

	Chahim, 2018	Filori, et al., 2018						
Did the study address a clearly focused research question?	Y	N	N	Y	Y	Y	Y	Y
Was the assignment of participants to interventions randomized?	Y	Y	Y	Y	Y	Y	Y	Y
Were all participants who entered the study accounted for at its conclusion?	Y	Y	Y	Y	Y	Y	Y	Y
Any aspects of study are blind?	N	N	N	N	N	N	Y	N
Were the study groups similar at the start of the randomized controlled trial?	Y	Y	Y	Y	Y	Y	N	Y
Apart from the experimental intervention, did each study group receive the same level of care (that is, were they treated equally)?	Y	Y	N	N	Y	Y	Y	Y
Were the effects of intervention reported comprehensively?	N	N	Y	Y	Y	N	N	Y
Do the benefits of the experimental intervention outweigh the harms and costs?	Y	N	Y	Y	Y	Y	N	N
Can the results be applied to your local population/in your context?	Y	Y	Y	Y	Y	Y	N	N

Each of these RCT studies demonstrated deficits in the quality of the evidence. AOTA guidelines for systematic reviews (AOTA, 2020) were used to determine the level and strength of the evidence (see Tables 3 and 4). Table 5 presents the level of evidence this author assigned each of the studies in this capstone systematic review.

Table 3. Types of Evidence

Level	Type of Evidence
1A	Systematic review of homogeneous RCTs (similar population, intervention, etc.) with or without meta-analysis
1B	Well-designed individual RCT (Not a pilot or feasibility study with a small sample size)
2A	Systematic review of cohort studies
2B	Individual prospective cohort study, low-quality RCT (e.g., <80% follow-up or low number of participants; pilot and feasibility studies); ecological studies; and two-group, nonrandomized studies
3A	Systematic review of case-control studies
3B	Individual retrospective case-control study; one-group, nonrandomized pre-posttest study; cohort studies
4	Case series (and low-quality cohort and case-control study)
5	Expert opinion without explicit critical appraisal

Note. RCT = randomized controlled trial. From OCEBM Levels of Evidence Working Group. (2009). The Oxford Levels of Evidence. Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653
Source: AOTA (2020). Guidelines for Systematic Reviews. https://research.aota.org/DocumentLibrary/AOTA%20SR%20instructions%20Dec2020.pdf

Table 4. Strength of Evidence

Strength	Description
Strong	Two or more Level 1A/B studies • The available evidence usually includes consistent results from well-designed, well-conducted studies. The findings as strong and they are unlikely to be strongly called into question by the results of future studies. (AOTA review parameters: Two or more Level 1 studies)
Moderate	Moderate • At least one Level 1A or Level 1B high-quality study or multiple moderate-quality studies (Level 2A/B, Level 3A/B, etc.) • The available evidence is sufficient to determine the effects on health outcomes, but confidence in the estimate is constrained by such factors as: – The number, size, or quality of individual studies. – Inconsistency of findings across individual studies. As more information (other research findings) becomes available, the

	magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion related to the usefulness of the intervention. (AOTA review parameters: At least one Level 1 high-quality study or multiple moderate-quality studies)
Low	• Small number of low-level studies, flaws in the studies, etc. • The available evidence is insufficient to assess effects on health and other outcomes of relevance to occupational therapy. Evidence is insufficient because of – The limited number or size of studies; – Important flaws in study design or methods; – Inconsistency of findings across individual studies; or – Lack of information on important health outcomes. More information may allow estimation of effects on health and other outcomes of relevance to occupational therapy

Note. The strength of the evidence is based on the guidelines of the U.S. Preventive Services Task Force (https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions).
Source: AOTA (2020). Guidelines for Systematic Reviews. https://research.aota.org/DocumentLibrary/AOTA%20SR%20instructions%20Dec2020.pdf

Table 5. Strength and Level of Evidence of Included Studies

	Benigni, Uhl, Balet, & Chahim, 2018	Benigni, Uhl, Balet, Filori, et al., 2018	Holmes et al., 2014	Mosti et al., 2015	Mosti & Partsch, 2013	Mosti et al., 2012	Riebe et al., 2015	Westphal et al., 2019
Type of Evidence	2B	2B	2B	2B	2B	2B	2B	2B
Strength of Evidence	Moderate	Moderate	Low	Moderate	Low	Moderate	Moderate	Low

Discussion

This systematic review showed there was limited evidence related to compression use for treating people with CVI. The studies that were available reflected the work of only a handful of researchers. A combined list of all eight articles produced 34 authors; however only 22 distinct names. Two authors, Mosti and Partsch, contributed to three of the eight articles, and eight other

authors each contributed to two articles. The study designs used small populations between 30 and 50 people. There was moderate level evidence that the use of Velcro wraps were a good option when treating people with CVI (C3-C5) during the decongestive phase (Mosti et al., 2015) and with poorly mobile patients (Benigni, Uhl, Balet, & Chahim, 2018; Benigni, Uhl, Balet, Filori, et al., 2018). Low level evidence suggested that the use of elastic kits with layers of compression garments (Mosti & Partsch, 2013) and use of garments embedded with skin care (Westphal et al., 2019) have potential benefits for some patients. There was moderate level evidence to support that traditional decongestion using inelastic short stretch bandages over layers of padding were not the only choice for decongestion and in some cases not the best choice for treating phlebolymphedema (Benigni, Uhl, Balet, & Chahim, 2018; Mosti & Partsch, 2013; Mosti et al., 2015; Mosti et al., 2012). There was moderate level of evidence that further studies on use of progressive elastic compression are needed to determine if there is any evidence prior to usage for treating CVD symptomology (Riebe et al., 2015). An additional concern regarding the Riebe et al. (2015) study was the results were published under a different title using the same data and editing the content (Riebe et al., 2019). These articles initially presented as two different studies, however during the methodological assessment it was evident that the same research was used for both articles.

