compression unravelled

jan schuren

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Compression Unravelled

Compressie Ontrafeld

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”Ulcers on the leg
form a very extensive
and important
class of diseases .....

..... the treatment of
such cases is generally
looked upon as an
inferior branch of
practice; an unpleasant
and inglorious task
where much labour
must be bestowed,
and little honour gained.”

1805 comment in:

The Inquirer.
What are the comparative advantages
of the different modes proposed for
the treatment of ulcerated legs?
Edinb Med Surg J 1805; 1: 187-193.

”Treatment of venous
leg ulceration is
associated with
a wide range of
challenges and
often uncertain
outcomes .....

..... these factors
contribute to
clinician feelings
of dissatisfaction,
frustration and
demotivation.”

2009 comment in:

Cullen GH, Phillips TJ.
Clinician’s perspectives
on the treatment of
venous leg ulceration.
Int Wound J 2009; 6: 367–378.

Table of content

Chapter 1

Introduction

”The remedy of which we are now speaking, namely, compression, proves so generally useful in the cure of ulcers, that after the inflammatory stage of sores is over, it ought in, perhaps, every instance to be employed. Cures may no doubt be effected by other methods; but I will venture to say, that in the most troublesome of all sores, habitual ulcers of the legs, more lasting cures may in general be obtained by a proper application of pressure, than by any other means with which practitioners are as yet acquainted.”

A statement from Benjamin Bell, a surgeon from Edinburgh, which can be found in his book ”A treatise on the theory and management of ulcers”, first published in 1778 (figure 1.1).

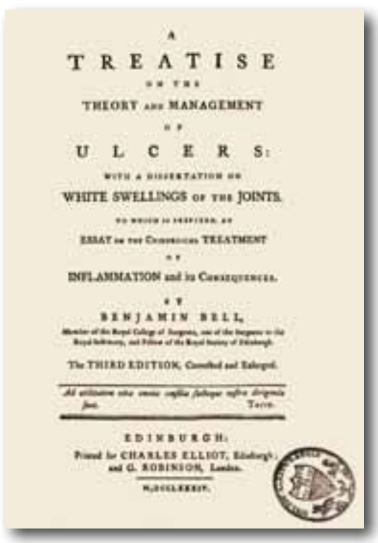

A
TREATISE
ON THE
THEORY AND MANAGEMENT
OF
ULCERS:
WITH A DISSERTATION ON
WHITE SWELLINGS OF THE JOINTS.
TO WHICH IS PREFIXED, AN
ESSAY ON THE CHIRURGICAL TREATMENT
OF
INFLAMMATION and its CONSEQUENCES.
BY
BENJAMIN BELL,
The THIRD EDITION, Corrected and Enlarged.
EDINBURGH:
Printed for CHARLES ELLIOT, Edinburgh; and G. ROBINSON, London.
M,DCCLXXXIV.

Figure 1.1: front page of Benjamin Bell’s book: A treatise on the theory and management of ulcers.

Bell continues: *”By means of a roller, compression can be made more directly on any particular part, than with the laced stocking; it is more conveniently applied too, and it generally gives less uneasiness to the patient. It is likewise more easily obtained: for the difficulty of fitting a laced stocking, with that exactness which this application requires, is so great, that very few tradesmen are capable of making it; whereas a roller may at all time be easily produced.”* [1].

In a lecture given in 1848, Critchett reminds his audience that the reason why ulcers are more frequently found in the lower extremity than in any other part of the body, are more difficult to heal and more liable to recur is on account of weight of the superincumbent column of blood weakening the vessels and impeding the circulation through the part. As a necessary consequence, he continued, the circulation of the lower limb should be placed on a par with the rest of the body and once this has been accomplished, there is no reason why these leg ulcers should not heal as readily and quickly as in any other part of the body [(2)].

In the first issue of the British Medical Journal published in 1857, the article ”On the treatment of ulcers of the leg without rest” can be found. It contains the text of a lecture from Thomas Hunt, held at the meeting of the Medical Society of London on December 13, 1856. In his lecture, Hunt describes the challenges of applying compression bandages.

”Modern surgery, therefore, is competent to the treatment of ulcerative diseases of the leg. There is, I believe, no essential defect in it, no necessity for anything new. Why then is it so notoriously unsuccessful? Mainly because the application of a bandage is looked upon as an easy and simple operation, which may safely be intrusted to the patient, the nurse, or the dresser; whereas I know of few operations in surgery more difficult to perform, or requiring more painstaking practice, than the application of a bandage to the human leg in such a manner as that every portion of the limb, from the toes to the knees (including especially the hollow between the heel and the inner and outer malleolus) shall receive equal and abiding support. In the careless manner in which a bandage is commonly applied, it often does more harm than good. If it be at all tighter round the leg, for instance, than round the foot, the foot and ankle will become swollen and oedematous; and on removing the bandage there will be seen deep tissue fissures where one edge of the bandage has been unduly tight, and a puffiness in other parts, which adds to the interruption of the circulation. And it is extremely difficult wholly to avoid this unequal pressure.” [(3)].

In the preface of a comprehensive manual on compression therapy published in 2007, one can read: *”Compression therapy has survived over centuries, mainly because of its impressive effects but leg ulcers still belong to the least respected chronic diseases and patients are often left alone suffering from their disabling disorders.”* [(4)].

In the introduction of a paper published in a South-African journal in 2008, is stated: *”Chronic venous leg ulcers are often associated with an ”emotional battlefield”, not only for the patient but also for the healthcare practitioner.”* [(5)].

Without changing the text of the Hunt’s lecture [(3)], it could have been the introduction of a thesis called ”compression unravelled”, written 155 years later. It seems that not much has changed in the treatment of leg ulcers since Hunt’s lecture.

In 1868, Gay explains that there is only one rule, which is universally applicable, namely that rest is an essential part of the treatment of venous leg ulcers with the foot elevated above the pelvis [(6)]. In 1878, Callender describes a method of treating leg ulcers with rubber bandages with just snugness enough not to slip down and to be applied in the morning before the patient rises from his bed [(7)]. According to the author, the limb is so increased in bulk by the increase of blood in the veins the moment the foot is put to the ground, that the bandage becomes of precisely the proper degree of tightness and, no matter how active the exercise or labour of the patient, it will remain in position all day. The bandage is to be removed when the patient undresses at night.

Paul Gerson Unna (figure 1.2), developed a technique of applying bandages impregnated with zinc paste [8]. The leg is covered with zinc paste after which strips of inelastic gauze-bandages are applied under full tension. This technique became very popular in Germany and although modified, nowadays the Unna boot is still widely used in the USA.

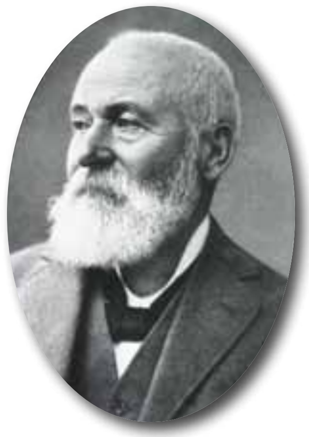


Figure 1.2: Paul Gerson Unna (1850-1929).

In 1930, Cutting summarises his experiences with the original Unna's paste boot, a method that, according to the author, eliminates the disadvantages of stockings and elastic bandages as it affords a better support [9]. Detailed application instructions are provided with highlighting the importance of strictly observing the technique. Even instructions on how the patient should be positioned during the application are given. One of the cardinal principles is that the finished boot confirms precisely to the shape of the leg and foot and that it allows the patient to dress and proceed with his regular duties.

In 1939, Baruch and co-workers report their ten-year' experience with leg ulcers for elderly, in which the compression therapy and the Unna paste boot play a crucial role [10]. They conclude their findings with the statement that it is of paramount importance that treatment must have as its prime objective to improve the circulation and that any local therapy is only of minor importance.

In 1958, Rivlin describes bandaging as an art and that: *"ideally, bandage technicians for varicose clinics should be specifically trained, as are orthopaedic plaster technicians at the moment"* [11]. With good reason, as Rivlin explains that the most inner layer of the system he uses, is applied in almost the same manner as a plaster-of-Paris bandage in that the ultimate aim is a smooth case of equal thickness throughout with the warning that any ruckle will be bandaged into the limb. Rivlin states that the use of bedrest has to be used only for patients who cannot walk and that unless there is continuous supervision by an enthusiastic physiotherapist who regards it as her duty to prevent her patient from stiffening up in bed, we are liable to end up with a healed ulcer in a desiccated mummy.

Regular bandaging however speeds up the healing process tremendously by taking up the slack left by the vanishing oedema and preventing its return in periods of inactivity. For that reason Rivlin believes that bandaging is essential but it is the ambulation and not the bandage that heals the ulcer.

In the hospital where I worked as an orthopaedic technician, patients that had been in a cast for longer than six weeks, received a zinc paste bandage to avoid joint swelling that was often seen after a prolonged period of immobilisation. The bandages stayed in place for two weeks. Most patients were active and post-immobilisation swelling was rarely observed. Another important observation was that slippage was hardly seen. For several reasons we started using these zinc-paste bandages in the treatment of leg ulcers and although no healing data were collected, these bandages were very satisfying, patients were mobile, while bandages were left in place for longer periods. In spite of the good results, the routine application of zinc paste bandages has some negatives. The material is messy, it takes a long time for the bandages to dry and it is an application that requires good bandaging skills.

In 1988, 3M introduced Scotchrap, a product unlike any other for immobilisation. After setting, it stayed semi-rigid; in other words flexible and resilient. The name of this product was later changed to Soft Cast, which more clearly described the properties of this unique product. While the material properties of Soft Cast were unique, the obvious indications were at the time limited. In 1989, 3M Netherlands asked some local orthopaedic technicians to investigate the treatment of lateral ankle sprains with Soft Cast compared with traditional taping and strapping techniques. During a pilot study of 250 patients with ankle lesions, other not so obvious indications for Soft Cast became apparent. The positive results of this study and the enthusiasm of the participants led to the introduction among the Dutch orthopaedic technicians [12]. I first saw Soft Cast in 1989, just one cured roll, and I knew that after fifteen years as an orthopaedic technician and twelve years as a football team trainer, with a strong belief in functional immobilisation and motion, Soft Cast was the product I had been searching for. New ideas and applications started developing in my mind and subsequently into my hospital practice. The door to a new approach in functional treatment was open. One of the consequences of this more functional approach in fracture care was that the use of zinc paste bandages for post cast immobilisation reduced significantly.

In 1990 I started working for 3M and in the first years in a new job, I met many orthopaedic technicians, orthopaedic and trauma surgeons in the Netherlands, Switzerland, Norway, the UK and Germany who helped to develop not only the various techniques but also a way of thinking which has contributed to a manual, a collection of ideas and techniques [13].

In 1998, Franks and Moffatt wrote in a letter to the editor of the British Medical Journal: *”we believe that, until manufacturers have to prove evidence of the effectiveness and cost-effectiveness of their products in a similar way to that required of the pharmaceutical industry, they will be content to continue producing ”me too” bandages, for which they know there is a market, rather than introducing innovations in bandage technology. Now seems to be the time to evaluate the methods of delivering this treatment, with the aim of avoiding undue waste and unnecessary suffering by the use of ineffective treatments.”* [14].

Working in an innovative environment also taught me to look at problems in a different way. The shortcomings of Soft Cast led to the development of modifications and some of the prototypes had the potential to be used as compression systems. These modifications also made me think of the shortcomings of the thousands of zinc paste bandages I had applied in clinical practice for many years. The so-called 15% culture at 3M, encourages every employee in a technical function to spend 15% of his/her time at an idea, allowed me to work on the development of a new compression system based on my clinical experience, not only with leg ulcer patients but more important, incorporating the years that I spent on optimising the functional treatment of fractures. It is not only in fracture care that function plays a crucial role in healing. Compression therapy supports the patient's functional activities to heal the ulcer.

In this thesis, an overview is provided on the ideas and research that has been performed in the development and commercialisation of the Coban 2 Layer compression systems (Coban 2 and Coban 2 Lite). That some of the content deals with research in fracture care should not be surprising. It is a logical consequence of what was written in 1958: *"ideally, bandage technicians for varicose clinics should be specifically trained, as are orthopaedic plaster technicians at the moment"* [(11).]

References

1. Bell B.
   On the effects of compression in the cure of ulcers.
   In: Bell B. A treatment on the theory and management of ulcers. Elliot & Robinson, Edinburgh, London 1778: 177-184.

2. Critchett G.
   Clinical lectures on the nature, causes and treatment of ulcers of the lower extremity.
   Lancet 1848; 52: 397-399.

3. Hunt T.
   On the treatment of ulcers of the leg without rest.
   BMJ 1857; 1(1): 4-6.

4. Partsch H.
   Foreword.
   In: Moffatt C. Compression therapy in practice. Wounds UK 2007: ix-x.

5. Naudé L.
   Chronic venous ulcers: compression therapy treating the underlying disease: a case study.
   Prof Nursing Today 2008; 12(1): 25-28.

6. Gay J.
   On varicosity and ulcer in the lower limb.
   Lancet 1868; 92: 495-496.

7. Callender GW.
Note on the treatment of ulcers and varicose veins by Martin's strong elastic bandage.
Lancet 1878; 112: 503.

8. Unna P.
Die Stauungsdermatosen des Unterschenkels und ihre Behandlung.
Dtsch Med Ztg 1885; 1-4, 13-17.

9. Cutting RA.
Chronic leg ulcers : treatment with Unna's paste boot.
Am J Surg 1930; 8: 743-749.

10. Baruch M, Glasser ST, Rosenthal J.
Ten years' experience with leg ulcers in the old age group.
Am J Surg 1939; 44: 601-607.

11. Rivlin S.
Gravitational leg ulcers in the elderly.
Lancet 1958; 271: 1363-1367.

12. Johannes EJ, Kaulesar Sukul DMKS, Spruit PJ, Putters JML.
Controlled trial of the semi-rigid bandage (Scotchrap) in patients with ankle ligament lesions.
Curr Med Res Opin 1993: 13: 154-162.

13. Schuren J.
Working with Soft Cast: a manual on semi-rigid immobilisation.
IF Publication Services, Düsseldorf 1994.

14. Franks PJ, Moffatt CJ.
Effectiveness and cost effectiveness of compression bandages should be shown.
BMJ 1998; 316: 860.

Chapter 2

Compression therapy: Coban 2 and Coban 2 Lite

2.1. Introduction

In 2010, I co-authored a 3M product monograph, which provides an overview on some aspects of compression therapy [1]. Parts of this monograph are included in this chapter.

2.2. The importance of compression therapy in healing venous leg ulcers

2.2.1. The costs are high

Venous leg ulcers are the most serious complication of venous hypertension. Epidemiological studies suggest that between 1-2% of the population will develop a venous ulcer at some time. These wounds have a high rate of recurrence [2] and are considered a major health care problem. The costs for treating venous leg ulcers to the US health care system alone are estimated to be $1 billion per year [3].

2.2.2. Venous leg ulcers reduce patient quality of life

Venous leg ulcers significantly reduce patient quality of life. In fact, 81% of patients with venous leg ulcers experience decreased mobility, and 50% report severely limited mobility. As a result, 68% of patients with impaired mobility experience fear, anger, depression and social isolation [3].

2.2.3. Compression therapy is proven effective

Compression therapy has been recorded from as early as the time of Hippocrates (460–377 BC) and is considered the standard of care for treating venous hypertension and venous ulceration [4]. The goal of compression therapy is to reduce oedema in the lower extremities by:

- reducing blood pressure in the superficial venous system;
- aiding venous return of blood to the heart by increasing the velocity of flow in the deep veins;
- reducing the pressure differences between the capillaries and the tissue to prevent backflow.

Compression therapy has been shown to improve the lives of patients by significantly reducing oedema, increasing mobility and reducing pain.

2.2.4. Challenges with current compression systems

2.2.4.1. Clinician-related challenges

- Clinicians have varying levels of experience applying compression bandages; training may be informal, inadequate or non-existent.
- Application techniques are different for each product.
- It can be difficult to attain the appropriate stretch (30-70%) for some elastic bandage systems.
- Clinicians may be concerned about potential for injury from bandages, and therefore, may not apply enough compression.
- Clinicians know their patients often poorly tolerate the systems because they are bulky, uncomfortable or painful.
- Application and removal of zinc paste bandages can be messy; application and removal of four-layer systems can be time consuming.
- Some patients require an unscheduled clinic visit between regularly scheduled visits, placing additional burden on the clinician and healthcare resources.

2.2.4.2. Patient-related challenges

- If a compression system is painful, hot or too bulky to wear with normal shoes, many patients remove the bandages and interrupt therapy.
- Some patients wait for their next clinic appointment without wearing any compression bandages.
- By removing or not wearing the bandages, patients prolong the healing of the ulcers.

2.3. Overview of the venous system

The venous system comprises several components that work together to return blood to the heart:

- veins (superficial, perforator and deep);
- one-way valves;
- calf and foot pump mechanisms.

The superficial veins act as a collection system returning blood via small perforator veins back to the heart through the deep veins, which lie within muscle and fascia. Veins have thin muscular walls that easily dilate to accommodate venous blood and one-way valves that prevent backflow (reflux). Venous circulation is assisted by the action of foot and calf muscles acting as ”pumps” squeezing the blood back to the heart via contraction (muscle systole) and relaxation (muscle diastole) [5].

2.3.1. Normal venous pressure

Blood pressure within the veins is usually low and is mainly determined by the weight of the blood column from the foot to the heart. Gravity, body position and movement affect venous pressure. When lying down, feet are level with the heart, so pressures are low, typically ranging between 0 and 10 mmHg. When sitting, pressures increase to around 40 mmHg. When standing, the pressures are higher, closer to 90 mmHg. Flexing foot or calf muscles propels the blood to the heart and the one-way valves prevent reflux.

2.3.2. Venous insufficiency
Damage to the veins or valves may lead to unrelieved high venous pressure. Over time, venous hypertension causes an upset in the normal balance that keeps fluids in the vessels, causing pooling of fluid in the lower extremities, which results in oedema [4]. If not managed, venous hypertension will ultimately result in venous leg ulcers.

2.4. Defining the ideal compression system

The ideal compression therapy system has been described in the 2003 European Wound Management Association (EWMA) Position Document [6] as one that:
- has proven clinical effectiveness;
- provides and maintains clinically effective levels of compression for at least one week during walking and at rest;
- enhances calf muscle pump function;
- is non-allergenic;
- is easy to apply;
- facilitates ease of training;
- is conformable and comfortable;
- does not slip;
- is durable.

2.4.1. The ideal physiology: giraffe skin
The distance between a giraffe's heart and feet is twice that of humans, giving it venous blood pressure twice as high as ours. Giraffes also have relatively smaller calf muscles, do not have moving or bending toes and their ankle joint movement is minimal. Yet giraffes do not experience venous hypertension and do not suffer from oedema. The secret is in the skin. Giraffe skin is extremely tough, fibrous and non-elastic. It creates a rigid sleeve that maximises the effect of every muscle movement, big and small, moving and resting, to optimise venous return [7,8]. These principles were applied when developing the Coban 2 layer compression systems by designing materials that work together to create a rigid sleeve, much like giraffe skin, to provide consistently the right amount of compression to reduce oedema.

2.5. Coban 2 layer compression systems: designed to provide ideal compression therapy

The Coban 2 Layer Compression Systems were engineered with intelligent compression dynamics to deliver ideal compression therapy for patients of all sizes, shapes and lifestyles.

2.5.1. Coban 2
The original Coban 2 is ideal for a majority of patients with venous leg ulcers, lymphoedema and other conditions where compression therapy is appropriate. This proprietary two-layer system is clinically proven to:
- provide sustained compression for up to 7 days [9];
- significantly reduce slippage and improve patients' daily living activities and physical symptoms [10];

- be preferred by patients for comfort [10];
- be easy to apply [11,15];
- enable patients to wear their own footwear and clothing [10].

2.5.2. Coban 2 Lite

Coban 2 Lite was developed to be more comfortable for patients less tolerant of compression therapy, including those who:

- have mixed aetiology with an ABPI greater than or equal to 0.5 [12];
- are new to compression, or where tolerance is not known;
- are frail;
- are less mobile.

Coban 2 Lite reduces the risk of tissue damage and necrosis on patients with an ABPI greater than or equal to 0.5.

2.6. Intelligent compression dynamics defined

In compression, dynamics refers to the difference between high and low working pressure points, reflecting intermittent changes in pressure caused by the patient's own muscle movement. Inelastic or rigid compression systems generate larger dynamics, or amplitudes, and therefore, more effective compression (see also chapter 3 on sub-bandage dynamics). With the development of Coban 2 and Coban 2 Lite, 3M advanced the science of compression therapy by designing materials engineered with intelligent compression dynamics to create a conformable, inelastic sleeve that stays in place and is comfortable to wear. These intelligent compression dynamics support the patient's muscle movements for effective venous return and reduction of oedema.

Amplitudes are unique to each person. The following illustrations simulate the amplitudes generated by applying Coban 2 and Coban 2 Lite. As illustrated in the figures 2.1 and 2.2, Coban 2 Lite provides working pressures similar to the original Coban 2, but with approximately 30% reduced resting pressure, making it a safe, effective, comfortable option for patients less tolerant of compression.

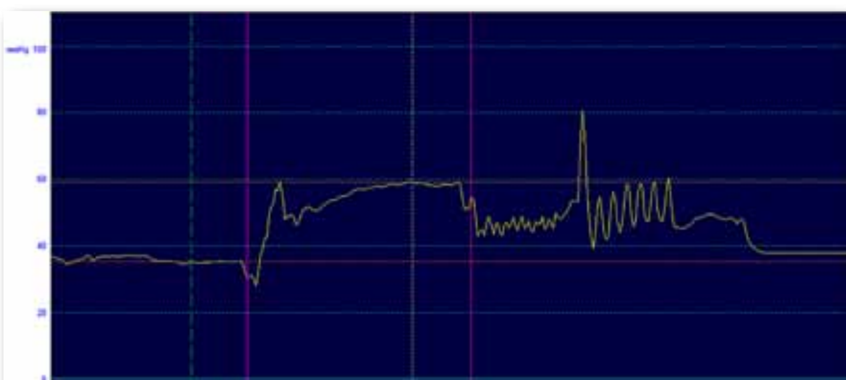


Figure 2.1: PicoPress measurements on B1 in Coban 2 in the supine and standing position and during ankle exercises (plantar and dorsal flexion).

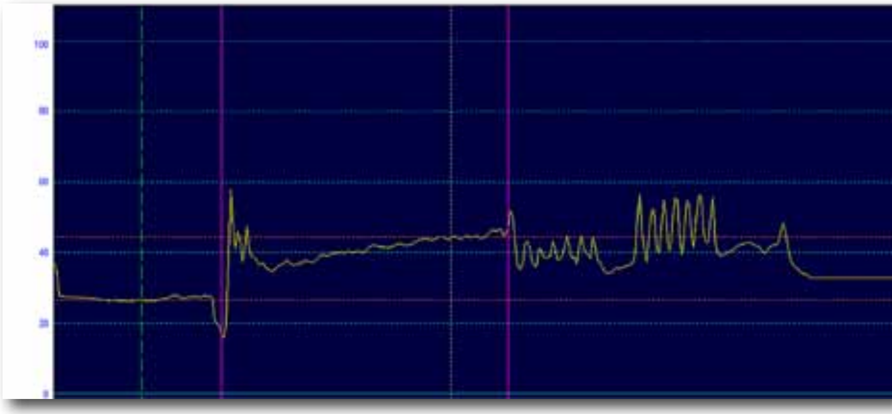


Figure 2.2: the same measurements as in figure 2.1 with the volunteer in Coban 2 Lite; the resting pressure is reduced with 30%, the stiffness and amplitudes show the same pattern as the ones in figure 2.1.

2.7. Materials science

True to 3M's rich heritage as an innovator and scientific leader, 3M scientists, with extensive research and new laboratory methods, offer new insights into the physics of compression to reduce lower extremity oedema. Contemporary research findings thus led 3M to engineer the unique and proprietary materials of Coban 2 and Coban 2 Lite, clinically proven to comfortably deliver sustained, therapeutic compression. The interlocking materials create an inelastic sleeve with the required stiffness to distribute muscle contraction forces equally beneath the bandage, supporting the muscle pumps to reduce oedema.

While compression therapy is not new, there is an emerging body of evidence providing a more contemporary understanding of the pathophysiology of compression. Research has identified that the effectiveness of a compression bandage can be predicted by the Static Stiffness Index (SSI). Bandages with an SSI greater than 10 provide enough support to keep the muscle contraction and relaxation forces inside the bandage (13). Many compression systems require multiple layers to achieve adequate stiffness, but as a result, impede a patient's mobility and quality of life by creating thick, bulky bandages that slip down.

In laboratory studies, other multi-layer systems can provide effective pressures immediately after application, but when patients become mobile the bandages slip and bunch at the ankle within a short period of time (14). This slippage is uncomfortable, even painful and often causes patients to remove the bandages, further reducing the potential for healing. Coban 2 and Coban 2 Lite were designed to stay in place to provide sustained compression during wear.

The inner comfort layer consists of a latex-free medical grade polyurethane foam laminated to a cohesive non-woven backing. When compressed, the foam grips the skin, and the non-woven backing provides a cohesive surface for the attachment of the outer compression layer. The proprietary interlocking materials cohere to each other, creating a rigid sleeve that conforms to the limb and reduces potential for uncomfortable slipping or bunching.

The materials used in other multi-layer compression systems or zinc paste bandages make them bulky, cumbersome and uncomfortable, often requiring patients to wear special footwear. Painful slippage can further impede patient mobility. Simple tasks like cleaning or walking the dog can become too difficult and patients resign themselves to inactivity to relieve the pressure. Coban 2 and Coban 2 Lite were designed to get patients ”back on their feet”. The materials used in the two-layer systems create a thin, lightweight, breathable sleeve enabling patients to wear their own shoes and clothing, so they can return to their regular daily activities.

The conformable, rigid sleeve generates sustained, therapeutic working pressures and comfortable resting pressures for effective, well-tolerated compression, regardless of activity level. Studies have shown that because Coban 2 Layer Compression Systems are more comfortable, patients are more likely to keep them on, increasing compliance and improving the potential for more effective treatment [9,14]. Recently a randomised controlled study was published in which patients with an active venous leg ulcer were treated with Coban 2 and an Unna boot, which is considered the prototype of inelastic bandages and consists of totally inelastic and inextensible materials [15]. The results reveal that both inelastic compression systems, applied with high pressure were extremely effective for ulcer healing. The rate of complete healing achieved within 12 weeks was 94% in the Coban 2 group and 92% in the Unna boot group. Both devices were equally comfortable, skin friendly and effective in reducing ulcer pain. In addition, the data indicate that Coban 2 showed a better capacity to maintain an effective pressure profile over time compared to the Unna boot.

2.8. Application techniques

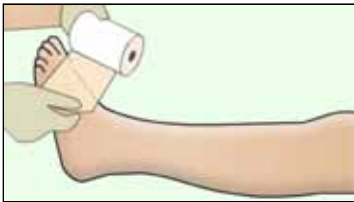
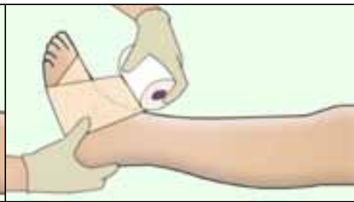
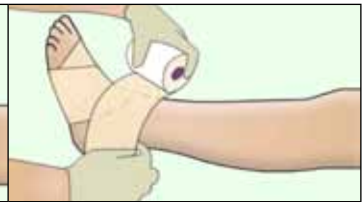
The application and removal instructions are the same for both Coban 2 and Coban 2 Lite compression systems. As in the next chapters much research is presented on the use of both systems, a detailed overview of the application is provided below.

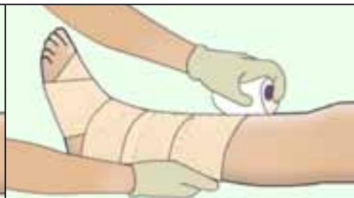
2.8.1. Basic application

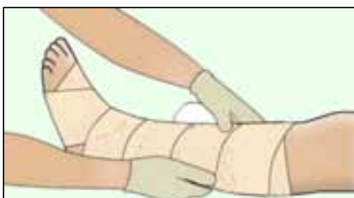
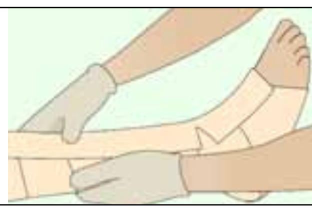
Coban 2 and Coban 2 Lite are developed in such a way that they provide a comfortable and tolerable resting pressure. Much of the comfort and tolerability depends on the properties of the material that is applied. After a material is applied, it wants to go back to its original relaxed position. The force with which this will happen, depends on the stretch of the material and how much of that stretch is used during the application. Both Coban 2 and Coban 2 Lite can and should be applied at full stretch as they are designed to. Laboratory tests taught that due to its design, Coban 2 Lite produces resting pressures that are 25-30% lower than Coban 2 while producing similar stiffness and amplitudes (figures 2.1 and 2.2).

2.8.1.1. The inner comfort layer

Apply this layer with the foam side against the skin, using just enough tension to conform to the shape of the leg with minimal overlap.

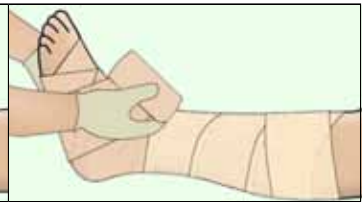
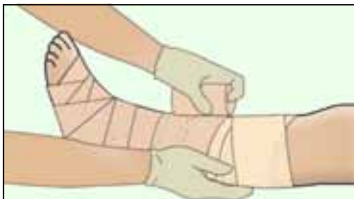
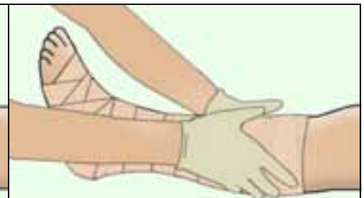
		
With the foot in a dorsiflexed position, start the application with a circular winding at the base of the toes, beginning at the fifth metatarsal head.	*The second circular winding should come across the top of the foot so that the middle of the bandage width approximately covers the articulating aspect of the ankle joint.*	*The next winding runs over the back of the heel. The posterior plantar surface of the foot is not completely covered.*

		
Please note that there may be a small fold of comfort layer material in the Achilles area. Guide this fold off the Achilles tendon and lay it into the adjacent convex area. This fold will lay down smoothly without causing pain or discomfort when covered by the compression layer.	*Proceed up the leg, to just below the fibular head, or the back of the knee with minimal overlap, using just enough tension to conform to the shape of the leg.*	*Cut off excess material.*

	
Light pressure applied at the end of the bandage ensures that it stays in place during application of the compression layer.	*For patients with very thin legs that have vulnerable bony prominences such as the tibial crest or the top of the foot, additional comfort and protection can be provided by cutting a piece of the comfort material and placing it over the top of the foot, running it up the leg to protect the tibial crest. At the articulating area, make a slit on each side of the strip to conform at the ankle. Gently press into place.*

2.8.1.2. The outer compression layer

Apply this layer at full stretch throughout its application. Hold the roll close to the foot and limb throughout the application for controlled, even compression.

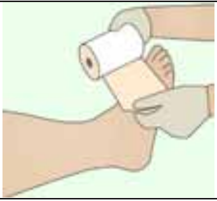
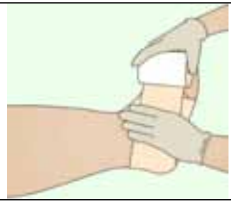
		
With the foot in a dorsiflexed position, start the application with a circular winding at the base of the toes, beginning at the fifth metatarsal head.	*The second circular winding should come across the top of the foot and around the back of the heel.*	*Using the "figure of eight" technique, bring the roll back over the top of the foot, across the bottom of the foot and back up to come around the back of the heel. Complete two or three figures of eight around the ankle, ensuring that the entire heel is covered.*
		
Proceed up the leg with 50% overlap to cover the entire inner comfort layer. Maintain consistent stretch throughout the process.	*End the wrap at the fibular head, or just below the back of the knee and even with the top edge of the comfort layer. Cut off any excess material.*	*Gently press and conform the entire surface of the application. This will ensure that the two layers will bond firmly together, which helps reduce slippage.*
		
If any gaps in the compression layer are detected, additional compression layer material may be applied at full stretch.	*Coban 2 and Coban 2 Lite may be removed with bandage scissors or by unwrapping.*	

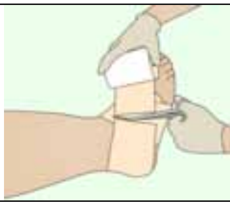
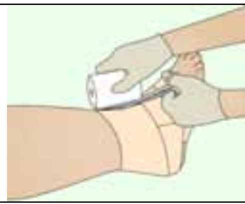
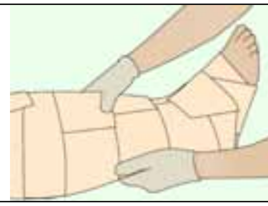
2.8.2. Specialty application for highly contoured leg

Application of Coban 2 and Coban 2 Lite can be easily adapted to achieve a conformable, sustained level of compression for a variety of limb sizes and shapes.

2.8.2.1. The inner comfort layer

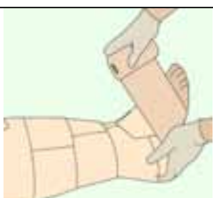
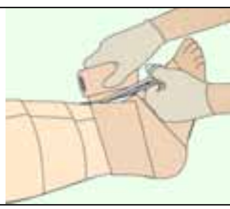
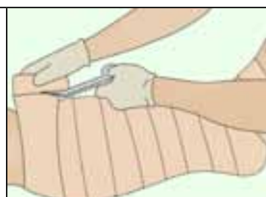
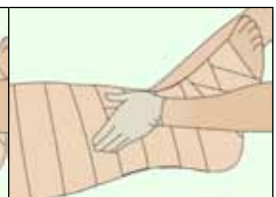
Apply this layer with the foam side against the skin, using just enough tension to conform to the shape of the leg with minimal overlap.

		
With the foot in a dorsiflexed position, start the application with a circular winding at the base of the toes, beginning at the fifth metatarsal head.	*The second circular winding should come across the top of the foot so that the middle of the bandage width approximately covers the articulating aspect of the ankle joint.*	*Bring this winding around the back of the heel and lay it over the top of the foot where it overlaps the underlying material.*

		
Cut the wrap and gently press into place.	*Apply the next winding by starting the roll at the previous cut edge. With minimal overlap, wind the wrap around the leg. Cut it when it overlaps the underlying material.*	*Proceed up the leg with individual windings using the same technique. End the application at the fibular head, or just below the back of the knee. Cut off excess material. Light pressure applied at the end of the bandage and down the leg ensures that it stays in place during application of the compression layer.*

2.8.2.2. The outer compression layer

Apply this layer at full stretch throughout its application. Hold the roll close to the foot and limb throughout the application for controlled, even compression.

			
With the foot in a dorsiflexed position, start the application with a circular winding at the base of the toes, beginning at the fifth metatarsal head.	*Using the "figure of eight" technique, bring the roll back over the top of the foot, across the bottom of the foot and back up to come around the back of the heel. Complete two or three figures of eight around the ankle ensuring that the entire heel is covered.*	*If needed for conformability and even coverage, you may cut the compression material and proceed up the foot and leg with individual windings at 50% overlap, making sure to press and conform each subsequent layer.*	*End the wrap at the fibular head, or just below the back of the knee and even with the top edge of the comfort layer. Cut off any excess material. Gently press and conform the entire surface of the application.*

2.9. References

1. 3M Product Monograph.
Engineered for comfort, designed for real life: 3M Coban 2 layer compression therapy designed with intelligent compression dynamics.
3M Health Care, Skin and Wound Care Division 2010.

2. Reeder SWI, Roos de K-P, De Maeseneer M, Sommer A, Neumann HAM.
Hospital admission for venous ulcers: what is it worth? (abstract).
Phlebology 2010; 25: 296-311.

3. Brem H, Kirsner RS, Falanga V.
Protocol for the successful treatment of venous ulcers.
Am J Surg 2004 Jul; 188 (1A Suppl):1-8.

4. Negus D.
Historical background.
In: Negus D. Leg Ulcers: a practical approach to management. Oxford: Butterworth-Heinemann 1991: 3-10.

5. Stranden E.
Edema in venous insufficiency.
Phlebolymphol 2011; 18(1): 3-14.

6. Marston W, Vowden K.
Compression therapy: a guide to safe practice.
EWMA Position Document. London: MEP 2003: 11-17.

7. Hargens AR, Millard RW, Pettersson K, Johansen K.
Gravitational haemodynamics and oedema prevention in the giraffe.
Nature 1987; 329 (6134): 59-60.

8. Pedley TJ.
Haemodynamics: how giraffes prevent oedema.
Nature 1987; 329 (6134): 13-14.

9. Schnobrich E, Solfest S, Bernatchez S, Zehrer C, Tucker J, Walters SA.
7-day, in-use assessment of a unique, innovative compression system.
Data on file at 3M.

10. Moffatt CJ, Edwards L, Collier M, Treadwell T, Miller M, Shafer L, Sibbald RG, Brassard A, McIntosh A, Reyzelman A, Price P, Kraus SM, Walters S-A, Harding K.
A randomised controlled 8-week crossover clinical evaluation of the 3M Coban 2 Layer Compression System versus Profore to evaluate the product performance in patients with venous leg ulcers.
Int Wound J 2008; 5: 267-279.

11. Collier M, Schuren J.
Ease of use and reproducibility of five compression systems.
J Wound Care 2007; 16 (3M supplement): 8-10.

12. Jünger M, Haase H, Ladwig A, Schwenke L, Bichel J, Schuren J.
Compression therapy in patients with peripheral arterial occlusive disease: a prospective clinical study with the 3M™ Coban™ 2 Layer Lite Compression System for ABPI ≥ 0.5
In: Engineered for comfort, designed for real life: 3M Coban 2 layer compression therapy designed with intelligent compression dynamics. 3M Health Care, Skin and Wound Care Division 2010: 18-19.

13. Partsch H, Clark M, Mosti G, Steinlechner E, Schuren J, Abel M, Benigni JP, Coleridge-Smith P, Cornu-Thénard A, Flour M, Hutchinson J, Gamble J, Issberner K, Jünger M, Moffatt C, Neumann HA, Rabe E, Uhl JF, Zimmet S.
Classification of compression bandages: practical aspects.
Dermatol Surg 2008; 34: 600-609.

14. Schuren J, Andreas C.
Pressure and slippage during 48 hours of compression therapy: a study on healthy volunteers.
SAWC Abstract Book Spring 2010: S36.

15. Mosti G, Crespi A, Mattaliano V.
Comparison between a new, two-component compression system with zinc paste bandages for leg ulcer healing: a prospective, multicenter, randomized, controlled trial monitoring sub-bandage pressures.
Wounds 2011; 23(5): 126-134.

Chapter 3

Sub-bandage dynamics

3.1. Introduction

There is a variety of methods to describe the properties of bandaging materials. Recently a consensus document was published, in which was stated that sub-bandage pressures and material stiffness characterises the elastic properties of the used materials and are the deciding parameters determining the dosage of compression treatment [1]. Therefore, it was recommended to measure and report these characteristics in future clinical trials. Proposals were made concerning methods for measuring the interface pressure and for assessing the stiffness of a compression device in an individual patient. In this chapter, a brief description is provided on the common terminology. In addition, a new method is presented to determine the properties of compression systems.

3.2. The B1-position

In the CEN European Prestandard document [2], an overview is provided on the anatomical locations to position pressure sensors on a leg. One of these locations is called cB1, the area at which the Achilles tendon changes into the calf muscles (approximately 10-15 cm proximal to the medial malleolus). Stolk et al [3] performed static measurements and showed 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 cB1 level or simplified: B1). The International Compression Club (ICC) consensus document proposes that location B1 should always be included in future pressure measurements, with the exact location of the sensor situated at the segment that shows the most extensive enlargement of the leg circumference during dorsiflexion or by standing up from the supine position [1]. Although B1 should always be included as a measurement location, other sites could be included in any measurement of pressures [1]. Figure 3.1 shows a screenshot of measurements with the PicoPress device and the sensor positioned at the B1 location.

3.3. Resting pressure

The resting pressure gives an indication on how much pressure is provided by a compression system when the subject is in a relaxed supine position. In figure 3.1, the resting pressure is in the column ”lay” and is around 40 mmHg. It is important that the calf muscles are not resting on a surface, as the resulting pressure may produce a too high resting pressure. A favourable patient position is presented in figure 10.3 in chapter 10 (safety and tolerability).

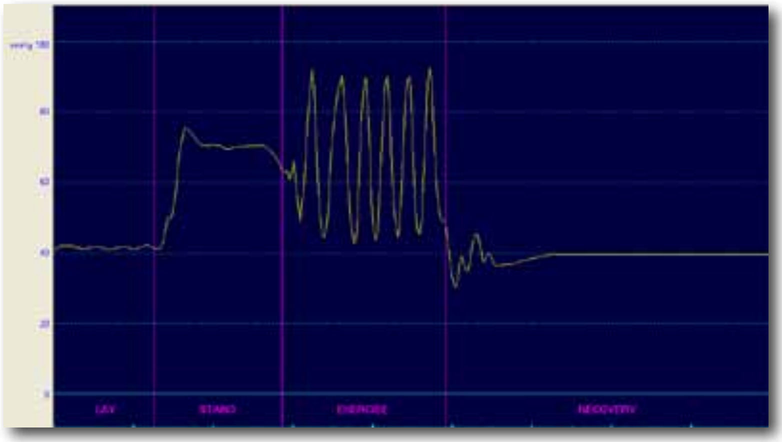


Figure 3.1: a typical PicoPress recording with the sensor positioned at the B1 location, showing the pressure under a Coban 2 application in the supine position (lay), in the standing position (stand) and during functional activities (exercise).

3.4. Static stiffness index

The CEN European Prestandard document for medical compression hosiery defines stiffness as the increase in pressure per 1 cm increase of leg circumference [2]. For compression bandages, the extensibility of materials is often used to determine their characteristics. Partsch [4] identified the need for a simple tool to assess both pressure and stiffness on the individual leg. He describes the method to measure the pressure at a defined position of the lower leg at rest (B1), when its circumference is minimal, and to repeat the measurement on the same spot, when the circumference has maximally increased by the muscles actively engaged to stand in the upright position. For measuring stiffness, the pressure in the supine position is subtracted from the pressure in stance. The resulting index indicates the effectiveness of the applied system [1]. This index is referred to as static stiffness index (SSI) and provides an indication of how well an applied compression system manages to keep forces produced by the muscle activity to stay in the upright position, inside the compressed area. In figure 3.1, the resting pressure is presented in the column ”lay” and is around 40 mmHg. The standing pressure can be taken from the column ”stand” and is around 70 mmHg. This means that the SSI in this measurement is 30 (70-40). However, as a consequence of measuring the muscle forces inside the compression system, the SSI tells more about the muscle forces of the person included in the system, rather than providing accurate information on the applied system or how well this system is applied. This can be easily demonstrated with the measurements presented in figure 3.2.

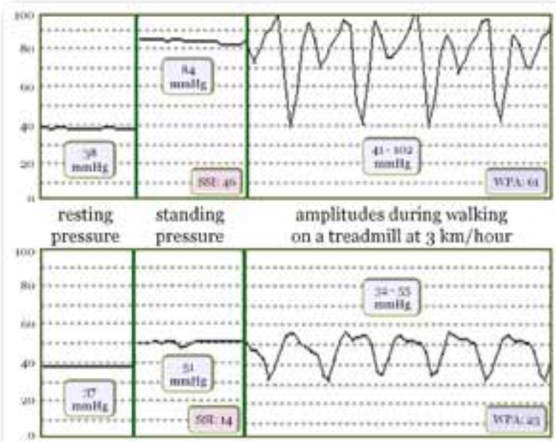


Figure 3.2: sub-bandage pressure recordings from two different volunteers with the same compression system.

These measurements are from a study on healthy volunteers, recorded with a Gaeltec strain gauge temperature-compensated (15–40°C) force transducer. The transducer was positioned on the centre of the medial head of gastrocnemius muscle and connected to a computer from which the data was recorded. The only difference in the two recordings is the volunteer. The same compression system was applied by the same experienced applicant. In both readings, a similar resting pressure was achieved. The SSI (14 versus 46) as well as the amplitudes (see chapter 3.5) during walking on a treadmill (23 versus 61) of the used system show big differences. This phenomenon can also be observed in studies in which actual SSI measurements are presented. A few studies present data on measurements on short-stretch bandages. Partsch [4] presents data on 12 volunteers. As can be seen in figure 3.3, the SSI values vary between 10 and >40 for both Unna's boot (Unna) and multilayer short-stretch bandages (2 SS).

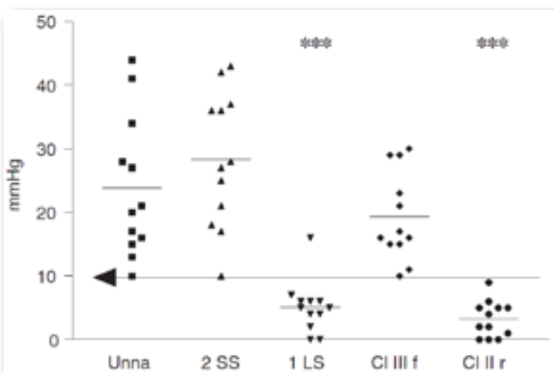


Figure 3.3: SSI's from twelve volunteers with different compression systems. (Reprinted with permission from: Partsch H. The static stiffness index: a simple method to assess the elastic property of compression material in vivo. Dermatol Surg 2005; 31: 625-630.)

Similar data differences are observed in publications by Mosti et al [5,6] and Partsch et al [7].

It can be concluded that measuring the SSI seems to be not as easy as often presented. The index gives a rough estimate of the possible effectiveness of an applied system, as it mainly depends on the leg that is included in a system. However, the well-established SSI is able to differentiate between elastic and inelastic materials and the suggested cut-off point of 10 by the International Compression Club [8], represents a very simple quotient that may be taken as a rule of thumb and is measurable in patients without major disfigurations of the legs due to severe obesity or lymphoedema.

3.5. Amplitudes

After the introduction of the simple, handheld and cost-efficient Kikuhime device it was possible to provide reliable and reproducible data to measure sub-bandage pressures, even from non-specialised centres [9]. Reporting of the SSI became a well-established method. One of the disadvantages of the instrument is the lack of a continuous readout of pressure, preventing it from making pressure measurements during exercise [15]. Veraart et al [10] demonstrated that there is a significant difference in working amplitudes between short-stretch and elastic bandages during walking on a treadmill. If a measuring device (like e.g. PicoPress) allows dynamic recording, it is advisable to measure also the amplitudes of a specified movement.

Possible movements include the following [1]:
- dorsal and plantar flexion of the ankle joint;
- walking, for example on a treadmill;
- adopting a ”tip-toe” stance, or flexing of the knees;
- passive ankle movement.

In figure 3.1, the amplitudes are presented in the column exercise. The range of pressure values is between 45 and 90 mmHg, which results in an amplitude of 45. It is easy to imagine that, similar to the SSI, also the amplitudes are not only determined by the stiffness of the applied compression system but more by the muscle forces that are produced inside the bandaged area. Measuring the amplitudes provides information on the possible effectiveness of an applied compression system during functional activities. However, the patient or volunteer inside the system heavily confounds each measurement. With the same system applied in the same way by the same experienced bandager, the amplitudes in figure 3.2 are 23 and 61.

3.6. The strain index

3.6.1. Introduction

Based on the above observations, it is difficult to have an SSI or an amplitude that is reproducible in different patients. The consequence is that making statements on the possible effectiveness of an applied system, is difficult. It is obvious that with so many available compression bandages and systems, there is a need to have a method that exactly determines the properties of an applied system and eventual modifications. Mosti et al state that the physical characteristics of bandage kits, in which different materials are combined, cannot be predicted by laboratory tests and can only be assessed in vivo by measuring the interface pressure and calculation of stiffness [6]. To support product development and have a controlled and reproducible way of testing prototypes, a special roll winder was developed with which an exact resting pressure can be measured, which is based on the physical properties of the used materials. Another advantage of measuring the material properties in a controlled laboratory setting is that exact information can be collected on material fatigueness over a certain time period (see chapter 11.5). This method was further modified to measure the capabilities of an applied compression system to keep the forces inside the system, similar to a static stiffness index. This index is well established, therefore a different description was needed for the value from this measurement. It was decided to name this outcome the strain index. As the pressure can be controlled over a longer period, also the effects of material fatigueness on the strain index can be investigated.

A study is presented in which the methods to investigate the sub-bandage pressure and strain indices of four different compression systems for venous leg ulcer treatment in completely controlled applications are explained.

3.6.2. Materials and methods

Twenty poly-oxymethylene test cylinders were designed and fabricated, ten with a radius of 4 cm and ten with a radius of 5 cm. They were designed in such a way that they could be fitted with fluid bags and sensor tubing, without a measurable effect on the final radius of the cylinder (figure 3.4.a). The fluid bags were made of 0.25 mm thick PVC-foil, sized 65 x 65 mm and filled with 11 grams of glycol. The maximum thickness of the filled bags is 2.5 mm. The mean weight of the used bags was 16.079 grams (n=40, sd 0.114). Two-sided adhesive tape was positioned in the area prepared for the bags. On top of the tape, a small Kikuhime sensor was positioned and connected to the Kikuhime device. A fluid bag was positioned on top of the sensor in such a way that the bag filled the entire indented area of the test cylinder. Because of the positioning of the adhesive tape, the Kikuhime sensor and fluid bag were not fixed to each other (figure 3.4.b). On top of the fluid bag, a PicoPress sensor was positioned and fixed with two-sided adhesive tape and connected to a PicoPress device (figure 3.4.c).

Figure 3.4.a: a poly-oxymethylene test cylinder that can be fitted with a fluid bag and space for sensor tubes without a measurable effect on the final radius of the cylinder.
Figure 3.4.b: a fluid bag is positioned on top of the sensor in such a way that the bag filled the entire indented area of the test cylinder.
Figure 3.4.c: on top of the fluid bag, a sensor is positioned and connected to a PicoPress device.

Via the 3-way luer lock stopcock of the Kikuhime device, the first sensor was connected to a pressure sphygmanometer. To measure the strain index after each application, the sphygmanometer connected to the sensor underneath the fluid bag is inflated to 133.33 mbar, which is 100 mmHg pressure on the Kikuhime device, (figure 3.5).

Figure 3.5: the sphygmanometer connected to the sensor underneath the fluid bag is inflated to 133.33 mbar, which is 100 mmHg pressure on the Kikuhime device.

On a tensile tester, the force needed to bring each individual component of the compression systems under investigation to the required percentage stretch, was calculated (figure 3.6.a). From this pressure force, the weight was calculated with which the individual components could be stretched with the exact amount of tension. Water filled bottles were used of which the weight was controlled to 0.01 grams precision on a calibrated digital scale (figure 3.6.b).

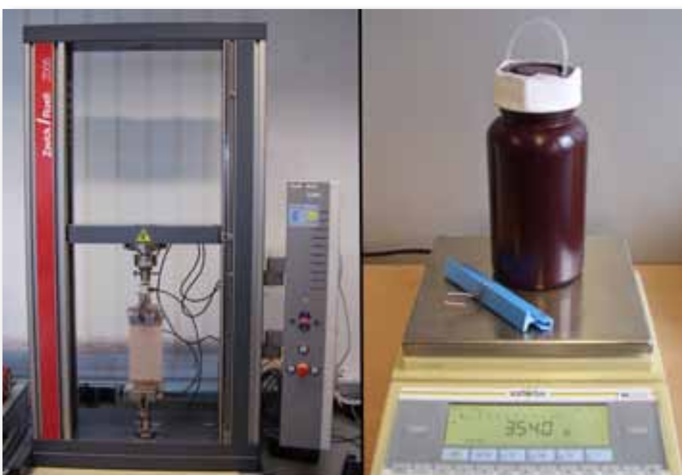


Figure 3.6.a: on a tensile tester, the force e.g. the weight needed to bring each individual component of the compression systems under investigation to the required percentage stretch, was calculated.
Figure 3.6.b: to stretch the individual components with the exact amount, water filled bottles were used of which the weight was controlled to 0.01 grams precision on a calibrated digital scale.

The cylinders were fitted in a special designed automated roll winder to wind the rolls in a completely controlled and reproducible manner (figures 3.7).

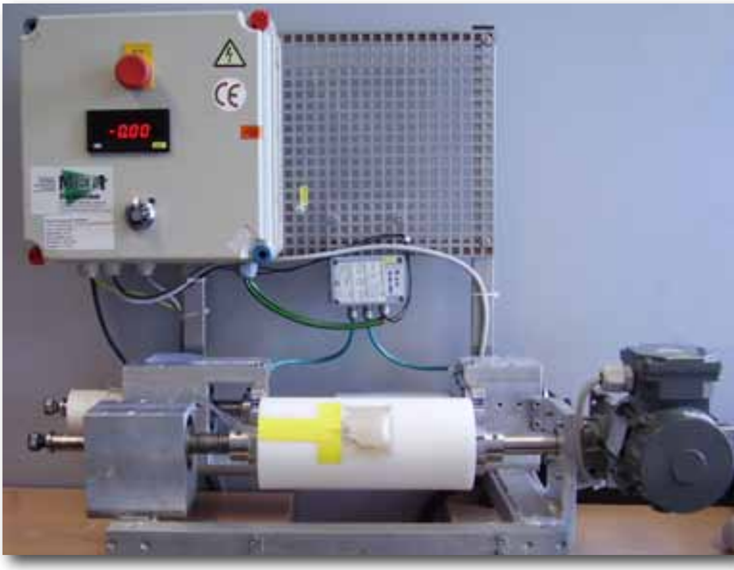


Figure 3.7: one of the cylinders fitted in the special designed automated roll winder.

The beginning of each individual bandage was attached to the prepared cylinder with poly-urethane masking tape, starting on a marked line exactly on the opposite of the centre of the fluid bag (figure 3.8.a). Next, the calculated weight was attached to the free hanging end of the roll with a bag clamp (figure 3.8.b). The number of layers was determined by the provided instructions for use, e.g. if the instructions suggested to apply the bandage with a 50% overlap, two complete circular windings were applied.

After application of each individual component, the roll was fixed with the poly-urethane masking tape exactly on the marked line where also the start was made. After fixation, the remainder of the roll was cut next to the tape, after which the cut end was fixed with another layer of tape (figure 3.8.c).

Figure 3.8.a: the beginning of the bandage is attached with masking tape.
Figure 3.8.b: the calculated weight is attached with a clamp.
Figure 3.8.c: after completion of the windings, the end is fixed with masking tape.

Immediately after the application, two pressure measurements were taken from the sensor on top of the fluid bag:

- the so called resting pressure without inflation;
- the pressure under strain after inflation of the sensor underneath the fluid bag.

The difference between the two values is called the strain index, which provides very precise and reproducible information of how well a compression system can hold the forces inside the wrapped area. The measurements can be taken at specified intervals. A typical pressure profile of a compression system is shown in figure 3.9.

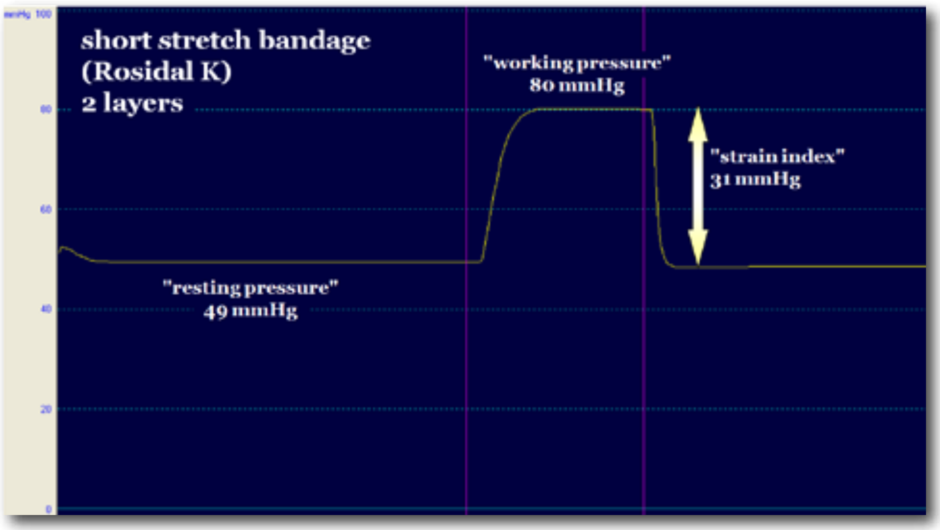


Figure 3.9: a typical recording of the sub-bandage pressure profile on measured on a cylinder; the resting pressure is 49 mmHg, the pressure after inflation to 100 mmHg of the inner sensor is 80 mmHg. The resulting strain index is 31.

