A Study Of Patient And Nurse Factors Influencing Sub-Bandage Pressure

E Andrea Nelson

2001

A thesis submitted in accordance with the regulations of the University of Strathclyde governing the award of Doctor of Philosophy in Bioengineering

Acknowledgements

This research was supervised by Professor J C Barbenel, and to him, many thanks for his tenacity. I am extremely grateful to all the members of the Lothian and Forth Valley Leg Ulcer Study; Dorothy Brown, Mike Callam, Binnie Dale, Barbara Gibson, Douglas Harper, Elaine Hill, Robin Prescott, Vaughan Ruckley and Gerry Young. Thank you for sharing your expertise in leg ulcer research and management. I would also like to acknowledge funding received from the Department of Education for Northern Ireland, the Smith and Nephew Foundation and the NHS Executive (North West).

Thanks also to Siv Sockalingham for his collaboration on the measurement of ambulatory sub-bandage pressure.

Finally, I am indebted to all the nurses and patients who have contributed to this work by giving freely of their time, experience, knowledge and wisdom. Without them this research would not have been possible. **This thesis is dedicated to you all.**

Table of Contents

Abstract

This thesis describes an investigation of sub-bandage pressure (SBP). It examines the characteristics of the Strathclyde Pressure Monitor, which incorporates a fluid-filled sensor and a piezo-electric transducer. The sensor volume was minimised, the variation in output with change in sensor position eliminated, and the time response of the system reduced.

The impact of changes in foot position on SBP was investigated using two compression bandages. The pressure at a site depended upon the interaction between the type of bandage (elastomeric or non-elastomeric) and the position of the foot.

The impact of changes in subject posture on SBP was studied. The SBP increased as the subject stood, from sitting. There was no consistent pattern in pressure change as the subject sat up from lying supine.

The sub-bandage pressures of patients with active venous ulcers were monitored at two sites on the leg for seven days. There was a decrease in SBP upon standing, in contrast to normal volunteer studies.

Three series of experiments investigated the impact of training in bandaging on SBP. A pilot study of 18 nurses assessed SBP on normal legs before and after training, as well as using a bandage printed with an extension guide. After training, significantly more nurses achieved acceptable pressure profiles. An additional 48 nurses were trained using three bandages (two elastomeric and one non-elastomeric). Training improved bandaging technique but more nurses applied satisfactory bandages with the elastomeric bandages than with the non-elastomeric bandage.

In the final investigation, 224 community nurses were trained applying a two-layer and a 4-layer compression system. After training, a higher proportion of nurses applied the 4-layer in a satisfactory manner.

This research highlights the different response to posture between patients and normal subjects, and the variable impact of training on nurses depending on the bandage system.

Glossary of Terms

ABPI	Ankle Brachial Pressure Index. This is the a ratio whose value is equal to the systolic pressure at the ankle divided by the systolic brachial pressure. In people with no significant arterial disease in the legs, this ratio is approximately 1.0. Values less than 1.0 indicate that there is a lower systolic blood pressure in the legs than the arms. Values lower than 0.8 indicate significant arterial insufficiency.
Allocation concealment	A method of assigning people entering a trial to the different treatment groups so that the person who is recruiting the person to the trial is not able to predict, or is not aware of the group to which the person will be allocated. Examples include remote telephone randomisation services, or opening sealed, sequentially numbered, opaque envelopes to reveal the treatment group allocation.
Doppler ultrasound	The use of the Doppler effect and ultrasound waves to record / measure blood flow. The outgoing wave of ultrasound is transmitted towards red blood cells in the arteries. A reflected wave of ultrasound can be compared with the original wave in order to ascertain how quickly the red blood cells are moving. The Doppler effect describes the change in frequency in waves between an object approaching the receiver and retreating from the receiver.
Dorsiflexion	Moving the foot so that the dorsal surface (top) of the foot is flexed. This is achieved by pointing ones toes towards the nose.
DVT	Deep vein thrombosis (DVT) refers to the formation of a thrombus (blood clot) within a deep vein, commonly in the thigh or calf. The blood clot can either partially or completely block the flow of blood in the vein.

Glossary contd.

Hysteresis	Hysteresis represents the history dependence of physical systems. When the output at a constant input depends on whether the input was increasing or decreasing, then the system is said to exhibit hysteresis.
NNT	Number needed to treat (NNT) is the number of patients who need to be treated to give one additional outcome of interest. For example, if the NNT in a trial looking at giving up smoking by using nicotine replacement therapy = 14, you need to treat 14 people for one additional person to stop smoking.
Plantar eversion	Moving the foot so that the plantar surface (sole) of the foot is turned out, away from the mid-line of the body.
Plantar inversion	Moving the foot so that the plantar surface (sole) of the foot is turned in, towards the mid-line of the body.
Plantar flexion	Moving the foot so that the plantar surface (bottom) of the foot is flexed. This is achieved by pointing the toes downwards, or away from the body.
Random effects model	When combining results from various trials in a meta-analysis, one may consider that there is a population of different effect sizes, not a single effect size. In this case, there is heterogeneity between the studies and a random-effects model should be used. This is a more conservative estimate than a fixed-effects model of meta-analysis.
Relative Risk	The risk (or probability) of an event happening in the treatment or exposed group, divided by the risk of the event happening in the control, on unexposed group.

Glossary contd.

Therapeutic ultrasound	The application of ultrasound to treat a wound, joint, or soft tissues. The ultrasound is usually transmitted from the probe to the skin via a water soluble gel.
Type 1 error	When one concludes from a statistical test that there is a significant difference, i.e. one rejects the null hypothesis, when in reality, there is no real difference and the finding is due to chance.
Type 2 error	In a situation where there is a real difference between two values but the statistical test leads one to conclude that there is no statistically significant difference, that is, the null hypothesis is wrongly accepted.

Introduction

It is estimated that around 1% of the adult population will have a leg ulcer at some time (Callam 1992). The majority of these are due to venous insufficiency and are described as venous, varicose or stasis ulcers (Nelzen et al 1991). Venous ulcers represent a considerable burden to people with ulcers and to the health service (Roe et al 1995, Bosanquet 1992).

The single most important aspect of treatment of venous leg ulcers is the application of compression (Alexander House Group 1992). In the majority of United Kingdom settings, this is achieved by nurses applying compression bandages (NHSE 1992). In other health care systems doctors, carers and patients themselves apply compression bandages or compression hosiery.

The aim of applying compression bandages is to produce sufficient pressure to help venous return without compromising arterial inflow. Low levels of pressure would allow the bandages to fall down and excessive pressure may produce pressure sores. Assessments of performance of compression systems are used to categorise bandage systems according to their ability to apply and sustain compression on a limb, thus allowing practitioners to choose bandages according to their functional requirements. The evaluation of in-vivo bandage performance characteristics requires accurate measurement of sub-bandage pressure.

Aims of this research

1. To explore the utility of the Strathclyde Pressure Monitor for measuring interface pressure. In particular - how would the height dependence, sensor thickness, or transmission fluid influence the calibration coefficient, accuracy and time response (chapter 3).

2. To describe the changes in sub-bandage pressure during foot movement and posture changes. In particular to determine whether pressure changes varied with measurement site and bandage characteristics (chapters 4 and 5).
3. To study the impact of training and feedback from a pressure monitor on nurse bandaging technique, in particular the pressure applied at the ankle and calf, with single layer and multi-layer bandages (chapter 6).

Structure of the thesis

The initial chapters of this thesis review the literature on venous ulcers; their epidemiology, aetiology and management, (chapter 1) and pressure measurement. (Chapter 2) The thesis then reports on four related projects:

1. an investigation of the performance of the Strathclyde Pressure Monitor (SPM) – chapter 3
2. the effect on sub-bandage pressures of changes in foot position, with two different bandages – chapter 4
3. the effect on sub-bandage pressures of posture changes with two different bandages - chapter 5
4. the effect of training and feedback on sub-bandage pressure profile with single layer and multi-layered compression regimens – chapter 6.

The Strathclyde Pressure Monitor had been developed by Barbenel and Sockalingham (1990) in order to measure sub-bandage pressures over 7 days. The first set of experiments in the thesis evaluates the impact of the sensor volume on calibration as this had not previously been established. It also describes the problem of the variation in sensor output with vertical height as well as with incident pressure, as well as its elimination.

The thesis describes the response of the Strathclyde Pressure Monitor to a step change in applied pressure, and proceeds to minimise the time taken for the sensor to respond to a change in applied pressure. These experiments also quantified the precision of the pressure measurement system.

The second series of experiments grew out of the observation that clinicians treating venous leg ulcers ask patients to flex their ankle regularly to aid ulcer healing. It reports, for the first time, the changes in pressure recorded beneath compression bandages, worn by normal volunteers, during active changes in foot position. Different bandages were used in order to determine whether there was a variation in response to exercise with bandage type.

The effect of alterations in posture on the pressure recorded beneath compression bandages, worn by normal volunteers, is investigated in the third experimental section. Different types of bandages, with and without elastic fibres, were used in order to determine whether any changes were related to the bandage characteristics. The final part of this section describes, for the first time, the change in sub-bandage pressure with different postures in *patients* being treated with compression bandages for venous leg ulcers.

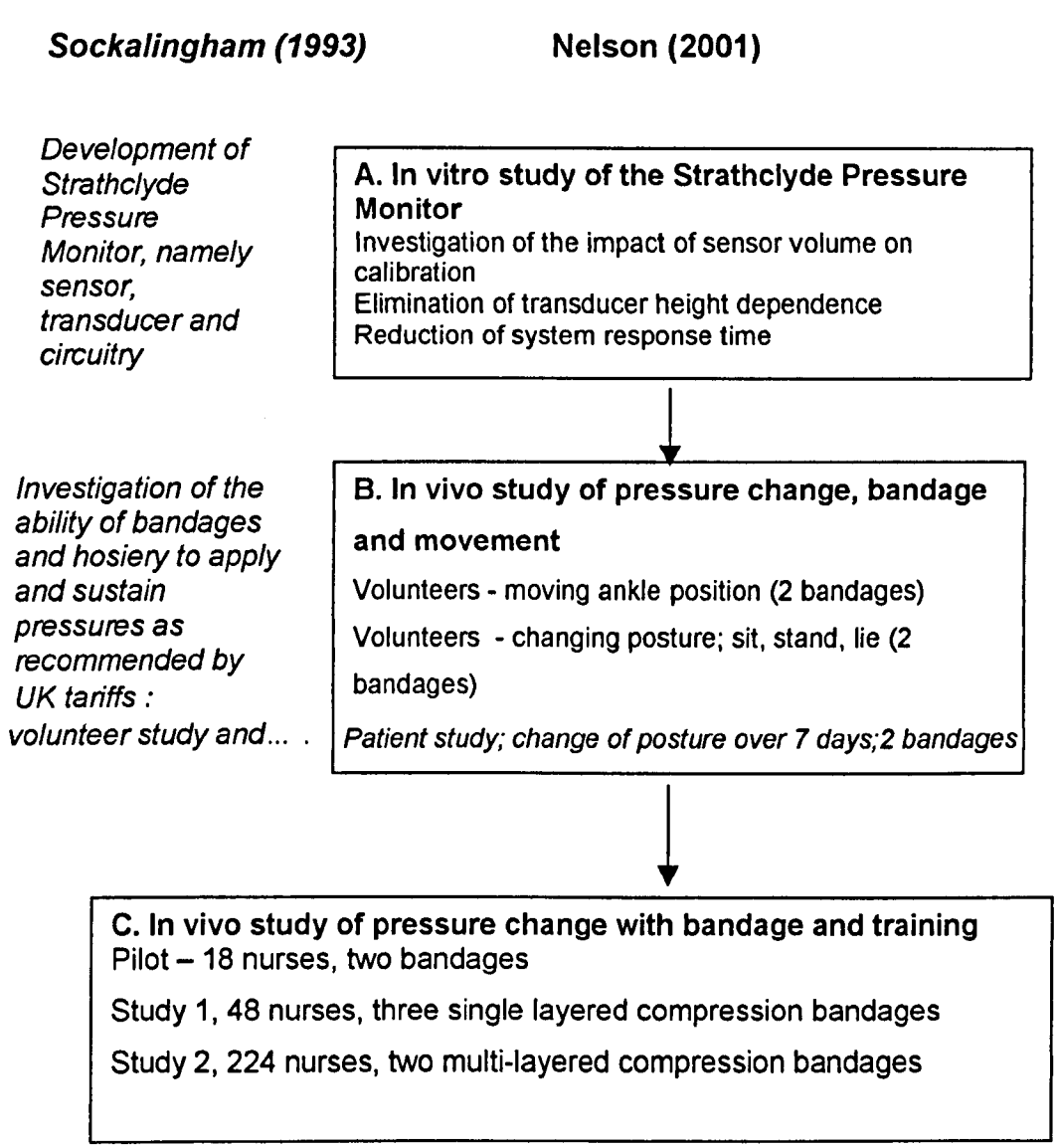
The fourth set of experiments investigates, for the first time, the impact of training on the ability of nurses to apply compression bandages by recording the sub-bandage pressures produced. Different types of bandages were used in order to investigate whether any improvement in technique is related to bandage characteristics. A pilot study is the predecessor of two large before and after studies examining the changes in bandaging technique with single layer (first study) and multi-layer bandages (second study). In addition, the studies investigate the interaction between bandage type and improvement in bandaging technique after training.

The programme of work developed over time, each section was planned after considering the findings from the previous experiments. The research took place over three phases, reflecting the setting in which the researcher was employed: initially the in vitro investigation of the pressure transducer (while based at the Bioengineering Unit), the measurement of

sub-bandage pressure and the changes in pressure with posture (while based at the Lothian and Forth Valley Leg Ulcer Study, Royal Infirmary Edinburgh) and the impact of training on the ability of nurses to apply compression bandages (while based both at the Lothian and Forth Valley Leg Ulcer Study, Royal Infirmary Edinburgh, and the University of Liverpool).

Siv Sockalingham developed the prototype pressure monitor and circuitry as well as a sensor to record patient posture. He used these to investigate the ability of a range of bandages to both apply and sustain the pressures specified in the UK Tariff. We collaborated on the measurement of sub-bandage pressure in patients being treated with compression bandages for venous leg ulcers. The remaining parts of the research presented within this thesis were undertaken solely by the author.

Figure 0.1 outlines the research undertaken and shows the relationship between the Sockalingham research and the material presented in this thesis.



Key: Material in Italics appeared in Sockalingham (1993)

Figure 0.1 Outline of Research and Relationship With Previous Investigations

1. Venous Ulceration: Epidemiology, Aetiology and Management

Leg ulceration is a common, recurrent, disabling condition. Leg ulcers mainly affect older people and are largely managed in a primary health care setting. It has been identified as a prevalent condition, which is expensive to manage and where there is a wide variation in care (Cullum and Roe 1995). In industrialised countries, leg ulcers are usually caused by venous disease, arterial disease and diabetes (Callam 1992). Venous ulcers, also known as varicose ulcers, stasis ulcers or venous leg ulcers, are the largest group and will be the topic of this thesis.

Compression accelerates the healing of venous leg ulcers but there are wide variations in the use of compression (Cullum and Last 1993). Increased use of effective compression regimens for venous ulceration is likely to improve healing rates (Fletcher et al 1997).

In the United Kingdom, patients with leg ulcers are largely managed by nurses (Callam et al 1985). It is stated that the single most important element of treatment of venous ulcers is the application of compression bandages (Alexander House Group 1992, Fletcher et al 1997). Previous work in this area has considered the influence of bandage characteristic on compression; this thesis describes the influence of bandage characteristics, posture and movement of the person wearing the bandage, *and* nurse bandaging technique on sub-bandage pressure profile.

1.1. Definitions

A leg ulcer can be defined as a non-healing wound on the leg. Leg ulcers are usually prefixed with a qualifying label that indicates a 'diagnosis' .The diagnosis does not refer to the injury that may have originally caused the wound but rather the pathology that is preventing it from healing. A wound resulting from trauma to the leg is not described as an

ulcer until it has failed to heal. Some definitions of 'ulceration' do not impose a qualifying period while others specify that the ulcer must be present for at least 6 weeks (Dale et al 1983). Callam (1992) notes that some, but not all investigators include ulcers confined to the foot.

Venous leg ulcers are due to venous incompetence and/or obstruction. In clinical practice, it may be difficult to establish the presence of venous pathology, and although some investigators have included screening for functional or anatomical signs of venous disease in their assessment, this is not widespread. Some patients with venous disease have ulcers due to concurrent conditions, e.g. arterial insufficiency, and these are described as mixed aetiology ulcers.

1.2. History of Venous Ulceration

1.2.1. Epidemiology

Loudon (1981) describes the prevalence and aetiology of leg ulcers in the eighteenth and early nineteenth centuries. Leg ulceration was more common then than now and occurred in much younger people, with most cases occurring in the 20-40 year old group. The burden on the voluntary hospitals and dispensaries was considerable; at Bristol, in 1800, 19% of surgical inpatient admissions and 42% of outpatients were people with leg ulcers (Loudon 1981).

The causes of leg ulcers in ancient times may have included a higher proportion of infection, trauma and malnutrition, e.g. scurvy.

1.2.2. Historical theories of ulcer aetiology

When an ulcer occurred there was a perception that it allowed toxic agents to escape, possibly due to the smell of the exudate. These toxic agents - or humours – were thought to harm the patient if they were not allowed to escape and therefore the emphasis was on keeping an ulcer open rather than healing it. It was believed that if the ulcer healed, then the patient would die.

Avicenna, in AD 900, recommended reopening an ulcer if it did heal (Underwood 1783). By 1306, however, Henri de Mondeville proposed that if a compression bandage healed an ulcer it was because it had expelled all the bad humours (de Mondeville 1893).

There are anecdotal reports of patients today who still believe that they will die if their ulcer should heal. This may be due to reports that a patient dies soon after their ulcer healed. This may happen if a long-standing ulcer healed after a patient was confined to bed due to a serious concurrent illness and died soon after. Bed rest may have helped heal the ulcer but it may be interpreted that the ulcer healing led to death rather than the fact that a severe illness led to death, but the treatment, bed rest, assisted the healing of the ulcer (*post hoc, ergo proctor hoc*).

1.2.3. Leg ulcer treatment pre - 1980

The treatment of leg wounds has been documented for at least 3500 years. Ancient texts refer to splints of bark and cloth steeped in resins being applied to the legs in order to heal wounds and fractures (Browse et al 1988). Hippocrates discussed effective and complex techniques of bandaging all parts of the body for the purpose of splinting fractures, stopping haemorrhaging and 'forcing humours out of wounds' (Majno 1975). He appeared to have shared this enthusiasm for bandaging with his students; he had to remind them that they should not bandage simply to show off their skill (Adams 1948, Phillips 1987). Hippocrates advised those with ulcers not to stand and stated that ulcers must only be wetted with wine. Water sources were rarely clean and so wine was probably a convenient cleansing fluid.

The Sushruta Samhita described the practice of medicine in India, in 200 BC. Necrotic tissue in wounds was debrided with maggots and they were dressed with leaves and bandaged with a Chinese cloth (Browse et al 1988). Debridement with maggots (larval therapy) has been enjoying a renaissance although modern proponents use sterile larvae (Thomas et al 1996).

Ambroise Paré cured the ulcer of his captor in 1553, by using bandaging (Paré 1649). He described the method of application that remains almost unchanged today,

'roule the leg beginning at the foote and finishing at the knee'.

One hundred years later, Richard Wiseman invented a lace up leather stocking for the treatment of a 'varicose ulcer'. He described how he preferred the lace up stocking, as this was a more reliable method of applying compression than with a roller bandage;

> *'...I ordered an laced Stocking to be put on, for that I could not with a Rowler make such a Compression to near the Ancle as I would, without causing a swelling in his foot.'*
>
> (Wiseman 1676).

Little has changed in the choice and application of compression: the method of applying a bandage is unchanged and the debate regarding the preference for bandages or stockings continues.

The extraction and processing of rubber in the late 19th century led to changes in the manufacture of both bandages and compression stockings. 'Elastomeric' bandages and stockings, containing rubber, could be made. These applied compression on the leg for longer periods (Sockalingham et al 1990). Unfortunately, they were bulky garments and deteriorated with washing.

The incorporation of elastomers in bandages means that they can exert and maintain high pressures for up to a week. Synthetic elastomers, e.g. Lycra (Elastane), do not deteriorate with washing at moderate temperatures (around 40°C) and they can be washed repeatedly. Some bandages used twisted cotton and/or wool fibres to provide the tension rather than rubber. These do not maintain their tension and need to be reapplied frequently, e.g. Elastocrêpe (Smith and Nephew, UK)(Raj et al 1980).

There is, however, debate about the relative merits of elastomeric and non-elastomeric bandages. Partsch (1984) states that non-elastomeric bandages are suitable for leg ulcer *treatment*, while elastomeric compression is appropriate for *prevention* of recurrence. This, however, is not supported by a systematic review of effectiveness of bandages (Fletcher et al 1997).

1.3. Contemporary theories of venous ulceration

There are numerous theories to account for the failure of wounds on the leg to heal. The humoural theory stated that ulcers allowed the release of vile humours. This idea remained influential for thousands of years. Contemporary theories are built upon investigations of differential anatomy and physiology of patients with and without venous ulcers.

1.4. Anatomy of the vascular system

The arterial system divides repeatedly from arteries into arterioles and finally capillaries, which have walls one cell thick. Arteries convey blood from the heart to the arterioles, which divide to form capillaries. The permeability of the capillaries allows the diffusion of fluid and nutrients out of, and the flow of waste products back into, the vascular system. Waste products are returned directly to the vascular system via the capillaries, venules and veins, or, indirectly, via the lymphatic system which empties into the vascular system at the inferior vena cava and subclavian vein and finally into the right atrium.

The veins and lymph vessels collect blood from the capillaries and fluid from the tissues and return them to the heart. There are two networks of veins in the leg, the superficial system and the deep system; the long and short saphenous veins lie between the muscles and the skin (the superficial system) and the popliteal and femoral veins lie deep to the muscles (the deep venous system). The superficial veins collect blood from the skin and muscles, draining into the deep veins via communicating or perforating veins, which perforate the calf muscles. Blood flow through the venous system is assisted by the one-way valves that allow blood to flow towards the heart.

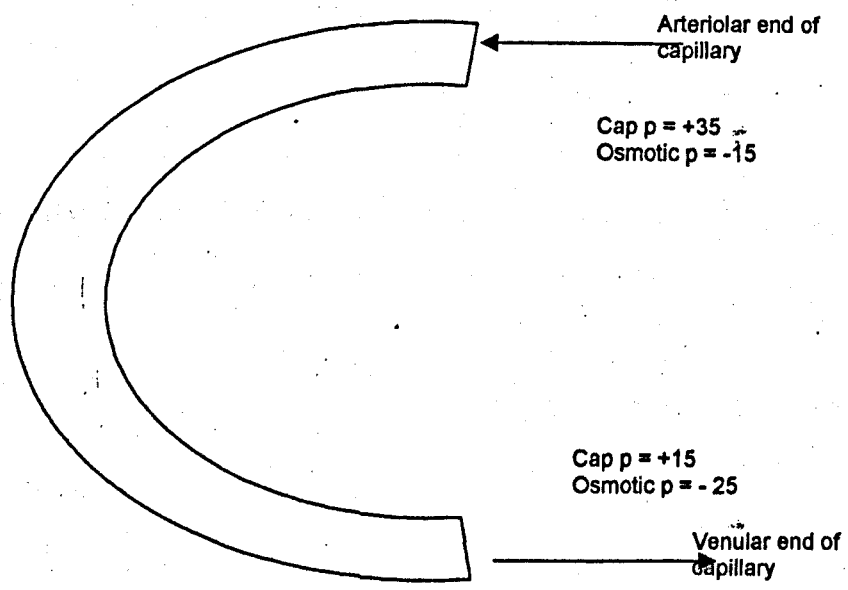
The pressure in the deep venous system varies according to the contraction of the calf muscle. At contraction, there is high interstitial pressure and blood is ejected towards the heart through the one-way valves. At relaxation, the pressure within the deep veins falls and they are refilled from the superficial system as the one-way valves only allow flow in this direction. The propulsion of blood from the foot to the heart therefore depends on the competence of the valves in the venous system, the deep veins remaining unobstructed and the ability of the calf muscle to contract.

Pressure within the superficial venous system is much lower than that in the arterial system. The pulsatility of the pressure and the mean pressure both fall along the length of the circulation. At the arterial end of a capillary, the pressure is around 35 mmHg (4.67 kPa) and at the venous end, it is around 15 mmHg (2.0 kPa).

These pressures help maintain a balance between fluid leaving the capillaries and re-absorption. Starling's equation describes the forces governing the fluid movement in the tissues (Caro et al 1978). Hydrostatic pressure in the blood vessels tends to force fluid out to the interstitial space through the capillary wall which is permeable to small molecules, i.e. water and solutes, but not proteins. The osmotic pressure within the capillary due to plasma proteins reduces fluid loss. The gradual increase in the osmotic pressure along the length of the capillary opposes filtration. This can be described as:

- Pf = net filtration force, the resultant force producing fluid loss from the capillaries
- Pc = capillary hydrostatic pressure, the force tending to drive fluid out of the capillary due to the 'head' of fluid from the heart to the capillary and the action of the heart muscle
- Pt = tissue hydrostatic pressure
- Oc = capillary osmotic pressure , the pressure due to the solution of proteins and ionic substances in the plasma
- Ot = tissue osmotic pressure

then $Pf = (Pc - Pt) - (Oc - Ot)$



	Capillary Pressure	Osmotic Pressure	Resultant Pressure
Normal artery	35 mmHg	15 mmHg	+20 mmHg
Normal vein	15 mmHg	15 mmHg	-10 mmHg

In chronic venous insufficiency, however, the capillary pressure at the venous end is increased, at around 40 mmHg, therefore:

	Capillary Pressure	Osmotic Pressure	Resultant Pressure
CVI artery	35 mmHg	15 mmHg	+20 mmHg
CVI vein	40 mmHg	15 mmHg	+15 mmHg

Therefore instead of a resultant pressure of –10 mmHg at the venous end of the capillaries (10 mmHg from the interstitial space towards the intra-vascular space) , the resultant pressure is 15 mmHg from the intra-vascular space

Figure 1.1 Starling's relationship describing the forces influencing blood flow between the vascular compartment and the interstitial space

Starling proposed that the interstitial space had a uniform hydrostatic pressure (Pt) and osmotic pressure (Ot). At the 'arterial' end of the capillary where the hydrostatic pressure (Pc) is high, filtration occurs as the resultant Pf is large. Conversely, at the 'venous' end of the capillary, the hydrostatic pressure (Pc) is lower and osmotic pressure (Oc) is higher, thus re-absorption of fluid takes place. This balance of filtration and re-absorption through the capillaries (and the lymph vessels) is dependent on the pressure within the venule, see figure 1.1.

The normal venous pressure is around 15 mmHg (2.0 kPa). Maintenance of this pressure depends on the forces that assist venous return, e.g. the action of skeletal muscles in the foot and the calf, and the variation in intra-thoracic pressure with respiration. Conditions that influence the capillary or osmotic pressure will change the fluid balance, for example;

- heart failure (when capillary pressure will be low)
- obesity or pregnancy (when intra-thoracic pressure will be elevated)
- low serum protein levels due to malnutrition (osmotic pressure will not limit filtration)
- incompetent venous valves (venous pressure is high)

In these circumstances, there is more filtration than re-absorption and thus the tissues become water logged and oedematous. In the healthy leg, the foot and calf pumps compress the superficial veins thus ejecting blood upwards. Upon relaxation, there is no reflux because of the one-way valves in the veins. When the valves are incompetent due to damage, inherited weakness or vein wall distortion, reflux occurs and the intra-vascular pressure increases. The resulting venous hypertension is associated with peri-capillary fibrin cuffs, and white cell trapping (see section 1.5), and these are thought to be the cause of venous ulceration.

1.5. Patho-physiological findings present in venous ulceration

Investigators have examined the skin surrounding venous ulcers and compared it to non-ulcerated skin to discern which patho-physiological findings are always associated with skin breakdown. It is hoped that by identifying the problem at the cellular level research can be directed at early identification of those legs that are at risk, improved therapy and prophylaxis. Fibrin cuffs, increased capillary permeability, 'tufting', white cell sequestration, reduced fibrinolysis, and disturbance in tissue pO_2 levels have all been found in association with venous ulceration.

1.5.1.1. Fibrin cuffs

Browse and Burnand (1982) reported that, when sectioned and stained, the skin surrounding venous ulcers revealed a pattern of peri-capillary fibrin cuffs. They asserted that venous hypertension led to increased intra-capillary pressure. The effect of this pressure on the capillaries was to increase the permeability of the capillary, allowing macromolecules to escape. Soluble fibrinogen was converted to fibrin in the extra cellular space and was deposited around the capillary. This 'fibrin cuff' was thought to be a barrier to transport of oxygen and waste products and therefore adjacent tissues became anoxic and died. These 'fibrin cuffs' may also be due to the reduced fibrinolytic activity in people with chronic venous insufficiency (Browse et al 1977).

In critiquing this theory, Scurr and Coleridge-Smith (1992) commented that there is no evidence that the fibrin cuffs act as a barrier to oxygen diffusion. Furthermore, the fibrin cuffs do not extend along the length of the capillary, making it unlikely that they alone could be responsible for extensive tissue damage. The presence of the fibrin cuffs cannot be confidently attributed to be the cause of venous ulceration; they may be a consequence of the disease process or may be unrelated to ulceration. In order to establish cause and effect one would require evidence of some or all of the following:

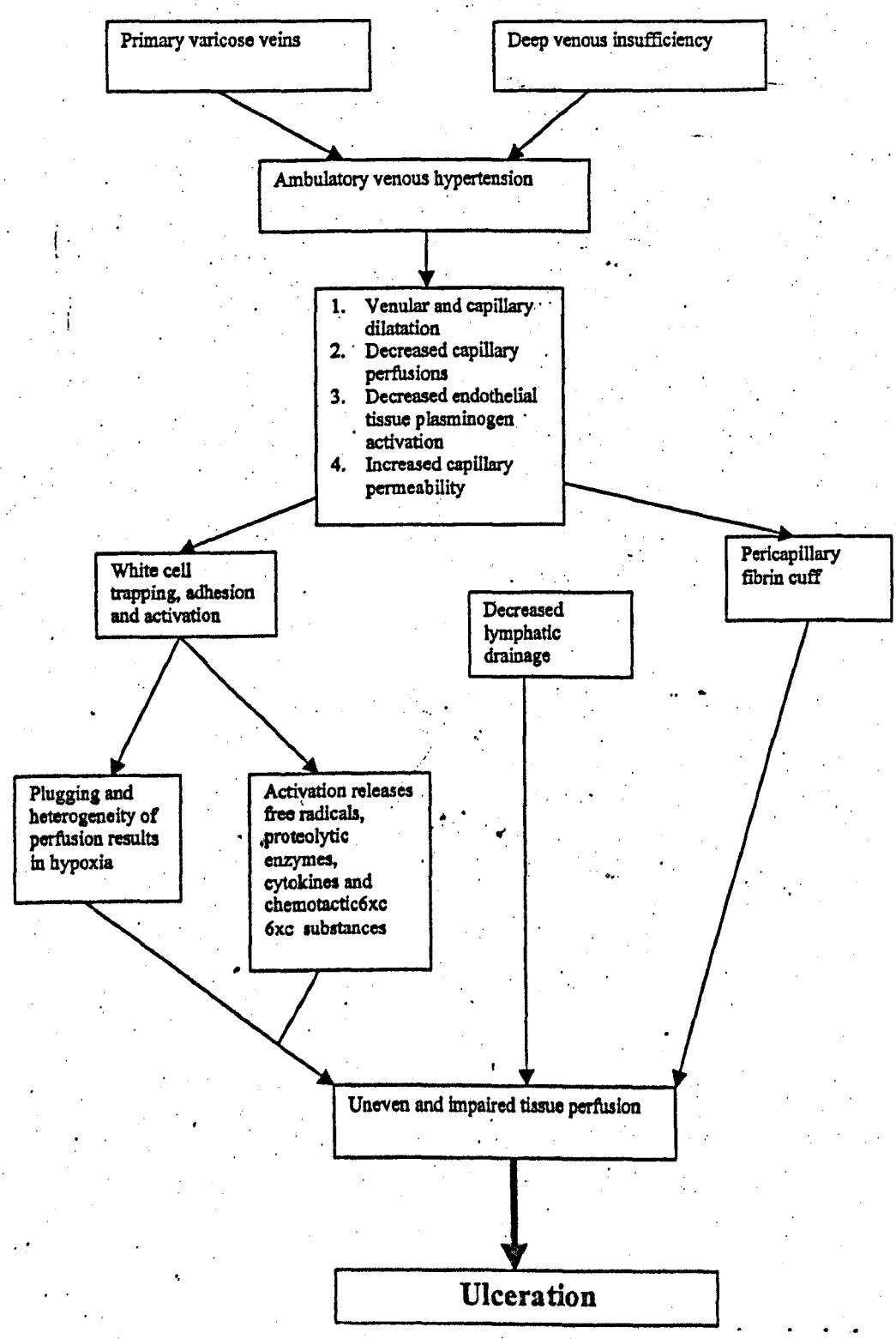


Figure 1.2. Integrated pathway of pathological and physiological changes leading to venous ulceration

- the formation of fibrin cuffs always preceded venous ulceration
- fibrin cuffs were a barrier to oxygen and waste products of respiration
- the presence of fibrin cuffs inevitably resulted in venous ulceration
- the removal of fibrin cuffs prevented venous ulceration, and
- that treatment which reduced the number of fibrin cuffs resulted in improved healing of venous ulcers.

1.5.1.2. White cell sequestration

Moyses et al (1987), Thomas et al (1988), and Coleridge-Smith et al (1988) measured white blood cell concentrations in blood flowing into and out of limbs. When the leg was dependent and very still for a time, there was a reduction in the numbers of white cells leaving the limb; the rest were 'trapped'. Coleridge-Smith et al (1988) described a 'White cell trapping' theory of venous ulceration. They proposed the following sequence of events:

1. Increased venous pressure leads to endothelial injury. Low blood flow allows white cells to accumulate at the capillary wall in the gaiter region of the leg. (Normally there is a high flow rate that acts to shear the white cells off the endothelium.)
2. The white cells block the capillary, preventing erythrocytes from passing, leading to ischaemia. The white cells become activated.
3. The activated white cells block capillaries and release proteolytic enzymes. These metabolites damage the endothelium, which increases its permeability thus allowing large molecules such as fibrinogen to accumulate in the subcutaneous tissues.
4. Both capillary occlusion and the release of chemical mediators lead to tissue breakdown.

Vowden and Vowden (1998) integrate a number of theories into a possible explanation for the development of chronic venous disease, Figure 1.2.

Figure 1.2 (After Vowden and Vowden) 1

The effectiveness of some drugs which scavenge the free radicals and alter white cell behaviour in treating ulceration, e.g. oxpentifylline or oxerutins, are used to support this theory (Colgan et al 1990, Wright et al 1991). There is also evidence that external compression increases leg pulsatile blood flow, which should lead to increased capillary flow velocities and decrease stasis and white cell marginalisation (Coleridge-Smith et al 1997). Compression has been shown to reverse the hypoxic state induced by high venous pressures (Gaylarde et al 1993) and to promote more efficient absorption of perimalleolar extracellular fluid (Nehler et al 1993).

Despite the lack of agreement on the pathology responsible for ulceration, all the investigators recognise the key role of increased venous pressure.

1.6. Epidemiology of Venous Ulceration

There have been several epidemiological studies of leg ulceration. These provide information on the prevalence of ulceration and on important etiological and demographic factors. Bobek et al (1961), distributed a questionnaire to the entire adult population of Klatov in Bohemia (adult population 16781, of whom 15060 were surveyed) to determine the point prevalence of venous disease. Persons with some indication of venous disease were examined and the prevalence of open or healed leg ulceration was 1%, and of venous disease, usually varicose veins, was 11.4%. The obvious limitation of this study is its questionnaire technique which may have led to under-reporting of ulceration but the 1% prevalence of active or healed ulcers is similar to that found in other surveys.

Widmer (1978) assessed the prevalence of problems of the lower limb amongst working men and women, aged 25-74, in Basle. Fifty six percent of men and 55% of women had some evidence of varicosity but only 1% had open or healed leg ulcers. The prevalence increased with age to 4.8% in women aged 65-74 years.

Cornwall et al (1986) identified 357 patients with leg ulcers in a survey in a district of London containing approximately 198,900 people. They assessed 100 randomly selected patients to confirm the diagnosis. The point prevalence of active leg ulceration was 1.8 per thousand.

The largest reported epidemiological study is the Lothian and Forth Valley Leg Ulcer Study (Callam et al 1985). Two regions of Scotland, incorporating a rural and an urban population of 1 million were surveyed. Patients suffering from leg ulceration were identified by asking hospitals, general practitioners, community nurses, and nursing homes to provide basic demographic information on anyone with a sore on the leg, anywhere below the knee, which was unhealed for 6 weeks. This identified 1477 patients, a 3-month period prevalence of 1477 / 1,000,000, or 1.48 per 1000. A non-random sample of 600 was assessed clinically. The median duration of ulceration was 9 months and 20% had had their ulcer for more than two years. Two thirds of the group had had recurrent ulceration. The remaining one third were suffering from their first ulcer but this had lasted up to 62 years. The pattern of ulceration, therefore, is of recurrence and quiescence. The population was mostly elderly but more than half reported that they were younger than 60 years old at first ulceration. This illustrates that ulceration may impact on the working population. The assessment included assessment of the systolic pressure of the arteries of the arm and foot using a hand-held Doppler ultrasound probe. A significant degree of impairment, as demonstrated by a difference between the systolic pressures in the arm and foot, was found in 21% of limbs.

Henry (1986) estimated the prevalence of varicose ulcers in Eire by adding a question to an EEC consumer survey administered by trained interviewers. From the 2012 questionnaires returned, the estimated prevalence of ulceration was 15.2 per 1000, and if the over 65 group is considered, the prevalence was 47 per 1000. This is the highest reported point prevalence in any survey, at almost seven times the next highest prevalence. There are a number of possible explanations, such as over reporting. Dale et al (1983) reported a false positive rate of 40% and a false negative rate of 5% in a postal questionnaire survey of leg ulceration in Stockbridge, in central Edinburgh. This means that a postal survey may conclude that the prevalence is around 35% higher than is truly the case. Respondents may regard any lesion or wound on the leg to be a 'leg ulcer', may misinterpret the question and report other ulcers (e.g. corneal, duodenal, gastric), or may fill in the survey wrongly.

One potential explanation for a true prevalence of leg ulceration in the Irish population would be a higher birth rate (as the incidence of varicose veins secondary to pregnancy is increased). The possibility that the Republic of Ireland has a higher prevalence due to a higher birth rate, however, is rendered less credible by the fact that the prevalence is higher in both the male and female population.

Baker et al (1991) screened a metropolitan population of 238,000 in Perth, Western Australia, for leg ulceration. The methodology was similar to that used by Callam et al (1985) - patients were identified by referral by health professionals, and institutions, and by self-referral. The prevalence of ulceration in the three-month study period was 1.05 per 1000, significantly lower than that reported in the other surveys. The authors and Callam (1992) suggest that this may be due to the younger age profile of the Australian population, as there is a clear association between ulceration and age. The prevalence of ulceration in the over 65-year population was 3.3 per 1000, in comparison with 3.6 per 1000 in the Lothian and Forth Valley Leg Ulcer Study (Callam et al 1985). The median duration of ulceration was 26 weeks and 76% of patients had recurrent ulceration.

Nelzen et al (1991) reported the results of a cross-sectional population study in a mixed urban and rural population. Eight hundred and twenty seven patients with leg and foot ulcers of at least 6 weeks duration were identified in a population of approximately 270,800, a point prevalence of 3.0 per 1000. The higher prevalence cannot be explained by difference in the age profile of the population. A random sample, stratified for geographic location, was examined and it was found that venous insufficiency was present in 72% of legs with active ulceration. Venous insufficiency was thought to be the 'dominating causative factor' in 54% of patients, this decision being made by the first author who performed the clinical assessment. As venous insufficiency is relatively common then it is likely to be present in patients with other major causative factors. This is the only study that identified the dominant causative factor.

Lees and Lambert (1992) surveyed the Newcastle Community Health District, population 240,000, using a questionnaire sent to all 70 district nurses. Two hundred and six ulcers

were identified and the prevalence, calculated using the 'at risk population' as those over 45 years of age, was 1.9 per 1000. The median ulcer duration was 6 months, and 47% of ulcers were recurrent. As hospital in-patients were not included in this survey, and the 'at risk' population was defined as over 45 year olds, the true prevalence may be different. It is interesting to note the shorter median duration of ulceration (6 months cf. 9 months) and lower recurrent ulcer rate in this survey (47% cf. 66%) compared with that of Callam et al (1985). This may be due to chance, to a different population, e.g. patients treated in hospital or nursing homes were not included in the Newcastle survey, or it may be due to improved treatment over the 7-year period between surveys.

One problem with surveys is the likelihood of under-reporting. Some patients are reluctant to see their nurse or general practitioner (GP) with an ulcer as they may attach some stigma to the condition. Thus, the real prevalence of ulceration is likely to be higher than that reported.

It is unclear whether the prevalence of ulceration will increase or decrease in future. This depends on the incidence of ulceration, the rate with which ulcers heal and the death rate of patients with ulcers. The fact that ulceration is largely a disease of the elderly and the proportion of the over 60's is increasing, means that the prevalence might be expected to increase. Improvements in the treatment and prevention of recurrence may reduce the prevalence.

The incidence of damage to the deep veins secondary to deep vein thrombosis may change with the numbers of patients having major abdominal operative procedures, operative techniques such as minimally invasive surgery, and changes in DVT prophylaxis. The largest increase in population over the next decades will be in the over 85 year old population (OPCS 1989). As arterial insufficiency increases with age, there may be an increase in the number of patients with arterial ulceration. There may also be a change in the proportion of non-venous ulceration in all age groups, due to increased venous ulcer healing rates.

There are no reported studies of leg ulcer incidence. Two prospective, inception cohort studies of subjects aged 45-60, one assessing the venous system and one the arterial system, are underway in Edinburgh (Evans et al 1997). The aims of these studies include

identifying risk factors associated with progression of vascular disease, e.g. from the non-symptomatic to ischaemia or ulceration. These may suggest interventions for secondary prevention, i.e. preventing the first ulcer.

There are only very limited results from the first case-control study of leg ulceration undertaken in Auckland, New Zealand. This identified that a history of deep vein thrombosis (DVT) or a risk factor for DVT formation (e.g. major surgery), increased the risk of developing a leg ulcer (Walker 2000).

1.6.1. Economic costs

The costs of ulceration include the loss of economic productivity by the patient, the cost of treatment materials and manpower, opportunity costs (the cost of not using the resources in other ways), as well as the personal costs. Epidemiological studies in the UK have found that the vast majority of patients are cared for in the community. Callam et al (1985) reported that 83% of patients were cared for in primary care and an additional 11% received both primary and secondary care. This pattern may be different in countries with different health care systems. In Australia, for example, patients and their families / carers are taught to dress and bandage their ulcers as visiting nurses visit infrequently in remote areas.

Leg ulcers form a large part of the caseload of district nurses and many patients require daily dressings and visits (Journal of District Nursing 1987, Nelzen et al 1994). Bosanquet (1992) reports that a survey in Rochester and Walsall found that district nurses spent 30-50% of their time dressing leg ulcers. District nursing time is therefore a large element of the cost of ulceration. A survey of nursing manpower activity in the community found that managing leg ulcers (assessment and dressings) was the most prevalent 'purpose of visit' in the four grades of staff studied (NHSE 1992). There are reports that manpower costs alone account for a budget of £100 -£180 million annually in the UK (Bosanquet 1992, Laing 1992). The addition of bandage, dressing, drug, and other costs doubles this to provide a conservative total estimate cost of around £300 million (Bosanquet 1992). The indirect costs of loss of productivity and increased welfare benefits are not generally estimated, probably due to the

perception that this is a condition affecting the elderly. Increasing importance is being attached to quality of life measures and the effect of leg ulceration on comfort, mobility, affect, social contact etc. have been assessed in recent studies (Franks et al 1992).

1.6.2. Results from quality of life studies

Moffatt et al (1991) found that patients with leg ulcers experienced pain and worry due to their leg ulcer and that it interfered with their ability to perform housework and engage in a social life. Patients with leg ulcers have been found to be more isolated and depressed than an age matched cohort of elderly persons without a leg ulcer (Roe et al 1995). In the study by Roe et al (1995), the majority of patients sampled, a random sample of 88 over 65 year olds, expressed negative feelings about having an ulcer, for example:

'It makes me into an invalid'.

There is some evidence that a few patients use their ulcer as a passport to social and health care as suggested by Muir Gray and Wilcock (1981) and (Moody 1984). Ten patients said there were good things about having an ulcer, for example, accessing the meals on wheels service:

'I get meals on wheels now'

Leg ulcer treatment also affected the patients' lifestyle, with some patients commenting that they could not get their shoes on, and had difficulty in bathing. Twenty patients (23%) said they had sometimes removed bandages and stockings because they were too hot, loose or tight. Roe et al (1995) stated that the high rate of satisfaction with treatment and low expectation of healing may have been due to the low level of provision of compression bandages in this area; only 7 (8%) patients had been provided with a suitable compression bandage.

Moffatt et al (1991) found that the provision of high compression bandaging in leg ulcer clinics, was associated with reductions in anxiety, depression and hostility, as judged by the Symptom Rating Test (Kellner 1986). As this was an uncontrolled study, these results cannot be attributed to any particular aspect of the treatment.

1.7. Treatment of Venous Ulceration

Effective treatment depends upon differential diagnosis and selection of appropriate interventions. The differential diagnosis includes the detection of diabetes, arterial insufficiency, varicose veins, medical history of vascular disorders and examination of the ulcer for atypical presentation. Suspected malignant ulcers, arterial or diabetic ulceration require specialist assessment as excision / re-constructive surgery or orthotics may be necessary.

In venous ulceration, the key is to reduce venous hypertension. This may be done with external support of the leg by compression hosiery, bandages or mechanical devices. In some patients, the venous pathology causing the ulcer may be rectified surgically - by surgical removal, sclerosis or by disconnecting the deep and superficial systems. Many patients, however, are not suitable for surgical intervention and waiting lists for vein surgery are long. Franks et al (1993) found that many patients did not wish to be considered for surgery.

The mainstay of the treatment of venous ulceration is the application of bandages or stockings. Deep venous reflux is rarely tackled surgically as the deep veins cannot be removed, and valvular reconstruction is still in its infancy.

1.7.1. The local environment

Before a dressing is applied, the wound is commonly cleaned. Various solutions used to cleanse wounds have been shown to be detrimental to cells in vitro, e.g. hypochlorites (Lineaweaver et al 1985). Warmed saline or water is usually recommended (Lindholm 1997) although there are no systematic reviews of the effectiveness of these solutions on wounds and a search of the Cochrane Library Central Trials Register in October 2000 found no trials comparing cleansing solutions or regimens in the treatment of venous leg ulcers.

A primary wound dressing is placed next to the wound and this might be covered with a secondary dressing. The main function of the dressing is to act as a physical barrier to

contamination, and allow removal of the dressing without disturbing granulation tissue. The dressing should allow excess exudate to escape from the ulcer, and do no harm to the patient, i.e. be comfortable and not cause allergies or contact dermatitis

Turner (1979) described the performance and handling characteristics of an ideal wound dressing, see Table 1.1.

1. To remove excess exudate and toxic compounds
2. To maintain high humidity at wound /dressing interface
3. To allow gaseous exchange
4. To provide thermal insulation
5. To afford protection from secondary infection
6. To be free from particulate or toxic contaminants
7. To allow removal without trauma at dressing change
8. Good range of sizes
9. Resistance to tear and disintegration when wet and dry
10. Ease of handling
11. Conformable
12. Sterilisable and disposable.

Table 1.1 Performance characteristics of an ideal dressing.

These 'ideal' performance properties were based on opinion or laboratory studies rather than clinical evidence that a dressing with these characteristics would aid healing. A dressing that does not allow gaseous exchange, e.g. hydrocolloids, is effective, see section 1.7.2 and therefore this property is not essential.

1.7.2. Dressings in the treatment of venous ulceration

A systematic review of the effectiveness of wound dressings and topical agents in the treatment of venous leg ulcers was conducted by searching for reports of randomised controlled trials in 17 electronic databases as well as hand searching conference proceedings and wound care journals up to December 1999 (Nelson et al, 2000). Reports were scrutinised for relevance by one reviewer (EAN) and rejected reports were checked by another reviewer (Bradley, MDB: Cullum, NC).

Trials were included if they reported that the ulcers were venous in origin, they reported objective outcome measures such as numbers of ulcers healing or change in ulcer area, and described the method of allocation to the interventions as 'randomised'. Data extraction was performed by one reviewer (EAN) and checked by a second (MDB/ NC) using a standardised proforma. Information on the quality of the trial was also collected, e.g. allocation concealment, blind outcome assessment, comparability of groups at baseline, reporting of withdrawals by treatment group and reasons for dropout. Forty-two reports of randomised controlled trials were found.

Hydrocolloid versus 'traditional' dressings

Nine trials report comparisons between hydrocolloid dressings and traditional dressings (Smith et al 1992, Nelson et al 1995, Moffatt et al 1992b, Backhouse et al 1987, Arnold et al 1991, Meredith and Gray 1985, Mansson et al 1990, Milward 1988 and Groenewald 1994);

- 3 were comparisons with povidone iodine impregnated gauze,
- 3 were comparisons with knitted viscose dressing,
- 2 were comparisons with paraffin impregnated tulle and
- One was a comparison with saline-soaked gauze.

