MEDICAL ELASTIC COMPRESSION STOCKINGS

ISBN: 978 90 5278 868 5

Layout en druk: Datawyse / Universitaire Pers Maastricht
Foto omslag: Ed Wassing

Financial support for the printing of this thesis was generously provided by **VARITEX N.V.**

MEDICAL ELASTIC COMPRESSION STOCKINGS

Therapeutisch elastische kousen

Proefschrift

ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
op gezag van de
rector magnificus

Prof. dr. H.G. Schmidt

en volgens besluit van het College voor Promoties.
De openbare verdediging zal plaatsvinden op

donderdag 22 oktober 2009 om 13.30 uur

door

Catharina Petronella Maria van der Wegen – Franken
geboren te Bergen op Zoom

ERASMUS UNIVERSITEIT ROTTERDAM

Promotiecommissie

Promotor: Prof.dr. H.A.M. Neumann

Overige leden: Prof.dr.ir. H.J.C.M. Sterenborg
Prof.dr. H.J.M. Verhagen
Prof.dr. H. Partsch

Copromotor: Dr. B. Tank

Contents

Chapter I

General introduction and aims of the thesis

INTRODUCTION

Since ancient times, physicians have used external pressure in their aim to achieve therapeutic goals. Although it was applied for a lot of indications in the past, nowadays it appears that physicians other than phlebologists have forgotten the special qualities of this simple and inexpensive treatment.

Today, it is impossible to imagine phlebology practice without compression therapy, because phlebologists consider compression therapy with its many indications as the **'therapia magna'**.[1] Compression therapy has improved over the years. It is highly remarkable that evidence-based literature on this subject is sparse and most of it is empirical. Fortunately, in recent years, considerable progress has been made on good quality studies on compression therapy.

Patients with venous disease often question the benefit of compression therapy and many of those who prescribe this kind of treatment are not aware of its background and possibilities.

For many compression therapy might seem simple, but nothing is further from the truth! Compression therapy with its complex working mechanism depends on many factors. Since compression therapy plays a key role in the treatment of venous disease, principles of this therapy should be taught and research on this fascinating subject should be continued.

CHRONIC VENOUS DISEASE

Chronic venous disease (CVD) is accompanied by a broad range of clinical symptoms. These symptoms may vary from varicose veins to a venous leg ulcer. Other characteristic symptoms for CVD include edema, venous eczema, hyperpigmentation of the skin, atrophy blanche and lipodermatosclerosis (Figure 1). Chronic venous disease can be classified according to the CEAP-classification. This descriptive classification was introduced in 1994 by the American Venous Forum and is based on clinical manifestations (C), etiologic factors (E), anatomic distribution of disease (A), and underlying pathophysiological findings (P).(Table 1) [2,3] The clinical signs are categorized into seven classes designated C0 to C6. Leg symptoms associated with CVD include aching, heaviness, a feeling of swelling, cramps, itching, tingling and restless legs. Limbs categorized in any clinical class may be symptomatic (S) or asymptomatic (A). Chronic venous disease encompasses the full spectrum of signs and symptoms associated with classes C0 to C6, whereas the term chronic venous insufficiency (CVI) is generally restricted to disease of greater severity (classes C4 to C6).[4]

Chronic venous disease is extremely common. The literature concerning the prevalence and incidence of CVD has varied greatly because of differences in the methods of evaluation, criteria for definition, and the geographic regions analyzed. Telangiectasias are highly prevalent in the healthy adult population. Varicose veins have an estimated prevalence from 2-56% in men and from 1 to 60% in women.[5] Chronic venous insufficiency was more common with increasing age. Venous ulcers have an estimated prevalence of 0.3%, although active or healed ulcers are seen in 1% of the adult population.[6] Risk factors found to be associated with CVI include age, female sex, a family history of varicose veins, obesity, pregnancy and a standing occupation. Environmental or behavioral factors such as prolonged standing and a sitting posture at work may also be associated with CVI.[7,8]

Figure 1 Clinical manifestations of chronic venous disease.
a) Telangiectasias (CEAP class C1), b) Varicose veins (CEAP class C2),
c) Lipodermatosclerosis (CEAP class C4b), and d) Active ulceration (CEAP class C6).

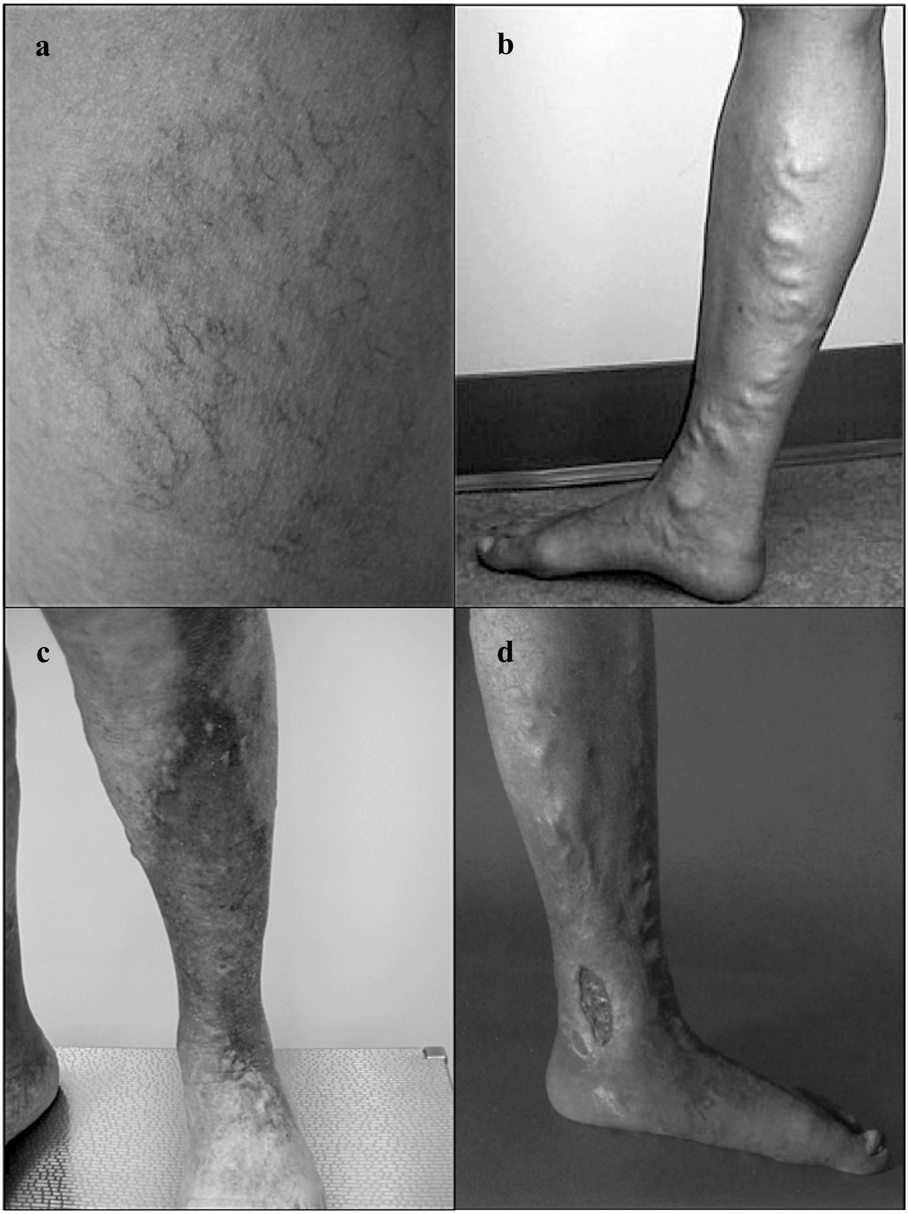


Table 1 Revised CEAP-classification of chronic venous disease: summary.[3]

Clinical classification	
C_0	No visible or palpable signs of venous disease
C_1	Telangiectasias or reticular veins
C_2	Varicose veins
C_3	Edema
C_{4a}	Pigmentation or eczema
C_{4b}	Lipodermatosclerosis or atrophy blanche)
C_5	Healed venous ulcer
C_6	Active venous ulcer
S	Symptomatic, including ache, pain, tightness, skin irritation, heaviness, and muscle cramps, and other complaints attributable to venous dysfunction
A	Asymptomatic
Etiologic classification	
Ec	Congenital
Ep	Primary
Es	Secondary (post-thrombotic)
En	No venous cause identified
Anatomic classification	
As	Superficial veins
Ap	Perforator veins
Ad	Deep veins
An	No venous location identified
Pathophysiologic classification	
Basic CEAP	
Pr	Reflux
Po	Obstruction
Pr,o	Reflux and obstruction
Pn	No venous pathophysiology identifiable
Advanced CEAP	
Same as basic CEAP, with addition that any of 18 named venous segments can be used as locators for venous pathology	

CHRONIC VENOUS INSUFFICIENCY

Chronic venous insufficiency of the legs is a complex of symptoms caused by the impairment of the venous return.[9] This results in a failure to reduce venous pressure with exercise or walking, which is known as ambulatory venous hypertension. In a standing position the pressure in the veins of the lower extremity corresponds to the weight of the blood column between the measuring point and the right heart which, in both healthy individuals and in patients with chronic venous insufficiency is approximately 80 to 100 mmHg in the dorsal foot vein and 50 to 70 mmHg at the calf level, depending on the body height. In healthy individuals the intravenous pressure decreases during walking to approximately 20 mmHg. However, in patients with venous insufficiency the intravenous pressure does not decrease adequately with exercise or walking.[10,11]

Effective venous return from the lower extremities requires the interaction of the heart, a pressure gradient, the peripheral venous muscle pumps of the leg and competent venous valves.[10] Venous pathology can result from reflux through incompetent valves, venous obstruction or a combination of these. However, an efficient muscle pump may compensate for some degree of reflux and obstruction. Effects of reflux and/or obstruction are exacerbated in the case of a dysfunctional muscle pump owing to obesity or leg immobility.

Incompetence of the valves results in a retrograde venous flow or reflux and increased hydrostatic pressures. Reflux may occur in the superficial or deep venous system or in both.

Obstruction of the deep veins may limit the outflow of blood causing increased venous pressure. Most common cause for obstruction is deep vein thrombosis. Dysfunction of the muscle pumps leads to venous blood not being effectively emptied out of the lower leg. This often occurs with severe reflux or obstruction.[4,6]

VENOUS MICROANGIOPATHY

Changes in the hemodynamics of the large veins of the lower extremity are transmitted into the microcirculation and eventually lead to the development of venous microangiopathy. The pathophysiology of venous microangiopathy is extremely complex and has been extensively studied. Several hypotheses for the development of venous microangiopathy have been postulated in the last decades. Most of these hypotheses aim at one aspect of venous microangiopathy.[12-15] In 1993, Neumann introduced a multi-causal theory which explained the evolution of microangiopathy in chronic venous insufficiency.[16]

The elevated ambulatory venous pressure is uniformly transmitted up to the venous side of the capillary bed and results in microangiopathy. Continuous pressure increase leads to dilatation of the capillaries. This is accompanied by changes in the composition of the capillary wall with widening of the inter-endothelial spaces and disintegration of the collagen-IV layer. The capillary filtration rate increases because of the high venous pressure and increased permeability. This results in transudation and exudation of fluid and macromolecules. The exudation of macromolecules leads to halo formation. The fibrin cuffs are only a signal that the capillaries in the skin are decompensated and do not form a diffusion barrier for oxygen as previously thought. A reduction in the blood flow velocity occurs when capillaries are dilated. This leads to an increase in the formation of the so-called 'coin-rolls' of the erythrocytes and mechanical white cell trapping and microstops develop on the walls of the capillaries, which finally lead to the formation of microthrombi. The exudation of, among others, more plasma proteins is also a luxation for a chronic, sub-clinically developing inflammatory reaction with the release of proteolytic enzymes from leukocytes and the release of free radicals. Clinically, this leads to dermato- et liposclerosis. Atrophy blanche manifests when many capillaries are lost. All these mechanisms result in hypoxia which can eventually lead to venous ulceration.[17,18]

TREATMENT

The treatment of CVI is based on the severity of the disease and guided by the anatomic and pathophysiological considerations.[6] The main target of any effective treatment of severe venous disorders is to lower ambulatory venous hypertension. This can be achieved by the elimination of venous refluxes through venous surgery, endovascular therapy, sclerotherapy or by compression therapy. One of the main intentions of adequate compression therapy of the lower extremities is to counteract gravity. Compression therapy is able to affect venous hemodynamics if the interface pressure is high enough to overcome the intravenous pressure, always adjusted to the body position. In the upright position this means that an interface pressure of more than 40 mmHg is needed for an intermittent occlusion of incompetent veins and for the reduction of ambulatory venous hypertension during walking.[19]

COMPRESSION THERAPY

Definition

Compression can be defined as the pressure that is applied by elastic or non-elastic material with tension to an area of the body surface. This is also-called the compression pressure. This exerted pressure is transmitted to the underlying tissue.[1]

Law of Laplace

The law of Laplace explains the basic physiologic mechanisms involved in compression therapy. The derivation of the law of Laplace is attributed to the noted French scientist and intellectual Pierre Simon Marquis de Laplace (1749-1827), who lived through the French Revolution and the rise and the fall of Napoleon Bonaparte. The statue of Pierre Simon Marquis de Laplace is found in Beaumont en Auge in Normandy, the place of birth of Laplace (Figure 2). Laplace, in fact, may not deserve the credit for the discovery of the relationship because many believe that one of the Bernouilli family had established the association almost 100 years earlier. Others claim that a case can be made that Lagrange, Helmoholtz, or other less well-known scientists deserve the credit. Nevertheless, the eponym is firmly rooted.[20]

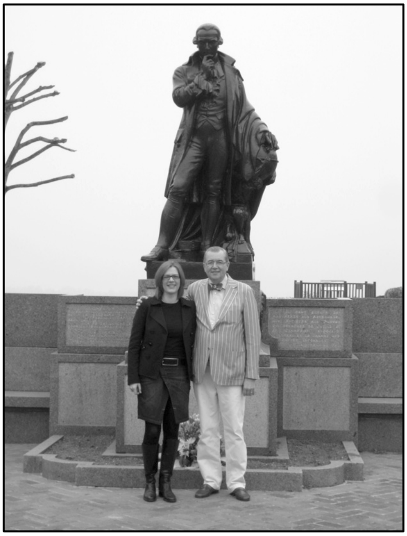


Figure 2 Statue of Pierre Simon Marquis de Laplace in Beaumont an Auge.

The law of Laplace applies to elastic bandages and medical elastic compression stockings (MECS) and illustrates that external pressure (P) is directly proportional to the tension (T) of the elastic material and is inversely proportional to the radius (r) of the leg: **P = T/r** (Figure 3).

In practice this means the following; at constant tension and increasing radius, pressure decreases. As a result the pressure at the lower extremity decreases in proximal direction.

On the contrary, at constant tension and decreasing radius, pressure increases. This explains why MECS or compression bandages can be uncomfortable at sites with a small radius such as the Achilles tendon, the tibia and the malleola. The exerted pressure over these areas will be inordinately high. The pressure can be reduced by increasing the radius by means of padding, the so-called *negative eccentric compression*.[21] However, high compression pressure may be used to advantage. For example, foam pelottes or narrow cylinders of soft cotton placed under MECS over the veins after sclerotherapy increase the pressure and enhance the treatment. This is known as *positive eccentric compression*. The radius of a plain area is infinite and elastic compression material will not exert pressure at all.

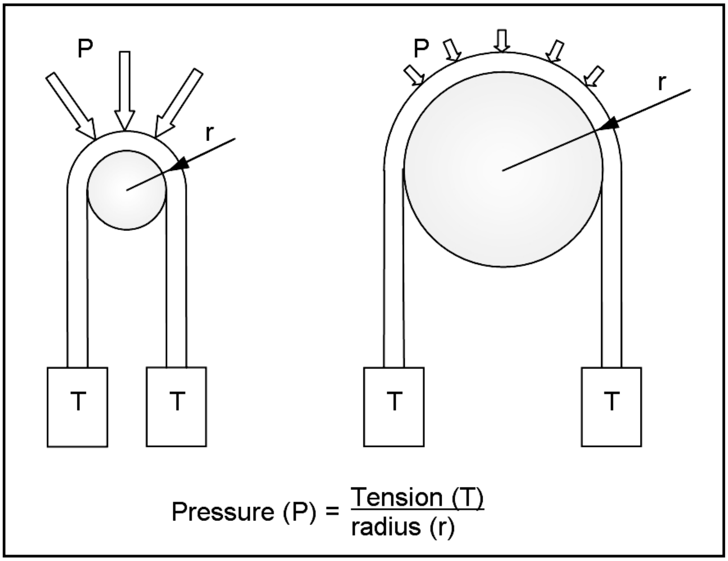


Figure 3 Law of Laplace.

Resting pressure and working pressure

Medical elastic compression stockings exert pressure on the leg. This so-called interface pressure changes with posture. This is because of the circumferential changes of the calf muscle. The pressure measured under static (resting) conditions is termed resting pressure; that measured on movement is known as working pressure. The static pressure depends on the gravity, thus there is a difference between the supine- and the standing position.

Compression therapy can either be elastic (bandages or stockings) or non-elastic (bandages). The differences between elastic and non-elastic compression is the resting and working pressure. The pressure that is exerted by a stocking or a bandage is not constant. The circumference of the calf changes during walking. Pressure pulsations occur under the MECS or the bandage when the circumference changes. Much resistance is offered against this increase in the circumference with inelastic or short-stretch compression. As a result large pressure pulsations occur with a high working pressure and a low resting pressure. However, in case of elastic compression, the compression material is able to adapt to the changes in the circumference. Pressure pulsations are low with a low working pressure and high resting pressure. The maximum and minimum pressures are termed working pressure and resting pressure respectively.[22]

THE HISTORY OF COMPRESSION THERAPY

The history of compression therapy began around 450 B.C. when **Hippocrates**, a famous Greek physician first mentioned various bandaging techniques in his *Corpus Hippocraticum*. [23,24] In the same period an adhesive bandage was mentioned for the first time in the *medici officina*. Thereafter, it was some time before **Guy de Chauliac**, an anatomist and surgeon from Montpellier in 1363 published his discussion in the *Chirurgica Magna*, a reference textbook used for 4 centuries, and in which the treatment of varicose veins with CT was mentioned for the first time.

In 1430 we encounter **Giovanni Michele Savonarola**. He is regarded as the founder of the conservative treatment of varicose veins. Bandaging from distal to proximal is described in his *Practica.* His successor **Fabricio d'aquapendente** introduced new bandaging methods. In his *Chirurgicis operationibus*, he described dog leather laced stockings for the first time. However, these stockings were already used since the 13th century for protecting the legs. In the same period **Ambroise Paré** pointed out the consequences of very tight bandages and the occurrence the so-called tourniquet effect.

Phlebology received a scientific basis in the 17th century. **William Harvey** discovered the blood circulation, the function of the venous valves and the calf muscle pump. **Richard Wiseman** wrote on deep venous thrombosis (DVT) in his book *Several chirurgical Treatise* and recommended that it should be treated with stockings. He also described the consequences of valve insufficiency and partial occlusion of the veins.

The concept of CT changed enormously in the late 18th century. At the end of the 18th century complete books were devoted to CT, whereas CT was hardly mentioned prior to this date. **Johann Christian Anton Theden** wrote on the advantages of bandaging the lower legs and explained the working mechanisms of compression therapy in his textbook.

In 1778, **B. Bell** demonstrated the effect of compression in the treatment of ulcers. He stressed the importance of bringing together the wound edges, because his hypothesis was that skin could not grow or expand. However, an anonymous German translator of his work was of the opinion that the skin could expand, particularly if it was stretched with adhesive bandages. **Thomas Baynton** jumped at this and published a crossed bandaging technique to bring together the wound edges through traction.

Rubber was first used for manufacturing stockings in 1820. However, the elasticity of rubber remained something to be desired. The stockings were difficult to put on and the pressure that was exerted was not effective. Rubber was brittle and not durable. This changed when **Charles Goodyear** discovered a method for making rubber softer and less brittle by heating (vulcanization). **William Brown** from Middlesex was the first to make stockings using four-sided rubber threads in 1848. He did this on a loom. To be exact, 26th of October 1848 is regarded as the 'birthday' of the modern elastic stocking. Patent number 12294 was granted to him on this day. However, since the stockings were made from pure rubber, they were painfully difficult to put on and to take off. This changed in 1851 when **Jonathan Sparks** hit on the idea of wrapping cotton or silk threads around the rubber threads (coating process). The next step came in 1861 from **William Saville** who proposed to manufacture custom-made stockings.

Rapid progress was made in the development of MECS thanks to all the innervations in the subsequent years. The introduction of the flat-knit improved the esthetic aspect of stockings. Seamless stockings have been manufactured since 1904. The first rubber-free stockings were manufactured in 1917. However, these stockings exerted insufficient pressure. The correct compression was achieved only in 1960 with the arrival of the synthetic elastomers. Since then stockings have been manufactured as we know them today.

INDICATIONS FOR COMPRESSION THERAPY

Indications for compression therapy can be venous and non-venous (Table 2).[25] Compression therapy may be implemented as short-term treatment in addition to surgery or sclerotherapy and may also be used as maintenance therapy. However, the most common indication for MECS is chronic venous insufficiency.

Table 2 Indications for compression therapy.

	Indications
Venous	Chronic venous insufficiency
	Leg ulcer treatment
	Deep venous thrombosis
	Superficial thrombophlebitis
	Addition to sclerotherapy, EVLT and surgery for varicose veins
Non-venous	Erysipelas
	Vasculitis
	Edema cruris; non-venous
	Posttraumatic conditions
	Lymphedema

The most important contraindication for compression therapy is arterial insufficiency with an ankle-brachial index (ABI) of less than 0.6 or an ankle pressure of less than 65 mmHg. Other contraindications for compression therapy are acute deep vein thrombosis without sufficient collaterals, severe congestive heart disease, contact allergy to components of the materials used in MECS or bandages and undefined ulcers such as carcinoma cutis (Table 3).[25]

Table 3 Contraindications for compression therapy.

Arterial insufficiency: ankle-brachial index < 0.6 and/or ankle pressure < 65 mmHg
Totally occluded deep venous system (e.g. deep vein thrombosis without sufficient collaterals)
Severe congestive heart disease
Contact allergy to one of the components in the MECS or bandages
Undefined ulcers (e.g. carcinoma cutis)

EFFECTS OF MEDICAL ELASTIC COMPRESSION STOCKINGS

The effects of MECS can be divided into acute and long-term effects. Various acute effects can be observed as soon as the stocking is put on. They can also disappear when the stocking is taken off. Table 4 shows the effects of compression therapy.[26,27]

Table 4 Effects of compression therapy.

1. Decrease in venous volume (reduction in venous diameter)
2. Increase in venous flow velocity
3. Reduction in venous reflux
4. Improvement in venous pumping
5. Decrease in edema
6. Prevention of edema
7. Reduction in ambulatory venous hypertension
8. Increase in arterial inflow
9. Improvement in microcirculation
10. Increase in lymph drainage

Macrocirculation

When compression is applied, venous blood shifts from the lower extremity towards other parts of the body. If the arterial inflow remains unchanged and the venous volume decreases due to compression, the venous flow velocity increases. Compression can prevent reflux by restoring the closure ability of the distended valves in superficial veins, by narrowing the superficial veins and by narrowing the deep veins through adequate high pressure. The tissue pressure increases because of the compression. This results in an increase in the transmural pressure with reabsorption of the edema.

Microcirculation

Several effects of compression on different microcirculatory parameters have been reported in the literature. MECS are able to reduce capillary filtration and pericapillary edema, to tighten intercellular junctions and to increase capillary density, thus improving tissue oxygenation. [27]

CHARACTERISTICS OF MEDICAL ELASTIC COMPRESSION STOCKINGS

Three characteristics determine the behavior and therefore the working mechanism of MECS. These are elasticity, stiffness and hysteresis.

I Elasticity

MECS are made of natural or synthetic rubber yarns. One of the most important aspects of rubber is its elasticity. This is the capacity of the material to return to its original shape after it has been stretched or elongated. MECS exert pressure on the leg because of this elasticity, which is related to its extension and the circumference of the leg.

II Stiffness

According to the European Committee of Normalization (CEN), stiffness is defined as the increase in the pressure at the B level (i.e. the smallest circumference of the ankle) if the circumference increases by 1 cm, expressed in hectopascals per centimeter and/or millimeters of mercury per centimeter.[28] Other frequently used synonyms for stiffness are elasticity coefficient and slope.

A typical relation between size (circumference) and pressure is given for two types of MECS in Figure 4. On the one hand, the higher the stiffness, the better the edema-preventive effect and the more it resembles the characteristics of a non-elastic material. On the other hand, the higher the stiffness, the more difficult it is to put on MECS. MECS that are acceptable to the patient should have a good balance between comfort and effectiveness. High stiffness is required when considerable edema formation is present. Low stiffness will do if compression is additional to other therapy, for example sclerocompression therapy.

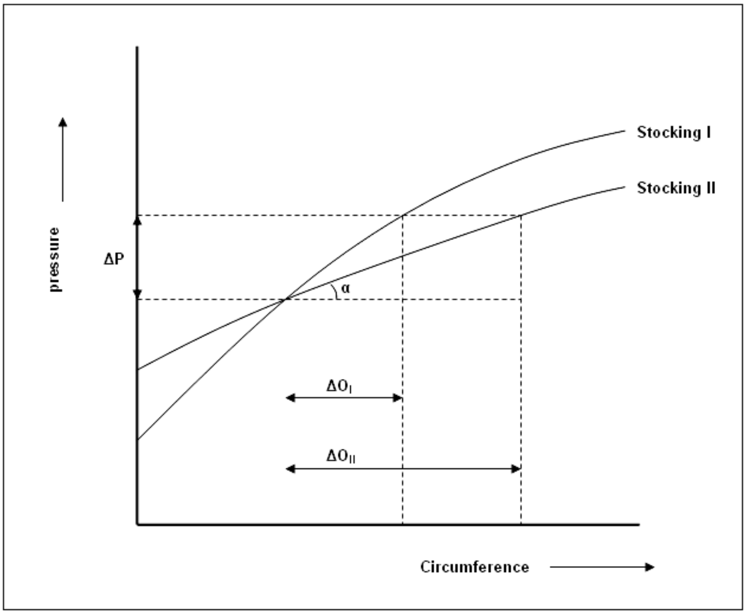


Figure 4 Pressure-circumference relation: stocking I has a high stiffness, stocking II has a low stiffness. Tan α = stiffness = ΔP/ΔO.

III Hysteresis

Hysteresis, which in Greek means lagging, is a characteristic of elastic material (in this case the knitwear), and a result of internal friction (friction between the different knitted loops). Hysteresis can be defined as the loss in recovered linear length of an elastic product when it recoils after exposure to repeated stretch-relaxation operations.[26] While walking the circumference of the leg changes continuously with every step and therefore the stocking is constantly active, being stretched and relaxed. The elastic compression material has to adapt to these changes. This can be explained as the massaging effect of MECS. This phenomenon is known as hysteresis and plays an important role in understanding the working mechanism of MECS. The phenomenon of hysteresis is illustrated in Figure 5.

Imagine a little brush on a rough surface. The brush is attached to a wall by means of a ‘spring’. When the brush is pulled the first thing that happens is that the direction of the hairs changes before the brush starts to move. In other words there is a short delay due to friction. This phenomenon occurs in every elastic material, whether you have one thread, a knit or a stocking. When the force is in the opposite direction and the brush is released, the same occurs again. In other words, friction is always in the opposite direction from the driving force. So if the stocking is being stretched, as is the case during walking or edema, this is prevented because of the friction. This is also the case when the stocking regains its original shape. Another way to illustrate hysteresis and stiffness, which is used in laboratories to determine hysteresis of elastic materials, is by means of a force-elongation curve (Figure 6). To elongate elastic material a force is required. After this, the material is relaxed. The area of the graph resembles the hysteresis, whereas the slope resembles stiffness.

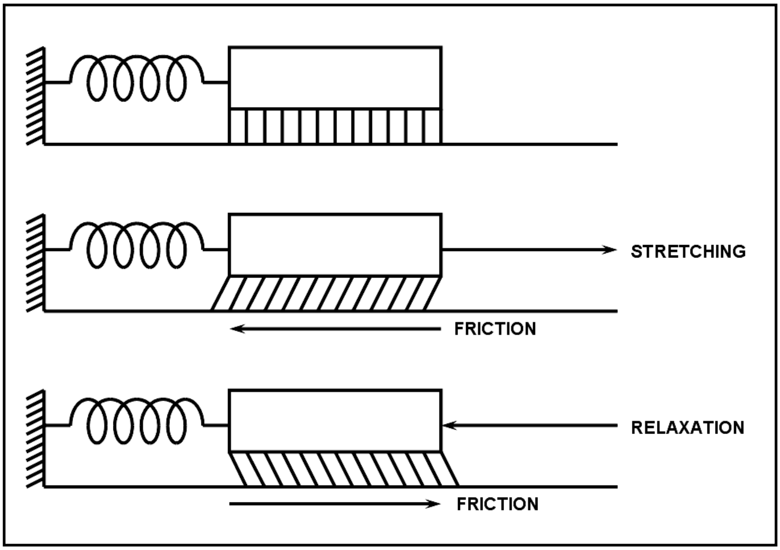


Figure 5 Schematic drawing of the phenomenon hysteresis.

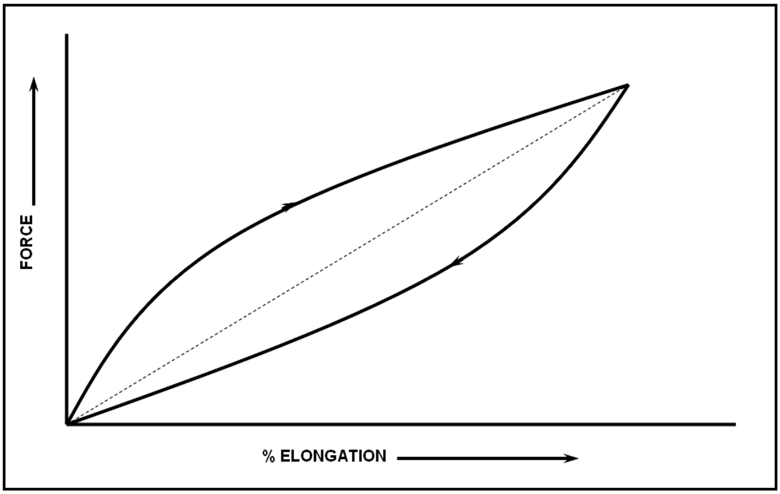


Figure 6 Force-elongation curve.

THE AIMS OF THE STUDIES DESCRIBED IN THIS THESIS

1. To determine the exerted pressure and to calculate the static stiffness in class II medical elastic compression stockings.
2. To introduce a new characteristic for more accurate classification of medical elastic compression stockings: the dynamic stiffness index.
3. To refine a method for measuring the dynamic stiffness index.
4. To examine whether medical elastic compression stockings can be classified according to their dynamic stiffness index.
5. To study the correlation between the static and the dynamic stiffness index of medical elastic compression stockings.
6. To study the correlation between the dynamic stiffness and the mass of medical elastic compression stockings.
7. To determine the pressure and to calculate the dynamic stiffness index of medical elastic compression stockings before and after having been worn for eight hours.
8. To determine the dynamic stiffness index of new generation ulcer stockings.

REFERENCES

1. Partsch H, Rabe E, Stemmer R. Kompressionstherapie der Extremitäten. Editions Phlébologique Francaises Paris, 1999.
2. Porter JM, Moneta GL. Reporting standards in venous disease: An update. J Vasc Surg 1995; 21: 635-645.
3. Eklöf B, Rutherford RB, Bergan JJ, Carpentier PH, Gloviczki P, Kistner RL, Meissner MH, Moneta GL, Myers K, Padberg FT, Perrin M, Ruckley CV, Coleridge Smith P, Wakefield TW. Revision of the CEAP classification for chronic venous disorders: Consensus statement. J Vasc Surg 2004; 40: 1248-1252.
4. Bergan JJ, Schmid-Schönbein GW, Coleridge Smith PD, Nicolaides AN, Boisseau MR, Eklof B. Chronic venous disease. N Engl J Med 2006; 355: 488-498.
5. Robertson L, Evans C, Fowkes FGR. Epidemiology of chronic venous disease. Phlebology 2008; 23: 103-111.
6. Eberhardt RT, Raffetto JD. Chronic venous insufficiency. Circulation 2005; 111: 2398-2409.
7. Robertson L, Evans C, Fowkes FGR. Epidemiology of chronic venous disease. Phlebology 2008;23:103-111.
8. Krijnen RMA, De Boer EM, Ader HJ, Bruynzeel DP. Venous insufficiency in male workers with a standing profession. Part I. Epidemiology. Dermatol 1997; 194: 111-120.
9. Neumann HAM. Flebologie in kort bestek. B.V. Zyma-Nederland, Mijdrecht, 19788.
10. Meissner MH, Moneta G, Burnand K, Gloviczki P, Lohr JM, Lurie F, Mattos MA, McLafferty RB, Mozes G, Rutherford RB, Padberg F, Sumner DS. The hemodynamics and diagnosis of venous disease. J Vasc Surg 2007; 46: 4S-24S.
11. Partsch H. Compression therapy of venous ulcers. Haemodynamic effects depend on interface pressure and stiffness. EMWA Journal 2006; 6: 16-20.
12. Browse NL, Burnand KG. The cause of venous ulceration. Lancet 1982; 2: 243-254.
13. Bollinger A, Jäger K, Geser A, Spier F, Seglias J. Transcapillairy and interstitial diffusion of Na-fluorescein in chronic venous insufficiency with atrophy. Int J Microcirc Clin Exp 1982; 1: 5-17.
14. Coleridge Smith PD, Thomas P, Scurr JH, Dormandy JA. Causes of venous ulceration: a new hypothesis. Br Med J 1988; 296: 1726-1728.
15. Falanga V, Eaglestein WH. The ‘trap’ hypothesis of venous ulceration. Lancet 1993; 341: 1006-1008.
16. Neumann HAM, Tazelaar DJ. Compression therapy. In: Bergan JJ, Goldman MP, editors. Varicose veins and telangiectasias. Diagnosis and treatment. St. Louis: Quality Medical Publishing Inc. 1993: 103-122.
17. Neumann HAM. Pathofysiologie van de veneuze microcirculatie. In: Neumann HAM, Tazelaar DJ. Leerboek flebologie. 1st ed. Lemma BV, Utrecht, 2003; 45-57.
18. Meissner MH, Gloviczki P, Bergan J, Kistner RL, Morrison N, Pannier F, Pappas PJ, Rabe E, Raju S, Villavicencio JL. Primary chronic venous disorders. J Vasc Surg 2007; 46: 54S-67S.
19. Partsch H. Effects of compression therapy of leg veins dependent upon pressure and material properties. Vasomed 2006; 18: 46-50.
20. Basford JR. The law of Laplace and its relevance to contemporary medicine and rehabilitation. Arch Phys Med Rehabil 2002; 83: 1165-1170.
21. Stemmer R. Konzentrische und exzentrische Kompression. Phlebol u Proktol 1984; 13: 53-57.
22. Veraart JCJM, Daamen E, Neumann HAM. Short stretch versus elastic bandages: effect of time and walking. Phlebologie 1997; 26: 19-24.

23. Hohlbaum GG. Zur Geschichte der Kompressionstherapie (I). Phlebol u Proktol 1987; 16: 241-255.
24. Hohlbaum GG. Zur Geschichte der Kompressionstherapie (II). Phlebol u Proktol 1988; 17: 24-37.
25. Neumann HAM. Compression therapy with medical elastic stockings for venous diseases. Dermatol Surg 1998; 24: 765-770.
26. Gardon-Mollard C, Ramelet AA. Compression therapy. Masson, Paris, 1999.
27. Partsch H, Flour M, Coleridge-Smith P, International Compression Club. Indications for compression therapy in venous and lymphatic disease. Consensus based on experimental data and scientific evidence. Under the auspices of the UIP. Int Angiol 2008; 27: 193-219.
28. European Committee for Standardization (CEN) Non-active medical devices. Working group 2 ENV 12718: European Prestandard ‘Medical compression hosiery’ CEN/TC205 Brussels: CEN, 2001.