3.6.3. Test method validation

To validate the reproducibility of the test method, four operators were instructed on the use of the device, the application and the measuring method. Each operator applied four different compression systems. Coban 2, Coban 2 Lite, Profore and Profore Lite were each applied twice on the cylinders with the radius of 5 cm and twice on the cylinders with the radius of 4 cm. The cylinders were numbered so that each operator applied the same system to the same cylinder. Immediately after application, the measurements were performed to determine the pressure and strain index.

The results of the validation for the rest pressure are presented visually in figure 3.10, for the strain index in figure 3.11. The data were analysed with the Software programme Minitab. The paired T-test for each individual operator versus the mean values of the three other operators gave the following p-values: operator 1: p=0.56, sd 1.6; operator 2: p=0.11, sd 1.3; operator 3: p=0.31, sd 1.7 and operator 4: p=0.78, sd 2.1.

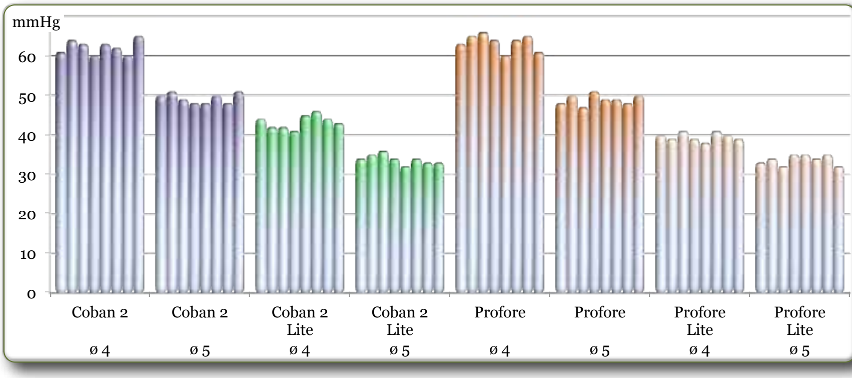


Figure 3.10: resting pressures generated by four different operators, each applying each system twice.

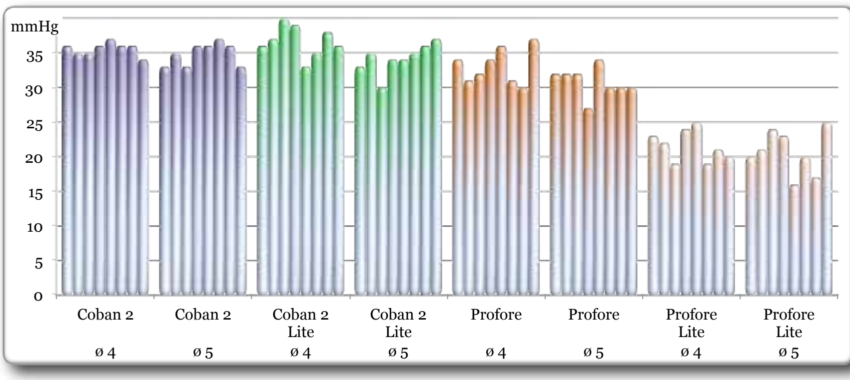


Figure 3.11: strain indices generated by four different operators, each applying each system twice.

Based on this validation, it can be concluded that the presented method for determining the pressure and strain of compression systems provides reproducible results when handled by different operators.

3.7. Discussion

There are many different ways to describe the physical properties of compression systems. The established methods like static stiffness index and amplitudes generated by different functional activities are helpful to provide some information on the possible effectiveness of an applied compression system. These tools however are difficult to use to provide comparative information on different systems and eventual modifications. The presented method and the resulting strain index provide valuable information on the physical properties of compression bandages and systems. In addition, the method allows measurements over longer periods to provide information on the material fatigueness of used systems.

3.8. References

1. Partsch H, Clark M, Bassez S, Becker F, Benigni JP, Blazek V, Caprini J, Cornu-Thénard F, Hafner J, Flour M, Jünger M, Moffatt Ch, Neumann HAM.
   Measurement of lower leg compression in vivo: Recommendations for the performance of measurements of interface pressure and stiffness: a consensus statement.
   Dermatol Surg. 2006; 32: 229-238.

2. European Committee for Standardisation (CEN).
   Non-active medical devices. Working group 2 ENV 12718: European pre-standard medical compression hosiery. CEN TC 205.
   Brussels: CEN 2001.

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

4. 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.

5. Mosti G, Mattaliano V.
   Simultaneous changes of leg circumference and interface pressure under different compression bandages.
   Eur J Vasc Endovasc Surg 2007; 33: 476-482.

6. Mosti G, Mattaliano V, Partsch H.
   Influence of different materials in multi-component bandages on pressure and stiffness of the final bandage.
   Dermatol Surg 2008; 34: 631-639.

7. Partsch H, Clark M, Mosti G, Steinlechner E, Schuren J, Abel M, Benigni JP, Coleridge-Smith P, Cornu-Thénard A, Flour M, Hutchinson J, Gamble J, Issberner K, Juenger M, Moffatt C, Neumann HA, Rabe E, Uhl JF, Zimmet S.
   Classification of compression bandages: practical aspects.
   Dermatol Surg 2008; 34: 600-609.

8. Partsch H, Clark M, Mosti G, Steinlechner E, Schuren J, Abel M, Benigni JP, Coleridge-Smith P, Cornu-Thénard A, Flour M, Hutchinson J, Gamble J, Issberner K, Juenger M, Moffatt C, Neumann HA, Rabe E, Uhl JF, Zimmet S.
   Classification of compression bandages: practical aspects.
   Dermatol Surg 2008; 34: 600-609.

9. 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.

10. Veraart JCJM, Daamen E, Neumann HAM.
    Short stretch versus elastic bandages: effect of time and walking.
    Phlebologie 1997; 26: 19-24.

Chapter 4

The importance of function

4.1. Introduction

There is a strong relation between venous return from the leg and functional activities. Gardner & Fox [1,2] have investigated the importance of weight bearing in detail. It is also a well-known phenomenon that muscular contractions are of crucial importance for promoting venous return to the heart. This is particularly the case in the dependent leg or in the leg of an upright individual, where muscle activities prevent pooling of blood in the venous system. Function is of utmost importance for a proper circulation in the leg. In this chapter, the importance of function for venous return in the lower leg is discussed as well as the effects of a lack of functional activities.

4.2. Reduced mobility

Black bears spend several months each winter confined to a small space within their den without food or water. When Hank Harlow, a physiologist from Wyoming, University, entered the shelter of a hibernating black bear, the bear stood up and ran away. The black bear was sleeping for 130 days. In non-hibernating mammals, these conditions typically result in severe muscle atrophy, causing a loss of strength and endurance. A patient, bedridden for such a period, can hardly stand, not to mention walk. Harlow et al [3] found that overwintering black bears loose less than 23% of their strength over 130 days, unlike humans, who are weakened by a predicted 90% strength loss over the same period.

In humans, muscle atrophy can be observed after a period of immobility, such as extended bed rest or being in a cast for a longer period. Normally this disuse atrophy can be reversed with exercise. Astronauts experiencing weightlessness must perform regular exercises to minimise atrophy. Apart from the mentioned forced disuses, many diseases like cancer and congestive heart disease cause atrophy. In addition, aging causes a gradual loss in muscle function and mass, known as sarcopenia. The two latter examples lead to irreversible atrophy. Sarcopenia is not a disease but a normal aspect of aging.

In a recently held consensus meeting of the the European Working Group on Sarcopenia in Older People (EWGSOP), a practical clinical definition for age-related sarcopenia was developed (4). Sarcopenia is defined as a syndrome characterised by progressive and generalised loss of skeletal muscle mass and strength, which is common in men and women, with prevalence ranging from 9% to 18% over the age of 65, with a risk of adverse outcomes such as frailty, reduced mobility, physical disability, poor quality of life, co-morbidities and death.

An obvious co-morbidity of sarcopenia is a disturbance of the venous return from the lower extremities. A major contributor to the venous return is the calf muscle pump. During functional activities, the calf muscles compress the deep venous system within their individual compartments and support the venous return to the heart. Gaylarde et al (5) report that reduced ankle mobility impairs the venous muscle pump, which leads to an increase in mean venous pressure in the lower leg and that the elevation of venous blood pressure in CVI patients may lead to arthropathy of the ankle joint.

In 1917, John Homans wrote: ”It is to be expected that skin, which is bathed under pressure in stagnant venous blood, will form permanent, open sores or ulcers” (6). That concept and the name ”stasis ulcer” remained widely accepted for many decades. Gourdin and Smith (7) suggest that because the aetiology of venous ulceration is far more complex than Homans' theory, the terms ”stasis dermatitis” and ”stasis ulcer” be dropped from medical parlance. The term ”venous ulcer” would seem more appropriate. After an analysis with air plethysmography of 120 patients, Gross et al (8) found that most patients (91%) with presumed venous abnormalities had musculoskeletal conditions, which might cause a dysfunction of the calf pump. They conclude that whether venous or musculoskeletal abnormalities or combinations are present, the final common pathway is the calf pump dysfunction. Therefore, it is suggested to consider changing the name ”venous ulcer” to ”calf pump dysfunction ulcers” or ”CPD ulcers”.

In the publication of the survey to determine the prevalence of leg ulceration in a defined UK health district with a population of approximately 200.000, Cornwall et al (9) present the age distribution of patients with leg ulcers per 1000 head of population (figure 4.1). It is easy to recognise that there is a strong relation between incidence and age.

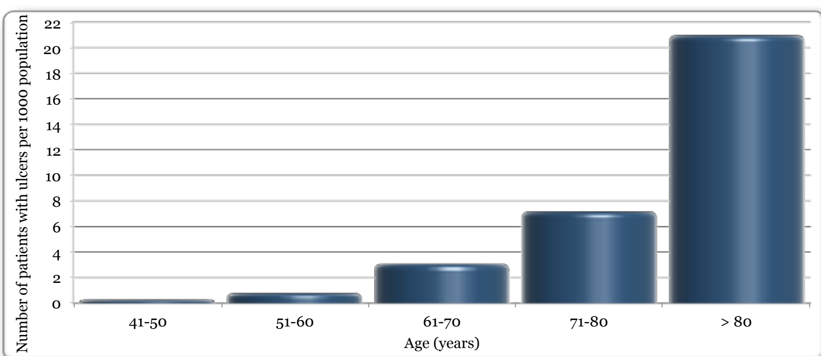


Figure 4.1: age distribution of patients with leg ulcers per 1000 head of population.
(Reprinted (modified) with permission from: Cornwall JV, Doré CJ, Lewis JD. Leg ulcers: epidemiology and aetiology. Br J Surg 1986; 73: 693-696.)

Using data from a large representative sample of the general population living in two small towns in Tuscany, Italy, Lauretani et al [10] examined how muscle function and calf muscle area change with aging and affect mobility in men and women free of neurological conditions. Among others lower extremity muscle power, and calf muscle area were investigated and sarcopenia, the loss of skeletal muscle mass, was considered present when the measure was larger than two standard deviations from the mean. The collected data are visualised in figure 4.2. Also here, it is obvious that the measures of muscle power and mass are progressively lower with increasing age, in both men and women.

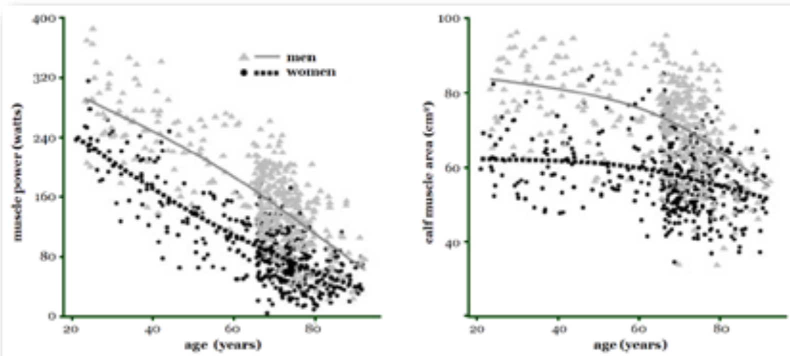


Figure 4.2: left: the relationship between weight specific lower extremity muscle power; right: the relationship between age and calf muscle area.
(Reprinted with permission from: Lauretani F, Russo CR, Bandinelli S, Bartali B, Cavazzini C, Di Iorio A, Corsi AM, Rantanen T, Guralnik JM, Ferrucci L. Age-associated changes in skeletal muscles and their effect on mobility: an operational diagnosis of sarcopenia. J Appl Physiol 2003; 95: 1851-1860.)

Moura et al [11] observed that there was a significantly higher mean age among the individuals classified as CEAP 4, 5 and 6 compared to those classified as CEAP 1, 2 and 3. The observations from this Brazilian study are confirmed by data on 100 patients from a study on 100 patients from Bangladesh [12]. The data from this study are presented in figure 4.3. It must be noted that in both the Brazilian and the Bangladesh study, the mean age of the included patients is low.

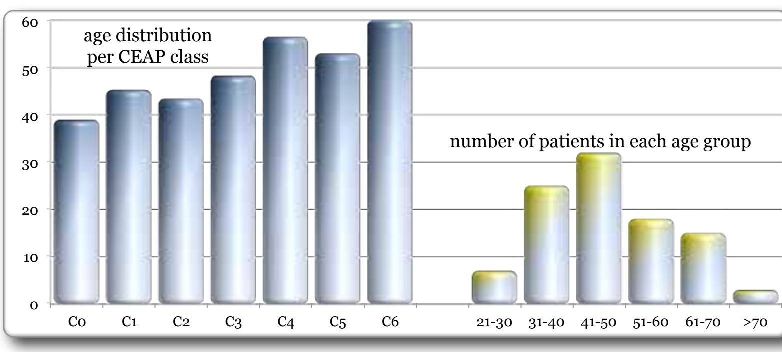


Figure 4.3: relation between age and CEAP classification.
(Data from: Shahin Ul Islam MM, Haque Z, Alam J, Noman M, Siddiqui FM. Chronic venous insufficiency (CVI): a study of 100 cases. J Medicine 2008; 9: 20-26.)

The price that has to be paid for aging is high. The number and size of particular muscles reduces and most of the lost material is replaced by fat and connective tissue. Aging atrophies skeletal muscles. Other than the atrophy that is observed after a period of immobility, sarcopenia is permanent. A young adult that has been in a below-knee walking cast with an immobilised ankle joint for a while, mostly needs only a few weeks to restore muscle mass and force to the pre-casting level. However, cast immobilisation of the knee joint gives rise to a fast and dramatic deterioration of thigh muscle performance [13]. Exercise is often recommended to strengthen muscle and improve joint stiffness. The result is hypertrophy, an effect that is easy to recognise in body-builders. Unfortunately, this phenomenon cannot be observed in the elderly dealing with sarcopenia.

A randomised controlled study on the effects of playing golf on sedentary men between 48 and 64 years old Parkkari et al [14], showed that the overall health and fitness of the study group improved significantly compared to the matched control group that was not exposed to two to three times weekly filling 18 holes. It would have been interesting if in this study muscle strength and mass had investigated. This however was the research question in a systematic review of research on strength, aerobic and balance training in older adults performed by Baker et al, [15]. Fifteen studies were included totalling 2,149 subjects; the mean cohort age ranging from 67 ± 8 to 84 ± 3 years. The relative effect sizes of multi-modal exercise programmes for strength measures ranged from -0.08 to 1.67, with a mean of 0.41 across all study strength measures. In other words: the limited data available suggests that multi-modal exercise programmes for older adults (67-84 years) have only a minimal effect on physical, functional and quality of life outcomes. The outcome is frightening. Exercises do not counteract sarcopenia. Aging is irreversible.

Since the beginning of the 20th century, our life expectancy has exploded in a spectacular way and continues to grow. In countries that are members of the Organisation for Economic Cooperation and Development (OECD), a newborn girl in 2007 in a typical OECD country could expect to live to age 81.9 years, that is, 10.9 years more than a baby girl born in 1960. Similarly in 2007, a newborn boy could expect to live up to age 76.2 years; 10.4 years more than a boy born in 1960 (from: www.oecd-ilibrary.org/content/chapter/factbook-2010-85-en).

4.3. Mobility of the ankle joint

Plantar and dorsiflexion of the ankle joint are the main contributors to an effective calf muscle pump. This chapter reviews the literature to identify evidence of an association between the range of motion (RoM) of the ankle joint and the severity of chronic venous insufficiency. The elevation of venous blood pressure in patients with venous insufficiency may lead to arthropathy of the ankle joint. Gaylarde et al [16] hypothesise that prolonged elevation of venous blood pressure causes injury to the ankle joint, explaining the frequent association between ankle arthropathy and venous leg ulcers. Back et al [17] studied the RoM and calf pump function in limbs with varying degrees of CVI, ranging from normal limbs to CVI with no ulceration in the history, CVI with a healed ulcer and CVI with active ulceration. It was concluded that limbs with CVI have a limited ankle RoM that decreases with increasing severity of clinical symptoms. Plantar flexion, dorsiflexion and ankle range of motion are significantly reduced in each CVI group compared with age-matched control groups. In addition, calf pump function, reflux and outflow obstruction was measured in the four groups with air plethysmography. The authors demonstrated that there is a significant correlation between severity of CVI, RoM and calf muscle pump function. The data from this publication are used in figure 4.4 to visualise this relation.

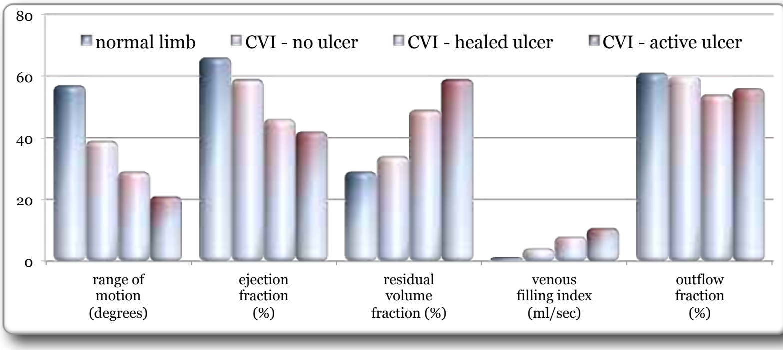


Figure 4.4: correlation between the severity of CVI and range of motion, and calf muscle pump function. (Data from: Back TL, Padberg FT, Araki CT, Thompson PN, Hobson RW. Limited range of motion is a significant factor in venous ulceration. J Vasc Surg 1995; 22: 519-523.)

Dix et al [18] also demonstrated this phenomenon. The data on range of motion from this study are visualised in figure 4.5.

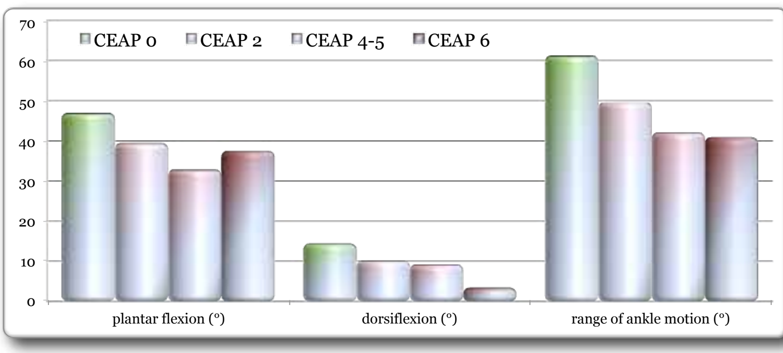


Figure 4.5: correlation between the severity of CVI and range of motion. (Data from: Dix FP, Brooke R, McCollum CN. Venous disease is associated with an impaired range of ankle movement. Eur J Vasc Endovasc Surg 2003; 25: 556-561.)

To measure the RoM of the ankle joint, many methods are described e.g.: portable handheld goniometers, isokinetic dynamometers, 3D electromagnetic tracking system, multi-joint testing and rehabilitation systems, pedal ergometer, magnetic resonance imaging (MRI), lateral radiographs and 3D video digitising technology. Most of these are too complicated to be used in combination with compression therapy. Martin et al [19] performed a literature review to assess the reliability of ankle goniometric measurements and conclude that the responsiveness of ankle joint range-of-motion measurements is uncertain and requires further studies using patient populations. White et al [20] used low profile, high sensitive, lightweight, portable electrogoniometers that were developed and manufactured (Biometrics Ltd. Gwent, UK) to study intracast movements (figure 4.6). The size of these devices allowed intracast placement to perform effective high sensitive and reproducible RoM measurements of the ankle joint. They gave accurate results with an adequate degree of resolution.

Figure 4.6: size of goniometer used in: White R, Schuren J, Konn D. Semi-rigid vs rigid glass fibre casting: a biomechanical assessment. Clin Biomech 2003; 18: 19-27.

In the following years, these goniometers evolved and are mainly used to collect and analyse biosignals in addition to electromyography data. These sensors are small enough to be positioned inside compression systems to study the effects of compression bandaging methods on range of motion of enclosed ankle joints.

The close correlation between CVI and calf muscle impairment is well documented in literature. However, the use of goniometry to document ankle RoM is hardly used in research on CVI and venous leg ulceration. The assessment of the RoM of the ankle joint provides valuable information on the status of the calf muscle pump function of CVI patients. Electrogoniometry is an easy to use non-invasive method, which provides high sensitive and reproducible measurements of plantar and dorsiflexion (RoM) of the ankle joint. Electrogoniometry may have a place in future research to monitor and document the effectiveness of e.g. rehabilitation programmes, or to study the immobilising effects of compression bandages when used for leg ulcer treatment. In future research, electrogoniometry might be an interesting methodology to investigate the immobilising effect of bandage slippage, which is often observed during prolonged bandage wear (Moffatt et al [21]).

4.4 Immobilisation of the ankle joint

4.4.1. Introduction

It is well known from various studies that immobilisation gives rise to a loss of muscle size and weight due to the disuse of the affected limb as a consequence of immobilisation [22-28]. Different methods have been used to measure these effects [23,28,30,31]. In addition, the functional properties of atrophied muscles are well studied; the majority of these studies have been performed on animals [32-35]. In most studies in which the lower leg muscles are investigated, the knee joint is included in the immobilised area and the degree of atrophy varies over a wide range [13,28,29]. The same can be said on the time needed for recovery [36]. Numerous studies have shown that the major changes take place in the beginning of the immobilisation treatment. Booth [37] found that muscle atrophy in immobilised limbs begins rapidly; half of the total muscle size loss is lost from the second to the ninth day. Veldhuizen and co-workers [13] found a decrease of 21% in cross-sectional area, accompanied by a 53% decrease in strength of the quadriceps muscle after immobilisation of the knee joint in healthy volunteers. Weight bearing was not allowed in this study. They conclude that the effect of immobilisation overshadows all other factors known to muscle atrophy. A wide variety of immobilisation methods and treatment regimes has been described to minimise the detrimental effects of immobilisation in the treatment of ankle fractures [30,31,37-42].

When a cast is applied for an ankle fracture, there are many possible reasons for the loss of muscle size and weight. The aim of the study presented in this chapter was to quantify the effects of immobilisation of the ankle alone. In order to eliminate all injury-related bias, these effects were studied on healthy volunteers. The study was performed in the Haukeland University Hospital in Bergen, Norway in cooperation with Arnbjørn Rodt, orthopaedic surgeon in the mentioned hospital and Alex Wisnes, physiotherapist from the Faculty of Health and Social Sciences, Bergen College, Bergen, Norway.

It was our objective to find an answer to the following questions:

- what is the effect of a below-knee walking cast on muscle function in the lower leg?
- is there a difference between a traditional rigid cast and a combicast?
- how long is needed to normalise muscle function after 5 weeks of immobilisation?

4.4.2. Materials and methods

Eight healthy subjects, all students physiotherapy, volunteered to participate in this study. The institutional Ethical Committee approved the procedures. All subjects gave their written informed consent to participate in this study. Before the study, the volunteers went through a clinical examination to ensure that they had no history of prior illness or injury to the lower extremities and that there were no signs of skin irritation or other abnormalities in the knee, lower leg and foot. The main characteristics of the subjects are listed in table 4.1.

volunteer	sex	age	weight	length	physical activity	weight / length
1	F	25	56	166	3	0.34
2	F	21	68	179	1	0.38
3	F	21	62	179	4	0.35
4	F	19	60	165	2	0.36
5	F	22	69	177	2	0.39
6	M	23	72	178	3	0.40
7	M	22	62	173	2	0.36
8	F	21	63	166	3	0.38
	6F / 2M	21.75	64	172.88	2.5	0.37

Table 4.1: characteristics of the subjects.

In preparatory training sessions, the subjects were accustomed to all measuring techniques. Before the cast application, all subjects went through the following tests:

- dynamic muscle function was evaluated with the dynamometer Ergopower; a dynamometer was used for evaluation of dynamic muscle work [43]; active and passive plantar and dorsal flexions were measured on the Cybex 6000;
- leg volume volume was measured by liquid displacement;
- MRI, the Magnetom Impact 1.0T was used to measure the area of the lower leg muscles;
- a slight modification of the Kaikkonen functional ankle was used to evaluate ankle function [44].

The volunteers were divided into two matched groups using the dynamic allocation method of minimisation where sex, age and level of physical activity were the main factors (table 4.2).

group	sex	age	weight	length	physical activity	weight / length
1	3F / 1M	22.5	62.5	170.5	2.5	0.37
2	3F / 1M	21.0	65.5	175.3	2.5	0.37

Table 4.2: mean characteristics of the groups.

Both groups were then given a below knee walking cast, the treatment that is routinely used for a closed non-dislocated ankle fracture. Group 1 had a rigid synthetic cast, which was made of 2 rolls (10 cm wide) of Scotchcast. The cast was minimally padded with 3M synthetic cast padding. There was no toe support and a Cellona shoecast was used. The weight of the rigid cast (without cast shoe) was approximately 450 gram. The weight of the Cellona shoecast can be compared to the weight of an average sport shoe. We believed that this was the most comfortable rigid below-knee walking cast [45].

Group 2 had a combicast as described by Schuren [39], made of 2 rolls (one 7.5, one 10 cm wide) of Soft Cast, reinforced with a rigid 7.5 cm wide Scotchcast Longuette, positioned as a U-splint around the ankle joint. No padding was used, the malleoli were protected with one layer of Microfoam. The weight of the combicast was approximately 475 gram. The thickness of this cast allowed wearing normal sport shoes. All casts were applied on the non-dominant leg by the same experienced orthopaedic technician (JS).

During the 5 week period all physical activities were allowed, including full weight bearing. The only restriction was that driving a car was not allowed. Once every week an MRI-examination took place to follow the development of any change in muscle volume. Leg volume examination took place by liquid displacement.

After 5 weeks the casts were removed and a new clinical examination was carried out. Careful gradually increasing functional activities of the ankle were allowed on the first day. On the second day after removal, all pre-immobilisation tests were repeated. From then, the volunteers started a rehabilitation program that was the same as would be carried out by any patient with an ankle injury. The exercises were instructed by a physiotherapist experienced in orthopaedic trauma (AW).

During the rehabilitation period, the volunteers' muscle function, ankle motion and ankle score were examined once every week. This program was continued until muscle function was normal (pre-test value +/-10%). Four weeks after cast removal, a final MRI examination was performed and the study was ended.

4.4.3. Results

All volunteers stayed in the same cast for a period of 5 weeks, no cast repair or replacement was necessary. No complaints were reported. There were no signs of reaction from the skin/leg/foot. There were no treatment related adverse events. Because of the limited number of participants, the data are presented as mean values. As all tests were taken in this small sample population, the results have to be regarded more as tendencies than as absolute values.

4.4.3.1. Muscle function

To evaluate the changes in muscle function, we calculated the change as percentage of the initial value. In this way the initial value = 0, any increase in movement gives a positive change, any decrease a negative change. The muscle function was in all tests back to the pre-immobilisation values within 1-3 weeks. The results are listed in table 4.3 and visualised in figure 4.7.

method	day 0	week 5	week 6	week 7	week 9
rigid cast:	0	-13.2%	-3.0%	-0.2%	18.8%
soft cast:	0	-4.3%	3.4%	6.9%	16.4%

Table 4.3: dynamic muscle work; % change.

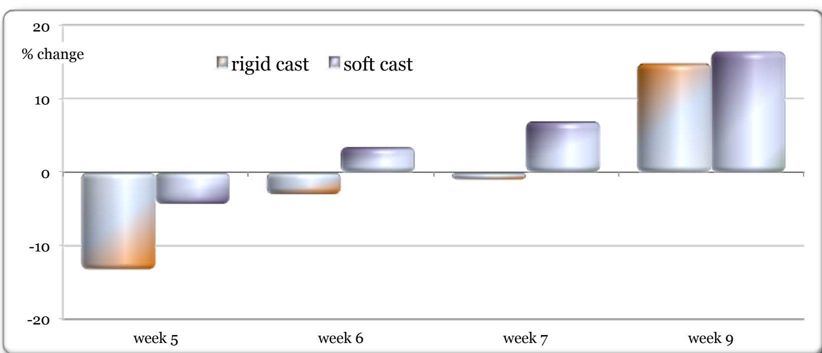


Figure 4.7: dynamic muscle work; % change.

4.4.3.2. Range of motion

To evaluate range of motion, we also calculated the change in range of movement as percentage of the initial value. In this way the initial movement = 0, and any increase in movement gives a positive change and any decrease a negative change. The range of motion was normal for both groups within 1-2 weeks of rehabilitation. The results are listed in the tables table 4.4 and 4.5 and in the figures 4.8 and 4.9.

method	day 0	week 5	week 6	week 7	week 9
rigid cast:	0	-6.1%	-4.2%	3.7%	4.5%
soft cast:	0	-10.2%	-2.3%	1.5%	9.7%

Table 4.4: active range of motion; % change.

method	day 0	week 5	week 6	week 7	week 9
rigid cast:	0	-2.0%	-5.8%	0.5%	3.5%
soft cast:	0	-5.3%	-3.8%	2.6%	4.9%

Table 4.5: passive range of motion; % change.

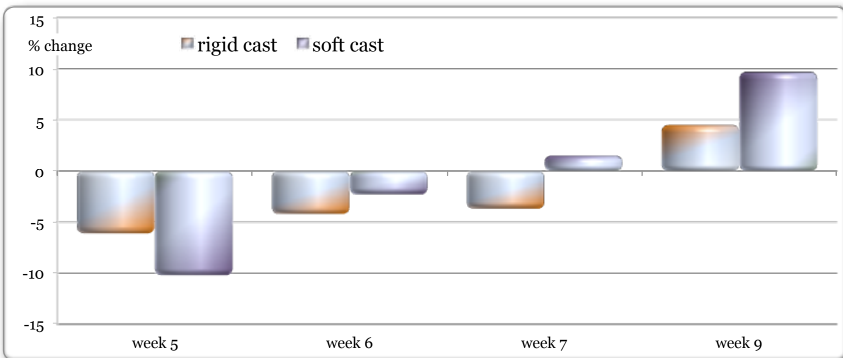


Figure 4.8: active range of motion; % change.

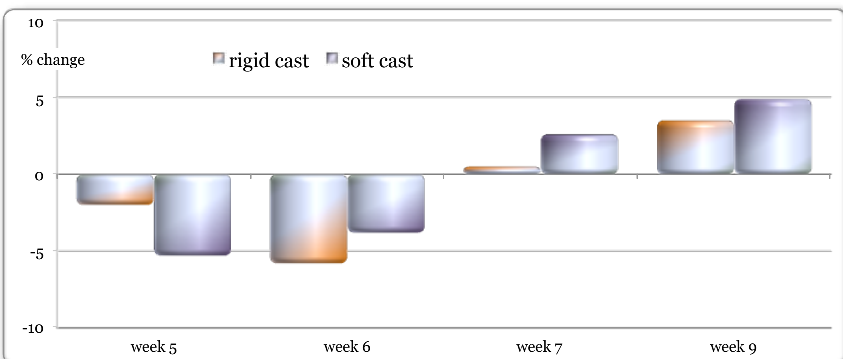


Figure 4.9: passive range of motion; % change.

4.4.3.3. Functional ankle score

The original Kaikkonen ankle score [44] has a maximum score of 100. We had to remove one of the tests (a test of stair climbing) because there was no staircase in the centre where the evaluations were performed. The test therefore had a maximum score of 90. The score was normal 1 week after cast removal in both groups. The results are listed in table 4.6 and visually displayed in figure 4.10.

method	day 0	week 5	week 6	week 7
rigid cast:	90	75	90	90
soft cast:	90	78.8	90	90

Table 4.6: functional ankle score.

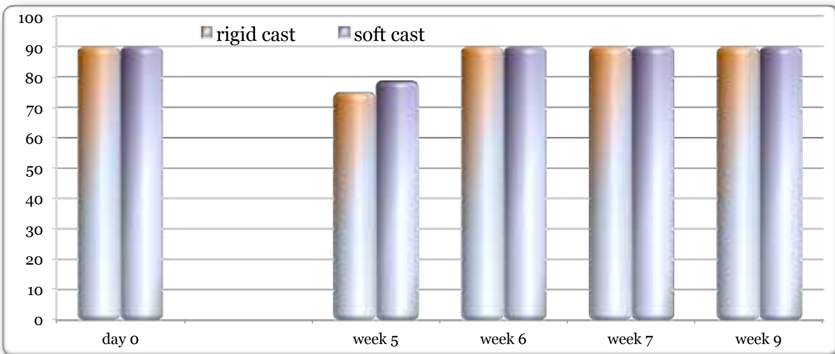


Figure 4.10: functional ankle score.

4.4.3.4. Leg volume

The leg volume was measured by liquid displacement. The reduction in leg volume was slightly higher in the rigid cast group. In both groups the decrease in leg volume was minimal. The results are listed in table 4.7 and figure 4.11.

method	day 0	week 5	difference
rigid cast:	4123	4022	-2.9%
soft cast:	3364.5	3352.5	-0.3%

Table 4.7: mean results liquid displacement in cm³.

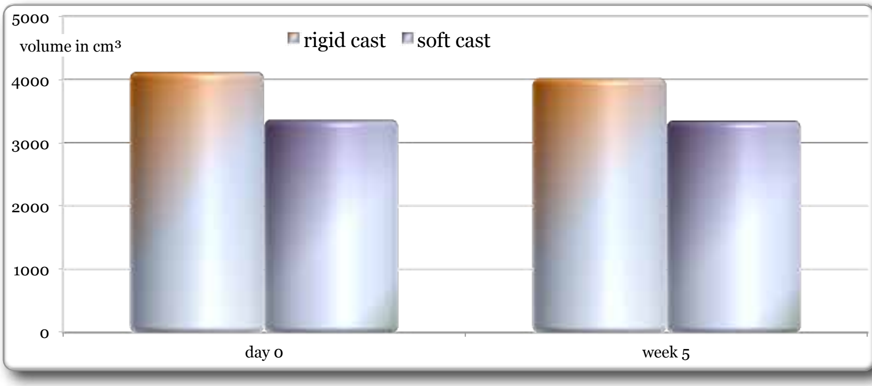


Figure 4.11: mean results liquid displacement in cm³.

4.4.3.5. MRI measurements

MRI examination took place before the application of the casts. Axial slices were reconstructed at three levels: 10, 14 and 17 cm. below the superior tibial plateau (figures 4.12.a, b and c). A standardised division was made between the anterior and posterior muscle group areas (figures 4.13.a, b and c).

Figures 4.12.a,b,c:
levels of the axial slices at 10, 14 and 17 cm underneath the tibial plateau.

Figures 4.13.a,b,c:
the standardised division between anterior and posterior area at the different levels.

These areas were then measured in cm²'s. The measurements were repeated at week 1, 2, 3, 5 and 9. The mean results of the anterior and posterior measurements are presented in table 4.8 and 4.9 and in the figures 4.14 and 4.15.

method	day 0	week 1	week 2	week 3	week 5	week 9
rigid cast:	31.8	31.6	31.4	31.4	32.8	33
soft cast:	28.7	29	28.8	29.5	29.8	30

Table 4.8: mean anterior MRI-examination results; area in cm².

method	day 0	week 1	week 2	week 3	week 5	week 9
rigid cast:	40.4	39.1	36.8	38.3	38.1	38.3
soft cast:	39.5	38.3	38.2	39.9	37.6	38.3

Table 4.9: mean posterior MRI-examination results; area in cm².

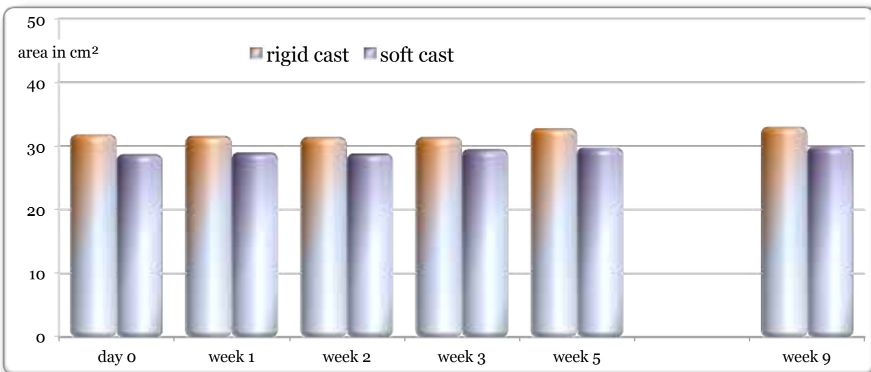


Figure 4.14: mean anterior MRI-examination results; area in cm².

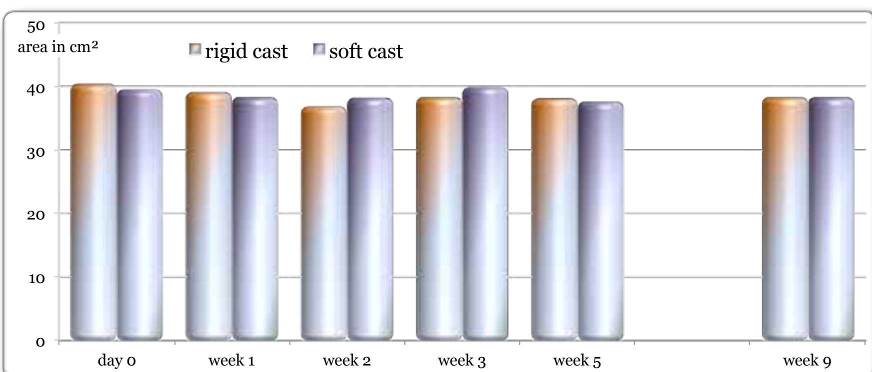


Figure 4.15: mean posterior MRI-examination results; area in cm².

4.5. Discussion

Muscles produce motion and this production maintains the size of the muscle. Muscles atrophy when they do not function, e.g. during a period of immobilisation. This is seen in normal clinical practice, where a considerable loss of muscular strength and performance can be observed after the application of a below-knee walking cast for four to six weeks. Recovery to normal function is generally known to be difficult and time-consuming [46].

In the presented volunteer study, it was found that the application of two different types of a below-knee walking cast on healthy volunteers did not result in a decline in muscle volume and approximately 10% reduction of performance and ankle function, which were both back to normal in 1-2 weeks. Probably the most important explanation for this observation is that full weight bearing and function was allowed during the period of immobilisation [36,47-49]. Therefore, it must be concluded that the effects observed in patients are the result of non weight bearing or functional limitations due to other immobilising factors like pain, fear or lack of stability, and not of the below-knee walking cast itself. The objective of every treatment in which this type of cast is used, must be to restore normal function, including full weight bearing, as soon as possible, as prevention of muscular atrophy is of utmost importance in the treatment of musculoskeletal injuries.

The immobilising effects of compression bandaging have not been studied before. It may be assumed however that if the effects of wearing a cast have only a minimal effect, the effects of wearing a compression bandaging system will be at least similar, provided that the system allows normal functional activities. Helliwell et al [50] showed that in elderly people, for every year of life, a loss in tibio-talar movement of 0.36 degree is observed. In elderly patients with venous ulceration, this loss is 0.78 degree for every year of active ulceration. In addition, the authors showed that the restriction of movement increased with duration of ulceration; the longer the period of ulceration, the greater the restriction of movement. Kügler et al [51] demonstrated that the degree of muscle activity, the extent of the calf muscle mass and maintaining a full-scale joint mobility is important to improve the efficiency of the muscle vein pump of the lower limb and counteract the development of CVI. Roaldsen et al [52] state that the potential of preventive measures and physical rehabilitation needs to be investigated in future research. The importance of active movements was demonstrated by Sochart et al [53], who showed that active combined movements of the ankle joint produced higher peak and mean velocities of blood flow than passive ones.

Moffatt et al [21] summarise the deficiencies with current compression bandaging systems, including inconsistency in application techniques resulting in inconsistent pressures, bulkiness, which can impede patients from wearing normal footwear, bandage slippage and bunching, leading to discomfort and finally a decrease in social activities. All of these shortcomings are more or less related to normal functional activities of patients. Clarke-Moloney et al [54] compared the mobility in patients with venous leg ulcers to matched controls and conclude that leg ulcer patients take fewer steps compared to controls, indicating that they have a reduced calf muscle pump function. Barwell et al [55] demonstrated a good ankle motility is an important factor for leg ulcer healing. Ulcer healing rates are significantly reduced with ankle range of motion below 35°. Lentner et al [56] showed that ankle movement restriction might be exacerbated by multi-layer compression therapy. Moffatt et al [21] studied slippage and physical symptoms and activities of daily living in a randomised crossover trial comparing a four-layer system with a long history of use in compression therapy (Profore) to a new two-layer system (Coban 2). The authors found significantly less bandage slippage in the Coban 2 group as well as a significantly greater improvement in the health-related quality of life score, especially in the domain that focused on daily functioning and comfort.

It can be concluded that the importance of maintaining normal function should not be underestimated when a compression system is applied, especially because the patient population that requires compression therapy is very vulnerable for developing detrimental effects as a result of a period if immobility. Bandaging alone will not heal many ulcers but ambulation will do so, provided the patient can walk in comfort [57].

4.6. References

1. Gardner AM, Fox RH.
The venous footpump: influence on tissue perfusion and prevention of venous thrombosis.
Ann Rheum Dis 1992; 51: 1173-1178.

2. Gardner AMN, Fox RH.
Peripheral venous pathology.
In: Gardner AMN, Fox RH. The venous system in health and disease.
2001; IOS Press Amsterdam etc: 33-61.

3. Harlow HJ, Lohuis TD, Beck TDI, Iaizzo PA.
Muscle strength in overwintering bears.
Nature 2001; 409: 997.

4. Cruz-Jentoft AJ, Baeyens JP, Bauer JM, Boirie Y, Cederholm T, Landi F, Martin FC, Michel JP, Rolland Y, Schneider SM, Topinkova E, M. Vandewoude M, Zamboni M.
Sarcopenia: European consensus on definition and diagnosis: report of the European working group on sarcopenia in older people.
Age Ageing 2010; 39: 412-423.

5. Gaylarde PM, Dodd HJ, Sarkany I.
Venous leg ulcers and arthropathy.
Br J Rheumatol 1990; 29: 142-144.

6. Homans J.
The etiology and treatment of varicose ulcers of the leg.
Surg Gynecol Obstet 1917; 24: 300-315.

7. Gourdin FW, Smith JG.
Etiology of venous ulceration.
South Med J 1993; 86: 1142-1146.

8. Gross EA, Wood CR, Lazarus GS, Margolis DJ.
Venous leg ulcers: an analysis of underlying venous disease.
Br J Derm 1993; 129: 270-274.

9. Cornwall JV, Doré CJ, Lewis JD.
Leg ulcers: epidemiology and aetiology.
Br J Surg 1986; 73: 693-696.

10. Lauretani F, Russo CR, Bandinelli S, Bartali B, Cavazzini C, Di Iorio A, Corsi AM, Rantanen T, Guralnik JM, Ferrucci L.
Age-associated changes in skeletal muscles and their effect on mobility: an operational diagnosis of sarcopenia.
J Appl Physiol 2003; 95: 1851-1860.

11. Moura RMF, Gonçalves GS, Navarro TP, Britto RR, Dias RC.
Relationship between quality of life and the CEAP clinical classification in chronic venous disease.
Rev Bras Fisioter 2010; 14: 99-105.

12. Shahin Ul Islam MM, Haque Z, Alam J, Noman M, Siddiqui FM.
Chronic venous insufficiency (CVI): a study of 100 cases.
J Medicine 2008; 9: 20-26.

13. Veldhuizen JW, Verstappen FTJ, Vroemen JPAM, Kuipers H, Greep JM.
Functional and morphological adaptations following four weeks of knee immobilization.
Int J Sports Med 1993; 14: 283-287.

14. Parkkari J, Natri A, Kannus P, Mänttäri A, Laukkanen R, Haapasalo H, NenonenA, Pasanen M, Oja P, Vuori I.
A controlled trial of the health benefits of regular walking on a golf course.
Am J Med 2000; 109: 102-108.

15. Baker MK, Atlantis E, Fiatarone Singh A.
Multi-modal exercise programs for older adults.
Age and Ageing 2007; 36: 375-381.

16. Gaylarde PM, Dodd HJ, Sarkany I.
Venous leg ulcers and arthropathy.
Br J Rheumatol 1990; 29: 142-144.

17. Back TL, Padberg FT, Araki CT, Thompson PN, Hobson RW.
Limited range of motion is a significant factor in venous ulceration.
J Vasc Surg 1995; 22: 519-523.

18. Dix FP, Brooke R, McCollum CN.
Venous disease is associated with an impaired range of ankle movement.
Eur J Vasc Endovasc Surg 2003; 25: 556-561.

19. Martin RL, McPoil TG.
Reliability of ankle goniometric measurements: a literature review.
J Am Podiatr Med Assoc 2005; 95: 564-572.

20. White R, Schuren J, Konn D.
emi-rigid vs rigid glass fibre casting: a biomechanical assessment.
Clin Biomech 2003; 18: 19-27.

21. Moffatt CJ, Edwards L, Collier M, Treadwell T, Miller M, Shafer L, Sibbald RG, Brassard A, McIntosh A, Reyzelman A, Price P, Kraus SM, Walters S-A, Harding K.
A randomised controlled 8-week crossover clinical evaluation of the 3M Coban 2 Layer Compression System versus Profore to evaluate the product performance in patients with venous leg ulcers.
Int Wound J 2008; 5: 267-279.

22. Appel HJ.
Skeletal muscle atrophy during immobilization.
Int J Sports Med 1986; 7: 1-5.

23. Appel HJ.
Morphology of immobilized skeletal muscle and the effects of a pre- and postimmobilization training program.
Int J Sports Med 1986; 7: 6-12.

24. Berg HE, Larsson L, Tesch PA.
Lower limb skeletal muscle function after six weeks of bed rest.
J Appl Physiol 1997; 82: 182-188.

25. Booth FW.
Effect of limb immobilization on skeletal muscle.
J Appl Physiol 1982; 52: 1113-1118.

26. Booth FW.
Physiological and biochemical effects of immobilization on muscle.
Clin Orthop 1987; 215: 15-20.

27. Buckwalter JA.
Should bone, soft-tissue, and joint injuries be treated with rest or activity?
J Orthop Res 1995; 13: 155-156.

28. Leblanc A, Gogia P, Schneider V, Krebs J, Schonfeld E, Evans H.
Calf muscle area and strength change after five weeks of horizontal bed rest.
Am J Sports Med 1988; 16: 624-629.

29. Häggmark T, Eriksson E, Jansson E.
Muscle fiber type changes in human skeletal muscle after injuries and immobilization.
Orthopedics 1986; 9: 181-185.

30. Finsen V, Benum P.
Osteopenia after ankle fracture: the influence of early weight bearing and muscle activity.
Clin Orthop 1989; 245: 261-268.

31. Finsen V, Saeterno R, Kibsgaard L, Farran K, Engebretsen L, Bolz KD, Benum P.
Early postoperative weight-bearing and muscle activity in patients who have a fracture of the ankle.
J Bone Joint Surg 1989; 71A: 23-27.

32. Booth FW.
Time course of muscular atrophy during immobilization of hindlimb in rats.
J Appl Physiol 1977; 43: 225-230.

33. Booth FW, Seider MJ.
Recovery of skeletal muscle after 3 months of hindlimb immobilization in rats.
J Appl Physiol 1979; 47: 435-439.

34. Józsa M, Järvinen M, Kannus P, Réffy A.
Fine structural changes in the articular cartilage of the rat's knee following short-term immobilisation in various positions: a scanning electron microscopical study.
Int Orthop 1987; 11: 129-133.

35. Józsa L, Kannus P, Thöring J, Réffy A, Järvinen M, Kvist M.
The effect of tenotomy and immobilisation on intramuscular connective tissue: a morphometric and microscopic study in rat calf muscles.
J Bone Joint Surg 1990; 72B: 293-297.

36. Chesworth BM, Vandervoort AA.
Comparison of passive stiffness variables and range of motion in uninvolved and involved ankle joints of patients following ankle fractures.
Phys Ther 1995; 75: 253-261.

37. Barnett SL, Bagley AM, Skinner HB.
Ankle weight effect on gait: orthotic implications.
Orthopedics 1993; 16: 1127-1131.

38. Port AM, McVie JL, Naylor G, Kreibich DN.
Comparison of two conservative methods of treating an isolated fracture of the lateral malleolus.
J Bone Joint Surg 1996; 78B: 568-572.

39. Schuren J.
Working with Soft Cast: a manual on semi-rigid immobilisation.
Minnesota, Mining and Manufacturing 1994.

40. Stuart PR, Brumby C, Smith SR.
Comparative study of functional bracing and plaster cast treatment of stable lateral malleolar fractures.
Injury 1989; 323-326.

41. Whitelaw G, Wetzler M, Segal D, Lee P, Menio G.
Postoperative management of ankle fractures with pneumatic braces versus short leg casts.
J Orthop Trauma 1991; 5: 243.

42. Zeegers AVCM, Raay van JJAM, Werken van der C.
Ankle fractures treated with a stabilizing shoe.
Acta Orthop Scand 1989; 60: 597-599.

43. Bosco C, Belli A, Astrua M, Tihanyi J, Pozzo R, Kellis S, Tsarpela O, Foti C, Manno R, Tranquilli C.
A dynamometer for evaluation of dynamic muscle work.
Eur J Appl Physiol 1995; 70: 379-386.

44 .Kaikkonen A, Kannus P, Järvinen M.
A performance test protocol and scoring scale for the evaluation of ankle injuries.
Am J Sports Med 1994; 22: 462-469.

45. Fowler PF, Botte MJ, Mathewson JW, Speth SR, Byrne TP, Sutherland DH.
Energy cost of ambulation with different methods of foot and ankle immobilization.
J Orth Res 1993; 11: 416-421.

46. Fitts RH, Brimmer CJ.
Recovery in skeletal muscle contraction after prolonged hindlimb immobilization.
J Appl Physiol 1985; 59: 916-923.

47. Ahl T, Dalén N, Holmberg S, Selvik G.
Early weight bearing of malleolar fractures.
Acta Orthop Scand 1986; 57: 526-529.

48. Ahl T, Dalén N, Holmberg S, Selvik G.
Early weight bearing of displaced ankle fractures.
Acta Orthop Scand 1987; 58: 535-538.

49. Eisele R, Weickert E, Eren A, Kinzl L.
The effect of partial and full weight-bearing on venous return in the lower limb.
J Bone Joint Surg 2001; 83B: 1037-1040.

50. Helliwell PS, Cheesbrough MJ.
Arthropathica ulcerosa: a study of reduced ankle movement in association with chronic leg ulceration.
J Rheumatol 1994; 21: 1512-1514.

51. Kügler C, Strunk M, Rudofsky G.
Venous pressure dynamics of the healthy human leg: role of muscle activity, joint mobility and anthropometric factors.
J Vasc Res 2001; 38: 20-29.

52. Roaldsen KS, Rollman O, Torebjork E, Olsson E, Stanghelle JK.
Functional ability in female leg ulcer patients: a challenge for physiotherapy.
Physiother Res Int 2006; 11: 191-203.

53. Sochart DH, Hardinge K.
The relationship of foot and ankle movements to venous return in the lower limb.
J Bone Joint Surg 1999; 81B: 700-704.

54. Clarke-Moloney M, Godfrey A, O'Connor V, Meagher H, Burke PE, Kavanagh EG, Grace PA, Lyons GM.
Mobility in patients with venous leg ulceration.
Eur J Vasc Endovasc Surg 2007; 33: 488-493.

55. Barwell JR, Taylor M, Deacon J, Davies C, Whyman MR, Poskitt KR.
Ankle motility is a risk factor for healing of chronic venous leg ulcers.
Phlebology 2001; 16: 38-40.

56. Lentner A, Spath F, Wienert V.
Limitation of movement in the ankle and talo-calcaneonavicular joints caused by compression bandages.
Phlebology 1997; 12: 25-30.

57. Rivlin S.
Gravitational leg ulcers in the elderly.
Lancet 1958; 271: 1363-1367.

Chapter 5

Laplace's law

5.1. Laplace's law

Pierre-Simon Laplace (1749-1827), a French mathematician and astronomer, was born in Beaumont-en-Auge in the south of Normandy (figure 5.1). He was among the most influential scientists in history. He is known for his technical contributions to exact science and for the leading part he took in forming the modern discipline of mathematical physics [1].

Figure 5.1: Sophie Feytaud (1842): posthumous portrait of Pierre-Simon Laplace.

In 1805, Laplace described a formula that defined the pressures exerted on curved surfaces [2]. Laplace's law describes the relationship between pressure, tension, radius, and thickness of a vessel wall. The law of Laplace states that the tension in the wall of a container, necessary to contain a given pressure on the contents, is inversely proportional to the curvature of the wall, or, in other words, directly proportional to the radius of curvature at any point [3]. This relation is expressed in the equation: $T = (P \times R) / M$, where T is the tension in the wall, P is the pressure difference across the wall, R is the radius of the vessel, and M is the thickness of the wall.

An example of the use of Laplace's law is seen when blowing up a balloon. The harder one blows, the higher the air pressure inside the balloon gets and the higher the difference will be between the pressures outside and inside of the balloon. When the difference increases, the pressure pushes outward, the tension in the wall of the balloon will rise and the material stretches lengthwise. When the balloon is made of thicker rubber like in a tire, it is harder to inflate it because more pressure difference is required to raise the tension in the wall. Pipes for household plumbing need to withstand a certain pressure; the wider gauges have thicker walls and therefore are much more expensive (4).

When blood flows through a blood vessel, the blood vessel wall is stretched because of the difference between the blood pressure inside the vessel and the surrounding pressure outside the vessel. It is obvious that the higher the pressure difference, the more tension there will be and the thicker the wall, the less tension there is. Also the larger the radius, the more tension there is.

Laplace's law is frequently used in medicine to explain the physics of respiratory physiology and shape of the ventricles of the heart or the pathology of vascular and gastrointestinal wall like aneurysms, varicose veins or bladder rupture, emptying the bladder or a gravid uterus and in the use of supportive devices for weight-lifters, low back pain and compressive support to control oedema or chronic venous insufficiency. From the cellular level to the skin, anywhere something is enclosed in a compliant membrane, the law of Laplace should apply (3).