Of these nine trials, only one found a statistically significant increase in the proportion of ulcers healed over the trial period under a hydrocolloid (Granuflex) in comparison with paraffin impregnated tulle (Jelonet) (Meredith et al 1988). Pooling similar studies by a random effects model failed to find a statistically significant difference in the proportion of

Relative risk meta-analysis

Author	Number of ulcers recruited	Healed	Number of ulcers recruited	Healed	Relative risk	95% CI (near exact)	
	Hydrocolloid		Control				
Arnold	35	14	35	11	0.7857	0.4142	1.4671
Backhouse	30	22	30	21	0.9545	0.678	1.3338
Meredith	24	6	25	19	3.04	1.5855	6.4966
Nelson	98	44	102	49	1.07	0.7947	1.4458
Smith	101	47	99	50	1.0853	0.8151	1.448
Mansson	49	7	48	5	0.7292	0.2584	2.0342
Milward	19	0	19	3	err	err	err
[Haldane approx.]					7	0.3861	126.9195

Chi-square ("combinability" for relative risk) = 11.6877 (df = 6) P = .0693

DerSimonian-Laird pooled relative risk = 1.110326
Approximate 95% CI = 0.85236 to 1.446364

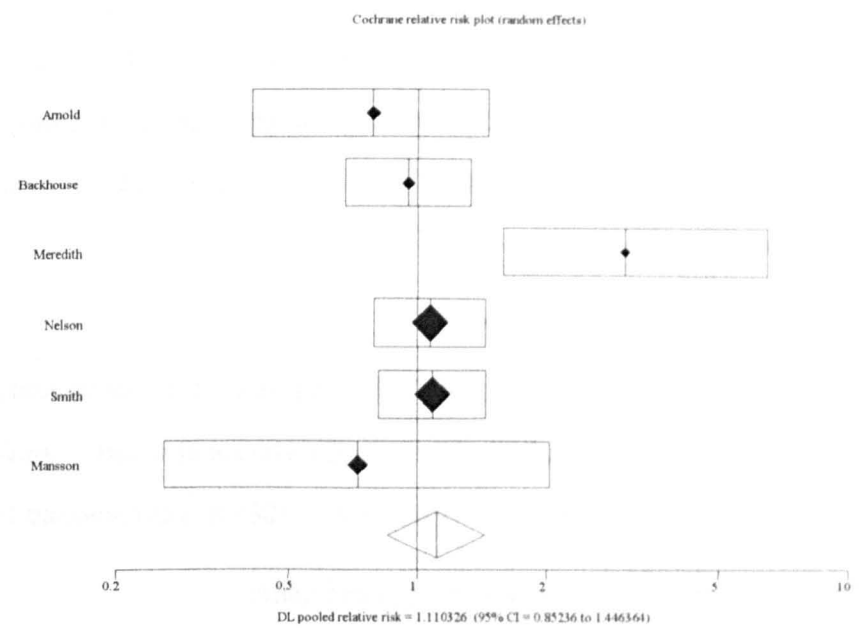


Figure 1.3 Forest plot showing relative risk of healing in hydrocolloid dressings versus simple dressings in venous leg ulcers. Relative risk greater than 1 indicates that there is a higher rate of healing in the hydrocolloid group.

ulcer healed over the trial period, pooled relative risk for healing 1.11 (95% confidence interval 0.85 to 1.44) (Bradley et al 2000). Hence it appears that there is no additional benefit from using a modern dressing in preference to a traditional dressing in the treatment of venous leg ulcers when compression therapy is used, see Figure 1.3.

Figure 1.3 Forest plot - healing rates

Hydrocolloid dressings versus modern dressings

One hydrocolloid dressing, Granuflex, has been shown to have a fibrinolytic action (Lydon et al 1989) but there is no evidence that this 'in vitro' action is important clinically. A number of trials with this dressing have failed to demonstrate any increase in healing rates over similar dressings.

A hydrocolloid (Granuflex E) did not heal significantly more ulcers than a lyophilised collagen dressing. There was an apparently larger reduction in wound area with the hydrocolloid but insufficient data was given to allow this to be tested for significance. There was no data given on ulcer area at randomisation in the two groups to allow one to determine whether this finding was due to different ulcer areas at baseline (Caprio et al 1995).

A hydropolymer dressing, Tielle, and hydrocolloid, Granuflex, healed similar numbers of leg ulcers in a trial by Banks (1994). Wounds in the Tielle group had a greater reduction in actual wound area but the larger baseline area of ulcers in the Tielle group may confound this. The percentage reduction in wound area favoured Granuflex E and this is as expected given the smaller area at baseline (Banks et al 1994).

Similarly, Smith (1994) failed to detect a difference in the proportion of ulcers healing or change in ulcer size in a comparison of an unnamed alginate and a hydrocolloid (Granuflex).

Two trials have compared hydrocolloid dressings for venous leg ulcers. Veraart et al (1994) found no significant difference in the proportion of ulcers healed using the newer formulation of Granuflex in comparison with a hydrocolloid incorporating calcium alginate (Comfeel Extra Absorbing dressing).

Burgess and Robinson (1993) compared three hydrocolloids: original formulation Granuflex, new formulation Granuflex and Comfeel hydrocolloid. They did not provide sufficient data to state whether the reported greater reduction in wound area with the newer Granuflex dressing was statistically significant. The mean reduction in ulcer area per day was highest in the new formulation Granuflex, and lowest with Comfeel, but there was no data provided on baseline size to determine whether these measures were confounded by baseline incomparability.

In two trials comparing the original formulation of Granuflex with foam dressings, Lyofoam and Allevyn (Zuccarelli 1992, Bowszyc et al 1993), both found no significant difference in the proportion of ulcers healed. Pooling the data resulted in no overall difference, pooled odds ratio for healing = 1.0 (95% confidence interval 0.43, 2.33).

Other dressings

As a leg ulcer *appears* similar to any other wound, the nurse may become more concerned with the dressing than with applying compression that will help redress the pathology. In the audit of treatment by the Lothian and Forth Valley Leg Ulcer Study (Callam et al 1985), many of the treatments used by nurses were harmful. More recent surveys of nurse practice document the minimal use of research-based practice (Luker and Kenrick 1992), and there is still a poor understanding of the need for compression. The dressing can be chosen according to the condition of the wound and nurses often use Leg Ulcer Assessment Charts (e.g. Dale and Gibson 1992) to guide their decisions. Given the lack of robust evidence from randomised controlled trials to indicate that dressings affect the healing of a venous ulcer stage, then these decision charts, based on expert opinion, should be considered as being weak guidelines for practice.

1.7.3. Treating the Whole Leg

Venous leg ulcers may be complicated by skin problems secondary to the venous insufficiency. In addition to the local dressing, the treatment of the venous leg ulcer requires care of the whole leg. Long-term inflammation leads to scar tissue being laid down and this makes the skin feel hard and woody. The breakdown products from haemoglobin leave a brown pigment (haemosiderin) in the skin and this combination of staining and hardening is called lipodermatosclerosis. Lipodermatosclerosis is characterised by discoloration, induration and eczema and is often seen as a precursor to venous ulceration. There may be irritant or allergic reactions to the exudate from the wound, or topical preparations.

1.7.3.1. Caring for the skin

The skin around the ulcer may be macerated due to prolonged contact with exudate. Away from the ulcer, the skin is often dry and inflamed due to inflammation and eczema although it remains unclear why poor tissue perfusion and high venous pressure cause eczema (Cameron 1995). Emollients can be used to rehydrate the skin in order to reduce the possibility that the skin may crack and ulcerate. Barrier preparations, e.g. zinc oxide based creams, are used to prevent the skin from becoming macerated.

Use of preparations on the skin around ulcers is associated with a high rate of irritant contact dermatitis and allergic contact dermatitis in this patient group (Cameron 1995). Irritant contact dermatitis is an inflammation of the skin, erythema, pustules and weeping. The dermatitis occurs only in the area of application and follows the first contact with the skin.

Allergic contact dermatitis, often confused with irritant contact dermatitis, is due to a delayed, type four, cell-mediated hypersensitivity. The resulting inflammation, pustules and weeping often extend beyond the area of initial contact and only arise after the person has been sensitised to the product by previous exposure.

In order to identify and prevent both irritant and allergic contact dermatitis some practitioners patch test their patients. This identifies allergens and irritants so that they can be avoided. Cameron (1998) has demonstrated that leg ulcer patients can develop allergies to products

to which they were previously not sensitive. Lanolin, preservatives, topical antibiotics and perfumes are common culprits and so these are usually avoided. Bandage materials and the chemicals used in the processing of rubber and Lycra® can also cause allergy.

1.7.3.2. Reducing oedema

Oedema arises because the loss of fluid from the arterial end of the circulatory system is greater than the re-absorption at the venous end. A level of equilibrium is eventually reached because the pressure of fluid within the interstitial tissues prevents further fluid loss.

Leg oedema is often present at the start of treatment. It can reduce mobility, as the limb is heavier than usual due to the additional fluid. Reduced mobility may lead to reduced calf muscle pump action and hence increase venous hypertension. Oedema will also delay healing as it increases the tissue tension (Chant 1990) and increases the diffusion distance between the capillaries and the tissues.

Extremely oedematous limbs will have very thin, papery, fragile skin and this is prone to damage and ulceration. For these reasons, oedema should be reduced. A period of bed rest may be necessary at first so that bandaging (Bourne 1992) does not damage the very fragile skin.

Oedema may be an important indicator of the efficacy of treatment. Duby et al (1993), in a randomised controlled trial of three compression systems, found that efficacy of each system was correlated to the reduction in limb volume. The proportion of ulcers healing in 12 weeks was 44% (4 layer), 40% (short stretch) and 23% (paste + support). The reduction in leg volume was 13%(4 layer), 9% (short stretch) and 5% (paste + support). The correlation between a decrease in volume and a decrease in the size of the ulcer was only significant for the short stretch and four layer systems.

Some investigators have used oedema reduction as an outcome measure in clinical trials although it must be remembered that the outcome of primary importance to clinicians and patients is likely to be ulcer healing. Oedema reduction would be an important surrogate

outcome measure if the relationship between reduction in oedema and healing were established.

External support can be provided by compression bandages or stockings. Some centres use stockings and these have the advantage that the level of compression can be determined by the prescriber. Many patients will be able to apply the stocking themselves and therefore not require visits by nurses to change the dressing. The stocking fabric may be damaged by exudate from the wound, however, and the size of stocking needed may change during the treatment. Compression bandages require skill to apply them appropriately. Treatment with bandages may be expensive due to the need for frequent dressing changes and the cost of the bandages. Compression bandaging will be discussed in detail in section 1.7.4

1.7.4. Other treatments

Therapeutic ultrasound

A search for RCTs of therapeutic ultrasound was conducted in June 1999, primary sources Cochrane Library, Medline, Embase, Cinahl. This identified seven RCTs comparing therapeutic ultrasound versus no ultrasound or sham ultrasound for venous leg ulcers. (Callam et al 1986, Dyson et al 1976, Eriksson et al 1991, Lundeberg et al 1990, Peschen and Vanscheidt 1996, Roche and West 1984, Weichenthal et al 1997) A meta-analysis of the four trials with similar interventions and outcomes (201 patients), using RevMan 3.1 and MetaView 2.0, suggested a benefit associated with ultrasound (relative increase in proportion of ulcers healed 43%, 95% CI –2% to +111%) (Nelson et al 2000). Mild erythema, local pain and small areas of bleeding have been reported in some trials. Further research is needed to confirm the results of this meta-analysis (Nelson et al 2000).

Drug treatments

Oxpentifylline

A search for RCTs of oxpentifylline was conducted in December 1999, primary sources Cochrane Library, Medline, Embase, Cinahl. It identified two RCTs comparing oxpentifylline

(400 mg three times a day) versus placebo in venous leg ulcers treated with compression. One trial reported accelerated healing and one trial reported no significant difference. (Dale et al 1995, Colgan et al 1990). Meta-analysis of these two trials gave a relative increase in the proportion of ulcers healing of 48% (95% CI 14% to 94%) (NNT 6, 95% CI 3 to 16) for six months treatment. In one trial of oxpentifylline versus placebo, 45% of patients receiving oxpentifylline and 33% of patients receiving placebo reported adverse effects such as depression, dyspepsia, vomiting, and diarrhoea (Colgan et al 1990).

Flavonoids

A search for RCTs of flavonoids was conducted in December 1999, primary sources Cochrane Library, Medline, Embase, Cinahl. It identified one RCT comparing a flavonoid versus placebo in venous leg ulcers (Guilhou et al 1997). This concluded that 1000 mg (900 mg diosmin and 100 mg flavonoids expressed as hesperidin) increased the rate of complete healing of small ulcers (< 10 cm in diameter). The relative increase in the proportion of ulcers healed was 150%, 95% CI 9% to 485%, after two months treatment. Adverse effects of flavonoids, such as gastrointestinal disturbances, were reported in 10% of patients (Guilhou et al 1997).

Thromboxane A_2 antagonists

A search for RCTs of thromboxane A_2 antagonists was conducted in December 1999, primary sources Cochrane Library, Medline, Embase, and Cinahl. It identified one RCT comparing an oral thromboxane A_2 antagonist versus placebo in venous leg ulcers. There was no difference in the proportion of ulcers healing in the two groups (54% *v* 55%) (Lyon et al 1998).

Vein surgery

A search for RCTs of vein surgery was conducted in December 1999, primary sources Cochrane Library, Medline, Embase, Cinahl. It identified one RCT (47 patients) comparing vein surgery (perforator ligation) versus no surgery or surgery plus skin grafting (Warburg et al 1994). There was no difference in the proportion of ulcers healed or the rate of ulcer

healing. The trial was too small to rule out a beneficial effect. Vein surgery carries the usual risks of surgery and anaesthesia.

1.8. Compression Therapy

The terms used to describe bandages are frequently confused. Bandages are variously described with reference to the fibres used in their construction and their response to extension.

Some important terms are:

Elasticity; the ability of a fibre (or bandage) to return to its original length after extension

Extensibility; the extent by which a fibre (or bandage) is extended due to the application of a force

Strength or power; the force required to stretch a fibre (or bandage) by a certain amount.

Clinical papers usually refer to bandages in terms of 'elasticity' or 'extensibility'. The relationship between these terms is demonstrated in Table 1.2.

Descriptor	Elastomeric bandages		Non-elastomeric bandages	
Functional description	So called 'highly extensible' or 'long stretch' bandages		So called 'minimally extensible' or 'short stretch' bandages	So called 'inextensible' or 'non-stretch' bandages
Functional fibres in weft	Elastane (Lycra)	Rubber	Crimped / twisted fibres, e.g. cotton, wool	Straight fibres, e.g. cotton
Proprietary example	Surepress (ConvaTec, UK)	Varico (Seton, UK)	Comprilan (Beiersdorf, UK)	Viscopaste PB7 (Smith and Nephew, UK)

Table 1.2. Bandage descriptor and construction

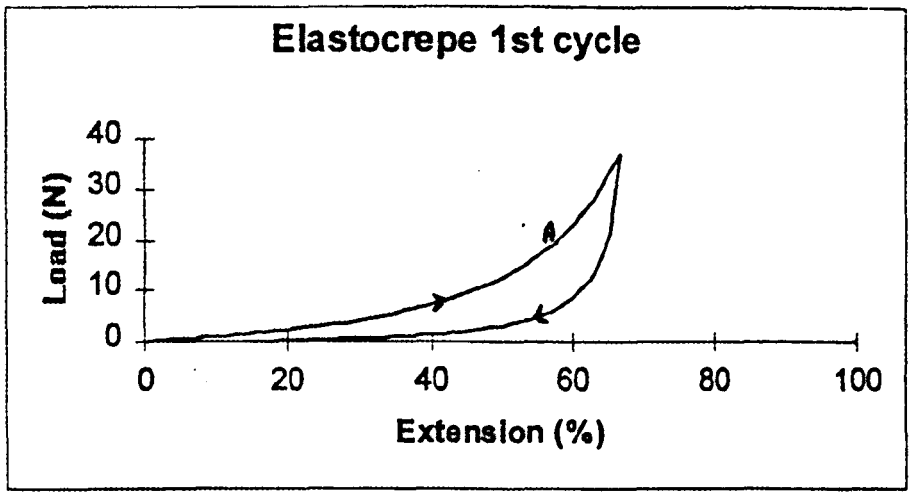


Figure 1.4 Load / extension curve for an Elastocrêpe bandage on the first cycle of extension and relaxation

Stemmer classifies bandages as being highly extensible, minimally extensible and inextensible by reference to the maximum extension (Stemmer 1980). Highly extensible, also called long stretch or 'long tension' bandages can be stretched by more than 140% of their resting length (Stemmer et al 1980). Compression stockings, some roller bandages and tubular compression bandages, e.g. Tubigrip, contain an elastomer such as Lycra ® or rubber; these are all highly extensible devices.

'Short-stretch' bandages are made from crimped or twisted fibres, and these can be extended by 70% -100% of their resting length. The bandage extends slightly under tension due to the straightening of the fibres. After a small extension, the limit of extension of the fibre is reached and the bandage becomes much harder to extend, see point A on figure 1.4. These are sometimes referred to, rather misleadingly, as minimally extensible bandages.

So called 'inextensible' bandages, e.g. impregnated woven cotton bandages (Viscopaste PB7), are, in fact, extensible by up to 70% of their resting length as fibres can be extended to some degree. These are sometimes referred to, rather misleadingly, as inextensible bandages. In clinical use in the UK, however, they are not applied while extended and are placed on the leg with regular folds to accommodate any increase in leg circumference.

1.8.1.1. Historical overview

Compression therapy in numerous forms has been used for centuries. Bandages (called wraps in the USA), were made initially from fabrics such as cotton, and therefore were non-elastomeric. Non-elastomeric compression remains the mainstay of treatment in the management of leg ulcers in much of Europe and Australia. In the UK, however, elastomeric compression bandages, containing either rubber or Elastane, are more popular. Synthetic elastomeric fibres such as Elastane (Lycra ®, Dupont) have gradually replaced rubber, as they are lighter, stronger and more easily washed.

Modern elastomeric bandages are designed to provide prescribed levels of compression according to standards that are performance-based rather than construction-based as in the

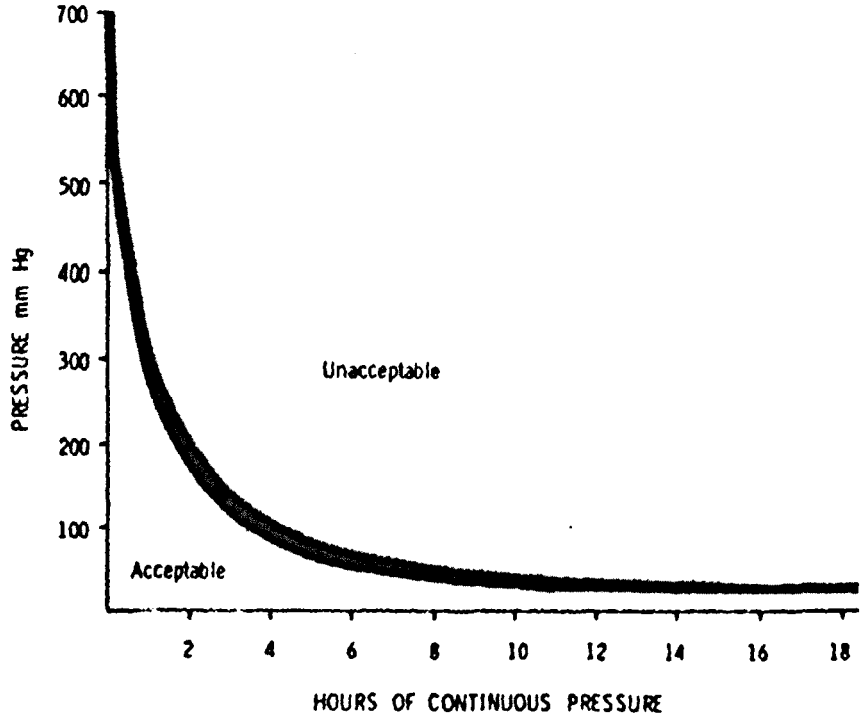


Figure 1.5 Relationship between interface pressure, time and skin damage (after Kosiak)

Modern elastomeric bandages are designed to provide prescribed levels of compression according to standards that are performance-based rather than construction-based as in the past. Bandages were previously classified according to the number and type of fibres in the warp and weft. A British Standard (BS6612; 1985) describes the tension that the bandage must exert in order to be classified as a retention bandage, support bandage, or light, moderate, high or extra high compression bandage. This tension is measured in laboratory test under simulated extension and relaxation.

This thesis concerns itself with roller bandages used to treat venous ulceration, including regimens using support bandages (class 2) and compression bandages (class 3).

1.8.2. Effect of pressure on skin

Pressure on the skin may produce harmful or beneficial results depending on its magnitude and distribution, and on the intrinsic characteristics of the skin and the patient. The application of a compression bandage to a leg with impaired arterial circulation can lead to skin damage and in the worst case, amputation. Research into the effect of pressure on skin has largely concentrated on the prevention of pressure sores. Both normal forces, acting at right angle to the surface of the body, and shear and friction forces, acting parallel to the surface of the body, produce pressure sores. Normal forces are relatively easy to measure and are used therapeutically, in contrast with shearing forces, which are difficult to measure and have no therapeutic benefit. This thesis is only concerned with normal forces.

Kosiak (1959) studied the pressure and time conditions necessary to damage the skin of animals and found an inverse relationship as demonstrated in Figure 1.5. This is useful as it represents the fact that pressure damage can occur through extremely high pressures applied for a short time or, lower pressures for a long period. Strategies for the prevention of pressure sores normally seek to reduce either the level of pressure, or its duration.

Figure 1.5 Kosiak's relationship- pressure/necrosis 1

Pressure *reducing* surfaces have a conformable surface which maximises the area of contact between the patients and the mattress / overlay. As pressure is inversely proportional to the area of contact, this has the effect of reducing the overall pressure. Replacement foam mattresses, which use different foam densities or contoured foam to maximise the area of contact with the patient, prevent the development of pressure sores in comparison with standards NHS foam mattresses (Gray and Campbell 1995).

Pressure *relieving* surfaces usually support the body on air-filled sacs, which are inflated and deflated in series. This results in each air sac being in contact with the skin for only a proportion of the inflation / deflation cycle. Alternating pressure mattresses were more effective at preventing pressure sore development than constant low-pressure supports in one trial (Gebhardt et al 1995) but the quality of trials in this area meant that a recent systematic review concluded that:

'Some types of large-cell alternating pressure devices (cell diameter 10 cm or greater) may be more effective than simple, low pressure mattresses but further research is needed' (Cullum et al 1999).

Moderating the magnitude and duration of the pressure may be insufficient to prevent the development of all pressure sores as patients can develop sores even when nursed on these systems. The presence of an existing pressure sore, immobility of the patient in bed, faecal incontinence, neutropaenia, and recent weight loss are powerful independent risk factors for skin damage (Maklebust et al 1994, Allman et al 1995).

Risk rating scales have been developed in order to identify those patients at increased risk of skin damage, e.g. Norton 1975, Andersen et al 1982, and Waterlow 1988. Despite the widespread use of risk indicators and their incorporation into policy documents there is no evidence that their use leads to the reduction in the number of patients developing sores or of the severity of the pressure sores developed.

Pressure is used therapeutically in the treatment of hypertrophic and keloid scars, the prevention of deep vein thrombosis (DVT), treatment of lymphoedema and the treatment and prophylaxis of venous ulceration. This thesis will concentrate on the investigation of those products that are used in the treatment of venous ulceration.

1.8.2.1. Static compression

Bandages and stockings are examples of static compression devices, as the applied compression does not vary *intentionally* over time. Compression stockings are designed to deliver a specified pressure profile to a limb. This depends on the stocking manufacture and the correct fitting and renewal on a regular basis (Burnand et al 1986). Measuring the limb and selecting the correct size of stocking and then applying it correctly are of utmost importance. Stocking position on the leg may influence the compression achieved (Peat 1988).

Roller bandages can be applied in such a way as to generate an infinite range of pressure profiles by varying extension, overlap and method of application.

The tension produced by a bandage is governed by the following factors:

- the type of elastomeric yarn used ('Lycra ® ' or rubber) and hence the force required to extend it
- the thickness of elastomeric yarn used
- the number of elastomeric threads used per unit bandage width
- the extension of the fibre in the extended fabric (if the fibre is at near maximum extension in the bandage then the fibre tension will be greatly affected by a small change in extension)

It is predicted that the tensile force generated in the elastic fibres when extended causes a pressure on the limb (assuming no friction) according to Laplace's Law:

Pressure is proportional to bandage tension and inversely proportional to limb radius

Hence it can be predicted that the bandage tension and shape of the leg will influence the pressure applied to a limb.

1.8.2.2. Application technique

Compression bandages can be harmful if they are applied incorrectly (Callam et al 1987). There is evidence that nurses do not select the appropriate bandage for a particular situation (Magazinovic et al 1993), and that their skill in bandage application is poor (Millard et al 1986). One potential advantage of stockings and tubular support bandages is the lower level of skill required to apply them. Stockings, tubular and roller bandages can result in tissue damage if applied to a limb with compromised arterial supply.

1.8.2.3. Time

The pressure that elastomeric bandages exert on a limb reduces due to stress relaxation within the elastomeric fibres after application. Bandages vary in their ability to maintain compression; some bandages exhibit more stress relaxation than others do. The limb shape, size and deformability may also change over time due to reduction in oedema, muscle activity and creep.

There is little research into the response of bandages to patient activity over long periods (Raj et al 1980, Fentem 1988). Sockalingham (1990) has studied the sub-bandage pressures continuously over a week.

In crêpe bandages, extending the bandage straightens the twisted fibres, and if the recoil is poor then the tension is short lived. These bandages do not maintain their pressure well over time (Sockalingham et al 1990, Dale et al 1983b, Raj et al 1980). This influences their clinical utility, as they need to be reapplied frequently in order to provide continuous high levels of pressure.

1.8.2.4. Posture and activity

Bandages generate a pressure on the limb depending on the magnitude of tension within the bandage. Patient posture will influence the shape of the musculature of the limb as well as the leg volume. Change in bandage extension and interface conditions both influence the sub-bandage pressure. As elastomeric bandages demonstrate only a small change in

tension due to a change in extension, when applied at a specific part of the load extension curve, then the sub-bandage pressure changes less with change in posture or activity than a non-elastomeric bandage (Callam et al 1991).

Non-elastomeric bandages do not contain elastomers. The constituent fibres have some extensibility, although this is small. They are applied to the leg to form a 'firm skin', against which the calf muscle pump can act, e.g. the Unna's Boot (a cotton woven bandage impregnated with a zinc oxide paste, it becomes rigid as it dries out – used in the USA). When the patient is at rest, interface pressure is low and when they are upright or using the calf muscles, interface pressure is high. These bandages may have a wider safety margin as they have a low resting pressure and a high working pressure (only work when they are needed). This is in contrast with extensible bandages that exert a higher pressure for a longer time (Callam et al 1991). Non-elastomeric bandages are widely used in continental Europe and Australia.

1.8.3. Dynamic compression

Dynamic compression devices apply deliberately varying levels of pressure. They generally consist of a plastic inflatable sleeve placed around the leg connected to a pneumatic pump. The sleeve is intermittently inflated and deflated in order to exert pressure on the limb. The pump controller is adjustable; the user sets the pressure within the inflatable sleeve and the inflation time. Early models had only one compartment and so the pressure was equal along the length of the leg. This resulted in the occlusion of popliteal veins before the distal veins could empty. The distal veins emptied incompletely and so venous outflow was reduced (Spiro 1970). Newer devices have multiple compartments; the distal compartments inflate first to the highest pressure; the more proximal compartments inflate to a lower pressure after the distal compartments thus providing graduated sequential compression. This empties the veins and increases the blood flow more effectively (Nicolaides et al 1980). Full length and knee length versions are available. There have been studies of the effectiveness of these devices in preventing deep venous thrombosis, in aiding the healing of venous leg

ulcers and into various physiological parameters, e.g. tissue oxygenation, fibrinolysis, venous blood flow and velocity (Coleridge-Smith et al 1990, McCulloch et al 1994).
A systematic review of the effectiveness of intermittent pneumatic compression in the treatment of venous leg ulcers was conducted by searching for reports of randomised controlled trials in 17 electronic databases as well as hand searching conference proceedings and wound care journals up to June 1999. Reports were scrutinised for relevance by one reviewer (EAN) and another reviewer (NAC) checked rejected reports. Trials were included if they reported that the ulcers were venous in origin, they reported objective outcome measures such as numbers of ulcers healing or ulcer area, and described the method of allocation to the interventions as 'randomised'. Data extraction was performed by one reviewer (EAN) and checked by a second (NAC) using a proforma. Information on the quality of the trial was also collected, e.g. allocation concealment, blind outcome assessment, comparability of groups at baseline, reporting of withdrawals by treatment group and reasons for dropout. Three trials were found which fulfilled the entry criteria (Coleridge-Smith et al 1990, McCulloch et al 1994, Schuler et al 1996). The three RCTs were sufficiently similar to pool results using a random effects model in which the effectiveness of the intervention being investigated is assumed to vary in each study. This showed no difference in the proportion of ulcers completely healing (relative increase in the proportion of ulcers healing associated with intermittent pneumatic compression 1.56 (95% CI –0.9% to 169%) for 3 to 6 months duration of treatment.

The use of dynamic compression devices is limited because the patient cannot carry on with their activities of daily living while treatment is taking place. Treatment may last for up to 4 hours daily and one of the acknowledged weaknesses in trials has been the lack of a control group who rested for this period daily but who did not receive intermittent compression (Coleridge-Smith et al 1990). They may be of more use in hospital settings, for the prevention of deep venous thrombosis and the treatment of intractable venous ulcers.

1.8.3.1. Effect of compression on vascular function

Compressing limbs will serve to increase blood flow velocity by tending to decrease the cross-sectional area of the limb and the veins. Compression will also affect the balance of fluid re-absorption and filtration (Starling equation, figure 1.1) and will serve to enhance re-absorption of plasma back into the capillaries. Compression will reduce arterial inflow if the level of pressure applied is of the same magnitude as the diastolic blood pressure or if peripheral vascular disease reduces the arterial circulation. There are difficulties in extrapolating the results from studies on vascular physiology of normal legs. It has been demonstrated that the results using patients are different from those using normal subjects (Dahn et al 1967). Commonly measured parameters have included deep venous blood flow, foot volume, venous pressure, and isotope clearance.

Deep venous blood flow

Blood flow in the deep veins is reduced during surgery and this venous stasis is thought to contribute to the formation of deep vein thrombosis. Hence, many studies of deep venous blood flow seek to investigate the influence of compressive devices used for DVT prevention on the normal, resting limb. Results from these studies may be specific to this population. The disappointing results from theoretically beneficial treatments, e.g. bandaging, may be due to the variability of the pressure profiles obtained and the difficulty in measuring them. In one study, the investigators abandoned the use of bandages, as they were not skilful enough in their application (Lewis et al 1972). Various methods have been used to measure the flow in the deep veins, e.g. thermal dilution (Clark and Cotton 1968), electromagnetic methods (Roberts et al 1972), and Duplex ultrasound imaging (combined B wave and Doppler ultrasound) (Strandness et al 1983). Different variables have been measured, e.g. flow rates (ml/ min), pulsatility of flow, and peak flow velocity.

Compression has been found to increase the velocity in the deep veins and the pulsatility of the flow (Coleridge-Smith 1997). Ambulatory venous pressure is reduced by graduated compression and this appears to be the most important pathway for the healing of venous

leg ulcers. At microvascular level there is also evidence that fibrinolysis is enhanced by external compression (Burnand and Layer 1986).

Volumetry

Foot volumetry is a simple procedure in which the feet are placed in a temperature controlled water bath (Thulesius et al 1973). The height of the water in the bath is continually measured and any change in the height of the water is due to changes in the volume of the limb. This method can only measure the volume of the feet and lower legs. Patients with ulcers may be difficult to investigate due to the possibility of cross-infection by contamination of the equipment. Other methods such as air plethysmography have been developed to measure the volume of the whole leg.

The parameters measured are the volume of blood expelled during exercise and the speed with which the volume returns to a pre-exercise setting. Compression has been shown to increase the volume of blood expelled from the calf during exercise in patients with superficial venous incompetence and those with post-thrombotic insufficiency (Gjores and Thulesius 1977).

Venous pressure measurement;

This is the most relevant investigation for the study of venous ulceration because the development of venous ulcers is attributed to an elevated ambulatory venous pressure. It is an invasive technique, however, and thus is not used in large studies. Compression reduces ambulatory venous hypertension (Somerville et al 1974).

These investigative techniques have all shown that compression is palliative rather than curative and so compression devices need to be worn for as long as the venous disease is present.

1.8.4. Effects of compression on leg ulcer healing

There are numerous compressive devices used in the treatment of leg ulcers, see table 1.3

Method of applying compression	Example	Advantage	Disadvantage
Roller bandages	Crêpe, Setopress	Can be used on any shape of leg. Can apply a wide range of pressures. Effective in ulcer healing (Cullum et al 1999)	Pressure depends on application technique
Tubular bandages	Shaped Tubigrip, Tensoshape	Apply graduated pressure. Relatively easy to apply. Effective in ulcer healing as part of a multi-layer system (Cullum et al 1999)	Lack of a pre-formed heel makes pressure high at front of foot
Compression hosiery	Venosan, Sigvaris, Duomed	Can be applied by non-professionals. Last 3-6 months. Can be removed for bathing / showering. Effective in ulcer healing and recurrence (Cullum et al 1999)	Require accurate fitting. Require strength and dexterity to apply
Pneumatic sleeves / boots	Flowtron	Accelerate the healing of venous leg ulcers. (Cullum et al 1999)	Patient must rest during treatment
Rigid devices	Circ-Aid	Apply low pressures when patient is resting and high pressures when patient is active	Not widely available. No clinical evidence of efficacy
Hydrostatic devices	Fluid filled stockings	Pressure applied is directly related to patient postures – high when patient is standing and lower when patient is sitting or supine	Not widely available. No clinical evidence of efficacy

Table 1.3 Methods of applying compression

This thesis will only consider roller bandages as they are most widely used to treat venous leg ulcers. This is probably due to their low initial cost and versatility – the person applying the bandage can adapt the compression applied according both to the preferences of the patient, and to the shape of the leg, both of which may change during treatment.

The effectiveness of therapeutic interventions designed to treat or prevent an outcome is best measured in a randomised controlled trial (RCT). The quality of published trials of compression therapy is poor, with small numbers, lack of control, and poor choice of concrete end-points (Alexander House Group 1992, Cullum 1996). The nursing literature, in particular, is full of case studies and case series that often claim to demonstrate effectiveness. One problem in conducting RCTs is the number of patients needed to detect the relatively small differences in efficacy. Furthermore, the variation in bandaging skill may confound the evaluation unless a pragmatic approach is taken. The larger RCTs have largely been conducted in hospital based or specialist clinics where the patients and nurses applying the bandages may not be representative of the wider population. There is an inevitable selection of patients for trials, e.g. subjects need to be able and willing to consent to enter the trial, but the vast difference in the healing rates across areas suggests that the care in the community could be improved.

Surveys of leg ulcer care have shown that many venous leg ulcer patients in some areas were not being treated with compression bandages (Cullum and Last 1991). Crêpe (BP) and Elastocrêpe (classified by Thomas (1990) as a *support* bandage) have been used extensively in the past, with only 25% of patients receiving compression bandaging in the survey by Cullum and Last (1991).

1.8.5. Results from clinical trials

A recent systematic review summarises the evidence for compression therapies, and the comparison between different regimens (Fletcher et al 1997, Cullum et al 1999).

1.Compression versus no compression (n=267)

Six trials compared compression with no compression. Three trials (Kikta et al 1988, Rubin et al 1990, and Sikes et al 1985) compared Unna's boot (a paste-impregnated bandage overlaid with a compression bandage) with a dressing. All found that the Unna's boot healed a higher proportion of ulcers although this was not statistically significant in the trial by Sikes et al. A further three trials (Taylor et al (unpublished), Charles et al 1991, and Eriksson et al 1984) compared other compression regimes with either a dressing (Eriksson et al), or 'usual non-compression treatment' (Taylor et al, and Charles 1991). Despite the trials being small, it can be seen that the trend is towards more rapid healing with compression. Given the results from these studies it is no longer acceptable to evaluate treatment for patients with venous leg ulcers without the concurrent application of compression, or to withhold compression from patients with venous insufficiency and adequate arterial supply.

The next question of interest, however is whether all compression regimens are equally effective? It would be relatively easy to answer this if there were standard regimens used in the clinical trials. In the recent systematic review, however, it was found that there were 21 RCTs describing 27 comparisons. The key comparisons were:

- multiple vs. single layered systems
- elastomeric vs. non-elastomeric systems (elastomeric vs. non-elastomeric)
- four layer vs. 'short-stretch' systems
- four layer vs. other high compression systems.

2.High compression multiple layers versus single layers (n=280)

Three trials report comparisons between 4-layer high compression and a single layer method of applying compression. The two smaller trials, Colgan et al (1997), comparing 4-layer compression bandaging with Setopress, and Kralj et al (1997) comparing it against Porelast, demonstrated no significant difference between the two treatments. The larger trial (Nelson

et al 1995), which compared it with a Granuflex bandage, demonstrated that the 4-layer bandage was more effective at healing leg ulcers. Combining these trials in a meta-analysis, Fletcher et al (1997) showed that the odds ratio for healing in a four-layer bandage was 2.2 (95% confidence interval 1.3 - 3.5). This indicates that the chances of healing in a 4-layer bandage are more than twice those of healing in a single-layer bandage. This may be due to the reluctance of nurses to apply similar pressures with a single layer of bandage on to unprotected skin compared with the application of three layers of compression over a wool-padding layer in the 4-layer system. A trial comparing a three-layer bandage and a single layer bandage did not demonstrate any difference between the treatments but in fact no patients healed in this trial (Travers et al 1992).

Comparing high compression systems

Elastic versus inelastic bandages (all multi-layers) (n=273)

Three studies compared elastic layered regimens with inelastic layered regimens (Northeast et al 1990, Callam et al 1992, and Gould et al 1997). All three trials showed higher healing rates in the elastic group. Combining these trials in a meta-analysis showed that the odds ratio of healing with elastic versus non-elastic bandaging was 2.2 (95% confidence interval 1.4 to 3.7) (Cullum et al 1998).

Unna's boot + bandage vs. stockings (n=74)

Two trials compared the effectiveness of Unna's boots with compression stockings. Hendricks and Swallow (1985) found no difference in healing rates but Horacova and Partsch (1994) found a significantly higher healing rate using a combination of a Thrombo stocking worn day and night, and a Sigvaris stocking applied during the day (Odds ratio 4.9, 95% CI 1.3, 18.3).

Four layer vs. 'short-stretch' bandages (n=120)

Three small studies compared 4-layer bandages with either an Unna's boot (Knight and McCulloch 1996) or a short-stretch system using Comprilan (Duby et al 1993, London and

Scriven). There was no difference in healing rates between the two systems. As only 120 patients were in the latter comparison this may represent lack of evidence of benefit rather than evidence of equivalence.

Four layer vs. other multi-layer high compression systems (n=285)

The original Charing Cross 4 layer bandage has been compared both to a kit that provides the constituent parts (McCollum et al 1997) and a regimen designed to provide the same padding and compressive characteristics using materials available on prescription (Wilkinson et al 1997). There was no significant difference in healing rates in these two studies. Another small trial compared a 4 layer regimen with a novel 4 layer system, made from 3 bandages and a compression sock, all available on prescription. It also found no difference in healing rates (Colgan et al 1996).

1.8.5.1. Conclusion

High compression is both effective (Fletcher et al 1997) and cost-effective (Taylor et al, cited in Cullum et al 1999) and is therefore recommended for patients with venous ulceration.

The quality of many trials in this area is poor with inadequate sample sizes, follow-up periods and comparison groups. Many did not describe how patients were allocated to the treatment groups and whether attempts were made to conceal the allocation prior to randomisation. Lack of allocation concealment prior to randomisation may inflate the effect size (Schulz et al 1994).

Many of the trials did not describe the method of bandage application (figure of eight, spiral etc.), the bandage overlap and tension, or the level of training of the applicator. This is an important omission as techniques, skill level and frequency of application influence the pressures generated by the bandage (Barbenel and Sockalingham 1990, Stockport et al 1997, and Logan et al 1992).

Despite the poor quality of studies, it is possible to conclude that compression is effective, and that high compression is probably more effective than low or medium compression. It is

not possible, however, to identify any one regimen as being consistently more effective than appropriate comparators, nor to identify an optimal compression profile. Given the cost of leg ulcer treatment, in terms of quality of life, nursing time, and dressing and bandaging materials, it is essential that high quality comparisons incorporating quality of life and cost effectiveness aspects be conducted.

The optimisation of compression therapy depends on selecting the appropriate bandage for the patient and applying it skilfully. Bandage selection relies on having information about performance criteria e.g. magnitude and duration of pressure, response to patient activity, and ability to exert pressure after laundering. Skilled bandage application is also required and the few studies that have investigated bandaging skill have reported a poor level of skill (Millard et al 1986, Logan et al 1991).

1.8.6. The Optimum Bandage Pressure

Optimal bandage pressure profiles have been suggested from experiments using the sequential compression devices. Nicolaides et al (1980), found an optimal increase in femoral venous blood velocity when the pressures at the ankle, calf and thigh were 35, 30 and 25 mmHg, (4.67, 4.0, and 3.33 kPa) respectively. These experiments, however, were not undertaken in people with venous insufficiency and it is unlikely that these findings can be directly applied to leg ulcer patients.

The optimum pressure profile is most commonly described as a pressure of 40 mmHg at the ankle, reducing up the leg towards the calf (Horner et al 1980, Jones et al 1987, Stemmer et al 1980). The recommended magnitude of pressure generated at the ankle, and the amount of graduation, however do not appear to have been determined through systematic investigation. The 'optimal' pressure needed to treat venous leg ulcers is not agreed internationally, those recommended by Stemmer et al (1980), for example, being up to 40% higher than the UK drug tariff, see table 1.4.

Clinical indications	Drug Tariff	Stemmer et al
Superficial or early varices (varicose veins)	14-17	18-21
Moderate varices, ulcer treatment and prevention, mild oedema	18-24	25-32
Gross varices, post thrombotic syndrome, gross oedema, ulcer treatment and prevention	25-35	36-46
Severe lymphoedema		35-50

Table 1.4 Recommended ankle pressure (mmHg) Thomas (1990)

This difference may be partly a reflection of the preference for higher pressures in some countries, and of the different techniques used to measure the performance of garments and bandages: the Hohenstein technique in Europe, the Hatra method in the UK and the Instron method in the United States. These methods measure tension, not pressure, and use Laplace's formula to derive the pressure from the tension.

A literature search was undertaken to identify randomised controlled trials in which the pressure beneath compression bandages was reported. The specialised trials register of the Cochrane Wounds Group was searched reports of randomised controlled trials up to Jan 2001. Trials were included if they reported that the ulcers were venous in origin, they reported the use of compression bandages, and reported measurements of sub-bandage. Only three trials reported sub-bandage pressures (Blair et al 1988, Danielsen 1998, Charles 1991). They reported the sub-bandage pressures at three different sites near the ankle, used two pressure measurement systems (the Oxford Pressure Monitor and the Medical Stocking Tester), and different subject postures (supine, 'dependent' and 'resting'), and therefore the results could not be directly compared.

Table 1.5 describes the compression bandages, measurement sites and pressures reported in these trials.

Study	Bandage	Site – distance above MM / LM	Initial SBP	SBP 24 hours	SBP at 7 days	Posture	Method of pressure measurement	Notes
			Units = mmHg					
Blair	Adhesive plaster	2cm MM	30	10	–	No info	MST	Different people applied these two bandages
	Four-layer	2cm MM	42	40	–	No info	MST	
Charles	Short-stretch	2cm LM	42	32	34	Resting	OPM	All bandages applied by one nurse
Danielsen	Long-stretch	4cm MM	31	30	28	Supine	OPM	Long-stretch bandages applied by study nurse; short-stretch bandages usually applied by community nurse
	Short-stretch	4cm MM	29	19	–	Supine	OPM	
	Long-stretch	4cm MM	39	41	38	'Dependent'	OPM	
	Short-stretch	4cm MM	36	26	–	'Dependent'	OPM	

KEY: SBP = Sub-bandage pressure
MM = medial malleolus
LM = lateral malleolus
OPM = Oxford Pressure Monitor
MST = Medical Stocking Tester

Note – none of the investigators reported calf pressures

Table 1.5 Sub-bandage pressures recorded in trials of compression therapy for venous leg ulcers.

Blair et al (1988) stated that patients initially treated with the adhesive plaster bandage failed to heal, but that changing them to treatment with the four-layer bandage resulted in them healing in an average of 6.3 weeks. As there was no concurrent control group and different nurses applied the two bandage regimens, one cannot attribute the increased healing solely to the increased pressure generated by the four-layer bandage.

Charles (1991) does not report the sub-bandage pressures in her control group and therefore one cannot conclude whether pressures were different between bandages.

Danielsen et al (1998) reported that 50% of the patients in the long-stretch group and 36% in the short-stretch group healed with 6 months. Although the initial sub-bandage pressures are similar, at around 31mmHg (supine) or 30 mmHg (dependent), the fall off in pressures at one day is significantly higher with the short-stretch bandage than the long-stretch bandage. They conclude that elastomeric bandages are more effective at healing venous ulcers than non-elastomeric bandages but the trial was rather small (43 patients), choice of bandage was not the only difference between the two groups (as the person delivering care also differed), and the two groups were not well matched for ulcer area at randomisation, therefore it is unclear whether the finding of a higher healing rate in one group is due to chance.

As none of these authors reported the pressure at the calf it is not possible to calculate whether there was any graduation in pressure from the ankle towards the calf. We cannot, therefore, determine whether this is a characteristic of an effective compression regimen. It seems reasonable to assume that an effective compression regimen would not have a higher pressure at the calf than at the ankle, as this tourniquet effect might be expected to reduce venous return, but there appears to be no reliable evidence for a graduated pressure profile.

In conclusion, therefore, there is no research from in vivo investigations of venous return in people with venous insufficiency, or from trials comparing effectiveness of difference compression regimens, to determine whether there is a level of ankle pressure for optimal reduction in intra-venous pressure, i.e. the ideal ankle compression, and whether this pressure should reduce towards the calf, and if so, by how much.

In the absence of any robust evidence establishing the optimal pressure profile, a generous definition of acceptable pressures will be used by combining the Thomas (1990) and Stemmer et al (1980) recommendations; ankle pressure between 25 and 46mmHg. With regards to the amount of graduation in pressure required between the ankle and the calf, although stocking standards (BS 6612:1985) require a graduation of 70% between ankle and calf, the only empirical evidence is that a dip in pressure, with the area above the pressure dip acting like a tourniquet, reduces venous function (Van Gerwen, 1994).

1.8.7. Treating the Whole Person

A number of co-existing conditions can complicate leg ulcer treatment. Poor mobility, arthritis, degenerative musculo-skeletal disorders, autoimmune disease, infection, obesity, non-compliance and other psychosocial disadvantages seem to be implicated (The Alexander House Group 1992). There are no trials of interventions aimed at treating these conditions in leg ulcer treatment (search date December 1999, sources: CINAHL, Cochrane Controlled Trials Register).

1.9. Prevention of Ulceration

Primary venous disease may be preventable through adoption of effective methods of prevention of deep vein thrombosis, e.g. anti-thrombotic agents and compression hosiery, and by preventing leg fractures. Prevention of DVT is already a key area for research and implementation as the thrombi in the legs can 'throw off' clots that progress to the lung, causing a pulmonary embolus, and in some cases, death.

Secondary prevention, attempting to ameliorate the effects of venous disease, e.g. varicose veins, or post thrombotic syndrome, is not practised universally. It is unclear how efficient it would be to intervene to prevent ulceration given the high prevalence of venous disease. Bobek et al (1966) reported a prevalence of venous disease of 11.4%, and given that only around 10% of people with venous disease will progress to ulceration, then the 'number needed to treat' (NNT) may be large. The number needed to treat can only be calculated from estimates of the incidence of first ulceration with and without compression hosiery. There are no estimates of the incidence of ulcers either with or without preventive measures.

The Edinburgh Venous Study is attempting to study the progression of venous disease and whether it is possible to identify patients who will progress to ulceration. The study will follow up a cohort of patients for 5 years, with assessments of their venous disease, demographic details and risk factors. It will also provide estimates of the incidence of ulceration (Evans et al 1997).

The re-ulceration rate has been reported as high as 67% in one year (Monk and Sarkany 1982).

1.9.1. Compression

A search for RCTs of compression hosiery or bandages for the prevention of ulcer recurrence was conducted in December 1999, primary sources Cochrane Library, Medline, Embase, Cinahl. It identified no trials comparing compression hosiery versus no compression (Nelson et al 1999). It identified two RCTs comparing different types of compression. One trial compared two brands of stockings which are designed to apply 18-25 mmHg compression at the ankle, known as Class 2 stockings, in 166 patients and found no difference in recurrence rates (Franks et al 1995). A large trial (300 patients) compared recurrence rates using high compression hosiery, capable of applying 25-35 mmHg at the ankle (known as Class 3) with those in patients wearing moderate compression hosiery, Class 2 stockings (Harper et al 1995). It reported a relative reduction in recurrence at three to five years of 34% associated with Class 3 stockings compared with Class 2 stockings, however, compliance was higher with the Class 2 stockings.

Ulcer recurrence depends on more than the class of compression hosiery used. Harper et al (1995) and Franks et al (1995) reported that patient non-compliance is a strong predictor of recurrence. Dale and Gibson, (1989), stress that accurate fitting of compression hosiery is essential. Van Gerwen (1994) has demonstrated that hosiery with a band of low pressure along its length leads to increased oedema. Peat (1988) points out that the level of compression exerted on a limb by a stocking will depend on its placement on the leg. The fabric should be evenly distributed along the length of the limb in order to prevent pressure peaks and troughs.

1.9.2. Systemic drugs (stanozolol, rutosides)

A search for RCTs of systemic drugs for the prevention of ulcer recurrence was conducted in December 1999, primary sources Cochrane Library, Medline, Embase, Cinahl. It identified two RCTs and concluded that there was no evidence that stanozolol or rutoside decreased recurrence rates. One trial, of stanozolol versus placebo in 60 patients, found no significant difference in recurrence rates (17% *v* 20%) (McMullin et al 1991). The other trial, of rutoside versus placebo in 138 patients, found no significant difference in recurrence rates (32% *v* 34%) (Wright et al 1991).

