e-Stockings

Clinical/Medical Requirements and Recommendations

Document version 1.0

Contents

Revision history

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1 Summary

This document shall provide the medical background and guideline to the e-stockings projects and tries to delineate the most commonly used compression stockings in a medical context. It concentrates on the clinical medical background and facts of compression stockings in the context of their therapeutic application. It identifies the major groups in terms of compression classes, stockings sizes, and other requirements in order to facilitate the development of e-stockings for its broad application. It should help to avoid developments for smaller application fields of specialized therapeutic uses in the initial development phase, but does not exclude its later targeting should they be considered of interest at a later time.

This document is not dealing with specific production details such as textile techniques, pressure distribution or grading peculiarities. It is also not considering regulatory requirements or medical certification issues, which will be handled by the consortiums' textile and manufacturing specialists in a separate document.

With the perspective to target a majority of patients wearing therapeutic compression stockings, the following recommendations should be considered in the projects system specification.

- Graded compression stockings
- Class II (approx. 23-35mmHg)
- Short stretch bandage behaviour
- Compliance with specific regulations (country specific)
- Washable at 60℃
- Several different sizes (lengths, circumference) to fit individual patients

2 Introduction

2.1 Definition and classification of chronic venous disease

Chronic lower extremity venous diseases occurs frequently and is associated with a wide clinical spectrum ranging from minor asymptomatic cosmetic problems based on incompetence of venous valves to severe symptoms, including ulceration.[1] In advanced chronic venous disease functional abnormalities of the venous system leads to chronic venous insufficiency producing venous stasis, venous hypertension, oedema, skin changes and eventually venous ulcers.
The CEAP-classification of venous disorders, which is mostly used in scientific publication, describes the items of clinical signs, etiology, anatomic distribution and pathophysiology (Table 1).[2] In addition, scoring systems of venous disease and quality of life instruments to evaluate the severity of venous disease are used in clinical outcome studies.[3]

Table 1 CEAP classification	
C	Clinical signs (C0-C6), supplemented by (A) for asymptomatic and (S) for symptomatic patients.
E	Etiology (congenital (Ec), primary (Ep), secondary (Es), no venous cause identified (En)
A	Anatomic distribution (superficial (As), deep (Ad), or perforator (Ap), alone or in combination), no venous location identified (An)
P	Pathophysiologic dysfunction (Reflux (Pr) or obstruction (Po), alone or in combination) no venous pathophysiology identified (Pn)

Table 2 Clinical classes of CEAP	
Class 0	Nor visible or palpable signs of venous disease
Class 1	Teleangiectases or reticular veins
Class 2	Varicose veins
Class 3	Oedema
Class 4	Skin changes ascribed to venous disease (C4a: pigmentation, venous eczema, C4b: lipodermatosclerosis, atrophie blanche)
Class 5	Skin changes as defined above with healed ulceration
Class 6	Skin changes as defined above with active ulceration

2.2 Epidemiology

The incidence of chronic venous in a West – European population has been evaluated in a large cohort of 3072 adults aged from 18 to 79 years from the urban and rural Bonn area using the CEAP classification and additional Duplex investigations.[4] The authors found that only 9.6% of the investigated population showed no venous changes. (Figure 1) isolated teleangiectatic or reticular veins (C1) were found in 59.1% and 14.3 % had varicose veins (C2) without any further signs of chronic venous insufficiency. Pretibial oedema (C3) was found in 13.4 % and skin changes associated with venous disease (C4) were present in 2.9%. Eventually, florid or healed crural ulcers were found in 0.7% (Figure 1).