5.2. Laplace's law and compression therapy

The pressure generated by a bandage application is a function of the tension in the fabric and the radius of curvature of the limb to which it is applied. The relationship between these factors is also governed by Laplace's law, as the sub-bandage pressure is directly proportional to bandage tension, but inversely proportional to the radius of curvature of the limb to which it is applied (5). This relation is expressed in the equation: $P=T/R$, where P is the sub-bandage pressure, T is the tension with which the bandage is applied and R is the radius of the curvature to which the bandage is applied (figure 5.11).

However, while Laplace's original formula provided a mechanistic view of the pressures exerted on curved surfaces, it did not take into account the adaptations that can occur in living organisms, for example, the human leg, which is neither solid nor has a constant curved structure (6). Therefore, the direct relationships that occur in solid objects may not apply to human bodies with deformable or irregular surfaces (7).

To include the importance of bandage width and the number of layers applied, Thomas (5) modified Laplace's law in such a way that it might be used in clinical practice. The modified equation below, often referred to as Laplace's law, is frequently used to calculate the sub-bandage pressures of compression systems:

$$\textit{pressure mmHg} = \frac{\text{tension (KgF)} \times \text{number of layers} \times 4620}{\text{circumference (cm)} \times \text{bandage width (cm)}}$$

In the examples of the blood vessel and the balloon, the tension in the walls acts throughout the entire area of the structure. In contrast, in the case of a bandage applied to a cylinder or limb, the pressure is only exerted upon that area covered by the bandage. This pressure will be determined by the total force applied to the fabric and the bandage width in accordance with the definition of pressure, which states that Pressure = Force/unit area. This means that a 10 cm wide bandage applied with a total force of ”F” Newton will produce only half the pressure developed beneath a 5 cm wide bandage applied with the same force as the force is distributed over twice the area. Bandage tension must therefore be expressed in the Laplace equation as force per unit width, which is why a value for bandage width must be included in the formula [5].

The use of this modified equation of Laplace’s law to calculate or predict sub-bandage pressure remains controversial and the consistent formation of an ideal pressure gradient has been difficult to demonstrate practically. It has been suggested that the failure to demonstrate graduated compression may reflect poor operator technique, poor measurement technique, or the practical problems of maintaining constant tension throughout the bandage during the application process [8]. Williams et al [9] state that the use of Laplace’s equation must be interpreted with care with regard to the complex application of bandages to the leg. This is because the leg is neither cylindrical nor comprised of fluid and therefore the tension around the limb is unlikely to be constant. Additionally, the equation may not take into account all of the factors that can operate beneath a compression bandage [7].

Also Thomas [5] recognises the weakness of the formula and states that the calculated value for sub-bandage pressure is the average pressure that will be exerted by a bandage on a limb of known circumference. A limb will exhibit marked differences in radius at various points around its circumference and pressure values determined using a direct measuring device at these locations would vary dramatically from the calculated average. The positioning of pressure sensors is therefore critical, as these will produce different results depending upon where they are placed around the leg. This is why pressures determined experimentally do not always correlate well with predicted calculated values. For this reason it is usually recommended that padding be applied beneath compression bandages to fill concavities and protect more prominent areas to reduce local variations in sub-bandage pressure to acceptable values. In daily practice, many practitioners use a variety of padding materials, not only for the suggested filling of concavities e.g. retro-malleolar, or to protect bony prominences e.g. the tibial crest, but also to reshape an irregularly shaped leg, which is often seen around and above the ankle joint due to lipodermatosclerosis (see also chapter 7.4).

5.3. Test methods

To study the applicability of Laplace’s law on the use of compression bandaging materials, data from three studies, in which measurements were taken from 744 compression bandages applied to artificial legs equipped with pressure transducers are presented. In these studies the same artificial leg and sensor positioning was used and the collected data could be pooled to provide information on a large number of applications by experts in compression bandaging.

5.3.1. Theoretical pressure values for studies 1, 2 & 3

Theoretical pressure values on the three pressure sensors (positioned at 22 cm, 27 cm and 33 cm leg circumference) were calculated using the modified Laplace's law equation. The physical properties of all the tested bandage materials were measured using a Hounsfield tensile tester, to record the force needed to stretch the included bandage materials to the elongation suggested by the manufacturer. If the manufacturer recommends a bandage to be applied at 50% stretch, the force needed to stretch this bandage to 50% was measured. This force value has been used for the calculation. The number of layers, as well as the amount of stretch at which individual layers were applied, were taken from manufacturers' recommendations.

5.3.2. Study 1

Thirty-two experts in the application of compression bandages for the treatment of venous leg ulcers were invited to participate in this study, the details of which have been described elsewhere [10]. Three small Kikuhime pressure transducers were used to monitor and record the forces operating under the compression bandages applied to an artificial leg. The transducers were positioned on fixed gel cushions on the artificial legs (figure 5.2). The first transducer was applied 10 cm above the medial malleolus, where the leg circumference was 22 cm. The second halfway between the first and third transducer at a leg circumference of 27 cm. The third transducer was applied at the leg's widest circumference (33 cm), which was approximately 15 cm below the anticipated top of the bandage.

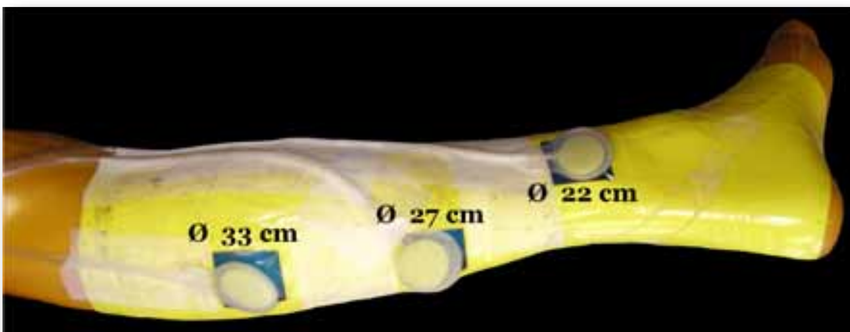


Figure 5.2: artificial leg with pressure transducers at three different circumference levels.

The study participants were asked to apply the compression bandage system they used most often to the artificial leg equipped with the transducers, they were asked to do this three times. Pressure forces at each of the three transducer locations were recorded immediately after each application. Data were collected from four separate compression bandage systems:

- Profore multi-layer compression bandage system;
- Actico cohesive short-stretch bandage;
- Unna's Boot compression system covered with a Coban bandage;
- Rosidal K short-stretch compression bandage.

After the participants finished applying the compression bandage system they used most often, the technique for applying the Coban two-layer compression system was demonstrated. The participants then applied this system to non-sensored artificial legs enough times to familiarise themselves with the application procedure. They were then asked to apply the Coban two-layer compression system to the artificial leg equipped with the transducers, again, they were asked to do this three times. Before each application, the pressure transducers were calibrated to a force of zero mmHg. The pressure was recorded immediately after each application.

5.3.3. Study 2

The second study was designed as a controlled laboratory screening evaluation of early two-layer compression bandage prototypes [11]. The prototypes tested in this study were similar in design and function to the commercially available Coban 2, but with minor modifications. Sub-bandage pressures were measured on an artificial leg using six Gaeltec strain gauge temperature-compensated (15–40° C) force transducers. The transducers were 13 mm in diameter and 3 mm thick and were connected via amplifiers and filters to a computer, from which the data was recorded.

Three 5 x 5 cm holes were cut in the artificial leg, into which thin aluminium plates were fitted. The location of the aluminium plates corresponded with the location of the transducers described in Study 1 (figure 5.2). On top of each plate, a sensor was fixed with 3M double-sided adhesive tape. In this way, the aluminium plates provided sufficient counterforce to avoid sensor movement. A small gutter carved into the artificial leg allowed the cable to be positioned without interfering with the pressure measurements (figure 5.3.a).

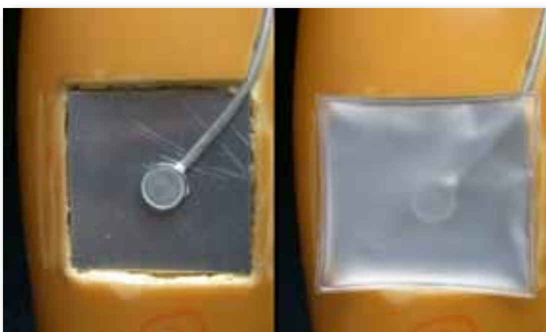


Figure 5.3.a:positioning of the Gaeltec pressure transducer on top of an aluminium plate.
Figure 5.3.b: the ethylene glycol bag on top of the Gaeltec sensor;
at the right top, the gutter for the cable positioning.

Three 5 x 5 cm plastic bags filled with ethylene glycol were positioned to fill the holes in such a way that the surface of the bags was just above the surface of the leg (figure 5.3.b). The bags were fixed at the borders with tape and a double 3M Synthetic Cast Stockinette was used to cover the leg.

Three orthopaedic technicians, experienced in the field of compression therapy, each applied 40 bandages to the artificial leg. Before each application, the pressure transducers were calibrated to a force of zero mmHg. Pressure values were immediately recorded after each application.

5.3.3. Study 3

The design of this study [11] was the same as Study 2, except that eight nurses experienced in the field of compression therapy each applied 54 Coban 2 Layer Systems with minor modifications. As in Study 2, pressure values were recorded immediately after each application.

5.4. Results

5.4.1. Theoretical pressure values for studies 1,2 & 3

The sum of the individual layers determined the final theoretical pressure values provided at the different circumferences (table 5.1). As can be seen in figure 5.4, the data from the Thomas equation show that all of the materials under investigation theoretically provide graduated compression.

	specifics on application	Kgf from tensile tester	x 4620	x nr of layers	at 22 cm: (22 x 10)	at 27 cm: (27 x 10)	at 33 cm: (33 x 10)
Profore layer 1	no stretch	0.075	346.5	693.0	3.15	2.57	2.10
Profore layer 2	50% stretch	0.502	2319.2	4638.5	21.08	17.18	14.06
Profore layer 3	50% stretch	0.382	1764.8	3529.7	16.04	13.07	10.70
Profore layer 4	50% stretch	0.334	1543.1	3086.2	14.03	11.43	9.35
					54.31	44.25	36.20
short stretch layer 1	minimal	0.075	346.5	693.0	3.15	2.57	2.10
short stretch layer 2	50% stretch	1.427	6592.7	13185.5	59.93	48.84	39.96
					63.08	51.40	42.06
Actico layer 1	no stretch	0.075	346.5	693.0	3.15	2.57	2.10
Actico layer 2	full stretch	1.630	7530.6	15061.2	68.46	55.78	45.64
					71.61	58.35	47.74
Unna boot layer 1	minimal	0.100	462.0	2772.0	12.60	10.27	8.40
Unna boot layer 2	50% stretch	0.334	1543.1	3086.2	14.03	11.43	9.35
					26.63	21.70	17.75
Coban 2 layer 1	no stretch	0.075	346.5	346.5	1.58	1.28	1.05
Coban 2 layer 2	full stretch	1.500	6930.0	13860.0	63.00	51.33	42.00
					64.58	52.62	43.05

Table 5.1: theoretical pressure values of the materials under investigation using the Thomas equation.

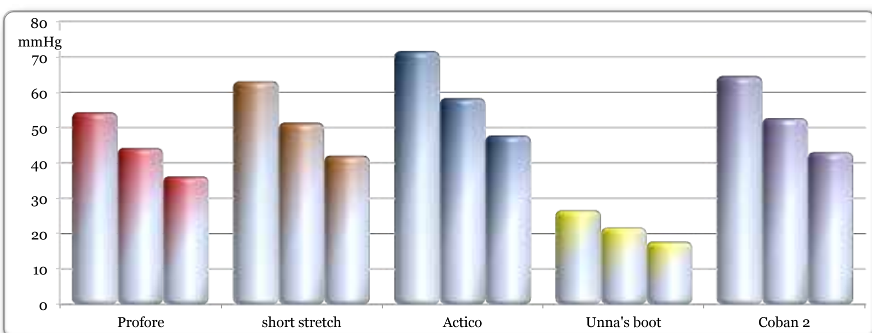


Figure 5.4: theoretical graduated compression according to the Thomas equation with from left to right, circumferences of 22, 27 and 33 cm.

5.4.2. Study 1

In Study 1, 192 applications of the five compression systems were included in the analysis. Graduated compression was only observed in one of the 24 Actico applications (4.2%); two of the 24 Profore applications (8.3%); one of the 24 Rosidal K short-stretch applications (4.2%); two of the 24 Unna's Boot applications (8.3%); and seven of the 96 Coban 2 applications (13.5%). Mean pressure values at the 22 cm, 27 cm and 33 cm circumference transducers for each of the tested products are provided in figure 5.5. None of the systems under investigation provided graduated compression.

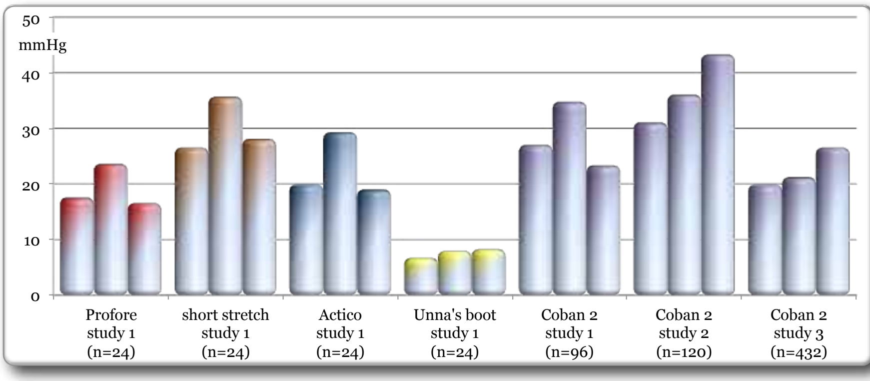


Figure 5.5: mean pressure values from all included studies.

5.4.3. Study 2

All 120 applications of the two-layer compression bandage were included in the analysis. Graduated compression could only be observed in nine (7.5%) of the applications. Mean pressure values for all 120 applications are provided in figure 5.5.

5.4.4. Study 3

All 432 applications of the two-layer compression bandage were included in the analysis. Graduated compression could only be observed in 31 (9.1%) of the applications. Mean pressure values for all 432 applications are provided in figure 5.5.

5.5. The effect of applied number of layers

5.5.1. Introduction

As mentioned in chapter 5.2, Thomas [5] modified Laplace's law in such a way that it can be used in clinical practice by including the importance of bandage width and the number of layers applied:

$$\textit{pressure mmHg} = \frac{\text{tension (KgF)}\ x\ \text{number of layers}\ x\ 4620}{\text{circumference (cm)}\ x\ \text{bandage width (cm)}}$$

In this equation, each applied layer multiplies the resulting pressure with its own number. It is obvious that there will be an effect of adding an extra layer. However, multiplying the outcome by a number that is equal to the number of layers can be questioned. To examine the applicability of the formula, a test was executed on the roll winder described in chapter 3, in which pressure and strain index were measured with different number of layers.

5.5.2. Materials and methods

The automatic roll winder and methods described in chapter 3 were used to measure the pressure and strain index of applications with only the outer compression layer of Coban 2 and Coban 2 Lite and with Rosidal K. All bandages were applied at full stretch. Pressure recordings were taken after adding 1-8 layers immediately after the application.

5.5.3. Results

One layer of the Coban 2 applied at full stretch gave a pressure of 25 mmHg, the same application for Coban 2 Lite 19 mmHg and for Rosidal K applied at full stretch, a pressure value of 22 mmHg was measured. Based on the pressure provided by the first layer, the theoretical values were calculated with the Thomas equation [5]. These values are presented in the dotted lines in the figures 5.6, 5.7 and 5.8. The actual measured pressures are presented as diamonds, the strain indices as triangles. Because the numbers of the strain indices are low, differences are difficult to identify on the large scale of the vertical axis. Therefore they are also presented on a smaller vertical axis scale in figure 5.9.

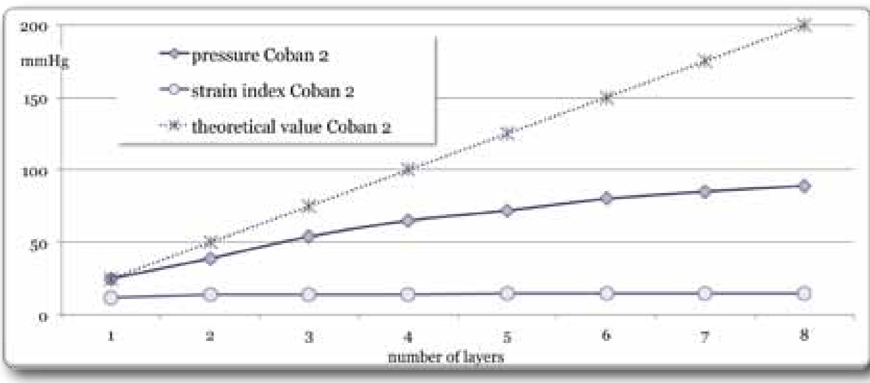


Figure 5.6: theoretical pressure values, measured values and strain indices of different number Coban 2 layers.

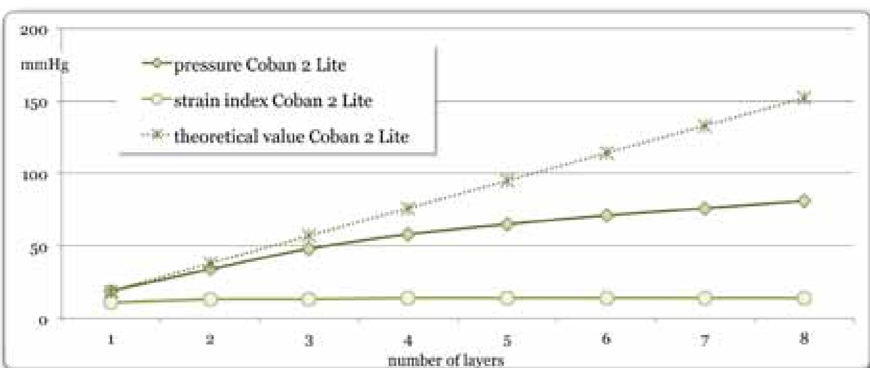


Figure 5.7: theoretical pressure values, measured values and strain indices of different number Coban 2 Lite layers.

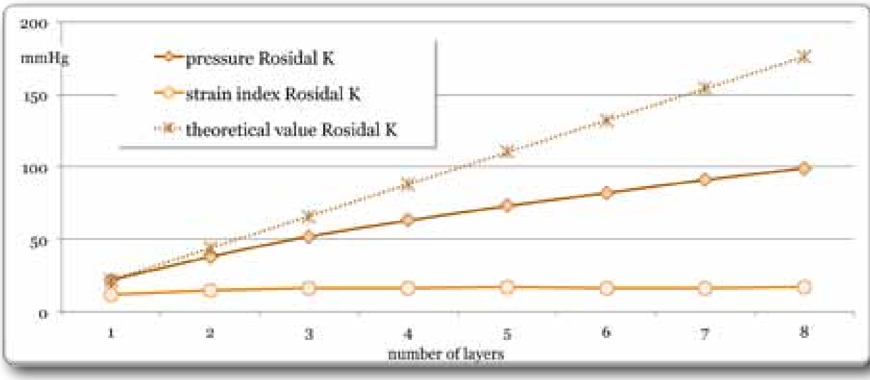


Figure 5.8:
theoretical pressure values, measured values and strain indices of different number Rosidal K layers.

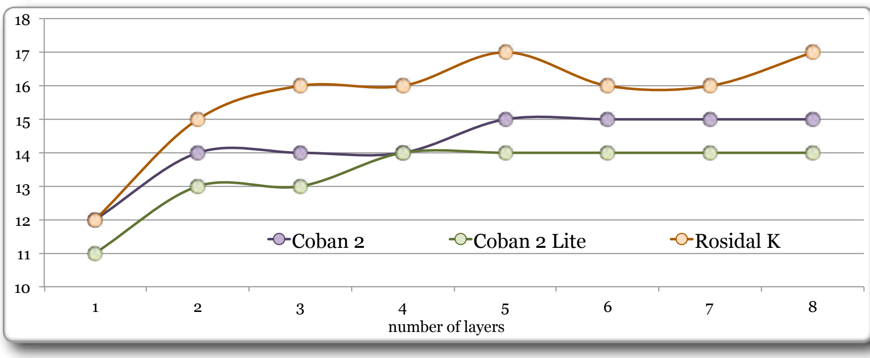


Figure 5.9:
strain indices for the three materials under investigation.

5.5.4. Discussion

Thomas explains that the application of two layers of a bandage, applied with constant tension, will double the number of yarns over any particular point on the surface of the leg and thus, for all practical purposes, double the pressure applied. For this reason the number of layers of bandage applied must be considered when calculating sub-bandage pressure [5]. The actual measurements that were performed after complete controlled applications reveal that this is not the case. In the above graphs, the lines of the theoretical and actual values have only a common starting point. Already from the second layer, the values deviate. A more interesting observation was identified with the measurements of the strain index in this study. As in all cases the bandages were applied at full stretch, there is only a small increase in the observed index between layer 1 and layer 2, after which the indices stay more or less stable by adding additional layers. In clinical practice, especially in lymphoedema bandaging, often more overlapping layers are applied to produce the desired pressure characteristics [12]. Looking at the measured strain indices, it is obvious that the effectiveness of a properly applied compression system is not determined by the number of layers but by the fact that these layers are applied at full stretch.

5.6. Discussion

There is a widespread belief that most of the compression systems currently on the market provide graduated compression, with a pressure of 35-40 mmHg at the ankle, dropping off to about 15 mmHg at the widest circumference of the calf.

The original Charing Cross four-layer compression system was developed to apply 40 mmHg of pressure at the ankle, graduating to 17 mmHg at the knee (13). Blair et al (14) state that because of the increased radius from ankle to calf, graduated compression will be applied automatically providing the same tension and overlap are used. They add that mistakes in the tension applied in any one layer of the four-layer system will tend to be averaged out. Much of the literature supports the 40–17 mmHg compression value as the ideal in healing venous leg ulcers (15). Many practitioners also take these values for granted and sub-bandage pressure measurements are rarely performed (16-20).

Cherry et al (21) state that oedema reduction is associated with improved ulcer healing. Therefore, measuring the limb circumference to assess whether there has been a reduction in oedema, is another way of monitoring whether pressure bandaging has been effective.

When pressure values are reported in the literature, the authors often refer to Laplace’s law, citing it as a reliable method for predicting sub-bandage pressure (5). Thomas (5) also explains that the pressures provided by compression bandages are the result of a very complex interaction between the properties of the materials used, the size and shape of the leg, the technique of the bandager and the activities of the patient.

How strong the belief in the reliability is, is demonstrated in a study in which 15 experienced UK district nurses, selected because their proven skills and expertise in routinely applying the Charing Cross four-layer bandaging system, were invited to apply K-Lite and K-Plus, two new multi-layer systems (22). Pressure was recorded in the supine position, while sitting with the knee at a 90° flexion, and while standing with the feet flat on the floor and in plantar flexion of the ankle joint during toe stance. Three pressure sensors were positioned 4 cm above the lateral malleolus, mid-calf at the widest circumference and 2 cm below the fibular head. The evaluation revealed that true graduated compression could only be observed in the sitting position, a position in which the calf muscles are maximally relaxed. The authors state that this unexpected observation must be due to the nurses unknowingly increasing the tension when applying the bandage around the calf.

It can be hypothesised that, if the properties of the materials as well as leg size and shape are controlled, as was the case in the the studies 1, 2 and 3 in this paper, the modified Laplace equation can be used with confidence. If deviations from the modified Laplace equation do occur, they could be explained by the differences in bandaging technique.

However, Wertheim et al (23), using the legs of healthy volunteers, measured the pressures exerted beneath compression stockings, where bandaging techniques are not influencing the measured pressures. They found that none of the measurements showed any graduated compression.

The discrepancies between the presented findings from the studies 1, 2 and 3, presented in figure 5.5 and the theoretical values presented in figure 5.4 may be explained by a major difference between Laplace's law and Thomas' modified equation. In the latter, the circumference of the leg is used to calculate the expected forces, whereas in Laplace's formula, the radius of curvature determines the final pressure. However, the artificial leg that was used in the studies 1, 2 and 3, as well as the volunteer's legs in study 7, have no consistently curved structure.

In a cross-sectional view of a leg, which is not a perfect circle (figure 5.10.a), many different radii of curvature can be seen (figure 5.10.b).

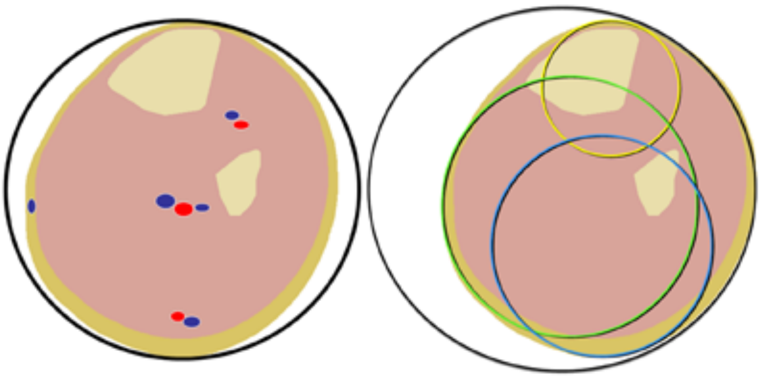


Figure 5.10.a: the cross-sectional view of the leg shows that the leg is not a perfect circle.
Figure 5.10.b: in the cross-sectional view, many radii of curvature can be seen.

Subsequently, for each individual radius, a pressure can be calculated using Laplace's law (figure 5.11.a). This means that the final pressure arrived at depends on the radius of the specific curvature on which a sensor is positioned, rather than on the circumference of the leg at the level of positioning (figure 5.11.b).

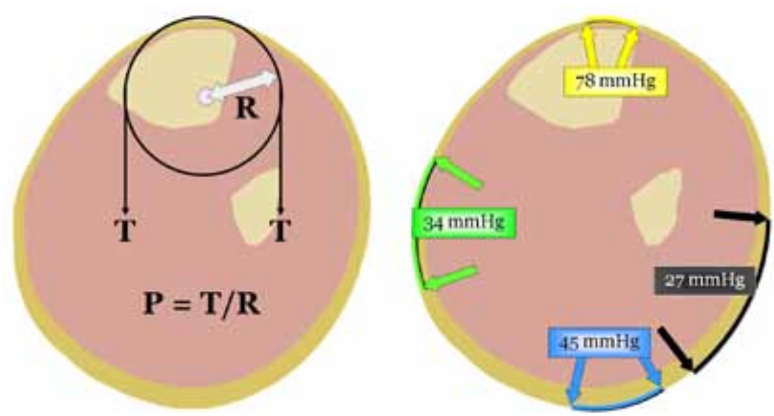


Figure 5.11.a: Laplace's law presented in the cross-sectional view using one of the circles from figure 5.10.b; the final pressure depends on the radius of that specific circle.
Figure 5.11.b: theoretical values for each of the circles from figure 5.10.b.

Thomas [5] explains that because the direct measurement of the radius is virtually impossible in a clinical setting and for that reason, the more familiar measure of circumference is preferred. De Bruyne and Dvořák present a device to measure the pressure exerted by an elastic stocking without upsetting the original application [24]. The method reveals that a cross-sectional pressure value, which is the result of the Thomas equation, is not a realistic value due to variation in curvature. The authors demonstrated that the radial pressure is only exerted on convex surfaces and the tested stocking cannot exert pressure if the surface is plane or concave.

The studies presented in this chapter have several limitations. First, the majority of the bandages were applied to artificial legs, which may or may not accurately model the human leg. Second, as discussed by Thomas [5], sub-bandage pressures can be influenced by the technique and experience level of the bandagers.

However, while this criticism is valid for compression studies in general, all of the bandages in the studies used in this article were applied by experts in the field of compression therapy. Furthermore, in Study 1, the experts applied the compression system they were most familiar with, minimising the potential for errors due to unfamiliarity.

Finally, the compression bandages in these studies were applied under controlled conditions and not in a true clinical environment. While this last criticism remains valid, it is true to say that these studies should have produced data that presented Laplace's law in its best light as the environment, subject, and bandagers were well controlled. However, the pressure calculations made using the modified Laplace's law equation did not accurately predict the pressure values found in these three studies. In fact, true graduated compression was observed in only 53 of the 744 (7.1%) applications.

Recently, Rabe et al [25] recommended measuring sub-bandage pressures in future clinical trials. The importance of measuring the static stiffness index (the pressure in standing position minus the pressure in supine position) to describe the physical properties of a compression system was discussed by Partsch et al [26]. In addition, measuring sub-bandage pressures widely gains popularity because of the availability of relatively inexpensive pressure measurement devices. The use of these devices is encouraged, but should be used to calculate the stiffness and thus the effectiveness of applied systems. Currently they are often incorrectly used to guide the applier to provide hypothetical levels of sub-bandage pressures.

The results of an application guided by pressure can be dramatic for the effectiveness of an applied compression system. When a bandage is applied, a major part of the effectiveness is determined by how relaxed the leg is during the application. The superficially positioned gastrocnemius muscle forms the prominent contour of the calf. This strong two-headed muscle passes two joints, its origin is on both femoral condyles, distally both heads form a broad aponeurosis, which with the tendon of the soleus muscle forms the Achilles tendon. Therefore the most relaxed position of this powerful muscle is achieved when the knee is flexed and the ankle joint is in plantar flexion. In most bandage applications, the leg is never in this position, the knee is flexed, the ankle in the 90° position. In addition, often the patient is asked to lift the leg to facilitate the application. In this position, the most prominent contributor to the calf muscle pump is completely under tension. It is obvious what the effect will be on the stiffness index and functional amplitudes of an applied compression system. When a bandage is applied guided by observed pressures and the objective is to achieve graduated compression, the bandage has to be more relaxed during the windings around the calf than during the turns around the ankle joint. If bandages are applied in this way, there is a great chance that a stiffness index measured in the calf area will be negative. In other words, there is no support at all of the calf muscle pump during functional activities. The nurses that were invited to participate in the evaluation of new compression systems by Taylor et al [22] were blamed for their unknowingly increasing of the bandage tension around the calf muscles. Actually they should have been complimented for their experience in handling compression bandages. The worst thing that could happen to them, would be that they were forced to have pressure sensors guiding their application.

5.7. Conclusions

The theoretical pressure values calculated by the modified Laplace's law equation do not accurately predict the values found when compression bandages were applied by experts in three separate studies. The data from the studies clearly indicates that in-vivo pressure values calculated by using Laplace's law should be interpreted with care.

In addition, none of the compression systems tested in these three studies provided dependable graduated compression on the artificial legs used in the studies. It can be concluded, therefore, that the widespread belief that correctly applied compression systems provide pressure values graduating from 40 mmHg at the ankle to 17 mmHg below the knee, is based solely on theoretical mathematical equations and is not supported by the results of the experimental studies in this chapter.

5.8. References

1. Gillispie CC.
Pierre Simon Laplace 1749–1827: a life in exact science.
Princeton: Princeton University Press 1997.

2. Pellicer J, Garcia-Morales V, Hernández MJ.
On the demonstration of the Young-Laplace equation in introductory physics courses.
Phys Educ 2000; 35: 126-129.

3. Stillwell GK.
The law of Laplace: some clinical applications.
Mayo Clin Proc 1973; 48: 863-869.

4. Vogel S.
The law of Laplace.
In: Vogel S. Vital circuits: on pumps, pipes, and the workings of circulatory systems. Oxford University Press 1993: 118-121.

5. Thomas S.
The use of the Laplace equation in the calculation of sub-bandage pressure.
EWMA J 2003; 3: 21-23.

6. Basford JR.
The law of Laplace and its relevance to contemporary medicine and rehabilitation.
Arch Phys Med Rehabil 2002; 83: 1165-1170.

7. Melhuish JM, Clark M, Williams RJ, Harding KG.
The physics of sub-bandage pressure measurement.
J Wound Care 2000; 9: 308-310.

8. Clark M.
Compression bandages: principles and definitions.
In: Calne S. (Ed.) EMWA Position Statement: Understanding compression therapy. Medical Education Partnership LTD 2003: 5-7.

9. Williams RJ, Wertheim D, Melhuish J, Harding KG.
How compression therapy works.
J Wound Care 1999; 8: 297-299.

10. Collier M, Schuren J.
Ease of use and reproducibility of five compression systems.
J Wound Care 2007; 16 (3M supplement): 8-10.

11. Schuren J, Mohr K.
The efficacy of Laplace's equation in calculating bandage pressure in venous leg ulcers.
Wounds UK 2008; 4: 38-47.

12. Strössenreuther RHK, Klose G.
Practical instructions for therapists: general requirements for compression bandages.
In: Földi M, Földi E (eds). Földi's textbook of lymphology. Elsevier GmbH, Munich, Germany 2006; 2nd edition: 599-602.

13. Moffatt CJ, Dickson D.
The Charing Cross high compression four-layer bandage system.
J Wound Care 1993; 2: 91-94.

14. Blair SD, Wright DD, Backhouse CM, Riddle E, McCollum CN.
Sustained compression and healing of chronic venous ulcers.
BMJ 1988; 297: 1159-1161.

15. Moore Z.
Compression bandaging: are practitioners achieving the ideal sub-bandage pressures?
J Wound Care 2002; 11: 265-268.

16. Bowering CK.
Use of layered compression bandages in diabetic patients: experience in patients with lower leg ulceration, peripheral edema, and features of venous and arterial disease.
Adv Wound Care 1998; 11(3): 129-135.

17. Eagle M.
Compression bandaging.
Nurs Stand 2001; 15(38): 47-52.

18. Ukat A, Konig M, Vanscheidt W, Münter KC.
Short-stretch versus multilayer compression for venous leg ulcers: a comparison of healing rates.
J Wound Care 2003; 12: 139-143.

19. Trent JT, Falabella A, Eaglstein WH, Kirsner RS.
Venous ulcers: pathophysiology and treatment options.
Ostomy Wound Manag 2005; 51: 38-54.

20. Kalodiki E, Ellis M, Kakkos SK, Williams A, Davies AH, Geroulakos G.
Immediate hemodynamic effect of the additional use of the SCD Express compression system in patients with venous ulcers treated with the four-layer compression bandaging system.
Eur J Vasc Endovasc Surg 2007; 33: 483-487.

21. Cherry GW, Hoffman D, Cameron J, Poore SM.
Bandaging in the treatment of venous ulcers: a European view.
Ostomy Wound Manag 1996; 42: 13-18.

22. Taylor AD, Taylor RJ.
A comparison of sub-bandage pressures produced with two multi-layer bandaging systems.
J Wound Care 1999; 8: 444-448.

23. Wertheim D, Melhuish J, Williams R, Lane I, Harding K.
Movement-related variation in forces under compression stockings.
Eur J Endovasc Surg 1999; 17: 334-337.

24. Bruyne de P, Dvořák T.
The pressure exerted by an elastic stocking and its measurement.
Med Biol Eng 1976: 14(1): 94-96.

25. Rabe E, Partsch H, Jünger M, Abel M, Achhammer I, Becker F, Cornu-Thenard A, Flour M, Hutchinson J, Issberner K, Moffatt Ch, 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.

26. Partsch H, Clark M, Mosti G, Steinlechner E, Schuren J, Abel M, Benigni JP, Coleridge-Smith P, Cornu-Thénard A, Flour M, Hutchinson J, Gamble J, Issberner K, Juenger M, Moffatt C, Neumann HA, Rabe E, Uhl JF, Zimmet S.
Classification of compression bandages: practical aspects.
Dermatol Surg 2008; 34: 600-609.

Chapter 6

Pascal's law

6.1. Pascal's law

Blaise Pascal (1623-1662), an influential French mathematician, physicist and religious philosopher, was born in Clermont-Ferrand in the Auvergne (figure 6.1). Pascal's most famous work in philosophy is "Pensées", a collection of personal thoughts on human suffering and faith in God, in which "Pascal's Wager" claiming to prove that belief in God is rational with the following argument: "If God does not exist, one will lose nothing by believing in Him, while if He does exist, one will lose everything by not believing." [1,2]. His inventions include the first digital calculator to help his father with his work collecting taxes, the hydraulic press and the syringe. In the international systems of units (SI), the pascal (symbol: Pa) is the unit of pressure, internal pressure, stress, Young's modulus and tensile strength. It is a measure of force per unit area, defined as one newton per square metre.

Figure 6.1: anonymous (17th century): portrait of Blaise Pascal.

Pascal's work on hydrodynamics and hydrostatics focuses on the properties of fluids in hydraulic systems. Pascal's law states that, when there is an increase in pressure at any point in a contained fluid, there is an equal increase at every other point in the container. Pascal's principle means that an incompressible fluid transmits applied pressure. It can be demonstrated by making a few similar openings in a closed toothpaste tube. If pressure is applied at any point on the tube, the toothpaste will come out evenly from all the holes.

In this chapter, it will be demonstrated that Pascal's law is also applicable if instead of a fluid, soft body tissues are transmitting applied forces. Three studies are presented; the first is a cadaver study to demonstrate that unstable tibia fractures are supported by the forces of an applied supporting brace, which are transmitted through the surrounding soft tissues (3). In addition, two experimental studies are presented, demonstrating that Pascal's law can be used with confidence to explain the dynamics of compression therapy, provided that the proper condition, i.e. a contained fluid, is available (4).

6.2. Pascal's law and soft tissue

6.2.1. Introduction

In orthopaedics, Pascal's physical law is often used in the treatment of diaphyseal fractures such as of the tibia or humerus. Another important principle in physics is that a fluid under normal circumstances, is incompressible. Sarmiento and Latta (5) found that soft tissue is comparable to a closed fluid column if these soft tissues are supported by a rigid fracture brace. Without the possibility of an increase of the circumference of the soft tissues, the tibia cannot shorten. The function of the brace is not to bear the applied load; only a small amount of the load is borne by the brace. The function of the brace is to prevent a change in the circumference of the soft tissues. If a load is applied on the fluid-like soft tissues, protected by a brace, this load will be transmitted equally in all directions. This means that the soft tissues carry most of the load. In this way, the fracture is supported and stabilised by the surrounding supported fluid column i.e. the braced soft tissues. Therefore, functional fracture bracing is possible in the treatment of long bone fractures, which are surrounded by soft tissues in not only the weight bearing bones such as the tibia and femur but also the bones of the forearm and the humerus (6).

Motion occurs when load is applied to the limb. In weight bearing bones, it is easy to understand when these load forces are present. In the non weight bearing bones, this motion occurs under the influence of different factors including the influence of muscle activity on the fractured bone. Gravity also plays an important role because it produces muscle activity in changing positions. In a freshly fractured bone, motion can be produced very easily. If a brace is applied and the load increases, motion does not increase. The reason for this is that during the application of the small amount of load there is also a small amount of pressure in the surrounding soft tissues. Increase in load also increases the pressure in the soft tissues. The fluid-like soft tissues are incompressible and the forces are transmitted equally in all directions. The load, which is transmitted to the soft tissues, is controlled and distributed by the surrounding cylinder containing them. Many studies have shown that controlled motion in a fracture has advantages for the quality of the fracture healing. When the muscle compartments around the fractured long bones are bound by a fracture brace, they will displace under load but only until all the gaps within the container are filled [5]. From then, the pressure created by functional activities will be transmitted to support and stabilise the fractured bone.

Even when a brace that is made of a flexible but non-stretchable material is used, fractures can be supported similarly to treatment with a completely rigid brace [3]. Sarmiento and Latta [5] demonstrated that the compliance of a piece of beefsteak could be significantly improved by tightly wrapping it with a sleeve of paper. The above findings demonstrate that soft tissues in the human body act as incompressible fluids. As a consequence, Pascal's Law may be used to explain the principles and dynamics of compression therapy. Functional cast bracing has been applied utilising a combination of hard and Soft Casting materials with documented clinical success. A "combicast brace" (CCB) is made of Soft Cast with an anterior slab of hard Scotchcast and split posteriorly with straps, which allow adjustment to maintain soft tissue compression [7].

To compare the initial stability provided to a tibial shaft fracture by a CCB to that of a conventional thermoplastic custom fracture brace (TFB) a study on cadaver legs was designed and executed.

6.2.2. Materials and methods

Five fresh cadaver legs with all soft tissues intact had fractures produced by drilling a stress riser on the anterior surface of the mid-shaft of the tibia, applying a torque to the limb and impacting the limb at the stress riser. Secondarily, the leg was bent to fracture the fibula at the same level as the tibia fracture. This consistently produces a closed, mid-shaft, spiral oblique fracture of the tibia with an associated transverse fracture of the fibula at the same level (figure 6.2.a and b). Further manipulation of each fracture created consistent soft tissue damage and an initial instability of about ± 30° angulation with gravity (figure 6.2.c and d).

Figure 6.2.a,b:
X-rays of a typical mid-shaft spiral oblique fracture of tibia with associated fractured fibula.
Figure 6.2.c,d: resulting initial instability with gravity.

Each limb had cyclic compression loads applied to measure the instability in angulation and rotation for the unsupported injury. Next internal and external torque was applied to the limb and the total rotation, spring-back angle and residual rotational deformity were measured. Next, a TFB was applied followed by a CCB with the measurements repeated for each (figure 6.3.a, b and c).

Figure 6.3.a: the braced area (from: Schuren J. Working with Soft Cast: a manual on semi-rigid immobilisation. IF Publication Services, Düsseldorf 1994).
Figure 6.3.b: the thermoplastic brace.
Figure 6.3.c: the combicast brace.

6.2.3. Results

Both braces provided similar excellent stability against angulatory deformities, moderate stability against rotational deformities and poor stability against shortening. The results are very similar to previous measurements by the investigators in plaster casts, custom and prefabricated fracture braces loaded in the same manner with fractures created in the same manner [(8)].

6.2.4. Conclusion

A properly applied combicast brace of soft and hard casting materials provides stability and control of fracture site motion, which is at least as good as, can be achieved with rigid custom or prefabricated braces for diaphyseal fractures of the tibia. The flexible soft brace, which creates an inelastic sleeve around the leg, keeps the forces that are created by the applied load within the leg and supports the fracture. The brace takes advantage of the intrinsic strength of the soft tissues and their incompressible fluid properties in such a way that the fracture fragments can be adequately controlled without limitation of the joints above and below the fracture [(5)]. Pascal's law explains this phenomenon.

6.3. Volunteer studies on compression therapy

6.3.1. Study 1

To demonstrate the effects of transmission of pressure within a compression system, three Gaeltec strain gauge temperature-compensated (15-40°C) force transducers, 13 mm in diameter and 3 mm thick, connected via amplifiers and filters to a computer, were positioned to the lower leg of a healthy volunteer (4). Two sensors were placed distally (sensor 1) and proximally on the musculus tibialis anterior (sensor 1 and 2), the third (sensor 3) on the B1 position. Posteriorly, a large Kikuhime pressure sensor was positioned (sensor 4). This sensor partially covered the lateral and medial head of the musculus gastrocnemius (figure 6.4.a). Next, a Coban 2 system was applied as discussed in chapter 2.8.1. After the application, the pressure on the Gaeltec transducers was zeroed so that only changes were recorded. The Kikuhime sensor was gradually inflated to 50, 100, 150, 200 and 250 mmHg and deflated. The pressure changes on the three sensors during inflation and deflation was recorded.

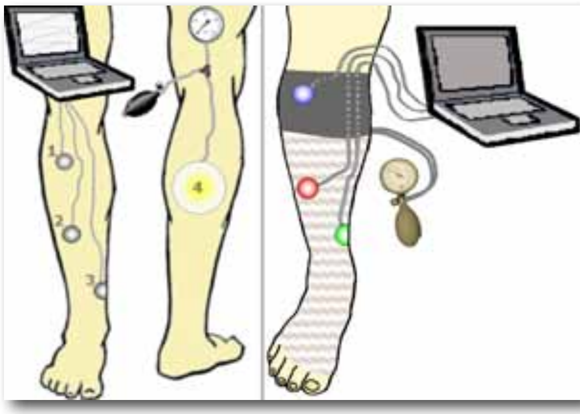


Figure 6.4.a: the positioning of the pressure sensors (1, 2 and 3) and the inflatable transducer (4) from study 1.
Figure 6.4.b: the positioning of the sensors and the blood pressure cuff used in study 2.

6.3.2. Study 2

The effects of transmission of pressure in a compressed lower leg were examined in a controlled laboratory study (4) to evaluate 3M Coban 2-layer Compression System prototypes. The study was approved by the ethics commission of the Freiburger Ethik-Kommission GmbH, Germany and 3M's Institutional Review Board. Each participant signed an informed consent. Three Gaeltec pressure sensors were positioned on the lower legs of twelve healthy volunteers (6 female and 6 male). Two sensors were placed distally and proximally on the musculus tibialis anterior, the third on the B1 position. 9 prototypes were tested on both legs, in total 216 systems with a high stiffness (static stiffness index > 10) were applied . After the application of each system, a blood pressure cuff was applied over the most proximal sensor. The two distal sensors were not covered (figure 6.4.b). Next, the blood pressure cuff was gradually inflated and pressure was recorded on the three sensors during 0, 20, 40, 60, 80 and 100 mmHg inflation.

6.4. Results

6.4.1. Study 1

The test with the inflatable transducer revealed that inflation of the transducer gives an increase of pressure throughout the leg. The recording at the three sensors is presented in figure 6.5.

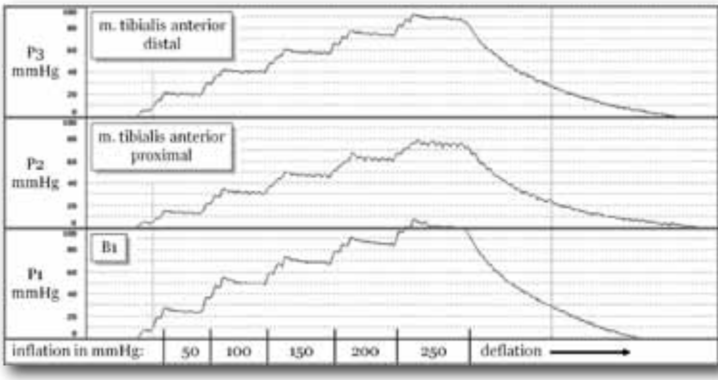


Figure 6.5: pressure recordings during gradual inflation of the inflatable transducer marked "4" in figure 6.4.a.

6.4.2. Study 2

The results of the study on the effects of the inflated blood pressure cuff are presented graphically in figure 6.6. Because a different starting value was measured on each sensor, the changes that were measured during the inflation of the cuff are not presented in mmHg, but as percent changes. It is clearly shown that the sensors that are not located under the blood pressure cuff (distally on the m. tibialis anterior and on B1), show pressure changes at each 20 mmHg increase of pressure, which are similar to the changes that are observed on the sensor under the cuff (proximal on the m. tibialis anterior).

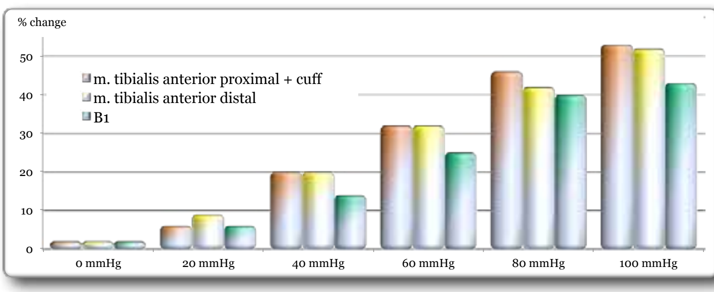


Figure 6.6: percent pressure changes under the compression bandage with gradual inflation of the blood pressure cuff (n=216).

6.5. Discussion

The human skin is made of a stretchable material. This can be easily demonstrated by comparing the circumference of the upper arm of a body-builder at rest and the same arm with the biceps muscles under tension. Because of this ability to stretch, human skin absorbs much of the forces produced by functional activity. To keep these forces inside the leg in the presence of venous insufficiency, the so-called muscle pump is often supported with additional compression around the leg to improve venous flow. Narrowing of veins is considered to be a basic objective of compression therapy [9]. Current concepts indicate that compression effectiveness for venous ulcers is partially linked to the amount of sub-bandage pressure exerted [10]. Clinical practice is based on achieving high enough compression to deliver the most favourable outcome in venous ulcer treatment [11,12]. Based on a combination of Starling's equation [13] and the known range of venous pressures measured at the ankle in normal, varicose and post-thrombotic legs, Backhouse et al [14] state that an external pressure of 35-40 mmHg at the ankle is theoretically required to prevent capillary transudation in legs with severe venous disease. As a result, it is advocated that, to reverse venous hypertension in an ambulatory patient, an average pressure of 40 mmHg is required at the ankle, with a graduated decrease up the leg to approximately 20 mmHg at the calf [15]. This is now commonly referred to as "40-17". Much of the literature supports these 40-17 mmHg compression values as the ideal in healing venous leg ulcers [16]. Many practitioners take these values for granted and sub-bandage pressures are therefore rarely measured [17-22]. The widespread belief that correctly applied compression systems provide pressure values graduating from 40 mmHg at the ankle to 17 mmHg below the knee, is based solely on theoretical mathematical equations [23]. In this light, it is interesting to see how a giraffe, with probably the most challenging venous return in nature, avoids pooling of blood and oedema in the extremities. Minimal movement, produced by only a small amount of calf muscles, creates great variations in pressure, which combined with a tight and non-stretchable skin layer, move fluid upward against gravity in a very effective way [24-25]. Similar to human skin, the skin of the giraffe is not tight, which means the resting pressure underneath the skin is very low. The effective return of fluid against gravity is produced with a very low resting pressure that is provided by the giraffe's natural compression system: its leather-like skin. This system does not allow the circumference changes during functional activities, which can be observed in the human leg. Mosti and Mattaliano [26] showed that the control of leg circumference changes by bandages of different elasticity, during functional activities is related to the stiffness of the bandage. The giraffe does not need resting pressures of 40 mmHg around the ankle joint to effectively move fluid to heights much greater than human.

Recently it was proposed that in the case of multilayer bandage systems, the terms "high or low stiffness" should be used to characterise the behaviour of the final bandage [27]. Stiffness may be characterised by the increase of interface pressure measured in the gaiter area when standing up from the supine position. A pressure increase of more than 10 mmHg measured in the gaiter area is characteristic for a stiff bandage system [28]. Compression systems with high stiffness have the effect of a non-stretchable second skin. This means that within a stiff compression system, muscle movement creates pressure, which is evenly distributed within the lower limb as if in a closed cylinder. These pressures can be measured by positioning pressure transducers between the skin and the compression system. Compression systems with high stiffness will have a similar effect on an included leg, as a tube on the included toothpaste. The paste can only be pressed out, if the wall of the tube cannot be stretched. A compression system with a high stiffness index does not only form a cylinder around the leg but also manages to keep the forces that are produced by functional activities, inside the cylinder. In return, these forces effectively compress the veins similar to the toothpaste. The blood in compressed veins will flow to the area were it can escape. Because the functional activities in the leg are dynamic and cyclic, also the tissue pressures are dynamic, cyclic and changing with every muscle contraction [29]. Due to the positioning of the valves in the veins, an increase of pressure will result in venous backflow to the heart. Bandages with a high static stiffness index result in the effect of an inelastic second skin after application. This means that the pressure, built up by the muscles during functional activities, works against a rigid tube and increases the pressure in this closed cylinder. The effect can be compared with emptying a tube in which the only opening in the closed system is the nozzle. In the lower leg, these are the blood vessels. The more the pressure in a tube is built up, the greater the force the fluid will be pressed out. If this force is built up within a compressed lower leg, the effects are equal and insufficient venous and lymphatic systems are optimally supported (figure 6.7.a and b).

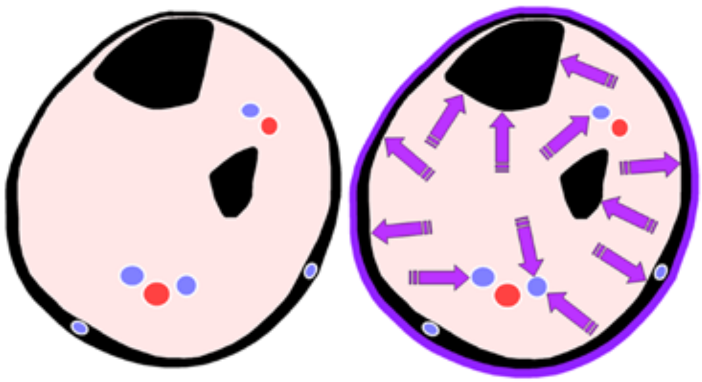


Figure 6.7.a: cross section of the lower leg.
Figure 6.7.b: when muscle activity creates pressure within the compressed leg (right), then according to Pascal's law, the pressure will be transmitted evenly within the compressed area.

6.6. Conclusion

The dynamics of effective compression therapy are explained by Pascal's Law, which states that when pressure is applied (functional activity) on a fluid (soft tissues, a muscle or muscle group) in a closed container (fascia muscularis, a fracture brace or a compression bandage), there is an equal increase at every other point in the container.

6.7. References

1. Coleman FXJ.
Neither angel nor beast: the life and work of Blaise Pascal.
New York 1986, Routledge & Kegan Paul Inc.

2. Mesnard J.
Pascal: his life and works.
London 1952: Harvill Press.

3. Schuren J, Milne EL, Zych GA, Sarmiento A, Latta LL.
Fracture stability in tibia braces: an analysis in anatomic specimens.
Proceedings of the 66th Annual Meeting of the American Academy of Orthopaedic Surgeons; 1999 Feb 4-8; Anaheim CA, USA. Rosemont ILL: AAOS; 1999: 96-97.

4. Schuren J, Mohr K.
Pascal's law and the dynamics of compression therapy: a study on healthy volunteers.
Int Angiol 2010; 29: 431-435.

5. Sarmiento A, Latta LL.
Functional fracture bracing.
Berlin, Heidelberg: Springer-Verlag; 1995.

6. Schuren J.
Functional bracing of upper limb fractures with Soft Cast.
In: Schuren J (ed). Working with Soft Cast: evidence-based fracture care, symposia proceedings & abstracts of publications. Rehms Druck Borken 2000: 67-70.

7. Schuren J.
Working with Soft Cast: a manual on semi-rigid immobilisation.
IF Publication Services, Düsseldorf 1994.

8. Zagorski JB, Latta LL, Finnieston AR, Zych GA.
Tibial fracture stability: analysis of external immobilization in anatomic specimens in casts and braces.
Clin Orthop 1993; 291: 196-207.

9. 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.

10. Mayrovitz HN, Sims N.
Effects of ankle-to-knee external pressures on skin blood perfusion under and distal to compression.
Adv Skin Wound Care 2003; 16: 198-202.

11. Blair SD, Wright DD, Backhouse CM, Riddle E, McCollum CN.
Sustained compression and healing of chronic venous ulcers.
BMJ 1998; 297: 1159-1161.

12. Moffatt CJ, Dickson D.
The Charing Cross high compression four-layer bandage system.
J Wound Care 1993; 2: 91-94.

13. Starling EH.
On the absorption of fluids from the connective tissue spaces.
J Physiol 1896; 19: 312-326.

14. Backhouse CM, Blair SD, Savage AP, Walton J, McCollum CN.
Controlled trial of occlusive dressings in healing chronic venous ulcers.
Br J Surg 1987; 74: 626-627.

15. Moffatt C.
Variability of pressure provided by sustained compression.
Int Wound J 2008; 5: 259-265.

16. Moore Z.
Compression bandaging: are practitioners achieving the ideal sub-bandage pressures?
J Wound Care 2002; 11: 265-268.

17. Bowering CK.
Use of layered compression bandages in diabetic patients: experience in patients with lower leg ulceration, peripheral edema, and features of venous and arterial disease.
Adv Wound Care 1998; 11: 129-135.

18. Eagle M.
Compression bandaging.
Nursing standard 1999; 13(20): 48-56.

19. Ukat A, Konig M, Vanscheidt W, Münter KC.
Short-stretch versus multilayer compression for venous leg ulcers: a comparison of healing rates.
J Wound Care 2003; 12: 139-143.