1.9.3. Vein surgery

A search for RCTs of vein surgery for the prevention of ulcer recurrence was conducted in June 1999, primary sources Cochrane Library, Medline, Embase, Cinahl. It identified one poorly controlled RCT (30 patients) comparing surgery plus compression hosiery versus compression hosiery alone for prevention of recurrence (Stacey et al 1988). It reported a reduced rate of recurrence when surgery was carried out in addition to the use of elastic stockings (5% *v* 24%; relative reduction in recurrence 79%, 95% CI 20% to 97%).

1.10. Summary

This chapter has summarised the epidemiology of venous ulceration, the possible theories for the genesis of venous ulcers and the treatments used in their prevention and treatment, the mainstay of therapy being compression.

2. Measurement of Sub-Bandage Pressure

2.1. Introduction

Chapter 1 has described the problem of venous ulceration and its management; the most important method of treatment being compression therapy. The magnitude, duration and distribution of pressure applied to a limb can be measured in order to:

- Determine how bandage characteristics change, e.g. over time, due to posture changes
- Investigate the in vitro / in vivo pressures achieved and the bandage characteristics which may impact on difference in performance, e.g. do adhesive and cohesive bandages exert the same pressure as those without special surface treatments?
- Examine the ability of operators to apply bandages with appropriate pressure profiles
- Examine the dose response between the magnitude and distribution of compression and effectiveness of bandages and stockings in prevention and treatment of venous ulceration.

This chapter will describe some methods for measuring interface pressure and their characteristics.

2.1.1. The Ideal Pressure Measurement System

The ideal transducer has the following characteristics:

- fixed (and known) relationship between input and output
- high sensitivity
- accurate
- show no hysteresis or time dependence
- insensitive to other forces
- insensitive to interface conditions (temperature, humidity, curvature)
- responsive to changes in pressure (rapid transient response time – in order to accurately reflect pressure changes while patients move)
- inexpensive
- easy to use
- safe to use on human subjects

No transducer is available to meet all these demands and one must choose that system which meets the priority requirements according to the particular application. For the measurement of pressures in a clinical setting the priority requirements are:

- safety
- fixed (and known) relationship between input and output,
- ease of use
- inexpensive

The presence of any sensor or transducer at a measurement site may affect the pressure at that point. For measurements of pressure to be considered valid, this effect must be minimised. Both sensor diameter and thickness will influence the readings. Sensor diameter needs to be small in order to resolve pressure gradients. The sensor needs to be thin, as protruding sensors influence the pressures at the interface. Appoldt et al (1969) reported that a protruding sensor overestimated interface pressures by as much as 300%. Ferguson-Pell (1977) discusses the shape of sensor required to resolve pressure with

The pressure under a thin plate is calculated from the tension acting normally on that plate and its area.

The normal tension Tr, varies according to the tension acting tangentially to the leg and the radius of curvature of the leg.

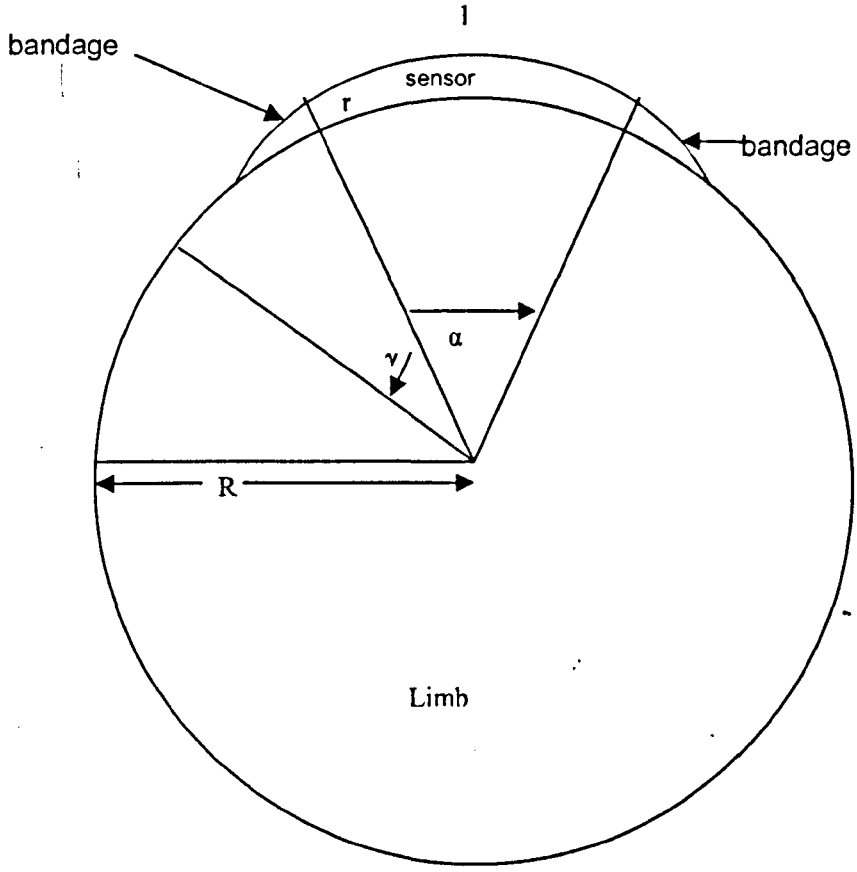


Figure 2.1 Stylised cross-section of a limb covered by a compression garment, with sensor in position

minimal influence on interface pressures. He calculated that in order to be able to resolve pressures where pressure gradients are high (around 0.2 kPa/mm) e.g. for seated subjects, the maximum sensor diameter is 2.5mm. Ferguson-Pell (1977) calculated the thickness of the sensor necessary for minimal disruption of pressure profiles. He concluded that a 0.25mm thick sensor was required to have a minimal impact on the pressure recorded. Ferguson-Pell (1977) used the term 'aspect ratio' to describe the thickness / diameter ratio. An aspect ratio of 1:10 was acceptable for interface measurement, as it was associated with a minimal impact on the measurements at the interface. As Ferguson-Pell was working at high pressure gradients then it is reasonable to assume that the sensor size of 2.5mm is a lower limit for pressure resolution. It was assumed that using his calculations of a 1:10 aspect ratio would minimise the error in the measurement of sub-bandage pressures.

Vinckx et al (1990), however, also calculated the impact of a flat plate pressure sensor at a skin/garment interface and they do not agree with Ferguson-Pell's assertions that an aspect ratio of 1:10 minimises perturbation. They calculated the 'pressure perturbation coefficient' (C_{pp}) for a thin plate transducer. The ratio of the pressure that would be exerted by the garment alone (calculated by Laplace's Law), and the pressure exerted by the thin plate sensor placed beneath the garment. The pressure is changed as the area of contact is reduced and the radius of the garment over the sensor is changed, see Figure 2.1.

For a thin plate with these dimensions:

l = length,

d = thickness of the sensor,

α = angle subtended by the sensor,

t = thickness of the protruding part of the sensor (d-indentation depth)

R = radius of the limb

$$\cos\gamma = \frac{R}{R+r}$$

$$\gamma = \arccos\frac{R}{R+r}$$

Normal tension when there is no perturbation = $\dfrac{T}{\sin\dfrac{\alpha}{2}}$

Normal tension when the interface is perturbed = $\dfrac{T}{\sin\left(\dfrac{\alpha}{2}+\gamma\right)}$

Therefore the perturbation coefficient Cpp = $\dfrac{\sin\left(\dfrac{\alpha}{2}+\gamma\right)}{\sin\left(\dfrac{\alpha}{2}\right)}$

$$\gamma = \arccos\frac{R}{R+r}$$

Therefore

$$\text{Cpp} = \frac{1+\sqrt{2(r/R)+\left(\left(\dfrac{r}{R}\right)^2/\tan\left(\dfrac{\alpha}{2}\right)\right)}}{1+(r/R)}$$

As r is much smaller than R, let r/R approximate zero

$$\text{So Cpp} = 1+\frac{1.41\sqrt{\dfrac{r}{R}}}{\tan\dfrac{\alpha}{2}}$$

The length of the sensor, l = Rα

The aspect ratio of the sensor, d/l = d/(Rα)

$$Cpp = 1 + \left(1.41 \sqrt{\left(\frac{r}{D}\right)} * \sqrt{\frac{d}{l}} * \left(\frac{\sqrt{\alpha}}{\tan\frac{\alpha}{2}} \right) \right)$$

$$= 1 + 1.41 f(a) \times \sqrt{(t/D) \times (d/l)}$$

Where $f(a) = \dfrac{\sqrt{a}}{\tan(a/2)}$

The maximum perturbation occurs when r=d, i.e. the sensor does not indent into the leg

$$Cpp\ max = 1 + 1.41 * f(\alpha) \sqrt{\frac{d}{l}}$$

If α is small, say around 10°, then the value of Cpp varies between just over 1 and 5 for ratios of t/R from 0.1 to 0.0001. A ratio of t/R of 0.1 means that the thickness of the protruding part of the sensor should be 10% of the radius of the limb (around 5cm at the ankle), i.e. a maximum thickness of 5mm. Note that this equation includes the radius of the limb as a value influencing pressure perturbation.

The above expression can be rewritten to provide an estimate of Cpp as a function of the sensor aspect ratio (d/l).

$$Cpp = 1 + 1.41 f(a) \times \sqrt{(t/D) \times (d/l)}$$

The Cpp depends both on the aspect ratio (d/l), and on the ratio of the thickness of the sensor to the protrusion of the sensor to the dimension of the limb. When simulating the

situation where a pressure sensor is placed beneath a garment, R=30mm, d=1.5mm, l=14mm, a = l/R = 0.47 (and assuming no indentation of the sensor into the tissues)

$$Cpp(max) = 1 + 1.41 f(a) \times \sqrt{(1.5/60) \times (1.5/14)}$$

= 1+(1.41*2.85*0.36)

= 2.44

This means that the maximum error expected is 144%. If the sensor does indent into the limb then this error is reduced.

It is not known what impact the application of padding over the whole circumference of the limb will have on the error introduced by the sensor. One or two layers of padding would cover the sensor and the load transference characteristics of this material may influence the error in the readings at the surface. It would seem sensible to regards the pressure readings as approximations. As the errors are functions of the limb and sensor dimensions one would still be able to make comparisons between pressure readings taken at the same point on the same limb over time, assuming no creep (no change over time in deformation / extension under stable loading).

2.2. Evaluating pressure sensors

The selection of transducers for particular applications is not straight forward, as investigators will require different performance characteristics for different situations. The use of different methods of evaluation also leads to further complications. Some workers state that the conditions for evaluation should bear close resemblance to the clinical situation (Reddy, 1984) while others do not attempt to simulate the clinical environment (Barbenel and Sockalingham, 1990). Reddy et al (1984) placed a sensor between gel and foam surfaces, applied a known force over a known area. They assumed a uniform pressure distribution over the interface, calculated the applied pressure (P = F /A) and compared this value with that measured. The recorded pressure exceeded the nominally applied pressure, due either to preferential loading of the sensor or a non-uniform

pressure distribution. The authors concluded that the gel / foam interface needed to be improved as further studies showed that the pressure sensor results correlated well with sub-cutaneous catheter readings. Interface properties, such as tissue stiffness (due to oedema and / or lipodermatosclerosis), are likely to vary with site and subject, thus confounding the search for a representative interface. A simpler approach is to employ hydrostatic calibration; either in a pressurised chamber (Ferguson-Pell 1977) or a column of water (Barbenel and Sockalingham, 1990). The latter approach has the advantage that one need not attempt to represent the interface. Ferguson-Pell suggests that such calibration methods are more suitable for comparative pressure measurements rather than absolute measurements. Allen et al (1993) evaluated the Talley SA500 pressure evaluator (with 28mm and 100mm sensor pads) and a fluid filled bladder system. All systems over-estimated the interface pressures and this was particularly problematic at heterogeneous surfaces. The error was proportional to the loading pressure, lowest errors being recorded with the Talley 28 mm sensor (12± 1%, equivalent to ± 0.5 mmHg). Given the problems in describing the range of leg characteristics necessary to develop a suitable model, viz; radius of central core, deformability of tissue overlying the core, variation in the radii of curvature of the leg horizontally and vertically, it was decided to calibrate the system hydrostatically. Furthermore, Barbenel and Sockalingham (1990) had previously ascertained that there was reasonable agreement between the hydrostatic calibration and the pressures applied by a sphygmomanometer.

2.3. Pressure measurement systems

The oldest systems capable of representing pressure levels were mechanical; e.g. Lindan's bed of nails (1965) or transparent support surfaces. The bed of nails consisted of a board through which nails, supported by springs, protruded. A body lying on the bed of nails would deflect the nails by a distance proportional to the weight of the body. These gave a crude quantitative impression of pressure levels. The transparent support surface, e.g. lying on a sheet of glass, demonstrated qualitatively where blood was expelled from

sub-cutaneous tissues under high pressure, as this tissue appeared pale. This technique was useful for allowing areas of high pressure to be visualised but provided no numerical estimate of pressure, and lacked reproducibility and sensitivity.

Both systems were not suitable for the measurement of pressure at other surfaces, e.g. beds, mattresses and seat cushions.

The most commonly used systems are pneumatic or electrical and these will be considered with reference to the characteristics of an 'ideal transducer'.

2.3.1. Pneumatic pressure measurement

These pressure measurement systems use a fluid filled sensor to measure pressure. The transmission fluid can be a liquid or a gas. They have been used for many years to measure interface pressures in pressure sore research and have been adapted to measure sub-bandage or sub-stocking pressures.

The simplest device, a Denne gauge, consists of an air filled bladder connected to a mercury sphygmomanometer.

A modification, the Talley or Scimedic system, has electrical contacts on the inner surfaces of the air bag or bladder. When the walls of the air-filled bladder are in contact, the electrical contacts meet, thus completing a circuit. Inflating the bladder with air until the inflation pressure is greater than that acting to compress the bladder separates the contacts and the circuit is broken. A light bulb is illuminated when the circuit is broken and a sphygmomanometer shows the air pressure and provides the air pumping mechanism. It is assumed that interface pressure equals the air pressure when the circuit light is extinguished. There are two sizes of sensor, circular with a diameter of 28 mm and oval with dimensions 90 x 100 mm. The smaller sensor has one electrical contact and thus measures pressure at one point only. The larger sensor has a grid contact and the registered pressure is said to be equal to the greatest pressure in the measurement area. This sensor has been widely used and thoroughly evaluated. Reddy et al (1984) reported good correlation between interface pressures measured with the Scimedic sensor and a

sub-cutaneous reading. It is difficult to make more than one reading with this system and developments from this system use an array of cells.

The Medical Stocking Tester (MST) is used to measure sub-stocking pressures along the leg (van den Berg 1982). It consists of a long bladder with electrical contacts at points along its length corresponding to the ankle, gaiter, calf and thigh. A pump inflates the bladder until contact is lost between the contacts along the leg. The pressures at which contact was lost along the leg length are displayed. Reports suggest that it is not easy to use, prone to failure and the pressure measurements are made at fixed sites due to the construction of the sensor strip (Stacey et al 1991).

The Oxford Pressure Monitor (Bader et al 1982) uses a microprocessor to control the sequential inflation of an array of cells. The pump controller measures the pressure in each cell as air is pumped in and the point at which the measured pressure differs from the expected pressure is registered, as at this point the cell is just beginning to inflate. This system is a definite advance from the simple sensor but the measurements are still intermittent rather than continuous. The cells remain deflated throughout and thus do not disturb the interface pressure profile to the same extent as the fluid filled sensors. The measurement frequency for a single cell is around 2 Hz, but for the array of 12 cells, this falls to one per minute (Bader and Hawken 1986). The overall accuracy of this system has been reported as 3% of full scale (250 mmHg or 33 kPa), although some users have reported errors of 12% of load (Allen et al 1993).

2.3.2. Electrical pressure transducers

These devices use the property of materials in which an applied force leads to a change in electrical characteristic, e.g. resistance, capacitance. They have the advantages of providing a continuous output and being small but each type has specific drawbacks.

2.3.2.1. Capacitive devices

Ferguson-Pell (1977) used a capacitive transducer that was very small and thin, the dielectric being a thin layer of adhesive. This conformed to his requirements for a small aspect ratio but Naismith (1980) later reported that the sensor was sensitive to changes in the radius of curvature of the measurement site. Patel et al (1989) describe a sensor of four mica capacitors arranged in parallel used to measure pressures of up to 1300 kPa. They report a maximum non-linearity of 8% and a worst-case repeatability of 7%. All capacitive devices exhibit hysteresis, therefore the output in response to an ascending pressure differs from that of a decreasing pressure.

Generally, capacitive transducers show history dependence, hysteresis, shear and temperature sensitivity, and therefore it is difficult to obtain an unambiguous measurement. They also require complex conditioning circuitry, thus increasing cost.

2.3.2.2. Piezoelectric devices

Piezoelectric materials produce a charge in response to an applied deformation. They are usually limited as interface sensors by their rigidity. Wytch et al (1980) describe a polyvinylidene fluoride sensor that is flexible, thin, lightweight, tough, inexpensive and easily formed.

2.3.2.3. Strain-gauge devices

These use the fact that a pressure or force applied to the device produces a strain. The strain alters the resistance of the device and thus there is a relationship between pressure and output. Patterson and Fisher (1979) found large errors using these transducers to measure pressures between 9.5 and 47.9 mmHg. The sensors were evaluated between a blood pressure cuff and a leg and this method may have contributed to the large errors.

2.3.2.4. Force sensitive resistors

A number of devices (F-Scan, EMED, Iscan) use a thin disposable pressure sensing sheet, consisting of a network of resistors printed with conductive ink. This can be shaped and trimmed, for example, to form an insole for measuring plantar pressure, or trimmed to measure pressure at a discrete point. For the F-Scan, for example, each contact point is less than 60μm thick and consists of ink in a Mylar substrate. The ink contains conductive particles suspended in a polymer-based binder. As pressure is applied, the particles are brought closer together, and electrical resistance through the ink is reduced. Current at 70 μA is cycled through the sensor every 0.02 sec. A microprocessor records the output from each row and column in a systematic fashion for 200 cycles (4 sec). F-Scan software converts the output into pressure. Mann et al (1997) report a mean difference between repeated measures of 5% for an applied mass of approximately 7kg. Woodburn and Helliwell (1996) reported poor repeatability of the in-shoe F-Scan; it consistently overestimated applied pressures.

These systems do have the advantage of being very thin and can record high rates of pressure change. When used as an in-shoe system the thinness of the sensors may mean that they are prone to wrinkling and bending. Ahroni et al (1998) suggests that the force-sensitive resistors may be prone to creep (increase in recorded load over time despite no increase in actual load) and their use over 7 days has not yet been established. Hedman (1991) reported a non-linear relationship between input and output, the presence of hysteresis, and viscous relaxation of the force sensitive resistor, meaning that complex conditioning circuitry would be required, thus increasing the cost of the system.

In addition, Smith and Hudson (1994) report that output from the force sensitive resistors varied after 'recent' use, with increases in temperature, and that there was a significant settling time for the 0.2inch and 0.5 inch diameter sensors. They also report that the output from experiments with an increasing load differed from those in which the load decreased values for increasing load (hysteresis) but the extent of error is not quantified.

They concluded that they should not be used for accurate or dynamic pressure measurements.

2.3.2.5. Hybrid devices

Van-Pijkeren et al (1980) described a pressure measurement system that used both pneumatic and electrical components. From the descriptions above it can be seen that the pneumatic sensors have the advantages of being conformable, thin, small, unaffected by interface environment and inexpensive. The electrical transducers that are placed at the measurement site have numerous disadvantages and yet they offer continuous accurate output. Thus, a combination of a pneumatic sensor to transmit the pressure to the measuring device might combine the best features of both systems. Barbenel and Sockalingham (1990) used a similar device to measure sub-bandage pressure and they concluded that the device showed good linearity, reproducibility, and accuracy, is conformable, shows little hysteresis, and is inexpensive. It also provides a continuous output and so this system was chosen for use in this study. The next chapter will describe further evaluation of the system and then details the other methods used in the study.

The Strathclyde Pressure Monitor (SPM) was chosen for use throughout the study because it is inexpensive, it can record dynamic pressures over long periods, and there was in-house expertise in its instrumentation. In addition, the ability to store the output of this transducer in a commercially available, light, compact data logging system, meant that sub-bandage pressure of patients could be monitored while they went about their normal activities.

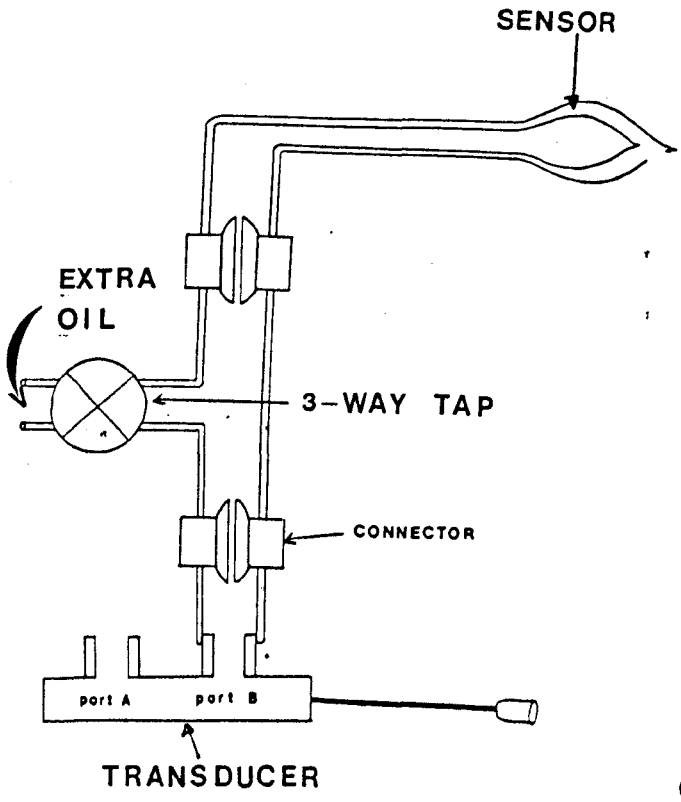


Figure 3.1 Stylised cross-section of pressure transducer, sensor and connecting tubing

3. The Strathclyde Pressure Monitor

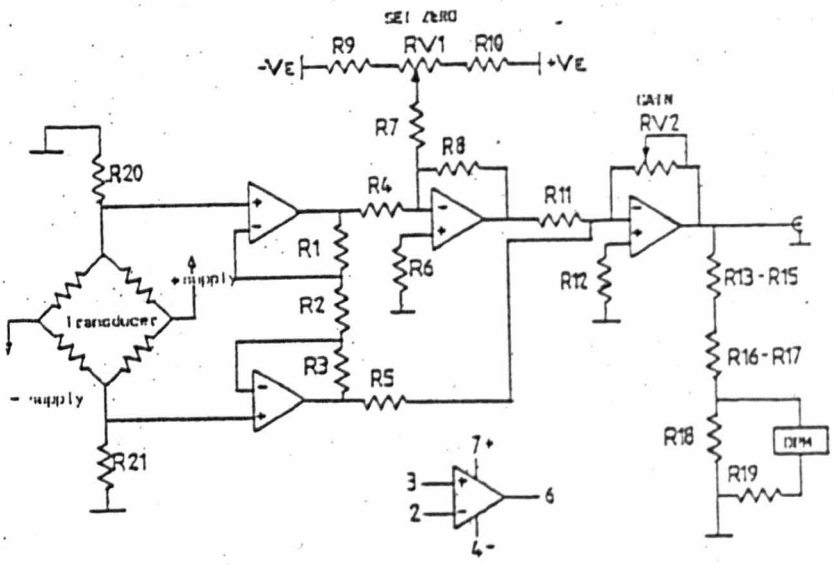
The Strathclyde Pressure Monitor, is a hybrid system that uses a fluid to transmit interface pressure to a transducer placed remotely from the site of measurement (Barbenel and Sockalingham, 1990). The fluid filled sensor is conformable, thin and small. It transmits the pressure from the measurement site, via a connecting tube, to the piezo-resistive transducer. The signal-conditioning unit can be connected to a digital display, personal computer interface or a commercially available data-logger.

3.1. The Transducer

A small, inexpensive, commercially available piezo-resistive device (Sensor Technics, UK), was chosen. The SCX05DN transducer has a suitable measuring range, 0-34.5 kPa (0-260 mmHg). The sensing element is an integral silicon diaphragm with four ion-implanted resistors in a Wheatstone bridge configuration. Flexure of the diaphragm converts the applied pressure into an electrical signal. It is internally calibrated, and does not require additional temperature compensation circuitry for temperatures up to 70°C. The transducer is differential and has two inlet nozzles or ports, port B for the pressure to be measured, and port A for the datum or reference pressure, see figure 4.1. Port B is filled with a fluid which transmits the pressure from the sensor to the sensing element. Port A is a reference port which is left open to atmosphere so that the recorded pressures are relative to atmospheric pressure.

Figure 3.1 - Transducer set up 1

STRATHCLYDE PRESSURE MONITOR



COMPONENT LIST

R1, R3	=	100K
R2	=	1K
R4, R5, R6, R8, R11	=	10K
R7, R12	=	4.7K
R9, R10	=	6.8K
R13, R14	=	3.9m
R15	=	1.2m
R16	=	820K
R17	=	82K
R18	=	100K
R19, R20, R21	=	1m

RV1	100K	10T
RV2	10K	
D.P.M.	=	Anders Electronics
Model		D.E.M. - 2 u
De-coupling capacitors		
0.1 u		
I.C.		3140

Figure 3.2 Circuit diagram for the Strathclyde Pressure Monitor

3.2. Signal Conditioning Unit

A power supply, amplification circuitry and an output device were already designed by Sockalingham (1993) and will be briefly described here. Figure 3.2 shows the power supply that delivers 6 volts. The prototype had a single digital display and the output of several sensors could be read via a switch circuit. Later versions had more complicated circuitry as they incorporated a digital display for each transducer, a zero control, a variable gain control and the option of an external printer port. Sockalingham (1993) describes the improvements made to the system.

Figure 3.2 Power supply to transducer 1

3.3. The Sensor

This was bought in already made from Talley Medical. The sensor was formed by bonding two 0.25 mm thick sheets of polyvinyl chloride (PVC). A central area was left unbonded and this formed the sensor area. There was also a slot for the insertion of the connecting tubing. The sensor and connecting tubing were filled with the transmission fluid. The materials in the transducer, tubing and sensor bag determined the choice of transmission fluid. The transducer components required that the fluid not be corrosive, ionic or silicone based. Section 3.4 reports the results of calibrating the system with different sensor volumes / thickness. Section 3.5 reports the removal of the transducer height dependence and section 3.6 reports the influence of tubing length and transmission fluid viscosity on the performance of the transducer, particularly the ability to respond to changes in pressure.

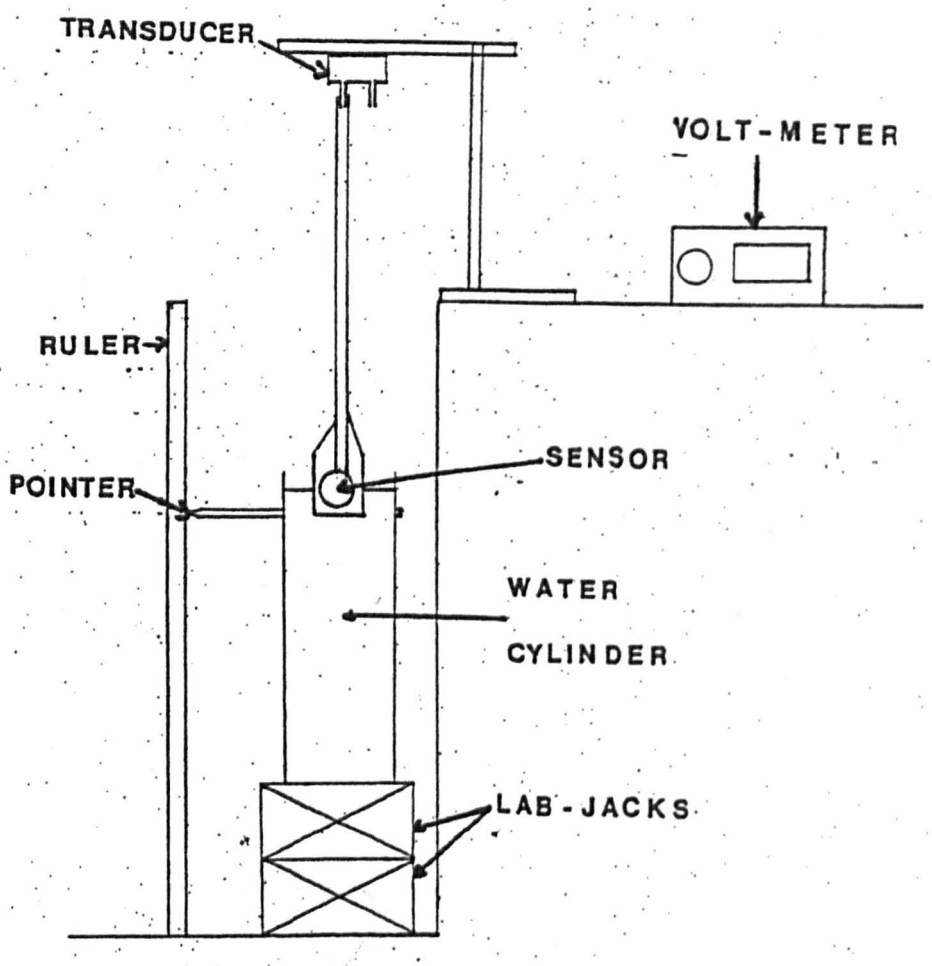


Figure 3.3 Equipment set-up for hydrostatic calibration of the Strathclyde Pressure Monitor

3.4. Calibration of the System

The system was initially calibrated hydrostatically. This does not attempt to simulate the conditions at the interface but does allow checking of stability of the calibration factor over time and in different configurations.

3.4.1. Method

The sensor was suspended vertically in a column of fluid. The height of water above the sensor and hence the hydrostatic pressure on the sensor was varied while the transducer output was recorded. Any variation in transducer output due to movement of the sensor relative to it was eliminated by fixing the transducer and suspending the sensor from it, see figure 3.3. The steps in calibration were:

1. the transducer was clamped above the laboratory bench with the sensor suspended beneath it.
2. a 10gm mass was attached with surgical tape to the leading edge of the sensor in order to prevent the sensor floating in the water container
3. a water-filled glass container positioned on a laboratory jack on the floor was positioned directly beneath the sensor
4. the transducer was lowered so that the leading edge of the sensing area was just touching the top of the water
5. the water container was raised using the laboratory jacks until the mid-point of the sensor, marked in indelible pen, was level with the meniscus
6. a flexible metal strip was taped to the container and the top edge of this was used as a pointer
7. a meter rule was placed adjacent to the glass container
8. at the point of zero hydrostatic pressure the rule was adjusted so that the top edge of the metal strip was level with the 500mm mark
9. the water container was raised by 20mm intervals up to 460 mm and the transducer output was recorded (referred to as increasing load output)

10. the water container was lowered by 20mm intervals and the transducer output was recorded (referred to as decreasing load output)

3.4.2. Results

The increasing and decreasing load outputs are tabulated for 2 of 10 data runs in Table 3.1.

	Sensor B3, 5.04 mm thickness		Sensor B4, 3.83 mm thickness	
Applied Hydrostatic Pressure (mmH_2O)	Output voltage (mV) *Increasing Load*	Output voltage (mV) *Decreasing Load*	Output voltage (mV) *Increasing Load*	Output voltage (mV) *Decreasing Load*
0	-172	-171	-172	-172
20	-172	-171	-172	-172
40	-169	-168	-169.5	-169
60	-165	-165	-166.5	-166
80	-162	-161	-162.5	-162
100	-159	-158	-159.5	-159
120	-155	-155	-156	-155
140	-152	-151	-152.5	-152
160	-148	-148	-149.5	-148.5
180	-145	-145	-146	-145.5
200	-142	-141	-142.5	-142
220	-138	-138	-139	-138.5
240	-135	-135	-135.5	-135.5
260	-131	-131	-132.5	-132
280	-128	-128	-128.5	-128.5
300	-124	-124	-125.5	-125.5
320	-121	-121	-122.5	-122.5
340	-118	-117	-119	-118.5
360	-114	-114	-115.5	-115.5
380	-111	-110	-112.5	-112
400	-108	-108	-109	-108.5
420	-104	-104	-105	-105
440	-100	-100	-102	-102
460	-97	-97	-98.5	-98.5

Table 3.1 Representative results of transducer output (mV)

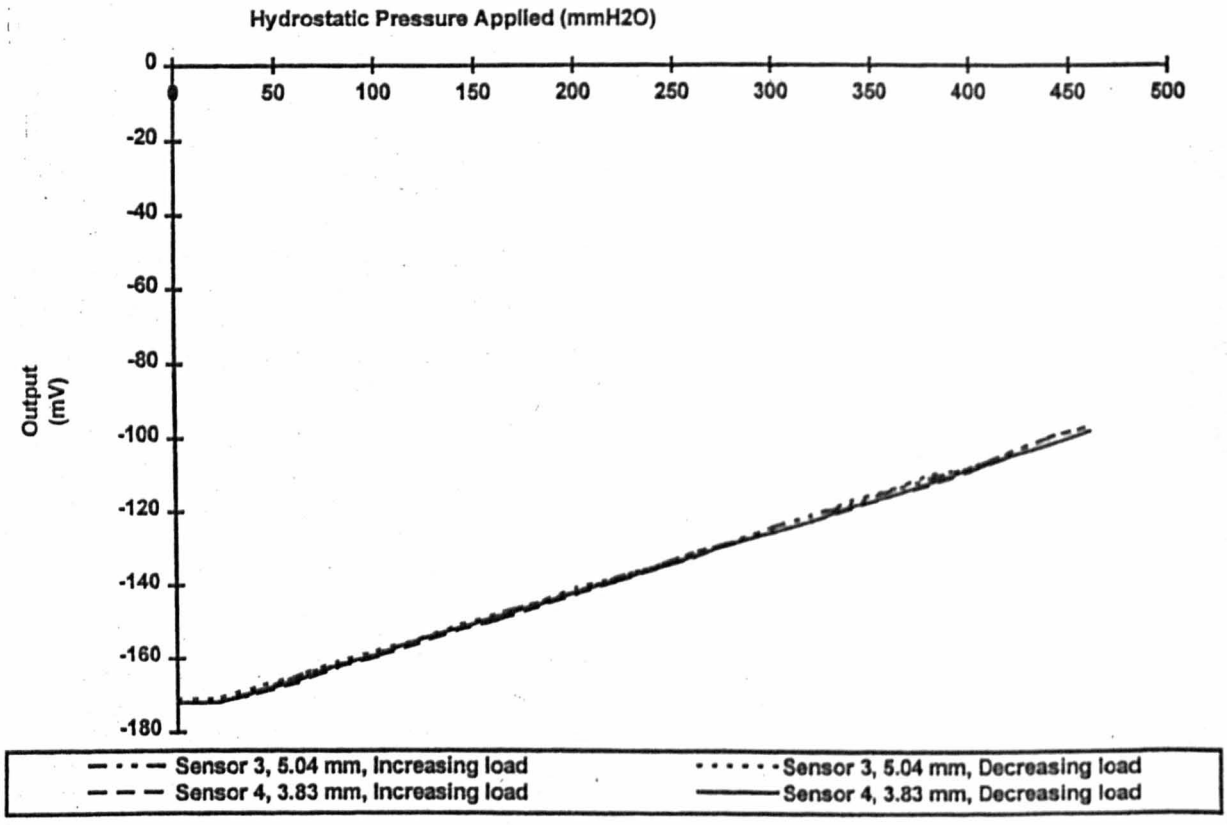


Figure 3.4 Calibration curves for two pressure sensors with different volumes

The hydrostatic pressure exerted on the sensor was calculated:

Calculated hydrostatic pressure = height of fluid * fluid density * g.

3.4.3. Analysis

The relationship between the output / hydrostatic pressure for the two sensors, table 3.1, remains stable regardless of whether the load was increasing or decreasing, I.e. there was no obvious hysteresis.

The output was plotted against applied hydrostatic pressure (mmH_20), see Figure 3.4.

Calculating the gradient of the line in figure 3.4 derived the calibration factor:

Output (mV) = hydrostatic pressure (mmH_2O) * calibration factor + k

Therefore hydrostatic pressure (mmH2O) = (output (mV) – k) / calibration factor.

3.4.4. Discussion

The transducer used in this investigation had a calibration factor which was stable over time, and was independent of direction of loading.

The limitations of this method include the height of water needed to calibrate the system up to high pressures (50 mmHg = 680 mmH_2O), whereas only 460mmH_2O loading was achievable in this experimental set up. Furthermore, the fact that the sensor was not kept horizontal meant that a pressure gradient rather than an even pressure was exerted over its surface. To overcome these problems Sockalingham (1993) devised a chamber, pressurised by air from a sphygmomanometer bulb, into which the system was placed and the electrical output was carried via contacts in the chamber wall and thus the calibration factor could be calculated. Barbenel and Sockalingham (1990) had previously confirmed that the hydrostatic calibration was similar to that obtained placing the sensor below a sphygmomanometer cuff.

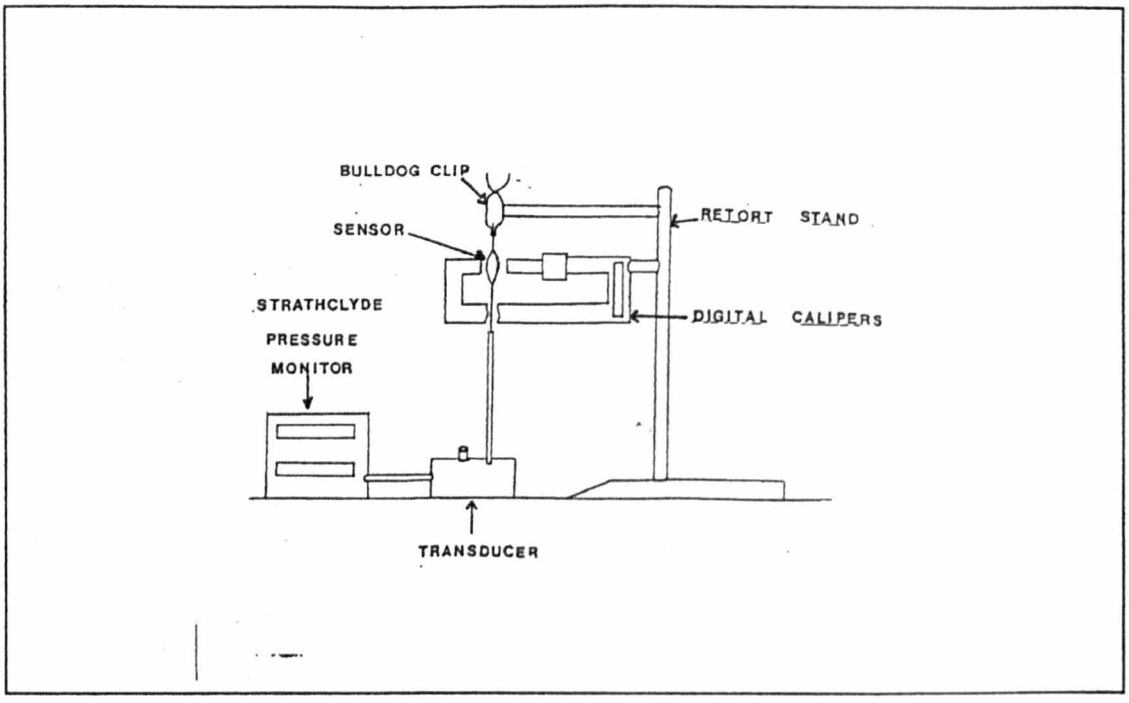


Figure 3.5a Original method for determining thickness of the sensor

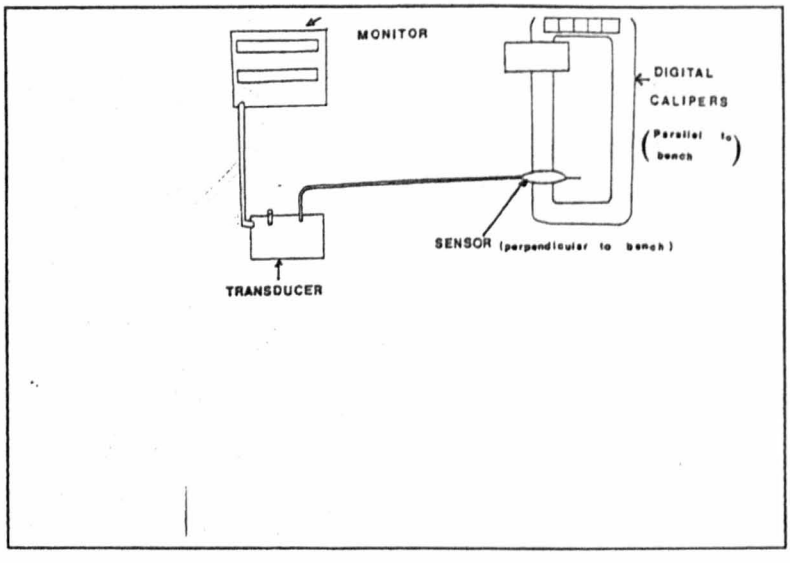


Figure 3.5b Revised method for determining thickness of the sensor

3.4.5. Relationship between sensor thickness and system calibration

3.4.5.1. Method

A sensor was connected to transducer A and was initially filled with oil. The calibration factor was determined hydrostatically as described in section 3.4.1. Subsequent experiments were performed with the same sensor but decreasing oil volumes.

Both increasing pressure and decreasing pressure readings were recorded and representative results are shown in table 3.1.

The thickness of the oil-filled sensor used in the pressure monitor was varied to determine whether it had any effect on the calibration. It was known from the work by Ferguson-Pell (1977) that a small aspect ratio (sensor thickness < 10% of sensor diameter) would minimise the error due to placing a sensor at the site and thus it was important to ascertain whether it was possible to use a very thin sensor with no impact on the calibration or linearity of the ratio of pressure to output. Thin sensors also conform more easily than thick sensors to curved surfaces, such as the leg.

3.4.5.2. Method of sensor thickness measurement

The sensor and transducer were arranged so that the transducer output was displayed on a voltmeter, and the sensor was placed on the laboratory bench with the centre of the fluid filled area between the jaws of a digital calliper. The jaws of the digital calliper were brought together until a signal was registered on the voltmeter, see figure 3.5(a). At this point the sensor thickness was recorded. The calibration factor of each sensor set-up was then determined as described in section 3.4.

3.4.5.3. *Results*

Table 3.2 shows the calibration factors (the gradient of the graph) for four data sets, labelled A1- A4, which were used with transducer A.

This method was satisfactory at high sensor volumes / thickness. It was possible to hold the sensor so that it was just touching the static calliper jaw and advance the moving jaw. At low sensor volumes, however, the sensor was not stiff enough to be held completely still. As it was rather 'floppy' it fell against the static jaw and the transducer registered an output before the moving calliper jaw had reached the sensor. Data sets prefixed with the letter A in table 3.2 were measured using this method. It was not possible to measure the thickness of sensor A4, which was thinner than 3.19 mm, as it was not possible to hold the thin sensor still without the sides touching the calliper edges.

Sensor code	Sensor Thickness (mm)	Gradient of best-fit line/Calibration Factor (mV/mmH_2O)	
		Increasing Pressure	Decreasing Pressure
A1	9.45	6.6 6.2	6.2 6.1
A2	6.75	5.8 6.0	6.0 6.1
A3	3.19	5.9 6.0	6.0 6.0
A4	Less than 3.19 but reading unavailable	6.0	6.0

Table 3.2 Calibration factors with varying sensor volumes – Sensor and transducer A

3.4.5.4. *Revision of sensor thickness measurement method*

Subsequently the sensor was steadied by suspending it from a clamp and clamping the digital callipers alongside it, see figure 3.5(b). The thickness was assumed to be the jaw

separation at the point when the output signal was equivalent to 1 mmHg. Sensors prefixed with a letter B, see table 3.3, were measured using this second method.

This also had the advantage that the sensor thickness was measured while loaded, if only by 1mmHg rather than completely unloaded. Hence it would be more symmetrical in shape than an unloaded fluid-filled sensor.

3.4.5.4.1. Results

Sensor code	Sensor Thickness (mm)	Gradient of best-fit line/Calibration Factor (mV/mmH_2O)	
		Increasing Pressure	Decreasing Pressure
B1	6.87	14.0	13.8
B2	5.36	13.8	14.0
B3	5.04	13.6	13.6
B4	3.83	13.8	13.5
B5	3.06	13.5	13.5
B6	2.43	13.3 13.7 13.2	13.3 13.4 13.4

Table 3.3 Calibration factors with varying sensor volumes – Sensor and transducer B

3.4.5.5. Discussion

The two different transducers had different gradients / calibration factors. This reiterates the need to calibrate each sensor prior to use. The calibration for each transducer, however, was independent of either direction of loading or thickness of sensor.

From Figure 3.4 it can be seen that there was no difference in the gradients, and hence calibration factors, for the two thin sensors. There is no systematic change in calibration factor with sensor thickness, therefore sensor thickness could be chosen to ensure that Ferguson-Pell's (1977) criterion for aspect ratio was fulfilled. As the sensor from Talley

Medical had a diameter of 28 mm, then a sensor thickness of less than 2.8 mm was obtainable.

3.4.5.6. Discussion

The variations in calibration factors may be due to errors in the calibration technique, e.g. determination of zero pressure point, reading sensor position through column of water. The resultant systematic error this would make to measurements in clinical practice can be illustrated by the following example:

Range of calibration factors = 13.6 ± 0.4 mV / mmH_2O (1.8± 0.05kPa)

Typical pressure applied = 300 mmH_2O (approx. 22 mmHg)

Pressure readings are 22.05 plus or minus 0.65 mmHg; (from 21.4 to 22.7 mmHg), this degree of error is considered as acceptable in this investigation.

The error at readings typical of compression bandage investigations, around 35 mmHg, will therefore be considered as having ± 1 mmHg error.

3.5. Transducer Height Dependence

When used in the set up as described in previous sections, the transducer output was proportional to the sum of the applied pressure and the hydrostatic pressure due to the position of the sensor relative to the transducer. This problem was minimised when static measurements were being taken, e.g. during calibration or when subjects were stationary, as the positions of the sensor and transducer were fixed. It was noted that if the system were used in a dynamic situation, then there would be an error due to variation in vertical distance between the sensor and transducer.

It was hypothesised that cancelling out the hydrostatic pressure by using port A to record only the hydrostatic pressure would eliminate this error.

A length of tubing was connected to transducer reference port A and it was filled with the same transmission fluid as was used in the sensor and transducer connected to port B.

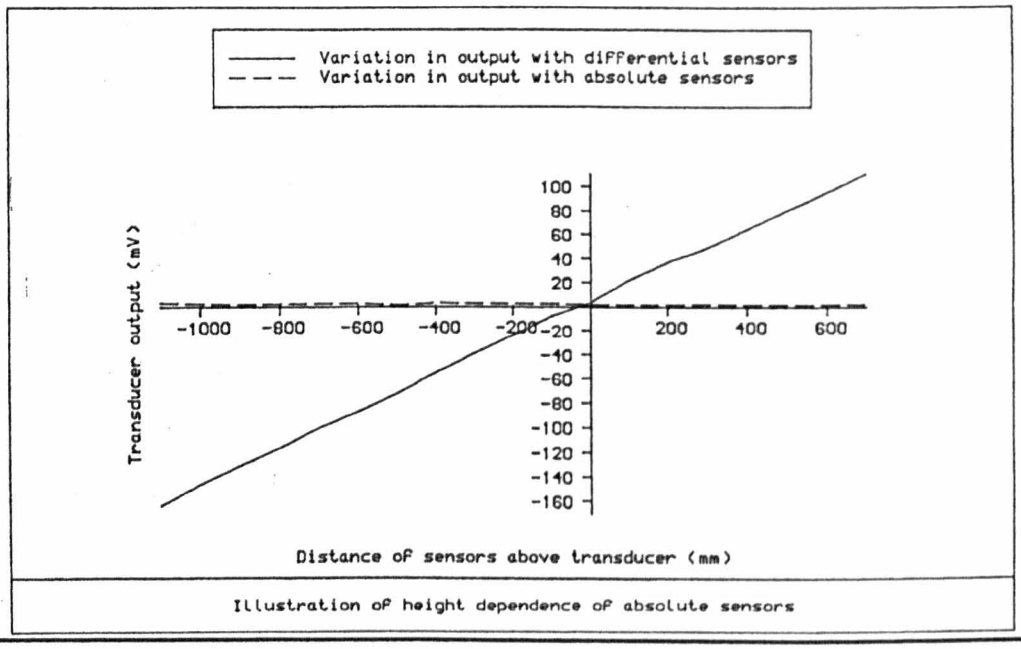


Figure 3.6 Transducer response with variation in height of sensor above transducer – demonstrating difference between differential (port A only connected) and absolute (port A and B connected) set-up

The second tube was positioned with the fluid /air interface at the end of the tubing at the same vertical level as the sensor. Initially the tubing connected to port A was sealed in order to prevent leakage of transmission fluid. In this set-up, however, moving the position of port A tubing did not exert a hydrostatic pressure, that is, there was no change in voltage with a change in the vertical position of the tubing.

Once the 'reference' tubing, attached to port A, was opened to the air it was able to record the hydrostatic pressure. This, however, allowed the transmission fluid to leak out. In order to prevent leakage a semi-permeable (hydrophobic) membrane was placed over the open end of the tubing and this was help in place by a cable tie. This arrangement allowed air but not the transmission fluid to pass through the membrane, thus allowing the reference port to record hydrostatic pressure. This is referred to as the differential set-up as the output was proportional to the difference between the pressure recorded at port B (hydrostatic plus applied pressure) and at port A (hydrostatic pressure alone).

