THE HONG KONG POLYTECHNIC UNIVERSITY

INSTITUTE OF TEXTILES AND CLOTHING (ITC)

DESIGN AND FABRICATION OF SHAPE MEMORY FILAMENTS INTO KNEE HIGH COMPRESSION STOCKINGS

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A thesis submitted in partial fulfillment of the requirements for the degree of Master of Philosophy

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CERTIFICATE OF ORIGINALITY

I hereby declare that this thesis is my own work and that, to the best of my knowledge and belief, it reproduces no material previously published or written, nor material that has been accepted for the award of any other degree or diploma, except where due acknowledgement had been made in the text.

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Pavithra Onkaraiah (Name of the Student)

ABSTRACT

Compression stockings are used for centuries as a prophylaxis method to treat thromboembolism, varicose veins and its complications for long term. Previous studies have shown that compression stockings should produce appropriate graduated pressure profile in order to relieve the symptoms of venous disorder. However, pressure profile and performance of the stockings are variable; compliance on their usage is poor and patients often find it ineffective in relieving the pain. Moreover, compression stockings are not free from risk and complications namely tourniquet effect, reversed pressure profile, wrinkling of stockings fabric with their usage. Lately, there have been very few attempts to effectively control these complications and application of shape memory fibers in the stockings is so never contemplated.

Henceforth, this study was carried out with the main objective to design and fabricate shape memory filaments in compression stockings and evaluate their performance by objective and subjective method. To successfully achieve this objective, a consolidative study was carried out involving 3 main segments, 1) objective evaluation of commercial compression stockings for pressure magnitude at ankle and pressure profile along the leg on human subjects, 2) Evaluation of shape memory effect of shape memory filaments and 3) Study on the implication of shape memory filaments in compression stockings by comparing the performance of commercial stockings and stockings with shape memory fibers.

Pressure delivered by graduated compression stockings from class I to class IV was evaluated at ankle on both legs of 20 human subjects. Each of the stockings delivered varied pressure on leg. The physical determinants of compliance issue were also estimated. It was noted that difficulty in

the application of stockings, high pressure sensation at bony prominences, welt and skin redness were the major compliance issues; the obtained results formed the basis to design the later study. Furthermore, a comprehensive experiment was carried out to evaluate the pressure profile of commercial compression stockings from ankle to welt on a sample of 10 human subjects. It was noted that the pressure profile was divergent in vertical and horizontal direction for different stockings with higher pressure at anterior direction. The evaluated pressure at the welt was significantly higher than the standard designated pressure.

The shape memory properties of the shape memory filaments were evaluated by cyclic thermomechanical testing on Instron which was fitted with a heating chamber. Furthermore, the influence of parameters namely deformation temperature, speed during the thermomechanical testing, pre-setting and stress relaxation were evaluated. The recovery percentage of filaments was least at lower temperature (less than 45 degree Celsius). The shape memory properties were stable after 5 cycles of elongation and recovery steps. The stress relaxation of fibers remained stable after 15 minutes. Finally, the mechanical properties of different counts of the shape memory core yarn spun with cotton fibers as sheath was tested. Although, the elasticity of yarn was improved with shape memory fiber as core, the total elasticity of yarn was limited to 11%. Henceforth, shape memory fabric knitted with bare shape memory filament and nylon fibers, tension set to 60 degree Celsius was applied in compression stockings.

Shape memory filaments were applied at ankle bow and welt as these sections form the substantive regions of stockings. In the final segment, the implication of shape memory filaments in stockings was verified and its performance was compared with commercial stockings. The results showed that circumferential pressure variation of stockings and the wrinkling at the ankle bow in stockings with shape memory filaments was lesser compared to commercial stockings. Moreover, in in-vivo mechanical testing of compression stockings with shape memory filaments at the ankle bow it was found that the slippage of the stockings was relatively easy and easy to apply on to the leg and the participants rated the stockings to be comfortable at welt region.

This study on the vital application of shape memory filaments into knee high compression stockings demonstrates the advantages of fabricating shape memory filaments with shape memory properties in compression stockings and add to our knowledge on performance of fibers in stockings. The stockings with shape memory fibers delivered uniform pressure across the girth. Nevertheless, the limitation of this study is that shape memory filaments were applied in elusive regions such as ankle and welt by sewing the fabric on to ready stockings rather than knitting the stockings.

LIST OF PUBLICATIONS

Conference Papers

1. Pavithra Onkaraiah, Lai Kuen Chan, Jinlian Hu, Pressure Evaluation at the ankle and compliance issues with the application of compression stockings used in the treatment of venous disorders. Fiber Society (Spring 2011), Hong Kong, pp. 122-124, 23-25 May 2011.

2. Pavithra Onkaraiah, Lai Kuen Chan, Jinlian Hu, Innovation in Shape Memory Polymers and its Application in Textiles. Managing Innovation In Textiles (2010), Manchester, 10-11 June 2010.

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SMFs-Shape memory filaments

SMP-Shape Memory polymer

VV-Varicose Veins

CVI-Chronic Venous Insufficiency

GCS-Graduated Compression Stockings

AES-Antiembolic Stockings

ROM-Range of Motion

VV- Varicose veins

DVT-Deep vein Thrombosis

CEAP -Clinical Ethiologic Anatomic and Pathophysiologic classification method

VAS-Visual analogue scale (pain scale)

USD-Ultrasound Doppler

CHAPTER 1. INTRODUCTION

1.1 INTRODUCTION

The subject of this thesis is shape memory fibers (SMFs) and their performance in compression stockings which are applied in controlling venous blood flow in leg. Hence, in this chapter SMFs and compression stockings are introduced along with their application examples. In addition, knowledge gap, and research objectives are presented. The chapter ends with a flow chart describing the framework of the complete study.

1.2 SHAPE MEMORY POLYMERS (SMPs) AND SMART TEXTILES

Shape memory polymers (SMPs) are polymeric smart materials functioning upon the action of appropriate stimulus such as temperature, water, light, electric and magnetic field (Behl and Lendlein, 2007). In contrast to their metal counterparts (Shape memory alloys), SMPs are lighter, posses high recoverability, economical and are easily manipulated for desirable application (Liu et al., 2007). SMPs store a deformed (temporary) shape and can recover back to original (permanent) shape; they are typically induced by change in temperature and are called temperature sensitive shape memory polymers. Thus, accidental deformation caused by an external force can be ironed out by heating above a defined transition temperature (Lendlein and Kelch, 2002).

Smart textiles are manufactured either by finishing fabric with these polymers (Hu et al., 2007a) or by fabricating shape memory filaments (manufactured by spinning the SMP solution) either by knitting, weaving (Meng et al., 2009) or bonding. In this study knitted SMFs are applied in compression stockings.

1.2.1 Temperature sensitive Shape Memory Filaments (SMFs)

Temperature sensitive SMFs spun from SMPs are novel filaments manufactured by melt, dry, wet spinning or reaction method (Meng et al., 2007); when heated above switching temperature (glass transition or melting temperature) can recall their set permanent shape in the filament form. The functionalization of the polymer depends on tailored processing and programming technology. Shape change over capabilities at macroscopic level are differentiated by shape memory effect and shape changing capabilities (Behl and Lendlein, 2007). The shape memory effect is not related to a single polymer but is a result of combination of polymer structure and morphology with the applied processing and programming technology (Lendlein, 2001).

Shape Memory Textiles Centre at The Hong Kong Polytechnic University operating under the chief investigator Prof. Jinlian Hu is determinedly involved in the production, testing and application of novel SMFs.

1.2.2 Characterizations of shape memory filaments and characterization of shape memory fabrics

SMFs can be stretched, deformed at about glass transition temperature and later by cooling to room temperature this deformed shape can be effectively maintained. Thus, the flexibility of the polymer segments is a function of the temperature and precision with which the programmed shape can be recovered is more than 99% under optimized programming conditions (Lendlein, 2001).

Shape memory effect is defined by unique parameters such as shape fixity and recovery evaluated by thermomechanical testing method using Instron (Hu et al., 2005). The Shape fixity is the ability of the fiber to remain in a set permanent shape and shape recovery is the ability of fiber to remember the set permanent shape. Thus, SMFs are characterized by unique properties such as shape fixity and shape recovery. Moreover, shape memory fabrics manufactured by finishing SMPs are associated with novel properties such as flat appearance, crease recovery and bagging recovery which is studied and quantified by Hu et al (2007a).

1.2.3 Applications of shape memory polymers

The applications of SMPs are widening, these polymers are systematically applied in mechanical, aerospace, bio-medical and textile engineering. Higher precision in the recovery make them suitable for demanding application as in sutures (Lendlein, 2001). The application of SMPs includes a broad spectrum: covering minimal invasive surgery, self repairing components, breathable fabric (Mondal and Hu, 2007), biomedical areas such as artificial tendon, artificial cornea, hernia repair, artificial bone joints, orthodontics, scaffold material, and wound dressing (Meng et al., 2009), sutures (Lendlein, 2001) intimate apparels (Hu et al., 2007b), mood changing fabrics (Stylios and Wan, 2007) and fashion goods. Although the functionality of textile materials is improved with application of SMPs, they have not reached their technological potential as very few studies have been made to apply them in textiles.

1.3 COMPRESSION THERAPY AND COMPRESSION STOCKINGS

In previous section shape memory polymers, fibers and their properties were discussed, in this section compression stocking which forms the major modality of compression therapy is introduced.

1.3.1 Compression therapy

Compression therapy is time-honored concept with an history of over 2000 years or more (Amsler and Blättler, 2008) and is recognized as the golden standard for the prophylaxis of venous disorders such as, deep vein thromboembolism (DVT) (Tan et al., 2006), varicose veins (VV) (Hakan UNCU, 2009), venous ulcers, and lymphatic disorder such as lymphoedema (see section 2.3), evening edema (Belczak et al., 2010). Compression therapy works by the application of external mechanical force on veins by modalities such as bandages, compression stockings or pneumatic compression devices as explained in section 2.4. Compression stockings forms the most widely accepted modality and are applied to treat the venous disorder of lower extremity in the management phase. They are comparatively safe and economical means of treating the disorders.

1.3.2 Compression Stockings

Overall there are about 200 different types of medical elastic compression stockings (van Geest et al., 2000). They are broadly classified as Graduated Compression stockings (GCS) and Anti embolic stockings (AES) (see section 2.6.1). In addition, these stockings are differentiated based on the effective pressure delivered at the ankle designated as B region (the minimum girth of leg at the ankle) (Partsch et al., 2006a). In this study pressure delivered by both the types of stocking on human subjects is measured.

1.3.3 Applications of compression stocking

Compression stockings are recommended in both patients undergoing surgical (vein surgery), non surgical treatment (supporting sclerotherapy)(Shouler and Runchman, 1989) and in the management of varicose veins. They are applied to treat varicose veins, edema in pregnant women, venous thromboembolism (Tan et al., 2006, Agu et al., 1999), venous ulcer, lymphoedema (Doherty et al., 2006), hypertrophic burn scar, prevent muscle soreness by increasing venous blood flow in deep veins; used as sportswear and increase transcutaenous oxygen pressure and expel calf volume with exercise.

1.4 MOTIVATION FOR THE RESEARCH

Patients diagnosed with venous disorder are recommended to apply the compression stockings for rest of their life. Inability to apply compression stockings, hot/itchy skin, tourniquet effect, pressure loss, and wrinkled stocking at the ankle were main concerns of patients using compression stockings. The same was also noted from blog entry (admin, 2010) and literature review discussed in CHAPTER 2. One of the patients in a blog entry describes her difficulty in wearing stockings: “takes me 10 minutes of odd, contorted ted positions to get into the stockings” (Femme, 2010). The stockings application is further difficult in aged people with joint problems.

Patients often discontinue and use it irregularly as it is painful to apply these stockings; by this the healing time is unnecessarily prolonged and can cause pain and agony. With this even the quality of life and the desire to live is gone astray. The major limitation is the difficult to apply stockings and complications with the improper usage of compression stockings. Thus, it becomes very much necessary to do research in this coarse area to help these patients as their count is considerably high in the world (see section 2.3.3).

1.5 STATEMENT OF PROBLEMS

By extensive literature review, the working mechanism and major problems associated with the application of compression stockings in patients were known. The complication issues with the use of compression stockings are contemplated along with the existing knowledge gap in the study on shape memory filaments and are presented below:

i. Shape memory fabrics manufactured by finishing SMPs are associated with novel properties such as flat appearance, crease recovery and bagging recovery. However, testing and application of shape memory filaments in fabric is still in its early stage.

ii. The skin-stocking interface pressure was inconsistent and large percentage of the stockings failed to deliver the standard graduated pressure on leg. Moreover, the mechanism of action, pressure profile of the stockings is precarious. The variation of pressure magnitude and the pressure profile in individuals of different leg configuration from different ethnic groups is uncertain.

iii. The pressure magnitude and pressure profile of the stockings inclusive of GCS and AES is not investigated profoundly in all the directions; at the critical region of ankle and major sections of leg. Furthermore, the pressure readings at the welt of stockings and the cutaneous blood constriction with skin redness is rarely considered and studied by previous researchers.

iv. The major compliance issue with the usage of compression stockings is the difficulty in applying them on. Though the problem is common and discussed widely, objective study on the application of compression stockings on human subjects is sparse.

v. Most of the patients wearing compression stockings complained the stockings being tight, constricting skin (pressure marks) at welt, itchy, and wrinkled easily at the ankle. Study on the comfort at welt is carried out for casual socks (Tsujisaka et al., 2004); however the comfort at the welt, wrinkling of the stockings at ankle is discussed but rarely evaluated. This is of importance as only 2 pairs of stockings are used for around 6 months round the clock except when in supine posture (Belczak et al., 2010) and also stockings should effectively function as a prophylaxis measure to prevent blood pooling in veins.

vi. The designing of the compression stockings with shape memory filaments which are associated with novel properties of shape recovery and shape fixity is so far never excogitated. It is hypothesized that major problems associated with application and usage of the stockings can be resolved with the use of shape memory filaments in them.

1.6 RESEARCH OBJECTIVES

Based on the complication issues and knowledge gap concerning the use of compression stockings in patients and SMFs respectively as stated in previous section, below objectives were framed for the current study:

1. To objectively evaluate the pressure performance of commercially available compression stockings on human subjects. Identify the current physical determinants of the non compliance (non adherence) issues; study the range of motion at ankle with the use of compression stockings in both patients and healthy subjects.
2. To evaluate the shape memory effect of filaments under different mechanical conditions namely pre setting, stress relaxation and to design and fabricate stockings with shape memory filaments.
3. To carry out in-vivo mechanical testing of compression stockings with shape memory fabric for ease of application and compare its comfort performance by psychological comfort analysis on Visual Analogue Scale (VAS) with that of the commercial compression stockings.

1.7 SIGNIFICANCE OF THE STUDY

Academic work on shape memory filament and fabric is relatively new and the significance of the current study is also.

i. This study aims to evaluate the efficacy of the shape memory fiber in compression stockings applied to treat the widespread problem of varicose veins; affecting the well being of patients, their social and cultural life styles.

ii. It is hypothesized that the compliance level associated with the usage of stockings can be improved with the application of shape memory filaments in compression stockings.

iii. In the long run, the study aims to tackle the widespread venous disorder by improving the comfort and quality of life of patients using compression stockings with the application of SMFs.

Researchers at Shape Memory Textiles Centre at the Hong Kong Polytechnic University are decisively involved in the processing, characterization and application of the SMFs. This study as a division, can intuitively add to our knowledge on the behavior of the SMFs in fabric and further aid in the improving the processing or the chemical formulation based on the experimental results of the final end product.

Application of SMFs is only limited to human ability to perceive the same. Absolutely the application of SMFs is multifold in sportswear, medical field, apparels, hosiery, and intimate garments. Henceforth, initial work to quantify and analyze its behavior can add to our knowledge in understanding and applying them effectively. At this point I would like to acknowledge that the SMFs used to produce fabric are from The Shape Memory Textiles Center, The Hong Kong Polytechnic University.

1.8 THESIS OUTLINE

This thesis consists of 7 chapters, in Chapter 1 as discussed previously, summarizes the research background with the introduction to SMFs, compression stockings and their applications. The current knowledge gap in the study on SMFs and compliance issues with the application of stockings are summarized along with research objectives. In addition, the contrived significance of the research study was also reported.

In Chapter 2, physiology of venous system and pathophysiology of venous disorders are introduced and the concept of compression therapy acting on venous blood is discussed. Furthermore, the basics of compression stockings, their mechanism of action are clearly illustrated along with the description of stockings manufacturing process. Moreover, the related work on SMFs, the stockings from previous researchers are analyzed and summarized. In addition, the problems, compliance issues, nature of ineffectiveness of the stockings and the novelties of SMFs are discussed in detail. Finally the chapter concludes with epilogue on the knowledge gap noted from literature review.

In Chapter 3, the pilot study was carried out to study the skin stocking interface pressure at ankle for GCS (class I to class IV) on 20 subjects is discussed. Moreover, compliance issues associated with their application as discerned during the study period. Influence of compression stockings on Range of Motion (ROM) in patients and healthy subjects is also discussed.

The skin stockings interface pressure from the stockings inclusive of AES and GCS at all major sections, directions of leg is given in chapter 4. The pressure evaluation procedure, data collection and analysis are discussed. Finally, the obtained results are compared with that of the standard profile advised in standard and suitable conclusion drawn are presented.

Chapter 5 reports the study concerning the influence of post spinning operation and thermomechanical testing conditions on shape memory effect in SMFs. Stress relaxation of SMFs and mechanical properties of shape memory core spun yarn are also presented.

In Chapter 6, the implication of shape memory fabric at ankle bow and welt is studied by objective and subjective method in in-vivo condition on Instron and questionnaire respectively. The load elongation values and the comfort ratings are presented. Moreover wrinkling of the stockings at the ankle is tested by cyclic flexing test on Instron and the results of the both the experiments are presented.

The chapter 7 summarizes the current findings of the research study with explanation on the mechanism of fit of the stockings with SMFs and the scope for further improvement. In addition, the limitations of the current study are specified.

The inter relation of all the chapters described above is presented in Figure 1-1, the framework of the study is given with details of each chapter underneath the topic heading.

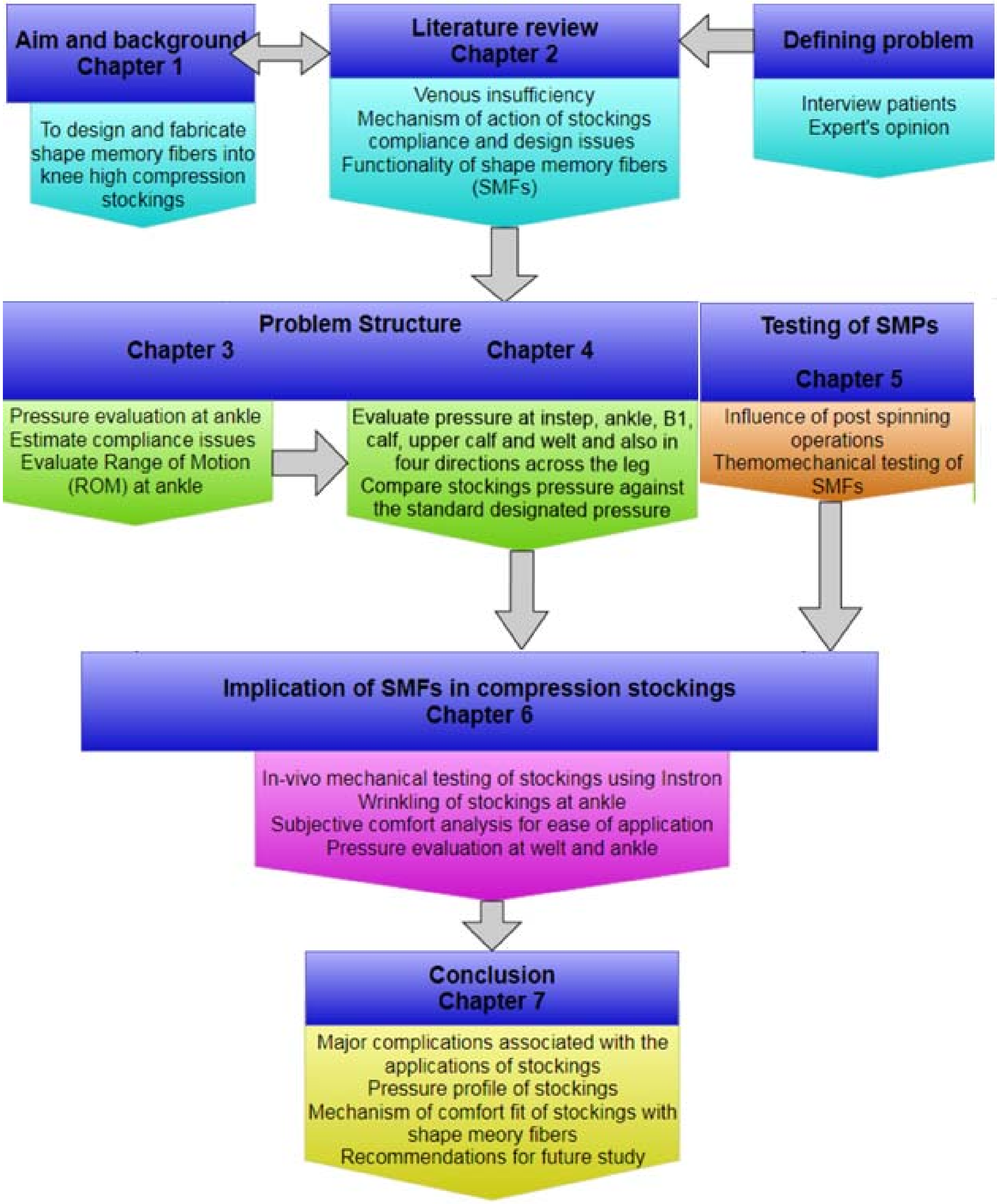


Figure 1-1 Research study framework

CHAPTER 2. LITERATURE REVIEW

2.1 INTRODUCTION

In the introduction chapter the fundamentals of compression stockings and SMFs applied in this study along with their application were discussed. In this chapter, venous system and venous disorders are introduced and the concept of compression therapy acting on venous blood is presented. At the same time, the uncertainty in the pressure magnitude and profile in stockings and styles are presented. In addition, their mechanisms of action of the stockings are clearly illustrated. Moreover, the related work on SMFs, compression stockings from previous researchers are analyzed and summarized to bring to light the decisiveness of the present research work. Furthermore, the problems, compliance issues and nature of ineffectiveness of the compression stockings are discussed in detail. The necessity for the current study and engineering design using SMFs in compression stockings is shown by illustrating the advantages of smart filaments over other manmade fibers.

2.2 VENOUS SYSTEM AND VENOUS PRESSURE

Blood circulation system in human mainly consists of arteries, veins, capillaries and lymphatic. Of these, arterial and venous system forms the major part of circulation system. The arterial system carries oxygenated blood from heart to rest parts of the body whereas the venous systems return the deoxygenated blood back to heart for purification (Robert Maggisano and Harrison, 2004). Capillaries interconnect the arteries and veins and help in microcirculation; lymphatic vessels return plasma and other substances including cells that leaked from the vascular system and transport lymph fluid back from the tissues to the circulatory system. Branches of circulations system in human is given in Figure 2-1.

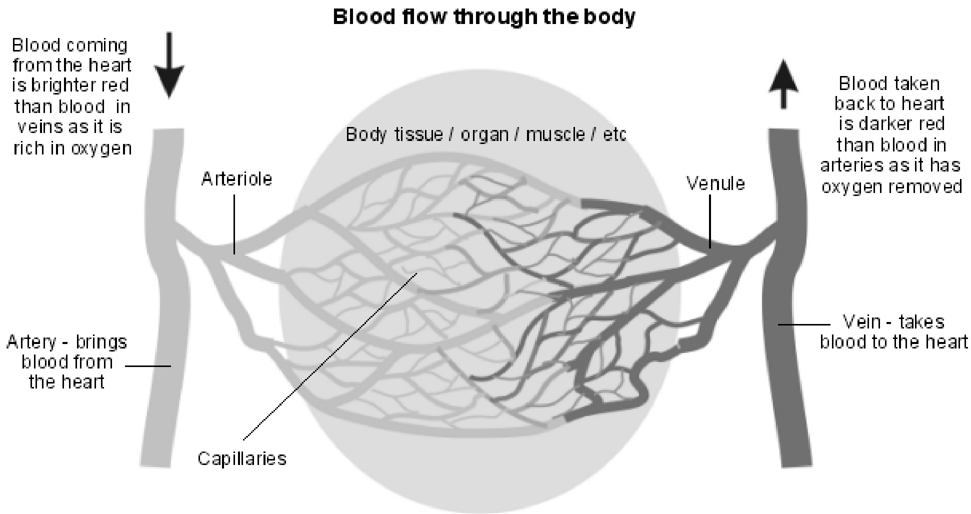


Figure 2-1 Branches of circulation system in human showing the blood vessels (Mariani, 2004)

2.2.1 Venous blood system

Before discussing the venous insufficiency it is essential to know the venous blood flow system, venous pressure and mechanism of venous flow in human body. In human 70% of the total blood volume is stored in veins (Philip D, 2006) and thus veins act as reservoir of blood. Veins are thin-walled structures with unidirectional bicuspid valves, carrying blood from the superficial veins (near the skin) to the deep veins found between the muscle and bones. These veins with the flapping action of bicuspid valves assist in the venous blood towards the heart from deep veins in leg (Valencia et al., 2001). The blood flow rate in the veins depends on the diameter of venous walls and elasticity of the walls. The blood flow is inversely proportional to the diameter of the veins given that the flow rate is constant. In human, the diameter of the superficial veins is known to vary the most, compared to deep veins.

In healthy patients with (competent) valves with the snap shut action, blood pooling and retrograde motion against the gravitational pull are prevented (Sherman, 1985). The venous blood returns from higher pressure gradient towards the lower pressure gradient. The velocity of the venous return is attributed to the kinetic energy supplied by the muscle action (Pollack and Wood, 1949), gravitational force and thoracic action (to a little extent). During expiration the pressure in the inferior vena cava declines thereby the blood pressure is released. Furthermore, the venous flow can be increased with the elevation of the legs (change in posture) (Pollack and Wood, 1949).

2.2.2 Venous blood pressure

Orthostatic venous pressure: The Orthostatic venous pressure is the pressure in immobile state in human. It is the residual pressure after the venous blood passes through the capillaries and the weight of the blood column based on the measuring points. This pressure is around 90-110 mm Hg at ankle (Philip D, 2006), depending on the height of the human. Static venous Pressure is high at ankle with 90 mm Hg and gradually reducing to 55 mm Hg at knee (Moffatt, 2007, Philip D, 2006) as shown in Figure 2-2.

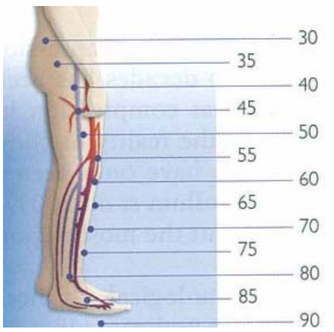


Figure 2-2 Static venous pressure in mm Hg (Moffatt, 2007)

Dynamic venous pressure: The venous pressure during calf and ankle motion or during exercise is referred as the dynamic venous pressure. There is much depreciation in venous pressure during walking in competent veins based on effective functioning of the calf muscles and the venous valves. With the tip-top motion of foot static pressure reduces to below 25 mm Hg and the venous velocity increases significantly with the combined movement as studied by Sochart and Hardinge (1999). The physiological changes in the venous pressure with the calf muscle pump at different regions along the leg is given in Figure 2-3 (Philip D, 2006). With calf muscle functioning, the venous pressure as high as 90 mm Hg can reduce to 20 mm Hg.

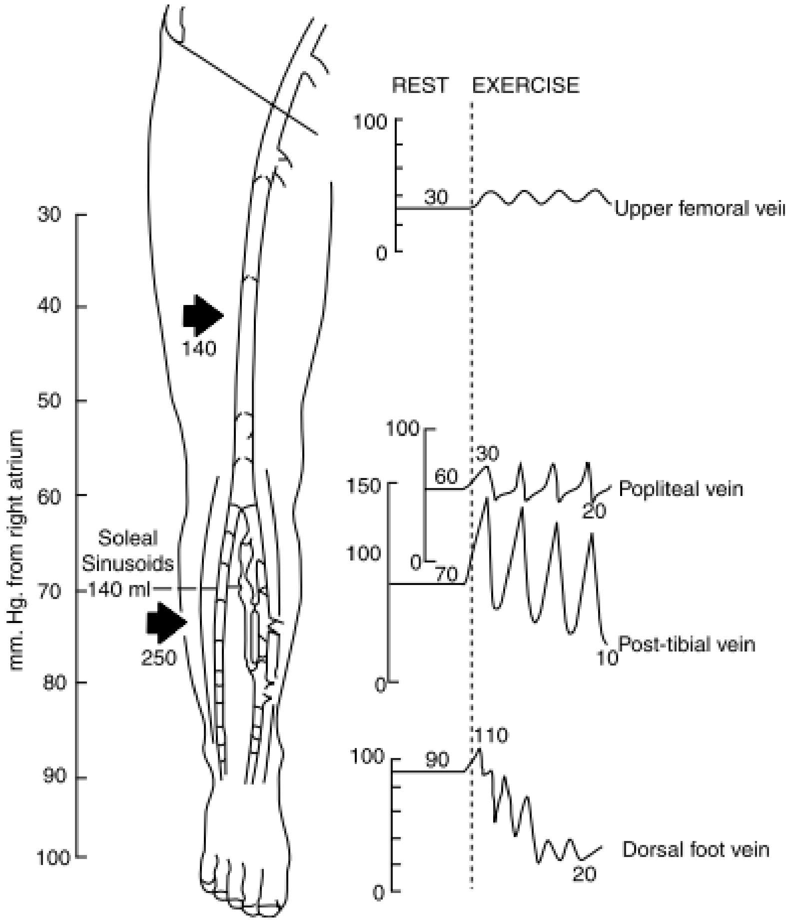


Figure 2-3 Venous pressure variation with calf muscle functioning (Philip D, 2006)

Venous refilling index (VRI): The qualitative measure used to define the difference of static and dynamic pressure is VRI. This reflects the rate of the blood volume increase by changing from supine to standing position or with exercise of calf and foot muscle (Robert Maggisano and

Harrison, 2004). The time taken for the veins to swell up is referred to as the" venous filling time" and the refill after ambulatory motion is called “venous refilling time”. With compression venous refilling index and its time is increased (Christopoulos et al., 1987).

2.2.3 Action of Leg Pump on venous blood flow

Leg pumping action is coordinated with series of the action of the foot pump, ankle pump and calf pump (Styf, 2008). These pumps mutually assist in order to effectively pump the venous blood towards the heart. These pumps can work actively or passively during walking and mechanic mobilization respectively (Robert Maggisano and Harrison, 2004). With the combined action of all the pumps the venous velocity was known to increase by 38% as studied by Sochart and Hardinge (1999). Proper functioning of the venous valves is essential in order to make the blood to flow in physiological centripetal direction.

Foot pump: The venous network of the foot lying between the sole and the bones are compressed by each foot step and the blood is squeezed by the body weight. Also, the veins are stretched by taking each step and the intravascular volume is reduced (Styf, 2008).

Ankle and calf pump: The veins in the region of ankle are under the airing effect of the tendons that change their position with dorsal and plantar flexion. With movement the tension in the fascial system is increased and the diameter of the small saphenous vein (superficial vein) is reduced. The venous blood flows from the superficial to the deep venous system and from there towards the heart in centripetal direction with ankle and calf pump. Poor calf pumps function and reduced Range of motion (ROM) was significantly correlated to decrease in ejection fraction and residual volume fraction of venous blood (Back and Padberg, 1995). Sparrow et al., (1995) showed the efficacy of compression stockings is related to the changes in calf compression even if ankle pressure is kept constant. The calf muscle functioning plays an important role in the venous flow and is divided into 2 phases (Philip D, 2006):

Phase I (calf relaxation)-, the pressure is the same in deep and the superficial venous system accounting, 90 mm Hg (80 mm Hg due to weight of the blood and 10 mm Hg due to the residual pressure in capillaries). The venous valves float in the lumen as there is no pressure difference.

Phase II (calf contraction) with contraction the muscle volume increases and squeezes the deep veins. As the deep veins cannot escape the region between the fascia and the bones, the valves of the perforating veins close. The pressure in the tibial veins increases to 200 to 250 mm Hg. With single contraction of the calf muscle the pressure increases to 100-150 mm Hg in the deep compartment and the flow is directed towards the heart by flapping action of venous valves.

2.3 VENOUS INSUFFICIENCY

With the brief introduction to venous pressure and the mechanism of physiological flow from leg towards heart by the action of leg pump in the previous section, this section shall proceed with the discussion on venous disorder, its pathophysiology along with risk factors and socio-economic problems posed the venous disorders. The Venous disorder is the commonest disorder of venous system and is clinically addressed as Chronic Venous Insufficiency (CVI) due to their recurrent nature. The subjective symptoms of CVI includes leg tiredness, cramps, pain aching, heaviness, itching, sensations of burning, swelling, the restless leg syndrome, dilatation or prominence of superficial veins with the skin color change (Nicolaides, 2000). The chronic microcirculatory changes may lead to the most severe manifestation in the form of venous ulcers and edema.

The venous values as shown in Figure 2-4, the values cannot perform if the venous walls are dilated or if valves are partly or completely damaged. The venous blood refluxes as venous walls are dilated and the valves are damaged preventing venous valves from inclining with each other (Valencia et al., 2001). For easy understanding the healthy vein with competent venous valves is also presented in the same figure.

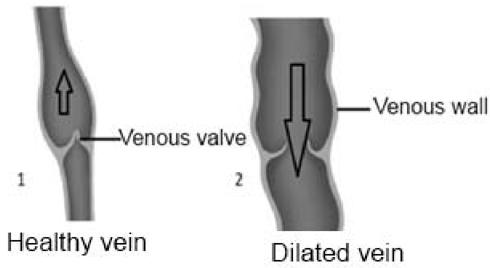


Figure 2-4 Cross-sectional view of venous vessel with bicuspid valves: 1.Healthy vein, 2. Dilated vein

Valve lesion with elongation and thickening are known to result in reflux in blood. With the development of the disorder (veins with incompetent valves), blood refluxes towards the distal end than to the proximal end under the influence of the gravity. As the blood oscillates between the segments of valves, even on walking the pressure is high and is called ambulatory venous hypertension. The pressure fall depends in the state of disorder in patients; used as an indication of CVI (see Figure 2-5).

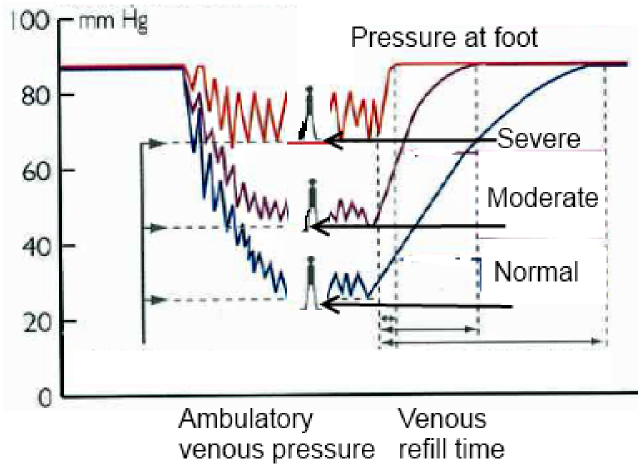


Figure 2-5 Incompetent venous ambulatory pressure and venous refill time modified from (Moffatt, 2007)

Venous disorder in patients assessed by CEAP (Clinical Etiologic Anatomic and Pathophysiologic) classification method and are broadly classified into varicose veins, Venous thromboembolism and venous ulcers discussed below,

Varicose veins (VV): The most commonly affected structure is venous valves (Philip D, 2006). The VV also referred as venous insufficiency is tortuous, dilated, twisted, or lengthened veins. However, enlargement in the size alone shall not specify insufficiency because size can vary depending on temperature and, in women on hormonal factors. Besides, normal superficial veins in a thin person can appear large, whereas varicose veins in an obese person may be hardly visible. VV is classified as primary and secondary VV. Primary VV occur because of congenitally defective superficial veins and are 3 times more common than secondary VV (Rooke, 2007). Secondary VV occur after DVT that has produced deep valvular incompetence and are clinically acknowledged as 'venous insufficiency'.

Venous thromboembolism: Venous thromboembolism (VTE) is a condition in which the emboli and the thrombi clots causes blockage in the blood vessels. While emboli can migrate and block the vessels, the thrombi clots blocks at the site of formation. Blood clots in deep veins are clinically addressed as Deep Veins thrombosis (DVT).

Venous ulcer: Venous ulcer is a painful wound developed due to improper functioning of the venous valves. Venous leg ulcers shares the major part in the development of ulcers in legs accounting to about 70% (Phillips and Dover, 1991) as given in Figure 2-6. The ulceration was high on left leg than the right leg (Baker et al., 1991) in addition the number of episodes of ulceration and duration of ulcer diathesis was 31.11% and 33.82% respectively for more than 10 years. Recurrence of venous ulcer is noted to be high as 36% by 5 years in 300 patients (Nelson et al., 2006) and healing rate is 20 times greater in patients who do comply with the use of stockings (Moffatt et al., 2009).

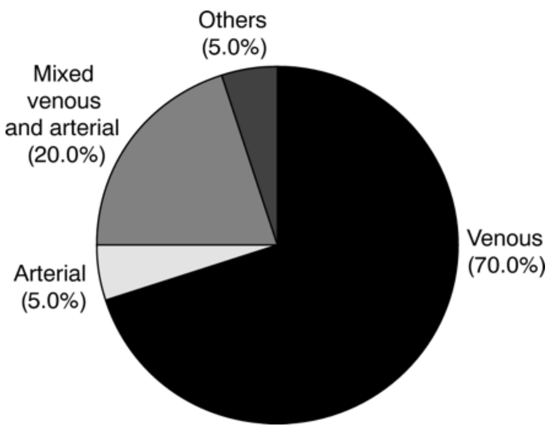


Figure 2-6 Pie diagram representing percentage shares of venous ulcers (Phillips and Dover, 1991)

The epidemiology, pathophysiology, clinical presentation, diagnostic assessment, and current therapeutic options for chronic venous insufficiency and venous ulceration were discussed by

Valencia et al., (2001). Compression stockings are also used to prevent reoccurrence of venous ulcers. The action of compression force on the superficial vein, deep veins, muscle-tissue compartment and thrombosis is discussed in many papers (Nicolaides, 2000, Bradley, 2001, Tan et al., 2006, Palfreyman and Michaels, 2009). Compression therapy mainly compresses the veins reducing their diameter (Morris and Woodcock, 2004) and thereby increasing the blood flow rate (Tan et al., 2006) see section 2.8.1 for the mechanism of action of compression stockings.

Pathophysiology: With the discussion on venous disorders the pathophysiology which deals with the genesis of disorder is discussed under this heading. Hippocrates was the first to deal with the pathogenesis and epidemiology of venous insufficiency and venous ulcers (Alberto, 2006, Choucair and Phillips, 1998). Valencia et al., (2001) explained the path physiological mechanism in of the venous hypertension as given in Figure 2-7 is either due to Dysfunction of the valves (label-A, in the superficial veins, deep veins or perforating veins), venous thrombosis (label-B, blood clots or emboli), Deep venous obstruction or Muscle dysfunction (label-C, calf muscle pump failure) (Valencia et al., 2001).

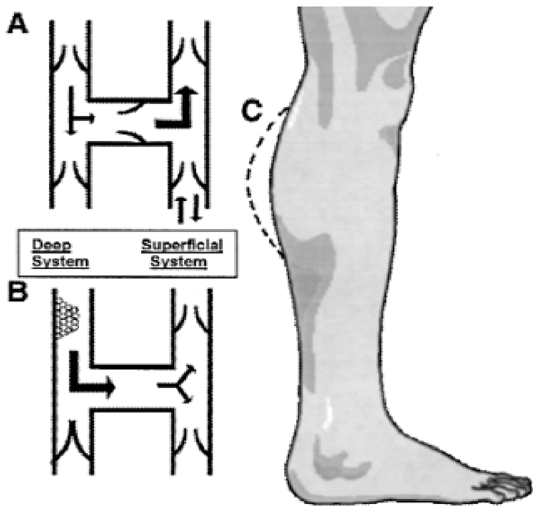


Figure 2-7 Pathophysiology of venous disorder (Valencia et al., 2001)

2.3.1 Range of motion at ankle in patients

It is clear with the understanding of venous physiology and pathophysiology of venous disorder that guided leg exercise which helps to function the calf muscles shall have a substantial impact on venous blood flow and healing of venous leg ulceration (Heinen et al., 2004).The functioning of the calf pump is major determinant to propel the venous blood towards the heart and its action is controlled by leg pump action as discussed in section 2.2.3. On this note, on contrary to the desired performance of calf muscle, previous researchers noticed that patients suffering from venous disorder have a limited range of motion (ROM) (total angle of flexion) at ankle and it further decreases with the increase in the severity of the disorder (Back and Padberg, 1995, Roaldsen, 2009). Moreover, the reduced ROM further increases the chance of calf muscle failure and effective functioning of the stockings on venous blood flow. Thus, it important to improve the calf muscle action by improved ROM at ankle.

2.3.2 Risk of developing venous disorder and associated key risk factors

Chronic venous disorders are an important cause of disability that is widespread in the industrialized countries. Moreover, the health care demand is massive, in France it is ranked as the seventh most often declared reason for consulting a general practitioner (Carpentier et al., 2004). Since it's a common disorder it is essential to note the risk factors involved in its development.

Though with evolution, man has evolved from being tetra pedal to bi pedal but the human physiology has not completely adapted as our species still have the tendency of developing back pain, hemorrhoids, and venous statis (Sumner, 1981). Venous insufficiency are only limited to human beings (Burkitt, 1972). In addition to this only in man calf is located in proximal end far from heart. In contrast all other animals with calf located up in leg, so high that the blood can easily move in horizontal passion into trunk; only in humans venous blood needs to be pushed though a sufficient height (Hohlbaum, 1989). However, in tetra pedal taller mammals like giraffe, have thick fascial layers and impermeable capillaries acting as antigravity suit (Goldman et al., 2001). With the modern western diet and sedentary lifestyle the incidence of varicose veins is increasing. Some of the influential risk factors in the development of CVI are summarized in Table 2-1

Table 2-1 Risk factors for developing varicose veins

Risk factors	Clinical explanation
Aging	90% of the patients where know to have venous disorder. With age the elasticity of the veins is lost (Naoum et al., 2007, Sansilvestri-Morel et al., 2001). However, age related prevalence was not found in a study by Baker et al., (1991).
Genetics	Family members with deep vein thrombosis or varicose veins are known to carry the traits in genes (Naoum et al., 2007)
Gender	Female hormones help in relaxing veins walls (Beebe-Dimmer et al., 2005). The prevalence in women is high (Naoum et al., 2007) due to hormonal changes in women during premenstruation, menopause are possible causes
Diet	Fecal arrest which is the result of a low-residue diet (Burkitt, 1972) . and nature of diet (Malhotra, 1972)
Occupational posture	Leg swelling after regularly sitting or standing for prolonged periods of time in addition the vein is put into considerable fatigue (Cario-Toumaniantz et al., 2007).
Obesity	With the obesity the fat deposition in the veins increases and as result the resilience in veins are lost and more pressure is put on (Beebe-Dimmer et al., 2005) .
Smoking	Smoking impairs endothelium-dependent relaxation of saphenous vein, impairment may increase vasomotor tone, platelet aggregation and smooth muscle proliferation (Higman et al., 1993)
Physical inactivity	With the decrease in the stretching activity the muscle and veins are known to lose its instinct characteristics of contraction and relaxation

In addition there are some more factors that not well documented (Beebe-Dimmer et al., 2005). Also, clothing constriction is also known to be an important factor (Burkitt, 1972). Beebe-Dimmer et al (2005) have reviewed the risk factors leading to the development of venous disorder from related scientific publications starting 1942 to 2005.

2.3.3 Socioeconomic problem posed by venous disorder

Venous insufficiency of lower extremity (leg) is a common condition presented to physicians in Western Europe and the United States (Beebe-Dimmer et al., 2005, Carpentier et al., 2004) and poses high rate of socioeconomic impact with reduced morbidity problem in patients. The socio economic problem posed by venous disorder is justified by its high prevalence among the masses, cost incurred to treat and total number of loss of effective working hours in patients (diagnosed with venous disorder) as explained below.

1. **High prevalence of the disorder**

The prevalence of the venous ulcer and disorder was high as 0.62 per 1000 population in western Australia (Baker et al., 1991). The prevalence of the venous disorder vary with geographical location, however some authors disagree to this statement (Carpentier et al., 2004). The estimated lifetime prevalence of leg ulceration in developed countries is 1% and the point prevalence is 0.1-0.2% (Ruckley, 1997). The prevalence of VV are higher for female with more than 1% to 73% and 2% to 56% in men (Beebe-Dimmer et al., 2005). Although in women the prevalence is higher than men by 1.5 to 2 times (Evans et al., 1999), the symptoms in men and women were not statically different. 3 to 33 % of human beings are proved to have edema and skin discoloration or pigmentation due to CVI. 0.3 % of adult population in western countries is known to have this disorder.

2. **Cost of investigation and treatment period**

The annual reoccurrence of CVI is projected to be between 6 and 15 %. 400 to 600 million Euros and more than 1 billion dollars are spent for the treatment in UK and US respectively(Moore and

Cowman, 2005). Due to its chronic nature it can only be managed but not cured. The UK Healthcare Commission has estimated that currently leg ulcer care costs the NHS £300-600m (€330-661m, $447-895m) a year (O'Meara et al., 2009).

3. **Loss of working days**

12.5 % of patience opted for early retirement due to disability and loss of pay. Besides disability with altered quality of life, it leads to cosmetic problem too; affecting the well- being of patients' worldwide (Phillips et al., 1994).