Challenges to the studies reviewed included the designs did not use comparable interventions. For example, in one study (Mosti & Partsch, 2013) the compression of 15 to 20 mmHg was compared to use of a different product with 40 mmHg. In another study, the Velcro wraps used by one group were readjusted throughout the study, while the group with bandages could not adjust their wraps (Mosti et al., 2015). In the skin moisture study, use of compression with embedded skin hydration was compared to not using any lotion (Westphal et al., 2019). Use

of lotion is part of CDT intervention (Zuther & Norton, 2018). In the study that impaired CLT versus no CLT (Holmes et al., 2014) there was no protocol or standardization of the CLT provided.

Overall, the studies that met inclusion criteria and were assessed for methodological quality were low quality RCTs based on the CASP checklist (2022). Most of the studies discussed how participants were randomly assigned and accounted for all participants at the end. Only one study (Riebe et al., 2015) had any aspect of blinding where the investigator or the participants were unaware of which intervention group to which they were assigned, and the study produced no evidence to support the intervention examined. In each of the other CASP checklist areas of quality assessment there was varied performance, and none of the studies met all criteria to be considered 1B level of evidence.

Implications For Practice

Based on the findings of this systematic review, the following recommendations are made regarding OT compression usage by CLTs when treating people with CVD:

1. There is moderately strong evidence for use of Velcro adjustable wraps to for decongestion and to treat phlebolymphedema symptomology of fluid volume and quality of life. It may be a good option for clients who are limited in mobility and/or are not able to participate in decongestion bandaging more frequently than one time a week (Benigni, Uhl, Balet, & Chahim, 2018; Benigni, Uhl, Balet, Filori, et al., 2018; Mosti et al., 2015).
2. There is moderately strong evidence to support the use of compression stockings during the decongestion phase as an alternate to bandaging (Holmes et al., 2014; Mosti & Partsch, 2013; Mosti et al., 2012).

3. There is low level evidence for skin hydration benefits from the use of compression garments that have skin hydration embedded into the garment. Clients with more advanced CVI are more likely to benefit (Westphal et al., 2019).
4. There is low level evidence that use of multilayer kits may be useful for decongestion (Mosti & Partsch, 2013).
5. There is no evidence to support usage of degressive compression stockings (Riebe et al., 2015) and the publishing of the same research in two different articles creates additional concern over quality (Riebe et al., 2015; Riebe et al., 2019).

Limitations

In an attempt to limit bias from product sponsored research, many studies were excluded. The remaining studies, however, did use the brand names of the product reviewed. In none of the studies were different brand name products compared to a comparable item from a different manufacturer. Including product sponsored research may have enabled comparison in findings between the different brands of similar products.

Future Research

As noted above, studies that examined the effectiveness and performance of different brands of specific products would aide in clinical decision making. Of specific interest would be identification of the lowest level of compression that would have an effective result for treating people with C3, C4, C5 and C6 during decongestion and then to sustain decongestion. Additional studies comparing the compliance of different products are comparable in symptom reduction outcomes is needed. Overall, studies with higher methodological quality with high levels of

evidence are needed to facilitate CPG development to elevate and standardize evidence-based client-centered care for people with phlebolymphedema.

Conclusion

CLTs who treat clients with CVI need up-to-date accessible high-quality evidence to provide evidence-based rehabilitation. Compression is one of the primary interventions that OTs who are CLTs can use to treat the symptomology from phlebolymphedema (Armstrong & Meyr, 2021; Attaran & Ochoa Chaar, 2016; Chatham et al., 2013; Das et al., 2022; Gloviczki et al., 2011; Lurie et al., 2022; Maeseneer et al., 2022; Rabe et al., 2020; Todd, 2015; Zuther & Norton, 2018). This systematic review reflects the lack of high-level evidence related to use of compression when addressing symptomology of phlebolymphedema. These findings are consistent with Das et al. (2022). The authors presented 21 recommendations for nonsurgical interventions for CVD with only two recommendations for non-wound use of compression, and the evidence supporting one of the recommendations is "less well established by evidence/opinion" (p.1250).

This systematic review highlighted the lack of available practice guidelines and clinical recommendations for modifying CDT treatment for phlebolymphedema (Grada & Phillips, 2017; Jackson et al., 2021; Lasinski et al., 2012) and the lack of research on phlebolymphedema to guide CLTs (Son et al., 2019). The systematic review of the evidence published within the last ten years reflects that lack of strong evidence regarding use of compression for treating symptomology of phlebolymphedema. Without RCTs with high methodological quality producing strong evidence, OTs who are CLTs are at risk for providing care that is not evidence based. Because phlebolymphedema symptomology impacts all aspects of self-care and occupational performance (Shier, 2014), it is important for OTs to address the occupational

deprivation (Christiansen, 2011) that may result from CVI that disrupts occupational engagement (American Occupational Therapy Association, 2020; Christiansen, 2011; Shier, 2014).