3.5.1. Evaluation of the differential set-up

The variation in transducer output with vertical position of the sensor above the transducer was investigated. The sensor was positioned at various heights, from 700mm above the transducer, at intervals of 20mm, to 1200mm below the transducer and the output was recorded. The variation in the output was less than 2mV, equivalent to a variation of less than 1mmHg (see figure 3.6). This is in contrast with the range of transducer output in the non-differential mode of 100mV to –160mV, equivalent to a change of approximately 100 mmHg. Recalibrating the system with the reference port connected resulted in no change in the calibration factor.

3.6. Transient Response Investigation

As modifications had been made to the original system, it was decided to investigate whether these had any influence on the time taken for the system to respond to changes in applied pressure, also called the transient response.

The response to a step unloading was monitored with the original set-up, in a differential mode set up, with transmission fluids of varying viscosity, and varying lengths of tubing.

3.6.1. Background.

An ideal response to a step input is a step output (figure 3.7(a)). In real systems there is rarely an instantaneous response, thus a lag can be seen, see figure 3.7(b). The test consists of monitoring the output while applying a step change (increase or decrease of input). A data acquisition programme (Acquire, 1.08, Graham Philips 1990) was used to collect and store the data at a rate of 100 Hz for 2 seconds. The same transducer was used throughout and it was decided to unload, rather than load the sensor instantaneously because the rapid application of a load often results in vibration of the sensor. In addition, for an instantaneous loading, a rig would be needed to guide the load onto the sensing area accurately. With an instantaneous unloading the sensor can be accurately placed on the sensing area and instantaneously unloaded without the need for a test rig.

3.6.2. Impact of transducer set-up on transient response

This investigation was planned in order to answer the following questions:

- Is the transient response load dependent?
- Is the response time of the system affected by using it in a differential mode?

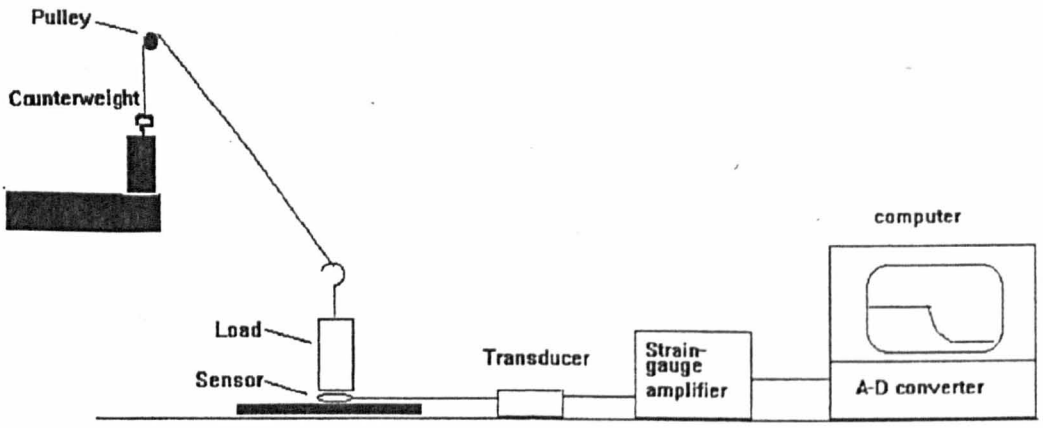


Figure 3.8. Experimental set-up for determining transient response

3.6.2.1. *Method*

The transducer and the sensor and its tubing were filled with oil and all air bubbles were removed. The sensor was connected to port B of the transducer via a 1m length of oil-filled tubing and this connection was reinforced with PTFE tape. In order to record the ability of the system to respond to a quick change in applied pressure, the output during a rapid unloading of the sensor was recorded (a step unloading). The output was recorded with three loads; 1.96 N, 3.82 N, or 5.78 N, in the following manner.

For each of these loads a step unloading was performed (see figure 3.8):

1. the oil-filled sensor, connected to the transducer, was placed on the laboratory bench and allowed to accommodate to ambient temperature for 1 hour
2. the transducer was connected to a power source
3. the transducer was connected to the input of a personal computer (PC) data on which logging software (Acquire) was running
4. a brass weight (1.96N) with a contact area of 25 mm diameter was connected to a 1kg counter weight via an inextensible cord and pulley
5. the counterweight was placed right on the edge of an adjacent shelf and the inextensible cord was adjusted so that there was no slack
6. the brass weight was carefully placed on the sensing area and the transducer output was allowed to reach a steady state
7. the data recording was started at a rate of 100 Hz
8. the load was removed as rapidly as possible by knocking the counterweight rapidly off the shelf
9. the data recording was stopped once the output had reached a steady state (after approximately 2 seconds)
10. steps 4 to 9 were repeated with weights of 3.82 N and then with 5.78 N
11. an oil-filled, 1m long open ended tube, diameter 2 mm, was connected to port A and this tubing was laid along the workbench (referred to as the differential mode)
12. steps 4 to 9 were repeated with the same three loads (1.96 N, 3.82 N and 5.78 N)

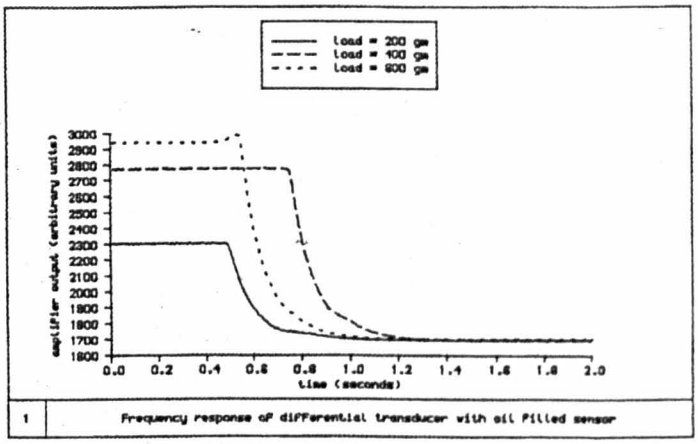


Figure 3.9 Demonstrating that the transducer output with time is not affected by load

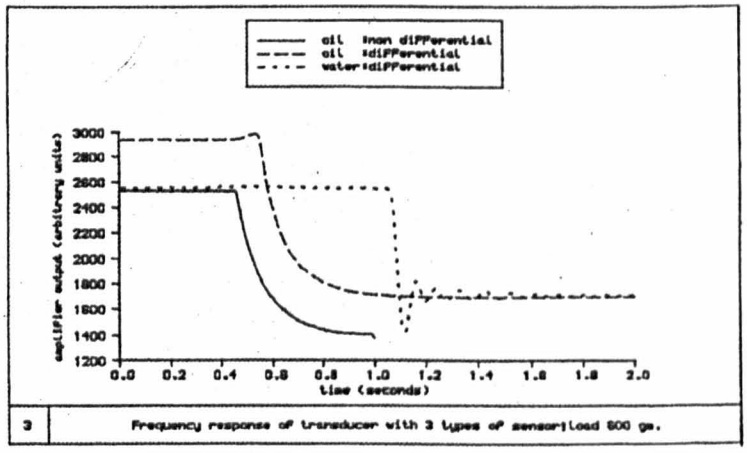


Figure 3.10 Frequency response with differential (i.e. only port A connected) and non-differential (both ports A and B connected)

3.6.2.2. Results

The transient response with varying loads is illustrated in figure 3.9. There appears to be no significant difference in response with load. The output fell to 50% of the loaded state in 0.08-0.09 seconds, and had reached the unloaded output after around 0.4 seconds. Likewise there was no difference in the response if the reference port was used or not, see figure 3.10. There was no statistical comparison of these curves.

3.6.2.3. Discussion

The response of sensor and transducer to a step unloading was recorded and it took approximately 0.4 seconds to fall to baseline. This response was independent of changes in both the loading weight and the addition of an oil-filled tube to the second port of the transducer. These findings mean that the next set of experiments can be undertaken with only one loading weight. In addition, the modification of the set-up to counteract variation in readings with vertical movement of the sensor relative to the transducer does not affect the response time.

3.6.3. Viscosity investigation: oil and water transmission fluid

This investigation was planned to answer the question:

- Does the viscosity of the transmission fluid influence the transient response?

It was intended to compare the transient response of a water and oil filled system with that of an oil-filled system. As the sensing element of the transducer, the silicone diaphragm, was incompatible with ionic fluids, including water, as a transmitter, both ports of the transducer were oil-filled.

3.6.3.1. Method

The instantaneous unloading method as described in section 3.6.2.1 was used. A load of 3.82N was used as it had been demonstrated that transient response was unaffected by load.

3.6.3.2. Results

The output signal following an unloading of a water-filled sensor is a different shape from that obtained using the oil-filled tubing and sensors, see figure 3.10. The time for the output to achieve a steady state with an oil-filled system is around 0.4 seconds.

With a water-filled sensor the initial drop in output is steep and then there is an undershoot, then a decreasing oscillation about the final level until the signal settles. A steady state is reached after about 1 second.

3.6.3.3. Discussion

The difference in the response to unloading between the water and oil-filled sensors can be explained by considering the dynamics of measurement.

The ideal response described earlier can be represented mathematically as a zeroth order system by saying that:

Input = F(t)

Output = x

and that

$$x = \frac{F(t)}{k} \qquad \text{Equation 1}$$

k is the constant of proportionality relating input to output.

Information supplied with the transducer indicates that this is around 12 psi / mV.

Real systems, however, have inertia and may be damped thus producing some delay in the response to an output. The oil-filled system may be taken to illustrate a typical first order system. This is represented as a zero order (or ideal) system that has the addition of a damping force. This damping force appears to be proportional to the rate of change of the output, thus having the form $c\dot{x}$ where c is a constant and $\dot{x}$ is the time derivative of x.

i.e. $$c\dot{x} + kx = F(t)$$

or $$\frac{c}{k}\dot{x} + x = \frac{F(t)}{k} \qquad \text{Equation 2}$$

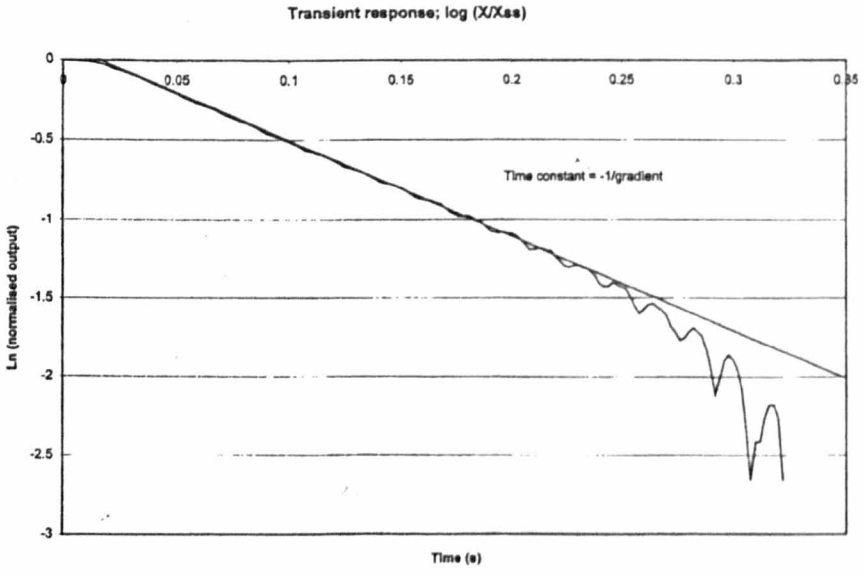


Figure 3.11 Log transform of standardised output after a step unloading

The term c/k has the dimension of time and may be replaced with τ, a time constant, then

$$\tau\dot{x} + x = \frac{F(t)}{k} \quad \text{Equation 3}$$

The time constant determines the rate at which the output signal attains the steady state.

Integrating equation 1 and noting that in our tests;

when t<0, F(t)=F; and when t>0, F=0, then;

$$\frac{x}{x}_{ss} = e^{-t/\tau}.$$, where x^{ss} = steady state value of x.

Thus τ can be determined from a graph of $\ln(x/x^{ss})$ against t, see figure 3.11.

For a system that will respond quickly to changes of input, τ should be as small as possible. As the transducer may be used in ambulatory studies then the time constant should be short enough to allow the output to respond in less time than the period of walking or running, say around 0.25 seconds. Otherwise it will not be possible to record interface pressure during high frequency dynamic activities.

The retarding force $c\dot{x}$, is proportional to the rate of change of the output, and can be described as a damping force. Increasing the tubing length and the transmission fluid viscosity could increase the damping force and therefore increase the time constant.

Using a water filled sensor there is an oscillatory response, which was again analysed mathematically. This can be represented as a second order system, a first order system with the addition of an additional force. This retarding force is proportional to the rate of acceleration of the output, $\ddot{x}$.

From Cook and Rabinowicz (1963);

$$m\ddot{x} + c\dot{x} + kx = F(t) \quad \text{Equation 4}$$

Dividing equation (4) by m and letting

$$\omega_n = \sqrt{\frac{k}{m}} = \text{natural frequency} \qquad \text{Equation 5}$$

$$\varepsilon = 2\sqrt{km} = \text{damping ratio} \qquad \text{Equation 6}$$

The solution depends on the value of ε:

ε < 1, the system is under damped (oscillatory)

ε > 1, the system is over damped

ε = 1, the system is critically damped.

When ε = 1;

$$\frac{x}{F/k} = (1+\omega_n t)e^{-\omega_n t}$$

Remembering that F / k is the steady state value of x for t < 0,

$$\frac{x}{x^{ss}} = (1+\omega_n t)e^{-\omega_n t}$$

$$\therefore \ln(x/x^{ss}) = \ln(1+\omega_n t)^{-\omega_n t} \qquad (7)$$

Equation (7) can be used to estimate the natural frequency from a plot of ln (x/x^{ss}) against time (as a straight line graph takes the general form of y=mx+c). This can be only be done for very small values of t so that the term $(1+\omega_n t)$ tends to one. In this case equation (7) can be approximated to

$$\ln(x/x^{ss}) = -\omega_n t \qquad (8)$$

[for critically damped systems and small values of t].

3.6.3.4. Conclusion

This investigation has reduced the response time by using water as a transmission fluid in the sensor and tubing but the output was oscillatory and therefore it may be under damped. A second set of experiments was undertaken to determine how increasing fluid viscosity and tubing length might influence the time constant and whether it was possible to achieve critical damping by changing the tubing length to increase retarding forces.

3.6.4. Evaluation of transient response with tubing length variation

The output from one transducer connected to a sensor using different lengths of connecting tubing was recorded using a data acquisition programme (Acquire, 1.08). Initially lengths of 2m, 3m, and 3.5m were filled with water.

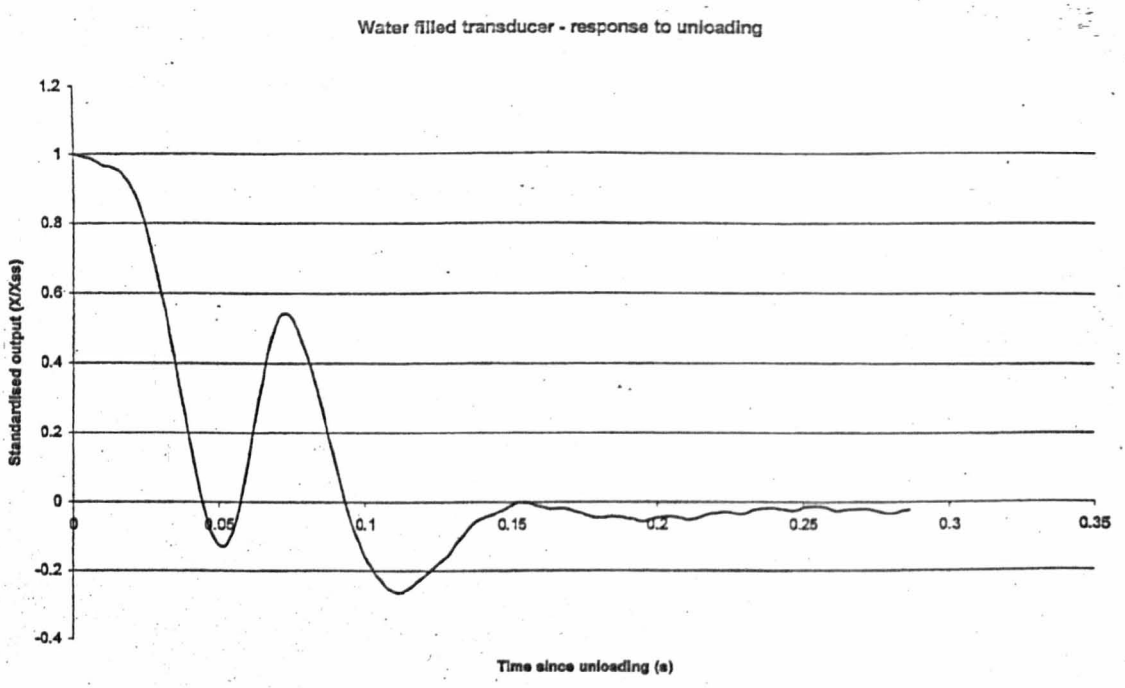


Figure 3.12 a. Water filled sensor, tubing length 3.45m (under-damped)

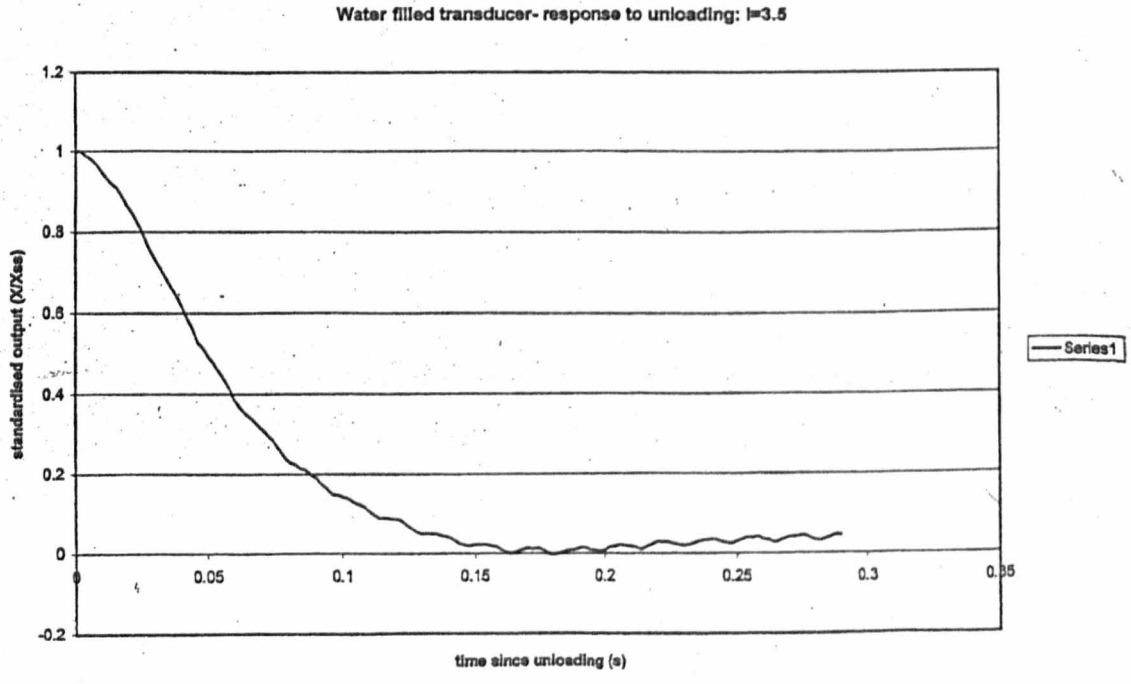


Figure 3.12 b. Water filled sensor, tubing length 3.5m (near critically damped)

3.6.4.1. *Methods*

The previously described unloading technique, see section 3.6.2.1, of transient response recording was carried out. The load used was 3.82N.

3.6.4.2. *Results*

With water-filled tubing of 2m, 3m and 3.45m in length there is a small undershoot, that is the system is under-damped (Figure 3.12a). At a tubing length of 3.5m (Figure 3.12b) there is no-undershoot and the output falls to a standardised output of zero in less than 0.2 seconds (standardised output = (output – min output)/(max output - min output)). It appears that critical damping occurs between 3.45 and 3.5 m tubing length.

Graphs were drawn of ln (x/x^{ss}) against time, figure 3.11. The gradient of the initial section of the straight-line portion is the natural frequency ω_n. The time constants from the two aforementioned systems are different, see table 3.3. The longer tubing had a higher time constant, as predicted.

Tubing length (m)	3.45	3.5
Frequency ω_n (Hz)	27.4	33.3

Table 3.3 Time constants

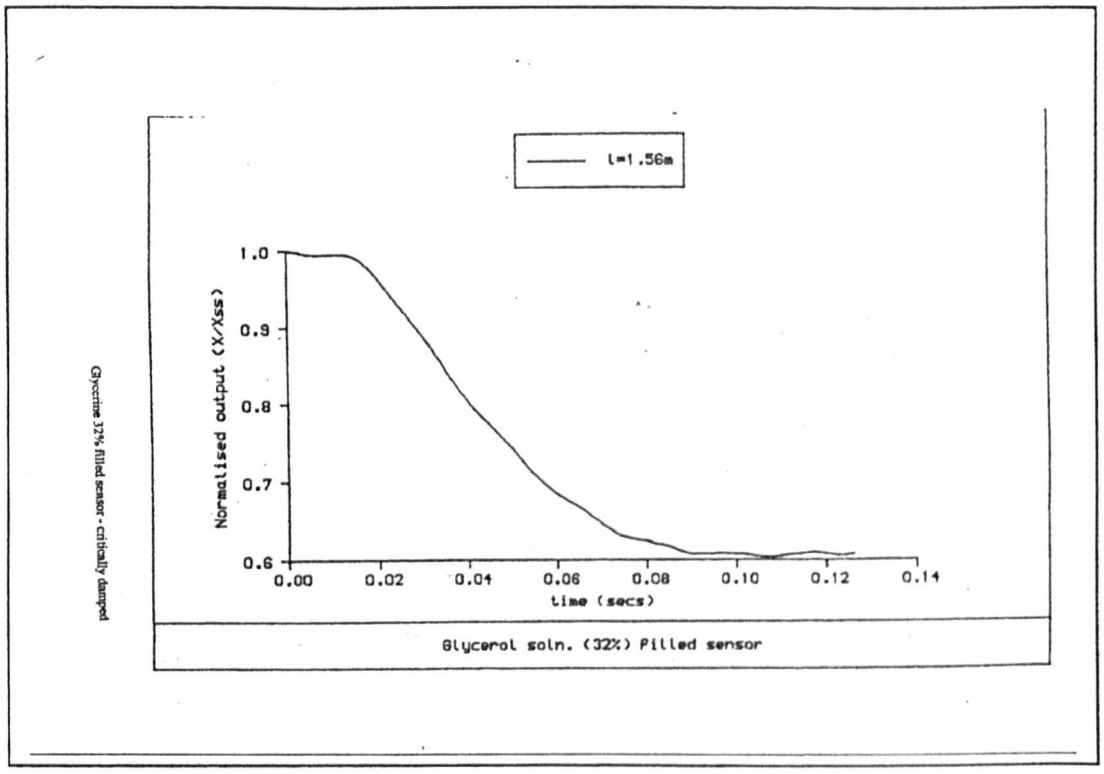


Figure 3.13. Response to step unloading with tubing length 1.56m, sensor and tubing filled with glycerol 32% (critically damped)

3.6.4.3. Discussion

There may be errors in these readings due to the difficulty in establishing the intercept of the y-axis, and therefore in calculating the gradient of the line. The instantaneous unloading is not completely instantaneous and therefore there this may also introduce an error in calculating the time constant.

3.6.5. Varying the fluid viscosity

While it had been possible to achieve a critically damped system by increasing the length of water-filled tubing to around 3.5m, this was unwieldy. The response of the measurement system to an increase in transmission fluid viscosity was investigated to determine whether critical damping could be achieved with a shorter tubing length but higher transmission fluid viscosity.

The viscosity of glycerine depends on its concentration, and data tables catalogue the viscosity / concentration relationship (CRC 1985).

3.6.5.1. Method

Three concentrations of glycerine were made up, 32%, 36% and 48% w/v.

Initially a sensor and tubing length of approximately 1.6m were filled with 32% glycerine and this was connected up to an oil-filled transducer. The distance between transducer and middle of sensing area was measured prior to the instantaneous unloading and recording of output as per section 3.6.2. The system was then disconnected and the tubing end nearest the transducer was trimmed in order to shorten the tubing length. The length of tubing was reconnected to the oil-filled transducer and the transducer to sensor distance was measured.

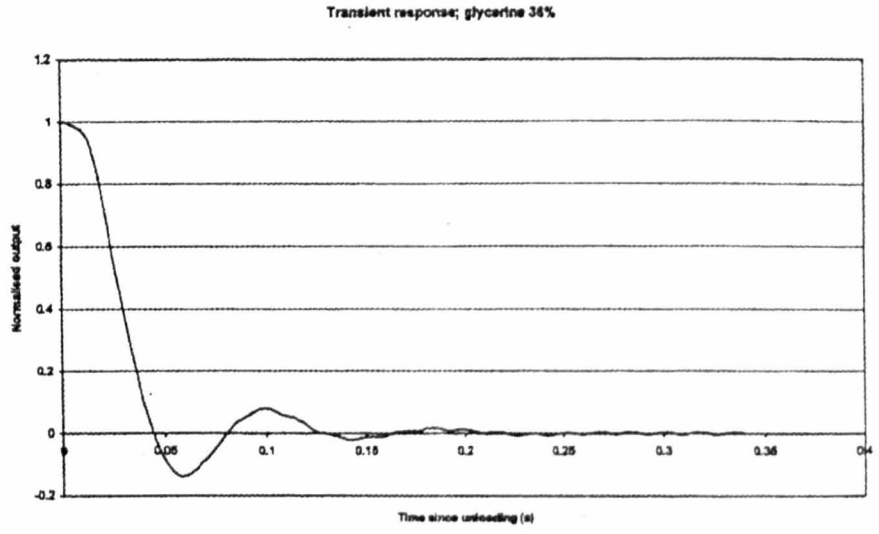


Figure 3.14 Transducer response to a step unloading, sensor filled with 36% glycerine, tubing length 1.56m (under-damped)

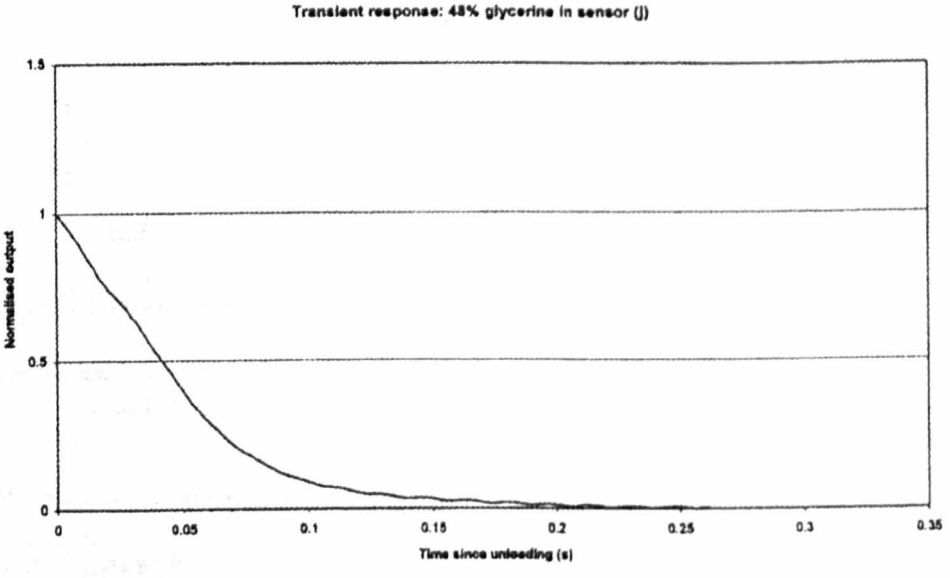


Figure 3.15 Transducer response to a step unloading, sensor filled with 48% glycerine, tubing length 1.56m (critically-damped)

This procedure was repeated until the system demonstrated an oscillatory response, demonstrating that it was under-damped.

The above procedure was repeated for concentrations of 36% and 48% glycerine.

3.6.5.2. Results

A 32% solution of glycerine has a viscosity of 2.8 times that of water. With this fluid a tubing length of 1.56m caused critical damping, figure 3.13. Steady state was reached in 0.1secs. This is in contrast with the length of tubing necessary to achieve critical damping with water.

A 36% glycerine and then a 48% glycerine solution were used, with tubing length 1.56m. The 36% solution resulted in an under-damped system (Figure 3.14), while the 48% solution was critically damped, figure 3.15. It can be noted that 50% of the signal is reached after 0.05 seconds, and therefore this investigation has identified a way of shortening the transient response time of the system. There may be scope for decreasing this further by also taking into account the temperature of the transmission fluid.

When faced with specific system requirements, e.g. tubing length, it could be possible to vary the fluid viscosity in order to minimise the time constant.

The optimal time response was achieved with a tubing of length 1.56m and a glycerine concentration of 32%. Steady state was achieved in 0.1 seconds.

3.6.5.3. Discussion

As the compliance of the system will also influence the time constant this should be further investigated. The compliance may increase with the volume of fluid in the system, irrespective of the length of tubing. The mass of fluid may also influence compliance and this will increase with more concentrated and hence viscous solutions. This part of the investigation has therefore shown some ways in which the time constant can be influenced but more work requires to be done. Future experiments could keep the mass of the fluid

constant while increasing the tubing length. It would also be possible to vary the viscosity of the fluid without changing its mass by undertaking the experiment at different temperatures.

3.7. Conclusions

This set of experiments has:

1. ascertained that there is no change in the calibration coefficient when the volume of fluid in the pressure sensor is reduced. The error within the system means that the readings can be expressed as ± 1mmHg.
2. reduced the transient response of the pressure measurement system so that recordings of pressure during fast movements of the leg can take place.
3. eliminated the error in the system due to relative changes in the vertical distance between the sensor and the transducer.

Taken together, these findings mean that the Strathclyde Pressure Monitor (SPM) can be used with a thin sensor, reducing the degree of perturbation of the compression bandage at the interface; that there is no error introduced by the movement of the person wearing the bandage from sitting to standing (where the vertical height of the bandages change); and that pressure measurements at the bandage / skin interface can be made while the patient is moving (as the time to respond to pressure changes has been reduced).

The next sections of the thesis use the SPM in order to investigate the impact of bandage choice, movement of the person wearing the bandage, and training the person applying the bandage on the interface pressures.

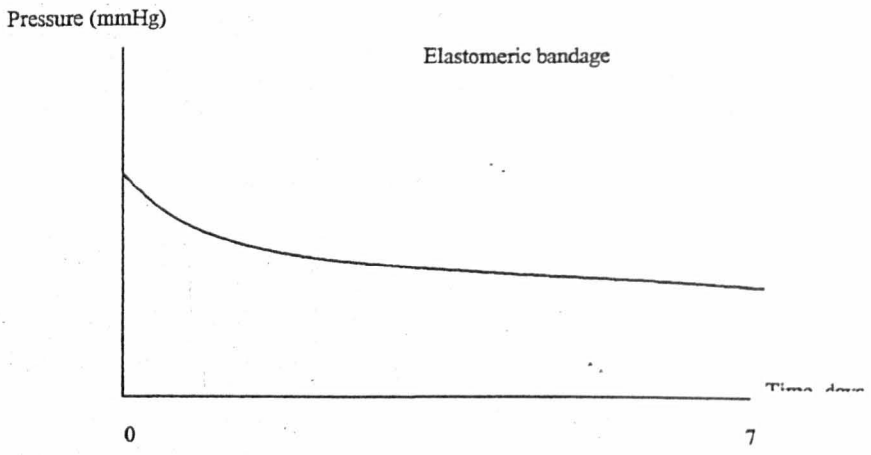
4. Sub-Bandage Pressure and Foot Movement

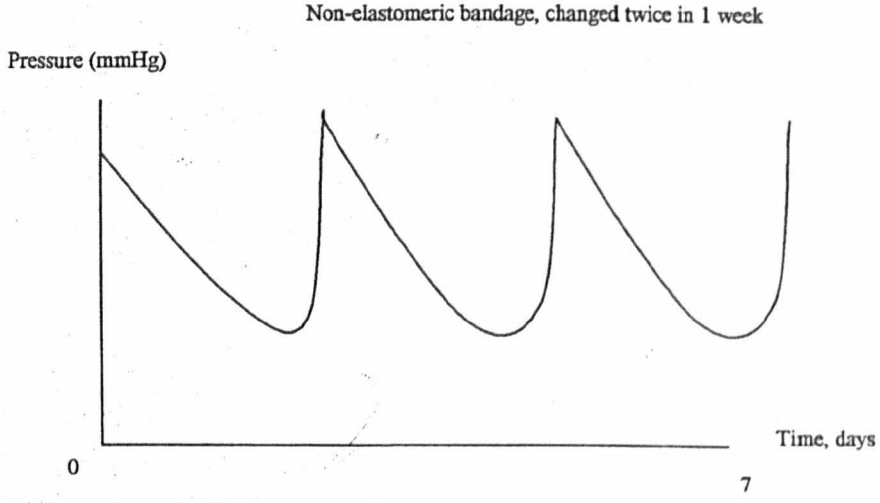
4.1. Bandage response to foot movements

The posture and activity of patients may be important when considering whether to treat a patient with elastomeric or non-elastomeric bandages. As non-elastomeric bandages exert low pressures when the patient is at rest and high pressures when the calf muscle is activated, then it may follow that for these bandages to be effective, patients wearing non-elastomeric bandages should be able to exercise their calf muscle pump. Patients who are unable or unwilling to exercise the calf muscle pump by walking or doing ankle exercises may fare less well in non-elastomeric bandages than in elastomeric bandages. Likewise, patients who are able to exercise their calf muscle pump may have higher healing rates in non-elastomeric bandages than in elastomeric bandages, although there is no evidence from healing studies to confirm this as no trials have stratified patients with respect to their mobility or ankle flexion.

Differences in effectiveness may be due to differences in application technique, patient characteristics, or the pressure / time profile (the product of the pressure exerted and the time over which it acted). The area beneath the pressure / time line is greater for a weekly application of an elastomeric bandage than a non-elastomeric bandage. Furthermore the area beneath the pressure / time line is greater for a frequently reapplied non-elastomeric bandage than a weekly application of a non-elastomeric bandage, see Figure 4.1.

Investigations of non-elastomeric bandages report that they exert low pressure when the patient is at rest or lying down, and high 'working pressure' when the patient is moving or standing (Stemmer et al 1980, Callam et al 1991, Hirai 1998). The aim of the first part of this investigation was to determine the magnitude of pressure changes under non-elastomeric and elastomeric bandages with foot movements.





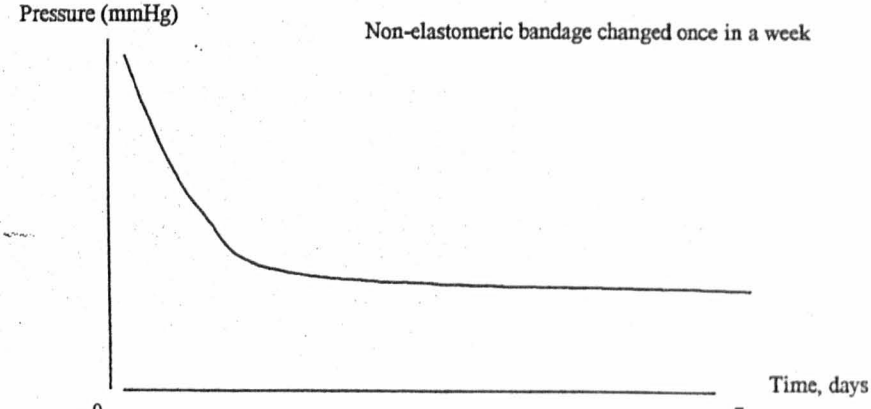


Figure 4.1 Pressure / time profiles for elastomeric and non-elastomeric bandages

4.1.1. Theoretical differences between elastomeric and non-elastomeric bandages

4.1.2. Response to extension

In order to generate a required pressure it is necessary to generate a specified tension. This is usually achieved by generating a specified extension that depends on the bandage. The relationship between the tension and extension, however, is imprecise, due to the hysteresis in the bandage (see Figure 4.2). This means that at a specified extension, the tension cannot be known precisely as the 'increasing extension' value is higher than the 'decreasing extension'. The hysteresis is reduced, but not eliminated altogether, by pre-conditioning, a process whereby the bandage is extended and relaxed a number of times.

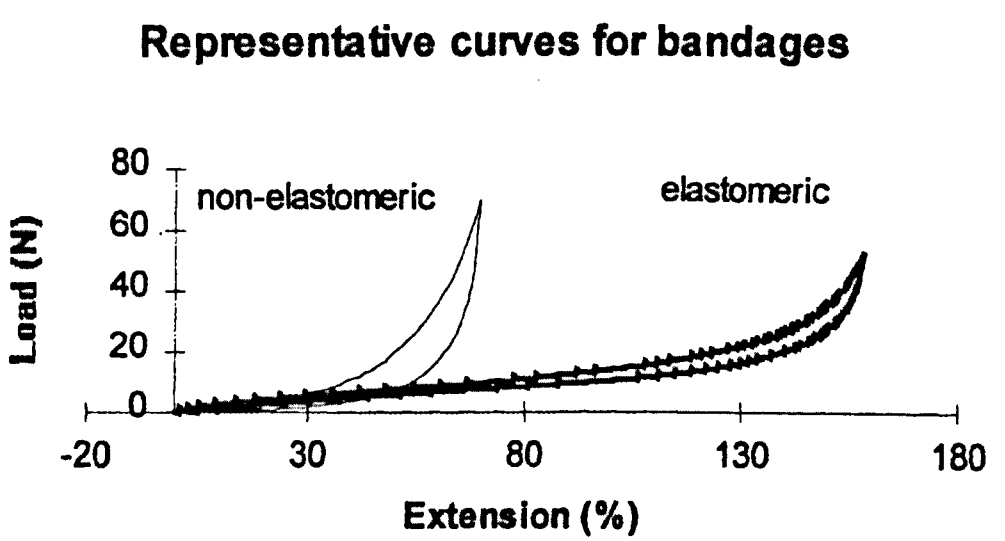


Figure 4.2. Representative curves demonstrating the response of elastomeric and non-elastomeric bandages to extension and relaxation

In addition, the actual extension will differ from the desired (or applied) extension due to movement of the patient and this will alter the pressure in a manner that depends on the gradient of the tension / extension relationship for the bandage. At extensions where the gradient of the tension / extension curve is relatively low, an increase in the extension of the bandage, e.g. due to an increase in the circumference of the calf muscle upon standing, will produce a relatively low increase in bandage tension. At high extensions, where the gradient of the tension / extension curve is higher, however, an increase in bandage extension will be accompanied by a higher increase in bandage tension.

4.2. Aims

The aim of this investigation was to answer these questions:

1. What pressures are generated beneath compression bandages when applied by a novice bandager?
2. Do sub-bandage pressures increase significantly when the foot is moved?
3. Are there differences in the changes in pressure with foot movements between elastomeric and non-elastomeric bandages?

4.2.1. Investigation of sub-bandage pressure and foot movement

The aim of this investigation was to determine whether sub-bandage pressures were related to the radius of the leg at the ankle and calf, and whether they changed significantly when the foot was moved in standard ways - plantar flexion, dorsiflexion, eversion and inversion.

4.2.2. Materials

Two bandages were studied, a non-elastomeric, cotton crepe BP bandage (10 cm wide Elastocrepe™, Smith and Nephew, UK), and an elastomeric, woven bandage, with elastomeric fibres in the weft and an adhesive coating of carboxymethylcellulose (10 cm wide Granuflex ACB™, ConvaTec, UK).

4.2.3. Methods

The Strathclyde Pressure Monitor, comprising four sensors and transducers, as described in chapter 3, was used. The transducers were filled with oil and the sensors were filled with water as this was easier to use than oil. A water filled reference tube (1m in length) was connected to port A to counteract any hydrostatic pressure effect, as described in chapter 3. The free end of the reference pressure tube was taped to the edge of the pressure sensor.

4.2.4. Experimental set-up

The level of the calf pressure measurement site was determined by measuring the point of maximum calf circumference of the subject while he / she stood in bare feet. The calf measurement site was identified as the intersecting point of this circumference and an imaginary line joining the malleolus and the tibial tuberosity.

The level of the ankle measurement site was determined by placing a tape measure along the line joining the malleolus and tibial tuberosity and marking a site 40mm proximal to the malleolus.

Sensors were placed laterally and medially, at the ankle and the calf. In order to measure the radius of curvature of the measurement sites, plaster casts were made of them using a Plaster of Paris impregnated bandage. The following steps were followed:

1. The sensing sites were marked in ink (lateral ankle, lateral malleolus, medial ankle and medial malleolus)
2. The leg was positioned so that the medial measurement sites were horizontal
3. The two measurement sites were covered with a thin layer of petroleum jelly so that the plaster would not adhere to the skin or hairs
4. Plaster of Paris bandage (5cm wide) was cut into strips approximately 30 cm in length and these were moistened in a basin of warm water. The bandage was squeezed to remove excess water.

5. The bandage was draped over the marked and greased measurement site in a concertina fashion and then smoothed down so that 6 layers of bandage were covering the site and there was close apposition of the bandage and the measurement site

6. Once the bandage was completely dry and hardened, it was carefully removed and labelled with the subject name, site and the cephalo-caudal direction

7. A flexible curve was placed in the internal diameter of the plaster cast and moulded into shape

8. The flexible curve was removed and placed onto a piece of paper

9. The outer diameter of the flexible curve was traced onto paper

10. The radius was measured using the technique of dissecting arcs of a curve – the point of intersection of two lines, which bisect a curve at right angles, is the centre of the radius.

The relationship between applied pressure and output voltage was determined by calibrating each system hydrostatically before the start of each data collection period (as in section 3.4). The sampling frequency of the data acquisition program (Acquire 1.08) was set at 20 Hz, with the amplifier set to remain within the limits of the A-D converter.

4.2.5. Test methods

Subjects were recruited from among students at the Bioengineering Unit. Four healthy volunteers were included. They were informed of the nature and purpose of the test, and gave verbal consent to participate. The position of the medial ankle, medial calf, lateral ankle, and lateral calf were marked on their legs, using washable ink, as defined in 4.2.4.

The pressure measurement protocol was as follows:

1. Subjects were seated on an examination couch with their legs hanging loosely over the edge of the couch. The position of the feet in the sitting position was marked on the foot rest using Micropore tape. The height of the foot rest was adjusted so that the knee was at right angles and the feet were placed flat on the foot rest.

2. Pressure sensors were placed at the medial ankle, medial calf, lateral ankle and lateral calf and the system was zeroed with the feet placed flat on the foot rest.

3. The Elastocrepe bandage under investigation was applied in a simple spiral technique with 50% overlap, by the investigator (EAN)

4. Immediately after application of the bandage the output from each of the four sensors was recorded (once a steady output had been reached, after about 4 seconds)

5. The subject was asked to stand upright and the output from each of the four sensors was recorded (once a steady output had been reached, after about 4 seconds)

6. The subject was asked to lie flat on the examination couch and the output from each of the four sensors was recorded.

7. The data logger was set to record the output from the transducers at a rate of 20Hz. Recording output was started by running the data acquisition programme.

8. With the subject flat on the examination couch they were asked to point their toes towards their nose and to hold that position for 2 seconds (counted by EAN) before returning the foot to the initial opposition (dorsiflexion). Recording was then stopped and the dorsiflexion data was saved to disc.

9. Steps 7 and 8 were repeated for plantar flexion, plantar eversion and finally plantar inversion.

10. Bandage application extension was measured by marking a 10cm line along the longitudinal axis of the extended bandage at all measurement sites .

11. The bandage was removed and the extension was calculated by measuring the length of this line (L) after the bandages were removed: %extension =100*[(10-L) / L]

12. Steps 3 to 11 were repeated with a second compression bandage, Granuflex Adhesive Compression Bandage (G-ACB, ConvaTec, UK Ltd)

13. The output files were imported into Quattro so that the pressure over time for each site, subject and bandage could be calculated and drawn

4.2.6. Results.

Plaster cast radii were as follows:

	Radius of curvature of measurement site (mm)			
	Medial		Lateral	
Subject	Ankle	Calf	Ankle	Calf
1	48	54	20	71
2	49	54	31	54
3	46	53	26	60
4	40	70	46	63

Table 4.1 Radius of curvature of measurement sites

The pressures recorded beneath the bandage in the sitting, standing and lying postures will be presented and analysed in a following section.

Sub-bandage pressures during specified foot movements were recorded and a theoretical output is displayed graphically in Figure 4.3. Examples of graphs for each foot position are in Figures 4.4 – 4.7.

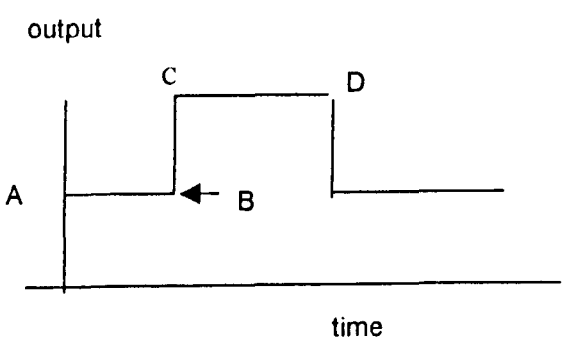


Figure 4.3 Stylised graph of output during foot movements

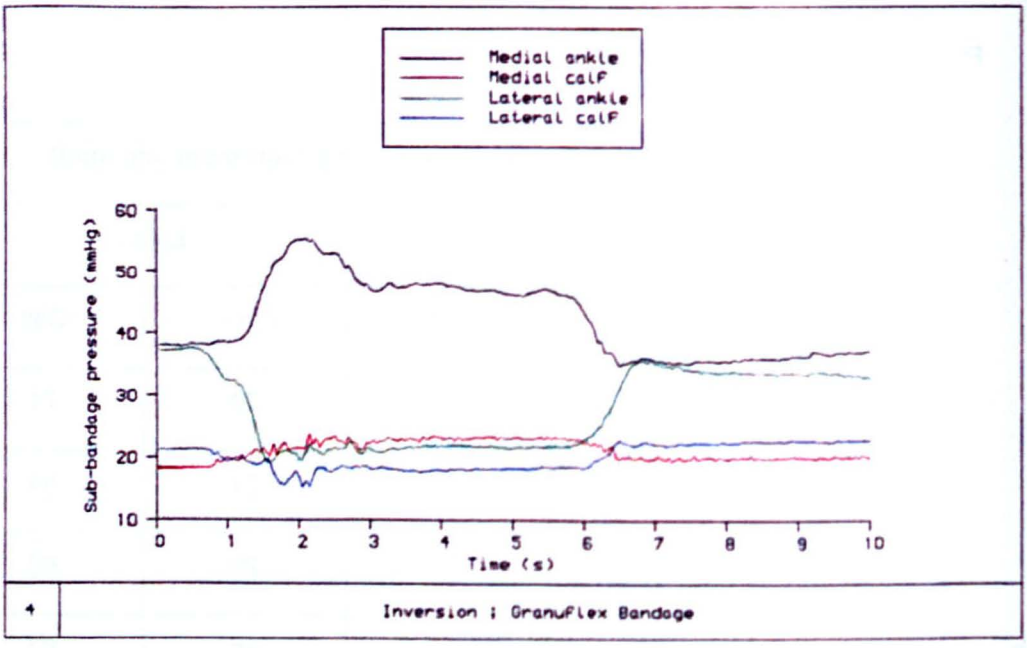


Figure 4.4 Sub-bandage pressures at 4 sites beneath elastomeric compression bandage during plantar inversion

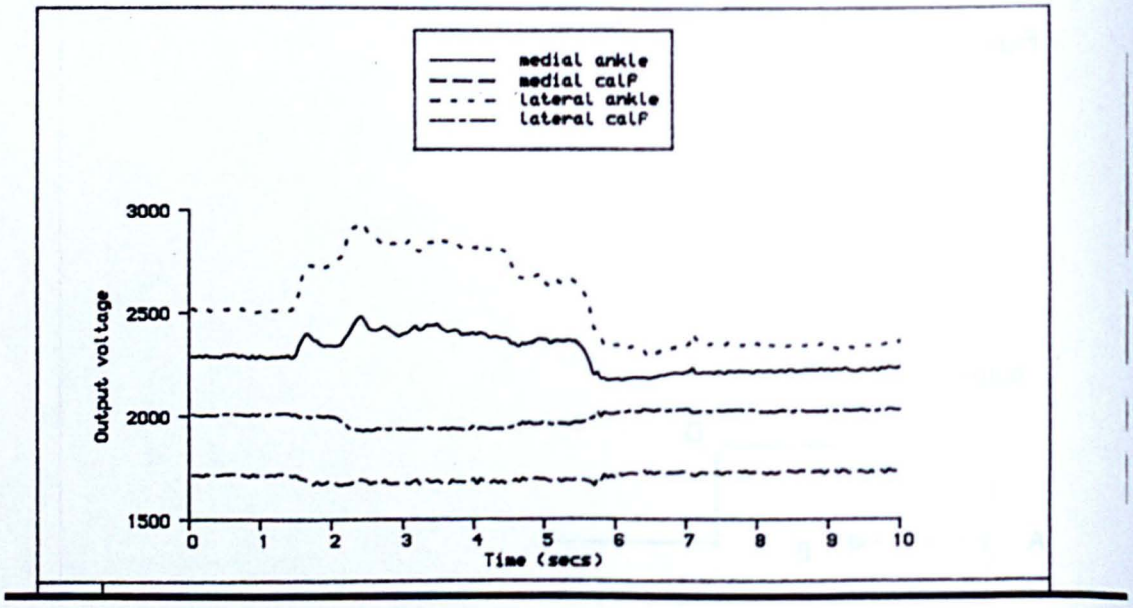


Figure 4.5 Sub-bandage pressures at 4 sites beneath elastomeric compression bandage during plantar flexion

The mean change in sub-bandage pressures for each bandage, for each movement, at each site were calculated. Visual inspection of the output in both Quattro spreadsheets and on the graphs allowed the time points B (first movement of the foot), and D (when the foot was returned to the neutral position) to be identified. This was done by firstly establishing a baseline output for period AB, O_{init}. The output at each reading between C and D was subtracted from $O_{init,}$ the baseline output, to obtain the mean change in sub-bandage pressure. This reading was averaged over the time period CD.