2.4 MODALITIES OF COMPRESSION THERAPY

In the previous sections the venous blood flow, venous insufficiency along with the risk factors and socioeconomic problems were discussed, in this section the modalities of compression therapy followed to control venous insufficiency is discussed. Compression therapy is a conservative treatment method followed for over two thousand year or more (Amsler and Blättler, 2008). Initially it was practiced for non scientific reason as Henry De Mondeville in 13th century conveyed that "compression expels bad humors that infiltrated legs and ulcer". Sir Astley Paston Cooper, in 1824 confirmed the therapy by stating that the venous valves regain their competence with compression therapy (Caggiati and Allegra, 2007).

The modalities of the compression therapy are elastic compression stockings, short stretch bandages and plaster bandages and compression pumps (Choucair and Phillips, 1998, Ramalet, 2002). However, compression stockings are superior to bandages as their application rule out the necessity of nurses to apply/reapply, economical and effective (Choucair and Phillips, 1998).

Table 2-2 Modalities of compression therapy

Criteria	Elastic compression stockings	Short stretch bandages	Plaster bandages
Stretch properties	Long stretch ability	Short stretch even with multi layer	Unna boot and Velcro band devices
Classification	-ready made (usually circular knitted) custom-made(flat knitted, sometimes circular knitted)	Short Medium Long stretch	-
Extensibility	Greater than 100%	Ranges from 70 to 140%	-
Stiffness	Low	Medium	High
Mechanism	Exerts pressure on stretch	Ambulatory pressure i.e. with muscle movement	Ambulatory pressure i.e. with muscle movement

Table 2-2, gives the detailed description of each of the modalities of compression therapy. The streachability, classification and mechanism of action of the each of the modality are compared and are presented in the table. Elastic compression stockings have elasticity higher than 100% so that they can be stretched with power and applied over disfigured leg. To suit special cases with disfigured leg with bulged calf, custom made stockings mostly knitted on flat bed knitting machine are advised. Since, the stockings are elastic the stiffness of the stockings fabric is relatively lesser than the bandages. Stockings are applied in both ambulatory and bed ridden patients. However physicians advice the patients to remove the stockings at the end of the day before going to bed as the undue resting pressure can occlude the blood flow in supine posture.

2.5 PHYSICS OF COMPRESSION PRESSURE ACTING ON HUMUN LEG AND PRESSURE MEASUREMENT METHOD

Having discussed the modalities of compression therapy, the physics of compression stockings which act by applying external mechanical force on the blood vessels is discussed in this section. The compression pressure from stockings is the external mechanical force acting on the body parts and is dependent on the geometrical shape of the applied area and the material properties of the stockings fabric. The external force applied can be either concentric or eccentric in nature.

Concentric compression- the pressure is applied in a circular fashion with the uniform elastic tension and the pressure is irregular depending upon the radius of curvature explained in the below.

Eccentric compression- basically the elastic tension is not concentric and the pressure is determined by the surface profile. The pressure can be negative or positive in nature based on the Laplace equation see Equation 2-1.

The magnitude of pressure is given by the Laplace's law

$$P = \frac{T}{R} \text{ mm Hg} \qquad \text{Equation 2-1}$$

Where, P-Pressure, T-tension of the material and R-radius of curvature.

The eccentric pressure principle is demonstrated in Figure 2-8.

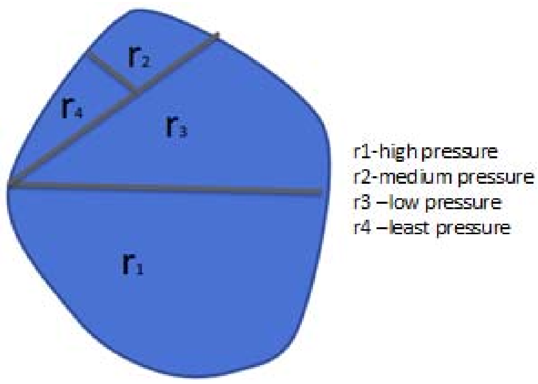


Figure 2-8 Eccentric pressure (Partsch et al., 2000)

The positive eccentric pressure increases the local pressure with the reduction of the radius of curvature. Negative eccentric pressure is applied to reduce the concentric pressure with the use of pad to increase the radius of curvature as presented in Figure 2-9.

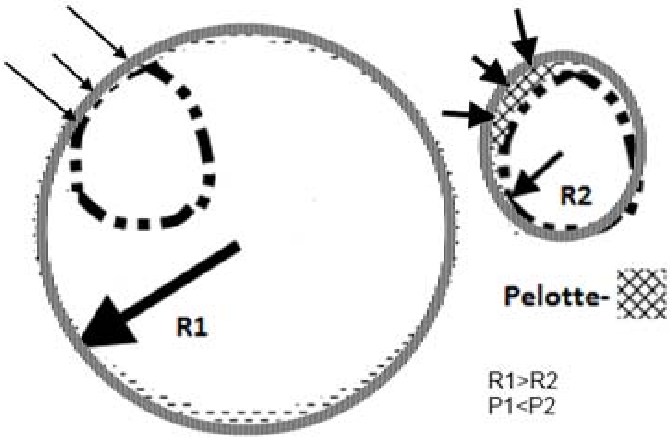


Figure 2-9 Pressure distribution at different radius of curvature based on Laplace law

Compression therapy is applied in the medical field under different modalities (see section 2.4) to treat the venous and thromboembolism (discussed in section 2.3). The pressure is applied on to tissue from the compression device and the pressure from the tissue is transferred from tissue to the blood and lymph vessels. While this forces act as external force, the internal pressure is applied to blood vessels by the action of calf muscles in legs and also the extension recovery of the elastic material with the calf muscle expansion adds up the external pressure on to skin.

Due to the elliptical nature of the ankle portion, the pressure at ankle is not uniform and usually less (Veraart et al., 2008). Hence, pelotte, pads rolls and specially designed devices are used to locally increase the pressure, whose method of action is demonstrated in Figure 2-9. With the use of pelotte, the radius of curvature is reduced due to which higher pressure is delivered according to Laplace law given in Equation 2.1 lesser the radius of curvature higher is the pressure applied.

Stockings can apply the pressure in resting and working phase as discussed below:

Resting pressure (contract pressure): Stockings are built with a reduction factor to and force is applied configure and conform to the body part. The stored elastic force in stockings acts on the body at rest. This force on unit area is referred as the resting pressure. The magnitude of the pressure depends upon the reduction factor considered while manufacturing the stockings (see section 2.6.3) and is directly proportional to the reduction factor. Resting pressure normally acts on superficial vessels.

Working pressure: Working pressure is the pressure resulting by the periodic expansion and relaxation of the stockings material with the functioning of the calf muscle. This pressure considerably affects the deeper tissue infiltration and is a function of the volume increase due to muscle contraction.

The compression pressure was not studied until the latter half of the 20th century. Un till, Van Der Molen who laid the foundation in 1955 for pressure measurement, the pressure was only estimated by the degree of the edema reduction, he also proposed the graduated elastic compression (Choucair and Phillips, 1998). Later dynamometers were used to measure the force; which was converted to pressure values. However, this was a destructive test and follow-up of the controls was not possible. In the due time, non destructive methods were made available.

In direct method, the pressure is read directly underneath the fabric, this is simple and economical method to evaluate the pressure delivered by stockings. The data obtained are only an approximation as the volume of the pressure receptor affects the radius of the curvature.

The specific requirements of the sensor for direct measurement method (Partsch et al., 2006a) are

i. Lowest possible volume of the pressure receptor
ii. Plain shaped with no bulge
iii. Easy handling
iv. Simultaneous pressure measurement at different points.

2.6 COMPRESSION STOCKINGS

In this section the classification of the stockings, functional and textile attributes of compression stockings along with the designing and manufacturing process are discussed.

2.6.1 Classification of compression stockings

Compression stockings also referred as compression hosiery are classified based on their application with respect to patients condition (recumbent and ambulatory) and also based on the functioning either to control embolism or venous disorder as Anti embolic stockings (AES) and Graduated Compression Stockings (GCS) by British Standard (Standards, 1985). AES also referred as flight stockings (Phillips and Dover, 1991).

AES are often used by recumbent patients (Partsch and Mosti, 2008) with competent valves while, GCS is prescribed to ambulatory patients. AES (low pressure) are often available without prescription whereas GCS (high pressure) are medically prescribed by a physician based on the complication and symptoms of CVI.

GCS are classified into 4 classes on the basis of pressure delivered at the ankle region (B region-minimum girth at the ankle) (Philip D, 2006).

These stockings are different from the non medical hosiery used as a fashion wear, support stockings. However, Ingram et al (2003) in their study referred AES to be GCS, as the pressure profile in both of them is graduated see section 2.7. In this study compression stocking is used to refer both types of stockings to avoid confusion. They can be of different styles (thigh high, knee high) see section 2.7.2 and in different countries different standards adhere to different pressure magnitude, pressure profile, the testing method to designate the pressure imposed by the stockings (Partsch, 2004) see Table 2-3.

2.6.2 Pressure magnitudes for commercial stockings advised in different standards

Based on the severity of the venous disorder in patients assessed by CEAP (Clinical Etiologic Anatomic and Pathophysiologic) classification method, different class of compression stockings are prescribed by physicians to counteract the disorder. However, the pressure standard range in different countries for the stockings is different. The standards followed in five different countries such as UK, USA, France, Germany and European region based on the pressure delivered at ankle (B level) are presented in Table 2-3. In each of the standard the pressure range for different compression class is different. It is noted that the upper pressure limit is not given for Class IV stockings except in UK and USA standards. Moreover, the testing methods followed to evaluate the pressure delivered by these stockings are different for each of the standards. The common method to test the stockings is on the leg mannequin with an ankle girth of 21 cm for pressure measurement (Veraart et al., 2008).

Table 2-3 Standard Pressure magnitudes as per different standards (Partsch, 2004)

Compression class	CEN(ENV12718; 2001)	UK(BS 6612)	USA	France(ASQUAL)	Germany (RAL-GZ 387,2008)
AES	10-14	-	-	-	10-14
Class I	15-21 (mild)	14-17(light)	15-20(moderate)	10-15	18-21(light)
Class II	23-32 (moderate)	18-24(medium)	20-30(firm)	15-20	23-32(medium)
Class III	34-46 (strong)	25-35(strong)	30-40(extra firm)	20-36	34-46(strong)
Class IV	More than 49 (very strong)	NA	NA	More than 36	More than 49 (very strong)
Testing method	-	HATRA	-	IFTH	HOSY

2.6.3 Basic designing and manufacturing process of compression stockings

Stockings with suitable pressure profile see section 2.7 can be build by following the standard procedure of designing compression stockings. The manufacturing of compression stockings mainly involves the following five stages yarn covering, knitting, sewing and boarding explained in below sub sections:

1. **Yarn covering**

The mechanical means of applying force by compression stockings is possible with the use of elastic fibers (elastane/spandex or elastodiane/rubber) which elongate under the influence of stress (force/unit area). Stiffness of the elastic material decides the compression force. The yarn covering improves the hand feel and comfort property of the compression stockings. Some of the method of yarn covering is given in Table 2-4. In this process the elastic yarn is covered either by natural fibers (cotton, wool) or synthetic material (nylon). The yarn covering certainly helps to protect the elastic yarn from breaking. While yarn covering is required for the stitching yarn in the stockings fabric, the inlay yarns (non stitching yarn in the fabric) with spandex or rubber yarn are used without any covering. The minimum linear density of the inlay filament is 156 dtex (Neumann, 1998).

Table 2-4 Types of yarn covering

Yarn covering method	Description
Single covering	Wrapping minimum of spiral of non-elastic thread around one elastic core
Double covering	Wrapping minimum 2 spirals of non elastic threads in opposite directions around an elastic core
Stitch covering	Knitting a chain stitch of minimum one non elastic yarn around on elastic core
Core spinning	Spinning staple fibers around an elastic core
Air twisting	Covering an elastic core with a non elastic yarn

i. Classification of multi component yarn

Multi component yarn can be divided into two class elastic soft yarn with elastic core such as elastane, spandex, SMP and non elastic hard core with non elastic yarn such as nylon, polyester. With the inclusion of shape memory filaments in the class of electrometric fibers the above method of classification need to be revised to soft yarns with recoverable shape as a result of shape memory effect.

ii. Advantages of core spun yarn

Elastic core spun have many advantages when compared to spun and synthetic yarns. The elasticity of the natural fibers is improved considerable by using elastic core filament while retaining the feel with good moisture absorption by sheath fibers. Natural fibers such as cotton, linen, silk and wool are used as sheath and manmade fibers such as nylon, polyester, acrylic and spandex as core filament. Due to protection of core filament by sheath fibers the core yarns cannot wear easily. Besides that the yarn has better anchorage in hosiery with reduced slippage.

Thus the final elastic core yarn can be of varying styles, hands, and functions which are applied in woven or knitted fabrics depending on needs. Core spun yarns are used to improve the strength, elongation at break, durability, abrasion resistance, knit ability and functional properties of the composite yarns. Bi-component yarns with elastic core are most preferred and once covered; the yarns must rest for at least two weeks in order to stabilize.

iii. Method of producing filament core spun yarn

Core spinning is different from the normal spinning of yarns as in this the machines parts have to control the staple fibers and also the filament which forms the core. In general elastic fibers with 22, 44, 70 and 150 decitex are used as filament. However in some special application as in high strength compression hosiery filaments of 420 decitex are used.

Core yarns can be manufactured on different spinning machines such as ring, friction, air jet and rotor. Amongst all these method, modified ring spinning is commercialized and easy to process on the available ring spinning machine with minor settings and changes (Sawhney et al., 1990).

Core yarns are produced using two roving's as sheaths which are drafted in parallel in the drafting zone. The elastic filament is then introduced in the front pair of drafting rollers by means of additional V grooved roller. Filament pre tension needs to be measured during yarn production; twisting and insertion of the filament thus take place in one process step. The v grooved guiding roller placed on roller weighting arm to the drafting zone of the front roller must be stable and perfectly parallel to the space between the roving being fed. The V grooved roller is made to move with the front top roller in order to prevent the additional frictional force between the filament and feeding device.

The attributes of the core yarn are its high strength, smooth surface and round yarn cross-section. While spinning care should be taken to feed the core to the centre of the drafting zone. Considerable research has being carried out in the area of core filament yarn spinning (Sawhney et al., 1990, Su et al., 2004). The previous research work illustrates the growth in the field of core spun yarns and the parameters influencing the final core yarn properties. The application of shape memory fiber as core to obtain yarn of greater elongation, tenacity with good shape recovery property is not studied. Moreover, it can find its application in multiple areas as in sportswear, leisure, industrial and medical textiles.

2. Knitting of compression stockings

The elasticated yarns so produced are fed into knitting machine either circular or flat knit machine. Three knit types are used to knit compression stockings and knitting stitches are given in Figure 2-10.

- Double faced flat knitted with seam and inlay yarn
- Single faced circular knitted with inlay
- And single or double faced without inlay

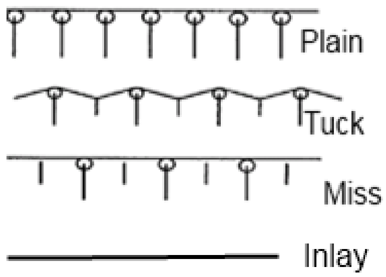


Figure 2-10 knitting stitches used in construct stockings fabric

Complete hose can be knit on a circular machine with a reduction factor (difference in the stockings girth to leg girth) of 20- 25% (Macintyre et al., 2004), while in flat machines only knitted fabric is obtained. The stitches in the knitted structure are usually with the combination of miss, tuck or float with inlay yarn as shown in Figure 2-10. The elasticity of the circular knit stockings is limited and is difficult to apply. In flat knitted, every second stitch in row is knitted with inlaid yarn (bare elastic yarn) and with covered yarn. The bare yarn can be spandex or rubber, usually for class III and class IV, rubber is used. Flat knitted stockings are custom made after taking leg measurement for disfigured legs.

3. **Sewing of compression stockings**

Sewing is necessary to configure the hosiery with toe closing and heel pocket. The top elastic welts are hem sewed. The flat knit fabric is stitched with a garment reduction factor to deliver pressure. The skill of the sewer decides the solidity in the final hosiery as it's difficult to sew elastic knitted material on a sewing machine with suitable elastic yarn.

4. **Boarding of compression stockings**

The method of developing different pressure at different portion of the stockings is achieved either by knitting with variation in stitch density, length of course yarn fed and yarn linear density. However, this involves complex knitting procedures; the method is simplified by heat setting the stockings on boarding machine and subjecting it to preselected thermal condition, different for different parts. The temperature applied depends on the yarn count, fiber content and fabric construction.

Furthermore, in the previous stages of manufacturing process, the elasticized yarns in the hosiery are stretched and relaxed to different extent. This often leads to improper sizing and disfiguration. Boarding process is carried out to stabilize the yarn and configure the knitted fabric to the desired configuration as given in Figure 2-11.

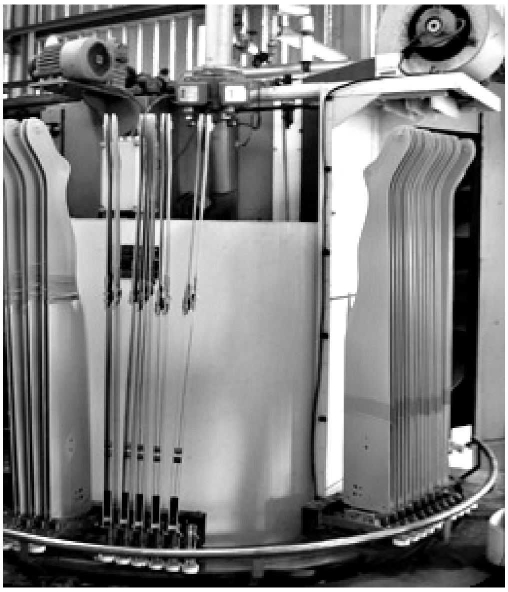


Figure 2-11 Boarding machines for stockings (International, 2009)

2.6.4 Types of stockings based on mechanical stretch ability

Compression stockings are classified based on their mechanical stretch ability as:

One way stretch stockings- these are heavy stockings with lease stretch ability and are only available in made to measure.

Two way stretch stockings- these stockings are stretchable in both horizontal and vertical directions and easier to put and take off.

Net stockings- These stockings are support stockings and cut out from net fabric and seamed to stockings they are usually warp knitted.

2.6.5 Mechanical and functional attributes of compression stockings

Fabric mechanical properties play an important role in generating effective pressure on the leg for optimal clinical results by improving the hemodynamics of the venous blood flow. Elastic compression or knitted garments are characterized by their ability to elongate easily under the influence of force and below mechanical attributes are used to define the stockings stretch ability and performance for which the numerical values are given in second row in Table 2-2.

Stiffness: The elasticity of a compression device may be characterized by its stiffness. In the European standard for medical compression hosiery (CEN), stiffness is defined as the increase in pressure per 1 cm increase in leg circumference (Comité Européen de Normalisation, 2001).

Elasticity: Extensibility or elasticity refers to increase in dimension of the stockings material when it is stretched, also its ability to recoil to its normal shape and size when the force is removed. Elastic fibers used, textured yarns renders the stockings material to be elastic.

Fatigue: With usage and number of elongation and recovery cycles the fabric loses its ability to recoil to normal shape and size. With washing the fabric can regain a quantity of the lost elasticity. However, with the time stockings loss its strength and is referred as fabric resilience given by the hysteresis curve.

Wear resistance: the ability to withstand the mechanical and thermal energy during wash and wear decides the wear resistance. The production technique of the yarns and the type of filament used in the construction of the stockings decides its wear resistance.

2.7 PRECARIOUSNESS IN PRESSURE PROFILE, PRESSURE MAGNITUDE AND STOCKINGS STYLE

With the discussion on the manufacturing process of compression stockings in the previous section, in this section the precariousness in the pressure magnitude and profile in stockings is presented in detail. The skin stockings pressure from ankle to welt (stocking band) is referred as pressure profile. Although, stockings are designed with maximum pressure at the ankle and gradually reducing towards the hip it is obvious that the compression pressure on skin is always high along the skin-stockings line.

The venous pressure can drastically rise with the malfunctioning of the venous valves (see Figure 2-5), in order to counteract this increased pressure higher pressure needs to be applied at the ankle. The pressure imposed on the skin by the stockings material can be effective in relieving the symptoms of venous and lymphatic disorder only if the pressure is graduated from the ankle to the groin region (Amsler and Blättler, 2008). Therefore, the pressure profiles need to be parallel to the increase in intravenous venous pressure of blood in leg below the phlebostatic level (see Figure 2-2). Moreover, the leg configuration is such with low girth at ankle and high girth at calf graduated pressure is obviously delivered based on the Laplace equation.

Although, the CEN and German standard follows the forwardly graduated pressure profile (maximum pressure at ankle and pressure reduces towards the proximal end) as shown in Table 2-5, principle of pressure profile in compression stockings is found to be varied. As in contrast to forwardly graduated pressure profile; to suit the physiology of athletes (with developed calf muscle) compression stockings with downward digressive are advised (Becker et al., 2006) i.e., pressure in middle proximal end is higher than that of ankle. Moreover the efficacy of the stockings is related to the changes in calf compression even if ankle pressure is kept constant (Sparrow et al., 1995).

Class I		Class II		Class III		Class IV	
CEN	German	CEN	German	CEN	German	CEN	German
30-60	20-60	20-50	20-50	20-40	20-40	20-40	20-40
60-80	50-80	60-80	50-80	50-70	50-70	50-70	50-70
80-100	70-100	80-100	70-100	80-100	70-100	80-100	70-100
100	100	100	100	100	100	100	100

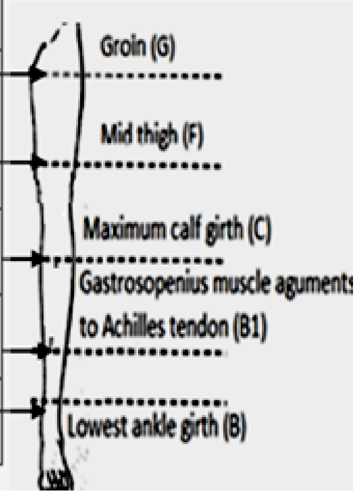


Table 2-5 Pressure profile of stockings as per CEN and German Standard for GCS

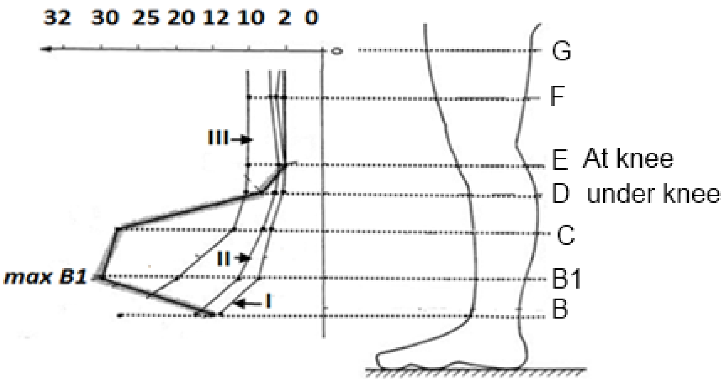


Figure 2-12 Pressure profile as per Patent from B.Francois (Becker et al., 2006)

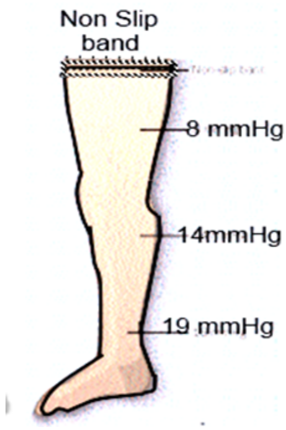


Figure 2-13 Pressure gradient for AES (Collier, 1999)

The difference in the pressure profile in stockings is due to the uncertainty in the mechanism of action of compression stockings; forwardly digressive pressure with uniform horizontal pressure is based on the fact that the intravenous pressure is digressive from ankle to calf to thigh (Simmons, 1968). However in downwardly, digressive profile, the action compression stockings are based on its efficiency to act as muscolo-aponeurotic pump of the calf with maximum pressure in the calf region (Sparrow et al., 1995). The pressure profile for AES is given in Figure 2-13 for thigh high stockings and the pressure at the popliteal region on popliteal vein (see) for AES is only 8 mm Hg (Collier, 1999).

Although, there are differences in the pressure profile standards, in market most of the commercial stockings are forwardly graduated and common ground in both principles (forwardly and downwardly digressive pressure profile) is that the tourniquet effect below the knee should be avoided, as its opposes the blood flow.

2.7.1 Dispute on effective pressure and its profile in compression stockings for maximized physiological function

Sigel et al., (1973) showed a pressure profile of 18mmHg at ankle and 6.5 mmHg at the upper thigh in thigh high knitted stockings significantly improved the femoral blood velocity around 30 % in recumbent state and the blood velocity was maintained for up to 30 min even after the removal of compression pressure. Tan et al., (2006) demonstrated that the application of compression stockings increased the mean velocity in the popliteal vein by 38.7% but produced only a slight statistically insignificant increase in velocity in the femoral vein and no particular stocking profile was superior. Thus, the medical functioning of the stockings is clear however, even to this date there is uncertainty on the pressure magnitude and profile as stated in the following paragraphs.

The magnitude of pressure is known to influence the rate of recovery in patients with venous disorder. Amsler and Blättler, (2008) in their meta analysis concluded that stockings with pressure of 10-20 mm Hg can be effective; while lower ankle pressure is ineffective and higher pressure did not produced better results. Blair et al., (1988) showed that the lower compression did not heal the venous ulcer for months and high pressure of 40 mm Hg rapidly healed the ulcer. Nevertheless, 30 mm Hg of compression pressure is shown to produce tourniquet effect thereby adding to the reflux venous blood flow. Studies have shown that that there is a pressure limit up to which there was improvement in blood velocity with compression but after exceeding this limit the pressure would reduce the blood flow (Sigel et al., 1973). Although, higher class of compression stockings (class 3 and 4) are recommended for worse condition, low compression stockings (15-30 mm Hg) are equally effective as high compression stockings and are more comfortable (Shouler and Runchman, 1989).

Amsler and Blattler (2008) in their meta analysis concluded that no study showed a difference between 10-20 and >20 mmHg stockings. Lightweight (low compression) gradient compression hosiery was very effective in improving symptoms of discomfort, swelling, fatigue, as well as leg tightness and the difference between the 8–15 mmHg and 15–20 mmHg compression was not statistically significant (Weiss and Duffy, 1999). Even to this date there is a debate on the pressure magnitude needed for clinical benefit (Bradley, 2001, Amsler and Blättler, 2008), majority of the studies clearly demonstrates that light compression stockings with low pressure can be effective to heal treat the venous disorder effectively and are widely acceptable by patients.

2.7.2 Knee high Vs thigh high compression stockings

Lawrence and Kakkar (1980) found no increase in deep venous blood flow velocity with application of thigh high compression of 18-8 mm Hg over below knee compression with 18-14 mm Hg. Agu et al.,(1999) in their review on the mechanism of compression stockings concluded that knee high stockings are effective and they should replace the above knee high stockings as complications are rare and avoidable. Knee length graduated compression stockings are similarly efficient in decreasing venous stasis, but they are more comfortable to wear, and they wrinkle less (Benkö et al., 2001). The stockings need to be applied for entire day rather than just half day as it has better results (Belczak et al., 2010). Therefore, physicians widely suggest knee high compression stockings to patients has the level of the compliance is high in them. In addition the medical functioning of the knee high compression stockings is as effective as thigh high compression stockings.

2.8 THE MECHANISM OF ACTION OF COMPRESSION THERAPY

The uncertainties in the pressure profile of compression stockings are discussed in previous section. It is necessary to investigate the mechanism of action of compression therapy so that suitable conclusion can be drawn and necessary improvement can be made based on the analysis.

Stockings constrict the dilated vein so that the venous valves are able to align with each other and mechanically prevent the distension of veins (Morris and Woodcock, 2004) and assists in uni-directional flow of blood. The possible mechanism of action of the stockings is by improving the venous valve function by occlusion of veins walls (Agu et al., 1999) and is represented in Figure 2-14.

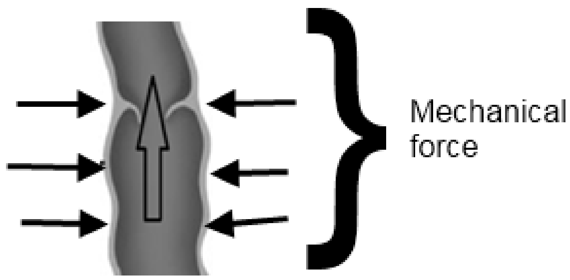


Figure 2-14 Mechanism of action of compression therapy on veins

With the reduction in vein diameter, the blood velocity increases. Furthermore, the viscosity and the velocity of the blood are inversely related and as a result the blood flows at faster rate with reduced diameter, blood becomes less viscous preventing DVT. They limit the extensibility of the venous wall and with the yielding power of the venous walls the blood moves in the forward direction. Moreover, the soft tissues and the tissue fluid are incompressible, there by the mechanical pressure from the stocking affects the permeability of the fluid in tissue and capillaries (Hafner et al., 2001). With the application of the external mechanical force on the skin the superficial and deep veins are compressed. Nevertheless, stockings do not propel the blood in upward direction; they assist by compressing veins. In addition the edema is also controlled with the application of external pressure (van Geest et al., 2000). Thus the disfigured leg can even be configured to proper shape.

As the calf muscles rises and works against the stockings and when it is relaxed the stockings works against the leg. Becker et al., (2006) suggested highest pressure at B1 region as the stockings effectiveness in compressing is to augment the muscolo-aponeuortic pump of the calf All the above mechanism may be collaterally working to prevent the blood reflux. Partsch et al., (1992) have shown the action of intermittent pressure acting as artificial valve is the effective mechanism of action of inelastic compression. The effect of compression is profound on the superficial veins and deep vein in the static and dynamic phase of stockings fabric respectively.

2.8.1 Action of exercise and ankle flexion on venous blood flow

The important mechanism of action of compression stockings or bandages on the venous blood flow is by the action of leg and foot muscles. The venous pumping system inclusive of foot and leg was given in section 2.2.1; as the leg pump acts on the stockings material and the material acts against the distension in the venous blood vessels the venous blood flow is increased. The functioning of the compression therapy is beneficial in patients with ambulation (movement). The calf muscle functioning is important factor in improving the venous pump (Becker et al., 2006)

The dysfunction of the calf muscle and reduced range of motion of at ankle in patients (Back and Padberg, 1995) further aggravates the venous disorder. Calf muscle dysfunction is a recognized factor in Chronic venous Insufficiency (Choucair and Phillips, 1998) and calf muscle functioning influences the ejection fraction(EF) and residual volume fraction(RVF) measured using plethysmography (Back and Padberg, 1995).

Dix et al., (2003) correlated the reduced ankle movement with that of the venous disorder in their study on 38 adults with 11 in control group, 12 patients in each group with Varicose veins, Chronic venous Insufficiency and active ulcer. Roaldsen's, (2009) doctoral research work on the physical activity on patients with venous ulcer it was suspected that the compression bandages and the walking shoes forms the external factors leading to reduced physical activity in patients and influences the venous disorder. Thus, in addition to compression therapy, ankle flexion and exercise has influential effect to heal venous disorder. Moreover, the effect of compression stockings on ROM is not discussed in literature.

2.8.2 The influence of heat on venous blood flow

Wertheim et al.,(1999) conducted preliminary investigation on the mechanism of action of compression stockings and posted their letter to the editor in chief of British Medical Journal describing the results on variation of skin temperature after wearing stockings. The skin temperature had increased by a median of 0.5 degree Celsius with a range of 0.3 to 0.6 Degree Celsius in 5 out of 6 volunteers and the pressure delivered by the stockings at calf was 16 with a range of 6-25 mm Hg (Wertheim D, 1999). They suggested the increase in skin temperature with the application of stockings can influence the hemodynamic of skin blood flow.

Cherry and Wilson (1999) suggested a warming regimen using Warm-Up wound therapy to treat venous ulcers, which could be easily used by patients in their home or work environment. A warming dressing with 38 degrees Celsius for 1 hour three times daily resulted in marked increase in granulation tissue as well as a decrease in pain one out of 5 patients. Venous ulcer in four of the five patients completely healed during the 12-week period.

Published clinical trial (Robinson and Santilli, 1998) and case report (Cherry and Wilson, 1999) support the effectiveness of the Warm-Up wound therapy applied to speed up the healing process in patients with pressure and venous insufficiency ulcers. Thus, the effect of temperature on venous ulcer and venous statis is prominent as demonstrated from the above stated clinical study.

2.8.3 Placebo effect of commercial stockings

In contrast to above mechanisms of action of compression stockings, some researchers have shown that the effect of stockings is known to be of placebo. Christopoulos et al.,(1987) found that the compression pressure did not produce any significant results on the ambulatory venous pressure and venous refill time in both control and affected groups. The same results were obtained by Mayberry et al., (1991). Henceforth, the working principle of compression stockings to heal the venous disorder is considered to be placebo. One study found 6 mmHg also effective to relieve venous symptoms on 125 females in a randomized trial as summarized by Partsch (2004).

Moreover, there is insufficient proof on the standard level of pressure needed to improve the venous velocity as some researchers estimate a low pressure can effectively control edema and venous insufficiency while, other tend to suggest high pressure of 30-40 mm Hg for better effects (see section 2.7).

2.9 COMPLIANCE ISSUES ASSOCIATED WITH THE APPLICATION OF COMPRESSION STOCKINGS

The action of compression stockings can be a placebo or by the action of mechanical force delivered by the elastic fabric as discussed in section 2.8. Even though compression stockings are relatively sage on their influence to heal CVI, they are not free from risk (Agu et al., 1999). Variation in the leg circumference can vary the amount of pressure delivered on to the leg. A leg circumference of 5 cm can double the amount of pressure being applied (Horner et al., 1980). Moreover, foot has little subcutaneous tissue to protect it from excessive pressure damage. Sites of pressure damage were reviewed by Moffatt (2007) and is shown in Figure 2-15.

Figure 2-15 Sites at risk of pressure damage on leg from stockings [redrawn from (Moffatt, 2007)]

Issues in the designing of compression stockings-The pressure in varied from the ankle to the calf; adding to this the pressure sensation of the stockings is high at different regions of leg namely, bunion, dorsal tendon, archiles tendon and tibial crest as represented in the Figure 2-15.

The pressure is usually not maintained throughout its use and also the non compliance in patients is high as many complications are associated with the improper usage of compression stockings in patients with venous disorder. This has led to decreased compliance level among patients. The pressure concentration at tibia and welt is demonstrated in the Figure 2-16 based on the Laplace equation. With the prominent sheen the radius of curvature at tibia is reduced due to which high pressure is delivered at tibial zone.

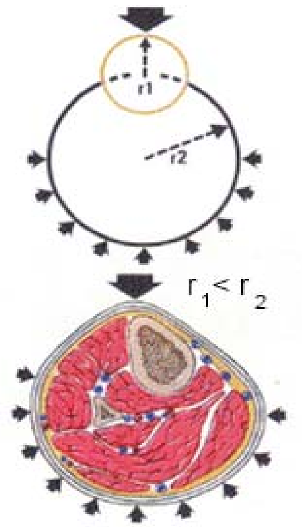


Figure 2-16 Pressure concentration at tibia and welt region of leg (Földi et al., 2006)

The importance of the designing with improved compression stockings is well understood as the majority of the patients using them are elderly, obese, some suffering from arthritic joints. In addition, numerous problems associated with the clinical use of the compression stockings The pressure is too high and sometimes is known to produce laceration marks, necrosis (Bradley, 2001), skin shearing Hermanson et al.,(2006), strangulation (Jobst, 1951) for which the venous and lymphatic return have an obstacle. Non uniform and inconsistent pressure magnitude is often noted by clinical study on pressure evaluation.

Tourniquet effect- 98% of tested stockings failed to produce the 'ideal' pressure gradient from the ankle to the knee, while 54% produced a 'reversed gradient (Best et al., 2000). Variable tension of the stockings material when applied is known to affect the pressure imposed on the venous system. Shearing force is high at the bony surfaces and is shown that the stockings can deliver a pressure of 60 mm Hg over bony prominences (Bradley, 2001). Pressure is not maintained for long time and the useable life of stockings is limited to 6 months. Loosening of the stockings can even lead to prominent and stubborn wrinkles and creasing at the region particularly the region with maximum angular movement like ankle and knee joints (Benkö et al., 2001). Moreover, the stockings can slide down and can bunch up at ankle, exacerbating the problem of tourniquet effect and the later stages sever skin erythema. Sparrow et al., (1995) studied the commercially available stockings and found that the pressure at the calf region was high and most of them produced tourniquet effect. The tourniquet effect might be due to higher count of the yarn used in the construction of stockings welt. Moreover, fabric at the welt region is folded and seamed, increasing the thickness and thereby the elasticity

Complaints by patients- All these factors are known to contribute to the non compliance. The complication and the suggested solutions which again are ineffective are tabulated in Table 2-6. Cotton fibers are used in the stockings improve the comfort properties; however, their inelasticity and low resilience often results in wrinkled and rucks. Benkö et al., (2001) assessed the Graduated compression stockings for wrinkling discomfort and patients' inability to manage the stockings independently on 200 patients and found that these parameters to be 13%, 16% 51%

respectively. Thus, the inability to apply the stockings forms the major determinant of non compliance in patients. Even though Compression stockings are used for centuries, the design and mechanical properties of the stockings is not studied in detail.

Table 2-6 Top complaints with suggested solutions and ineffectiveness of the suggested problems

Top complaints	**suggested solutions**	**Ineffectiveness of suggested solutions**
Difficult to apply (other conditions arthritis, back problem, weight issue)	Donning aids	Donning aids can damage the stockings as they overstretch and hold for long time.
too hot	Open toed and Sheerest	The open toed band delivers undue pressure on bunion region
uncomfortable to wear	Proper fit	The legs are completely disfigured are stockings are not readily available and custom made stockings suiting this type of leg will be costlier
Expensive	Look for brand with lower price	physiological effect is lower
slips and wrinkles	thigh high or pantyhose, professional fitter	Still aggravates the problem with high pressure on knee cap and waist band. Problematic to wear, expensive and not much added benefits
skin dry and itchy	Apply moisturizing lotion	these lotion can damage the elastic yarn in stockings

As per the Laplace law the tension in the textile fiber is directly proportional to imposed pressure, and the tension obtained by stockings depends on the mechanical properties of the stockings fabric and yarn modulus. Liu et al., (2006) studied the comfort aspects of compression stockings based on the mechanical attributes of the stockings fabric and concluded that the pressure at the ankle region is influenced by the material properties of the stockings fabric.

Moreover, Johnson Jr et al., (1982) concluded that the stockings with low modulus yarn produced uniform pressure than stockings with high modulus yarn. Therefore to summarize, stockings with low modulus yarn and controllable tension can effectively improve the stockings performance. Thus, the designing of stockings which can produce uniform, consistent pressure profile with improved compliance level is necessary.

2.10 FUNCTIONALITY OF SHAPE MEMORY TEXTILES

Creative solutions by combining the advantages and effectiveness of *different materials* and *application methods* on *different parts* of a diseased leg is one way to overcome deterioration of skin changes in patients with odd leg shapes (Flour, 2008). With the above thought it was hypothesized that the creative solutions can be delivered by the application of SMFs in compression stockings.

The mechanical, optical, water vapor permeability of the polymers varies at above and below switching temperature of the polymer, these unique properties are applied to develop innovative products (Hu et al., 2007b). The biocompatibility of shape memory filaments was tested by Meng et al., (2009) and the test results were negative to cytotoxic, hemolytic and irritation. In addition, their mechanical properties are reasonably competent to other manmade fibers with shape memory effect (Hu et al., 2007b).

Shape memory fabrics manufactured by finishing the fabric with waterborne shape memory polymers were evaluated for crease retention, wrinkle recovery and bagging recovery with the variation in temperature via air and water (Hu et al., 2007a). The shape memory effect was noted to be functionally efficient at 60 Degree Celsius in water. Besides, tumble drying process did enhance the shape memory effect of treated fabric. Due to the inherent nature of the shape memory polymer used to treat the fabric creased, wrinkled and bagged fabric recovered to its initial shape by heating the fabric above the switching temperature.

At the Shape Memory Textile Centre, SMPs are efficiently applied in textile sector by fabric and garment finishing; fiber spinning both by melt spun and wet spun method adding novel shape memory effect on to the fabric. Meng et al., (2007) evaluated the mechanical properties of SMFs prepared by melt and wet spinning method and concluded that melt spun fibers perform better than wet spun fibers. However, the effect of SMFs in compression stockings in never contemplated and studied.

2.10.1 Distinction between shape memory effect and elasticity in textile fabric

The recovery property of textiles is influenced varying degree of elasticity and inelasticity including visco-elasticity and inter-fiber friction deriving from the visco-elastic nature of the constituent fibers and their rearrangement within the fiber, yarn and fabric structure (Hu et al., 2010). However, in SMP treated fabric, the recovery is initiated with the simulation of temperature; temperature sensitive SMP posses' high recovery ability at relatively at low temperatures (Mondal, 2009), with the entropy change the necessary stress for fabric to recover is developed with the absorption of heat from the source. Two distinctive natures in SMP with the molecular movement leading to macroscopic deformation are differentiated as shape memory effect and shape changing capability (Behl and Lendlein, 2007).

The elasticity of the SMP textiles is due to the shape-memory effect of shape memory polymer is it is results of combination of the morphology, polymer structure, and intra/inter molecular interaction forces between the polymer chains (Lendlein and Kelch, 2002). Moreover processing and programming technology during shape memory testing influences the shape memory effect (Hu et al., 2005).

2.10.2 Mechanism of action of shape memory fabric and elastic fabric

Hu et al., (2007b) at the Shape Memory Textile Centre studied the uniqueness of SMFs over manmade fibers and concluded that the filaments can adapt to various size with low vertical tension with their novel thermal responsive shape recovery. In addition the comfort sensation can be improved with their use in intimate apparels. The mechanism of stretch and fixation of the SMP fabric and elastic fabric is illustrated in Figure 2-17.

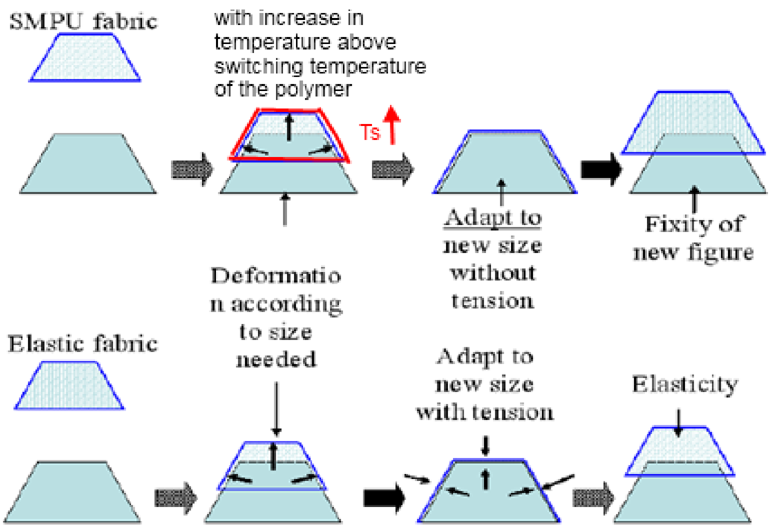


Figure 2-17 Mechanism of fit of SMP fabric and elastic fabric (modified from (Hu et al., 2007b))

As demonstrated in the above figure, the shape memory are advantages over elastic fabric as they fix to the given size by its ability to elongate and fix at a temperature above switching temperature and the undue pressure at the surface region is controlled. However, the study did not involve testing of SMP fabric on human skin as SMP fabric interface pressure was evaluated on circular cylinder. The distinction of elastic recovery in textile fiber and shape memory fabric is discussed by Liu et al., (2008) (Liu, 2006) in her research study stated “stockings-available in a large range of sizes” as one of the criteria for effective designing of the stockings and optimal clinical effect. However, the clinical effect of stockings is wholly dependent on the pressure delivered by the stockings. Again, if stockings are manufactured with higher size range it is quite obvious that the elastic stockings can deliver different pressure on patients with different leg sizes (size within the stockings range).

2.10.3 Characteristics of shape memory fabrics

Shape memory effects on textile were characterized by subjective and objective method for wrinkle recovery and flat appearance. Moreover, bagging recovery of treated fabric was also evaluated by Hu et al., (Hu et al., 2007a). Woven fabrics treated with different recipes of SMP and were compared with an untreated sample for the shape memory effect. Flat Recovery % and Crease Recovery % were used to quantify the shape memory effect (Meng et al., 2009) on textiles after evaluating the parameters by taking temperature into account. Moreover the influence of temperature on treated fabric by using air and water as a media was evaluated. The shape memory fabrics exhibited good wrinkle recovery, flat recovery, and crease retention after repeated laundering and drying at about 60 Degree Celsius (Liu, 2008) .

2.11 SUMMARY OF LITERATURE REVIEW

The principal sections with their interconnection and the influence of Shape memory fibers on the commercial stockings discussed in the literature is represented by a flowchart as given in Figure 2-18. Each of these sections were discussed in detail the literature review, demonstrating the mechanism of action of compression stockings, precariousness in this field and complications, compliances issues on their application to suitably apply shape memory filaments to improve their performance and comfort.