Chapter II

The importance of stiffness of medical elastic compression stockings: *A systematic review of the literature and implications for daily practice*

Van der Wegen-Franken CPM, Tank B, Neumann HAM. The importance of stiffness of medical elastic compression stockings: A systematic review of the literature and implications for daily practice. *Submitted for publication in Phlebologie.*

ABSTRACT

Background: It has become clear that knowledge on the characteristics of compression therapy is imperative in its application. This means that not only the exerted pressure, but also the stiffness of the compression material is important. In recent years several methods for measuring stiffness have been published. Furthermore, data on the effect of stiffness on hemodynamic parameters and on the implications for daily practice have been reported. It is important for prescribers of medical elastic compression stockings (MECS) to apply this knowledge and use it in future investigations.

Objective: To systematically review the studies reporting the stiffness of compression bandages and/or MECS in the literature.

Methods: We searched three databases (MEDLINE, MEDLINE advanced and the EMBASE computer database) for studies in English, French, German and Dutch, which were published between 1980 and the first six months of 2008. Furthermore, the reference lists of the publications found were also screened for additional studies. All studies that dealt with stiffness of bandages and/or MECS were included.

Results: Overall, 17 studies were found, which were classified into three different categories: 1) studies in which different methods for measuring stiffness were described; 2) studies in which the effects of stiffness on venous parameters were reported; and 3) studies in which the implication of stiffness for daily practice were mentioned.

Conclusions: Reported studies on stiffness are sparse and show methodological heterogeneity. Several methods for measuring stiffness have been described and discussed. The results of the studies showed that the higher the stiffness, the larger was the improvement in hemodynamic parameters and the more effective was the reduction in edema. Besides the pressure, stiffness of bandages and MECS was of additional value to predict their effectiveness.

INTRODUCTION

The efficacy of compression therapy by means of medical elastic compression stockings (MECS) is mainly determined by two important characteristics. The first characteristic is the elasticity, which is the capacity of the material to return to its original shape after it has been stretched. MECS can exert pressure on the leg because of this elasticity. Pressure is defined as the amount of force of the compression material per surface area. The unit of pressure is Pascal (Pa) defined by 1 N/m^2. Medical pressure units are usually expressed as mmHg, 1 N/m^2 being 75 mmHg.[1] The pressure underneath a stocking or bandage is known as the interface pressure. When the pressure is measured under static (resting) conditions, it is called resting pressure, and when it is measured while the patient is moving, it is called working pressure.[2]

The second characteristic is the stiffness, which is closely related to the elasticity and linked to the extension of the knit and the circumference of the leg. According to the European Committee of Normalization (CEN), stiffness is defined as the increase in pressure at the B level, if the circumference at this level increases by 1 cm, and reflects the elasticity of the material.[3]

The relationship between circumference and pressure of two different types of MECS is shown in Figure 4 chapter I. One stocking has a low stiffness and the other stocking has a high stiffness. The steeper is the slope of the graph, the higher is the increase in pressure. The slope of the graph resembles the stiffness. In case of bandages, two more parameters are responsible for their effectiveness; tension in the bandage and the number of layers.[4]

Several terms for stiffness have been used in the past; ‘coefficient de résistance (CdR)’, ‘Indice de rigidite (IdR)’, slope, elasticity coefficient etc. The term was first described by Cornu-Thenard in 1985.[5]

In recent years, more interest has been focused on the stiffness of different compression devices. Slowly but certainly it has become clear that stiffness plays an important role in the efficacy of compression therapy. As a consequence, various methods for determining stiffness were developed.

Evidence-based literature on the topic of compression therapy is sparse. This is also valid for the technical aspects of this subject. Recommendations and guidelines for clinical studies with compression devices have been recently published with an eye on the future.[2,6]

The aim of this article was to compile an overview of the literature on stiffness of compression bandages and MECS published between 1980 and the first six months of 2008.

METHODS

We systematically reviewed all studies that reported stiffness of compression bandages and / or MECS for the treatment of venous disease. The MEDLINE and MEDLINE advanced computer database (National Library of Medicine, Bethesda, US) and the EMBASE computer database (Elsevier Science BV, Amsterdam, the Netherlands) were searched for articles that were published between 1980 and the first six months of 2008. The following key words (including analogies and derivatives) were used: (static or dynamic) stiffness, (static or dynamic) stiffness index, slope, elasticity coefficient in combination with compression therapy, medical elastic compression stockings, and bandages. Several studies on stiffness were published in journals not listed in the MEDLINE and EMBASE databases. Therefore, the references that were cited in the encountered studies and those presented in the proceedings of scientific meetings were also screened for any additional studies. In addition, references cited in guidelines and recommendations concerning stiffness were also examined.
All the studies on the stiffness of bandages and / or MECS that were published in English, French, German or Dutch were included.

RESULTS

In total, 17 studies, published between 2000 and the first six months of 2008 were eligible according to the pre-defined criteria. (Table 1). Of these 17 studies, two were published in two different journals. Reports published prior to 2000, were considered not to be eligible for inclusion, because they did not include any prospective experimental work. Of these 17 studies, ten were found in the MEDLINE database and an additional study in the EMBASE database. A screening of the references cited in these studies or in other papers concerning compression therapy and stiffness revealed the six additional studies.

Three different types/categories of studies were distinguished; 1) Technical studies in which methods for determining stiffness were investigated; 2) Studies in which the effect of stiffness on different hemodynamic parameters were investigated; 3) Studies in which the effect of stiffness for daily practice was examined.

1a Methods for measuring stiffness

Eleven studies introduced and / or investigated a method for measuring stiffness.[7-18] In two studies static stiffness was determined in a laboratory setting. In another two studies dynamic stiffness was also determined in a laboratory setting. Stiffness was determined in vivo in the remaining studies. Stiffness at the B level, the ankle at the point of its minimum girth, in accordance with the European Committee of Standardization (CEN) was determined in only two studies. Stiffness at the B1 level, the point at which the Achilles tendon changes into the calf muscles was determined in seven studies. Determination of stiffness at this point was recommended and reported by the International Compression Committee (ICC). In two studies stiffness was determined at other levels. Stiffness of MECS was determined in six studies, stiffness of bandages was determined in three studies and stiffness of both determined in two studies.

One study, in which static stiffness was determined in vitro at the B level, all according to the CEN, showed that different brands of MECS, all belonging to compression class II (23-32 mmHg), had stiffness ranging from 1.38 mmHg/cm to 7.04 mmHg/cm. The variation in the stiffness was not only between the nine different brands, but also within the three different categories.

Stolk et al. introduced a new method for measuring the dynamic stiffness index (DSI). This method was based on a method approved by the CEN, and developed for simulating the walking speed and walking pattern of the real leg. This study showed that the largest change in circumference during walking is at the B1 level. Furthermore, it was shown that because of these small increments in circumference, the pressure pulsations were large and thus the dynamic stiffness index was high - much higher than the static stiffness. Similar data were also reported by Benigni et al. However, these authors measured the interface pressures of different MECS while walking on a treadmill during the different phases of walking. The dynamic stiffness index (DSI) was defined as the difference between the higher and the lower pressures recorded during walking.

In two studies, Partsch described a simple approach providing useful information concerning both the pressure and the stiffness of different compression materials in vivo. This was done by measuring the pressure at a defined position on the lower leg at rest, when its circumference is minimum and repeated during active standing, when its circumference is maximum due to muscle contraction. Higher indices were found for Unna boot bandages and short-stretch bandages compared with the long-stretch bandages and MECS. A clear cut-off point was found to be 10 mmHg. The static stiffness index (SSI) values were lower than 10 mmHg for elastic, long-stretch

material and higher than 10 mmHg for inelastic, short-stretch material. Furthermore, it became clear that the stiffness of a compression bandage not only depended on the material, but also on the pressure at which it was applied.
Mosti et al investigated whether a more accurate differentiation between compression devices could be achieved when the actual increase of the leg circumference is taken into account compared with the simple SSI; the so-called modified SSI (mSSI). They compared the pressure differences (pressure indices) with modified indices corrected for the individual increase in leg circumference. The circumference increase during dorsiflexion, standing and tip-toeing was inversely proportional to the stiffness of the bandage: the stiffer the bandage, the lower the circumference increase. However, the plethysmographic parameters are not useful in assessing bandage stiffness because of the wide overlap between the data. The mSSI showed an increase of specificity and positive predictive value compared with the SSI. However, neglecting the changes in circumference yielded a slightly less accurate differentiation between compression devices, which makes the SSI a useful tool.

Ib Comparison of in vivo and in vitro pressure measurements

Partsch compared the pressure and the stiffness of ready-made MECS of different compression classes at the B1 level, measured on the leg in vivo and by laboratory tests in vitro.[19] A Zwick dynamometer was used for in vitro testing and the medical stocking tester (MST) was used for measuring interface pressures on the leg. The static stiffness index (SSI) was then calculated. The correlation between the in vitro and in vivo pressure measurements was highly significant.

2 The effect of stiffness on hemodynamic parameters

To obtain hemodynamic improvement in patients with severe chronic venous insufficiency, the pressure peaks of the compression material should intermittently exceed the local intravenous pressure on the leg during walking. This can be achieved by using compression devices with high stiffness.[20]

The effect of stiffness of MECS on different hemodynamic parameters was demonstrated in four studies.[21-25]
In 2000, Häfner and Jünger introduced a new parameter of MECS to describe the elastic properties or compliance of the MECS in vivo. It was defined as the quotient for maximum active pressure during exercise divided by resting pressure on standing (pA/pR). A strong and positive correlation was found ($r = 0.98$) between the elastic

properties and improvement in venous filling time (VFT). Another correlation between expelled volume and pressure gradient was found (r = -0.76). A larger volume is ejected during exercise with a graduated pressure profile.

3 Effect of stiffness for daily practice

The effect of MECS with different stiffness indices on edema was reported in one study.[26] This was done by measuring the capillary filtration rate (CFR) using air-plethysmography (APG) while patients were wearing their MECS. Patients with chronic venous insufficiency have a significantly higher CFR compared with venous healthy patients. Stiffness was measured by the manufacturer using the Hohenstein test method. The study showed a statistically significant decrease in CFR while wearing MECS. MECS with a high stiffness showed a larger decrease in CFR compared with MECS with a low stiffness. However, results of MECS with a low stiffness but higher pressure were comparable with those obtained with MECS with a high stiffness.

Table 1 Studies included in the review

Study	Participants	Design	Interventions	Methods	Compression materials	Definition stiffness
Van der Wegen-Franken 2006	n.a.	Experimental study	Static stiffness in vitro	Pressure (Instron tester = modified tensiometer) at B level	9 class II MECS: 3 flat-knitted custom-made MECS 3 classic round-knitted ready-made MECS 3 modern (ultrathin) round-knitted ready-made MECS	Increase in pressure at the B level per 1 cm increase in circumference.
Hirai 2008	13 female volunteers (mean age 22)	Experimental study	Static stiffness in vitro	1 Interface pressure (Air Pack Type Analyzer) during posture changes and exercise Pressure Hohenstein testing device (Hosy, Germany) (at B1 level)	4 round-knitted class II MECS 3 round-knitted class III MECS 1 flat-knitted class II MECS 1 flat-knitted class III MECS	Increase in pressure at B level? Per 1 cm increase in circumference
Häfner 2001	15 healthy volunteers (9 women, 6 men; mean age 26.7)	Open, randomised, prospective study	Static stiffness in vivo	Static pressure & dynamic pressure fluctuations (MCDM pressure transducer) at B level	ready-made ulcer stocking short-stretch bandage long-stretch bandage	Quotient for maximum active pressure / resting pressure on standing.
Jünger 2003	20 patients (14 women, 6 men; mean age 52.6) CEAP Cs0-4	Experimental study	Static stiffness in vivo	Interface pressure (MCDM pressure transducer) at two different levels	ready-made ulcer stocking	Quotient for maximum active pressure / resting pressure on standing.
Stolk 2004	5 healthy volunteers (3 women, 2 men; mean age 50)	Experimental study	Dynamic stiffness index (DSI) in vitro	1 On treadmill: Circumference (strain gauge plethysmography) & ankle angle (biometrics ankle sensor) 2 Pressure (dynamic leg-segment model) & circumference (strain gauge plethysmography) at B1 level	class II MECS (30 mmHg)	Increase in pressure at the B1 level per 1 cm increase in circumference.
Van der Wegen 2008	n.a.	Experimental study	Dynamic stiffness index (DSI) in vitro	Pressure (dynamic leg-segment model) & circumference (strain gauge plethysmography) at B1 level	4 round-knitted class II MECS 7 flat-knitted class II MECS 2 round-knitted class III MECS 3 flat-knitted class III MECS 2 flat-knitted class IV MECS	Increase in pressure at the B1 level per 1 cm increase in circumference.
Benigni 2005	healthy subjects	Experimental study	Dynamic stiffness index (DSI) in vivo	Interface pressures (Kikuhime) during the different phases of walking on a treadmill at 2 different levels	class I MECS (21-24 mmHg) class III MECS (21-36 mmHg) 2 class MECS superimposed 2 class III MECS superimposed	Difference between the higher and the lower pressures recorded during walking.
Partsch 2005	12 legs from 10 healthy volunteers (5 women, 5 men; mean age 46)	Prospective, controlled study	Static stiffness index (SSI) in vivo	Interface pressure (Kikuhime) at B1 level	class II round-knitted ready-made MECS (23-32 mmHg) class III flat-knittted ready-made MECS (34-46mmHg) long stretch bandages (extensibility 170%) Unna boot bandage + short stretch bandage 2 short stretch bandages (extensibility < 40%)	Difference between the interface pressure when standing and lying divided by 1 cm.
Partsch 2005	12 legs from 6 healthy volunteers (3 women, 3 men; aged between 26 and 65 years) CEAP; 10 C0, 2 C1	Prospective, experimental study	Static stiffness index (SSI) in vivo	Interface pressure (Kikuhime) at B1 level	long-stretch and short-stretch bandages	Difference between the interface pressure when standing and lying divided by 1 cm.
Mosti 2007	50 patients (28 women. 2 men; mean age 54) CEAP C2-3	Experimental study	Modified static stiffness index (mSSI) in vivo	Interface pressure (Kikuhime) & circumference (strain gauge plethysmography) at B1 level	long-stretch, short-stretch and inelastic bandages	Increase in pressure per actual increase in circumference.

Table 1 Studies included in the review

Study	Participants	Design	Interventions	Methods	Compression materials	Definition stiffness
Benigni 2007*	3 male subjects (mean age 55)	Experimental study	Dorsiflexion stiffness index (DSI) in vivo	Interface pressure (Kikuhime) at B1 & C level	2 medium-stretch bandages (extensibility 138% & 125%)	Difference between the pressure on contraction and the resting pressure.
Partsch 2006	12 legs from 6 healthy volunteers (5 women, 1man; mean age 43.2) CEAP 6 C0, 4 C1, 2 C2	Experimental study	Static stiffness index (SSI) in vivo & static stiffness in vitro	Interface pressure in vivo (medical stocking tester) Interface pressure in vitro (Zwick dynamometer) at B1 level	class I MECS 2 class I MECS superimposed class II MECS class III MECS	SSI= Difference between the interface pressure when standing and lying divided by 1 cm. Static stiffness in vitro= increase of pressure due to an increase of the circumference of 1 cm (B1 level)
Häfner 2000**	22 patients (11 women, 11men, mean age 55.1 C1-4)	Open, randomised, prospective study	Acute effect of 6 different class II MECS on venous haemodynamics	Interface pressure (MCDM pressure transducer) Expelled volume and venous refilling time (SGP)		Quotient for maximum active pressure / resting pressure on standing.
Häfner 2001	22 patients (11 women, 11men, mean age 55.1 C1-4)	Open, randomised, prospective study	Acute effect of 9 different class II MECS on venous haemodynamics	Interface pressure (MCDM pressure transducer) Expelled volume and venous refilling time (SGP)	9 different ready-made class II MECS of diferent materials	Quotient for maximum active pressure / resting pressure on standing.
Häfner 2001	42 patients (22 women, 20 men, mean age 55.1 C1-4)	Open, randomised, prospective study	Acute effect of 11 different class II MECS on venous haemodynamics	Interface pressure (MCDM pressure transducer) Expelled volume and venous refilling time (SGP)	11 different class II MECS; 9 ready-made MECS, 2 custom-made MECS	Quotient for maximum active pressure / resting pressure on standing.
Strölin 2007	42 patients (22 women, 20 men, mean age 55.1 C1-4)	Open, randomised, prospective study	Acute effect of 13 different class II MECS on venous haemodynamics	Interface pressure (MCDM pressure transducer) Expelled volume and venous refilling time (SGP)	13 different MECS: 9 ready-made class II MECS 2 custom-made class II MECS 1custom-made class III MECS 1ready-made class III ulcer stocking	Quotient for maximum active pressure / resting pressure on standing.
Van Geest 2000	29 legs from 25 patients (13 women, 12 men, mean age 66, CEAP C4-6)	prospective, controlled trial	Acute effect of different MECS on edema formation Static stiffness in vitro	Capillary filtration rate (CFR) air-plethysmography (APG) Stiffness (Hohenstein method) at B level	Class II MECS; low stiffness; pressure B level 30 mmHg Class II MECS; high stiffness; pressure B level 30mmHg Class III MECS; low stiffness; pressure B level 34.5 mmHg	Increase in pressure at the B level per 1 cm increase in circumference

* This study was also published in Int Angiol 2008; 27: 68-73.

** This study was also published in Orthopädie-Technik 2000; 11: 976-984.

DISCUSSION

Compression therapy is able to affect hemodynamic parameters if the interface pressure is higher than the intravenous pressure. This results in narrowing or closing of the lower leg veins. The pressure peaks of a compression device intermittently exceed the local intravenous pressure on the leg during walking, which results in hemodynamic improvement in patients with chronic venous insufficiency.[20] These pressure peaks can narrow or close the lower leg veins. Inelastic or low-elastic compression materials produce higher pressure peaks when standing or walking compared with elastic compression material. In patients with chronic venous insufficiency, inelastic bandages reduce venous refluxes, venous volume and ambulatory venous hypertension more effectively than elastic bandages.[27-29]

This review deals with studies on stiffness or a related characteristic. Literature is sparse and shows methodological heterogeneity. Several methods to assess stiffness have been published. This was initially achieved in vitro with different test methods. Since compression therapy is effective under dynamic conditions, new methods were developed to approach the dynamic actual situation as close as possible. Partsch considered the standing position as an equivalent to a snapshot during the course of a step and introduced a simple in vivo method to assess the static stiffness index (SSI). Dynamic stiffness measurements in vitro require sophisticated instrumentation and cannot be used in daily practice. The problem with dynamic in vivo measurements on a treadmill is the movement of the pressure probe under the compression material. Foot movement can be associated with clear changes in pressure under compression stockings and rapid changes in pressure may occur during walking.[30,31]

It has become clear that classification of compression bandages as well as MECS on the basis of the exerted pressure alone is not sufficient. In was reported in the studies by Van der Wegen et al. that MECS belonging to the same compression class had different stiffness.[7,12] It has been known for sometime now that not every class II stocking is the same and that the difference can probably be explained on the basis of differences in stiffness. Therefore, the stiffness is a valuable and additional characteristic for distinguishing bandages and MECS from different brands. The question remains whether measurements should be conducted under dynamic conditions considering that compression therapy is mainly effective under such conditions. New methods were introduced for dynamic measurements. Stolk et al. introduced a laboratory method for simulating walking speed and patterns.[11] This method can measure the dynamic stiffness index very precisely, but is not suitable in the daily practice and requires sophisticated equipment and is time consuming. In a study by Benigni et al. interface pressure measurements during the different phases of walking were conducted.[13] Unfortunately, the pressure device could not record the data continuously, and the changes in circumference were neglected. In our opinion the change in circumference is very important because pressure and circumference are related.

Partsch introduced a simple in vivo method to assess the SSI, which is defined as the pressure difference between active standing and lying.[14] He considers the standing position equivalent to a snapshot during the course of a step. Data have shown that there is an excellent correlation between the systolic pressure during walking and the pressure during active standing. He also made the assumption of an arbitrary increase in the leg circumference of 1 cm by standing up from the lying position and disregards the increase in leg circumference caused by calf muscle contraction, which is an important factor for the pressure increase during standing or walking.

Häfner et al. published three studies in which the effect of MECS with different elastic properties on venous hemodynamics was measured.[21-24] MECS that exert the same pressure at the ankle can still have different effects on venous hemodynamics. The efficacy of the various compression materials on the hemodynamics is determined above all by the degree of stiffness, which can be characterized in vivo as the ratio of maximum working pressure to resting pressure (pW/pR) while standing.

The study by van Geest et al. clearly showed that the higher the stiffness of MECS, the more capable they are in the prevention of edema.[26] Other important data were also shown. MECS with a low stiffness and high pressure showed a similar decrease in capillary filtration rate compared with MECS with a high stiffness and low pressure.

It is clear once again that there is much interest in the field of compression therapy, particularly on the characteristics of MECS. More focused research can be undertaken in the future because of the recent appearance of guidelines and recommendations.

Clinical implications

A recommendation paper for measuring pressure and stiffness, and guidelines for clinical studies with compression devices were published initiative of Partsch, Rabe and other members from the International Compression Committee.[2,4] Compression devices should counteract the intravenous pressure to narrow and occlude veins of the lower leg in order to obtain hemodynamic improvement in patients with chronic venous insufficiency. In the upright position this means a pressure of 50 to 70 mmHg.[20] These pressures can be obtained intermittently during walking. It was shown that the higher the stiffness, the better was the improvement in the hemodynamic parameters. It has become clear from several studies that there is a wide range of variation between the stiffness of MECS belonging to the same compression class.[7-12] This means that the current classification for MECS classified according to the pressure they exert at the ankle falls short.[32] A refinement of this classification with the stiffness index is warranted. This also means that manufacturers should mention the pressure and the stiffness on the packaging of MECS.

REFERENCES

1. Partsch H, Rabe E, Stemmer R. Kompressionstherapie der Extremitäten. Editions Phlébologique Francaises Paris, 1999.
2. Partsch H, Clark M, Bassez S, Benigni J-P, Becker F, Blazek V, Caprini J, Cornu-Thénard A, Häfner J, Flour M, Jünger M, Moffatt C, Neumann M. Measurement of lower leg compression in vivo: recommendations for the performance of measurements of interface pressure and stiffness. Dermatol Surg 2006; 32: 224-233.
3. CEN document: CEN/TC205/WG2/N229. Commission medical compression hosiery. February 2001.
4. Partsch H, Clark M, Mosti G, Steinlechner E, Schuren J, Abel M, Benigni J-P, Coleridge-Smith P, Cornu-Thénard A, Flour M, Hutchinson J, Gamble J, Issberner K, Jünger M, Moffatt C, Neumann M, Rabe E, Uhl JF, Zimmet S. Classification of compression bandages: Practical aspects. Dermatol Surg 2008; 34: 600-609.
5. Cornu-Thénard A. Réduction d'un œdème veineux par bas élastiques, unique ou superposés. Phlébologie 1985 ; 38 : 159-168.
6. Rabe E, Jünger M, Abel M, Achhammer I, Becker F, Cornu-Thenard A, Flour M, Hutchinson J, Issberner K, Moffatt C, Pannier F. Guidelines for clinical studies with compression devices in patients with venous disorders of the lower limb. Eur J Vasc Endovasc Surg 2008; 35: 494-500.
7. Van der Wegen-Franken CPM, Roest W, Tank B, Neumann HAM. Calculating the pressure and the stiffness in three different categories of class II medical elastic compression stockings. Dermatol Surg 2006; 32: 216-223.
8. Hirai M, Iwata H, Ishibashi H, Ota T, Nakamura H. Interface pressure and stiffness of various elastic stockings during posture changes and exercise. Vascular 2008; 16: 95-100.
9. Häfner HM, Götzke N, Kohnen R, Jünger M. Anpressdruck eines zirkulären Fertigverbandes im Vergleich zu phlebologischen Kompressionsverbänden. Hautarzt 2001 ; 52 : 867-872.
10. Jünger M, Häfner HM. Interface pressure under a ready made compression stocking developed for the treatment of venous ulcers over a period of six weeks. VASA 2003; 32: 87-90.
11. Stolk R, van der Wegen-Franken CPM, Neumann HAM. A method for measuring the dynamic behaviour of medical compression hosiery during walking. Dermatol Surg 2004; 30: 729-736.
12. Van der Wegen-Franken CPM, Mulder P, Tank B, Neumann HAM. Variation in the dynamic stiffness index of different types of medical elastic compression stockings. Phlebology 2008; 23: 77-84.
13. Benigni JP, Cornu-Thénard A, Uhl JF, Schadeck M. Compression stockings: walking pressures and proposal of a dynamic stiffness index. (abstract) Phlebology 2005; 20(3): 150-151.
14. Partsch H. The static stiffness index: a simple method to assess the elastic property of compression material in vivo. Dermatol Surg 2005; 31: 625-630.
15. Partsch H. The use of pressure change on standing as a surrogate measure of the stiffness of a compression bandage. Eur J Vasc Endovasc Surg 2005; 30: 415-421.
16. Mosti GB, Mattaliano V. Simultaneous changes of leg circumference and interface pressure under different compression bandages. Eur J Vasc Endovasc Surg 2007; 33: 476-482.

17. Benigni JP, Uhl JF, Cornu-Thénard A, Blin E. Bandages de compression. Influence des techniques de pose sur leur efficacité et leur tolérance cliniques. [Compression bandages. Influence of techniques of use on their clinical efficiency and tolerance.] Phlébologie 2007; 60: 85-92.
18. Benigni JP, Uhl JF, Cornu-Thénard A, Blin E. Compression bandages: influence of techniques of use on their clinical efficiency and tolerance. Angiol 2008; 27: 68-73.
19. Partsch H, Partsch B, Braun W. Interface pressure and stiffness of ready made compression stockings: comparison of in vivo and in vitro measurements. J Vasc Surg 2006; 44: 809-814.
20. Partsch H. Compression therapy of venous ulcers. EWMA Journal 2006; 6: 16-20.
21. Häfner HM, Jünger M. The haemodynamic efficacy of six different compression stockings from compression class 2 in patients suffering from chronic venous insufficiency. Phlebology 2000; 15: 126-130.
22. Häfner HM, Jünger M. Hämodynamische Effekte von medizinischen Kompressionsstrümpfen unterschiedlichen Materials in Bezug auf den Arbeitsdruck in vivo. Orthopädie-Technik 2000; 11: 976-984.
23. Häfner HM, Eichner M, Jünger M. Medizinische Kompressionstherapie. [Medical compression therapy] Zentralbl Chir 2001; 126(7): 551-556.
24. Häfner HM, Piche E, Jünger M. The ratio of working pressure to resting pressure under compression stockings: its significance for the development of venous perfusion in the legs. Phlebologie 2001; 30: 88-93.
25. Strölin A, Häfner HM, Jünger M. Biophysical characteristics of medical compression stockings: An indicator of heamodynamic effectiveness in patients with decreased venous function parameters. Phlebologie 2007; 36: 197-204.
26. Van Geest AJ, Veraart JCJM, Nelemans P, Neumann HAM. The effect of medical elastic compression stockings with different slope values on edema. Derm Surg 2000; 26: 244-247.
27. Partsch H, Menzinger G, Mostbeck A. Inelastic leg compression is more effective to reduce deep venous refluxes than elastic bandages. Dermatol Surg 1999; 25: 695-700.
28. Spence RK, Cahall E. Inelastic versus elastic leg compression in chronic venous insufficiency: a comparison of limb size and venous hemodynamics. J Vasc Surg 1996; 24: 783-787.
29. Partsch H. Improvement of venous pumping function in chronic venous insufficiency by compression depending on pressure and material. VASA 1984; 13: 58-64.
30. Wertheim D, Melhuish J, Williams R, Lane I, Harding K. Movement-related variation in forces under compression stockings. Eur J Vasc Endovasc Surg 1999; 17: 334-337.
31. Hirai M. Interface pressure under elastic stockings with compression pads during posture changes and exercise. Phlebology 1999; 14: 71-76.
32. Cornu-Thénard A. La pression est une indication nécessaire mais insufficiante pour apprécier les caracteristiques d'un bas élastique : la courbe 'Hystérésis est obligatoire. Swiss Med 1988 ; 4a : 64-66.

Chapter III

Calculating the pressure and the stiffness in three different categories of class II medical elastic compression stockings

Van der Wegen-Franken CPM, Roest W, Tank B. Neumann HAM. Calculating the pressure and the stiffness in three different categories of class II medical elastic compression stockings. Dermatol Surg 2006; 32: 216-223.

ABSTRACT

Background: Medical elastic compression stockings (MECS) are currently classified according to the pressure they exert at the ankle at the point of its minimum girth (B level). Despite this classification, there are considerable differences between MECS belonging to the same compression class from the same manufacturers and between different manufacturers. This makes it difficult for the clinician to choose the most suitable MECS for the patient. The stiffness may be used to distinguish between MECS of different brands.

Objective: To calculate the pressure and the stiffness at the B level in three categories of class II MECS from nine different brands.

Methods: Nine different brands of class II MECS that were divided into three categories (flat-knitted custom-made, classic round-knitted ready-made and modern (ultrathin) round-knitted ready-made) were tested. The tension of the textile of the MECS was measured with the Instron® tester. The pressures and stiffness at the B level were calculated.

Results: The pressures exerted by flat-knitted custom-made MECS were higher than those exerted by the ready-made round-knitted MECS. Surprisingly, the former showed higher pressures than those published by the European Committee for Standardization (CEN). A wide range of stiffness was observed within the different brands and within the three different categories of MECS.

Conclusion: Despite their assignment to compression class II, all nine brands of MECS that were tested had widely ranging stiffness. This would indicate that the stiffness is an additional important characteristic for distinguishing between MECS from different brands, which should be taken into account by the clinician in selecting the most suitable MECS for the patient.

INTRODUCTION

Medical elastic compression stockings (MECS) are prescribed worldwide and are important in the treatment of chronic venous insufficiency (CVI).[1-3] A large selection of MECS is available. In the Netherlands alone there are 170 different brands of MECS to choose from. Therefore, it is important to know the differences between MECS from a single manufacturer and between different manufacturers. As each type of MECS has its own characteristics depending on the material, type of knit (flat-knitted or round-knitted) and knitting method, one should be familiar with them for their suitability for the treatment of patients. The most important characteristics of MECS are elasticity, hysteresis and stiffness. Medical elastic compression stockings are made of natural or synthetic rubber yarns. One of the most important characteristics of rubber is its elasticity, because of which MECS are able to exert pressure on the leg. Apart from elasticity, rubber also shows the so-called phenomenon of hysteresis, which is the loss in recovered linear length of an elastic product after it has been subjected to repeated stretching and relaxation.[4]

The pressure exerted by the elastic yarns in MECS is related to the extension of the yarns, which implies that there is a relationship between the pressure exerted by the non-extended stocking and the circumference of the leg. When the circumference increases, as during walking or edema formation, the pressure will also increase. This is a direct result of elasticity and correlated with the stiffness of the elastic yarns used to manufacture MECS. Stiffness is defined as the increase in pressure at the B level, i.e. the ankle at the point of its minimum girth, when the circumference at the B level increases by 1 cm.[2, 5] The stiffness of MECS is medically important for preventing edema.[6] The higher the stiffness, the more difficult it is to put on and pull off the MECS, but at the same time it is more effective in preventing edema, reducing refluxes and improving ambulatory venous hypertension. The MECS that are acceptable to the patient should have a correct balance between comfort and effectiveness.

As far as the knit is concerned, there are two types of MECS available. These are the flat-knitted MECS with a seam and the round-knitted seamless ones. Both types are available either as ready-made or custom-made, but the best-fitting MECS is the flat-knitted custom-made. Flat-knitted MECS are made by knitting loops without influencing the tension of the threads, sewing the sides together and making a seam. A good fit is achieved by varying the number of loops. Round-knitted MECS, which are generally thinner and seamless, are cosmetically more acceptable to the patient. Varying the tension of the threads during the manufacture determines the size and the fit of round-knitted MECS.

The current classification of MECS by the European Committee for Standardization (CEN) depends on the pressure exerted by the MECS at the B level. Experience has shown that the therapeutic effect of MECS on the prevention of edema varies considerably between the MECS of the same compression class. This is not only limited to MECS from a single manufacturer but also between different manufacturers. Therefore, knowledge of the different characteristics such as the stiffness of MECS, is important. Ideally, knowing the stiffness of different types of MECS would be highly desirable and would enable the clinician to distinguish between them and to select the most suitable MECS for the patient. This would also help in refining the current classification.

The aim of this study was to determine the exerted pressure and the stiffness at the B level in three categories of class II MECS from nine different brands.

MATERIALS AND METHODS

Medical elastic compression stockings

We arbitrarily chose MECS of nine different brands. All MECS belonged to the same compression class (class II) and were divided into the following three categories based on the type of the knit.

1. Flat-knitted custom-made MECS (brand names: Elvarex II, Eurostar, Flebovar).
2. Classic round-knitted ready-made MECS (brand names: Bellavar, Juzo 3512 soft, Venotrain strong).
3. Modern (ultrathin) round-knitted ready-made MECS (brand names: Ultrasheer, Mediven Elegance, Venotrain micro).

The sizes of the standard leg that were used in the study corresponded with a B size of 20 cm at the ankle (B level), and did not differ from the sizes of the round-knitted MECS cited in the manufacturer's standard size table. Therefore, ready-made round-knitted MECS were obtained. All flat-knitted MECS were custom-made. From each of the nine brands, six pairs of MECS from six different lots were tested (a total of 54 MECS). The MECS were obtained every six weeks to assure that each pair of the same brand was from a different lot. The manufacturers were not aware that the MECS were being tested.

Test procedure

Before testing, all MECS were washed according to the European guidelines, followed by hydroextraction (maximum for two minutes) and flat drying. The MECS were conditioned at least 12 hours prior to the measurements.

Marking the measuring positions

A device was used to mark the measuring positions. This consisted of a marking-board on which an adjustable clamp was mounted. This clamp enabled one to fix the lower end of the round-knitted MECS to a system of clamps, or for flat-knitted MECS to a metal foot frame. The device is shown in Figure 1.

The Instron® tester

The Instron® tester (Instron International Ltd., Edegem, Belgium) has been described in detail elsewhere,[5] but the method is discussed briefly. The Instron® tester is a modified tensiometer with which the tension in a section of the MECS held between two movable T-pins can be measured (Figure 2). After marking the MECS and determining its circumference, the MECS is stretched between two bars with a circumference of 19 mm. To avoid constriction of the knit, the upper bar consists of three separate parts. Only the middle part is attached to a tension tester load cell. The knit is stretched to its maximum circumference six times with a speed of 200 mm/min. The maximum force in the sixth cycle is used to calculate the exerted pressure.

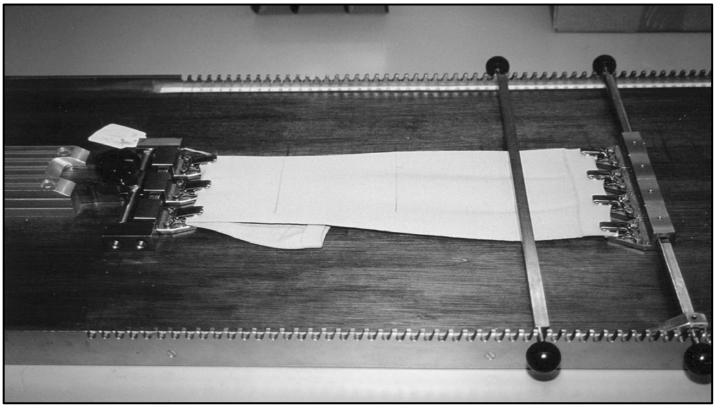


Figure 1 Device for marking the measuring points according to the CEN. In this case a round-knitted MECS is clamped.