4.2.6.1. Non-elastomeric bandage

4.2.6.1.1. Resting pressures – non-elastomeric bandage

The pressures recorded while the subjects were seated are set out in Table 4.2.

Subject	Medial ankle pressure (mmHg)	Medial calf pressure (mmHg)	Lateral ankle pressure (mmHg)	Lateral calf pressure (mmHg)
1	18	13	6	10
2	14	19	33	17
3	21	33	33	35
4	17	21	21	9

Table 4.2 Resting sub-bandage pressure (seated) with a non-elastomeric bandage.

These values represent the baseline sub-bandage pressures. It is interesting to note the large difference between values at the same level.

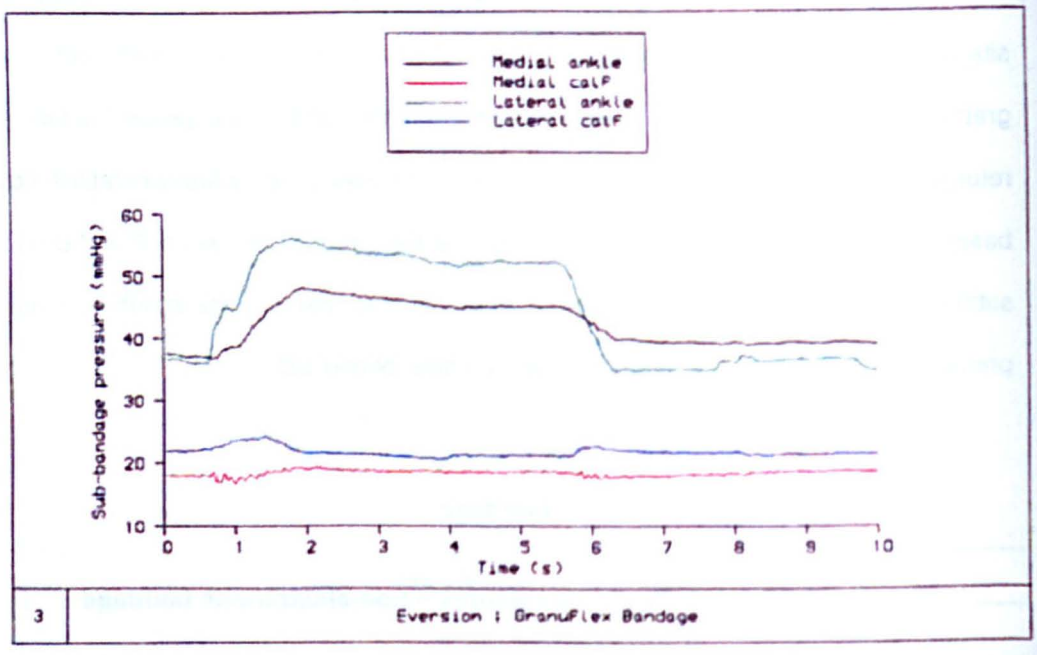


Figure 4.6 Sub-bandage pressures at 4 sites beneath elastomeric compression bandage during plantar eversion

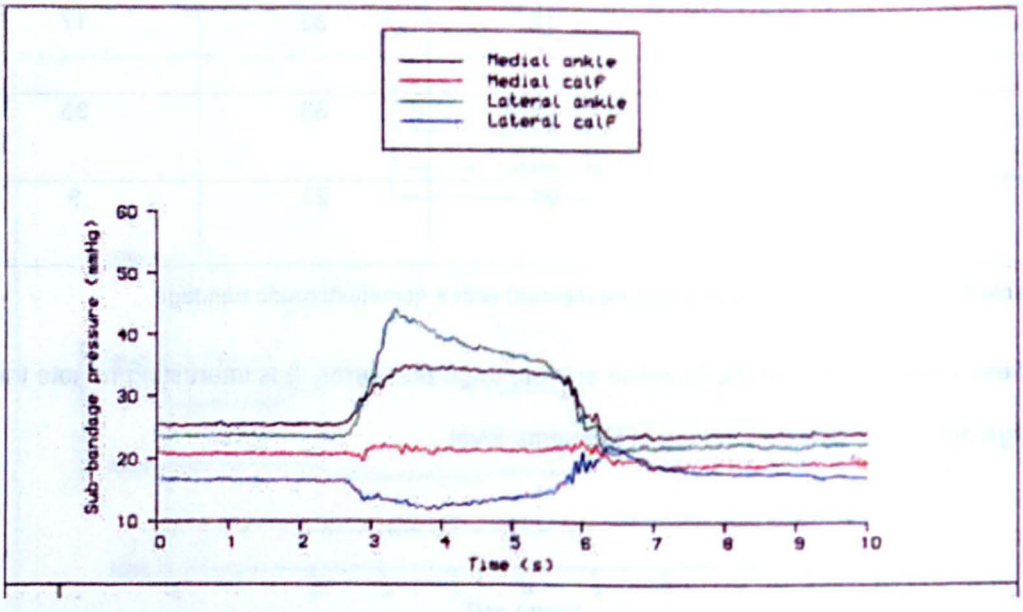


Figure 4.7 Sub-bandage pressures at 4 sites beneath elastomeric compression bandage during dorsi-flexion

4.2.6.1.2. Pressure changes with ankle movement – non-elastomeric bandage

Plantar flexion

During plantar flexion of the foot the sub-bandage pressure at both ankle sites of measurement increased from a baseline level and fell once the foot was returned to the neutral position. Immediately after plantar-flexion, the sub-bandage pressure at the ankle was lower than the baseline although it gradually recovered.

The sub-bandage pressures at the calf sites changed on plantar-flexion, with an initial rapid fall from the baseline level followed by recovery towards the baseline. When the foot was returned to the neutral position the baseline pressure was recorded.

Dorsi-flexion

During dorsi-flexion of the foot, the sub-bandage pressure at both ankle sites increased, the increase being greater at the lateral ankle than the medial ankle. At the calf sites a transient increase in pressure was seen immediately when the foot was moved, i.e. during muscle action. This was followed by a fall in pressure towards the baseline during a steady state while the foot was held in dorsi-flexion, and finally a transient change in pressure as the foot was returned to the neutral position.

Eversion

During plantar eversion both ankle sub-bandage pressures increased initially, then decreased slightly during the steady state plantar eversion, and returned to a sub-bandage pressure slightly lower than the baseline value before returning to the baseline.

Inversion

The medial ankle sub-bandage pressure increased during inversion whereas the lateral ankle sub-bandage pressure decreased. After the foot returned to a neutral position, both rapidly reached their baseline value. The medial calf sub-bandage pressure was largely

unchanged by plantar inversion and the lateral calf sub-bandage pressure fell during inversion and returned to the baseline value when the foot returned to the neutral position.

4.2.6.2. Elastomeric bandage

4.2.6.2.1. Resting pressures – elastomeric bandage

The pressures recorded while the subjects were seated are set out in Table 4.3. These values represent the baseline sub-bandage pressures. Note the large difference between values at the same level.

Subject	Medial ankle pressure (mmHg)	Medial calf pressure (mmHg)	Lateral ankle pressure (mmHg)	Lateral calf pressure (mmHg)
1	13	14	15	16
2	39	17	34	29
3	29	19	25	19
4	38	31	32	40

Table 4.3 Resting sub-bandage pressure (seated) with an elastomeric bandage.

4.2.6.2.2. Pressures with ankle movements – elastomeric bandage

Plantar flexion

During plantar flexion of the foot the sub-bandage pressure at both ankle sites increased and those at the calf sites fell. When the leg was returned to its neutral position the pressures returned to their baseline level.

Dorsi-flexion

During dorsi-flexion of the foot, the sub-bandage pressure at both ankle sites increased while those at the calf sites remained relatively unchanged. The ankle sub-bandage pressures returned to the baseline level when the leg was returned to the neutral position.

Eversion

During eversion, the sub-bandage pressure at both ankle sites increased while those at the calf sites remained relatively unchanged, there being only a transient change in pressure while the foot moved. The ankle sub-bandage pressures returned to the baseline level when the leg was returned to the neutral position.

Inversion

During inversion the medial ankle pressure increased while the lateral ankle sub-bandage pressure decreased. Sub-bandage pressure at the calf sites remained relatively unchanged, there being only a transient change in pressure while the foot moved. The ankle sub-bandage pressures returned to the baseline level when the leg was returned to the neutral position.

Table 4.4 summarises the changes in sub-bandage pressure with foot movement for both bandages to allow comparison.

Bandage	Movement	Mean change in sub-bandage pressure (mmHg) and [95% confidence interval for the mean.]			
		Medial		Lateral	
		Ankle	Calf	Ankle	Calf
Elastomeric (Granuflex ACB)	Plantar flexion	**4 * [3, 6]**	**-2 * [-3, -1]**	**7 * [5, 8]**	**-3* [-4, -2]**
	Dorsi flexion	**4 * [1, 7]**	-0.0 [-3, 2]	6 [-4, 12]	**4* [1, 7]**
	Eversion	**5 * [2, 9]**	1 [-0, 2]	**18 * [10, 26]**	**-4 * [-7, -1]**
	Inversion	**8 * [5, 11]**	-0.0 [-4, 3]	2 [-7, 10]	**-3 * [-3, -2]**
Non-elastomeric (Elastocrepe)	Plantar flexion	**4 * [1, 7]**	-1 [-2, 1]	**13 * [5, 14]**	**-3 * [-4, -1]**
	Dorsi flexion	**8 * [0, 16]**	-2 [-4, 1]	**14 * [7, 22]**	-0.0 [-5, 5]
	Eversion	**4 * [3, 6]**	-1 [-3, 1]	**20 * [9, 30]**	-3 [-6, 1]
	Inversion	**6 * [2, 9]**	1 [-1, 4]	2 [-3, 8]	**-5 * [-8, -1]**

* Denotes a significant difference from stationary position ($p<0.05$)

Table 4.4 Summary of pressure changes with foot movements

4.2.7. Analysis

From Laplace's law we see that pressure is proportional to bandage tension (and hence related to bandage extension) and inversely proportional to site radius. Therefore a graph plotting pressure times radius (P*r) against bandage extension should produce a straight line through the intercept. Plots for both bandages were drawn, see Figures 4.4 and 4.5 below. It can be seen that in the non-elastomeric bandage there does not appear to be a proportional relationship between P*r and extension (Figure 4.8) whereas the trend for the elastomeric bandage is that P*r increases with bandage extension (Figure 4.9), as predicted by Laplace's Law.

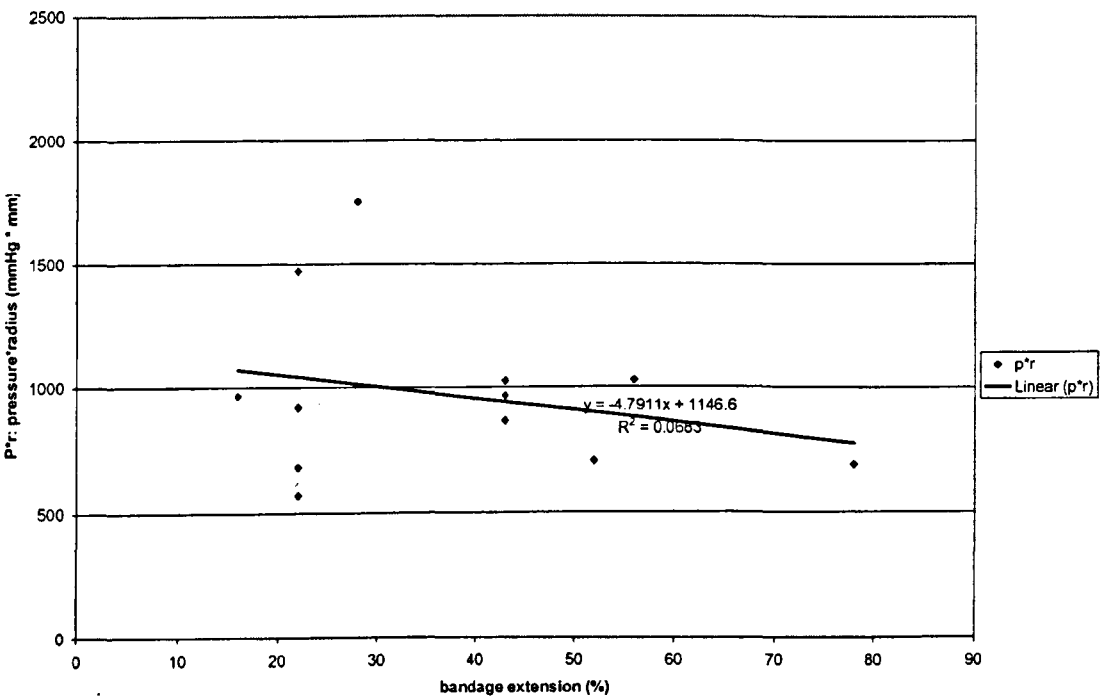


Figure 4.8 Non-elastomeric bandage: relationship between bandage extension, site radius and pressure

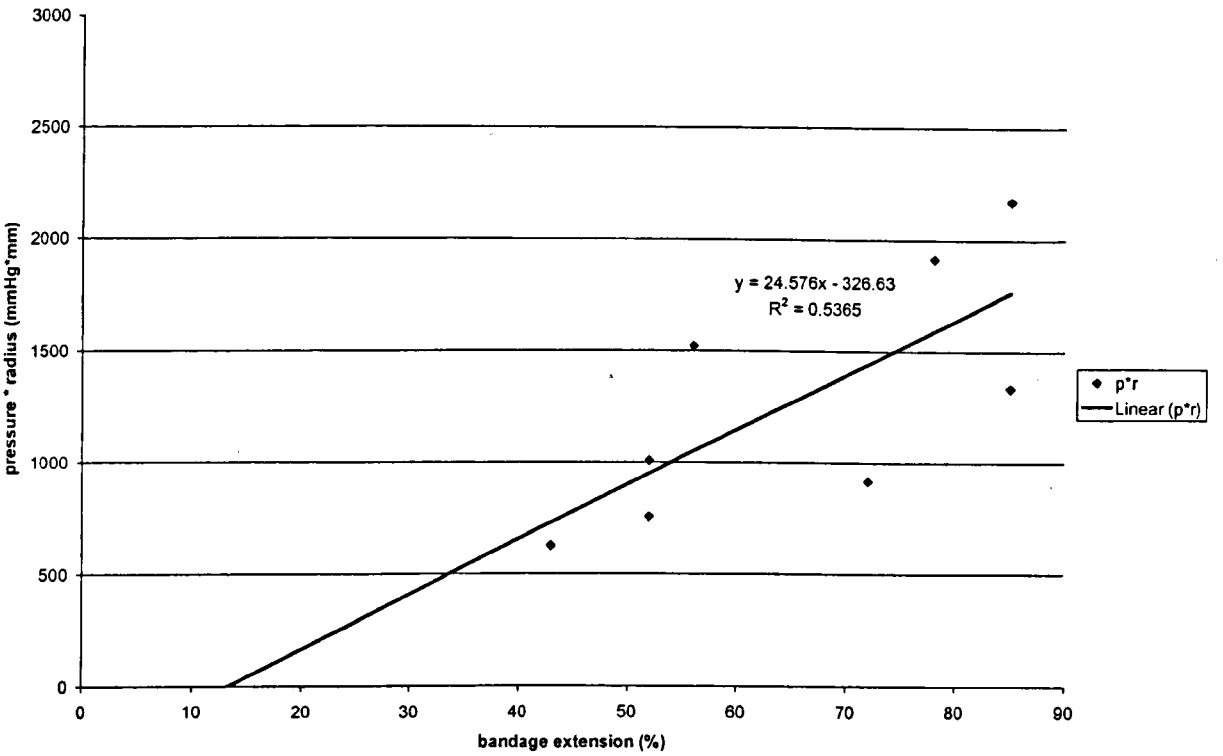


Figure 4.9: Elastomeric bandage: relationship between bandage extension, site radius and pressure

There appears to be an increase in ankle pressure and a decrease in calf pressure with the first three movements reported (plantar-flexion, dorsi-flexion, and plantar eversion), although there is variation between subjects and the changes are, on the whole, small. The only consistent change in pressure is the increase in medial ankle sub-bandage pressures with any movement of the foot.

During plantar inversion there was a pressure decrease at the lateral ankle and a pressure increase at the medial ankle, in both bandages.

Plantar-flexion, dorsi-flexion and plantar eversion tend to increase the ankle pressure, furthermore, they decrease, or leave unchanged, the calf pressure. The net effect of these changes is a change in the pressure ratio (calf p / ankle p).

4.2.7.1. Were the pressure changes different for the two bandages?

Examining the influence of the factors bandage, site, sub-bandage pressure and foot position on the change in bandage pressure had to take into account the potential interaction between them. Four-way analysis of variance revealed that the site and foot position were significant factors influencing pressure changes; (site; $f=37.3$; $p<0.001$: position; $f=5.2$, $p < 0.005$).

Combinations of factors that interacted were:

Bandage and site;	f=3.36	p=0.023
Bandage and foot position	f=3.56	p=0.018
Site and foot position	f=7.37	p<0.001

At any given site, therefore, the main determinant of pressure change is the position of the foot and the bandage. The changes in pressure with position are summarised in Table 4.5.

Bandage	Movement	Direction of change in sub-bandage pressure			
		Medial Ankle	Medial Calf	Lateral Ankle	Lateral Calf
Elastomeric (Granuflex ACB)	Plantar flexion	⇧	⇧	⇧	⇩
	Dorsi flexion	⇧			⇧
	Eversion	⇧		⇧	⇩
	Inversion	⇧			⇩
Non-elastomeric (Elastocrepe)	Plantar flexion	⇧		⇧	⇩
	Dorsi flexion	⇧		⇧	
	Eversion	⇧		⇧	
	Inversion	⇧			⇩

Table 4.5. Pattern of pressure change with foot movement

⇧ Indicates a significant increase in pressure

⇩ **Indicates a significant decrease in pressure**

4.2.8. Discussion

4.2.8.1. Static pressure

The lack of evidence of a relationship between measurement site radius, bandage extension and sub-bandage pressure with the non-elastomeric bandage does not allow one to state that there is no relationship between these factors. The sample size is too small to be able to confidently relate the difference in pressure with varying site radii. Other possible explanations for the lack of a relationship between these variables include:

1. The radius of curvature of the **limb** at the level of measurement is the independent variable rather than the radius of curvature at the **site.**

2. The effective radius of curvature is that perpendicular to the direction of application of the bandage. Bandages are not applied horizontally as an angle of application is essential to allow the bandage to spiral up the leg with 50% overlap. As the angle of overlap will change depending on the circumference of the limb then the comparison between ankle and calf sites is confounded by this factor.

3. The plot of pressure*radius against bandage extension does not represent Laplace's' Law, as the bandage tension rather than extension should be plotted. There was no way of measuring the bandage tension and the relationship between tension and extension varies with degree of extension, whether extension is increasing or decreasing, and any pre-conditioning of the bandage. As the relationship between p*r and bandage extension appeared to hold for the elastomeric bandage (in which there is less variation between bandage extension and tension) then this is likely.

4.2.8.2. Foot position

Foot exercises do appear to change the sub-bandage pressure recorded and this leads to a change in ankle-calf pressure ratio. Thus, these foot exercises may contribute to venous return, which has been found to be dependent on a graduated pressure from ankle to calf (Nicolaides et al 1980). The increased pressure ratio (ankle pressure / calf pressure) can be seen in Figure 4.6.

Also apparent is the large transient pressure change, which might have a clinical effect of 'milking' the veins. This must be confirmed by simultaneously monitoring sub-bandage pressure and blood flow by, e.g. Duplex ultrasound or venography.

The impact of foot movement on sub-bandage pressure had not previously been reported. Investigators in Cardiff have subsequently reported a similar finding (Nelson 1992, Williams et al 1997). Elsewhere, Danielsen et al (1998) and Hirai (1998) have investigated changes in pressure during walking but not with simple foot exercises. Changes in pressure during walking may be due to both postural changes and changes due to the position of the foot.

The response of bandage pressure to foot movements may have an impact on the treatment of leg ulceration if it can be determined that foot movements are therapeutic. Some practitioners recommend foot exercises, e.g. using a long rubber band, which is looped over the feet and held in the hands, against which one exercises the ankle (Heatley 1991). It is not known, however, how important calf muscle pump exercises are in promoting the healing of venous leg ulcers and whether the foot movement must be active or whether passive foot exercises would suffice. Arthropathy is a risk factor for slow ulcer healing (Franks et al 1995) and this would tend to support the premise that foot movements are beneficial. In addition, foot movements may be easy for patients to integrate into their daily routine.

The findings of this investigation into posture changes found a greater change in pressure beneath a non-elastomeric bandage than an elastomeric bandage at the lateral ankle but not at other sites. The differences between these findings and other reports may be due to the different sites of measurement – Callam et al (1991) placed sensors on the malleolus, and 8

and 19 cm proximal to the malleolus, and Hirai (1998) placed one sensor on the postero-medial area of the mid-calf. It may, however, be due to the difference between bandage responses at sites other than the lateral ankle. Further investigation with larger numbers of subjects and replications of measurements would be required to determine whether the lack of difference between the bandages at other sites is a type two error (i.e. failing to detect a significant difference as such).

4.2.9. Limitations of this investigation

The muscle bulk and tissue stiffness in the sample of students chosen is likely to be unrepresentative of that found in leg ulcer patients. The ankle and gaiter area of venous leg ulcer patients is usually affected by lipodermatosclerosis - deposition of fibrin and haemosiderin in the interstitial tissues resulting in staining and fibrosis of the tissues and wasting of the muscle. There are likely to be differences at this site in the response to foot movements.

It is hypothesised but not established that foot movements may cause a change in sub-bandage pressure and hence changes in blood flow characteristics. This aspect of the study was not pursued because of the need to enrol sufficient patients to establish a relationship between the bandage pressures and blood flow. The variability in the pressures recorded here would require a large sample in order to have sufficient power to detect any relationship. There were no local facilities to measure blood flow accurately.

The ankle mobility in this sample of students is likely to be unrepresentative of that in leg ulcer patients as a whole. Given the high prevalence of arthropathy in people with leg ulceration it is acknowledged that patients may not be able to generate similar changes in foot position (Gaylarde et al 1990). Changes in ankle stiffness might precede and influence, precede but not influence, or antecede leg ulceration. In an elderly population, it may be more important to look at gross posture changes than changes in foot position.

At the start of this investigation it was assumed that the person applying the bandages (EAN), because they were a trained nurse, would be competent in bandage application. Examination of the pressures generated beneath both bandages in this investigation, however, suggest that this was not the case. It was still not known whether the general level of bandage application competency was greater than that demonstrated in this experiment. Further studies were therefore planned to examine the ability of nurses involved in leg ulcer care to apply compression bandages.

5. Sub-bandage Pressure and Posture

In the presence of incompetent valves the venous pressure has an additional hydrostatic component, the magnitude of which is dependent on the vertical distance between the point of measurement and the heart. Sitting or standing places the feet below the heart and leads to venous hypertension and its sequelae. Physical therapies for venous insufficiency should therefore be effective in both sitting and standing postures. There is little need for external support when venous hypertension is not present, e.g. if the legs are level with the heart. One of the treatments for recalcitrant ulceration is complete bed rest but this is costly in terms of both direct and indirect costs such as opportunity costs, complications from bed rest and the impact on quality of life (Allen et al 1999).

Some previously published evaluations of compression bandaging systems in which sub-bandage pressures were presented (e.g. Charles 1991, Blair et al 1988) have failed to provide information on the posture of the subjects when sub-bandage pressures were recorded, although Charles (1991) states that the readings were taken 'in the resting phase'. If sub-bandage pressure varies significantly with posture then these evaluations are of limited use.

It may be stated that an occupation in which one stands still or sits may predispose to venous ulceration. There are, however, no epidemiological studies which have followed up a cohort to support or refute this, due to the difficulties in carrying out prospective studies which are sufficiently large to detect differences in ulceration rates between occupations / lifestyles while accounting for any confounding variables. One such study started in Edinburgh 1994 but the results of the initial screening only are available at present (Evans et al 1997). The incidence of ulceration cannot be ascertained until after the subjects have been reviewed in 1999.

Advice given to patients specifies that they sit with their feet elevated (Dale and Gibson, 1986). If patients comply with advice given by nurses and doctors, then they should have

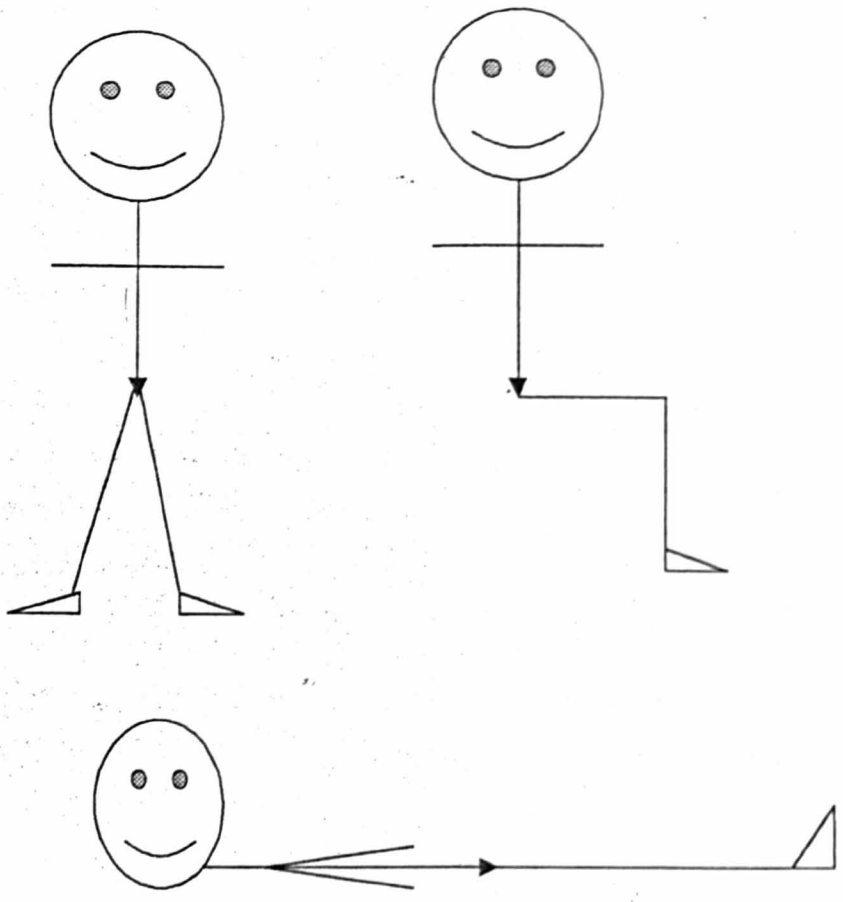


Figure 5.1 Stylised representations of postures in which pressures were measured, from top left: standing, sitting and lying supine.

their feet dependent for only a small proportion of the day. Compliance with this advice may be a prognostic factor for healing, although this relationship has not been established.

The posture and activity of patients may be important when considering whether to treat a patient with elastomeric or non-elastomeric bandages. As non-elastomeric bandages exert low pressures when the patient is at rest and high pressures when the calf muscle is activated, then it may follow that for these bandages to be effective, patients wearing non-elastomeric bandages should be able to exercise their calf muscle pump. Patients who are unable or unwilling to exercise the calf muscle pump by walking or doing ankle exercises may fare less well in non-elastomeric bandages than in elastomeric bandages. Likewise, patients who are able to exercise their calf muscle pump may have higher healing rates in non-elastomeric bandages than in elastomeric bandages, although there is no evidence from healing studies to confirm this as no trials have stratified patients with respect to their mobility or ankle flexion.

Differences in effectiveness may be due to differences in application technique, patient characteristics, or the pressure / time profile (the product of the pressure exerted and the time over which it acted). The area beneath the pressure / time line is greater for a weekly application of an elastomeric bandage than a non-elastomeric bandage. Furthermore the area beneath the pressure / time line is greater for a frequently reapplied non-elastomeric bandage than a weekly application of a non-elastomeric bandage, see Figure 4.1.

Posture is also a factor for consideration in evaluating treatments for ulceration. Randomised controlled trials of leg ulcer treatments such as low level laser therapy, therapeutic ultrasound or sequential compression, have rarely used a 'sham' treatment where the patient rests for an equal period of time (Callam et al 1987, Coleridge-Smith et al 1990). Anecdotally it is reported that sitting with feet elevated higher than the heart helps venous ulcers heal but again there is no evidence to support this from clinical trials.

There are considerable difficulties in determining posture of patients over a long period. Clinically, it may be possible to assess whether a patient has spent a long time with their

feet elevated if the exudate leakage on the dressing is proximal to the ulcer, rather than distal. This is not a sensitive measure of compliance with instructions to rest, as it requires that the ulcer has produced more exudate than the dressing can handle (either through absorption or evaporation), to act as an indicator.

Investigations of non-elastomeric bandages report that they exert low pressure when the patient is at rest or lying down, and high 'working pressure' when the patient is moving or standing (Stemmer et al 1980, Callam et al 1991, Hirai 1998). The aim of this investigation is to describes the influence on sub-bandage pressure of subject posture, with both elastomeric and non-elastomeric bandages, applied to a normal limb. Finally, the influence of time since application on the magnitude of sub-bandage pressure changes with posture was studied in patients wearing compression bandages for 7 days.

5.1. Measurement of posture

In the final part of this investigation, it was necessary to remotely record patient posture. A method of posture measurement was used which incorporates a fluid filled tube connected to a piezo-electric transducer (Sockalingham, 1993). The output from the transducer is proportional to the hydrostatic pressure caused by the height of the fluid above the transducer and hence the position of the subject, whether sitting, standing or lying, can be derived (Sockalingham, 1993). This allows one to record posture using a commercially available data logger. Thus, the data provided simultaneous readouts of pressure and vertical distance between the sensor and the reference point at the hip. The information obtained was easily classified as leg elevated / lying flat / sitting and standing postures by considering the change in sensor output produced by changes in the distance between the sensing tube and the position of the transducer. One further category was divined by looking at the time of day and the position. Thus, a lying position for more than one hour after 11pm was redefined as sleeping. Patients also kept a short diary noting times at which

they sat down for prolonged periods, elevated their legs, went to bed and rose in the morning. This validated the findings from the posture monitor.

5.2. AIMS

1. How do sub-bandage pressures change with posture changes, i.e. rising from lying to sitting and moving from sitting to standing?
2. Is any change in pressure with posture dependent on the type of bandage and / or the measurement site?
3. What happens to pressure differences with posture over the period of wearing a bandage - are the changes the same at end of a week when compared with those found at the start of the week?

5.3. Change in pressure with posture- pilot study

The effect of gross posture changes was also studied using the two bandages previously described; a non-elastomeric bandage (Elastocrepe), and an adhesive, elastomeric bandage (Granuflex ACB). Sensors were placed at the ankle and calf, laterally and medially and the transducers and recording were the same as described in the previous section.

5.3.1.Methods

There were five subjects in total. Four subjects were students at the Bioengineering Unit, and an additional subject with no history of venous disease was recruited to increase the number of observations. The full test methods are described in detail in section 4.2.5. In brief, however, two bandages were used; Granuflex Adhesive Compression Bandage (GACB) and Elastocrepe. The sub-bandage pressure was measured, using the Strathclyde Pressure Monitor, connected to a personal computer which recorded the output

at 20Hz, at four sites; the medial ankle, medial calf, lateral ankle and lateral calf sites. Each bandage was applied in a simple spiral with the subject sitting. Before the subject was asked to perform foot exercises (which took place with them supine; reported in chapter 4), the subjects were asked to stand for approximately 5 seconds and then to lie on the examination couch. The steady state output voltages in each posture were recorded using Acquire 1.08 and were analysed using a spreadsheet program (Quattro). Results are presented as sub-bandage pressures at the four measurement sites in each of the three postures.

5.3.2.Results

The table of raw data is included in Appendix A. Each bandage will be reported separately in order to determine whether their response to changes in posture are different.

5.3.2.1. Non-elastomeric bandage.

The average pressures at the four measurement sites and three postures are reported in Table 5.1.

	Sit	Stand	Lie
Medial Ankle	22	32	21
Medial Calf	20	24	22
Lateral Ankle	39	51	40
Lateral Calf	21	28	24

Table 5.1 Non-elastomeric bandage (Elastocrepe™); Mean sub-bandage pressure (mmHg)

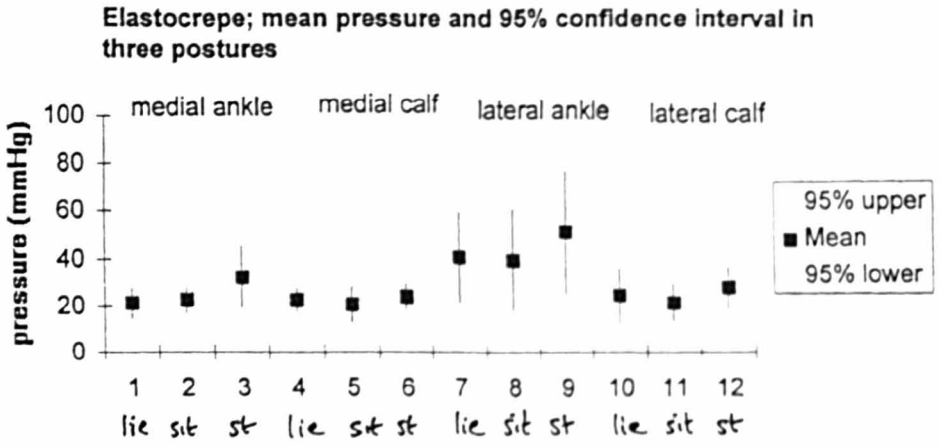


Figure 5.2 Sub-bandage pressures in three postures, at four sites, beneath Elastocrêpe bandage – plot shows mean and 95% confidence intervals

The mean sub-bandage pressures recorded at the ankle (in the sitting posture) were 22 mmHg medially and 39 mmHg laterally. These values are within generally accepted therapeutic ranges (BS:6612, 1985). The mean sub-bandage pressures recorded at the calf (in the sitting posture) were 20 mmHg medially and 21 mmHg laterally. The mean pressure and the 95% confidence interval for the changes in pressure for the non-elastomeric bandage are illustrated in Figure 5.2.

5.3.2.2. Elastomeric bandage

The mean pressures in the three postures are reported for this bandage, in Table 5.7.

	Sit	Stand	Lie
Medial Ankle	36	39	32
Medial Calf	18	20	19
Lateral Ankle	21	32	31
Lateral Calf	17	23	22

Table 5.2 Elastomeric bandage (Granuflex ACB™); Mean sub-bandage pressure (mmHg)

The mean sub-bandage pressures at the ankle sites (in the sitting posture) were 36 and 21 mmHg and these are within generally accepted therapeutic ranges (BS:6612, 1985). The mean sub-bandage pressures and changes in pressure on changing posture for the elastomeric bandage are summarised in Figure 5.3.

5.3.3.Analysis

5.3.3.1. Sitting pressures:

The lateral ankle sub-bandage pressure, 39 mmHg, was higher than that found medially, 22 mmHg, for the Elastocrepe™ bandage. The medial ankle sub-bandage pressure, 36 mmHg, was higher for the Granuflex ACB™ bandage than that found laterally, 20 mmHg. The reasons for this difference are not apparent. If the curvature of the measurement site were

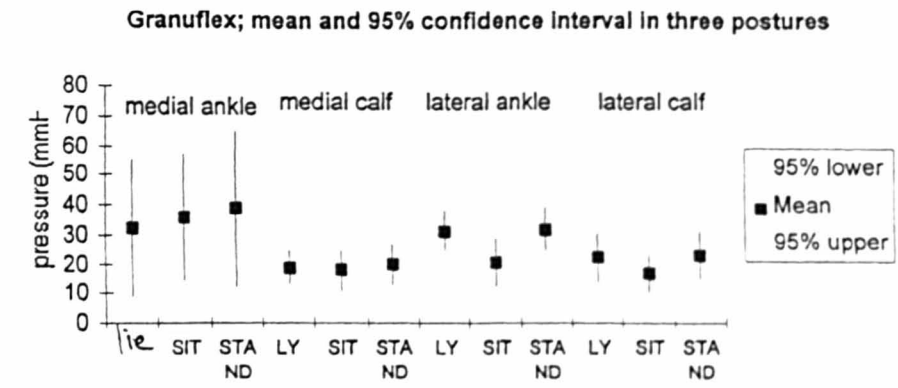


Figure 5.3 Sub-bandage pressures in three postures, at four sites, beneath Granuflex bandage – plot shows mean and 95% confidence intervals

the most important factor then the lateral pressures would be higher than the medial pressures as the lateral radii of curvature are smaller.

5.3.3.2. Are the two aspects of the leg similar?

Table 5.3 shows the increase in pressure with change in posture for the elastomeric bandage.

	Site							
Mean pressure (mmHg)	Medial ankle		Medial calf		Lateral ankle		Lateral calf	
Movement	Rise	Stand	Rise	Stand	Rise	Stand	Rise	Stand
posture 1/ posture 2	32/ 36	36/ 38	19/ 18	18/ 20	**31/ 21**	**21/ 32**	**22/ 17**	**17/ 23**
Df	23	12	23	12	**23**	**12**	**23**	**12**
t statistic	0.453	1.696	0.484	1.00	**3.98**	**6.82**	**2.17**	**5.03**
p (two tailed)	0.65	0.12	0.63	0.34	**<0.001**	**<0.0001**	**0.04**	**<0.001**

Table 5.3 Elastomeric bandage (Granuflex ACB™); change in pressure with posture (mmHg)

KEY; rise = moving from lying to sitting
stand = moving from sitting to standing
Bold text indicates a statistically significant change in pressure.

It can be seen that there is an increase in pressure at the lateral aspect of the leg upon standing and a decrease in recorded pressure upon rising (moving from lying to sitting postures). Upon standing, the pressure increase at the calf is smaller than the pressure increase at the ankle and hence the relative pressure ratio of calf pressure / ankle pressure (17/22 cf. 23/32) is maintained. For the non-elastomeric bandage a similar table of results is reported below, Table 5.4.

	Site							
Mean pressure (mmHg)	Medial ankle		Medial calf		Lateral ankle		Lateral calf	
	Rise	Stand	Rise	Stand	Rise	Stand	Rise	Stand
posture 1 / posture 2	21/ 22	**22/ 32**	22/ 20	**20/ 24**	40/ 39	**39/ 51**	24/ 21	**21/ 28**
Df	22	**12**	21	**12**	23	**12**	21	**12**
t statistic	0.60	**3.85**	0.85	**2.79**	0.13	**3.98**	0.79	**3.69**
p (two tailed)	0.55	**0.002**	0.40	**0.016**	0.9	**0.002**	0.44	**0.003**

Table 5.4 Non-elastomeric bandage (Elastocrepe™); change in pressure with posture (mmHg)

Key: rise = moving from lying to sitting

stand = moving from sitting to standing

Bold text indicates a consistent change in pressure.

The magnitude and direction of pressure changes are summarised in table 5.5.

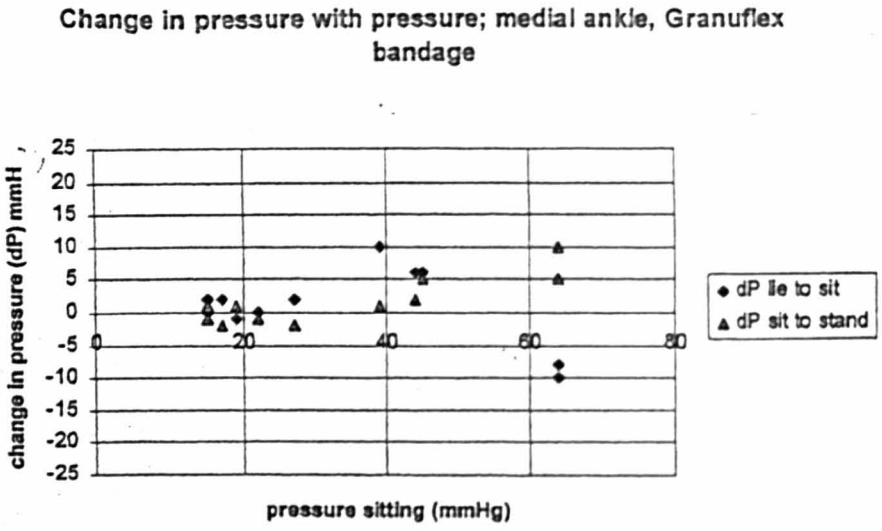


Figure 5.4. Graph showing the relationship between sitting pressure (P) and increase in pressure upon standing (dP), beneath a Granuflex bandage

Pressure change (mmHg)	Medial ankle		Medial calf		Lateral ankle		Lateral calf	
	Rise	Stand	Rise	Stand	Rise	Stand	Rise	Stand
Posture 1/ posture 2 Granuflex ACB					↓ 10	↑ 11	↓ 5	↑ 6
Posture 1 / posture 2 Elastocrepe		↑ 10		↑ 4		↑ 12		↑ 9

Table 5.5 Pattern of pressure change with posture

5.3.3.3. Dependence of pressure change upon initial pressure

In theory, due to the shape of the tension / extension curve, it can be predicted that the change in pressure with posture, dP, varies with the initial pressure, P. This is because at high extensions, and hence high pressure, the stiffness of the bandage is high. Therefore a small increase in extension would produce a large increase in tension. The sitting pressure (P) was compared with the change in pressure (dP) recorded in the lying and standing postures. The relationship between dP and p, at the medial ankle can be seen in Figure 5.4.

The lack of a relationship between dP at the medial ankle upon standing and the sitting pressure, P, can be seen in this graph. Furthermore, there is no obvious correlation between sitting pressure and change in pressure at the lateral ankle or calf. There does appear to be a correlation between the resting pressure and the change in pressure at the medial calf. The correlation coefficients are summarised in Table 5.6.

Correlation coefficients for dP and P		Medial ankle	Medial calf	Lateral ankle	Lateral calf
Granuflex bandage;	lie to sit,	-0.4	**0.708***	**0.766***	-0.249
	sit – stand	**0.839***	**-0.645***	-0.499	0.085
Elastocrepe bandage	lie to sit,	0.57	**0.658***	0.183	-0.184
	sit – stand	0.067	**-0.634***	-0.557	-0.467

Key: * indicates that the probability of finding this value of r for two samples from a population in which there is no real correlation is less than 5%

Table 5.6 Correlation coefficient, r, for dP and P

The correlation coefficient can be evaluated by calculating the t-statistic and examining the probability that this value of r would occur by chance using the formula $t = r\sqrt{\frac{n-2}{1-r^2}}$ (Swinscow 1996). The critical value of r with a sample size of 12 such that the probability of finding that value when there is no correlation is 5% is 0.575. At the medial calf, there is a proportional increase in pressure from lying to sitting. The change in pressure upon standing, however, is inversely proportional to the sitting pressure; i.e. the magnitude of the pressure change from sitting to standing is smaller when the sitting pressure is high.

Also of interest is the fact that the shape of the load extension curves for the two bandages are different in that the non-elastomeric bandage has a steeper gradient at the working extension. It has already been postulated that this might be expected to produce a greater change in pressure with extension than the elastomeric bandage. The non-elastomeric bandage does not demonstrate a significantly greater increase in pressure upon rising (moving from lying to sitting) than the elastomeric bandage according to Table 5.5. It does, however have a slightly higher pressure rise with standing than the elastomeric bandage.

5.3.4.Discussion

5.3.4.1. Sitting pressures

As the same subjects were used for both bandages, the difference in resting ankle pressure distribution is not due to any difference in ankle sizes. Further investigation is required to determine whether this effect is replicated in clinical studies. If it remains, then it reinforces the need to provide information on the sites used in sub-bandage pressure measurement when bandage systems are compared. One of the problems in comparing these results with those from previous studies is the choice of ankle site. Some investigators (Blair et al 1988, Callam et al 1992,) use the malleolus as the ankle site, whereas in this study the point 4 cm immediately above the malleolus was chosen. Thus, it is not possible to compare directly the ankle pressures achieved in these investigations. Only Danielsen et al (1998) report measuring at both sites although they reported only the pressures at the medial malleolus.

The elastomeric bandage (Granuflex ACB™) is classified as a class 3b bandage which could be expected to apply 18-24 mmHg at the ankle when applied in a simple spiral technique (Thomas, 1990; British Standard BS1612: 1986). A minimum of this level of compression was achieved in 10/13 cases at the medial ankle (sitting) and 8/13 at the lateral ankle (sitting). The non-elastomeric bandage (Elastocrepe™) is classified as a class 2 (support) bandage, and thus is not expected to apply *and maintain* such high resting pressures (Thomas 1990). The initial pressures were above 18 mmHg in 11/13 cases at the medial ankle and 12/13 cases at the lateral ankle. Practitioners use these bandages successfully (Stacey et al 1997) and the reduction in pressure can be addressed by reapplying the bandage more often than every 7 days and using it over a paste impregnated bandage (Dale et al 1983).

5.3.4.2. Change in pressure with posture

The pressure measured at the medial ankle site increases (not significantly) upon moving from lying, to sitting and from sitting to standing. This pattern is not found at the three other

sites where the *sitting* pressure is the lowest. This may be due to the deformation of the site when the subject is lying. If the subject lies down and rests the leg on a bed / couch, then the lateral ankle may touch the support surface and the sensor is compressed by the weight of the legs, hence recording a higher pressure. The calf pressures may be affected by the fact that the calf muscle will be deformed upon lying down. Changing the cross section of the calf muscle from approximating a circular shape to an oval, with the sensors at the points with smallest radius of curvature, may influence the pressure readings.

The predicted pattern of pressure change, that pressure would increase from lying to sitting, to standing was not observed at all sites. Pressure did increase, however, from the sitting to the standing posture. The physiological basis for this increase lies in the microcirculatory response to standing. As one becomes increasingly upright there is a tendency for fluid to accumulate in the legs due to Starling's Law. Patients with chronic venous insufficiency are particularly prone to this due to poor function of the muscle pump. The leg becomes larger, therefore, and the sub-bandage pressure increases as the bandage is extended. The arterio-venous reflex controls the tendency for the blood to 'pool' in the limbs upon standing. The degree to which this reflex is functioning in leg ulcer patients could be investigated in conjunction with sub-bandage pressure measurements to study further the increase in pressure.

The non-elastomeric bandage demonstrates an increase in pressure at every site only when the subject moves from sitting to standing. There is no evidence of a change in pressure when moving from lying supine to sitting. The elastomeric bandage, in contrast, shows only a change in pressure at the lateral aspect of the leg. There is a decrease in pressure at the lateral sites upon moving from lying to sitting and an increase when moving from sitting to standing. There is no significant change in pressure at the medial sites. Hence, the two bandages appear to respond differently to changes in posture. This has implications for future investigations of pressure changes with posture, as the choice of measurement sites may influence the results obtained. If the results for the elastomeric

bandage were upheld in a larger scale study then it is possible the measurements at the medial aspect may fail to record the changes in pressure occurring at the lateral aspect. For this reason, further investigations were carried out with measurements at the lateral aspect of the leg in order to capture the possible changes in pressure.

For the non-elastomeric bandages, the pressure changes at the medial aspect mirrored those at the lateral aspect and hence we expected there would be no loss of information by measuring the pressures only at the lateral aspect of the leg in future.

The variation in dP with P depends on the pressure being achieved by the bandages being at a particular point of the load extension curve. If the required pressure were achieved by applying many layers at a lower extension, then this relationship would not apply.

5.3.5.Conclusion

There appears to be an increase in sub-bandage pressure from sitting to standing, the magnitude of the change does not appear to be proportional to the original pressure. The observed fall in pressure from lying to sitting however has not previously been reported. The two bandages showed different responses to posture change.

There are a number of limitations to this study. The use of different volunteers meant that any errors in the pressure measurement due to perturbation of the skin / bandage interface by the pressure sensor, as described by Vinckx (1990) could not be ignored. Also, the deformation of the calf muscle while lying was thought to confound the calf site measurements. For these reasons, therefore, the main study excluded the lying posture and used a single subject.

5.4. Influence of bandage on pressure change with posture – main study

Three commonly used bandages were used in this phase of the investigation, two contained elastomers and one did not, therefore it was hoped to explore further the relationship between bandage composition and response to changes in posture. The bandages were applied to one leg (EAN) by 48 qualified nurses, and the sub-bandage pressure was measured in the sitting and the standing postures. The nurses applied the bandages on three occasions, before training, two weeks after training and then again six weeks later (18 nurses). The effect of training on bandaging technique will be considered in chapter 6.

5.4.1. Method

Forty-eight qualified hospital and community nurses were recruited to the study by asking local nurse managers to nominate staff to attend 2 full study days in the management of leg ulceration. There were no entry criteria or fees for attending the study days. The programme for the study days is in Appendix B.

The sub-bandage pressures at the lateral ankle and calf sites (as previously defined) were recorded using the Strathclyde Pressure Monitor, in the sitting and the standing positions at the start of the first study day.

5.4.2. Materials

Three compression bandages were used – Rosidal K, a non-elastomeric (100% cotton) bandage with no surface markings, Tensopress, an elastomeric bandage with a central line along its length indicating 50% overlap, and Setopress, an elastomeric bandage with printed rectangles along its length indicating when the bandage had been extended sufficiently. All the bandages were 10cm nominal width and were non-adhesive.

5.4.3.Experimental set-up

The following experimental arrangements were set-up.