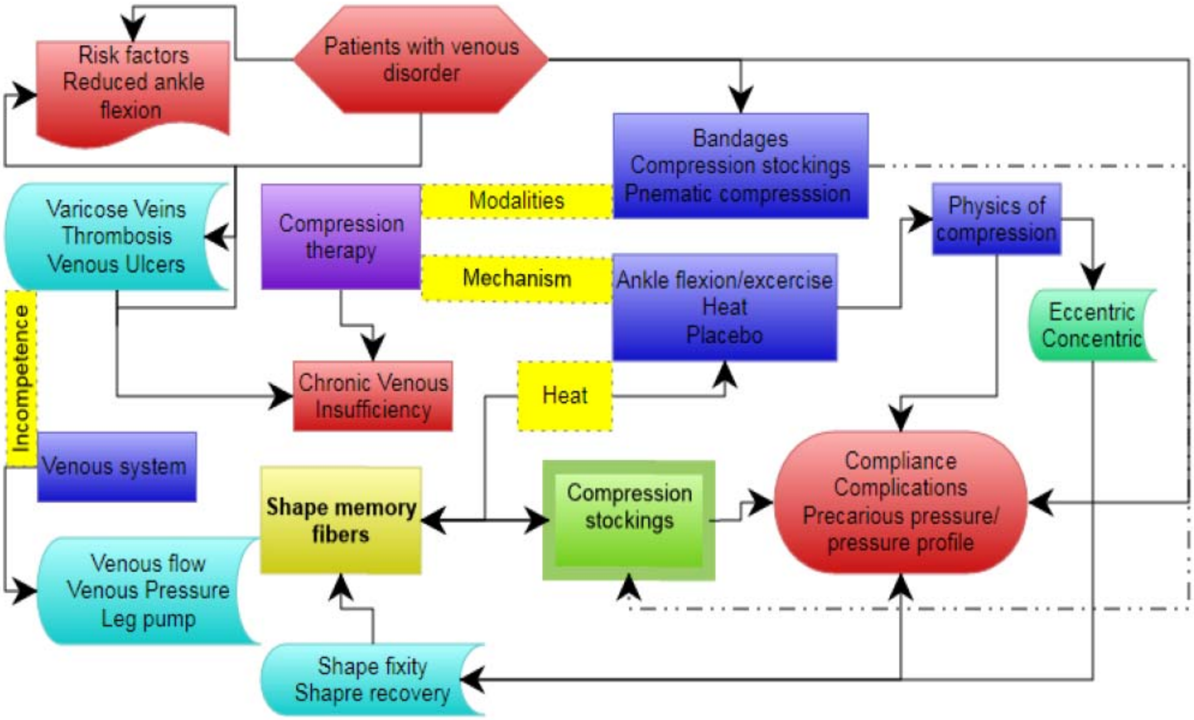


Figure 2-18 Principal sections of current study and their interconnections

It can be concluded compression stockings forms the primary modality of compression therapy. Although, the mechanism of action of compression stockings is precarious, the action of external force, heat and calf muscle functioning forms the principal factors acting on venous system to improve the blood flow in patients affected with venous disorders. Identically, compression pressure profile of the stockings over leg need to be graduated starting from ankle to welt for effective functioning leading to increased venous blood flow in patients with venous disorder. Graduated pressure profile is obtained by designing stockings free from tourniquet effect whether at ankle, calf or welt.

The pressure profile along the length and girth of the stockings is studied by few. The results from these studies show that most of the stockings failed to produce graduated pressure profile from ankle. Furthermore, the tourniquet effect is the common problem in most of the stockings used by patients as noted by high pressure at calf. Moreover, pressure evaluation at welt is rarely studied. In addition, the non compliance issues associated with the usage of the stockings is not studied and smart material application in compression stockings is never contemplated.

The relationship between the stockings class and pressure performance need to be objectively quantified and it is essential to identify the key problematic regions with a logical study in in-vivo condition. Therefore, it is of important to conduct research in this coarse area and design compression stockings with positive functions and minimize the negative effects on the human body and skin. The designing of stockings is of importance to control the discussed complications associated with their use are for proper fit and comfort.

The functionality of the textiles treated with SMPs and properties of SMFs were reviewed. The added functioning in smart textiles with shape recovery and shape fixity can be effectively applied in compression stockings. The stockings constructed with shape memory filaments are applied in compression stockings and the planned research objectives given in section 1.6. are evaluated in the study.

CHAPTER 3. PRESSURE EVALUATION OF COMMERCIAL COMPRESSION STOCKINGS AND RANGE OF MOTION AT ANKLE WITH THE STOCKINGS- A PILOT STUDY

3.1 INTRODUCTION

Compression stockings have been used for centuries to treat varicose veins and its complications which function by applying mechanical pressure on leg. Although pressure standards for stockings from different countries conform to the forwardly graduated pressure profile (Partsch, 2004), Becker et al., (2006) accede to the downwardly graduated with maximum pressure at the B1 region; acceptable for athletes with developed calf muscle.

This disagreement on pressure profile is to suit the needs of particular user and differences in the approach on the working mechanism of compression stockings. Nonetheless, it is well established concept that the medical functioning of the stockings mainly depends on the pressure magnitude at the ankle (Partsch, 2004). The importance of pressure evaluation at the ankle is well documented in the literature (Veraart et al., 2008, Johnson Jr et al., 1982, Liu et al., 2006, Partsch et al., 2006a).

Ankle is considered to be the critical region in the development of venous ulcer (Veraart et al., 2008) and also few published data exists on pressure evaluation on human subjects from different ethnic group (Wildin et al., 1998). For this reason, the pressure evaluation at ankle on human subjects for compression stockings is important. Therefore, pressure delivered by commercially available Graduated Compression Stockings (GCS) from class I to class IV stockings at ankle on 20 subjects was studied in this experiment.

Recurrence of venous ulcer is noted to be high as 36% by 5 years in 300 patients (Nelson et al., 2006) and healing rate is 20 times greater in patients who do comply with the use of stockings (Moffatt et al., 2009). Many a times stockings fail as patients are unable or unwilling to use them as prescribed (Raju et al., 2007). Thus, it is accepted that poor patients' compliance has resulted in ineffectiveness of compression therapy (Ramalet, 2002).

The human skin is sensitive to irritation, pressure and moisture. The pressure is rather directly related to the skin comfort especially in case of compression stockings. Textiles referred to as second skin is known to influence the comfort level based on the body hugging properties and comfort attributes like water vapor permeability, fit, ease of movement etc. Wearing discomfort is a necessary parameter to be assessed as some of the researchers have asserted that compression stockings do work by placebo effect (Christopoulos et al., 1987, Mayberry et al., 1991).

The complications and non compliance issues associated with the usage of compression stockings is not discussed widely (Merrett and Hanel, 1993). The degree of non compliance is undefined (Seshadri, 2008) and the reasons are not stated clearly. Therefore, in addition to pressure evaluation at ankle, compliance issues associated with the use of stockings shall be estimated in the stage I of pilot study.

Active movement of ankle also referred as Range Of Motion (ROM) of ankle plays a major role for calf muscle functioning and is an important factor to eliminate venous statis and prevent DVT (Sochart and Hardinge, 1999); effecting the functioning of the compression stockings. As the calf muscle works against the stockings, the elastic stockings compress the leg during its recovery phase. Although, ROM at ankle is the key determinant controlling calf muscle functioning and to carry out leg exercises. The influence of stockings on the ROM at ankle is so far not studied. Thus, the influence of stockings on ROM in patients and healthy subjects of same age group was studied in stage II of this pilot.

Henceforth, in this chapter, a pilot study was carried out to evaluate the pressure delivered at ankle and discuss the determinants of compliance issues with the application of GCS (class I to class IV) and ROM at ankle. The study was scheduled for two stages with 3 main objectives and is stated as following:

1. To evaluate skin-stockings interface pressure at ankle-B region (the minimum girth of leg at the ankle region) using kikuhime pressure sensor for GCS class I to class IV (pilot study-stage I),

2. To estimate the determinants of poor compliance by comments from subjects during pressure evaluation (pilot study- stage I)

3. Objective evaluation of ROM at ankle in patients with venous disorder and healthy subjects of same age group using Goniometer with and without the GCS stockings class I and class IV (pilot study-stage II).

The first two objectives were achieved in stage I of the pilot study and the last objective in the stage II of pilot study. The complete study framework for this pilot study is represented in diagram as shown in Figure 3-1. The obtained results from the both the stages can be effectively applied to design the further study on the application of shape memory filaments in compression stockings.

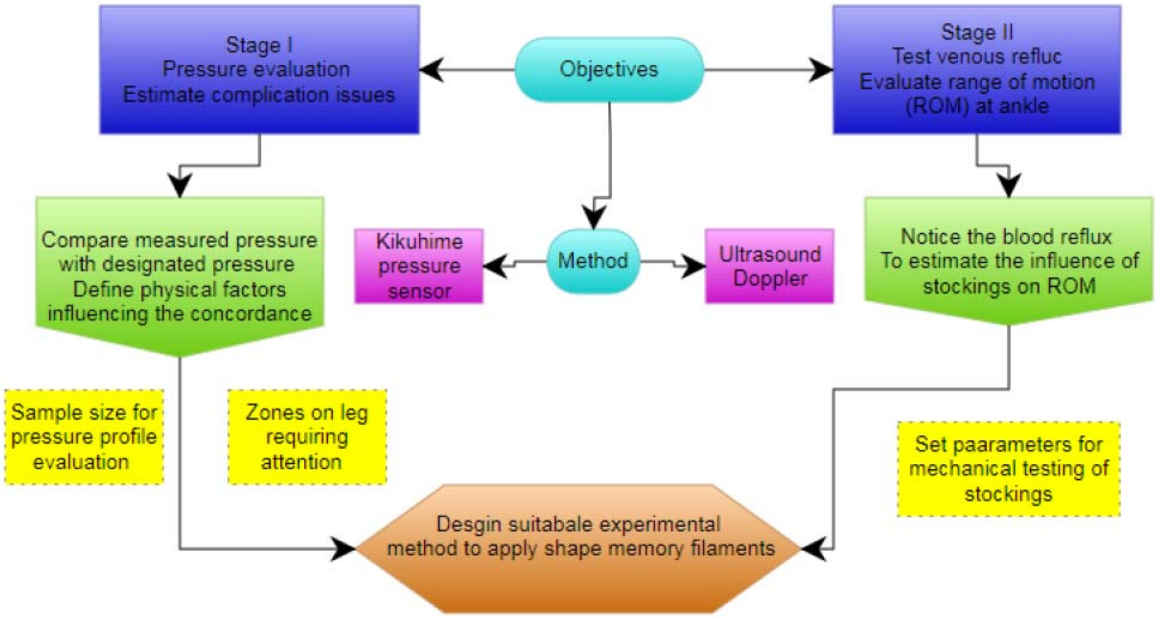


Figure 3-1 Study framework for the pilot study

In stage I of pilot study the skin stockings interface pressure was evaluated for GCS class I, II, III, and IV on both the legs of 20 subjects from different ethnic groups. The pressure value was measured using kikuhime pressure sensor at anterior direction of B region in compression stockings. Furthermore, while the study was carried out current problems associated with the donning and usage of compression stockings for short time was discerned and subjects were invited to give comments in last session of the stage I. These comments were further confirmed by telephonic interview of patients using compression stockings.

In stage II, color Doppler ultrasound (USD) was used to estimate venous blood reflux in patients suffering from venous insufficiency. The ROM at ankle was measured using Goniometer positioned at heel of the leg in each of the five patients suffering from venous disorder and also in five healthy subjects. These goniometric measurements were taken with class I and class IV stockings and without the stockings.

3.2 PRESSURE EVALUATION AT B REGION (STAGE I)

3.2.1 Experimental material and method for stage I

The skin-stocking interface pressure was tested on 20 subjects from different ethnic groups (Chinese, Malaysians, Indian, and Philippines) using a simple pressure sensor by direct method of pressure evaluation on both the legs of the subjects. The stockings materials, their medical function, subjects and the experimental protocol followed in the pressure evaluation at B region in stage I of pilot study are stated below:

3.2.1.1 Materials-commercial compression stockings with graduated pressure profile

Graduated compression stockings used in the present study were knee high stockings purchased in Hong Kong from an authorized dealer, a commonly advised brand by physicians inclusive of class I to class IV; manufactured in Switzerland. The pressure values delivered by the stockings at B region as specified by the manufacturer and recommended functions as noted from the product brochure are given in last four rows of Table 4-1.

In Table 4-1, the first column gives the class of graduated compression stockings, the second column specifies the designated pressure range for stocking by manufacturer; the recommended medical functioning are presented in the last column. The pressure readings are given both in mmHg and SI unit of N/m2.

3.2.1.2 Conditioning of the stockings samples

Before each test measurement the stockings samples were conditioned for 2 hours at a temperature of 22 $\pm$ 2 Degree Celsius and humidity level of 65 $\pm$ 2 % to control the instability in the stockings and further relax the fabric from previous mechanical stresses and distortion.

3.2.1.3 Rationale for selecting Knee high stockings style

As discussed in section 2.7.2, knee high compression stockings were efficient as thigh high compression stockings and were preferred by patients (Byrne, 2001). Knee high style of stockings is relatively easy to apply, comfortable (Benkö et al., 2001) and wrinkled less than the thigh high compression stockings (Hayes et al., 2002). Since, knee high compression stockings perform better and are preferred by patients; in this research study we chose knee high stockings. In the hope that, if the newly designed stockings with shape memory filaments supersedes the knee high stockings it is evident that newly designed stockings can perform better than thigh high compression stockings as the complications with the use of thigh high compression stockings is higher than the knee high compression stockings (Benkö et al., 2001).

3.2.1.4 Kikuhime pressure senor

Kikuhime pressure sensor (TT Medi Trade,Soleddet 15, DK 4180 Soro) (see Figure 3-2) was used to measure the skin stocking pressure at the B region delivered by GCS inclusive of class I to class IV.

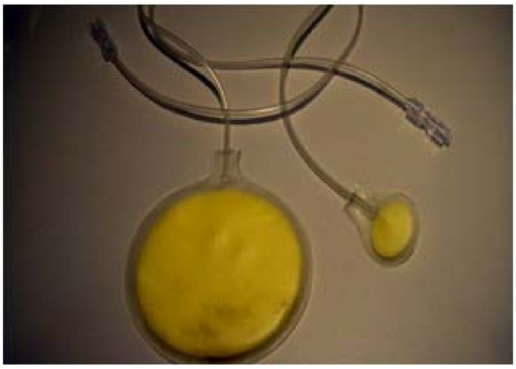


Figure 3-2 Kikuhime pressure sensor

Kikuhime senor is electronically simple pneumatic pressure sensor (Partsch et al., 2006a), easy to use and is of low cost. The sensor kit included two pressure sensors, small and large with the dimensions of 3 x 2.5 cm and 8 x 10 cm respectively and a display unit. The small kikuhime pressure sensor is 3 mm in thickness and is flexible enough to prevent the erroneous higher pressure with the increase in circumference of leg. Hence, small sensor was used to measure pressure in this experiment.

A screwdriver was also provided along with the kit to calibrate the sensor for zero reading before each measurement. With the changes in the atmospheric pressure, the pressure senor is known to show variability of more than 1 mmHg. Therefore, screw driver was used to set the pressure reading to zero mmHg. As noted from instrument manual the sensor is accurate with ± 1 mm Hg. The steps for connecting the sensor to the display unit are described below and the same is presented in Figure 3-3.

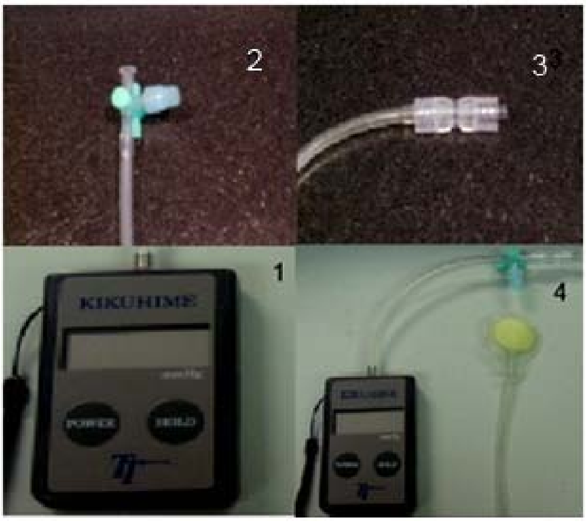


Figure 3-3 Connections to set the pressure sensor in working mode (1-Display unit, 2-three way tube, 3-Lucer lock, 4-sensor with display unit)

Steps for connecting the sensor are:

1. The three way tube was first connected to the display unit.

2. The sensor or the balloon was then connected to the three way value Lucer Lock.

3. The Lucer lock was finally connected to the three way tube to complete the connection from sensor to display unit.

4. Later, the three way valve was turned to the closed position and the senor was calibrated to zero before measurement.

3.2.1.5 Calibration of Kikuhime pressure sensor using sphygmomanometer

The kikuhime pressure sensor was calibrated initially using the clinical blood pressure monitor (sphygmomanometer see Figure 3-4). The sensor was placed underneath the pressure cuff of sphygmomanometer and the cuff was inflated to pressure from 10 to 90 in steps of 10 mmHg, and pressure readings from the kikuhime sensor was noted against each pressure value on sphygmomanometer.

Figure 3-4 Calibration of Kikuhime sensor using sphygmomanometer

3.2.1.6 Subjects for pressure evaluation

Subjects who appeared to meet the inclusion criteria of B region (ankle region with minimum girth) in the range of 19 to 23 cm which is the size of the commercial stockings and expressed their wish to participate were chosen. Out 28 subjects twenty healthy subjects (12 men and 8 women) met the criteria and their mean leg height and B region-ankle girth was 38.9 and 20.32 cm respectively and age range was 24 to 31 years with a mean of 27.5 years (see Table A-1 in Appendix). Each of the subjects then signed the informed consent form which was reviewed by The Institutional Ethics board. Many of the subjects were students from different ethnicities (China, India, Philippines and Malaysia). Based on the average value of the height and weight the BMI was calculated by table from National Heart Lung and Blood Institute (NHLB, 2009) and was noted to be between 21-22 which falls within the normal range of 18.5 - 24.9

3.2.1.7 Measuring region and posture for pressure evaluation

The skin stockings interface pressure was measured at anterior of B region. The height of the B region can vary among individuals; the discrepancy can be attributed to the considerable differences in the age, ethnicity and growth in individuals. Leg length and the girth at B region were measured in subjects to see if the stockings suited their leg measurement. After wearing the stockings the subjects sat on a chair with their knee bent to 90 degrees to the floor see Figure 3-5 and all the measurements were taken in this posture after placing sensor underneath the stockings. The pressure was evaluated on both the legs in each subject.

Figure 3-5 Posture for pressure evaluation

3.2.1.8 Experimental method

The experiment was carried out in a controlled environment where the temperature was 25 ± 3 Degree Celsius and relative humidity 60 ± 5 %. The sensor was carefully placed underneath the stockings at the marked anterior direction of B region using a cello tape and later the subjects were asked to wear the stockings at random over the placed sensor and the pressure reading was noted. The systematic study protocol followed and the duration for each process in the stage I of pilot study is given in the Table 3-1.

Table 3-1 Study protocol for pressure evaluation (Stage I)

Process	Intended purpose	Duration
Anthropometric measurement	To verify the ankle girth at B region to be within 19 to 23 cm	5 min
Real time pressure evaluation	Measure pressure using Kikuhime sensor	10 min
Open comments	Estimate the compliance issues	15 min

3.2.1.9 Statistical analysis

One way ANOVA was carried out using SPSS software package (version 16; SPSS Inc., Chicago, IL); T test and nonparametric wilcoxon's signed ranks test using Graphpad prism V2.0 (GraphPad Software, San Diego, CA) was used to compare the median of the measured pressure for each compression class with that of the standard designated pressure by manufactures. Significant differences were evaluated at $p<0.05$. In addition, mean, confidence interval and SEM are also calculated.

3.2.2 Results of stage I pilot study

The results of the stage I pilot study are analyzed and presented in detail in this section. At first, the results of the calibration of kikuhime pressure sensor and measured pressure readings compared with the designated pressure are described. Secondly, the observed complications and issues as noted from the comments from subjects are presented.

3.2.2.1 Calibration of Kikuhime pressure sensor using sphygmomanometer

The difference in pressure readings of kikuhime pressure sensor from the sphygmomanometer readings are given in Figure 3-6. As shown in the figure, the pressure difference of the kikuhime pressure sensor against the sphygmomanometer is high at pressure value of 80 mm Hg and low at lower pressure reading from 10 to 40 mm Hg.

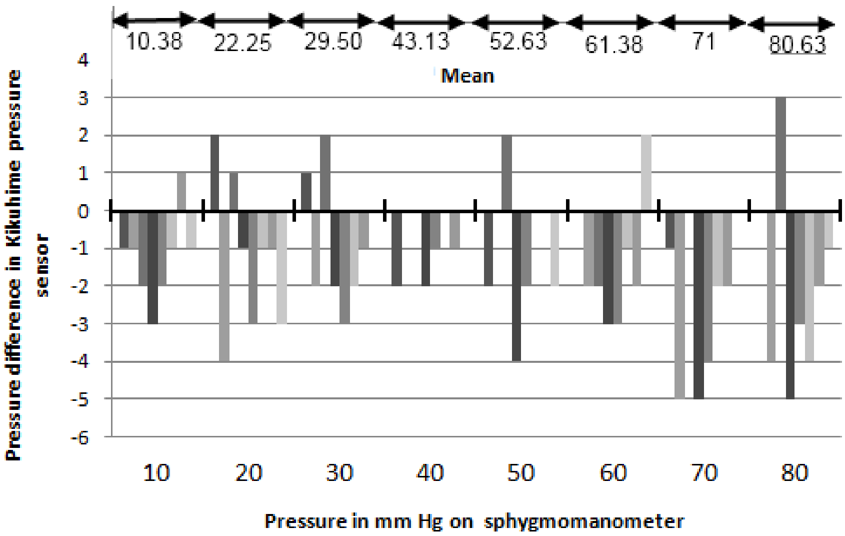


Figure 3-6 Pressure difference between sphygmomanometer and kikuhime pressure sensors

The results of the calibration test is represented by X-Y plot as given in the

Figure 3-7, a linear relationship was found between the pressure values from the Sphygmomanometer and Kikuhime pressure sensor in the pressure range from 10 to 90 mm Hg with a correlation factor of 0.99. Thus, the obtained pressure reading from kikuhime sensor was as accurate as sphygmomanometers (see Table A-2 in Appendix).

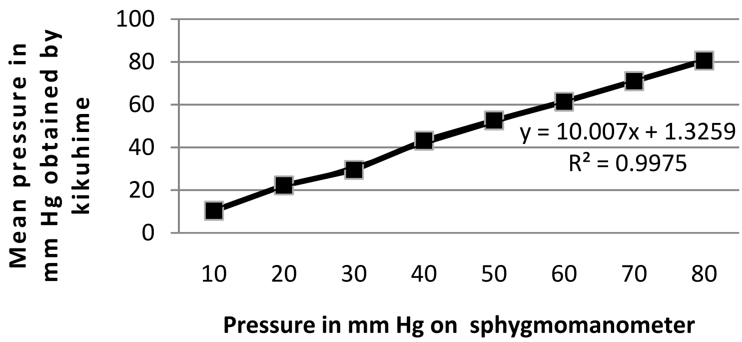


Figure 3-7 Correlation of pressure reading of Kikuhime pressure sensor and Sphygmomanometer

3.2.2.2 Measured pressure at ankle-B region

The results of the mean pressure obtained from both the legs of the 20 subjects are presented in Figure 3-8. In the figure obtained pressure values using kikuhime pressure sensor for all classes with the standard error of mean are presented, the standard error was high for class IV (+1.387) and for class I to III the standard error was less than 0.9. Furthermore, the standard deviation of pressure reading for compression class II (+2.4) classes IV (+8.7) was high thus the variation in pressure reading for class II is higher than class I and class III (see Table A-3 in Appendix).

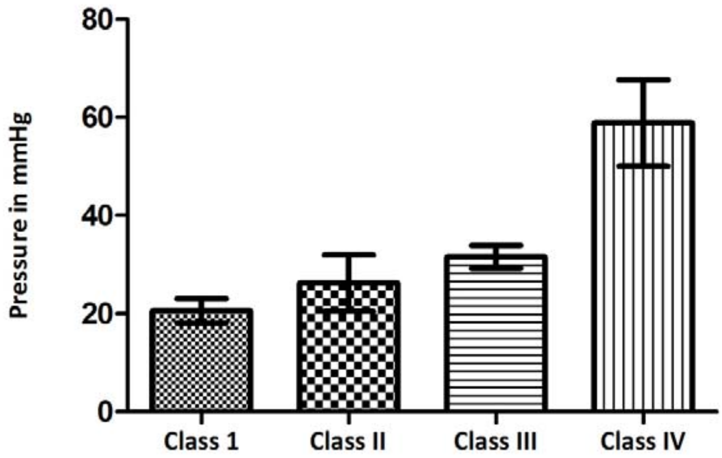


Figure 3-8 Pressure reading from stockings with the standard error

95% Confidence interval (CI) plot was used to compare the obtained pressure values from compression stockings class I to class IV as given in Figure 3-9. From the figure it can be noted that the CI of class IV is significantly different from other compression class. ANOVA test results showed a significant difference between the mean in compression class with F (3,155) =379.6 with p value less than 0.05. Moreover, Turkey's and Gabriel post hoc showed significant differences between each compression class with the each other (see Table A-4 in Appendix).

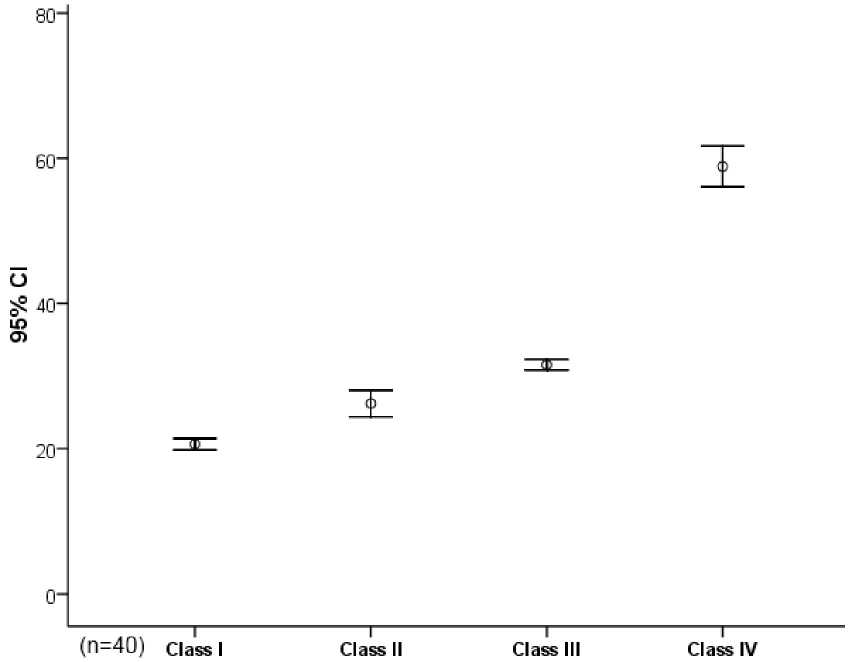


Figure 3-9 95% confidence intervals for the average pressure values at B region in four classes of compression stockings

3.2.2.3 Comparison of obtained pressure reading to the designated pressure

The mean and the range as per the designated pressure value by manufacturer for each stockings class is given in Figure 3-10, represented by triangular marker point and grey color band respectively. The grey band represents the standard pressure range for each class according to German standard (RAL-GZ 387/1), it should be noted that there is no higher limit for Class IV and the pressure value should be more than 49 mm Hg for the same. The measured pressure values represented by square marker point in the figure; class II (26.23 mm Hg) and class III (31.55 mm Hg) delivered lesser pressure than the designated value. Extremely higher pressure was noted for class IV (58.88 mm Hg), Class I (20.63 mm Hg) stocking effectively delivered higher pressure than the designated pressure (17 mm Hg).

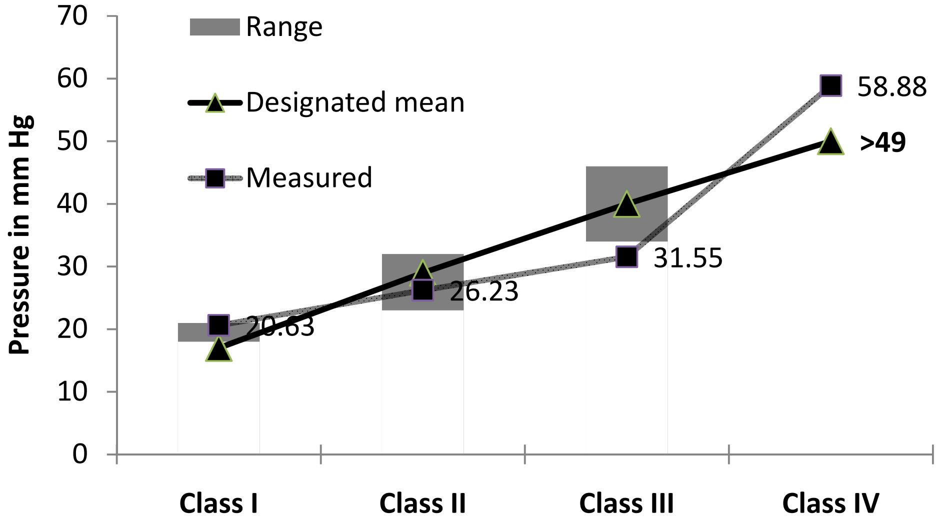


Figure 3-10 Comparison of average of evaluated pressure to the designated pressure in compression stockings (n=40)

Independent t test showed significant difference for measured and designated mean pressure and the results are given in Table 3-2.

Table 3-2 T test results for stockings (n=40)

Class I	Class II	Class III	Class IV
t=9.293	t=3.062	t=22.93	t=6.397

Wilcoxon signed rank test showed significant difference for the median of the measured value in all compression stockings when compared with that of the designated pressure (see in Appendix Table B-6) in which the positive and negative ranks are given for all the tested stockings based on which p value is calculated to measure difference of measured pressure and the standard pressure.

3.2.2.4 Compliance issues identified by comments from the subjects

In addition to the pressure evaluation, compliance issues with the usage of stockings for 20 minutes (total time for which the subject wore stockings) were assessed during the study on 20 subjects. In the last session of the study the subjects were asked to share their experiences on the application of stockings. The session lasted for 15 minutes and the comments from subjects was analyzed for common criteria and summarized as listed in Table 3-3. The methodology for further study shall be designed based on these comments.

Table 3-3 Comments from subjects on the application of stockings (n=20)

Sl. No	Comments	Number of subjects
1	The stockings is small for my leg size	20
2	It is not easy to apply and walk with stockings	20
3	The pressure at the bony surfaces (technically the malleolus, tibia) and foot is high during the application process	16
4	Pressure marks at the ankle and the welt region	12
5	Wrinkling at the flexing point (technically ruck) near ankle and is not easy to correct them	8
6	white bits developed on skin (technically dead cells) after taking off the stockings	6
7	Pressure sensation was high at the instep region especially at the lateral region	3

During the study, photographs were taken as a part of visual assessment when the subjects wore stockings and soon after removing the stockings which are presented in Figure 3-11. In addition, legs of patients with varicose veins (subjects of stage II see section 3.3.1.1) with stockings were also photographed to complement the comments received from subjects.

As shown in Figure 3-11, the stockings folding marks are seen at the ankle (picture no 2), this is due to ruck of stockings (picture no. 4) with prominent wrinkling and folded fabric at ankle. The same observation was also noted at welt (stockings band with high elastic-seamed fabric) region on subjects (picture no. 9). It was noted that the wrinkling of the stockings fabric is common for all the compression stockings classes (picture no. 2 for Class I stockings and picture no. 7 for Class IV stockings). Skin erythema (skin redness) at the bunion is given in picture no. 2 and welt due to the friction of coarse elastic yarn. Moreover, the folding of stocking welt and the skin depression caused by the welt is given in picture no. 3 and 9 also in patient with varicose veins (picture no. 8). Only few subjects suffered from skin dryness and dead skin peeling after removing the stockings (picture no. 5).

Figure 3-11 Compliance issues on the application of compression stockings

To ascertain the comments from the subjects and provide a logical conclusion; 15 patients prescribed with compression stockings as they were diagnosed from varicose veins were interviewed. Most of the patients commented that they cannot put on the stockings easily; one patient commented "it takes my life off when wearing it! Patients complained of warm legs, felt itchy underneath stockings welt and stockings to be uncomfortable and painful. There were stockings marks on the skin especially at ankle and welt due to folded stockings fabric. All the patients revealed that they do not wear it regularly.

3.2.3 Discussion

The skin stockings interface pressure was evaluated at the most prominent and critical region for venous disorder development-the B region using a simple pressure sensor on both the legs of 20 healthy subjects from different ethnic groups. The accuracy of the kikuhime sensor was reasonable as noted from the results of the calibration test against the sphygmomanometer and the correlation factor was 0.99.

While, the class IV stockings produced the maximum pressure at B region, class I delivered the least pressure. Pressure values obtained from class II and class III fell between class I and class IV; with class III higher than the class II. The measured pressure values for each of the stockings class was compared to standard designated pressure as per German standard, Class I and class IV did produce higher pressure than standard designated pressure by the manufacturer. However, class III failed to produce the necessary pressure. Hence, the stockings pressure on subjects is variable compared to the designated pressure.

Stockings confirming to German standard are tested on HATRA and load elongation values are used to designate the pressure. The tension of stockings fabric is directly related to the delivered pressure as per the Laplace law but with the cycles of use (application and removal) the stockings can lose its elasticity leading to reduced pressure on skin and also their performance is influenced by the pre historic variation in the manufacturing stages as in sewing and boarding.

Thus, the relatively lower pressure obtained for class II and class III than class I and class IV is justified. On the other hand, class I and class IV stockings delivered high pressure than the standard. Class I stockings was replaced after measuring the pressure at B region in 14 subjects as it was damaged at heel see Figure 3-12 and for 6 more subjects new pair was used and hence the tension was retained and they were able to deliver effective pressure as per standard. Since the standard does not specify the upper limit for class stockings class IV stockings still meets the limit of the standard pressure. However, the redundant pressure can logically add to the discomfort in application and use of stockings in patients.

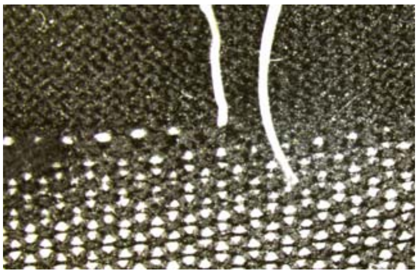


Figure 3-12 Damaged stockings fabric at heel

The pressure sensation was different at various regions as observed by the subjects. Pressure sensation at tibial crest and bunion regions was commented to be high however this was not noted visually, these observations matched with the issues presented by Bradley (2001) in his clinical review as given in Figure 3-13 showing necrosis at the tibial crest due to high pressure.

Higher pressure sensation at malleolus, dorsum of the foot and ankle was noted. It is said that compression stockings are known to produce a pressure of 60 mm Hg over bony prominence (Roe et al., 1995).

Figure 3-13 Pressure necrosis on tibial crest due to compression stockings (Bradley, 2001)

Wrinkling of the stockings at the ankle region was common for all the classes of stockings, tested in this experiment. The stockings had permanent creases and which were not recovered even after conditioning them for 2 hours before each test measurement. These wrinkled stockings in few subjects caused tourniquet effect as seen from the pressure marks at the ankle, same result was also noted by Doherty et al., (2006) in their study. It is obvious that the pressure sensation at the ankle was high due to the graduated profile of the stockings.

The confronting issues with the use of compression stockings noted in the stage I of pilot study correlated with the results from previous studies (Merrett and Hanel, 1993, Winslow and Brosz, 2008, Bradley, 2001, Doherty et al., 2006). The physical factors such as pain, skin irritation, redness, discomfort at welt and ankle forms the major attributing physical factors affecting the functional performances and compliance level on the application of compression stockings. Skin redness at welt was commonly found, this was more prominent if the experiment duration prolonged.

Since pressure sensation as commented by subjects was variable along the leg and it is necessary to further study the complete pressure profile for pressure variability in order to suitably apply the shape memory filaments.

3.3 RANGE OF MOTION AT ANKLE (STAGE II)

People who are aged and bound to work for prolonged period either by standing or sitting are most widely affected by venous insufficiency (Naoum et al., 2007, Cario-Toumaniantz et al., 2007). The primary mechanism of action of compression stockings is by elastic compression preventing distension of dilated veins. However, the effective method to prevent venous statis (pooling) is to involve in active ankle flexion in order to actuate the calf muscle thereby propelling the blood towards the heart. The stockings can function by acting against the calf muscle. For effective calf muscle functioning Range of Motion (ROM) at ankle is a major determinant.

Since, skin redness and discomfort was noted at the ankle with stockings, it is suggested these issues can hinder the ROM in patients applying compression stockings. Also, as it is important to improve the ROM to relieve the protracted functional disability related with CVI (Chronic Venous Insufficiency), clinical study was carried out in the stage II of pilot study involving patient with varicose veins to evaluate the active ROM with stockings class I, class IV and without stockings using Goniometer. Moreover Color Doppler Ultrasound (USD) was used to obtain the Doppler images of the dilated of veins in patients with varicose veins.

3.3.1 Materials and method

Materials, clinical instrument and method followed to evaluate the ROM in subjects are described in detail in below section namely subjects, instrument and methods. Patients were recruited by publicizing the research study with a poster describing the study objective and selection criteria for the stage II of pilot study. The poster was stuck to University, vascular hospital and Radiology Laboratory notice board. The clinical evaluation was carried out using Doppler Ultrasound (USD).

3.3.1.1 Subjects for evaluation of range of motion at ankle

To obtain rational results, the subjects recruited for this study were patients with venous disorder. Patients with ulcers, wound and with BMI more than 30 were excluded from the study. Totally 10 subjects were chosen this study, five with venous disorder and five healthy subjects of about same age group to measure ROM with and without stockings. The Doppler images were taken for 2 out of 5 patients at the Radiology Laboratory in the University and clinic under the assistance of professor, technicians and care takers. The age of the two patients was 45 and 58 years; their average BMI was 25.24. Only 2 patients were scanned under Doppler instrument as in one patient the visibility of the varicose vein was not prominent and the other patient had varicose vein clearly visible from outside. The mean age of the healthy subjects and patients with varicose veins chosen for this study was 48 years and 57 years respectively (see Table A-6 in Appendix).

3.3.1.2 Experimental protocol for evaluating range of motion

The clinical test was carried out after explaining the subjects about the experimental protocol and method. The subjects were asked to sign in the consent document in agreement for their approval as volunteers for this experiment. The consent document was approved by the University Ethics Committee for the use of the human subject for the research study. The subjects were refrained from heavy exercises, alcohol and high salt diet prior to experiment as this can influence the blood flow in veins and fatigue in legs.

Table 3-4 Study protocol for stage II of pilot study

Subjects	Process	Parameter	Equipment
	Anthropometric evaluation	height	Self reported by subjects
		weight	
2 patients with varicose vein	Physiological study in patients	Venous and arterial flow	Color Doppler Ultrasound
		Venous reflux	
		Dilated vein structure	
5 healthy and 5 patients (with class I and class IV stockings without stockings	Goniometric study	Dorsi flexion	Goniometer
		Plantar flexion	
		ROM	

3.3.1.3 Experimental instrument used to study venous reflux in patients

The hemodynamic of blood in healthy subjects and patients suffering from venous disorder was noted using Doppler Ultrasound (USD) (HDI 5000 Ultrasound System, Philips Medical Systems Company, USA) as shown in Figure 3-14. This is a non invasive test that gives information on the blood flow through the circulatory vessels underneath the skin. A 7.0 MHz linear-array transducer was used to obtain the real time 2D scan of the blood circulation at B mode displaying tissue structure and blood flow in vessels and the measurement were carried out by sonographist.

Figure 3-14 Doppler Ultrasound with its peripherals

The equipment is considered to the gold standard for the analysis of the venous blood circulation underneath the skin for patients suffering from venous disorder and diagnoses specific body parts for blood reflux.

3.3.1.4 Working Principle and diagnosis using Doppler Ultrasound

The USD (Figure 3-14) works on the principle of Doppler Shift also called as Doppler Effect (see Figure 3-15). The probe of USD has piezoelectric crystals and continuous cyclic electrical signal is used to emit high frequency ultrasound beam from crystals. When this ultrasound beam is directed towards the body tissues via water based gel; it is scattered or reflected by moving particles within the body and there is a shift in its frequency. With the movement of the blood in the blood vessels there is shift in the frequency of the incident beam this is compared with the frequency of incident beam and then the flow rate is calculated by computation with the inbuilt software in the system. The measurement of the Doppler shift is from the reflected ultrasonic beam off from the flowing blood cells. The beam reflected from the static tissue and the moving blood cells is collected and mixed on a photo detector. The photocurrent so obtained is processed to get the blood flux, concentration and velocity. The frequency shift is the indicator of the true flow rate. The flow towards the transducer is considered to be positive and away from it is to be negative.

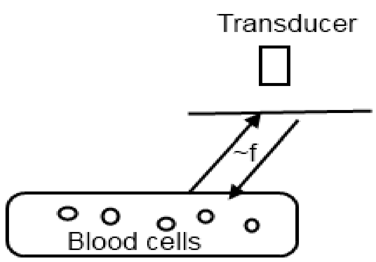


Figure 3-15 Doppler Effect

A wider transducer is needed only to measure flow rate, independent of the cross sectional area. For the Doppler principle to work in a flow meter it is mandatory that the flow stream should contains sonically reflective materials, such as solid particles like in our case blood cells. Doppler shifts in the range of 100 Hz to 11 KHz are obtained at the Doppler angle of 30 to 60 degrees and the operating frequency ranging from 2 to 10 M Hz. In this clinical diagnosis the chosen Doppler angle was 60 degree.

3.3.1.5 Testing regions and posture for evaluate venous reflux

The common femoral vein (CFV) is identified using USD at the points where it bifurcates into the superficial femoral veins (SFV) and proffunda femoris vein (PFV). The blood reflux is noted at this CFV and GSV after applying water based gel on skin and scanning was carried out in transverse direction along the vein see Figure 3-16.

Figure 3-16 Testing posture to evaluate venous reflux in patients

Subjects were asked to maintain normal breathing cycles as it can affect the blood flow in vein and arteries. The transducer was periodically turned to longitudinal direction at nearly 60 degree when the subject was in supine position as given in Figure 3-16 to obtain the Doppler signal. Moreover, the Doppler image for Common femoral artery (CFA) was also obtained using the same procedure.

3.3.1.6 Evaluation of range of motion at ankle (ROM)

As described in section 2.2.1 (Venous blood system D. Venous pressure/leg pump) the blood flow in the venous system is initiated by the ankle and leg pumps. It is important to know if the patient with varicose veins had different range of motion (ROM) at ankle inclusive of dorsi flexion and plantar flexion than that of the healthy subjects. In addition the ROM at the ankle was also noted with and without the class I and class IV stockings. ROM is obtained by the summation of dorsi and plantar flexion angles (see section 3.3.1.7).

3.3.1.7 Instrument to measure range of motion- Goniometer

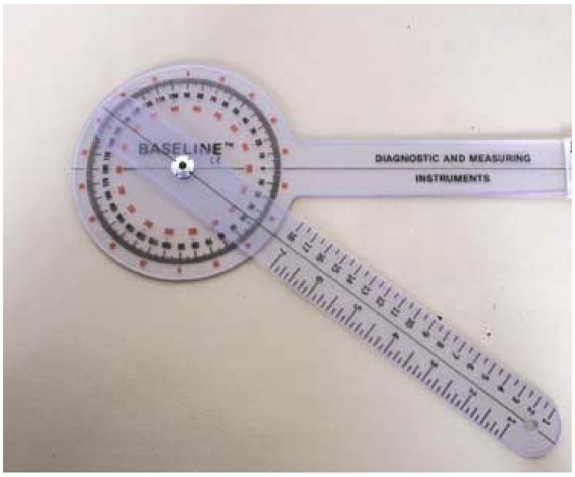


Figure 3-17 Goniometer

Goniometer as shown in Figure 3-17 is used to evaluate dorsi flexion and plantar flexion at ankle as shown in Figure 3-18; ROM is obtained by adding both the flexion angles which represents the maximal voluntary movement of the ankle to plantar and dorsi flexion in supine (non weight bearing position). Dorsi flexion refers to the angle of flexing the foot upward and likewise plantar flexion refers to angle of flexing of the foot in downward direction.

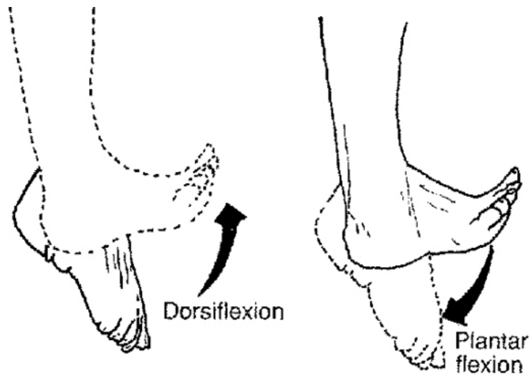


Figure 3-18 Ankle flexion motion

In Goniometer two linear scales are pivoted to form angular scale and one of the linear scales is aligned to foot at ankle freely held at supine position is considered to be the 90 degree position and other scale is aligned to the maximum flexed position after dorsi and plantar flexion. The subjects asked to occupy supine position and flex the ankle within their comfortable level but not to overstretch with full power leading to undesirable pain.

3.3.2 Results and discussion

The results of the experiment method as described previous section are presented in below sub sections. The difference in the arterial and venous waveforms, blood reflux and measured angle of flexion are given are stated below.

3.3.2.1 Differences in the arterial and venous waveforms in leg

After the patient occupied the supine state, the waveforms of arterial and venous blood flow were noted using USD following the procedure as described in section 3.3.1.5.