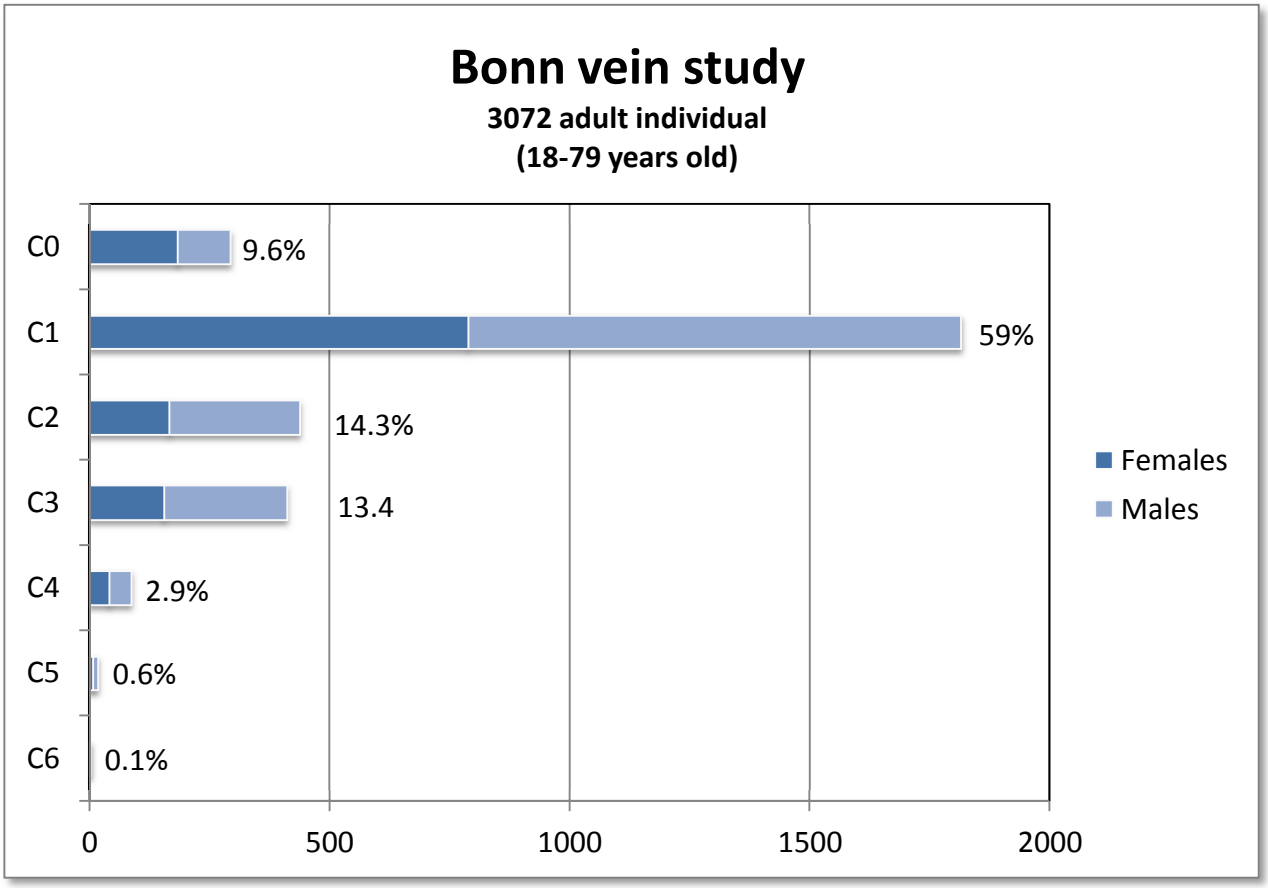

Figure 1: Prevalence of clinical CEAP classes according to the Bonn study.