Appendix: Article Appraisal Summaries

Appraisal Summary 1

Benigni, J.-P., Uhl, J.-F., Balet, F., & Chahim, M. (2018). Treatment protocol on stasis edema in poorly mobile nursing home patients. *International Angiology*, *37*(5). https://doi.org/10.23736/s0392-9590.18.04025-7

This randomized pilot trial compared use of Velcro adjustable compression wraps for 30 days to use of same Velcro wraps for 15 days followed by use of 15-20mmHg elastic compression stocking. Compression was applied at least 8 hours a day. Leg volume was assessed using circumference measurements using Leg-O-Meter with affixed tape measures.

The inclusion criteria for residence of a nursing home with poor mobility or more unable to walk independently able to unable to walk at all. 30 patients including with T+ 2 the group receiving CircAid juxta lite treatment from baseline today 30 set and 40 mmHg, the second group of 15 wore the CircAid from baseline to day 15 at 40 mmHg, followed by day 15-30 wearing 15 to 20 mmHg Mediven micro tech compression stockings. Participants were randomized in assignment to group, and lower leg that received treatment was also randomized. The CEAP class for the participants was C3-C5. 7 people were excluded from the data due to withdrawal.

At baseline and at day 15 there was a volume decrease in both groups, that was not clinically significant between the 2 groups. At day 30, although not statistically signific compression stocking ant, the participants continuing use to CircAid juxta lite had further volume decrease by 1%, compared to the participants who transitioned to using the compression stockings leg volume increased by 1.3%.

The authors suggested that using 15 to 20 mmHg compression stockings might maintain edema reduction. Further research would be required to have evidence and not just a suggestion.

Relevance to study question: The population in this study were poorly mobile and presented with C3-C5 CVD. This population is highly relevant to the study as the progression of CVD is associated with decline in mobility**.** Poorly mobile patients with C3-C5 demonstrated edema reduction with application of CircAid juxta lite 40 mmHg for 8 hours a day over 30 days. They also demonstrated similar edema reduction when wearing the CircAid for only 15 days followed by 15 days of a 15 to 20 mmHg Mediven Microtec compression hose. The sustainability of decongestion was not resolved question so although these findings are relevant for the initial decongestion and reduction of edema, it does not provide any guidance of treatment for sustainability. It raised the question of what further volume increase would result by further use of the 15 to 20 mmHg after the 30 days, considering that although not a significant difference statistically, after 30 days the CircAid continue to result in volume reduction while the compression hose resulted in increased edema.

Practice implications: For patients with C3-C5 who have poor mobility, the use of a CircAid juxta lite produces limb volume reduction in the first 30 days. Although use of a 15 to 20mmHg Mediven Microtec after initial reduction phase may help support sustaining decongestion, it is questionable if the use of compression hose is comparable to continued use of the CircAid juxta lite to sustaining volume reduction over time. Further studies would need to look at if transitioning to a higher compression elastic stocking would be a comparable option to continued use of the CircAid juxta lite.

Appraisal Summary 2

Benigni, J.-P., Uhl, J.-F., Balet, F., Filori, P., & Chahim, M. (2018). Evaluation of three different devices to reduce stasis edema in poorly mobile nursing home patients. *International Angiology*, *37*(4). https://doi.org/10.23736/s0392-9590.18.03928-7

This randomized pilot trial measured and compared leg circumference using a Leg-O-Meter and calculated volume and used a Picopress to measure interface pressure after two hours. Four different interventions were compared on poorly mobile nursing home residents with CEAP stage C3-C5. The participants were randomly assigned to one of four groups:

8 participants: Velcro adjustable compression wraps (Circaid Justafit) alone versus in combination with a Veinoplus electrical stimulation device

8 participants: Multilayer (Rosidal K) compression bandage alone versus in combination with a Veinoplus electrical stimulation device

8 participants: Use of Veinoplus electrical stimulation device vs no usage. (1 patient dropped out)

14 participants: Use of Velcro adjustable compression wraps (Circaid Juxtafit) versus Multilayer (Rosidal K) compression bandage

There was no explanation for why one group consisted of 14 participants while the other groups were each assigned 8 participants. For each group, each participants legs were randomized to receive one of the two treatments.

Results: The use of the Veinoplus device did not have a statistically significant difference on leg circumference or volume. This finding however is not provided with any context, as the protocol for usage of the Veinoplus was not discussed. There is no information on the Veinoplus

regarding any findings of any studies on volume reduction in people with C3 to C5. The only study the authors discussed had results concluding that 21 days usage of the Veinoplus was required to achieve results, and the population in that study was pregnant women. The application of any intervention during this study was limited to two hours with poorly mobile residents of a nursing home with CVD.

Due to lack of significant differences in the treatment groups that looked at usage of the Veinoplus, the authors stated they intentionally focused on the 14 participants who compared the Circaid Juxta lite to the Rosidel multilayered bandage. After 2 hours of application, there were significant differences in interface pressure between the 2 interventions, and a significant difference (P=0.04) in whole leg volume reduction with the Juxta fit resulting in a 86 mL reduction while the Rosidel had a 59.4 mL reduction. When the circumference differences in measured segments are compared, the data provided further details on which portions of the legs resulted in a statistically significant decrease in volume from use of the Velcro wraps compared to bandages. Interface pressure measurement change reflects stiffness, and the authors concluded that the bandage sustained it's stiffness over the two hours, while the Circaid was never stiff.