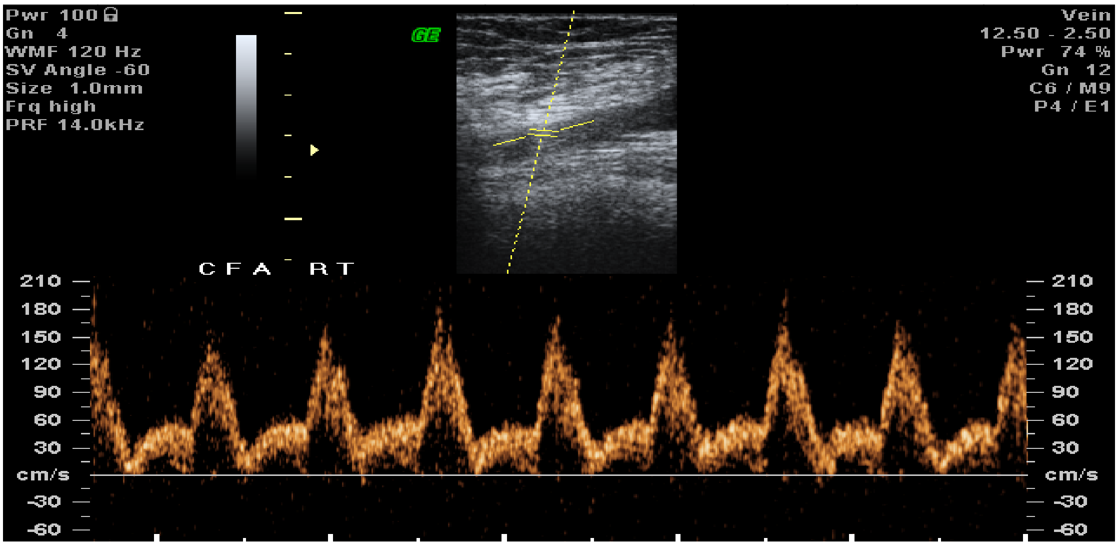


Figure 3-19 Arterial blood flow waveforms

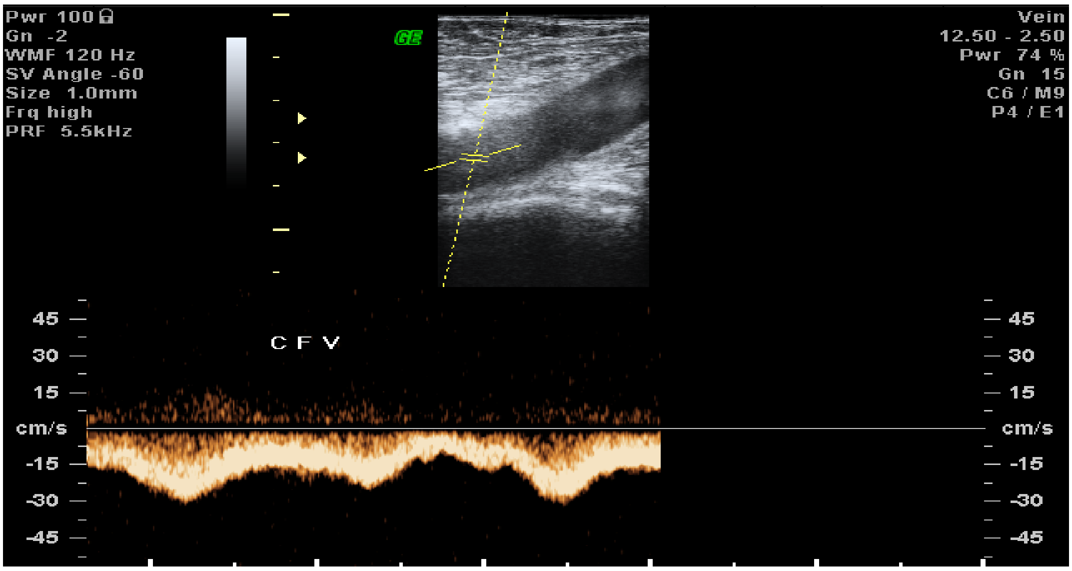


Figure 3-20 Venous blood flow waveforms

Figure 3-19 and Figure 3-20 are the Doppler image showing the differences in the flow patterns of blood flow in (cm/sec) in the arterial and venous vessels respectively as obtained from USD. The flow pattern of the arterial blood flow varies in the form of wave with high amplitude (sinusoidal waveform) as blood flow in them is influenced by inspiration and expiration of air and also by the pumping action of heart. However, the venous blood flow pattern was stable with lower amplitude in a supine posture. As the action of muscles is the driving force for venous blood flow and in supine position the venous flow is stable. Thus, the arterial blood flow is pulsated and venous blood flow is more or less continuous in supine posture. Moreover, the flow rate is negative for venous flow and positive for arterial blood flow this is due to the direction of blood flow- arterial blood flow is from the heart whereas venous blood flow is towards the heart.

3.3.2.2 Blood reflux due to varicose veins in patients

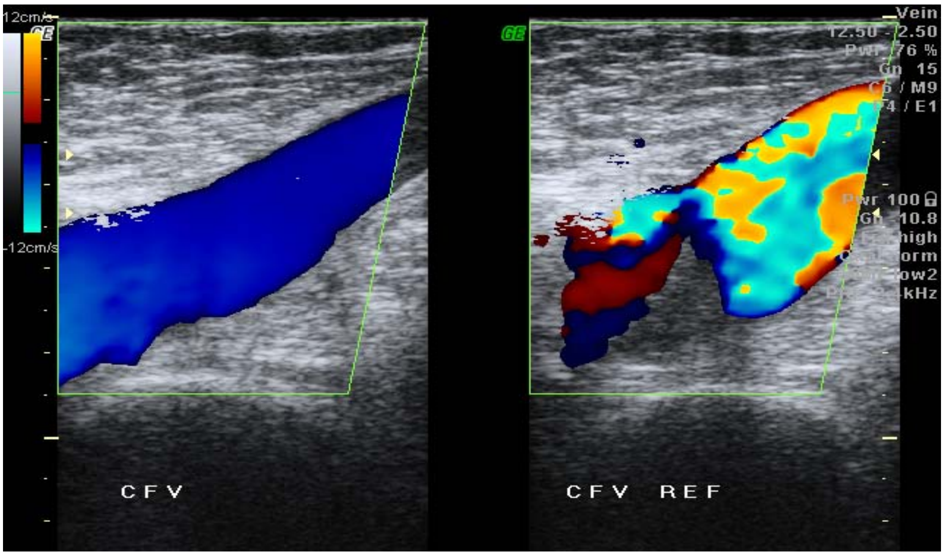


Figure 3-21 Reflux in venous blood flow in patient

The abnormal blood flow i.e. refluxes in venous blood flow in patients with varicose veins are given in Figure 3-21; the dilated veins prevent the venous valves (not shown in figure) to align resulting in venous statis (as described in section 2.3). Venous incompetence is clearly demonstrated by the reflux or retrograde motion in blood flow in downward direction at Common Femoral Vein.

3.3.2.3 Dilated veins in patients

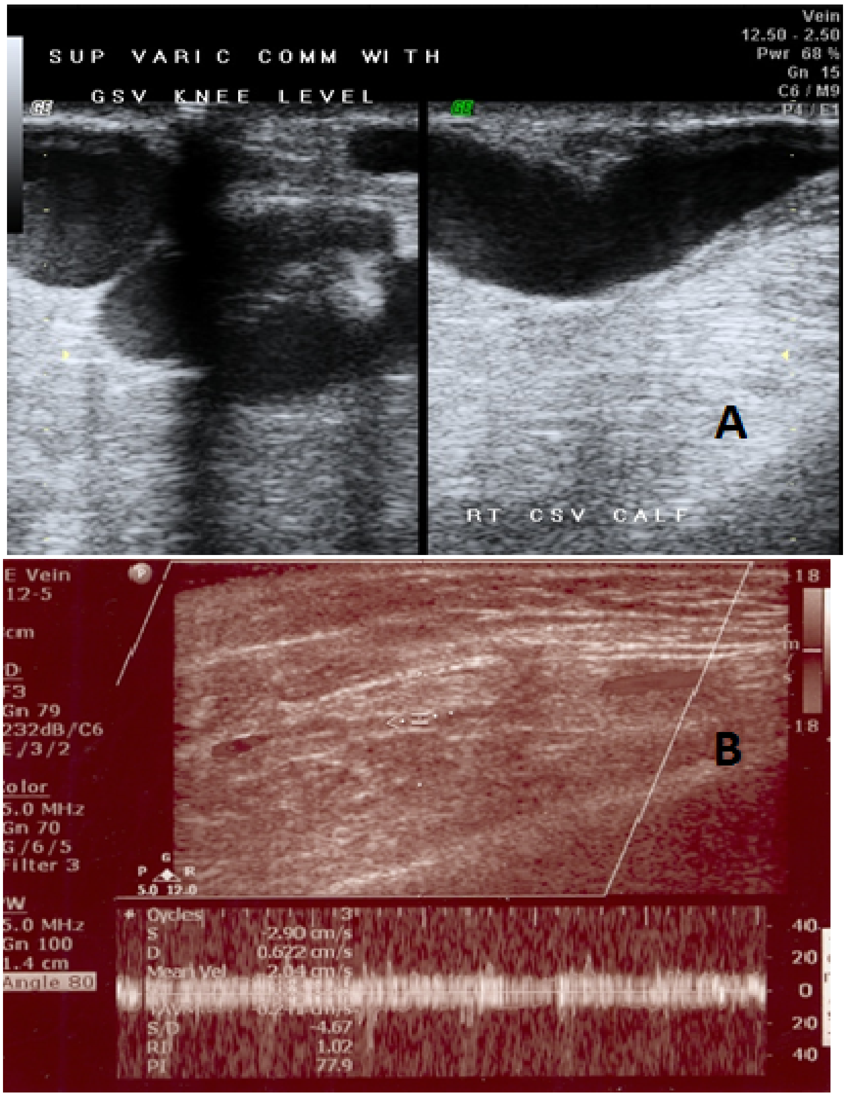


Figure 3-22 A. Dilated veins and B. Normal vein

Figure 3-22 gives the image of the A).Dilated superficial veins common with Greater Saphenous vein at knee level and B) the normal vein structure in patients with varicose veins (patient had developed VV on one leg). The torturous and dilated superficial vein is clearly seen in patients with varicose veins in the figure. The first image in A) shows the dilation of vein deep inside under the skin and second image with dilation at the surface near to the skin.

3.3.2.4 Angle of flexion at ankle in subjects

The results of the angle of motion during plantar flexion, dorsiflexion in healthy subjects and patients with venous disorder are given in Figure 3-23 and Figure 3-24 respectively. Besides, the angular flexion with stockings class I and class IV in all the chosen subjects is presented in the same figure. Obtained values for the angle of flexion are given in Table A-7 in appendix.

Plantar flexion: The angle of plantar flexion without stockings in healthy subjects ranged from 42 to 44 degree and in patients from 28 to 42 degree. However, with class I stockings the maximum angle of plantar flexion was 52 degree in healthy subjects and 42 in patients with venous insufficiency. Likewise, for class IV the maximum angle of plantar flexion was 50 and 38 in healthy subjects and patients respectively. Thus, the angle of plantar motion increased with application of class I stockings in healthy subjects as more power was delivered to act against the stockings elasticity, plantar flexion decreased in patients with venous insufficiency with the application of class IV. On contrary, with the application of class IV angle of plantar motion reduced in both healthy subjects and patients with venous insufficiency.

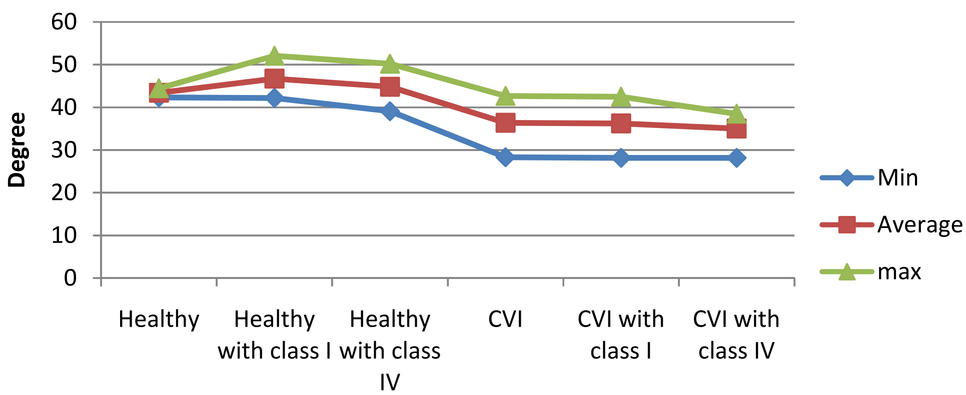


Figure 3-23 Angle of plantar flexion motion at ankle

Dorsi flexion motion: The angle of dorsi flexion in healthy subjects is 12 degree whereas in patients the average of the dorsiflexion motion was 9 degree. Thus, the difference in the angle of dorsiflexion is 3 degree between healthy subjects and patients. With the application of high strength stockings the angle of dorsiflexion reduced to 8 and 7 degree for healthy subjects and patients respectively. Thus, class IV stockings had profound effect on healthy subjects

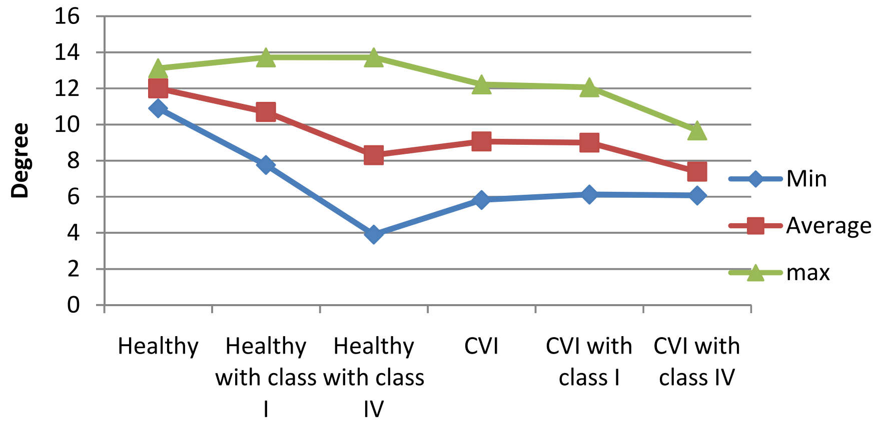


Figure 3-24 Angle of dorsi flexion motion at ankle

Range or motion at ankle: Moreover, range of motion (ROM) was calculated by adding both directional flexion that is plantar and dorsiflexion and the results are presented in Figure 3-25. ROM in patients and healthy subjects was significantly different as ANOVA test results for ROM gave F (5, 159.609) = 7.198 and p value less than 0.05 ($p>0.001$) was obtained. The difference in the flexion was also significant in subjects with and without CVI, with CVI ($p<.022$), CVI with class I ($P<0.02$) and class IV ($P<.008$) compared to healthy subjects. The obtained results matched with the results of previous work (Dix et al., 2003). However, stocking class strongly influenced the ROM in subjects with venous disorder see Table A-8 in Appendix. Influence of the stockings class in healthy subjects on ROM was insignificant.

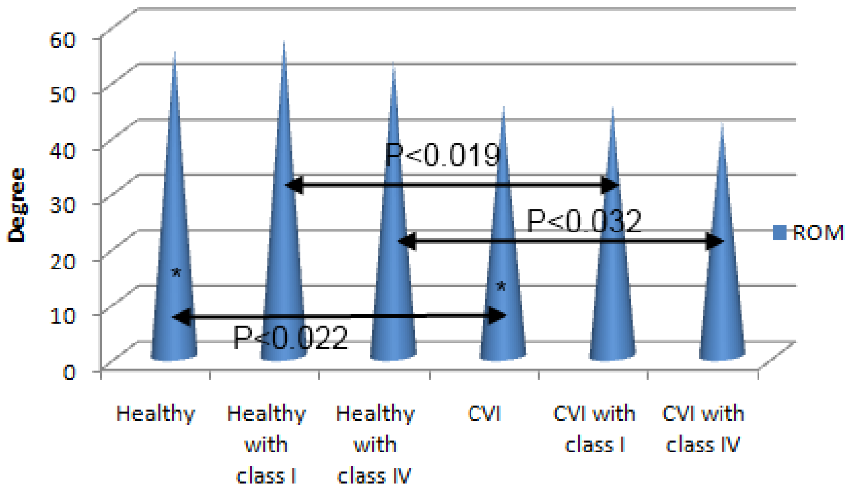


Figure 3-25 Range of motion at ankle

Much of the reduced ROM in patients is attributed to the reduced plantar flexion rather the dorsi flexion motion. Based on the results obtained it can be concluded that ROM of ankle was significantly different in patients with CVI when compared to healthy subjects and the influence of the stockings class was significant in subject with venous disorder see Figure 3-25. It is suspected that constriction at ankle by the stockings as noted by comments (see Table 3-3) influenced the angle of flexion of leg.

Greater the ROM higher is the ejection fraction and residual volume fraction of blood with proper functioning of the calf muscle (Back and Padberg, 1995). Reduction in the ROM and calf functioning is known to aggravate the clinical condition of the patients. Hence, it is important to improve the ankle flexion motion in patients.

3.4 CONCLUSION AND FURTHER WORK

In this experiment, skin stocking interface pressure was evaluated using the Kikuhime sensor and the pressure was compared to the pressure designated by manufactures to determine if there is any variation in the delivered pressure in practice on 20 subjects. 75% of tested stockings failed to deliver the recommended standard pressure (some delivered high pressure and some low) and obtained pressure was variable. Also, the measurement methodology used to evaluate the pressure delivered by the stockings at ankle is not standardized with respect to the sensor, its placement on leg, in-vivo/vitro condition, and posture during the evaluation process and hence pressure evaluation by different studies cannot be used to compare and conclude the performance of stockings.

Stockings need to confine and maintain irritation free condition with the skin after application. However, the current results obtained shows that thicker elastic fibers has led to uncomfortable sensation, irritation at welt and subdue pressure at ankle bow by wrinkled stockings as known by the comments from subjects and witnessed by visual examination. Patient's motivation to wear the stockings is directly related to the comfort. Compression stockings class III and classes IV are usually applied by patients with fragile, broken skin and venous ulcers. The application of the stockings should not further lead to pain and agonies by adding subdue pressure on sensitive skin.

It is recommended to test the pressure profile along the leg to suitable verify the high pressure sensation at instep, tibia, malleolus and welt across all the possible directions to correlate the comments with that of the pressure values by objective testing method.

The uncomfortable sensation was further confirmed by the reduced ROM in subjects wearing compression stockings. Potential causes of limited ROM in patients were due to leg trauma and arthritis (Back and Padberg, 1995). High strength stockings (Class IV) further led to reduced ROM in patients compared to healthy subjects.

CHAPTER 4. CONSUMMATE STUDY OF PRESSURE PROFILE IN COMMERCIAL COMPRESSION STOCKINGS

4.1 INTRODUCTION

Compression therapy can be applied as a mono therapy or in conjunction with sclerotherapy (Scurr et al., 1985) and medication like heparin. Correspondingly application of compression stockings as a prophylaxis method is widely accepted method to treat variants of venous disorders including varicose veins, edema and venous ulcer by compression therapy. Compression stockings inclusive of Graduated compression stockings (GCS) and Antiembolism stockings (AES) are advised by physicians to treat the disorders.

While, GCS are prescribed based on the pathological condition of patients (see Table 4-1); class I and II are used to treat minor indication of venous wall or valve dysfunction, class III and class are prescribed in the management of edema and moderate CVI, Class IV stockings are prescribed to treat severe CVI, edema and chronic venous ulcers. AES are applied to prevent DVT (Deep Vein Thrombosis) in immobile patient at supine posture after surgery.

It is eminent that the effectiveness of the stockings to heal the venous disorders depends on the magnitude of the pressure delivered and its graduated pressure profile (see section 2.7) along the leg length. Although, previous research works accede to the graduated pressure profile in compression stockings (Bradley, 2001, Hayes et al., 2002, Amsler and Blättler, 2008), (Becker et al., 2006) work on stockings contend to a different profile with high pressure at B1 (were the tendon changes into muscular part of the gastrocnemius muscle) instead at B region. Moreover there has been debate on the magnitude and duration of pressure (Scurr et al., 1985).

In the first place, the pressure evaluation at B, B1 and calf is considered to be important (Partsch et al., 2006b). Markedly, as noted in chapter 3, the regions which needed necessary attention is the instep (open toe end of stockings), B and welt portion (seam stockings to hold the stockings over leg) and at anterior direction of leg as known from the comments see Table 3-3. From the observation made in pilot study, welt region is quite close to calf but its girth measurement is different from that of welt (girth at welt < girth at calf). Hence, upper calf just below the welt region needs to be considered for pressure evaluation.

Accordingly, in this study the pressure delivered by the stockings AES and GCS inclusive of class I, II, III and class IV in all the directions (anterior, medial, lateral and posterior) along the major portions of leg namely instep, B, B1, calf, upper calf and welt was evaluated using reliable pressure sensor (X Pliance pressure sensor) on ten healthy subjects. On contrary to the previous studies (Wildin et al., 1998, Mosti and Partsch, 2010) where the number of subjects for pressure evaluation were chosen at random, in the current experiment the precise number of subjects required for this experiment was evaluated by power analysis based on the standard deviation of the results from pressure evaluation of GCS in stage I of pilot study.

4.2 EXPERIMENTAL METHOD

The experimental procedure with the specifications of the material, instrument used to evaluate the pressure profile, subjects and the measuring regions considered are given in below sub sections:

4.2.1 Commercial compression stockings

Anti embolic stockings (AES) and Graduated Compression Stockings (GCS) used in the present study were purchased in Hong Kong from authorized dealer. AES (closed toe) was warp knitted see Figure 4-1 and GCS (open toe knee high) from class 1and class II; class III and class IV was weft knitted as shown in Figure 4-2 **and**

Figure 4-3 respectively.

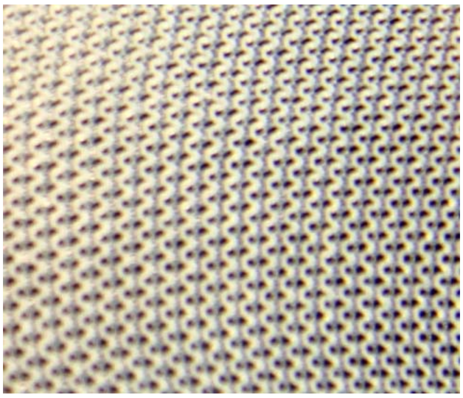


Figure 4-1 Warp knitted Anti Embolic stockings (AES)

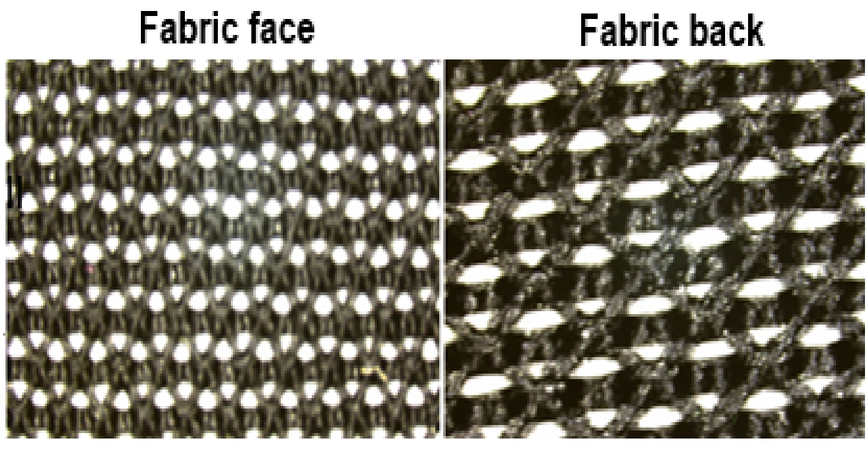


Figure 4-2 Class I and Class II Stockings fabric

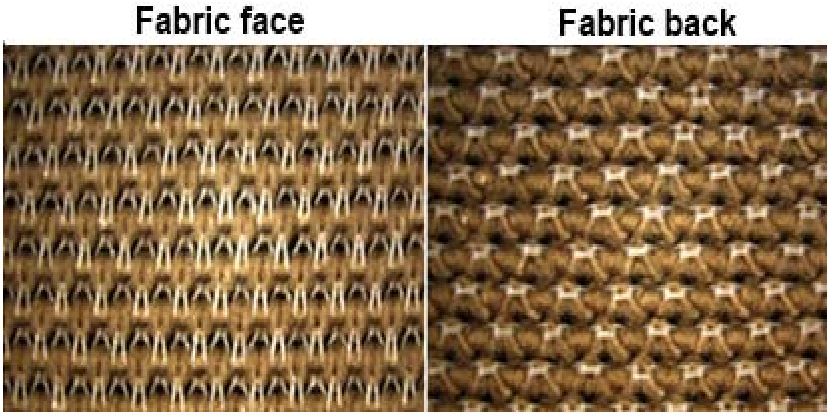


Figure 4-3 Class III and Class IV Stockings fabric

The AES stockings were manufactured in France and GCS in Switzerland. Table 4-1 gives the pressure values and recommended functions of each of the stockings considered in this study. The information was noted from the product brochure provided by the manufacturer of the stockings along with the stockings samples.

Table 4-1 Designated pressure value of commercial compression stockings and their suggested medical indications

Compression class and indication	Code used in results	Specified pressure as per German standard mm Hg(a)	kPa(b)	Suggested medical indications for which stockings are applied	Fiber content	WPI	CPI
Anti embolic stockings (AES)	AES	15-19	1.99-2.53	Support stockings, prevent blood clots during traveling and relieve discomfort from achy legs	78% polyamide and 22% elastan		
Graduated Compression Stockings (light)	Class I	18 to 21	2.4 to 2.8	heaviness, fatigue, mild varicosities, post sclerotherapy and Initial varicose during pregnancy	78% polyamide and 22% elastan	62	60
Graduated Compression Stockings (medium)	Class II	23 to 32	3.1 to 4.3	Post sclerotherapy, post surgical stripping, prophylaxis of Thrombosis, pregnant with previous phlebitis, oedema, burn scar and stasis dermatitis	78% polyamide and 22% elastan	60	60
Graduated Compression Stockings (strong)	Class III	34 to 46	4.5 to 6.1	Emphasized oedema from above causes, correctable lymphoedema, severe chronic venous insufficiency and venous ulcers	62 % polyamide and 38% elastodien	36	28
Graduated Compression Stockings (very strong)	Class IV	More than 49	6.5 and higher	Primary and secondary Lymphoedema, elephantiasis and venous ulcers	62 % polyamide and 38% elastodien	43	25

4.2.2 Conditioning of stockings sample

All the stockings types (AES and GCS) were conditioned in a standard laboratory environment for 2 hours at a temperature of 22 $\pm$ 2 o C and humidity of 65 $\pm$2% to control the instability of the stockings and further relax the fabric from pre-mechanical stresses before each test measurement.

4.2.3 Effective number of subjects based on by statistical power analysis for pressure profile evaluation

The results from the pilot study stage I as described in chapter 3 was used to calculate effective sample size of subjects for the current experiment. The difference in standard deviation between the class I and class II of the GCS was noted to be 3.26 mm Hg and between class III and class IV was 6.44 mmHg. The average of the both the standard deviation was considered to calculate the effective sample size. Graph Pad StatMate Tool (version 2.00, Graph-Pad Software, San Diego, CA, USA; www.graphpad.com) was used to calculate the effective sample size by power ranging from 99% to 80%. Figure 4-4 shows the plot of difference in the mean standard deviation (Y axis) against sample size (x axis) for power ranging from 99 to 80%. For our experiment we choose a sample size of 10 so that the power of detecting the difference is at 90% with an error of probability $p<5\%$. p value less than 0.05 is termed to statistically significant.

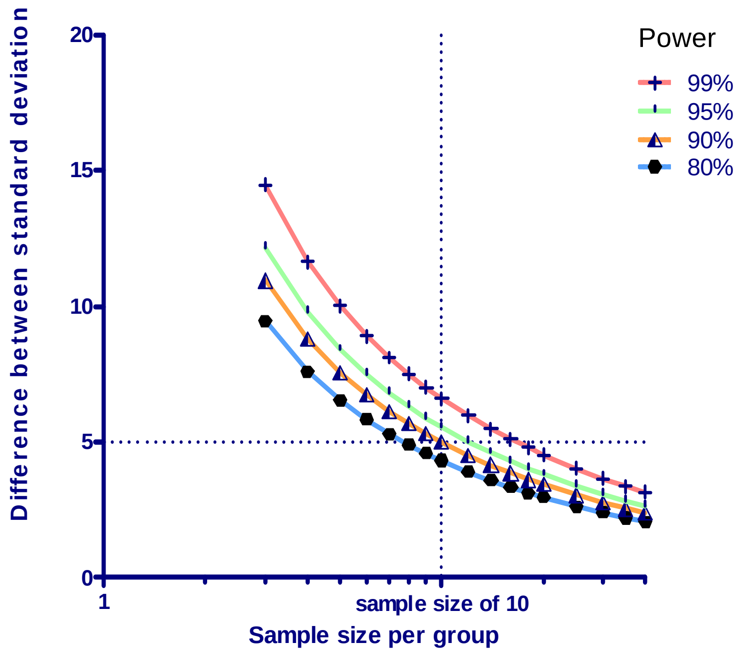


Figure 4-4 Sample size calculation using power analysis

4.2.4 Subjects for pressure profile evaluation

All the subjects (5 Men and 5 women) contemplated for the designed experiment were healthy subjects. Subjects were not permitted to take part if they were known to have nervous system impairment, fracture or leg surgery as the compression stockings with high pressure can affect their physical wellbeing. Each subject read and later signed an institutionally (The Hong Kong Polytechnic University) approved informed consent form from the University's ethics committee before participating in this study. The experimental procedure was explained and all their queries were answered to make them feel comfortable during the experiment. The average of self reported age, height; weights and measured anthropometric measurement of all regions along the leg are given in Table B-1 in Appendix and Table B-2 in Appendix respectively. Average BMI of all the subjects was 23.3 which falls in the normal range.

4.2.5 Pressure profile evaluation equipment-X Pliance pressure sensors

The pressure magnitude was obtained using Novel Pliance X Pressure sensing system from Germany (Novel electronics, Munich, Germany). The complete system kit consisted of electronic pressure analyzing software, Bluetooth device, and the sensors as shown in Figure 4-5. The sensors are a capacitive transducer with a diameter of 10 mm and are ultra-thin with thickness less than 1 mm thick. The sensing area is connected to the computer system via conductive pressure strip, these strips makes it convenient to measure the skin stocking pressure by assisting the placement of sensor underneath the stockings. The system is effective to measure interface pressure generated by pressure garment on to the skin. The accuracy and the reliability of the sensor with respect to linearity and repeatability were reported by Lai and Li-Tsang (2009); they concluded that it can be used in comparative clinical trials to evaluate pressure from pressure garments. The sensing resistor, sensor strips measures the normal force perpendicular to the sensor surface. The pressure reading unit can be either set to pascals or mm Hg.

In this study 4 sensor strips were used, the data from the sensor is retrieved and read by software via Bluetooth (see Figure 4-5). All the sensors used were calibrated before performing the measurement their accuracy of the sensor was tested against standard weight. It was convenient to use this sensor as 4 sensors utilized to measure the pressure across the leg at a time; also the least count for pressure reading is much small in this system compared to kikuhime pressure sensor. Furthermore, the sensor was thin, flexible, and sensitive with higher resolution.

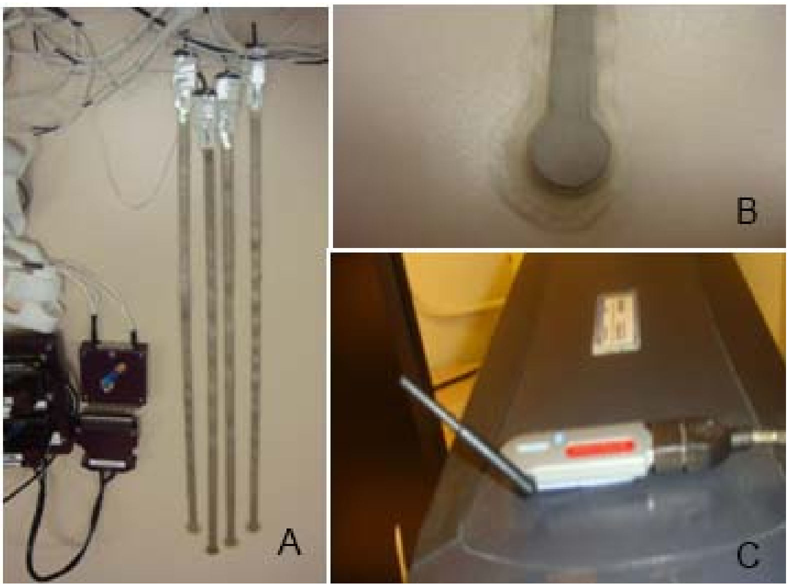


Figure 4-5 Novel X Pliance sensor (A-Sensor strips, B-sensor, C-Bluetooth)

4.2.6 Calibration and correlation of X Pliance pressure sensors with standard weight

The sensor was calibrated by placing them on a flat surface and external force was applied by using standard weights as shown in Figure 4-6. The pressure reading was correlated with standard pressure.

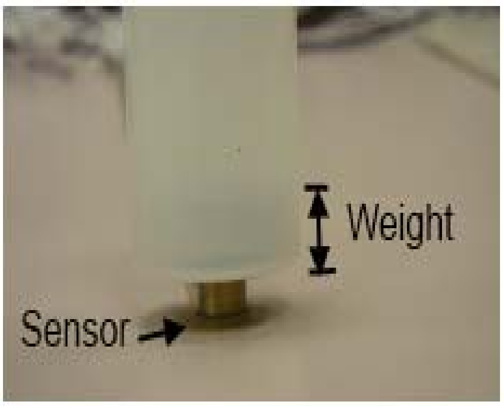


Figure 4-6 Calibration of X-Pliance sensor against standard weight

4.2.7 Measuring regions considered for pressure profile evaluation

The complete leg profile was considered at major regions such as instep, B, B1, calf, upper calf and welt as discussed in section 4.1. for pressure profile evaluation and is shown in Figure 4-7 at posterolateral direction.

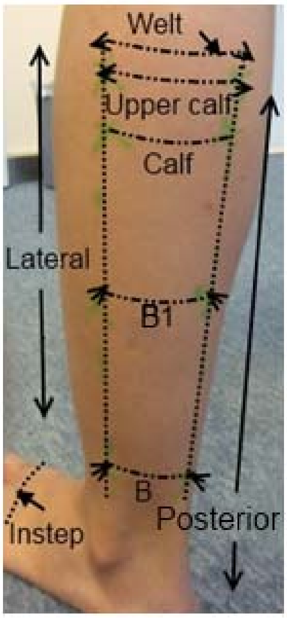


Figure 4-7 Anatomical markings for pressure measurement at posterolateral view on subject leg

The B region for measuring the pressure was noted by taking the least possible girth of leg at the ankle. The B1 (were the tendon changes into muscular part of the gastrocnemius muscle) was noted from the bulged region by ankle flexion motion after noticing the Soleus and Gastroc muscles see Figure 4-8 by marking the soleus and Gastroc muscle, C region with maximum girth at the calf, upper calf just above the calf girth (1.5 cm below welt) and welt region where the stockings band is positioned. The measuring sites were marked in all four directions (anterior, medial, posterior and lateral) using a permanent marker.

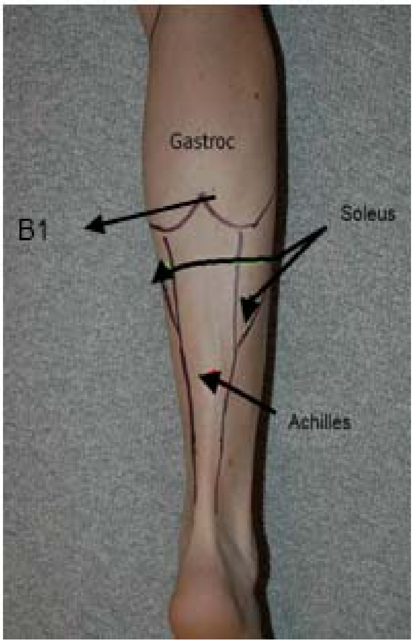


Figure 4-8 Markings on leg to identify B1 region of subject leg

4.2.8 Procedure for pressure profile evaluation

The experiment was carried out in a controlled environment with a temperature of 22 $\pm$ 5 degree Celsius and a relative humidity of 65 $\pm$ 6%. At first, the anthropometric measurements were taken to see if the stockings size suited the subject and the measurements were taken by the same person to eliminate the inter observer variability. Then, the sensors were placed on the anatomical marking over leg at any one of the measuring regions in all four direction and the subjects were asked to put on the stocking over it. Figure 4-9 shows the subject wearing stockings with the pressure sensor placed at B1 region. Subject position on chair with their knee bent to 90 degree to the floor. After about a minute the steady reading was considered. The total measuring time for each subject with all the stockings types was about 3 hours.

Figure 4-9 Subject wearing stockings with the pressure sensor placed at B1 region

4.2.9 Data analysis of obtained results

The average values with the quartile range of the evaluated pressure are used to indicate the difference between the different types of stockings (GCS and AES) and the variation within each stockings type. ANOVA was used to test the variance between stockings types. Comparison of the evaluated pressure along the circumferential direction was also done by Dunn's Multiple Comparison Test.

4.3 RESULTS

Major regions of leg and stockings parts were considered to completely measure the pressure profile starting from the instep to the welt as the pressure sensation was different at different regions during the pilot study. The results of calibration test and pressure profiles are given in the following sections.

4.3.1 Results of calibration of X Pliance pressure sensor

The correlation of X Pliance pressure reading against standard weight is given in Figure 4-10. The variability and the accuracy of the pressure sensor were assessed and the obtained values are given in Table B-5 of Appendix. The wilcoxon matched-pairs signed rank test showed no significant difference between the pressure reading ($P < 0.05$) (see Table B-6 in Appendix). The pressure reading from X Pliance sensor highly correlated with the standard weight with a correlation factor of 0.99 as given in Figure 4-10.

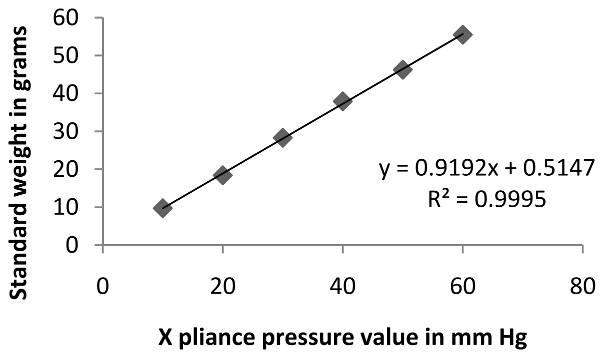


Figure 4-10 Correlation of pressure against the standard weight

4.3.2 Average of pressure magnitude at all region in commercial stockings

The obtained pressure values from X Pliance pressure sensor for each of the tested stockings on each subject is given in Appendix (see Table B-7 in Appendix). The mean of pressure values for each class from the four directions (anterior, medial, lateral and posterior) at all regions (instep, B, B1, calf, upper calf and welt) considered are shown in Figure 4-11. The figure also gives the standard error bars; the evaluated pressure for the stockings is of increasing order starting from AES to GCS and for GCS from class I to class IV. Class I and class II relatively produced same level of pressure as the standard error coincide with each other, like class III and class IV also produced similar pressure.

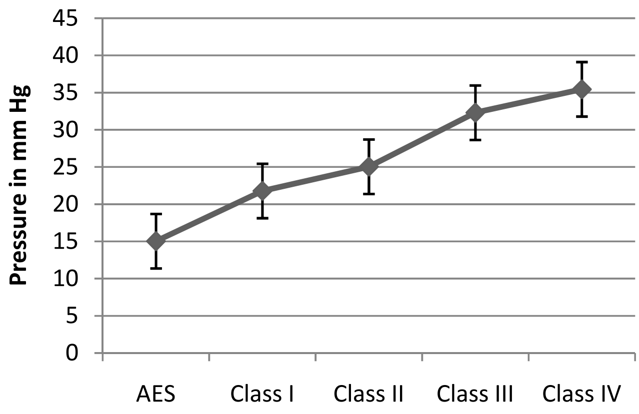


Figure 4-11 Mean pressure of measured regions from instep to welt

4.3.3 Pressure delivered at B region compared against the standard for commercial stockings

The AES and GCS class II, class III and class IV did fall within the error bar of standard designated pressure. However, the pressure delivered by class I overshoots the mean of range of the standard designated pressure as seen in Figure 4-12

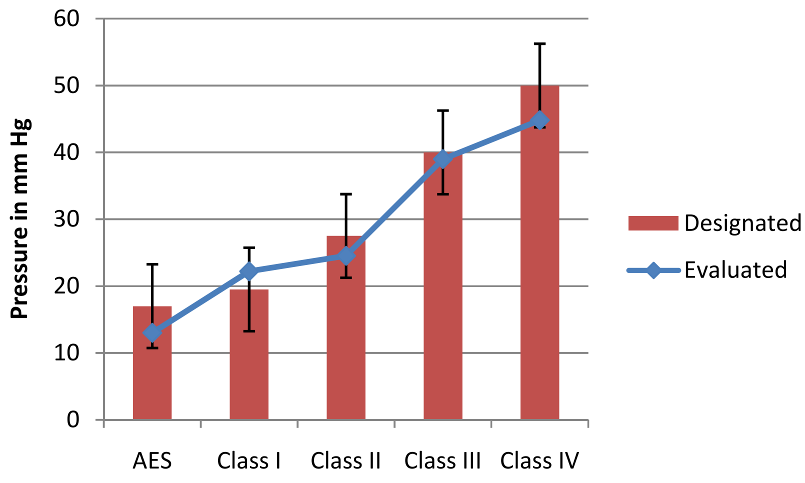


Figure 4-12 Evaluated pressure reading against the designated pressure

4.3.4 Factors influencing the pressure delivered by commercial stockings

Direction, stockings class and measuring region were considered to be the major factors influencing the pressure distribution. For analysis of variance, measured pressure was considered to be the dependent variable and subjects to be independent factor. ANOVA test results as shown in Table 4-2; GCSs of different classes deliver significantly different pressure on the leg (P<0.001). The influence of the position (P<0.001) on the delivered pressure is comparatively higher than the directional pressure variation (P<0.61). Also the factors did interact with each other, the influence of the class and the region of pressure measurement was significant (P<0.001).

Table 4-2 ANOVA test for factors influencing pressure from stockings

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	451531.3253	1	451531.3253	1625.82177	0.00
	Error	2763.120345	9.949124153	277.7249839		
Direction	Hypothesis	662.4214624	3	220.8071541	0.62104207	0.61
	Error	8311.697942	23.37747681	355.5429874		
Position	Hypothesis	3669.819227	5	733.9638455	7.66796026	0.00
	Error	3794.112526	39.63833402	95.71826414		
Class	Hypothesis	16399.05246	3	5466.350819	118.212922	0.00
	Error	987.7427779	21.36049517	46.24156743		
subjects	Hypothesis	2088.500931	9	232.055659	0.55502038	0.82
	Error	10265.75468	24.55317446	418.1029502		
Direction * Position	Hypothesis	366.4087745	9	40.71208606	0.59101254	0.80
	Error	2479.871388	36	68.88531634		
Direction * Class	Hypothesis	137.9764352	9	15.33071502	0.7115803	0.70
	Error	1792.471295	83.19815848	21.544603		
Position * Class	Hypothesis	4351.827163	15	290.1218109	7.37305063	0.00
	Error	4702.132884	119.4983022	39.34895137		
Direction * Position * Class	Hypothesis	279.7581257	27	10.36141206	0.84819747	0.68
	Error	1319.306577	108	12.21580164		
Direction * subjects	Hypothesis	9171.354693	22	416.8797588	6.69378545	0.00
	Error	3371.005556	54.12780897	62.27862572		
Position * subjects	Hypothesis	3821.31126	40	95.53278151	1.02245034	0.46
	Error	6047.219291	64.72104497	93.43513063		
Direction * Position * subjects	Hypothesis	2479.871388	36	68.88531634	5.63903364	0.00

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
	Error	1319.306577	108	12.21580164		
Class * subjects	Hypothesis	1234.23257	27	45.71231742	1.12165937	0.33
	Error	4948.496289	121.4230117	40.75418837		
Direction * Class * subjects	Hypothesis	1526.931194	66	23.13532112	1.47066064	0.02
	Error	4914.129826	312.3802464	15.73124384		
Position * Class * subjects	Hypothesis	4701.250157	120	39.17708464	3.08493155	0.00
	Error	1613.793185	127.0753441	12.69949884		
Direction * Position * Class * subjects	Hypothesis	1319.306577	108	12.21580164	0.51799874	1.00
	Error	9433.0744	400	23.582686		

4.3.5 Distribution of the pressure along the leg in measured region for commercial stockings

The distributions of measured pressure for all stockings at different measuring regions are compared with that of standard pressure range as per the German standard and the same is represented in Figure 4-13 for instep, B, B1, calf, upper calf and welt. Since the standard pressure at instep is not given, rest of the regions considered for the study was compared to the designated pressure profile. The grey band in the figures represents the designated pressure range as per the standard see Table 2-3 for the standard pressure profile.

At instep the pressure for class III (32.48 mm Hg) and class IV (30.48 mm Hg) was relatively higher than that of Class I and Class II. At B region, the obtained pressure value did fall within the range of the standard pressure for class II and class III whereas for class I stockings the pressure did overshoot the range, on contrary for AES the pressure was lower than the recommended pressure. The pressure distribution for B1 region was nearly as per the standard. For calf and upper calf the pressure did overshoot for class I, however for rest of the stockings the pressure was within the range. Notwithstanding for welt region the pressure was significantly higher than that of the standard for all the stockings.