20. Trent JT, Falabella A, Eaglstein WH, Kirsner RS.
Venous ulcers: pathophysiology and treatment options.
Ostomy Wound Manage 2005; 51(5): 38-54.

21. Grey JE, Harding KG, Enoch S.
Venous and arterial leg ulcers.
BMJ 2006; 332: 347-350.

22. Kalodiki E, Ellis M, Kakkos SK, Williams A, Davies AH, Geroulakos G.
Immediate hemodynamic effect of the additional use of the SCD Express Compression System in patients with venous ulcers treated with the four-layer compression bandaging system. Eur J Vasc Endovasc Surg 2007; 33(4): 483-487.

23. Schuren J, Mohr K.
The efficacy of Laplace's equation in calculating bandage pressure in venous leg ulcers.
Wounds UK 2008; 4 (2): 38-47.

24. Hargens AR, Millard RW, Pettersson K, Johansen K.
Gravitational haemodynamics and oedema prevention in the giraffe.
Nature 1987; 329 (6134): 59-60.

25. Pedley TJ.
Haemodynamics: how giraffes prevent oedema.
Nature 1987; 329 (6134): 13-14.

26. Mosti GB, Mattaliano V.
Simultaneous changes of leg circumference and interface pressure under different compression bandages.
Eur J Vasc Endovasc Surg 2007; 33 (4): 476-482.

27. Partsch H, Clark M, Mosti G, Steinlechner E, Schuren J, Abel M, Benigni JP, Coleridge-Smith P, Cornu-Thénard A, Flour M, Hutchinson J, Gamble J, Issberner K, Juenger M, Moffatt C, Neumann HA, Rabe E, Uhl JF, Zimmet S.
Classification of compression bandages: practical aspects.
Dermatol Surg 2008; 34: 600-609.

28. Partsch B, Partsch H.
Calf compression pressure required to achieve venous closure from supine to standing positions.
J Vasc Surg 2005; 42 (4): 734-738.

29. Hardy AE.
Force and pressure recordings from patients with femoral fractures treated by cast-brace application.
J Med Eng Technol 1981; 5 (1): 30-36.

Chapter 7

The effects of padding

7.1. Introduction

In 1881, Richard von Volkmann described a paralysis and contractures as a result of a tight application of a cast to an injured extremity [1]. Volkmann's contracture is always mentioned as one of the complications of circular casts. Another dangerous complication that is often described and referred to as a complication of a circular cast, is the compartment syndrome, which is defined as a condition where high pressure within a closed fascial space reduces capillary blood perfusion below the necessary level for tissue viability. The end-result of an untreated compartment syndrome can be an irreversible soft tissue injury or the Volkmann's contracture. All this means that there are some arguments against a circular cast in the acute stage of the fracture treatment. That is why backslabs or split and spread casts are often used for the initial fracture treatment. In spite of these concerns, the skin-tight cast has proven its advantages throughout the years.

In the hospital where I was educated as an orthopaedic technician, displaced distal radius fractures, mostly referred to as Colles' fractures, were repositioned and treated with a padded, circular plaster of Paris. After setting, the plaster, padding and stockinette were split and an elastic bandage was applied. After a job rotation, I was introduced to another approach. The late orthopaedic surgeon A. Busch used an eight-layer backslab of plaster of Paris, which encircled 90% of the forearm. He applied this splint directly to the skin after reduction. A wet Cambric bandage, a non-elastic bandage, was wrapped on the setting plaster. Then the plaster was moulded precisely to the anatomy. The distal and proximal borders were well defined. Because there was no elasticity in the Cambric bandage, this application could be referred to as a skin-tight circular application in an acute phase. The advantage of this application was the perfect stabilisation of the fracture. Patients experienced this plaster as comfortable. On X-rays, the perfect anatomically applied plaster of Paris was visible. I have never seen paralytic or serious vascular complications with this treatment from using this technique. These techniques evolved with the introduction of new materials [2].

If a patient has a need for a cast for whatever reason, he actually needs stabilisation. The best way to stabilise is to connect a few points to avoid specific movements. Every layer of padding between a chosen point and the applied cast decreases the optimal stabilisation [2]. The X-ray in figure 7.1.a shows a typical cast that is applied for a Colles' fracture after repositioning. In figure 7.1.b, the space between the skin and the plaster-of-Paris is highlighted. This space allows intracast movement of the fracture, which is very painful. Patient instructions to move fingers and elbow joint as much as possible to avoid stiffness and improve the circulation are useless. Pain and function are not the best partners and pain often causes an involuntary immobilisation, which limits the attempts to avoid the negative effects of immobilisation [3]. The X-ray in figure 7.1.c shows a Soft Cast combicast applied without padding as described by Schuren [2]. It is easy to imagine that the fracture is stabilised significantly better in this cast compared to the one on the left. Movements of fingers and elbow are less painful, patients are encouraged to be functional and it is obvious what the effects on circulation will be of these improved functional activities.

Figure 7.1.a: distal radius fracture treated with a padded plaster of Paris.
Figure 7.1.b: the area between the patient's skin and the plaster is marked.
Figure 7.1.c. the same fracture treated with an unpadded circularly applied combicast.

In a prospective randomised study, Breznik [4] compared the above technique with the traditional padded plaster of Paris on 102 patients with displaced distal radius fractures. The results revealed that there were fewer complications in the course of the treatment in the combicast group, that less corrective actions were required. The patients in this group were more capable of performing everyday tasks and taking care of themselves, thus being less dependent on the help of a third party. At 18 weeks post injury, the treatment results in the Soft Cast group, evaluated according to Sarmiento's score [5], were significantly better than those in the plaster of Paris group (figure 7.2)

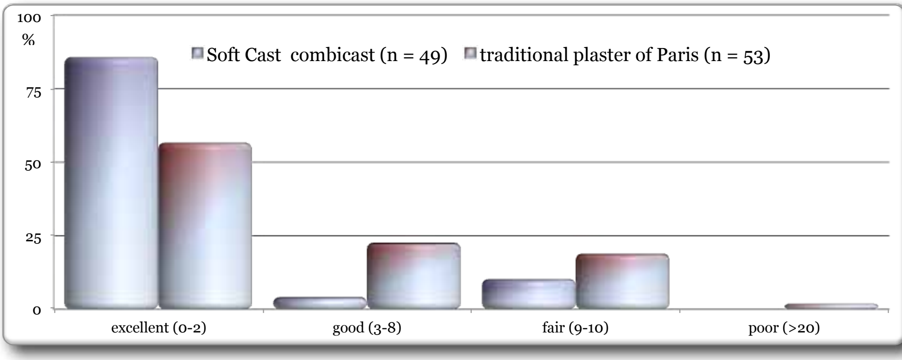


Figure 7.2: evaluation of the results of distal radius fractures 18 weeks post injury.

Van Thiel [6] applied the unpadded combicast immediately after repositioning and compared the anatomical results with those from the routinely used padded and split plaster of Paris. It was found that there was no difference of complaints during the treatment as well as that there was no difference in functional outcome and in performing activities of daily living after 3 months follow up.
However, for the anatomical features radial length, radial deviation and volar tilt at cast removal [5], there was a significant difference favouring the combicast group (figure 7.3).

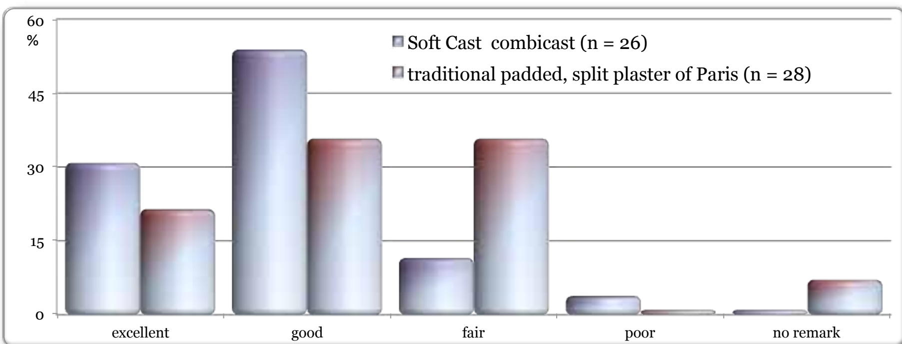


Figure 7.3: evaluation of anatomical features at cast removal.

Padding materials are applied for two reasons: to protect bony prominences and to accommodate post-traumatic swelling. With the available synthetic materials, it is possible to apply smooth and wrinkle-free padding. However, a critical look at the surface of carefully applied padding shows that there is a certain degree of irregularity. If a plaster-of-Paris or a rigid synthetic cast is applied over this padding and it is moulded to the anatomy, it is impossible to detect this irregularity from the outside of the application. This means that the moulding of the cast results in an unequal internal pressure. If this moulding is done in areas with very superficial vessels like the dorsum of the hand, one can imagine what the effect of this unequal internal pressure will be on the venous backflow and the development of finger oedema.

Dr. Lorenz Böhler (1885-1973), a well-known trauma surgeon from Vienna (figure 7.4) has published many books on fracture treatment. In all of them, one key message can be found: functional activities are crucial for effective fracture care. On the use of padding, he had a very clear message: ”a padded cast is only for transport; not for the treatment of fractures” [7].

Figure 7.4: Lorenz Böhler (1885-1973).

Sir John Charnley (1911-1982), an orthopaedic surgeon from the UK has written an important manual on the closed treatment of the most common fractures [8] Referring to Böhler’s work, he states: ”so powerful were his convictions that even now the word padding is still regarded in many circles as something unmentionable or as something for which to apologise”.

For many reasons, compression therapy for chronic venous ulceration can be compared to cast treatment for fractures. Maintaining or improving circulation as well as functional activities are common objectives. Historically and similar to the application of plaster-of-Paris, the use of padding materials has not been common practice for compression therapy. And similar to the application of plaster-of-Paris, with good arguments.

7.2. Test methods

The effects of padding were studied on healthy volunteers wearing different types of cast. In addition, three laboratory tests were designed:

- two studies in which data were collected specially designed irregularly shaped artificial legs to study the effects of padding materials; one leg has a so called inverted champagne bottle shape, the other a skin fold around the ankle joint as is often seen in lymphoedema patients;
- one study in which data were collected on cylinders to study the effects of adding additional layers of padding materials.

These four studies are presented in this chapter.

7.3. Padding in orthopaedic casts

7.3.1. Introduction

A study was performed at the Grampian Gait & Movement Analysis Centre of the University of Aberdeen, Scotland to determine if semi-rigid synthetic casts, being applied without padding materials, provide any measurable advantages compared to rigid synthetic casts where routinely padding materials are used [9]. In this study, below-knee and below-arm casts were applied to healthy volunteers. As in the below-knee casts pressure transducers were only positioned around the ankle joint, only the results are presented from the measurements on the forearm as in this application, the sensors were positioned on the entire casted area, using the technique described by Moir et al [10]. The main objective of the study was to measure the immobilising effects of the different casts by evaluating the three-point loading pattern recommended by Charnley [8] for a Colles' fracture, a displaced fracture of the distal radius. The collected data however present an excellent overview of the pressure profile over the entire arm, especially because padded and unpadded casts are compared during different functional activities.

7.3.2. Materials and methods

Prior to cast application goniometers and pressure transducers were attached to the forearm. Five members of the orthopaedic department from the University of Aberdeen Grampian University Hospitals Trust, two orthopaedic technicians, two orthopaedic specialist registrars and an orthopaedic surgeon, each applied rigid and a semi-rigid below elbow so called Colles' cast to a single volunteer subject using the synthetic bandages normally used in this hospital and following their normal application technique. A single volunteer arm was used to ensure consistency for comparison of cast application. The orthopaedic technicians and the orthopaedic surgeon were considered to be expert or regular cast applicators, the registrars to be non-expert or occasional cast applicators. The purpose of establishing these two groups was to determine if the procedure for cast application of the functional cast could be easily acquired after a single demonstration by both expert and non-expert cast applicators.

The standard conservative method of treatment for a Colles' fracture used in this hospital is a below elbow cast with the wrist in slight palmar flexion. The cast comprises a stockinette sleeve with wool padding and a 5 cm spirally wrapped rigid glass fibre bandage (Dynacast Extra). However, these casts do not hold the wrist in a functional position and they enclose the metacarpal heads. Furthermore, the entire cast is rigid, often with sharp edges and has a rough surface finish. Hand and finger function is limited and this can lead to the problems of rigid immobilisation. These casts can therefore be uncomfortable to wear and it is often necessary to use a significant amount of wool padding to protect delicate skin. This prevents the cast from fitting closely to the limb and therefore may not give the intended degree of immobilisation. The cast roughness can also restrict movement due to skin abrasion. It is for these reasons that combination casts have gained in popularity in the past few years [11]. Schuren [2] developed a technique of functional casting that uses a combination of glass fibre bandages. The casts are based on a soft flexible cast (Soft Cast) reinforced with a rigid synthetic cast splint (Scotchcast) both being glass fibre / polyurethane resin bandages but with differing resin compositions. This technique is known as a Combicast. No wool padding is used, only stockinette and foam pads over bony prominences between the skin and the cast. This application technique was demonstrated to each applicator prior to use by one of the authors (JS). In the Colles' cast, the wrist was placed in a neutral position to allow hand function and the cast was wrapped spirally without tension to allow the bandage to conform to the limb. It was applied without constricting the fingers, and cut below the distal palmar crease to allow full finger function. The rigid dorsal reinforcing splint was applied between layers of Soft Cast to prevent wrist dorsiflexion and moulded into the palm of the hand to prevent palmar flexion. This technique allows a Colles' cast to be anatomically moulded to the wrist, permitting a few degrees of palmar flexion but preventing dorsiflexion, due to the reinforcing strip on the dorsal side. Movement of the fingers is possible as the metacarpals are not enclosed and the cast is flexible and has soft edges. The flexibility permits adaptation of the cast to a changing muscle shape during finger movements and this may encourage blood flow [12]. All casts were left to cure for 40 minutes and the volunteer was allowed time to adjust to wearing a cast before measurements were taken. Joint immobilisation and functional movement was assessed using electrogoniometry and limb support using pressure transducers.

The Oxford Pressure Monitor (OPM) was used to record interface pressures between the skin and the cast to provide a quantitative measure of the support offered to the limb. Intracast pressures were recorded at key positions during functional movements. prior to cast application, Eight flat, circular (20 mm diameter), inflatable pressure cells were attached to the skin with non-allergenic adhesive spray, at the positions shown in figure 7.5. The pressure transducers were calibrated against a digital manometer prior to use and were shown to give results that were accurate to ± 1 mmHg. However, the sampling rate of the OPM is 2-3 Hz and this limits its use to static measurements.

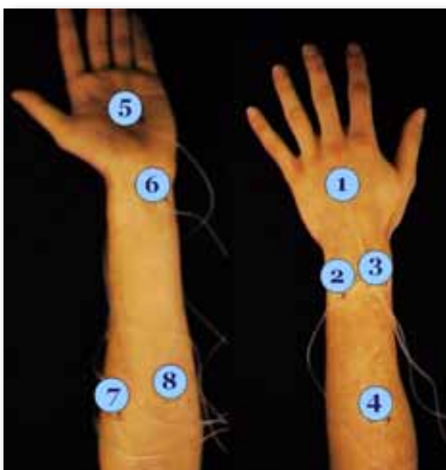


Figure 7.5: the positioning of the eight pressure sensors.

Intracast pressures were recorded with the volunteer seated, the shoulder in a neutral position, the elbow flexed at 90° and the fingers outstretched. The volunteer clenched his fist and maximally extended the fingers. The maximum pressure for each movement was recorded. Intracast pressures were also recorded during palmar flexion and dorsiflexion and radial and ulnar deviation. An average of three repeat tests was calculated. The degree of immobilisation produced by both types of cast was recorded from the electrogoniometer when the volunteer palmar and dorsiflexed the wrist sub-maximally five times.

7.3.3. Results

The goniometer measurements revealed that four out of five applicators achieved a significantly greater degree of immobilisation of the wrist when they applied a combicast, than when they applied their normal cast ($p < 0.05$). The other applicator's combicast showed greater wrist immobilisation than his normal cast, but did not achieve statistical significance. The degree of wrist immobilisation achieved was more consistent in the combicasts and furthermore, the mean dorsiflexion recorded in the combicasts was significantly lower than in the rigid casts ($p < 0.05$).

Loading in the forearm and wrist recorded by the eight pressure cells showed that the combicasts gave high pressures on the dorsal side of the cast in palmar flexion and on the volar side during dorsiflexion; similarly in radial and ulnar deviation high pressures were recorded on the lateral and medial side respectively. These results confirmed the pressure patterns expected intuitively and in line with the three-point loading pattern recommended by Charnley [8] for a Colles' fracture.

In the combicasts, the interface pressures in gauges 3, 4 and 6 consistently recorded higher pressures when the range of wrist movements described above were carried out. This indicated that the casts were providing three-point loading. The rigid casts showed little specificity and variation in interface pressure during wrist movements. A typical set of interface pressure readings is shown in the figures 7.6 for a rigid cast and 7.7 for a combicast. The graphs show that the pressure cells 3, 4 and 6 (the green bars), which represent the three loading points, gave significantly higher pressure values in the combicasts ($p < 0.001$). The mean intracast pressure readings from the pressure cells 7 and 8 on the forearm the red bars) were significantly greater in the combicasts than in the rigid casts ($p < 0.001$).

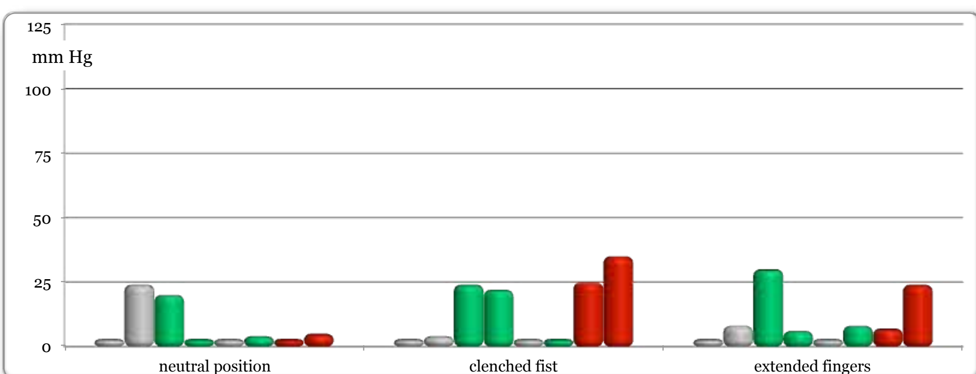


Figure 7.6: a typical set of interface pressure readings in a rigid cast.

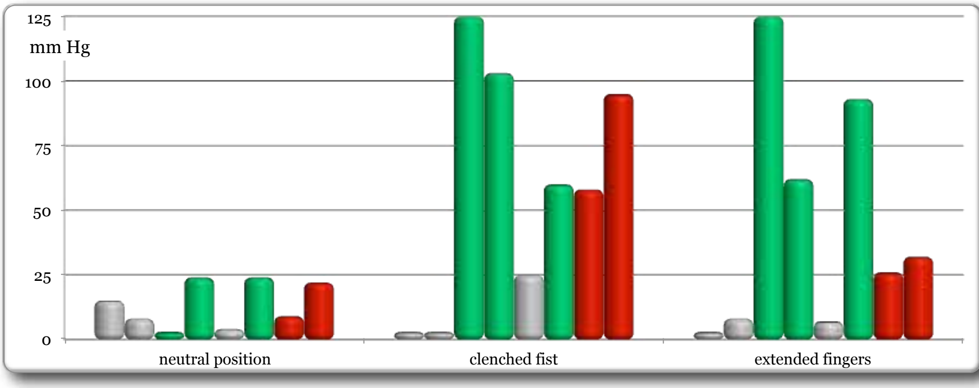


Figure 7.7: a typical set of interface pressure readings in a semi-rigid cast.

7.3.4. Discussion

It was found that the combicasts had a higher degree of immobilisation than the rigid casts probably due to the close-fitting Soft Cast with a reinforcing dorsal slab and moulding into the palm of the hand. The performance of the rigid cast was probably affected by the amount of wool padding that was deemed necessary by the applicators to minimise discomfort due to the roughness and sharp edges of the rigid glass fibre casts. Dorsiflexion of the wrist was lower in the semi-rigid casts and it is this movement that these casts are primarily designed to prevent as it potentially redisplaces the typical distal radius fracture. The clinical significance of the better fracture stabilisation provided by the combicasts may be of little consequence in the case of a Colles' cast, but shows that a more precise mechanical structure can be achieved. However, of greater value is the ability to mould the casts to achieve the three-point loading. Without this support during function, the fracture fragments may move relative to each other, which is likely to cause pain and discomfort, inhibit function and possibly cause atrophy or the fracture to redisplace.

The combicasts also had higher pressures around the forearm girth during fist clenching and finger extension. This may aid the muscle pump function in supporting the venous backflow, which is achieved by the snug fit of the cast around the muscle. With the fist clenched as well as with the fingers in full extension, the muscle bulk increases enough to cause a significant increase in pressure in combicasts and a modest increase in the rigid glass fibre casts. This observation leads to the conclusion that the unpadded combicasts provide a significantly higher support to the muscle pump and therefore significantly better support venous return.

7.4. Compression on an artificial leg with an inverted champagne bottle shape

7.4.1. Introduction

A limb deformity that is often seen in leg ulcer patients is the so-called inverted champagne bottle leg [13]. This condition occurs when lipodermatosclerotic skin becomes so sclerotic that swelling is not strong enough to widen the leg in that area. The result is that swelling occurs below and above the affected area. Often the leg is re-contoured by using padding materials.

7.4.2. Materials and methods

To study the effects of the use of padding materials to reshape an irregularly shaped leg on sub-bandage pressures, an artificial leg was developed with narrowed area around and above the ankle as is often seen with lipodermatosclerosis. Six PicoPress pressure sensors were positioned in such a way that a pressure profile could be created of the area around the narrowed area of the leg. The sensors were covered with a loose Rosidal tg stocking to avoid sensor movement during subsequent bandage applications (figure 7.8).

Figure 7.8: the artificial inverted champagne bottle shaped leg with the sensor positioning.

Next, four different methods of bandaging were used with different usage of filling the narrowed area:

- Rosidal K, a short-stretch compression bandage, applied at full stretch with circular windings with a 50% overlap and no padding.
- Rosidal K, applied at full stretch with circular windings with a 50% overlap over two layers of circularly applied 3M Synthetic Cast Padding (figure 7.9.a and b).

Figure 7.9.a: two circular layers of padding.
Figure 7.9.b: Rosidal K applied at full stretch over two layers of padding.

➠ The narrowed area was reshaped with 3M Synthetic Cast Padding (figure 7.10.a), followed by two layers of circularly applied padding 3M Synthetic Cast Padding (figure 7.10.b), covered with Rosidal K, applied at full stretch with circular windings (figure 7.10.c).

Figure 7.10.a: the reshaped narrowed area.
Figure 7.0.b: the entire area covered with two layers of padding.
Figure 7.10.c: Rosidal K applied at full stretch over two layers of padding after re-contouring the narrowed area.

➠ Coban 2, applied at full stretch, covering the area as anatomically as possible (figure 7.11.a and b).

Figure 7.11.a: the Coban 2 application, layer 1.
Figure 7.11.b: the Coban 2 application, layer 2.

Immediately after each application, the pressure was recorded with a PicoPress measuring device.

7.4.3. Results

The pressure profile of the different applications is presented as line graphs. The application of two layers Rosidal K without any further padding in a spiral manner is visualised in figure 7.12. The application results in an even distribution of pressure over the entire area with only on elevated pressure level on the forefoot.

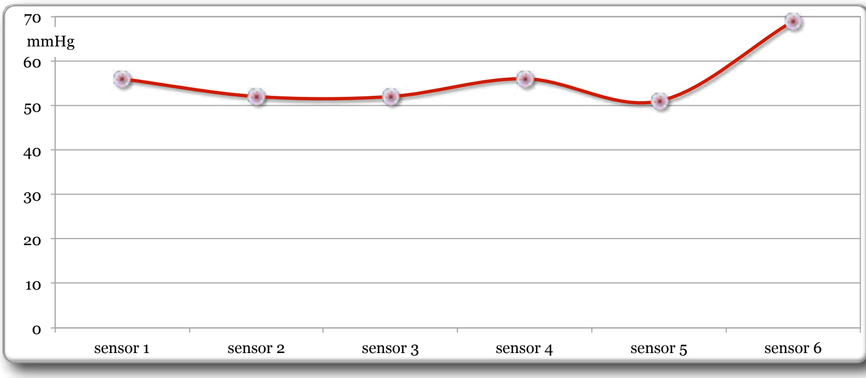


Figure 7.12:
pressure profile of the two layers of Rosidal K applied in a spiral manner without any further padding.

The two layers of padding underneath the short stretch bandage have an immediate effect on the pressure profile. Sensor 4 shows a significant drop as can be seen in figure 7.13. The blue line represents the pressure measurements after the application of the padding materials.

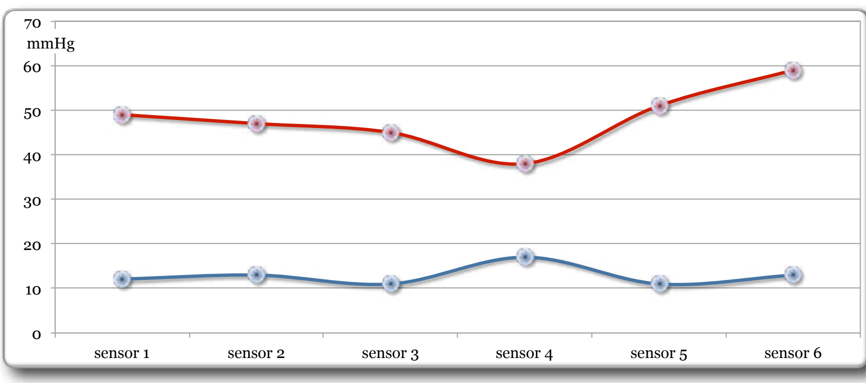


Figure 7.13:
pressure profile of the two layers of Rosidal K applied in a spiral manner on top of two layers of padding.

Filling the gap with padding and an additional two circular layers of padding prevents the short stretch bandage from adding any pressure to sensor 4, as can be seen in figure 7.14. The pressure provided by the padding, represented by the blue line, is nearly the same as the pressure provided by the additional layers of short stretch material. Also, the sensors 3 and 5 show a significant drop.

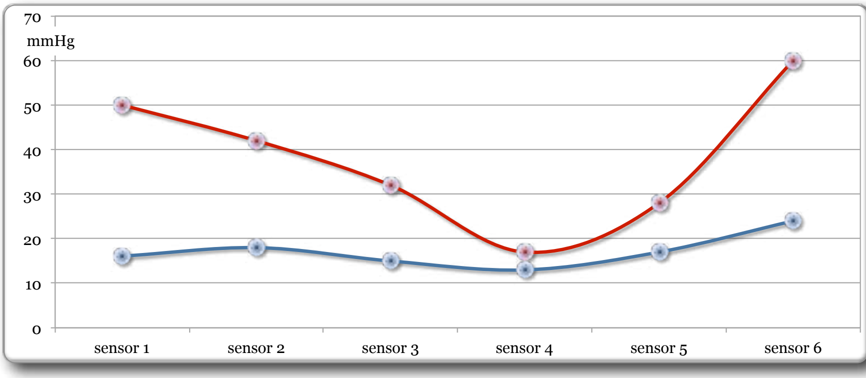


Figure 7.14: pressure profile of the two layers of Rosidal K applied at full stretch over two layers of padding after re-contouring the narrowed area.

The pressure profile of the Coban 2 application is shown in figure 7.15. The higher pressure on the forefoot is still observed. The overall pressure profile reveals an evenly distributed pressure.

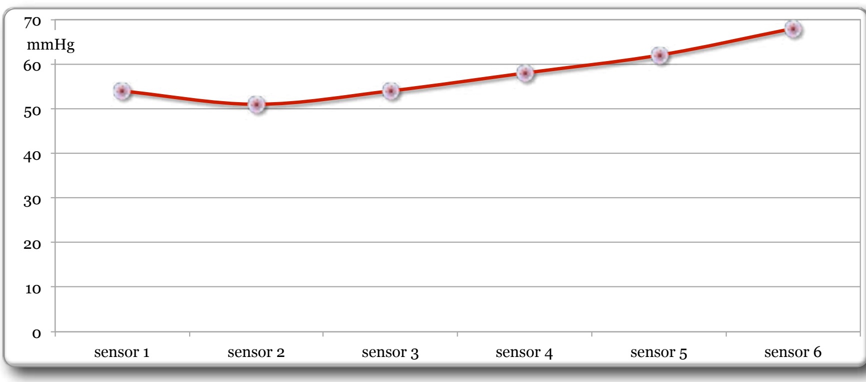


Figure 7.15: pressure profile of the Coban 2 application.

7.3.4. Discussion

The test on the inverted champagne bottle shaped artificial leg revealed that re-contouring has a dramatic effect on the even distribution of pressure over the wrapped area. These effects will be similar to what can be observed on a patient's leg. The area that is hardened by the lipodermatosclerotic skin does not need pressure, the areas distally and proximally from the sclerotic skin however do. According to Pascal's law (see chapter 6), the uneven pressure profile created by re-contouring the leg, results in a reduced control of the forces that are built up in the leg during functional activities.

7.5. Compression on an artificial leg with a skin fold

7.5.1. Introduction

Another limb deformity that is sometimes seen in leg ulcer patients and more often in patients with severe lymphoedema, is the skin fold or apron. Often this serious distortion is re-contoured by using padding materials.

7.5.2. Materials and methods

To study the effects of the use of padding materials to fill cavities on sub-bandage pressures, an artificial leg was developed with a large skin fold above the ankle joint. Five PicoPress pressure sensors were positioned in such a way that a pressure profile could be created of the area around the skin fold. The sensors were covered with a loose Rosidal tg stocking to avoid sensor movement during subsequent bandage applications (figure 7.16).

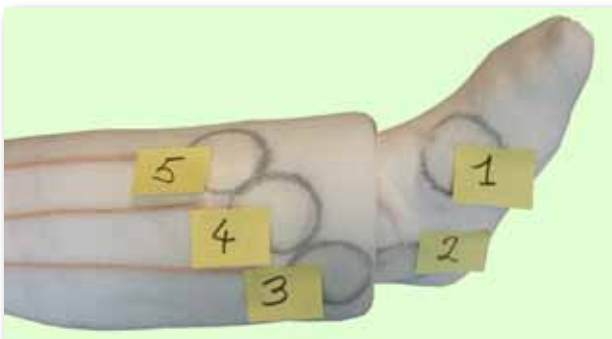


Figure 7.16: artificial leg with skin fold and the positioning of the five pressure transducers.

Next, four different methods of bandaging were used with different usage of filling the skin fold:

- Rosidal K, a short-stretch compression bandage applied at full stretch with circular windings with a 50% overlap and no padding (figure 7.17).

Figure 7.17: Rosidal K, applied spirally at full stretch with 50% overlap and no padding.

- Two layers of circularly applied 3M synthetic cast padding (figure 7.18.a), followed by two layers of Rosidal K, applied at full stretch with circular windings with a 50% overlap (figure 7.18.b).

Figure 7.18.a: 2 layers of padding, applied with 50% overlap.
Figure 7.18.b: padding applied with 50% overlap.

- The skin fold filled with padding, followed by two layers of circularly applied 3M synthetic cast padding), covered with Rosidal K, applied at full stretch with figure-of-eight windings (figure 7.19.a, b, c).

Figure 7.19.a: the skin fold flattened with padding.
Figure 7.19.b: 2 layers of padding, applied with 50% overlap.
Figure 7.19.c: Rosidal K applied at full stretch with figure-of-eight windings.

- Coban 2 applied at full stretch, covering the fold as anatomically as possible (figure 7.20.a, b, c, d and figure 21).

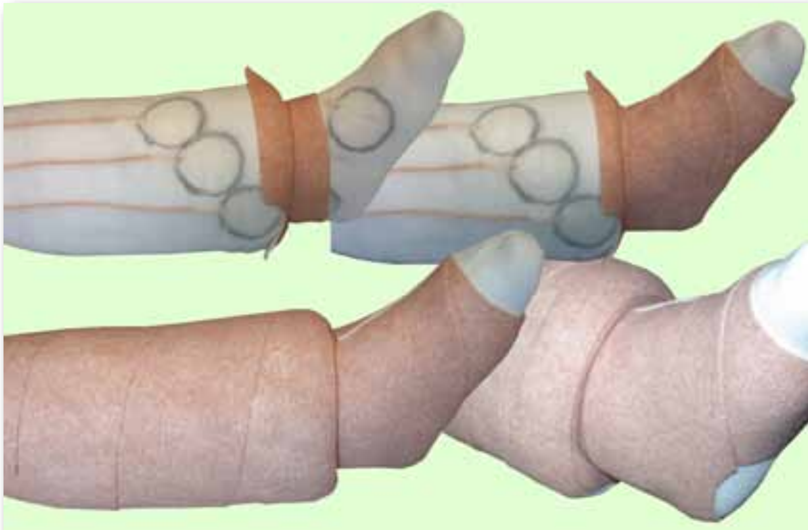


Figure 7.20.a,b,c,d: Coban 2, layer 1 application steps.

Figure 7.21: Coban 2, layer 2 applied at full stretch.

Immediately after each application, the pressure was recorded with a PicoPress measuring device.

7.5.3. Results

The pressure profile of the different applications is presented as line graphs. The application of two layers Rosidal K without any further padding in a spiral manner is visualised in figure 7.22. It is clear to see that the lowest pressure is provided on sensor 2, the sensor, which is positioned just distally of the fold. Sensor 4, positioned in a small indent also shows a pressure that is a little less that the values of the sensors 1, 3 and 5.

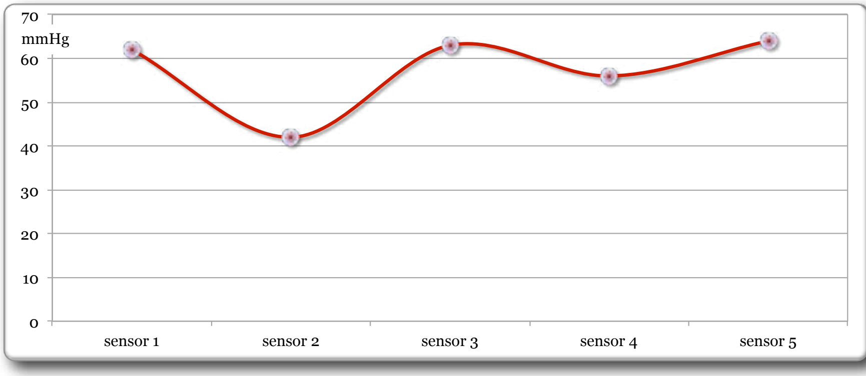


Figure 7.22:
pressure profile of the two layers of Rosidal K applied in a spiral manner without any further padding.

The two layers of padding underneath the short stretch bandage have an immediate effect on the pressure profile. Sensor 2 and 4 show a significant drop as can be seen in figure 7.23. The blue line represents the pressure measurements after the application of the padding materials.

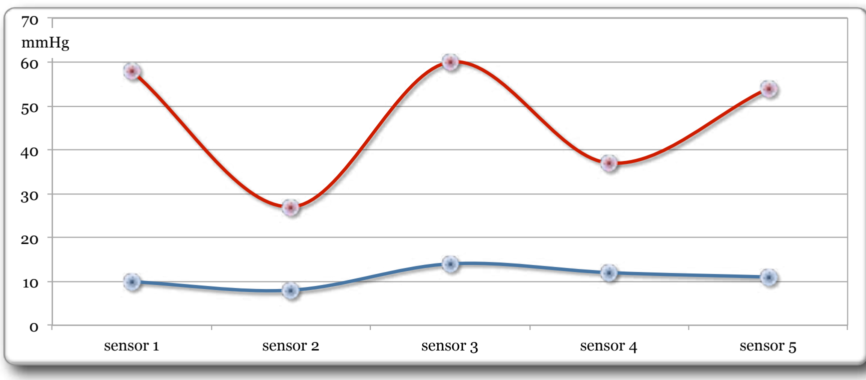


Figure 7.23:
pressure profile of the two layers of Rosidal K applied in a spiral manner on top of two layers of padding.

Filling the gap with padding and an additional two circular layers of padding prevents the short stretch bandage from adding any pressure to sensor 2. As can be seen in figure 7.24, in the skin fold, the pressure provided by the padding, represented by the blue line, is the same as the pressure provided by the additional layers of short stretch material. Also, the surrounding sensors 1 and 3, are affected by the extra layers of padding used for filling the skin fold and show a significant pressure drop. Even the application of the short stretch bandage with figure-of-eight windings, which normally results in a higher pressure than when bandages are applied in a spiral manner, reveals this effect.

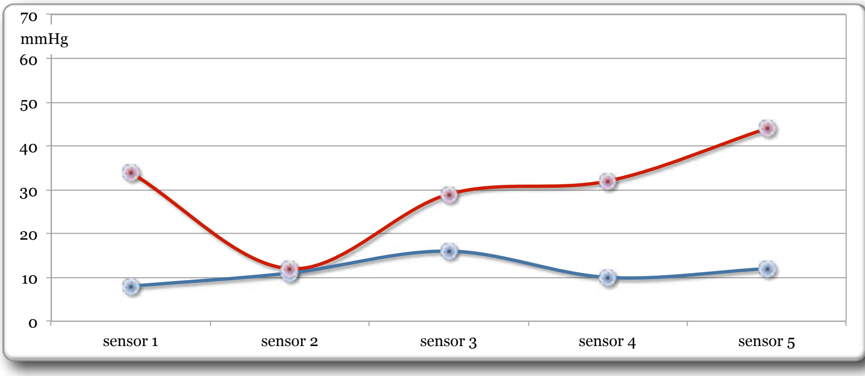


Figure 7.24: pressure profile of the two layers of Rosidal K applied in a spiral manner on top of two layers of padding after the skin-fold was filled with padding.

The pressure profile of the Coban 2 application is shown in figure 7.25. There is still a pressure drop in sensor 2 but the overall profile reveals a more evenly distributed pressure.

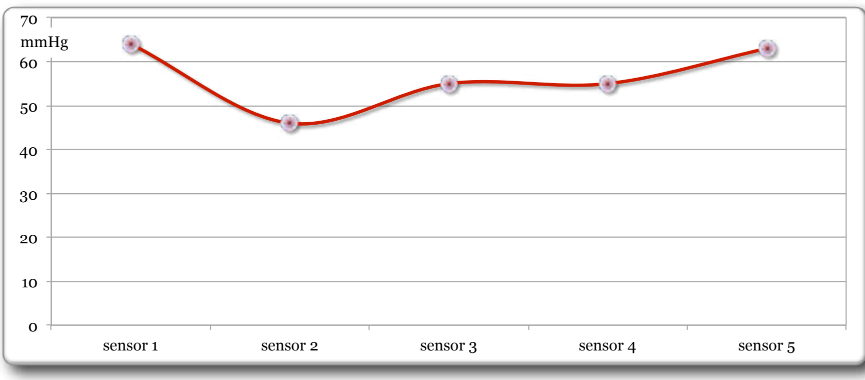


Figure 7.25: pressure profile of the Coban 2 application.

7.5.4. Discussion

The test on this artificial leg revealed that using padding materials has a dramatic effect on the even distribution of pressure over the wrapped area. These effects will be similar to what can be observed on a patient's leg. The uneven pressure profile created by re-contouring a leg result in reduced control of the forces that are built up in the leg during functional activities.

7.6. Cylinder study

7.6.1. Introduction

The overall objective of compression therapy is to improve the venous return by supporting the calf muscle pump. It is well-documented that systems with a high stiffness provide a better support [14]. Most commercially available compression systems have some kind of padding material included; the amount of padding that will be included, often depends on the person that applies the system. This means that there may be quite some variation in individual applications as is documented in chapter 12 (ease of use and reproducibility). To study the effects of the use of padding materials on sub-bandage pressure and system stiffness in a completely controlled manner, the test method described in chapter 3.6.2 was used.

7.6.2. Materials and methods

Ten poly-oxymethylene test cylinders were used, five with a radius of 4 cm, the other five with a radius of 5 cm. Two layers of Rosidal K, a short-stretch bandage were applied by the roll-winder at full stretch without padding and subsequently with 1, 2, 3, 4 and 5 layers of padding. Immediately after each application, the pressure was recorded with a PicoPress measuring device.

7.6.3. Results

The mean values of the pressure measurements are presented in table 7.1 and visualised in figure 7.26.

resting pressure	Ø 4 (mmHg)	Ø 5 cm (mmHg)	mean % change
short stretch 2 layers / no padding	48.8	38.2	
short stretch 2 layers / 1 layer of padding	46.2	34.2	7.90
short stretch 2 layers / 2 layers of padding	41	30	20.43
short stretch 2 layers / 3 layers of padding	38.6	26.8	31.44
short stretch 2 layers / 4 layers of padding	35	23.2	45.86
short stretch 2 layers / 5 layers of padding	29.2	20.4	66.36

Table 7.1: pressure measurements with different layers of padding.

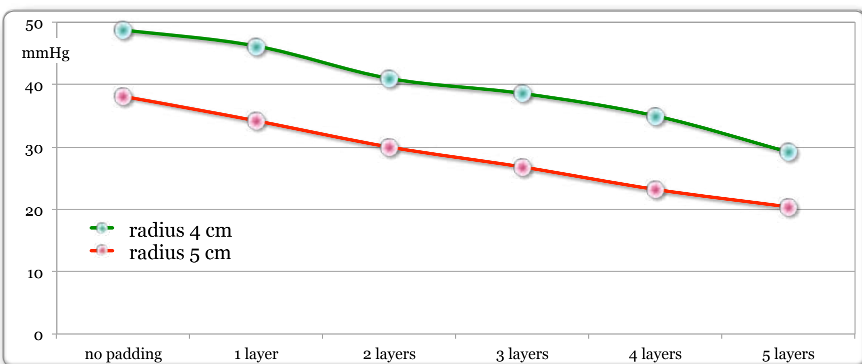


Figure 7.26: pressure measurements with different layers of padding.

The mean values of the strain measurements are presented in table 7.2 and visualised in figure 7.27.

strain index	Ø 4 (mmHg)	Ø 5 cm (mmHg)	mean % change
short stretch 2 layers / no padding	16.6	15.0	
short stretch 2 layers / 1 layer of padding	15.2	14.0	7.55
short stretch 2 layers / 2 layers of padding	11.0	11.8	29.85
short stretch 2 layers / 3 layers of padding	9.2	7.8	64.14
short stretch 2 layers / 4 layers of padding	8.4	5.4	106.10
short stretch 2 layers / 5 layers of padding	6.0	4.0	164.95

Table 7.2: strain indices with different layers of padding.

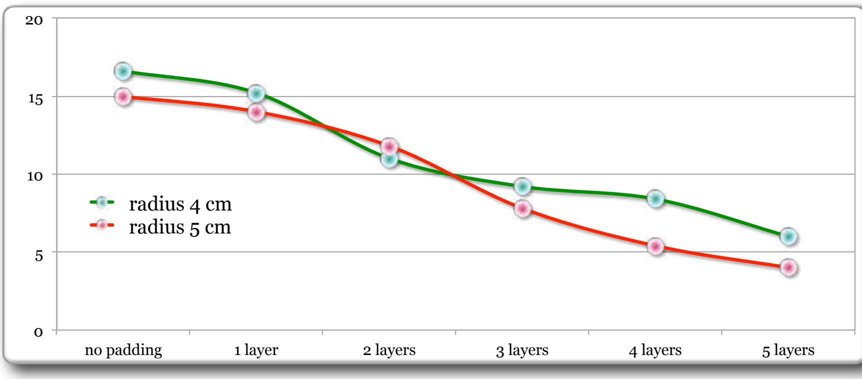


Figure 7.27: strain indices with different layers of padding.

7.6.4. Discussion

The pipe test on the effects of padding revealed that every layer of padding has not only an effect on the final pressure of the bandage but also on the strain index of an applied system. This can also be observed when an attempt is made to reduce the resting pressure with a few extra layers of padding materials, like is often practised in patients with low ABPI's. The resulting reduced stiffness will have an effect on the effectiveness of the system, as a part of the forces that are produced by functional activities will be absorbed by the padding materials and therefore not be used to support the calf muscle pump.

7. 7. Discussion

Historically padding materials have not been very popular underneath casting nor under bandaging systems. Like in the manuals of Böhler [7] and Charnley [8] in which detailed instructions are provided on how the most effective casts are applied, in the historical literature on compression therapy, many detailed instructions can be found on how to use compression therapy to support venous return [15-24]. And like in Böhler's and Charnley's publications, padding materials are not used. It is an interesting observation that padding materials are nowadays routinely used underneath casting materials as well as underneath compression bandages. One can only guess for reasons, not for consequences. Imagine how much support or comfort the patient on the X-ray in figure 7.1 will have from the padded cast. Take a look at figure 7.28 and imagine how much support and comfort the four-year old boy with the forearm greenstick fracture had from the plaster-of-Paris cast that was just removed and replaced by an unpadded Soft Cast. Exactly, none. Rather than being properly treated, the poor little boy was punished with a very heavy cast that did not support his fracture at all.

Figure 7.28: a four-year old boy with a forearm greenstick fracture after a cast change.

The study on pressures underneath different casting materials presented in this chapter revealed that the use of padding materials has a detrimental effect on the stabilisation of a fracture in a cast. It was also demonstrated that the forces that are created inside a cast during functional activities are absorbed used padding. Ideally, these forces are held within the cast and support the included muscles in their pumping function required for venous return. The same mechanism forms the principle of compression therapy.

The three laboratory studies presented in this chapter, clearly demonstrate that the use of padding materials should be limited. The pipe study confirmed that padding not only has an effect on the resting pressure but also on the stiffness of an applied system and with that on the final effectiveness of compression therapy.

7.8. Conclusions

When looking at padding materials and compression therapy, it can be concluded that:

- padding materials have an effect on an even distribution of sub-bandage pressures, especially if they are used to ”flatten” or ”fill” irregularly shaped legs;
- padding materials have an effect on the stiffness of applied compression systems;
- padding materials have an effect on the calculation of sub-bandage pressure measurements with the modified Laplace-equation.

7.9. References

1. von Volkmann R.
Die ischaemischen Muskellähmungen und -Kontrakturen.
Centralblatt für Chirurgie 1881: 8: 801-803.

2. Schuren J.
Working with Soft Cast: a manual on semi-rigid immobilisation.
IF Publication Services, Düsseldorf 1994.

3. Videman T.
Connective tissue and immobilization: key factors in musculoskeletal degeneration.
Clin Orthop 1987: 26-32.

4. Breznik A.
Clinical outcome of distal radius fractures: Soft Cast versus plaster-of-Paris.
In: Schuren J. (ed). Working with Soft Cast 2. Minnesota, Mining and Manufacturing 2000: 92-93.

5. Sarmiento A, Pratt GW, Berry NC, Sinclair WF.
Colles' fracture: functional bracing in supination.
J Bone Joint Surg 1975: 57A: 311-317.

6. Thiel van T.
The immediate application of an unpadded circular Soft Cast combicast in displaced distal radius fractures.
In: Schuren J. (ed). Working with Soft Cast 2. Minnesota, Mining and Manufacturing 2000: 91.

7. Böhler L.
Technik der Knochenbruchbehandlung.
Wien, Verlag von Wilhelm Maudrich; 1929.

8. Charnley J.
The closed treatment of common fractures.
Edinburgh, E&S Livingstone Ltd; 1950.

9. White R, Schuren J, Konn D.
Semi-rigid vs rigid glass fibre casting: a biomechanical assessment.
Clin Biomech 2003; 18: 19-27.

10. Moir JS, Wytch R, Ashcroft GP, Ross N, Wardlaw D.
Intracast pressure measurements in Colles' fractures.
Injury 1991; 22, 446-450.

11. White R, Schuren J, Wardlaw D, Diamondopolous Z, Anderson R.
Biomechanical assessment of gait in below knee walking casts.
Prosthet Orthot Int 1999; 23: 142-151.

12. Schuren J.
Functional fracture treatment with Soft Cast combicasts.
In: Schuren J (ed). Working with Soft Cast: evidence-based fracture care, symposia proceedings & abstracts of publications. 2000: Rehms Druck Borken: 77-79.

13. Moffatt C.
Managing the disproportionate limb.
In: Moffatt C. Compression therapy in practice. Wounds UK 2007: 101-113.

14. Partsch H, Clark M, Bassez S, Becker F, Benigni JP, Blazek V, Caprini J, Cornu-Thénard F, Hafner J, Flour M, Jünger M, Moffatt Ch, Neumann HAM.
Measurement of lower leg compression in vivo: recommendations for the performance of measurements of interface pressure and stiffness: a consensus statement.
Dermatol Surg. 2006; 32: 229-238.

15. Bell B.
On the effects of compression in the cure of ulcers.
In: Bell B. A treatment on the theory and management of ulcers. Elliot & Robinson, Edinburgh, London 1778: 177-184.

16. Critchett G.
Clinical lectures on the nature, causes and treatment of ulcers of the lower extremity.
Lancet 1848; 52: 397-399.

17. Hunt T.
On the treatment of ulcers of the leg without rest.
BMJ 1857; 1(1): 4-6.

18. Gay J.
On varicosity and ulcer in the lower limb.
Lancet 1868; 92: 495-496.

19. Callender GW.
Note on the treatment of ulcers and varicose veins by Martin's strong elastic bandage.
Lancet 1878; 112: 503.

20. Unna P.
Die Stauungsdermatosen des Unterschenkels und ihre Behandlung.
Dtsch Med Ztg 1885; 1-4, 13-17.

21. Cutting RA.
Chronic leg ulcers : treatment with Unna's paste boot.
Am J Surg 1930; 8: 743-749.

22. Homans J.
The etiology and treatment of varicose ulcers of the leg.
Surg Gynecol Obstet 1917; 24: 300-315.

23. Baruch M, Glasser ST, Rosenthal J.
Ten years' experience with leg ulcers in the old age group.
Am J Surg 1939; 44: 601-607.

24. Rivlin S.
Gravitational leg ulcers in the elderly.
Lancet 1958; 271: 1363-1367.

Chapter 8

Coban 2 and Coban 2 Lite: haemodynamic effects

8.1. Introduction

There are several methods to investigate the effectiveness of compression therapy. Nicolaides [1] present a comprehensive overview of methods and their usefulness in a consensus statement. One of the described methods is ambulatory strain gauge plethysmography (ASGP), of which detailed instructions are provided. It is stated that ASGP is suited for the assessment of compression therapy. The ambulatory volume changes that can be documented with ASGP provide information about the function of the calf muscle pump and the venous system.

Fernandes et al [2] investigated whether ambulatory calf volume plethysmography, which is non-invasive, could distinguish between normal limbs, limbs with superficial valvular incompetence only, limbs with deep valvular incompetence and limbs with deep valvular incompetence and occlusion, as a non-invasive test that has achieved this, had not been reported previously. The authors found that by measuring the ambulatory volume change and either the maximum venous outflow or venous volume, it was possible to differentiate between the degrees of severity. They conclude that ASGP is a useful screening test for limbs with suspected venous incompetence and is an aid in providing an accurate diagnosis without the need for invasive tests, which may also be used to study the effects of compression therapy.

To evaluate how the externally recorded ASGP corresponds to blood displacement within the leg during exercise, Struckmann et al [3] compared ASGP to ambulatory blood volume scintimetry (ABVS), an isotope plethysmographic method. Venous return time recordings of both methods were similar and although the values of expelled volume differed substantially in both methods, they showed the same pattern.

To assess the effect on venous return of a water-pad included in a plaster cast immobilisation, Poelkens et al [4] used strain gauge plethysmography and described how they calculated the ejection fraction from standardised venous volume measurements and ejected volume after a standardised exercise protocol. Mosti et al [5-8] adopted and slightly modified this method to evaluate the effectiveness of different compression therapy systems.

The same procedure was utilised to study the haemodynamic effects of Coban 2 and Coban 2 Lite, which is reported in this chapter. The main objective of this study was to identify eventual differences in the support of venous function between two materials with different resting pressures, both being applied at full stretch.

8.2. Materials and methods

8.2.1. Subjects

Nineteen patients, 12 male and 7 female were informed on the procedures of the study and gave their consent to participate in the study. The mean age was 55.0 years [28-73]. All patients were affected by a reflux in the vena saphena magna. One patient (male, 72 years) had both legs investigated. The 20 examined legs were classified according to the CEAP classification [9], five legs were CEAP C2, nine CEAP C3, four CEAP C4 and two CEAP C5. Mosti et al [5] performed baseline measurements on 15 healthy volunteers and 30 patients. The baseline results of these groups and those from the subjects in this study are presented in table 8.1. The study was performed at the Angiology Department of the Barbantini Hospital in Lucca, Italy in cooperation with Giovanni Mosti, MD and Hugo Partsch, MD.

	normal legs in study Mosti et al	patient legs in study Mosti et al	legs in this study
n	15	30	20
VV (mL%)	4.4 (3.9-5.1)	5.1 (4.2-6.3)	6.13 (2.9-9.6)
EV (mL%)	3.0 (2.5-3.4)	1.6 (1.3-2.1)	2.2 (0.8-3.8)
EF%	65.0 (63.7-67.8)	33.1 (27.0-38.3)	36.5 (26.3.-39.3)

Table 8.1: venous volume (VV), ejected volume (EV) and ejection fraction (EF) in 15 healthy legs and 30 patient legs from Mosti et al [5] and in the 20 legs in this study (median and interquartile range).

8.2.2. Compression bandaging

The legs of the subjects were bandaged with Coban 2 and Coban 2 Lite. A computer generated randomisation list determined the sequence of the measurements at baseline and following the applications. The bandages were applied by an experienced orthopaedic technician (JS) and an experienced vascular surgeon (GM) according to the method described in chapter 2.8.1.

8.2.3. Sub-bandage pressure measurements

The pressure underneath the bandages was measured using PicoPress pressure sensors consisting of a flat pressure probe with a diameter of 5 cm. The probe is connected to a device that inflates the probe with 2 ml of air and transforms the pressure as well as fluctuations into an electronic signal, which can be stored on a computer for analysis. The sensors were positioned at the B1 region and pressure was measured in the supine and standing position and during the standardised exercise protocol to calculate the walking pressure amplitudes (WPA). Recording took place simultaneous with the plethysmography measurements (figure 8.1). An explanation of the sub-bandage pressure measurements is presented in chapter 3 and in a detail of figure 8.1, which is provided in figure 8.2.

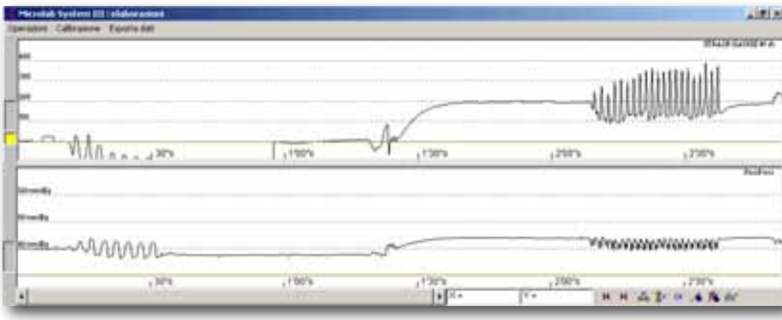


Figure 8.1: simultaneous recording of strain gauge (upper trace) and sub-bandage dynamics (lower trace).

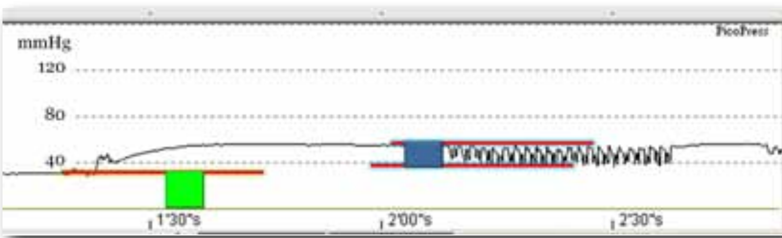


Figure 8.2: sub-bandage pressure measurement (detail of figure 8.1) showing the resting pressure (green box) and working pressure amplitude (blue box).