The authors indicated there was variations in the amount of reduction in each leg segment on legs with the Velcro Juxta lite application. They opined this was due to difficultly applying each strap with uniform interface pressure. The authors also stated in their findings that this study confirms that the Juxta fit requires only a very short learning curve is required to use these Velcro wraps, and minimally trained nursing staff can apply these. This study did not reflect assessment with any measures related to the training or competency or any qualifications of who applied any of the interventions. Their conclusion was that after two hours, in elderly

poorly mobile people with C3-C5, the Veinoplus device had no impact, pressure is more important than stiffness, and the Juxta lite Velcro wrap seems more effective than use of Rosidel bandage to reduce leg volume.

Relevance to study question: The population in this study were poorly mobile and presented with C3-C5 CVD. This population is highly relevant to the study as the progression of CVD is associated with decline in mobility**.** The inclusion of assessing the impact of a Veinoplus electrical stimulation device presents as meaningless to both the original study and for the purposes of this review. The findings that are reflected in the data are also limited in usage, as a reduction of volume in two hours has questionable value. Additionally, the authors stated findings related to competence and training of staff applying the Velcro wrap that was not measured or assessed in the study.

Practice implications: For patients with C3-C5 who have poor mobility, use of CircAid juxta lite applied for 2 hours may provide some reduction in limb volume. This may be useful if a CLT intends to fit compression garments and wants to measure the leg circumference after brief decongestion instead baseline, or as part of education on how to readjust the Velcro straps after wearing for 2 hours. Comparing amount of leg volume reduction over 2 hours to usage of MLD would increase usefulness.

Appraisal Summary 3

Holmes, C. E., Bambace, N. M., Lewis, P., Callas, P. W., & Cushman, M. (2014). Efficacy of a short course of complex lymphedema therapy or graduated compression stocking therapy in the treatment of post-thrombotic syndrome. *Vascular Medicine, 19*(1), 42–48. https://doi.org/10.1177/1358863x14521883

This investigator blind, randomized controlled study compared the severity of symptomology and quality of life (QOL) in patients with post-thrombotic syndrome (PTS). While not all people with chronic venous insufficiency have had a deep venous thrombosis that led to PTS, people with PTS leads to CVD.

Thirty-one participants with PTS were randomized into 2 groups. Group A wore a 30-40mmHg graduated compression stocking during the day for 3 months. Group B received treatment in an outpatient clinic by a Certified Lymphedema Therapist (CLT) for 3 months. The CLT treatment was divided into two phases, phase 1 included manual lymph drainage, compressive therapy with bandaging and compression garments, lymphedema exercise and patient education. targeted decongestion, phase 2 was the maintenance phase, where patients completed home exercise programs and self-administered compression therapy as instructed by their CLTs. There was no protocol for the CLT treatment, the number and frequency of visit, the percentage of time and application details of the manual drainage, nor the product or techniques used for drainage, compression, nor specific exercises not included education provided was standardized or examined. Of note, 4 participants dropped out of the study stating time and travel constraints to attending CLT treatments. The additional dropouts were 3 participants with

new DVTS, 1 person with stocking allergy and 1 with superficial thrombophlebitis, and 2 from the compression group that withdrew with no explanation. 16 participants remained at the end of the study, 7 in group receiving CLT treatment and 9 in the compression usage only group. The authors stated that results from the sensitivity analysis were consistent for the intent to treat analysis

The study lasted three months, used two different outcome measures. PTS severity was measured using the Villalta score and QOL outcome used the disease specific VEINES-QOLs. Data was analysed comparing baseline to 1- and 3-month changes. The data reflected that there were no significant differences between treatments. Neither treatment significantly impacted the QOL score except for patients with severe disease. The findings indicated that participants in both groups with moderate to severe PTS benefited more from treatment compared to participants with less severe PTS, regardless of which treatment they received.

Relevance to study question: The inclusion and exclusion criteria allowed for establishing baseline compatibility, however the population studied is not generalizable to patients with CVD that did not have PTS or history of DVT, and the study size was too small to generalize to all PTS populations. The Villalta severity score of PTS rates patient symptoms of heaviness, pruritus, pain cramps and paraesthesia, and clinically rated edema, hyperpigmentation, venous ectasia, skin induration, skin redness, and pain during calf compression. Although the rated symptoms may also be present in people with CVD without PTS, however this assessment is validated to measures severity of PTS. The VEINES-QOL is a disease specific quality of life measure for people with chronic venous disorders of the leg. This measure is validated for usage with the population focus of this systematic review (Lamping et al., 2003). Thus, the findings of

this study can provide some useful data regarding patients with CVD, more specifically to a subset of the CVD population: those with a history of DVT and diagnosed with PTS.

Practice implications: Over course of three months, compared to people with less severe PTS, people with more severe symptomology of PTS benefit more from treatment, regardless of if provided by a CLT or compression only. People with moderate to severe PTS will benefit from compression 30-40mmHg even if unable to participate in hands on CLT treatment. Education on risks of new DVTs or superficial clots and allergy to materials is warranted.