1. The subject (EAN) sat on a regular stacking chair with feet flat on the floor – position of the feet and the chair were marked with masking tape on the floor
2. The subject's ankle and calf sites (4 cm above the lateral malleolus and at the widest part of the calf) were located using a tape measure and were marked in ink
3. The pressure sensors were taped at the two measurement sites and the sensor tubing was brought up to the knee where it was taped in place
4. The pressure transducers were placed on a table beside the subject and the pressure readings were zeroed with no bandage in place. The pressure monitor display was positioned so that the subject could see it but it could not be seen by the nurse.
5. The nurses were asked to apply a layer of orthopaedic wool and each of the 3 compression bandages to the subjects leg while they remained seated. The order of application of the bandages for each nurse had previously been determined by using a random number table
6. Immediately after the wool and bandage were applied the seated sub-bandage pressure at the ankle and calf sites were recorded from the display of the Strathclyde Pressure Monitor
7. The subject stood up and the standing sub-bandage pressure at the two sites was recorded
8. The bandage was removed and steps 5-7 were repeated with the remaining two bandages
9. When all readings had been taken, then the display was uncovered and the nurse was given feedback on their application technique and pressure achieved.

Feedback took the form of positive comments on placement, overlap and extension, and suggestions for improvement in placement, overlap and extension.

The assessment of sub-bandage pressure was repeated at the end of the second study day (2 weeks later), and for 18 nurses, 6 weeks later. This provides information on the impact of the training on sub-bandage pressures and these will be considered in Chapter 6, only the changes in pressure recorded during the move from sitting to standing are considered here.

5.4.4.Results

5.4.4.1. Non-elastomeric bandage

The sub-bandage pressures recorded beneath the non-elastomeric bandage, Rosidal K, in the sitting and the standing posture, is detailed at two time points (at first attendance at the study day = baseline, and at the =end of the second study day = after training). The initial resting ankle pressure was 27 mmHg (3.65 kPa), and this increased to 34 mmHg (4.52 kPa) upon standing. At the calf the initial resting pressure was 34 mmHg (4.56 kPa), rising to 42 mmHg upon standing (5.6 kPa), see Table 5.7.

	Lateral Ankle		Lateral Calf	
Mean [SEM]	Sit	Stand	Sit	Stand
Baseline (n=48)	27 [1.9]	34 [2.2]	34 [2.4]	42 [3.0]
Immediately after training (n=46)	24 [1.1]	27 [1.6]	25 [1.6]	28 [2.1]

Table 5.12 Inelastic bandage, Rosidal K, mean pressure, sitting and standing postures (mmHg) (SEM = standard error of mean)

5.4.4.2. Elastomeric bandages

Two elastomeric bandages were used in the investigation. One incorporated a visual extension indicator (Setopress) and one had a visual overlap indicator (Tensopress). The sitting and standing pressures for both bandages were recorded immediately after application.

Setopress

The mean sub-bandage pressures are summarised in Table 5.8. Using the Setopress bandage nurses initially produced a mean ankle pressure of 35 mmHg (4.7 kPa) and a mean calf pressure of 40 mmHg (5.3kPa) in the sitting posture. These pressures increased to 40 mmHg (5.3 kPa) at the ankle to 48 mmHg (6.5 kPa) at the calf upon standing.

After training the mean ankle pressure was 29 mmHg (3.7 kPa), and the calf pressure 25 mmHg (3.3 kPa). The majority of nurses no longer produced an unfavourable pressure ratio. Upon standing the ankle pressure increased to 32 mmHg (4.3 kPa) and the calf pressure to 28 mmHg (3.7 kPa).

	Lateral Ankle		Lateral Calf	
Mean [SEM]	Sit	Stand	Sit	Stand
Baseline (n=48)	35 [2.3]	40 [2.5]	40 [2.1]	48 [2.5]
Immediately after training (n=46)	29 [1.4]	32 [1.8]	25 [1.3]	28 [1.7]

Table 5.8 Sub-bandage pressures recorded under Setopress in two postures (mmHg)
SEM = standard error of mean

Tensopress

The sub-bandage pressures are summarised in Table 5.9. Using the Tensopress bandage nurses initially produced a mean ankle pressure of 30 mmHg (4.0 kPa) in the sitting posture and this increased to 34 mmHg (4.5 kPa) upon standing. The initial calf pressure was 34 mmHg (4.6 kPa); hence the nurses initially produced an unfavourable pressure ratio. Upon standing the mean calf pressure increased to 42 mmHg (4.7 kPa).

After training the mean ankle pressure was 29mmHg (3.8 kPa), and the calf pressure 23 mmHg (3.1 kPa), and the majority of nurses no longer produced an unfavourable pressure ratio. Upon standing the ankle pressure increased to 30 mmHg (4.0 kPa) and the calf pressure to 26 mmHg (3.5 kPa).

	Lateral Ankle		Lateral Calf	
Mean [SEM]	Sit	Stand	Sit	Stand
Baseline (n=48)	30 [2.2]	34 [2.3]	34 [1.7]	42 [2.2]
Immediately after training (n=46)	29 [1.6]	30 [1.9]	23 [1.2]	26 [1.5]

Table 5.9 Sub-bandage pressures recorded under Tensopress in two postures (mmHg)
SEM = standard error of mean

5.4.5.Analysis

Non-elastomeric bandage

The significance of the changes in sub-bandage pressure for the non-elastomeric bandages was evaluated by performing paired t-tests for the sitting and standing pressures. The results of the analysis are summarised in Table 5.10.

	Lateral Ankle				Lateral Calf			
Mean [SD]	Sit P (mmHg)	Stand P (mmHg)	t (paired t test)	p (two-tailed)	Sit P (mmHg)	Stand P (mmHg)	t (paired t test)	p (two-tailed)
Baseline (n=48)	27 [13.3]	34 [15.0]	6.92	<0.001	34 [16.7]	42 [20.8]	6.84	<0.001
Immediately after training (n=46)	24 [7.7]	27 [10.5]	3.53	<0.001	25 [11.1]	28 [14.4]	4.07	<0.001

Table 5.10 Inelastic bandage, Rosidal K, change in pressure from sitting to standing

SD = standard deviation

The sub-bandage pressures were significantly lower on the second try, (ankle 27mmHg c.f. 24 mmHg, $t=2.1$, $p<0.05$; calf 34 mmHg c.f. 25 mmHg, $t=2.44$, $p<0.05$). The subjects may have been relaxing the bandage at the calf on their second try in order to correct the unfavourable pressure ratio produced on the first try. The magnitude of the change in sub-bandage pressure is estimated by calculating the 95% confidence interval for the change in pressure. Results of the statistical analysis are shown in Table 5.11.

	Lateral Ankle Baseline, n=48	Lateral Calf, Baseline, n=48	Lateral Ankle, Immediately after training n=46	Lateral Calf, Immediately after training n=46
dP sit – stand (mmHg)	7	7	3	2
t (paired t-test)	6.92	6.84	3.53	4.07
p (two tailed)	<0.001	<0.001	<0.001	<0.001
95% confidence interval for change in pressure (mmHg)	5, 8	5, 10	1, 5	1, 4

Table 5.11 Rosidal K; Change in pressure with standing

5.4.5.1. Elastomeric bandages

5.4.5.1.1. Setopress

The significance of the changes in sub-bandage pressure between sitting and standing was evaluated by performing a paired t-test for the sitting and standing pressures. The results of this analysis are summarised in Table 5.12.

	Lateral Ankle				Lateral Calf			
Mean[SD]	Sit	Stand	T	P	Sit	Stand	t	P
Baseline (n=48)	35 [16.1]	40 [17.5]	7.1	**<0.001**	40 [14.3]	48 [17.6]	10.1	**<0.001**
Immediately after training (n=46)	29 [9.7]	32 [12.4]	3.0	**0.004**	25 [8.7]	28 [11.3]	5.08	**<0.001**

Table 5.12 Sub-bandage pressures recorded under Setopress in two postures

SD = Standard deviation

The pressure appears to increase upon standing. Statistical analysis was performed to determine whether these increases in pressure were significant. The results of the statistical analysis indicate that pressure increased significantly upon standing. It should be noted, however, that the magnitude of the changes is small and the 95% confidence interval for the change in pressure is shown in Table 5.13.

	Lateral Ankle Baseline, n=48	Lateral Calf, Baseline, n=48	Lateral Ankle, Immediately after training n=46	Lateral Calf, Immediately after training n=46
dP sit – stand (mmHg)	5	9	3	3
t (paired t-test)	7.09	10.08	3.0	5.08
p (two tailed)	<0.001	<0.001	0.005	<0.001
95% confidence interval for change in pressure (mmHg)	4,6	7, 10	1, 4	2, 4

Table 5.13 Statistical analysis of changes in pressure for Setopress

Tensopress

The second elastomeric bandage, Tensopress, was similarly investigated with the sitting and standing pressures recorded immediately after application at each assessment period. The results are in Table 5.14

	Lateral Ankle				Lateral Calf			
Mean[SD]	Sit	Stand	T	P	Sit	Stand	t	P
Baseline (n=48)	30 [14.9]	34 [16.2]	7.2	<0.001	35 [11.7]	42 [15.2]	10.1	<0.001
Immediately after training (n=46)	29 [11.0]	30 [12.9]	2.5	0.015	23 [8.1]	26 [10.2]	4.9	<0.001

Table 5.14 Sub-bandage pressure under Tensopress in two postures

SD = Standard deviation

The ankle and calf pressures increase significantly upon standing. The statistical analysis of the changes in pressure, to determine the magnitude of the changes in pressure are shown in Table 5.15

	Lateral Ankle Baseline, n=48	Lateral Calf, Baseline, n=48	Lateral Ankle, Immediately after training n=46	Lateral Calf, Immediately after training n=46
dP sit – stand (mmHg)	4	8	2	3
t (paired t-test)	7.2	10.1	2.5	4.9
p (two tailed)	<0.001	<0.001	0.015	<0.001
95% confidence interval for change in pressure (mmHg)	3, 5	6, 10	0, 3	1, 4

Table 5.15 Statistical analysis of changes in pressure with posture for Tensopress

Note both ankle and calf pressure changes with moving from sitting to standing are lower after training. As sub-bandage pressure can be achieved by high tension and few layers or low tension and many layers this may account for the difference in posture pressure change. A bandage applied with high extension would be expected to exhibit a larger increase than one applied at the same resting pressure but with low bandage tension and high number of layers.

This was investigated by performing an analysis of variance using SPSS for MS Windows (Release 6.1). The four factors, bandage (Rosidal K, Setopress or Tensopress), Site (ankle or calf); Posture (sitting or standing); Time of application (try 1 or try 2).

Source of Variation	Sum of Squares	DF	Mean Square	F	Sig. Of F
Main Effects	**36925.217**	**5**	**7385.043**	**39.335**	**0.00**
BANDAGE.	4008.228	2	2004.114	10.674	0.000
POSTURE	6010.858	1	6010.858	32.016	0.000
SITE	1226.297	1	1226.297	6.532	0.011
TIME	25543.911	1	25543.911	136.054	0.000
2-Way Interactions	**9304.417**	**9**	**1033.824**	**5.506**	**0.000**
BANDAGE / POSTURE	28.945	2	14.473	.077	0.926
BANDAGE / SITE	512.911	2	256.456	1.366	0.256
BANDAGE / TIME	1114.861	2	557.431	2.969	0.052
POSTURE / SITE	156.568	1	156.568	.834	0.361
POSTURE / TIME	1086.097	1	1086.097	5.785	0.016
SITE / TIME	6419.873	1	6419.873	34.194	0.000
3-Way Interactions	**507.104**	**7**	**72.443**	**.386**	**0.911**
BANDAGE / POSTURE / SITE	83.738	2	41.869	.223	0.800
BANDAGE / POSTURE / TIME	1.189	2	.594	.003	0.997
BANDAGE / SITE / TIME	304.289	2	152.144	.810	0.445
POSTURE / SITE / TIME	116.035	1	116.035	.618	0.432
4-Way Interactions	**6.207**	**2**	**3.104**	**.017**	**0.984**
BANDAGE/POSTURE/SITE/TIME	6.207	2	3.104	.017	0.984
Explained	47053.710	23	2045.	10.897	0.000
Residual	206710.	1101	187.748		
Total	253764.048	1124	225.769		

1137 cases were processed; 12 cases (1.1 pct) were missing.

Table 5.16

Analysis of variance using repeated measures was not possible as there were different numbers of subjects at each measurement point.

This analysis of variance indicates that pressure varied with bandage, posture, site and training (time). The two-way interactions between posture and time and site and time were significant. These indicate that:

1. Pressure distribution between ankle and calf varied with training
2. Pressure variation with posture varied with training.

5.4.5.2. Dependence of dP on initial pressure.

In order to determine whether the increase in pressure observed with standing was proportional to the sitting pressure the change in pressure, dP, was compared with the sitting pressure, P. The following table (Table 5.17) summarises the correlation between dP and P.

Correlation coefficient for posture change sit → stand dP vs. P				
Bandage	Lateral ankle baseline	Lateral calf baseline	Lateral ankle after training	Lateral calf after training
Rosidal K	0.046	**0.399 ***	0.08	**0.66 ***
Setopress	0.164	**0.419 ***	0.2	**0.478 ***
Tensopress	0.194	**0.51 ***	0.193	**0.342 ***

Table 5.17 Correlation coefficients, r, between dP and P, three bandages (* denotes that the value of r indicates that this correlation coefficient is significant at 0.05)

Using the formula $t = r\sqrt{\frac{n-2}{1-r^2}}$, with a value of t=2.011 corresponding to p=0.05, and n=48, then the critical value of r is 0.28.

5.4.6.Discussion

This work has shown that qualified nurses can apply a bandage so that the bandage pressure changes with posture. The response to shifts in posture is different after training, maybe due to changes in initial sub-bandage pressures or in the application technique. It failed to confirm previous findings, e.g. Callam et al (1991) that change in pressure depended on bandage type and posture. This may be due to the study having low power (insufficient sample size), other factors, such as training and site, may have been more influential, or other findings were type 1 errors.

Although the first pilot study has been improved by recruiting a large number of nurses in clinical practice to apply the bandages, and there is one leg used throughout, this leg does not have venous insufficiency. This means that these findings might not be relevant to patients. There may be changes in the circulation in patients with venous hypertension, for example, arterio-venous shunting, which may change the response to changes in posture. A patient with venous hypertension may have, on standing, a larger increase in limb volume that would serve to increase the rise in sub-bandage pressure. On sitting or lying down the pressure may not change quickly, however, depending on the speed of return of the interstitial fluids into the intravascular compartment. As changes in posture may not be followed by instantaneous changes in sub-bandage pressure, it is necessary to study the changes in sub-bandage pressure in patients.

Another limitation on the previous study is that it only looks at changes in pressure immediately after application. As the bandage response (the shape of the load / extension curve) changes after pre-conditioning it is also likely to change after being worn. This effect may have a larger influence on some bandages than others depending on the physical composition. Elastomeric / non-elastomeric and knitted / woven bandages may have different responses to posture changes over time.

In order to address these limitations a study of bandage pressure and posture was undertaken on patients over a period of one week.

5.4.6.1. Monitoring of pressure and posture for 7 days

Two patients attending Falkirk and District Royal Infirmary leg ulcer clinic who were receiving compression bandaging for venous ulcers were asked to take part in this investigation. The intention was to measure the posture, sub-bandage pressure at the ankle and at the calf, over a period of seven days. To achieve this pressure sensors were applied to the patient's lateral ankle site (40mm above the malleolus) and the lateral calf (at the widest part of the calf). In addition, a third tube, open to the atmosphere and not ending in a pressure sensing bulb, was applied along the leg, from the knee to the ankle. This provided an output proportional to the vertical distance of the end of tube (at the ankle) was placed relative to the knee (the position of the transducer). Inspection of the output, therefore, could provide information on the posture of the patient.

The transducers for all three sensing tubes were positioned at the knee, supported on a rigid plastic gaiter. The transducer cable was taped at 15 cm intervals along the thigh, ending at the data logger. The battery-powered data logger was placed inside a 'bum-bag' and this was worn around the waist. Patients wore the system continuously for 7 days, placing the 'bum-bag' on the bedside while sleeping.

Day 1 – set up – patient is bandaged with pressure sensors in place and data logger is started

Day 4 – data download - patient is visited and the data from the data logger is downloaded to a portable computer. Bandage is left t in place.

Day 8 – end of data collection – patient has bandage removed. Data is downloaded from data logger to portable computer

The data logger was set up in order to record the data input (ankle pressure, calf pressure and 'posture') every 30 seconds for 7 days. The data files were separated so that the sub-bandage pressures in the sitting, standing, lying and sleeping postures were identified.

It was only possible to record data from the sensors for a maximum of 4 days because of the memory capacity of the data logger. The subjects had the sensors and data loggers fitted and were bandaged on day 1. They were visited for a downloading of the data, replacement of batteries and reconnection on day 4, and then seen on day 8 for the final downloading and removal of the bandage, sensors and data logger.

One patient wore both bandages under evaluation and a further patient wore one type of bandage, hence there are three sets of data.

The data was analysed to ascertain whether any change in sub-bandage pressure when the subject was standing, as reported in the previous sections, was reflected in this data. See Sockalingham (1993) for further interrogation of the data.

5.4.7.Results

The mean pressure over each day of monitoring is reported in Table 5.18 (ankle pressures) and Table 5.19 (calf pressures). Data sets 1 and 3 are for the multi-layered bandage and data set two was from the single layered bandage. Both bandaging systems contained elastomeric fibres. Only three complete data sets were available due to the difficulties in recruiting subjects to take part in the study and due to the fragility of the sensing equipment which meant that data collection was incomplete on a further 3 occasions. There were competing requirements for the recruitment of subjects in that younger subjects were asked to take part as they were perceived to be more likely to have transport to the clinic for the resetting of the data logger on day 4 and to be willing to return to the clinic for the interim visit. These subjects were the most active and hence there was a higher risk of equipment failure. The equipment failure tended to be in the wires connecting the data logger to the transducers.

			Mean pressure (mmHg)		
Bandage	Data set	Day	Lying	Sitting	Standing
4 layer	1	1	22	30	28
4 layer	1	2	19	30	29
4 layer	1	3	15	28	28
4 layer	1	4	13	28	28
4 layer	1	5	15	30	28
4 layer	1	6	14	28	29
4 layer	1	7	14	31	29
G ACB	2	1	24	46	30
G ACB	2	2	20	44	26
G ACB	2	3	15	43	24
G ACB	2	4	24	40	23
G ACB	2	5	20	34	21
G ACB	2	6	19	45	22
G ACB	2	7	28	42	22
4 layer	3	1	13	31	30
4 layer	3	2	15	33	26
4 layer	3	3	10	33	26
4 layer	3	4	21	35	30
4 layer	3	5	22	35	29
4 layer	3	6	25	35	30
4 layer	3	7	23	34	29

Table 5.18 Mean ankle pressures in lying, sitting and standing posture over seven days

4 layer = Four layer bandage; G ACB = Granuflex adhesive compression bandage

			Mean pressure (mmHg)		
Bandage	Data set	Day	Lying	Sitting	Standing
4 layer	1	1	9	18	15
4 layer	1	2	11	15	11
4 layer	1	3	13	15	12
4 layer	1	4	4.0	11	13
4 layer	1	5	10	20	18
4 layer	1	6	10	18	18
4 layer	1	7	6	17	16
G ACB	2	1	15	22	24
G ACB	2	2	15	22	23
G ACB	2	3	16	23	23
G ACB	2	4	14	20	22
G ACB	2	5	13	17	21
G ACB	2	6	15	23	24
G ACB	2	7	19	26	29
4 layer	3	1	14	27	23
4 layer	3	2	16	31	26
4 layer	3	3	18	30	24
4 layer	3	4	16	28	22
4 layer	3	5	13	27	21
4 layer	3	6	18	28	22
4 layer	3	7	15	26	21

Table 5.19 Mean calf pressures in lying, sitting and standing postures over seven days.
4 layer = Four layer bandage; G ACB = Granuflex adhesive compression bandage

It can be seen from Tables 5.18 and 5.19 that the lowest pressures are recorded in the lying posture for both sites, subjects and for all 7 days of data collection. The highest pressures, however, are recorded in the sitting postures for all but 2 days (days 3 and 6 for data set 1). The highest mean ankle pressures are observed in the sitting posture for all but one day of

data set 1. The highest calf pressures are recorded in the sitting posture for subjects 1 and 3 (except for day 4 for subject 1) and for the standing posture for subject two.

The amount of time these subjects spend sitting is noteworthy. This may make their results unrepresentative of the leg ulcer population but in reality we do not know how active many patients are. Although the majority of leg ulcer patients are above retirement age, many have responsibility for caring for their own home or caring for members of the family. It is interesting to see the proportion of each day spent in each posture. The data logger records the position of the leg below the hip every 30 seconds. From the subjects' contemporaneous diaries it is possible to identify those days when the subjects were not at their normal employment. The number of hours spent standing on these days is lower as they both worked in shops and hence work days had a very high number of hours spent standing. Table 5.20 shows the estimate of the time spent in each posture.

subject	day	Sitting pressure (mmHg)	SD	n	Standing pressure (mmHg)	SD	n	t	p
1	1	**18.449**	5.36	407	15.259	5.089	1259	-10.85	<0.001
1	2	**14.677**	4.333	285	11.294	4.178	904	-11.82	<0.001
1	3	**15.324**	4.605	385	11.739	3.858	733	-13.79	<0.001
1	4	10.861	3.994	221	**13.202**	5.34	1185	6.2	<0.001
1	5	**20.482**	9.02	216	18.016	5.77	1530	-5.42	<0.001
1	6	18.217	6.59	267	17.83	5.96	1536	-0.96	>0.05
1	7	**17.168**	6.07	207	16.26	4.81	1518	-2.46	<0.02
2	1	22.426	3.379	227	**23.657**	2.637	1484	6.29	<0.001
2	2	22.358	2.388	238	**22.812**	2.48	1469	2.63	<0.01
2	3	22.641	2.979	223	**23.175**	2.557	1304	2.81	<0.01
2	4	19.92	2.652	371	**22.37**	4.753	1121	9.45	<0.001
2	5	17.054	2.884	241	**21.431**	3.186	576	18.4	<0.001
2	6	22.796	3.469	272	**23.574**	3.01	1575	3.84	<0.001
2	7	26.009	5.07	285	**29.044**	3.63	1465	12.02	<0.001
3	1	**26.731**	4.881	202	23.284	6.011	903	-7.61	<0.001
3	2	**31.352**	5.57	307	25.684	5.89	1393	-15.41	<0.001
3	3	**29.753**	5.65	420	24.414	5.817	1403	-16.61	<0.001
3	4	**28.48**	6.22	266	22.458	5.899	1613	-15.31	<0.001
3	5	**26.743**	6.242	207	21.351	5.869	1485	-12.28	<0.001
3	6	**28.221**	5.72	237	22.0385	5.796	1410	-15.22	<0.001
3	7	**25.822**	5.119	285	21.025	5.5859	804	-12.73	<0.001

Key: SD = standard deviation bold figures = higher pressure

Table 5.21 Comparison between sitting and standing pressures at the calf for all three patient sets

	Hours spent in each posture						
Data set	**Day**	**Lying**	**Sitting**	**Standing**	**Sleeping**	**Elevated**	**Total**
1	Fri.	3.03	3.39	10.49	6.68	0.23	23.83
1	*Sat*	*4.98*	*2.38*	*7.53*	*7.44*	*1.57*	*23.90*
1	*Sun*	*5.89*	*3.21*	*6.11*	*7.34*	*1.39*	*23.94*
1	*Mon.*	*3.71*	*1.84*	*9.88*	*7.58*	*0.08*	*23.08*
1	Tu.	3.08	1.80	12.75	6.04	0.18	23.85
1	Wed	3.83	2.23	12.80	4.84	0.30	24.00
1	Th.	2.55	1.73	12.65	5.79	0.04	22.76
2	Th.	0.32	1.89	12.37	8.83	0.53	23.93
2	Fri.	0.63	1.98	12.24	8.91	0.23	23.99
2	Sat	0.07	1.86	10.87	11.64	0.65	25.08
2	*Sun*	*0.84*	*3.09*	*9.34*	*7.54*	*0.50*	*21.32*
2	*Mon.*	*1.05*	*2.01*	*4.80*	*11.38*	*4.73*	*23.97*
2	Tu.	0.89	2.27	13.13	7.43	0.30	24.01
2	Wed	0.78	2.38	12.21	8.09	0.22	23.68
3	*Mon.*	*6.82*	*1.68*	*7.53*	*7.93*	*0.00*	*23.95*
3	Tu.	0.71	2.56	11.61	8.34	0.78	23.99
3	Wed	0.66	3.50	11.69	8.09	0.02	23.96
3	Th.	1.04	2.22	13.44	7.29	0.00	23.99
3	Fri.	2.44	1.73	12.38	7.44	0.00	23.98
3	Sat	1.10	1.98	11.75	9.18	0.00	24.00
3	*Sun*	*0.37*	*2.38*	*6.70*	*8.96*	*0.00*	*18.40*

Key: Italics = days off work

Table 5.20 Hours spent in various postures

Elevated = posture in which patient had ankle higher than knee, e.g. feet up on stool

subject	day	sitting pressure (mmHg)	SD	n	standing pressure (mmHg)	SD	n	t	p
1	1	29.71	9.398	407	27.97	7.253	1259	-3.89	<0.001
1	2	29.822	10.233	285	28.781	8.329	904	-1.737	>0.05
1	3	27.675	7.72	385	28.405	7.507	733	1.5298	>0.05
1	4	28.448	7.587	221	28.15	8.177	1185	-0.503	>0.05
1	5	29.584	9.299	216	28.124	6.721	1530	-2.833	<0.01
1	6	28.177	7.771	267	28.936	6.53	1536	1.701	>0.05
1	7	30.96	9.86	207	28.52	6.42	1518	-4.758	<0.001
2	1	45.789	14.33	227	29.851	8.453	1484	-23.68	<0.001
2	2	44.477	13.579	238	25.99	7.8	1469	-29.95	<0.001
2	3	43.378	11.83	223	24.396	7.745	1304	-30.95	<0.001
2	4	39.82	14.55	371	22.923	8.727	1121	-26.92	<0.001
2	5	34.016	19.539	241	21.349	10.385	576	-12.02	<0.001
2	6	44.719	16.605	272	22.012	7.991	1575	-35.48	<0.001
2	7	41.739	13.269	285	21.552	7.562	1465	-35.65	<0.001
3	1	30.661	6.101	202	29.963	4.129	903	-1.969	<0.05
3	2	32.538	5.43	307	26.492	2.969	1393	-27.079	<0.001
3	3	32.868	5.54	420	26.181	2.933	1403	-32.499	<0.001
3	4	34.97	6.81	266	29.596	3.418	1613	-19.943	<0.001
3	5	35.097	7.45	207	28.518	3.6	1485	-20.817	<0.001
3	6	35.224	6.95	237	29.603	3.205	1410	-20.189	<0.001
3	7	34.338	6.94	285	28.779	4.208	804	-15.917	<0.001

SD = standard deviation

Table 5.22 Comparison between sitting and standing pressures at the ankle for all three patient sets

5.4.8.Analysis

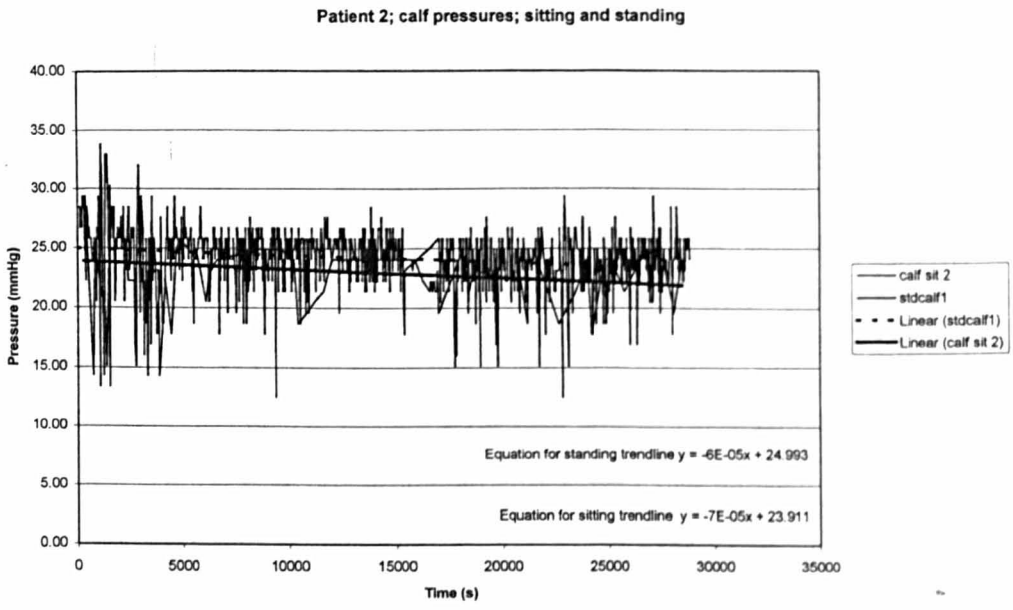
Due to the large number of data points available for analysis it was not possible to perform a four way analysis of variance on the raw data (posture (2 states), site (2 states), bandage (2 states) and time (168 hours). The sitting and standing pressures were plotted over the first few hours of the investigation to determine whether there was a point at which the previously recorded increase in pressure from sitting to standing reversed, see Figures 5.5 to 5.6.

In Figure 5.5 the linear trend for the pressures is included. This allows one to see that for data set 2 (Granuflex adhesive compression bandage on patient 2) the mean calf pressure in a standing posture is greater than the mean calf pressure in a sitting posture. Note that in the very early data collection points (see 5.5) there are a number of data points where the sitting pressure is higher than the standing pressure (at around 900 seconds).

The overall picture of standing pressures being greater than sitting pressures is not demonstrated in figure 5.6. There the linear trend for mean calf pressures is also shown. For data set three (four layer compression bandage on patient 2) one can see that the mean calf pressure in a sitting posture is higher than the mean calf pressure for a standing posture. Again, early data points, under 1000 seconds, have sections in which the standing pressure is larger and other sections where the sitting pressure is larger.

Analysis of the difference in calf pressures in the sitting and standing postures was performed using a t-test. The results of these analyses are presented in Table 5.21.

Further comparison was made between the sitting and lying ankle pressures to determine whether they were statistically significantly different. The results are summarised in Table 5.22.



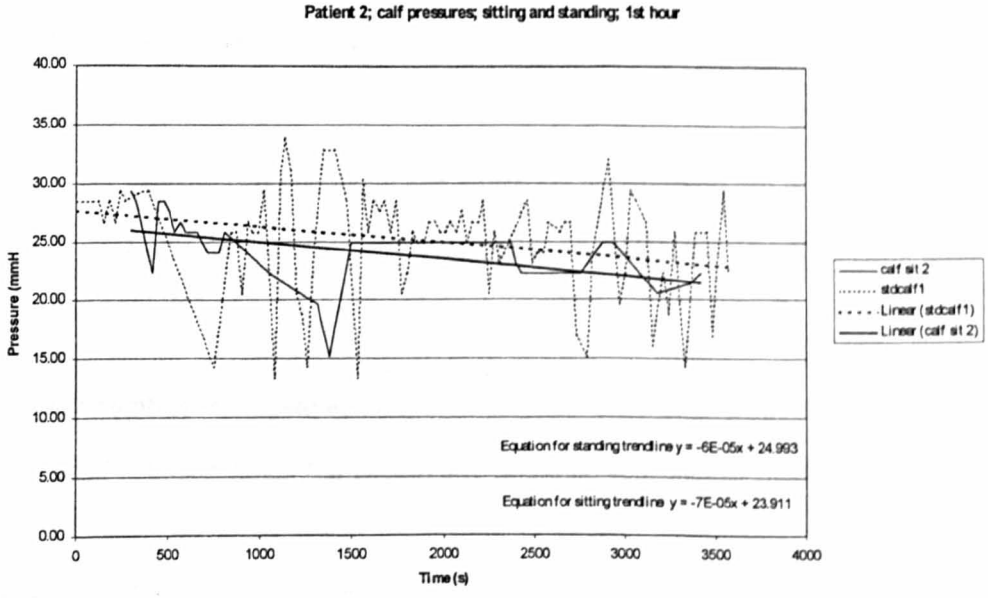


Figure 5.5 Sub-bandage pressure at calf site while patient is sitting and standing; point pressures recorded beneath the Granuflex bandage (top graph = hours 0-8, bottom graph = hours 0-1).

5.4.9.Discussion

This section has demonstrated that there is, for certain sites and bandages, a change in sub-bandage pressure upon changing posture. In most cases, there is a fall in pressure upon lying and upon standing (from the sitting posture). The results from the ambulatory monitoring do not corroborate the results from the static tests previously reported and the direction of pressure change is not consistent.

This work has been done with only two patients and hence needs to be replicated with larger numbers of patients. Due to the fragility of the measuring equipment, it is necessary to develop a different measurement protocol or to improve the resilience of the equipment. It would be possible to measure sub-bandage pressure over the period of bandage wear without recording the sub-bandage pressure frequently as in this ambulatory monitoring if it could be arranged such that the sensors and transducers remained in situ but the recording equipment remained detached. The subject would then be visited daily for data recording. This may make the process easier for subjects who, in this study, had to sleep with a data logger attached.

The large number of t-tests performed in order to analyse the significance of the different pressure in each posture is problematic as repeating the data analysis compounds the type 1 error. Repeated measures analysis of variance (ANOVA) was not possible as the SPSS programme (9.0) could not deal with the large number of data points.

Furthermore, it should be noted that the data logger does not provide ideal data as the lying, sitting and standing pressures are not provided for subsequent measurement points. There may be hours when the patient is standing followed by a few minutes in which they are sitting. Furthermore, it is possible that the pressure for a certain period is dependent on the posture of the subject in the previous hours. Thus, the assumption that the data is independent could be questioned.

The highest pressures seen in the sitting posture had not previously been reported. These results tend to contradict the results from the other studies reported in this chapter. Callam

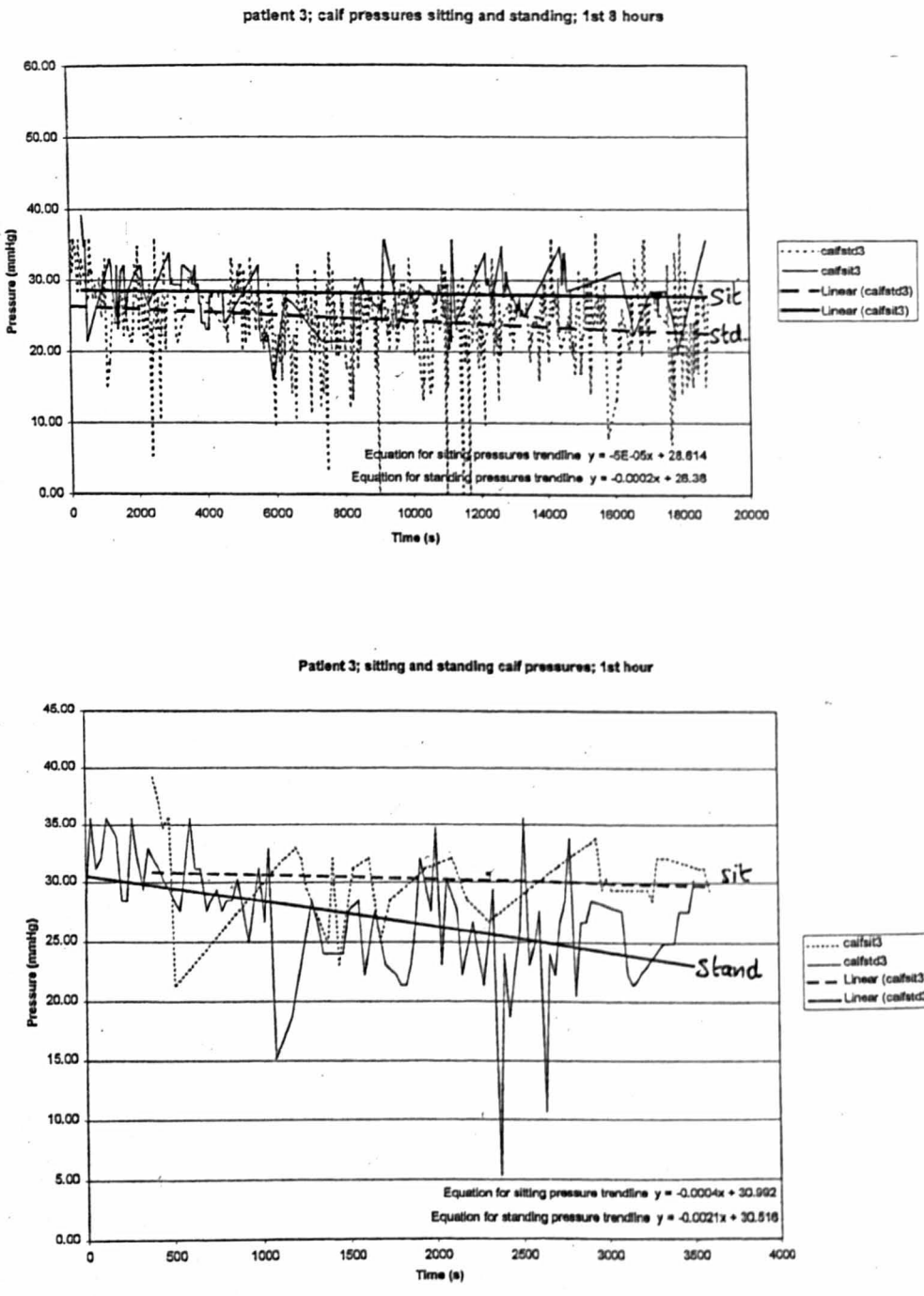


Figure 5.6 Sub-bandage pressure at calf site while patient is sitting and standing; point pressures recorded beneath the four-layer bandage (top graph = hours 0-8, bottom graph = hours 0-1).

et al (1991) reported that the lying pressure was lower than the standing pressures, a finding borne out by all the studies in this chapter but they do not report on the sitting pressure. It may be that the reported pattern of pressure changes is only as previously reported initially, i.e. immediately after bandage application.

There are numerous factors that may be influencing sub-bandage pressure as recorded from patient data, e.g. oedema formation, bandage slippage. There may be a relationship between the type / extent of venous insufficiency and the impact of posture changes on sub-bandage pressure. This requires more investigation. One way to investigate this would be to compare the response to posture changes for subjects with and without venous insufficiency. If there appears to be a dampened response or no response to posture changes in the presence of venous insufficiency then it could be hypothesised that the bandage conditioning might be responsible for this effect. This could be validated by comparing the response to extension, in a fixed rate of traverse tensometer, of the 'worn' bandage and a new bandage. If there still appeared to be no response to changing posture then one could measure the response to changes in posture in patients wearing a compression bandage over a period of 1 week.

6. Impact of Training on Sub-Bandage Pressure

6.1. Introduction

This study of bandaging techniques was undertaken to investigate the influence of nurse factors (e.g. training or expertise) on sub-bandage pressures. Pressure measurement was proposed as both a method of assessing nurses' expertise and of providing specific feedback during training.

Bandaging technique is a necessary but not sufficient skill in the management of leg ulceration. Assessment of the underlying aetiology, skin and ulcer management as well as patient education and after care are important. Some of these elements may interact with the implementation of compression therapy. This is because nurses may not feel confident to apply compression bandages at high pressures if they are not confident in excluding contra-indications to compression such as arterial impairment or if there are skin problems such as eczema. The safe application of compression therapy therefore requires that the clinician excludes contra-indications to compression, selects a suitable bandage and then, applies it using the appropriate application technique to generate a safe, therapeutic compression profile.

It is reported that nurses' knowledge of the various types of bandages, e.g. the role of support and retention bandages and how they differ from that of compression bandages, is poor and that nurses may choose inappropriate bandages for a particular application (Magazinovic et al 1993). The amount of compression produced and the way in which it is graduated has been found to be unsatisfactory (Logan et al 1992, Millard et al 1986). Improving management therefore needs to address the problems of knowledge deficits and poor bandaging technique. Manufacturers have sought to help nurses to improve their bandaging technique by incorporating tension and overlap indicators into bandages, e.g. Setopress (Seton), Tensopress (Smith and Nephew) and SurePress (ConvaTec). These application aids may be useful in helping nurses reduce the variability in their technique, but

used in isolation they cannot assure the practitioner that he or she is producing the correct sub-bandage pressure. Sub-bandage pressure depends on three parameters; the number of bandage layers (i.e. percentage overlap and application method), leg shape, and bandage tension (i.e. extension). Improving only one or two aspects of application may still result in a poorly applied bandage (defined as an incorrect sub-bandage pressure profile). The person applying the bandage can modify all three factors; the application tension, the degree of overlap, and by padding the leg to change the resultant shape of the leg. In the United Kingdom, only SurePress (ConvaTec) incorporates both an extension indicator and a central line to guide overlap.

The pilot study reported in section 6.2 examines the impact of two training aids, i.e. extension indicators and feedback from a pressure monitor, on nurses' bandaging skills. The second phase of this investigation, reported in section 6.3, goes further to examine whether the physical characteristics of the bandage influence the frequency with which nurses apply a bandage with an appropriate sub-bandage pressure profile.

This study question is derived from the hypothesis that a bandage will be applied with adequate pressure and correct graduation if the nurse consistently produces the required extension during bandage application. It has been proposed that this is easier if the extension / tension relationship of the bandage, within its recommended working range, is characterised by a shallow curve. This means that a change in the extension of the bandage results in a very small change in the bandage tension. Therefore small changes in extension are accompanied by small changed in sub-bandage pressure, i.e. the bandage has a low incremental stiffness. One bandage manufacturer has reported developing a bandage with an extension / tension curve which displays this property, and a pilot study reports that consistent bandage extensions were produced (Carter et al 1992). However Carter et al (1992) used Laplace's Law to *derive* the pressures rather than measuring the pressures generated and although they concluded that the bandage enabled nurses to apply a graduated compression bandage they did not actually measure pressure. Their study needs to be followed up by one in which the pressures are measured as the bandage

characteristics are concerned with the production of tension and hence pressure from extension, and not the production of an even extension, the only variable measured.
Part 6.3 of this investigation extends the pilot study by using a larger sample of community nurses and a longer follow up period. It also uses bandages with different extension / tension profiles to determine whether this might influence the number of nurses who apply bandages with an appropriate ankle pressure and ratio.

In many of the investigations reported to date, only single layered bandaging regimens have been studied. A recent systematic review of the effectiveness of compression bandaging regimens concludes that multi-layer high compression systems are more effective than single layer systems (Cullum et al 1999) and hence this investigation concludes with a study of the application of multi-layered bandaging regimens, section 6.4. The majority of the effective compression regimes incorporate both padding and compressive layers in order to allow high pressures to be applied to the majority of the limb while protecting areas with a small radius of curvature and minimal sub-cutaneous padding, such as the malleoli, from very high pressures. The best known of these is the 'Charing Cross' 4 layer system. A simpler regimen, consisting of a layer of orthopaedic wool and a class 3c compression bandage, was also used. These regimens were used to evaluate the bandaging skills of 224 community and hospital nurses before and after training.
Throughout this chapter pressure measurements are expressed both in mmHg, as these are widely used in the clinical literature and the bandage classification system, and in kPa, the SI unit (1 mmHg = 0.1333 kPa).

6.2. Pilot study; Bandaging training

The investigation was designed to answer the following questions:-

1. What pressure profiles do qualified nurses generate when using compression bandaging?
2. What effect does a bandage tension indicator have on sub-bandage pressure profiles?
3. Does feedback from a pressure monitor and training improve sub-bandage pressure profiles?
4. To what extent are improvements in bandaging technique sustained?

In this pilot study, it was decided to study a **single** layer bandage as problems with technique would not be obscured by the application of subsequent layers.

6.2.1. Methods

6.2.1.1. Subjects

Eighteen nurses attending leg ulcer study days were recruited to the study. This represents an opportunistic sample of nurses and is not intended to be representative. Five of the nurses worked on dermatology wards, six were trained district nurses and the remaining seven were qualified nurses undertaking a further qualification in district nursing. A record was also made of the length of time they had been qualified and how many of their current patients had leg ulcers. There were 3 volunteers legs used in the study.

6.2.1.2. Equipment

The Granuflex Adhesive Compression Bandage (ConvaTec, UK) was used throughout. This bandage was selected for investigation as it had been shown to sustain its compression over a week (Sockalingham and Barbenel 1990). It is described as a 3b bandage as in laboratory testing it has conformed to the specifications for this classification. Thomas (1990) states that class 3b bandages are capable of generating an ankle pressure of around 24 mmHg (3.2 kPa). For one part of the study the bandage was marked by hand using an oval rubber stamp so that the oval pattern would become a circle when the extension recommended by the manufacturers was reached.

Sub-bandage pressures were measured using the Strathclyde Pressure Monitor (Barbenel and Sockalingham 1990) at three points along the lateral aspect of a volunteer's leg on a line between the tibial tuberosity and the lateral malleolus. The measurement sites were the ankle (4 cm above the malleolus), the calf (at the widest circumference). Initially it had been intended to also measure the pressure at the gaiter, at a point midway between the ankle and calf, however this was not possible due to repeated failures of senors. The subject remained seated throughout the study period with the bandaged leg dependent, the bandage was applied in a spiral technique and the measurements were made immediately after application of the bandage.

6.2.2. Plan of Investigation

The following assessments were made:-

Baseline; Each nurse was asked to apply the bandage to a volunteer's leg using his or her normal bandaging technique. The pressure monitor display was covered during bandaging and the first pressure measurements, the baseline reading, were recorded immediately after the bandage application without revealing the display to the bandager. (single measure of pressure taken at each site)

Marked bandage; Each nurse applied a marked bandage and was informed that when the recommended extension had been reached the oval mark on the bandage would appear

circular. No feedback from the pressure monitor was given at this stage. The pressure monitor was covered during bandaging and the pressure measurement was recorded immediately after the bandage application. After the sub-bandage pressures were recorded they were revealed to the subject and any problems were highlighted.(single measure of pressure taken at each site)

Feedback; Before this measurement was made the bandager was given feedback on the actual pressures achieved during their previous attempts. They were told how to achieve an acceptable pressure profile by rectifying previous mistakes of extension and/or overlap, the guidance being provided by the investigator, an experienced bandager. The guidance was given by describing, in turn, the changes required in bandage placement on the leg, bandage extension and overlap. Each nurse was then able to practise bandaging while receiving continuous feedback from the monitor. Once the nurse had practised for up to 30 minutes, a final reading with the unmarked bandage was taken while the pressure monitor display was covered. (single measure of pressure taken at each site) Bandages were supplied to the nurses for practice at home.

The same nurses were invited back for reassessment of their technique after two weeks.

Two weeks later; At the final assessment the subject applied the unmarked bandage with no feedback from the monitor and the sub-bandage pressure measurements were recorded immediately after application of the bandage. (single measure of pressure taken at each site)

6.2.3. Outcomes

The outcomes of interest in this study were:

1. The pressure measured at the lateral ankle site (40 mm above the malleolus)
2. The degree of graduation of pressure from the ankle site, to the calf site (at the widest part of the calf along the line joining the lateral malleolus and the tibial tubersoity)

These were chosen in order to reflect the prevalent perceptions of what formed the ideal pressure profile:

(a) An ankle pressure that was sufficient to reduce ambulatory venous hypertension yet was low enough to allow adequate arterial flow in the arteries serving the leg.

(b) A reduction in pressure from the ankle towards the calf in line with the recommendations used to classify compression hosiery (calf pressure should be less than 70% of the ankle pressure). This was called the calf / ankle pressure ratio, and ideally would be ;less than 0.7. If the ratio is greater than 1.0, the pressure at the calf is higher than that at the ankle. It is stated that this may reduce venous return due to a tourniquet effect at the calf but this has not been confirmed clinically.

6.2.4. Results from pilot study

Initial tests were carried out with 18 nurses of whom 11 returned after two weeks. There are results available for all 18 subjects for the measurements taken before training (baseline), using a marked bandage, and after training. For those who returned there are also pressure measurements taken two weeks after training. Individual pressure measurements at the ankle and calf are presented in **Table 6.1**.

Subject	Baseline		Marked bandage		After training		After 2 weeks	
Pressure (mmHg)	Ankle	Calf	Ankle	Calf	Ankle	Calf	Ankle	Calf
1	19	18	25	24	36	14	39	24
2	23	9	38	17	28	13	45	35
3	18	23	42	34	32	19	39	26
4	71	51	36	23	26	24	20	19
5	28	35	34	32	25	35	30	44
6	9	13	27	20	35	22	*	*
7	11	17	20	30	19	21	*	*
8	36	39	9	18	52	26	*	*
9	17	18	12	26	47	13	*	*
10	22	28	19	29	12	15	*	*
11	47	42	24	30	28	22	25	25
12	24	35	18	13	34	26	*	*
13	53	35	24	13	16	14	34	12
14	17	19	12	14	29	16	*	*
15	27	50	17	22	36	24	59	25
16	18	10	17	17	23	14	36	15
17	22	27	31	28	24	19	41	16
18	13	14	20	43	22	22	34	22

Key, * = missing data.

Table 6.1 Ankle and calf pressures at each stage of pilot study.