8.2.4. Ejection Fraction

Ejection fraction was measured three times, at baseline and after the application of both compression systems. Venous volume and ejected volume were recorded using strain gauge plethysmography with an indio-gallium alloy probe measuring the changes of the leg volume (Angioflow 2). Before the measurements, the subjects were familiarised with the procedure and the exercises to be performed during the measurements, The gauge was positioned 5 cm distal to the patella with the subject in a relaxed supine position. Next, the equipment was calibrated. For the baseline measurement, the calibration took place after the patient was in a relaxed position. For the measurements of the compression systems, calibration took place after the applications. To achieve a minimum volume, the leg was elevated above heart level with the subject in a complete supine position. Once a new stable recording was observed, the patient was asked to change to a standing position with the full weight on the opposite leg, again until a stable signal could be observed. The difference between the two stable recordings represents the volume increase or venous volume (VV) after refilling of the veins in the upright position. Next, the patient was asked to perform 20 standardised steps in 20 seconds and return to the standing position. The volume decrease following the exercises represents the ejected volume (EV). From the recordings, the ejection fraction (EF) in percentage can be calculated using the formula: 100(EV/VV).

For the measurements of the compression systems, recording took place simultaneous with the sub-bandage pressure measurements (figure 8.1) An explanation of the strain gauge measurements is presented in a detail of figure 8.1, which is provided in figure 8.3.

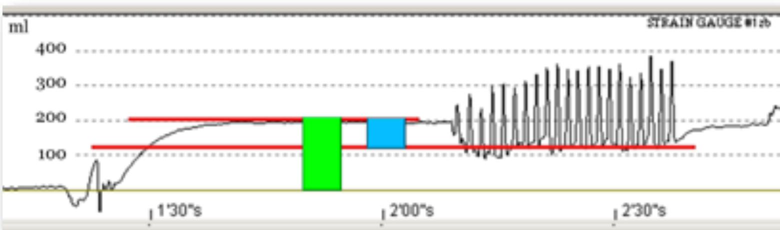


Figure 8.3: strain gauge trace (detail of figure 8.1) showing the venous volume (green box) and ejected volume (blue box).

8.2.5. Statistical analysis

Data were statistically analysed using the statistical software package Minitab, to identify differences between the compression systems under investigation, as well as to identify the relation between observations. Graphs were created in Minitab and Excel.

8.3. Results

8.3.1. Sub-bandage pressure measurements

To determine the differences between Coban and Coban 2 Lite, the resting pressure and WPA's during the plethysmography measurements were evaluated. The mean resting pressure of Coban 2 was 44.85 mmHg, for Coban 2 Lite it was 31.75 mmHg (paired t-test: $p<0.001$). Both the SSI's and The WPA's were higher for Coban 2. For the SSI it was 13.15 versus 10.55 (paired t-test: $p=0.03$); for the WPA it was 11.70 versus 10.00 (paired t-test: $p=0.27$). The differences between the two compression systems are shown in figure 8.4.

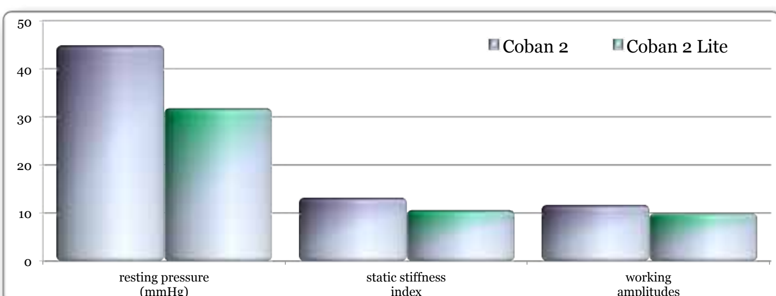


Figure 8.4: sub-bandage pressure profile for Coban 2 and Coban 2 Lite.

8.3.2. Ambulatory strain gauge plethysmography

As shown in figure 8.5, both Coban 2 and and Coban 2 Lite gave similar EF's: 62.94 versus 59.69. The comparison between both systems revealed that there was no significant difference between the two (paired t-test: p=0.07).

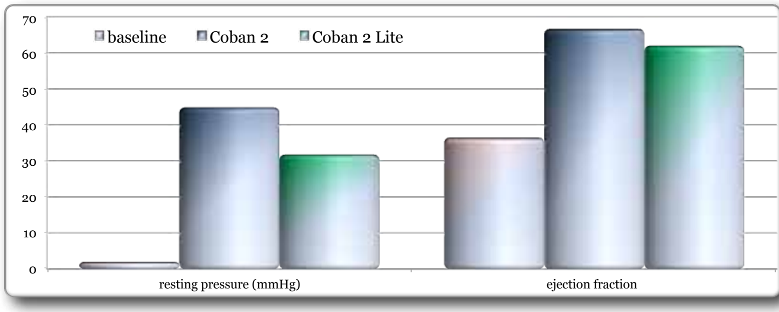


Figure 8.5: resting pressure and ejection fraction of Coban 2 and Coban 2 Lite.

The difference in improvement to the baseline EF is also shown in the boxplot graph in figure 8.6. Both systems gave a significant improvement of the EF (paired t-test: Coban 2 versus baseline: p=<0.001; Coban 2 Lite versus baseline: p=<0.001).

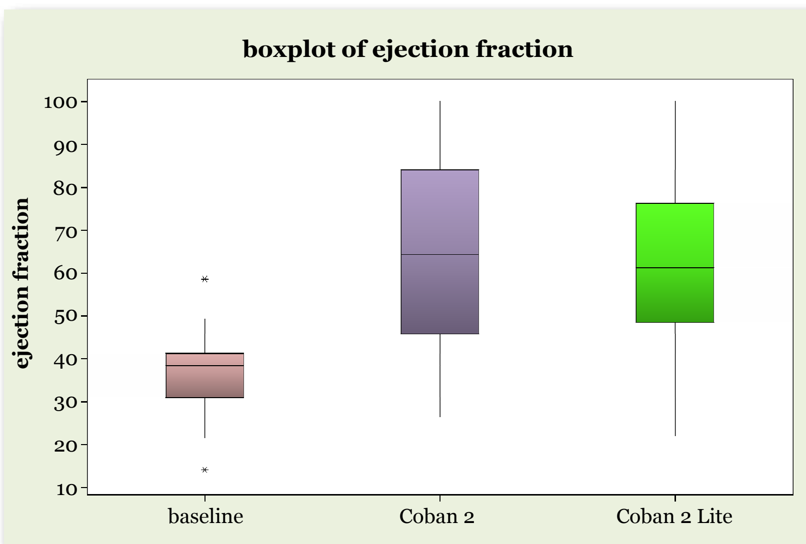


Figure 8.6: boxplot of baseline ejection fraction and the improvement with Coban 2 and Coban 2 Lite.

8.3.3. Relation of observations

To visualise the relation between the resting pressure and EF, the data are presented in a fitted line plot in figure 8.7 (Pearson correlation: r=0.20, p=0.28).

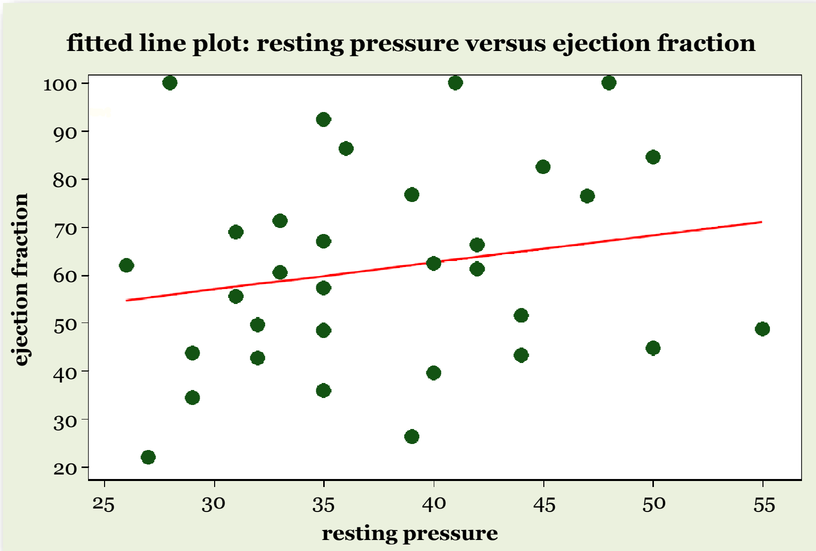


Figure 8.7: fitted line plot for resting pressure and ejection fraction.

To visualise the relation between the working amplitudes and EF, the data are presented in a fitted line plot in figure 8.8 (Pearson correlation: r=0.09, p=0.63).

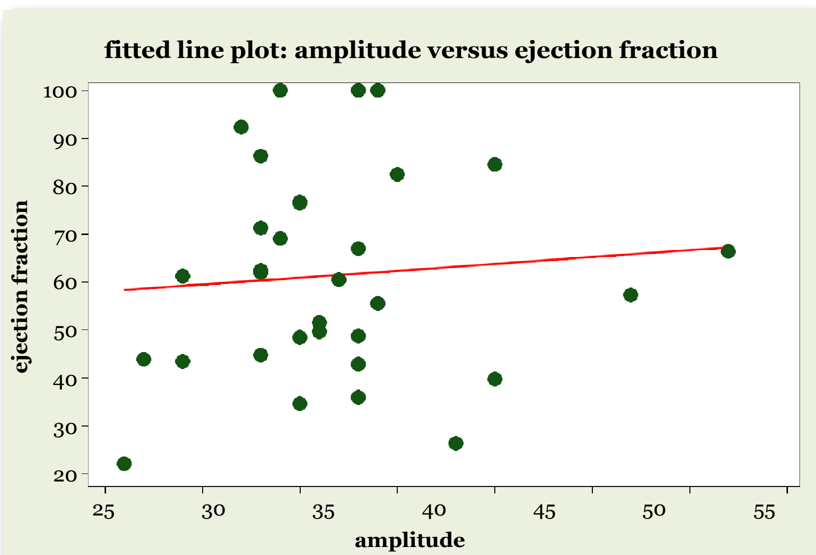


Figure 8.8: fitted line plot for working pressure amplitudes and ejection fraction.

8.4. Discussion

It is well documented that ASGP can be used to evaluate the function of the venous pump [1,2, 5-8, 10-12], as well as the effectiveness of compression systems [1,2, 5-8]. The method is non-invasive and easy to perform.

Mosti et al [5-8] adopted the method to study the effects of different compression systems and especially the relations between resting pressure, static stiffness index (SSI) and WPA. The authors demonstrated that ASGP is able to measure venous function but more importantly, that it is a valuable method to assess the effectiveness of different compression systems. It is not surprising that it could be demonstrated that the elastic properties, especially the stiffness of an applied compression system shows a significant correlation with the improvement of the venous pumping function, expressed by the EF and that attempts to improve the haemodynamic effect of the elastic bandages by providing higher resting pressures, did not provide any further functional benefit [5].

Evaluating inelastic materials with resting pressures of 20, 40 and 60 mmHg however revealed that an increase could be observed in WPA's. Pressures in the range of 40 and of 60 mmHg achieved significantly higher WPA's than those with 20 mmHg. The different pressure levels were achieved by applying the short-stretch bandages (Mollelast) in a more or less tight manner and by applying more layers. The EF with the three different resting pressures increased significantly compared to compression stockings. A further increase of resting pressure, and with that an increase of the WPA, resulted in a further increase in EF. The increase of EF versus baseline was 61.5%, 91% and 98% respectively. The authors conclude that not only the elastic properties of compression systems play a crucial role, but that there is also a significant correlation between the standing pressure and EF and between WPA and EF but not between resting pressure and EF [5].

Menzinger et al [12] used air plethysmography (APG) to study the effects of long (Sigvaris 503 compression stocking) and short stretch compression (Rosidal K) on venous reflux assessed by the velocity of volume increase in ml/sec (venous filling index (VFI), in 46 patients with active or healed ulcers with popliteal vein incompetence. They adjusted the pressure of the bandages to the pressure of the stocking in every single case and could show that, with equal resting pressures, VFI was reduced by 32% with the stockings and by 55% by the short stretch bandages ($p<0.05$).

Partsch et al [11] used APG to study the effects of different compression systems on VV and VFI, a method described by Christopoulos et al [10]. They demonstrated that the short stretch bandages (Rosidal K) were much more effective in reducing VV and VFI than the long stretch bandages (Perfekta), although the resting pressures were intentionally held exactly in the same range. In addition, they also looked at the effects of different resting pressures with short stretch bandages and present the outcome of measurements at 20, 40 and 60 mmHg. The baseline median VFI, taken as a global parameter for venous reflux in the 21 patients with deep venous incompetence was 8.45 ml/sec (normal values < 2.0 ml/sec). At each pressure level, inelastic bandages were more effective in reducing VFI than long stretch material. The authors do not explain how the difference in resting pressure was obtained [11].

Because of their ability to sustain pressure, some clinicians believe that elastic materials may be more effective than inelastic materials for immobile patients or those with a fixed ankle [13]. In a venous leg ulcer management plan that is included in the WUWHS consensus document on compression in venous leg ulcers [14], it is recommended that elastic compression combined with intermittent pneumatic compression is considered for immobile patients. In the EWMA position document on compression therapy, it is stated that compression with inelastic bandages is not recommended for immobile patients as these bandages cannot perform properly if the calf muscle pump is weak or ineffective as they will fail to generate adequate levels of compression [15]. Mosti [16] examined if elastic compression is really more effective compared with inelastic in 20 patients with reduced mobility and concludes that the concept that only elastic compression is effective in the supine position in patients with reduced mobility is a misconception.

In all research so far on the effects of different resting pressures with short stretch materials, adjustments were made to achieve different pressures levels. This was achieved by applying the material with less stretch, by adding additional layers or by adding layers of padding underneath the material. Each of these adjustments however, has an influence on the initially intended behaviour of the system (SSI and WPA). As in the referenced research in this paragraph, it has been well demonstrated that there is a strong correlation between resting pressure, SSI and WPA on one side and EF and VFI on the other, it can be concluded that adjustments made to modify one of the parameters, will have an effect on each of the others. The relation between pressure levels of compression therapy and effectiveness was also studied by Vanscheidt et al [17]. The authors demonstrated a close relationship between pressure and volume reduction; higher pressures are associated with a greater volume reduction in patients with chronic venous oedema. A relation between different sub-bandage pressure values and leg ulcer healing rates was demonstrated by Milic et al [18].

In the investigation presented in this chapter, Coban 2 and Coban 2 Lite were evaluated, products designed to be applied at full stretch with different resting pressures. It is demonstrated in the chapters 2 and 9 that both products have similar SSI's and WPA's. In addition, in chapter 9 it will be demonstrated that the volume reducing effects of both products is the same. The observed difference in SSI's and WPA's in this study may be explained by the fact that during the application, the pressure was recorded and the application might have been influenced by aiming at desired pressures of around 40 mmHg for Coban 2 and 30 mmHg for Coban 2 Lite.

Partsch showed that inelastic bandages, applied with a pressure over 50 mmHg, are able to significantly reduce ambulatory venous hypertension in patients with severe chronic venous disease [19]. This effect can be explained by an increase of the EF of the venous calf pump achieved by inelastic bandages and additionally by a reduction of the venous reflux [20]. Partsch et al [21] demonstrated that in the standing position, a pressure of about 70 mmHg is required to occlude superficial and deep leg veins completely. To demonstrate this phenomenon, the authors modified a blood pressure cuff with a transparent acetate window in such a way that ultrasound visualisation of the veins was possible. This cuff was positioned around the calf while the rest of the leg was left unwrapped. As was demonstrated in Chapter 6 (Pascal's law), there is an even distribution of forces throughout the compressed leg. It can be hypothesised that the stretchability of the skin in the unwrapped area absorbed some of the applied forces used to inflate the blood pressure cuff. In other words, not all the applied force to achieve the 70 mmHg pressure, was used to occlude the visualised small saphenous vein and that, if the entire leg would have been included in the cuff, perhaps a lower pressure could have been sufficient.

In the investigation presented in this chapter, pressure was measured at the B1-level in the standing position as well as during a 20-steps walking exercise. The average standing pressure underneath the applied Coban 2 was 58 mmHg (range 49-71) and 42.3 mmHg (range 29-50) underneath Coban 2 Lite. In the 40 applications, a pressure of 70 mmHg could be observed only once. The peak values during walking revealed more or less the same. The average systolic walking pressure was 57.2 mmHg underneath Coban 2 (range 41-83) and 42.1 underneath Coban 2 Lite (range 28-62). During walking, a pressure of 70 mmHg or above was observed only twice. In spite of these findings, both systems were very effective in improving the ejection fraction. This leads to the conclusion that a pressure of 70 mmHg or higher in the upright position is not an absolute requirement for effective compression.

The research presented in this chapter was designed to study the effects of a difference in resting pressures with equal additional characteristics. The outcome indicates that there is no significant difference in EF between the two products. This observation leads to the conclusion that it is not the resting pressure that determines the effectiveness of compression therapy but the possibility of applying a compression system at full stretch to create a non-stretchable sleeve with an anatomical fit around the limb.

Applied in this way, compression therapy provides a second skin around the leg, referred to as an ”intelligent bandage” [20] as it raises its pressure just by standing up from the supine position. This intelligence to immediately adjust to the need for compensating an increased intravenous hydrostatic pressure in the upright position, can be compared to the tight skin of the giraffe leg, referred to by Hargens et al [22] as a ”functional antigravity suit”.

8.5. References

1. Nicolaides AN.
Investigation of chronic venous insufficiency: a consensus statement.
Circulation. 2000; 102: 126-163.

2. Fernandes J, Fernandes E, Horner J, Needham T, Nicolaides A.
Ambulatory calf volume plethysmography in the assessment of venous insufficiency.
Br J Surg 1979; 66: 327-330.

3. Struckmann JR, Vissing SF, Hjortsø E.
Ambulatory strain-gauge plethysmography and blood volume for quantitative assessment of venous insufficiency.
Clin Physiol. 1992; 12: 277–285.

4. Poelkens F, Thijssen DH, Kersten B, Scheurwater H, van Laarhoven EW, Hopman MT.
Counteracting venous stasis during acute lower leg immobilization.
Acta Physiol 2006; 186: 111-118.

5. Mosti G, Mattaliano V, Partsch H.
Inelastic compression increases venous ejection fraction more than elastic bandages in patients with superficial venous reflux.
Phlebology 2008; 23: 287-294.

6. Mosti G, Partsch H.
Inelastic bandages maintain their hemodynamic effectiveness over time despite significant pressure loss.
J Vasc Surg 2010; 52: 925-931.

7. Mosti G, Partsch H.
Is low compression pressure able to improve venous pumping function in patients with venous insufficiency?
Phlebology 2010; 25: 145-150.

8. Mosti G, Partsch H.
Measuring venous pumping function by strain-gauge plethysmography.
Int Angiol 2010; 29: 421-425.

9. Eklöf B, Rutherford RB, Bergan JJ, Carpentier PH, Gloviczki P, Kistner RL, Meissner MH, Moneta GL, Myers K, Padberg FT, Perrin M, Ruckley CV, Smith PC, Wakefield TW.
Revision of the CEAP classification for chronic venous disorders: consensus statement.
J Vasc Surg. 2004; 40: 1248-1252.

10. Christopoulos D, Nicolaides AN, Szendro G.
Venous reflux: quantification and correlation with the clinical severity of chronic venous disease.
Br J Surg 1988; 75: 352-356.

11. Partsch H, Menzinger G, Mostbeck A.
Inelastic leg compression is more effective back to deep venous refluxes than elastic bandages.
Dermatol Surg 1999; 25: 695-700.

12. Menzinger G, Horakowa M, Mayer W, Partsch H.
Reduction of venous reflux by compression: a comparison between short and long stretch material.
Phlebology 1995; 19 (suppl 1): 888-891.

13. World Union of Wound Healing Societies (WUWHS).
Principles of best practice: compression in venous leg ulcers: a consensus document.
London: MEP Ltd, 2008: 2.

14. World Union of Wound Healing Societies (WUWHS).
Principles of best practice: compression in venous leg ulcers: a consensus document.
London: MEP Ltd, 2008: 6.

15. Marston W, Vowden K.
Compression therapy: a guide to safe practice.
In: European Wound Management Association. Understanding compression therapy: position document 2003: 11-16.

16. Mosti G.
Compression therapy in patients with reduced mobility following trophic lesions of the lower limbs.
Acta Vulnol 2009; 7: 197-205.

17. Vanscheidt W, Ukat A, Partsch H.
Dose-response of compression therapy for chronic venous edema: higher pressures are associated with greater volume reduction: two randomized clinical studies.
J Vasc Surg 2009; 49: 395-402.

18. Milic DJ, Zivic SS, Bogdanovic DC, Jovanovic MM, Jankovic RJ, Milosevic ZD, Stamenkovic DM, Trenkic MS.
The influence of different sub-bandage pressure values on venous leg ulcers healing when treated with compression therapy.
J Vasc Surg. 2010; 51: 655-661.

19 Partsch H.
Improvement of venous pumping function in chronic venous insufficiency by compression dependant on pressure and material.
VASA 1984; 13: 58-64.

20. Partsch H.
Why should wounds on the lower extremities be treated by compression?
J Wound Technol 2010; 8: 10-13.

21. Partsch B, Partsch H.
Calf compression pressure required to achieve venous closure from supine to standing positions.
J Vasc Surg 2005; 42: 734-738.

22. Hargens AR, Millard RW, Pettersson K, Johansen K.
Gravitational haemodynamics and oedema prevention in the giraffe.
Nature 1987; 329: 59-60.

Chapter 9

Coban 2 and Coban 2 Lite: volumetry

9.1. Introduction

It is well documented that bandages loose some pressure over time. This loss may be caused by material fatigueness, loss of leg volume or a combination of both. To evaluate the possible causes of pressure loss, a volunteer study was designed and executed to evaluate the sustainability of pressure in relation to an eventual volume reduction.

9.2. Materials and methods

Twelve normal, healthy subjects, six male and six female were informed on the procedures of the study and gave their written consent to participate in the study. The study was approved by 3M's Institutional Review Board.

9.2.1 Compression bandaging

Both legs of the volunteers were wrapped with two different compression systems: Coban 2 and Coban 2 Lite by the same experienced orthopaedic technician (JS). All systems were applied with full stretch of the compression layer following the instructions for use as presented in chapter 2.8.1. Leg volume measurements were obtained prior to the first bandage application and then were repeated after bandage removal at 24 and 48 hours. A new bandage was applied at each assessment. The volunteers were randomised in such a way that each system was applied six times to the dominant and six times to the non-dominant leg and to a sequence distributing gender equally over the day. A time schedule was prepared with 45 minutes sessions, so all volunteers could be seen in one day to allow an analysis on the effect of the time of the day the bandages were applied.

9.2.2. Volumetry

Before the first bandage application, the leg volume was measured using water displacement. The method of water displacement is based on the principle that the volume displaced by an object equals the volume of that object. This principle was first described by Archimedes. The volume of the water and its density are determined by the temperature. In literature, different temperatures can be found. Deltombe et al [1] used water of 20° C, where Damstra et al [2] used water of 38° C. The displaced water is weighted and the calculation of the displaced volume is based on the assumption that 1 gram equals 1 ml. The device used in this study consists of a plexiglass container filled up to 23.5 cm from the bottom with 30° C warm tap water. The lower leg is positioned slowly into the apparatus in the standing position with the foot resting on the floor and the heel touching the back wall of the container. The volunteers were instructed to divide the body weight equally over both legs. The device precisely measures the total amount of leg volume including the volume of the foot and toe. The volume measurements were performed at the start of the study immediately before the application of the bandages, as well as after 24 and 48 hours immediately after bandage removal. The water in the container was replaced after each measurement. Water displacement is the gold standard in leg volumetry and has a good reproducibility and very small inter-observer variability [2].

9.2.3. Pressure measurements

The pressure underneath the bandages was measured using PicoPress pressure sensors consisting of a flat pressure probe with a diameter of 5 cm. The probe is connected to a device that inflates the probe with 2 ml of air and transforms the pressure as well as fluctuations into an electronic signal, which can be stored on a computer for analysis. Because the sensors stayed in place for 48 hours, the connecting tube was positioned on a thin layer of Tegaderm foam to avoid the risk of pressure damage. The sensors were positioned at the B1 region and pressure was measured in the supine and standing position as well as during active plantar and dorsal flexion of the ankle joint. From these measurements the static stiffness index and exercise amplitudes were calculated.

9.2.4. Statistical analysis

To identify differences between the bandage systems under investigation as well as to identify the relations between the observations, the data were statistically analysed using the statistical software package Minitab. Graphs were created in Minitab and Excel.

9.3. Results

9.3.1. Sub-bandage pressure

Sub-bandage pressure measurements were performed immediately after the application at the beginning of the study, after 24 hours before removal, at 24 hours immediately after the application of the second bandage and after 48 hours. The results of the measurements and the paired t-test results are presented in table 9.1 and graphically displayed in the figures 9.1, 9.2, 9.3 and 9.4.

	application 1 rest: t = 0	application 1 rest: t = 24	application 1 ssi: t = 0	application 1 ssi: t = 24	application 1 ampl: t = 0	application 1 ampl: t = 24
Coban 2	44.08	26.00	15.42	13.33	20.58	19.00
Coban 2 Lite	31.17	17.50	15.75	13.58	20.08	18.25
paired t-test	*p = < 0.01*	*p = < 0.01*	*p = 0.77*	*p = 0.88*	*p = 0.65*	*p = 0.64*
	SD: 2.93	*SD: 3.99*	*SD: 3.80*	*SD: 5.40*	*SD: 3.68*	*SD: 5.43*
	application 2 rest: t = 24	application 2 rest: t = 48	application 2 ssi: t = 24	application 2 ssi: t = 48	application 2 ampl: t = 24	application 2 ampl: t = 48
Coban 2	45.33	29.08	16.58	15.75	21.83	20.92
Coban 2 Lite	32.58	20.50	15.75	15.67	20.92	20.42
paired t-test	*p = < 0.01*	*p = < 0.01*	*p = 0.43*	*p = 0.94*	*p = 0.53*	*p = 0.66*
	SD: 4.07	*SD: 4.34*	*SD: 3.49*	*SD: 3.70*	*SD: 4.83*	*SD: 3.85*

Table 9.1: sub-bandage pressure profile for the applied systems.

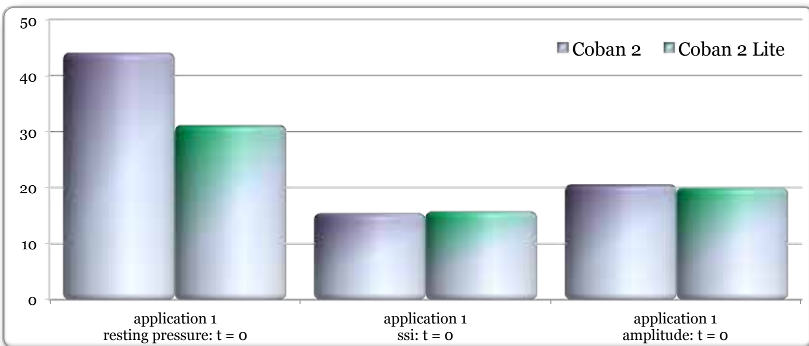


Figure 9.1: pressure profile of the applied systems immediately after the first application.

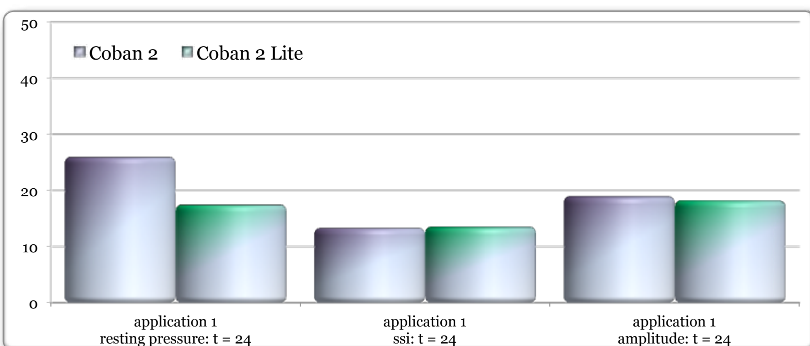


Figure 9.2: pressure profile of the applied systems before removal of the first application.

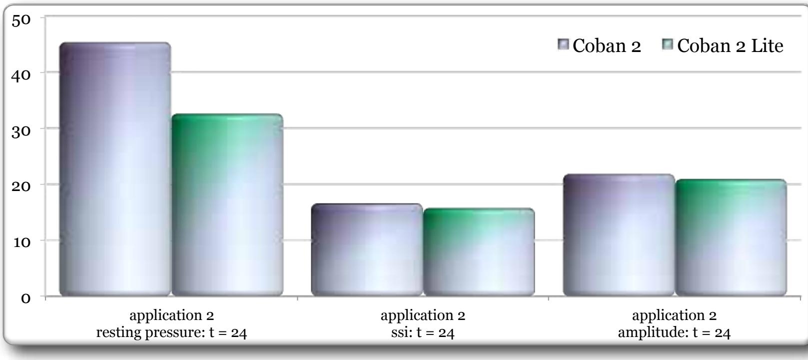


Figure 9.3: pressure profile of the applied systems immediately after the second application.

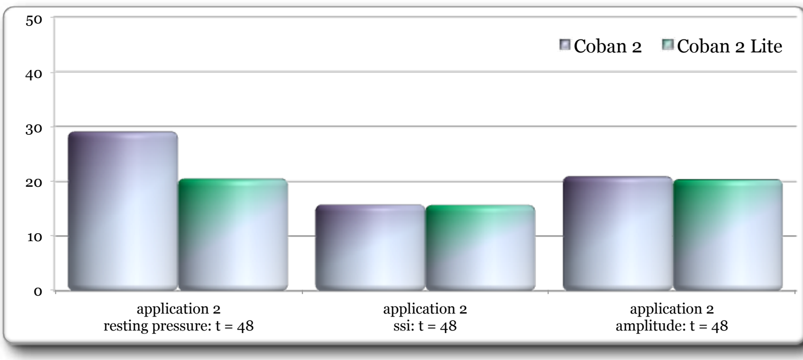


Figure 9.4: pressure profile of the applied systems before removal of the second application.

9.3.2. Volume reduction

Volume measurements were performed immediately before the application at the beginning of the study, at 24 hours after bandage removal, immediately before the application of the second bandage and after 48 hours immediately after removal of the second bandage. The results of the measurements as percentage change to the initial volume are presented in table 9.2.

time	gender	material	% change 0-24	% change 24-48	% change 0-48
08:00	male	Coban 2	2.52	1.12	3.61
		Coban 2 Lite	2.28	0.89	3.14
08:45	female	Coban 2	2.70	0.83	3.50
		Coban 2 Lite	2.82	0.96	3.76
09:30	male	Coban 2	2.54	1.42	3.92
		Coban 2 Lite	2.33	1.02	3.33
10:15	female	Coban 2	3.71	1.60	5.25
		Coban 2 Lite	3.94	1.58	5.46
11:00	male	Coban 2	2.95	1.98	4.87
		Coban 2 Lite	3.31	1.85	5.09
11:45	female	Coban 2	3.39	1.86	5.18
		Coban 2 Lite	3.55	1.82	5.31
13:00	male	Coban 2	3.06	1.15	4.18
		Coban 2 Lite	2.83	1.17	3.97
13:45	female	Coban 2	2.84	0.30	3.13
		Coban 2 Lite	2.99	1.69	4.63
14:30	male	Coban 2	3.56	1.18	4.70
		Coban 2 Lite	4.13	1.14	5.23
15:15	female	Coban 2	4.36	1.43	5.73
		Coban 2 Lite	4.81	2.14	6.85
16:00	male	Coban 2	3.84	1.26	5.06
		Coban 2 Lite	3.56	1.23	4.74
16:45	female	Coban 2	4.73	2.64	7.24
		Coban 2 Lite	5.06	2.71	7.63

Table 9.2: results of the measurements as percentage change to the initial volume.

The results sorted to the materials reveal that there is no difference in reduction between Coban 2 and Coban 2 Lite. The data are expressed as percentage change to the initial volume and as well as the paired t-test results are presented in table 9.3, and graphically displayed in figure 9.5.

	0-24 hours	24-48 hours	0-48 hours
Coban 2	3.35	1.40	4.70
Coban 2 Lite	3.47	1.52	4.93
paired t-test	*p = 0.19*	*p = 0.41*	*p = 0.22*
	SD: 0.30	*SD: 0.48*	*SD: 0.62*

Table 9.3: volume reduction of the applied systems.

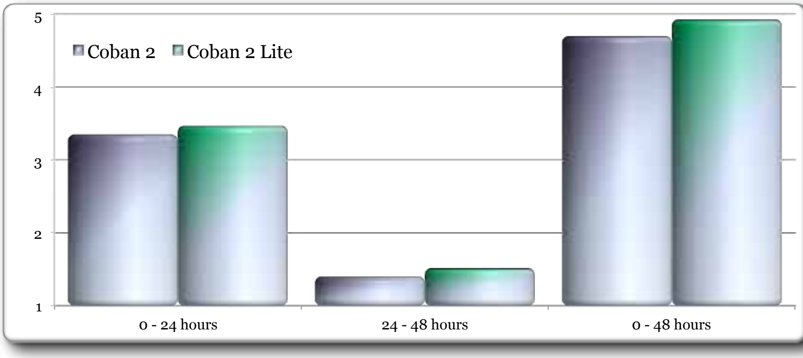


Figure 9.5: volume reduction of the applied systems.

The results sorted to the gender of the volunteers reveal that there is a significant difference in reduction between male and female volunteers. The data are expressed as percentage change to the initial volume and are presented in table 9.4, and graphically in figure 9.6.

	0 - 24 hours	24 - 48 hours	0 - 48 hours
female	3.74	1.63	5.31
male	3.08	1.28	4.32
paired t-test	*p = < 0.01*	*p = 0.11*	*p = < 0.01*
	SD: 0.56	*SD: 0.69*	*SD: 0.31*

Table 9.4: volume reduction of male and female subjects.

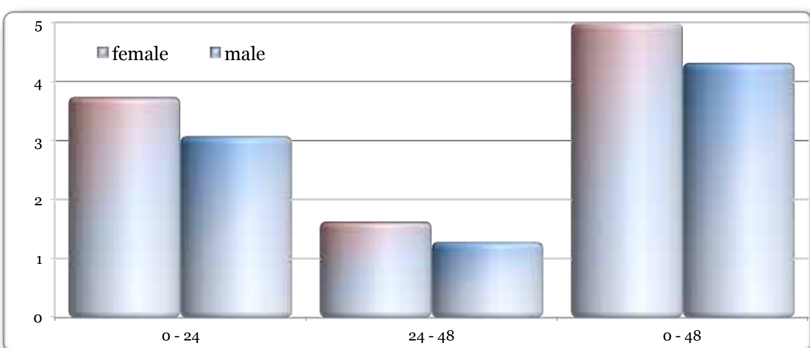


Figure 9.6: volume reduction of male and female subjects.

9.3.3. Relation of observations

To describe the statistical relationship between the different outcomes, a general linear model (GLM) was used. GLM is an ANOVA (analysis of variance) procedure, which can perform multiple comparisons between factor level means to find significant differences. The analysis is graphically presented in main effect plots. The analysis of variance reveals that:

- there is a significant effect of time of application (p = < 0.001), day of application (p=0.01) and gender (p=<0.001) on the % volume change;
- there is a significant effect of compression system (p=<0.001) and day of application (p=0.01) on the resting pressure;
- there is a significant effect of gender (p=<0.001) on the SSI;
- there is a significant effect of gender (p=<0.001) on the exercise amplitudes.

The above data are presented in table 9.5, and graphically displayed in main effect plots in the figures 9.7, 9.8, 9.9 and 9.10.

analysis of variance for % change	*f*	*p*
time of application	27.2	< 0.001
gender	6.77	0.01
compression system	< 0.01	0.99
day of application	171.07	< 0.001
analysis of variance for resting pressure	***f***	***p***
time of application	0.36	0.55
gender	0.02	0.89
compression system	162.08	< 0.001
day of application	6.79	0.01
analysis of variance for ssi	***f***	***p***
time of application	0.79	0.37
gender	19.35	< 0.001
compression system	< 0.01	0.94
day of application	1.41	0.24
analysis of variance for amplitude	***f***	***p***
time of application	0.15	0.7
gender	25.77	< 0.001
compression system	0.21	0.41
day of application	1.12	0.29

Table 9.5: effects of time of application, gender, compression system and day of application on percentage volume change, resting pressure, ssi and amplitude.

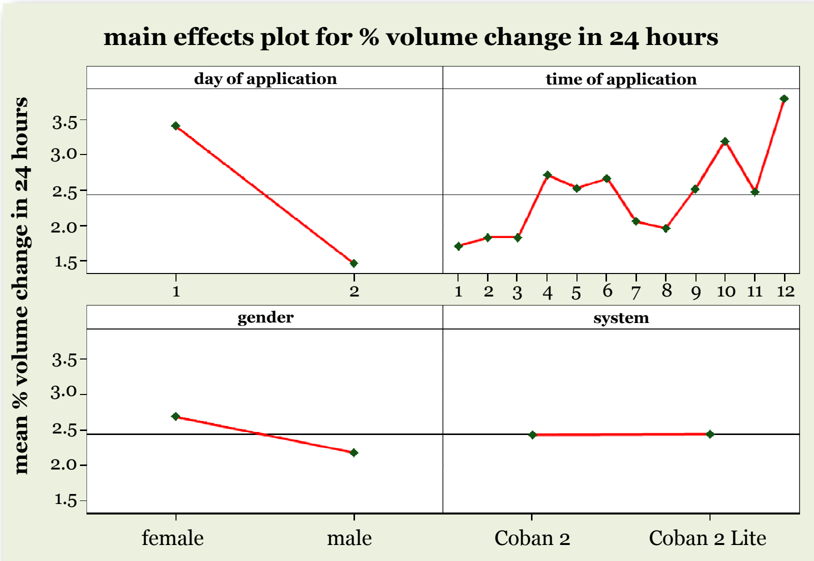


Figure 9.7: effects of day of application, time of application, gender and used system on volume change.

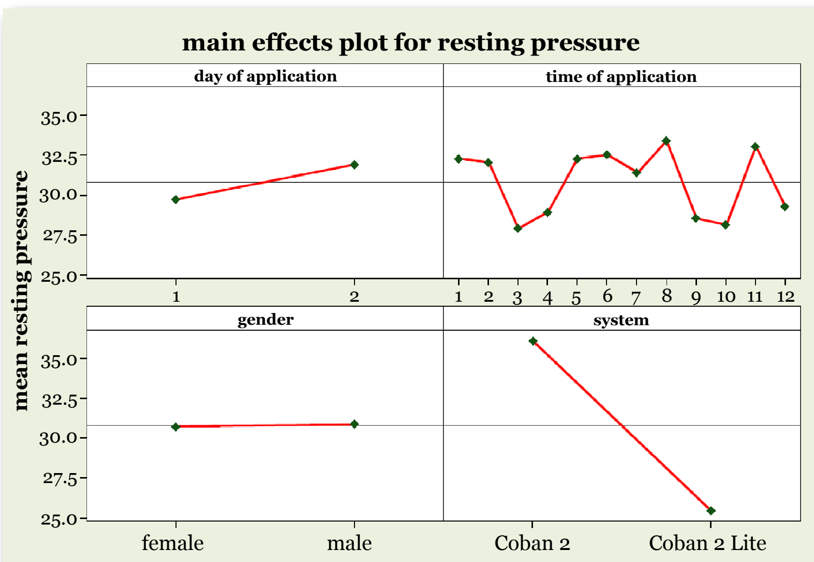


Figure 9.8: effects of day of application, time of application, gender and used system on resting pressure.

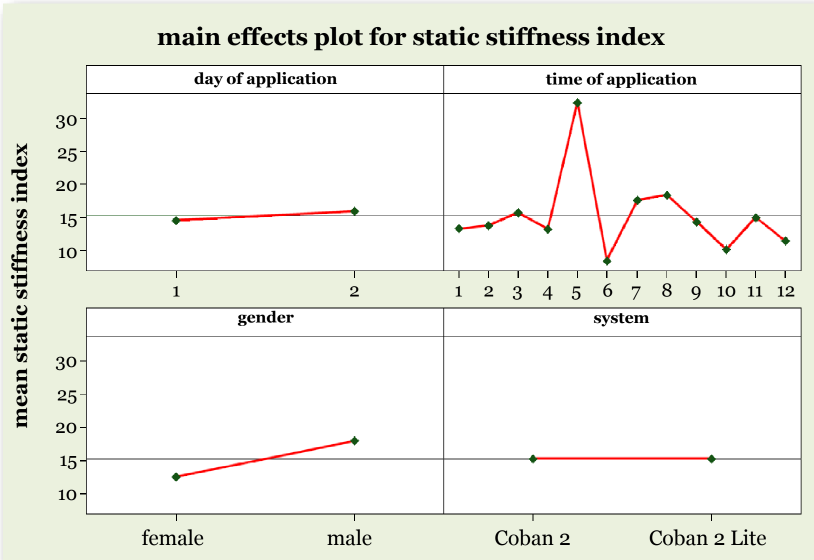


Figure 9.9: effects of day of application, time of application, gender and used system on ssi.

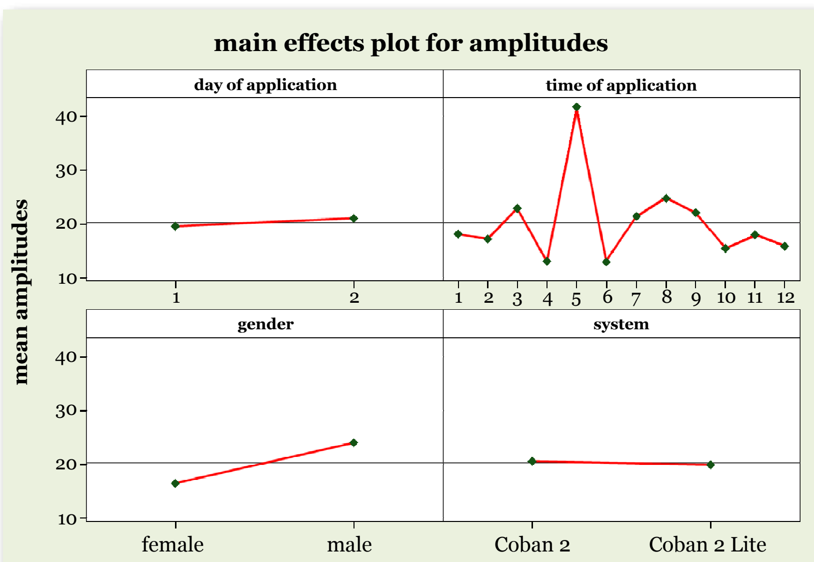


Figure 9.10: effects of day of application, time of application, gender and used system on amplitudes.

To visualise the relation between the time of application and percentage volume change, the data are presented as fitted line plot in figure 9.11. The Pearson correlation for this relation was significant ($r = 0.36$, $p = 0.01$).

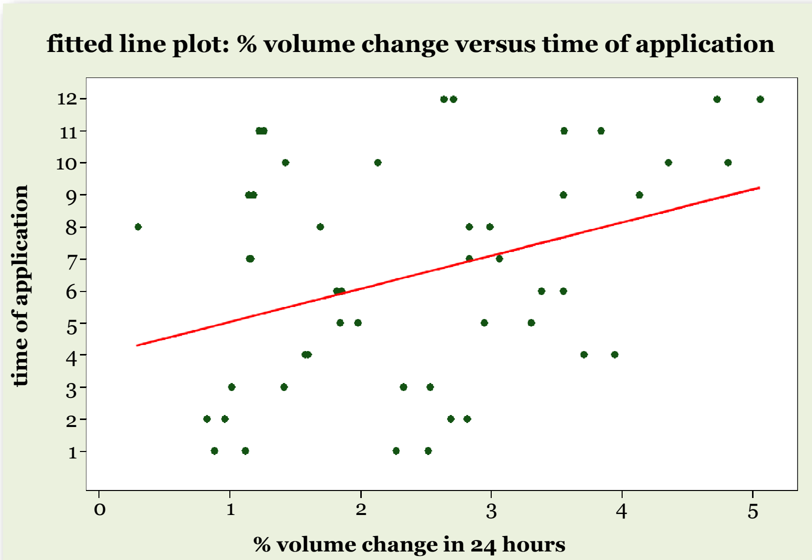


Figure 9.11: fitted line plot for time of application and percentage volume change.

9.4. Discussion

Occupational leg swelling is the phenomena that can be observed in the legs after longer periods of standing or sitting with minimal movement, or even at the end of a more or less active working day. Everyone is familiar with a minor impression of the border of socks when they are removed in the evening. It is caused by an increasing venous pressure due to gravity, which leads to extravasation of fluid. It is more likely to occur during pregnancy or with venous insufficiency, but is also a common experience in healthy persons. Hands et al [(3)] found a significant increase in leg volume during the day in fit young adults. Partsch et al [(4)] investigated what compression pressure is necessary to prevent this occupational leg swelling in healthy volunteers. Four different support stockings were applied over a four-day period and evening oedema was reduced by 50% on average. The amount of evening oedema ranged between 10.2 and 220.3 ml, where there was no single volunteer with a lower volume in the evening. The stockings with the higher pressures (>10 mmHg at the ankle level) were able to reduce the leg volume to values lower than the morning values. Damstra et al [(5)] studied the volume reducing effects of compression therapy with an inelastic, multilayer, multicomponent compression system in nine healthy volunteers. They report a significant reduction of 2.6% after two hours, combined with a 37.5% reduction in sub-bandage pressure measured at B1 in the supine position. The authors comment that the observed volume reduction can only be explained by a reduction of the fluid content of the compressed area. Hands et al [(3)] found that almost three quarters of this swelling occurred in the morning. The observed volume changes of the leg at the end of the morning, rising to 0.64% in the late afternoon. Similar findings were reported by Belczak et al [(6)]. They investigated the rate of occupational leg swelling depending on the time of the working shift in hospital employees. They found a significantly higher fluid accumulation in the morning shift workers compared to the afternoon shift workers (110 ml versus 59 ml). The measured volume increase per hour was 21 ml in the morning and 9.5 ml in the afternoon. Pannier et al [7] used an optoelectric volume measurement system to study the leg volume changes in the leg after 10 minutes of standing. In the group of 20 healthy subjects, a significant increase of 2.48% could be observed. Tsang et al [8] used water displacement to study the effects of elevation and intermittent pneumatic compression on oedema in patients with postacute ankle sprains. After 30 minutes of leg elevation or leg elevation with intermittent compression, there was a significant volume decrease after both procedures. However, repeated measurements after 5 minutes revealed that the volume returned to the pre-treatment level. Norgren et al [9] used an open water-filled plethysmograph for foot volumetry on healthy subjects to study the effects of exercise. The subjects performed 20 knee-bends in 40 seconds, which led to a volume reduction of 1.5 ml per 100 ml of foot tissue mass. This reduction was significantly less in patients with varicose veins (12.1 ml per 100 ml) and chronic venous insufficiency (0.7 ml per 100 ml). Using the same method to evaluate the effects of different elastic compression stockings in patients with varicosis and superficial venous insufficiency, Norgren [10] could show a significant improvement for this group of patients.

Vanscheidt et al [11] used water displacement to measure the volume reducing effects of different levels of compression provided by either intermittent (IPC) or by sustained pneumatic compression (SPC), with both methods being applied graduated and non-graduated. They found that the oedema reduction was related to the dose of compression. The 30 mmHg pressure in the gaiter area gave a significantly higher reduction than the 20 mmHg ($p < 0.001$); 40 mmHg was significantly better that 30 mmHg ($p < 0.001$). The most effective reduction was achieved with non-graduated SPC of 40 mmHg. This observation is different from the results in the volunteer study in this chapter where no difference could be observed between compression doses of 30 and 40 mmHg in the gaiter area. The different findings may be explained by the fact that the volunteers in the study in this chapter had similar working amplitudes. In chapter 8, it could be demonstrated that the ejection fraction has no relation with resting pressures as long as the working amplitudes are similar. This may lead to the assumption that an improvement of the ejection fraction may also contribute to an improvement of the volume reducing effects of compression therapy.

Kecelj Leskovec et al [12] retrospectively analysed clinical data on 18 patients that were treated with four different compression systems. Pressure was measured 30 minutes and 12 hours after the application. Based on their findings, the authors conclude that the best volume reduction of the limb was achieved with one of the systems because the highest pressure drop was observed in that group (n=4). The conclusion was supported with the statement that a mean pressure drop can be a measure of the therapeutically intended volume reduction of the limb.

Partsch et al [4] report an interesting additional observation in their sample of eight women and four men. The average leg volume of the left legs was significantly larger than for the right leg ($p < 0.01$). In the study volunteers reported in this chapter (6 women, 6 men), this difference was not significantly present ($p=0.66$). However, when the data are analysed on dominancy, a significantly higher volume for the non-dominant leg was observed ($p < 0.01$).

Blair et al [13] studied the sustainability of two different compression systems. The first, a combination of a zinc paste bandage held firmly in place with an adhesive bandage was used, unfortunately there is no further information provided on the properties of the used adhesive bandage. Secondly, a four layer system, which is described in detail and can be compared with currently commercially available four-layer systems like Profore. The pressure of the combined zinc paste and adhesive bandage showed a rapid decrease of pressure from just below 40 mmHg measured at the ankle joint to 15 mmHg after 4 hours. Surprisingly, the pressure of about 40 mmHg of the four-layer system was sustained for at least a week with even a slight increase in pressure after 8 hours and a final mean pressure drop of 3.7 mmHg after 1 week. These results are very different from those presented in this chapter, where it has been shown that effective compression leads to significant drop in resting pressure after 24 and 48 hours, even in healthy subjects. These results are also very different from the results on among others Profore presented in chapter 11.2, with pressure data collected during two hours of controlled functional activities and from those in chapter 11.3, in which pressure data were collected over a two-day period. In these two studies, experts in the specific applications were invited to apply the bandages. It is interesting to see that the study of Blair and co-workers [13] is one of the most referenced studies in literature on compression therapy and in many publications, much is assumed based on the findings presented in this paper.

Lamprou et al used Coban 2 in a prospective, randomised trial and compared it to an inelastic multicomponent compression system and in which the effectiveness in terms of volume reduction was investigated in patients with leg lymphoedema [14]. After 2 hours of compression, the median volume reduction was 2.9% in the Coban 2 group versus 1.8% in the group treated with conventional multicomponent system. After 24 hours of compression, the volume reduction was 8.4% and 4.4% respectively. It is not surprising that in both groups there was a significant loss of sub-bandage pressures measured at the B1 location (see figure 10.2). In this study the median initial standing pressures were lower in the Coban 2 Layer group (54 mmHg versus 60 mmHg) but the dynamic stiffness index (in this study the highest peak of the walking amplitudes minus the resting pressure) was higher in this group (25 versus 12). These different pressure profiles indicate that the differences in volume reduction are not determined by the sub-bandage pressure but by the possibility of an applied compression system to keep the forces that are created by functional activities, within the system.

Mosti et al compared Coban 2 and a modified Unna's boot in patients with venous leg ulcers [16]. Among others, they looked at volume reduction and found that with both systems with excellent stiffness profiles, leg oedema rapidly decreased with 8.5% and 7.3% respectively. In addition, the authors observed healing rates of over 90% in both groups after 3 months.

Like in most of the the above studies, the volume reduction due to compression therapy was also significant in the volunteer study presented in this chapter. Wearing the compression systems over 24-hour periods resulted in an average reduction of leg volume of 59.87 ml (3.41%) in the first 24 hours and an additional 24.70 ml (1.46%) in the following 24-hour period.

There is a large variation in volume changes in the different studies referenced in this discussion. This may have to do with the height of the used cylinders in the individual reports. Looking at the referenced studies, the volume was measured in containers of 23 cm [8], 34 cm (5), 43 cm [4], 45 cm [6] and 46 cm [3].

The strong relation between the SSI's and WPA's of Coban 2 and Coban 2 Lite in the study presented in this chapter can be explained by the perfect match of the study subjects. All systems were applied to both legs of the volunteers and randomised to the dominancy of the legs.

9.5. Conclusions

The presented results in this chapter clearly demonstrate that a significant volume reduction can be achieved with compression therapy, even in healthy volunteers. The loss in pressure observed in this study was significantly higher than the pressure drop that was observed in the laboratory study reported in chapter 3. This means that it can be concluded that not only material fatigueness but also volume reduction contributes to the pressure drop that is observed after the application of compression bandaging, regardless of the used materials. As this phenomenon is observed more with inelastic bandages than with elastic materials or stockings, it implies that these materials have to be changed more frequently when they are used in patients with oedematous legs.

The significant relation between the time of the day that the compression system is applied and the amount of volume reduction, implies that in clinical situations compression therapy will be more effective in reducing oedema when it is applied early in the morning when the exposure to gravity has been the lowest or even better, immediately after a prolonged period of leg elevation.

It could also be shown that compression therapy applied immediately following a period of compression, shows a significantly lower loss of volume with a resulting lower pressure drop. This implies that the application of bandaging systems is most effective when subsequent applications immediately follow each other.

The most important finding from this volumetry study is that no relation could be identified between volume reduction and applied systems. As both systems have significantly different resting pressures, it can be concluded that it is not the resting pressure that determines the effectiveness of an applied compression system. This observation combined with the findings on ejection fraction (see chapter 8), may lead to the conclusion that the stiffness and working amplitudes are determining the effectiveness of an applied compression system.

9.6. References

1. Deltombe T, Jamart J, Recloux S, Legrand C, Vandenbroeck N, Theys S, Hanson P.
   Reliability and limits of agreement of circumferential, water displacement, and optoelectronic volumetry in the measurement of upper limb lymphedema.
   Lymphology 2007; 40: 26-34.

2. Damstra RJ, Brouwer ER, Partsch H.
   Controlled, comparative study of relation between volume changes and interface pressure under short-stretch bandages in leg lymphedema patients.
   Dermatol Surg 2008; 34: 773-778.

3. Hands L, Collin J.
   Legs that swell and ache: volume changes during the day in healthy young adults.
   BMJ 1984; 288: 447-448.

4. Partsch H, Winiger J, Lun B.
   Compression stockings reduce occupational leg swelling.
   Dermatol Surg 2004; 30: 737-743.

5. Damstra RJ, Glazenburg EJ, Hop WCJ.
   Validation of the inverse water volumetry method: a new gold standard for arm volume measurements.
   Breast Cancer Res Treat 2006; 99: 267-273.

6. Belczak CE, de Godoy JM, Ramos RN, de Oliveira MA, Belczak SQ, Caffaro RA.
   Rate of occupational leg swelling is greater in the morning than in the afternoon.
   Phlebology 2009; 24: 21-25.

7. Pannier F, Rabe E.
   Optoelectric volume measurements to demonstrate volume changes in the lower extremities during orthostasis.
   Int Angiol 2010; 29: 395-400.

8. Tsang KKW, Hertel J, Denegar CR.
   Volume decreases after elevation and intermittent compression of postacute ankle sprains are negated by gravity-dependent positioning.
   J Athl Training 2003; 38: 320-324.

9. Norgren L, Thulesius O, Gjöres JE, Söderlundh S.
   Foot-volumetry and simultaneous venous pressure measurements for evaluation of venous insufficiency.
   VASA 1974; 3: 140-147.

10. Norgren L.
    Elastic compression stockings: an evaluation with foot volumetry, strain-gauge plethysmography and photoplethysmography.
    Acta Chir Scand 1988; 154: 505-507.

11. Vanscheidt W, Ukat A, Partsch H.
    Dose-response of compression therapy for chronic venous edema: higher pressures are associated with greater volume reduction: two randomized clinical studies.
    J Vasc Surg 2009; 49: 395-402.

12. Kecelj Leskovec N, Pavlović MD, Lunder T.
    A short review of diagnosis and compression therapy of chronic venous insufficiency.
    Acta Dermatoven APA 2008; 17: 17-21.