Pressure

The pressure exerted by MECS was determined by measuring the force required at the B level to stretch the MECS to its full extent conforming to its B size. The measured force is converted into pressure using the Laplace formula; T = P x R, where T is tension or traction, P is pressure and R is radius. The pressure was expressed in mmHg.

Stiffness

To determine the stiffness, three different measurements per MECS were taken. First, the pressure was measured for a girth that was 1 cm smaller than the B size. Secondly, the pressure was measured for the B size (the so-called 'real girth'). Thirdly, the pressure for the girth that was 1 cm larger than the B size was measured. Thus, the pressure exerted by each flat-knitted custom-made MECS was measured at the B level for three different girths. The MECS were made for a B size of 20 cm and they were tested for the girths of 19, 20 and 21 cm. The stiffness was then calculated using the following formula:

$$\text{stiffness} = \frac{\text{pressure at B size, girth 21} \quad - \quad \text{pressure at B size, girth 19}}{2}$$

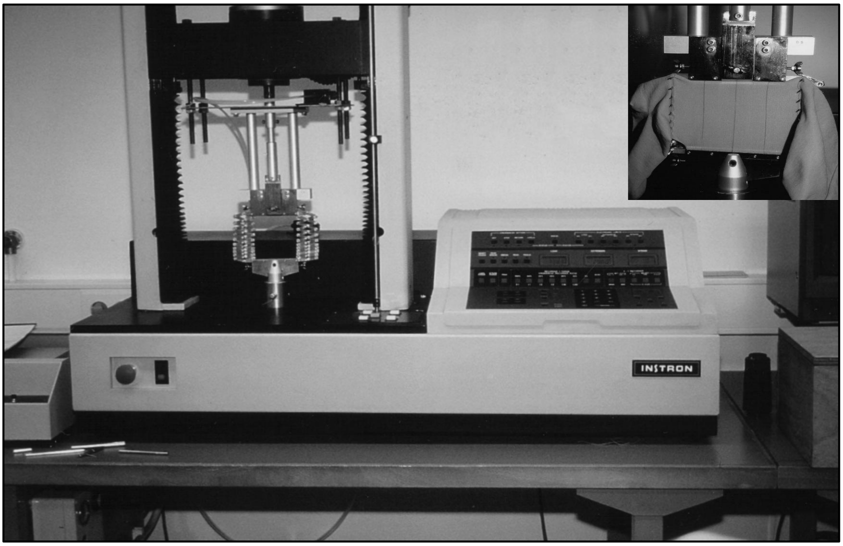


Figure 2 Instron® tester. Inset: compression measurement device with a round-knitted MECS.

With regard to the ready-made MECS, the manufacturers provided a range of girths and/or lengths for every size. The size that correlated with a B size 20 and its range in the standard-size table was used for measuring the stiffness of the minimum B size, the maximum B size and B size 20. This meant that when the B size ranged from 19 to 22 cm, the stiffness at sizes 19, 22 and 20 was determined.

Statistics

The stiffness and corresponding standard deviation (SD) in the nine brands of MECS were calculated. This was done by measuring six different MECS per type. The mean stiffness (μ_p) and SD (σ_p) was calculated for each type of MECS. The reliability of the Instron® tester (σ_e) was provided by the manufacturer and was 0.020. The influence of measurement flaw of the Instron® tester on σ_p was tested by calculating the reliability (Rel) using the following formula:

$$\mathrm{Rel} = \frac{1}{1 + \sigma_e^2 / \sigma_p^2}$$

ANOVA analysis and post hoc LSD method were used to compare the differences between the three groups of MECS.

RESULTS

Pressure at the B level

According to the CEN, the exerted pressure at the B level for a class II MECS ranges from 23 to 32 mmHg (or 31-43 hectopascals (hPa)) as indicated by the shaded area in the graph shown in Figure 3. The mean pressure and the SDs for the different girths of all the nine brands of MECS are shown in Table 1, and a graphic representation is shown in Figure 3. The flat-knitted custom-made MECS exerted much higher pressures than the round-knitted ready-made MECS at the B level. Surprisingly, the flat-knitted custom-made MECS exerted pressures that were all higher than those according to the CEN. The slope of the graphs represents the stiffness. The steeper the slope, the higher the stiffness.

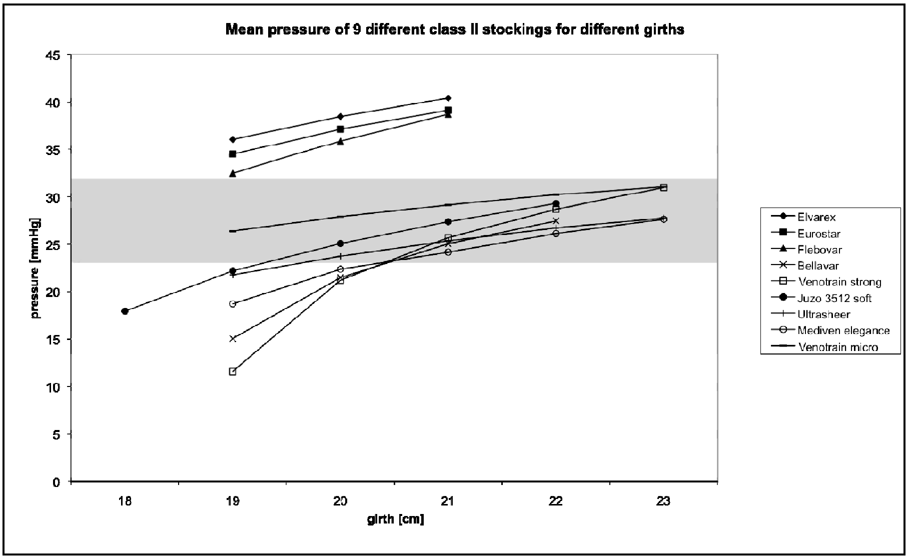


Figure 3 The shaded area in the graph shows the pressure range of a class II MECS according to the European Committee for Standardization (CEN). The slope of the graph represents the stiffness. The steeper the slope, the higher the stiffness.

Table 1 Mean pressure at different girths of 9 different brands of class II MECS.

	B size 18cm	*B size 19cm*	*B size 20cm*	*B size 21cm*	*B size 22cm*	*B size 23cm*
Brand of MECS	*Mean [mmHg] ± SD*	*Mean [mmHg] ± SD*	*Mean [mmHg] ± SD*	*Mean [mmHg] ± SD*	*Mean [mmHg] ± SD*	*Mean [mmHg] ± SD*
Elvarex*		36.07±1.25	38.47±0.96	40.39±0.75		
Eurostar*		34.48±3.13	37.15±2.97	39.13±3.13		
Flebovar*		32.47±4.94	35.90±4.98	38.71±5.08		
Bellavar**		15.03±2.49	21.47±1.26	25.03±1.07	27.44±1.05	
Venotrain strong**		11.60±6.16	21.19±2.65	25.68±2.03	28.66±2.04	31.01±2.26
Juzo 3512 soft**	17.91±2.64	22.17±2.44	25.05±2.47	27.35±2.60	29.29±2.69	
Ultrasheer**		21.74±2.29	23.72±2.13	25.34±1.98	26.69±1.95	27.75±1.96
Mediven elegance**		18.69±2.41	22.34±1.91	24.14±2.28	26.11±2.17	27.62±2.11
Venotrain micro**		26.37±2.08	27.89±1.80	29.13±1.56	30.22±1.37	31.09±1.17

* For the custom-made MECS, the pressure for a B size 19, 20 and 21 cm was calculated.

** For the ready-made MECS, besides the pressure for B size 19, 20 and 21 cm, it was also calculated for the minimum and maximum B size according to the manufacturer's size-table.

Table 2 Mean stiffness of 9 different brands of class II MECS.

	**stiffness at min B size*	*stiffness at B size 20 cm*	**stiffness at max B size*
Brand of MECS	***Mean ± SD [mmHg/cm]*	***Mean ± SD [mmHg/cm]*	***Mean ± SD [mmHg/cm]*
Elvarex		2.16 ± 0.26	
Eurostar		2.33 ± 0.20	
Flebovar		3.12 ± 0.22	
Bellavar	5.00 ± 0.97	5.00 ± 0.97	2.98 ± 0.27
Venotrain strong	7.04 ± 2.73	7.04 ± 2.73	2.66 ± 0.61
Juzo 3512 soft	3.56 ± 0.35	2.59 ± 0.20	2.12 ± 0.15
Ultrasheer	1.80 ± 0.17	1.80 ± 0.17	1.21 ± 1.21
Mediven elegance	2.72 ± 0.09	2.72 ± 0.09	1.74 ± 0.14
Venotrain micro	1.38 ± 0.31	1.38 ± 0.31	0.98 ± 0.20

The stiffness is calculated as follows: stiffness= Δp/Δo (where Δp is the change in pressure and Δo the difference in circumference.

* For the ready-made MECS, the stiffness of the minimum B size, maximum B size and the B size were measured at size 20.

** Figures are the means ± SD of 6 different MECS from 9 different brands.

Stiffness

Seven out of the nine brands of MECS that were measured showed a consistent stiffness as shown in Figure 4. Both the Bellavar and the Venotrain strong MECS showed high stiffness, but there was a large variation within the individual brands. The mean stiffness and the SDs in the nine different brands of class II MECS are shown in Table 2. It can be seen that the stiffness in the nine different brands ranged from 1.38 ±0.35 mmHg (Venotrain micro) to 7.04 ±3.56 mmHg (Venotrain strong). The SD of the latter was high (2.73 mmHg). Moreover, it can be seen that within the three individual categories, the flat-knitted custom-made MECS had stiffness ranging from 2.16 ±0.35 mmHg (Elvarex) to 3.12 ±0.29 (Flebovar), those in the classic round-knitted ready-made MECS ranged from 2.59 ±0.29 mmHg (Juzo 3512 soft) to 7.04 ±3.56 mmHg (Venotrain strong), and those in the modern round-knitted ready-made MECS ranged from 1.38 ±0.35 mmHg (Venotrain micro) to 2.72 ±0.13 mmHg (Mediven elegance). Thus, there was not only a variation in the stiffness between the nine different brands, but there was also variation within the three different categories. The difference between flat-knitted custom-made and classic round-knitted ready-made MECS ($p<0.05$) and between classic round-knitted ready-made and modern round-knitted ready-made MECS ($p<0.05$) were statistically significant. With regard to the stiffness of the ready-made MECS at the minimum, maximum B size and B size 20, it was observed that the larger the B size, the smaller was the stiffness. This may be explained by the relatively small increase in girth from 21 to 22 compared with the increase from 19 to 20.

The statistical analysis showed that there was a considerable heterogeneity within the two brands Bellavar $\sigma_p = 0.98$ and Venotrain strong $\sigma_p = 2.72$ of MECS. The same was also true for the Venotrain micro MECS with a $\sigma_p = 0.27$. These results were based on a sample of six MECS per brand. Reliability measurements showed that the heterogeneity in the above-mentioned groups did not depend on the method used for measuring, but on the actual difference in stiffness of the MECS.

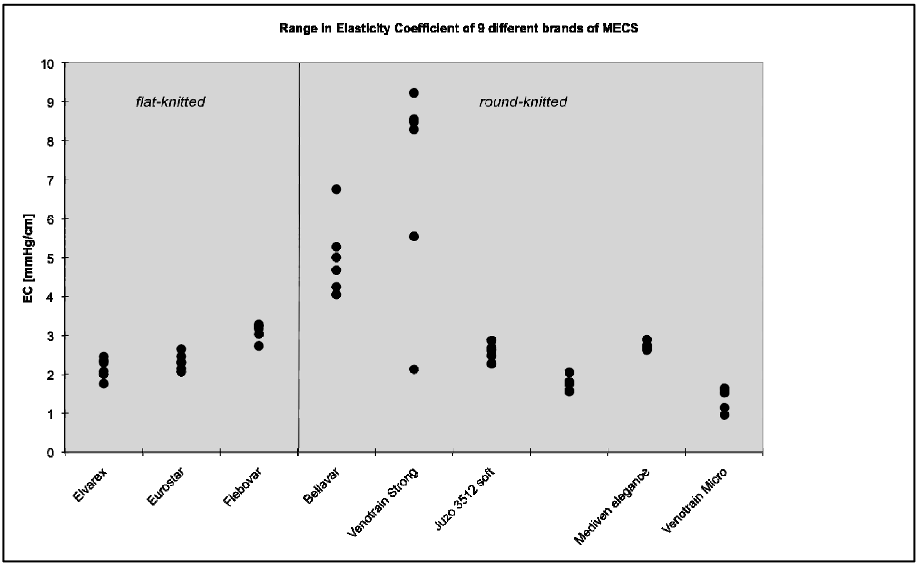


Figure 4 Each dot represents one MECS. Six different MECS from six different lots from each brand were measured.

DISCUSSION

Compression therapy with MECS has a long history and plays an important role in the treatment of venous diseases. From a clinical point of view, compression therapy may either be used as an additional treatment following sclerotherapy and surgery, or to reduce symptoms, treat and prevent edema, and to prevent the occurrence of a venous leg ulcer in patients with CVI. For prescribing MECS, several factors such as the severity of the CVI, the required pressure at the B level, the size of the MECS and the patient's preference must be taken into consideration. However, in our view, the characteristic pressure at the B level alone is not enough to select the most appropriate MECS for the patient. To be able to select the most appropriate MECS from the large selection of MECS that are commercially available, one should take another characteristic, namely the stiffness into consideration. We know that there is a relationship between the stiffness and the edema preventive effect of MECS. Van Geest et al. reported the effect of MECS with different stiffness on edema and observed a statistically significant difference in the capillary filtration rate, and consequently, in the development of edema between MECS belonging to the same compression class with a low and a high stiffness.[6] The higher the stiffness of MECS, the better the edema preventing effect together with a possible reduction in refluxes and an improvement in ambulatory venous hypertension. The results of our study showed that there were considerable differences in the exerted pressure and the stiffness between the class II MECS from nine different brands. According to the CEN, they all belonged to the same compression class.

Several manufacturers currently have their own classification system for the stiffness of MECS. This makes meaningful comparison between MECS belonging to the same compression class from different manufacturers difficult if not impossible. Therefore, in our view, an ideal universal classification system for stiffness would enable an easy comparison and permit an accurate selection of MECS from different manufacturers.

There are several devices such as the Hosy (Forschungsinstitut Hohenstein) and the Hatra (Segra Design) for testing compressive properties. Although, the Instron® tester is a validated test method with a high degree of reproducibility and is accepted as the reference method by the CEN[5], many manufacturers still use other devices, which is highly confusing. In our opinion, the Instron® tester is the most suitable method for determining the stiffness of MECS. In comparison with the other devices, in the Instron® tester the MECS are clamped only once, after which the compression for several girths can be measured. This means that once the MECS has been clamped correctly in the device, there are no other factors that interfere with the measurements.

We recommend classifying MECS according to their stiffness in terms of low, medium or high instead of absolute numbers as indicated by the results of our study. It is essential that the manufactures clearly mention the stiffness of the MECS on the packaging. Thus, the stiffness of MECS would be an additional refinement to the current classification. This is important for the clinician and enables the appropriate choice of MECS for the patients. Flat-knitted custom-made class II MECS exert higher pressures at the B level compared with round-knitted ready-made ones. This may be explained by the pressure profile and its tolerance.[7] On the one hand, round-knitted ready-made MECS have a high tolerance. This means that these MECS are made to fit a wider clientele. As a consequence, the exerted pressure cannot be the maximum allowed pressure. On the other hand, flat-knitted custom-made MECS have a low tolerance (they are made to fit an individual patient) and therefore the exerted pressure is at the upper permitted limit.

In this study, although most of the MECS that were examined showed consistent stiffness, MECS of two brands showed a considerable variation in the stiffness and MECS of one brand showed less variation. As mentioned earlier, this was because of the product itself and not because of faulty measurements. This meant that those two particular brands of MECS, which had consistent high stiffness, did not always show the same characteristic, and their effectiveness in patients may therefore also vary. This may be explained by the fact that there are differences in the manufacturing process of MECS. Manufacturers work toward producing MECS with relatively high stiffness. Because the manufacturing of round-knitted ready-made MECS is less reproducible than the manufacturing of flat-knitted custom-made MECS, it is technically more difficult to produce round-knitted ready-made MECS with consistent high stiffness. There is considerable variation in the stiffness of MECS between the various brands. The higher the stiffness, the more difficult it is to put on the MECS, but at the same time it is more effective in preventing edema.[1,7] Every phlebological disorder requires its own specific compression treatment.[8] When edema formation is expected, for example, in post-thrombotic syndrome (PTS), MECS with a high stiffness are prescribed. Medical elastic compression stockings with a low stiffness may suffice, for example, in sclerotherapy.

For preventing edema, MECS with a high stiffness are required. Theoretically, it seems logical that MECS with a high stiffness should also exert high pressures at the B level. In relation to the results of this study, it would mean that flat-knitted custom-made MECS are preferred to round-knitted ready-made ones because the brands in the flat-knitted category exerted high pressure and had a high stiffness. However, the role of the exerted pressure at the B level may not be as clear as assumed. Therefore, the clinical implications of the pressure exerted at the B level are rather obscure. If a high edema preventive effect and/or a reduction in refluxes and/or an improvement in ambulatory venous hypertension are required, should one prescribe MECS with a high stiffness that exerts a high pressure at the B level, or would MECS with a high stiffness that exerts a low pressure at the B level be enough? Perhaps both are equally effective. Further studies are necessary to clearly establish the criteria for making a choice for the most appropriate MECS for the patient. Some of the round-knitted ready-made MECS (Juzo 3512 soft and Mediven elegance) used in this study had high stiffness, but the pressure exerted at the B level was lower compared with the pressure exerted by the flat-knitted custom-made MECS.

Although the results of this study were obtained via in vitro measurements, we believe that these results may also reflect and serve as surrogate parameters for in vivo data of vital importance to the clinician. However, this remains to be investigated and validated in future studies.

Another characteristic that was not mentioned before but may be important is hysteresis.[4] This is the loss of ‘energy’ of an elastic material when it recoils after repeated stretch and relaxation (massaging effect). The importance of hysteresis and its role in clinical practice also requires further investigation.

We calculated the exerted pressure and determined the stiffness at the B level in three different categories of class II MECS from nine different commercially available brands. We can conclude that, despite the current classification that depends on the pressure exerted at the B level, there is a considerable variation in stiffness within the different categories of MECS. Therefore, we assign an important role to the stiffness for making a correct choice of MECS in the clinical practice. When prescribing MECS, mentioning the pressure at the B level alone is not enough. A more precise classification is necessary. Clinicians should be aware of the different characteristics of MECS when selecting the most suitable MECS for patients. Manufacturers should define their product more accurately and ideally a uniform measuring and classification system would be desirable. In an attempt to measure the ‘real’ dynamic stiffness in order to approach the behavior of MECS in daily practice, we recently introduced a new characteristic of MECS; the dynamic stiffness and a new method for determining the dynamic stiffness. The results showed that the active behavior of the MECS during normal walking differed considerably from its passive behavior. Insertion of non-elastic materials into the MECS overlying the expanding muscles increased the dynamic stiffness.[9] Further prospective comparative studies with different types of MECS from different manufactures are imperative to establish the value of dynamic stiffness. To our knowledge, this is the first study in which pressure and stiffness at the B level have been calculated. We hope to further determine the role of the different characteristics of MECS, in particular the role of the stiffness, either static or dynamic, and to adjust the current classification to enable a more accurate selection of MECS in the future.

REFERENCES

1. Neumann HAM. Compression therapy: European regulatory affairs. Phlebology 2000; 15: 182-187.
2. Ramelet AA. Compression therapy. Dermatol Surg 2002; 28: 6-10.
3. Van Geest AJ, Franken CPM, Neumann HAM. Medical elastic compression stockings in the treatment of venous insufficiency. In: Elsner P, Hatch K, Wigger-Alberti W, eds. Textiles and the skin. Curr Probl Dermatol. Basel: Karger, 2003; vol 31: 98.
4. Gardon-Mollard C, Ramelet AA. Compression Therapy. Paris: Masson, 1999; 57.
5. European Committee for Standardization (CEN) Non-active medical devices. Working group 2 ENV 12718: European Prestandard ‘Medical compression hosiery’ CEN/TC205 Brussels: CEN, 2001
6. Van Geest AJ, Veraart JCJM, Nelemans P, Neumann HAM. The effect of medical elastic compression stockings with different slope values on edema. Dermatol Surg 2000; 26: 244-247.
7. Neumann HAM. Compression therapy with medical elastic stockings for venous diseases. Dermatol Surg 1998; 24: 765-770.
8. Partsch H.(ed.) Evidence-based compression therapy. VASA 2003; 32: S63.
9. Stolk R, van der Wegen-Franken CPM, Neumann HAM. A method for measuring the dynamic behavior of medical compression hosiery during walking. Dermatol Surg 2004; 30: 1-8.

Chapter IV

Introduction of a new characteristic of medical elastic compression stockings and a method for measuring it

Stolk R, van der Wegen- Franken CPM, Neumann HAM. A method for measuring the dynamic behavior of medical compression hosiery during walking. Dermatol Surg 2004; 30: 729-736.

ABSTRACT

Background: Compression therapy is effective in patients suffering from venous disease. This therapy has proven to be especially effective in the ambulant patient. Therefore, the dynamic behavior of the medical compression hosiery (MCH) is more important than the static one in the treatment of patients.

Objective: The objective of this study was to develop a method for investigating the dynamic behavior of MCH during walking.

Methods: The changes in the circumference of the lower leg equipped with a MCH are registered on a treadmill. The dynamic movement is then exactly simulated using an artificial leg-segment model equipped with the same MCH. The dynamic behavior of the MCH can thus be investigated using this artificial leg-segment model. The dynamic stiffness index can be calculated from the dynamic pressure and circumference signals.

Results: The expansion of the MCH was only limited to the area underlying the expanding muscles and did not spread circularly. This resulted in relatively high pressure exerted by the MCH on the underlying tissues during walking. Insertion of non-elastic material into the MCH overlying the expanding muscles increased the dynamic pressure.

Conclusions: The active behavior of the MCH during normal walking differed considerably from its passive behavior. We defined a new characteristic of the MCH: the dynamic stiffness index based on the dynamic pressure profile. Insertion of non-elastic materials into the MCH overlying the expanding muscles increased the dynamic stiffness index.

INTRODUCTION

Medical compression hosiery (MCH) is characterized by the pressure it exerts on the leg. In the European Committee for Standardization prenorm, MCH are classified in compression classes according to the pressure exerted on the leg (the so-called B pressure).[1] To date this is the only way for distinguishing one MCH from another. Nevertheless, in daily practice it is well known that the behavior of a class II MCH can significantly differ from another class II MCH for instance in the prevention of edema. The determination of pressure values of MCH at textile laboratories is calculated from semi-static tension values.[1] Although these values provide a good indication of the passive pressure that the hosiery exerts on the relevant leg of the patient, unfortunately, they do not provide information on the dynamic behavior of the hosiery during walking. Such information is very essential for effective compression therapy that has been proven to be especially effective in an ambulant patient (the so-called *ambulatory compression therapy).*[2-4]

Therefore, MCH should be investigated under ambulatory conditions to establish their real biologic effect. To date, the direct measurement of this dynamic behavior of the MCH is physically impossible. The pressure that is exerted depends on the shape of the leg. This shape is irregular and changes during walking. In an effort to overcome the technical problems, we developed a simple artificial leg-segment model with a more uniform circular leg shape to investigate the dynamic behavior of the MCH. Using this model it was hoped to establish a new parameter that may explain the differences in MCH behavior in one compression class during walking.

The aim of this study was to determine the dynamic behavior of MCH. The pressure exerted by MCH during walking was determined and it was examined whether this pressure was different than the static pressure routinely measured at the textile laboratories.

MATERIALS AND METHODS

Five healthy volunteers (two men aged 46 and 64 years and three women aged 29, 50 and 59 years) with normal leg morphology and without any signs of vascular disease were investigated. Informed consent was obtained from all five subjects in our study. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki. Changes in the circumference of the leg at the site of transition from the gastrocnemius muscle into its aponeurosis (the so-called B1 level according to the European Committee for Standardization) were registered with strain gauge plethysmography with the volunteer wearing MCH as shown in Figure 1.[5] The registration of this dynamic signal was also simulated in the artificial leg-segment model (Figure 2) comprising an air-filled drum sealed with a thin rubber skin with the same circumference as the volunteer.[6] The MCH was put over the thin rubber skin in exactly the same manner as that on the 'walking' leg on the treadmill. The movement of the artificial leg-segment was created by means of an adjustable air pressure generator (Figure 3). It provides the drum with precise pressure in such a way that the dynamic circumference movement of the MCH section equals the dynamic movement of the same MCH part on the treadmill. According to the third law of physics, "at equilibrium, reaction force equals action force", we may assume that the air pressure equals the pressure exerted by the MCH. The rubber skin does not generate any pressure because of its physical dimensions. We were able to determine the dynamic behavior of the MCH from the circumference signal (moving exactly like the volunteer's leg on the treadmill) and the dynamic air pressure signal in the drum. The investigation comprised the following points.

Figure 1 Volunteer with MHC. Registration of the circumference of the leg and the ankle angle.

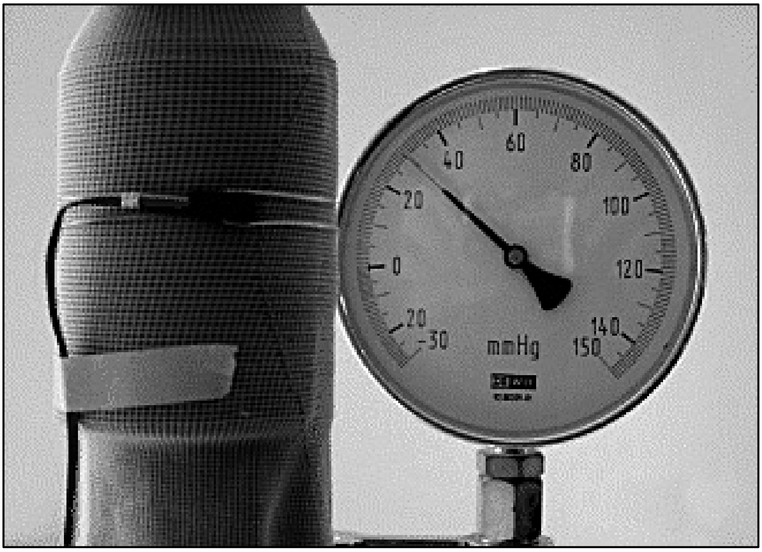


Figure 2 Air-filled drum sealed with a thin rubber skin. The MCH is put over the drum. The circumference is registered using the mercury-filled rubber tubes.

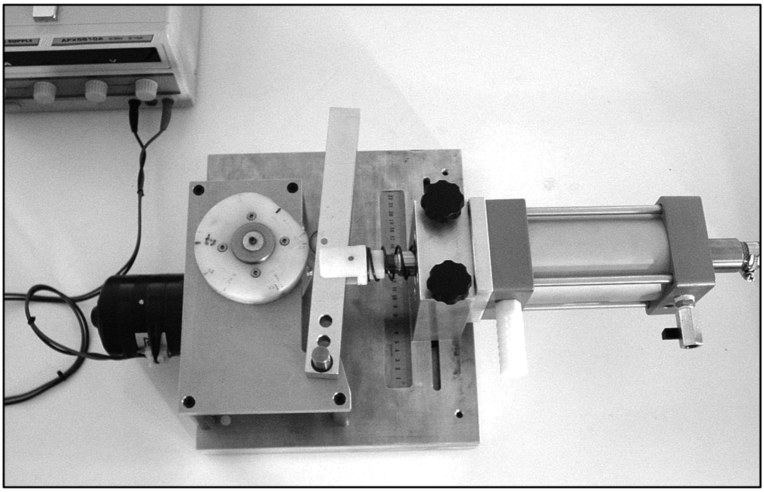


Figure 3 Air-pressure generator creating a precise dynamic pressure pattern to equalize the circumference of the leg on the treadmill. All variables of the pressure pattern can be adjusted (frequency, form of the pressure pattern, amplitude).

Static measurement of the circumference of the lower leg in volunteers

To investigate the magnitude of the generated signals, the circumference of the lower leg was recorded using a flexible metal measuring tape, which was placed horizontally at 2 cm intervals from the foot to the knee of the standing volunteer. These measurements were performed with the ankle at 90° flexion with the foot, with the foot in maximal dorsiflexion and with the foot in maximal plantar flexion. The measuring tape was not removed from the skin during these three measurements.

Dynamic measurements of the changes in circumference during walking

It is apparent from the static measurements that the largest differences in the circumference between the maximal dorsiflexion and maximal plantar flexion positions of the foot occur at the level of the transition from the gastrocnemius muscle into its aponeurosis (the B1 level). These changes in circumference were registered while the volunteer walked on a treadmill (Walker Proaction, Heerhugowaard, The Netherlands).

Mercury-filled rubber gauges around the limb were used (Figure 1). This technique, which is used in strain-gauge plethysmography, was for the first time described by Whitney in 1953[3] and was further developed.[7] The leg was measured both with and without MCH. The ankle angle was registered with the XM110/A Biometrics ankle sensor (Biometrics Ltd, Gwent, UK) while the volunteer walked on the treadmill. The electrical signals were fed into a computer system: the Fysio Flex system, built at the instrumentation service unit of the University of Nijmegen, The Netherlands.

Simulation of the dynamic leg movement in artificial leg-segment model

The circumference signal determined during walking was simulated on an artificial leg-segment model consisting of an air-filled drum covered with a rubber skin (Figure 2). The same MCH as used by volunteers during walking was put on the drum in exactly the same manner as it was put on the walking leg of the volunteer on the treadmill. The circumference of the leg changes during walking, primarily as a result of the movement of the calf muscles. This was considered in designing the relevant measuring device and we allowed the leg in the model to expand only on the posterior side of the MCH. In our previous measurements we noted that on the average 35% of the leg circumference at the B1 level expanded at the posterior side, whereas 65% did not expand at all during walking. Therefore, we allowed expansion of only 35% of the circumference by applying a firm shield to the leg-segment model covering 65% of the circumference. The specially designed air-pressure generator (Posthumus Products, Haarlem, The Netherlands) delivered a dynamic pressure signal to the drum, which could be adjusted for all its parameters (gait cycle, amplitude and form of signal) by means of an individually manufactured form wheel.

The pressure from the air-pressure generator was delivered into the barrel in such a way that the circumference of the MCH displayed the same dynamic curve as the MCH worn by the volunteer. The circumference of the MCH on the air-filled drum was plotted again with the mercury-filled rubber tube strain gauge. The pressure in the air-filled drum was recorded with a TruWave Pressure Transducer (Baxter Healthcare Corporation, Irvine, CA), which can be used in an air circuit up to 100 Hertz (normal walking frequency equals about 1 Hz).

Determination of the dynamic behavior of the medical compression hosiery

Figure 4 gives a schematic representation of our study of the dynamic behavior of MCH on the lower leg during exercise. To quantify the dynamic behavior of the MCH we introduce a new characteristic: the dynamic stiffness index. This is defined in analogy to the 'stiffness index' as defined in the prenorm mentioned above indicating the pressure increase of the MCH when the circumference of the leg increases by 1 cm. The dynamic stiffness index, like the stiffness index, is expressed in mmHg/cm.

The dynamic behavior of the MCH was determined from the recorded pressure and the circumference signal. The pressure and circumference time recordings gave a hysteresis curve relating the dynamic pressure and the dynamic circumference of the MCH. From the dynamic pressure changes and the changes in the circumference we determine the dynamic stiffness index of the hosiery. An increase in the dynamic stiffness index was obtained by inserting non-elastic material into the MCH overlying the expanding muscles during walking.

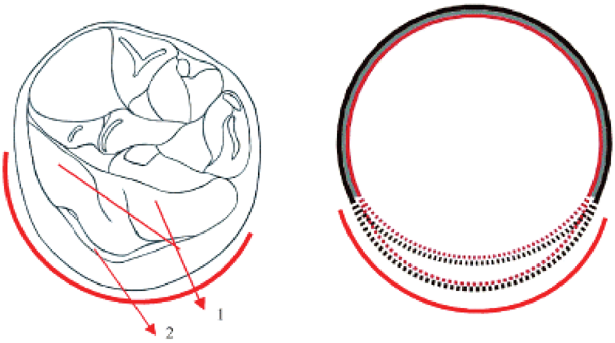


Figure 4 Schematic representation of our study of the dynamic behavior of MCH on the lower leg during exercise. (Left) Cross-section lower leg at the B1 level: 1) soleus muscle, 2) gastrocnemius aponeurosis. A red line indicates the part of the circumference that changes during exercise. (Right) Cross-section of the air-filled drum. From the inner side of the drum we have, respectively, the thin rubber skin, the shield (covering only 65% of the circumference), and the hosiery. The MCH can expand over 35% of its circumference. This corresponds to the expanding part of the MCH on the real leg. A minimal and a maximal circumference are indicated.

RESULTS

Static measurement of the circumference of the lower leg in volunteers

The static lower leg dimensions of volunteer 5 in standing position are shown in Table I. The maximum difference between the maximal dorsiflexion and maximal plantar flexion circumference was observed at the point where the gastrocnemius muscle passes over into its aponeurosis. The difference in the volunteers was, for the five volunteers 1.3, 1.0, 1.1, 0.7 and 1.8 cm, respectively, at the transition point gastrocnemius-aponeurosis.

Table 1 Leg measurements of volunteer 5 in standing position and measured with the foot, respectively, at 90° flexion with the lower leg, with the foot in maximal dorsiflexion and with the foot in maximal plantar flexion.

	Leg circumference (cm) with			
Length measured from the floor (cm)	*Foot at 90° flexion with the leg*	*Foot in maximal dorsal flexion (MDF)*	*Foot in maximal plantar flexion (MPF)*	*MDF – MPF in cm*
16	22.9	23.1	22.8	+ 0.3
18	23.9	24.1	23.6	+ 0.5
20	25.5	25.7	24.9	+ 0.8
22	27.4	27.6	27.1	+ 0.5
24	30.3	30.9	29.7	+ 1.2
26	33.4	33.9	32.1	+ 1.8
28	35.2	35.9	34.8	+ 1.1
30	37.7	38.3	37.5	+ 0.8
32	39.1	39.7	39.1	+ 0.6
34	40.5	40.8	40.5	+ 0.3
36	40.4	40.2	40.4	– 0.2
38	39.8	39.6	40.0	– 0.4
40	37.7	37.6	37.6	0.0
42	35.5	35.5	35.7	– 0.2

Dynamic measurement of the changes in circumference during walking

The dynamic circumference and ankle angle of volunteer 3 on the treadmill are shown in Figure 5. The circumference at the B1 level was 25 cm. The change in circumference during walking was 2.81% (0.70 cm) of the circumference at the B1 level. The ankle angle changed between $+7^0$ and -23^0 (the 90° flexion between ankle and leg is here considered as the zero position). Treadmill speed was 5.0 km/h. The cursor covered 4 gait cycles; the left side started at the moment where the heel touched the ground (this is defined as the beginning of the gait cycle). One horizontal block represented 200 ms. The spike in the registration of the circumference was due to the shock of first heel contact. In the second part of the gait cycle a clear trough was visible. At this moment the toes left the treadmill (toe-off moment). The circumference of the leg then decreased because the underlying muscle mass had moved proximally.