The sub-bandage pressure at the ankle and the ratio of the calf pressure to the ankle pressure (called the calf / ankle pressure ratio, or the pressure ratio) are two criteria by which bandaging proficiency can be summarised. In order to represent the results graphically, the

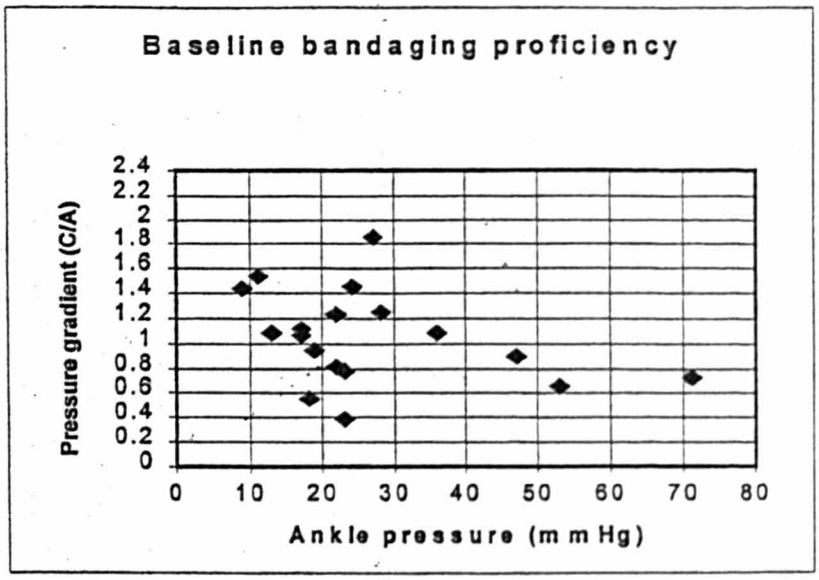


Figure 6.1 Distribution of ankle pressure and pressure ratio between ankle at calf at baseline

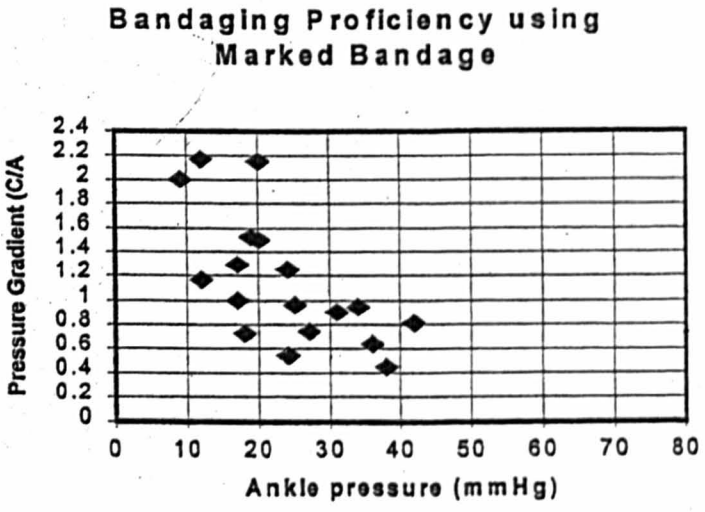


Figure 6.2 Distribution of ankle pressure and pressure ratio between ankle at calf, marked bandage

calf / ankle pressure ratio (calf pressure / ankle pressure) was plotted against ankle pressure. Figure 6.1 shows the ankle pressures and graduation in pressure and the proficiency categories for the baseline readings. It can be seen that the pressure profiles have improved in figure 6.2, the points have moved towards the x axis (indicating a reduction in the pressure ratio) and there is also a smaller spread of pressures.

Guidance provided by an extension indicator on the bandage reduced the spread of ankle pressures but not the range of pressure ratios. In figure 6.3 the reduction in pressure ratio becomes obvious. In figure 6.4 the pressure ratio remains the same but the ankle pressures are higher.

The results are summarised in Table 6.2 Mean values of ankle pressure (mmHg) and pressure ratio., below.

Mean [95% CI]	Baseline	Marked bandage	After feedback	Two weeks later
Ankle pressure in mmHg	26.4 [18.4,34.3]	23.6 [18.9,28.3]	29.1 [24.1,34.1]	36.5 [29.6,43.4]
Pressure ratio (C/A)	1.1 [0.9, 1.3]	1.2 [0.9, 1.4]	0.8 [0.6, 0.9]	0.7 [0.5, 0.9]

[95% CI] = 95% Confidence Interval for the mean.

Table 6.2 Mean values of ankle pressure (mmHg) and pressure ratio.

6.2.5. Analysis of results from pilot study

6.2.5.1. (a) Sub-bandage pressures

Analysis of variance (one way) for the calf pressure revealed that there appeared to be no significant change in calf pressure over the period of investigation ($F = 1.58$, $p=0.202$, $df = 64$). At the ankle site, however, pressure was found to vary during training ($F=2.856$, $p=0.044$, $df = 64$). Further analysis showed that the mean ankle pressure was not

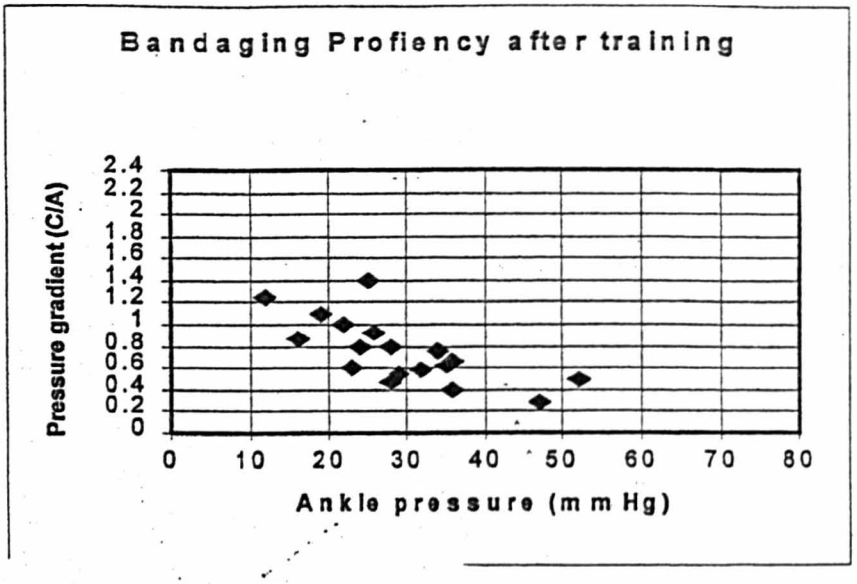


Figure 6.3 Distribution of ankle pressure and pressure ratio between ankle at calf after training

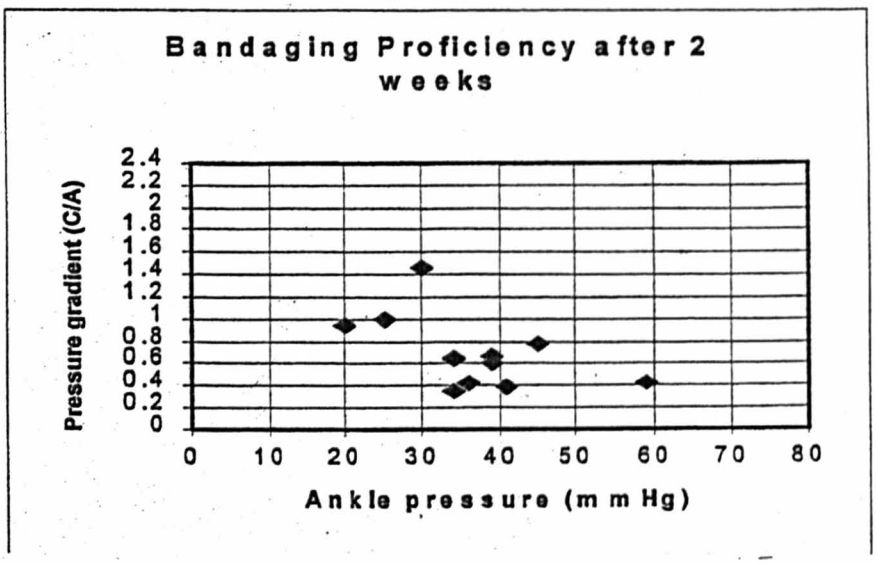


Figure 6.4 Distribution of ankle pressure and pressure ratio between ankle at calf after two weeks

significantly altered at the first assessment after training, initially 26.4 mmHg (3.52 kPa) and 29.1 mmHg (3.88 kPa) after training (paired t = 0.587, p = 0.56). Those nurses who returned after two weeks produced slightly higher pressures, mean 36.5 mmHg (4.87 kPa), an increase of 10.2 mmHg (1.36 kPa) compared to the initial pressures (t = 2.07, p=0.048 – unpaired t test used as unequal numbers in two groups). The range of pressures produced also reduced with training, initially 62 mmHg (8.27 kPa), decreasing to 30 mmHg (4 kPa) after training. The reduction in the spread of pressures was significant for both the marked bandage (F=2.86, p=0.018) and after training (F=2.54, p=0.031). The mean initial ankle pressures produced are not significantly higher than the quoted pressures which a 3b bandage is expected to produce and sustain (18-24 mmHg (2.4 - 3.2 kPa)), but after training the mean pressure of 29.1 mmHg (3.88 kPa) is significantly higher than the upper limit of ankle pressure expected from a class 3b bandage of 24 mmHg (3.2 kPa) (t = 2.16, p <0.05). These initial pressures will reduce over time due to stress relaxation of the fibres, however, and they are not sufficiently high to cause constriction of arterial inflow. The eleven nurses who returned after two weeks produced a mean pressure of 36.5 mmHg (4. 86 kPa) which is higher than the 24 mmHg (3.2 kPa) expected from a 3b bandage. This demonstrates the range of pressure than can be produced by a bandage, regardless of its classification.

SUMMARY

Groups	*Count*	*Sum*	*Average*	*Variance*
Baseline	18	475	26.38889	256.7222
marked bandage	18	425	23.61111	89.6634
after training	18	524	29.11111	100.9281
later after training	11	402	36.54545	107.0727

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	1218.386	3	406.1285	2.855754	0.044363	2.755485
Within Groups	8675.061	61	142.2141			
Total	9893.446	64				

Table 6.3 Ankle pressure - ANOVA Single Factor

SUMMARY

Groups	*Count*	*Sum*	*Average*	*Variance*
Baseline	18	483	26.83333	175.6765
marked bandage	18	433	24.05556	66.99673
after training	18	359	19.94444	34.76144
later after training	11	263	23.90909	84.49091

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	433.2559	3	144.4186	1.584079	0.20241	2.755485
Within Groups	5561.298	61	91.16882			
Total	5994.554	64				

Table 6.4 Calf pressures - ANOVA Single Factor

SUMMARY

Groups	*Count*	*Sum*	*Average*	*Variance*
Baseline	18	19.83112	1.101729	0.136304
marked bandage	18	20.75858	1.153254	0.282682
after training	18	13.57461	0.754145	0.089044
later after training	11	7.707135	0.700649	0.11304

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	2.53219	3	0.844063	5.271667	0.002677	2.755485
Within Groups	9.766904	61	0.160113			
Total	12.29909	64				

Table 6.5 Pressure ratio (C/A) – ANOVA **Single Factor**

6.2.5.2. Sub-bandage pressure ratios

Analysis of variance of the pressure ratios - calculated by dividing the calf pressure by the ankle pressure - revealed that there was a change in ratio over the period of assessment, F= 5.27, p=0.0027, df = 64. The average pressure ratio reduced from 1.1 (an unfavourable pressure ratio), to 0.75 after training for the 18 subjects and this difference was statistically significant (t=2.83, p=0.01). After two weeks, the mean ratio was 0.7, a satisfactory graduation. The ideal graduation is not known, however physiological measurements suggest that it should reduce from ankle towards calf (Cornwall et al 1987). Thus, the training resulted in a reduction in the mean pressure ratio.

The proportion of nurses producing a unfavourable pressure ratio may be more important than the mean pressure ratio as the latter is sensitive to outliers. The proportion of nurses producing a pressure ratio >1 reduced from 12 /18 at baseline to 3/ 18 after training and 0/11 at late follow-up. The reduction in the proportion of nurses producing a unfavourable pressure ratio after training is statistically significant (McNemars χ^2 = 7.11, df = 1, p<0.01).

6.2.5.3. Bandaging Scores

The ankle pressure and pressure ratios taken together allow one to determine whether bandaging was good, bad, or borderline. A composite score was devised to reflect these categories and to allow basic statistical analysis that would encompass both aspects of bandaging. It is undoubtedly more valid to discuss the primary measure of sub-bandage pressure as reducing a ratio measure to an ordinal one reduces the amount of useful information. In this case, however, a composite measure was proposed as good bandaging requires **both** adequate pressure **and** a graduated distribution.

The following criteria and scoring system were adopted, taking into account the pressure required to reduce venous hypertension and the optimal pressure ratio (calf pressure < 70% ankle pressure) derived from the British Standards for compression hosiery (BS1612 1985), see Table 6.6.

Bandaging	Ankle pressure mmHg (*kPa*)		Calf/ ankle pressure (ratio)	Proficiency score
Good	25-50 (*3.33-6.66*)	*and*	<0.7	3
Borderline	18-24 or 51-60 (*2.4-3.2 or 6.8-8*)	*and*	<0.7	2
Borderline	25-50 (*3.33-6.66*)	*and*	0.7-1.0	2
Poor	<18 or >60 (*<2.4 or >8*)	*or*	>1.0	1

Table 6.6 Criteria for classification of bandage pressures

Sub-bandage pressures were coded using Table 6.6. Good, borderline and poor bandaging were scored 3, 2, and 1 respectively so that non-parametric statistical analysis could be performed. Bandaging proficiency scores are presented in Table 6.7.

Subject	Baseline	Marked bandage	After training	After 2 weeks
1	2	2	3	3
2	2	3	3	3
3	1	3	3	3
4	1	3	2	2
5	1	2	1	1
6	1	3	3	*
7	1	1	2	*
8	1	1	3	*
9	1	1	3	*
10	1	1	1	*
11	2	1	2	2
12	1	2	3	*
13	2	2	2	3
14	1	1	3	*
15	1	1	3	2
16	2	1	2	3
17	1	2	2	3
18	1	1	2	3

Table 6.7 Bandaging proficiency scores from pilot study (Key, * = missing data)

Analysis of variance indicated that the bandaging proficiency score did vary over the period of investigation, $F = 11.8$, $p < 0.001$. The bandaging scores obtained pre-training (baseline) were compared with those obtained while using the marked bandage, and after pressure monitor feedback and advice. The Wilcoxon Sign Rank Sum test was used to test the difference in the bandage proficiency score between the baseline and the post-training readings and this was significant at 99% confidence ($p<0.01$). This difference was maintained after two weeks ($p<0.01$). There was no significant difference in bandage proficiency scores using the marked bandage ($p>0.1$).

6.2.6. Nurses' experience and bandaging proficiency

Nurses were asked how many patients they were currently treating with leg ulcers and how long they had been trained. The number of years since qualification ranged from 0-16, median = 10. Most of them had current patients with leg ulcers (12/18), number of current patients ranged from 0-10, median = 2. Statistical analysis of bandaging proficiency and time since qualification was not undertaken as in this small sample there was a high proportion (13/18) achieving a score of 1 at baseline. There was no relationship between baseline bandage proficiency and whether nurses were currently treating leg ulcer patients.

6.2.7. Summary of results

Summary of results will be presented as answers to the questions asked initially.

1. What are the bandaging skills of qualified nurses?

Of the 18 nurses initially tested, none produced a 'good' pressure profile, i.e. correct ankle pressure and calf pressure < 70% of ankle pressure. Twelve produced an unfavourable pressure ratio, 6 produced a pressure reduction from ankle to calf, but of these 3 had an insufficient ankle pressure, two produced an excessive ankle pressure, and 1 had an acceptable ankle pressure but insufficient graduation between ankle and calf.

2. What effect does a bandage tension indicator have on bandaging skill?

The bandage tension guide did not significantly increase bandaging skill as measured by the bandaging proficiency score. The variance in ankle pressures decreased with the use of the marked bandage from 256 to 89 ($F=2.86$, $p=0.02$).

3. Does feedback from a pressure monitor and training enhance bandaging skill?

Feedback from a pressure monitor did result in a significantly improved pressure ratio, with 14 subjects achieving a graduated pressure from ankle to calf and of these 9 combined it with an acceptable ankle pressure.

4. To what extent are improvements in bandaging technique sustained?

Despite the fact that only 11 subjects returned for the second assessment, the improved bandaging profile was sustained for two weeks.

6.2.8. Discussion

Both single and multi-layer bandages are used in the treatment of venous ulceration and both are capable of maintaining their pressure for 7 days (Sockalingham et al 1990, Blair et al 1988). In this study, it was decided to study a **single** layer bandage as problems with technique would not be obscured by the application of subsequent layers. Although repeat testing at two weeks was only achieved in 11 of the 18 subjects it was possible to show that the improvements effected by training had been sustained. The bandage skill appeared to be best at the final assessment. This may be due to bias, where only 'good' bandagers returned for assessment, or due to real improvements in technique due to the nurses practising this skill.

The proficiency score was devised to allow statistical analysis of the results. It was derived from the British Standard for compression hosiery (BS6612:1985) which requires a reduction in pressure from the ankle to the calf by at least 70%. There are different ankle pressures recommended in the United Kingdom (BSI 1985) and Continental Europe (Stemmer et al 1980) and to encompass both these standards a wide range of pressures were adopted as acceptable (25-50 mmHg). Marginally high or low ankle pressures resulted in a lower proficiency score as did poor graduation from ankle to calf. The scores, though, inevitably

reduced the precision of the results and would not be used in future studies in this thesis. The reduction in variance in ankle pressure with the marked bandage and training was significant when compared to the baseline reading, using a marked bandage $F=2.86$, $p = 0.018$; after training $F= 2.54$, $p=0.031$.

The nurses experience in treating leg ulcers was determined by means of a short questionnaire, and there seemed to be no relationship between bandaging technique and experience, probably due to the small sample size and the skewed distribution of bandage proficiency scores. It was therefore intended to study this further by obtaining more information on nurse's knowledge and experience in the second study.

6.2.9. Conclusions

A group of nurses who had recently attended a study day on the subject was shown, by direct sub-bandage pressure measurements, to be achieving unsatisfactory standards of bandaging technique. It is possible that this group is self selected and consists of those interested in and competent at leg ulcer management. There is also a possibility that those nurses who volunteered to attend the leg ulcer study day did so because they knew their bandaging skills were poor. The former explanation may be more likely as we know that family doctors asked for continuing medical education in topics in which they were relatively competent and neglected topics in which they were less competent (Sibley et al 1982). Thus self-reporting was not used to determine whether nurses were 'competent' at leg ulcer management.

After training and feedback there was a measurable improvement in bandage proficiency. The bandaging performance was maintained at two weeks, a relatively short follow-up period.

Limitations of the pilot study included the use of 3 volunteers' legs and also that the bandage overlap was not recorded. The use of an adhesive bandage may have made it more difficult for nurses to maintain constant bandage tension all the way up the leg as there is more force required to remove the bandage from the roll nearer the bandage core, where the bandage

is applied to the calf. Nurses use both adhesive such as Elastoplast (Smith and Nephew) and non-adhesive bandages in the management of leg ulcers but it was decided to use non-adhesive bandages in future studies to rule out the effect of the potentially increased bandage tension generated at the calf.

The next investigation was planned in order to study a longer follow-up period and to assess community nurses technique using bandages commonly used in the community. The assessment of nurses' knowledge was thought to be important and therefore this would be evaluated more rigorously in the main study.

6.3. Effect of Training on Nurses' Application of Single-Layer Bandages

Community nurses care for the majority of patients with leg ulcers (Dale et al 1983) and hence it was decided to study the way in which *community* nurses apply bandages, and the extent to which their technique improves after training. It was also intended to test whether bandage characteristics significantly affected bandage application.

6.3.1. Main study hypotheses

1. The mechanical characteristics of a compression bandage influence the ability of nurses to apply it correctly.
2. Nurses' ability to apply a compression bandage will not be related to their knowledge of the management of leg ulcers as tested by a validated questionnaire.
3. Bandaging training will improve the bandaging skills of nurses using a range of bandages.
4. There will be no difference in the improvement in bandaging technique between the different types of bandages chosen.

6.3.2. Plan of investigation

1. Investigation of the load/extension response of six bandages.

Elset (Seton), Elastocrepe (Smith & Nephew), SurePress (ConvaTec), Setopress (Seton), Tensopress (Smith & Nephew), Rosidal K (Vernon-Carus)

2. Three representative bandages from part 1. selected.

Rosidal K (Lohmann) a cotton bandage with no elastomeric fibres.

Setopress (Seton), an elastomeric bandage incorporating an extension guide.

Tensopress (Smith and Nephew), an elastomeric bandage with a line to guide overlap.

These three bandages have been evaluated in clinical studies and are all effective in the treatment of venous leg ulceration, see section 1.8.5.

3. Community nurses applied bandages and the pressure generated recorded.

The participants were district and practice nurses attending study days on the management of leg ulcers. The final sample, of 48 nurses, was a convenience sample, consisting of all attendees at a study day for nurses in the management of venous leg ulcers.

4. Training in compression bandaging using feedback from pressure monitor.

This was provided by EAN at the first study day. Nurses were also provided with bandages to practise with at home.

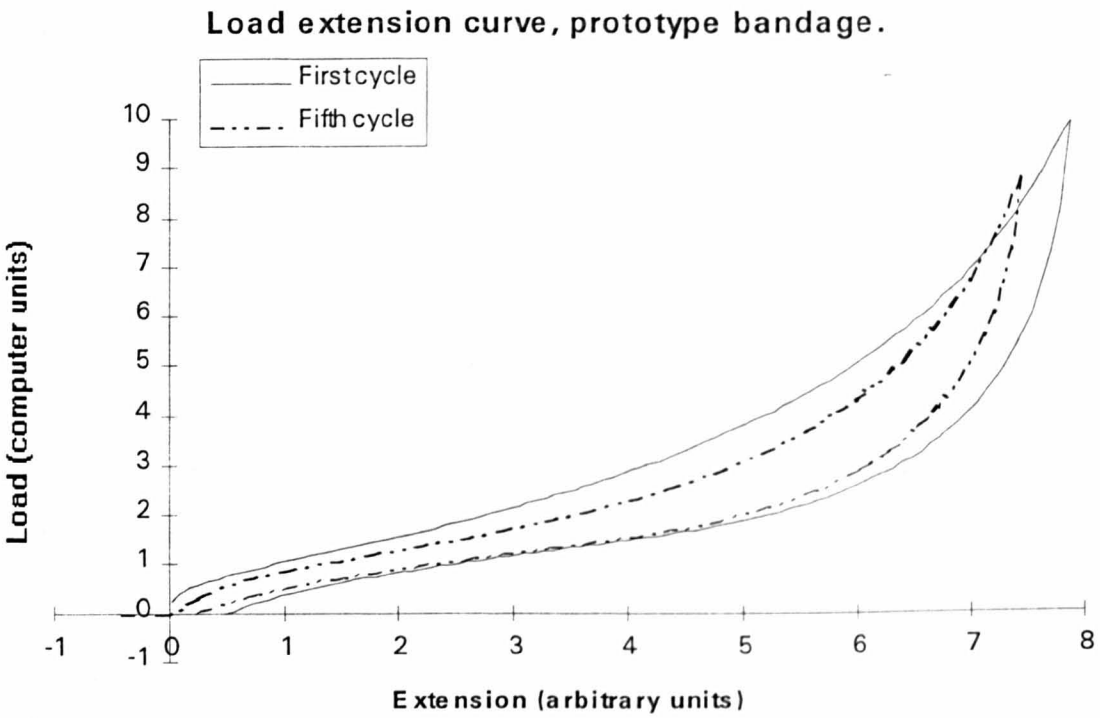
5. Post-training bandaging technique reassessed after 2 weeks.

Immediately on returning for a second study day the nurses reapplied all three bandages and the resultant sub-bandage pressures were recorded. The same leg, sensor sites and pressure monitor was used as at the initial assessment.

6. Late post-training technique tested 8 weeks after first study day.

The nurses were invited to have their bandaging reassessed 6 weeks after the second study day.

Figure 6.5 Shows hysteresis, cycles 1 and 5; prototype bandage



6.3.3. Methods;

An Instron mechanical tester allows one to measure the force required to extend or compress a material by a known amount. It was used in this investigation to measure the load / extension characteristics of various bandages. A sample of bandage was carefully cut from a bandage taking care not to extend the bandage and was then acclimatised to the test room for 3 hours before being placed in the test rig. The test rig consisted of pneumatic clamps, the upper one of which was fixed and attached to a load cell, the lower clamp could be moved vertically at a defined rate. The bandage extension was calculated by setting the specimen in the rig and accurately measuring the distance between the clamps, then setting the speed of travel for the bottom clamp. As the clamp moved down at a predetermined rate the amount of extension and thus percentage extension could be calculated. The computer controlling the test rig was set to record the distance moved by the lower clamp (cross head travel) at a pre-determined frequency, (100 points per second in this case) and the tension in the bandage was measured simultaneously by a load cell placed above the top cross head. This cell generates a voltage proportional to the load applied to the cell and hence the tension in the bandage. The electrical signal passes through an analogue to digital converter, and the output was stored on a computer disc. The sample was cycled 5 times by increasing the extension and reducing it back to zero, a process known as conditioning, as the response to extension changes over the first few cycles. Figure 6. 5 demonstrates the hysteresis - the area between the two lines, and the conditioning, the change in shape of the two curves.

Hysteresis reduces with conditioning and therefore the 5th cycle is represented for all the bandages tested, see figures 6.6-11. Samples of 10 cm wide bandages were used in each case (nominal width).

6.3.3.1. *Sub-bandage pressure measurement*

The pressure exerted on the subject's leg was measured using the Strathclyde Pressure Monitor (Barbenel and Sockalingham 1990). This consists of an oil-filled sensor, 28 mm in diameter, connected to a piezo-electric transducer. It provides a constant display output and is accurate to ± 1 mmHg (0.133 kPa). Measurement sites were the lateral aspect of the leg, 40 mm above the centre of the lateral malleolus, and at the widest point of the leg, along a line joining the lateral malleolus and the tibial tuberosity. See chapter 2 for a fuller discussion of pressure measurement, and chapter 3 for details of the pressure monitor used.
For all the pressure measurements reported these are based on a single reading of the pressure from the pressure monitor.

6.3.3.2. *Knowledge score*

Nurses' knowledge of venous ulcer aetiology, assessment and treatment was assessed using a questionnaire developed in the Department of Nursing, University of Liverpool (Luker and Kenrick 1992). It consists of a self administered questionnaire that assesses both knowledge and reported practice. The knowledge score is the total number of questions answered correctly and hence this score is a ratio measure. The design of the questionnaire is such that in part (a) of each question the respondent is asked what they would normally do in each situation, e.g. what information would you normally record about the leg when assessing a patient with a leg ulcer. In part (b) the subject is asked, what would they do if they had unlimited time and resources. This allows participants who have extensive knowledge but do not usually perform recommended tasks for any reason (e.g. due to lack of resources) to gain a credit for this answer. The questionnaire, therefore does not audit what nurses actually do, rather, it is a measure of their knowledge and reported practice. The questionnaire takes approximately 45 minutes to complete, see Appendix C.
The questionnaire was assessed for face validity by nurses with expertise in leg ulcer research and by clinical nurse specialists in leg ulcers.

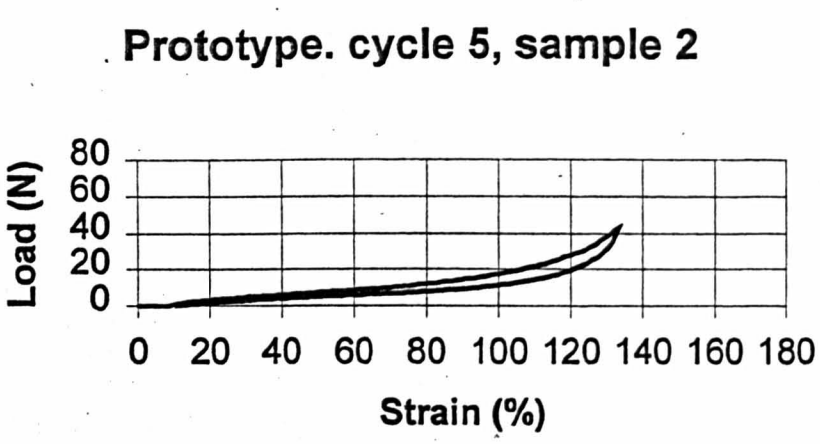


Figure 6.6 Load extension relationship for Surepress bandage

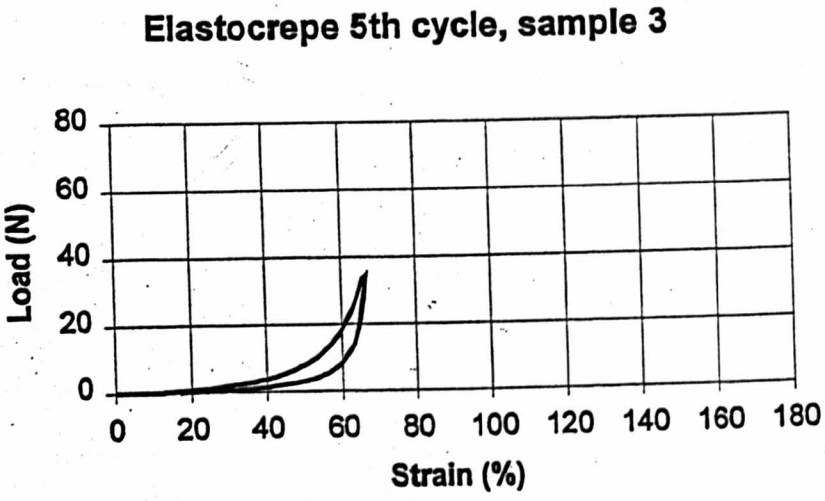


Figure 6.7 Load extension relationship for Elastocrepe bandage

6.3.4. Results of bandage testing

SurePress

This woven class 3c bandage incorporates both a central line to indicate correct overlap and woven rectangles which become square when the bandage is extended to a specified extension. The load or force / extension curve shows that there is only a small increase in tension with increasing extension until the tension is around 20 N, where the non-linear nature of the elasticity of the elastomeric bandage becomes obvious, see figure 6.6. The upper curve corresponds to the increasing extension cycle and the lower curve to the decreasing extension cycle. This bandage was not chosen for the next part of the investigation as it was intended to study the central line and rectangles as separate application aids.

Elastocrepe

This woven bandage is made of cotton fibres and the warp consists of twisted fibres. The load extension curve has an initial section in which the increasing extension results in a small increase in tension, which corresponds to the untwisting of the bandage fibres see figure 6.7. At around 10 N, however, there is an increase in the ratio of the curve as the fibres themselves are extended. The large difference between the increasing and decreasing load curves, hysteresis, is typical of non-elastomeric bandages. When predicting sub-bandage pressures from the load extension curve one needs to be aware that a wide range of pressures is possible due to the range of bandage tensions possible at one extension value. This bandage was not chosen for further investigation due to the small loads produced. At the time of investigation it was one of the few bandages available to community practitioners and was widely used in the management of leg ulcers.

Elset

This is a class 3a woven bandage with elastomeric fibres in the warp. The bandage is woven with the elastomeric fibres extended so that on relaxing the non-elastomeric warp fibres are brought close together. Elset was chosen because it is a key constituent of a widely used bandage regimen (Charing Cross 4 Layer bandage). The load extension curve demonstrates that increasing extension leads to a small increase in tension, see Figure 6.8. A much lower force is required to extend this bandage compared to the SurePress bandage. At around 10 N the non-linearity of the elasticity of the rubber in the bandage becomes apparent as at this point small increases in extension lead to an increasing change in tension. This bandage had uneven extension of the elastomeric fibres in the relaxed state, the elastomeric fibres at the edges being tighter than those in the centre of the bandage. This bandage, therefore, did not lie flat when unrolled and left to acclimatise. To reach the point of zero extension for the bandage fibres at the centre it was necessary to extend the bandage edges. It was difficult to place the samples in the jaws of the Instron under no extension yet still achieve a rectangular sample. It also produced much smaller loads than the other bandages.

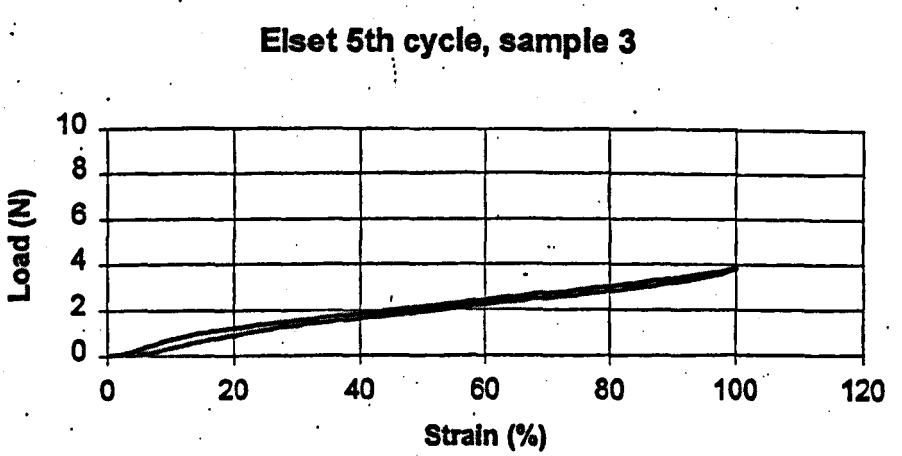


Figure 6.8 Load extension relationship for Elset bandage

Rosidal K

This woven cotton bandage has warp fibres which zigzag across the weft. The load extension curve shows an initial section in which the warp fibres are straightened and small increases in extension lead to small increases in tension. At tensions of around 10 N the ratio of the load / extension curve increases as the fibres are extended, figure 6.9. This bandage was selected for assessment in the next step of the investigation as it had a load extension curve typical of non-elastomeric bandages and the forces produced were similar to the 3c compression bandages and were higher than the Elastocrepe bandage. Both are classified as class 2 or light support / light compression bandages and exhibit considerable hysteresis.

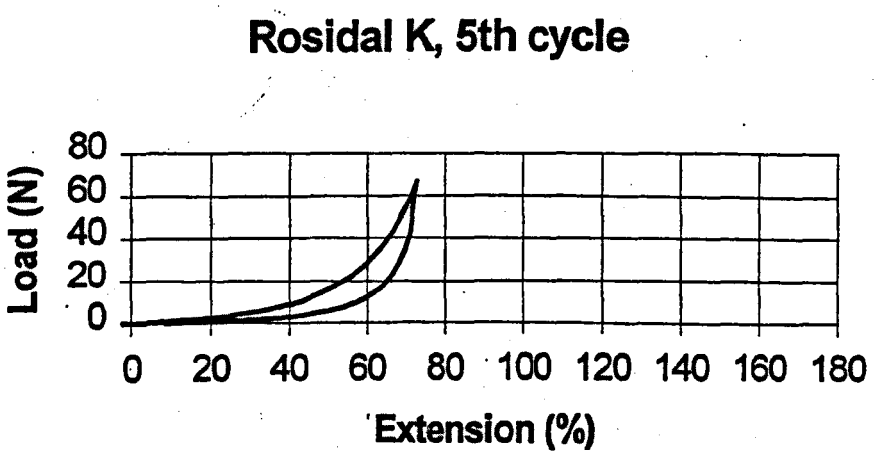


Figure 6.9 Load extension relationship for Rosidal K bandage

Setopress

The Setopress bandage is woven with elastomeric fibres in the warp. It also incorporates a tension guide in the form of printed rectangles which become square at the correct extension that may assist the novice bandager. This was therefore chosen as the third bandage in order to determine the impact of the tension guide on technique. It is classified as a 3c compression bandage as the manufacturers state that it is capable of producing and maintaining pressures of around 35 mmHg (4.67 kPa) on normal sized limbs (ankle circumference 180 - 250 mm). See figure 6.10.

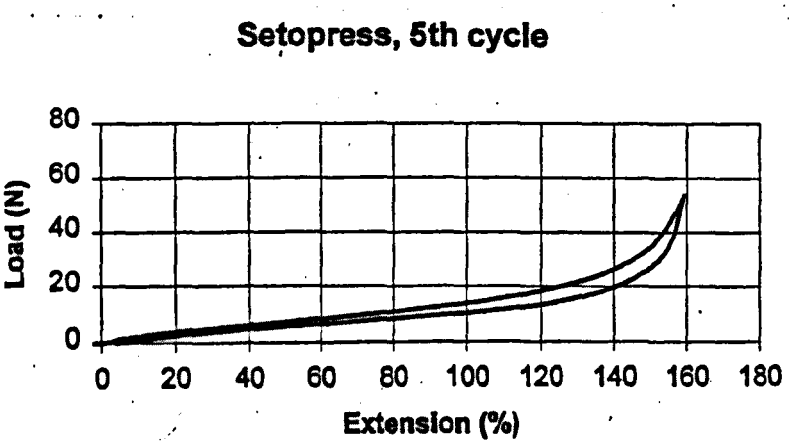


Figure 6.10 Load extension relationship for Setopress bandage

Tensopress

This bandage is knitted with elastomeric and polyamide fibres. This is the only knitted bandage studied. The long shallow load extension curve indicates that there is a small increase in tension (or load) with extension as the elastomeric fibres are extended, figure 6.11. This bandage was chosen for inclusion in the next step of the investigation as it had a load / extension curve typical of elastomeric bandages, incorporated a central guideline to aid correct bandage overlap, and was capable of producing similar pressures to the other 2 bandages selected. It is classed as a type 3c bandage.

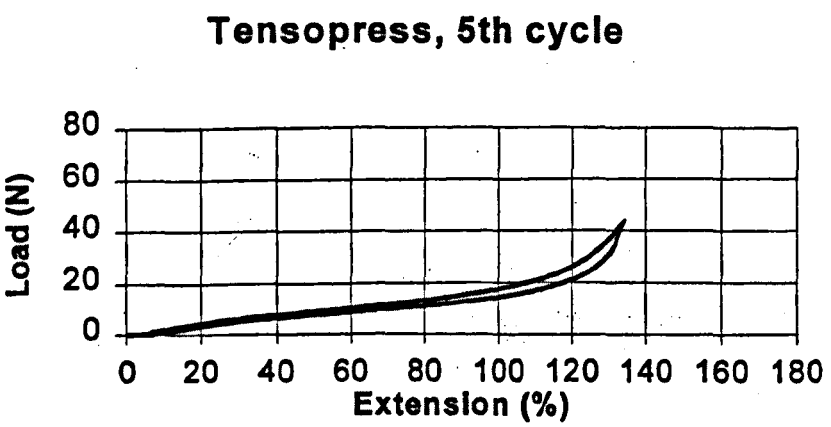


Figure 6.11 Load extension relationship for Tensopress bandage

6.3.5. Nurses' bandaging skills

Nurses were asked to apply the three chosen bandages in a random, pre-defined, order to the investigator's right leg. The experimental set up was reported in section 6.2.2
In brief, however, one subject was used throughout. The position of the lateral ankle and calf sites were marked and the sensors taped in position. Reproducibility of measurement position was achieved by marking the position of the feet and chair on the floor with masking tape. Nurses were not told how to apply any of the bandages prior to their application. They were handed the bandages and asked to apply them to my leg as they would normally apply a compression bandage. The bandages were in their original packaging containing the manufacturer's leaflet detailing application technique. No nurses read the leaflet prior to application of the bandage. The nurses were not permitted to see the results of the pressure monitor at any point during the application of the bandage.
After the nurse had applied all three bandages they were told the sub-bandage pressures that they had achieved, as well as any problems with bandage placement. Advice was given on how to counteract these problems and the nurse was provided with bandages to take for practicing at home. An acceptable pressure profile was defined as an ankle pressure of 25-46mmHg with a calf pressure less than the ankle pressure.

6.3.6. Results

Bandaging was assessed both visually and by recording the sub-bandage pressures produced. The table of raw sub-bandage pressure data can be found in Appendix A. In order to apply an effective compression bandage which will not damage the skin, it is necessary to produce the recommended pressure profile and to place the bandage such that there are no gaps, i.e. a constant overlap of 50% and correct spiral placement on the leg. The results will be presented in two parts therefore, pressure readings and visual assessment. Finally both

criteria will be combined to determine whether nurses produced satisfactory results using both criteria.

6.3.6.1. Ankle and Calf Pressures

The initial bandaging was unsatisfactory. The most common mistake was the production of higher mean calf pressure than ankle pressure, see Table 6.8 Initial ankle and calf pressures for three bandages (sitting posture). The wide range of pressures found here was also a feature in the pilot study.

Pressure (mmHg)		**Bandage**		
		Rosidal K	**Setopress**	**Tensopress**
Ankle	**Mean**	27	35	30
	[95% CI]	[24,31]	[30,39]	[26,34]
	(Range)	*10-65*	*10-86*	*10-73*
Calf	**Mean**	34	40	34
	[95% CI]	[29,39]	[36,44]	[31,38]
	(Range)	*14-90*	*15-92*	*17-63*

[95% CI] = 95% Confidence Interval for mean

Table 6.8 Initial ankle and calf pressures for three bandages (sitting posture)

6.3.6.2. *Discussion of initial pressures;*

Pressure at ankle;

There was a wide range of pressures exerted at the ankle, from 10 to 86 mmHg (1.33 - 11.47 kPa). The mean pressures, however, fell within the UK recommended pressures for a 3c bandage (25-35 mmHg (3.33 - 4.67 kPa)). As Rosidal K is classed as a light support / light compression bandage it should be noted that this classification refers to the ability to apply and sustain pressures; non-elastomeric bandages lose their pressure rapidly after application (Raj et al 1988). Around one third of subjects produced either ineffective (low) or dangerously high pressures and this emphasizes the need for training.

Pressure ratio

The mean calf pressures were greater than the mean ankle pressures (paired t test) for each bandage (e.g. Rosidal K, ankle pressure ≠ calf pressure , paired $t=3.6$, $p<0.01$; Tensopress, ankle pressure ≠ calf pressure, paired $t=2.41$, $p=0.02$). The number of subjects producing an acceptable ratio (<1.0) in each bandage was as shown in Table 6.9 Proportion of nurses producing correct pressure ratio

Bandage	Proportion (%) with pressure ratio <1 (calf / ankle)	95% Confidence interval for proportion
Rosidal K	15 / 48 (31.2%)	[0.18 - 0.45]
Setopress	17 / 48 (35.4%)	[0.22 - 0.49]
Tensopress	14 / 48 (29.2%)	[0.16 - 0.42]

Table 6.9 Proportion of nurses producing correct pressure ratio

The three bandages, therefore, produced similar numbers of unacceptable pressure ratios. Correct pressure ratio and acceptable ankle pressure, i.e. an acceptable pressure profile,

was achieved by very few subjects. Table 6.10 illustrates the small proportion of nurses achieving both an acceptable ratio and pressure at the ankle.

Bandage	Number with a ratio < 1 (calf/ankle)	Number with ankle pressure (18-50 mmHg (2.4 - 6.67 kPa)	Proportion with both an acceptable pressure and ratio.
Rosidal K	15 / 48	32 / 48	11 / 48 (22.9%)
Setopress	17 / 48	39 / 48	12 / 48 (25%)
Tensopress	14 / 48	38 / 48	10 / 48 (20.8%)

Table 6.10 Proportion of nurses achieving both acceptable pressure and ratio at initial application

The acceptable sub-bandage pressure profiles rarely combined both an ideal pressure and an ideal ratio, only 2 subjects achieved this with the Rosidal K bandage and 1 subject using the Tensopress bandage achieved this. Thus it can be seen that few nurses achieved acceptable sub-bandage pressure profiles prior to training.

6.3.7. Visual inspection

This analysis of the bandaging technique does not, however, take into account the placement of the bandage and the likely pressures on the leg distant from the sensor sites. Visual inspection of the bandage can help to determine whether a bandage is acceptable by providing another assessment which can be 'triangulated' with the pressure profiles so that those bandages identified as being acceptable have both an acceptable pressure profile and are placed on the leg such that the pressure is graduated from ankle to knee with no gaps. For this purpose all bandages were inspected for gaps, proper placement at the toes, proper

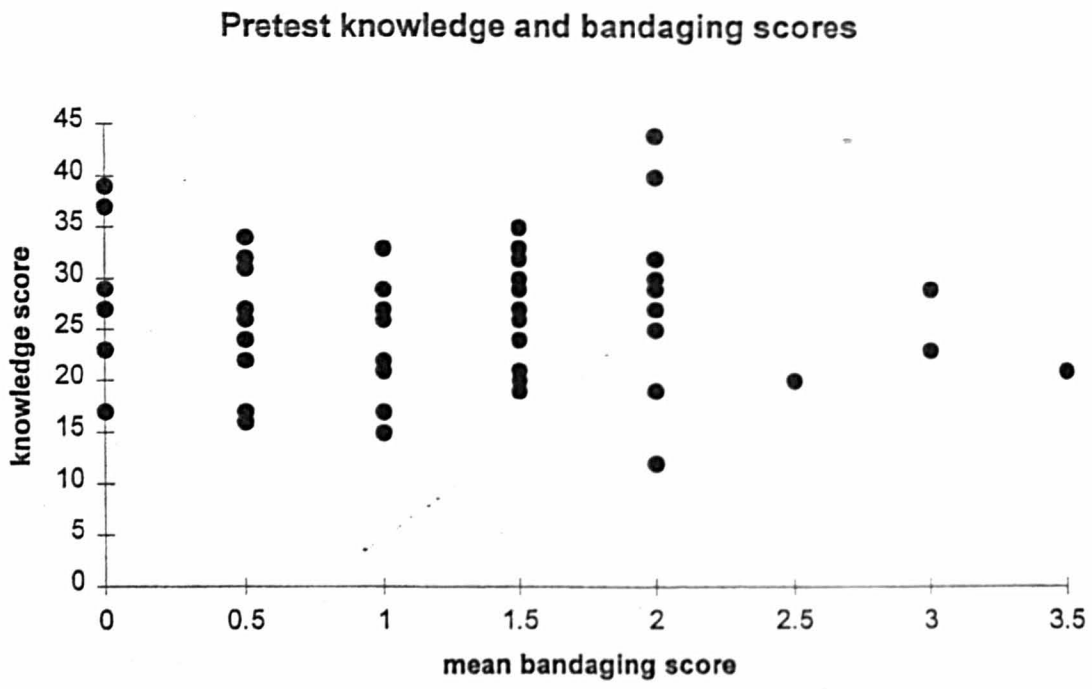


Figure 6.12 **Distribution of nurses knowledge score and bandaging proficiency score**

placement at the knee, and overlap of 50%. Considering the 11, 12 and 10 nurses who achieved acceptable pressure profiles in table 6.10, it became apparent that this reduced the proportion of acceptable bandages even further; of the 11 initially acceptable Rosidal k bandages, 5 were excluded - 1 due to gaps in the bandage, 2 due to <50% overlap and 1 had 66% overlap and 1 due to poor bandage placement at the knee.

Of the original 12 in the Setopress group a further 7 were excluded, 4 for inconsistent or too generous overlap, 1 for gaps in the bandage, 1 for excessive bandage turns and constriction on the foot and 1 for starting the bandage high up on the foot thus allowing formation of oedema.

Of the original 10 in the Tensopress bandage group, a further 8 were excluded, 1 for gaps, 3 for overlap > 50 %, 2 for variable overlap and 2 for placement - leaving 2 which fulfilled both sets of criteria.

Applying the strict criteria of pressure profile and visual inspection means that a very small proportion of nurses produce a satisfactory bandage. Of the 11 nurses who applied a good bandage on both pressure and visual criteria, only 2 were able to repeat this in 2 bandages.

6.3.7.1. Nurses' knowledge scores

The nurses' knowledge of leg ulcer aetiology and treatment was also tested to ascertain whether ability to apply bandages was better in more experienced, knowledgeable nurses. The questionnaire used had been validated and tested for reliability in a population of community nurses (Luker and Kenrick 1992). The mean score was 25.9 with a total possible score of 62. In their study, Kenrick and Luker (1992) found an average initial score of 24, thus the two groups of nurses appear initially comparable in terms of knowledge and reported practice.

It was hypothesised that those nurses who scored highly on the questionnaire may be more likely to apply a bandage well, however there was no correlation between knowledge score and the bandaging score, see figure 6.12. After the training day the mean score increased to 32.5.

6.3.8. Effect of training on bandaging pressures

It can be seen that the main problem with the initial bandaging technique was the production of a reverse pressure ratio (ankle pressure less than calf pressure). The ankle pressure was also lower than the widely recommended 40 mmHg (5.33 kPa). Thus in examining the impact of training on bandaging we will analyse how the pressure ratio and ankle pressure changes. Table 6.11 Nurses producing correct ratio during training summarises the ankle, calf and ratios both pre and post training.

	Proportion with ratio <1.00		
Bandage	Before Study Day	t = 2 weeks	t = 8 weeks
Rosidal K	15 / 48	25 / 47	8 / 18
Setopress	17 / 48	35 / 47	12 / 18
Tensopress	14 / 48	34 / 47	11 / 18

Table 6.11 Nurses producing correct ratio during training

The proportion of subjects producing an unfavourable pressure ratio changed significantly from t=0 to t=1 in all three bandages;

- Rosidal K (McNemar's χ^2 = 6.36, df = 1, p<0.025),
- Setopress (McNemar's χ^2 = 12.45, df = 1, p< 0.001)
- Tensopress (McNemar's χ^2 = 17.28, df = 1, p<0.001).

There was no difference between the bandages with respect to the proportion of bandages exerting a pressure ratio of greater than 1 at t=2 weeks. (χ^2 = 0.05, p>0.05)

Pressure (P), (mmHg) / ratio;									
	Pre training			Immediately post training			Weeks after training		
Bandage	Ankle P	Calf P	Ratio	Ankle P	Calf P	Ratio	Ankle P	Calf P	Ratio
Rosidal K	27 24-31	34 30-39	1.3 1.2-1.5	**24 *** **22-26**	25 22-28	1.2 0.9-1.4	29 24-34	26 21-31	**1.0 *** **0.8-1.3**
Setopress	35 30-39	40 36-44	1.1 0.9-1.2	**29 *** **26-32**	25 23-28	**0.9 *** **0.8-1.0**	33 28-38	27 24-30	**0.9 *** **0.7-1.1**
Tensopress	30 26-34	34 31-38	1.3 1.2-1.4	29 29-32	25 21-26	**0.9 *** **0.8-1.0**	31 24-38	25 21-29	**1.0 *** **0.7-1.2**

95% Confidence Interval = [ ]

Bold * = this value, after training, is significantly different from the initial value.