13. Blair SD, Wright DD, Backhouse CM, Riddle E, McCollum CN.
Sustained compression and healing of chronic venous ulcers.
BMJ 1988; 297: 1159-1161.

14. Lamprou DAA, Damstra RJ, Partsch H.
Prospective, randomized, controlled trial comparing a new two-component compression system with inelastic multicomponent compression bandages in the treatment of leg lymphedema.
Dermatol Surg 2011; 37: 1-7.

15. Mosti G, Crespi A, Mattaliano V.
Comparison between a new, two-component compression system with zinc paste bandages for leg ulcer healing: a prospective, multicenter, randomized, controlled trial monitoring sub-bandage pressures.
Wounds 2011; 23(5): 126-134.

Chapter 10

Compression therapy: safety & tolerability

10.1. Introduction

National guidelines, such as those from the Scottish Intercollegiate Guidelines Network (SIGN), recommend that patients with an Ankle-Brachial Pressure Index (ABPI) or Ankle-Brachial Index (ABI) of less than or equivalent to 0.8 should be assumed to have peripheral vascular disease [1]. These guidelines, produced through a multidisciplinary structure using formal methods and strict criteria for the evaluation and inclusion of evidence, are widely regarded as the "gold" standard [2]. In addition, a confusing variety of recommendations for treatment of patients with mixed arterio-venous disease can be found. Mayrovitz et al [3] studied the effect of foot-to-knee, four-layer compression bandaging on below-knee arterial pulsatile blood flow with nuclear magnetic resonance flowmetry. In 14 healthy supine subjects, bilateral flow measurements at five below-knee sites without and with compression, revealed a potentially important new phenomenon. The forefoot-to-knee compression bandaging caused a highly significant ($p<0.001$) increase in the bandaged leg pulsatile blood flow owing to increases in both peak flow and pulse width. The authors conclude that whatever the mechanism(s), the finding of a compression-associated pulsatile flow increase suggests a previously undiscovered arterial linkage, which may play a role in the well-documented beneficial effects of compression bandaging in venous ulcer treatment. To date there is almost no information on the actual sub-bandage pressures provided to patients with venous leg ulcers and ABPI's between 0.5 and 0.8. Consequently, there is a lack of information on the physical properties of the applied materials. In this chapter, two studies are presented. The first is a short summary of a study performed on patients suffering from peripheral arterial occlusive disease (PAOD) with an ABPI of 0.5-0.8 [4]; the second is a study to assess the safety and tolerability of compression therapy applied to patients in the same ABPI range [5].

10.2. Coban 2 Lite for patients with PAOD

10.2.1. Aim of the study

The purpose of this study was to assess the safety and tolerability of Coban 2 Lite in patients with an ABPI between 0.5 and 0.8, and to evaluate blood microcirculation during wear [4].

10.2.2. Materials and methods

A single-centre, open-label study was performed on 15 patients suffering from peripheral arterial occlusive disease with an ABPI of 0.5-0.8. Coincident chronic venous disease was allowed but not necessary for recruitment. All patients received treatment with Coban 2 Lite, which was applied at full stretch according to the method described in chapter 8.2.1. The applied systems stayed in place for one to four days. The system was reapplied by study personnel at each clinical visit (days 1, 2, 3, 4, 7, 10 and 14). Study participation stopped after 14 days. Results were summarised from 101 bandage applications. At each clinical visit, safety assessments were performed: Measurement of toe pulsation to detect macrocirculation, laser doppler fluxmetry at the forefoot to assess microcirculation of the dermal capillary system, clinical signs of pressure-related skin damage, substantiated by transepidermal water loss (TEWL), painful sensations as potential signs of underperfusion and sub-bandage pressure was measured at the B1 location. In addition, at baseline and at the end of the study limb volume was measured. A comfort questionnaire was completed at the end of the study.

10.2.2. Results

- Of the 15 patients, five had an ABPI of ≥0.5 and ≤0.6, four of >0.6 and ≤0.7 and six >0.7 and ≤0.8). Six of 15 patients suffered from chronic venous insufficiency.
- Coban 2 Lite was safe for, and well tolerated by, patients with ABPI's between 0.5 and 0.8.
- An average supine sub-bandage pressure of approximately 28 mmHg was measured immediately after bandage application (figure 10.1).
- Coban 2 Layer Lite System demonstrated beneficial effects on the dermal capillary system.
- No pressure-related skin damage occurred in patients with reduced arterial perfusion.
- No pain related to tissue hypoxia was reported.
- Measurements of limbs indicated reduced volume at the end of the study compared to baseline.
- The patient comfort questionnaire revealed that Coban 2 Lite was well tolerated with high wearing comfort, even though most patients currently were not used to wearing compression bandages.
- Results of laser doppler fluxmetry measurements indicate significant improvements of dermal microcirculation under Coban 2 Lite.

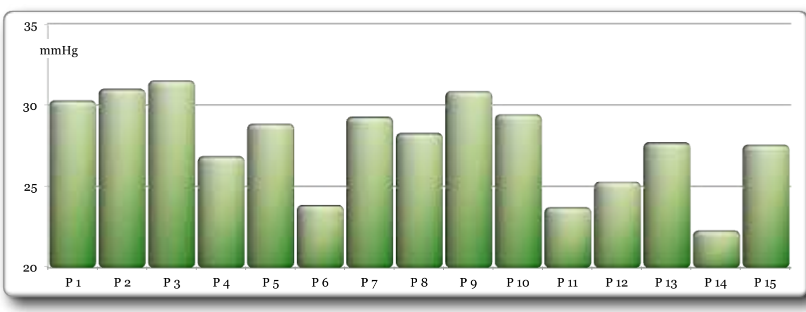


Figure 10.1: average sub bandage resting pressure of 101 Coban 2 Lite applications on 15 patients; the pressures are measured immediately after the application.

10.2.3. Discussion

Under daily routine conditions, Coban 2 Lite was applied at full stretch in this study. Reduced sub-bandage pressure was evident as advised for patients with a lower ABPI. The tolerability and comfort was high, especially with regard to the fact that many study participants did not have experience with compression treatments before the study. It can be concluded that Coban 2 Lite was safe in use for patients with reduced arterial perfusion. Additionally beneficial effects on the dermal vascular system where shown. This implies that Coban 2 Lite may contribute to enhanced capillary flow. Sufficient vascular supply with high tissue nutrition and oxygenation is a prerequisite for an active wound metabolism and healing environment of chronic leg ulcer [6,7].

10.3. Venous leg ulcer patients with low ABPI's: how much pressure is safe and can be tolerated?

10.3.1. Aim of the study

To get a better understanding of the safety and tolerability of compression bandages applied to venous leg ulcer patients with low ABPI's as well as some physical properties of the applied bandages.

10.3.2. Materials and methods

PicoPress measuring devices and data collection forms (figure 10.2) with written instructions of the measuring procedures (figures 10.3 and 10.4) were provided to eight experienced wound care nurses in Canada and the Netherlands.

patient ID number:	....	compression system used: (please describe in detail)	....
patient age:	....		
patient gender:	male / female		
ABI:	....		
date ABI measurement:	..... / ..... /	form completed by:	
date application:	..... / ..... /	....	
resting pressure:	.... mmHg		
standing pressure:	.... mmHg		
date removal:	..... / ..... /	....	
complications:	yes / no		
if yes, please describe:	....		

Figure 10.2: the data collection form.

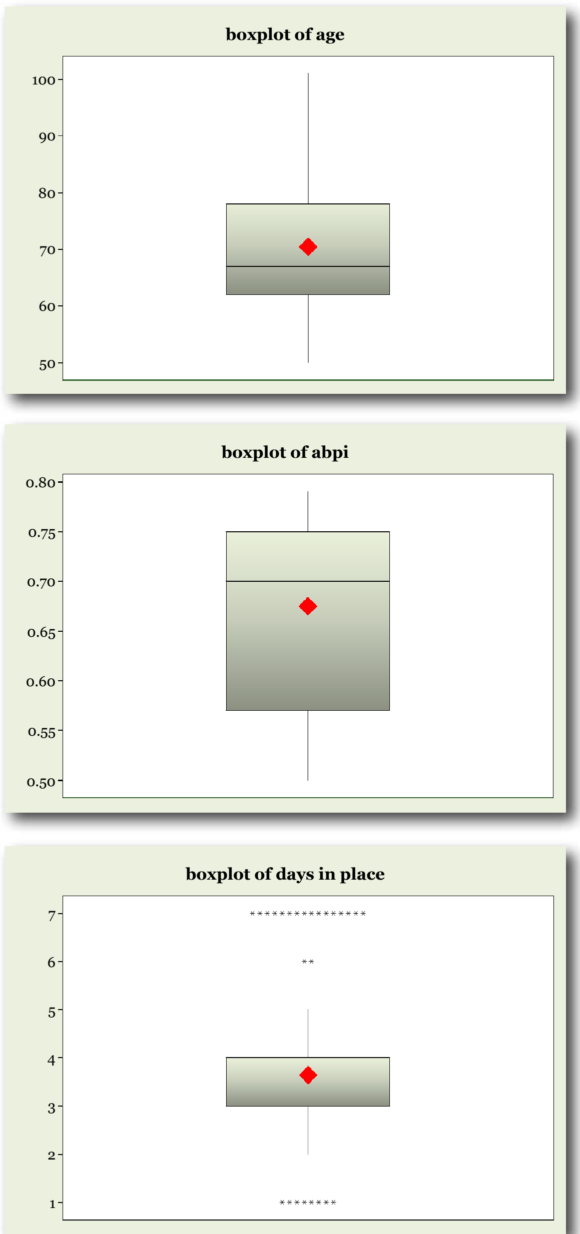
Figure 10.3: the sensor is positioned at "B1"; this is the area at which the Achilles tendon changes into the calf muscles (approximately 10-15 cm proximal to the medial malleolus).

Figure 10.4: during the measurement of the resting pressure, the foot rests relaxed on the bed, the knee is slightly flexed and the calf is completely free of the bed surface.

The participating clinicians were asked to measure sub-bandage pressures in the supine and standing position for each applied compression system to all patients in treatment with ABPI's between 0.5 and 0.8. As a consequence, data from several applications to the same patient can be included in the analysis. In addition, wear time and adverse events were recorded. The clinicians were instructed to have their application techniques not influenced by the measurements. The software programme Minitab 15.1 was used for statistical analysis and to create the graphs. An analysis was performed on 140 applications.

10.3.3. Results

The participating centres returned questionnaires on 140 applications on 86 patients. A variety of materials were applied, most were short stretch systems, typically combined with padding materials or with the comment that bandages were applied at less than full stretch. Several multi-layer systems were reported as well as modifications thereof. Because of the use of many techniques and modifications, it was impossible to perform an analysis of each subgroup. The mean age of the patients was 70.0 years (range 50-101). The average ABPI of the patients was 0.68 (range 0.5-0.79). 37 bandages were applied to patients with an ABPI between 0.5 and 0.59, 23 to patients with an ABPI between 0.6 and 0.69 and to 80 patients with ABPI's between 0.7 and 0.8. The average wear time was 3.7 days (range 1-7). The average resting pressure was 24.9 mmHg (range 6-40), the average standing pressure 32.2 mmHg (range 6-52) and the average static stiffness index 7.2 (range 0-14). These data are graphically displayed in figures 10.5.a, b, c and 10.6.



Figures 10.5.a,b,c: boxplots of age, abpi and days of bandage wear time; the diamonds represent the mean values.

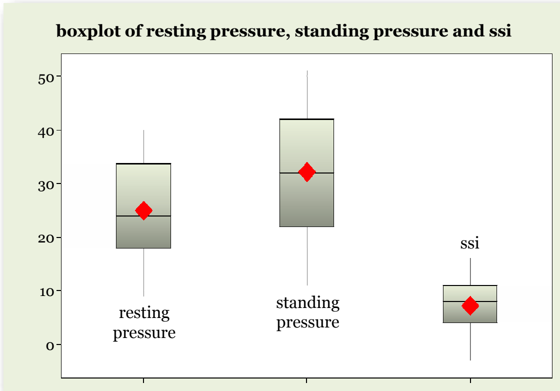


Figure 10.6: boxplots of resting and standing pressure and ssi; the diamonds represent the mean values.

There was a strong correlation between resting and standing pressure (analysis of variance: $p<0.001$, figure 10.7) and between resting pressure and static stiffness index (analysis of variance: $p=0.001$, figure 10.8).

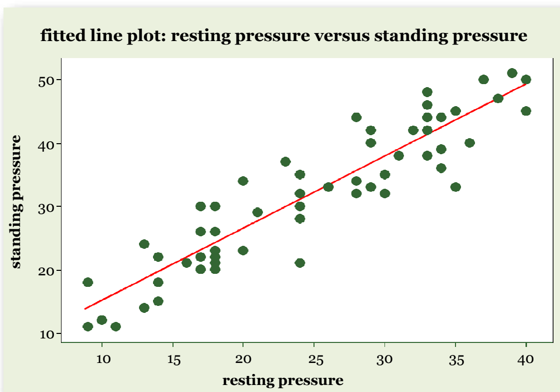


Figure 10.7: fitted line plot of resting and standing pressure.

Figure 10.8: fitted line plot of resting pressure and static stiffness index.

It was observed that each mmHg increase of resting pressure resulted in a 1.2 mmHg increase of standing pressure. There was no significant correlation between resting pressure and ABPI (analysis of variance: p=0.63, figure 10.9).

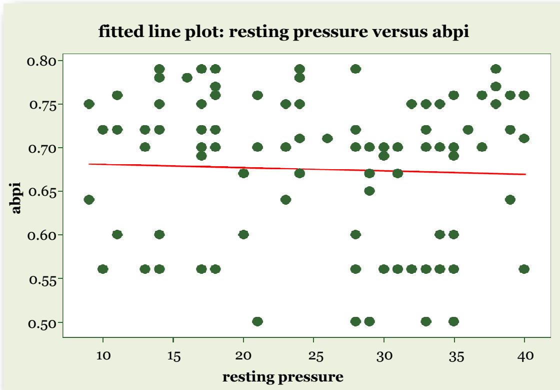


Figure 10.9: fitted line plot of resting pressure and ABPI.

Two adverse events were reported, both being pain in the foot. For one patient (age: 67, ABPI: 0.76, resting pressure: 40 mmHg) additional padding was used in subsequent applications, after which no further pain was reported. The other patient (age: 52, ABPI: 0.71, resting pressure: 26 mmHg) was referred to a vascular surgeon and compression therapy was discontinued.

10.4. Discussion

One of the simplest and most useful parameters to assess lower extremity arterial perfusion objectively is the ABPI. The ABPI helps to define the severity of the disease and successfully screens for haemodynamically significant disease [8]. In a position document of the society of interventional radiology [8], it is stated that ABPI's as high as 1.10 are considered normal; abnormal values are those less than 1.0, that the majority of patients with claudication have ABPI's ranging from 0.3 to 0.9, that rest pain or severe occlusive disease typically occurs with an ABPI lower than 0.50 and that indices lower than 0.20 are associated with ischemic or gangrenous extremities. Caruana et al [9] summarised what is known about ABPI's and concluded that in particular, care needs to be taken with methodology and training, reproducibility, interpretation, clinical recording and scientific reporting.

Mixed arterio-venous disease is present in a large percentage of the patients with ulcerated legs. In 1985, Cornwall et al [10] report a percentage of 22; others present similar numbers. In 1987, Callam et al [11]: 21%, in 1993, Anderson et al [12]: at least 20%, in 1994, Nelzén et al [13]: 22% and in 1998, Morrell et al [14]: 23%. In 1999, Zimmet [15] states that arterial insufficiency may co-exist in up to one-third of venous ulcer patients. In spite of these decades of continuous attention, there is still a dearth of hard data to support evidence-based clinical decisions on the use of compression therapy for these patients. In the listed exclusion criteria in almost every published clinical study on venous leg ulceration, an ankle-brachial pressure index (ABPI) or ankle-brachial index (ABI) of less than 0.8 can be found. Published guidelines for conducting studies to assess the efficacy of compression in venous disease, state that asymptomatic and symptomatic peripheral occlusive arterial disease with an ankle/arm index <0.8, may be carefully considered as an exclusion criterion [16]. A Cochrane review on the treatment of venous leg ulcers revealed that in only 4 of 39 studies that were included in the review, an ABPI of less than 0.8 was not included in the exclusion criteria. In these four studies however, arterial disease was mentioned [17]. In the ESCHAR study, a large randomised controlled multi-centre trial in the UK, 276 of 1418 patients (19.5%) were excluded because of an ABPI < 0.85 [18]. Similar numbers can be found in many other trials: e.g. Morrell et al [19], in which 93 of 393 patients (23.7%) were excluded because of an ABPI < 0.8.

In addition, a confusing variety of recommendations for treatment of patients with mixed arterio-venous disease can be found. Grey et al [20] state that patients may have a combination of venous and arterial diseases, resulting in ulcers of mixed aetiologies, which will limit the degree of compression (if any) that can be used. In the above mentioned Cochrane review, the ABPI cut-off point for application of compression was 0.8 in the majority of the included studies (23 out of 33), other values being 0.7 and 0.75 in one trial each, 0.9 in seven trials and 1.0 in one trial [17]. Clinical practice guidelines published by the Royal College of Nursing (RCN) comment that although the cut-off point below which compression is not recommended is often quoted as 0.8, vascular surgeons may use a lower cut-off point, for example 0.6 or 0.7 [21]. The International Leg Ulcer Advisory Board recommends that patients with arterial insufficiency (ABPI 0.5-0.8) can be treated with reduced compression (15-25 mmHg) [22]. The World Union of Wound Healing Societies (WUWHS) consensus document on compression in venous leg ulcers, recommends mild to moderate compression for these patients using inelastic bandages with extra padding. They remark that in some countries mild to moderate elastic bandages may be used with caution for certain patients [23]. Valencia et al [24] suggest that compression therapy is contraindicated in patients with a low ABPI. Reichenberg et al [25] recommend avoiding compression below an ABPI of 0.7. Kunimoto [26] states that long-stretch bandages are relatively safe in the presence of moderate arterial insufficiency, that they may be used if the ABI is greater than 0.5 and require only a minor degree of training. On the contrary, Sackheim et al [27] suggest that for patients with arterial insufficiency, such as those with an ankle brachial pressure index ≤0.9, compression bandages should be modified and that inelastic compression may be preferred.

In literature, some evidence can be found that mixed venous/arterial leg ulcers heal with compression therapy. However, in the few studies that report healing data, no sub-bandage pressure measurements were performed on the patients [28-33]. Bolton [34] concludes that further research is needed to identify appropriate level(s) of compression to optimise clinical outcomes for venous leg ulcer patients with varying degrees of ischemia and determine the clinical predictive validity and reliability of the ABPI value cut-off point(s) for making these decisions.

In addition to the exerted resting pressure of a bandage, the textile elastic property of its material is of decisive importance for the efficacy of compression treatment [35]. The increase in pressure (measured in the gaiter area) when standing up from the supine position, is defined as the static stiffness index (SSI). A consensus document to define the deciding characteristics of a compression bandage recently suggested that a pressure increase of more than 10 mmHg (SSI >10) is characteristic of a stiff bandage system [36].

In the presented observational study, it became obvious that the majority of the applied bandages could not be characterised as a stiff bandaging system (SSI > 10). Only 41 of 140 applications (29.3%) reached a SSI of 10 or higher, 60 applications (42.8%) reached a value of 5 or below. Mosti et al [37] demonstrated that there was a strong correlation between the SSI on one side and an improvement of venous pumping function as reflected by ejection fraction (EF) on the other side. In a more recent study, Mosti et al [38] showed that a significant improvement in venous pumping function (i.e. EF) was achieved with inelastic bandages even at resting pressures of 20 mmHg, provided by a system with sufficient stiffness. This observation leads to the suggestion that still much can be improved in this field. Patients with low ABPI's, for which the common belief is that they cannot tolerate routinely applied sub-bandage pressures, will benefit from effective compression. This observational study also revealed that there is a significant correlation between the provided resting pressures and the SSI's: the lower the resting pressure, the lower the SSI.

The most important finding of this observational study is that a wide range of sub-bandage pressure values (between 6 and 40 mmHg) has been safely applied by experienced nurses to patients with an ABPI between 0.5 and 0.8. These pressure values were well tolerated and the applied compression systems were left in place over longer periods (up to 7 days). Before this study started, the participating nurses did not measure pressure after application, but always applied their compression systems based on their experiences with these patients at risk. They were taught to observe clinical signs of underperfusion and modified existing techniques to their individual needs. Now that in this study the actual pressures of these modifications are revealed, there is a conflict between the observation on one side and what we have been taught and believe on the other. A large number of the applied compression systems provided resting pressures between 30 and 40 mmHg (49 of 140: 35%), a range of which many recommendations state that they should not be used. In this study, there was no relation between provided resting pressures and ABPI. This implicates that also patients in the lower ABPI range (0.5-0.6) were treated with these pressures.

Caruana et al [9] state that the apparent simplicity of the ABPI may beguile the unwary and that absolute pressures are probably more valuable in patients with critical limb ischemia. After a presentation of these study results at a congress [39], this observation was also the main point of criticism in the discussion. Based on that, the questionnaire was changed and in future data collection for this study the absolute values on ankle pressure will be reported and analysed.

The results of the observational study reveal that the majority of the patients in this study tolerated a variety of applied resting pressures and the applied materials were safe to use. The results also revealed that, with the compression bandaging materials that were used in this study, there is a significant correlation between the observed resting pressure and the SSI.

The ideal compression system is one that combines a low, tolerable resting pressure with an effective SSI. Especially patients with low ABPI's would benefit from this combination. The results from the observational study [5] demonstrate that many patients with low ABPI's received and tolerated compression therapy. However, with an average SSI of 7.2 and values ranging from 0 to 14, the majority of these patients could have been treated in a more effective way. The results of the Coban 2 Lite study on patients with PAOD [4] reveal that a full stretch application was well tolerated and indicate significant improvements of dermal microcirculation. These observations require further research to document the effects of eventual improvements on oedema reduction and ulcer healing.

In the instructions for use, which are included in many commercially available compression bandages and systems, often the statement can be found that the product should not be used in patients with ABPI's below 0.8. This is also the case for the instructions for use Coban 2. Coban 2 Lite was developed to deliver resting pressures of approximately 25-30% below those of Coban 2. Because both products are applied at full stretch, the SSI and WPA's are the same, as was presented in chapter 9. In the instructions for use for Coban 2 Lite is stated that the system can be used in patients with ABPI's above 0.5. Since the introduction in May 2010, several thousands of these systems have successfully been used for these patients. Serious adverse events have not been reported.

10.5. References

1. SIGN.
   The care of patients with chronic leg ulcer: a national clinical guideline.
   Scottish Intercollegiate Guidelines Network, Edinburgh, 1998.

2. Coull A, Tolson D, McIntosh J.
   Class-3c compression bandaging for venous ulcers: comparison of spiral and figure-of-eight techniques.
   J Adv Nursing 2006; 54: 274–283.

3. Mayrovitz HN, Larsen PB.
   Effects of compression bandaging on leg pulsatile blood flow.
   Clin Physiol 1997; 17: 105-117.

4. Jünger M, Haase H, Ladwig A, Schwenke L, Bichel J, Schuren J.
   Compression therapy in patients with peripheral arterial occlusive disease: a prospective clinical study with the 3M™ Coban™ 2 Layer Lite Compression System for ABPI ≥ 0.5
   In: Engineered for comfort, designed for real life: 3M Coban 2 layer compression therapy designed with intelligent compression dynamics. 3M Health Care, Skin and Wound Care Division 2010: 18-19.

5. Schuren J, Vos A, Allen J.
   Venous leg ulcer patients with low ABPI's: how much pressure is safe and can be tolerated?
   EWMA J 2010; 10(3): 29-34.

6. Hopf HW, Hunt TK, West JM.
   Wound tissue oxygen tension predicts the risk of wound infection in surgical patients.
   Arch Surg 1997; 132: 997-1005.

7. Myers WT, Gould L.
Animal models of tissue ischemia to evaluate the importance of oxygen in wound healing environment.
Wounds 2008; 20: 1-5.

8. Sacks D, Bakal CW, MD, Beatty PT, Becker GJ, Cardella JF, Raabe RR, Wiener HW, Lewis CA.
Position statement on the use of the ankle brachial index in the evaluation of patients with peripheral vascular disease: a consensus statement developed by the standards division of the society of interventional radiology.
J Vasc Interv Radiol 2003; 14: S389.

9. Caruana MF, Bradbury AW, Adam DJ.
The validity, reliability, reproducibility and extended utility of ankle to brachial pressure index in current vascular surgical practice.
Eur J Vasc Endovasc Surg 2005; 29: 443–451.

10. Cornwall JV, Doré CJ, Lewis JD.
Leg ulcers: epidemiology and aetiology.
Br J Surg 1986; 73: 693-696.

11. Callam MJ, Harper DR, Dale JJ, Ruckley CV.
Arterial disease in chronic leg ulceration: an underestimated hazard? Lothian and Forth Valley leg ulcer study.
BMJ 1987; 294: 929-931.

12. Andersson E, Hansson C, Swanbeck G.
Leg and foot ulcer prevalence and investigation of the peripheral arterial and venous circulation in a randomised elderly population: an epidemiological survey and clinical investigation.
Acta Derm Venereol 1993; 73: 57-61.

13. Nelzén O, Bergqvist D, Lindhagen A.
Venous and non-venous leg ulcers: clinical history and appearance in a population study.
Br J Surg 1994; 81: 182-187.

14. Morrell CJ, Walters SJ, Dixon S, Collins KA, Brereton LM, Peters J, Brooker CG.
Cost effectiveness of community leg ulcer clinics: randomised controlled trial.
BMJ 1998; 316: 1487-1491.

15. Zimmet SE.
Venous leg ulcers: modern evaluation and management.
Dermatol Surg 1999; 25: 236-241.

16. Rabe E, Partsch H, Jünger M, Abel M, Achhammer I, Becker F, Cornu-Thenard A, Flour M, Hutchinson J, Issberner K, Moffatt Ch, 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.

17. O'Meara S, Cullum NA, Nelson EA.
Compression for venous leg ulcers.
Cochrane Database of Systematic Reviews 2009, Issue 1. Art. No.: CD000265. DOI: 1 0.1002/14651858. CD000265.pub2.

18. Gohel MS, Barwell JR, Taylor M, Chant T, Foy C, Earnshaw JJ, Heather BP, Mitchell DC, Whyman MR, Poskitt KR.
Long term results of compression therapy alone versus compression plus surgery in chronic venous ulceration (ESCHAR): randomised controlled trial.
BMJ 2007; 335: 83. Epub 2007 Jun 1.

19. Morrell CJ, Walters SJ, Dixon S, Collins KA, Brereton LML, Peters J, Brooker CGD.
Cost effectiveness of community leg ulcer clinics: randomised controlled trial.
BMJ 1998; 316: 1487–1491.

20. Grey JE, Enoch S, Harding KG.
ABC of wound healing: venous and arterial leg ulcers.
BMJ 2006; 332: 347-350.

21. Royal College of Nursing.
The nursing management of patients with venous leg ulcers: recommendations.
London: Royal College of Nursing, 2006.

22. Stacey M, Falanga V, Marston W, Moffatt C, Phillips T, Sibbald RG, Vanscheidt W, Lindholm C.
The use of compression therapy in the treatment of venous leg ulcers: a recommended management pathway.
EWMA Journal 2002; 2: 9-13.

23. World Union of Wound Healing Societies (WUWHS).
Principles of best practice: Compression in venous leg ulcers: a consensus document.
London: MEP Ltd, 2008.

24. Valencia IC, Falabella A, Kirsner RS, Eaglstein WH.
Chronic venous insufficiency and venous leg ulceration.
J Am Acad Dermatol 2001; 44: 401-421.

25. Reichenberg J, Davis M.
Venous Ulcers.
Semin Cutan Med Surg 2005; 24: 216-226.

26. Kunimoto BT.
Management and prevention of venous leg ulcers: a literature-guided approach.
Ostomy Wound Manage 2001; 47: 36-49.

27. Sackheim K, De Araujo TS, Kirsner RS.
Compression modalities and dressings: their use in venous ulcers.
Dermatol Ther 2006; 19: 338-47.

28. Moffatt CJ, Franks PJ, Oldroyd M, Bosanquet N, Brown P, Greenhalgh RM, McCollum CN.
Community clinics for leg ulcers and impact on healing.
BMJ 1992; 305: 1389-1392.

29. Ghauri ASK, Nyamekye I, Grabs AJ, Farndon JR, Poskit KR.
The diagnosis and management of mixed arterial/venous leg ulcers in community-based clinics.
Eur J Vas Endovasc Surg 1998; 16: 350-355.

30. Marston WA, Carlin RE, Passman MA, Farber MA, Keagy BA.
Healing rates and cost efficacy of outpatient compression treatment for leg ulcers associated with venous insufficiency.
J Vasc Surg. 1999; 30: 491-498.

31. Arthur J, Lewis P.
When is reduced-compression bandaging safe and effective?
J Wound Care 2000; 9: 469-471.

32. Humphreys ML, Stewart AH, Gohel MS, Taylor M, Whyman MR, Poskitt KR.
Management of mixed arterial and venous leg ulcers.
Br J Surg 2007; 94: 1104-1107.

33. Top S, Arveschough AK, Fogh K.
Do short stretch bandages affect distal blood pressure in patients with mixed aetiology leg ulcers?
J Wound Care 2009; 18: 439-442.

34. Bolton L.
Compression in venous ulcer management.
J Wound Ostomy Continence Nurs 2008; 35: 40-49.

35. 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.

36. Partsch H, Clark M, Mosti G, Steinlechner E, Schuren J, Abel M, Benigni JP, Coleridge-Smith P, Cornu-Thénard A, Flour M, Hutchinson J, Gamble J, Issberner K, Juenger M, Moffatt C, Neumann HA, Rabe E, Uhl JF, Zimmet S.
Classification of compression bandages: practical aspects.
Dermatol Surg 2008 May;34(5):600-609.

37. Mosti G, Mattaliano V, Partsch H.
Inelastic compression increases venous ejection fraction more than elastic bandages in patients with superficial venous reflux.
Phlebology 2008; 23: 287–294.

38. Mosti G, Partsch H.
Is low compression pressure able to improve venous pumping function in patients with venous insufficiency?
Phlebology 2010; 25: 145-150.

39. Schuren J.
Venous leg ulcer patients with low ABPI's: how much pressure is safe and can be tolerated?
Proceedings of the 20th Conference of the European Wound Management Association; 2010, May 26-28; Geneva Switzerland: EWMA; 2010: 41.

Chapter 11

Compression bandaging systems: slippage and sustainability

11.1. Introduction

Compression therapy is widely used in the treatment of chronic venous leg ulcers. Much of how this therapy works is still unclear. An assessment of the forces over a longer period may help understanding the physics of action of compression therapy. In this chapter, two studies on healthy subjects are presented. The first is a comparison of pressure profiles of different compression systems during two hours of controlled functional activities. The objectives of the second study presented in this chapter were to evaluate resting and working pressures under different compression systems over a 48-hour period. In addition, slippage and reproducibility of application of the applied systems was recorded [1]. Integrated in the second study was a 7-day wear study on Coban 2 Lite. The collected data from this study are also presented. As material fatigueness is often mentioned when the sustainability of provided pressures is discussed, an experimental study was performed to study the effects of material fatigueness on pressure and strain index (see chapter 3.6) over a one-week period.

11.2. The effects of two hours controlled functional activities

11.2.1. Introduction

The objective of this study was to evaluate sustainability of pressure, comparing currently marketed systems over a two-hour period of controlled functional activities. This study was approved by 3M's Institutional Review Board (IRB) and was performed in the 3M Medical

Laboratory facilities in Neuss, Germany and St. Paul, USA. For each comparison, bandages were applied to both legs of eight healthy volunteers by invited experts who routinely use the materials under investigation.

11.2.2. Material and methods

Each of the compression systems under investigation was applied to one leg of eight healthy volunteers. Each volunteer had both legs wrapped with two different systems. A computer-generated randomisation list determined which leg was wrapped with which product. The sub-bandage pressures were measured using six strain gauge temperature-compensated (15-40°C) force transducers, 13 mm in diameter and 3 mm thick (Gaeltec) connected via amplifiers and filters to a computer. The sensors were secured with 3M Micropore tape. After positioning the sensors to both legs of the healthy volunteer, the sensors were set to zero mmHg. The sensors were positioned at the following anatomical locations:

- the so-called B1-area, at the junction of Achilles tendon and calf muscles;
- on the centre of the caput mediale M. gastrocnemius where the calf is at its maximum girth;
- 10 cm. below the fibular head on the centre of the M. tibialis anterior.

After sensor positioning, the bandages were applied and the volunteer performed controlled functional activities during a two-hour period according to the following schedule, which was repeated four times:

- 20 minutes walking on a treadmill at a controlled speed of 3 km/hour;
- 5 minutes stair climbing (50 stairs up, 50 stairs down);
- 5 minutes rest in a supine position.

Pressure was recorded at 0, 30, 60, 90 and 120 minutes. All pressure recordings were stored on a computer for further analysis.

The following compression systems were included in the evaluation:

- Actico;
- K-Two;
- Profore;
- Rosidal Sys;
- Biflex, a long stretch bandage;
- Unna's boot, an inelastic zinc paste bandage covered with Coban;
- Sigvaris 503 CII, class 2 compression stocking;
- Coban 2.

11.2.3. Results

A typical reading from the 6 positioned Gaeltec sensors is presented in figure 11.1. The sensors P1, 2 and 3 are on one leg, the sensors P4, 5 and 6 on the other. The sensors P1 and 4 are positioned at B1, the sensors P2 and P5 on the gastrocnemius muscle and sensors P3 and P6, 10 cm below the fibular head on the centre of the M. tibialis anterior. The picture shows the recording of two periods of 30 minutes. During stair climbing the recording was interrupted. For data analysis, the Gaeltec computer allows to stretch the recordings to facilitate the collection of pressure values at any specific period. Stretched recordings are presented in figure 11.2, which is a typical picture during controlled walking on the treadmill.

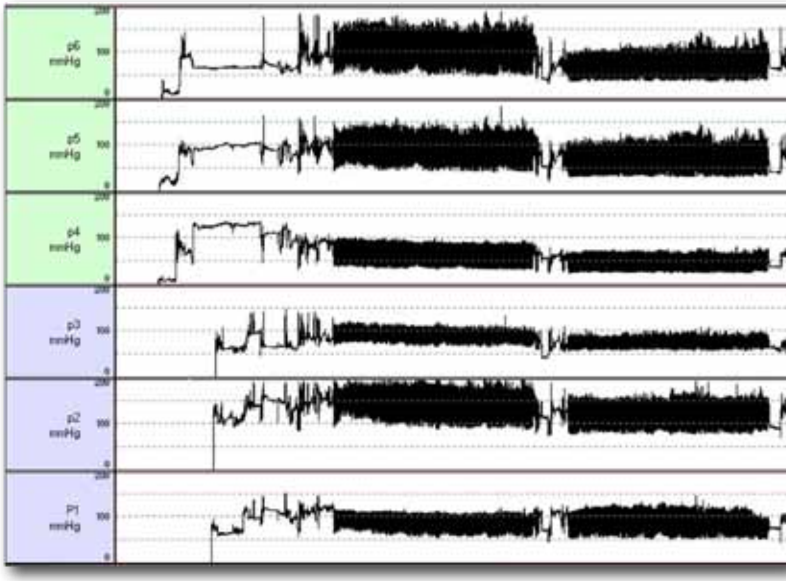


Figure 11.1: 6-channel pressure recording over two periods of 30 minutes.

Figure 11.2: 6-channel pressure recording during walking at 3 km/hour, stretched to allow data collection; each amplitude represents one step.

The pressure recordings took place over 3 channels on each leg. The patterns that were observed on each of them were very similar. Therefore only results are presented from the measurements on B1. This to allow a comparison with other data presented in this thesis. The mean resting pressure values are presented in figure 11.3, the mean SSI for each product in figure 11.4 and the mean amplitudes for each individual system in figure 11.5.

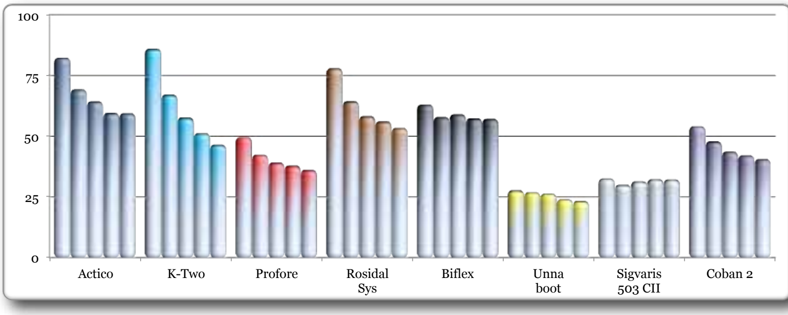


Figure 11.3: mean resting pressures in mmHg; for each product the 5 columns represent the measurements after 0, 30, 60, 90 and 120 minutes.

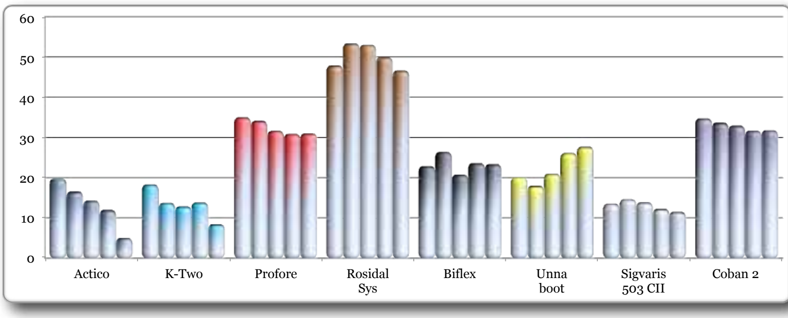


Figure 11.4: mean static stiffness indices; for each product the 5 columns represent the measurements after 0, 30, 60, 90 and 120 minutes.

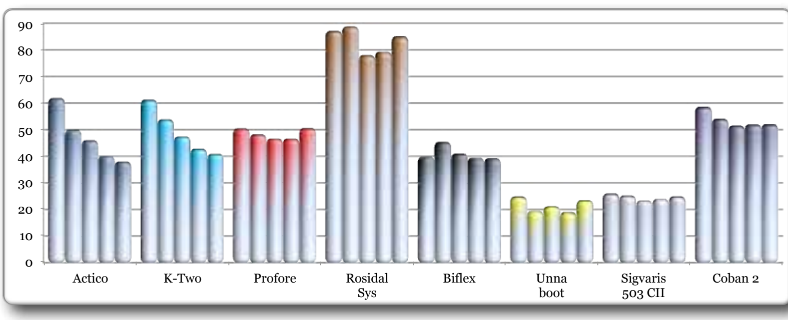


Figure 11.5: mean walking amplitudes; for each product the 5 columns represent the measurements after 0, 30, 60, 90 and 120 minutes.

11.3. The effects of two day wear time

11.3.1. Introduction

The objective of this study was to evaluate sustainability of pressure, comparing currently marketed systems over a two-day period of wear. The study was approved by 3M's Institutional Review Board and the Freiburger Ethical Committee in Germany and was performed in the 3M Medical Laboratory facilities in Neuss, Germany. For each comparison, bandages were applied to both legs of twelve healthy volunteers by invited experts who routinely use the materials under investigation [1].

11.3.2. Materials and methods

Both legs of 60 healthy volunteers were wrapped with different compression bandages. Experienced nurses from the UK, Germany and the Netherlands, who routinely use the systems listed below, were invited to apply the bandages. Each system was applied 12 times. The following compression systems were included in the evaluation:

- Actico;
- K-Two;
- Profore;
- Profore Lite;
- Proguide;
- Rosidal K;
- Rosidal Sys;
- Dauerbinde F;
- Coban 2;
- Coban 2 Lite.

Where possible, the bandages were left in place for 48 hours. The volunteers were instructed to wear sport shoes and instructed to keep the bandages dry. Special cast protectors (AquaProtect) were provided to facilitate showering. There were no restrictions in physical activities. Volunteers were instructed to remove the system in case of discoloration of the toes, pain, numbness, tingling or other changes in sensation and swelling.

Pressures were recorded with the PicoPress device with the sensor positioned at the B1-level in the supine position and during stance, as well as the amplitude of maximum plantar and dorsal flexion of the ankle joint in the supine position with an extended knee. Measurements were taken immediately after the application and at 24 and 48 hours. To avoid pressure damage, the connecting tubes of the pressure sensor were positioned on a 2 cm wide strip of 3M Tegaderm foam.

11.3.3. Results

Most bandages were well tolerated by the volunteers (100 of 120, 83.3%) over the entire 48 hours. 6 bandages were removed by the volunteers on day 1 because of discomfort during the night (1 Actico, 2 Proguide, 2 Rosidal, and 1 Dauerbinde). 13 bandages were removed after 24 hours because of serious slippage (4 Actico, 1 Profore, 4 Profore Lite, 1 Proguide, 1 Rosidal K, 1 Dauerbinde F). One bandage was removed because of pain underneath the sensor (Coban 2 Lite).

11.3.3.1. Pressure

In this study, the resting pressure was measured with the leg resting on the bed with the knee extended. In this position, there is quite some pressure on the gastrocnemius muscle, resulting in higher resting pressures than would have been seen if the leg has been positioned with flexed knee and the foot resting on the calcaneus (see figure 10.3). This phenomena can be explained by Pascal’s law (chapter 6). The high resting pressure also affected the measurements of the static stiffness index, which in a large number of calculations resulted in a negative number. Therefore the static stiffness data are not included. The mean values of the resting pressures in mmHg are presented in figure 11.6.

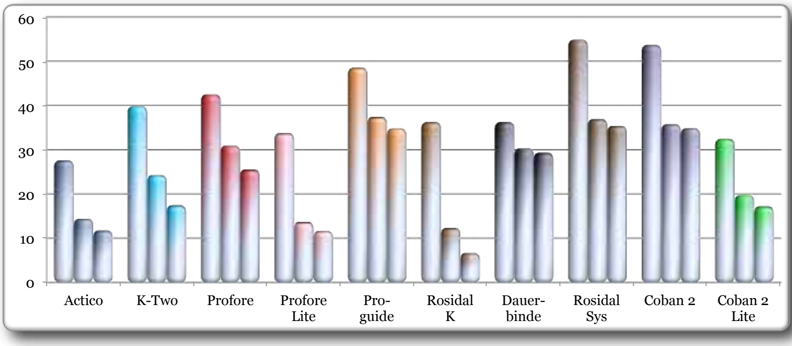


Figure 11.6: resting pressures in mmHg after application, 24 and 48 hours.

The mean values of the amplitudes (highest - lowest working pressure) are presented in figure 11.7. It must be noted that in some measurements after 24 and 48 hours, slippage caused bulging of several layers in the area where the pressure sensor was positioned. It was observed that this bulging influenced the measurements as several bandages with significant slippage still produced unrealistic high amplitudes.

It must also be noted that the observed differences in amplitudes are heavily influenced by the fact that for each compression system different volunteers were included in this study (see also chapter 3: 3.4 static stiffness index and chapter 3.5: amplitudes). In this study, the twelve volunteers having Actico applied to one leg, had K-Two applied to the other, twelve had Profore and Proguide applied, twelve Rosidal Sys and Coban 2, twelve Rosidal K and Dauerbinde and twelve volunteers were wearing Profore Lite and Coban 2 Lite.

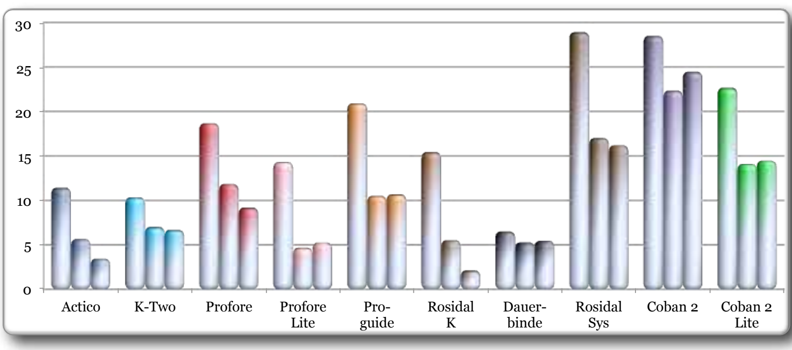


Figure 11.7: amplitudes after application, 24 and 48 hours.

11.3.3.2. Slippage

The mean values of slippage in cm are presented in figure 11.8. The first column for each system represents the analysis of the 114 bandages in place after 24 hours; the second column shows the mean values of the remaining 100 bandage systems still in place after 48 hours. Pictures of typical examples of observed slippage in this study are presented in the figures 11.9 and 11.10. All pictures were taken before bandage removal at 48 hours.

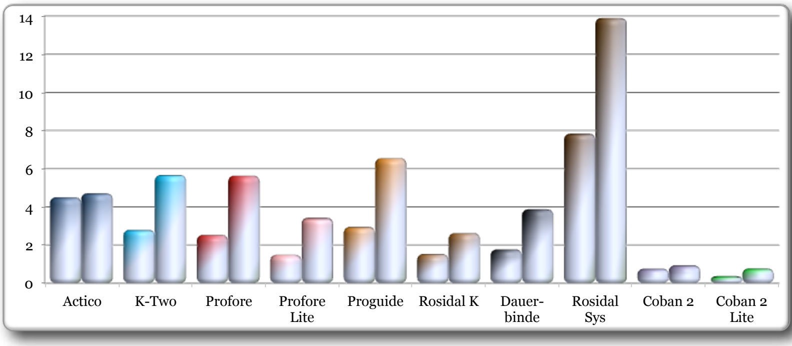


Figure 11.8: slippage in cm after 24 and 48 hours.

Figure 11.9: typical examples of observed slippage of five compression systems.

Figure 11.10: typical examples of observed slippage of five compression systems.

11.4. Seven day pressure and slippage study on Coban 2 Lite

11.4.1. Introduction

To support a claim on 7-day wear time, the Coban 2 Lite systems applied to the volunteers from the study in chapter 11.3, were not removed after 48 hours but stayed in place for 7 days. In addition to the 24 and 48-hour measurements, these volunteers returned after 72, 96 and 168 hours for additional measurements.

11.4.2. Results

Coban 2 Lite was well tolerated by the volunteers. In total, 9 bandages stayed on the leg for the entire 7 days. One bandage was removed after 72 hours because of an unexpected change in the working shift of the volunteer, as he could not return for the control measurements. Two bandages were removed in the weekend after the control at 96 hours by the volunteers because it was too hot for them in that weekend (temperatures > 30°C).

Pressures in mmHg and amplitudes are presented in figure 11.11. In the graph, also the two-day data of Coban 2 are shown for comparison. Compared to Coban 2, Coban 2 Lite had a significantly lower resting pressure after 0 ($p=<0.001$), 24 ($p=0.001$) and 48 hours ($p=0.001$). The data on slippage of Coban 2 Lite over a 7-day wear period are presented in figure 11.12.

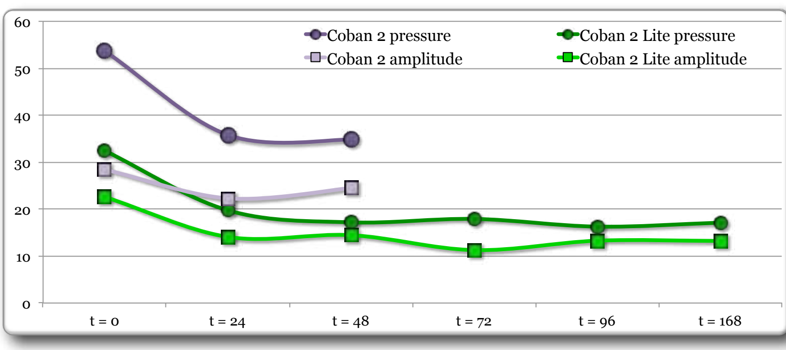


Figure 11.11: resting pressure and amplitudes of Coban 2 (48 hours) and Coban 2 Lite (168 hours).

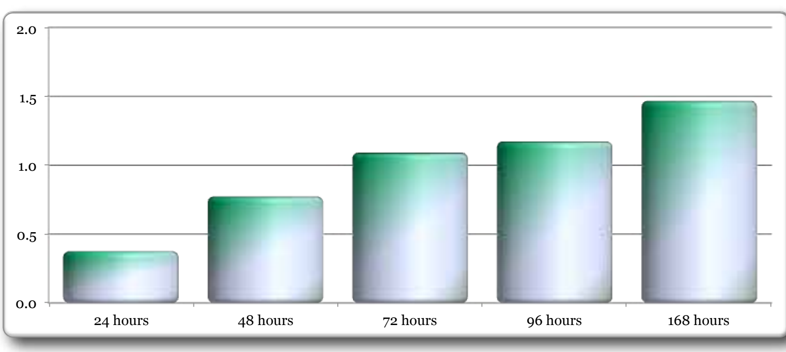


Figure 11.12: slippage of Coban 2 Lite in cm over a 7-day period.

11.5. Material fatigueness

11.5.1. Introduction

Most materials that are exposed to repeated variations or continuous stress show a certain amount of weakness. This phenomenon is called material fatigueness. Also bandaging materials are expected to be effected by material fatigueness when exposed to application under a certain amount of tension. In the 2-, 48- and 168-hour wear studies presented in this chapter, a significant pressure loss is observed. This can be explained by a loss of leg volume, as could be shown in chapter 9, material fatigueness or a combination of both. To study the isolated effects of material fatigueness on pressure and strain index, the test method described in chapter 3.6.2. was used. The only difference with the described method is that in this study new fluid bags with a lower profile were used.

11.5.2. Materials and methods

Ten poly-oxymethylene test cylinders, five with a radius of 4 cm and five with a radius of 5 cm were wrapped with Coban 2, Coban 2 Lite, Profore and Profore Lite. The wrapped cylinders were stored under controlled room temperature conditions. Pressure and strain index were measured immediately after application, after 2 and 4 hours. Next measurements were taken at 24, 48. 72, 96 and 168 hours.

11.5.3. Results

The data on the pressure measurements are presented in figure 11.13. The values represent the mean of the pressures measured on both cylinders. It is easy to observe that the four systems under investigation all loose some of the initial pressure. Most of the pressure loss takes place in the first four hours. The measurements after 48 hours and the ones that follow until 168 hours reveal that the pressure stays more or less stable over a longer period.

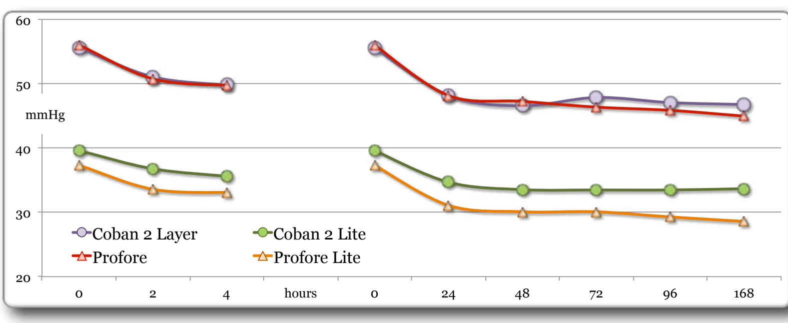


Figure 11.13: pressure loss in mmHg over a one-week period.

Figure 11.14 shows the percent changes in pressure to the initial resting pressure.

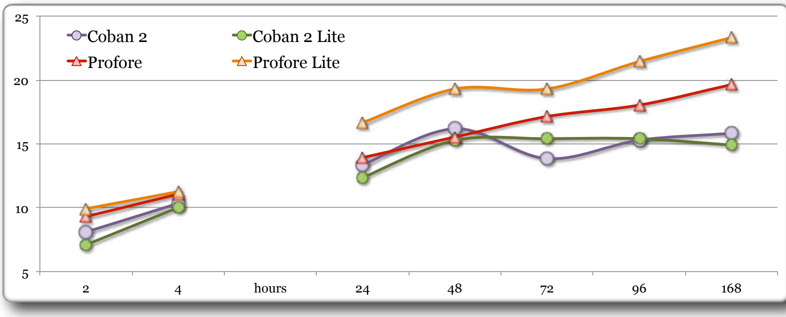


Figure 11.14: percent changes in pressure over a one-week period.

The data on the strain index are presented in figure 11.15. It is clear to see that Profore, Coban 2 and Coban 2 Lite maintain their strain index in spite of the pressure loss. Profore Lite shows a larger loss in it strain index. The strain indices in this study differ from those presented in chapter 3.6.3. In that validation test fluid bags were used with a slightly higher profile, which explains the difference in performance.

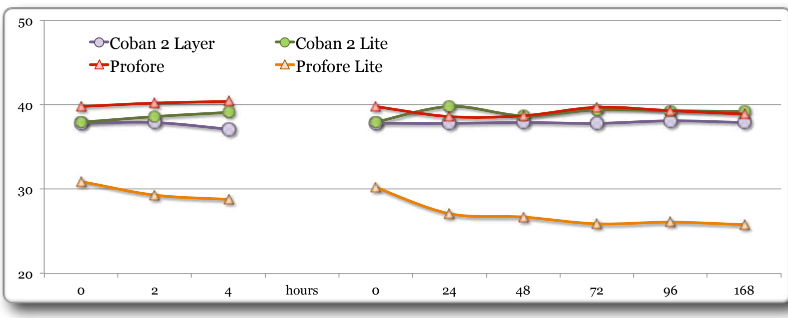


Figure 11.15: changes in strain index over a one-week period.

Figure 11.16 shows the percent changes in strain index compared to the initial one, negative values indicate an increase of the strain index.

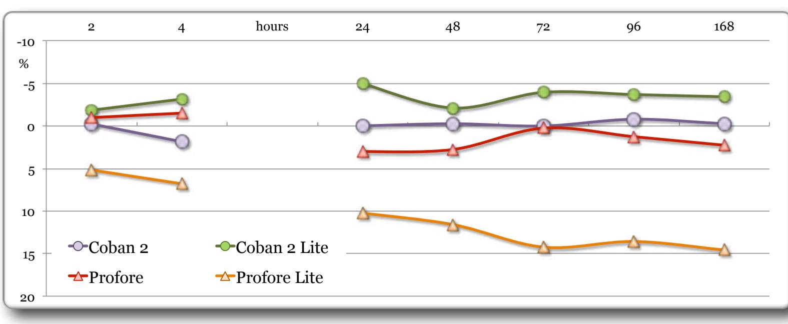


Figure 11.16: percent strain index changes over a one-week period.

11.6. Discussion

In the 2003 EWMA Position Document, Marston and Vowden describe the ideal compression therapy system as one that among some other features, provides and maintains clinically effective levels of compression for at least one week during walking and at rest [2]. In 1988, Blair et al [3] presented the results of a randomised controlled study with as primary endpoint of the study a comparison of pressures achieved at the ankle for up to one week. The results were promising. The four layer bandage achieved pressures of about 40 mm Hg, which depended less on the bandager and were sustained for at least one week. According to the authors, the compression by adhesive plaster bandaging seems to be inadequate (30 mm Hg), to depend on the technique of application, and to dissipate rapidly after a few hours. These results would fulfil the above feature of sustained compression.

However, in the development of Coban 2 Layer, many volunteer studies were performed in which Profore was used, a four layer compression system very similar to the one described by Blair and co-workers [3]. In none of them the results of the data presented by Blair et al [3-5] could be reproduced. Each measurement resulted in a decrease of the resting pressures, which can easily be explained not only by the fact that each bandaging system shows a certain amount of material fatigueness (see chapter 11.5), but also by the observation that effective compression leads to a volume reduction, even in healthy volunteers (see chapter 9: volumetry). The data from the studies presented in this chapter reveal that a reduction in resting pressure is also observed for Profore (figures 11.3 and 11.6). This reduction is partly the result of effective compression therapy.