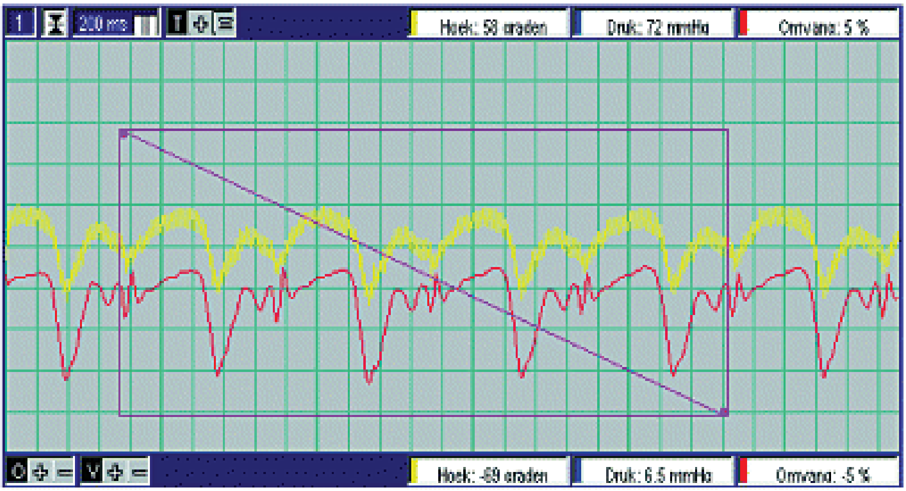


Figure 5 Treadmill registration. The ankle angle (in yellow) changes from +7 (maximal dorsiflexion) to -23 (maximal plantar flexion). The circumference (in red) shows a maximum value at maximal plantar flexion. The pressure of the MCH changes accordingly.

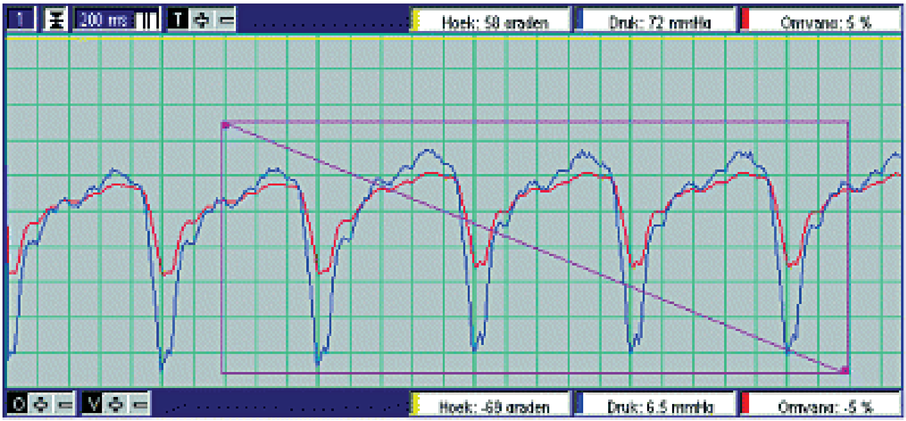


Figure 6 Simulation of the treadmill experiment shown in Figure 5. Gait cycle is 1.0s. The bleu signal is the pressure pattern that was applied to the leg-segment model in order to simulate the circumference signal from the treadmill. One horizontal block represents 200 ms.

Simulation of leg movement in the leg-segment model

The simulated circumference variation upon leg movement in the leg-segment model with the same air-filled drum circumference (25 cm) as that of volunteer 3 (Figure 5) is shown in Figure 6. The preset gait cycle was 1.0 s. The pressure in the leg-segment is shown by the blue signal. This variable pressure pattern gave rise to the simulated circumference variation shown by the red signal. The pressure of the MCH varied between 10.8 and 51.2 mmHg. The same dynamic circumference variation in the MCH worn by the volunteer on the treadmill was generated with this dynamic pressure from the air-pressure generator. The circumference in the leg-segment model changed by 0.70 cm (2.82 % of 25.0 cm); that is the same variation as that was measured in the volunteer on the treadmill.

Calculation of the dynamic stiffness index

The dynamic stiffness index (DSI) was calculated as follows. The pressure exerted by the MCH as a function of the circumference is presented in Figure 8. The tangent of the long axis of the hysteresis curve represents the DSI and equals 58 mmHg/cm. The stiffness index value of the compression class II MCH used in this study was 2.5 mmHg/cm. To allow this DSI to increase further, we inserted a non-elastic material in the same MCH over the expanding muscle mass. Expansion against nonexpanding MCH caused the DSI to increase (Table 2 and Figure 9). The sural expansion against this part of the MCH increased the dynamic stiffness to 81 mmHg/cm. The results are summarized in Table 2.

Table 2 Determination of the DSI of a compression class II MCH (30 mmHg at the ankle) at the B1 level on the air-filled drum with a circumference of 25.0 cm.

Experiment	*Circumference variation of the MCH [cm]*	*Pressure changes in the air-filled drum [mmHg]*	*Calculated DSI [mmHg/cm]*
150: MCH without non-elastic material	2.82 % x 25.0 = 0.70	10. 8 - 51.2 (change 40.4)	40.4/0.70 =58
151: MCH with non-elastic material	2.75 % x 25.0 = 0.69	1.5 - 57.3 (change 55.8)	55.8/0.69 =81

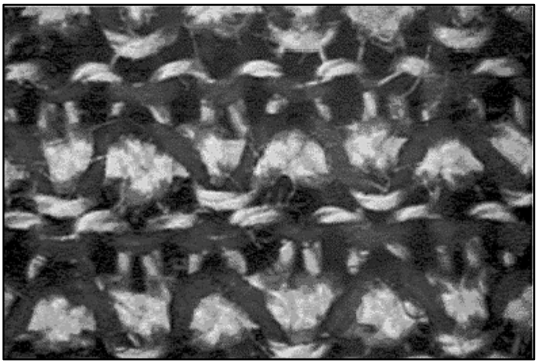


Figure 7 Photomicrograph of a MCH. Various threads can be distinguished, forming stitches. We can also distinguish thick covered inlaid threads that are ‘captured’ by these stitches. In stretching this knitwear we have to overcome not only the elastic forces but also the high friction forces between stitches and between stitches and the inlaid thread.

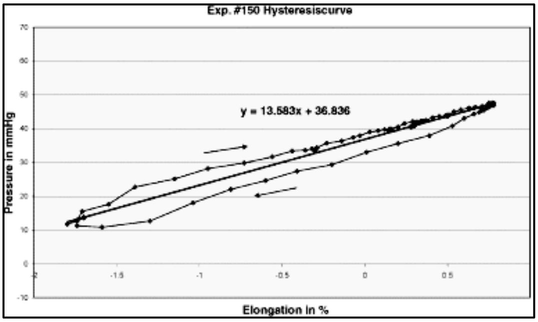


Figure 8 Pressure of the MCH as a function of the circumference expressed as a percentage of B1 = 25.0 cm. One gait cycle (100 measurements points) is shown. This is used to calculate the DSI.

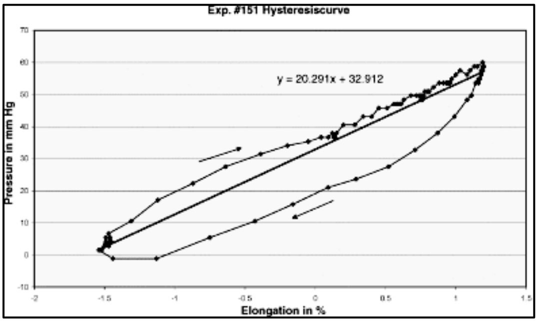


Figure 9 The same volunteer is now wearing the MCH as used in experiment 150 (Figure 5), but the MCH now has non-elastic material overlying a part of the expanding sural muscles.

DISCUSSION

The results of this study show that there is a large difference between the pressure of the MCH with the patient in rest and in the ambulant situation. In the European standard for MCH, the pressure values of the MCH are measured indirectly in a laboratory setting.[1] In fact it is not the pressure but the circumference tension of the MCH that is measured under semistatic conditions. Laplace's law, which relates the pressure, the circumference tension and the radius of the leg, was used to calculate the pressure of the MCH in resting position.

The CEN has approved the pneumatic pressure-determining device as one of the methods for determining the static pressure of the MCH.[4] This device is also the basis of the apparatus used for dynamic pressure measurements in this study and seems therefore an ideal apparatus for measuring as well the static as the dynamic pressure behavior of the MCH.

The MCH was tested under normal walking conditions. A walking speed of 5 km/h corresponds approximately to 1 gait cycle per second (equals one step with the right leg and one step with the left leg). In our study the stretching of the MCH in the leg-segment model corresponded exactly with the dynamic movement of the MCH worn by the volunteer on the treadmill. The circumference of the MCH moves only a few centimeters. The internal frictional forces play a relatively important role in the small circumference variations around the working point of the MCH. The stitches of the MCH must slide along each as the muscles expand, giving rise to internal frictional forces that oppose this expansion. In the opposite direction – when the circumference of the leg is decreasing – the elastic threads pull the MCH into a narrower shape. Again, the internal frictional forces between the stitches oppose these elastic forces. Figure 7 shows a photomicrograph of a MCH. Friction forces between the threads are evident. We believe that these friction forces cause the high DSI values. These internal frictional forces cause hysteresis in the pressure-elongation curve as shown in Figures 8 and 9.

For the determination of the static pressure, massage is essential for the elimination of the sticky internal frictional forces inside the MCH. This is done before reading the static pressure on a calibrated mechanical manometer.[6] In determining the DSI, however, it is essential not to neutralize these frictional forces because they are largely responsible for the high DSI values and are therefore essential for understanding the dynamic characteristics of the MCH during the wearing by the patient. This is the main reason why the DSI deviates from the stiffness index as determined according to the CEN and it can give also a logical explanation for the differences in the behavior of different MCH belonging to the same compression class but having different DSI values.

The tensile testing machine used in the laboratory for determining the static pressure of the MCH ensures a uniformly increasing stretch in the circumference, ranging from relaxed MCH (0% stretch) to MCH with the same stretch as that on the leg. During the stretching on the tensile testing machine, the MCH can stretch freely. This implies that the tension of the MCH can be assumed to be equal in the circumference direction. This free stretching of the MCH does not occur on the leg. This was also observed in the leg-segment model. Local increase in the circumference of the artificial leg (in reality caused by the underlying expanding muscles) does not cause uniform stretching in the circumference direction of the MCH.

Thus only where underlying muscle movements occur do changes occur in the circumference of the MCH and therefore in the circumference tension. This appears to be the case even in the leg-segment model when we maximize the smoothness of the 'skin' by covering the rubber skin with smooth spinnaker cloth. It must be assumed that the muscle movements will not equalize lateral tension because the skin is certainly less smooth than the spinnaker cloth. These local muscle expansions therefore cause relatively large local pressure changes. On the basis of the local stretching of the MCH resulting from local muscle expansion it may be anticipated that the resistance to circumference increase of the MCH will become significantly greater if the expansion of the muscles occur against non-elastic material in the MCH (see Figure 9).

The circumference signal and the ankle angle signal plotted on the treadmill appeared to be of similar shape (Figure 5). The ankle angle plot is similar to the plot that is reported in the literature.[8] From an analysis of the signals it can be deduced that maximal dorsiflexion coincides with the contraction phase of the gastrocnemius and soleus muscles. Dorsal flexion of the ankle increases in the first part of the gait cycle. According to Perry, maximal dorsiflexion coincides with maximum sural activity during the stance phase.[8] At this moment the MCH exerts maximal pressure. Maximal plantar flexion occurs at the end of the stance phase, when the toes leave the treadmill. The B1 circumference is then minimal and the MCH accordingly exerts minimal pressure. The therapeutic effect of the MCH will depend on the difference between minimum pressure and maximum pressure during walking. The difference depends on the circumference changes of the leg during walking but also on the DSI value of the MCH. If manufacturers of MCH are able to produce MCH with a high DSI in compression class II, then it will benefit the patient with a ‘compressive effect” of a compression class III MCH.

Briefly, the changes in the circumference of the lower leg of the volunteers during walking do not exceed 1 to 2 cm. The maximum difference between the maximal dorsiflexion and maximal plantar flexion circumference was found at the point where the gastrocnemius muscle passes over into its aponeurosis. The muscle mass of the soleus muscle is still clearly present at this place. The variation of the circumference measured at this point during walking is primarily due to the fact that the gastrocnemius muscle passes underneath the measurement site. In maximal dorsiflexion of the foot the circumference of the leg is at its maximum. According to Perry, the activity of the sural muscles is at its maximum at maximal dorsiflexion. The positive pressure pulse of the MCH is therefore synchronous with the contraction of the sural muscles. At maximal plantar flexion of the foot the toes leave the ground.[8] At this moment the circumference of the leg is at its minimum and the pressure exerted by the MCH is at its lowest.

Despite the relative small change in the circumference of the lower leg during walking, this change causes relatively high-pressure pulses of the MCH on the leg. The pressure pulses are limited to the area of the underlying expanding sural muscles. In contrast to what has been assumed to date, the circumference of the MCH does not stretch uniformly during walking. Internal frictional forces in the MCH play an important part during walking. These forces produce the relatively important pressure changes during walking and this may be the main reason why compression therapy is particularly effective in the ambulatory patient.

Inserting non-elastic material at the location of the expanding muscles increases the DSI of the MCH. The DSI must be measured dynamically at the rhythm of the gait cycle and at realistic amplitudes. The maximum change in circumference of our volunteers during walking did not exceed 2 cm.

In practice, the pressure changes of the MCH during walking are more important than was realized to date. For instance, from simulation we deduced (see Table 2) that the dynamic pressure at the B1 level varied from 10.8 to 51.2 mmHg with a static pressure of 27 mmHg.

In this study, a new parameter, the DSI, is introduced. It expresses the change in pressure owing to the change in circumference of the lower leg during walking. A high DSI implies that the MCH generates relatively high-pressure pulses during walking. The characteristics of the MCH with insertion of non-elastic material covering the expanding calf muscles produces higher pressure pulses on the skin of the ambulatory patient.

REFERENCES

1. European Committee for Standardization (CEN). Non-active Medical Devices Working Group 2 ENV 12718: European Prestandard 'Medical Compression Hosiery.' CEN TC 205. Brussels: CEN, 2001.
2. Neumann HAM, Tazelaar DJ. Compression therapy. In: Goldman MP, Weiss RA, Bergan JJ, eds. Varicose Veins and Telangiectasias. St. Louis: Quality Medical Publishing, 1999: 127-149.
3. Neumann HAM. Compression therapy with medical elastic stockings for venous diseases. Dermatol Surg 1998; 24: 765-770.
4. Lentner A, Wienert V. Influence of medical compression stockings on venolymphatic drainage in phlebologically healthy test persons and patients with chronic venous insufficiency. Int J Microcirc Clin Exp 1996; 16: 320-324.
5. Whitney RJ. The measurement of volume changes in human limbs. J Physiol 1953; 121: 1-27.
6. Stolk R, Salz P. A quick pressure-determining device for medical stockings based on the determination of the counter-pressure of air-filled leg-segments. Swiss Med 1988; 10: 91-96.
7. Brakkee AJM, Vendrik AJH. Strain-gauge plethysmography: theoretical and practical notes on a new design. J Appl Physiol 1966; 21: 701-704.
8. Perry J. Gait Analysis, Figures 4.1 and 4.4. Thorofare, NJ: Slack Incorporated, 1992.

Chapter V

Variation in the dynamic stiffness index of different types of medical elastic compression stockings

Van der Wegen-Franken CPM, Mulder P, Tank B, Neumann HAM. Variation in the dynamic stiffness index of different types of medical elastic compression stockings. Phlebology 2008; 23: 77-84.

ABSTRACT

Objective: To calculate the dynamic stiffness index (DSI) of 18 different brands of medical elastic compression stockings (MECS).

Methods: In all, 18 different brands of MECS that were divided into five categories (class II round-knitted, class II flat-knitted, class III round-knitted, class III flat-knitted and class IV flat-knitted MECS) were tested. The static pressure and dynamic pressure pulsations at the B1 level were measured with a newly developed dynamic pressure-determining device. The DSI was calculated.

Results: The DSI of all 18 brands of MECS showed higher values compared with the static stiffness. A wide range of dynamic stiffness indices was observed not only between all brands of MECS, but also within the five categories.

Conclusions: The DSI of MECS is independent of the compression class and the type of knit. The variation in the DSI between MECS is not because of any measurement error and would indicate that different therapeutic effectiveness may be expected within one compression class. Therefore, a refinement in the current classification system for MECS with other characteristics such as the DSI is warranted.

INTRODUCTION

Medical elastic compression stockings (MECS) have been used to treat venous disorders since the granting of the patent number 12294 to William Brown on 26 October 1848, the day which has been regarded as the birthday of the 'rubber'stocking.[1] From that day on lots of different types of MECS have been developed leading up to the MECS as we know them today. One of the important clinical applications of MECS is the prevention of edema. This is achieved by the physical characteristics of the materials used in the manufacture of MECS. Three main characteristics of MECS are important for their effectiveness; elasticity, stiffness and hysteresis. Hysteresis is due to internal friction between the stitches and is defined as the loss in recovered linear length of an elastic product after it has been subjected to repeated stretching and relaxation.[2] Pressure is exerted on the leg because of the elasticity of MECS. The pressure is related to the extension of the MECS. When the circumference increases, as during walking or edema formation, the pressure will also increase. This phenomenon is known as stiffness which is medically important.[3] The stiffness, which is also known as slope or elasticity coefficient, is defined according to the European Committee of Normalization (CEN), as the increase in pressure at the B level, if the circumference increases by 1 cm.[4] Stiffness of MECS not only plays a role in edema prevention, but was also reported to affect the venous hemodynamics particularly in dynamic condition.[5,6] The higher the stiffness, the better the edema preventive effect. To date, this parameter is measured under semi-static conditions in a laboratory. Different devices and methods are used to determine the stiffness and in general are as follows: the MECS is positioned in a relaxed condition and is then elongated / stretched to the circumference of the B level. This procedure is repeated several times and the stretching increased by 1 cm. The difference in force required to elongate the MECS is used to calculate the stiffness. We recently published the widely ranging static stiffness of nine different brands of class II MECS, and concluded that the static stiffness is an additional important characteristic for distinguishing between MECS from different brands.[7] However, the static stiffness does not reflect the dynamic condition, and the differences between the therapeutic effectiveness of MECS belonging to the same compression class cannot be explained on the basis of static stiffness alone. Compression therapy is mainly effective during walking and MECS behave differently under dynamic conditions as illustrated in Figure 1. As already mentioned, under static conditions MECS are relaxed (0% elongation) and then stretched to a certain extent. In reality, MECS are not relaxed on the leg and changes in circumference or percentage of stretch are much less than in a laboratory setting.

As is shown in Figure 1, the smaller the change in circumference, the steeper the slope. The slope represents the stiffness. We assumed that during walking, because of the smaller changes in circumference, the dynamic stiffness index (DSI) would be higher. Thereby, we expected the differences between the DSI of the different brands of MECS larger compared with the differences we found earlier between the static stiffness.[7] A variety in therapeutic effectiveness can be expected on the basis of the differences between the DSI, which is very important in selecting the most suitable MECS for the patient.

The aim of the study was to calculate the dynamic stiffness of 18 different brands of MECS belonging to three different compression classes.

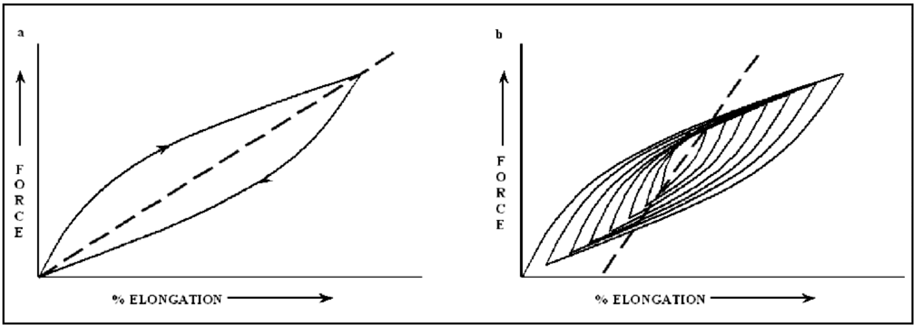


Figure 1 Static and dynamic force elongation curves of MECS. The slope of the curve resembles the stiffness. a) Under (semi-)static conditions the MECS is elongated from a state of total relaxation to the stretch that is required at the B1 level. b) Under dynamic conditions as during walking the circumference changes of the leg are small. This curve shows the smaller the elongation increments, the steeper the curve meaning a higher the dynamic stiffness index.

MATERIALS AND METHODS

Medical elastic compression stockings

We arbitrarily chose MECS of 18 different brands, 11 brands belonging to compression class II, five brands belonging to compression class III and two brands belonging to class IV. All brands from various manufacturers as shown in Table 1, were divided into five categories based on the type of the knit: class II round-knitted MECS, class II flat-knitted MECS, class III round-knitted MECS, class III flat-knitted MECS and class IV flat-knitted MECS. There was no specific reason for choosing different numbers in the three compression classes. Generally, there is more choice in class II and class III MECS. In all experiments B1 leg-size of 22 cm was used. The manufacturers were not aware that the MECS were being tested.

Table 1 Brands and manufacturers of MECS.

Brand of MECS	*Compression class*	*Type of knit*	*Manufacturer*	*City (Country)*
Luxovar Prestige	II	Round-knitted	Varitex	Haarlem (the Netherlands)
Mediven® Elegance	II	Round-knitted	Medi	Bayreuth (Germany)
Mediven® Plus	II	Round-knitted	Medi	Bayreuth (Germany)
Venotrain® Soft	II	Round-knitted	Bauerfeind	Zeulenroda (Germany)
Neo Duna	II	Flat-knitted	Varitex	Haarlem (the Netherlands)
Flebosense	II	Flat-knitted	Varitex	Haarlem (the Netherlands)
Flebovar	II	Flat-knitted	Varitex	Haarlem (the Netherlands)
Mediven® 550	II	Flat-knitted	Medi	Bayreuth (Germany)
Eurostar	II	Flat-knitted	Varodem®	Saint-Léger (Belgium)
Juzo® 3022	II	Flat-knitted	Juzo	Aichach (Germany)
Juzo® 3052	II	Flat-knitted	Juzo	Aichach (Germany)
Luxovar Prestige	III	Round-knitted	Varitex	Haarlem (the Netherlands)
Mediven® Forte	III	Round-knitted	Medi	Bayreuth (Germany)
Neo Durelna	III	Flat-knitted	Varitex	Haarlem (the Netherlands)
Mediven® 550	III	Flat-knitted	Medi	Bayreuth (Germany)
Euroform	III	Flat-knitted	Varodem®	Saint-Léger (Belgium)
Euroform Speciaal	IV	Flat-knitted	Varodem®	Saint-Léger (Belgium)
Neo Durelna Speciaal	IV	Flat-knitted	Varodem®	Saint-Léger

Test procedure

Before testing, all MECS were washed according to the European guidelines, followed by hydroextraction (maximum for two minutes) and flat drying. The MECS were conditioned at least 12 hours prior to the measurements.

Measuring point

Measurements were performed at the B1 level; this is the point at which the Achilles tendon changes into the calf muscles. We chose the B1 level because the results of our earlier study showed that the largest differences in the circumference during walking occurred at this level.[8] The results reported in that study corroborate those reported by Blättler et al.[9] A device was used to mark the measuring positions. This consisted of a marking-board on which an adjustable clamp was mounted. This clamp enabled to fix the lower end of the round-knitted MECS to a system of clamps, or for flat-knitted MECS to a metal foot frame. The device is shown in Figure 1, chapter III.

Dynamic leg-segment model

The new dynamic leg-segment model was described in details elsewhere, but the method is discussed briefly.[8] An artificial leg-segment model based on an air-filled drum was developed to investigate the dynamic behavior of MECS.[10] The dynamic leg-segment model simulates the walking speed and walking pattern of the real leg during walking and consists of four components:

1) A form wheel for simulating walking patterns. The circumference of the leg changes during walking, primarily as a result of the movement of the calf muscles.

2) An air-pressure generator (Figure 2). This air-pressure generator (Posthumus Products, Haarlem, the Netherlands) is connected to the form wheel, can be adjusted for the frequency and the amplitude of the signal and provides the air-filled drum of the artificial leg-segment with precise pressure in such a way that the dynamic variation in circumference of the MECS equals 1 cm.

3) An artificial leg-segment consisting of an air-filled drum covered with a rubber skin (Figure 3). We used an air-filled drum with the same circumference as the leg-circumference at the B1 level. The MECS is put over the leg-segment. Changes in the circumference are registered with strain-gauge plethysmography. The pressure in the air-filled drum was recorded with a TruWave pressure-transducer (Baxter Healthcare Corporation, Irvine, CA).

4) The pressure and the changes in circumference were measured simultaneously and fed into a computer system: the Fysio Flex system, built at the instrumentation service unit of the University of Nijmegen, the Netherlands. A registration curve of a dynamic measurement is shown in Figure 4.

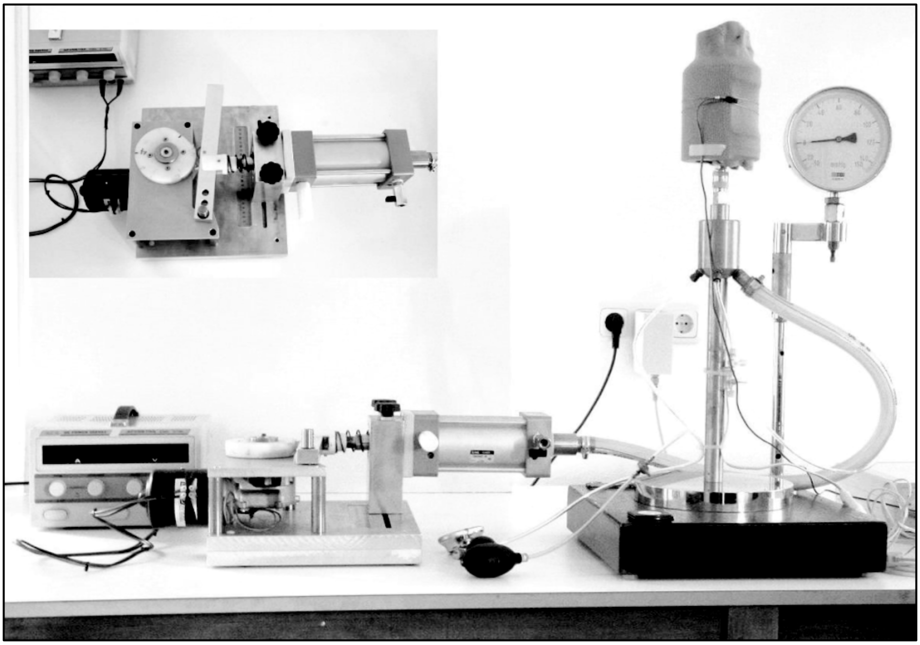


Figure 2 Measuring instrument with the dynamic leg-segment model. Inset: Adjustable air-pressure generator.

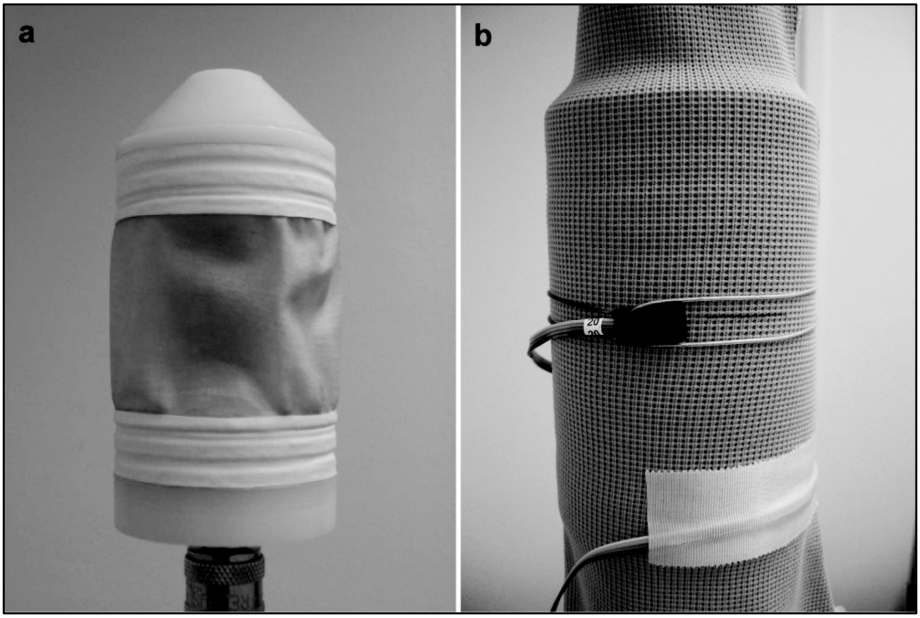


Figure 3 Artificial leg-segment model without (a) and with (b) MECS. The dynamic changes of the MECS are determined with strain-gauge plethysmography.

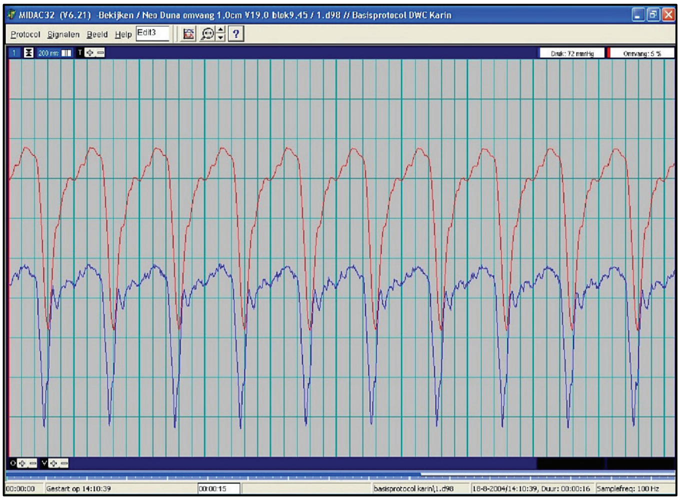


Figure 4 Registration curve of a dynamic measurement. The red signal represents the circumference variation. The amplitude of this signal equals 1 cm. The blue signal represents the pressure variation in the air-filled drum.

Dynamic stiffness index

A new definition for DSI, based on the current definition of stiffness as mentioned by the CEN, is introduced. Dynamic stiffness index is defined as the increase in pressure when the variation of circumference equals to 1 cm at a frequency of 1 Hertz* (mmHg/cm measured at 1Hz). The DSI was then calculated. Three repeated measurements were conducted per MECS.

* 1Hertz = 1 gait cycle per second.

Statistics

The mean pressure with standard deviation (SD) and DSI with SD were calculated from these three replicate measurements per brand of MECS.

A components of variance analysis was used to judge the reliability and the reproducibility of the DSI. The reliability (Rel) of the measurements was calculated using the following formula:

$$\mathrm{Rel} = \frac{\sigma_e^2}{\sigma_e^2 + \sigma_p^2}$$

σ_e^2 = variance between the DSI of MECS, and σ_p^2 = variance due to measurement error/flaw and is equal to reproducibility.

RESULTS

Pressure at the B1 level

According to the CEN, the exerted pressure at the B level for a class II MECS ranges from 23 to 32 mmHg, for a class III MECS from 34 to 46 mmHg and for a class IV MECS 49 mmHg and higher. These values indicate a hypothetical cylindrical ankle of 20 cm. With regard to the pressure profile, the CEN defines a residual pressure at the B1 level as 70 to 100% compression at the ankle.[4] This means that the value for class II MECS varies from 16 to 32 mmHg, for class III MECS from 24 to 46 mmHg, and for class IV MECS 34 mmHg and higher. The mean pressure and the SDs of the 18 brands of MECS at the B1 level are shown in Table 2. It can be seen that almost all, but the class III Mediven® Forte stocking, exert pressures within the accepted range. The overall tendency in both class II and III MECS is that flat-knitted MECS exerted higher pressures compared with round-knitted MECS. Furthermore, it is notable that three class II MECS (Neo Duna, Juzo® 3022 and Juzo® 3052) exerted pressures, which are similar to those exerted by several class III MECS.

Dynamic Stiffness Index

The mean DSI and SDs of 18 different brands of MECS are shown in Table 3, and a graphical representation is shown in Figure 5. It can be seen in Figure 5 that there is a large variation in DSI irrespective of the compression class or the type of knit. The DSI in the 11 different brands of class II MECS ranged from 16.1 ±0.27 mmHg (Venotrain® Soft) to 32.2 ±1.19 mmHg (Mediven® 550). The DSI in the five different brands of class III MECS ranged from 19.1 ±0.53 (Luxovar Prestige) to 30.0 ±0.92 mmHg (mediven® 550). The DSI in the two brands of class IV MECS ranged from 22.2 ±0.59 (Neo Durelna Speciaal) to 26.0 ±0.59 (Euroform Speciaal). The variation in the range of DSI in the five categories of MECS is shown in Table 4. Although there is a large variation in all five categories of MECS, it can be seen that the SDs in the two categories of class II and class III flat-knitted MECS are higher compared with the other groups. Results of the statistical analysis showed that the reliability index was high for all five categories of MECS and the reproducibility of the measurements was excellent (Table 4).

Table 2 Mean pressures at B1 level of 18 different brands of MECS.

Brands of MECS			*Mean DSI* ± SD [mmHg/cm]*
Class II 23 to 32 mmHg	*Round-knitted*	Luxovar Prestige	20.52 ± 2.25
		Mediven® Elegance	18.55 ± 1.71
		Mediven® Plus	15.37 ± 2.34
		Venotrain® Soft	16.00 ± 0.74
	Flat-knitted	Neo Duna	27.53 ± 1.86
		Flebosense	21.02 ± 0.92
		Flebovar	23.64 ± 2.46
		Mediven® 550	17.86 ± 1.10
		Eurostar	21.23 ± 1.44
		Juzo® 3022	30.09 ± 0.62
		Juzo® 3052	26.55 ± 0.34
Class III 34 to 46 mmHg	*Round-knitted*	Luxovar Prestige	27.24 ± 1.26
		Mediven® Forte	23.01 ± 1.01
	Flat-knitted	Neo Durelna	36.94 ± 1.78
		Mediven® 550	39.13 ± 1.08
		Euroform	27.50 ± 0.79
Class IV >49 mmHg	*Flat-knitted*	Euroform Speciaal	38.81 ± 1.13
		Neo Durelna Speciaal	53.07 ± 0.69

* Figures are the means ± SD calculated from three replicate measurements per brand.

Table 3 Mean dynamic stiffness index of 18 different brands of MECS.

Brands of MECS			*Mean DSI* ± SD [mmHg/cm]*
Class II 23 to 32 mmHg	*Round-knitted*	Luxovar Prestige	18.45 ± 0.40
		Mediven® Elegance	16.15 ± 0.92
		Mediven® Plus	17.89 ± 0.15
		Venotrain® Soft	16.06 ± 0.27
	Flat-knitted	Neo Duna	18.62 ± 1.04
		Flebosense	26.26 ± 1.06
		Flebovar	23.34 ± 1.09
		Mediven® 550	32.21 ± 1.19
		Eurostar	23.62 ± 0.89
		Juzo® 3022	19.45 ± 0.40
		Juzo® 3052	22.79 ± 0.79
Class III 34 to 46 mmHg	*Round-knitted*	Luxovar Prestige	19.06 ± 0.53
		Mediven® Forte	23.06 ± 0.35
	Flat-knitted	Neo Durelna	21.23 ± 0.26
		Mediven® 550	29.95 ± 0.92
		Euroform	24.22 ± 1.63
Class IV >49 mmHg	*Flat-knitted*	Euroform Speciaal	26.00 ± 0.59
		Neo Durelna Speciaal	22.23 ± 0.59

The dynamic stiffness index was calculated as follows: DSI = Δp/Δo (where Δp is the change in pressure and Δo the difference in circumference (equals 1cm) at a frequency of 1 Hertz.

* Figures are the means ± SD calculated from three replicate measurements per brand.

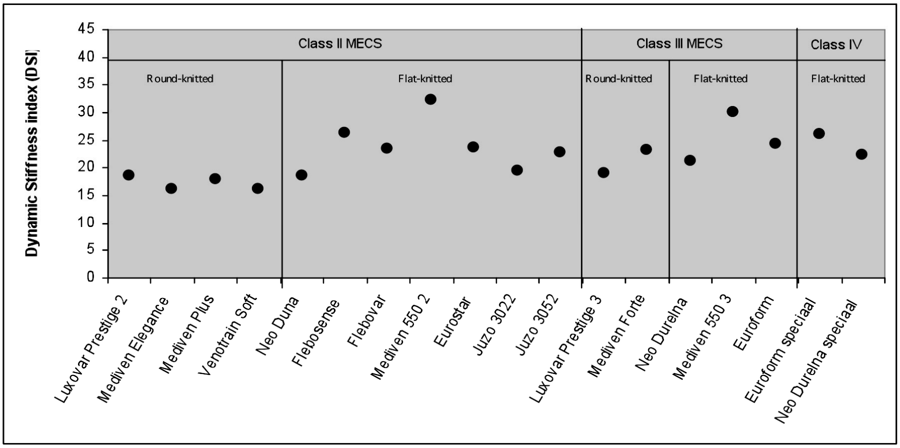


Figure 5 Distribution of dynamic stiffness index of 18 different brands of class II, class III MECS. Each dot represents one MECS.