Appraisal Summary 4

Mosti, G., Cavezzi, A., Partsch, H., Urso, S., & Campana, F. (2015). Adjustable Velcro® compression devices are more effective than inelastic bandages in reducing venous edema in the initial treatment phase: A randomized controlled trial. *European Journal of Vascular and Endovascular Surgery*, *50*(3), 368–374. https://doi.org/10.1016/j.ejvs.2015.05.014

This randomized control study compared the use of Velcro wraps at 40 mmHg compared to use of non-elastic bandages short stretch applied at 60mmHg over 4 weeks worn day and night. The assessment included leg volume using circumference measures, interface pressure measured by a pico press device, and a questionnaire using a visual analogue scale (VAS) for comfort index, which was derived from responses to pain, sensations of heaviness and swelling, edema related discomfort, itching and restless leg symptomology. Additional parameters regarding the specific device were also questioned regarding worsening of symptoms, application and reapplication of the device, cosmetic appearance and ease of putting on shoes.

The inclusion and exclusion criteria were appropriate for the study, all participants were affected by chronic venous disease and were classed as CEAP stage C3. 36 patients were randomized into 2 groups, with 40 legs participating in the study. Group A participants had their included legs decongested thru use of inelastic short stretch Rosidel bandages over a cotton padded layer and a short stretch non adhesive layer. Group B participants treatment legs were wrapped using Circaid Juxtafit Velcro wraps. No lining or other padding was discussed. Prior to the study, there was a washout period where any relevant drugs or compression devices were stopped for all participants, and all were encouraged to maintain their usual lifestyle throughout

the study. Measurements were taken at baseline, on day 1, and on day 7. All measurements were taken each of the study days.

One challenge to this study was that the difference in IP was established at the beginning. The bandages were always applied at a strong stretch by trained professionals that was assessed by the Pico Press as 60 mmHg. Between assessment days, there was no readjusting of the bandages. The Velcro wraps were applied at 40 mmHg, and participants were trained and allowed to readjust as needed to achieve that sustained compression. The authors did acknowledge this concern and provided in their discussion and justification of how allowing patients to readjust their compression during the decongestion phase instead of returning to the clinic requiring time-consuming professionally applied wrapping would have both financial and logistic benefits to the clients. The findings of the study reflected that both devices produced decrease in volume and comfort for both similar. However, the interface pressure of the bandage did decrease over the 7 days while the interface pressure of the adjustable wrap did not; again there was no readjustment of the bandages while the participants self-adjusted the Velcro wraps when they felt loose. Thus, the authors conclusion that the Velcro wraps were more effective than the bandages in reducing venous leg edema is an interpretation of the results, as the actual interventions were not comparable. A more comparable study design would have been setting the original Velcro compression to the same as the bandages, and not adjusting the Velcro wraps for the same length of time that the bandages were not adjusted. Or conversely, adjusting both the Velcro wraps and the bandages at the same frequency and time of day by professionals. Additionally, only one specific named brand product of Velcro wrap was used, so findings cannot be generalized to all Velcro wraps without further evidence provided.

Relevance to study question: Velcro wraps at 40mmHg and continuously self-adjusted produce reduction in venous leg edema in patients with CEAP stage C3 during the first week of decongestion and are a practical option to use instead of elastic bandages if the patient is not returning to the clinic for rebandaging for 7 days.

Practice implications: Velcro wraps offer a compression option during week 1 of decongestion by a CLT, when follow up appointment is in 7 days. Velcro wraps produce reduction in venous leg edema in patients with CEAP stage C3 during the first week of decongestion that is comparable to one sustained application of a multilayer compression bandaging.

Appraisal Summary 5

Mosti, G., & Partsch, H. (2013). Bandages or double stockings for the initial therapy of venous oedema? A randomized, controlled pilot study. *European Journal of Vascular and Endovascular Surgery*, *46*(1), 142–148. https://doi.org/10.1016/j.ejvs.2013.04.015

This randomized controlled study compared the use of an elastic kit compared to for the initial decongestion phase for compression treatment of venous edema. The study lasted for 4 weeks with measurements taken at baseline, after 1 week, after 2 weeks, and after 4 weeks.

The assessment included leg volume using water displacement, circumference measures, interface pressure measured by a PicoPress device, and a questionnaire using a VAS for comfort index, which was derived from responses to pain, sensations of heaviness and swelling, edema related discomfort, itching and restless leg symptomology. Additional parameters regarding the specific device were also questioned regarding worsening of symptoms, application and reapplication of the device, cosmetic appearance and ease of putting on shoes.

The inclusion and exclusion criteria were appropriate for the study, all participants were affected by chronic venous disease and were classed as CEAP stage C3. 28 patients were randomized into 2 groups, with 40 legs participating in the study. Group A participants had their included legs decongested thru use of inelastic short stretch Rosidel bandages over a cotton padded layer and a short stretch non adhesive layer. Group A's treatment legs were wrapped in inelastic short stretch bandages that were applied on day 1, worn day and night for 1 week, removed and reapplied for week 2, and removed at week 3. During week 3 and 4, a 23-32 mmHg Mediven Forte knee-high compression stocking was worn only during the daytime. Group B's treatment legs were decongested using a liner from the Mediven Ulcer kit, which

exerted 20mmHg, for one week, day and night. For the next three weeks, a second layer was applied, the Mediven Plus, also exerting 20mmHg. This second layer could be removed overnight. Prior to the study, there was a washout period where any relevant drugs or compression devices were stopped for all participants, and all were encouraged to maintain their usual lifestyle throughout the study. Measurements were taken at baseline, on day 7, day 14, and day 28. All measurements were taken each of the study days.