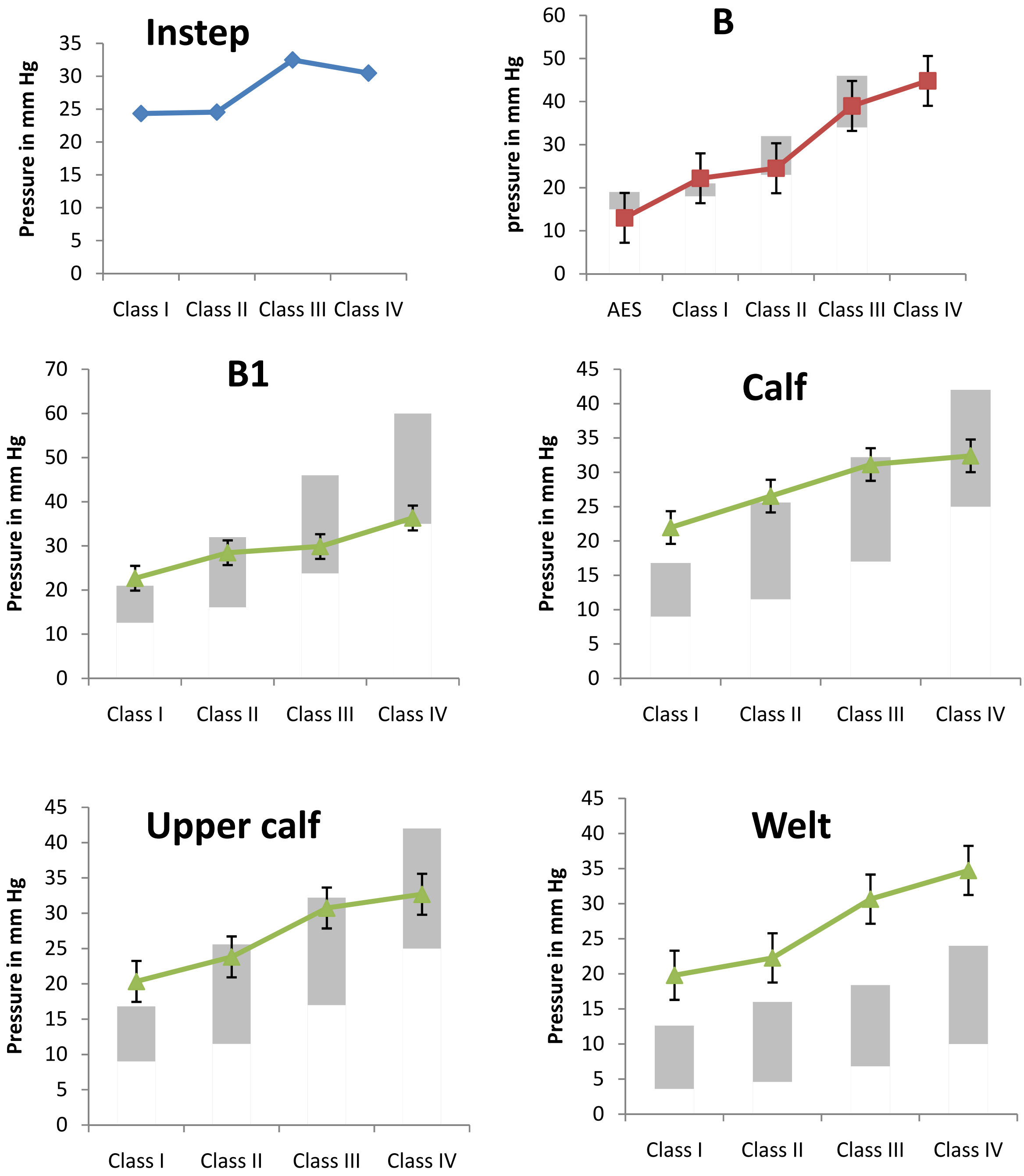


Figure 4-13 Pressure distribution at each of the measured regions

4.3.6 Pressure distribution at each of the measured region in commercial stockings

The overall pressure distribution for all the compression stockings at each region is given in Figure 4-14. As per the standard the pressure reading should be graduated with higher pressure at the B region and gradually reducing towards the calf. AES produced reversed pressure profile from B region to welt with high pressure at welt. Amongst GCS class I, III and class IV produced forwardly graduated pressure profile with higher pressure at B region. However, class II stockings produced maximum pressure at B1 region. The pressure reading at the welt was relatively same as the pressure delivered at the B1 region except for class II and AES stockings. Thus, the stockings welt produced higher pressure than required. The pressure at the instep was lower for class III and class IV than B region.

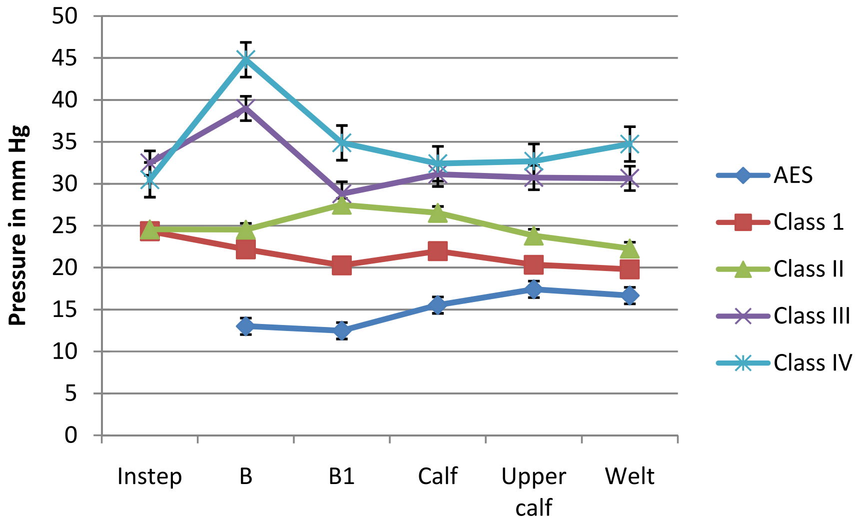


Figure 4-14 Pressure distribution for each region in each of the stockings

4.3.7 Overall pressure at each of the measured regions in commercial stockings

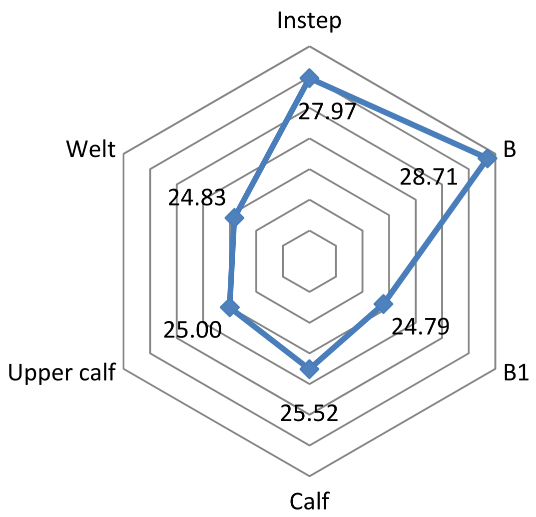


Figure 4-15 Overall pressure at each measuring regions in mm Hg

The overall pressures from the stockings are shown in Figure 4-15.pressure at B region was highest followed by instep and calf. Overall the pressure profile was forwardly graduated till the B1 region. However, the pressure at the calf and upper region was higher than that of the B1. The pressure at the welt was the least averaging the pressure reading for all classes. The observation is due to the inclusion different direction and types of stockings (AES and GCS).

4.3.8 Pressure distribution at each direction for measured regions in commercial stockings

The pressure distribution at different direction (anterior, posterior, medial and lateral) at all the measured regions is given in Figure 4-16. At anterior direction, the pressure profile from B region to welt was forwardly graduated for class I, II and IV and AES; Class III showed reversed profile with maximum pressure at calf. At posterior region the pressure more or less uniform, class II stockings maximum pressure at B1 region. In medial direction the pressure was completely reversed for AES and the pressure at the instep was nearly equal to the pressure at the B region for class IV. In lateral region, the pressure was nearly forwardly-gradient for GCS, however, AES showed completely reversed pressure profile.

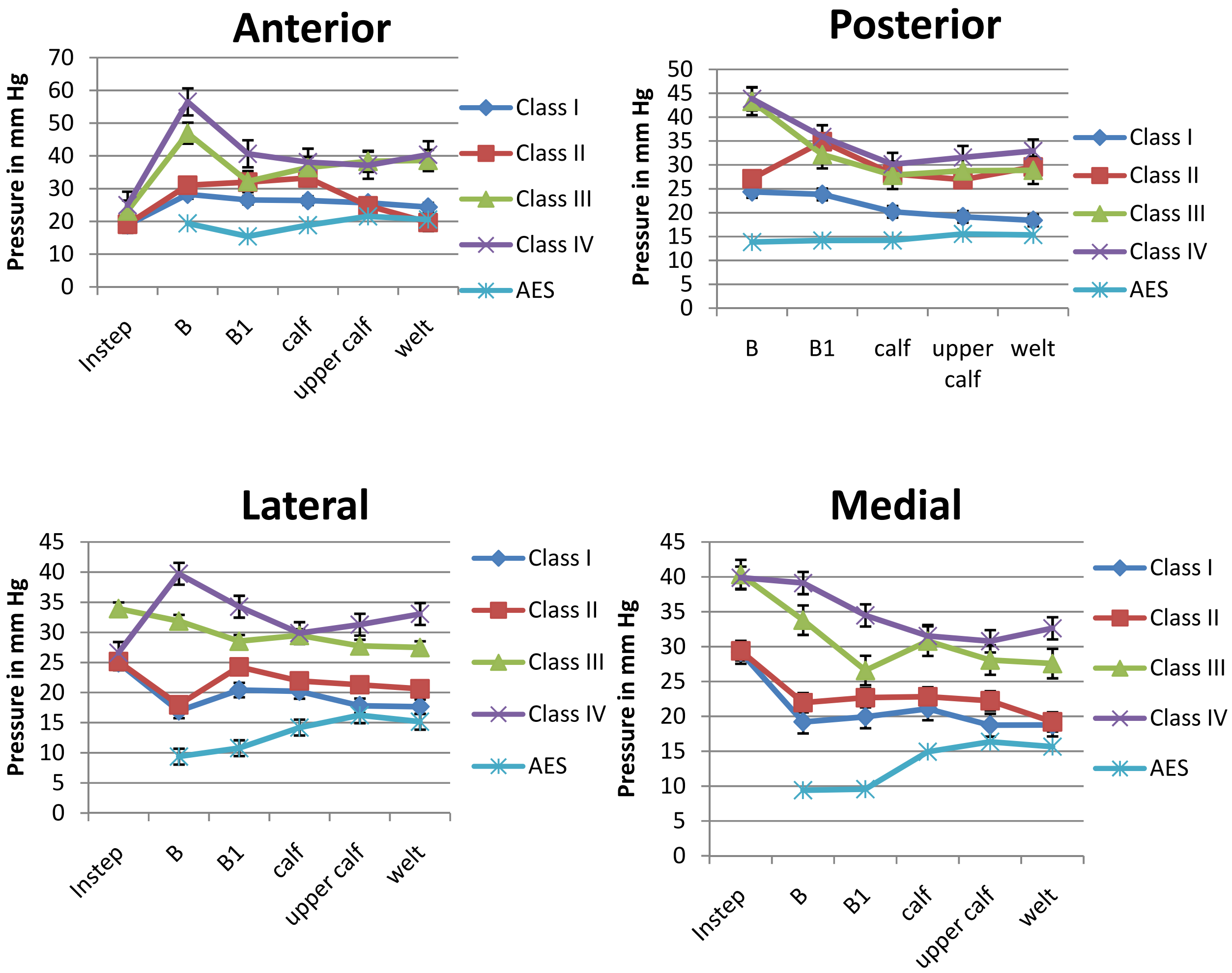


Figure 4-16 Pressure distribution at different region for all the stockings in each of the direction.

Although the pressure was high at anterior and posterior region, the pressure at the medial and lateral was low. It is clear from the figure that the pressure at the anterior and the posterior region was the high for all the stockings. Wilcoxon Signed Rank Test showed significant difference in all four directions for all class of GCS and AES ($p < 0.05$). The pressure at the anterior region is high due to the sheen structure of the tibia of the leg. Thus, due to the unnecessary high pressure at the anterior region this region is likely to form necrosis.

4.3.9 Pressure distribution at each direction for B and welt region in commercial stockings

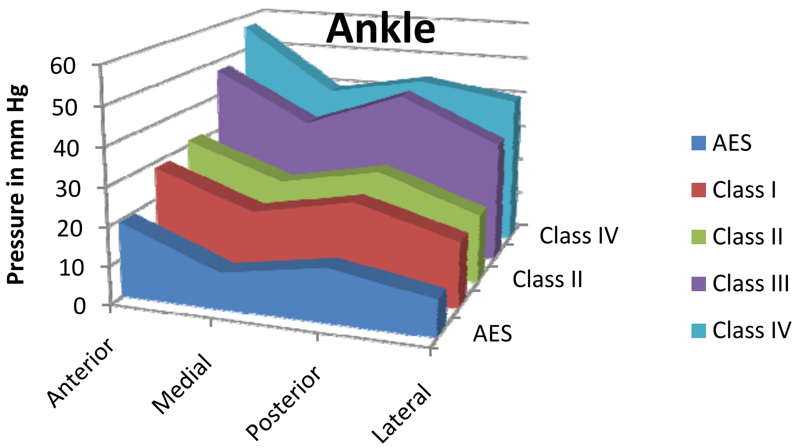


Figure 4-17 Pressure distribution at each direction against each stockings at B region

From pervious figure it was noted that the pressure distribution is different at different directions. However, the variation of direction pressure variation on different stockings at ankle and welt was not know. Hence, the pressure distribution across the girth at B region and welt is plotted for all the tested stockings and is given in Figure 4-17 and Figure 4-18 respectively, the pressure profile was similar for all types of stockings across the ankle girth-B region with maximum pressure at the anterior direction and minimum at the medial direction due to the difference in radius of curvature. In contrast, the pressure profile across the welt was different for different stockings. The pressure at the anterior and posterior region was high even at welt region. AES produced higher pressure in all directions at welt than the B region. The pressure at the lateral direction was nearly the same at posterior direction for AES, class I and class II. Higher pressure at lateral direction was noted for stockings as the leg configuration of leg at welt is uniformly elliptical.

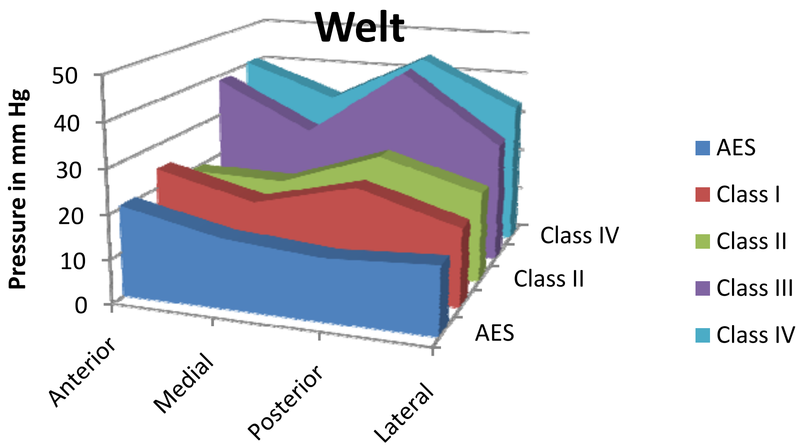


Figure 4-18 Pressure distribution at each direction against each stockings at welt

4.3.10 Overall pressure distribution at each direction in commercial stockings

The pressure distribution across different direction is studied by plotting the graph as given in Figure 4-19, representing the overall pressure distribution at each direction for GCS. Again maximum pressure was noted at anterior region and the pressure at the medial and lateral was nearly same while lateral region showed slightly higher pressure than that of medial and lateral. The maximum pressure noted was nearly equal to 60 mm Hg at the anterior direction.

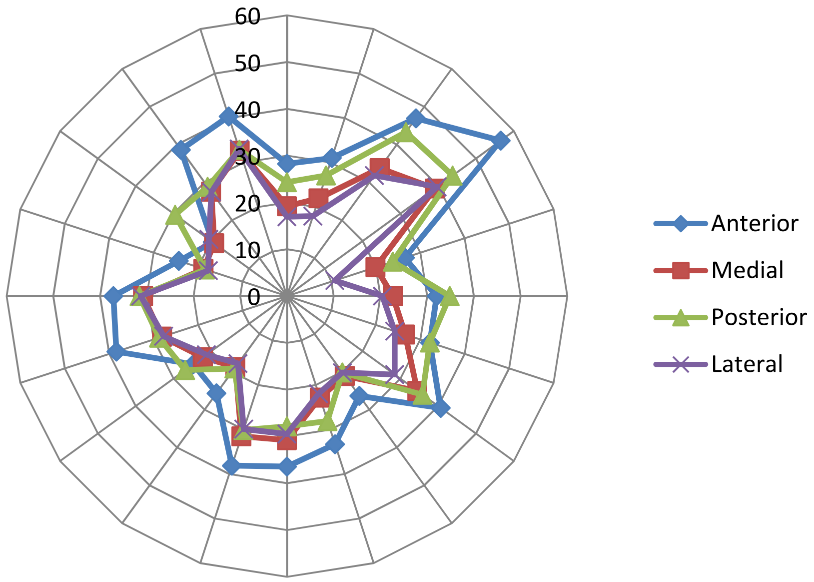


Figure 4-19 Pressure distribution in mm Hg at each direction

4.3.11 Pressure distribution at different directions for each region in commercial stockings

Figure 4-20 shows the pressure for each region in different region against all stockings. In all regions except for welt region, class IV showed highest pressure. At welt, Class III delivered high pressure. The pressure distribution was highest at anterior region for all the classes except at instep region where the medial region showed highest pressure. At instep the pressure at the medial region was high compared to the pressure reading at the anterior and lateral for all stockings. At ankle class IV stockings delivered high pressure at the anterior region followed class III, class II, class I and AES. Likewise, the pressure at the B1 region was high at the anterior and posterior region for class IV and other stockings in the same manner. However, the pressure at the calf and upper calf was just about uniform in all the regions. Furthermore, the pressure at the welt region for class III was high than class IV at anterior region and posterior. High pressure was noted at the posterior portion for welt regions for class II.

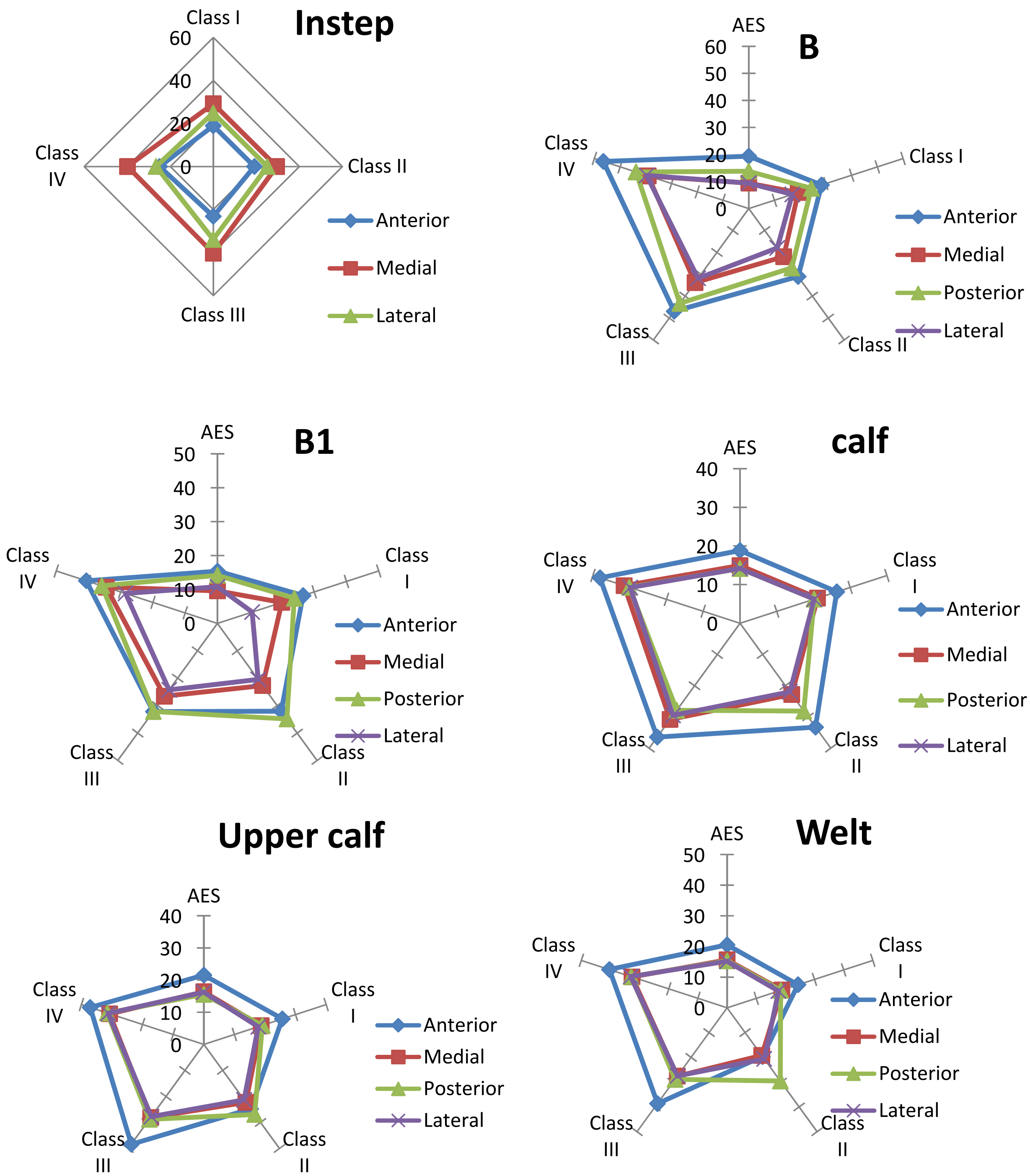


Figure 4-20 Pressure distribution in mm Hg for GCS at different directions for each region

4.4 DISCUSSION AND CONCLUSION

In this experiment pressure was evaluated at 24 positions for 5 different stockings samples on ten subjects and 1200 pressure reading were taken. In contrast to the results obtained in the pilot study, majority of the stockings did produce the necessary pressure this might due to the number of trials carried out on each of the stockings.

The circumferential pressure across B region, B1, calf, upper calf, welt and instep considered in the experiment was non uniform as the configuration of the leg is elliptical. The longitudinal pressure for the measured regions was also variable. The pressure recorded at the medial and lateral position was lowest for all the stockings as the leg was conical in shape. As the malleolus region elongates the stockings to greater extent the immediate point do not receive sufficient pressure.

The negative gradient pressure was noted for class II and AES stockings. Moreover, significantly high pressure was delivered at the welt and instep region by stockings when compared to the standard pressure readings (it is assumed that the pressure at the welt should be as same as pressure at G (Groin) region for knee high stockings). In addition, the pressure at the anterior direction for all the measured regions was high.

From the results obtained it can be concluded that the compression stockings do not apply sufficient pressure at the medial and lateral position at the B region and most of them fall at the lower pressure limit of the standard pressure specified. Probably this is the main reason in the development and reoccurrence of the venous ulcer at the malleolus region and is often termed as the gaiter area corresponding to the gaiter region of the boots. In order to deliver effective pressure at the medial and lateral region some of the physicians advice class III or IV after noting that the ulcer as not healed with time.

The shape of the leg is modified by the application of compression pressure, with higher pressure more uniform radii is formed (Blattler et al., 2007), hence uniform pressure was noted for class III and class IV at calf. The possible explanation for the variable gradient pressure is that the human leg is not standard and leg configuration varies amongst individuals. With the increased girth at the calf region the tension of the fabric increases and also at the welt region the fabric elasticity is high with seam. Thus, higher pressure is delivered at the welt of the stockings. Moreover the yarn and technique of knitting is also known to influence the pressure.

The class III or IV can be uncomfortable and most of the patients discontinue using them as the pressure on the bony surface at the malleolus region is extremely high. Thereupon, pelotte are usually applied to local vary the radius of curvature and thereby increase the pressure delivered (Veraart et al., 2008). This can sometimes even complicate the situation as the patient might find it difficult to place them in the proper position over the specified region while wearing the stockings. Thus, in the long run high pressure at welt, instep and low pressure at medial and lateral region at ankle needs necessary attention.

The results of the present study highly correlated with the commentary from the subjects of pilot study. In further study, the efficiency of the shape memory filaments at the B region and welt is tested (see Chapter 6) as they form the critical regions with reduced medical functioning and high complication of skin redness as noted in chapter 3 and chapter 4.

CHAPTER 5. THERMOMECHANICAL TESTING, PRE-SETTING AND STRESS RELAXATION OF SHAPE MEMORY FILAMENTS

5.1 INTRODUCTION

The main aim of this study is to suitably apply smart filaments in compression stockings and eliminate the current undesirable variations and improve their properties. The study aims is to reduce the level of complications issues in patients applying compression stockings. The influence of fabric properties defined by shape memory effect such as recovery and fixity in shape memory fabric on the compliance level can be prominent.

In the literature review it was noted that boarding of stockings see section 2.6.3 is one of the main process in designing of compression stockings. During boarding of stockings high temperature is applied to heat set the stockings to leg configuration. Moreover, shape memory filaments post spinning operation like pre-setting is used to control the fiber shrinkage and relieve pre occupied stress in filaments during manufacturing process. Furthermore, thermomechanical testing is used to study the shape memory effects.

Henceforth, it is important to study the influence of post spinning operations like pre-setting and thermomechanical properties of filaments and fabric. Moreover, it is necessary to quantify the novel properties of the shape memory filaments (SMf's) used in compression stockings. In this chapter, a detailed analysis of properties of shape memory filaments (SMf's) with respect to shape memory effect were carried out by evaluating the influence of the pre-setting temperature and parameters of the thermomechanical testing on Shape Memory Effect (SME). Stress relaxation and fiber shrinkage by heat treatment is also evaluated. Finally, core spun yarns of different counts were manufactured and their mechanical properties were also evaluated.

5.2 METHODOLOGY

The method of testing of shape memory fibers including thermomechanical testing, heating setting, stress relaxation and mechanical testing of shape memory core yarn is presented in following sections.

5.2.1 Thermomechanical testing of shape memory filaments at different temperatures

Cyclic thermomechanical testing method is used to evaluate the shape memory properties, this is not single phase test but includes cycles of tests as the testing objective is to evaluate the deformation and recovery properties when the polymer is deformed, fixed and recovered in cycles. In this chapter the influence of various testing parameters on the shape memory effect were tested in a controlled environment. The testing variables considered for the experiment were deformation temperature, deformation and recovery speed, pre-setting, and stress relaxation.

As noted from literature, melt spun shape memory filaments are superior to wet spun filaments (Meng et al., 2007). Melt spun filaments were tested for the shape memory effect i.e., shape fixity and shape recovery on Instron 5566 installed with a heating chamber by which the temperature can be set to desired value during testing using the thermostat attached to Instron. The deformation temperature was set to 5 different temperatures (30, 40, 50, 60 and 70 Degree Celsius).

The thermomechanical cyclic testing was carried out for 2 cycles to evaluate the best range of shape fixity and shape recovery in the above said temperatures. This cyclic test involves 5 steps;

1. The filaments are heated to the set temperature and then elongated to 100% strain at a speed of 10 mm/min by moving the clams
2. Later, the filaments are cooled to the room temperature while maintaining the strain level for about 15 minutes
3. Then, the filaments are allowed to recover to zero strain by moving the jaws back to the set gauge length.
4. Finally, the filaments are reheated to the same set temperature
5. Once again the step 1 is repeated to initiate 2nd cycle.

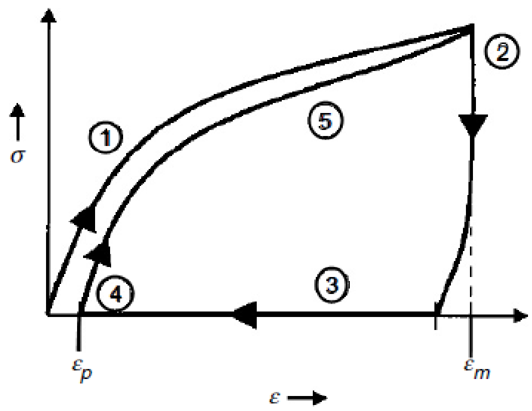


Figure 5-1 Thermomechanical testing of shape memory filaments

Figure 5-1, shows the schematic representation of the cyclic test with εm (maximum elongation), εu (strain after unloading the filaments) and εp (the residual strain after recovery), with these strain valve shape memory properties such as shape fixity (R_f) and shape recovery (R_r) are calculated using the formula given in equation given below,

$$R_f(N) = \frac{\varepsilon_p(N)}{\varepsilon_m}$$ .... Equation 5-1

$$R_r(N) = \frac{\varepsilon_m - \varepsilon_p(N)}{\varepsilon_m - \varepsilon_p(N-1)}$$ .... Equation 5-2

5.2.2 Multiple cyclic test of shape memory filaments

The thermomechanical testing is repeated at optimum temperature based on the results of 2 cycle's thermomechanical testing of filaments at different deformation temperature. Shape fixity and shape recovery for 20 cycles was studied to test the variation in shape memory effect with number of cycles.

5.2.3 Sample preparation

The filament studied was obtained from Shape memory Textile Centre, The Hong Kong Polytechnic University. The filaments were melt spun on a spinning machine. The schematic representation of the spinning machine used to manufacture the filaments is shown in Figure 5-2. The polymer was prepared by bulk polymerization using poly (ε-caprolactone) diol (PCL) as the soft segment, and diphenylemethane-4,4'-diisocyanate and 1,4-butanediol as the hard segments; melt spinning method was used to spin filaments from shape memory chips after drying them at 90° C. for 6 hour until the moisture level reached less than 100 ppm (parts per million). The shape memory filaments were spun in highly pure nitrogen environment using extruder with a temperature range from 175 to 202 Degree Celsius. Winding speed used was 600 m/min.

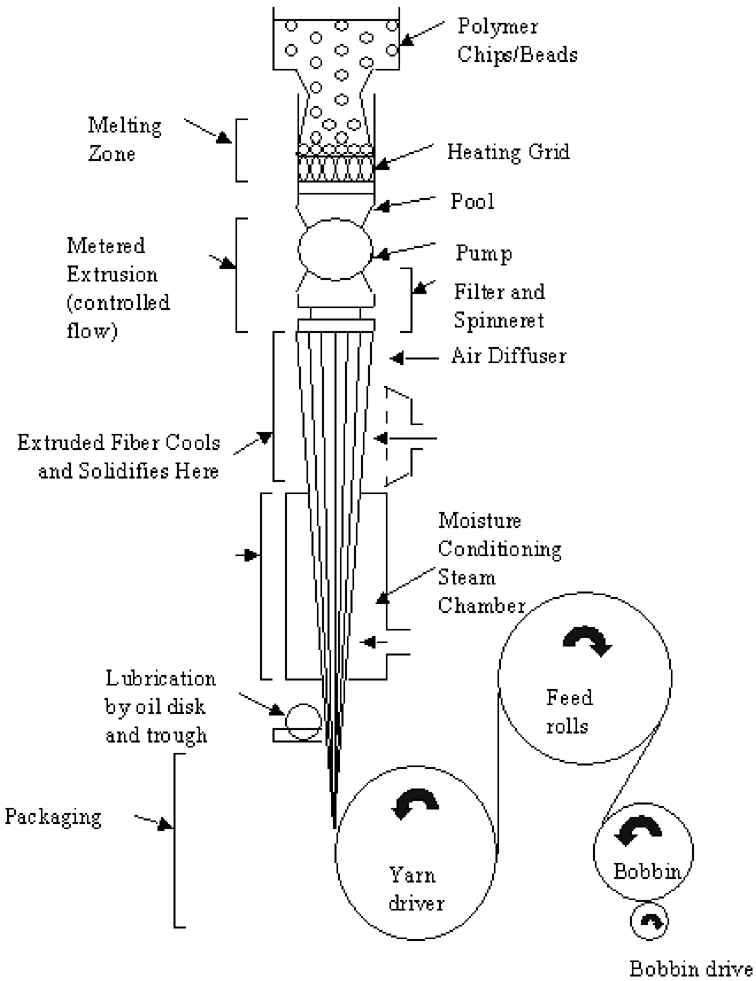


Figure 5-2 Shape memory fibers spinning method (Dooley, 2009)

The Tg of the melt spun filaments chosen in this study was around 50-60 degree Celsius. The minimum linear density necessary to manufacture compression stockings is 156 dtex. Hence, the fiber sample with 200 denier were sampled from fiber roll and cut to a length of 40 mm with 20 mm allowance for both ends of the holding clamp, since the chances of slippage was high from the mechanical clams in Instron 5566, the filaments were glued to thick paper using epoxy resin (see Figure 5-3) and then it was held between the jaws for about 20 minutes to set the filaments perpendicular to the clams and with minimum retention stress. The prepared samples were then tested for thermomechanical properties after cutting the supporting paper at each of the ends.

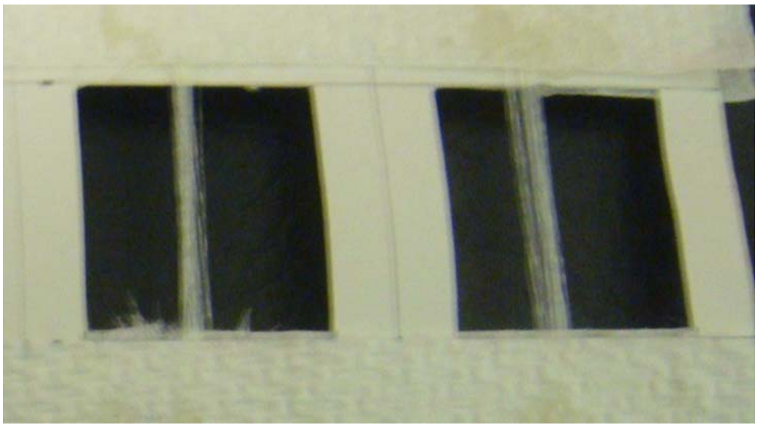


Figure 5-3 Sample of SMF's for testing on Instron

5.2.4 Pre-setting of the filaments using heated rollers

Filaments were heat set on a series of hot roller at different temperature 45, 55, 65, 75 and 85 Degree Celsius to evaluate the optimum temperature for pre-setting the filaments. The schematic representation of the pre-setting machine is shown in Figure 5-4, the equipment also included the guide and the winder, which winds the heat set filaments automatically by gear and motor arrangement. Totally 3 rollers were used to heat set fiber. The guide roller can be heat set to desired temperature level and rotational speed can also be set based on the requirement. In this experiment only the temperature was changed, the speed of the roller was set constant to 10mm/sec.

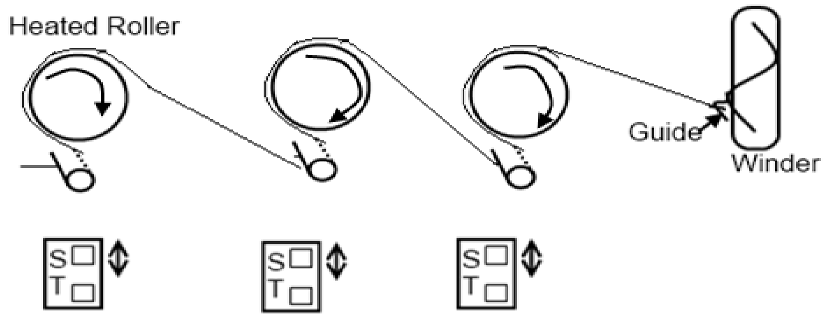


Figure 5-4 Pre-setting of shape memory filaments

5.2.5 Shrinkage in the filaments after heat-setting

The filaments were tested for shrinkage after pre-setting by measuring the initial and final length after they were heat set using the below equation,

$$\text{Percentage fiber shrinkage} = \frac{(\text{Final length} - \text{initial length}) X\ 100}{\text{initial length}} \ldots\ldots\ldots\ldots\ldots\ldots \text{Equation 5-3}$$

5.2.6 Mechanical testing of shape memory filaments

The influence of the pre-setting treatment on the tenacity, elongation and shape memory effect (Figure 5-1) is tested by mechanical testing of the treated filaments in Instron models 4411 and 5566 respectively.

5.2.7 Stress relaxation of shape memory filaments

It is important to study the stress relaxation of shape memory filaments in order to apply them in compression stockings as stockings are usually worn more than 8 hours. In stress relaxation experiment the filament is held at constant load after extending it to 100% elongation. Stress relaxations of the filaments were tested at different temperatures; at Tg, lower than Tg and higher than Tg in Instron 5566 attached with a heating chamber.

5.2.8 Core spun yarn with shape memory filaments as core

Shape memory core spun yarns of different count were manufactured on a ring spinning machine Core yarns are produced using two cotton roving's as sheaths which are drafted in parallel in the drafting zone on a modified Ring spinning machine see Figure 5-5. The elastic filament is then introduced in the front pair of drafting rollers by means of additional V grooved roller. Filament pre tension needs to be measured during yarn production; twisting and insertion of the filament thus take place in one process step. The V grooved guiding roller placed on roller weighting arm to the drafting zone of the front roller must be stable and perfectly parallel to the space between the roving being fed. The V grooved roller is made to move with the front top roller in order to prevent the additional frictional force between the filament and feeding device. While spinning care should be taken to feed the core to the centre of the drafting zone.

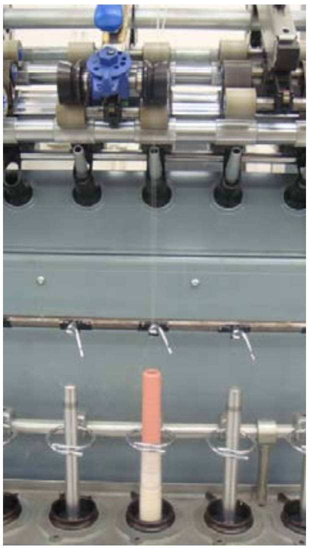


Figure 5-5 Modified Ring spinning machine with V guide to manufacture shape memory core yarn

5.3 RESULTS

The result obtained from the experimental methodology explained in section 5.2 is given and analyzed in below sub sections:

5.3.1 Thermomechanical testing of shape memory filaments at different temperatures

The preliminary testing of filaments in differential scanning calorimeter it was noted that the Tg and Tm of the filaments was 55 and 150 degree respectively. Since the application of the filaments is in compression stockings, testing of filaments at over 70 Degree is considered to be unreasonable. The thermomechanical cyclic stress strain curves of the filaments are shown in Figure 5-6, at 30, 40, 50, 60, and 70 Degree Celsius for 2 cycles (see Table C-1 of Appendix). From the graph it is clear that that shrinkage of filaments increased with the increase in the deformation temperature as given by negative stress value during the recovery cycle.

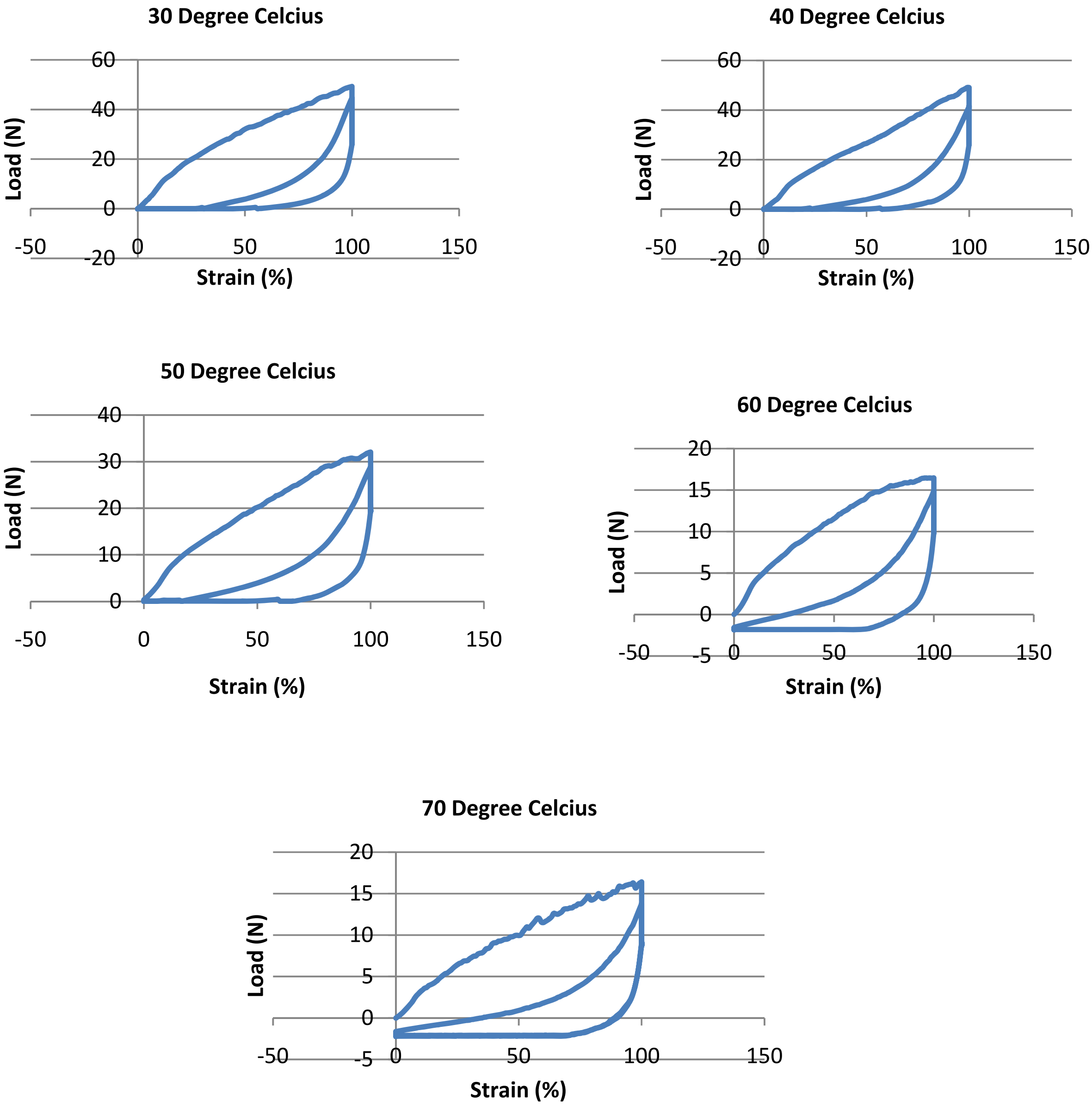


Figure 5-6 Thermomechanical testing of SMF at different temperatures

The shape fixity and shape recovery of filaments were calculated, values obtained are given in Table C-2 and their plot against temperature is given in Figure 5-7. The shape memory effect defined by shape fixity and shape recovery values were inversely related after the deformation temperature was over 55 Degree Celsius (Tg). The shape recovery percentage reduced at temperature over 55 Degree Celsius and increasing trend up to 55 Degrees Celsius from 30 Degree Celsius. The increasing trend in recovery percentage up to 55 degree Celsius as both the hard and soft segment of the polymer was rigid at lower temperature However, with the increase in temperature over 55 Degree Celsius, the soft segment deforms and the modulus of the polymer with the deformation of the soft segment. Hence, the recovery percentage was rather difficult with the deformation of the soft segment.

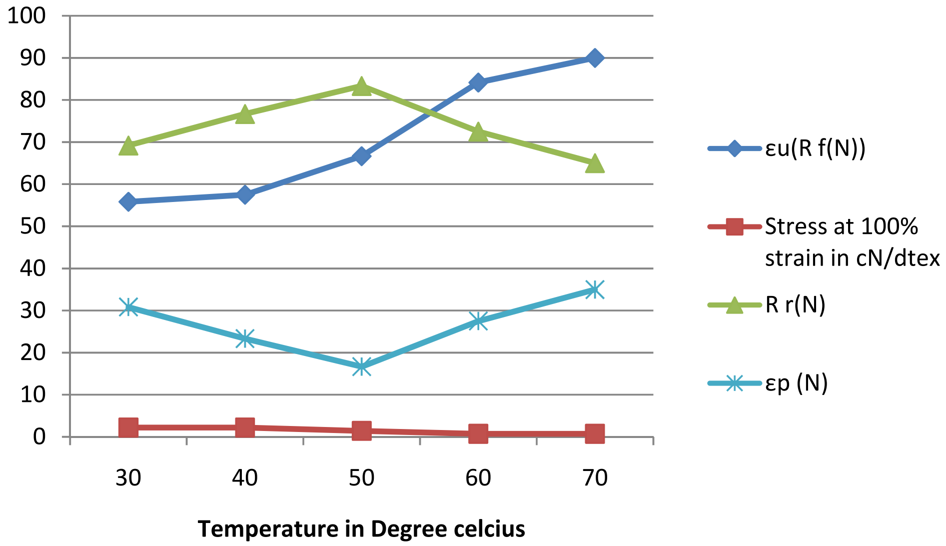


Figure 5-7 Shape memory properties against deformation temperature

In contrast, the shape fixity of the filament increased with the increase in deformation temperature, as the temperature increased the percentage deformation of the soft segment increased, by cooling the filament the at room temperature deformed soft segment structure was fixed by which the fixity percentage value increased. Although the increasing trend is seen for shape fixity percentage at above 55 Degree Celsius, the value can be decrement at deformation temperature at about the melting temperature of the filament.

5.3.2 Influence of deformation temperature on shape memory effect

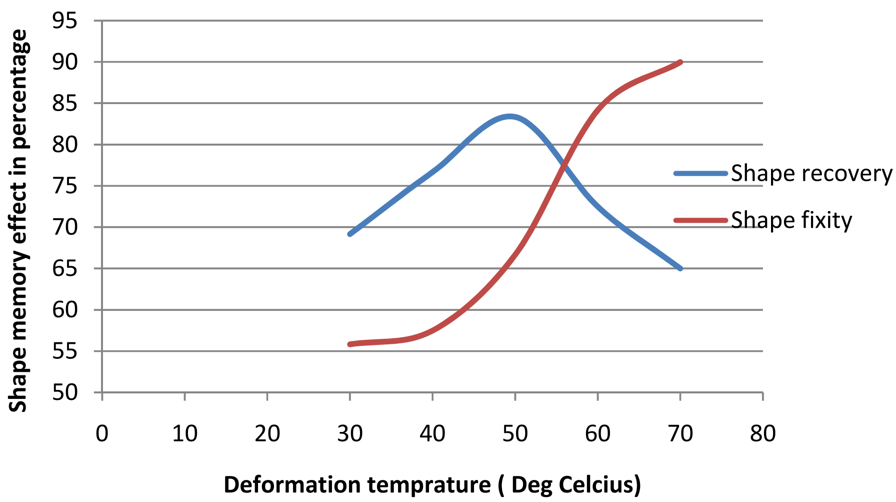


Figure 5-8 Shape fixity and recovery at different deformation temperature

As shown in the Figure 5-8, it is clear that at 55 Degree Celsius, the shape memory filament had reasonable shape fixity with and recovery values of 78%. However, the maximum percentage of shape recovery of 83.34 % was noted at deformation temperature of 55 Degree Celsius. Moreover, at room temperature the filament showed reasonable shape fixity and recovery percentage of 56 and 70% respectively. Since, the shape memory effect was high at 55 degree Celsius, multiple cyclic the temperature for 25 cycles was carried out this temperature.