2.3 Therapy

Beside the abolishment venous refluxes in the superficial venous system by surgical and interventional procedures, sustained (“chronic”) compression therapy, especially in combination with walking exercise is the pivotal basic management in chronic venous insufficiency (C3-C6) in order to reduce oedema and skin changes, to heal venous ulcers and to avoid recurrence.[1] Using of graduated elastic compression stockings is one of the most important compression therapies.[5]

It has been demonstrated that wearing graduated elastic compression stockings is an effective, non-operative option to relieve the symptoms associated with venous disorders in the lower limb.[5] Furthermore, compression stockings improve venous venous dynamics during orthostasis, reduce oedema and skin discoloration, and improve the quality of life in patients with chronic venous disease.[6, 7] A Cochrane meta-analysis of 22 trials showed that compression stockings were more effective than no compression in healing venous ulcers, and higher compression pressure were more effective than lower ones.[8] The rate of efficacy of compression stockings for ulcer healing raged from 23% to 845 (average, 50%) at 3 months to 1 year.

Once an ulcer heals, lifelong maintenance is recommended to reduce the risk of recurrence. In a review involving 466 patients followed after initial healing of ulcers,[9] the recurrence rate at 3 to 5 years was significantly higher among patients who were noncompliant with stocking than among those who were compliant (ranging from 32% to 64% vs. 19% to 34%, respectively, in different series).

Graduated elastic compression stockings provide an external, controlled pressure gradient and support from the ankle to the thigh for the superficial venous system to reduce the increased hydrostatic pressure and help the veins contract without muscle activity and pump the venous blood up towards the heart.[5, 10-12]

Graduated elastic compression stockings provide circumferential, graduated pressure with the highest amount of pressure located distally.[13] Compression stockings come in different lengths, including knee-high, low-thigh, high-thigh, and panty hose, as well as multiple compressive strengths. Generally, varicose veins require 20 to 30 mmHg, and sometimes 30 to 40 mmHg. Patients who have active ulcers (and ankle-brachial indices greater than 0.8) generally tolerate a compression stocking of up to 30 to 40 mmHg of compression. More resistant chronic venous insufficiency in the setting of lymphedema may require 40 to 50 mmHg or more (Table 3).[13]

Table 3 Recommended compression of elastic compression stockings and associated indications

Class	Compression (mmHg)	Indications
I	10-20	Prophylactic use during pregnancy Mild venous disease Combined arterial and venous disease
II	20-35	Stasis dermatitis Chronic venous insufficiency Venous ulcers Moderate varicosities Postphlebitic syndrome
III	35-50	Severe varicosities Severe oedema Recurrent venous ulceration Chronic lymphedema
IV	50-60	Primary lymphedema

Although compression stockings are clinically effective, they may not be usable for a wide variety of reasons, including application difficulty particularly in elderly patients (because of frailty or arthritis), physical constraints (e.g., limb obesity, contact dermatitis, or tender, fragile, or weepy skin), and

coexisting arterial insufficiency.[7] In a large community clinic, nearly 50% of patients were not able to use stockings for these reasons.[14] Many patients who can wear stockings abandon them after initial use for a variety of stated reasons, such as tightness and warmth. Reported rates of noncompliance have ranged from 30 to 65%, even under clinical supervision in venous-ulcer clinics.[15]
The use of e-stockings may therefore improve adherence to compression therapy.

3 General Requirements

Several general requirements were discussed at the initial project meeting in Odense. These general requirements should allow for the planning and development of the first prototype. They need to be discussed and re-evaluated during the project in a iterative process and further specified by the consortiums' textile and manufacturing specialists.
The following general requirements are advised for the prototype development:

- Graded compression stockings
- Must comply current standards and regulations
- Different sizes must be made available
- Inflation within few (e.g. 2) minutes to target pressure
- Washable at 60℃ for hygienic reasons
- Hypo-allergic material advisable
- Short stretch bandage behaviour

4 Compression Classes

Compression classes are defined by the amount of compression at the ankle level. It must be emphasized, that there are differences in classification systems between different countries (s. Figure). In a medical therapeutic context, compression pressures above about 23mmHg are used. Pressure levels below 20mmHg are mainly used for comfort or prophylactic reasons within hospital settings. The major indications for therapeutic compression stockings (chronic venous insufficiency, deep vein thrombosis, post-thrombotic syndrome) require stockings with pressure values between 23-33mmHg, most often referred as class II. Higher compression classes are only used in special cases (therapy resistant, lymphedemas).