The findings of the study reflected that both devices produced decrease in volume, and there was no statistical difference in the percent of reduction between the two interventions. Comfort was similar for both interventions, however there were some findings as the weeks progressed. When the second layer of the EK was applied, some participants did not tolerate wearing it overnight, thus removed it and reapplied before getting out of bed. Group A did not have the option to remove any portion of the wraps.

The findings presented indicated that there was no statistical significance between either intervention over the 4-week study, for volume measured by water displacement or circumference, or comfort. One isolated finding of statistical significance was at week 2 the circumference around the "gaiter" area of the calf (between the malleoli and the calf) the reduction was statistically greater in group B, however by week 4 there was no statistically significant difference in circumference.

The authors conclude that use of a liner at 20-30mmHG worn day and night for 2 weeks, with addition of a compression stocking 20mmHg during the daytime during week 2, was comparable in volume reduction to application of application of strong 60mmHg inelastic short stretch bandages professionally applied on day 1 and day 7. Baseline, week 1 and week 2 volume resulted in no significant differences between group A and B.

During week 3 and 4, although not a significant difference, group A using elastic stockings of 23-32mmHg had slightly less maintenance of their volume reduction, compared to group B who continued to have a combined 40mmHg compression with use of both the 20mmHg liner and20 mmHg stocking layer. There was no follow up to assess the sustainability of decongestion over time. In general, the findings at week 1 and week 2 were more emphasized during the conclusion compared to week 4 findings.

Thus, the authors conclusion that the use of the EK liner is comparable to use of IB during the first week of decongestion, and that application of the second layer of the EK, the 20mmHg elastic sock, is also comparable to using IB for additional decongestion in week 2. The authors did not address findings comparing volume reduction maintenance of week 3 or 4 in their conclusion, a decision that is logical since the question of sustainability is raised by their data.

Relevance to study question: To achieve volume reduction during the first two weeks of compression therapy for patients with C3 venous disease, The Mediven Ulcer Kit liner of 20mmHg applied for 1 week day and night followed by addition of the MedivenPlus (daytime only) one size smaller than the liner exerting an additional 20mmHg pressure was as effective as professionally applied compression wrapping on day 1 and day 7, used day and night, as measured on day 7 and day 14. Volume reduction and maintenance continues over the next 2 weeks with continued use of the liner day and night and the 2nd layer stocking on during the day.

Practice implications: EK may be a good option during the initial decongestion phase of CLT. For patients with CEAP stage C3, use of EK kits, when during the first week of 2 weeks of decongestion and are a practical option to use instead of elastic bandages if the patient is not returning to the clinic for rebandaging more than 1 x a week. The liner must be worn day and

night, when the one size smaller second layer elastic compression is added in week 2, it can be removed at night. Continued use of the EK kit is also beneficial for 2 more weeks.

Appraisal Summary 6

Mosti, G., Picerni, P., & Partsch, H. (2012). Compression stockings with moderate pressure are able to reduce chronic leg oedema. *Phlebology, 27*(6), 289–296. https://doi.org/10.1258/phleb.2011.011038

This Randomized control study compared the use of elastic compression stockings 23-32mmHg to use of non-elastic bandages short stretch applied at 60mmHg over 7 days, worn day and night. The assessment included leg volume using circumference measures and using a water displacement measure, interface pressure measured by a PicoPress press device, and measurement of skin thickness at different leg segments by a Duplex scanner. Wearing comfort was assessed using a visual analogue scale rating 0 very poor comfort to 10 optimal comfort. Pictures of each leg were taken at every visit. Each measurement was taken at baseline, day 2 and day 7.

The inclusion and exclusion criteria were appropriate for the study, all participants were affected by chronic venous disease and were classed as CEAP stage C3. 30 patients were randomized into 2 groups, with 42 legs participating in the study. The bandage group participants had their included legs professionally wrapped thru use of inelastic short stretch Rosidel bandages over a cotton padded layer and a short stretch non adhesive layer. The compression stocking group participants treatment legs were compressed using Mediven Forte 23-32 mmHg ready-made knee-high stockings. Prior to the study, there was a washout period where any relevant drugs or compression devices were stopped for all participants, and all were encouraged to maintain their usual lifestyle throughout the study. The compression was removed

on day 2 and reapplied after measurements were taken. Measurements were taken at baseline, on day 2, and on day 7. All measurements were taken each of the study days.

The findings indicated there was no statistical significance between the effect of the bandages and the stockings after 2 days use and 7 days use regarding volume measured by water displacement and leg circumference, or skin thickness. Both interventions achieved significant difference from baseline compared to day to end date 7 and reduction of volume. There was no change in the visual analogue scales regarding comfort over the course of the week for either group.

The authors stated that although they expected that the higher compression produced by the bandage would result in faster volume reduction compared to a lower compression elastic stocking, the results did not support that expectation. The authors elaborated on this finding, commenting that this study 'surprisingly' showed that the reduction in edema with use of elastic slight stockings was only slightly less pronounced than the long high-pressure bandages. The skin thickness changes however presented with less detail for extrapolation of data.

One statement in the protocol in the Methods section under Timing it stated that patients were always seen at the same time of day in the late afternoon, while under Measurements it stated that the measurements were recorded during morning time using the 3 different methods to assess for leg edema. It is unclear if this is relevant.