5.3.3 Influence of deformation and recovery speed on shape memory effect

The influence of the fiber deformation and recovery speed are shown in Figure 5-9 and the values obtained are given in Table C-3, deformation and recovery speed effect the shape fixity and recovery of the fiber in the same manner at a speed of 5, 10 and 50 mm/min.

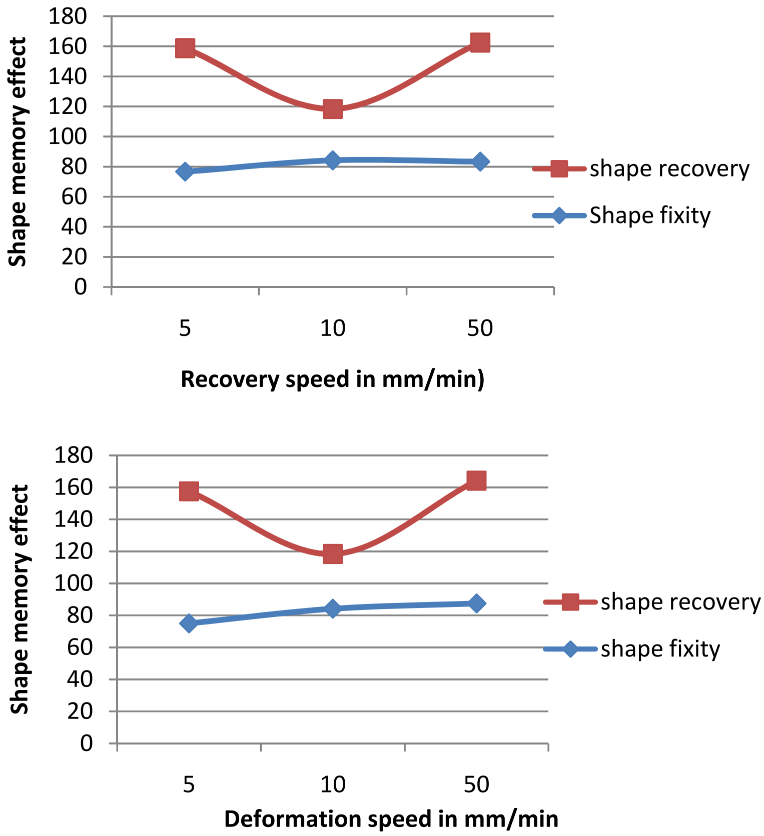


Figure 5-9 Influence of recovery speed and deformation speed on shape memory properties

The shape recovery percentage reduced at 10 mm/min and increased at 50 mm/min whereas; the shape fixity is stable with the deformation and recovery speed. The increase in the shape recovery of filament at higher deformation and recovery speed is due to the retention of stress by elastic entropy with the reduction in deformation and recovery speed. On contrary at low speed much of the stress is lost by stress relaxation with increased time as the recovery speed in low.

5.3.4 Multiple thermomechanical testing of shape memory fibers

The shape fixity and recovery percentage are given for each cycle up to 20 cycles of thermomechanical testing of filament at a deformation temperature of 55 Degree and at a deformation and recovery speed 5 mm/min in Appendix Table C-4. Figure 5-10 gives the stress strain curves for 20 cycles and Figure 5-11 shows the plot of shape memory fixity and recovery percentage against the number of cycles respectively see Table C-4 for all the values.

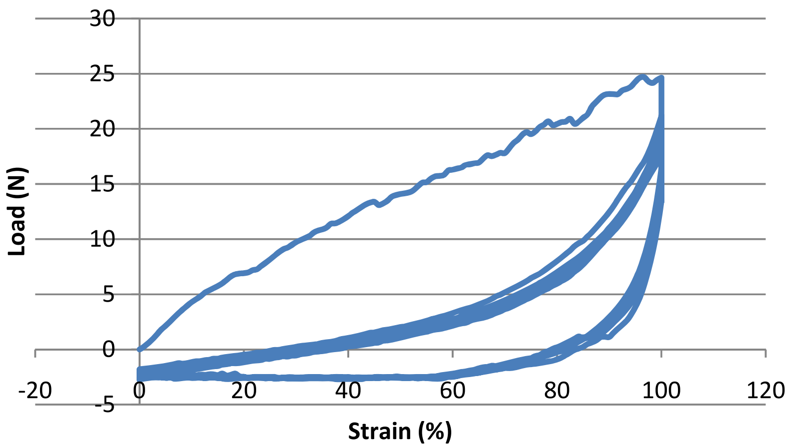


Figure 5-10 Multiples thermomechanical test of shape memory filaments

The variation in the shape recovery with the number of cycles of testing as presented Figure 5-11 is high compared to shape fixity. Shape recovery drastically reduced within 5 cycles from 69 to 62%. However, the shape fixity of the fiber reduced from 87 to 81% as given in the figure. The shape memory properties were stable after 5 cycles. Hence, the stability of the filaments with respect to the shape memory effect is clear with multiple thermomechanical experiment this is due to the stable nature of the polymer after the stress relaxation and fiber shrinkage. Thus, the filament can be successfully employed in stockings after pre-setting by which the internal stress developed during the manufacturing process in them is relieved by heat treatment.

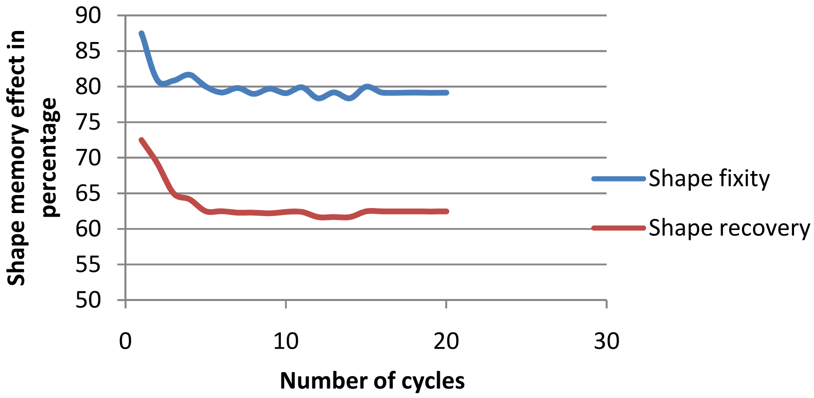


Figure 5-11 Shaper recovery and shape fixity against number of testing cycles

5.3.5 Pre-setting of shape memory filaments

Shape memory filaments used in this research are temperature sensitive hence the influence of pre-setting temperature on the shape memory and thermomechanical properties along with the shrinkage was studied. The obtained test results are presented and discussed in below sections.

5.3.6 Influence of pre-setting temperature on shape memory effect

The shape memory properties of the filaments defined by shape fixity and shape recovery expressed in percentage values are determined by cyclic thermomechanical testing of filaments. The shape recovery and shape fixity of filaments was tested in heat set filaments to different temperature as described in section 5.2.4. The deformation temperature was set to 55 Degree Celsius and speed to 5 mm/min for all the samples. The results are shown in **Figure 5-12**. The filament set at Tg showed higher values for both shape fixity and recovery, this is due to the increased elastic modulus of the polymer at over Tg from 55 to 65. As the soft segment is deformed at over 55 Degree Celsius the shape recovery value the filament reduced to 34%.

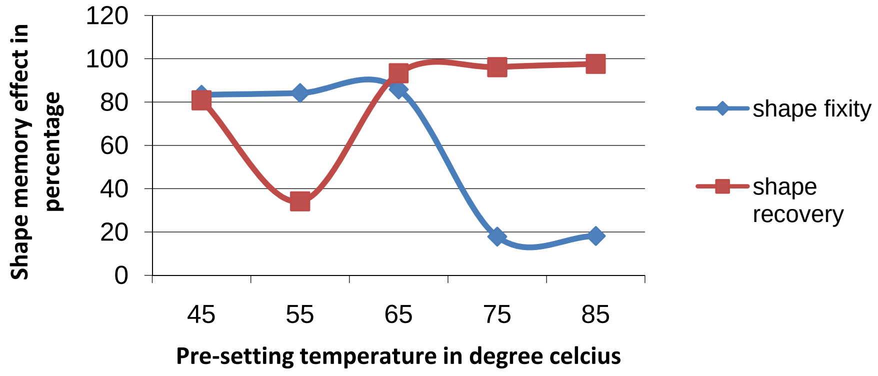


Figure 5-12 Influence of pre-setting temperature on shape memory properties

5.3.7 Influence of pre-setting temperature on filament mechanical properties

The load elongation curve of heat set filaments from 45 to 85 degree Celsius is presented in Figure 5-13, as the temperature of pre-setting increases, the elongation of the filament also increases. Fiber heat set at 45 degree showed a breaking elongation of 133% whereas fiber heat set at 85 degree Celsius showed a breaking elongation of 450%. However, the stress value decreased with increase in heat set temperature. Hence to obtain nominal mechanical properties the fiber can be set to a temperature from 55 to 66 degree Celsius.

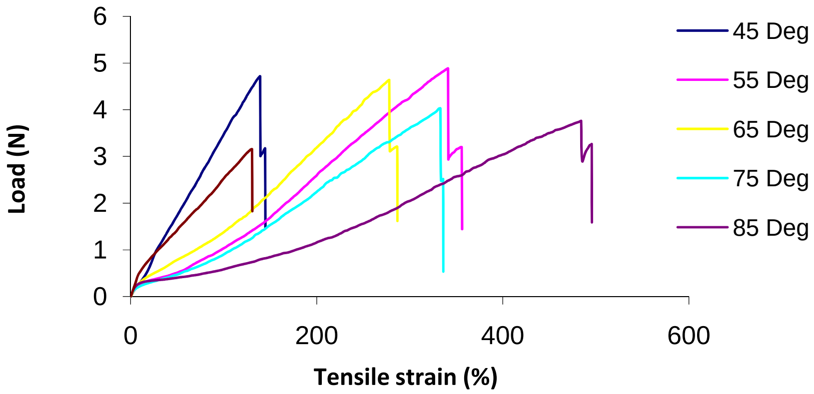


Figure 5-13 Load extension curves of heat set shape memory filaments

Figure 5-14 gives the tenacity of heat set filaments, higher the temperature of heat set treatment lower was the tenacity of the filaments. The results shown that at Tg, the tenacity of the filaments is high and as the temperature increases from Tg, the fiber tenacity reduces. This is due to the deformation of the soft segment of the shape memory polymer with increase in temperature. If the temperature of the fiber is increased above the deformation of the hard segment the filament further reduces drastically to 17 gf/tex from 22 gf/tex.

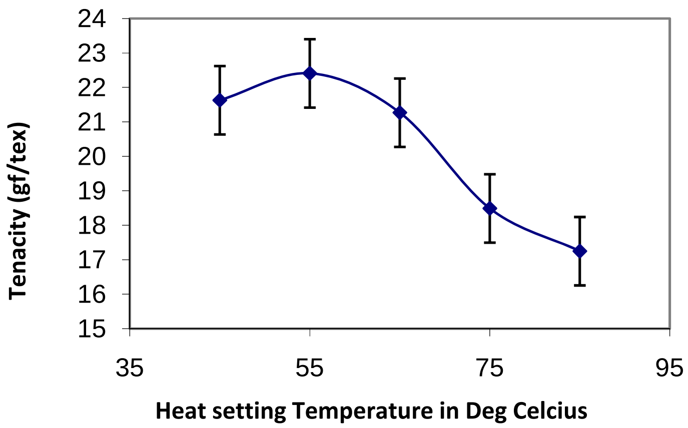


Figure 5-14 Influence of pre-setting treatment on tenacity of shape memory filaments

The filaments reformed to a ringlet structure as the molecular chain coiled which is common to other synthetic filaments after pre-setting see Figure 5-15. The shrinkage of the shape memory filaments heat set at different temperature given in Table C-5 is presented in Figure 5-16, the percentage of fiber shrinkage is high at Tg. The filaments did show instability at Tg as the shrinkage is high in the range of the Tg. The percentage of shrinkage in filaments had a linear relationship with the pre-setting temperature with a correlation of 0.88 as given in the figure.

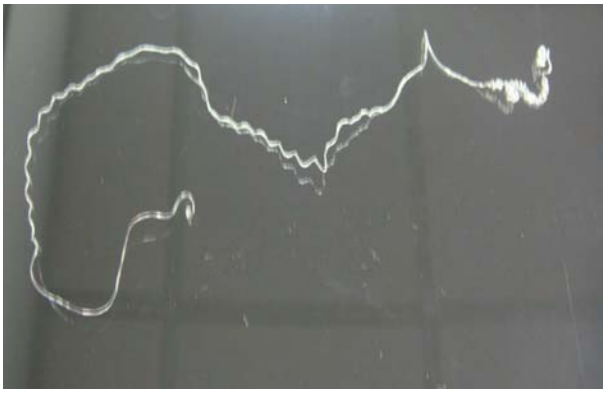


Figure 5-15 Shape memory filaments reformed to a ringlet structure after pre-setting

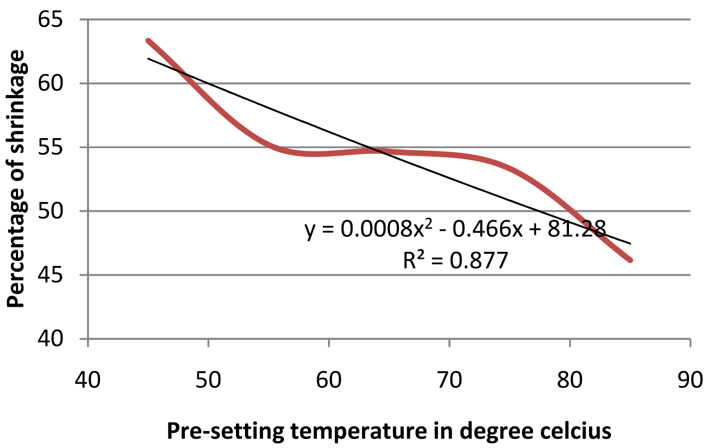


Figure 5-16 Influence of pre-setting temperature on fiber shrinkage in shape memory filaments

5.3.8 Stress relaxation of shape memory filaments

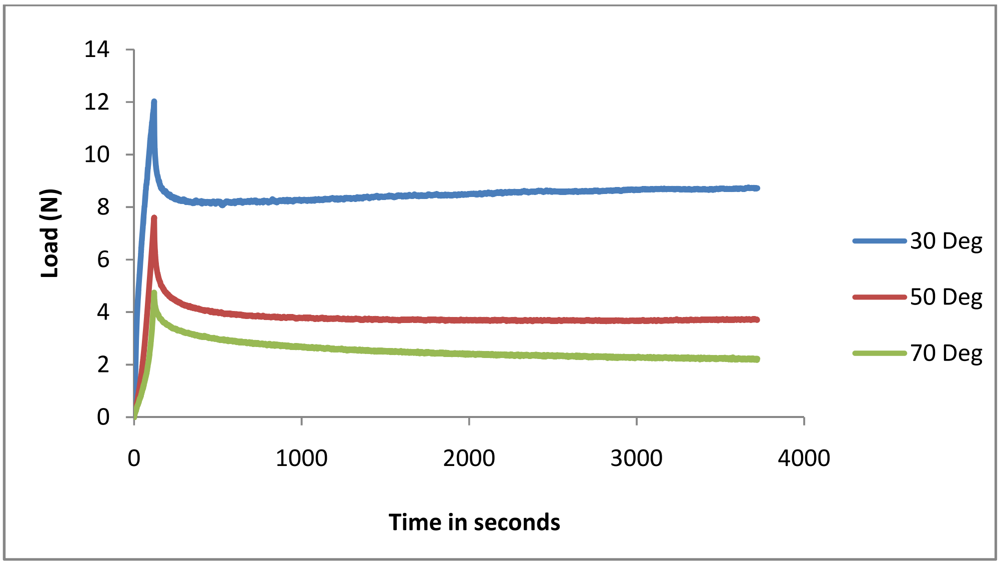


Figure 5-17 Stress relaxation of shape memory filaments at different temperature

Figure 5-17, given the stress relaxation of shape memory filaments at different temperature, the initial stress relaxation is high for sample which was allowed from stress relaxation at 30 degree. It should be noted that the load of the fiber was high at 30 degree Celsius than at 70 degree Celsius. The stress relaxation remained stable after 15 minutes of stress relaxation and reduced drastically at the initial 4 minutes of the test. Hence during the shape memory filaments were heat set to about 3 minutes and later used to knit the fabric.

5.3.9 Shape memory core yarn

Table 5-1 Mechanical properties of shape memory core yarn

Average cotton count of yarn	**30 count**				**40 count**				**50 count**			
SMP fiber count in Denier	0	20	70	150	0	20	70	150	0	22	33	44
yarn count	30.1	29.7	29.9	29.6	39.9	39.8	39.6	39.7	49.9	49.4	49.6	49.7
CV%	16.11	17.19	16	15.39	17.32	17.61	16.85	16.94	19.066	18.82	18.04	18.12
Thin	44.3	66	36	21.25	138.3	175	114	147	415	346	237.5	270.2
Thick	101.3	169	110	87.5	163	246	160	169	393	314	250.3	229.6
Yarn mechanical properties												
Tenacity cN/Tex	12.99	11.14	10.74	10.51	12.96	11.64	11.02	10.1	12.3	11	11.02	11.19
CV	10.61	9.08	7.69	7.17	10.73	9.82	9.87	9.79	11.8	12.96	10.4	11.71
B.elongation	6.34	5.76	6.94	6.93	5.58	6.26	7.22	9.34	5.15	8.29	9.38	10.76
CV	7.62	7.12	10.16	8.67	10.38	15.18	16.59	24.14	10.74	59.97	37.3	33.52

The shape memory core yarn manufactured by the process was tested for mechanical properties and is given in Table 5-1. The elastic properties of the yarn were improved by core spinning with shape memory filaments as core with cotton as sheath. However, the breaking elasticity of the yarn for all the count did not exceed from 11 %. Due to low elasticity of the yarn, the study on the application of core yarn to construct compression stockings was ceased and application of shape memory filaments as bare fiber is considered during rest of the study.

5.4 SUMMARY

Shape memory polymers are a two phase structure with hard and soft segments; also referred as frozen and reversible phase. While the hard segment has higher transition temperature and is responsible of shape recovery property of the polymer, soft segments with lower phase transition temperature is responsible for remembering the temporary shape and act as molecular switch (Lendlein and Kelch, 2002). When the polymer is heated in the temperature range between the T g and T perm, larger deformation can be obtained.

At the deformation temperature lower than Tg the polymer deformed by the deformation of the soft phase but in the recovery phase since the hard phase did not deform, filament was able to recover with shrinkage in length. However as the deformation temperature neared to the Tg of the hard segment, the polymer showed higher shape recovery near the Tg and gradually reduced at temperature higher than the Tg. This was expected as the hard segments were totally deformed at higher temperature. Shape recovery of filaments changes with the variation in extension and deformation speed where as the shape fixity of filaments remained constant at different testing speed.

The SMP filaments shrinkage was high at pre-setting temperature near to the Tg of the polymer; this is due to the deformation of the hard segments. The linearity of the percentage shrinkage with pre-setting temperature was noted to be 0.87.

The shape fixity and recovery were highest for filaments heat set from 55 to 65 degrees. Furthermore, the mechanical properties of the filaments were tested on Instron. With the increase in the pre-setting temperature the elongation of the fiber increased and the stress value decreased.

This is due to deformed hard segment at higher temperature. The fiber strength was high at 55 degree which is close the Tg of the polymer. At this temperature maximum force is required to deform the polymer chains as at this temperature the hard segment is at the final stage of deformation.

The stress relaxation of SMP filaments were tested for about 60 min on Instron at different temperatures, the relaxation temperature was set below Tg, at Tg and greater than Tg. The stress relaxation of filaments is dependent on temperature of relaxation. Higher the temperature lesser is the relaxation in stress value at constant load. The stress relaxation remained stable after 15 minutes of stress relaxation and reduced drastically at the initial 4 minutes of the test

Thus, the testing parameters influence the shape memory effect of the fiber and hence before application of these filaments in specific areas it is important to quantify the properties. The elastic properties of core yarn were improved with the application of shape memory filaments as core in which cotton fibers was used as sheath. However, the breaking elasticity of the yarn for all the count obtained with varying count of shape memory filament did not exceed from 11 %.

CHAPTER 6. IMPLICATIONS OF SHAPE MEMORY FABRIC IN COMPRESSION STOCKINGS AT ANKLE BOW AND WELT

6.1 INTRODUCTION

Reoccurrence of the venous disorder or venous ulcer is high (Heinen et al., 2007, Moffatt, 2008, Van Hecke et al., 2009) due to which compression therapy has not been effective in clinical practice as has been is in research studies (Hayes et al., 2002). Even though, compression stockings are advantageous over the bandages in terms of application without the assistance of nurse, cost, aesthetics, and reusability. Nevertheless, studies show that the compliance in the use of stockings in patients is poor and often use them irregularly (Nelson et al., 2006, Raju et al., 2007) thereby the healing rate is unnecessarily prolonged and reoccurrence of the disorder is witnessed.

Raju et al., (2007) in their study on compliance level with the use of compression stockings in a large cohort of 3,144 patients seen from 1998 to 2006 concluded that the main reasons for noncompliance issues were wear-comfort factors and intangible sense of restriction imposed by the stockings. In addition, skin irritation and redness with the application of stockings were common in patients using compression stockings (Winslow and Brosz, 2008). In most of the cases compression stockings are applied by elderly patients for whom the application of stockings with high strength can be troublesome and the skin discomfort is intolerable. Furthermore, the ease of application of compression stockings and discomfort sensation is not studied widely and there are no standards to evaluate the ease of application of the stockings (Willenberg et al., 2010).

The mechanical properties and novel shape memory properties such as shape fixity and shape recovery were evaluated in shape memory filaments and were reported in chapter 5; wrinkling at ankle and high pressure at welt in commercial stockings was noted from results in chapter 3 and chapter 4 respectively. The discomfort sensation at ankle and welt in the compression stockings can be controlled with the application of these fibers with novel properties. Therefore, to verify the above statement, in this experiment an effort is made to study the implication of shape memory filaments at ankle and welt on nine subjects.

To determine the implication of shape memory filaments, newly designed stockings with shape memory filaments were applied to Class I commercial stockings at the ankle bow and welt. Application ease of stockings, mechanical properties and load required to pull the stockings off from human subjects were evaluated using Instron 4411. Moreover, mechanical properties, wrinkling at ankle, pressure at welt and subjective comfort (by questionnaire) of the newly designed stockings were compared to the commercial stockings (class I to class IV) on nine healthy subjects.

6.2 TESTING MATERIALS

The stockings sample inclusion criteria, sample preparation and subjects considered for to analyze the mechanical properties while mechanically taking off the stockings from human subjects is explained in the below sections

6.2.1 Stockings sample inclusion criteria

Graduated Compression stockings (GCS) and Anti embolic stockings (AES) were conceptualized to be tested in the designed experiment. All the stockings samples considered for the experiment need to be open toed as shown Figure 6-1 so that they can easily attached to the inelastic women material and whose other end is clamped to the upper movable jaw for mechanical testing on Instron 4411 (see section 6.3.1). However, manufacturer of the AES stockings do not manufacture open toed stockings, reason being that they can be easily applied. Besides, it is insignificant to evaluate the AES since they can be easily applied as they are of low strength. Hence, only GCS from class I to class IV were chosen for mechanical testing in this experiment.

Figure 6-1 Open toed stockings

6.2.2 Stocking sample preparation

The stockings samples were prepared for mechanical testing by attaching stockings with woven fabric of same width (20 cm) and length (150 cm plus 4 cm for clamp allowance) to open end at the toe for each of the stockings with 3 threads stitch as this stitch type provides reliable elasticity. The open toed stocking was held at least tension while sewing it to the woven fabric; care was taken not to distort the fabric while sewing and was stitched uniformly along the seam allowance. Additional care was taken while preparing the stockings for the experiment as unequal and distorted fabric can result in false data for strain and stress valves during mechanical testing. The sample prepared after joining the woven fabric with stockings is given in Figure 6-2.

Figure 6-2 Stockings joined to woven fabric

The characteristics of the stockings sample considered for the mechanical testing is given in Table 6-1. The stocking were tested directly on human leg rather than a leg model. The stockings stitch structure was same for all the GCS but the percentage of each fiber type were different and the fabric thickness was high for class III and Class IV with coarse yarn compared to class I and class IV.

Table 6-1 Textile characteristics of stockings samples chosen for mechanical testing

Compression class	Fiber content	Fabric thickness in mm	Wales/inch	Courses/inch
Class I	78% polyamide and 22% elastan	1.13	62	60
Class II		1.08	60	60
Class III	62 % polyamide and 38% elastodien	2.2	36	28
Class IV	62 % polyamide and 38% elastodien	2.21	43	25
AES	78% polyamide and 22% elastan	.6	-	-
SMP	44.5% SMPFs(250D) +Nylon(70D)	.4	44	47

6.2.3 Stockings sample with SMF's

Class I compression stockings from the same manufacturer was modified by applying knitted shape memory fabric with a structure of 4 float and one tuck to imitate the inlay structure was used. Microscopic image of the shape memory fabric applied at ankle bow and welt is presented in **Figure 6-3**.

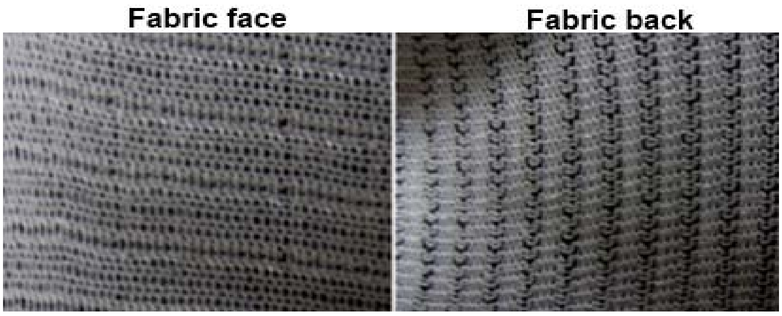


Figure 6-3 Shape memory fabric

The stockings with shape memory fabric at ankle bow and welt is given in **Figure 6-4**.

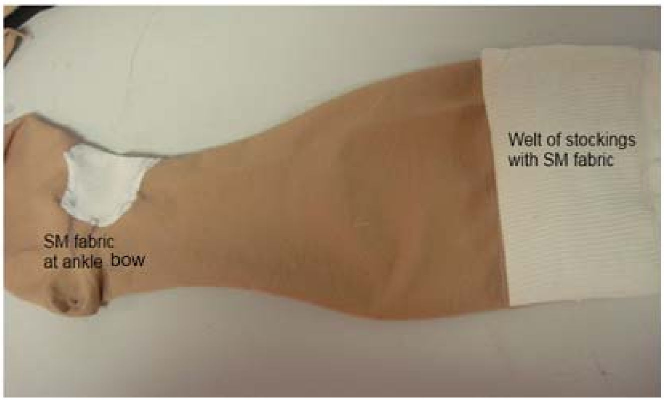


Figure 6-4 Stockings with shape memory filaments

This method was employed due to the unavailability of stockings knitting machine at the University. However, in future it is recommended to design stockings with shape memory filaments at ankle bow to knit stockings on knitting machine as a complete part. The sample was cut at the ankle bow and was stitched with the tension set piece of shape memory fabric with known shape memory properties (heat set to defined structure) and stockings welt was also replaced by SMP fabric manufactured with shape memory filaments. The welt girth was heat set to average leg girth at welt for the chose subjects (see Table B-4 in appendix) for welt girth measurement.

The newly designed stockings with shape memory filaments at ankle bow and welt was heat set on a leg mannequin in a heating chamber for 3 minutes at a temperature of 45 degree to board the stockings to shape. The mannequin was covered with soft outer layer see Figure 6-5 and had ankle girth of 21.8 cm and calf girth of 32.2 cm.

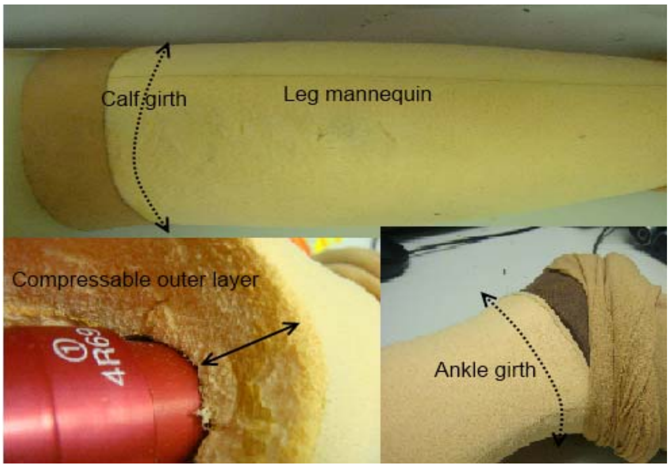


Figure 6-5 Leg mannequin used to board the stockings with shape memory filaments

All the stockings samples were conditioned to laboratory environment for 2 hours before test measurement. The experiment was carried in a blind fold manner i.e., to conceal the sample considered for the testing; this was done by removing the tags and sample labels on the stocking samples.

6.2.4 Subjects

The mechanical testing was planned to be carried out on the same 10 subjects considered in the pressure evaluation experiment in CHAPTER 4. Subjects with known joint problems, previous history of ankle injury and nervous impairment were excluded from the study. Out of the 10 subjects one of the subject was suffering from ankle sprain hence was excluded from the study. The experiment procedure was explained to the subjects who later signed the informed consent form from University Ethics Committee. The anthropometric measurement and subjects details are given in Table 6-2.

Table 6-2 Anthropometric measurement of subjects

Parameter	Mean	Standard deviation
Age	26.16	1.72
Weight	5.71	8
Height	162	6.57

Position	Girth	Standard deviation
Instep	23.8	1.92
B	21.5	1.56
B1	30.2	1.98
Calf	34.4	3.57
Upper calf	32.9	2.44
Welt	32.0	2.99

6.3 METHODOLOGY

The mechanical testing was carried out in nine healthy subjects to evaluate the comfort level while mechanically removing the stockings and the methodology followed is discussed below

6.3.1 Mechanical testing

Mechanical testing of stockings was carried out in fabric objective measurement laboratory using Inston 4411 on the nine healthy subjects. The testing method followed was similar to the one designed by Willenberg et al., (2010). However, the method was standardized to obtain accurate readings. In their experiment the lower end of the testing jaw had a hole through which the stockings was pulled which led to erroneous reading due to undue friction of the stockings fabric, whereas in this experiment the lower jaw had a roller pin so that the frictional force was controlled. Since, there is no norm on the testing of compression stockings to evaluate the comfort in removing stockings from human subjects; revisions can be applied to this testing method in future to suit specific needs. While the stocking was removed from the leg the load, slippage point and elongation of the stockings were assessed for all the stockings samples. The Instron 4411 was programmed to provide slippage points during testing.

6.3.2 Testing posture and method

Instructions were given to each of the subjects on the standard method of application of compression stockings before hand and product brochure was also shown before supplying the stockings in which the standard application procedure was clearly illustrated and no aids were provided for applying the stockings. There was no time restriction to apply the stockings and they were not forced to apply them as per the standard method so that the subjects can come up with their own method for the easy application without damaging the stockings sample. The stockings with shape memory filaments were applied in the same manner; later blow-dryer was used to locally increase the temperature by blowing hot air at the ankle bow to confirm the stockings around the leg of subject. Finally, they were asked to sit on a chair placed at a distance of 150 cm from the Instron 4411 holding a support opposing the pulling force from the Instron and aligned their leg towards the instrument with ankle held to an angle of their choice so that the stockings can slide from their leg with minimum restriction. The free end of the inelastic woven fabric was then passed over frictionless static pin roller and later held by the upper clamp of the tester. Figure 6-6 shows the testing position and sample attachment to Instron 4466.The stocking was then pulled off the leg and foot at a speed of 50cm min^{-1} and the stress and strain values were obtained using Bluehill software from Instron. Tests were repeated for subjects who happened to move the leg abruptly during the experiment. For stockings with shape memory filaments the removal was studied under two conditions unheated and heated condition. In heated condition blow-dyer was used to blow hot air at the welt and bow before the experiment.

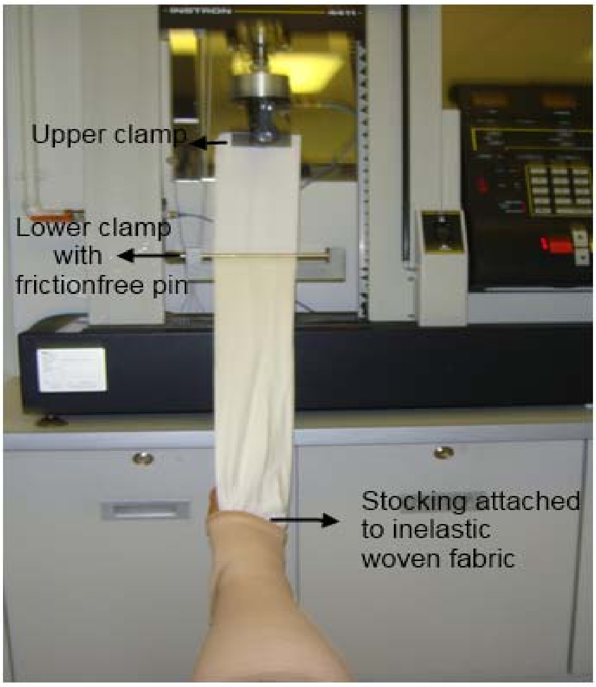


Figure 6-6 Testing position for mechanical testing of stockings

6.3.3 Subjective assessment

From the literature review and the pilot study it was noted that the difficulty in applying stockings was one of parameter influence the compliance level in patients using compression stockings. While wearing stockings, it comes in contact with skin dynamically and the above testing method stated can only objectively quantify the stress, strain and slippage of the stockings while pulling it off the leg. However, the subjects comfort while donning and removing the stockings can only assessed by subjective analysis by designing suitable questionnaire. Hence, subjective comfort analysis was assessed by the questionnaire given in the section 6.3.5 specially developed to analyze the donning comfort and pressure sensation at different portion of leg.

6.3.4 The Pain visual analogue scale (VAS)

The pain visual analogue scale is widely used to measure the pain intensity in medical field. This scale is used to rate the pain level and is given in Figure 6-7, the scale ranged from 0 to 5; 0 was used to designate the complete satisfaction and 5 for very poor performance with maximum level of pain. The pictorial representation of the pain level was user friendly and the rating is accurate.

Figure 6-7 Pain visual analogue scale (VAS)

6.3.5 Subjective comfort analysis questionnaire

In this experiment different stockings class were evaluated for subjective comfort level at different regions. Subjects were asked to rate each of the stockings sample on the visual pain analogue scale as described in section 6.3.4. Totally 7 questions were asked to analyze the subjective comfort level tightness and restriction for movement while wearing and after wearing the stockings (see Table 6-3). Finally, the subjects were also asked to rate the stockings for overall satisfaction on the same pain visual analogue scale and sensation of temperature for hot air from the blow-dryer.

Table 6-3 Questionnaire for assessing subjective comfort level on visual analogue scale

Comfort	Sl. No.	How uncomfortable was it while wearing
Tightness	1	How difficult was it to don the stockings at ankle
	2	Pain due to tightness around heel
	3	Pain due to tightness around the malleolus
	4	Pain due to tightness at the welt
Movement	5	Did you feel restrict your movement at ankle
Overall satisfaction	6	All over the leg
Stockings with SMFs	7	Sensation of temperature

6.3.6 Joint motion simulator

The joint motion simulator (L. K. Chan, 2008) is used to test the stockings wrinkling level with flexion motion; it is covered by soft foam and fitted with stockings before testing it on Instron. The simulator had a flexing joint to imitate the ankle motion as shown in Figure 6-8. The flexing of the joint similar to the human ankle flexion and was controlled by Inston machine setting as the end of the simulator was connected to the Instron jaws.

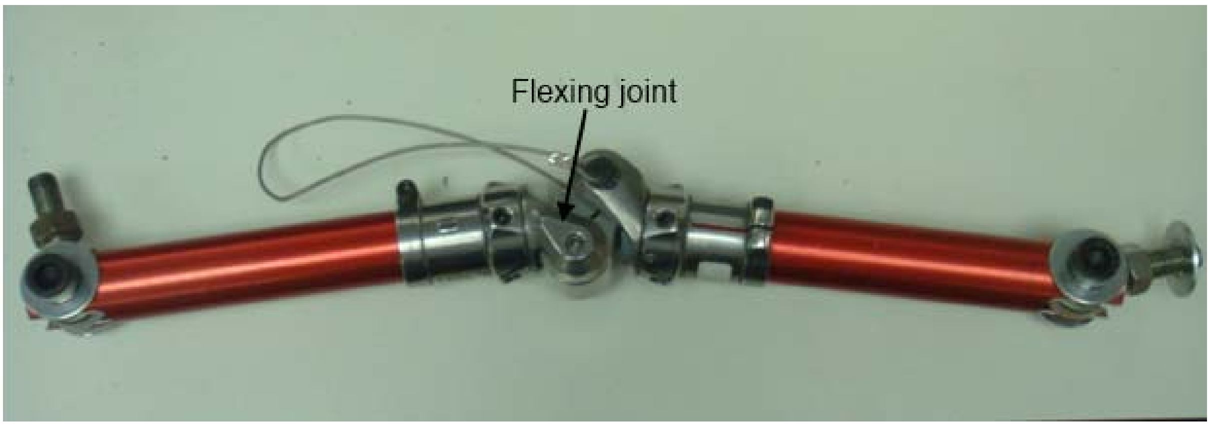


Figure 6-8 Ankle joint flexing simulator

6.3.7 Wrinkle behavior of stockings at ankle

Two points were marked on the leg at ankle bow close to each other on 9 healthy subjects and they were asked to flex the ankle for dorsiflexion motion to measure the final distance in the extended state between the points. The measured distance was set for elongation on Instron 4411 and the leg mannequin fitted with stockings was tested for wrinkling after 25 cycles see Figure 6-9. The samples after flexing test were compared to the standard samples (wrinkle replicas) after heat treatment for 1 minute using blow-dryer according to AATCC 128. Wrinkle test was not followed as stated in AATCC 128 standard as it is severe and does not appear to be useful. The test apparatus for wrinkling shall twist the sample at 180 Degree and might permanently distort the yarns. Moreover, weight on the sample for 20 minutes may be excess to simulate the wrinkling at ankle. Hence flexing using joint motion simulator was used to study the stockings wrinkling at ankle.

Figure 6-9 Testing of wrinkling at ankle bow on Instron 4411

6.3.8 Pressure evaluation at welt for newly designed stockings with shape memory filaments

The modified stockings with shape memory fabric at welt and ankle were evaluated for pressure at ankle and welt using pressure senor.

6.4 RESULTS AND DISCUSSION

The results obtained from the mechanical testing and the subjective comfort assessment for stockings samples are presented in below sections:

6.4.1 Load against extension of stoking fabric from leg with slipping points

The load and extension curves for each of the compression stockings are given in Figure 6-10. The slippage points are marked with an arrow on the curves. While class I and class II showed only one slippage point when removing the stockings from the leg using Instron, class III and class IV had three slipping points and stockings with shape memory filaments had two and three slippage points at unheated and heated condition respectively as shown in the figure. The slippage points were distinctive for each of the stockings type, class I and class II stockings slippage point was at the point of complete slip of the stockings from leg. For class III and class IV the 1, 2 and 3rd slippage points were at an extension of 280 to 350 mm, 380 to 510 mm and 480 to 580 mm respectively. Compression stockings with shape memory filaments under non heated condition showed slippage at 300 mm extension similar to class III and class IV stockings, whereas under heated condition the slippage at the ankle is shown by the first slipping point and the other two slipping points was at the welt. Moreover, class I and class II stockings samples showed higher initial elongation as the strength of the spandex yarn used was less whereas class III and class IV showed higher initial load and less elongation at the beginning of the test due to higher strength of the elastic fabric with coarse rubber filaments.

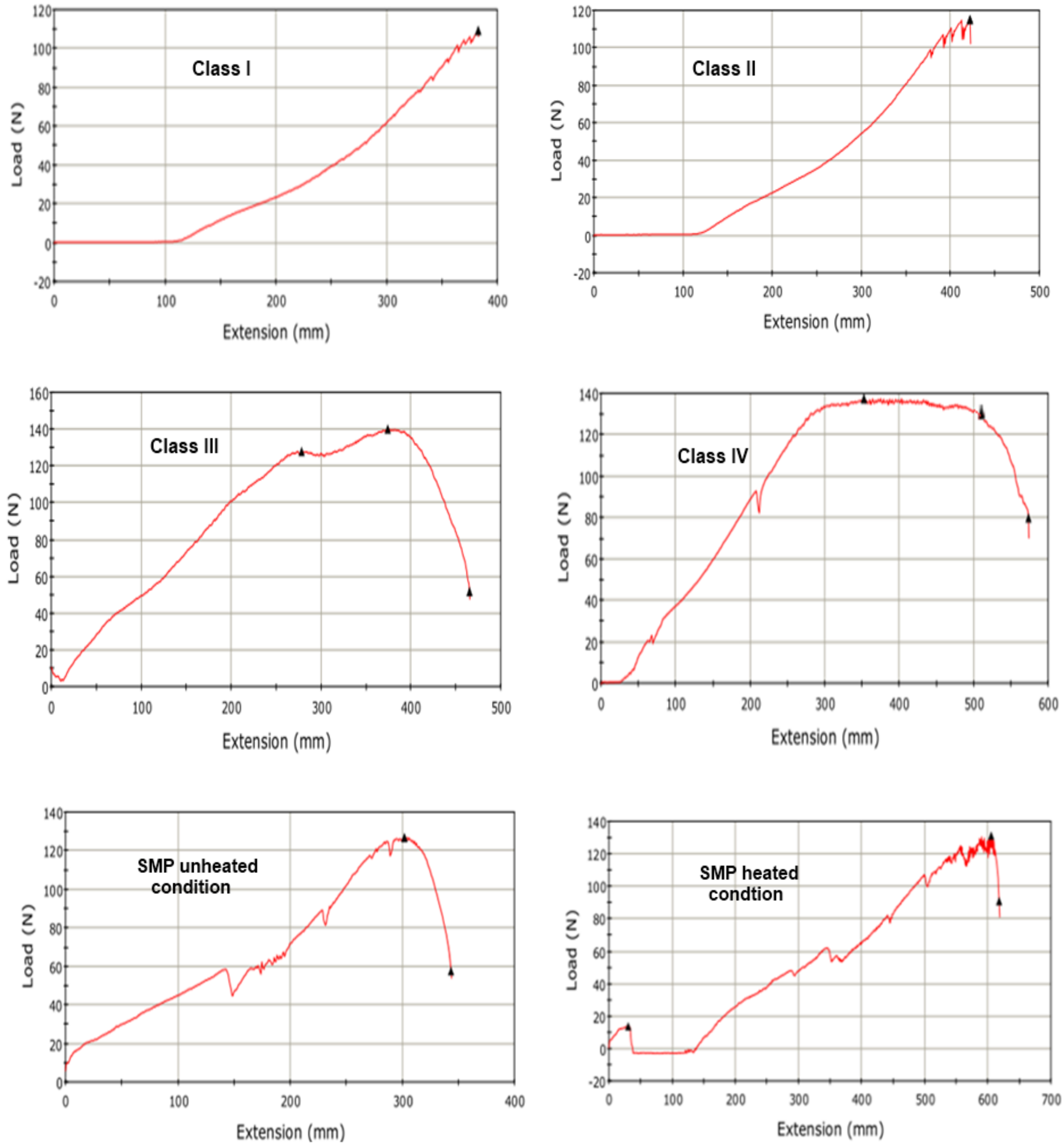


Figure 6-10 Load extension curve with designated slippage points of stockings

6.4.2 Mechanical testing of stockings

The load and extension values for all the stockings samples tested using Instron 4411 is given in Figure 6-11. The load elongation behavior of class I and class II; class III and class IV showed quite similar profile as noted from the curve in the graph. As noted from the load elongation curve, elongation of class I and class II was higher than class III and class IV at the initial stage. Class I and class II stockings were elongated with the application of load during the initial stage of the testing whereas class III and class IV stockings were elongated under higher load. The difference in the load elongation of class I, class II and class III, class IV stockings is due to the differences in the fiber content. However, stockings with shape memory fabric at the ankle bow at flexing point showed distinctive curve with easy slippage at ankle and welt. Moreover the load and elongation curve of the stockings with shape memory fabric under heated and unheated condition was different. Under heated condition the stockings elongated to 620 % whereas under unheated condition the elongation was limited to 400%.

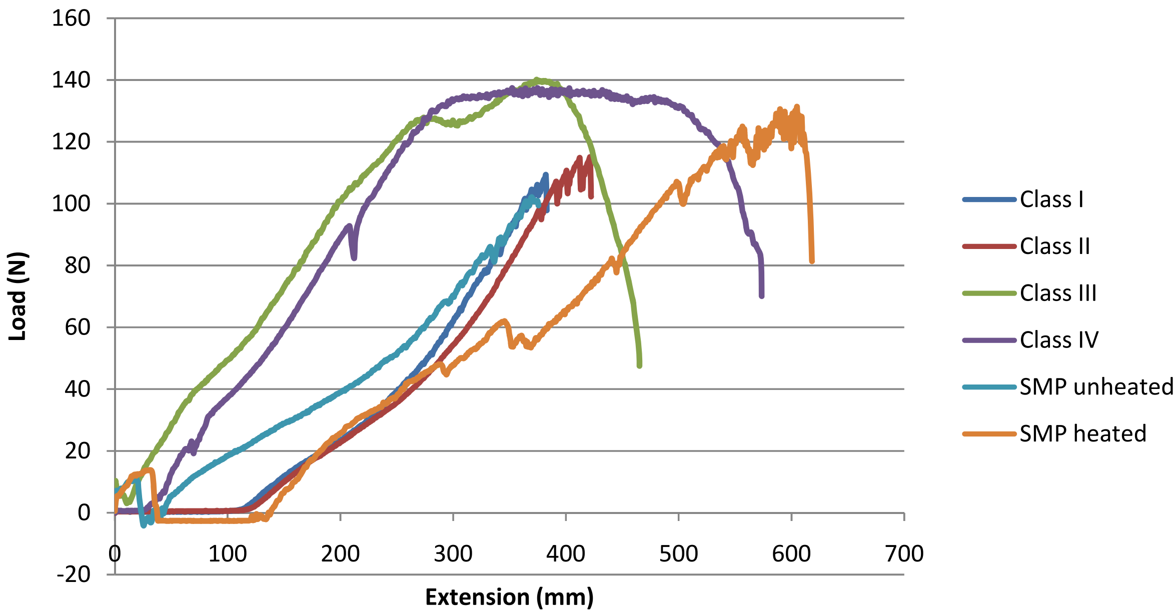


Figure 6-11 Mean load extension curves for stockings samples

Class I and class II showed fall and raise in the load at the complete slippage point this is due to the high level of the friction of welt portion of the stockings on the skin. Nevertheless, class III and class IV showed much elongation before complete slippage this is due to the high elasticity (strain level) of the rubber filament from ankle to the calf. Stockings with shape memory filaments showed higher load at the initial stage due to rigid shape memory filaments and also the elongation was high for SMP stockings under heated condition. This is due to high elasticity of the fiber at higher temperature. For shape memory stockings in heated condition the elastic, slippage was restricted. Moreover, it was easy to apply the stockings at ankle due to shape memory effect of the fabric at ankle bow.