An important question remains after reviewing these data. How can the pressure in the studies of Blair et al [3-5] have a pressure drop of only 9.25% (from 40.0 mmHg after the application, to 36.3 mmHg after one week), where in the completely controlled measurements that are presented in this chapter, material fatigueness alone already is responsible for a pressure drop of 19.6% (from 56 mmHg after the application to 45 mmHg after one week, as is shown in figure 11.13)? What can cause the difference between the studies of Blair et al [3-5] and the data on volunteers in this chapter where Profore shows a 27.2% pressure drop after two hours of controlled activities (see figure 11.3) or even 39,9% after two days of wear (see figure 11.6)? The question is of particular importance as in almost every publication in which the topic of sustained compression is highlighted, the study of Blair et al [3] is referenced.

The data presented in this chapter are in line with what can be found in literature. Callam et al [6] studied the effect of time on pressure profiles, After 4 hours of wear in 20 active volunteers, a short-stretch system produced 66% of the initial pressure, where a long stretch system was at 94%. Damstra et al [7] measured the pressure loss for a short stretch system after 2 hours in 9 healthy subjects. The loss in resting pressure was 37.5% in the supine position and 21% in the standing position. Also Danielsen et al [8] found significant differences in pressure loss between short and long stretch bandages. The pressure drop for the long-stretch bandage was 3.6% after 2 hours and 1% after 24 hours, where the short stretch loss was 21.5% and 34% respectively in the supine position. After 7 days wear, the pressure underneath the long-stretch system was at 89.6% of the initial value. The authors conclude that the results suggest that elasticity has a positive influence on the capability of the bandage to maintain a high sub-bandage pressure. As in the two-hour study presented in this chapter, where the resting pressure of the tested stockings stayed at the same level, Jünger et al [9] showed that the resting pressure of ready-to-wear compression stockings remained constant over a period of 6 weeks.

Jünger et al [10] also studied the loss of interface pressure of K-Two, Profore and Actico after 1, 3 and 7 days in healthy volunteers. All systems achieved a significant reduction of the volume of the lower leg after 7 days. At the end of the trial period there was no significant difference between the systems for the loss of supine pressure or the maximum working pressure. These findings are similar to what is presented in this chapter. Larsen et al [11] performed a study in which the sub-bandage pressure of among others short and long stretch bandages were measured. For the long stretch bandages, the pressure dropped 14% after 3 and 29% after 11 hours and 44 and 50% for the short stretch bandages. The pressure loss for the three tested stockings in this study: Sigvaris 503 Class II, 504 Class III and 222 Class II was 9-29%, 10-16% and 11-18% respectively. Where two hours of functional activities in this study had a significant drop for the systems with a high stiffness, the materials with lower stiffness like the long-stretch bandage and the Sigvaris 503 Class II stocking maintained the pressure over the entire test period.

Rollman et al [12] monitored the pressure over 8 hours of long and short stretch bandages, Profore and a ZipZoc/Co-Plus combination (a zinc paste impregnated stocking covered with an cohesive bandage) in healthy volunteers. The long-stretch bandage and Profore were superior in maintaining the pressure as compared to the short stretch and the Zipzoc/Coplus bandage (15-25% loss versus 30-40%). Veraart et al [13] investigated the pressure loss of short and long stretch bandages over a three-hour period in patients. It could be demonstrated that there was a rapid fall in pressure underneath the short stretch bandages, where the elastic bandages continued to give the same pressures. In this study 12 pressure sensors were positioned at different locations, including areas with a small radius where the risk of too much pressure is highest. The difference in pressure loss between the two systems was also shown in these areas. The authors conclude that the drop in pressure in the supine position for short stretch bandages ensures a continuation of arterial influx and the bandages can stay on during the night. Travers et al [14] measured the pressure drop of adhesive bandages (Panelast) in patients after varicose vein surgery. They found a fast drop after 24 and 48 hours after which the pressure stayed at the 48-hour level at 7 days. They also showed that these bandages were equally effective in healing compared to their traditionally used three-layer system.

The studies presented in this chapter confirm most of what is known from compression systems, they loose not only a certain amount of resting pressure but also the properties that determine the effectiveness are affected by wear. The problem with these studies is that the groups of patients or volunteers are different, the SSI's and amplitudes of the included subjects are mainly determined by the muscle forces inside the systems under investigation. This implies that a one to one comparison is difficult to perform (see also chapter 3.4: static stiffness index and chapter 3.5: amplitudes). The data presented in this chapter should therefore be interpreted with care in terms of making statements like ”product A is more effective than product B because it generates a higher stiffness or better amplitudes”. The objective of the presented studies were to find an indication of how well products perform over a certain period and to find a relation between slippage and sustainability.

The test that was performed on the cylinders revealed that material fatigueness causes loss of pressure. The observation that the pressure loss is higher in the volunteer studies than in the cylinder study, can be explained by the loss of leg volume during wear. The observation that the strain index hardly changed in the compression systems with an initial high strain index applied to the cylinders, can be explained by the fact that there is some fatigueness but the fibres in the compression systems remain under full stretch and cannot be further stretched by the inflation of the sensor underneath the fluid bag positioned on the cylinders. The reduction in stiffness and amplitudes that was observed in the volunteer studies in this chapter, can therefore be explained by the loss in leg volume, which leaves some space for extension of the applied bandaging systems. The result is that a certain amount of the forces that are caused by functional activities, are absorbed or get lost in the space that is created by the volume loss. Figure 11.17 shows the percent pressure changes for Coban 2 and Profore after 2, 24 and 48 hours. The graph was composed with the data from the studies presented in this chapter. It is clear to see that the pressure loss in the volunteer studies is much higher than the pressure loss on the cylinders. The pressure loss on the cylinders is solely caused by material fatigueness, which only partly explains the loss observed in the volunteer studies. Volume loss is the most likely explanation but also slippage can have a significant contribution.

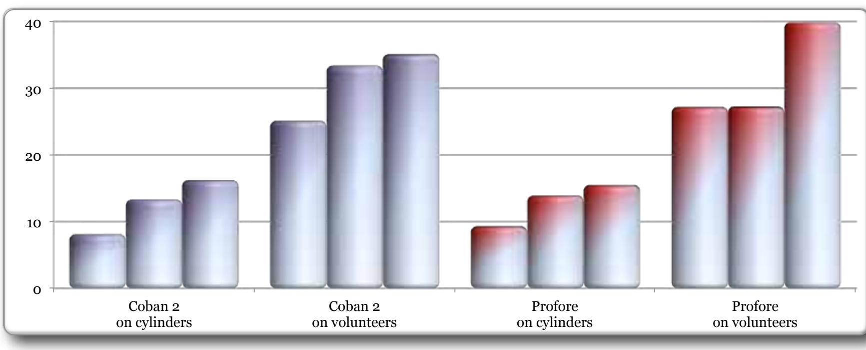


Figure 11.17: percent pressure changes of Coban 2 and Profore when used on cylinders and volunteers; the three bars represent data collected at 2, 24 and 48 hours after application.

It may be superfluous to state that the amount of slippage observed in healthy active volunteers will be much higher than in the average patient population requiring compression therapy. Differences in slippage observed in volunteer studies however do tell a story. Figure 11.18 shows both legs from a volunteer in a study on wear time performed during development. A better match of a control is not possible, if one leg walks, runs, bikes or performs another physical activity, the other does as well. Both legs were wrapped for two days, the leg on the right with Coban 2, the left picture shows the result of Profore, a significant difference.

Figure 11.18: slippage on the legs of a volunteer after two days: left Profore, right Coban 2.

The effects of that observation are more concerning. In figure 11.19, the same legs are shown immediately after removal of the systems. The leg on the left side shows the wrinkled skin, the effect of uneven compression presented as little walls of oedema, even observed in a young healthy volunteer with an undisturbed circulation. It represents an obvious sign of discomfort, which in return has an effect on functional activities.

Figure 11.19: the volunteer from figure 11.17 after bandage removal; the leg on the left reveals that a slipped bandage has been worn for a longer period.

This phenomenon was very frequently observed in the volunteer studies that were performed during the development of Coban 2 and Coban 2 Lite. An example is presented in figure 11.20, a picture taken immediately after removal of Profore worn for two days. It is obvious that these observations are caused by unevenly distributed pressure. In most cases, the volunteers described this result of uneven pressure as uncomfortable.

Figure 11.20: the leg of a young healthy volunteer immediately after removal of a Profore bandage worn for two days.

Also in the published literature or in daily practice, often signs of slippage can be identified. If pictures are presented of leg ulcers, often the same effects can be observed. Figure 11.21 shows two examples, both taken from 3M brochures. It is not mentioned in these brochures, but it is obvious that both patients just had their slipped compression bandages removed. The effects of the resulting uneven, uncomfortable compression are obvious.

Figure 11.21: two examples of the effects of slippage.

In a larger randomised cross-over trial comparing Profore and Coban 2, Moffatt et al [15] found a significant difference in slippage in favour of Coban 2 at days 3-7 ($p<0.001$) and hypothesised that it is possible that the decreased slippage observed with the two-layer system translated into improved comfort to the patient because the health-related quality of life assessments observed during the study period revealed that both compression systems showed improved scores, but the improvement was much greater for the Coban 2 than for Profore ($p<0.05$). The authors state that it is possible that differences in effectiveness between the two systems in promoting healing of venous leg ulcers do exist but that their study was not sufficiently powered or designed to detect this difference.

Based on the findings presented in this chapter, it can be hypothesised that bandages that stay in place longer, provide more consistent and uninterrupted compression therapy, e.g. effective compression, resulting in improved wound healing. Further research is required to support further conclusions. What can be concluded from the presented studies in this chapter, is that Marston and Vowdens description of the ideal compression therapy system as one that among some other features, provides and maintains clinically effective levels of compression for at least one week during walking and at rest (2) can be achieved with some of the investigated materials. Although not mentioned in the description, avoiding slippage is an essential part of fulfilling this crucial feature.

11.7. References

1. Schuren J, Andreas C.
   Pressure and slippage during 48 hours of compression therapy: a study on healthy volunteers.
   SAWC Abstract Book Spring 2010: S36.

2. Marston W, Vowden K.
   Compression therapy: a guide to safe practice.
   In: European Wound Management Association. Understanding compression therapy: position document 2003: 11-16.

3. Blair SD, Wright DD, Backhouse CM, Riddle E, McCollum CN.
   Sustained compression and healing of chronic venous ulcers.
   BMJ 1988; 297: 1159-1161.

4. Blair SD, Backhouse CM, Wright DDI, Riddle E, McCollum CN.
   What compression heals venous ulcers?
   Br J Surg 1987; 74: 529.

5. Blair SD, Backhouse CM, Wright DDI, Riddle E, McCollum CN.
   Do dressings influence the healing of chronic venous ulcers?
   Phlebology 1988; 3: 129-134.

6. Callam MJ, Haiart D, Farouk M, Brown D, Presscott RJ, Ruckley CV.
   Effect of time and posture on pressure profiles obtained by three different types of compression.
   Phlebology 1991; 6: 79-84.

7. Damstra RJ, Brouwer ER, Partsch H.
   Controlled, comparative study of relation between volume changes and interface pressure under short-stretch bandages in leg lymphedema patients.
   Dermatol Surg 2008; 34: 773-778.

8. Danielsen L, Madsen SM, Henriksen L, Sindrup J, Petersen LJ.
   Subbandage pressure measurements comparing a long-stretch with a short-stretch compression bandage.
   Acta Derm Venereol 1998; 78: 201-204.

9. 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.

10. Jünger M, Ladwig A, Bohbot S, Haase H.
Comparison of interface pressures of three compression bandaging systems used on healthy volunteers.
J Wound Care 2009; 18: 474-480.

11. Larsen A, Futtrup I.
Watch the pressure: it drops!
EWMA J 2004; 4(2): 8-12.

12. Rollman O, Frenning L.
Sub-bandage pressure profiles produced with elastic compression bandaging of the lower leg.
Proceedings of the 16th Conference of the European Wound Management Association, 2010, Prague. EWMA; 2010: 250.

13. Veraart JCJM, Neumann HAM.
Interface pressure measurements underneath elastic and non-elastic bandages.
Phlebology 1996; 1 (suppl): S2-S5.

14. Travers J, Dalziel K, Makin G.
Assessment of new one-layer adhesive bandaging method in maintaining prolonged limb compression and effects on venous ulcer healing.
Phlebology 1992; 7: 59-63.

15. Moffatt CJ, Edwards L, Collier M, Treadwell T, Miller M, Shafer L, Sibbald RG, Brassard A, McIntosh A, Reyzelman A, Price P, Kraus SM, Walters S-A, Harding K.
A randomised controlled 8-week crossover clinical evaluation of the 3M Coban 2 Layer Compression System versus Profore to evaluate the product performance in patients with venous leg ulcers.
Int Wound J 2008; 5: 267-279.

Chapter 12

Compression bandaging systems: ease of use and reproducibility

12.1. Introduction

Venous leg ulcers are a common clinical problem that increases in prevalence as the population ages. Venous insufficiency is the underlying condition responsible for the majority of leg ulcers [1]. They are typically a recurring condition [2] and compression therapy is considered the most effective treatment for such ulcers [3]. In addition, it is generally believed that compression is also beneficial to reduce the recurrence of this condition [4]. The cost of venous leg ulcers is high because of the ongoing care that they require [5-7]. At the beginning of the 21st century, there remain wide variations in the management of venous leg ulcers [3,4,8]. In the USA, Unna's boot (a non-compliant zinc paste bandage covered with a cohesive bandage) is favoured and multi-layer systems gain popularity. In the UK, multi-layer elastic compression is widely used. In most European countries and Australia, the inelastic, short-stretch bandage is standard practice. In Belgium and France, long-stretch bandages are mainly used. The original Charing Cross four-layer bandage system was developed to apply a pressure of 40 mmHg at the ankle, graduated to 17 mmHg at the knee [9]. Research has shown that this pressure sustained for at least a week [10]. Much of the literature seems to advocate this level of compression as the ideal pressure to heal venous leg ulcers and many practitioners take these values for granted [11,12]. Often a reference is made to the Laplace equation [13]. However, because the leg is neither cylindrical nor fluid, and bandage tension around the limb is unlikely to be constant, the Laplace equation must be interpreted with care [9,14,15]. Many studies have explored the sub-bandage pressures using a variety of measuring devices and a wide range of pressure values have been reported [16-29]. Recently recommendations were provided on measurements of lower leg compression in vivo [30]. The value of training and the use of pressure measurement devices has been reported by several authors [20,31-35].

To evaluate ease of use and reproducibility of Coban 2 when compared to established systems, a study was designed and executed [36]. In addition, data from two larger studies [24-25] are presented in this chapter, to have a better understanding of the challenge of applying consistent compression therapy.

12.2. Materials and methods

12.2.1. Study 1

32 experts in the application of various compression bandages for the treatment of venous leg ulcers were invited for participation in this study. An artificial leg was used for the pressure recordings. Three small Kikuhime pressure transducers were used to monitor and record the forces, expressed as pressure, under the applied bandages (figure 12.1). The pressure transducers were applied to the artificial leg, positioned on fixed gel cushions at the following areas:

- 5 cm above the lateral malleolus, leg circumference: 22 cm;
- in the middle of sensor 2 and 3, leg circumference: 27 cm;
- at the calf's widest circumference, leg circumference: 33 cm.

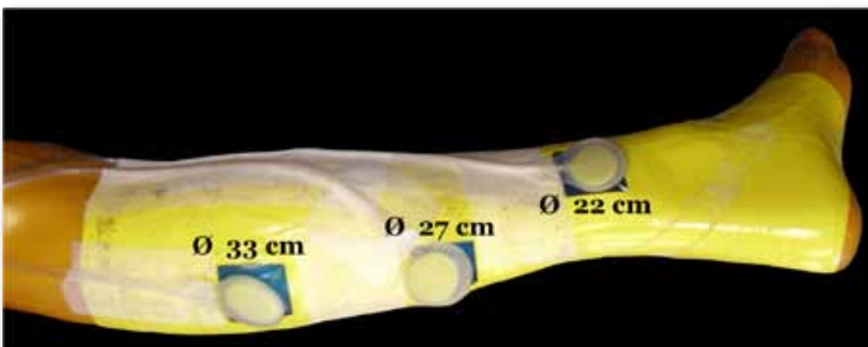


Figure 12.1: artificial leg with pressure transducers at three different circumference levels.

First, each panellist was asked to apply his/her most commonly used system three times to the sensored artificial leg. Next, the technique of applying Coban 2 was demonstrated and the panellist could apply the bandage a few times to a non-sensored leg, until he/she felt comfortable with the application. The panellist was then invited to apply the presented technique with Coban 2 three times to the sensored leg. Before each application, the pressure transducers were set at a force of zero mmHg. Pressure was recorded immediately after each application.

The pressure values of each application at the three sensors were compared to the two other applications (1 vs 2, 1 vs 3 and 2 vs 3). The differences were calculated as % change. For each comparison, reproducibility was calculated as the difference between the subsequent applications. In this way, 72 values were available for the analysis.

The reproducibility of the applications was evaluated by measuring the stretch that was produced during the application of the outer layer of each system. Before removal, two marks at a distance of 10 cm were made on the second last circular winding, using a paper ruler to allow the marking on the curved surface of the leg (see figure 12.3). Because Profore has written instructions to apply the 3rd and 4th layer at 50% stretch, this procedure was also performed with the third layer.

After the final removal of the bandages, the areas with the marks were separated and allowed to relax for at least 24 hours before the distance between the lines was measured (see figure 12.4). The distance values of each application were compared to the values of the two other applications (1 vs 2, 1 vs 3 and 2 vs 3). In this way, 24 values were available for the analysis.

Before and after the bandage applications, the panelist was interviewed on his/her most commonly used technique. The questions that were asked before the bandage applications were:
- How much pressure do you believe is provided by your current system?
- Why do you believe this pressure is provided by this system?
- Do you measure the pressure?

The questions that were asked after the bandage applications:
- How easy was it to reach and reproduce the desired pressure with your current system?
- How easy was it to reach and reproduce the desired pressure with Coban 2?

Four bandage systems for venous leg ulcers were tested in a direct comparison to Coban 2:
- Profore, applied by eight experts from Birmingham and Lincolnshire (UK);
- Actico, applied by eight experts from Birmingham and Lincolnshire (UK);
- Unna's boot compression system, an inelastic Medicopaste zinc paste bandage covered with a Coban bandage, applied by eight experts from Minnesota (USA);
- Rosidal K, applied by four experts from Germany and four from the Netherlands.

12.2.2. Study 2

For this investigation, the same artificial leg was used as in investigation 1, but for this investigation equipped with pressure transducers in such a way that resting and working pressures could be recorded at three levels with different circumferences. Three PicoPress pressure transducers were applied positioned on three glycol-filled cushions located 5 cm above the lateral malleolus, at the calf's widest circumference and in the middle of sensor 2 and 3 (figure 12.1).

Pressure was recorded immediately after the application. Underneath the glycol-filled bags, Kikuhime sensors were positioned. These pressure transducers were inflated to 100 mmHg, to imitate muscle activity. The pressure was recorded immediately after inflation. The difference between the two recorded pressures is defined as strain index (see chapter 3.6).

Ten experienced wound care nurses from the Netherlands were invited to apply three times the compression system, which routinely is applied for a patient with an ABPI of 0.6, to the artificial leg. Next, they were introduced to Coban 2 Lite, a system developed to be applied at full stretch and to provide reduced sub-bandage resting pressures. This system was also applied three times. The pressure values of each application at the three sensors were compared to the two other applications (1 vs 2, 1 vs 3 and 2 vs 3). For each comparison, reproducibility was calculated as the % difference between the subsequent applications. In this way, 90 values were available in each group for the analysis of both pressure and stiffness. The differences between the applications of the individual nurses were evaluated, comparing the %-difference of each individual subsequent application to that of the other nine nurses. In this way, 405 values were available in each group. For the evaluation of resting pressure and strain index, 90 values were available in each group for evaluation.

The statistical software Minitab Release 15.1 was used to analyse the data (paired T-tests) and to create the box- and interval plots.

12.2.3. Study 3

Five nurses from the UK, Germany and the Netherlands, all experts in the application of various compression bandages for the treatment of venous leg ulcers were invited for participation in a two-day observational study on pressure and slippage (see chapter 11.3). Both legs of 60 healthy volunteers were wrapped with different compression bandages. The following systems were tested: Actico, K-Two, Profore, Profore Lite, Proguide, Rosidal K, Rosidal Sys, Dauerbinde F, Coban 2 and Coban 2 Lite. Each system was applied 12 times. Each of the invited panellists applied two systems that routinely are used in their daily practice. The study was approved by 3M's Institutional Review Board and the Freiburger Ethical Committee in Germany.

The reproducibility of the applications was evaluated by measuring the stretch that was produced during the application of the outer layer of each system. Immediately after the application, two marks at a distance of 10 cm were made on the second last circular winding and on the layer located 10 cm above the ankle joint, using a paper ruler to allow the marking on the curved surface of the leg (figure 12.2).

After the final removal of the bandages, the areas with the marks were separated and allowed to relax for at least 24 hours before the distance between the lines was measured (figure 12.3). The standard errors to the mean of the resulting 24 values allow a comparison.

Figure 12.2: a paper ruler was used to mark two lines at 10 cm distance at two levels on each bandage.

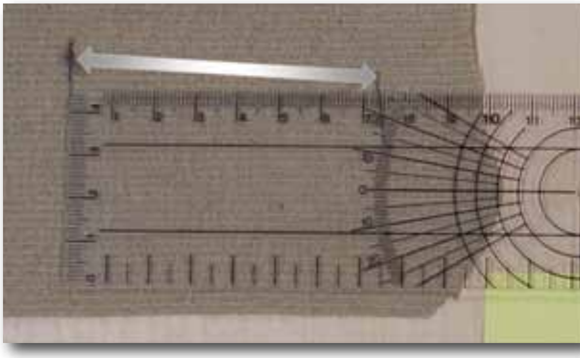


Figure 12.3: after relaxation of the removed bandage (24 hours); the distance between the marks is measured, in this case 7.4 cm.

To guarantee that all measurements could be taken, the volunteers were instructed to bring eventually removed bandages because of discomfort, to the next appointment.

12.3 Results study 1

12.3.1 Pre-application questionnaire

The invited experts applied their routinely used system on an average of 6.7 per week (short stretch: 11, Profore: 9.8, Actico: 2.9, Unna's boot: 3). Most of them (59.4%) believed that their system gave a graduated pressure with a value of around 40 mm Hg at the ankle joint. The most given reason (34.4%) for the belief in the 40 mm pressure was "manufacturer's information". Only one of the invited experts has used a pressure measurement device (Kikuhime) in practice.

12.3.2. Reproducibility of provided pressures

12.3.2.1. Profore users

The mean difference in pressure between applications was 2.25 mmHg (sd 0.19) for Coban 2 and 5.92 mmHg (sd 0.53) for Profore. The observed reproducibility of pressure for the Coban 2 applications was significantly better when compared to the Profore applications (paired t-test: $t= 6.31$; $p<0.001$).

12.3.2.2. Actico users

The mean difference in pressure between applications was 1.86 mmHg (sd 0.16) for Coban 2 and 4.25 mmHg (sd 0.53) for Actico. The observed reproducibility of pressure for the Coban 2 applications was significantly better when compared to the Actico applications (paired t-test: $t=4.22$; $p<0.001$).

12.3.2.3. Short-stretch users

The mean difference in pressure between applications was 4.14 mmHg (sd 0.45) for Coban 2 and 7.53 mmHg (sd 0.68) for the short stretch bandages. The observed reproducibility of pressure for the Coban 2 applications was significantly better when compared to the short stretch applications (paired t-test: t=4.03; p<0.001). It must be mentioned that the used techniques for the application of the short stretch bandages varied widely between the appliers as well as between the two countries.

12.3.2.4. Unna's boot users

The mean difference in pressure between applications was 4.61 mmHg (sd 0.47) for Coban 2 and 3.17 mmHg (sd 0.34) for Unna's boot. The observed reproducibility of pressure for the Unna boot applications was better when compared to the Coban 2 applications (paired t-test: t=1.47; p<0.147). It must be mentioned that the pressure values of the Unna's boot applications were very low and that differences in pressure expressed in percentage change between the three subsequent applications were very high.

The above data on provided pressure are presented in table 12.1. and figure 12.4.

	Mean	St Dev	SE Mean	Variance	Coef Var	Range
Profore	5.92	0.53	4.53	20.53	76.58	22
Coban 2 by Profore users	2.25	0.19	1.60	2.56	71.06	7
Actico	4.25	0.53	4.51	20.33	106.09	23
Coban 2 by Actico users	1.86	0.16	1.31	1.73	70.61	5
short stretch	7.53	0.68	5.76	33.21	76.55	28
Coban 2 by short stretch users	4.14	0.45	3.83	14.63	92.41	16
Unna boot	3.17	0.34	2.92	8.54	92.26	14
Coban 2 by Unna boot users	4.61	0.47	4.02	16.19	87.25	16

Table 12.1: descriptive statistics of the differences in applied pressure.

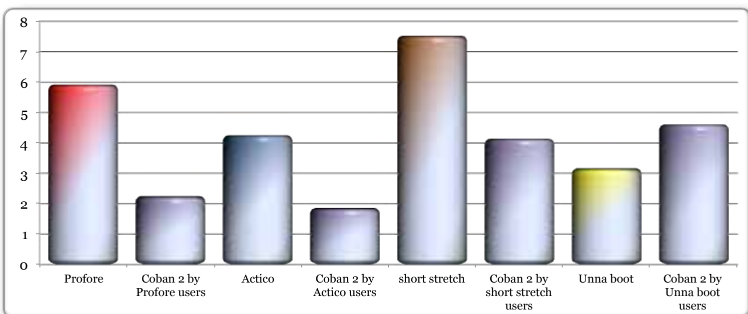


Figure 12.4: mean values of the differences in mmHg in applied pressure.

12.3.3. Reproducibility of stretch for application

12.3.3.1. Profore users

For Profore applications, the third and fourth layer contribute most to the final compression level of the system. An analysis was therefore made of the two outer layers. For the third layer, the mean difference was 5.00 mm (sd 0.74), for the outer layer 16.87 mm (sd 1.02). For Coban 2 the difference was 1.71 mm (sd 0.35). The observed difference in applied stretch for the Coban 2 applications was significantly better when compared to both layer 3 and layer 4 of the Profore applications (paired t-test for layer 3: t= 3.83; p=0.001; for layer 4: t=4.94; p<0.001).

12.3.3.3. Actico users

The measurements on the Actico applications revealed a mean difference of 3.33 mm (sd 0.54). The Actico users were the most precise group in the applications of Coban 2 with a mean change of 0.75 mm (sd 0.15). The observed difference in applied stretch for the Coban 2 applications was significantly better when compared to the Actico applications (paired t-test: t= 4.63; p<0.001).

12.3.3.2. Short-stretch users

The measurements on the short stretch applications revealed a mean difference of 6.08 mm (sd 1.19). The observed differences for the Coban 2 applications gave a mean difference of 1.21 mm (sd 0.24). The observed difference in applied stretch for the Coban 2 applications was significantly better when compared to the short stretch applications (paired t-test: t= 3.69; p=0.001).

12.3.3.4. Unna's boot users

The measurements on the Unna boot applications revealed a mean difference of 3.46 mm (sd 0.58). The observed differences for the Coban 2 applications gave a mean difference of 2.92 mm (sd 0.46). There was no significant difference in applied stretch for the Coban 2 applications when compared to the Unna boot applications (paired t-test: t= 0.74; p=0.467).

The above results are presented in table 12.2 and figure 12.5.

	Mean	St Dev	SE Mean	Variance	Coef Var	Range
Profore layer 3	5.00	0.74	3.64	13.22	72.71	14
Profore layer 4	6.87	1.02	4.98	24.81	72.45	19
Coban 2: Profore users	1.71	0.35	1.71	2.91	99.88	5
Actico	3.33	0.54	2.65	7.01	79.45	9
Coban 2: Actico users	0.75	0.15	0.74	0.54	98.29	2
short stretch	6.08	1.19	5.81	33.73	95.47	21
Coban 2: short stretch users	1.21	0.24	1.18	1.39	97.55	4
Unna boot	3.46	0.58	2.83	8.00	81.78	9
Coban 2: Unna boot users	2.92	0.46	2.26	5.12	77.60	8

Table 12.2: descriptive statistics of the differences in applied pressure.

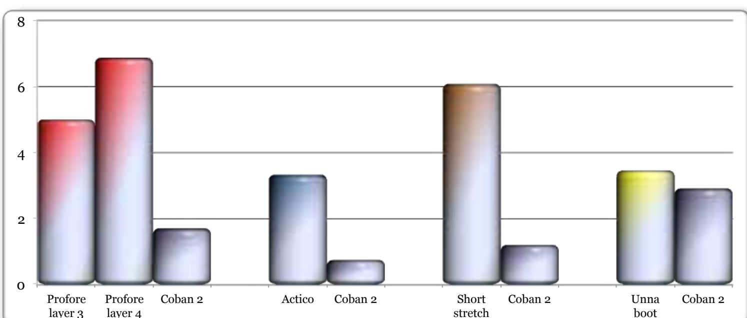


Figure 12.5: mean values of the differences in mm in applied stretch.

12.3.4. Post-application questionnaire

After the 6 applications, the invited panellists were asked how easy it was to reach and reproduce the desired pressure with their current system as well as with Coban 2. The answers were given on a scale from 1-5 (1: very difficult, 5: very easy. The mean of all combined answers was 2.63 (sd 1.34) for the currently used systems and a mean of 3.31 (sd 0.97) for Coban 2 (p=0.005). The results for the individual systems were:

- Profore users: 1.50 (sd 0.76) versus 3.37 (sd 0.92), p=<0.001;
- Short stretch users: 2.88 (sd 1.36) versus 3.75 (sd 0.71), p=0.02;
- Actico users: 2.50 (sd 0.76) versus 2.87 (sd 0.99), p=0.35;
- Unna's boot users: 3.38 (sd 1.68) versus 3.25 (sd 1.17), p=0.86.

12.4. Results study 2

Eight nurses applied short stretch bandages (Comprilan), of which seven were applied with some kind of padding around the malleoli, over the tibial crest, or both. Two nurses applied a 2 layer system (Coban 2). All these systems were applied with less than full stretch, which is typically done for patients with an ABPI below 0.8.

The reproducibility of sub-bandage pressures for each individual nurse was significantly better when Coban 2 Lite was compared to routinely used methods. The mean % change of applied pressure between the subsequent applications was 8.40% (sd 7.38 for the routinely used methods versus mean 3.46% (sd 2.60) for the Coban 2 Lite applications (paired t-test: n=90, t=5.96, p=<0.001).

The evaluation of the nurse-to-nurse differences revealed that there is a wide variation in provided pressure for all systems. However, the differences between all individual applications were significantly less with Coban 2 Lite (8.64%, sd 7.78) compared to the nurse-to-nurse differences of the routinely used systems (11.52%, sd 9.83). The paired t-test of the 405 data points in both arms revealed a t-value of 4.58, resulting in a p value <0.001. The data of the observed differences from the applications of each nurse individually as well as the nurse to nurse differences are graphically displayed in figure 12.6.

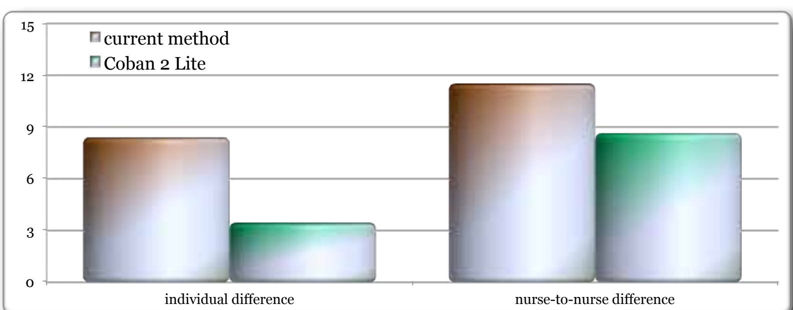


Figure 12.6: % change variations in applied pressure.

Finally, the evaluation revealed that the resting pressures of the routinely used systems (mean 68.57 mmHg, sd 18.70) were similar to those of Coban 2 Lite (mean 66.9 mmHg, sd 21.1), (paired t-test: t=1.30; p=0.195). The strain index of the Coban 2 Lite (18.86, sd 5.16) was significantly higher than the strain index of the currently used methods (16.84, sd 4.90), (paired t-test: t=4.78; p=<0.001). versus mean 18.9, sd 4.9; p<0.001). It should be mentioned that the measured resting pressures are higher than would be expected on a human leg because of the somewhat lifted positioning of the sensors on top of the glycol-filled bags, which was required for the most optimal data collection. The data are presented in figure 12.7.

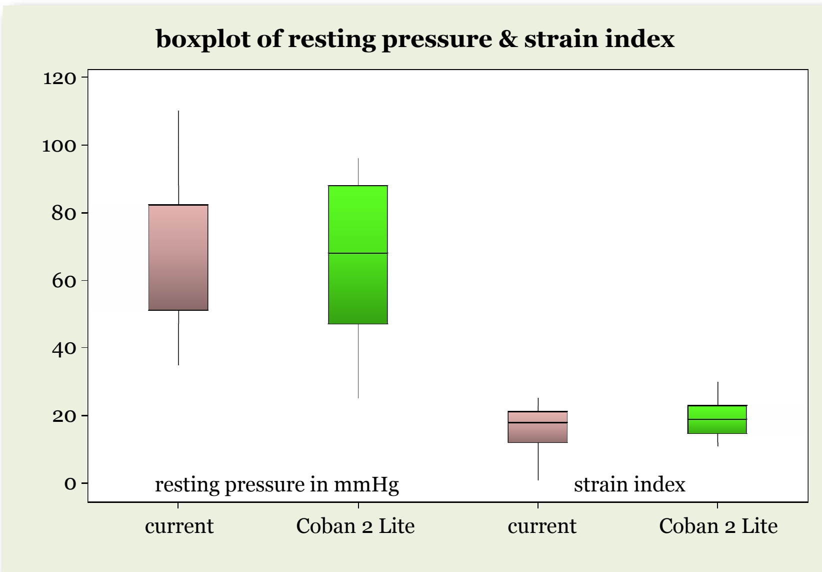


Figure 12.7: boxplot of applied pressures and strain indices.

12.4. Results study 3

The individual measurements of the distance between the marks after relaxation are displayed in the boxplot in figure 12.8. The relevant descriptive statistics of the reproducibility of stretch are presented in table 12.3. The coefficient of variation, which is graphically displayed in figure 12.9, is a measure of relative variability and equals the standard deviation divided by the mean. Table 12.4 allows a comparison of the significance levels of the reproducibility between the individual systems.

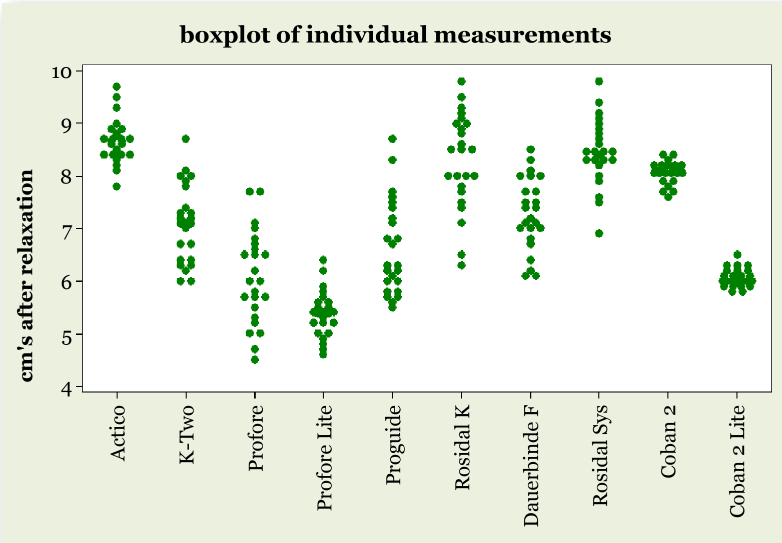


Figure 12.8: individual value plot of all application stretch measurements.

	Mean	St Dev	SE Mean	Variance	Coef Var	Range
Actico	8.66	0.42	0.09	0.18	4.90	1.9
K-Two	7.09	0.73	0.15	0.54	10.32	2.7
Profore	6.06	0.88	0.18	0.78	14.53	3.2
Profore Lite	5.38	0.44	0.09	0.19	8.15	1.8
Proguide	6.63	0.89	0.18	0.79	13.44	3.2
Rosidal K	8.29	0.91	0.19	0.83	10.97	3.5
Dauerbinde F	7.28	0.69	0.14	0.47	9.42	2.4
Rosidal Sys	8.46	0.63	0.13	0.40	7.44	2.9
Coban 2	8.06	0.21	0.04	0.04	2.56	0.8
Coban 2 Lite	6.07	0.17	0.04	0.03	2.86	0.7

Table 12.3: descriptive statistics of variation in reproducibility of application stretch.

	Actico	K-Two	Profore	Profore Lite	Pro-guide	Rosidal K	Dauer-binde F	Rosidal Sys	Coban 2	Coban 2 Lite
Actico		0.01	< 0.01	0.44	< 0.01	< 0.01	0.01	0.03	< 0.01	< 0.01
K-Two	0.01		0.19	0.01	0.18	0.15	0.38	0.24	< 0.01	< 0.01
Profore	< 0.01	0.19		< 0.01	0.48	0.44	0.12	0.06	< 0.01	< 0.01
Profore Lite	0.44	0.01	0.00		< 0.01	< 0.01	0.02	0.04	< 0.01	< 0.01
Proguide	< 0.01	0.18	0.48	< 0.01		0.46	0.11	0.05	< 0.01	< 0.01
Rosidal K	< 0.01	0.15	0.44	< 0.01	0.46		0.09	0.04	< 0.01	< 0.01
Dauerbinde F	0.01	0.38	0.12	0.02	0.11	0.09		0.34	< 0.01	< 0.01
Rosidal Sys	0.03	0.24	0.06	0.04	0.05	0.04	0.34		< 0.01	< 0.01
Coban 2	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01		0.20
Coban 2 Lite	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.20	

Table 12.4: significance table of variation in reproducibility of application stretch.

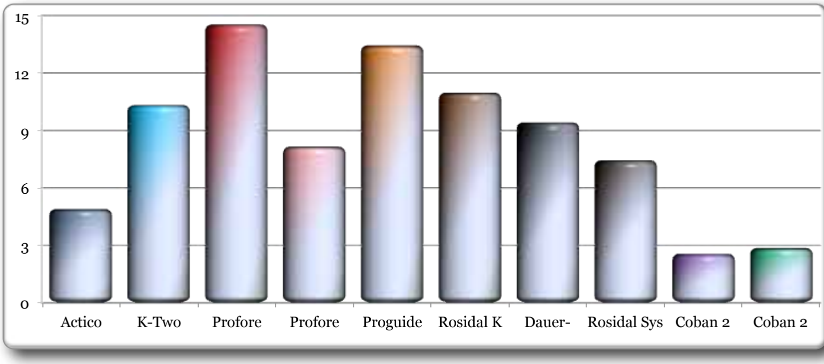


Figure 12.9: coefficient of variation for reproducibility of application stretch.

12.5. Discussion

Two of the studies presented in this chapter were performed on an artificial leg, where three sensors were positioned on gel cushions to imitate a positioning on soft tissues. An application to this leg is not influenced by confounding factors like patient movements, position and leg shape. Variations in pressure during subsequent applications on this artificial leg can therefore only be caused by variations in the interaction between bandager and bandage. These variations could not only be demonstrated by analysing the pressure recordings in both investigations, when in the first investigation the applied stretch during application was measured, the differences were obvious.

In the first study, four currently used compression systems were compared to Coban 2. None of the invited bandagers managed to achieve the same pressure levels in subsequent applications. In this investigation, the reproducibility of provided pressures with Coban 2 was significantly better compared to four currently used systems. In addition, this evaluation revealed that the technique of application of Coban 2 was easy and fast to learn. Based on these findings, it can be concluded that Coban 2 is easy to use and provides more consistent pressure values than four currently used compression systems.

In the second study, it was found that for experienced nurses, it is easier to reproduce sub-bandage resting pressures during subsequent applications with Coban 2 Lite, when compared to routinely used systems for patients with ABPI's <0.8. In addition, where the resting pressures are the same, the strain index, which indicates the effectiveness of applied compression, is higher for Coban 2 Lite.

In the third study on healthy volunteers, the reproducibility of resting and working pressures could not be studied, as the different leg shapes, muscle volume and strength of the volunteer would confound an eventual outcome. However, also in this study, it was obvious that the application of Coban 2 and Coban 2 Lite showed the lowest variability, in all cases significantly lower than the other systems under investigation.

The amount of stretch that an experienced nurse uses during an application should be more or less constant and can be measured by evaluating a predefined length after removal. Some of the systems in this study provide build-in tools to facilitate a perfect stretch profile throughout the application, like K-Two or Proguide. The evaluated applications however revealed that these tools do not guarantee reproducible pressure profiles. Other systems have instructions that one or more layers should be applied at a certain percentage of stretch, like Profore, Profore Lite and some long-stretch bandages. Blair et al [10] state that in a multilayer system the mistakes in tension in any one layer will tend to be averaged out. Among others, they analysed the variation in pressure achieved by different caregivers and in a sample of 20 patients, they found a mean pressure of 42.5 mmHg at the ankle joint with a standard error of 1, graduating to a value of 17.2 below the knee with a standard error 1.7. These results in addition to the observation that the achieved pressures were less depending on the bandager, led the authors to conclude that the used four layer bandage system seems to be unique in producing the necessary compression. This conclusion could not be supported by the data in this chapter, in which also a four-layer system (Profore) was analysed. The Profore applications in study 1 presented in this chapter, reveal a much higher standard error when compared to those presented by Blair et al [10] (4.53 versus 1). In addition, the differences and the evaluation of the reproducibility of stretch in study 1 and 3 showed that it was difficult for the invited experts to provide a reproducible stretch, which leads to a variation in sub-bandage pressure.

The systems that may or even should be applied at full stretch, like Rosidal, Rosidal K, Actico, Coban 2 and Coban 2 Lite, in potential should have the best reproducibility as a full stretch application leaves little space for error. It is interesting to see however that this is not a guarantee for that assumption. The traditional short stretch system that is most used in Europe, in this study represented by Rosidal K, shows a large variability in applied pressure and stretch values. Actico, Coban 2 and Coban 2 Lite, systems that have been recently introduced, consistently demonstrated to have the lowest variation. The effect of introduction training may have played a role in this observation [31-35].

12.6. References

1. Abbade LP, Lastoria S.
Venous ulcer: epidemiology, physiopathology, diagnosis and treatment.
Int J Dermatol. 2005; 44(6): 449-456.

2. Reeder SWI, Roos de K-P, De Maeseneer M, Sommer A, Neumann HAM.
Hospital admission for venous ulcers: what is it worth? (abstract).
Phlebology 2010; 25: 296-311.

3. Cullum N, Nelson EA, Fletcher AW, Sheldon TA.
Compression for venous leg ulcers.
Cochrane Database of Systematic Reviews 2001, Issue 2. Art. No.: CD000265.

4. Nelson EA, Bell-Syer SEM, Cullum NA.
Compression for preventing recurrence of venous ulcers.
Cochrane Database of Systematic Reviews 2000, Issue 4. Art. No.: CD002303.

5. Nicolaides AN.
Investigation of chronic venous insufficiency: a consensus statement.
Circulation 2000; 102: e126-e163.

6. Reichenberg J, Davis M.
Venous ulcers.
Semin Cutan Med Surg 2005; 24(4): 216-226.

7. Tennvall GR, Hjelmgren J.
Annual cost of treatment for venous ulcers in Sweden and the United Kingdom.
Wound Rep Reg 2005; 13: 13-18.

8. Sackheim K, De Araujo TS, Kirsner RS.
Compression modalities and dressings: their use in venous ulcers.
Dermatol Ther 2006; 19(6): 338-347.

9. Moffatt CJ, Dickson D.
The Charing Cross high compression four-layer bandage system.
J Wound Care 1993; 2(2): 91-94.

10. Blair SD, Wright DD, Backhouse CM, Riddle E, McCollum CN.
Sustained compression and healing of chronic venous ulcers.
BMJ. 1988; 297(6657): 1159-1161.

11. Eagle M.
Compression bandaging.
Nursing standard 1999; 13(20): 48-56.

12. Ukat A, Konig M, Vanscheidt W, Münter KC.
Short-stretch versus multilayer compression for venous leg ulcers: a comparison of healing rates.
J Wound Care 2003; 12(4): 139-142.

13. Thomas S.
The use of the Laplace equation in the calculation of sub-bandage pressure.
EWMA Journal 2003; 3(1): 21-23.

14. Schuren J, Mohr K.
The efficacy of Laplace's equation in calculating bandage pressure in venous leg ulcers.
Wounds UK 2008; 4: 38-47.

15. Williams RJ, Wertheim D, Melhuish J, Harding K.
How compression therapy works.
J Wound Care 1999; 8(6): 297-298.

16. Barbenel JC, Sockalingham S, Queen D.
In vivo and laboratory evaluation of elastic bandages.
Care Sci Pract 1990; 8(2): 72-74.

17. Dale JJ, Ruckley CV, Gibson B, Brown D, Lee AJ, Prescott RJ.
Multi-layer compression: comparison of four different four-layer bandage systems applied to the leg.
Eur J Vasc Endovasc Surg 2004; 27: 94-99.

18. Hafner J, Botonakis I, Burg G.
A comparison of multilayer bandage systems during rest, exercise and over 2 days of wear time.
Arch Dermatology 2000; 136: 857-863.

19. Lee AJ, Dale JJ, Ruckley CV, Gibson B, Prescott RJ, Brown D.
Compression therapy: effects of posture and application techniques on initial pressures delivered by bandages of different physical properties.
Eur J Vasc Endovasc Surg 2006; 31(5) :542-552.

20. Moore Z.
Compression bandaging: are practitioners achieving the ideal sub-bandage pressures?
J Wound Care 2002; 11(7): 265-268.

21. Mosti GB, Mattaliano V.
Simultaneous changes of leg circumference and interface pressure under different compression bandages.
Eur J Vasc Endovasc Surg 2007; 33(4): 476-482.

22. 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.

23. Rollman O, Frenning L.
Sub-bandage profiles produced with elastic compression bandaging of the lower leg.
Proceedings EWMA conference 2006, Prague; P108: 250.

24. Schuren J, Andreas C.
Pressure and slippage during 48 hours of compression therapy: a study on healthy volunteers.
SAWC Abstract Book Spring 2010: S36.

25. Schuren J, Vos A.
Reproducibility of sub-bandage resting and working pressures when reduced pressure is required.
Symposium proceedings EWMA congress: EWMA 2010: 193.

26. Sockalingham S, Barbenel JC, Queen D.
Ambulatory monitoring of the pressures beneath compression bandages.
Care Sci Pract 1990; 8(2): 75-79.

27. Stockport JC, Groarke L, Ellison DA, McCollum C.
Single-layer and multilayer bandaging in the treatment of venous leg ulcers.
J Wound Care 1997; 6(10): 485-488.

28. Taylor AD, Taylor RJ.
A comparison of sub-bandage pressures produced with two multi-layer bandaging systems.
J Wound Care 1999; 8(9): 444-448.

29. Wertheim D, Melhuish J, Williams R, Harding K.
Measurement of forces associated with compression therapy.
Med Biol Eng Comput 1999; 37(1): 31-34.

30. Partsch H, Clark M, Bassez S, Benigni JP, Becker F, Blazek V, Caprini J, Cornu-Thenard A, Hafner J, Flour M, Junger M, Moffatt C, Neumann M.
Measurement of lower leg compression in vivo: recommendations for the performance of measurements of interface pressure and stiffness: consensus statement.
Dermatol Surg 2006; 32(2): 224-232.

31. Hafner J, Lüthi W, Hänssle H, Kammerlander G, Burg G.
Instruction of compression therapy by means of interface pressure measurement.
Dermatol Surg 2000; 26(5): 481-486.

32. Keller A, Müller ML, Calow T, Kern IK, Schumann H.
Bandage pressure measurement and training: simple interventions to improve efficacy in compression bandaging.
Int Wound J 2009; 6: 324-330.

33. Melhuish JM, Clark M, Williams R, Harding KG.
The physics of sub-bandage pressure measurement.
J Wound Care 2000; 9(7): 308-310.

34. Nelson EA, Ruckley CV, Barbenel JC.
Improvements in bandaging technique following training.
J Wound Care 1995: 4(4): 181-184.

35. Reynolds S.
The impact of a bandage training programme.
J Wound Care 1999; 8(2): 55-60.

36. Collier M, Schuren J.
Ease of use and reproducibility of five compression systems.
J Wound Care 2007; 16 (3M supplement): 8-10.

Chapter 13

Abbreviations, materials, devices & software

In this chapter an alphabetical list is provided with the used abbreviations in this thesis. In addition, an alphabetical overview is provided on the included compression bandages and systems, the additional used materials, the used devices and software programmes, with their trade names and manufacturers.

13.1. Abbreviations

- ABI: ankle brachial index
- ABPI: ankle brachial pressure index
- ABVS: ambulatory blood volume scintimetry
- ANOVA: analysis of variance
- APG: air plethysmography
- ASGP: ambulatory strain gauge plethysmography
- CCB: combicast fracture brace
- CEAP: Clinical severity, Etiology or cause, Anatomy and Pathophysiology; a classification system for the severity of venous disease
- CEN: Comité Européen de Normalisation (European Committee for Standardisation)
- CPD: calf pump dysfunction
- CVI: chronic venous insufficiency
- EF: ejection fraction
- EV: ejected volume
- EWGSOP: European Working Group on Sarcopenia in Older People
- EWMA: European Wound Management Association
- GLM: general linear model
- ICC: International Compression Club

- IPC: intermittent pneumatic compression
- IRB: Institutional Review Board
- IRR: initial recovery rate
- MLB: multi-layer bandaging
- MRI: magnetic resonance imaging
- OECD: Organisation for Economic Cooperation and Development
- OPM: Oxford pressure monitor
- PAOD: peripheral arterial occlusive disease
- pW: working pressure
- pR: resting pressure
- RCN: Royal College of Nursing
- RoM: range of motion
- RT: recovery time
- SDD: systolic diastolic difference
- SIGN: Scottish Intercollegiate Guidelines Network
- SSI: static stiffness index
- SPI: sustained pneumatic compression
- TEWL: trans epidermal water loss
- TFB: thermoplastic fracture brace
- VFI: venous filling index
- VV: venous volume
- WPA: walking pressure amplitude
- WUWHS: World Union of Wound Healing Societies

13.2. Compression bandages and systems

- 3M™ Coban™ 2 Layer Compression System
  3M™ HealthCare, St. Paul, MN, USA

- 3M™ Coban™ 2 Layer Lite Compression System
  3M™ HealthCare, St. Paul, MN, USA

- 3M™ Coban™ Self-Adherent Wrap
  long stretch cohesive bandage
  3M™ HealthCare, St. Paul, MN, USA

- Actico®
  short stretch cohesive compression bandaging system
  Activa® Healthcare Limited, Staffordshire, United Kingdom

- Biflex™
  long-stretch compression bandage
  Thuasne SA, Levallois Perret, France
- Co-Plus™
  long stretch cohesive bandage
  Smith & Nephew Medical Limited, Hull, United Kingdom

- Dauerbinde®
  long stretch cotton bandage
  Lohmann & Rauscher International GmbH & Co KG, Rengsdorf, Germany

- Gelocast®
  inelastic zinc paste bandage
  BSN-JOBST GmbH, Emmerich am Rhein, Germany

- K-Two™
  two layer compression system
  Laboratoires URGO, Chenôve Cedex, France

- Medicopaste™
  inelastic zinc paste bandage
  Graham-Field Health Products Inc, Atlanta GA, USA

- Mollelast®
  elastic conforming bandage
  Lohmann & Rauscher International GmbH & Co KG, Rengsdorf, Germany

- Panelast®
  lengthwise and widthwise elastic adhesive bandage
  Lohmann & Rauscher International GmbH & Co KG, Rengsdorf, Germany

- Perfekta®
  long-stretch compression bandage
  Lohmann & Rauscher International GmbH & Co KG, Rengsdorf, Germany

- Profore™
  four-layer compression bandage system
  Smith & Nephew Medical Limited, Hull, United Kingdom

- Profore™ Lite
  three-layer compression bandage system
  Smith & Nephew Medical Limited, Hull, United Kingdom

- Proguide™
  two-layer compression bandage system
  Smith & Nephew Medical Limited, Hull, United Kingdom

- Rosidal® K
  short stretch cotton bandage
  Lohmann & Rauscher International GmbH & Co KG, Rengsdorf, Germany
- Rosidal® sys
  short stretch compression system
  Lohmann & Rauscher International GmbH & Co KG, Rengsdorf, Germany

- Sigvaris™ 503CII
  class 2 compression stocking
  Sigvaris™ AG, St.Gallen, Switzerland

- Venotrain®
  compression stocking
  Bauerfeind® AG, Zeulenroda-Triebes, Germany

- ZipZoc™
  zinc oxide impregnated medicated stocking
  Smith & Nephew Medical Ltd, Hull, United Kingdom

13.3. Medical devices miscellaneous

- 3M™ Double-Coated Tape
  3M™ HealthCare, St. Paul, MN, USA

- 3M™ Microfoam™ Medical Tape
  elastic foam tape
  3M™ HealthCare, St. Paul, MN, USA

- 3M™ Scotchcast™ Longuette
  splint made of 3 layers of 3M™ Scotchcast™ Plus Casting Tape
  3M™ HealthCare, St. Paul, MN, USA

- 3M™ Scotchcast™ Plus Casting Tape
  poly-urethane coated glass fibre casting tape
  3M™ HealthCare, St. Paul, MN, USA

- 3M™ Scotchcast™ Soft Cast Casting Tape
  poly-urethane coated glass fibre semi-rigid casting tape
  3M™ HealthCare, St. Paul, MN, USA

- 3M™ Synthetic Cast Padding
  non-woven polyester padding
  3M™ HealthCare, St. Paul, MN, USA

- 3M™ Synthetic Cast Stockinette
  tubular bandage
  3M™ HealthCare, St. Paul, MN, USA

- 3M™ Tegaderm™ Foam Dressing (nonadhesive)
  absorbent, breathable polyurethane foam wound dressing
  3M™ HealthCare, St. Paul, MN, USA

- 3M™ Transpore™ White Medical Tape
  hypoallergenic medical tape with bi-directional tear
  3M™ HealthCare, St. Paul, MN, USA

- AquaProtect®
  water protection for bandages
  Prämeta GmbH & Co. KG, Troisdorf, Germany

- Cellona® shoecast
  walking sole
  Lohmann & Rauscher International GmbH & Co KG, Rengsdorf, Germany

- Dynacast™ Extra
  poly-urethane coated glass fibre casting tape
  Smith and Nephew Medical, Hull, United Kingdom

- Fluid bags
  0.25 mm thick PVC-foil, sized 65 x 65 mm and filled with 11 grams of glycol
  Göckener GmbH, Ahaus, Germany

- Rosidal® tg®
  tubular bandage
  Lohmann & Rauscher International GmbH & Co KG, Rengsdorf, Germany

13.4. Test equipment

- Angioflow2®
  strain gauge plethysmography
  Microlab Elettronica SAS, Ponte S. Nicolò, Italy

- Cybex 6000
  Lumex Inc., Ronkokoma, NY, USA

- Digital scale
  Sartorius AG, Göttingen, Germany

- Ergopower
  Ergotest Technology A.S. Norway

- Gaeltec®
  pressure monitor
  Gaeltec Devices Ltd, Dunvegan, Isle of Skye, Scotland

- Kikuhime®
  pressure monitor
  TT MediTrade, Sorø, Denmark

- Magnetom Impact 1.0T
  Siemens AG, Erlangen, Germany

- Oxford Pressure Monitor
  Talley Medical Ltd, UK

- PicoPress®
  pressure monitor
  Microlab Elettronica SAS, Ponte S. Nicolò, Italy

- Poly-oxymethylene test cylinders
  Hauck GmbH, Düsseldorf, Germany

- Roll winder
  MEM Maschinenbau GmbH, Ahaus, Germany

- Tensile tester
  Zwick GmbH & Co KG, Ulm, Germany

13.5. Software programmes

- Microsoft® Excel®
  Microsoft® Corporation, Redmond, WA, USA

- Minitab® 15.1
  statistical software
  Minitab® Inc, State College PA, USA

Chapter 14

Summary

In **Chapter 1**, a general introduction is presented on this thesis. It provides some historical aspects and opinions on venous leg ulceration and compression therapy in the last centuries. It also explains how my orthopaedic education has supported the development of a novel compression system; a system of which not only the ease of application is improved, but also includes improved material properties, focusing on effectiveness and patient comfort.