Relevance to study question: This study presidents data to support the option to use ready to made 23-32 compression hose elastic stockings is a good alternative to professional strong bandaging when focusing on volume reduction in patients with C3, over the course of the week.. This study compared to different compression interventions used by CLT's when treating people with C3 stage CVD. Only one specific named brand product of compression hose was used, thus

findings cannot be generalized to all elastic stockings 23 to 32 mmHg without further evidence provided. More details comparing the impact of the two interventions on both skin thickness and clinical symptomology would add to the applicability of the findings. For example, if the authors had added the CVD disease specific VEINES-QOLs as a measure it would have provided useful data. Additionally, although the authors addressed skin changes, it did not provide detail on what other studies have found regarding the amount of time compression is needed to provide significant difference in skin thickness.

Practice implications: Readymade 23-32 elastic compression worn day and night offers a convenient option for volume reduction over the course of the week. Elastic compression knee-high stockings 23 to 32 mmHg produce reduction in venous leg edema in patients with CEAP stage C3. It produces volume reduction over one week that is comparable to application of a multilayer compression bandaging that is applied on day 1 and reapplied on day 2, not reapplied again until day 7.

Appraisal Summary 7

Riebe, H., Konschake, W., Haase, H., & Jünger, M. (2015). Interface pressure and venous drainage of two compression stocking types in healthy volunteers and in patients with hemodynamic disturbances of the legs. *Clinical Hemorheology and Microcirculation, 61*(2), 175–183. https://doi.org/10.3233/ch-151989

Riebe, H., Konschake, W., Haase, H., & Jünger, M. (2016). Advantages and disadvantages of graduated and inverse graduated compression hosiery in patients with chronic venous insufficiency and healthy volunteers: A prospective, mono-centric, blinded, open randomised, controlled and cross-over trial. *Phlebology: The Journal of Venous Disease*, *33*(1), 14–26. https://doi.org/10.1177/0268355516682885

This study was presented in 2 different articles. The first was published in 2015, the second was published 2016. The second article was also published in 2018 and 2019. The 2015 article was published with a different title compared to 2016th version, and the authors documented their study differently. They used the same randomized controlled trial as the basis for both articles and presented their findings in different formats. A quick scan of abstracts does not reflect that this was a reused study to publish the same findings. Without a deeper dive into the study, it might be incorrectly inferred that there is more evidence regarding usage of PECs. For the purposes of this study, the original 2015 version was reviewed.

This blinded, open randomized controlled at crossover trial assessed the impact of leg volume when comparing the use of graduated elastic compression stockings (GECS) to inverse graduated elastic compression stocking (PECS). The primary outcome was as measured using an image 3D system and a water displacement measurement. Interface pressure was measured

using the Picopress. The secondary outcome of side effects and wear comfort was assessed by a questionnaire asking about skin dryness sweating and itching side effects, and wearing comfort items of cold sensations, tingling, feeling of warmth, burning sensations, restrictions on movement, tightness, constrictions, slipping down, and strenuous donning. The severity of symptomology was assessed by the VCSS, the Venous Clinical Severity Score questionnaire.

Participants included 32 healthy volunteers and 32 patients with disease who were diagnosed with CEAP C3-C4. Each participant wore a stocking for 7 days at least 8 hours a day. There was a 1 week break without compression, and then followed by a week wearing the other compression. Thus, there were 4 groups. 1 group of 16 healthy volunteers wearing GECS for 1 week then after a break wearing PECS. The second group of 16 healthy volunteers wore PECS for a week and then after a break wore GECS for a week. The third and fourth groups were comprised of patients with CVI similarly distributed into the 2 groups of 16 alternating the sequence of wearing PECS then GECS or GECS then PECS. All participants had been randomized within their respective healthy volunteer or CVI patient group to which type of compression they started with. Additional aspects of the study were blinded including assigning different responsibilities to different investigators so that each measurement was blinded to the results to the other measurements until the study had concluded.

This study was conducted over 3 weeks, with outcome measurements on day 1 and 7 before and after each participant had trialed their first compression garment. The outcome measurements were repeated on day 14 and 21 when the participants trialed their second compression garment.

The GECS stocking had a maximal interface pressure of 23-32 mmHg exerted over the ankle, with graduated compression that declined from distal to proximal. Conversely, the PECS

exerted a maximal interface pressure of 23- 32 mmHg exerted over the widest part of the calf and had a declining interface pressure from proximal to distal with ankle compression of 15-20 mmHg.

Two participants were excluded due to noncompliance prior to the start of the trial. The patient group reflected 6 males and 26 females, while in the healthy volunteer group there were 13 males in 19 females. The median age range for the healthy volunteers was 26, while the median age range for the patient's with CVI was 49.5.

Findings: Both the GECS and PECS resulted in a statistically significant decrease in volume of the lower leg, there was no significant difference between the 2 types of compression regarding lower leg volume reduction. The volume of the distal leg and foot however was reduced with use of GECS in both the healthy and patient participants while PECS usage did not have significant impact on patient's volume reduction in distal lower leg or foot and less pronounced volume reduction in healthy volunteers compared to the GECS usage.

Secondary outcomes for side effects and wearing comfort using the VCSS questionnaire reflected both types of compression significantly reduced reported symptomology. Of note however the clinical symptomology of patient with CVI reduced more with use of GECS than with PECS usage. The PECS was rated as more frequent slipping down than the GECS, though it was also rated as easier to don. More data presented to the distribution of the VCSS results would have provided more insight to the applicability and generalization of the findings of this study.