The mechanical properties including maximum load, tensile strain, strain and load at slippage for the tested stockings samples are given in Figure 6-12. Class IV showed the highest value for maximum load and tensile extension. However, class I and class II stockings load at slippage was high this is due to the higher width of the welt at the stockings upper end in class I and II than in class III and class IV see Figure 6-14. Under heated condition stockings with shape memory fabric the load of slippage was the least (-8.19 N), whereas the load at slippage for the same stockings under unheated condition was 91.14 N. The strain at maximum load of these stockings was 86.4% under heated condition.

It should be noted that the stitch density and the fabric thickness value for class III and class IV was high when compared to class I and class II stockings. The variation in the tightness factor of the stockings highly influences the pressure delivered by the stockings on skin when worn. Of all the mechanical properties obtained by mechanical testing, the mean tensile extension at slippage was relatively high for class IV when compared to class III, class II and class I. This is due to the elongation the coarser rubber filament in this type of stockings.

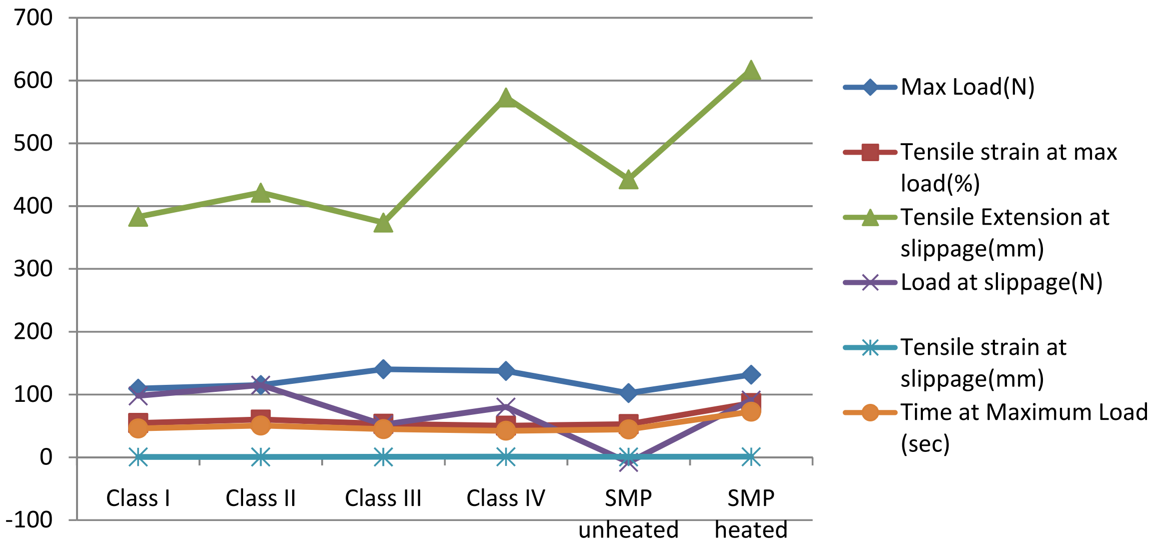


Figure 6-12 Mechanical properties of stockings

6.4.3 Subjective comfort analysis of stockings

Subjective comfort analysis was carried out by questionnaire. The subjects were asked to fill in the questionnaire form soon after the mechanical testing and rate on the pain/comfort level on visual analogue scale (VAS), higher the VAS value higher is the pain and vice versa. The results of their rating on the comfort level are discussed in below

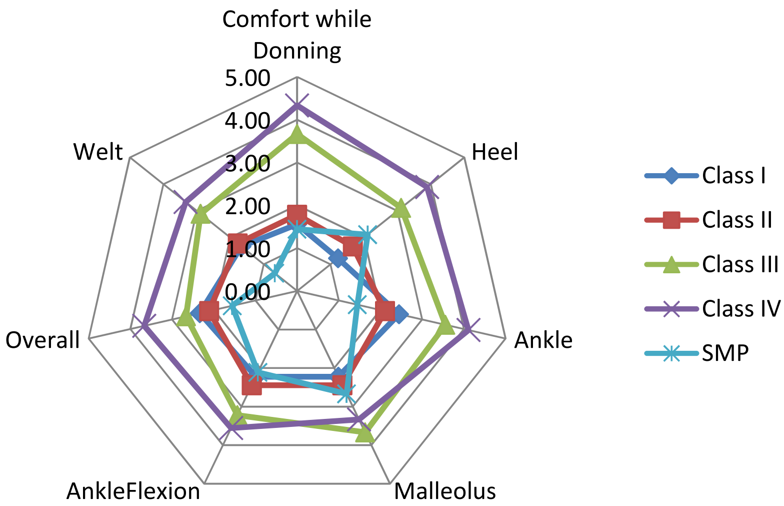


Figure 6-13 Subjective comfort analysis of stockings on VAS

Comfort while Donning: **Most of the subjects felt comfortable to wear class I and class II, but suffered much difficult and problematic when wearing class III and class IV stockings as the stockings rubber strength was high compared to class I and class II. The observation was obvious as the stockings pressure and the reduction factor for from class III and class IV is relatively high when compared to class I and class II. Moreover, class III and class IV were thick and not so easy to slide over skin as they contained course rubber filament see**

Figure 4-3. Newly designed stockings was rated low with least pain and high level of comfort while donning, this was observed as this stockings was fit at the ankle and welt by the application of temperature using blow-dryer.

Stocking fit at ankle: The subjects rated the stockings to be too tight for all the stockings at ankle. Class I-II and class III-IV stockings were rated to be difficult and too difficult to apply respectively. The stocking with shape memory fiber at ankle bow was rated to be hurts a little with an average value of 1.44 on Visual Analogue Scale (VAS). However, since temperature was used to fit the stockings at the ankle to the curvature and need not to pull the stockings at the ankle region for this small portion (ankle bow) subjects rated this stockings to be easy to apply but the ankle bow seam did cause discomfort after wearing.

Heel, malleolus and welt fit: The tightness around the heel and malleolus was least for class I and class II, novel stockings with shape memory fiber produced higher pressure sensation at the malleolus and heel than class I and class II. For class III and class IV the pressure sensation was high at both heel and malleolus. However, the pressure sensation at the welt (Figure 6-14) was significantly less for the stockings with SMP fabric as temperature was used to fit the stockings welt and the pressure sensation for class I and II was less compared to class III and class IV. The discomfort at welt for class IV was high compared to class I again this is due to high rubber content at the welt of stockings. Moreover with large welt portion given in Figure 6-14 for stockings with SMP fabric, with least thickness see Table 6-1, it fitted correctly over the calf and slipping was less as the reduced girth above the calf held the stockings in place with lesser irritation.

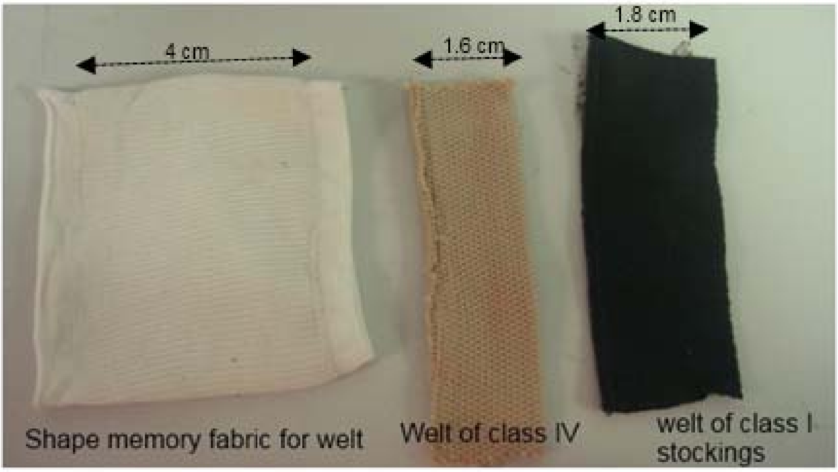


Figure 6-14 Stockings welts

Ankle flexion: All the stockings class I to III was nearly rated the same for ankle flexion and class IV was more rated to be highest with an average of 3.56 (VAS) in the difficult level and new design using SMP was the least with 2.11 (VAS). Although the pain for ankle flexion was the least for novel stockings the rating description seems that it too hurts a little. This sensation might be due to the thickness of seam used to attach the shape memory fabric to the stocking.

6.4.4 Overall rating of stockings application

The subjective comfort analysis showed that the overall comfort level for class III and class IV was different. Class IV was rated the least for overall satisfaction followed by class III. Newly designed stockings was rated the least for pain and the class I, II stockings were rated nearly to same value but higher level of difficulty when compared to stockings with SMP fabric. Hence SMP stockings was thought to be intelligent fabric and designed to fit human leg configuration and was rated high for comfort, application and ankle flexion.

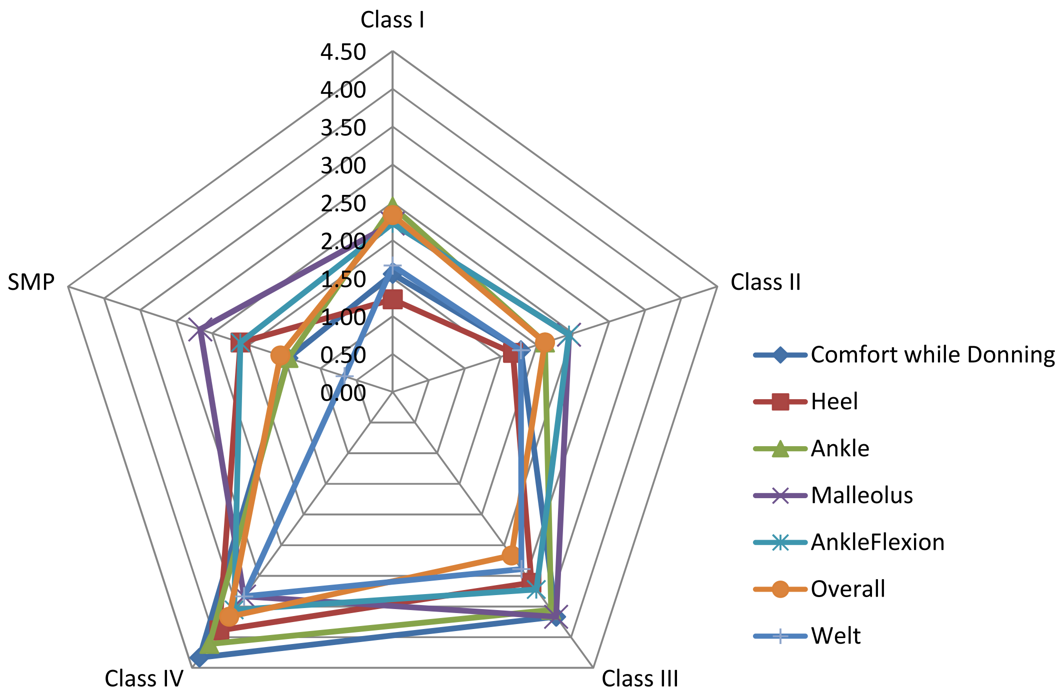


Figure 6-15 Subjective comfort analysis at different regions

Sensation to temperature: Since heat was used to fit the stockings at the ankle. Sensation to the applied temperature was also assessed on the same visual analogue scale. It was rated 2 (VAS) on an average and one subject rated it 3 (VAS). During the application of the stockings the blow-dryer used to locally increase the temperature of the stockings was held close to the malleolus which did hurt this subject. With the standardization of the usage of either blow-dyer or any instrument to locally increase the temperature the sensation of high temperature can be controlled. Also, if the Tg of the SMP falls within the range of the ambient temperature in future the application of these novel stockings would be free from pain.

As seen the class IV and class III was nearly rated the same while class II and class I also formed a pair in the satisfaction level for all the parameters considered for the subjective comfort analysis. The performance of the SMP stockings was variable with the pain sensation at the malleolus being high and at the welt the least. The Mean with SD of the results of all the parameters considered is given in Table 6-4. Moreover the factor analysis showed the influence of the all the parameters to be significant (see Table D-5 in Appendix).

Table 6-4 ANOVA results for comfort analysis at different regions of leg

		Comfort while donning	Heel	Ankle	Malleolus	Anle flexion	overall stocking rate	Welt
Class I	Mean	0.53	0.44	0.73	0.67	0.67	0.50	0.50
	SD	1.39	1.16	2.19	2.07	2.07	2.17	1.50
Class II	Mean	1.78	1.67	2.11	2.44	2.44	2.11	1.78
	SD	1.75	1.63	2.12	2.49	2.49	2.12	1.75
Class III	Mean	3.67	3.11	3.56	3.67	3.22	2.67	2.89
	SD	3.63	3.12	3.51	3.63	3.25	2.63	2.88
Class IV	Mean	4.33	3.89	4.11	3.33	3.56	3.67	3.33
	SD	4.37	3.88	4.01	3.48	3.62	3.63	3.26
SMP	Mean	1.44	2.11	1.44	2.67	2.11	1.56	0.67
	SD	1.38	2.12	1.38	2.63	2.12	1.62	0.74
One way ANOVA	F value(4,40)	65.11	51.78	34.03	9.742	9	24.244	47.78
Sig		P<0.05	P<0.05	P<0.05	P<0.05	P<0.05	P<0.05	P<0.05

The difference between ratings due to different subjects was small for stocking as the Cronbach alpha was 0.92 and interclass correlation was 0.621 even if the interaction is present or absent (see Table D-3and Table D-4 in Appendix).

6.4.5 Wrinkles at ankle in stockings

The maximum extension during the ankle flexion was calculated on the healthy subjects. As noted the results of Range of motion at ankle in chapter 3, the range of motion was less in patients with venous disorder when compared to the healthy subjects. Hence, extension of the fabric in real case would be lesser than the one considered for the experiment. The extension during plantar and dorsiflexion was calculated and the percentage of flexion was noted to evaluate the wrinkle level at the ankle. Results of for ankle extension and recovery are given in Table D-7 in Appendix. Based on these results Instron 4411 was set and stockings were tested for wrinkle level discussed in 6.3.7

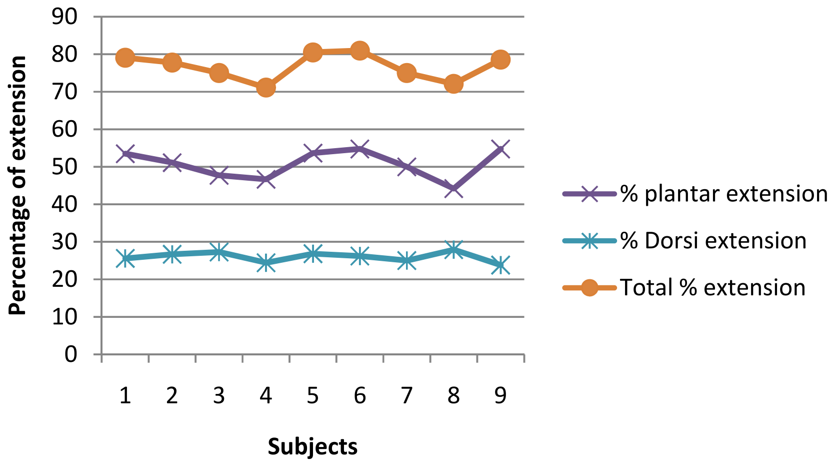


Figure 6-16 Percentage of extension at ankle bow

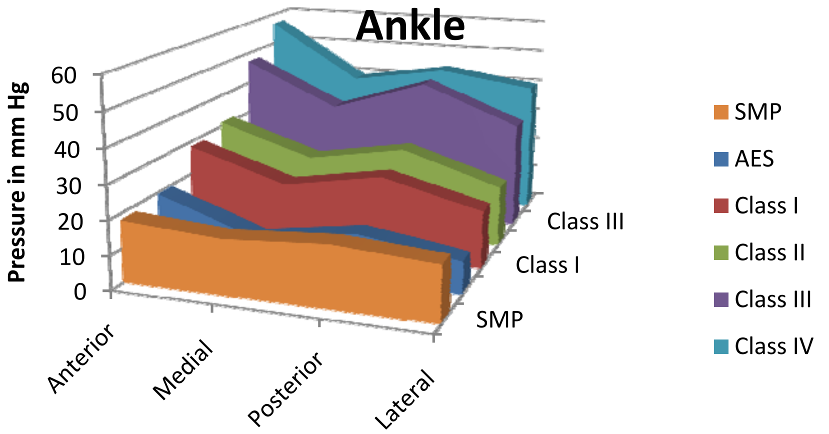
The stockings are analyzed for fabric wrinkling at ankle after 25 cycles of flexion motion on Instron and heat treatment for a 1 minute at the ankle region using blow-dryer where the temperature of treatment ranged from 50 degree to 60 degree. At this temperature the recovery percentage was SMP fabric was optimal. The Figure 6-17 and Figure 6-18 shows the commercial stockings and newly designed stockings using shape memory filaments respectively. The wrinkled samples were compared to standard replicas according to AATCC 128 standard and were rated. Class III and class IV was rated low for the wrinkle level followed by class II and class I this is due to the low resilience of the coarser yarn in class III and class IV stockings. Hence, it is advised that custom made class III and class IV stockings should be fitter after proper measurement of leg size as improper fit can aggravate the wrinkle level in these types of stockings. Moreover, stockings with shape memory filaments was rated high as the fabric creases were removed by temperature simulation.

Figure 6-17 Stocking samples after 25 cycles of flexing on Instron

Stocking type	Class I	Class II	Class III	Class IV	SMP
Wrinkle ranking	5	4	2	1	5

Figure 6-18 Shape memory stockings sample after 25 cycles of flexing on Instron

6.4.6 Pressure evaluation at ankle and welt for newly designed stockings with shape memory filaments



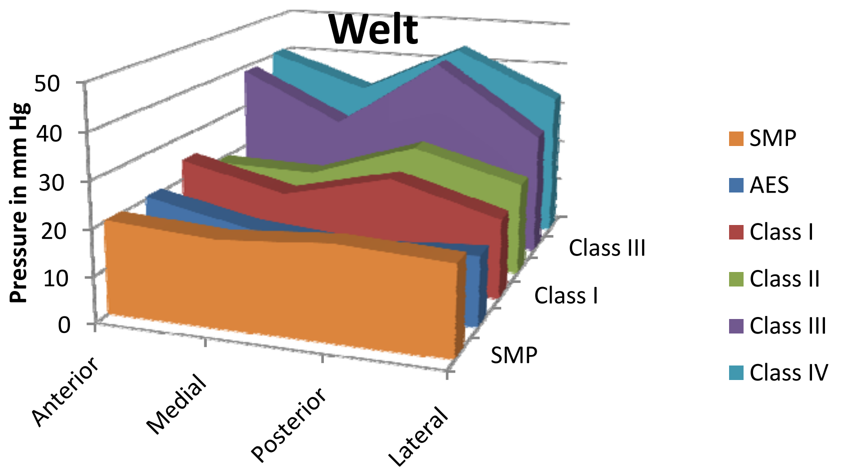


Figure 6-19 Circumferential pressure distribution at ankle and welt

The pressure distribution across the girth at ankle and welt is given in the Figure 6-19, the pressure profile along the circumferential direction at the welt region was variable for all the stockings classes. The pressure at the anterior and posterior region was high however the pressure variation was less for stockings with shape memory filaments. The uniformity in the pressure across the girth is due to the shape fixity of the filament with the application of high temperature using blow-dryer. Although, uniform pressure is delivered by the SMP stockings, the pressure magnitude is varied; the average pressure delivered ankle is 17 mm Hg and at welt it is 20 mm Hg. The variation is due to the variation in the fabric dimension, time and the temperature applied on to the stockings using blow-dyer to fit the stockings with SMP fabric on leg.

Stockings fabric with SMFs at ankle bow desirably configures itself to the ankle with distorted fabric wale to accommodate the excessive fabric extension by prominent malleolus at lateral and medial direction. However, commercial stockings with nylon and spandex fibers folds to fit the stockings at ankle see **Figure 6-20**. In fact, stockings with shape memory filaments showed uniform pressure distribution and are associated with novel properties of shape fixity percentage of 90 % and shape recovery of 83 %.

Figure 6-20 Stockings with shape memory filaments at ankle

The method of application of temperature to fit the stockings at the ankle bow and welt can be thought to be a revolutionary as known by the fact the application of stockings is easy and fit was comfortable see Figure 6-21.

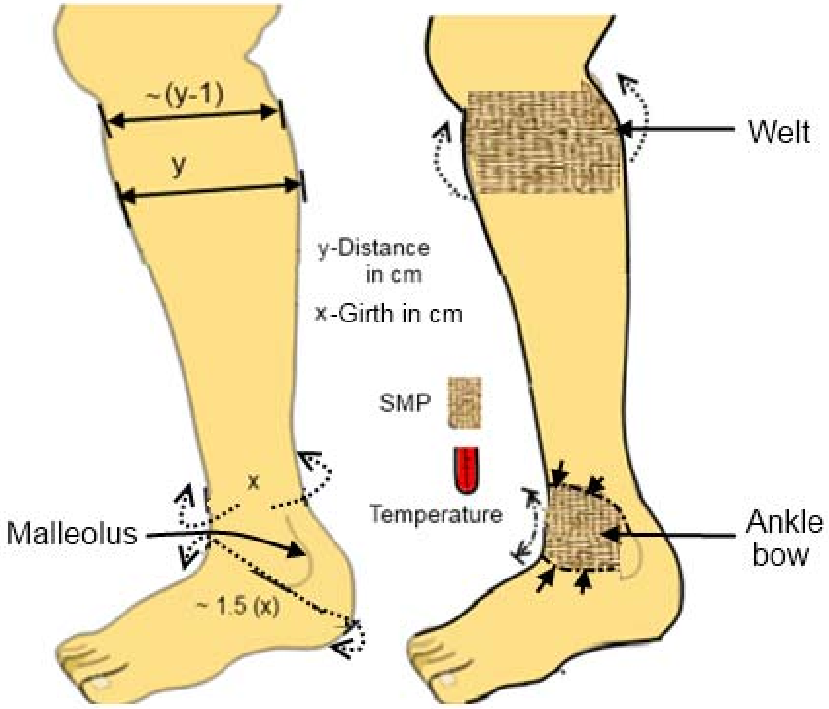


Figure 6-21 Fitting of Stocking with shape memory filaments at ankle bow at welt

As presented in the above figure the heel to ankle girth is 1.5 times the ankle girth due to which stockings needs to be elongated to about 20-30% at the heel to apply them. However, in case of stockings with SMFs the stockings can fit by applying temperature after the stockings at ankle is pulled on leg. Moreover, the welt with SMFs can fit in the same way as ankle with the application of temperature the welt binds to the leg as the girth above calf is basically 1 cm lesser than the calf girth. As demonstrated by line with arrow head at both ends in **Figure 6-22**, shape memory stockings is curvilinear where as the other stockings are tubular in shape.

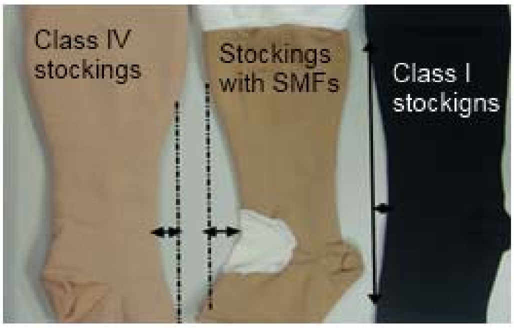


Figure 6-22 Fabric at the ankle bow in class I, IV and shape memory stockings

6.5 CONCLUSION

There are no standard to evaluate the ease of application of stockings even though compression stockings are applied since 19th century. The testing of mechanical properties on the stockings samples on human subjects to evaluate the comfort and compliance level on usage of compression stockings by objective testing method using Instron 4411 is a revolutionary method to analyze and correlate the objective results with the subjective comfort analysis.

During the current mechanical testing it was noted that the elongation of class III and class IV stockings was high and the maximum load of elongation was also greater when compared to class I and class II. Stockings with shape memory filaments showed relatively lower level of elongation and maximum load for elongation. Although, in stockings with shape memory fabric the elongation was high under heated condition, the fabric remained stiff in unheated condition. Henceforth, shape memory filaments can intermittently deliver pressure with elongation and the variation in the pressure with elongation after pre-setting is high as the elongation against the load is low i.e., more load is required to work against the stockings extension and hence pressure is delivered to the skin with its recoil is high.

Newly designed stockings with shape memory filaments at the ankle bow are relatively associated with low compliance level in terms of fit, donning and ease of motion as tested by subjective questionnaire, high wrinkle recovery when compared to the commercial stockings. Although, the pressure delivered by the stockings with SMP fabric on leg is uniform across the girth of leg due to its shape fixity property, the pressure delivered by this stocking is a variable of dimension of SMP fabric fabricated in the stockings, time and temperature applied to set the stockings with SMP on leg.

The added advantage of using shape memory filaments at the ankle was that the novel shape memory effect can form a curvilinear configuration at the ankle bow to fit the stockings at well at ankle, however, other stockings purchased from market showed almost linear tubular structure as a results of which the excessive fabric at just above the ankle bow falls back and folds back within the fabric to fit the stockings. This is one of the main reasons for wrinkling of all the stockings samples tested in practice in the stage I of pilot study.

CHAPTER 7. CONCLUSION AND FUTURE WORK

7.1 INTRODUCTION

Compression stockings are applied for centuries together; however they are not free from risk and complications. The compliance issues associated with application of compression stockings is discussed in literature but very few attempts were made on engineered designing of stockings to improve the compliance level using new fibers. The application of Shape Memory Fibers (SMFs) in compression stockings is so far never contemplated. Therefore, this study was carried out to design and fabricate shape memory filaments in knee high compression stockings with the objective of evaluating the pressure magnitude, pressure profile and determinants of compliance issues. Moreover, the applied SMFs were tested for mechanical properties and the performance of the stockings with SMFs was mechanically tested.

In this chapter primary outcome of the study is described briefly. At first the irregularities of the stockings with regard to pressure and compliance is given followed by results on the performance of stockings with SMFs. Furthermore, limitations and future study is described.

7.2 PRESSURE MAGNITUDE, PROFILE AND COMPLIANCE ISSUES ON THE USAGE OF COMPRESSION STOCKINGS

Pressure performance and noncompliance on the application of compressive stockings was reviewed and reported. In view of the results from Raju et al (2007) who grouped the reason for non compliance to (1) wear-comfort factors, and (2) intangible sense of restriction imposed by the stockings. Pilot study was carried on 20 human subjects and the subjects commented on complications and problems with the application of stockings while stockings were tested for pressure magnitude.

Pressure magnitude- The pressure delivered by the each stocking was diverse and 75% of the stockings failed to deliver the standard designated pressure at ankle. The stockings pressure on subjects was variable compared to the designated pressure. The pressure sensation was variable in different region of leg, hence a complete study on the pressure profile was necessary to logically analyze and conclude the findings.

Compliance issues-The generalized comments from the subjects were difficulty in *applying stockings at ankle, wrinkled stocking fabric at ankle and skin redness at welt* due to high pressure and folded coarse elastic fibers. Welt fabric was coarse and folded fabric at welt with high elasticity, thus imposing high pressure. The folded coarse rubber filament at welt caused tourniquet effect.

The increased pressure at welt is due to the leg configuration with a prominent sheen as per the Laplace law. These comments were ascertained by patients with venous disorder prescribed with compression stockings. Moreover the wrinkling at the ankle bow was common for all the stockings tested (class I to class IV) which led to pressure marks. The wrinkled stockings at ankle induced higher pressure sensation at ankle and reduced range of motion of ankle in human subjects. These comments correlated with work from other researchers (Seshadri, 2008, Hayes et al., 2002).

Pressure profile- The complete pressure profile of stockings was evaluated on 10 human subjects using pressure sensor at a time along the four directions of leg. From the results of the skin –stocking interface pressure on human subjects it was concluded that compression stockings do not apply sufficient pressure at the medial and lateral position at the ankle and most of them fall at the lower pressure limit of the standard pressure specified. Moreover, the pressure at the anterior direction and welt for all the stockings was high.

7.3 APPLICATION OF SHAPE MEMORY FILAMENTS

It was proposed that the sensation of tightness due to folded fabric can be controlled with the application of shape memory filaments at the specific regions so to effectively improve the variants that needed attention as these fibers are associated with shape fixity and shape recovery properties. Furthermore, the wrinkling of the stockings at the ankle as noted during the pilot study can be controlled with the application of shape memory filaments. SMFs with novel shape memory effect viz inherent property of the fiber to deform and recovery with variation in temperature is applied to control the undue constraints and for effortless application. Moreover, the elastic modulus of the fiber can be varied suitably with the application of temperature.

Stockings with shape memory filaments- Shape memory filaments with nylon filaments were used to knit fabric with 4 float one tuck design and the fabric was applied to knee high compression stockings at ankle bow and the welt of class I stockings (from the same manufacture of commercial stockings). This method was employed to apply SMFs in compression stockings due to the unavailability of the stockings knitting machine in the university. The stockings were stitched with care so that the stockings material is not damaged in the process of sewing. Through a boarding process the stockings with SMFs was pre-set at a temperature of 50 degree to form curvilinear structure at ankle on a leg model, whereas the commercial stockings had tubular structure.

From the results of the mechanical testing of stockings on human subjects it can be concluded that the stockings effectively fit and easily slip off the leg with the application of heat from blow-dryer. Moreover compliance level in terms of fit, donning and ease of motion as tested by subjective questionnaire on visual Analogue Scale is low for stockings with SMFs and showed relatively high wrinkle recovery when compared to the commercial stockings.

In the final analysis, from literature it is noted that the application of temperature further influence the blood flow. Cherry and Wilson (1999) have showed the efficacy of warming therapy by application of heat and resulting in reduced pain and improved healing rate. Thus, future study on the variation in venous blood flow with temperature and stockings with shape memory filaments can confirm the effectiveness of these stockings to improve the medical functioning and compliance level in patients suffering from venous disorder.

Given these points, from the results of this study the efficacy of the novel stockings with improved design is ascertained. The stockings with shape memory fabric at the ankle bow and welt improved the wearing comfort as noted from subjective evaluation on visual analogue scale.

7.4 Limitations of the study

During the study of the wrinkling of the stockings at ankle, Knee flexing joint simulator was used rather than the ankle joint. This is justified as the rare end of the knee joint simulates the ankle flexion.

In the designed stockings with shape memory filaments, the shape memory knitted fabric was attached by cut and sew method rather than knitting the stockings on stockings knitting machines.

Blow-dryer was used to fit the stockings at ankle and temperature was not monitored while the stockings were fitted to leg. The distance at which the blow-dryer was held from the stockings was not standardized. Nevertheless, constant wind speed and temperature slide switch on the blow-dryer was used during the mechanical testing on human subjects.

7.5 CONCLUSION

The implication of SMFs in compression stockings were evaluated and compared with commercial stockings by designing and fabricating SMFs in the stockings. It was noted that circumferential pressure variation of stockings with shape memory filaments compared to commercial stockings and the wrinkling at the ankle bow was considerably low. Moreover, from the mechanical testing of compression stockings with shape memory filaments at the ankle bow on human subjects it was noted that the slippage of the stockings was relatively high and the participants rated the stockings to be comfortable at ankle and welt regions when compared to commercial stockings.

This research study on the application of shape memory filaments into knee high compression stockings shows the advantages of using shape memory filaments with novel shape memory properties in compression stockings. However, the limitation of this research study is that shape memory filaments is only applied in elusive regions such ankle and welt by cut and sew and the process of locally increasing the temperature using blow-dryer was not standardized.

7.6 RECOMMENDATIONS FOR FUTURE WORK

The main objectives proposed in this thesis were achieved by designed methodology to effectively utilize shape memory filaments in designing knee high compression stockings. Some of the future work is recommendations to improve the present work

i. Clinical evaluation of stockings with shape memory filaments at ankle and welt for ROM

ii. Since the temperature is major parameter in designing the stockings by boarding process and also for activation of shape memory properties, evaluation of boarding process on stockings and shape set in stockings manufactured from shape memory filaments can add to the knowledge on the behavior of stockings with shape memory filaments.

iii. Influence of temperature on skin flow- warming therapy, Static and dynamic stiffness factor of stockings manufactured with shape memory filaments at ankle, welt, knee cap (thigh high compression stockings) can prove the efficacy of the fibers.

APPENDIX

A. PRESSURE EVALUATION OF COMMERCIAL COMPRESSION STOCKINGS AND RANGE OF MOTION AT ANKLE - A PILOT STUDY

Table A-1 Anthropomorphic data of subjects

Subject	Age (years)	Height (cm)	Weight (Kg)	Leg height (cm)t	Ankle girth (cm)
1	26	165	54	38.2	21.5
2	25	166	48	36.5	21.7
3	27	162	52	41.3	21
4	30	164	50	37.1	21.3
5	30	152	56	35.6	22.6
6	27	158	48	38.3	21.3
7	27	153	53	39.2	20.5
8	31	168	51	39.1	21.7
9	29	157	49	36.6	21.3
10	28	150	57	41.1	19.9
11	26	151	49	36.8	20.8
12	27	160	60	39.1	19.4
13	31	167	59	43.1	19.6
14	31	160	59	37.1	20.8
15	26	151	51	43.1	19.4
16	24	160	52	39.2	20.2
17	24	165	59	35.5	21.3
18	29	160	59	39.1	21.5
19	29	153	54	42.1	19.5
20	24	155	57	40.3	20.2
Mean	27.55	158.85	53.85	38.92	20.325
SD	2.37	5.87	4.12	2.34	2.33
CV	0.09	0.04	0.08	0.06	0.11

BMI Categories
Below 18.5 Underweight
18.5 - 24.9 Normal
25 - 29.9 Overweight
30.0 & Above Obese

Table A-2 Calibration of Kikuhime pressure sensor

Sphygmomanometer readings in mm Hg	Kihuhime in mm Hg								Mean
10	11	8	9	12	12	10	11	10	10.38
20	21	24	22	20	20	22	25	24	22.25
30	32	29	28	30	28	32	30	27	29.50
40	43	41	42	42	44	43	45	45	43.13
50	52	53	53	51	52	53	54	53	52.63
60	61	61	62	60	60	61	62	64	61.38
70	69	71	71	71	70	72	72	72	71.00
80	81	83	80	80	82	78	80	81	80.63

Sphygmomanometer readings in mm Hg	Pressure difference in Kikuhime							
10	-1	2	1	-2	-2	0	-1	0
20	-1	-4	-2	0	0	-2	-5	-4
30	-2	1	2	0	2	-2	0	3
40	-3	-1	-2	-2	-4	-3	-5	-5
50	-2	-3	-3	-1	-2	-3	-4	-3
60	-1	-1	-2	0	0	-1	-2	-4
70	1	-1	-1	-1	0	-2	-2	-2
80	-1	-3	0	0	-2	2	0	-1

Table A-3 Descriptive statistics of pressure readings of stockings

Labels	Class 1	Class II	Class III	Class IV
Number of values	40	40	40	40
Minimum	15	13	26	37
25% Percentile Q1	19	22.25	30	53
Median	20.5	26	31.5	58.5
75% Percentile Q3	23	29.75	33	64.75
Maximum	25	39	36	77
Mean	20.63	26.23	31.55	58.88
Std. Deviation	2.467	5.731	2.331	8.774
Upper Outliers	0	0	0	0
Lower Outliers	0	0	0	0
Std. Error	0.3901	0.9062	0.3686	1.387
Lower 95% CI of mean	19.84	24.39	30.8	56.07
Upper 95% CI of mean	21.41	28.06	32.3	61.68
CV	8	5	13	7
One sample t test				
Theoretical mean	17	29	40	50
Actual mean	20.63	26.23	31.55	58.88
Discrepancy	-3.625	2.775	8.45	-8.875
95% CI of discrepancy	2.836 to 4.414	-4.608 to -0.9417	-9.196 to -7.704	6.068 to 11.68
t, df	t=9.293 df=39	t=3.062 df=39	t=22.93 df=39	t=6.397 df=39
P value (two tailed)	< 0.0001	0.004	< 0.0001	< 0.0001
Significant (alpha=0.05)?	Yes	Yes	Yes	Yes

Table A-4 ANOVA Test for pressure evaluation in pilot study

ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	34548.119	3	11516.04	379.6	0
Within Groups	4732.625	156	30.337		
Total	39280.744	159			

			Mean Difference (I-J)	Std. Error	Sig.
Tukey HSD	Class I	Class II	-5.600*	1.232	0
		Class III	-10.925*	1.232	0
		Class IV	-38.250*	1.232	0
	Class II	Class I	5.600*	1.232	0
		Class III	-5.325*	1.232	0
		Class IV	-32.650*	1.232	0
	Class III	Class I	10.925*	1.232	0
		Class II	5.325*	1.232	0
		Class IV	-27.325*	1.232	0
	Class IV	Class I	38.250*	1.232	0
		Class II	32.650*	1.232	0
		Class III	27.325*	1.232	0
Gabriel	Class I	Class II	-5.600*	1.232	0
		Class III	-10.925*	1.232	0
		Class IV	-38.250*	1.232	0
	Class II	Class I	5.600*	1.232	0
		Class III	-5.325*	1.232	0
		Class IV	-32.650*	1.232	0
	Class III	Class I	10.925*	1.232	0
		Class II	5.325*	1.232	0
		Class IV	-27.325*	1.232	0
	Class IV	Class I	38.250*	1.232	0
		Class II	32.650*	1.232	0
		Class III	27.325*	1.232	0

Table A-5 Wilcoxon signed rank test for stockings

wilcoxon Signed Rank Test				
Theoretical median	17	29	40	50
Actual median	20.5	26	31.5	58.5
Discrepancy	-3.5	3	8.5	-8.5
Sum of signed ranks (W)	748	-357	-820	708
Sum of positive ranks	764	154.5	0	764
Sum of negative ranks	-16	-511.5	-820	-56
P value (two tailed)	< 0.0001	0.0051	< 0.0001	< 0.0001
Significant (alpha=0.05)?	Yes	Yes	Yes	Yes
Coefficient of variation	11.96%	21.85%	7.39%	14.90%
Geometric mean	20.48	25.56	31.46	58.21
Lower 95% CI of geo. mean	19.68	23.68	30.71	55.41
Upper 95% CI of geo. mean	21.3	27.58	32.23	61.16
Skewness	-0.3304	-0.1787	-0.4183	-0.0701
Kurtosis	-0.4987	0.1995	0.4176	0.09035
SEM	825	1049	1262	2355

Table A-6 Participants age for stage II pilot study

Participant	**Healthy**	**CVI**
1	49	60
2	47	61
3	45	58
4	48	63
5	51	45
AVG	48	57
SD	2	7

Table A-7 Plantar and dorsi flexion at ankle

	Plantar			**Dorsi**			**ROM**
	Min	**Average**	**max**	**Min**	**Average**	**max**	
Healthy	42.3	43.4	44.5	10.9	12.0	13.1	55.4
Healthy with class I	42.2	46.7	52.1	7.8	10.7	13.7	57.4
Healthy with class IV	39.1	44.8	50.2	3.9	8.3	13.7	53.1
CVI	28.3	36.4	42.7	5.8	9.1	12.2	45.4
CVI with class I	28.2	36.2	42.5	6.1	9.0	12.1	45.2
CVI with class IV	28.2	35.0	38.5	6.1	7.4	9.7	42.4

Table A-8 ANOVA for ROM

ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	798.047	5	159.609		.000
Within Groups	532.212	24	22.176	7.198	
Total	1330.259	29			

ROM Tukey HSD

(I) Subject	(J) ROM	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
Healthy	CVI	10.30200*	2.97829	.022	1.0933	19.5107
	Healthy class I	-.05200	2.97829	1.000	-9.2607	9.1567
	CVI class I	10.46200*	2.97829	.020	1.2533	19.6707
	Healthy class IV	1.85600	2.97829	.988	-7.3527	11.0647
	CVI class IV	11.65000*	2.97829	.008	2.4413	20.8587
CVI	Healthy	-10.30200*	2.97829	.022	-19.5107	-1.0933
	Healthy class I	-10.35400*	2.97829	.021	-19.5627	-1.1453
	CVI class I	.16000	2.97829	1.000	-9.0487	9.3687
	Healthy class IV	-8.44600	2.97829	.085	-17.6547	.7627
	CVI class IV	1.34800	2.97829	.997	-7.8607	10.5567
Healthy Class I	Healthy	.05200	2.97829	1.000	-9.1567	9.2607
	CVI	10.35400*	2.97829	.021	1.1453	19.5627
	CVI class I	10.51400*	2.97829	.019	1.3053	19.7227
	Healthy class IV	1.90800	2.97829	.987	-7.3007	11.1167
	CVI class IV	11.70200*	2.97829	.007	2.4933	20.9107
CVI class I	Healthy	-10.46200*	2.97829	.020	-19.6707	-1.2533
	CVI	-.16000	2.97829	1.000	-9.3687	9.0487
	Healthy class I	-10.51400*	2.97829	.019	-19.7227	-1.3053
	Healthy class IV	-8.60600	2.97829	.077	-17.8147	.6027
	CVI class IV	1.18800	2.97829	.999	-8.0207	10.3967
Healthy Class IV	Healthy	-1.85600	2.97829	.988	-11.0647	7.3527
	CVI	8.44600	2.97829	.085	-.7627	17.6547
	Healthy class I	-1.90800	2.97829	.987	-11.1167	7.3007
	CVI class I	8.60600	2.97829	.077	-.6027	17.8147
	CVI class IV	9.79400*	2.97829	.032	.5853	19.0027
CVI class IV	Healthy	-11.65000*	2.97829	.008	-20.8587	-2.4413
	CVI	-1.34800	2.97829	.997	-10.5567	7.8607
	Healthy class I	-11.70200*	2.97829	.007	-20.9107	-2.4933
	CVI class I	-1.18800	2.97829	.999	-10.3967	8.0207
	Healthy class IV	-9.79400*	2.97829	.032	-19.0027	-.5853

B. CONSUMMATE STUDY OF PRESSURE PROFILE IN COMMERCIAL COMPRESSION STOCKINGS

Table B-1 Age, weight and height of subjects

Age	Weight	Height
28.2	52.02	168.75
25.6	59.48	155.26
26.5	46.34	149.18
24.5	54.3	165.33
26.7	59.73	169.95
28.5	55	162.7
23.6	44.87	165.18
24.5	47.36	160.78
27.3	46.77	164.08
32.8	60.2	172.47

Table B-2 Anthropometric measurement for pressure profile evaluation

Instep	B	B1	Calf	Upper calf	Welt
24.7	20.4	31.3	31.7	32.1	31.1
22.8	21.9	30.0	28.5	33.8	33.7
23.5	21.5	32.3	37.2	30.3	29.7
22.0	19.9	30.8	31.7	34.3	33.9
24.6	20.8	26.6	31.7	31.0	31.0
24.7	22.9	27.5	36.4	32.5	36.8
20.1	20.4	32.6	37.6	37.4	32.5
26.1	24.9	30.2	38.8	30.0	33.0
25.9	21.0	30.3	36.4	35.0	26.2
26.1	23.1	29.4	37.1	31.3	31.7
24.0	21.7	30.1	34.7	32.7	32.0
1.95	1.55	1.89	3.47	2.36	2.82

Table B-3 Age, weight and height of subjects

Parameter	Mean	Standard deviation
Age (years)	22.82	2.65
Weight (Kg)	52.6	6.01
Height (Cm)	163.3	6.96

Table B-4 Anthropometric measurement

Position	Girth in cm	Standard deviation
Instep	24.1	1.95
B	21.7	1.55
B1	30.1	1.89
Calf	34.7	3.47
Upper calf	32.7	2.3
Welt	32	2.82

Table B-5 Calibration against standard weight of X-Pliance pressure sensor

Standard weight	X-Pliance pressure reading	mean difference	SD
10	9.74	1.48	0.62
20	20.36	2.15	0.64
30	29.88	1.25	0.65
40	39.92	1.02	0.52
50	50.26	1.46	0.43
60	60.18	2.12	0.31

Table B-6 Results of wilcoxon ranked test

Table Analyzed	Data 1
Standard Weight vs. X Pliance	
wilcoxon matched-pairs signed rank test	
P value	0.6875
P value summary	ns
Are medians significantly. different? (P < 0.05)	No
One- or two-tailed P value?	Two-tailed
Sum of positive, negative ranks	8.000 , -13.00
Sum of signed ranks (W)	-5.000
rs (Spearman)	1.0000
P Value (one tailed)	0.0014
P value summary	**
Was the pairing significantly effective?	Yes