DISCUSSION

We recently introduced a new parameter for MECS, the DSI and showed that the values of DSI were much higher than those of the static stiffness.[8] In addition, the results of the present study showed that there was considerable variation in the DSI between various brands of MECS and within the five categories, irrespective of the compression class and type of knit (round-knitted or flat-knitted). Does this large variation in the DSI of MECS belonging to the same compression class explain the differences in their therapeutic effectiveness? The results of our investigations reported here would indicate that the answer is yes and that the differences between DSI are as important if not more important than the differences between the compression classes, which would vary according to the clinical indication. Häfner and Jünger showed in their randomized study that MECS of the same compression class do have different acute effects on venous hemodynamics.[11] The explanation for these different effects was the stiffness, which was defined as the ratio between maximum pressure exerted during exercise and the resting pressure when standing. A positive correlation between this ratio and the improvement in venous refilling time was found. However, the current differences between MECS of the same compression class cannot be explained on the basis of static stiffness, because these differences are within the tolerance limits of manufacturing. Perhaps the DSI would enable a more accurate classification for MECS. Generally, MECS may be divided into four categories according to their DSI: a) MECS with low compression and low DSI, b) MECS with low compression and high DSI, c) MECS with high compression and low DSI, and d) MECS with high compression and high DSI as shown by the 4 different types of registration curves in Figure 6.

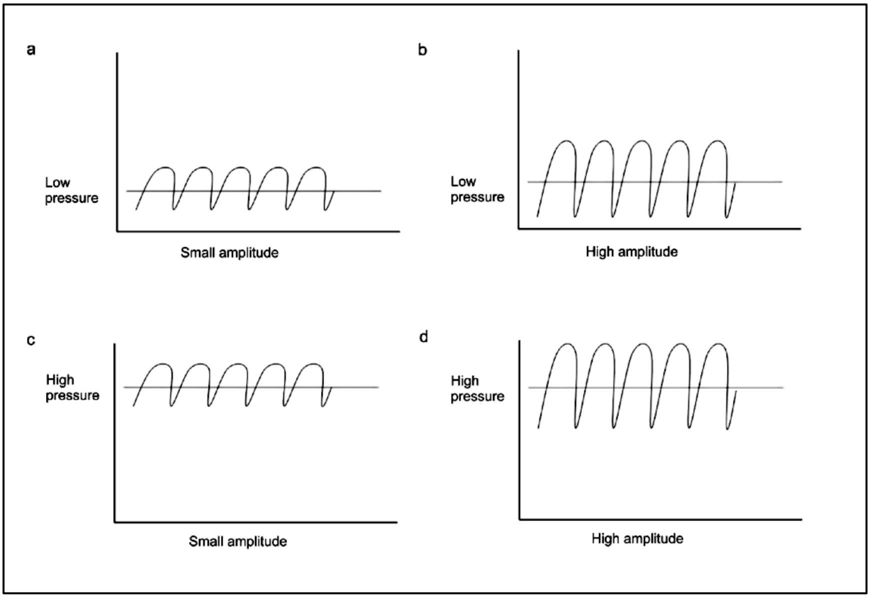


Figure 6 Four types of registration curves: a) MECS with low compression and low DSI, b) MECS with low compression and high DSI, c) MECS with high compression and low DSI, d) MECS with high compression and high DSI.

Each category has its own specific medical indication for treating venous disorders.[12] In general, the choice for a certain MECS is only based on the compression class. Adding the DSI to the compression class may allow a wider choice of MECS for the particular clinical indication of the patient. For example, for deep venous reflux, a class III MECS is generally prescribed. However, there are patients with deep venous reflux who will have the same beneficial effect from a class II MECS with high stiffness as compared with a class III MECS with medium or even low stiffness. Moreover, MECS of a lower compression class are generally more appreciated by the patient. MECS that are acceptable to the patient should have a correct balance between comfort and effectiveness. On the one hand, the higher the stiffness of the MECS, the more they resemble inelastic material and the more effective they are in preventing edema, decreasing venous refluxes, and improving calf muscle pump function.[5,6] On the other hand, they are less patient friendly because they are more difficult to put on and pull off.

However, the question still remains whether the exertion of high pressure is necessary or will exertion of lower pressure be sufficient to achieve the desired therapeutic effect? The compression class of MECS has proven to be important in the prevention of recurrence of venous ulceration.[13] Moreover, it is known from studies on compression bandages that the so-called massaging effect, which is directly related to the elasticity and the stiffness, is important for optimizing venous return.[6,14] The massaging effect will increase and the effectiveness of MECS will improve by increasing the pressure and the stiffness. We have developed an in vitro method, which simulates the behavior of MECS during walking as closely as possible. However, we do realize that the method is time-consuming and not easy to implement in daily practice. Nonetheless, the manufacturers can easily conduct such measurements. Advantages of the dynamic leg-segment model are that the model is based on a method that was approved by the CEN. Measurements can be easily adjusted with regard to the frequency, changes in circumference and amplitude. Pressure is measured under the MECS within the air-filled drum and the pressure-sensor remains unaffected. In contrast, pressure-sensors used for interface pressure measurements (this is the pressure between the MECS and the skin) are affected by test location, interface conditions and anatomic leg shape. Liu et al. investigated the objective skin pressure distribution of MECS and reported on the various factors that influenced the skin pressure.[15]

The leg-segment model used in the present study is an air-filled closed system. Since air can be compressed, measurements should be conducted under standardized conditions. Nonetheless, the leg-segment model still requires further refinements and validation for routine use. At present, the pressure cannot be read directly. Partsch recently introduced a simple in vivo method to assess the static stiffness index (SSI), which is defined as the pressure difference between active standing and lying.[16] However, pressure differences were divided by 1 cm for reasons of simplicity, assuming that the increase in the circumference was 1 cm. Unlike the calculation reported by Partsch we conducted our measurements with an actual increase in circumference of 1 cm. In our opinion the change in circumference is very important because a small increase in circumference results in higher stiffness (Figure 1). Our measurements were in vitro. However, it would be desirable also to conduct such measurements in vivo in order to be able to compare such measurements with those reported in other studies. Mosti and Mattaliano studied simultaneous changes of leg circumference and interface pressure under compression bandages in vivo.[17] They used the modified SSI as the pressure difference between the standing and the lying condition corrected for the actual increase of leg circumference. In a recent study by Partsch et al., it was clearly shown that in vivo measurements of the interface pressure and the SSI correlated well with in vitro laboratory measurements of static stiffness.[18] Benigni et al. proposed to define a DSI as the difference between the high and the low pressures recorded during walking.[19] Measurements were performed on a treadmill using a pressure transducer with two sensors. The measured interface pressures were the mean pressures of both sensors. However, they did not take into consideration the change in circumference during walking and measurements were not conducted at the B1 level. This meant that the results of their study could not be compared with those reported in other studies.

There is little or no evidence-based literature for evaluating the role of stiffness of MECS in patients with chronic venous insufficiency. The reported clinical trials were of poor design and confusing. The compression that was used was often not clearly defined, which made the comparison of results difficult if not impossible. As a direct result, considerable interest has arisen in the physical properties of MECS and their relationship with the therapeutic effectiveness. In our opinion it is essential to pursue well-designed clinical trials and investigations concerning MECS and compression therapy in general. Insight into the differences between the different types of MECS that are commercially available is required in order to develop or refine a more accurate classification that would clearly reflect the therapeutic effectiveness of MECS for treating chronic venous insufficiency.

Table 4 Variation in the range of dynamic stiffness index of 18 different brands of MECS with reliability and reproducibility of the measurements

Type of MECS	*Minimum DSI [mmHg/cm]*	*Maximum DSI [mmHg/cm]*	*Mean DSI [mmHg/cm]*	*±SD**	*Reliability index*	*Reproducibility** [mmHg/cm]*
Class II round-knitted (n=4)	16.1	18.5	17.1	1.3	0.83	1.5
Class II flat-knitted (n=7)	18.6	32.2	23.8	4.6	0.96	2.7
Class III round-knitted (n=2)	19.1	23.1	21.1	2.0	0.95	1.2
Class III flat-knitted (n=3)	21.2	30.0	25.1	4.5	0.93	3.3
Class IV flat-knitted (n=2)	22.2	26.0	24.1	2.7	0.95	1.6

* SD of a single measurement of DSI

** 95th percentile of the absolute difference between duplicate measurements

REFERENCES

1. Hohlbaum GG. Zur Geschichte der Kompressionstherapie (II). Phlebol u Proktol 1988; 17: 24-37.
2. Gardon-Mollard C, Ramelet AA. Compression Therapy. Paris: Masson, 1999.
3. Van Geest AJ, Veraart JCJM, Nelemans P, Neumann HAM. The effect of medical elastic compression stockings with different slope values on edema. Dermatol Surg 2000; 26: 244-247.
4. European Committee for Standardization (CEN) Non-active medical devices. Working group 2 ENV 12718: European Prestandard 'Medical compression hosiery' CEN/TC205 Brussels: CEN, 2001.
5. Spence RK, Cahall E. Inelastic versus elastic leg compression in chronic venous insufficiency: a comparison of limb size and venous hemodynamics. J Vasc Surg 1996; 24: 783-787.
6. Partsch H, Menzinger G, Mostbeck A. Inelastic leg compression is more effective to reduce deep venous refluxes than elastic bandages. Dermatol Surg 1999; 25: 695-700.
7. Van der Wegen-Franken K, Roest W, Tank B, Neumann M. Calculating the pressure and the stiffness in three different categories of class II medical elastic compression stockings. Dermatol Surg 2006; 32: 216-223.
8. Stolk R, van der Wegen-Franken CPM, Neumann HAM. A method for measuring the dynamic behavior of medical compression hosiery during walking. Dermatol Surg 2004; 30: 729-736.
9. Blättler W, Lun B, Uhl JF, Bringer Y. Determinants of pressure exerted by medical compression stockings. (abstract) Int Angiol 2005; 24 Suppl. 1 to No.3: 159.
10. Stolk R. A quick pressure determining device for medical stockings based on the determination of the counterpressure of air filled segments. Swiss Med 1988; 4a: 91-96.
11. Häfner HM, Jünger M. The heamodynamic efficacy of six different compression stockings from compression class 2 in patients suffering from chronic venous insufficiency. Phlebology 2000; 15: 126-130.
12. Neumann HAM. Compression therapy with medical elastic stockings for venous diseases. Dermatol Surg 1998; 24: 765-770.
13. Nelson EA, Harper DR, Prescott RJ, Gibson B, Brown D, Ruckley CV. Prevention of recurrence of venous ulceration: randomized controlled trial of class 2 and class 3 elastic compression. J Vasc Surg 2006; 44: 803-808.
14. Veraart JCJM, Daamen E, Neumann HAM. Short stretch versus elastic bandages: effect of time and walking. Phlebol 1997; 26: 19-24.
15. Liu R, Kwok YL, Li Y et al. Objective evaluation of skin pressure distribution of graduated elastic compression stockings. Dermatol Surg 2005; 31: 615-624.
16. Partsch H. The Static Stiffness Index: A simple method to assess the elastic property of compression material in vivo. Dermatol Surg 2005; 31: 625-630.
17. Mosti GB, Mattaliano V. Simultaneous changes of leg circumference and interface pressure under different compression bandages.
18. Partsch H, Partsch B, Braun W. Interface pressure and stiffness of ready made compression stockings: comparison of in vivo and in vitro measurements. J Vasc Surg 2006; 44: 809-814.
19. Benigni JP, Cornu Thénard A, Uhl JF, Schadeck M. Compression stockings. Walking pressure and proposal of a dynamic stiffness index. (abstract) Int Angiol 2005; 24 Suppl. 1 to No. 3: 21.

Chapter VI

Correlation between the static stiffness and the dynamic stiffness indices of medical elastic compression stockings

Van der Wegen-Franken CPM, Tank B, Neumann HAM. Correlation between the static and dynamic stiffness indices of medical elastic compression stockings. Dermatol Surg 2008; 34: 1477-1485.

ABSTRACT

Background: Compression therapy with medical elastic compression stockings (MECS) has been used effectively for treating patients with chronic venous insufficiency for many years.

Objective: To study the correlation between the static stiffness and the dynamic stiffness index (DSI) of 18 different brands of MECS.

Methods: In all, 18 different brands of MECS that were divided into five categories (class II round-knitted, class II flat-knitted, class III round-knitted, class III flat-knitted and class IV flat-knitted) were tested. To determine the static stiffness, the tension of the textile of the MECS at the B1 level was measured according to the Institut de Textile France method to calculate the static stiffness index. The dynamic pressure pulsations were measured with a newly developed dynamic pressure-determining device to calculate the DSI.

Results: The results showed that there was a positive correlation between the static stiffness index and the dynamic stiffness index. The dynamic stiffness indices were higher than the static stiffness indices.

Conclusion: Although the stiffness of MECS is a further refinement to the current classification, which classifies MECS according to the pressure they exert at the B level, the DSI does not have any additional value over the static stiffness index as far as the classification of MECS is concerned. Either or both of these characteristics should be used to select the most suitable MECS for the patient.

INTRODUCTION

Medical elastic compression stockings (MECS) are effective in the treatment of chronic venous insufficiency and are particularly effective under dynamic conditions. They work among other things, by improving venous hemodynamics and reducing edema.[1,2] This can be ascribed to their characteristics, the most important being elasticity and stiffness. MECS exert pressure on the leg because of their elasticity, and they can prevent and treat edema because of their stiffness. According to the European Committee for Standardization (CEN) stiffness is defined as the increase in pressure at the B level if the circumference increases by 1 cm and is expressed in millimeters of mercury per centimeter or hectopascals per centimeter.[3] There are several devices and methods, such as the Hatra and the Hohenstein methods for determining the static stiffness of MECS.[4] These methods are based on the same principle; the MECS is clamped into the device, and the force that is required to stretch the MECS can be used to calculate the static stiffness. However, these laboratory techniques are far from actual use. Therefore, other methods have been developed to determine the dynamic stiffness of MECS in order to explain their behavior and how they work in actual use, such as during walking.

In the evaluation of compression therapy in general and MECS in particular, it is important to reach consensus. Most of the literature on MECS is unfortunately neither evidence-based nor comparable. There is a need for easy and internationally comparable evaluation methods and consensus on the classification of MECS. In a recently published consensus statement, several recommendations were reported.[5] It was proposed that measurements at the B1 level should always be included in all measurements with compression devices in the future, with the exact location of the sensor situated at the segment that shows the largest increase in circumference during dynamic conditions, such as maximum dorsiflexion, standing up from the supine position and walking.

There has been an increasing interest in the characteristics of MECS, and new aspects on this topic such as the DSI have been studied. However, one must remain critical and question the additional value of a DSI over the static stiffness index.

The aim of this study was to determine whether there was any correlation between the static and the dynamic stiffness indices in 18 different brands of MECS from well-known manufacturers, with the intention of establishing a parameter, namely the dynamic stiffness that would enable the exact behavior of MECS to be predicted under dynamic conditions. It is essential in daily practice to know whether there is any correlation between the static and dynamic stiffness indices, because although static stiffness is much easier to determine, it does not reflect the dynamic condition, and static stiffness alone cannot explain the difference between the therapeutic effectiveness of MECS belonging to the same compression class.

MATERIALS AND METHODS

Medical elastic compression stockings

We arbitrarily chose 18 different brands of MECS from well-known manufacturers. All MECS were custom-made for B1 leg-size of 22 cm and were divided into the following five categories based on the compression class and type of the knit: class II round-knitted MECS, class II flat-knitted MECS, class III round-knitted MECS, class III flat-knitted MECS and class IV flat-knitted MECS. There was no specific reason for choosing different numbers in the three compression classes. There is usually more choice in class II and class III MECS. None of the manufacturers were aware that the MECS were being tested.

Test procedure

Before testing, all MECS were washed according to the European guidelines, followed by hydroextraction (maximum for two minutes) and flat drying. The MECS were conditioned at least 12 hours prior to the measurements.

Measuring point

Measurements were performed at the B1 level, this is the point at which the Achilles tendon changes into the calf muscles. We chose the B1 level because the largest differences in circumference during dynamic changes occur at this level. Moreover, measurements at this level are according to the recently published recommendations by Partsch et al.[5] A marking-board with an adjustable clamp to fix the MECS was used to mark the measuring positions.

Static Stiffness

To determine the static stiffness, we used the Institut de Textile France method. This method uses a dynamometer with which the tension in a section of the MECS held between two movable T-pins can be measured (Figure 1). After the MECS was marked, it was stretched between two bars. To avoid constriction of the knit, the upper bar consisted of three separate parts. Only the middle part was attached to a tension tester load cell. The knit was stretched to its maximum circumference six times. The maximum force that was required in the sixth cycle to stretch the MECS to its full extent conforming to its B1 size is converted into pressure using the Laplace formula; T = P x R where T is tension or traction, P is pressure and R is radius. The pressure was expressed in mmHg.

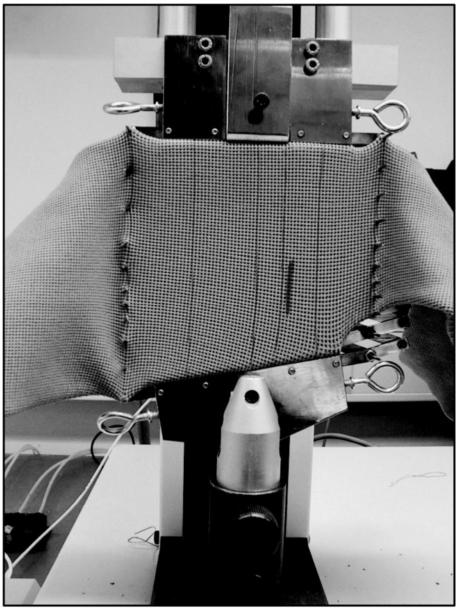


Figure 1 Institut de Textile France method. The B1 section of the MECS is clamped between the two bars. Note the middle part of the upper bar, which is attached to the tension tester load cell.

The static stiffness was calculated after three different measurements per MECS were taken. First, the pressure was measured for a girth that was 1 cm smaller than the B1 size. Second, the pressure was measured for the B1 size (the so-called 'real girth'). Third, the pressure for the girth that was 1 cm larger than the B1 size was measured. The MECS were made for a B1 size of 22 cm and they were tested for the girths of 21, 22 and 23 cm. The static stiffness was then calculated using the following formula as described in our previous study.[6]

$$\text{stiffness} = \frac{\text{pressure at Bl size, girth 23} \quad - \quad \text{pressure at Bl size, girth 21}}{2}$$

Dynamic Stiffness Index

To determine the DSI, a dynamic leg-segment model was used to simulate walking and to investigate the dynamic behavior of MECS. This model has been described in detail elsewhere, but the method is discussed briefly.[7] The measuring device consists of four components and is shown in Figure 2, chapter V.

1) A form wheel for simulating walking patterns. In a previous study, we analyzed changes in the circumference of the leg during walking with regard to the gait cycle, amplitude and form of the signal. For this purpose, volunteers walked on a treadmill with mercury-filled rubber gauges around the leg at the B1 level. Changes in circumference were measured with strain-gauge plethysmography.

2) An air-pressure generator (Posthumus Products, Haarlem, the Netherlands) is connected to the form wheel that delivers a dynamic pressure signal to the air-filled drum. The air-pressure generator can be adjusted for the frequency and the amplitude of the signal and provides the air-filled drum of the artificial leg-segment with precise pressure in such a way that the dynamic variation in circumference of the MECS equals 1 cm.

3) An artificial leg-segment consisting of an air-filled drum covered with a rubber skin. An air-filled drum with the same circumference as the leg-circumference at the B1 level was used for our measurements. Then the MECS was put over the leg segment. Changes in the circumference were registered with strain-gauge plethysmography. The pressure in the air-filled drum was recorded with a TruWave pressure-transducer (Baxter Healthcare Corporation, Irvine, CA).

4) The pressure and the changes in circumference were measured simultaneously and fed into a computer system: the Fysio Flex system, built at the instrumentation service unit of the University of Nijmegen, the Netherlands. A registration curve of a dynamic measurement is shown in Figure 4, chapter V.

The DSI was defined as the increase in pressure when the variation of circumference equalled 1 cm at a frequency of 1 Hertz (1Hertz = 1 gait cycle per second). The DSI was then calculated. Each brand of MECS was measured three times.

Statistics

The static stiffness and dynamic stiffness with corresponding standard deviation (SD) in the 18 brands of MECS were calculated. The mean DSI with SD was calculated from these three replicate measurements. SPSS 12.0.1 software was used for statistical calculations. To study the correlation between the static and dynamic stiffness indices, Pearson correlation coefficients (r) were determined.

RESULTS

Static stiffness

The results of the static stiffness at the B1 level of 18 different brands of MECS are shown in Table 1. It can be seen that the static stiffness index ranges from 1.70 mmHg/cm (Venotrain® Soft) to 6.11 mmHg (Mediven® Forte) with 1 outlier of 10.32 mmHg (class II Mediven® 550). There was variation in static stiffness not only between the five different categories of MECS, but also within the five different categories. The static stiffness was independent of the compression class and the type of knit.

The dynamic stiffness values at the B1 level were much higher and are also shown in Table 1. The mean DSI ranged from 16.06 mmHg/cm at 1 Hz (Venotrain® Soft) to 32.21mmHg/cm at 1 Hz (class II Mediven® 550) If the Mediven® 550 stocking is removed from the calculation because of its outlier status in static stiffness, then the maximum mean DSI is 29.95mmHg/cm at 1 Hz (class III Mediven® 550). Variation in the DSI was noted not only between the five different categories of MECS, but there was also variation within the five different categories. Thus, the DSI is also independent of the compression class and the type of knit.

Dynamic stiffness index

Table 2 shows the variation in the range of the static and dynamic stiffness indices in the five different categories. With the exception of the class II round-knitted MECS, the mean static stiffness and dynamic stiffness of the categories lie close together. Although there is a large variation in the static stiffness as well as in the DSI in all five categories of MECS, SDs it can be seen that the SDs of the static stiffness in the two categories of class II round-knitted MECS and class IV flat-knitted MECS are lower than those in the other categories. The SDs of the DSI in the three categories of class II round-knitted, class III round-knitted and class IV flat-knitted MECS are lower than those in the other categories. The overall tendency was toward a larger variation in static and dynamic stiffness in the flat-knitted categories. The number of MECS in the various categories was small.

Table 1 The static and the dynamic stiffness index of 18 different brands of MECS.

Brands of MECS			*Static stiffness [mmHg/cm]*	*Mean DSI* ± SD [mmHg/cm]*
Class II 23 to 32 mmHg	*Round-knitted*	Luxovar Prestige	2.63	18.45 ± 0.40
		Mediven® Elegance	2.87	16.15 ± 0.92
		Mediven® Plus	3.52	17.89 ± 0.15
		Venotrain® Soft	1.70	16.06 ± 0.27
	Flat-knitted	Neo Duna	2.88	18.62 ± 1.04
		Flebosense	3.95	26.26 ± 1.06
		Flebovar	2.95	23.34 ± 1.09
		Mediven® 550	10.32	32.21 ± 1.19
		Eurostar	2.91	23.62 ± 0.89
		Juzo® 3022	3.78	19.45 ± 0.40
		Juzo® 3052	3.39	22.79 ± 0.79
Class III 34 to 46 mmHg	*Round-knitted*	Luxovar Prestige	3.18	19.06 ± 0.53
		Mediven® Forte	6.11	23.06 ± 0.35
	Flat-knitted	Neo Durelna	2.60	21.23 ± 0.26
		Mediven® 550	6.72	29.95 ± 0.92
		Euroform	4.88	24.22 ± 1.63
Class IV >49 mmHg	*Flat-knitted*	Euroform Speciaal	4.42	26.00 ± 0.59
		Neo Durelna Speciaal	5.55	22.23 ± 0.59

* Figures are the means ± SD calculated from three replicate measurements per brand.

Table 2 Variation in the range of the static and the dynamic stiffness index per category of MECS.

Type of MECS	Min SSI	Max SSI	Mean SSI	±SD	Min DSI	Max DSI	Mean DSI	±SD
	[mmHg/cm]							
Class II round-knitted (n=4)	1.70	3.52	2.68	0.75	16.15	18.36	17.25	1.07
Class II flat-knitted (n=7)	2.88	10.32	4.31	2.68	18.63	32.30	23.65	4.53
Class III round- knitted (n=2)	3.18	6.11	4.64	2.07	19.14	22.92	21.03	2.67
Class III flat-knitted (n=3)	2.60	6.72	4.73	2.06	21.23	29.95	25.18	4.42
Class IV flat-knitted (n=2)	4.42	5.55	4.99	0.80	22.27	26.04	24.16	2.67

SSI= Static Stiffness Index
DSI= Dynamic Stiffness Index

Correlation

A strong and positive Pearson correlation coefficient (r = 0.79) with a clinical significance at the .01 level between static and dynamic stiffness index was observed as shown in Figure 2.

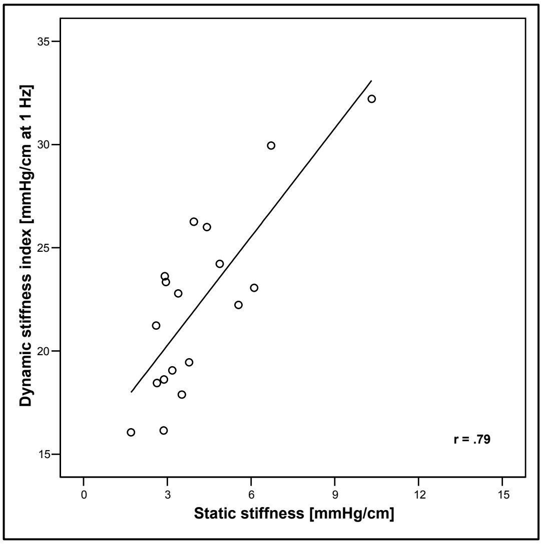


Figure 2 Correlation between the static and the dynamic stiffness indices at the B1 level of 18 brands of MECS.

DISCUSSION

Compression therapy with MECS is highly effective under dynamic conditions, although most of our knowledge about the effectiveness of MECS is based on static (laboratory) testing. Because measuring dynamic pressure and stiffness on the human leg is difficult, there is an increasing need for accurate and reproducible laboratory methods for investigating the behavior of MECS under dynamic conditions. In the current study, we compared the static stiffness using a slightly modified, approved technique with the dynamic stiffness measured using a new device.

A large variation in the static stiffness and the dynamic stiffness indices was observed not only between the five different categories of MECS, but also within the categories. Such large variations in the static stiffness between and within compression classes corroborate those reported in our previous study.[6] This means that the static stiffness and dynamic stiffness indices of MECS are independent of their compression class or the type of knit and therefore may be of an additional value to the current classification of the compression classes. Therefore, it would be highly desirable for the manufacturers to mention both the stiffness and the pressure of the MECS on the packaging.

A positive correlation between the static and dynamic stiffness indices at the B1 level was observed. This means that, when a stocking has high static stiffness, it will also have high dynamic stiffness. The same is true when the static stiffness is low. For that matter, a stocking is no different from a compression bandage. The higher the stiffness or the stiffer the material, the bigger the pressure differences and thus the bigger the pressure amplitude. This is what we refer to as the massaging effect of MECS. Partsch et al. reported that inelastic bandages were more effective in reducing deep venous refluxes than elastic bandages.[8] On the one hand, the higher the stiffness of MECS, the more they behave as inelastic material and the more effective they are in preventing edema, decreasing venous refluxes and improving the calf muscle pump function. [8,9] On the other hand, they are less patient friendly because they are more difficult to put on and take off. We also know that, as the pressure of the MECS increases, they will be less comfortable for the patient. It is well known that patients in wheelchairs with dependency edema are difficult to treat. One is able to create more options for optimal treatment for the patient by varying pressure and stiffness.

If one seeks an explanation for the underlying working mechanism of MECS, then one must focus on the dynamic method, because this method closely approaches actual use. The observed differences between static stiffness do not contribute to this, because these differences are within the tolerance limits of manufacturing. Several methods are available to measure the static stiffness. We chose the Institut de Textile France method because it is a validated and highly reproducible method, as we reported earlier.[6] Above all, the CEN accepts this method as the reference method. Various studies have been published on different methods for measuring stiffness dynamically.[2,10,11] All these methods have their advantages and disadvantages. Although the method that was used in this study is time-consuming and not applicable in daily practice, the problem with interface-pressure measurements is that the test locations, which are determined by the specific anatomic structure and body shape of the individual human leg, easily influence the pressure.[12] Therefore, we consider our method to be the most exact method to determine the DSI.

To our knowledge, this is the first study in which static and dynamic stiffness indices were both calculated to see whether there was any correlation between them. No correlation studies on static and dynamic stiffness indices are available. We have used the method approved by the CEN to determine static stiffness, although it was measured at the B1 level, and according to the CEN, static stiffness should be determined at the B level. Although there is no difference in pressure between the B and B1 level, there is a difference in the circumference. This would mean that the method used for measurements in this study is not comparable with other methods in which measurements are conducted at the B level.

It is not surprising that there was a positive correlation between the static and dynamic stiffness. Stiffness is a characteristic of the material, in this case the knit, and this material does not alter under static or dynamic conditions. However, we should not ignore the role of hysteresis. Stiffness and hysteresis are important characteristics of MECS and are closely related. Putting it more strongly, they can neither be regarded nor measured independently of each other, and although there is a correlation between static and dynamic stiffness, the influence of hysteresis is probably greater under dynamic conditions than static conditions.

The way stiffness is measured is a point of discussion. In a recent study, we calculated the static stiffness of different class II MECS.[6] The difference between the minimum and the maximum static stiffness of class II MECS was approximately 5.5 mmHg. In the current study, the difference between the minimum and maximum static stiffness for all MECS was approximately 8.5 mmHg. However, if we exclude the class II Mediven® 550, because it is an outlier and is more than 10 mmHg/cm, then the difference is approximately 5 mmHg. These differences are within the tolerance limits of manufacturing. The effectiveness of the MECS cannot be explained based on these differences. It does not matter for the classification whether static or dynamic measurements are conducted as long as one strives for a comparative method. It is unnecessary to calculate the DSI for daily practice. The prescriber has adequate information to assess how the MECS is likely to behave on the basis of three categories of static stiffness, namely low, medium and high.

Finally, based on the results reported here, we would recommend that the manufacturers mention both the stiffness (static, dynamic, or both) and the pressure of MECS on the packaging. The DSI may be of additional value for the current classification. We believe that the combination of stiffness (static and/or dynamic) would enable the prescribing physician to evaluate the effectiveness of MECS for a given venous insufficiency more accurately in daily clinical practice.

REFERENCES

1. Ibegbuna V, Delis K, Nicolaides AN, Aina O. Effect of elastic compression stockings on venous hemodynamics during walking. J Vasc Surg 2003; 37: 420-425.
2. Häfner HM, Jünger M. The haemodynamic efficacy of six different compression stockings from compression class 2 in patients suffering from chronic venous insufficiency. Phlebology 2000; 15: 126-130.
3. European Committee for Standardization (CEN) Non-active medical devices. Working group 2 ENV 12718: European Prestandard ‘Medical compression hosiery’ CEN/TC205 Brussels: CEN, 2001.
4. Wienert V. Die medizinische Kompressionstherapie.Vom phlebologischen Kompressionsverband bis zum medizinischen Kompressionsstrumpf. Berlin Wien: Blackwell Wissenschafts-Verlag; 1999.
5. Partsch H, Clark M, Bassez S, Benigni J-P, Becker F, Blazek V. Measurement of lower leg compression in vivo: recommendations for the performance of measurements of interface pressure and stiffness. Dermatol Surg 2006; 32: 224-233.
6. Van der Wegen-Franken K, Roest W, Tank B, Neumann HAM. Calculating the pressure and the stiffness in three different categories of class II medical elastic compression stockings. Dermatol Surg 2006; 32:216-223.
7. Stolk R, van der Wegen-Franken CPM, Neumann HAM. A method for measuring the dynamic behavior of medical compression hosiery during walking. Dermatol Surg 2004; 30: 1-8.
8. Partsch H, Menzinger G, Mostbeck A. Inelastic leg compression is more effective to reduce deep venous refluxes than elastic bandages. Dermatol Surg 1999; 25(9): 695-700.
9. Spence RK, Cahall E. Inelastic versus elastic leg compression in chronic venous insufficiency: a comparison of limb size and venous heamodynamics. J Vasc Surg 1996; 24: 783-787.
10. Partsch H. The Static Stiffness Index: A simple method to assess the elastic property of compression material in vivo. Dermatol Surg 2005; 31: 625-630.
11. Benigni JP, Cornu Thénard A, Uhl JF, Schadeck M. Compression stockings. Walking pressure and proposal of a dynamic stiffness index.(abstract) Int Angiol 2005; 24 (Suppl. 1): 21.
12. Liu R, Kwok YL, Li Y et al. Objective evaluation of skin pressure distribution of graduated elastic compression stockings. Dermatol Surg 2005; 31: 615-624.

Chapter VII

Correlation between the dynamic stiffness index and the mass of medical elastic compression stockings

ABSTRACT

Objective: To study the correlation between the dynamic stiffness index (DSI) and the mass of medical elastic compression stockings (MECS) and thereby to predict their therapeutic value.

Materials and methods: Seventeen different brands of commercially available MECS were arbitrarily selected. All MECS were made to measure for a standardized leg. For each brand of MECS two identical stockings were made. One stocking was used to measure the DSI, the other stocking was used to determine the mass (mg/cm^2).

Results: A wide range of DSI values was found independent of the compression class, the type of materials and the type of knit. There was also a considerable variation in the mass between different brands of MECS. A positive and significant correlation between the DSI and the mass was found.

Conclusion: Determining the DSI of MECS is very time-consuming and requires sophisticated equipment. In our search for a simplified and easy to determine parameter related to the stiffness we found that the mass of MECS was highly correlated with its DSI and thus has, as is the case for the dynamic stiffness index, a predictive value for the dynamic behavior of MECS on the leg during walking. This means that manufacturers of MECS can influence their therapeutic effect by simply changing the mass of the MECS.

INTRODUCTION

There is a wide range of commercially available medical elastic compression stockings (MECS) today. This complicates making the right choice in the daily practice. Choosing on the basis of the compression class appears to be inadequate. Several studies have shown that MECS belonging to the same compression class show a large variation in both static and dynamic stiffness.[1,2] Practically, this means that MECS belonging to the same compression class can have a different therapeutic effect. Van Geest et al showed a difference in the edema preventive effect. This was done by measuring the capillary filtration rate using air-plethysmography.[3]

In recent years, more attention has been paid to the stiffness of compression material and its role in daily practice. This has resulted in the introduction of several methods to measure stiffness and several studies on this topic. In 2006 members of the International Compression Committee (ICC) published recommendations on the measurements of the stiffness.[4] Although several devices are available to measure stiffness and several methods of calculation exist, such sophisticated equipment is not available to everyone. Moreover, measuring stiffness can be time-consuming. The wide variety and complexity of the different methods used to determine stiffness initiated us to search for a simplified and easy to determine parameter that is directly related to the stiffness. The dynamic behavior of MECS is mainly determined by the design of the knit. This means flat-knitted or round-knitted, type of threads (loop threads and weft threads) and type of stitches used as illustrated in Figure 1. There are no large differences between the threads from various manufacturers. It is probably the way the threads are knitted that distinguishes one MECS from another (Figure 2). We assumed that there was a correlation between the mass and the DSI of MECS and believe that the mass of MECS may be a simple characteristic to predict the therapeutic effect of MECS. The more material used, the more friction between the stitches, the thicker the MECS and thus the higher the stiffness. In this study we determined the correlation between the DSI and the mass of MECS.