Relevance to study: The inclusion of healthy volunteers in the control group enhanced the generalization of findings; however, the gender and age distribution of the healthy volunteers was not comparable to the patient group. Comparing graduated progressive versus inverse

degressive compression hose is a valuable addition to consider compression appropriateness for CLT's treating people with CVD. The alters of this study, in addition to findings of other studies, support that compliance with wearing compression hose is impacted by comfort and ease of donning. This study is provocative to the traditional compression related teachings at CLT's receive. More studies are needed using the updated findings on lymphatic fluid mobilization/compression/etc. etc. regarding progressive versus digressive compression.

Practice implications: More studies are needed before any consideration of implementation of PECS, for any population.

Appraisal Summary 8

Westphal, T., Konschake, W., Haase, H., Vollmer, M., Jünger, M., & Riebe, H. (2019). Medical compression stockings on the skin moisture in patients with chronic venous disease. *Vasa*, *48*(6), 502–508. https://doi.org/10.1024/0301-1526/a000812

This randomized control study assessed the impact on skin hydration comparing medical compression stocking 23-32mmHg with and without integrated skin care. No additional skin lotion or anything applied on legs wearing the hose without the integrated skin care. The study compared skin hydration on day 1 to wearing the assigned compression hose for 28 daily for 8 hours a day. Leg volume was calculated using a 3D Bodytronic600 device. Skin hydration was measured with a Corneometer CM825. Trans epidermal water loss was measured by a Tewameter MPS580. Skin roughness was measured using a FOITS optical measuring device. The Picopress was used for interface pressure measurements, and quality of life was measured using the disease specific three-part TLQ-CVI questionnaire. Photos were also taken to document outcomes. All outcome measures were used on day 1 and day 28.

The inclusion and exclusion criteria were appropriate for the study, all participants were affected by chronic venous disease and were classed as CEAP stage C1 to C4. The authors stated they were unsuccessful at recruiting anyone with C5 for this study. The 50 participants were randomized into 2 groups of 25. The MCS group received a 23-32mmHg knee high medical grade compression stocking (Venotrain micro), the MCS-SC group received medical grade compression stocking with the same 23-32mmHg compression with the addition of integrated skincare substances MCS-SC (Venotrain cocoon). There were no dropouts.

The findings indicated there was no statistical significance between changes in skin moisture when comparing the groups, there was statistically significant findings in some of the subgroups. These included:

Participants with low baseline skin moisture who used the MCS-SC showed a significant increase in skin moisture compared to the MCS, those with C3 benefitted from use of the MCS-SC, and male participants had significantly significant baseline drier skin than female participants, and the males who wore the MSC-CS had a significant increase in skin moisture compared to male MCS subject.

- Transepidermal Water loss: no significant differences between groups.
- Skin Roughness: no significance between the groups, however there was a significant increase in skin roughness from day 1 to day 28 in the MCS group. The increase in skin roughness for the MCS-SC group had only a slight increase that was not statistically significant.
- Interface Pressure was maintained by both compression stockings over the 28 days of the study.
- Leg volume: Participants in both groups significantly reduced leg volume. There was no significance difference between the two groups.
- Wear comfort: Some measures of comfort had significant results. The MSC-CS was rated more comfortable for donning, though the ease of donning was associated with more slippage, the tightening of the MCS-SC was faster, and the constriction in the "bond?" area was more comfortable. Bond area was not defined, this author suggests that

it refers to the band at the top of the stocking. Regarding the MCS, in the ankle area the tightness, constriction and reduced mobility were rated significantly better than the MCS-SC.

- Quality of Life: Both stockings resulted in patient rated QOL statistically significant improvements. There was no significant difference between the groups.

Relevance to study question: This study presents data to support the option to use ready-made 23-32 compression hose elastic stockings with integrated skin care. The integration of skin care product into the compression hose statistically increased the skin moisture for people who had baseline skin dryness and those with C3. Both compression with and without integrated skin care significantly reduced leg volume and were comparable in maintaining intended interface pressure (23-32mmHg), and both significantly improved self-reported quality of life ratings in a disease specific questionnaire. The population of the study ranges from C1 to C3 CVD. The findings of this study did not break down the data into subgroups for each CEAP class, though some data related to subgroups were presented in the results summaries. Edema is a defining symptom for progression from C2 to C3, and CLT treatment is targeted for treatment of edema. Thus, the findings from participants in this study who have C1 or C2 are not relevant to the study question. Additionally, CLT treatment includes training and treatment with skin care, included regular application of pH neutral lotion. This study did not compare integrated skin care to applied skin care, thus some of the findings are not applicable to patients that wear MCS who include application of lotion daily to their self-management routines.

Practice implications: This study presents an option for facilitating skin hydration in patients who are unable or unwilling to apply lotion as part of their daily self-maintenance, or

those whom despite lotion application continue to have challenges with skin hydration. Complete decongestive therapy provided by CLT's includes skin care, and as disease severity progresses skin roughness and other skin symptomology also progressive in severity. Although the findings were not significant, the use of the MCS-SC decreased skin roughness while the MCS without the integrated skin care increased roughness. As stated previously, the findings are not related to patients who apply lotion daily. Regardless, if further assessment of the product with integrated skin care demonstrates no additional risks or concerns compared to the comparable blood product without integrated skin care, it would seem reasonable to initiate usage of products that have integrated skin care in clinically appropriate patients who have no allergies to the products used or other relevant contraindications.

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