Chapter 2 summarises the 3M monograph I co-authored in 2010, which provides some aspects of compression therapy. The products Coban 2 and Coban 2 Lite are introduced, as well as their application techniques.

The sub-bandage dynamics and different ways to describe the physical properties of compression systems are presented in **Chapter 3**. The shortcomings of established methods like static stiffness index and amplitudes generated by different functional activities, are discussed. A newly developed method is presented, which makes it possible to provide controlled and repeatable comparative information on different compression systems and eventual modifications. The validated test method not only gives a resting pressure but also a strain index, which provides valuable information on the physical properties of compression bandages and systems. In addition, the method allows measurements over longer periods to provide isolated information on the material fatigueness of compression systems.

In **Chapter 4**, the importance of function for venous return in the lower leg is discussed as well as the effects of a lack of functional activities, especially because the patient population that requires compression therapy is very vulnerable for developing detrimental effects as a result of a period if immobility. Functional activities and muscular contractions are of crucial importance for promoting venous return to the heart. The calf muscles are the main contributor of an effective muscle pump in the leg. Because of the strong relation between the range of motion of the ankle joint and calf muscle function, an overview of the literature on the function of the ankle joint in venous ulceration patients is provided. In this chapter,

research is presented on the effects of five weeks of voluntary ankle joint immobility in healthy volunteers is presented. The results reveal that wearing a below-knee walking cast, had only a minimal effect on ankle function, which was back to normal in 1-2 weeks. This leads to the assumption that the effects observed in patients are the result of non weight bearing or functional limitations due to other immobilising factors like pain, fear or lack of stability, and not on the below-knee walking cast itself. It can be hypothesised that, if the effects of wearing a cast have only a minimal effect, the effects of wearing a compression bandaging system will be at least similar, provided that the used system allows normal functional activities. It is concluded that the importance of maintaining normal function should not be underestimated when a compression system is applied. Bandaging alone will not heal ulcers; ambulation does, provided the patient can walk in comfort.

Chapter 5 deals with Laplace's law and more specifically how this physical law can be used to calculate the pressure generated by compression therapy. Data from three studies demonstrate that the theoretical pressure values calculated by the modified Laplace's law equation do not accurately predict the values found when experts applied compression bandages. In addition, it is observed that none of the compression systems tested in these three studies provides dependable graduated compression. It is concluded that the widespread belief that correctly applied compression systems provide pressure values graduating from 40 mmHg at the ankle to 17 mmHg below the knee, is based solely on theoretical mathematical equations.

Another way to explain the dynamics of effective compression therapy is by Pascal's Law, which is presented in **Chapter 6**. A study on tibia fracture support in anatomic below-the-knee specimens is presented to demonstrate that the physical properties of soft tissues are fluid-like and therefore act as incompressible fluids. Data from experimental volunteer studies confirm that the dynamics of effective compression therapy are explained by Pascal's Law, which states that if pressure is applied (functional activity) on a fluid (soft tissues, a muscle or muscle group) in a closed container (fascia muscularis, a fracture brace or a compression bandage), there is an equal increase at every other point in the container.

For many reasons, compression therapy for chronic venous ulceration can be compared to cast treatment for fractures. Maintaining or improving circulation as well as functional activities are common objectives. Historically and similar to the application of plaster-of-Paris, the use of padding materials has not been common practice for compression therapy. In **Chapter 7**, research is presented to study the effects of padding. First a study is presented, in which healthy volunteers wearing different types of casts with different amounts of padding were studied. This study revealed that padding materials have a significant effect on the stabilising effects of the casts, as well as on the support of venous return by the muscular pump. Next two studies are presented on specially designed, irregularly shaped artificial legs to study the effects of padding materials; one leg has a so-called inverted champagne bottle shape, the other a skin fold around the ankle joint as is often seen in lymphoedema patients. These studies reveal that a variety of padding methods show different sub-bandage pressure profiles. Based on these findings, it is concluded that padding materials have an effect on an even distribution of sub-bandage pressures, especially if they are used to ”flatten” or ”fill” irregularly shaped legs. Finally, data are presented that were collected on cylinders to study the effects of adding additional layers of padding materials. In this study, it is demonstrated that every additional layer of padding not only reduces the sub-bandage pressure but also the strain index, which indicates the effectiveness of an applied compression system.

In **Chapter 8**, a study is presented that was performed on patients with chronic venous insufficiency. The study was designed to investigate the effects of a difference in resting pressures with equal additional characteristics like the static stiffness index and amplitudes during functional activities. Ambulatory strain gauge plethysmography (ASGP) is suited for the assessment of compression therapy as it provides information on the function of the calf muscle pump and the venous system under different conditions. In the presented study, ASGP was used to evaluate the baseline situation as well as the haemodynamic effects of Coban 2 and Coban 2 Lite. It could be concluded that both product established a significant improvement in the initial ejection fraction and that there is no difference in effectiveness between the two products. This observation may lead to the conclusion that it is not only the resting pressure that is important to determine the effectiveness of compression therapy but more the possibility of applying a compression system at full stretch to create a non-stretchable sleeve with an anatomical fit around the limb.

In **Chapter 9**, a volunteer study is presented, in which leg volume changes were investigated. The results clearly demonstrate that a significant volume reduction can be achieved with compression therapy, even in healthy volunteers. The significant relation between the time of the day that the compression system is applied and the amount of volume reduction, implies that in clinical situations compression therapy will be more effective in reducing oedema when it is applied early in the morning when the exposure to gravity has been the lowest or, immediately after a prolonged period of leg elevation. In addition, the data reveal that compression therapy applied immediately following a period of compression, shows a significantly lower loss of volume with a resulting lower pressure drop. This implies that the application of bandaging systems is most effective when subsequent applications immediately follow each other. The most important finding from this volumetry study is that no relation could be identified between volume reduction and the application of Coban 2 or Coban 2 Lite. As both systems have significantly different resting pressures, it can be concluded that it is not the resting pressure that determines the effectiveness of an applied compression system but the stiffness index and amplitudes, e.g. the possibility to keep the effects of function inside the compression bandage.

Coban 2 Lite was initially developed for the treatment of patients with venous leg ulcers also suffering a peripheral arterial occlusive disease with ABPI's between 0.5 and 0.8. In **Chapter 10**, two studies are presented. The first is a short summary of a study performed on patients suffering from a peripheral arterial occlusive disease with ABPI's between 0.5-0.8. It can be concluded that Coban 2 Lite was safe in use for patients with reduced arterial perfusion. The results of the measurements indicate significant improvements of dermal microcirculation under Coban 2 Lite. The second study in this chapter was designed to get a better understanding of the safety and tolerability of compression bandages applied to venous leg ulcer patients with low ABPI's as well as some physical properties of the applied bandages. Eight experienced wound care nurses in Canada and the Netherlands were asked to measure sub-bandage pressures in the supine and standing position for each applied compression system to all patients with ABPI's between 0.5 and 0.8 in treatment.

The most important finding of this observational study is that a wide range of sub-bandage pressure values (between 6 and 40 mmHg) has been safely applied. These pressure values were well tolerated and the applied compression systems stayed in place for up to 7 days. The results also revealed that, with the compression bandaging materials that were used in this study, there is a significant correlation between the observed resting pressure and the static stiffness indices.

Chapter 11 focuses on the effects of functional activities on slippage and sustainability. Three studies are presented; the first two are performed on healthy volunteers looking at the effects of two-hour controlled functional activities and two-day wear time. Integrated in the second study was a 7-day wear study on Coban 2 Lite. As material fatigueness is often mentioned when the sustainability of provided pressures is discussed, an experimental study was performed to study the effects on pressure and strain index of material fatigueness over a one-week period. The volunteer studies confirm most of what is known from compression systems, they do not only loose a certain amount of resting pressure, but also the properties that determine the effectiveness, are affected by wear. Most of the compression systems under investigation gave serious slippage. The amount of slippage observed in healthy active volunteers will be much higher than in the average patient population requiring compression therapy, but the observation is important. Also in patients slippage is often observed, which leads to discomfort and therefore reduced activity. In the two volunteer studies in this chapter, a significant pressure loss is observed. This can be explained by a loss of leg volume, material fatigueness or a combination of both. Therefore, a study was performed on cylinders to investigate the isolated effects of material fatigueness on pressure and strain index. The results reveal that the pressure loss is much lower on the cylinders than on the volunteers. Volume loss is the most likely explanation for this difference, but also slippage can have a significant contribution. Based on the findings presented in this chapter, it can be hypothesised that bandages that stay in place longer provide more consistent and uninterrupted compression therapy, e.g. effective compression, resulting in improved wound healing.

In **Chapter 12**, on overview is provided on the research that was performed to evaluate the ease of use and reproducibility of the Coban 2 compression systems when compared to established methods. Three studies are presented; two of them were performed on an artificial leg, where three sensors were positioned on gel cushions to imitate a positioning on soft tissues. An application to this leg is not influenced by confounding factors like patient movements, position and leg shape. Variations in pressure during subsequent applications on this artificial leg can therefore only be caused by variations in the interaction between bandager and bandage. The third study was performed on healthy volunteers. In all three studies, nurses were invited to apply the compression systems they routinely use in their clinical practice. It could be demonstrated that the application of Coban 2 and / or Coban 2 Lite showed the lowest variability, in all cases significantly lower than the other systems under investigation.

In **Chapter 13**, an alphabetical overview is provided on the used abbreviations in this thesis. In addition an overview is provided on the mentioned compression bandages and systems, the additional materials, equipment and software programmes that are mentioned in this thesis, with their trade names and manufacturers.

Chapter 15

Samevatting

Hoofsjtök 1 ómvatj ’n algemein introductie euver dit proofsjrif. ’n Aantal historische aspecte van en meininge euver ’t chronische veneuze aope bein en cómpressietherapie inne lèste ieëwe waere gepresenteerdj. Daonaeve wurtj oetgelagdj wie mien orthopaedische sjoealing de óntwikkeling van ’n nuuj cómpressieverbandj haet óngersjteundj; ’n verbandj womit neet allein ’t aanlègke wurtj vergemekkeliktj, mer wovan ouch de materiaaleigesjappe verbaeterdj zeen, wobie veural gekeke is nao de effectiviteit en ’t comfort veur de patiënt.

Hoofsjtök 2 is ’n samevatting van ’n 3M monografie oet 2010 wo ich aan mitgesjreve höb en wo-in get aspecte van cómpressietherapie belichtj waere. De producte Coban 2 en Coban 2 Lite waere geïntroduceerdj es ouch de technieke van aanlègke.

De dynamiek van cómpressietherapie en versjillendje menere óm de fysische eigesjappe van cómpressiesysteme te besjrieve, waere in **Hoofsjtök 3** gepresenteerdj. De tekortkómminge van gevestigdje methodes, zoea wie de sjtatische sjtugheidsindex en amplitudes waere besjpraoke. ’n Nuuj óntwikkeldje testmethode wurtj veurgesjtèldj die ’t meugelik maaktj gecontroleerdje en reproduceerbare vergeliekendje informatie te verzamele euver versjillendje cómpressiesysteme en eventueel modificaties. De gevalideerdje testmethode guftj neet allein ’ne rösdrök mer ouch ’ne sjpanningsindex dae waerdevol informatie guftj euver de fysieke eigesjappe van cómpressieverbenj en -systeme. Daonaeve kinne mit de methode maetinge verrichtj waere euver ’n langer tiedsbesjtek en zoea geïsoleerdje informatie versjaffe euver materiaalmeugigheid van cómpressiesysteme.

In **Hoofsjtök 4** wurtj ’t belang belichtj van functie veur de veneuze aafveur van oet ’t óngerbein, es ouch de effecte van ’t óntbraeke van functioneel activiteite. Veural de patiëntepopulatie die cómpressietherapie nuuëdig haet, is erg geveulig veur ’t óntwikkele van sjadelike effecte van ’n periode van immobiliteit. Functioneel activiteite en sjpiercontracties zeen van cruciaal belang veur de óngersjteuning van ’n effectieve sjpierpómp. Ómdet d’r ’n sjterke relatie besjtuit tösse de bewaegingsoetsjlaeg van ’t inkelgewrich en de kuutsjpierfunctie, wurtj ’n euverzich gegaeve vanne literatuur euver de inkelfunctie bie patiënte mit ’n chronisch veneus lieje. In dit hoofsjtök wurtj óngerzeuk gepresenteerdj nao de effecte van vief waeke vriewillige immobilisatie van ’t inkelgewrich bie gezónj vriewilligers. De resultate laote zeen det ’t drage van ’n óngerbeinloupgips mer minimaal gevolge haet op de inkelfunctie, die nao ein toet twieë waeke trök is op zien normaal waerdes. Dit lètj toet de aanname det de effecte die waere waorgenómme bie patiënte, veroorzaaktj waere door anger immobiliserendje factore wie pien, angs, of te weinig sjtabiliteit en neet door ’t óngerbeingips. ’t Kin daoróm verióngersjtèldj waere det, es de effecte bie ’n gipsverbandj sjlechs minimaal zeen, dees bie ’n cómpressieverbandj tenminste geliek zeen, d’r van oetgaondje det ’t gebroekdje systeem normaal functioneel activiteite toeluuëtj. ’t Kin geconcludeerdj waere det, es ’n cómpressieverbandj wurtj aangelagdj, ’t belang van ’t behaoje van functie neet óngersjatj moog waere. Cómpressie allein duit gèn aope bein genaeze, ’t is de ambulantie die ’t ’m duit, d’r van oetgaondje det de patiënt comfortabel ziene gank kin gaon.

Hoofsjtök 5 behanjeltj de wèt van Laplace en mieër sjpecifiek wie dees natuurkundige wèt gebroektj kin waere óm de drök te beraekene die door cómpressietherapie wurtj gegenereerdj. Resultate van drie sjtudies laote zeen det de theoretische waerd die beraekendj zeen mit de gemodificeerdje Laplace calculatie, gein accurate aafsjpegeling gaeve van de waerd zoea wie die waorgenómme waere bie ’t aanlègke van cómpressieverbenj door experts. Geconcludeerdj kin waere det ’t wiedverbrèdje geluif det tegooj aangelagdje cómpressieverbenj drökwaerd gaeve van 40 mmHg róndj ’t inkelgewrich, aafnummendj toet 17 mmHg ónger ’t kniegewrich, allein mer gebaseerdj is op theoretische beraekeninge.

’n Anger meneer óm de dynamiek van effectieve cómpressietherapie te verklaore, is de wèt van Pascal te besjouwe. Dit wurtj gedemonsjtreerdj in **Hoofsjtök 6**. D’r wurtj ’n sjtudie gepresenteerdj nao de óngersjteuning van tibiafracture in anatomische óngerbeinspreparate óm aan te tuuëne det de fysische eigesjappe van weike deile euvereinkómme mit die van vloeisjtoffe en es zoeadanig te kinmerke zeen. Resultate van sjtudies op vriewilligers bevestige det de dynamiek van effectieve cómpressietherapie verklaordj wurtj door de wèt van Pascal, die sjtèltj det es d’r drök wurtj oetgeoefendj (door ’n functioneel activiteit) op ’n vloeisjtóf (weike deile, ’n sjpier of ’ne sjpiergroep) in ’ne aafgesjlaote container (fascia muscularis, ’n fractuurbrace of ’n cómpressieverbandj), dizze drök zich geliekmaotig verdeildj euver idder puntj in dae container.

D’r zeen hieël get rejene te bedinke óm cómpressietherapie te vergelieke mit de behanjeling van fracture mit gipsverbenj. ’t Behaoje of verbaetere vanne circulatie es ouch de functioneel activiteite, zeen gemeinsjappelike doelsjtèllinge. Historisch gezeen wurtj, net wie bie de fractuurbehanjeling gèn gebroek gemaaktj van polstermateriale bie cómpressietherapie. In **Hoofsjtök 7** wurtj óngerzeuk gepresenteerdj nao de effecte van polstermateriaal. Allerieës ’n sjtudie wobie op gezónj vriewillgers versjillendje saorte gipsverbenj aangelagdj wórte mit op versjillendje menere aangelagdj polstermateriaal. De resultate laote zeen det polstermateriale neet allein ’n significant effec höbbe op ’t sjtabiliserendj vermoge van de gipsverbenj, mer ouch op de óngersjteuning van de veneus circulatie door de sjpierpómp. Verder ware twieë sjtudies gepresenteerdj die oetgeveurdj wórte op twieë sjpeciaal óntwórpe kunsbein óm de effecte van polstermateriaal te óngerzeuke. Ein bein haet ’n zoeagenumdje ómgedrejdje champagneflesvorm, ’t anger ’n velploeaj róndj ’t inkelgewrich, zoea wie det dök gezeen wurtj bie lymphoedeem. Dees sjtudies laote zeen deet versjillendje menere van polstere toet ’n versjeienheid aan drökprofiele leie en laote concludere det polstermateriale ’n effec höbbe op ’n geliekmaotige drökverdeiling ónger cómpressietherapie, veural es polstering gebroektj wurtj óm ónregelmaotig gevörmdje lichaamsdeile oet te vlakke of op te vulle. Tensjlotte waere resultate gepresenteerdj die verkrege zeen op cylinders óm de effecte van opeinvolgendje laoge polstering te besjtudere. Mit dit óngerzeuk wórt aangetuuëndj det idder opeinvolgendje laog polstering neet allein de drök ónger de bandage reduceertj, mer ouch de sjpanningsindex, dae ’n indicatie is veur de effectiviteit van ’n gebroektj cómpressiesysteem.

In **Hoofsjtök 8** wurtj ’n sjtudie gepresenteerdj die verrichtj is op patiënte mit ’n chronische veneuze insufficiëntie. De sjtudie is óntwikkeldj óm de effecte te óngerzeuke van verbenj mit ’n versjil in rösdrök mer mit geliekblievendje karakteristieke wie sjtatische sjtugheidsindex en amplitudes bie functioneel activiteite. Mit ambulante strain gauge plethysmografie (ASGP) kin ’t effec van cómpressietherapie óngerzóch waere ómdet informatie wurtj verkrege euver de functie vanne kuutsjpierpómp en ’t veneuze systeem ónger versjillendje condities. In de gepresenteerdje sjtudie wórt ASGP gebroektj óm de oetgangssituatie te bepaole es ouch de haemodynamische effecte van Coban 2 en Coban 2 Lite. De resultate laote zeen det allebei de producte ’n significante verbaetering gaeve en det d’r gèn versjil is in effectiviteit tösse de twieë producte. Dees vassjtèlling lètj toet de conclusie det ’t neet allein de rösdrök is dae belangriek is óm de effectiviteit van cómpressietherapie te bepaole mer det ’t mieër de meugelikheid is óm ’n cómpressiesysteem op volle rek aan te lègke en zoea ’ne neet rekbare kaoker mit ’n anatomische pasvorm.

In **Hoofsjtök 9** wurtj ’n sjtudie gepresenteerdj die wórt oetgeveurdj op gezónj vriewilligers, wobie volumeverangeringe wórte besjtudeerdj. De resultate laote dudelik zeen det zoeagaar bie gezónj proofpersone ’n significante reductie in volume kin waere bewèrksjtèlligdj mit cómpressietherapie. De significante relatie tösse de tied vanne daag det ’n cómpressieverbandj wurtj aangelagdj en de huuëgdje vanne volumereductie, beteikentj det cómpressieverbenj in de klinische praktijk veur waat betruftj volumereductie ’t meis effectief zeen es ze vreug inne mörge aangelagdj waere es de bloeatsjtèlling ane zjwaortekrach ’n minimaal effec haet gehadj, of drek nao ’n periode van hoeaghaoje van ’t bein. Daonaeve laote de resultate zeen det cómpressietherapie die aangelagdj wurtj drek volgendj op ’n periode van veuraafgaondje cómpressietherapie ’t meis effectief is es opeinvolgendje verbenj drek nao ein aangelagdj waere. De meis belangrieke vassjtèlling van dees volumetriesjtudie is det d’r gèn relatie aangetuuëndj kin waere tösse ’t gereduceerdje volume en de applicatie van Coban 2 of Coban 2 Lite. Aangezeen de twieë systeme significant versjillendje rösdrökke höbbe, moog geconcludeerdj waere det ’t neet de rösdrök is dae de effectiviteit van ’n cómpressiesysteem bepaoltj, mer de sjtugheidsindex en amplitudes, mit anger wäörd de meugelikheid óm de effecte van functie binne ’t cómprimerend verbandj te haoje.

Coban 2 Lite wórt oearsjprunkelik óntwikkeldj veur de behanjeling van patiënte mit ’n veneus aope bein die daonaeve ouch lieje aan ’n perifeer arterieel occlusie mit ’ne inkel-ermindex tösse de 0.5 en 0.8. In **Hoofsjtök 10** waere twieë sjtudies gepresenteerdj. De ieëste is ’n korte samevatting van ’n óngerzeuk bie patiënte mit ’n perifeer arterieel occlusie mit ’ne inkel-ermindex tösse de 0.5 en 0.8. De resultate laote zeen det Coban 2 Lite veilig in ’t gebroek woor bie dizze groep patiënte mit ’n verminderdje arterieel perfusie. De resultate vanne óngerzeuke lete verder ’n significante verbaetering zeen van de dermaal microcirculatie bie ’t gebroek van Coban 2 Lite. De twieëdje sjtudie in dit hoofsjtök wórt oetgeveurdj óm ’n baeter inzich te verkriege euver de veiligheid en tolerantie van cómpressieverbenj die in de dagelikse praktijk waere aangelagdj bie patiënte mit ’ne lieëge inkel-ermindex, es ouch euver get fysische eigesjappe van de aangelagdje systeme. Ach ervare wónjverpleegkundige oet Canada en Nederland wórt gevraogdj de drök in de ligkendje en sjtäöndje positie te maete ónger idder aangelagdj cómpressiesysteem bie alle patiënte mit ’ne inkel-ermindex tösse 0.5 en 0.8. De belangriekste vassjtèlling van dees observatiesjtudie is det d’r ’n groeate variatie in rösdrök wórt gemaete (tösse de 6 en 40 mmHg) en det dees drökke aangelagdj wórte zónger nummeswaerdige complicaties. Dees drökwaerdes wórte good getolereerdj en de verbenj bleve aangelagdj toet zeve daag toe. De resultate lete ouch zeen det, mit de cómpressiesysteme die in dees sjtudie gebroektj wórte, d'r 'n significante correlatie aangetuuëndj kós waere tösse de gemaete rösdrök en de sjtatische sjtugheidsindex.

Hoofsjtök 11 behanjeltj de effecte van functioneel activiteite op roetsje en behaod van drök. D'r waere drie sjtudies gepresenteerdj. De ieëste twieë wórte oetgeveurdj op gezónj proofpersone wobie gekeke is nao de effecte van respectievelik twieë oer gecontroleerdje activiteite en twieë daag draagtied. In de twieëdje sjudie wórt verder gekeke nao zeve daag draagtied van Coban 2 Lite. Ómdet materiaalmeugigheid dök genumdj wurtj es gesjpraoke wurtj euver behaod van drök, wórt 'n experimenteel sjtudie oetgeveurdj nao de effecte van materiaalmeugigheid op rösdrök en sjpanningsindex euver 'n periode van ein waek. De sjtudies op de proofpersone bevestige 't meiste waat bekindj is van cómpressieverbenj, ze verleze neet allein 'n bepaoldj gedeilte vanne rösdrök, mer ouch de eigesjappe die de effectiviteit bepaole, waere beïnvloedj door draagtied. De meiste cómpressieverbenj lete 'n ernstig roetsje zeen. De erns van roetsje die waorgenómme wurtj bie jóng gezónj vriewilligers, zal aanzeenlik grótter zeen es bie de doorsjnee patiëntepopulatie die cómpressietherapie veurgesjreve kriegtj, mer de observatie is belangriek. Ouch bie patiënte wurtj roetsje dök waorgenómme, waat toet óngemaak lètj en daomit toet gereduceerdje activiteit. In de twieë sjtudies op gezónj proofpersone in dit hoofsjtök wórt 'n significant drökverlees waorgenómme. Dit kin verklaordj waere door 'n reductie vanne beinómvang, materiaalmeugigjheid of 'n combinatie van die twieë. Daoróm wórt 'n sjtudie oetgeveurdj op cylinders óm de geïsoleerdje effecte van materiaalmeugigheid op rösdrök en sjpanningsindex te óngerzeuke. De resultate tuuëne aan det 't verlees aan rösdrök aanzeenlik lieëger ligktj op de cylinders, vergeleke mit 't verlees bie de proofpersone. Volumeverlees is de meis veur de handj ligkendje verklaoring veur dit versjil, mer ouch roetsje kin 'n significant biedrage levere. Gebaseerdj op de oetkómste van de sjtudies in dit hoofsjtök, zów gesjtèldj kinne waere det verbandjmateriale die langer blieve zitte zoea wie ze aangelagdj wórte, 'n mieër consistente en ónóngerbraoke cómpressie gaeve, mit anger wäörd 'n effectiever cómpressietherapie, waat weer resulteertj in 'n verbaeterdje wónjgenaezing.

In **Hoofsjtök 12** wurtj 'n euverzich gegaeve van de óngerzeuke nao 't gemaak van aanlègke en de reproduceerbaarheid van de Coban 2 cómpressiesysteme in vergelieking mit besjtäöndje methodes. Drie sjtudies waere gepresenteerdj; twieë daovan wórte oetgeveurdj op 'n kunsbein wo-op drie sensore op gelkösses wórte geplaatsj óm 'n positionering op weike deile te imitere. 't Aanlègke van 'n verbandj op dit bein wurtj neet beïnvloedj door sjtuuërendje factore wie bewaeginge vanne patiënt of de positie en vorm van 't bein. Variaties in drök bie opeinvolgendje applicaties kinne derhalve allein veroearzaaktj waere door variatie in de interactie tösse daegene dae 't verbandj aanlègktj en 't verbandj zelf. De derdje sjtudie wórt oetgeveurdj op gezónj proofpersone. In alle drie de sjtudies wórte verpleegkundige genuuëdj óm 't cómpressiesysteem aan te lègke det routinemaotig in häör praktijk gebroektj wurtj. D'r kós waere vasgesjtèldj det Coban 2 en Coban 2 Lite de geringste variatie gove, in alle gevalle woor dit significant lieëger es de anger systeme die óngerzóch zeen gewaore.

In **Hoofsjtök 13** wurtj 'n alfabetisch euverzich gegaeve vanne aafkortinge die in dit proofsjrif gebroektj zeen. Daenave waere 'n euverzich gegaeve vanne cómpressiebandages en -systeme, de verder producte, tesmateriale en softwareprogramma's die in dit proofsjrif genumdj waere, alles mit häöre hanjelsnaam en leverancier.

Chapter 16

Samenvatting

Hoofdstuk 1 omvat een algemene introductie over dit proefschrift. Er worden een aantal historische aspecten van en meningen over het chronische veneuze open been en compressietherapie gedurende de laatste eeuwen gepresenteerd. Daarnaast wordt uitgelegd hoe mijn orthopaedische scholing de ontwikkeling van een nieuw compressieverband heeft ondersteund; een verband waarmee niet alleen het aanleggen wordt vergemakkelijkt, maar waarvan ook de materiaaleigenschappen zijn verbeterd, waarbij vooral gekeken is naar de effectiviteit van de therapie en het comfort voor de patiënt.

Hoofdstuk 2 is een samenvatting van een 3M monografie uit 2010 waarvan ik co-auteur was en waarin enkele aspecten van compressietherapie belicht worden. De producten Coban 2 en Coban 2 Lite worden geïntroduceerd alsook de technieken van aanleggen.

De dynamiek van compressietherapie en verschillende manieren om de fysische eigenschappen van compressiesystemen te beschrijven, worden in **Hoofdstuk 3** gepresenteerd. De tekortkomingen van gevestigde methodes, zoals de statische stugheidsindex en amplituden worden besproken. Een nieuw ontwikkelde testmethode wordt voorgesteld die het mogelijk maakt gecontroleerde en reproduceerbare vergelijkende informatie te verzamelen over verschillende compressiesystemen en eventuele modificaties.

De gevalideerde testmethode geeft niet alleen een rustdruk maar ook een spanningsindex die waardevolle informatie verstrekt over de fysische eigenschappen van compressiebandages en -systemen. Daarnaast kunnen met de methode metingen verricht worden over een langer tijdsbestek en zo geïsoleerde informatie verschaffen over de materiaalmoeheid van compressiesystemen.

In **Hoofdstuk 4** wordt het belang belicht van functie voor de veneuze afvoer vanuit het onderbeen, alsmede de effecten van het ontbreken van functionele activiteiten. Vooral de patiëntenpopulatie die compressietherapie nodig heeft, is zeer gevoelig voor het ontwikkelen van schadelijke effecten van een periode van immobiliteit. Functionele activiteiten en spiercontracties zijn van cruciaal belang ter ondersteuning van een doelmatige veneuze circulatie. De kuitspieren leveren de belangrijkste bijdrage aan een effectieve spierpomp. Vanwege de sterke relatie tussen de bewegingsuitslagen van het enkelgewricht en de kuitspierfunctie, wordt een overzicht gegeven van de literatuur betreffende de enkelfunctie bij patiënten met een chronisch veneus lijden. In dit hoofdstuk wordt onderzoek gepresenteerd naar de effecten van vijf weken vrijwillige immobilisatie van het enkelgewricht bij gezonde vrijwilligers. De resultaten laten zien dat het dragen van een onderbeenloopgips slechts minimale effecten heeft op de enkelfunctie, die na een tot twee weken terug is op zijn normale waarde. Dit leidt tot de aanname dat de effecten die worden waargenomen bij patiënten, veroorzaakt worden door andere immobiliserende factoren als pijn, angst of te weinig stabiliteit en niet door het onderbeengips. Het kan daarom verondersteld worden dat, als de effecten bij een gipsverband slechts minimaal zijn, deze bij een compressieverband tenminste gelijk zullen zijn, ervan uitgaande dat het gebruikte systeem normale functionele activiteiten toelaat. Het mag geconcludeerd worden dat het belang van het behoud van functie niet onderschat mag worden als een compressieverband wordt aangelegd. Compressie alleen doet geen open been genezen, het is de ambulantie, ervan uitgaande dat de patiënt comfortabel zijn gang kan gaan.

Hoofdstuk 5 behandelt de wet van Laplace en meer specifiek hoe deze natuurkundige wet gebruikt kan worden om de druk te berekenen die door compressietherapie wordt gegenereerd. Resultaten van drie studies laten zien dat de theoretische waarden die berekend zijn met de gemodificeerde Laplace calculatie, geen accurate afspiegeling geven van de waarden zoals die waargenomen worden bij het aanleggen van compressieverbanden door experts. Verder laten de resulaten zien dat geen van de onderzochte compressiesystemen een graduele compressie geeft. Geconcludeerd kan worden dat het wijdverbreide geloof dat correct aangelegde compressieverbanden drukwaarden laten zien van 40 mmHg rond het enkelgewricht, afnemend tot 17 mmHg onder het kniegewricht, louter gebaseerd is op theoretische berekeningen.

Een andere manier om de dynamiek van effectieve compressietherapie te verklaren, is de wet van Pascal te beschouwen. Dit wordt gedemonstreerd in **Hoofdstuk 6**. Er wordt een studie gepresenteerd naar de ondersteuning van tibiafracturen in anatomische onderbeenspreparaten om aan te tonen dat de fysische eigenschappen van weke delen overeenkomen met die van vloeistoffen en als zodanig als niet comprimeerbare vloeistoffen te kenmerken zijn. Resultaten van studies op vrijwilligers bevestigen dat de dynamiek van effectieve compressietherapie verklaard wordt door de wet van Pascal, die stelt dat wanneer druk wordt uitgeoefend (middels een functionele activiteit) op een vloeistof (weke delen, een spier of een spiergroep) in een afgesloten container (fascia muscularis, een fractuurbrace of een compressieverband), deze druk zich gelijkmatig verdeeld over elk punt binnen die container.

Er zijn veel redenen te bedenken om compressietherapie te vergelijken met de behandeling van fracturen middels gipsverbanden. Het behouden of verbeteren van de circulatie alsook de functionele activiteiten, zijn gemeenschappelijke doelstellingen. Historisch gezien wordt, net als de bij de fractuurbehandeling, geen gebruik van gemaakt van polstermaterialen bij compressietherapie. In **Hoofdstuk 7** wordt onderzoek gepresenteerd naar de effecten van polstermateriaal. Allereerst een studie waarbij op gezonde vrijwilligers verschillende soorten gipsverbanden aangelegd werden met verschillende hoeveelheden polstermateriaal. De resultaten laten zien dat polstermaterialen niet alleen een significant effect hebben op het stabiliserend vermogen van de gipsverbanden, maar ook op de ondersteuning van de veneuze circulatie middels de spierpomp. Verder worden twee studies gepresenteerd die uitgevoerd werden op twee speciaal ontworpen kunstbenen om de effecten van polstermateriaal te onderzoeken. Een been heeft een zogenaamde omgekeerde champagneflesvorm, het andere een huidplooi rond het enkelgewricht, zoals dat vaak gezien wordt bij lymphoedeem. Deze studies laten zien dat verschillende manieren van polsteren tot een verscheidenheid aan drukprofielen leiden en laten concluderen dat polstermaterialen een effect hebben op een gelijkmatige drukverdeling onder compressietherapie, vooral als polstering gebruikt wordt om onregelmatig gevormde lichaamsdelen uit te vlakken of op te vullen. Tenslotte worden resultaten gepresenteerd die verkregen zijn op cylinders om de effecten van opeenvolgende lagen polstering te bestuderen. Met dit onderzoek werd aangetoond dat iedere opeenvolgende laag polstering niet alleen de druk onder de bandage reduceert, maar ook de spanningsindex, die een indicatie is voor de effectiviteit van een gebruikt compressiesysteem.

In **Hoofdstuk 8** wordt een studie gepresenteerd die verricht is op patiënten met een chronische veneuze insufficiëntie. De studie is ontwikkeld om de effecten te onderzoeken van verbanden met een verschil in rustdruk maar met gelijkblijvende karakteristieken als statische stugheidsindex en amplitudes gedurende functionele activiteiten. Middels ambulante strain gauge plethysmografie (ASGP) kan het effect van compressietherapie worden onderzocht omdat informatie wordt verkregen over de functie van de kuitspierpomp en het veneuze systeem onder verschillende condities. In de gepresenteerde study werd ASGP gebruikt om de uitgangssituatie te bepalen alsook de haemodynamische effecten van Coban 2 en Coban 2 Lite. De resultaten laten zien dat beide producten een significante verbetering van de initiële ejectiefractie geven en dat er geen verschil is in effectiviteit tussen beide producten. Deze vaststelling leidt tot de conclusie dat het niet alleen de rustdruk is die belangrijk is om de effectiviteit van compressietherapie te bepalen, maar dat het meer de mogelijkheid is om een compressiesysteem op volle rek aan te leggen en daarmee een niet rekbare koker met een anatomische pasvorm.

In **Hoofdstuk 9** wordt een studie gepresenteerd die uitgevoerd werd op gezonde vrijwilligers, waarbij volumeveranderingen werden bestudeerd. De resultaten laten duidelijk zien dat zelfs bij gezonde proefpersonen een significante reductie in volume kan worden bewerkstelligd middels compressietherapie. De significante relatie tussen de tijd van de dag dat een compressieverband wordt aangelegd en de hoogte van de volumereductie, betekent dat compressieverbanden in de klinische praktijk voor wat betreft volumereductie het meest effectief zijn wanneer ze vroeg in de ochtend aangelegd worden wanneer de blootstelling aan de zwaartekracht een minimaal effect heeft gehad, of direct na een periode van hooghouden van het been. Daarnaast laten de resultaten zien dat compressietherapie die aangelegd wordt direct volgend op een periode van voorafgaande compressietherapie, een significant lagere volumereductie geeft met een daarbij behorend lager verval in rustdruk. In de praktijk betekent dit dat het aanleggen van compressietherapie het meest effectief is wanneer opeenvolgende verbanden direct na elkaar worden aangelegd. De meest belangrijke vaststelling van deze volumetriestudie is dat er geen relatie kon worden aangetoond tussen het gereduceerde volume en de applicatie van Coban 2 of Coban 2 Lite. Aangezien beide systemen significant verschillende rustdrukken hebben, mag worden geconcludeerd dat het niet de rustdruk is die de effectiviteit van een compressiesysteem bepaalt, maar de stugheidsindex en amplitudes, met andere woorden de mogelijkheid om de effecten van functie binnen het comprimerende verband te houden.

Coban 2 Lite werd oorspronkelijk ontwikkeld voor de behandeling van patiënten met een veneus open been die daarnaast ook lijden aan een perifere arteriële occlusie met een enkel-armindex tussen 0.5 en 0.8. In **Hoofdstuk 10** worden twee studies gepresenteerd. De eerste is een korte samenvatting van een onderzoek bij patiënten met een perifere arteriële occlusie met een enkel-armindex tussen 0.5 en 0.8. De resultaten laten zien dat Coban 2 Lite veilig in het gebruik was bij deze groep patiënten met een verminderde arteriële perfusie. De resultaten van de onderzoeken lieten verder een significante verbetering zien van de dermale microcirculatie tijdens het gebruik van Coban 2 Lite. De tweede studie in dit hoofdstuk werd uitgevoerd om een beter inzicht te verkrijgen over de veiligheid en tolerantie van compressieverbanden die in de dagelijkse praktijk aangelegd worden bij patienten met een lage enkel-armindex, alsmede over enkele fysische eigenschappen van de aangelegde systemen. Acht ervaren wondverpleegkundigen in Canada en Nederland werd gevraagd de druk in de liggende en staande positie te meten onder elk aangelegd compressiesysteem bij alle patiënten in behandeling met een enkel-armindex tussen 0.5 en 0.8. De belangrijkste vaststelling van deze observatiestudie is dat een grote variatie in rustdruk werd gemeten (tussen 6 en 40 mmHg) en dat deze drukken zonder noemenswaardige complicaties werden aangewend. Deze drukwaarden werden goed getolereerd en de verbanden bleven aangelegd tot zeven dagen toe. De resultaten lieten ook zien dat, met de de compressiesystemen die in deze studie gebruikt werden, er een significante correlatie aangetoond kon worden tussen de gemeten rustdruk en de statische stugheidsindex.

Hoofdstuk 11 behandelt de effecten van functionele activiteiten op afzakken en drukbehoud. Er worden drie studies gepresenteerd. De eerste twee werden uitgevoerd op gezonde proefpersonen waarbij gekeken is naar de effecten van respectievelijk twee uur gecontroleerde activiteiten en twee dagen draagtijd. In de tweede studie werd verder gekeken naar zeven dagen draagtijd van Coban 2 Lite. Omdat materiaalmoeheid vaak wordt genoemd wanneer gesproken wordt over behoud van druk, werd een experimentele studie uitgevoerd naar de effecten van materiaalmoeheid op rustdruk en spanningsindex gedurende een periode van een week. De studies op de proefpersonen bevestigen het meeste wat bekend is van compressieverbanden, ze verliezen niet alleen een bepaald gedeelte van de rustdruk, maar ook de eigenschappen die de effectiviteit bepalen, worden beïnvloed door draagtijd. De meeste compressieverbanden laten een ernstig afzakken zien. De ernst van afzakken dat waargenomen werd bij jonge gezonde vrijwilligers, zal aanzienlijk groter zijn dan bij de doorsnee patiëntenpopulatie die compressietherapie voorgeschreven krijgt, maar de observatie is belangrijk. Ook bij patiënten wordt afzakken vaak waargenomen, hetgeen leidt tot ongemak en daarmee tot gereduceerde activiteit. In de twee studies op gezonde proefpersonen in dit hoofdstuk werd een significant drukverlies waargenomen. Dit kan verklaard worden door een reductie van beenomvang, materiaalmoeheid, of een combinatie van beide. Derhalve werd een studie uitgevoerd op cylinders om de geïsoleerde effecten van materiaalmoeheid op rustdruk en spanningsindex te onderzoeken. De resultaten tonen aan dat het verlies aan rustdruk aanzienlijk lager ligt op de cylinders, vergeleken met het verlies bij de proefpersonen. Volumeverlies is de meest voor de hand liggende verklaring voor dit verschil, maar ook afzakken kan een significante bijdrage leveren. Gebaseerd op de uitkomsten van de studies in dit hoofdstuk, zou gesteld kunnen worden dat verbandmaterialen die langer blijven zitten zoals ze werden aangelegd, een meer consistente en ononderbroken compressie geven, met andere woorden een effectievere compressietherapie, hetgeen resulteert in een verbeterde wondgenezing.

In **Hoofdstuk 12** wordt een overzicht gegeven van de onderzoeken naar het gemak van aanleggen en de reproduceerbaarheid van de Coban 2 compressiesystemen in vergelijking met bestaande methodes. Drie studies worden gepresenteerd; twee daarvan zijn verricht op een kunstbeen waarop drie sensoren op gelkussens werden geplaatst om een positionering op weke delen te imiteren. Het aanleggen van een verband op dit been wordt niet beïnvloed door storende factoren als bewegingen van de patiënt of de positie en vorm van het been. Variaties in druk bij opeenvolgende applicaties op dit kunstbeen kunnen derhalve alleen veroorzaakt worden door variatie in de interactie tussen aanwender en verband. De derde studie werd uitgevoerd op gezonde proefpersonen. In alle drie studies werden verpleegkundigen uitgenodigd om het compressiesysteem aan te leggen dat routinematig in hun praktijk gebruik wordt. Er kon worden vastgesteld dat Coban 2 en Coban 2 Lite de geringste variatie gaven, in alle gevallen was dit significant lager dan de andere systemen die onderzocht werden.

In **Hoofdstuk 13** wordt een alfabetisch overzicht gegeven van de afkortingen die in dit proefschrift gebruikt worden. Daarnaast wordt een overzicht geveven van de compressiebandages en -systemen, de verdere producten, testmaterialen en softwareprogramma's die in deze thesis genoemd worden, met hun handelsnaam en leverancier.

Chapter 17

Curriculum Vitae

Jan Schuren (Christian names: Joannes, Franciscus, Henricus, Maria) was born on February 1, 1951, in Linne, a little village in the province Limburg in the Netherlands. He attended the secondary school in Roermond. From 1969 to 1973, he was educated as a general nurse in the hospital ”de Goddelijke Voorzienigheid” in Sittard, after which he served as sergeant in different medical departments in the Dutch army. From 1975 to 1977, he was educated as an OR nurse in Eindhoven and Sittard. He worked as an OR nurse until 1979. In these two years, he attended internal education programmes for Intensive Care Nursing and Orthopaedic Technician.

From 1979 to 1990, he worked as an orthopaedic technician in the Laurentius Hospital in Roermond. In these years, he also held a private practice as bandagist for the treatment and prevention of sports injuries. In 1988 he graduated as an Orthopaedic Technician in Leiden and Rotterdam. In 1990, he graduated in Higher Management Health Care at the IBW in Eindhoven.
In 1990 he started working for 3M in the Netherlands to support the commercialisation of 3M’s orthopaedic product range. In 1992 he took a European role as a technical service specialist for the immobilisation product range. He was one of the founders of the Association for Rational Treatment of Fractures (ARTOF).

In 2002, he received a master’s degree in Evidence-based Health Care from the University of Oxford. In his MSc dissertation he suggested to include non-randomised research in systematic reviews and meta-analyses on fracture care. As an example a systematic review and meta-analysis on the treatment of the humeral shaft fractures was presented.

From 2002, he got involved in the development of new products for chronic wound care and has patents on an off-loading method for diabetic foot ulceration and a compression system for chronic venous ulceration.

The last seven years he writes a weekly column in the Limburgian language in the regional newspaper ’de Limburger’.

Bibliography

Publications in italic are non-medical and written in the Limburgian language.

1. Schuren J.
Poliomyelitis in Kananga, Zaire.
NVG 1989: 6(3): 18-36.

2. Schuren J.
Working with Soft Cast: a manual on semi-rigid immobilisation.
(translated into 15 languages).
IF Publication Services, Düsseldorf 1994.

3. Schuren J.
A semi-rigid bandage for the functional immobilisation of ankle ligament injuries.
Klinik Magazin Sonderheft 1995: 43-45.

4. Schuren J.
A removable Soft Cast cylinder.
Klinik Magazin 1996: 12: 57-58.

5. Schuren J, Latta LL, Milne EJ, Corona J, Sarmiento A, Zych GA.
In vitro evaluation of stability provided to a closed tibial fracture in cadaver legs, comparing rigid bracing methods to a Soft Cast/combicast brace.
AAOS 66th Annual Mtg Proc 1998: 199.

6. Latta LL, Schuren J, Corona J, Milne EL, Sarmiento A, Zych GA.
Soft vs. hard cast materials for functional fracture management of tibial shaft fractures: in vitro fracture stability.
J Bone Joint Surg Orthop Trans 1998; 22: 298.

7. Schuren J, Milne EL, Zych GA, Latta LL.
The stability and rigidity of ankle fracture control in soft casts: a biomechanical study in cadavers.
Trans 45 Ann Mtg Orthop Res th Soc 1999; 263.

8. Schuren J, Latta LL, Milne EJ, Corona J, Sarmiento A, Zych GA.
Biomechanical effects of standard casting methods compared to a Soft Cast combicast in the treatment of unstable ankle fractures in cadaver legs.
AAOS: 66th Annual Mtg Proc 1999: 96-98.

9. Herzig S, Müller J, Schuren J.
A comparative study of the number of replacements required and application times for synthetic casts, combicasts and plaster-of-Paris casts.
J Orthop Nursing 1999: 3: 193-196.

10. White R, Schuren J, Wardlaw D, Diamandopoulos Z, Anderson R.
Biomechanical assessment of gait in below knee walking casts.
Prosth Orthot Int 1999: 23: 142-151.

11. Schuren J (ed).
Working with Soft Cast: symposia proceedings & abstracts of publications.
2000: Rehms Druck Borken.

12. Schuren J (ed).
Working with Soft Cast: evidence based fracture care, symposia proceedings & abstracts of publications.
2000: Rehms Druck Borken.

13. Schuren J.
Evidence-based fracture care.
In: Schuren J (ed). Working with Soft Cast: evidence-based fracture care, symposia proceedings & abstracts of publications.
2000: Rehms Druck Borken: 23-31.

14. Schuren J.
Is the routine use of operative repair of closed displaced ankle fractures justified?
In: Schuren J (ed). Working with Soft Cast: evidence-based fracture care, symposia proceedings & abstracts of publications.
2000: Rehms Druck Borken: 32-37.

15. Schuren J.
Functional bracing of upper limb fractures with Soft Cast.
In: Schuren J (ed). Working with Soft Cast: evidence-based fracture care, symposia proceedings & abstracts of publications.
2000: Rehms Druck Borken: 67-70.

16. Schuren J.
Functional fracture treatment with Soft Cast combicasts.
In: Schuren J (ed). Working with Soft Cast: evidence-based fracture care, symposia proceedings & abstracts of publications.
2000: Rehms Druck Borken: 77-79.

17. Rodt A, Schuren J, Wisnes A, Hordvik M.
The effects of immobilisation in short leg walking casts: Soft Cast combicasts vs traditional rigid casts in healthy volunteers.
In: Schuren J (ed). Working with Soft Cast: evidence-based fracture care, symposia proceedings & abstracts of publications.
2000: Rehms Druck Borken: 83-84.

18. Schuren J.
The chronic wound: where is the evidence?
MedReport 2002: 26(14): 12.

19. Schuren J.
The chronic wound: where is the evidence?
J Wound Healing 2002: 3: 71.

20. Schuren J.
Evidence based fracture care: has this led to improved patient outcomes?
Symposium proceedings ETRS focus meeting, 2002.

21. Schuren J.
The challenges of using non-randomised research in systematic reviews and meta-analyses: the acute humeral shaft fracture.
MSc Thesis. University of Oxford, 2002.

22. White R, Schuren J, Konn D.
Semi-rigid vs rigid glass fibre casting: a biomechanical assessment.
Clinical Biomechanics 2003; 18: 19-27.

23. Schuren J, Spruit P, Prešeren M.
Total-contact casting for diabetic foot ulcers.
In: Urbančič-Rovan V, Koselj M. (eds). Oskrba Diabetičnega Stopola. 2003: Izdano v Ljubljani.

24. Schuren J.
The acute humeral shaft fracture: non-randomised evidence.
Symposium proceedings congres evidence-based fracture care: Delft, April 2004.

25. Issberner K, Schuren J.
A comparative study of the skin protective performance of five barrier films.
3M Publication 2004.

26. Schuren J.
3M™ Cavilon™ no sting barrier film for peri-wound protection: a systematic review and meta-analysis.
Symposium proceedings world congres of wound Care: Paris, July 2004.

27. *Schuren J.*
Druimentaere: a weekly column on a variety of topics in one of the larger regional newspapers in the Netherlands.
De Limburger 2004 - to date; ongoing weekly publication.
www.druimentaere.nl.

28. Schuren J, Becker A, Sibbald G.
3M™ Cavilon™ no sting barrier film for peri-wound protection: a systematic review and meta-analysis.
Int Wound Journal 2005 2(3): 230-238.

29. Bliss D, Zehrer C, Savik K, Ding L, Hedblom E, Schuren J.
An economic evaluation of skin damage prevention regimens among nursing home residents with incontinence: product and labor costs.
MHP Verlag GmbH Wiesbaden. Symposium proceedings DGfW/EWMA/ETRS congress; Stuttgart, 2005: 121-122.

30. Schuren J.
3M™ Cavilon™ no sting barrier film for incontinence care: a systematic review and meta-analysis.
Symposium proceedings DGfW/EWMA/ETRS congress: Stuttgart, 2005.

31. *Schuren J.*
Einen apaarten aovendj.
Roerstreek 2005; 39: 167-170.

32. Schuren J, Mohr K.
Sub-bandage pressures: the Laplace law revisited.
3M Publication 2006.

33. Schuren J, Mohr K.
The 3M™ Coban™ 2 Layer Compression System: sub-bandage pressures at reduced tension.
3M Publication 2006.

34. Schuren J, Collier M.
Ease of use and reproducibility of provided pressures, comparing 3M Coban 2 Layer Compression System with four currently marketed compression systems.
3M Publication 2006.

35. Schuren J.
Sub-bandage pressures: the Laplace law revisited.
Symposium proceedings Wounds UK 2006 conference: Harrogate UK, 2006.

36. Schuren J, Partsch H.
Compression therapy: the how and why.
Symposium proceedings EWMA congress: Glasgow 2007.

37. *Schuren J.*
Bang det ich wakker waer.
In: Custers T. Aope deure: 't verhaol. 2007: Marlstone BV, Bunde: 2-3.

38. *Schuren J.*
Euverpienzing.
In: Custers T. Aope deure: 't verhaol. 2007; Marlstone BV, Bunde: 4-5.

39. Collier M, Schuren J.
Ease of use and reproducibility of five compression systems.
J Wound Care 2007; 3M Supplement: 8-10.

40. Partsch H, Clark M, Mosti G, Steinlechner E, Schuren J, Abel M, Benigni JP, Coleridge-Smith P, Cornu-Thénard A, Flour M, Hutchinson J, Gamble J, Issberner K, Juenger M, Moffatt C, Neumann HA, Rabe E, Uhl JF, Zimmet S.
Classification of compression bandages: practical aspects.
Dermatol Surg 2008; 34: 600-609.

41. Schuren J.
Sub-bandage pressures: the physics of compression therapy.
Symposium proceedings EWMA congress: Lissabon 2008: 74.

42. Schuren J, Mohr K.
The efficacy of Laplace's equation in calculating bandage pressure in venous leg ulcers.
Wounds UK 2008; 4(2): 38-47.

43. *Schuren J.*
Limburgs sjrieve
In: Kuipers W. Platbook 1. 2008: Uitgeverij TIC, Maastricht: 42-43.

44. *Schuren J.*
Sjpellentaere.
In: Kuipers W. Platbook 1. 2008: Uitgeverij TIC, Maastricht: 44-45.

45. Partsch H, Flour M, Coleridge Smith P, Benigni JP, Cornu-Thénard A, Delis K, Gniadecka M, Mariani F, Mosti G, Neumann HAM, Rabe E, Uhl F, Benhamou AC, Brandjes D, Cavezzi A, Clark M, Schuren J.
Indications for compression therapy in venous and lymphatic disease: consensus based on experimental data and scientific evidence.
Int Angiol 2008; 27(3): 193-219.

46. Schuren J, Mohr K.
De dynamiek van compressietherapie: de wetten van Laplace en Pascal.
WCS 2009; 25(3): 20-25.

47. Jünger M, Haase H, Ladwig A, Schwenke L, Bichel J, Schuren J.
Compression therapy in patients with peripheral arterial occlusive disease: a prospective clinical study with the Coban 2 Layer Lite compression system for ABPI 0.5.
3M Publication 2010.

48. *Schuren J.*
Tante Betje.
Roerstreek 2010; 42: 125-128.

49. Schuren J, Vos A.
Reproducibility of sub-bandage resting and working pressures when reduced pressure is required.
Symposium proceedings EWMA congress: EWMA 2010:193.

50. Schuren J, Andreas C.
Pressure and slippage during 48 hours of compression therapy: a study on healthy volunteers.
SAWC Spring 2010 Abstract Book: S36.

51. Schuren J.
Venous leg ulcer patients with low ABPI's: how much pressure is safe and can be tolerated?
Symposium proceedings EWMA congress: EWMA 2010: 41.

52. Partsch H, Stout N, Forner-Cordero I, Flour M, Moffatt C, Szuba A, Milic D, Szolnoky G, Brorson H, Abel M, Schuren J, Schingale F, Vignes S, Piller N, Döller W.
Clinical trials needed to evaluate compression therapy in breast cancer related lymphedema (BCRL): proposals from an expert group.
Int Angiol 2010; 29: 442-453.

53. Schuren J, Mohr K.
Pascal's law and the dynamics of compression therapy: a study on healthy volunteers.
Int Angiol 2010; 29: 431-435.

54. Schuren J, Vos A, Allen J.
Venous leg ulcer patients with low ABPI's: how much pressure is safe and can be tolerated?
EWMA J 2010; 10(3): 29-34.

55. Jünger M, Haase H, Ladwig A, Schwenke L, Bichel J, Schuren J.
Safety and tolerability of a new compression system for patients with chronic venous insufficiency combined with peripheral arterial occlusive disease.
Phlebology 2011; accepted for publication.

56. Schuren J, Bernatchez S, Tucker J, Schnobrich E, Parks P.
3M™ Coban™ 2 layer compression therapy: intelligent compression dynamics to suit different patient needs.
Wound Healing Society Yearbook Series 2011: accepted for publication.

Chapter 18

Acknowledgements

As an orthopaedic technician, I have used compression therapy for many years in clinical practice. In the days where it was common practice to have orthopaedic and orthopaedic trauma patients in casting material for long periods, the post-treatment routine consisted of an inelastic zinc paste bandage for two weeks. Later I started to use these techniques for patients with venous leg ulceration. The results were very satisfying, which created my interest in a new area in medicine. My view on compression therapy has evolved over a good many years. It arose, initially, not out of any desire to contribute to research and development, but rather out of my own attempts to understand how compression works. Much of what has been written in this thesis would not have been possible without the support of others. I owe a great deal to the clinicians and colleagues who, through their own research, comments, and questions have encouraged, supported, and enlightened me. Without a doubt there will be errors, omissions and over-simplifications in this thesis. For this I take absolute responsibility while hoping that the rest of the material will stimulate further research. I could not possibly name everyone who has contributed significantly to my understanding of the subject, but I would be remiss if I did not mention at least some of them.

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