Recommendations: The project should set the primary focus on class II (in the range of 20-35mmHg) compression stockings for the initial phase. At a later stage, it might be an option to target higher compression levels, as they are even harder to put on and off.

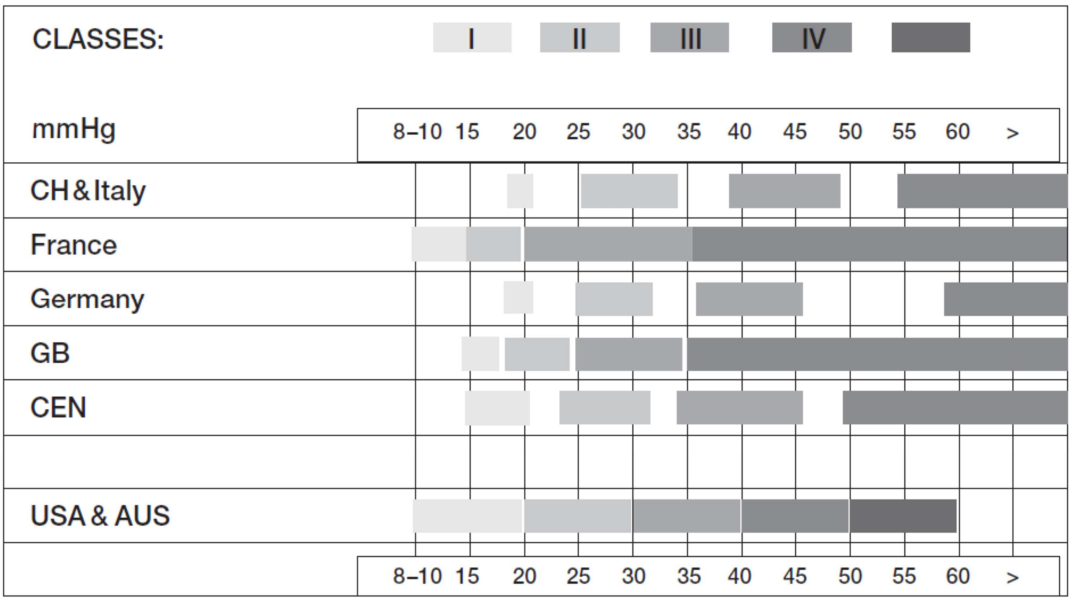

Fig. 1: Comparison of compression pressure at b-level (mmHg) and compression classes (I–IV) in different countries (A. Cornu-Thénard). In the European CEN concept a class A is proposed additionally (3).

Source: Partsch, VASA 2004[16]

5 Stocking Sizes

Current compression stockings must be fitted to the patient's size and adapted to the medical needs in order to achieve the desired pressures. The range of lower limb sizes a specific compression stocking can fit is specific to each manufacturer depending on the material, production process and regional normative specifications. In the following the sizing used at our institution is described in detail to give an approximate overview of the variability to expect for the development process in the e-stockings project. It must be taken into consideration that the numbers may vary between different regions even within Europe, as the height and body mass can vary considerably between different countries.

Considerations: Ranges of compression stocking size measurements vary between manufacturers and presumably countries stockings, which must be considered during the project.

5.1 Length

Even though several lengths of compression stockings are being used, mainly below-knee (A-D) and thigh-length (A-G) are currently in use at the Department of Angiology at the UHB.
About 80% of the stockings used are below-knee (A-D) stockings, 20% are thigh-length (A-G) stockings. Most of the thigh-length stockings can be switched to below-knee stockings after the initial months of therapy. Other stocking sizes are used only for special cases.