Table B-7 Pressure values

Instep			B				B1				Calf				Upper calf				welt			
Anterior	Medial	Lateral	Anterior	Medial	Posterior	Lateral	Anterior	Medial	Posterior	Lateral	Anterior	Medial	Posterior	Lateral	Anterior	Medial	Posterior	Lateral	Anterior	Medial	Posterior	Lateral
AES																						
			18.7	9.45	12.89	10.56	8.51	9.52	12.51	8	22.45	16.8	11.8	14.51	17.51	14.2	13.2	13	25.51	20.8	14.88	16
			19.51	5.76	14.74	9.56	15.7	7.2	20.52	8.2	17.51	11.76	17.45	13.76	17.45	13.76	12.8	12.76	19	14.76	16.45	15.76
			20.52	8.34	12.24	12.29	14.12	7.2	13.7	9.1	19.45	13.2	14.2	13.51	19	19.2	17.45	19.51	20.45	14.88	13.8	14.51
			17.57	10.68	13.57	8.96	16.52	8.6	11.52	12.2	15.51	12.76	10.8	13.2	19.51	14	11.88	16.2	14.51	12.8	11.45	14.2
			21.09	8.48	15.68	5.81	19.51	11	18.51	14.32	15	12.8	11.45	12.76	27.45	18.76	17.2	19.76	24.45	18.76	15.8	19.76
			17.52	9.65	15.71	8.78	11.7	6.2	11.52	9.52	20.45	17.2	19.2	17.2	27.45	18.88	22.45	18.76	16	11.88	11.88	11.51
			19.89	8.66	14.86	8.48	10.52	9.8	6.7	9.2	17.51	13.76	15.45	11.76	26	17.76	15	16	22.45	17.76	18.45	17.76
			17.36	12.18	10.89	9.92	21.51	19.52	17.51	19	21.45	19	18.45	18.51	17.45	13.8	14.45	14.76	19.51	15.2	12	15.51
			20.26	11.97	12.4	9.27	17.52	9.2	13.52	10.2	18.51	15.8	10.8	14.76	23	16.88	16.88	19.2	23	15.8	20.45	14.76
			21.52	8.95	15.48	10.18	18.51	7.52	15.51	8	20.45	16.2	12.2	12	20.51	16.2	14	12.51	20.51	13.88	18	12
Class I																						
24.62	28.43	28.62	26.94	21.64	22.47	16.64	30.12	20.62	27.12	22.62	27.94	22.44	17.56	20.07	29.42	17.96	16.64	19.64	27.82	18.18	14.54	17.82
15.32	26.17	20.32	36.69	21.63	22.34	11.11	28.25	21.82	27.25	16.62	24.44	23.06	18.63	20.44	18.58	17.42	18.58	13.96	19.74	16.74	15.46	12.74
18.43	39.62	30.62	27.11	13.03	28.54	15.74	27.12	19.62	22.18	17.82	23.56	20.07	18.06	19.94	28.04	16.12	22.04	16.58	23.18	13.82	16.82	16.18
16.17	27.32	29.23	31.3	17.62	24.73	13.29	20.62	18.18	16.12	16.25	21.07	16.94	17.07	16.07	17.96	16.64	16.42	16.68	20.54	14.46	12.46	13.54
15.62	30.62	20.32	31.03	20.79	24.95	19.86	25.82	22.12	21.62	19.18	28.44	19.07	19.06	20.44	23.64	18.58	20.04	13.12	16.18	17.82	17.74	15.82
20.62	25.62	22.43	26.9	20.85	20.22	15.27	29.62	17.25	25.25	24.62	24.94	20.56	28.54	24.56	27.42	17.12	18.96	17.64	25.74	24.18	31.18	27.18
18.17	26.32	23.62	22.86	18.51	25.28	18.73	18.25	12.82	19.18	20.25	33.06	22.44	19.94	20.07	34.04	19.64	17.42	22.58	26.82	15.46	15.82	17.54
20.25	29.43	22.43	21.92	21.36	25.03	22.19	29.82	25.62	29.62	23.62	26.56	24.06	19.44	20.94	19.58	21.65	24.04	18.96	31.46	22.18	24.61	19.82
19.62	28.25	25.17	27.42	15.42	22.21	20.77	29.12	20.25	24.12	21.25	28.07	22.44	28.56	21.44	27.96	22.42	18.58	17.42	25.54	20.24	17.46	15.18

Instep			B				B1				Calf				Upper calf				welt			
20.25	30.17	26.62	30.63	21.2	27.69	15.97	26.62	21.18	25.86	22.12	25.44	19.94	15.07	18.07	30.04	19.96	18.64	21.64	26.46	24.74	17.82	20.74
Class II																						
24.83	28.64	28.83	29.71	24.41	25.24	13.29	30.64	20.36	32.42	23.27	38.22	22.54	34.38	32.15	32.85	22.15	31.89	20.53	18.11	16.58	31.42	25.42
15.53	26.38	20.53	39.46	24.4	25.11	16.25	35.2	17.58	32.69	20.32	36.17	20.86	33.68	28.85	32.15	26.53	20.69	21.89	21.42	16.89	25.38	20.82
18.64	39.83	30.83	29.88	15.8	31.31	19.36	41.64	33.76	32.89	25.65	45.95	20.45	24.15	19.68	20.53	21.85	31.42	20.18	19.89	21.42	29.18	20.58
16.38	27.53	29.44	34.07	20.39	27.5	14.15	29.48	19.58	37.67	21.11	26.75	21.22	18.38	18.15	16.68	17.15	20.11	18.89	15.69	16.11	23.57	15.82
15.83	30.83	20.53	33.8	23.56	27.72	18.64	30.2	21.36	38.42	27.43	25.69	28.36	28.32	22.85	21.32	21.85	25.14	17.58	19.89	20.18	29.38	19.42
20.83	25.83	22.64	29.67	23.62	22.99	20.18	28.65	20.64	39.78	29.86	33.07	27.15	28.15	13.68	19.53	20.53	28.89	29.89	25.42	21.89	33.57	17.82
18.38	26.53	23.83	25.63	21.28	28.05	18.21	33.84	28.4	40.24	19.49	34.35	20.13	28.85	16.32	24.85	24.68	28.58	20.89	18.15	18.58	32.38	20.58
20.46	29.64	22.64	24.69	24.13	27.8	22.15	30.56	16.52	31.56	26.32	29.38	19.98	30.68	25.53	29.15	23.53	27.89	22.42	20.89	20.11	27.57	25.42
19.83	28.46	25.38	30.19	18.19	24.98	18.25	28.48	25.48	30.45	25.41	32.65	22.45	29.15	19.85	24.68	21.53	29.11	22.11	21	20.58	29.82	21.58
20.46	30.38	26.83	33.4	23.97	30.46	19.08	31.45	23.15	32.45	23.74	30.56	25.07	25.32	22.24	26.15	22.68	25.42	18.58	16.11	19.89	33.38	18.82
Class III																						
26.28	48.39	37.28	43.35	36.59	49.57	33.24	30.28	33.38	43.94	28.06	44.82	32.58	32	36.58	42.2	32	32.2	33.2	44.2	31.88	31.2	28.88
29.72	48.28	29.39	46.73	32.76	37.62	30.97	37.62	19.72	35.28	32.38	30.84	33.12	30.82	31.84	42.18	31.76	29.76	26.76	42.12	29.8	32.12	26.8
24.39	57.61	64.61	43.5	35.31	45.3	29.26	33.94	25.38	21.94	22.72	40.82	35.58	27.84	29.1	38.4	28.2	32.2	31.2	37.2	28.88	30.12	27.88
22.72	38.39	35.72	51.23	35.34	43.33	29.93	20.62	19.06	18.28	17.38	31.84	26.42	27.82	30.58	30.2	24.18	22	22.76	32.19	24.7	26.2	26.14
20.61	37.72	28.39	51.29	32.09	42.76	37.38	26.28	24.72	28.62	29.06	51.82	43.58	39.12	37.84	44.21	31.2	32.2	32.1	43.12	27.8	31.12	29.88
22.28	35.61	32.28	45.67	30.05	37.07	28.96	15.94	11.06	12.28	18.25	33.15	21.58	19.82	21.58	38.12	21.76	26.2	25.2	40.18	21.88	26.85	21.8
21.39	33.84	29.61	44.74	32.78	48.05	27.29	39.28	34.72	29.94	25.38	34.58	29.12	23.84	25.58	33.2	27.2	28.18	23.21	33.12	25.12	25.2	27.6
21.61	41.2	30.39	50.57	34.19	43.11	38.47	40.62	34.38	46.28	39.06	37.82	30.58	28.82	30.58	41.21	29.76	27.18	32.2	40.2	30.88	28.12	31.88
19.85	30.84	25.48	45.54	35.74	39.19	29.02	36.28	27.72	36.94	29.72	29.84	28.19	22.02	27.58	32.2	27.2	25.2	27.76	32	26.8	25	27.8
22.85	31.45	26.15	47.05	33.24	47.18	34.15	40.94	35.82	48.12	43.26	28.82	27.2	26.41	23.58	41.85	27.61	32.65	23	42.12	28.12	32.92	26.18

Class IV																						
33.2	48.1	34.2	58.64	40.34	39.8	44.36	39.32	40.68	53.32	43	44.4	31.6	32.4	35.4	42.28	30.88	31.28	34.88	38.4	32.82	33.6	32.82
27.4	58.18	20.45	54.44	45.47	49.45	44.75	49.86	43.2	56.86	48.68	31.17	32.4	30.17	31.6	30.72	35.72	33.72	31.72	34.6	32.82	29	30.82
24.8	42.15	21.4	55.83	40.76	52.47	33.34	41.32	34.68	21.86	26.2	40.4	34.6	28.4	28.4	43.28	27.72	37.28	30.88	42.4	31.82	38.4	31
22.15	35.19	22.4	60	42.3	49.93	39.94	29.86	25.2	20.32	24.68	32.4	26	27.4	29.6	30.72	26.88	26.28	29.72	33.6	31	30.6	28.82
28	36.12	28.21	60.97	43.75	38.65	39.23	61.86	47.68	39.86	48.68	51.4	42.6	39.17	36.6	41.28	34.88	32.28	39	46.4	35.82	35.4	40
24.16	34.15	28.18	60.49	31.55	47.38	36.91	39.32	27.2	27.32	26.2	34.17	27.4	26.4	21.4	36.72	26	29.72	21.88	46.4	27.82	32.6	30.82
25.98	41.96	29.47	55.94	30.68	46.17	35.27	30.12	28.14	28.16	29.15	37.4	31	29.17	28.6	32.28	30.72	31.28	27.72	31.6	32.82	31.4	29.82
21.47	41.06	30.25	56.75	36.56	32.45	40.36	38.86	34.68	28.86	26.2	35.17	29.6	28.4	27.6	45.28	35.88	32.72	37.88	48.4	33.82	33.6	34.82
19.71	30.7	25.34	52.13	40.95	43.55	36.22	40.32	35.2	46.32	39.68	40.17	33.4	31.17	32	34.72	27.72	29.28	29.72	35.6	31.82	29.4	31.82
22.71	31.31	26.01	50.21	38.9	38.58	46.9	35.86	28.2	35.86	30.2	34.4	26.6	28.4	27.6	34.28	31.38	31.62	29.38	46.4	35.82	35	39.82

C. THERMOMECHANICAL TESTING, PRE-SETTING AND STRESS RELAXATION OF SHAPE MEMORY FILAMENTS

Table C-1 The shape fixity and recovery ratios at different temperature

Temperature	εp (N)	εu(R f(N))	Stress at 100% strain in cN/dtex	R r(N)
30	30.83	55.83	2.21	69.17
40	23.33	57.5	2.20	76.67
50	16.66	66.66	1.44	83.34
60	27.5	84.16	0.74	72.5
70	34.99	89.99	0.73	65.01

Table C-2 Shape memory properties of filaments heat set at different temperatures

Pre-setting temperature	Shape fixity	Shape recovery	Filament tenacity
45	83.33	80.84	21.63
55	84.16	34.17	22.41
65	85.83	93.34	21.27
75	17.83	96.17	18.49
85	18.16	97.67	17.25

Table C-3 Shape memory properties of filaments at different deformation and recovery speed

Deformation speed	Shape fixity	Shape recovery
5	76.66635	82.08425
10	84.16675	34.1669
50	83.33405	79.16705

Recovery speed	shape fixity	shape recovery
5	74.9995	82.49935
10	84.16675	34.1669
50	87.4999	76.6675

Table C-4 Multiple thermomechanical test of shape memory filaments

Trial no.	Shape fixity	Shape recovery
1	87.4996	72.49935
2	80.8322	69.16765
3	80.8336	64.99925
4	81.66635	64.1657
5	80.00005	62.49995
6	79.1676	62.49995
7	79.80005	62.29995
8	78.9676	62.29995
9	79.70005	62.19995
10	79.0676	62.39995
11	79.90005	62.39995
12	78.3476	61.67995
13	79.18005	61.67995
14	78.3476	61.67995
15	79.98005	62.47995
16	79.1476	62.47995
17	79.1356	62.46795
18	79.1356	62.46795
19	79.1246	62.45695
20	79.1366	62.46895

Table C-5 Fiber shrinkage at different pre-setting temperature

Hot roller temperature	45	55	65	75	85
Fiber Shrinkage	63.33	55.17	56.67	53.33	46.15

D. IMPLICATIONS OF SHAPE MEMORY FILAMENTS IN COMPRESSION STOCKINGS

Table D-1 Mechanical properties of stockings

Class	Max Load(N)	Tensile strain at max load(%)	Tensile Extension at slippage(mm)	Load at slippage(N)	Tensile strain at slippage(mm)	Time at Maximum Load (sec)
Class I	109.26	54.6	383.05	97.85	0.547	45.9
Class II	115.03	60.2	421.4	115.03	0.6	50.6
Class III	140.13	53.43	373.81	51.94	0.66	44.9
Class IV	137.44	50.33	573.12	80.13	0.81	42.3
SMP unheated	102.14	52.83	442.7005	-8.19	0.63243	44.4
SMP heated	131.4	86.4	617.3116	91.14	0.88187	72.6

Table D-2 Descriptive Statistics for subjective analysis on VAS of compression stockings

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Welt	Class I	9	1.6667	0.5	0.16667	1.2823	2.051	1	2
	Class II	9	1.7778	0.44096	0.14699	1.4388	2.1167	1	2
	Class III	9	2.8889	0.33333	0.11111	2.6327	3.1451	2	3
	Class IV	9	3.3333	0.5	0.16667	2.949	3.7177	3	4
	SMP	9	0.6667	0.5	0.16667	0.2823	1.051	0	1
	Total	45	2.0667	1.05313	0.15699	1.7503	2.3831	0	4
Comfort while Donning	Class I	9	1.5556	0.52705	0.17568	1.1504	1.9607	1	2
	Class II	9	1.7778	0.44096	0.14699	1.4388	2.1167	1	2
	Class III	9	3.6667	0.5	0.16667	3.2823	4.051	3	4
	Class IV	9	4.3333	0.5	0.16667	3.949	4.7177	4	5
	SMP	9	1.4444	0.52705	0.17568	1.0393	1.8496	1	2
	Total	45	2.5556	1.30655	0.19477	2.163	2.9481	1	5
Heel	Class I	9	1.2222	0.44096	0.14699	0.8833	1.5612	1	2
	Class II	9	1.6667	0.5	0.16667	1.2823	2.051	1	2
	Class III	9	3.1111	0.33333	0.11111	2.8549	3.3673	3	4
	Class IV	9	3.8889	0.33333	0.11111	3.6327	4.1451	3	4
	SMP	9	2.1111	0.60093	0.20031	1.6492	2.573	1	3
	Total	45	2.4	1.0745	0.16018	2.0772	2.7228	1	4

Ankle	Class I	9	2.4444	0.72648	0.24216	1.886	3.0029	1	3
	Class II	9	2.1111	0.33333	0.11111	1.8549	2.3673	2	3
	Class III	9	3.5556	0.52705	0.17568	3.1504	3.9607	3	4
	Class IV	9	4.1111	0.60093	0.20031	3.6492	4.573	3	5
	SMP	9	1.4444	0.52705	0.17568	1.0393	1.8496	1	2
	Total	45	2.7333	1.116	0.16636	2.3981	3.0686	1	5
Malleolus	Class I	9	2.2222	0.66667	0.22222	1.7098	2.7347	1	3
	Class II	9	2.4444	0.52705	0.17568	2.0393	2.8496	2	3
	Class III	9	3.6667	0.5	0.16667	3.2823	4.051	3	4
	Class IV	9	3.3333	0.70711	0.2357	2.7898	3.8769	2	4
	SMP	9	2.6667	0.5	0.16667	2.2823	3.051	2	3
	Total	45	2.8667	0.78625	0.11721	2.6305	3.1029	1	4
AnkleFlexion	Class I	9	2.2222	0.66667	0.22222	1.7098	2.7347	1	3
	Class II	9	2.4444	0.52705	0.17568	2.0393	2.8496	2	3
	Class III	9	3.2222	0.66667	0.22222	2.7098	3.7347	2	4
	Class IV	9	3.5556	0.72648	0.24216	2.9971	4.114	3	5
	SMP	9	2.1111	0.60093	0.20031	1.6492	2.573	1	3
	Total	45	2.7111	0.84267	0.12562	2.4579	2.9643	1	5
Overall	Class I	9	2.3333	0.5	0.16667	1.949	2.7177	2	3
	Class II	9	2.1111	0.33333	0.11111	1.8549	2.3673	2	3
	Class III	9	2.6667	0.5	0.16667	2.2823	3.051	2	3
	Class IV	9	3.6667	0.5	0.16667	3.2823	4.051	3	4
	SMP	9	1.5556	0.52705	0.17568	1.1504	1.9607	1	2
	Total	45	2.4667	0.84208	0.12553	2.2137	2.7197	1	4

Table D-3 Reliability statistics

Case Processing Summary			
		N	%
Cases	Valid	45	71.4
	Excluded a	18	28.6
	Total	63	100
a. Listwise deletion based on all variables in the procedure.			

Reliability Statistics	
Cronbach's Alpha	N of Items
0.92	7

Item-Total Statistics				
	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
ComfortwhileDonning	15.2444	21.462	0.92	0.89
Heel	15.4	25.291	0.727	0.911
Ankle	15.0667	23.836	0.846	0.898
Malleolus	14.9333	28.882	0.568	0.924
AnkleFlexion	15.0889	27.628	0.673	0.916
Overall	15.3333	27.227	0.724	0.912
Welt	15.7333	24.427	0.842	0.898

Table D-4 Interclass correlation coefficient

Intraclass Correlation Coefficient							
		95% Confidence Interval		F Test with True Value 0			
	Intraclass Correlation[a]	Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.621[b]	0.508	0.735	12.492	44	264	0
Average Measures	.920[c]	0.878	0.951	12.492	44	264	0
Two-way mixed effects model where people effects are random and measures effects are fixed.							
a. Type C intraclass correlation coefficients using a consistency definition-the between-measure variance is excluded from the denominator variance.							
b. The estimator is the same, whether the interaction effect is present or not.							
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.							

Table D-5 Factor analysis

Communalities		
	Initial	Extraction
Comfort while Donning	1	0.894
Heel	1	0.633
Ankle	1	0.807
Malleolus	1	0.42
Ankle Flexion	1	0.572
Overall	1	0.643
Welt	1	0.795
Extraction Method: Principal Component Analysis.		

Total Variance Explained						
	Initial Eigen values			Extraction Sums of Squared Loadings		
Component	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	4.765	68.069	68.069	4.765	68.069	68.069
2	0.852	12.17	80.239			
3	0.451	6.44	86.68			
4	0.38	5.429	92.109			
5	0.264	3.769	95.878			
6	0.189	2.705	98.582			
7	0.099	1.418	100			
Extraction Method: Principal Component Analysis.						

Component Matrix[a]	
	Component
	1
Comfort while Donning	0.946
Heel	0.796
Ankle	0.899
Malleolus	0.648
Ankle Flexion	0.757
Overall	0.802
Welt	0.892
Extraction Method: Principal Component Analysis.	
a. 1 components extracted.	

Table D-6 ANOVA for subjective comfort analysis

		Sum of Squares	df	Mean Square	F	Sig.
Welt	Between Groups	40.356	4	10.089	47.789	0
	Within Groups	8.444	40	0.211		
	Total	48.8	44			
Comfort while Donning	Between Groups	65.111	4	16.278	65.111	0
	Within Groups	10	40	0.25		
	Total	75.111	44			
Heel	Between Groups	42.578	4	10.644	51.784	0
	Within Groups	8.222	40	0.206		
	Total	50.8	44			
Ankle	Between Groups	42.356	4	10.589	34.036	0
	Within Groups	12.444	40	0.311		
	Total	54.8	44			
Malleolus	Between Groups	13.422	4	3.356	9.742	0
	Within Groups	13.778	40	0.344		
	Total	27.2	44			
Ankle Flexion	Between Groups	14.8	4	3.7	9	0
	Within Groups	16.444	40	0.411		
	Total	31.244	44			
Overall	Between Groups	22.089	4	5.522	24.244	0
	Within Groups	9.111	40	0.228		
	Total	31.2	44			

Table D-7 Percentage of extension at ankle bow

Subject	Plantar flexion	Dorsi Extension	Initial distance	% plantar extension	% Dorsi extension	Total % extension
1	6.6	3.2	4.3	53.49	25.58	79.07
2	6.8	3.3	4.5	51.11	26.67	77.78
3	6.5	3.2	4.4	47.73	27.27	75.00
4	6.6	3.4	4.5	46.67	24.44	71.11
5	6.3	3	4.1	53.66	26.83	80.49
6	6.5	3.1	4.2	54.76	26.19	80.95
7	6.6	3.3	4.4	50.00	25.00	75.00
8	6.2	3.1	4.3	44.19	27.91	72.09
9	6.5	3.2	4.2	54.76	23.81	78.57
Mean	6.51	3.20	4.32	50.71	25.97	76.67

REFERENCES

ADMIN. 2010. Top Complaints About Wearing Compression Stockings. *compression stockings and more* [Online]. Available from: http://www.compressionstockingssite.com/index.php/2010/08/13/top-complaints-about-wearing-compression-stockings/ [Accessed August 20 2010].

AGU, O., HAMILTON, G. & BAKER, D. 1999. Graduated compression stockings in the prevention of venous thromboembolism. *British Journal of Surgery,* 86**,** 992-1004.

ALBERTO, C. 2006. Historical Background. *In:* NICOS, L. & GERARD, S. (eds.) *Venous and Lymphatic diseases*

New York: Taylor and Francis Group.

AMSLER, F. & BLÄTTLER, W. 2008. Compression therapy for occupational leg symptoms and chronic venous disorders-a meta-analysis of randomised controlled trials. *European journal of vascular and endovascular surgery,* 35**,** 366-372.

BACK, T. & PADBERG, F. 1995. Limited range of motion is a significant factor in venous ulceration. *Journal of Vascular Surgery,* 22**,** 519-523.

BAKER, S., STACEY, M., JOPP-MCKAY, A., HOSKIN, S. & THOMPSON, P. 1991. Epidemiology of chronic venous ulcers. *British Journal of Surgery,* 78**,** 864-867.

BECKER, F., CROS, F. & FULLANA, J.-M. 2006. *Knitted Compressive Orthosis of the Lower Limb for Treating Chronic Venous Insufficiency*

BEEBE-DIMMER, J. L., PFEIFER, J. R., ENGLE, J. S. & SCHOTTENFELD, D. 2005. The Epidemiology of Chronic Venous Insufficiency and Varicose Veins. *Annals of Epidemiology,* 15**,** 175-184.

BEHL, M. & LENDLEIN, A. 2007. Actively moving polymers. *Soft Matter,* 3**,** 58-67.

BELCZAK, C., DE GODOY, J., RAMOS, R., DE OLIVEIRA, M., BELCZAK, S. & CAFFARO, R. 2010. Is the wearing of elastic stockings for half a day as effective as wearing them for the entire day? *British Journal of Dermatology,* 162**,** 42-45.

BENKÖ, T., COOKE, E., MCNALLY, M. & MOLLAN, R. 2001. Graduated compression stockings: knee length or thigh length. *Clinical orthopaedics and related research,* 383**,** 197.

BEST, A., WILLIAMS, S., CROZIER, A., BHATT, R., GREGG, P. & HUI, A. 2000. Graded compression stockings in elective orthopaedic surgery: an assessment of the in vivo performance of commercially available stockings in patients having hip and knee arthroplasty. *Journal of Bone and Joint Surgery-British Volume,* 82**,** 116.

BLAIR, S., WRIGHT, D., BACKHOUSE, C., RIDDLE, E. & MCCOLLUM, C. 1988. Sustained compression and healing of chronic venous ulcers. *British Medical Journal,* 297**,** 1159.

BLATTLER, W., LUN, B., UHL, J. F. & BRINGER, Y. 2007. Determinants of pressure exerted by medical compression stockings. *Phlebologie,* 36**,** 237–244.

BRADLEY, L. 2001. Venous haemodynamics and the effects of compression stockings. *British journal of community nursing,* 6**,** 165.

BURKITT, D. P. 1972. Varicose Veins, Deep Vein Thrombosis, and Haemorrhoids: Epidemiology and Suggested Aetiology. *British Medical Journal,* 2**,** 556-561.

BYRNE, B. 2001. Deep vein thrombosis prophylaxis: the effectiveness and implications of using below-knee or thigh-length graduated compression stockings. *Heart & Lung: The Journal of Acute and Critical Care,* 30**,** 277-284.

CAGGIATI, A. & ALLEGRA, C. 2007. Historical Introduction. *In:* BERGAN, J. J. (ed.) *The Vein Book.* Amsterdam; Boston: Elsevier Academic Press., 2nd.

CARIO-TOUMANIANTZ, C., BOULARAN, C., EACUTE, DRIC, SCHURGERS, L. J., HEYMANN, M.-F., CCEDIL, OISE, LE CUNFF, M., GER, J., LOIRAND, G. & PACAUD, P. 2007. Identification of Differentially Expressed Genes in Human Varicose Veins: Involvement of Matrix Gla Protein in Extracellular Matrix Remodeling. *Journal of Vascular Research,* 44**,** 444-459

CARPENTIER, P. H., MARICQ, H. R., BIRO, C., PONÇOT-MAKINEN, C. O. & FRANCO, A. 2004. Prevalence, risk factors, and clinical patterns of chronic venous disorders of lower limbs: a population-based study in France. *Journal of Vascular Surgery,* 40**,** 650–659.

CHERRY, G. & WILSON, J. 1999. The treatment of ambulatory venous ulcer patients with warming therapy. *Ostomy/wound management,* 45**,** 65.

CHOUCAIR, M. & PHILLIPS, T. 1998. Compression therapy. *Dermatologic Surgery,* 24**,** 141-148.

CHRISTOPOULOS, D., NICOLAIDES, A., SZENDRO, G., IRVINE, A., BULL, M. & EASTCOTT, H. 1987. Air-plethysmography and the effect of elastic compression on venous hemodynamics of the leg. *Journal of vascular surgery: official publication, the Society for Vascular Surgery [and] International Society for Cardiovascular Surgery, North American Chapter,* 5**,** 148.

COLLIER, M. 1999. Brevet tx: anti-embolism stockings for prevention and treatment of DVT. *British journal of nursing (Mark Allen Publishing),* 8**,** 44.

COMITÉ EUROPÉEN DE NORMALISATION, A. E. P. M. C. H. 2001. ENV 12718. Brussels: Comité Européen de Normalisation.

DIX, F., BROOKE, R. & MCCOLLUM, C. 2003. Venous Disease is Associated with an Impaired Range of Ankle Movement* 1. *European journal of vascular and endovascular surgery,* 25**,** 556-561.

DOHERTY, D., MORGAN, P. & MOFFATT, C. 2006. Role of hosiery in lower limb lymphoedema. *Lymphoedema Framework. Template for Practice: compression hosiery in lymphoedema. London: MEP Ltd***,** 10-21.

DOOLEY, K. M. 2009. *Polymer rheology - basic equations and flow behavior* [Online]. Available: http://www.che.lsu.edu/faculty/dooley/rheo1.htm [Accessed].

EVANS, C., FOWKES, F., RUCKLEY, C. & LEE, A. 1999. Prevalence of varicose veins and chronic venous insufficiency in men and women in the general population: Edinburgh Vein Study. *British Medical Journal,* 53**,** 149.

FEMME. 2010. My Sclerotherapy Experience: What I did for Prettier Legs. Available from: http://postduty.com/].

FLOUR, M. 2008. Seminar Review: Creative Compression Treatment in Challenging Situations. *The International Journal of Lower Extremity Wounds,* 7**,** 68.

FÖLDI, M., FÖLDI, E. & KUBIK, S. 2006. Földi's Textbook of Lymphology: For Physicians and Lymphedema Therapists. Fischer Gustav Verlag GmbH & Co. KG.

GOLDMAN, M., BERGAN, J. & GUEX, J. 2001. *Sclerotherapy: treatment of varicose and telangiectatic leg veins*, Mosby.

HAFNER, H., PICHE, E. & JUNGER, M. 2001. The ratio of working pressure to resting pressure under compression stockings: Its significance for the improvement of venous perfusion in the legs. *PHLEBOLOGIE-STUTTGART-,* 30**,** 88-93.

HAKAN UNCU 2009. Following Varicose Vein Surgery, Graduated Compression Stockings Should Be Preferred Elastic Compression Bandages Or? *Journal of Medical Sciences,* 29.

HAYES, J., LEHMAN, C. & CASTONGUAY, P. 2002. Graduated compression stockings: updating practice, improving compliance. *Medsurg nursing: official journal of the Academy of Medical-Surgical Nurses,* 11**,** 163.

HEINEN, M., ACHTERBERG, T., REIMER, W. & KERKHOF, P. 2004. Venous leg ulcer patients: a review of the literature on lifestyle and pain related interventions. *Journal of Clinical Nursing,* 13**,** 355-366.

HEINEN, M., VAN DER VLEUTEN, C., DE ROOIJ, M., UDEN, C., EVERS, A. & VAN ACHTERBERG, T. 2007. Physical activity and adherence to compression therapy in patients with venous leg ulcers. *Archives of dermatology,* 143**,** 1283.

HERMANSON, J., TIPTON, J. & YORK, W. 2006. Therapeutic stocking. Google Patents.

HIGMAN, D. J., GREENHALGH, R. M. & POWELL, J. T. 1993. Smoking impairs endothelium-dependent relaxation of saphenous vein. *British Journal of Surgery,* 80**,** 1242-1245.

HOHLBAUM, G. 1989. *The medical compression stocking*, John Wiley & Sons Inc.

HORNER, J., LOWTH, L. & NICOLAIDES, A. 1980. A pressure profile for elastic stockings. *British Medical Journal,* 280**,** 818.

HU, J., CHUNG, S. & LI, Y. 2007a. Characterization about the shape memory behaviour of woven fabrics. *Transactions of the Institute of Measurement & Control,* 29**,** 301.

HU, J., JI, F. & WONG, Y. 2005. Dependency of the shape memory properties of a polyurethane upon thermomechanical cyclic conditions. *Polymer International,* 54**,** 600-605.

HU, J., ZHU, Y., LU, J., YEUNG, L. & YEUNG, K. Year. Uniqueness of shape memory fibers in comparison with existing man-made fibers. *In*, 2007b.

HU, J. M., H.; ZHU, Y.; LIU, Y.; LV, J.; JI, F.; LIU, B.; YEUNG, L.; SHEN, L.; HU, Y.; HAN, J.; LI,, W.; KENNEDY, J. F. O., P.; LIU, Y.; ZENG, W.; LUO, H.; CHEN, S.; LI, Y.; ZHUO, H.; ZHENG, & Y.; ZHANG, C. 2010. An overview of stimuli-responsive polymers for smart textile applications. *Carb.Polymer*

INGRAM, J. 2003. A review of thigh-length vs knee-length antiembolism stockings. *British journal of nursing,* 12**,** 845-851.

INTERNATIONAL, L. S. 2009. *Boarding* [Online]. Available: http://www.youleg.com/process.html [Accessed].

JOBST, C. 1951. SURGICAL STOCKING. Google Patents.

JOHNSON JR, G., KUPPER, C., FARRAR, D. & SWALLOW, R. 1982. Graded compression stockings: custom vs noncustom. *Archives of Surgery,* 117**,** 69.

L. K. CHAN, M. S. W., Z. DONG1, J.L. HU, AND S.P. CHUNG. Year. A new method for estimation of garment bagging. *In:* Polymer Processing Society 24th Annual Meeting, 2008 Salerno (Italy).

LAI, C. & LI-TSANG, C. 2009. Validation of the Pliance X System in measuring interface pressure generated by pressure garment. *Burns,* 35**,** 845-851.

LAWRENCE, D. & KAKKAR, V. 1980. Graduated, static, external compression of the lower limb: a physiological assessment. *British Journal of Surgery,* 67**,** 119-121.

LENDLEIN, A. 2001. Tailor-made intelligent polymers for biomedical applications. *Smart fibres, fabrics and clothing***,** 278.

LENDLEIN, A. & KELCH, S. 2002. Shape-memory polymers. *Angewandte Chemie International*

Edition, 41**,** 2034-2057.
LIU, C., QIN, H. & MATHER, P. 2007. Review of progress in shape-memory polymers. *Journal of Materials Chemistry,* 17**,** 1543-1558.
LIU, R. 2006. *Comfort and mechanical function of compression stockings.* Thesis, HONG KONG POLYTECHNIC UNIVERSITY.
LIU, R., KWOK, Y., LI, Y., LAO, T., ZHANG, X. & DAI, X. 2006. Objective evaluation of skin pressure distribution of graduated elastic compression stockings. *Dermatologic Surgery,* 31**,** 615-624.
LIU, X. 2008. Elasticity and Shape Memory Effect of Shape Memory Fabrics. *Textile Research Journal,* 78**,** 1048.
MACINTYRE, L., BAIRD, M. & WEEDALL, P. 2004. The study of pressure delivery for hypertrophic scar treatment. *International Journal of Clothing Science and Technology,* 16**,** 173-183.
MALHOTRA, S. L. 1972. An Epidemiological Study of Varicose Veins in Indian Railroad Workers from the South and North of India, with Special Reference to the Causation and Prevention of Varicose Veins. *Int. J. Epidemiol.,* 1**,** 177-183
MARIANI, F. 2004. *Consensus conference on Compression therapy* [Online]. Available: http://www.societaitalianaflebologia.it/banner/consensus.pdf [Accessed 2008].
MAYBERRY, J., MONETA, G., DEFRANG, R. & PORTER, J. 1991. The influence of elastic compression stockings on deep venous hemodynamics. *Journal of vascular surgery: official publication, the Society for Vascular Surgery [and] International Society for Cardiovascular Surgery, North American Chapter,* 13**,** 91.
MENG, Q., HU, J., ZHU, Y., LU, J. & LIU, B. 2009. Biological Evaluations of a Smart Shape Memory Fabric. *Textile Research Journal*.
MENG, Q., HU, J., ZHU, Y., LU, J. & LIU, Y. 2007. Morphology, phase separation, thermal and mechanical property differences of shape memory fibres prepared by different spinning methods. *Smart Materials and Structures,* 16**,** 1192.
MERRETT, N. & HANEL, K. 1993. Ischaemic complications of graduated compression stockings in the treatment of deep venous thrombosis. *Postgraduate Medical Journal,* 69**,** 232.
MOFFATT, C. 2008. Variability of pressure provided by sustained compression. *International Wound Journal,* 5**,** 259-265.
MOFFATT, C., KOMMALA, D., DOURDIN, N. & CHOE, Y. 2009. Venous leg ulcers: patient concordance with compression therapy and its impact on healing and prevention of recurrence. *International Wound Journal,* 6**,** 386-393.
MOFFATT, C. J. 2007. *Compression therapy in practice*, Wounds UK.
MONDAL, S. 2009. Recent developments in temperature responsive shape memory polymers. *Mini-Reviews in Organic Chemistry,* 6**,** 114-119.
MONDAL, S. & HU, J. 2007. Water vapor permeability of cotton fabrics coated with shape memory polyurethane. *Carbohydrate Polymers,* 67**,** 282-287.
MOORE, Z. & COWMAN, S. 2005. The need for EU standards in wound care: an Irish survey. *Burns,* 20**,** 26.5-40.8.
MORRIS, R. & WOODCOCK, J. 2004. Evidence-based compression: prevention of stasis and deep vein thrombosis. *Annals of surgery,* 239**,** 162.
MOSTI, G. & PARTSCH, H. 2010. Inelastic bandages maintain their hemodynamic effectiveness over time despite significant pressure loss. *Journal of Vascular Surgery*.

NAOUM, J. J., HUNTER, G. C., WOODSIDE, K. J. & CHEN, C. 2007. Current Advances in the Pathogenesis of Varicose Veins. *Journal of Surgical Research,* 141**,** 311-316.

NELSON, E. A., HARPER, D. R., PRESCOTT, R. J., GIBSON, B., BROWN, D. & RUCKLEY, C. V. 2006. Prevention of recurrence of venous ulceration: Randomized controlled trial of class 2 and class 3 elastic compression. *Journal of Vascular Surgery,* 44**,** 803-808.

NEUMANN, H. 1998. Compression therapy with medical elastic stockings for venous diseases. *Dermatologic Surgery,* 24**,** 765-770.

NHLB. 2009. *Aim for a healthy weight* [Online]. Bethesda: National Heart, Lung, and Blood Institute. Available: http://www.nhlbi.nih.gov/guidelines/obesity/bmi_tbl.htm [Accessed 2009].

NICOLAIDES, A. N. 2000. Investigation of chronic venous insufficiency: a consensus statement. *Circulation,* 102**,** 123-163.

O'MEARA, S., TIERNEY, J., CULLUM, N., BLAND, J., FRANKS, P., MOLE, T. & SCRIVEN, M. 2009. Four layer bandage compared with short stretch bandage for venous leg ulcers: systematic review and meta-analysis of randomised controlled trials with data from individual patients. *British Medical Journal,* 338**,** b1344.

PALFREYMAN, S. & MICHAELS, J. 2009. A systematic review of compression hosiery for uncomplicated varicose veins. *Phlebology,* 24**,** 13.

PARTSCH, B., MAYER, W. & PARTSCH, H. 1992. Improvement of ambulatory venous hypertension by narrowing of the femoral vein in congenital absence of venous valves. *PHLEBOLOGY-LONDON-,* 7**,** 101-101.

PARTSCH, H. 2004. Evidence based compression therapy. *Vasa-Zeitschrift fur Gefasskrankheiten-Supplementum,* 63.

PARTSCH, H., CLARK, M., BASSEZ, S., BENIGNI, J., BECKER, F., BLAZEK, V., CAPRINI, J., CORNU-THÉNARD, A., HAFNER, J. & FLOUR, M. 2006a. Measurement of lower leg compression in vivo: recommendations for the performance of measurements of interface pressure and stiffness. *Dermatologic Surgery,* 32**,** 224-233.

PARTSCH, H. & MOSTI, G. 2008. Thigh compression. *Phlebology,* 23**,** 252.

PARTSCH, H., PARTSCH, B. & BRAUN, W. 2006b. Interface pressure and stiffness of ready made compression stockings: comparison of in vivo and in vitro measurements. *Journal of Vascular Surgery,* 44**,** 809-814.

PARTSCH, H., RABE, E. & STEMMER, R. 2000. *Compression Therapy of the extremities*, Éd. phlébologiques françaises.

PHILIP D, C. S. 2006. Physiology of the Veins and Lymphatics. *In:* NICOS, L. & GERARD, S. (eds.) *Venous and Lymphatic diseases*

New York: Taylor and Francis Group.

PHILLIPS, T., STANTON, B., PROVAN, A. & LEW, R. 1994. A study of the impact of leg ulcers on quality of life: Financial, social, and psychologic implications*. *Journal of the American Academy of Dermatology,* 31**,** 49–53.

PHILLIPS, T. J. & DOVER, J. S. 1991. Leg ulcers. *Journal of the American Academy of Dermatology,* 25**,** 965–987.

POLLACK, A. & WOOD, E. 1949. Venous pressure in the saphenous vein at the ankle in man during exercise and changes in posture. *Journal of Applied Physiology,* 1**,** 649.

RAJU, S., HOLLIS, K. & NEGLEN, P. 2007. Use of compression stockings in chronic venous disease:

patient compliance and efficacy. *Annals of vascular surgery,* 21**,** 790-795.
RAMALET 2002. compression therapy. *Dermatologic Surgery,* 28**,** 6-10.
ROALDSEN, K. 2009. *Factors Influencing Physical Activity in Patients with Venous Leg Ulcer.* Ph.D, Karolinska Institutet.
ROBERT MAGGISANO & HARRISON, A. W. 2004. The venous system. *The Workplace Safety and Insurance Appeals Tribunal.*
ROBINSON, C. & SANTILLI, S. 1998. Warm-Up Active Wound Therapy: A novel approach to the management of chronic venous stasis ulcers* 1. *Journal of Vascular Nursing,* 16**,** 38-42.
ROE, B., CULLUM, N. & HAMER, C. 1995. Leg Ulcers: Nursing Management: a Research-Based Guide. Scutari Press Harrow.
ROOKE, T. 2007. *Vascular Medicine and Endovascular Interventions*, Wiley-Blackwell.
RUCKLEY, C. 1997. Socioeconomic impact of chronic venous insufficiency and leg ulcers. *Angiology,* 48**,** 67.
SANSILVESTRI-MOREL, P., RUPIN, A., BADIER-COMMANDER, C., EACUTE, CILE, KERN, P., FABIANI, J.-N., EUML, VERBEUREN, T. J. & VANHOUTTE, P. M. 2001. Imbalance in the Synthesis of Collagen Type I and Collagen Type III in Smooth Muscle Cells Derived from Human Varicose Veins. *Journal of Vascular Research,* 38**,** 560-568
SAWHNEY, A., FOLK, C. & ROBERT, K. 1990. System for producing core/wrap yarn. Google Patents.
SCURR, J. H., COLERIDGE-SMITH, P. & CUTTING, P. 1985. Varicose veins: optimum compression following sclerotherapy. *Ann R Coll Surg Engl,* 67**,** 109-11.
SESHADRI, R. 2008. Compliance with Compression Stockings in Chronic Venous Disease. *prevention of postthrombotic syndrome,* 15**,** 103-106.
SHERMAN, M. 1985. Thrombophylaxis with Antiembolisin Stockings. *Orthopaedic Nursing,* 4**,** 33.
SHOULER, P. & RUNCHMAN, P. 1989. Varicose veins: optimum compression after surgery and sclerotherapy. *Annals of The Royal College of Surgeons of England,* 71**,** 402.
SIGEL, B., EDELSTEIN, A., FELIX JR, W. & MEMHARDT, C. 1973. Compression of the deep venous system of the lower leg during inactive recumbency. *Archives of Surgery,* 106**,** 38.
SIMMONS, J. 1968. MAN S SUPPORT SOCK AND METHOD OF FORMING SAME. Google Patents.
SOCHART, D. & HARDINGE, K. 1999. The relationship of foot and ankle movements to venous return in the lower limb. *Journal of Bone & Joint Surgery, British Volume,* 81**,** 700.
SPARROW, R., HARDY, J. & FENTEM, P. 1995. Effect of ‘antiembolism’compression hosiery on leg blood volume. *British Journal of Surgery,* 82**,** 53-59.
STANDARDS, B. 1985. British standards specification for graduated compression hosiery (BS 6612.). London: British Standards Institution.
STYF, J. 2008. The venous pump of the human foot. *Clinical Physiology and Functional Imaging,* 10**,** 77-84.
STYLIOS, G. K. & WAN, T. 2007. Shape memory training for smart fabrics. *Transactions of the Institute of Measurement and Control,* 29**,** 321.
SU, C., MAA, M. & YANG, H. 2004. Structure and performance of elastic core-spun yarn. *Textile Research Journal,* 74**,** 607.
SUMNER, D. S. 1981. Venous dynamics-varicosities. *Clinical Obstetrics and Gynecology,* 24**,** 743.
TAN, J., LOCKHART, S., SMITH, A. & BURNAND, K. 2006. Venous haemodynamic effects of anti-thromboembolism stockings. *Phlebology,* 21**,** 74.

TSUJISAKA, T., AZUMA, Y., MATSUMOTO, Y. & MOROOKA, H. 2004. Comfort pressure of the top part of men's socks. *Textile Research Journal,* 74**,** 598.

VALENCIA, I. C., FALABELLA, A., KIRSNER, R. S. & EAGLSTEIN, W. H. 2001. Chronic venous insufficiency and venous leg ulceration. *Journal of the American Academy of Dermatology,* 44**,** 401–424.

VAN GEEST, A. J., VERAART, J. C., NELEMANS, P. & NEUMANN, H. A. 2000. The effect of medical elastic compression stockings with different slope values on edema. Measurements underneath three different types of stockings. *Dermatologic Surgery: Official Publication for American Society for Dermatologic Surgery [et Al,* 26**,** 244-247

VAN HECKE, A., GRYPDONCK, M. & DEFLOOR, T. 2009. A review of why patients with leg ulcers do not adhere to treatment. *Journal of Clinical Nursing,* 18**,** 337-349.

VERAART, J., PRONK, G. & NEUMANN, H. 2008. Pressure differences of elastic compression stockings at the ankle region. *Dermatologic Surgery,* 23**,** 935-939.

WEISS, R. & DUFFY, D. 1999. Clinical benefits of lightweight compression: reduction of venous-related symptoms by ready-to-wear lightweight gradient compression hosiery. *Dermatologic Surgery,* 25**,** 701-704.

WERTHEIM D, H. G., MELHUISH JM,WILLIAMS RJ, HARDING KG,WHISTON RJ 1999. In vivo pressure profiles of thigh-length graduated compression stockings. *British Journal of Surgery.* John Wiley & Sons.

WERTHEIM, D., MELHUISH, J., WILLIAMS, R. & HARDING, K. 1999. Measurement of forces associated with compression therapy. *Medical and Biological Engineering and Computing,* 37**,** 31-34.

WILDIN, C., HUI, A., ESLER, C. & GREGG, P. 1998. In vivo pressure profiles of thigh-length graduated compression stockings. *British Journal of Surgery,* 85**,** 1228-1231.

WILLENBERG, T., LUN, B., AMSLER, F. & BAUMGARTNER, I. 2010. Ease of Application of Medical Compression-stocking Systems for the Treatment of Venous Ulcers. *European Journal of Vascular and Endovascular Surgery*.

WINSLOW, E. & BROSZ, D. 2008. Graduated compression stockings in hospitalized postoperative patients: correctness of usage and size. *AJN The American Journal of Nursing,* 108**,** 40.