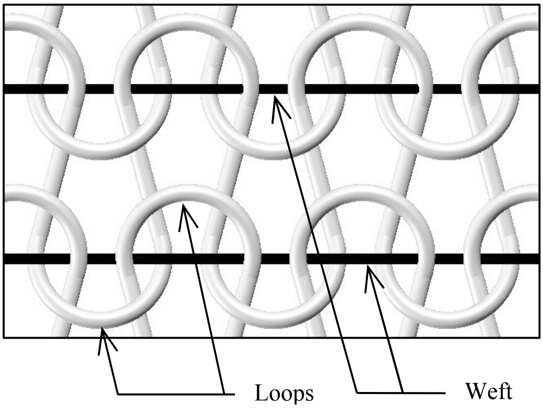


Figure 1 Loops and weft threads.

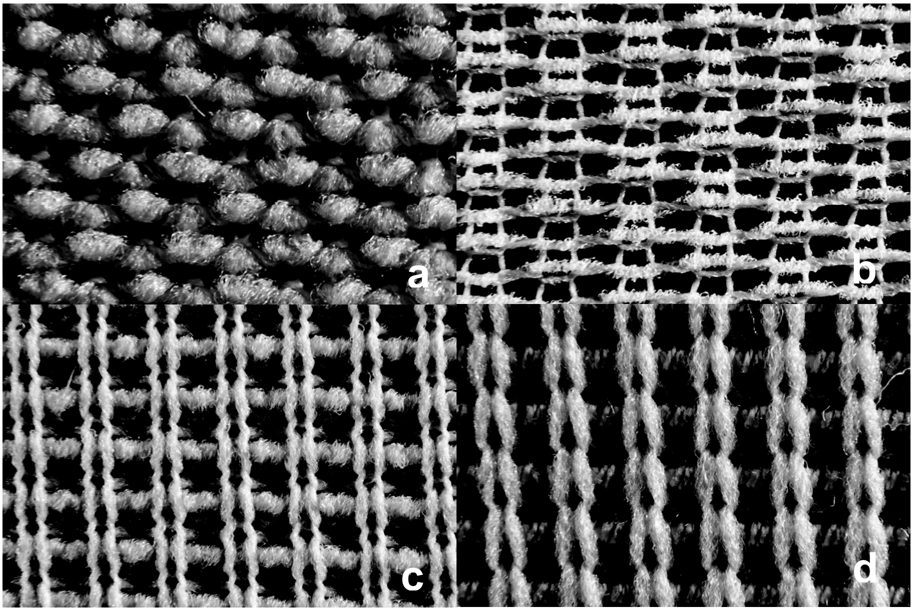


Figure 2 4 Different types of knit: a) and b) round-knitted class II MECS, c) and d) flat-knitted class II MECS.

MATERIALS AND METHODS

Medical elastic compression stockings

We arbitrarily chose MECS of seventeen different brands, 11 brands belonging to compression class II and six brands belonging to class III. All brands are commercially available in the Netherlands and are shown in Table 1. All MECS were made to measure for a standardized leg. For each brand of MECS two identical stockings were made. One stocking was used to determine the DSI, the other stocking was used to determine the mass. The manufacturers were not aware that the MECS were being tested.

Test procedure

Before testing, all MECS were washed according to the European guidelines, followed by hydroextraction (maximum for two minutes) and flat drying. The MECS were conditioned at least 12 hours prior to the measurements.[5]

Mass

A marking device was used to mark the B and B1 level (Figure 3). This device consisted of a marking-board on which an adjustable clamp was mounted. This clamp enabled to fix the lower end of the round-knitted MECS to a system of clamps, or for flat-knitted MECS to a metal foot frame. The mass of each brand of MECS was determined by cutting the B – B1 part of the MECS and weighing it using the Mettler PE360 scale (Figure 4). The surface of the B-B1 part was calculated using the following formula: Surface (cm^2) = (lB1-lB) x (*c*B + cB1) / 2
Mass is given as milligram per square centimeter (mg/cm^2).

Table 1 Brands, manufacturers and composition of MECS.

Brand of MECS			*Manufacturer*	*City (Country)*	*Fibers used*				
					Polyamides	*Elastane*	*Rubber*	*Cotton*	*Viscose*
Class II 23 to 32 mmHg	*Round-knitted*	Luxovar Prestige	Varitex	Haarlem (the Netherlands)	63%	37%			
		Mediven® Elegance	Medi	Bayreuth (Germany)	65%	35%			
		Mediven® Plus	Medi	Bayreuth (Germany)	69%	31%			
		Venotrain® micro	Bauerfeind	Zeulenroda (Germany)	55%	45%			
		Venotrain® Soft	Bauerfeind	Zeulenroda (Germany)	65%	35%			
		Venotrain® Strong	Bauerfeind	Zeulenroda (Germany)	70%	30%			
	Flat-knitted	Neo Duna	Varitex	Haarlem (the Netherlands)	36%		28%	36%	
		Flebosense	Varitex	Haarlem (the Netherlands)	78%	22%			
		Flebovar	Varitex	Haarlem (the Netherlands)	52%		48%		
		Mediven® 550	Medi	Bayreuth (Germany)	28%	32%		40%	
		Eurostar	Varodem®	Saint-Léger (Belgium)	44%		32%		24%
Class III 34 to 46 mmHg	*Round-knitted*	Luxovar Prestige	Varitex	Haarlem (the Netherlands)	56%	44%			
		Mediven® Forte	Medi	Bayreuth (Germany)	74%	26%			
		Venotrain® Strong	Bauerfeind	Zeulenroda (Germany)	69%	31%			
	Flat-knitted	Neo Durelna	Varitex	Haarlem (the Netherlands)	19%		24%	57%	
		Mediven® 550	Medi	Bayreuth (Germany)	26%	36%		38%	
		Euroform	Varodem®	Saint-Léger (Belgium)	32%		42%		26%

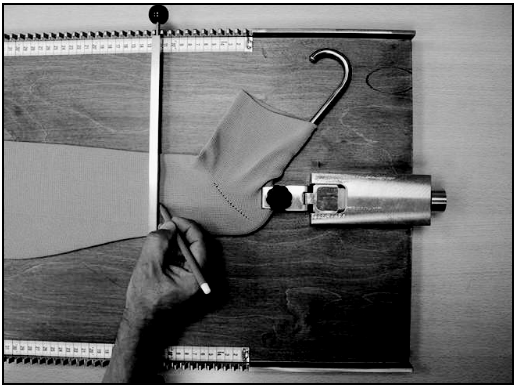


Figure 3 Marking board.

Figure 4 The Mettler PE360 scale.

Dynamic leg-segment model (Figure 2, chapter V)

A new dynamic leg-segment model based on a method with an air-filled drum approved by the CEN was developed to investigate the dynamic behavior of MECS.[6] The dynamic leg-segment model simulates the walking speed and walking pattern of the real leg during walking. This means the circumferential changes during walking and the amplitude of these changes. The model consists of four components:

1) A form wheel for simulating walking patterns. The circumference of the leg changes during walking, primarily as a result of the movement of the calf muscles. We previously analyzed these movements with regard to the gait cycle, amplitude and form of the signal. For this purpose healthy volunteers walked on a treadmill with mercury-filled rubber gauges around the leg at the B1 level. Changes in circumference were determined using strain-gauge plethysmography. In order to imitate these changes for our model, a form wheel was designed.

2) An air-pressure generator. This air-pressure generator (Posthumus Products, Haarlem, the Netherlands) is connected to the form wheel and can be adjusted for the frequency and the amplitude of the signal and provides the air-filled drum of the artificial leg-segment with precise pressure in such a way that the dynamic variation in circumference of the MECS equals 1 cm.

3) An artificial leg-segment consisting of an air-filled drum covered with a rubber skin. We used an air-filled drum with the same circumference as the leg-circumference at the B1 level (22 cm). The MECS is put over the leg-segment. The air-filled drum is connected with a TruWave pressure-transducer (Baxter Healthcare Corporation, Irvine, CA) to determine the air-pressure in the drum and thus the pressure exerted by the MECS. Changes in the circumference are registered with strain-gauge plethysmography.

4) The pressure and the changes in circumference were measured simultaneously and entered into a computer system: the Fysio Flex system, built at the instrumentation service unit of the University of Nijmegen, the Netherlands.

Dynamic stiffness index

The DSI was defined as the increase in pressure when the variation of circumference equals 1 cm at a frequency of 1 Hertz (1 Hertz equals 1 gait cycle per second). The DSI was then calculated.

Statistics

The DSI and corresponding standard deviation of the seventeen different brands of MECS were calculated. This was done by measuring each brand of MECS three times. SPSS 15.0 was used for statistical calculations. To establish the correlation between the dynamic stiffness index and the mass of MECS, Pearson correlation coefficients (*r*) were determined.

RESULTS

The results of the DSI at the B1 level and the mass of the 17 different brands of MECS are shown in Table 2. It can be seen that the dynamic stiffness index of a class II MECS ranged from 12.63 mmHg/cm at 1 Hz (Venotrain® Soft) to 28.09 mmHg/cm at 1 Hz (Venotrain® Strong). The DSI of the class III MECS ranged from 15.89 mmHg/cm at 1 Hz (Luxovar Prestige) to 28.61 mmHg/cm at 1 Hz. For both classes of MECS, the DSI was independent of the compression class and the type of knit. The mass of all seventeen MECS ranged from 1.65 mg/cm^2 to (Venotrain® Soft) to 5.33 mg/ cm^2 (Euroform). In both compression classes the flat-knitted MECS have a higher mass compared with the round-knitted MECS, although the results of the mass are in general higher in the class III MECS compared with the class II MECS.

Table 2 DSI at the B1 level and the mass of 17 different brands of MECS

Brands of MECS		*Mean DSI* ± SD [mmHg/cm]*	*Mass** [mg/cm^2]*	
Class II 23 to 32 mmH	Luxovar Prestige	15.37 ± 0.39	2.28	*Round-knitted*
	Mediven® Elegance	13.37 ± 0.39	1.83	
	Mediven® Plus	14.76 ± 0.67	2.14	
	Venotrain® micro	14.89 ± 1.01	1.82	
	Venotrain® Soft	12.63 ± 0.45	1.65	
	Venotrain® Strong	28.09 ± 1.43	3.55	
	Neo Duna	14.89 ± 0.38	3.62	*Flat-knitted*
	Flebosense	22.62 ± 0.59	3.72	
	Flebovar	20.45 ± 0.72	4.01	
	Mediven® 550	25.75 ± 0.98	5.19	
	Eurostar	20.32 ± 0.90	3.88	
Class III 34 to 46 mmHg	Luxovar Prestige	15.89 ± 0.23	2.52	*Round-knitted*
	Mediven® Forte	18.58 ± 1.85	3.27	
	Venotrain® Strong	28.61 ± 0.80	3.73	
	Neo Durelna	18.02 ± 0.42	4.78	*Flat-knitted*
	Mediven® 550	25.66 ± 1.16	4.99	
	Euroform	21.01 ± 1.08	5.33	

* Calculated from three replicate measurements per brand

** The mass of MECS was determined by weighing the B-B1 part and calculating mg/cm^2

Correlation

A strong and positive correlation coefficient ($r = 0.69$) with a clinical significance at the .01 level between the DSI and mass of all seventeen brands of MECS was observed, as shown in Figure 5. The correlation between the DSI and mass of the various subcategories of all seventeen brands is shown in Table 3.

Table 3 Correlation between the DSI and the mass of the various subcategories of all 17 brands of MECS.

Type of MECS	*Correlation*	*Level of significance*
All brands of MECS (n=17)	0.690	0.01
Round-knitted MECS (n=9)	0.923	0.01
Flat-knitted MECS (n=8)	0.533	n.s.*
MECS with natural rubber (n=5)	0.479	n.s.*
MECS with elasthane (n=12)	0.865	0.01

n.s. = not significant.

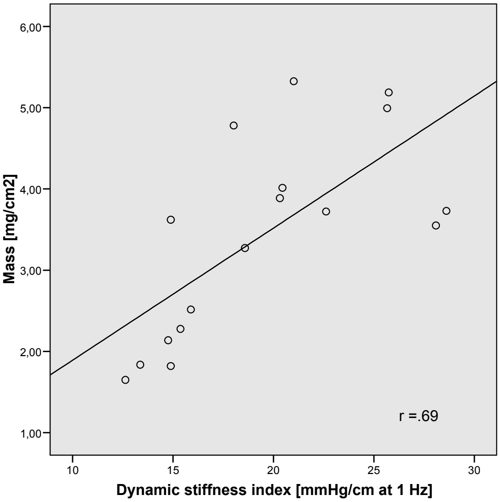


Figure 5 Correlation between the dynamic stiffness index at the B1 level and the mass of the 17 brands of medical elastic compression stockings.

DISCUSSION

Since compression therapy with MECS is still the cornerstone in the long-term treatment of chronic venous insufficiency, it is important to determine the compression as accurately as possible. MECS distinguish themselves by compression class (interface pressure), type of knit (flat-knitted or round-knitted), length and the fact that they are custom-made or ready-made. MECS consists of elastic threads, which are nearly all from the same manufacturer (DuPont). These threads are coated with cotton, synthetic or silk threads. The knitting process, which is nowadays nearly always automatic, is characterized by the type of stitch and the number of stitches per cm^2 (Figure 2). The physical characteristics of the knit of the MECS are: elasticity, hysteresis and stiffness. Following the years during, which only the (interface) pressure of MECS was studied, more interest has been focused on the stiffness. Investigations on this important characteristic of MECS have contributed in further understanding compression therapy.

Stiffness is defined as the increase in pressure when the circumference of the leg increases by 1 cm at the B level.[5] Compression therapy is mainly effective during walking and MECS behave differently under dynamic conditions. We introduced a new characteristic of MECS to determine its dynamic behavior as accurately as possible: the dynamic stiffness index (DSI).[6]

Stiffness depends on the material of the compression device. A strong negative correlation exists between the stiffness and the elasticity of compression material. The more inelastic the material, the higher the stiffness and vice versa. It has been shown that inelastic bandages have significantly higher pressure pulsations during walking compared with elastic bandages.[7,8] This so-called massaging phenomenon is one of the most important working mechanisms of MECS in chronic venous insufficiency. Stiffness can be increased by applying more layers of bandage, applying adhesive and cohesive bandages, and/or by applying two MECS over each other. In all of these situations, an increase in the mass of the compression materials occurs.

Since the composition of MECS with its threads and stitches is of such importance for the stiffness, we assumed that the weight per square centimeter (mass) of MECS may be a simple characteristic for indicating the stiffness.

This study clearly showed a significant positive correlation between the DSI and the mass of MECS. Natural rubber is more difficult to handle than synthetic threads. Normalization institutes such as the British Standards Institution (BSI) and the German Institute for Standardization (DIN) use protocols for testing textiles made from natural rubber. For example, after washing the textile, a relaxation period is required. However, our measurements closely resemble daily situation with no relaxation of the textile. This could explain the non-significant results in the flat-knitted and natural rubber MECS subcategories. Moreover, the number of these subcategories is low. The majority of the prescribed MECS is made of elasthane (synthetic rubber).

Determining the mass of MECS in contrast to the DSI is an easy and quick method for indicating the stiffness. In a previous study we showed a large variation in the stiffness independent of the compression class of MECS.[2] Therefore, knowledge on stiffness is essential when prescribing MECS. With the mass of MECS as an alternative characteristic for the stiffness, together with the interface pressure, two important characteristics for predicting the dynamic behavior of MECS are known. Both can be measured quickly and easily in daily practice.

We mentioned another important characteristic of MECS previously; the hysteresis. Hysteresis is the loss in recovered linear length of an elastic product when it recoils after exposure to repeated stretch-relaxation operations.[9] In case of MECS, hysteresis is caused by the internal frictional forces between the stitches and can be reflected in a force-elongation curve. Although, we know that hysteresis influences the behavior of MECS, this influence it is not easily measured. Hysteresis and its influence on MECS and the correlation between hysteresis and stiffness should be investigated in future studies. Manufacturers are challenged not only to mention the compression pressure of MECS on the packaging, but also the stiffness, or as we have shown the mass of the MECS!

REFERENCES

1. Van der Wegen-Franken CPM, Roest W, Tank B, Neumann HAM. Calculating the pressure and the stiffness in three different categories of class II medical elastic compression stockings. Dermatol Surg 2006; 32: 216-223.
2. Van der Wegen-Franken CPM, Mulder P, Tank B, Neumann HAM. Variation in the dynamic stiffness index of different types of medical elastic compression stockings. Phlebology 2008; 23: 77-84.
3. Van Geest AJ, Veraart JCJM, Nelemans P, Neumann HAM. The effect of medical elastic compression stockings with different slope values on edema. Derm Surg 2000; 26: 244-247.
4. Partsch H, Clark M, Bassez S, Benigni J-P, Becker F, Blazek V, Caprini J, Cornu-Thénard A, Häfner J, Flour M, Jünger M, Moffatt C, Neumann M. Measurement of lower leg compression in vivo: recommendations for the performance of measurements of interface pressure and stiffness. Dermatol Surg 2006; 32: 224-233.
5. European Committee for Standardization (CEN) Non-active medical devices. Working group 2 ENV 12718: European Prestandard ‘Medical compression hosiery’ CEN/TC205 Brussels: CEN, 2001.
6. Stolk R, van der Wegen-Franken CPM, Neumann HAM. A method for measuring the dynamic behavior of medical compression hosiery during walking. Dermatol Surg 2004; 30: 1-8.
7. Partsch H. Improvement of venous pumping function in chronic venous insufficiency by compression depending on pressure and material. VASA 1984; 13: 58-64.
8. Veraart JCJM, Daamen E, Neumann HAM. Short stretch versus elastic bandages: effect of time and walking. Phlebologie 1997; 26: 19-24.
9. Gardon-Mollard C, Ramelet AA. Compression therapy. Paris: Masson, 1999: 57.

Chapter VIII

Changes in the pressure and the dynamic stiffness index of medical elastic compression stockings during the day

Van der Wegen CPM, Tank B, Nijsten T, Neumann HAM. Changes in the pressure and the dynamic stiffness index of medical elastic compression stockings after having been worn for eight hours: a pilot study. Phlebology 2009; 24:31-37.

ABSTRACT

Objective: There is no data available at present on the changes in the exerted pressure together with the dynamic stiffness index (DSI) of medical elastic compression stockings (MECS). The objective of this pilot study was to measure the pressure and calculate the DSI of 12 different brands of MECS before and after having been worn for eight hours.

Methods: In all, 12 different commercially available brands of MECS that were divided into two categories (class II round-knitted and class II flat-knitted MECS) were tested. The pressure was measured, and the DSI of the MECS was first calculated at the B1 level before wearing in the morning and again eight hours after they had been worn. All laboratory measurements were performed using a newly developed dynamic leg-segment model.

Results: The pressure at the B1 level dropped significantly in all the 12 brands of MECS after having been worn for 8 hours, whereas the DSI remained unchanged.

Conclusions: The DSI of MECS reflects an important and a particularly consistent therapeutic effect. As the pressure drops during the day, the pressure amplitude or pulsations remain the same. The pressure drop may be due to fatigue of the elastic material. The DSI would therefore form a valuable indicator for prescribing the most effective MECS for the patient.

INTRODUCTION

The dynamic stiffness index (DSI) of medical elastic compression stockings (MECS) is an important parameter in understanding the efficacy of compression therapy. MECS with a low interface pressure may be more effective than expected only by the pressure they exert. This can be explained by the fact that a high DSI induces high pressure amplitudes during walking.[1] The effectiveness of ambulatory compression therapy mainly depends on the pressure peaks during walking. Due to these pressure peaks, venous drainage is ameliorated and edema is reduced.[2-4] Non-ambulatory patients do not have the benefit of the extra effect of compression, such as a high DSI. A well-known observation is the difficulties encountered in the treatment of dependency edema in patients confined to wheelchair with compression therapy despite the high interface pressure. This can be explained by the absence of pressure peaks because of immobility.

Manufacturers of MECS generally mention the pressure exerted at the ankle (B level), according to the European Committee of Standardization (CEN), but the DSI is not mentioned on the packaging. This lack of information hampers the prescriber in choosing the most effective MECS and in providing the most appropriate information to the patient. The quality of compression therapy is expected to improve when prescribers can base their choice on both the important characteristics of MECS; the interface pressure and the DSI.

It is known from the literature that interface pressure decreases with time.[5-8] For example, the interface pressure underneath short stretch bandage drops by 46% at the B level during the first three hours of wearing and with 37% of the original pressure remaining after 7 days.[9] This can be explained by a reduction in edema and the resulting loosening of the bandage. To our knowledge, no data are available on the behavior of the DSI or stiffness of MECS over a period of time. The aim of this study was to measure the pressure and calculate the DSI of 12 different commercially available brands of MECS before and after having been worn for eight hours. To clarify, it was not the intention of this study to evaluate the wear-and-tear of MECS after eight hours wear.

MATERIALS AND METHODS

Medical elastic compression stockings

We arbitrarily chose MECS of 12 different commercially available brands. All MECS belonged to compression class II (pressure at the ankle 23 to 32 mmHg). All the brands from the various manufacturers are shown in Table 1.They were divided into two categories based on the type of the knit: class II round-knitted MECS and class II flat-knitted MECS. In all experiments B1 leg-size of 22 cm was used. The manufacturers were not aware that the MECS were being tested.

Table 1 Brands and manufacturers of MECS.

Brand of MECS	*Compression class*	*Type of knit*	*Manufacturer*	*City (Country)*
Luxovar Prestige	II	Round-knitted	Varitex	Haarlem (the Netherlands)
Mediven® Elegance	II	Round-knitted	Medi	Bayreuth (Germany)
Mediven® Plus	II	Round-knitted	Medi	Bayreuth (Germany)
Venotrain® Micro	II	Round-knitted	Bauerfeind	Zeulenroda (Germany)
Venotrain® Soft	II	Round-knitted	Bauerfeind	Zeulenroda (Germany)
Venotrain® Strong	II	Round-knitted	Bauerfeind	Zeulenroda (Germany)
Neo Duna	II	Flat-knitted	Varitex	Haarlem (the Netherlands)
Flebosense	II	Flat-knitted	Varitex	Haarlem (the Netherlands)
Flebovar	II	Flat-knitted	Varitex	Haarlem (the Netherlands)
Mediven® 550	II	Flat-knitted	Medi	Bayreuth (Germany)
Eurostar	II	Flat-knitted	Varodem®	Saint-Léger (Belgium)
Juzo® 3022	II	Flat-knitted	Juzo	Aichach (Germany)

Measuring point

Measurements were performed at the B1 level, the point at which the Achilles tendon changes into the calf muscles. We chose the B1 level because the results of our previous study showed that the largest differences in the circumference during walking occurred at this level.[10]

Measurements

Of the 12 brands of MECS, the static pressure of each MECS was measured twice. The MECS were prepared in accordance with the CEN.[11] Prior to putting on the MECS in the morning, the pressure and the DSI were measured and calculated, respectively. Both these measurements were done using a new dynamic leg-segment model. Subsequently, the MECS were worn for eight hours during the normal daily activity and the measurements were repeated within 10 minutes after taking off the MECS. Each of the MECS was worn by the same investigator (CvdW).

Dynamic leg-segment model (Figure 2, chapter V)

A new dynamic leg-segment model based on a method with an air-filled drum approved by the CEN was developed to investigate the dynamic behavior of MECS.[10,11] The dynamic leg-segment model simulates the walking speed and walking pattern of the real leg during walking, which denotes the circumferential changes during walking and the amplitude of these changes. The model consists of four components:

1) A form wheel for simulating walking patterns. The circumference of the leg changes during walking, primarily as a result of the movement of the calf muscles. We previously analyzed these movements with regard to the gait cycle, amplitude and form of the signal. For this purpose healthy volunteers walked on a treadmill with mercury-filled rubber gauges around the leg at the B1 level. Changes in circumference were determined using strain-gauge plethysmography. In order to imitate these changes for our model, form wheel was designed.

2) An air-pressure generator. This air-pressure generator (Posthumus Products, Haarlem, the Netherlands) is connected to the form wheel, can be adjusted for the frequency and the amplitude of the signal and provides the air-filled drum of the artificial leg-segment with precise pressure in such a way that the dynamic variation in circumference of the MECS equals 1 cm.

3) An artificial leg-segment consisting of an air-filled drum covered with a rubber skin (Figure 3, chapter V). We used an air-filled drum with the same circumference as the leg-circumference at the B1 level (22 cm). The MECS is put over the leg-segment. The air-filled drum is connected with a TruWave pressure-transducer (Baxter Healthcare Corporation, Irvine, CA) to determine the air-pressure in the drum and thus, the pressure exerted by the MECS. Changes in the circumference are registered with strain-gauge plethysmography.

4) The pressure and the changes in circumference were measured simultaneously and entered into a computer system: the Fysio Flex system, built at the instrumentation service unit of the University of Nijmegen, the Netherlands. A registration curve of a dynamic measurement is shown in Figure 4, chapter V.

Dynamic stiffness index

A new definition for DSI, based on the current definition of stiffness as mentioned by the CEN, is introduced. DSI (mmHg/cm measured at 1Hz) is defined as the increase in pressure when the variation of circumference equals 1 cm at a frequency of 1 Hertz (equals 1 gait cycle per second). The DSI was then calculated. The variation in the DSI was 4% based on repeating the DSI measurement of the same MECS on ten consecutive days.

Statistics

To test for statistical significant differences in the continuous pressure and DSI data, a paired Student t-test was used. A two sided p-value <0.05 was considered as significant. SPSS software 12.0.1 for Windows was used. To assess the variability of the pressure and DSI measurements, one MECS was measured ten times on ten consecutive days to determine the variation in both measurements.

RESULTS

Pressure at the B1 level

According to the CEN, the exerted pressure at the B level for a class II MECS ranges from 23 to 32 mmHg. With regard to the pressure profile, the CEN defines residual pressure at the B1 level as 70 to 100% compression at the ankle.[11] This means that the value for class II MECS varies from 16 to 32 mmHg.
Of the 12 MECS studied, four MECS did not fulfill the CEN criteria of a class II MECS (one stocking was less than 70% of 23 mmHg and three MECS showed pressures above 32 mmHg; Table 2 and Figure 1). A statistical significant decrease in the pressure exerted by the MECS was noted after having been worn for eight hours (mean 26.4 mmHg [SD 7.8] vs 20.9 mmHg [SD 8.0]; $p<0.0001$). All MECS showed a pressure decrease after eight hours. The majority of the MECS (8/12) demonstrated a loss of 20% or more of pressure measured prior to use. Of the 8 MECS that were eligible for class II stockings, four MECS demonstrated pressures below 18.4 mmHg after having been worn for eight hours. Two out of three MECS

that showed high initial pressures were considered to show pressures within the limits of class II stockings. The variation in the pressure of the Mediven Plus was 4% (mean 20.52 [SD 0.91]).

Table 2 Pressures at B1 level of 12 different brands of class II MECS measured in the morning and after been worn for eight hours.

Brands of MECS		*Morning pressure [mmHg]*	*Evening pressure [mmHg]*	*Percentage of pressure drop [%]*	
Class II *23 to 32 mmHg*	Luxovar Prestige	24.14	19.29	20.1	*Round-knitted*
	Mediven® Elegance	21.9	15.48	29.3	
	Mediven® Plus	20.69	14.44	30.2	
	Venotrain® Micro	11.31	6.24	44.8	
	Venotrain® Soft	22.68	16.82	25.8	
	Venotrain® Strong	23.10	16.36	29.2	
	Neo Duna	38.47	34.89	9.3	*Flat-knitted*
	Flebosense	26.36	20.76	21.2	
	Flebovar	33.49	28.64	14.5	
	Mediven® 550	31.99	29.48	7.8	
	Eurostar	25.12	21.05	16.2	
	Juzo® 3022	37.82	27.46	27.4	

Dynamic Stiffness Index

There was no significant difference between the DSI of MECS before and after having been worn for eight hours (mean 20.4 [SD 4.5] vs 21.0 [SD 5.7]; p=0.31). (Table 3 and Figure 2) The mean difference in change in DSI is 0.54 [SD 1.74] and 9/12 showed less than 5% change after eight hours. The variation in the calculated DSI of the Mediven Plus was 4% (mean 17.3 [SD 0.65]). Although, there was a wide variation in the DSI of the round-knitted MECS as well as the flat-knitted MECS, the mean DSI of the flat-knitted MECS was higher than the mean DSI of the round-knitted MECS (mean 18.6 [SD 5.0] vs 22.2 [SD 3.5] in the morning and mean 19.6 [SD 7.0] vs 22.3 [SD 4.4] after eight hours).

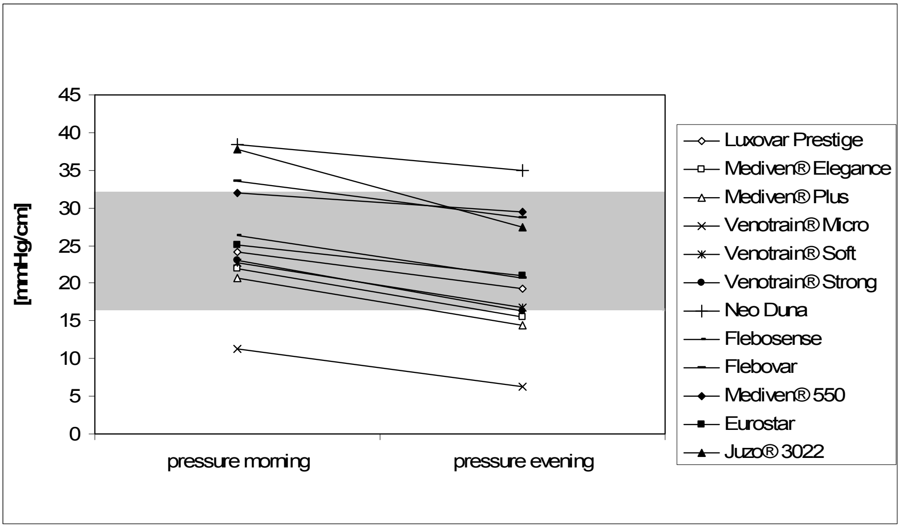


Figure 1 Change in pressure of 12 different brands of class II MECS after having been worn for eight hours. The shaded area in the graph shows the pressure range of a class II MECS according to the CEN at the B1 level.

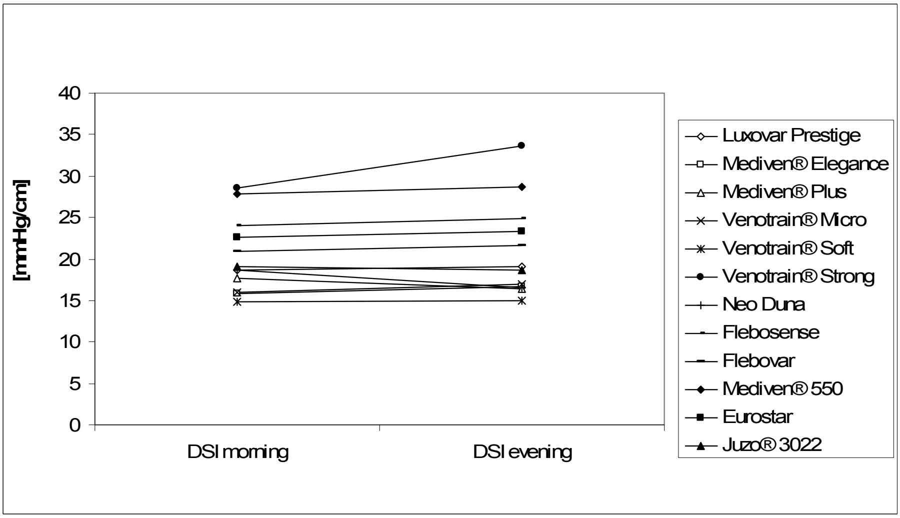


Figure 2 Change in DSI of 12 different brands of class II medical elastic compression stockings after having been worn for eight hours.

Table 3 Dynamic stiffness index of 12 different brands class II MECS calculated in the morning and after eight hours.

Brands of MECS		*Morning DSI [mmHg/cm]**	*Evening DSI [mmHg/cm]**	*Percentage of change [%]***	
Class II *23 to 32 mmHg*	Luxovar Prestige	18.63	19.1	+ 2.5	*Round-knitted*
	Mediven® Elegance	15.89	16.67	+ 4.9	
	Mediven® Plus	17.71	16.41	- 7.3	
	Venotrain® Micro	16.02	16.93	+ 5.7	
	Venotrain® Soft	14.85	14.98	+ 0.9	
	Venotrain® Strong	28.52	33.69	+ 18.1	
	Neo Duna	18.62	16.54	- 11.2	*Flat-knitted*
	Flebosense	24.09	24.89	+ 3.3	
	Flebovar	20.96	21.62	+ 3.1	
	Mediven® 550	27.87	28.65	+ 2.8	
	Eurostar	22.66	23.31	+ 2.9	
	Juzo® 3022	19.15	18.62	- 2.8	

* Measured at a frequency of 1 Hz.

** The variability of the DSI measurement was 4%. This was determined by measuring one brand of MECS ten times on ten consecutive days.

DISCUSSION

Medical elastic compression stockings (MECS) are designed to be worn during the daytime and especially during walking. They are most effective in combination with motion. The combination of compression and walking is known as ‘ambulatory compression therapy’. Ibegbuna et al. were the first authors who studied the hemodynamic effects of elastic compression during walking on a treadmill using air-plethysmography in order to reflect more accurately the daily physiologic conditions.[12] They showed that MECS significantly improved venous hemodynamics in patients with chronic venous insufficiency at different walking speeds.

Previous studies reported that the interface pressure under compression bandages decreased in time.[7] In recent years, more information on the influence of stiffness with regard to compression therapy has become available. The stiffness of MECS is responsible for pressure changes during walking. The higher the stiffness, the higher the pressure-amplitude.[10] This so-called massaging effect due to these pressure pulsations is extremely important in the treatment of leg edema, for blocking reflux and in reducing ambulatory venous hypertension. In the study by Partsch et al., stiffness was measured *in vivo* to assess the elasticity of compression material.[13] A clear distinction was shown between elastic, long stretch material and inelastic, short-stretch material. Inelastic bandages showed higher pressure peaks compared with elastic bandages and stockings. This means that the massaging effect for inelastic bandages is higher. In the present study only MECS were used to measure pressure and calculate the DSI.

Treatment or prevention of leg edema is considered to be the main aim of compression therapy in venous diseases. MECS with a high DSI are more effective in the treatment of venous diseases than those with a low DSI.[2-4]

To our knowledge, unlike studies on interface pressure, there are no reported studies in the literature on the changes in DSI of MECS after they have been worn for a period of time. It was the objective of this study, to assess the change(s) in the characteristics of MECS and not to determine the wear-and-tear of MECS after eight hours wear. We are aware that the elastic material of the MECS may return to the baseline (as is the case before wearing the MECS) after relaxation of the knit.

The results of the present pilot study showed that the pressure of all tested MECS had dropped significantly after having been worn for eight hours. Moreover, it has to be remarked that only one stocking per brand was measured. This was based on the results of our previous studies in which the same brands of MECS were investigated.[1] However, it is noticeable that eight of the 12 brands of MECS do not fulfill the criteria of a class II stocking at a certain point during the day. What does this mean in daily practice? In our opinion it is not the pressure but the pressure pulsations created by the stiffness of the MECS that is important. In contrast to the pressure alterations, the changes in DSI are not significant and are likely to be due to the variation in the measurement. This is also confirmed by the observation that the changes in DSI were noted to be either positive or negative. Interestingly, there were no differences between the round-knitted and the flat-knitted MECS as far as the change in DSI was concerned. We can explain the pressure drop on the basis of fatigue of the elastic materials. Since stiffness is a characteristic of all materials and particularly of elastic materials, its role can best be explained as the result of internal friction between the threads, stitches and the resistance against deformation. Since neither friction nor resistance is related to elasticity, stiffness will not alter during the eight hours of wear (day).