Recommendations: The project should set the primary focus on below-knee stockings for the initial phase

5.2 Patient adaption

Adjusting compression stockings to patients' anatomy is either done selecting one of many. The adjustable size variation for a stocking varies greatly between manufacturers. The larger the variation, the less different sizes need to be manufactured.

At present the fabric characteristics of the e-stockings are unknown. Hence it is not yet foreseeable how many stocking sizes will be needed to adapt most patients' needs. To provide an indication about the range of sizes currently in use as standard stockings, we have performed a survey at our department. Included in this statistics are only off-the-shelf standard sizes. Extra sizes and custom made stockings were not included in the calculation.

For standard sizes, four parameters are required to correctly fit a stocking to the patients' needs:

1. Length type: below-knee, thigh-length, trousers (s. above)
2. Length adaption to the patients height
3. Ankle circumference
4. Calf circumference

For length adaption, we currently use two lengths (41-45cm, 35-40cm), both lengths are used equally. The major factor is the adaption to the ankle circumference, currently we use three sizes (22-24cm, 24-26cm, 26-29cm), most often the small and medium sizes are used, whereas the larger size is only used occasionally. The forth parameter of calf circumference is adjusted in two sizes for each of the ankle sizes (s. Table 1).

Table 1: Stocking sizes used at the Department of Angiology at UHB (size-ranges in cm)

		AnkleSize	CalfAdaption					
		L 26-29		M 24-26		S 22-24		*Total*
LenghtType	LenghtAdaption	37-44	PL 41-48	34-41	PL 37-44	31-38	PL 34-41	
A-D	Long 41-45	2%	1%	11%	13%	9%	6%	*42%*
	Short 35-40	1%	1%	8%	9%	11%	10%	*38%*
A-D Total		*3%*	*2%*	*18%*	*23%*	*19%*	*16%*	*80%*
A-G	Long 75-84	3%	1%	5%	2%	5%	4%	*20%*
A-G Total		*3%*	*1%*	*5%*	*2%*	*5%*	*4%*	*20%*
Total		*6%*	*3%*	*24%*	*25%*	*24%*	*19%*	*100%*

Recommendations: Most ankle circumferences are expected to be in the range between 22-26cm (in Switzerland), calf circumferences between 31-48cm. These values might need adjustment according to different countries and populations.
Depending on the e-stocking design, several lengths/sizes must be foreseen for production.

6 Pressure Distribution

The compression stockings targeted in the e-stockings project require a grading in the pressure distribution with lower pressures in the proximal parts compared to the distal parts. The proximal pressure below the knee is often in the range of 20-30% compared to the ankle region, but the specific details are at the discretion of each manufacturer. Specific details will be provided by the consortiums' textile and manufacturing specialists.

The pressure distribution depends on the leg anatomy and is often not homogenous in the circumference. It decreases with a higher diameter and/or radius. Thus areas with protrusions such a bone structure may experience higher pressures than desired. This must be considered as in usual compression stockings, where in certain cases, the geometry of the leg is being changed using covering material (pelottes) to distribute the pressure more evenly.

In case of ulcerations or areas prone to ulcerations, higher local pressures are sometimes generated on purpose to ameliorate healing. This is also done by changing the leg geometry underneath the stocking.

Recommendations: Compression stockings should be graded with lower values below the knee. Circular pressure should normally be homogenous, but the system should allow increasing or decreasing localised pressure values in special cases.

7 Optional Developments of Interest

The following ideas developed within the consortium during the kickoff-meeting. They should be considered as being interesting for the development and further research. They are not considered as strong requirements, but give indications for further developments and improvements after the initial prototype creation.

- Different/individual pressure gradient adjustments along the leg
- Different (higher/lower) compression pressure over certain areas (e.g. ulcer areas)
- Volume measurement
- Pace count per day
- Timed pressure (e.g. lowering during night/week end)
- Pressure adjustments during the day (e.g. in-/decrease in the evening)
- Logging of stockings use
- Logging of pressure distribution
- Antimicrobial properties

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