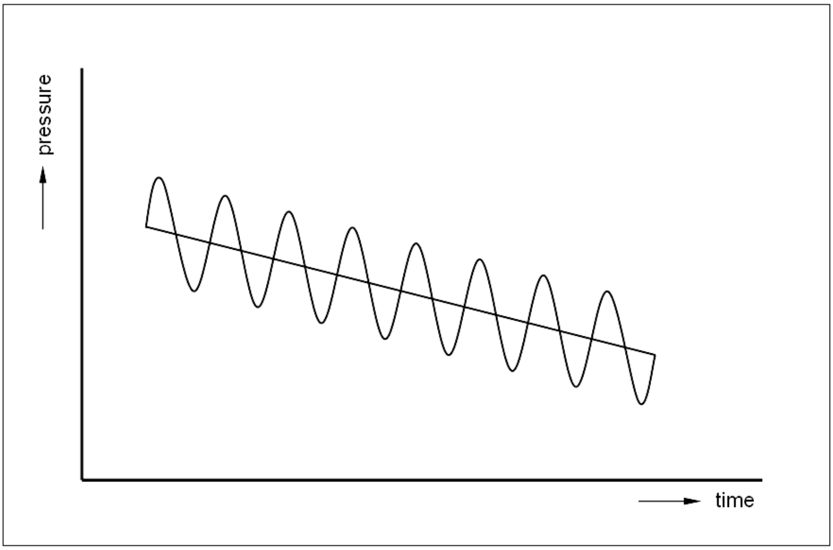


Figure 3 Example of a stocking that shows a decrease in pressure and continuous pressure pulsations (dynamic stiffness index) during the day.

This information on the stiffness of MECS is essential in daily practice. A correct combination of interface pressure, as indicated by the CEN compression classes and the DSI is essential for prescribing optimal ambulatory compression therapy with MECS. On the one hand, MECS with low DSI will not only lose the pressure they exert during daytime, but will also have a low walking pressure-amplitude. Patients who wear such MECS have a risk of developing edema during the day. Formation of edema is related to the severity of venous insufficiency. On the other hand, MECS with a medium pressure and high stiffness are perfectly able to prevent edema because of the high pressure amplitudes during walking.

The results reported here clearly shows that the DSI is highly important for sufficient compression during daytime. The natural decrease in interface pressure can be compensated with an appropriate DSI. An example of this is shown in Figure 3. Although the pressure drops at the and of the day below the minimum pressure allowed at the B1 level of a class II stocking, under ambulatory conditions, the pressure pulsations provide adequate pressures during most part of the day.

Therefore, we recommend prescribing MECS with a high DSI and high pressure to all patients with a strong tendency towards the formation of edema and in whom a constant high pressure is necessary, for instance in patients suffering from a post-thrombotic syndrome. In patients with mild venous problems, such as patients suffering from mild venous symptoms (C0-C1), prescription of MECS with a lower DSI and lower pressure will be sufficient. Thus, a physician can choose an appropriate MECS by choosing a higher stiffness for treating severe chronic venous insufficiency, without increasing the pressure. Further well designed clinical studies are warranted to establish whether this in fact is the case.

REFERENCES

1. Van der Wegen-Franken CPM, Mulder P, Tank B, Neumann HAM. Variation in the dynamic stiffness of different types of medical elastic compression stockings. Phlebology 2008; 23: 77-84.
2. Partsch H, Menzinger G, Mostbeck A. Inelastic leg compression is more effective to reduce deep venous refluxes than elastic bandages. Dermatol Surg 1999; 25: 695-700.
3. Van Geest AJ, Veraart JCJM, Nelemans P, Neumann HAM. The effect of medical elastic compression stockings with different slope values on oedema. Derm Surg 2000; 26: 244-247.
4. Häfner HM, Piche E, Jünger M. The ratio of working pressure to resting pressure under compression stockings: its significance for the development of venous perfusion in the legs. Phlebologie 2001; 30: 88-93.
5. Hafner J, Botonakis I, Burg G. A comparison of multilayer bandage systems during rest, exercise, and over 2 days of wear time. Arch Dermatol 2000; 136: 857-863.
6. Callam MJ, Haiart D, Farouk M. Effect of time and posture on pressure profiles obtained by three different types of compression. Phlebology 1991; 6: 79-84.
7. Veraart JCJM, Neumann HAM. Interface pressure measurements underneath elastic and non-elastic bandages. Phlebology Suppl 1996; 1: S2-S5.
8. Raj TB, Goddard M, Makin GS. How long do compression bandages maintain their pressure during ambulatory treatment of varicose veins? Br J Surg 1980; 67: 122-124.
9. Veraart JCJM, Daamen E, Neumann HAM. Short stretch versus elastic bandages: effect of time and walking. Phlebology 1997; 26: 19-24.
10. Stolk R, van der Wegen-Franken CPM, Neumann HAM. A method for measuring the dynamic behavior of medical compression hosiery during walking. Dermatol Surg 2004; 30: 1-8.
11. European Committee for Standardization (CEN) Non-active medical devices. Working group 2 ENV 12718: European Prestandard ‘Medical compression hosiery’ CEN/TC205 Brussels: CEN, 2001.
12. Ibegbuna V, Delis KT, Nicolaides AN, Aina O. Effect of elastic compression stockings on venous hemodynamics during walking. J Vasc Surg 2003; 37: 420-425.
13. Partsch H. The static stiffness: a simple method to assess the elastic property of compression material in vivo. Dermatol Surg 2005; 31: 625-630.

Chapter IX

Calculating the dynamic stiffness index of ulcer compression stockings

Van der Wegen-Franken CPM, Tank B, Neumann HAM. Calculating the dynamic stiffness index of ulcer compression stockings. *Submitted for puclication in Phlebologie.*

ABSTRACT

Background: Compression therapy is the most important part in the treatment of venous leg ulcers. This is generally achieved by means of compression bandages. There are lots of different types of bandages available and they are applied using different methods. Since application of compression bandages is time consuming and require trained personnel, the new ulcer stockings which are currently available on the market are most welcome by patients both from a health care as well as budget points of view.

Objective: To measure the pressure and to calculate the dynamic stiffness index of four different brands of commercially available ulcer compression stockings for treating leg ulcers in an attempt to determine their position within the currently offered compression therapy.

Methods: In all, four different brands of ulcer compression stockings were tested. The static pressure and the dynamic pressure pulsations at the B1 level were measured with a newly developed dynamic pressure-determining device. The dynamic stiffness index was then calculated.

Results: The pressure exerted by the combination of the day and the night stocking was the sum of both pressures and ranged from 14.34 mmHg (Venotrain® Ulcertec) to 38.06 mmHg (Mediven® Ulcer kit). The dynamic stiffness index of the combination of the day and the night stocking was approximately 21 mmHg. The dynamic stiffness index of the Tubulcus®, which consists of 1 stocking, was 15.3 mmHg.

Conclusion: It is not the high pressure that is required for the effectiveness of ulcer compression stockings, but it is the exertion of continuous pressure during the day and at night. The capillary filtration rate diminishes because of this continuous pressure and results in a decreased edema and a subsequent healing of the venous leg ulcer. This makes ulcer compression stockings good alternative for compression bandages in the treatment of venous leg ulcers.

INTRODUCTION

The value of compression in the treatment of venous leg ulcers has long been recognized and evidence can be found in literature.[1] Hippocrates described the use of compression bandages in the fourth century B.C. Various materials and methods of application have been developed and used to the present day. In 1676, Wiseman compressed the leg with a leather laced stocking in an attempt to heal leg ulcers.[2] Compression bandaging requires time and skills from health care workers and lots of different types of bandages and different methods of application exist. The disadvantage of all bandages is that objective control of application is difficult and that technique often depends on personal experience. This results in differences in interface pressure on the leg by various health care workers. Given that such differences can influence the healing rates of venous leg ulcers, routine practice by health care workers over a longer period of time is imperative.[3]

The use of medical elastic compression stockings (MECS) in case of venous ulceration has always been a contra-indication. This is partly, because of the controversy surrounding the effectiveness of elastic versus non-elastic compression. Nevertheless, several authors reported successful treatment of venous ulcers using MECS.[4,5] However, the problem with regular MECS is that they get dirty rather quickly and that wound dressings are difficult to fixate.

The expected increase in the elderly population in the next decades is also expected to impose severe financial burden on the health services. At present, 1% of the population suffers from a venous leg ulcer, which is a typical disease of the elderly requiring a simple and cheap solution.

The commercial arrival of the so-called ulcer compression stocking (UCS), which in most cases consists of an inner and an outer stocking, allow patients more freedom of movement, is easy to handle and cheap. An adequate pressure is not only obtained, but also maintained because these UCS require no special application techniques as compared with short stretch bandages.[6] Moreover, the ulcer is easier to examine.

Recently, several studies on the excellent effectiveness of UCS in the treatment of venous leg ulcers have been reported.[7,8,9] The working mechanism of compression therapy is known to depend on two main characteristics. These are the interface pressure which is known for all commercially available MECS including the UCS, and the dynamic stiffness index, which is unknown for most compression stockings.

The aim of the present study was to measure the pressure and to calculate the dynamic stiffness index of four different brands of commercially available UCS.

MATERIALS AND METHODS

Ulcer compression stockings

We arbitrarily chose four different brands of commercially available ulcer compression stockings (UCS). The UCS belonging to three brands (Jobst® Ulcercare, Mediven ® Ulcer Kit and Venotrain® Ulcertec) consisted of an inner and an outer stocking. The UCS belonging to the fourth brand (Tubulcus®) consisted of one stocking. In all experiments B1 leg-size of 22 cm was used. Inner and outer stockings were first measured separately and then they were measured together according to the manufacturer's instructions. From each of the four brands, three pairs from three different lots were tested (a total of 12 UCS). None of the manufacturers were aware that their UCS were being tested.

Measuring point

Measurements were performed at the B1 level according to the European Committee for Standardization (CEN).[10] This is the point at which the Achilles tendon changes into the calf muscles. We chose the B1 level because the results of our earlier study showed that the largest differences in the circumference during walking occurred at this level.[11] Measuring at this B1 level is also recommended and published by the international compression club (ICC).[12] The measuring points were marked after the UCS were put on in sitting position.

Dynamic leg-segment model (Figure 2, chapter V)

The new dynamic leg-segment model was described in details elsewhere, but the method is discussed briefly.[11] An artificial leg-segment model was developed to investigate the dynamic behavior of MECS. This model is based on an air-filled drum, which was developed by Stolk in 1988 for measuring the static pressures of MECS. The dynamic leg-segment model simulates the walking speed and walking pattern of the real leg during walking.

The dynamic leg-segment model consists of four components:

1) A form wheel for simulating walking patterns. The circumference of the leg changes during walking, primarily as a result of the movement of the calf muscles. In our previous measurements we analyzed these movements with regard to the gait

cycle, amplitude and form of the signal. For this purpose volunteers walked on a treadmill with mercury-filled rubber gauges around the leg at the B1 level. Changes in circumference were measured with strain-gauge plethysmography. A form wheel was designed to simulate these changes in our artificial leg-segment model.
2) An air-pressure generator. This is a specially designed air-pressure generator (Posthumus Products, Haarlem, the Netherlands) connected to the form wheel, which delivers a dynamic pressure signal to the air-filled drum. The air-pressure generator can be adjusted for the frequency and the amplitude of the signal and provides the air-filled drum of the artificial leg-segment with precise pressure in such a way that the dynamic variation in circumference of the UCS equals 1 cm.
3) An artificial leg-segment consisting of an air-filled drum covered with a rubber skin (Figure 3, chapter V). Several air-filled drums with different circumferences were available. We used an air-filled drum with the same circumference as the leg-circumference at the B1 level for measurements in this study. The UCS is put over the leg-segment with the corresponding B1 size. Changes in the circumference are registered with strain-gauge plethysmography. The pressure in the air-filled drum was recorded with a TruWave pressure-transducer (Baxter Healthcare Corporation, Irvine, CA).
4) The pressure and the changes in circumference were measured simultaneously and fed into a computer system: the Fysio Flex system, built at the instrumentation service unit of the University of Nijmegen, the Netherlands. A registration curve of a dynamic measurement is shown in Figure 4, chapter V.

Dynamic stiffness index

A new definition for the DSI, based on the current definition of stiffness as mentioned by the CEN[10], is as follows:
Dynamic stiffness index (DSI) = Increase in pressure when the variation of circumference equals 1 cm at a frequency of 1 Hertz* [mmHg/cm measured at 1Hz]
* 1Hertz = 1 gait cycle per second. The dynamic stiffness index was then calculated.

Statistics

The pressure at the B1 level and pressure pulsations in the four brands of UCS was measured. Inner and outer stockings were first measured separately and then they were measured together according to the manufacturer’s instructions. The mean pressure with standard deviation and dynamic stiffness index with standard deviation were calculated for each ulcer stocking.

RESULTS

Pressure at the B1 level

The mean pressures of the four brands of UCS at the B1 level are shown in Table 1. The UCS belonging to two brands (Jobst® Ulcercare and Venotrain® Ulcertec) exerted relative low pressure at night. The UCS belonging to the Mediven® Ulcer kit and Tubulcus® exerted a relative high pressure at night of approximately 20 mmHg. A similar pressure was exerted by all three extra day stockings. The pressure exerted by the combination of the day and the night stocking was the sum of both pressures according to the classic law of physics.

Dynamic Stiffness Index

The results of the DSI of the night stocking belonging to the Jobst® Ulcercare and the Mediven® Ulcer kit were noted to be close to each other. With the exception of Tubulcus®, the DSI of the combination of the day and the night stocking was approximately 21 mmHg. The DSI of the Rosidal® Mobil / Tubulcus® was consideraby lower (15.3 ± 0.47 mmHg). In contrast to the pressure, the DSI is a different characteristic and cannot be counted up like pressure.

Table 1 Mean pressure at B1 level in the four different brands of ulcer compression stockings.

	Mean pressure [mmHg] ± SD					
Brand	*Night stocking*		*Extra day stocking*		*Combination*	
Jobst® Ulcercare	5.13	± 0.97	11.53	± 0.61	19.86	± 3.1
Mediven® Ulcer kit	18.9	± 0.59	11.56	± 2.13	38.06	± 3.7
Venotrain® Ulcertec	< 5*	n.a.	9.05	± 0.86	14.34	± 1.15
Tubulcus® **	19.42	± 0.88	n.a.	n.a.	n.a.	n.a.

* The apparatus is not reliable for measuring below 5 mmHg

** Tubulcus® consists of one stocking that is worn day and night. This stocking is also sold as Rosidal® Mobil.

n.a. = not applicable

Table 2 Mean DSI at B1 level in the four different brands of ulcer compression stockings

	Mean DSI [mmHg] ± SD					
Brand	*Night stocking*		*Extra day stocking*		*Combination*	
Jobst® Ulcercare	12.94	± 0.67	17.49	± 1.04	20.4	± 1.18
Mediven® Ulcer kit	13.02	± 0.52	13.33	± 0.45	21.27	± 0.92
Venotrain® Ulcertec	<5*	n.a.	17.54	± 0.84	20.93	± 0.15
Tubulcus®**	15.3	± 0.47	n.a.	n.a.	n.a.	n.a.

* The apparatus is not reliable for measuring below 5 mmHg.

** Tubulcus® consists of one stocking that is worn day and night. This stocking is also sold as Rosidal® Mobil.

The DSI was calculated as follows: DSI = Δp/Δo (where Δp is the change in pressure and Δo the difference in circumference (equals 1cm) at a frequency of 1 Hertz.

n.a. = not applicable

DISCUSSION

Compression therapy is the most important component in the treatment of venous leg ulcers. Over the years various forms of bandages and bandaging have been used. Disadvantages of a compressive bandage are that trained personnel is required and personal hygiene is difficult because the bandages stay in place for several days. As an alternative for bandages one can use medical elastic compression stockings (MECS). Treatment of venous leg ulcers with MECS was already published by Cornu-Thénard in 1983 and again by Samson et al. in 1985.[4,5] Advantages are that the patients could put on the stockings themselves thus increasing the compliance. However, the high pressures exerted by the MECS are not tolerated very well during the night, and many elderly find it difficult to put on the MECS.

As an alternative solution, a two layer stocking was developed that consists of an inner stocking for the day and the night and an outer stocking that exerts additional pressure during the daytime. The two stockings together exert high pressure on the leg and can be put on individually quite easily. Jünger et al. reported that the interface pressure exerted by ulcer compression stockings (UCS) was comparable with that of short-stretch compression bandages applied by an experienced bandager immediately after application.[13] Similar results were reported by Häfner and

Eichner, and by Partsch and Partsch.[14,15] On the one hand, the efficacy of UCS relies on the exertion of relatively low pressures together with the dynamic stiffness index during the day, and on the other hand on the continuous low pressure at night that provides a reduction in the capillary filtration during supine position and probably has a strong edema preventive effect. It is known that the formation of edema is one of the most important inhibitory factors in wound healing, thus also for venous leg ulcers.[16]

It is known from the literature that the interface pressure of short-stretch compression bandages drop significantly (46%) at the ankle during the first 3 hours.[17] The relative low ambulant pressure with regard to the theoretical pressure of a compression bandage appears to be realistic. After all, the study by Jünger was a field study in which many nurses bandaged the legs of the patients. Therefore, it is reasonable to assume that the average pressure of the compression bandages is considerably lower both in the absolute sense as well as that achieved in time compared with the pressure achieved at an expertise center. It appears that the optimal compression therapy seems to be very effective in the treatment of venous leg ulcers. Unfortunately, we also know that applying this treatment broadly leads to a loss in its effectiveness. It also appeared in the study by van Gent et al. that compression pressure at an expertise center was significantly higher than those at other centers.[18] However, this is the everyday reality.

In the past one switched from bandaging at home to bandaging in a hospital in order to increase patient compliance.[19] Nowadays patient compliance can be increased by prescribing modern, effective, and patient-friendly products. Thereby, patients are self-conscious and want to participate actively in their treatment.

The results of this study showed that the ultimately achieved DSI was in the same range as that measured in our previous study in the majority of class II round-knitted MECS and several class II and III flat-knitted MECS.[20] The UCS because of this high DSI, exert maximum pressure at the desired level, namely at the B1 level with ambulant high pressure pulsations. These have a strong positive effect on the venous return.[21] Partsch already mentioned the major advantage of stockings over short stretch bandages.[6] Namely, stockings maintain a continuous and adequate pressure during the treatment. Ulcer compression stockings offer a good alternative for compression bandages in the treatment of venous leg ulcers. Although, various clinical studies on UCS have been reported, further evidence-based studies are warranted to establish their exact position in the treatment of venous leg ulcers.[7,8,9]

The following conclusions can be drawn from the results of this study. High pressure at night is apparently unnecessary because Venotrain exerts low pressure at night, whereas Tubulcus exerts high pressure at night. It appeared from the literature that both were equally effective in the healing of venous ulcers.[7,9] Adding more layers to a bandage or putting on several MECS, one above the other, will not only increase the pressure, but will also increase stiffness, mainly because of the changes in the friction between the layers and an increase in volume.[12]

The results of this study showed that a high DSI because of the combination of stockings produced adequate pressure pulsations during walking and that limited pressure at night was adequate to prevent the formation of edema. For the time being, it appears that UCS are the treatment of choice for venous leg ulcers in community health care, because hardly any training is required in their use. The specialized ulcer-clinics with extensive experience in ambulant compression therapy will continue to depend on high compression pressure for venous leg ulcers that are difficult to treat. In practice, it appears that much training is essential for effectively bandaging the legs of the patients.

REFERENCES

1. Cullum N, Nelson EA, Fletcher AW, Sheldon TA. Compression for venous leg ulcers. The Cochrane Database of Systematic Reviews 2001, Issue 2.
2. Hohlbaum GG. Zur Geschichte der Kompressionstherapie (I) Phlebol u Proktol 1987; 16: 241-255.
3. Hafner J, Lüthi W, Hänssle H, Kammerlander G, Burg G. Instruction of compression therapy by means of interface pressure measurement. Derm Surg 2000; 26: 481-487.
4. Cornu-Thenard A, Paris JP, Gironin D. Traitement ambulatoire des ulcères de jambe a l'aide d'une contention permanente par bas elastiques. Plébologie 1983 ; 36 : 77-88.
5. Samson RH, Scher LA, Veith FJ, Ascer F, Gupta SK. Compression stocking therapy for patients with chronic venous insufficiency (CVI). J Cardiovasc Surg 1985; 26.
6. Partsch H, Horakova MA. Compression stockings in treatment of lower leg venous ulcers. Wien Med Wochenschr 1994; 144(10-11): 242-249.
7. Jünger M, Partsch H, Ramelet AA, Zuccarelli F. Efficacy of a ready-made tubular compression device versus short-stretch compression bandages in the treatment of venous leg ulcers. Wounds 2004; 16: 313-320.
8. Häfner HM, Vollert B, Schlez A, Jünger. Kompressionsstrumpf zur Behandlung des venösen Ulcus cruris. Hautartz 2000; 51: 925-930.
9. Jünger M, Wollina U, Kohnen R, Rabe E. Efficacy and tolerability of an ulcer compression stocking for therapy of chronic venous ulcer compared with a below-knee compression bandage: results from a prospective, randomized, multicentre trial. Curr Med Res Opin 2004; 20(10): 1613-1623.
10. European Committee for Standardization (CEN) Non-active medical devices. Working group 2 ENV 12718: European Prestandard 'Medical compression hosiery' CEN/TC205 Brussels: CEN, 2001.
11. Stolk R, van der Wegen-Franken CPM, Neumann HAM. A method for measuring the dynamic behavior of medical compression hosiery during walking. Dermatol Surg 2004; 30: 1-8.
12. Partsch H, Clark M, Bassez S, Benigni J-P, Becker F, Blazek V, Caprini J, Cornu-Thénard A, Häfner J, Flour M, Jünger M, Moffatt C, Neumann M. Measurement of lower leg compression in vivo: recommendations for the performance of measurements of interface pressure and stiffness. Dermatol Surg 2006; 32: 224-233.
13. Jünger M, Häfner HM. Interface pressure under a ready made compression stocking developed for the treatment of venous ulcers over a period of six weeks. VASA 2003; 32: 87-90.
14. Häfner HM, Eichner M. Clinical validation of the interface pressure of different sizes of the ready-made tubular bandage Tubulcus®. Phlebologie 2002; 31: 108-111.
15. Partsch B, Partsch H. Compression stockings for treating venous leg ulcers : measurement of interface pressure under a new ulcer kit. Phlebology 2008; 23(1): 40-46.
16. Mortimer PS. Evaluation of lymphatic function: Abnormal lymph drainage in venous disease. Int Angiol 1995; 14(3) Suppl.1 : 32-35.
17. Veraart JCJM, Daamen E, Neumann HAM. Short stretch versus elastic bandages: effect of time and walking. Phlebology 1997; 26: 19-24.
18. Van Gent WB, Hop WC, van Praag MC, Mackaay AJ, de Boer EM, Wittens CH. Conservative versus surgical treatment of venous leg ulcers: A prospective, randomized, multicenter trial. J Vasc Surg 2006; 44: 563-571.
19. Sigg K. Beinleiden Entstehung und Behandlung. 2nd ed. Berlin Heidelberg New York: Springer-Verlag; 1976.

20. Van der Wegen-Franken CPM, Mulder P, Tank B, Neumann HAM. Variation in the dynamic stiffness of different types of medical elastic compression stockings. Phlebology 2008; 23: 77-84.
21. Partsch H, Menzinger G, Mostbeck A. Inelastic leg compression is more effective to reduce deep venous refluxes than elastic bandages. Dermatol Surg 1999; 25: 695-700.

Chapter X

Prescription of medical elastic compression stockings

Van der Wegen-Franken CPM, Tank B, Neumann HAM. Prescription of medical elastic compression stockings. *Submitted for publication in Dermatologic Surgery.*

INTRODUCTION

Many types of medical elastic compression stockings (MECS) have been developed over the years and today a wide variety is available on the market. For example, in the Netherlands more than 170 different types of MECS are available. This means that a physician should be aware of the differences between the types of MECS in order to achieve the best treatment possible. A lot of prescriptions for MECS only mention the compression class, which is determined by the pressure exerted on the leg. However, this parameter by itself is not enough to guarantee the optimum treatment for the patient. Besides the type of knit (flat-knitted or round-knitted), and the difference between the ready-made and the custom-made MECS, the material used for manufacturing and the knitting method contribute highly to its characteristics and its behavior. Each MECS has its own characteristics that are fundamental to their working mechanism. An overview on the different aspects that need to be considered when prescribing MECS is given in this chapter.

PRESCRIPTION OF MECS

The prescription of MECS is a very important part of phlebology practice and must be taken seriously because in many cases such as chronic venous insufficiency and lymphatic disease the stockings must be worn for life.[1,2] Furthermore, one must fully explain, instruct and motivate the patient at the beginning of the therapy in order to achieve optimum patient compliance and a successful treatment. Compliance is enhanced by prescribing well-fitting and optimally working MECS.

Step 1 Establishing the indication

The first step in prescribing MECS is establishing the indication. MECS may be used: a) as a prophylactic,[3,4] b) as compression support during phlebological interventions such as surgery, endovenous laser treatment and/or sclerotherapy, c) as maintenance therapy, particularly when other interventions are not possible. Even special MECS for leg ulcer treatment are available on the market.[5-8] MECS can replace compression bandages in most cases. However, bandaging or external pneumatic intermittent compression therapy is more effective in reducing edema.[9]
Major indications for compression therapy are shown in Table 1. Chronic venous insufficiency is the most common indication. The role of MECS in posttraumatic conditions such as fractures or 'coup de fouet' is highly underestimated from all non-venous indications.[10]

Table 1 Indications for compression therapy.

	Indications
Venous	Chronic venous insufficiency
	Leg ulcer treatment
	Deep venous thrombosis
	Superficial thrombophlebitis
	Addition to sclerotherapy, EVLT and surgery for varicose veins
Non-venous	Erysipelas
	Vasculitis
	Edema cruris; non-venous
	Posttraumatic conditions
	Lymphedema

The most important contraindication is arterial insufficiency with an ankle-brachial-index (ABI) of less than 0.6 or an ankle pressure of less than 65 mmHg. Contra-indications for compression therapy are shown in Table 2.

Table 2 Contraindications for compression therapy.

Arterial insufficiency: ankle-brachial index < 0.6 and/or ankle pressure < 65 mmHg
Totally occluded deep venous system (e.g. deep vein thrombosis without sufficient collaterals)
Severe congestive heart disease
Contact allergy to one of the components in the MECS or bandages
Undefined ulcers (e.g. carcinoma cutis)

Step 2 Selecting the MECS

Compression class (the amount of desired interface pressure)

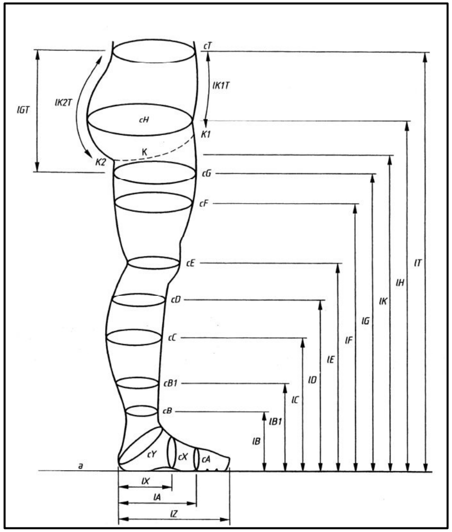
MECS are classified according to the pressure they exert at the B level. This is the ankle at the point of its minimum girth (Figure 1). Considerable variation exists in the designation of compression classes (Table 3).[11] The European Committee for Standardization (CEN) has prepared a standard with regard to MECS.[12] This European standard specifies the requirements for MECS. All available stockings are divided into five different compression classes (Table 4). The CEN remarks that class A reflects the practice in some European countries because MECS exerting a pressure of lower than 15 mmHg are prescribed in some countries. Class I can be divided into two subclasses: class I low (15-17 mmHg) and class I high (18-21 mmHg).

Low compression MECS (< 15 mmHg) are not automatically anti-thrombosis stockings (ATS). ATS are not included in the compression class classification system. In contrast with MECS, ATS do not have a graduated pressure profile from distal to proximal because they are designed mainly for wearing in bed. ATS exert a maximum pressure of 18 mmHg at the

B level. The CEN has prepared a pre-norm for ATS.[13] These types of stockings are not discussed in this chapter.

Pressure profile

The pressure profile of MECS can be defined as representing the compression exerted by the MECS along the leg and should decrease from distal to proximal in the same range as the decrease of the influence of gravitation to avoid damming.[14] The remaining pressure corresponds to the pressure at a defined measurement point and is expressed as a percentage of the ankle pressure, which is assumed to be 100%. The European pressure profile is shown in Figure 2 and the ranges of the pressure profiles are shown in Table 5. For example, the exerted pressure at the thigh (G level) can be as low as 20% of the pressure at the B level. A class II MECS with a pressure of 28 mmHg at the ankle has only 5.6 mmHg remaining at the thigh. It is obvious that these types of MECS have almost no effect on the upper leg.



a	sole of the foot at the heel
A	forefoot at the implantation of the toes
B	ankle at the point of its minimum girth
B1	point at which the Achilles tendon changes into the calf muscles
C	calf at its maximum girth
D	just below the tibial tuberosity
E	centre of the patella and over the back of the knee
F	between K and E
G	5 cm below K with the patient in the upright position
H	greatest lateral trochanteric projections of the buttock
K	centre point of the crutch
K1	level at the pubic symphysis
K2	level at the intra-gluteal fold
T	natural waistline
X	middle of the foot
Y	instep
Z	tip of toe

Figure 1 Measurement points, lengths and girths on the human leg. (ref CEN)

Table 3 Compression classes of MECS used in four different countries.

Compression class	USA	UK	France	Germany
I	15-20 (moderate)	14-17 (light)	10-15	18-21 (light)
II	20-30 (firm)	18-24 (medium)	15-20	23-32 (medium)
III	30-40 (extra firm)	25-35 (strong)	20-36	24-46 (strong)
IV	40+		> 36	>49 (very strong)

Values in mmHg, 1 mmHg = 1,333hPa. The values indicate the compression pressure exerted by the MECS at a hypothetical cylindrical ankle

Table 4 Compression classes according to the CEN.[12]

Compression class	*Compression at the ankle*	
	hPa **	mmHg
Ccl A light	13 to 19	10 to 14
Ccl I mild	20 to 28	15 to 21
Ccl II moderate	31 to 43	23 to 32
Ccl III strong	45 to 61	34 to 46
Ccl IV very strong	>65 a	>49

* The values indicate the compression pressure exerted by the MECS at a hypothetical cylindrical ankle

** 1 mmHg = 1.333 hPa (the official European pressure value is in hectopascals)

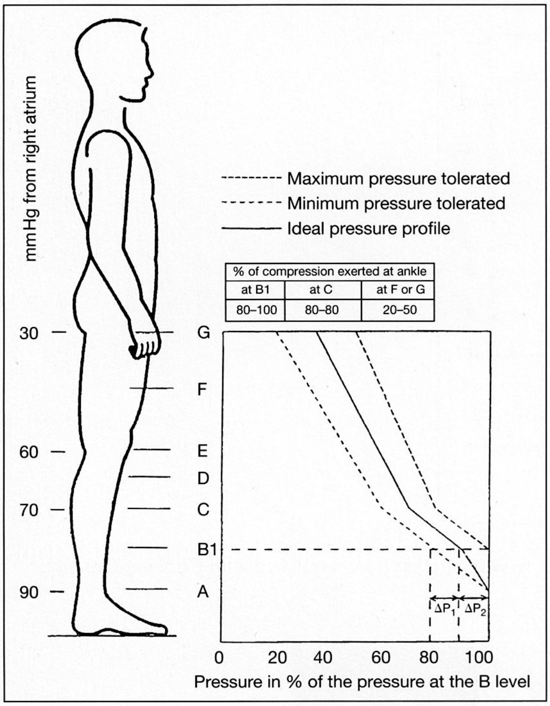


Figure 2 European pressure profile along the leg.

Table 5 Ranges of pressure profiles.

Compression class	*% of compression exerted at the ankle*		
	at B1	at C and D	at F or G
Ccl A	70-100	50-80	20-60
Ccl I	70-100	50-80	20-60
Ccl II	70-100	50-80	20-50
Ccl III	70-100	50-80	20-40
Ccl IV	70-100	50-80	20-40

Fitting

Since ready-made MECS are mostly prescribed, fitting for a larger group of patients is only possible if a) the manufacturer produces different sizes, b) the MECS has a certain tolerance, which means that within a defined range of circumferences at the B level, for example B level 20 to 23 cm as mentioned in the size-table and c) the MECS exerts the desired compression.

The shape of the MECS is smaller than the leg circumference once it is knitted. A certain tension is required to elongate the MECS to the correct fitting size because they are elastic. MECS with a low stiffness generally have a large tolerance. This enables the manufacturer to produce MECS of a few sizes that will fit all patients. The tolerance of MECS is high because of low stiffness. However, low stiffness results in low pressure pulsations during walking. This type of MECS is less effective in preventing edema. This type of MECS is perfect in situations where interface pressure is the main aim, such as an additional compression treatment in sclerotherapy for varicose veins. In contrast, well-fitting high stiffness MECS are required for a high edema preventive effect in case of severe chronic venous insufficiency such as post-thrombotic syndrome. For this indication flat-knitted custom made MECS are preferred.

Flat-knitted versus round-knitted MECS

Generally, two different types of MECS are used: flat-knitted MECS with seam and round-knitted seamless ones. Both types can be ready-made or custom-made. Most custom-made stockings are flat-knitted because with this technique MECS with precise tension and circumference can be manufactured. Round knitted stockings, which are generally thinner, are cosmetically more acceptable to the patients. Changing the tension of the weft thread creates the size during the manufacture. Therefore, the pressure exerted by the round-knitted MECS is not as exact as that by the flat-knitted MECS. Round-knitted ready-made MECS are prescribed most frequently worldwide.

Stiffness

Besides the size and the pressure, stiffness is a parameter of MECS that is important in the daily practice. However, stiffness is not stated on the packaging in a standard way. Stiffness is defined as the increase in pressure at the B level, i.e. the ankle at the point of its minimum girth, when the circumference at the B level increases by 1 cm.[12] The circumference of the lower leg changes continuously during walking. The largest differences in the circumference occur at the B1 level.[15,16]

The elastic threads in MECS should adapt to these circumferential changes during walking with the same speed. The stiffness together with the hysteresis, which is the loss in recovered linear length of an elastic product after it has been subjected to repeated stretching and relaxation, will cause pressure pulsations.[17,18] The higher the stiffness, the higher the pressure pulsations. This so-called phenomenon of massaging effect is well known for compression bandages.[19,20] This is less known for MECS. Stiffness is important in prescribing MECS: relatively low compression MECS with high stiffness can replace high compression MECS as long as the patient is ambulant. For the mobile patient MECS with low compression are often more comfortable. It is also true that two thin low compression MECS can replace one high compression MECS, due to the fact that the pressure exerted by two MECS is equal to the sum of the pressures exerted by each of the MECS.[21] Moreover, two MECS worn over each other result in an increase in hysteresis and stiffness. Stiffness is independent of compression and not influenced by wearing the MECS.[22,23] This is in contrast with the pressure, which decreases during the day.[24] However, the stiffness is correlated with the mass of the MECS.

Ready-made or custom-made MECS

Several factors are important in choosing between ready-made and custom-made MECS. These are the leg size, the type of knit (flat-knitted or round-knitted), the compression class and the stiffness. Normally, flat-knitted MECS are custom-made. For ready-made MECS tolerance and therefore stiffness has to be taken into consideration, because these stockings are available in all pressure classes.

Length

MECS of various lengths can be manufactured. These are below-knee stockings, mid-thigh stockings, thigh stockings and panty stockings. Since the most important factor for venous return is the calf muscle pump and the most complications of chronic venous insufficiency are located in the lower third of the lower leg, below-knee stockings will suffice in most cases. Usually thigh stockings are used in the acute phase of a deep vein thrombosis as an additional treatment to sclerotherapy or surgery and in the treatment of lymphedema. One has to realize that thigh stockings will often have a low interface pressure at the thigh level because of the larger circumference at this level. Pregnant women often prefer panty stockings.

Co-morbidity

Co-morbidity should be considered in order to achieve optimum patient compliance. The most important problems are arterial insufficiency, arthritis, skin diseases and neuropathy. In case of arterial insufficiency MECS exerting low pressure should be prescribed. When patients are not able to put on the MECS, two MECS of a lower compression class can be worn over one another. Roughly, the pressure of two stockings worn over one another can be added together and the stiffness will increase.[21] In immobile patients MECS are less effective because of the lack of pressure pulsations during walking. Various topical creams or ointments may damage MECS. Patients are asked to use skin products in the evening for practical reasons. Patients with neuropathy are instructed to inspect their skin frequently.

Step III The prescription

Once the decision for MECS has been made, all aspects should be mentioned in the prescription, which must be as accurate as that for a drug. The ideal prescription should include at least:

- Indication
- Compression class
- Stiffness
- Type of knit; round-knitted or flat-knitted
- Length of the MECS
- Co-morbidity

Measuring

Once the indication for MECS has been determined and contraindications have been excluded, the MECS can be measured on the edema-free leg. This is usually done after the edema has been removed by means of compression bandages. All legs are measured at the official measuring points as shown in Figure 1. Measurements are often taken in a sitting- or supine position. Using a measuring board may be helpful. It is better to measure MECS in a standing position from a physiological point of view.[25] The CEN prefers taking measurements at the patients' leg in a standing position.[12]

Evaluation

MECS are generally prescribed for maintenance therapy and therefore for life. It is important to check this therapy frequently, motivate the patient and encourage its compliance. The most important clinical parameter for appropriate MECS is the absence of edema. Patients should be examined late in the afternoon for this reason. It should be determined whether the MECS fit properly. This means that the stitches of the knit are evenly spaced at all levels and that there is an even elongation of the knit when the MECS is worn. MECS of a higher compression class and/or with a higher stiffness should be prescribed in case of edema. Another possibility is wearing two stockings over one another.

CONCLUSION

Compression therapy with MECS plays a main role in the treatment of phlebological diseases and non-venous edema. A careful selection from the large variety of available MECS should be made in order to achieve the most effective treatment. Clinical knowledge on indications and contraindications, working mechanism of compression therapy, the different materials used in the manufacture of MECS and their characteristics together with patient's features is absolutely essential. Despite many reported studies on MECS and compression therapy in general, evidence-based literature is sparse. Although medical knowledge for prescribing MECS is of utmost importance, one should not forget that 'practice makes perfect'!

REFERENCES

1. Neumann HAM. When therapy can only be…a stocking: prescription requirements for medical compression stockings. Scripta Phlebologica 1996; 4: 30-35.
2. Neumann HAM. Compression Therapy: European regulatory affairs. Phlebology 2000; 15: 182-7.
3. Partsch H, Winiger J, Lun B. Compression stockings reduce occupational swelling. J Derm Surg 2004; 30: 737-743.
4. Clarke M, Hopewell S, Juszczak E, Eisinga A, Kjeldstrøm M. Compression stockings for preventing deep vein thrombosis in airline passengers. Cochrane database of systematic reviews. 2006, Issue 2.
5. Häfner HM, Vollert B, Schlez A, Jünger. Kompressionsstrumpf zur Behandlung des venösen Ulcus cruris. Hautartz 2000; 51: 925-930.
6. Jünger M, Wollina U, Kohnen R, Rabe E. Efficacy and tolerability of an ulcer compression stocking for therapy of chronic venous ulcer compared with a below-knee compression bandage: results from a prospective, randomized, multicentre trial. Curr Med Res Opin 2004; 20(10): 1613-1623.
7. Partsch B, Partsch H. Compression stockings for treating venous leg ulcers : measurement of interface pressure under a new ulcer kit. Phlebology 2008; 23(1): 40-46.
8. Gardon-Mollard C. Tubular compression in the treatment of venous ulcers of the leg: A new graduated tubular device. Phlebology 2000; 15: 169-174.
9. Neumann HAM et al. Scripta phlebological
10. Coup de fouet. Derm Surg
11. Rabe E, Jünger M, Abel M, Achhammer I, Becker F, Cornu-Thenard A, Flour M, Hutchinson J, Issberner K, Moffatt C, Pannier F. Guidelines for clinical studies with compression devices in patients with venous disorders of the lower limb. Eur J Vasc Endovasc Surg 2008; 35: 494-500.
12. European Committee for Standardization (CEN) Non-active medical devices. Working group 2 ENV 12718: European prestandard 'Medical compression hosiery' CEN/TC205 Brussels; 2001.
13. European Committee for Standardization (CEN) Non-active medical devices. Working group 2 ENV 12719: European prestandard 'Medical thrombosis prophylaxis hosiery' CEN/TC205 Brussels; 2001.
14. Van Gerwen D. Pressure gradient tolerance in compression hosiery. Thesis 1994; Nijmegen: 55-77.
15. Stolk R, van der Wegen-Franken CPM, Neumann HAM. A method for measuring the dynamic behavior of medical compression hosiery during walking. Dermatol Surg 2004; 30: 729-736.
16. Blättler W, Lun B, Uhl JF, Bringer Y. Determinants of pressure exerted by medical compression stockings. Phlebologie 2007; 36: 237-244.
17. Gardon-Mollard C, Ramelet AA. Compression therapy. Paris: Masson, 1999: 57.
18. Van der Wegen-Franken CPM, Mulder P, Tank B, Neumann HAM. Variation in the dynamic stiffness index of different types of medical elastic compression stockings. Phlebology 2008; 23: 77-84.
19. Partsch H. Effects of compression therapy of leg veins dependent upon pressure and material properties. Vasomed 2006; 18: 46-50.
20. Veraart JCJM, Daamen E, Neumann HAM. Short stretch versus elastic bandages: effect of time and walking. Phlebologie 1997; 26: 19-24.
21. Cornu-Thénard A, Boivin P, Carpentier PH, Courtet F, Manager RD, Ngo P. Superimposed elastic stockings: pressure measurements. Dermatol Surg 2007; 33: 269-275.

22. Van der Wegen-Franken CPM, Roest W, Tank B, Neumann HAM. Calculating the pressure and the stiffness in three different categories of class II medical elastic compression stockings. Dermatol Surg 2006; 32: 216-223.
23. Van der Wegen-Franken CPM, Tank B, Nijsten T, Neumann HAM. Variation in the dynamic stiffness index of medical elastic compression stockings. Phlebology 2008; 23: 77-84.
24. Van der Wegen-Franken CPM, Tank B, Nijsten T, Neumann HAM. Changes in the pressure and the dynamic stiffness index of medical elastic compression stockings after having been worn for eight hours: a pilot study. Phlebology 2009; 24: 31-37.
25. Wienert W, Hansen R. Anmessen von medizinischen Kompressionsstrümpfen am liegenden oder stehenden Patienten? Phlebologie 1992; 21: 236-238.\

Chapter XI

Summary and general discussion

Medical elastic compression stockings have been successfully used to treat venous diseases over the years. The effectiveness of medical elastic compression stockings depends on the pressure they exert on the leg, particularly the ankle (B level) and the level of resistance to deformation. The latter is referred to as the elasticity coefficient or stiffness and may be clinically translated as the edema preventive effect. One of the pursued working mechanisms of medical elastic compression stockings is edema prevention. The current classification system of medical elastic compression stockings is based on the pressure they exert at the ankle without any consideration for stiffness.

A general overview of chronic venous disorders is given in chapter I. The clinical manifestations, the classification, the epidemiology and the risk factors of chronic venous diseases are all dealt with. The pathophysiology of chronic venous insufficiency and venous microangiopathy are dealt with in depth. The definitions and backgrounds of compression are provided followed by a historical overview of this therapy. Furthermore, the indications for compression therapy and its working mechanisms are given. Finally, three specific characteristics namely elasticity, stiffness and hysteresis of medical elastic compression stockings are described. The aims of the investigations that were pursued are given at the end of this chapter.

In chapter II, an overview of the published literature on stiffness of compression bandages and/or medical elastic compression stockings is presented. Literature on stiffness is sparse and available studies showed a large degree of methodological heterogeneity. Finally, 17 studies appeared to satisfy pre-established criteria and the literature could be divided into three categories: 1) studies in which a method for measuring stiffness was described, 2) studies that reported the effect of stiffness on various venous parameters, and 3) studies in which the effect of stiffness for the daily practice was described. Various methods for measuring stiffness were described. The results showed that the improvement in the hemodynamic parameters and the edema preventive effect increased with increasing stiffness.

The results of an investigation into the pressure and static stiffness of nine different brands of class II medical elastic compression stockings are presented in chapter III. A laboratory method approved by the European Committee for Standardization was used for the measurements. The medical elastic compression stockings were divided into three categories based on the type of the knit: flat-knitted custom-made, classic round-knitted ready-made and modern (ultra thin) round-knitted ready-made medical elastic compression stockings.

The results showed that flat-knitted stockings exerted higher pressures compared with the round-knitted stockings at the B level. A wide range of stiffness was observed within the different brands and within the three different categories.

A large variation in stiffness was observed in medical elastic compression stockings belonging to the same compression class. This variation may probably also explain the difference in the effectiveness of medical elastic compression stockings belonging to the same compression class. In our opinion, this means that the characteristic pressure alone is insufficient in the classification system of medical elastic compression stockings and that stiffness would be an important additional characteristic in refining this classification. This leads to a better prescription and thus higher effectiveness.

A new characteristic of medical elastic compression stockings and a method for measuring it is described in chapter IV. Different laboratory tests have been developed to determine the stiffness of medical elastic compression stockings. This concerns static measurements. It is obvious that measurements should be conducted dynamically considering that medical elastic compression stockings are effective during walking and movement (ambulant compression therapy). The dynamic leg-segment model was developed to measure the dynamic stiffness index (DSI) of medical elastic compression stockings and is based on a technique that is approved by the European Committee for Standardization. This dynamic leg-segment model can simulate the walking behavior and walking speed. The walking behavior of healthy volunteers on the treadmill was initially analyzed. Changes in the circumference of the leg were registered with standard strain-gauge plethysmography. The highest variations in the circumference during walking occurred at the B1 level. This corroborated the results of other investigations. The dynamic measurements showed that the dynamic stiffness index was higher than the static stiffness. It also appeared that only around 35% of the knitwear was stretched at the back at B1 level, whereas 65% remained unchanged. This phenomenon was imitated on the dynamic leg-segment model by placing a stiff sleeve that covered 65% of the area. This made it possible to optimally simulate the changes in the shape of the lower leg during walking in the in vitro measurements. With this in mind, one may expect an even higher dynamic stiffness index by knitting a non-elastic part at the back of a medical elastic compression stocking.

The results of an investigation into the dynamic stiffness index of 18 different brands of medical elastic compression stockings belonging to five categories are presented in chapter V. A wide range of dynamic stiffness indices was observed not only between all brands of stockings, but also within the five categories. The results showed that the dynamic stiffness index of medical elastic compression stockings is independent of the compression class and the type of knit (flat-knitted and round-knitted). One may expect a difference in the therapeutic effectiveness because of the variation in the dynamic stiffness index within the same compression class. It would be possible for the physician to prescribe the most suitable stockings for the individual patient by choosing an appropriate combination of the pressure and the dynamic stiffness index.

Correlation between the static and dynamic stiffness indices of medical elastic compression stockings is presented in chapter VI. Both the static and dynamic stiffness indices of medical elastic compression stockings are independent of the compression class and the type of knit (flat-knitted and round-knitted), similar to that in the previous studies. However, the difference in the effectiveness of medical elastic compression stockings cannot be explained on the basis of static stiffness considering that the differences in static stiffness are within the tolerance limits of manufacturing.

The dynamic stiffness indices were higher than the static stiffness indices, but a strong and positive correlation between the static stiffness index and the dynamic stiffness index was found. An explanation for this is the fact that stiffness is a material property of the knit and does not change under dynamic conditions. This linear correlation is sufficient for the manufacturers to only determine the static stiffness of the final product.

Correlation between the dynamic stiffness index and the mass of 17 different brands of medical elastic compression stockings is described in chapter VII. The aim of the study was to investigate whether there was a simpler and an easier way to determine a characteristic of medical elastic compression stockings that correlated with the dynamic stiffness index and thus would have a predictive value for the behavior of the stocking. It appeared from the literature and the results of our own studies that the material from which the stockings were manufactured was important for its working mechanism. The used threads would differ little from each other. The design of the knit or its mass determines the difference. A positive correlation between the dynamic stiffness index and the mass of medical elastic compression stockings was noted. We found a simple method to predict the dynamic behavior of the knit considering that the mass is easy to determine, whereas calculating the dynamic stiffness index is complex.

The results of an investigation into the pressure and the dynamic stiffness index of 12 different brands of medical elastic compression stockings in the morning and after been worn for eight hours are described in chapter VIII. It is known that the interface pressure under compression bandages decreases in time. There is already a statistically significant decrease after three hours. An explanation for this is the fatigue of the elastic materials. It appeared from the results of our pilot study that there was a significant decrease in the pressure after eight hours. The dynamic stiffness index remained almost the same and showed no significant difference. The observed differences in dynamic stiffness index were attributed to the variation in the measurement. Although the pressure decreased, the constant dynamic stiffness index and thereby the generated pressure pulsations provided adequate (therapeutic) pressures during the day.

The pressure and the dynamic stiffness index of four different brands of ulcer compression stockings for treating leg ulcers were investigated in the study described in chapter IX. An insight into the pressure and the stiffness is important for an explanation on the therapeutic effect because this type of stocking is new and earlier investigations showed that ulcer compression stockings are effective.
Compression therapy is highly important in the treatment of venous leg ulcers. Ulcer compression stockings have been developed in recent years because compression bandaging is time consuming and requires trained personnel. From the four brands of ulcer compression stockings used in this study, three brands consisted of an inner and an outer stocking and one brand consisted of a single stocking.
The dynamic stiffness index of the ulcer compression stockings corresponded with the dynamic stiffness index of most of the class II round-knitted medical elastic compression stockings or with the dynamic stiffness of a number of class II and class III flat-knitted stockings as noted from the results of the study described in chapter V. It is not the high pressure, but the continuous low pressure during the night and the high stiffness to generate adequate pressure pulsations that is required for the effectiveness of ulcer compression stockings. They are a good alternative for the compression bandages in the treatment of venous leg ulcers.

Finally, in chapter X, various aspects that are important in the prescription and the appropriate measurements of medical elastic compression stockings are described. The first step is establishing the indication. The indications and the contra-indications that are present and the type of therapy that is instituted: therapeutic, supportive of another treatment or prophylactic. The second step is selecting the medical elastic compression stocking. Various aspects of medical elastic compression stockings such as compression class, stiffness, type of knit (round-knitted or flat-knitted), ready-made or custom-made and the length that are important in the choice of a certain type of stocking are evaluated. Patient-dependent factors such as co-morbidity should also be considered. The next step is the prescription mentioning the above aspects. Stiffness has an additional value in the classification of medical elastic compression stockings. We advice manufacturers to mention both the pressure and the stiffness (static and / or dynamic) on the packaging. The chapter closes with recommendations concerning the check of medical elastic compression stockings.

The results of the investigations described in this thesis showed that the current classification system of medical elastic compression stockings based on the pressure exerted at the ankle (B level) is inadequate. Besides the pressure, the stiffness also plays a determining role in the choice of the most appropriate stocking. Therefore, the manufacturers of medical elastic compression stockings should mention the stiffness in addition to the pressure on the packaging. A new method to calculate the dynamic stiffness index of medical elastic compression stockings was introduced in this thesis. In our view, it is the most accurate measuring method that mimics the daily reality as closely as possible.

Various guidelines on measuring pressure and stiffness have already been published as a result of continuing interest on compression therapy. Future investigations into the various characteristics of medical elastic compression stockings and their clinical relevance should provide answers to the unsolved problems in this **‘therapia magna’** that have been used successfully over the centuries.

Chapter XII

Samenvatting en algemene discussie

Therapeutisch elastische kousen worden sinds jaren succesvol ingezet voor de behandeling van veneuze aandoeningen. De werkzaamheid van therapeutisch elastische kousen is afhankelijk van de druk die zij uitoefenen op het been, in het bijzonder op de enkel (B niveau), en daarnaast de mate waarin een kous weerstand biedt tegen vervorming. Dit laatste wordt de elasticiteitscoëfficiënt of stiffness genoemd en kan klinisch vertaald worden als het oedeem preventief effect. Eén van de nagestreefde werkingsmechanismen van therapeutisch elastische kousen is namelijk oedeempreventie. Het huidige classificatiesysteem van therapeutisch elastische kousen is gebaseerd op de druk die zij uitoefenen op de enkel. De stiffness wordt hierbij volledig buiten beschouwing gelaten.

In hoofdstuk I wordt een algemeen overzicht gegeven van veneuze aandoeningen met chronisch beloop. In het kort komen achtereenvolgens de kliniek, classificatie, epidemiologie en risicofactoren van chronische veneuze ziekten aan bod. Er wordt dieper ingegaan op de pathofysiologie van chronische veneuze insufficiëntie en veneuze microangiopathie. Definities en achtergronden van compressie worden gegeven, waarna een historisch overzicht van deze therapie volgt. Voorts wordt ingegaan op de indicaties voor compressietherapie en zijn werkingsmechanismen.
Tot slot worden drie specifieke karakteristieken van therapeutisch elastische kousen beschreven: elasticiteit, stiffness en hysteresis. Aan het eind van het hoofdstuk wordt het doel van het onderzoek beschreven.

In hoofdstuk II wordt een literatuuroverzicht gegeven van datgene wat gepubliceerd is op het gebied van stiffness van compressieverbanden en/of therapeutisch elastische kousen. Literatuur betreffende stiffness is spaarzaam en de voorhanden zijnde studies toonden methodologisch een grote heterogeniteit. Uiteindelijk bleken 17 studies te voldoen aan de vooraf gestelde criteria en kon de literatuur ingedeeld worden in drie categorieën: 1) studies waarin een methode om stiffness te meten werd beschreven, 2) studies die het effect van stiffness op diverse veneuze parameters meldden, en 3) studies die het effect van stiffness voor de dagelijkse praktijk beschreven. Diverse methoden om stiffness te meten werden beschreven. De resultaten toonden dat naarmate de stiffness hoger was, de verbetering van de hemodynamische parameters en het oedeem preventieve effect groter was.

In hoofdstuk III worden de resultaten gepresenteerd van een studie naar de druk en statische weerstandscoëfficiënt van negen verschillende klasse II therapeutisch elastische kousen. Hiervoor werd gebruik gemaakt van een door het Europese

Normalisatie Comité goedgekeurde laboratorium meetmethode. De therapeutisch elastische kousen konden over drie categorieën verdeeld worden: 1) vlakbrei maatwerkkousen, 2) klassieke rondbrei confectiekousen en 3) moderne extra dunne rondbrei confectiekousen.

De resultaten toonden dat vlakbrei kousen een hogere druk gaven op het B niveau vergeleken met rondbrei kousen. De stiffness liet een grote variatie zien, zowel tussen de verschillende typen kousen, maar ook binnen de drie categorieën.

Therapeutisch elastische kousen behorende tot eenzelfde drukklasse laten een grote variatie in stiffness zien. Deze variatie is waarschijnlijk ook de verklaring voor het verschil in effectiviteit van therapeutisch elastische kousen behorend tot eenzelfde drukklasse. Naar onze mening betekent dit dat de parameter druk alleen onvoldoende is voor de classificatie van therapeutisch elastische kousen en dat stiffness een belangrijke aanvullende karakteristiek is waardoor een verfijning van de classificatie mogelijk wordt. Dit zal leiden tot een beter voorschrijf gedrag en daarmee een hogere effectiviteit.

In hoofdstuk IV wordt een nieuwe karakteristiek van therapeutische elastische kousen en een methode om deze te meten geïntroduceerd. Er zijn verschillende laboratorium tests ontwikkeld om de stiffness van therapeutisch elastische kousen te bepalen. Het betreft hier statische metingen. Aangezien therapeutisch elastische kousen werkzaam zijn tijdens lopen en bewegen (ambulante compressie therapie) lijkt het voor de hand te liggen dynamisch te meten. Het dynamische model werd ontwikkeld om de dynamische stiffness index van therapeutisch elastische kousen te kunnen meten en is gebaseerd op een techniek die goedgekeurd is door het Europese Normalisatie Comité. Dit dynamische model kan het loopgedrag en de loopsnelheid simuleren. In eerste instantie werd het loopgedrag van gezonde vrijwilligers op de loopband geanalyseerd. Hierbij werd gebruik gemaakt van standaard kwik-rek plethysmografie om de omvangvariaties van het onderbeen te registreren. De grootste omvangvariatie tijdens lopen bevindt zich op het B1 niveau. Dit is conform de resultaten van andere onderzoeken. De dynamische metingen toonden aan dat de dynamische stiffness index vele malen hoger is dan de statische stiffness. Tevens bleek dat slechts circa 35% van het breiwerk op B1 niveau uitrekt aan de achterzijde en 65% rekt niet uit. Dit fenomeen werd op het dynamische model nagebootst met het plaatsen van een stevige koker die 65% van de omvang bedekte. Hierdoor is de in vitro meetopstelling in staat de vervorming van het onderbeen tijdens lopen goed te simuleren. Met dit gegeven kan men door aan de achterzijde van een

therapeutisch elastische kous een niet-elastisch stuk in te breien een nog hogere dynamische stiffness index verwachten.
In hoofdstuk V worden de resultaten gepresenteerd van een studie naar de dynamische stiffness index van 18 verschillende typen therapeutisch elastische kousen, verdeeld over vijf categorieën. Hierin wordt duidelijk dat de dynamische stiffness index een grote variatie toont zowel tussen de verschillende typen kousen, maar ook binnen de vijf categorieën. De resultaten laten zien dat de dynamische stiffness index onafhankelijk is van de drukklasse en het type breiwerk (vlakbrei en rondbrei). Men kan met de variatie in dynamische stiffness index binnen eenzelfde drukklasse een verschil in therapeutisch effect verwachten. Door een goede combinatie van druk en dynamische stiffness index te kiezen zal het voor de arts mogelijk zijn een meer op de individuele patiënt aangepaste kous voor te schrijven.

Hoofdstuk VI geeft de correlatie tussen de statische en dynamische stiffness indices van therapeutisch elastische kousen weer. Zowel de statische als dynamische stiffness is onafhankelijk van de drukklasse en het type breiwerk (vlakbrei en rondbrei), zoals ook uit voorgaande studies bleek. Op grond van de statische stiffness is echter niet het verschil in effectiviteit te verklaren, aangezien de verschillen in statische stiffness binnen de tolerantie van de productie van kousen vallen.
De dynamische stiffness index is vele malen hoger dan de statische stiffness, maar er is wel een sterke en positieve correlatie tussen de statische en dynamische stiffness. Een verklaring hiervoor is het feit dat de stiffness een materiaaleigenschap is van het breiwerk en dit verandert niet onder dynamische omstandigheden. Deze lineaire correlatie biedt de fabrikant de mogelijkheid om bij de eindcontrole van zijn product alleen de statische stiffness te bepalen.

In hoofdstuk VII wordt de correlatie tussen de dynamische stiffness index en de massa van 17 verschillende typen therapeutisch elastische kousen weergegeven. Het doel van dit onderzoek was om te kijken of er een simpeler en makkelijker te bepalen karakteristiek van therapeutisch elastische kousen bestaat die gecorreleerd is met de dynamische stiffness index en dus ook een voorspellende waarde heeft voor het gedrag van de kous. Uit de literatuur en onze eigen studies is gebleken dat het materiaal van kousen belangrijk is voor zijn effectiviteit. De gebruikte draden zullen weinig van elkaar verschillen. Het ontwerp van het breiwerk of de massa van het breiwerk bepaalt het verschil. Er is een positieve correlatie aangetoond tussen de dynamische stiffness index en de massa van therapeutisch elastische kousen.

Aangezien de massa heel eenvoudig te meten is en het bepalen van de dynamische stiffness index complex is, hebben wij een eenvoudige techniek gevonden om van een breiwerk het dynamische gedrag te voorspellen.

Hoofdstuk VIII laat de resultaten zien van een onderzoek naar de druk en dynamische stiffness index van 12 verschillende typen therapeutisch elastische kousen aan het begin van de dag en nadat ze acht uur gedragen zijn.
Het is bekend dat de druk onder een compressief verband na verloop van tijd afneemt. Er is al een statistisch significante afname na drie uur. Een verklaring hiervoor is de moeheid van het elastische materiaal. In dit pilot-onderzoek werd ook een significante afname van de druk na acht uur gevonden. De dynamische stiffness index bleef vrijwel gelijk en liet geen significant verschil zien. De gevonden verschillen in dynamische stiffness index waren toe te schrijven aan de variatie van het meetinstrument. Ondanks de drukafname zorgt de constante dynamische stiffness index en de daardoor gegenereerde drukpulsaties voor adequate (therapeutische) drukken gedurende de gehele dag.

In hoofdstuk IX wordt de druk en de dynamische stiffness index van vier verschillende typen ulcus-kousen bepaald. Omdat dit type kous nieuw is en eerder onderzoek heeft aangetoond dat ulcus-kousen effectief zijn, is inzicht in druk en stiffness belangrijk om een therapeutische werking te kunnen verklaren.
Compressietherapie is het belangrijkste in de behandeling van het veneuze ulcus cruris. Omdat het aanleggen van een compressief verband arbeidsintensief is en ervaren personeel vereist, zijn er de afgelopen jaren zogenaamde ulcus-kousen ontwikkeld. Van de vier gebruikte typen ulcus-kousen in dit onderzoek, bestonden drie typen ulcus-kousen uit een onder- en bovenkous en één type bestond slechts uit één kous.
De dynamische stiffness index van de ulcus-kousen komt overeen met die van de meeste klasse II rondbrei kousen of een aantal klasse II en III vlakbrei kousen zoals aangetoond in de studie uit hoofdstuk V. Het is niet de hoge druk die vereist is voor de effectiviteit van ulcus-kousen, maar de combinatie van een continue lage druk tijdens de nacht en een voldoende hoge stiffness om adequate drukpulsaties tijdens lopen gedurende de dag te genereren. Ulcus-kousen zijn een goed alternatief voor het compressief verband in de behandeling van het veneuze ulcus cruris.

Tot slot worden in hoofdstuk X diverse aspecten besproken die van belang zijn bij het voorschrijven en het aanmeten van een therapeutisch elastische kous. De eerste stap is de indicatiestelling. Welke indicaties en contra-indicaties zijn er, en hoe wordt de behandeling ingezet: therapeutisch, ondersteunend aan een andere behandeling of profylactisch. De tweede stap is het typeren van de kous. Er wordt ingegaan op de diverse aspecten van therapeutisch elastische kousen die van belang zijn voor de keuze voor een bepaalde kous bij de individuele patiënt: drukklasse, stiffness, type breiwerk (rondbrei of vlakbrei), confectie of maatwerk en de lengte van een kous. Er dient rekening gehouden te worden met patiëntafhankelijke factoren zoals co-morbiditeit. De volgende stap is het uitschrijven van een recept waarop de hierboven genoemde aspecten vermeld moeten worden. De stiffness heeft een meerwaarde bij de classificatie van therapeutisch elastische kousen. Vanuit klinisch oogpunt is het wenselijk dat fabrikanten naast de druk ook de stiffness (statisch en/of dynamisch) op de verpakking vermelden. Het hoofdstuk eindigt met adviezen voor de controle van kousen.

De resultaten van de studies in dit proefschrift hebben aangetoond dat het huidige classificatiesysteem naar druk op de enkel (B niveau) van therapeutisch elastische kousen ontoereikend is. Naast de druk speelt de stiffness een bepalende rol bij de keuze voor een kous. De fabrikant van therapeutisch elastische kousen zal naast de druk ook de stiffness op de verpakking moeten weergeven. In dit proefschrift werd een nieuwe meetmethode geïntroduceerd om de dynamische stiffness index van therapeutisch elastische kousen te meten. Deze in vitro meetmethode is naar onze mening de meest nauwkeurige die de dagelijkse praktijk zo goed mogelijk nabootst.
Met de toenemende interesse in compressietherapie en zijn karakteristieken zijn diverse richtlijnen over het meten van druk en stiffness gepubliceerd. Toekomstig onderzoek naar de diverse karakteristieken van therapeutisch elastische kousen en de klinische relevantie hiervan zal de resterende vraagstukken van deze **‘therapia magna’** die al eeuwen succesvol wordt toegepast moeten oplossen.

DANKWOORD

Velen hebben mij de afgelopen jaren direct of indirect geholpen en gesteund bij de verwezenlijking van dit proefschrift. Graag wil ik iedereen daarvoor hartelijk bedanken.

Professor Neumann, u weet als geen ander dat de start van mijn wetenschappelijke carrière niet zonder slag of stoot ging en bent degene die altijd vertrouwen in mij heeft gehad. Altijd en overal kon ik bij u terecht voor steun en advies. Op de momenten dat ik er zelf geen heil meer in zag, lukte het u steeds weer mij te inspireren en te motiveren. Ik bewonder u om uw kennis en ben trots door u te zijn opgeleid. Ik geloof dat het nu tijd is je Martino te noemen.

Bob Tank, ik wil je bedanken voor je wetenschappelijke begeleiding die mij in staat stelde om mijn proefschrift op een uiterst gestructureerde manier te voltooien. Jouw punctuele correcties van de Engelse taal hebben bijgedragen aan de leesbaarheid van dit proefschrift.

Een speciaal dankwoord aan *Ir. R. Stolk*. Beste meneer Stolk, zonder u geen proefschrift over de dynamische stiffness index, want u bent de echte Willie Wortel en het brein achter de apparatuur.

Rob Bot, bedankt voor je gastvrijheid in de fabriek, de onuitputtelijke discussies over kousen en natuurlijk alle gezellige etentjes die daar vaak mee samen hingen.

Carla Wester en Ed Wassing. Dank voor jullie geduld, precisie en hulp om mij in te wijden in de wereld van de kousenmetingen. Daar kwam ze weer met een tas vol kousen! Maar ging altijd weer tevreden naar huis met waardevolle data. En Ed, bedankt voor je mooie foto voor de kaft van dit boekje. Ik vind het prachtig.

Paul Mulder, Tamar Nijsten en Wim Roest, bedankt voor jullie hulp bij de statistiek.

Mark Oldekamp. Bedankt voor je inbreng in dit proefschrift en niet te vergeten voor je nuchtere kijk op kousen. We kunnen trots zijn op ons artikel. Ik weet niet of we geselecteerd worden voor die ene prijs, maar wat mij betreft hebben we al gewonnen.

Fransje, Ellen en Joris, mijn nieuwe dermatologiefamilie in ‘Hellimond’. Ik prijs me gelukkig met jullie als maten!

De stafleden, arts-assistenten en alle verpleegkundigen en medewerkers van de afdeling dermatologie in Maastricht, Rotterdam en Helmond dank ik hartelijk voor hun begrip, steun en interesse gedurende de afgelopen jaren.

Mijn paranimfen en vriendinnen. *Lieve Melanie en Sarah*, wat fijn dat jullie me willen bijstaan op zo’n belangrijke dag. Ik hoop dat we nog lang vriendinnen zullen zijn.

Anja, alweer een tijdje geleden stond ik als paranimf naast je. Nu heb ik de eer mijn proefschrift te verdedigen en maak jij onderdeel uit van mijn commissie. Dank voor je enthousiasme en inspiratie.

Lieve familie en vrienden. Bedankt voor jullie vriendschap, steun en interesse. Nu dit afgerond is wordt het tijd weer eens een ouderwets gezellige spelletjesavond te organiseren!

Lieve mama, lieve Bianca, ik weet dat jullie trots op me zijn. Ik ben evenzo trots op jullie. Bedankt voor jullie onvoorwaardelijke steun en vertrouwen. *Lieve papa,* ik weet niet hoe de ontvangst is daarboven, maar dit boekje is ook voor jou!

Tot slot mijn meest dierbare schatten *Mark en Julia*. Een dikke kus. Ik hou van jullie!

Karin

CURRICULUM VITAE

Catharina Petronella Maria Franken werd op 29 mei 1972 geboren te Bergen op Zoom. Ze groeide daar op en behaalde in 1990 haar VWO diploma aan het gymnasium Juvenaat Heilig Hart. In 1991 startte zij haar studie geneeskunde aan de rijksuniversiteit Limburg in Maastricht. Na het behalen van het artsexamen in 1997, werkte zij gedurende 7 maanden als AGNIO niet snijdende specialismen in het Franciscus ziekenhuis in Roosendaal. In 1998 keerde zij terug naar de afdeling dermatologie in het academisch ziekenhuis Maastricht om daar haar wetenschappelijke carrière te starten.

In juni 2001 startte zij de opleiding tot dermatoloog bij prof. Neumann in het academisch ziekenhuis Maastricht. Vanaf januari 2002 werd deze voortgezet in het Erasmus Medisch Centrum te Rotterdam. Na haar registratie als dermatoloog in 2006 bleef ze daar nog een aantal maanden werkzaam als staflid. In oktober 2006 maakte ze de overstap naar de periferie en werd lid van de maatschap dermatologie in het Elkerliek te Helmond.

Zij is sinds 2003 getrouwd met Mark van der Wegen en hebben samen een dochter, Julia. In Januari 2010 verwachten zij hun tweede kindje.

BIBLIOGRAPHY

International Journal references

Andersen KE, Franken CPM, Gad p, Larsen AM, Larsen JR, van Neer PAFA, Vuerstaek J, Wuite J, Neumann HAM. A randomized, controlled study to compare the effectiveness of two foam dressings in the management of lower leg ulcers. Ostomy Wound Management 2002; 48(8): 34-41.

Stolk R, van der Wegen-Franken CPM, Neumann HA. A method for measuring the dynamic behavior of medical compression hosiery during walking. Dermatol Surg 2004; 30(5): 729-736.

Van der Wegen-Franken K, Roest W, Tank B, Neumann M. Calculating the pressure and the stiffness in three different categories of class II medical elastic compression stockings. Dermatol Surg 2006; 32: 216-223.

Van der Wegen-Franken CPM, Tank B, Mulder P, Neumann HAM. Variation in the dynamic stiffness index of different types of medical elastic compression stockings. Phlebology 2008; 23: 77-84.

Van der Wegen-Franken CPM, Tank B, Neumann HAM. Correlation between the static stiffness and dynamic stiffness indices of medical elastic compression stockings. Dermatologic Surgery 2008; 34: 1477-1485.

Van der Wegen-Franken CPM, Tank B, Neumann HAM. Changes in the pressure and the dynamic stiffness index of medical elastic compression stockings after having been worn for eight hours: a pilot study. Phlebology 2009; 24: 31-37.

National journal references

Franken CPM, Neumann HAM. Vochtige versus droge wondbehandeling. De voordelen van occlusie. Pharmaceutisch weekblad 2001; 31: 1127-1132.

Franken CPM, Neumann HAM. State of the art. Moist versus dry wound treatment. Wondmilieu 2002; 1: 6-10.

Van der Wegen-Franken CPM. Het LEOPARD-syndroom. Nederlands Tijdschrift voor Dermatologie & Venereologie 2003; 13: 423-424.

Van der Wegen-Franken CPM, Neumann HAM. De dynamische stiffness index van therapeutische elastische kousen. Nederlands Tijdschrift voor Dermatologie & Venereologie 2006; 16: 15-17.

Van der Wegen-Franken CPM. Acroangiodermatitis. Nederlands Tijdschrift voor Dermatologie & Venereologie 2007; 17: 93-95.

Raes MPE, Nijsten TEC, van der Wegen-Franken CPM, Neumann HAM. Nederlandse consensus. Compressietherapie na flebologische ingrepen. Themanummer compressietherapie 2008; 3-5.

Chapters

Van Geest AJ, Franken CP, Neumann HA. Medical elastic compression stockings in the treatment of venous insufficiency. Curr Probl Dermatol 2003; 31: 98-107.