Table 6.12 Sub-bandage pressures (sitting) pre and post training

These results are also summarised in the following charts showing the change in pressure ratio and ankle pressure after training. Thus at the first visit, the ankle pressures were lower than the calf pressures, ($p<0.05$), i.e. there was an unfavourable pressure ratio effect for all 3 bandages, i.e. the ratio was >1.0. After training the ratio was less than 1 for both elastomeric bandages, and in all three bandages it had fallen significantly since the first visit. The tourniquet effect persisted in the non-elastomeric bandage.

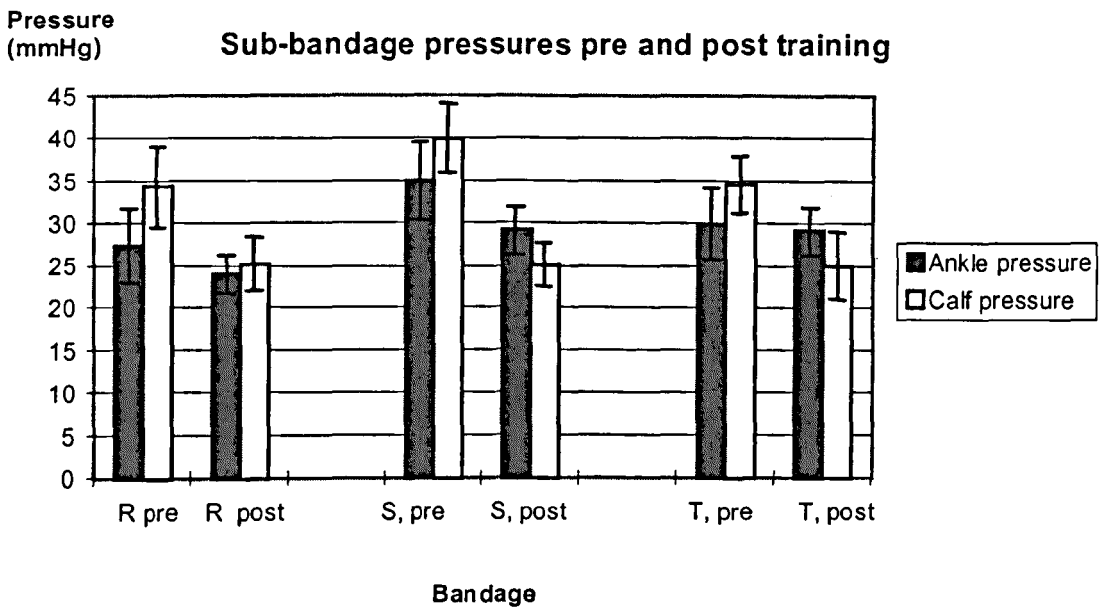


Figure 6.13 Effect of training on sub-bandage pressure at ankle and calf

KEY:R = Rosidal K, S = Setopress, T = Tensopress; error bars = 95% Confidence interval

The change in the pressure ratio was achieved by decreasing the calf pressure rather than increasing the ankle pressure. The ankle pressure remained marginally low throughout the study at around 25 - 30 mmHg (3.33 - 4.0 kPa) compared to that recommended by some workers (Stemmer et al 1980) (40 mmHg (5.33 kPa)). The elastomeric bandages produced a higher mean ankle pressure of 29 mmHg (3.87 kPa) than the non-elastomeric bandage, 24 mmHg (3.2 kPa). As the pressure exerted by the Setopress bandage fell during training then training may need modification as the pressures were already marginally acceptable. A reduced ankle pressure in the short term may be the cost of achieving a more acceptable pressure ratio. The late increase in ankle pressure as seen in both studies reiterates the need for assessment of nurses bandaging technique to include a sufficiently long follow-up period.

6.3.9. Discussion

The non-elastomeric bandage may have been initially difficult to apply as the nurses were not familiar with it. At the time of the investigation it was not available on GP prescription and not used widely in local hospitals. The nurses were expected to learn this technique easily, however, as the recommended method of application is that it be applied at full extension with a 50% overlap. Thus there was no requirement to 'find the correct extension', and nurses could not over extend this bandage. Furthermore the bandage has a similar load / extension curve to that of Elastocrêpe which has been used by community nurses for many years. The experimental hypothesis was that the two elastomeric bandages would be easy to apply and that technique would improve after training.

A larger sample size would be required to reduce the possibility of a type 1 error, that is concluding that there is a real difference in the proportion of nurses applying a bandage appropriately, when none, in fact, exists. The sample size of 48 was convenient and the pilot study data could have been used to estimate the sample size require to be able to find a significant difference.

6.3.10. Analysis of Results

When selecting a bandage it may be important to look at the percentage of bandages applied badly - the non-elastomeric bandage appeared to fare worst in this regard, with 47% of bandages applied badly even after training. There was no statistical difference, however, in the proportion of nurses applying the bandages badly either pre-training (χ^2= 0.22, p=0.9) or after training (χ^2 = 0.63, p= 0.9). This may be due to low power of the study.

All these pressures were measured in the sitting position - if the standing position is considered, then ankle and calf pressures increase significantly but this results in no significant change in pressure ratio.

6.3.11. Summary

The nurses performed poorly initially and there appears to be no difference in the proportion of nurses, around 60%, who applied ineffective or dangerous bandages with the three bandages evaluated. Similarly, the proportion applying a good bandage, around 10%, did not vary with bandage type.

After training fewer nurses applied the bandages in an ineffective or dangerous manner. Moreover, the proportion applying the bandage well increased in all bandages. The increases in bandaging scores were significant in all three groups, but did not vary within the groups.

6.4. The Effect of Training on Nurses' Application of Multi-Layered Compression Bandages

6.4.1. Background

It is possible to improve bandaging technique by providing nurses with feedback on their performance but this has, until now, only been achieved with single layer bandages (section 6.2 and 6.3: Nelson et al 1995). This study uses two multi-layered bandaging regimes and reports on the change in bandaging technique recorded in nurses participating in a leg ulcer management course in Liverpool and Wirral. Changes in knowledge and reported practice are reported elsewhere (Jones and Nelson 1997).

6.4.2. Methods of Assessment

Sub-bandage pressure was measured at the ankle and the calf using the Strathclyde Pressure Monitor (Barbenel et al 1990) as in the previous sections. One leg (EAN) was used throughout the study. Bandage placement was also noted. The bandages used were the Charing Cross four layer system (Blair et al 1988) and a two layer system consisting of orthopaedic wool and a Tensopress bandage.

Four layer system = orthopaedic wool, crepe BP, Elset, Coban.

Two layer system = orthopaedic wool, Tensopress bandage.

All bandages were applied in a spiral technique except the Elset which is applied in a figure of eight. Both systems are, in theory, capable of applying 25-40 mmHg (3.33 – 5.33 kPa) at the ankle, the level of compression reported to heal leg ulcers and to be derived from physiological studies as being required to limit oedema formation (Stemmer et al 1980).

Pressure measurements were made at the start of two study days on leg ulcer management and repeated at the end of the second study day.

Procedure for recording

1. investigator sits and has sensors applied.
2. pressure monitor 'zeroed'
3. research assistant applies orthopaedic wool and crepe to limb in a spiral fashion.
4. foot placed in 'neutral' position and this is marked on floor.
5. subject invited to apply top two layers of 4 layer bandage to limb
6. recordings made of method of application of layers 3 and 4.
7. immediately after application foot placed in neutral posture and pressure recorded once it had stabilised
8. bandage overlap recorded
9. top 3 layers of bandage removed
10. subject invited to apply single layer bandage
11. immediately after application pressure recorded
12. bandage position recorded in terms of POE – mnemonic for
    - placement at the toes, heel, and tibial tuberosity
    - overlap – measured the distance between successive layers of bandage
    - extension – assessing the amount of extension by placing a finger beneath successive turns of the bandage, particularly noting tight and loose bands
13. compression bandage removed
14. nurse given feedback on pressures achieved and positioning of bandage

The 2 study days consisted of lectures and workshops on compression bandaging and use of hand-held Doppler ultrasound in the assessment of arterial circulation, case-studies and small group discussions. Learning materials were provided for the use of the subject between the study days - a specially written learning pack and video, made by the

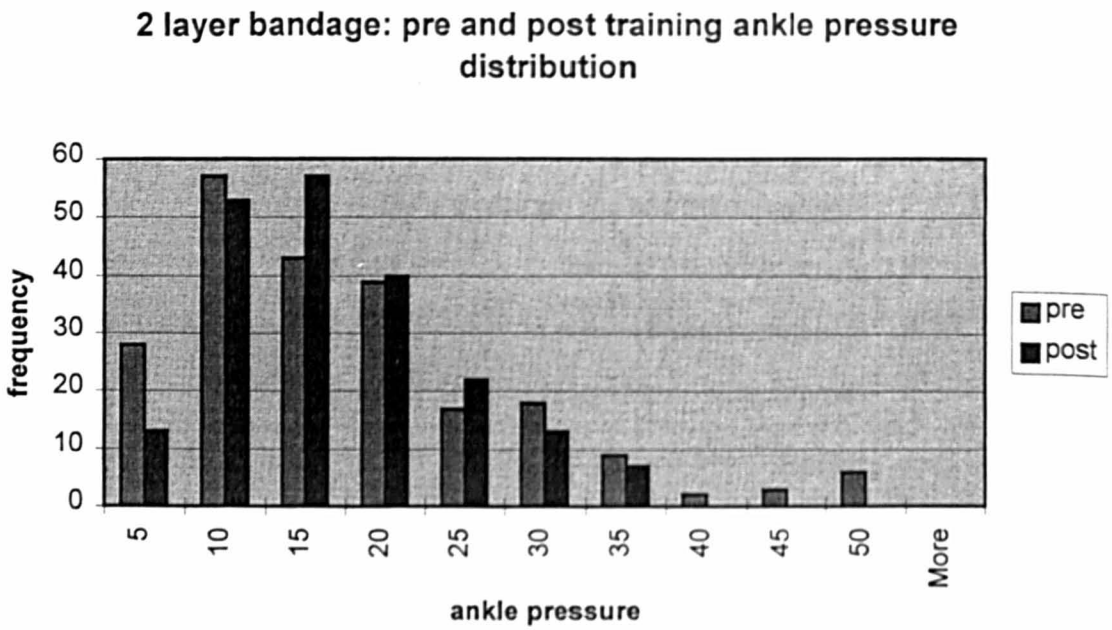


Figure 6.14 Distribution of ankle pressures generated by nurses before and after training; 2 layer bandage

investigator, demonstrating bandaging techniques. The subjects all made accompanied visits to leg ulcer clinics where both types of compression bandaging were being used. There was an interval of approximately 6 weeks between study days to allow for practice at home and clinic visits.

6.4.3. Study Design

The study was designed as a single group, pre and post intervention measures. The period of follow-up was 6 weeks.

Sample

The subjects were an opportunistic sample of nurses currently involved in leg ulcer management in Liverpool and Wirral who were recruited to attend study days (n=224). The vast majority worked in the community as district or practice nurses. A small number of nursing home and hospital nurses also attended.

6.4.4. Initial results

The following charts illustrate the distribution of bandage pressures at the ankle and the pressure ratio for the two layer bandage (Figure 6.14 Ankle pressure distribution : 2 layer bandage)

From this distribution one can see that the modal pressure produced at the ankle before training was 10 mmHg (1.33 kPa) and after training this was 15 mmHg (2.0 kPa). The number of nurses producing pressures of greater than 35 mmHg (4.67 kPa) decreased also from 8 before training to none after training.

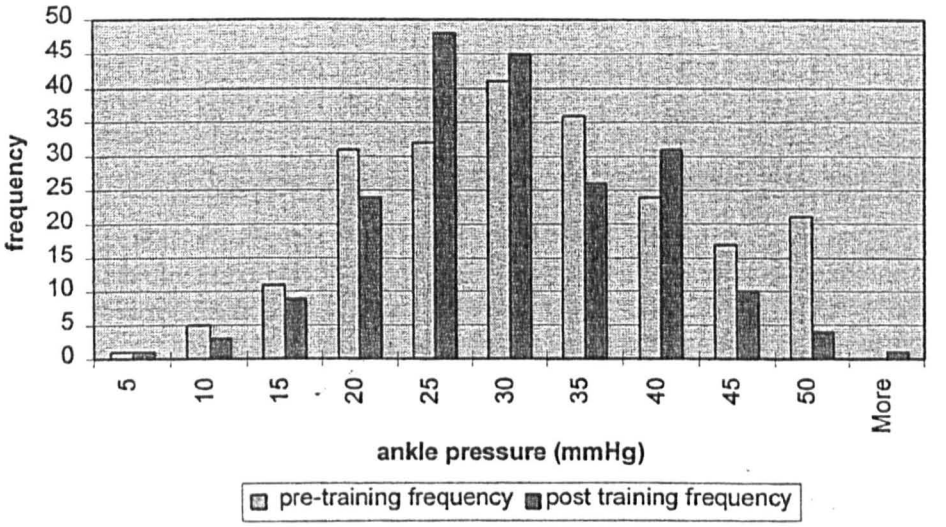


Figure 6.15 Ankle pressure distribution : 4 layer bandage

From this graph it can be seen that the mode pressure produced at the ankle decreased from 30 mmHg (4.0 kPa) before training to 25 mmHg (3.33 kPa) after training. The number of nurses producing ankle pressures of more than 40 mmHg (5.33 kPa) reduced from 38 pre-training to 15 after training.

The ankle pressure is not the only indicator of bandaging proficiency. The pressure ratio produced must also be taken into account.

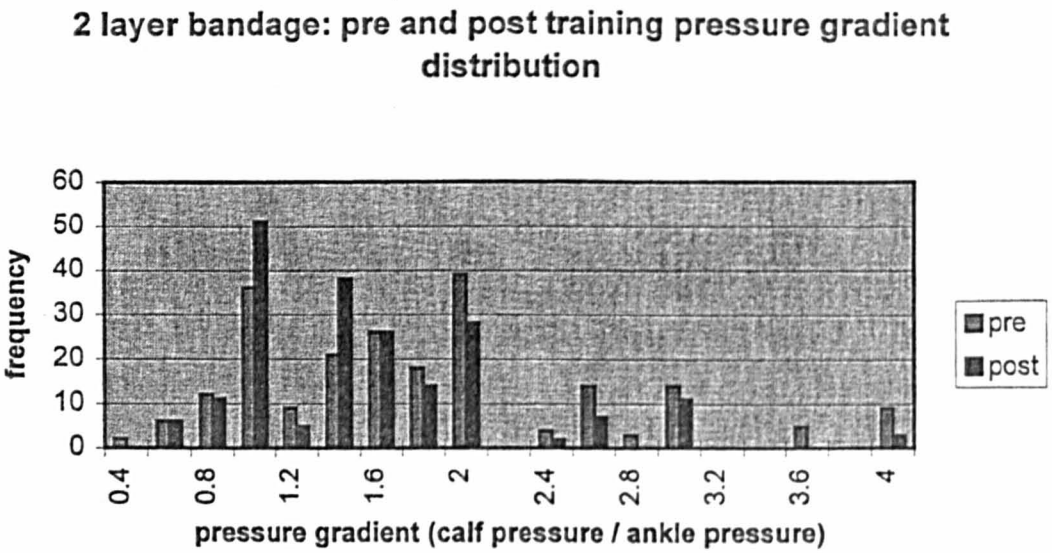


Figure 6.16 Distribution of ankle/calf pressure ratios generated by nurses before and after training; 2 layer bandage

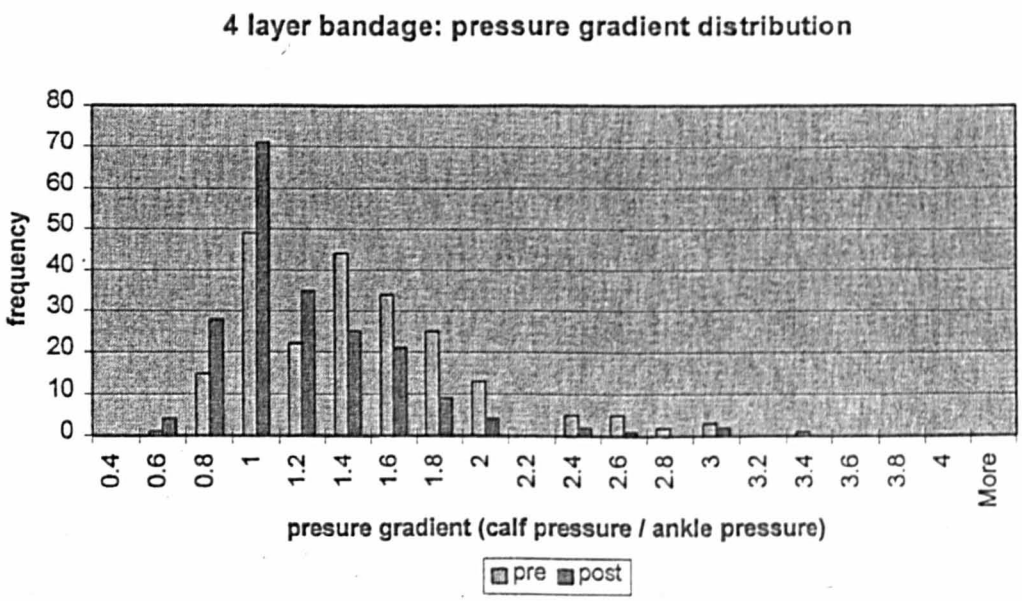


Figure 6.17 Distribution of ankle/calf pressure ratios generated by nurses before and after training; 4 layer bandage

Figure 6.16 shows the pressure ratios pre and post-training for the two layer bandage. The mode ratio before training was 2, i.e. calf pressure was twice that at the ankle. After training the mode had decreased to 1. The number of nurses producing a pressure ratio >1.0 (i.e. an unacceptable pressure ratio) was 144 initially and this reduced to 136 after training.

Figure 6.17 demonstrates the shift towards a lower pressure ratio under the four layer bandage after training. Although the modal ratio for each assessment was 1.0 there are fewer nurses achieving a high pressure ratio after training, reducing from 153 pre training to 102 after.

6.4.5. Analysis

6.4.5.1. Impact Of Training On Sub-Bandage Pressure

In the two layer system initially 75% of nurses produced a pressure such that the calf pressure was higher than the ankle pressure (an unfavourable pressure ratio). After training 64% still produced an unfavourable pressure ratio. This difference was not statistically significant, $\chi 2.= 0.61$, $p=0.43$.

In the 4 layer system there was a similar proportion of nurses applying an unfavourable pressure ratio initially, at 71%. This reduced after training to 40% and this difference was statistically significant ($\chi 2= 23.4$, $p<0.001$).

6.4.5.2. Impact of Training on Sub-Bandage Ankle Pressure

For the two layer system there was no significant change in mean pressure, initially it was 17.6 mmHg (2.35 kPa) and after training this was 16.7 mmHg (2.23 kPa). These pressures are also lowered than cited for this class of bandage. Some practitioners apply an additional layer of shaped tubular bandage in order to apply a further 10 mmHg (1.33 kPa) at the ankle, and this aids bandage retention (Callam et al 1992, Cornwall et al 1987). Despite the

Tensopress bandage being classified as a class 3c bandage and is used in the treatment of venous leg ulcers, it produced low pressures in this investigation.

In the 4 layer bandage, initially the mean ankle pressure was 31.5 mmHg (4.2 kPa). This is lower than the 40 mmHg (5.33 kPa) often quoted for this system. After training ankle pressure was 30.1 mmHg (4.01 kPa). Training did not result in a change in ankle pressure.

6.4.6. Discussion

This work confirms previous findings that nurses' bandaging technique is poor (Millard et al,1986) and that it improves after training (Nelson et al 1995).Training resulted in an improvement in bandaging but a significant proportion of nurses (49%) still produced an unacceptable pressure ratio. The nurses recruited to this study are usually deemed capable of treating leg ulcer patients. Given that they possess the appropriate professional qualification for this role it appears that the professional preparation does not appear to be appropriate, or if the skills learnt during training are lost and need to be maintained through regular updates. We may also need to consider whether all nurses should be allowed to apply compression bandages given the low level of competence.

Particularly noteworthy is the relative lack of success of the bandaging training. This training was intensive, with 2 skilled leg ulcer specialists each spending around two days for a cohort of approximately 15 nurses. Nurses were provided with objective measurements of their bandaging skill, from the pressure monitor, as well as individual advice on modifying any elements of poor application technique. One explanation is that the method of training was inappropriate; it may be preferable to have 'on the job' training' rather than study days. There is no part of this study relating performance with outcomes; this may be required before we consider whether nurses are fit for purpose in this area of practice.

The pressures achieved at the ankle were lower for both bandaging regimes. This may be due to different sensing sites having been used in previous papers (Blair et al 1988). There are issues of transferability of findings to limbs with chromic venous insufficiency where the underlying tissue is fibrosed and therefore the sensors may record higher pressures, as they

do not sink into the soft tissues. Furthermore, there is a wide range of padding materials available and Rigby at al (1997) demonstrated widely differing load transference characteristics in these materials. One brand of padding was used throughout this study but it is not known if the load transfer characteristics of padding materials influences clinical outcomes such as incidence of pressure damage. One further problem may be with the comparison of nurses bandaging proficiency against poorly validated criteria. We know that very high pressures lead to ischaemic damage and that tourniquets lead to oedema formation but we do not have positive criteria from trials in which high healing rates were achieved against which to validate the criteria described here. Particularly problematic is the lack of comparison on pressure profiles described in various studies particularly the use of different measurement sites, patient posture and the use of numerous pressure monitors.

6.4.7. Conclusions

Intensive training was able to improve the sub-bandage pressure profiles generated by a proportion of qualified nurses using single layer bandages, determined by both interface pressure measurement and the appearance of the bandage. Bandaging training as part of a two-day course in leg ulcer care led to an increase in the proportion of nurses applying the correct sub-bandage pressure ratio in 4 layered but not 2 layer bandage regimes.

The effectiveness of compression therapy depends on both the pressure levels achieved and the distribution of the pressure, therefore bandaging training must be offered if clinicians are to realise to the potential of the modern bandaging products available today. It has already been established that inappropriately or inexpertly applied compression is hazardous and therefore training should be mandatory rather than optional.

A large proportion of qualified nurses remain unable to apply a compression bandage satisfactorily after intensive training. This may be due to the difficulty in training nurses to apply bandages, due to the course being poorly designed and/or delivered. Whether this poor educational outcome was reflected in patient outcomes is unknown.

7. Summary

This final chapter will set out the findings of the three main investigations; modification of the pressure measurement system (Chapter 3), posture and foot movement influencing sub-bandage pressure (Chapters 4 and 5) and the impact of training on sub-bandage pressure (Chapter 6). It will also discuss the role of sub-bandage pressure measurement in evaluating bandages and training nurses, with particularly reference to sensor geometry and position of the bandages on the leg. It will conclude by highlighting implications for practice and research.

7.1. Aims of the investigation

There were three main aims:

1. To explore the utility of the Strathclyde Pressure Monitor for measuring interface pressure. In particular - how would the height dependence, sensor thickness, or transmission fluid influence the calibration coefficient, accuracy and time response (chapter 3).

2. To describe the changes in sub-bandage pressure during foot movement and posture changes. In particular to determine whether pressure changes varied with measurement site and bandage characteristics (chapters 4 and 5).

3. To study nurse bandaging technique, in particular the pressure applied to a limb at the ankle and calf (chapter 6). There were three parts to this investigation:

    a. A pilot study with one bandage to determine whether bandaging technique changed after training and feedback (a before and after study).

b. A study of 3 single layer bandages to determine whether bandage technique changed after training and feedback and whether these changes were dependent on the bandage used (a before and after study).

c. A study of two multi-layered bandaging regimens to determine whether there was any difference in ability to apply these, or any difference in the changes in bandaging technique after training and feedback (a before and after study).

7.2. Chapter 3: The pressure monitor

The characteristics that affected the response to a step change in pressure were investigated.

The pressure measurement system responds quickly to changes in pressure. This is important in the clinical situation where there are rapid changes in leg shape secondary to muscle action.

The viscosity of the fluid in the system changed the response with time, as did the length of the tubing and the mass of fluid in the system. This allowed critical damping to be determined for one likely situation in which longer tubing than the previously used 1m was used by using a different transmission fluid. The initial time to achieve steady state with an oil-filled sensor and tubing was reduced from 0.4 seconds to around 0.1 seconds with a system using 32% glycerine. This quick response would be of importance in investigations where the length of tubing needs to be pre-set in order to allow movement or, in ambulatory monitoring where it needs to be short.

These investigations were not pursued further as it was apparent that the limitations of the measurement system were such that it could be used to measure pressures at a frequency of around 1 measurement per second.

The height dependence of the measurement system was eliminated by adding a fluid filled tube in parallel with the pressure sensor that was open to the atmosphere. The end of this tube was placed beside the pressure sensor so that the height between the transducer and both ends of tubing was equal. The second piece of tubing was attached to the reference port of the transducer and hence the hydrostatic pressure at both ports was equal and opposite.

7.3. Chapter 4: Variation in sub-bandage pressure with foot position

The impact of foot position on sub-bandage pressures was initially considered in a pilot study on 4 subjects using two bandages. The Granuflex Adhesive Compression Bandage was chosen to represent elastomeric bandage as previous work by Sockalingham had demonstrated that it could apply and sustain high pressures at the ankle. An Elastocrêpe bandage represented non-elastomeric bandages because it had previously been investigated by numerous investigators and was used widely at that time.

The foot position was found to influence sub-bandage pressure. The change in pressure led to an increase in the difference between the ankle and the calf pressures. As blood flow enhancement is related to pressure gradient then this may have a therapeutic effect. Sub-bandage pressures at lateral sites on the leg were more affected by foot movement than at the medial site. Therefore future measurements were made at the lateral aspect of the leg.

7.4. Chapter 5: Pressure variation with posture

There was an increase in sub-bandage pressure, immediately after application, from the sitting to the standing postures underneath all 5 bandages tested (Granuflex Adhesive Compression bandage, Elastocrêpe, Rosidal K, Setopress and Tensopress). The first two bandages were chosen in the pilot study as previous research indicated that they were representative of elastomeric and non-elastomeric bandages. The latter three bandages were chosen after undertaking load / extension tests of six bandages used in the treatment of

venous leg ulcers. These bandages were chosen as they represented non-elastomeric (Rosidal K), woven elastomeric (Setopress) and knitted elastomeric (Tensopress) bandages. The change in pressure with posture did not appear to be related to the presence of elastomeric fibres in the bandage. At the lateral site the changes in pressure beneath the non-elastomeric bandages were greater than the pressure changes beneath the elastomeric bandage. Changes in pressure with posture changes were smaller after training than before training.

The change in sub-bandage pressure with posture was also assessed in patients wearing bandages for 7 days. The pressures were higher when the patient was sitting than when they were standing. This has not previously been reported and needs further investigation. Throughout this investigation it was noted that the changes in pressure with posture were much smaller than the pressure variations between nurses.

7.5. Chapter 6: Nurses' bandaging technique

7.5.1. Pilot study

The bandaging technique of 18 nurses was improved by training, measured by a bandaging score derived from the ankle pressure and the pressure gradient from ankle to calf (**both** being necessary for effective compression bandaging). The 11 nurses who returned for retesting sustained the improvement in technique after 2 weeks. Marking a bandage with a tension indicator appeared to make a small improvement in bandaging technique but this was not significant when subjected to statistical analysis.

7.5.2. Study of single-layer bandaging regimens

This investigation included 48 nurses each using three bandages and longer intervals between the bandage assessments. The nurses' level of knowledge and qualifications were also recorded so that any association between level of educational preparation and

bandaging skill could be identified. The three bandages chosen were representative elastomeric and non-elastomeric bandages (as determined by mechanical testing). One of the elastomeric bandages incorporated an extension indicator so that the impact of this visual aid could be further investigated.

The sub-bandage pressures initially were poor with very few nurses achieving both an appropriate ankle pressure *and* a pressure gradient from ankle to calf. The bandage with the extension indicator did appear to have a small impact on the number of nurses generating an appropriate pressure gradient. The proportion of nurses in each bandage group who achieved the correct gradient or pressure increased after training when measured 6 weeks later. A sample of nurses were further tested 3 months after the initial measurements and their bandaging technique remained better than initially. The non-elastomeric bandage appeared to have the smallest proportion of competent nurses after training. This bandage was not available to the community nurses recruited at the time of this study in contrast to the two elastomeric bandages selected. Furthermore the bandage is applied at a different working extension, which is at full extension, in marked contrast to the elastomeric bandages, which are never applied at full extension. This may account for the poor performance of the nurses using a non-elastomeric bandage.

It was discovered that a bandage could be applied in such a way that although the pressure sensors indicated that the bandage was applied correctly, the position of the bandage on the rest of the leg, away from the pressure sensors was less important. In order to achieve a therapeutic compression bandage is it necessary to apply an evenly reducing pressure from the ankle to the calf. This requires that the number of layers of bandage remains constant on the leg (as pressure is proportional to the number of layers of bandage). Bandage layers can be assessed by looking at the distance between bandage edges, a 50% overlap produces 2 layers of bandage along the leg whereas a 40% overlap will produce some areas where there are two layers of bandage and some layers where there is one layer of bandage. The bandage overlap needs to be investigated to determine if it becomes regular after training.

The training provided in this study was intensive, yet it still resulted in half of the nurses still applying a bandage with an unacceptable pressure gradient. Further research is needed into cost-effective methods for training nurses in application of compression bandages. One reason for the small increase in numbers of nurses applying a bandage correctly may have been the relative ineffectiveness of the training. A trial in which different methods of training nurses to apply a bandage is required. This should ideally collect outcome data on sub-bandage pressure profiles, bandage placement and patient outcomes (healing times, adverse event rates).

7.5.3. Study of multi-layer bandage regimens

A further study of bandaging skill in applying a 4 layer and a 2 layer compression regimens was carried out to determine whether any mistakes in bandage application were 'cancelled out' with the subsequent application of other bandage layers. A sample of 224 qualified nurses had their bandaging skills using both a 4 layer and a 2 layer regimen were assessed both before and after a 2 day course in leg ulcer management. At the pre-intervention assessment, there were similar proportions of nurses (71 and 74%) applying a tourniquet with both bandages. The ankle pressures produced with both bandages were lower than recommended for the bandage regimens. After training the ankle pressures generated did not change significantly but the proportion of nurses applying a tourniquet with the 4-layer bandage did fall significantly to 40%. The proportion of nurses who produced a tourniquet with the 2-layer bandage changed slightly (not significantly to 64%). The intervention - 2 study days including bandaging workshops, a 'fact pack' and a bandaging video demonstrating both bandaging techniques was successful in improving the bandaging skills of nurses using the 4 layer bandage regimen but not the 2 layer bandage system. The high 'failure rate' (40 % and 64%) after training certainly prompts the question 'can bandaging training be improved?'; for if it cannot, then one should consider whether it is cost-effective.

This research provides data to confirm that different bandages are easier to apply than others. In addition, more nurses improved their technique after training with the four-layer

bandage system than with the two-layer system. One of the reasons for the difference in the response to training may be that the nurses may have practised the 4-layer bandage system more than the other, that the 4 layer is easier to apply correctly, or that errors in bandaging are cancelled out by the addition of more layers.

7.5.4. Other findings from nurse bandaging study

An acceptable pressure profile as determined by measuring at a minimum of two sites on the leg is necessary but not sufficient to declare that bandaging technique is good. This is of great import as more training courses are set up to teach leg ulcer management and bandaging. While this training is probably necessary, inappropriate feedback has the potential to convince practitioners who have applied a bandage badly that they are competent. It is relatively easy to 'achieve' a high ankle pressure by careful positioning of the pressure sensor over the malleolus where the radius of curvature is small and therefore the pressure will be high (Laplace's law). The visual indicators of a competent bandage should also be validated to determine the relative importance of bandage pressures and bandage appearance in assessing bandage application. There may be some situations in which nurses can assess their bandaging competence by the use of a bandaging checklist alone rather than the use of a pressure monitor. Pressure monitors may be more useful in bandaging training than a checklist but this needs to be determined in further study.

One of the advantages of teaching nurses to assess their own bandaging is that they may be able to maintain a high level of competence over time whereas those who rely on periodic checks with a pressure monitor may not internalise the feedback.

7.6. Recommendations for clinical practice

Changing the position of the foot did result in changes in sub-bandage pressure to increase the pressure gradient and hence these exercises should be evaluated.

The education of nurses should include the selection and application of compression bandages as nurse skill in applying bandages is poor.

Assessment of bandaging skill should not be based solely on sub-bandage pressure measurement. Patient assessment and inspection of bandage placement, overlap and extension should be included.

7.7. Recommendations for future study

7.7.1. Transducer characteristics

The response of transducer with a step input was investigated and the time to reach 50% full scale deflection was reduced by reducing tubing length or fluid viscosity. It was not possible, however, to separate out the impact of tubing fluid mass and tubing length on the response to loading. It is suggested that if a number of fluids were used with varying density but equal viscosity (e.g. by varying the temperature) then this could be investigated. Also using tubing with a different friction or internal architecture such that the surface area, and hence friction effect, but an equal length, were used this could investigate this further.

7.7.2. Response to posture changes in patients and control subjects

The investigation of sub-bandage pressure and posture changes found that pressures increased when normal subjects rose from sitting to standing, in a controlled environment. This was not found in the investigation patients with chronic venous insufficiency wearing compression bandages and going about their normal activities. This has not been reported elsewhere and deserves further investigation.

7.7.3. Measuring nurses' bandaging techniques

The key problem identified during this investigation is the lack of a robust 'gold-standard' pressure profile against which measured pressures can be compared. No relationship

between ankle pressure or pressure gradient (calf pressure / ankle pressure) has been demonstrated in clinical trials. This means that we may be training nurses to achieve pressure profiles that are not ideal.

The use of training and feedback improved the proportion of nurses applying a compression bandage correctly. Even after training, though, a substantial minority remained unable to apply the compression bandages appropriately. The role of feedback from the pressure monitor needs further study. Given the cost of obtaining pressure monitors for training all nurses, then the use of alternative feedback mechanisms, such as a checklist, should be investigated.

7.7.4. Problems in sub-bandage pressure measurement

Pressure steps due to the shape of the leg

One problem, which emerged during the study of bandaging pressure, was the fact that the initial experimental set up, in which pressure was measured at the ankle, gaiter and calf, did not yield expected results. The value of the pressure at the gaiter did not lie between the ankle and calf pressures despite the bandage appearing to be applied with an even tension and appropriate overlap by an expert bandager. Recalibrating the sensor and changing position did not resolve this and therefore the shape of the measurement site was considered. The gaiter site was found by drawing a straight line between the ankle point (4 cm above the lateral malleolus) and the calf (at the widest point of the calf on the vertical between the malleolus and the tibial tuberosity). This meant that it was on the part of the leg where the cylindrical part of the lower leg is widening out to form the cylindrical part of the calf muscle. The bandages applied at this point, therefore, had their lower border encircling a small radius (ankle) and the upper border encircling a much wider cylinder (calf). If a sensor is placed such that it is covered by the top edge of one bandage and the bottom edge of another bandage then the resultant pressure will be the sum of the pressures due to the tensions in the 2 bandage layers. In a situation where the leg is approximately conical then

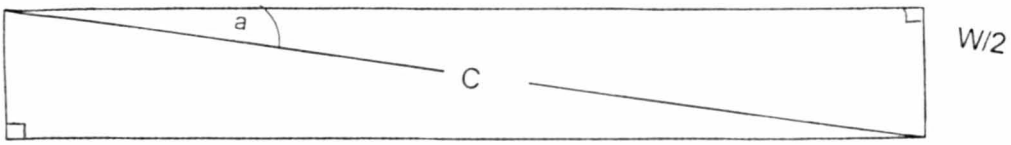
the tensions in both bandage layers will be the same across the length of the bandage. The distribution of tension in each bandage layer will be very different, however, if the shape of the leg is changing in a direction perpendicular to the wrapping of the bandage. This can lead to a step-wise pressure profile.

If the sensor was just above the centre of the lower bandage layer then the pressure exerted by this would be t/r, where tension (t) is averaged over the whole of the bandage width. If positioned just above the centre line the tension will be lower than the average as the upper edge of this bandage turn will be on the calf, i.e. stretched around a large circumference and hence will be subjected to a higher tension. The top layer of bandage will also compress the sensor. The sensor will be at the lower edge of this bandage and hence will also be at an area of lower tension than the bandage width as a whole. Clinicians may notice a stepped application of pressure upon removing a bandage. It may, in severe cases, lead to a constricting layer that could reduce venous outflow and may limit the therapeutic effect of the bandage. Theoretically this effect would be minimised by doing two things; padding the leg in order to achieve a conical shape, or using a narrow bandage.

In this investigation the pressure sensor at the bottom of the leg is on a surface with one main radius of curvature whereas the sensor at the gaiter and the calf are placed on surfaces with 2 radii of curvature. The pressure recorded is due to the sum of the incident forces and hence the calf sensor may record higher pressures than predicted due to tension in the warp and weft. The different physical construction of the bandages tested means that the pressures may vary according to resultant bandage tension rather than the tension recorded in the Instron at a known extension.

Padding layers

The pressure applied will also depend on the characteristics of the padding layer. Rigby et al (1997) have found that different padding bandages have widely differing properties in terms



C = leg circumference
W = bandage width
A = angle of application

Tan a = W / (2C)

Figure 7.1 Relationship between angle of application, leg circumference and bandage width

of load transmission and load absorption. Clinical trials of bandage regimens should specify what materials are used for each layer, along with method of application. This would allow investigators to replicate studies. It is apparent that the description of materials in terms of their physical characteristic as is required in the Tariff / British Pharmacopoeia may not be sufficient for practitioners to make informed choice about substituting bandaging products as they may perform similarly in vitro but not in vivo. This is in contrast to the area of pharmaceuticals where similar products are more readily substituted.

Padding layers may reduce the 'step in pressure' and thus there is a theoretical proposition for explaining why bandages that incorporate a padding layer perform better than bandages without a padding layer but which appear to deliver similar amounts of pressure (Nelson et al 1995). It would be instructive to evaluate the impact of the padding layer on the blood flow in the deep veins. If there is evidence that this improves the pressure profile then there appears to be as strong empirical case for recommending that bandaging regimens should incorporate these. The Pütter technique used in applying continental European systems such as the minimal stretch bandages do not need padding because of the different method of application. This method places the bandage at an oblique angle along the line of largest circumference of the leg. This means that 'steps' in pressure are not produced.

Angle of application

If a bandage is applied to a limb at a large angle to the horizontal it will not apply the same pressure as one applied at a small application angle. There is a minimum application angle that must be used in order to ensure that the bandage advances by 50% of its width with each turn. The response of the bandage to extending forces perpendicular to the line of extension may influence this characteristic.

The angle of application is dependent on the relationship between the circumference of the leg and the width of the bandage, see figure 7.1. If a = angle of inclination to horizontal, W = width of bandage, and C = circumference of leg then;

$\tan a = W / (2 * C)$

The bandage tension, in turn, is dependent on the angle of application. The bandage tension, which should be used to derive the resultant pressure from Laplace's Law, is:

$P \propto T \cos a$ / radius of curvature (x) + T sin a / radius of curvature (y)

now at the ankle R (y) = very large, therefore this becomes

$P \propto T \cos a / R(x)$.

If the angle of application is very small, i.e. the bandage is applied perpendicular to the long axis of the leg, then the relationship becomes:

$P = kT / R$

At the calf, however, the second part of the equation is significant and therefore

$P \propto T \cos a / R(x) + T \sin a / R(y)$

This means that the pressure at the calf may be larger than that at the ankle if the bandage tension is held constant and the circumference is the same due to the curvature of the calf muscle. The contribution of the second part of the equation can be minimised by minimising the angle of application, a, either by using a narrower bandage, or teaching nurses to apply bandages with a minimum angle of application.

The inability of the bandages to replicate the theoretical response to extension derived from the load extension curve obtained on the Instron mechanical tester may be due to the fact that woven elastomeric bandages are non-elastomeric in the perpendicular direction. Similarly woven, non / minimally extensible bandages are more extensible along axes at an angle to the primary direction of extension on the Instron. Therefore the response of each of these bandages will be less dramatic in vivo than in vitro.

Figure of eight techniques may place the bandages at a steeper angle than the spiral. This may account for the fact that although a figure of eight bandaging technique places 4 layers of bandage on a limb at any one time the pressure achieved is not twice that produced in a spiral (due to the reduced pressure caused by the steeper angle of application).

Bandage application: what is the controller for the feedback?

We do not know whether nurses apply a bandage according to the amount of extension, i.e. by extending bandage until they see the extension indicator achieve the right shape, or whether they apply a bandage according to the amount of tension felt in the arms during application. This is the feedback controller. If we find that tension is the prime feedback mechanism then we can propose that once nurses can assess levels of tension then they can apply a range of bandages at the same extension. It would be interesting to see if expert nurses are able to apply bandages at different levels of tension according to bandage type. For example, an inextensible bandage may require a greater initial application tension than an elastomeric bandage. Additionally, nurses might be able to adjust the bandage application according to the patient characteristics - some patients will require / tolerate lower levels of tension and hence pressure. It also has implications for the teaching of nurses and the selection of bandages. The application of a bandage at a set tension produces sub-bandage pressures that will vary with bandage layers, bandage width, leg curvature. Therefore if nurses apply a bandage according to tension and they change to a narrower bandage then there is the possibility that higher pressures will be generated. This may be an argument for having extension indicators on all bandages.

As mentioned previously the 'step' in bandage pressures would be reduced by using narrower bandages but any move towards encouraging nurses to choose from a range of bandage widths should be cautioned by this possible danger.

If nurses apply bandages according to the *tension* rather than *extension* then they will be able to generate high pressures regardless of the classification of the bandage used.

Therefore the bandage classification system may not be a valid indicator of pressures generated.

Sensor placement

There is no agreement about where to place sensors though so results from some studies are not comparable. Placing sensors on bony prominences such as the malleoli will result in a high reading due to the small radius of curvature at that point (Laplace's law); hence in this case it is relatively easy to demonstrate a pressure gradient from ankle to calf.

The potential for error due to the perturbation of the measurement site by the sensor may be dependent on the radius of curvature of the site (after Vinckx et al 1990). This may mean that errors are larger at the ankle than the calf. This is an important area for investigation as without confidence in the accuracy of sub-bandage pressure measurements then bandages cannot be reliably be evaluated in this way. We would then have to initially test bandages in vitro, e.g. using Instron mechanical testing programmes, and then progress straight to clinical trials. On the other hand, if the accuracy of sub-bandage pressure measurements can be established it would be possible to describe the characteristics of an effective bandaging regimen and hence compare new bandage regimens to an 'ideal'. At present it is not possible to use sub-bandage pressure profiles to predict the effectiveness of a bandage regimen.

The results of research reported in this thesis suggest that some bandages may be easier to apply than others and if confirmed these findings may have an impact on the provision of bandaging systems. Thus, the provision of optimal treatment requires not only the most effective regimen but also a regimen that can be implemented easily.

These factors have influenced the focus of investigation. It has shifted from the relatively uncomplicated investigation of the sub-bandage pressures and the impact of patient posture and movement upon these, to a more complex investigation of the manner in which the sub-bandage pressure is determined by the nurses' application technique.

Studies on the constraints on practice in leg ulcer management point to the fact that there are numerous elements which need to be addressed, e.g. knowledge, equipment availability, collaboration with professional colleagues, support from managers. This study indicates that bandaging skill is lacking in these nurses. Unfortunately, the development and evaluation of training packages for improving bandaging technique revealed that only modest improvements could be made despite intensive input. Therefore, one cannot necessarily, expect improvements in clinical outcomes after training nurses in bandaging training. Indeed, one must be aware that a nurse who has attended training may have a similar level of competence as 'untrained' colleagues, yet may have a greater level of (misplaced) confidence. The provision of more resources, whether these be training courses or compression bandage systems, without the necessary skills to utilise them properly is likely to be wasteful if not dangerous.

7.8. Conclusions

This investigation has eliminated the errors associated with movement of the sensor relative to the transducer of the Strathclyde Pressure Monitor. It also reduced the response time of the measurement system by modifying tubing length and transmission fluid viscosity. The overall error in measuring sub-bandage pressures was estimated to be plus or minus 1mmHg.

Moving from sitting to standing was associated with a significant increase in sub-bandage pressure when volunteers were investigate but the opposite pattern was seen in patients with venous ulcers wearing compression bandages. This has not been reported before.

Three investigations demonstrated that bandage application technique was improved after training and feedback. This has not previously been demonstrated. In addition there was a differential response to training and feedback, according to the type of bandage used. More nurses applied single layer elastomeric bandages appropriately than applied short-stretch bandages correctly. Four-layer bandages were easier to apply than two-layer elastomeric bandages.

Overall, however, bandaging skill was poor, with significant number of nurses still applying bandages poorly after training and feedback. This ought to prompt commissioners of nursing services to consider whether all nurses should apply compression bandages. A more robust evaluation, e.g. a randomised controlled trial, of the cost-effectiveness of bandaging training needs to be undertaken, using patient outcomes, e.g. compliance, safety and healing rates.

Further research is needed to ascertain what are the characteristics of an optimal pressure profile, and whether the changes in sub-bandage pressure caused by movements of the foot and posture changes identified here are clinically significant.

References

Adams EF (1949) *The genuine works of Hippocrates*. London. Sydenham Press.

Ahroni JH, Boyko EJ, Forsberg R. Reliability of F-Scan In-Shoe Measurements of plantar pressure. *Foot and Ankle International* 1998;19(10): 668-673.

Alexander House Group (1992) Consensus paper on venous leg ulcers. *Phlebology*; 7: 48-58.

Allen C, Glasziou P, Del Mar C. Bed rest: a potentially harmful treatment needing more careful evaluation. *Lancet* 1999; 354:1229-33.

Allen V, Ryan DW, Lomax N, Murray A (1993) Accuracy of interface pressure measurement systems. *J Biomed Eng*;15:344-348.

Allman RM, Goode PS, Patrick MM, Burst N, Bartolucci AA (1995) Pressure sore risk factors among hospital patients with activity limitation. *JAMA*; 273(11): 865-70.

Andersen KE, Jensen O, Kvorning SA, Bach E (1982) Prevention of pressure sores by identifying patients at risk. *Brit Med J*; 284: 1370-71.

Appoldt FA, Bennet L, Contini R (1969) Socket pressure as a function of pressure transducer protrusion. *Bulletin of Prosthetics Research*; Spring: 236-249.

Arnold TE, Stanley JC, Fellows EP, Moncada GA, Allen R, Hutchinson JJ, Swartz WM, Bolton LL, Vickers CFH, Kerstein MD (1994) Prospective, multi-centre study of managing lower extremity venous ulcers. *Ann Vasc Surg*; 8: 356-62.

Backhouse CM, Blair SD, Savage AP, Walton J, McCollum CN (1987) Controlled trial of occlusive dressings in healing chronic venous ulcers. *Br J Surg*; 74: 626-7.

Bader DL (1982) Interface pressure measurement. *Care Science and Practice*; 1: 22-24.

Bader DL, Hawken MB (1986) Pressure distribution under the ischium of normal subjects. *J Biomed Eng*; 8: 353-357.

Baker SR, Stacey MC, Jopp-McKay AG, Hoskin SE, Thomson P J (1991) Epidemiology of chronic venous ulcers. *Br J Surg*; 78: 864-7.

Banks V, Fear M, Orpin S, Hagelstein G, Colgate J, Humphreys L, Disley S, Bale S, Thomas S, Harding KG (1996) A comparative open multi-centred trial of Tielle hydropolymer dressing and Granuflex Improved Formulation. In Cherry GW, Gottrup F, Lawrence JC, Moffatt CJ, Turner TD (eds) *Proceedings of the 5th European Conference on Advances in Wound Management*. London, Macmillan Magazines. 163-167.

Barbenel JC, Sockalingham S (1990) Device for measuring soft tissue interface pressures. *J Biomed Eng*; 12: 519-522.

Barbenel JC, Sockalingham S, Queen D (1990) In vivo and laboratory evaluation of elastic bandages. *Care Science and Practice*; 8: 72-74.

Blair S, Wright D, Backhouse C, Riddle E, McCollum C (1988) Sustained compression and healing of chronic venous ulcers *Br Med J*; 29: 1159-1161.

Bobek K, Cajzl L, Capelak V, Slaisova V, Opatzny K, Barcal R. (1966) Etude de frequence des maladies phlebologies et de l'influence de quelques facteurs etiologiques. *Phlebologie*; 19: 217-30.

Borgnis F, de Bruyne P, Dvarak J. *A simple method for the measurement of compression in support hose and bandage.* Institute fur Hochfrequenztechnic, Zurich, Switzerland.

Bosanquet N (1992) Costs of venous ulcers: from maintenance therapy to investment programmes. *Phlebology* Suppl: 1:44-46.

Bourne IHJ (1992) Treatment of leg ulcers. *J Royal Soc Med* ; 85: 733-735.

Bowszyc J, Silny W, Bowszyc-Dmochowska M, Kazmierowski M, Ben-Amer HM, Garbowska T, Harding E (1994) A randomised controlled comparative clinical trial of Lyofoam versus Granuflex in the treatment of venous leg ulcers. In Harding KG, Dealey C, Cherry GW, Gottrup F (eds) *Proceedings of the 4th European Conference on Advances in Wound Management.* London. Macmillan Magazines. 34-37.

Bradley MD, Nelson EA, Petticrew M, Torgerson DJ, Cullum N, Sheldon TA (1999) A systematic review of dressing and topical agents in the treatment of chronic wounds. *Health Technology Assessment.*Vol 17 Part 2.

British Standards Institution (1985) *British Standard specification for graduated compression hosiery.* British Standards Institution (BS 6612) London.

Browse NL, Burnand KG, Lea-Thomas M (1988) *Diseases of the veins, pathology, diagnosis and treatment.* London. Edward Arnold.

Browse NL, Burnand KG (1982) The cause of venous ulceration. *Lancet*; ii: 243-245.

Browse NL, Gray L, Jarrett PEM, Morland M (1977) Blood and vein wall fibrinolytic activity in health and vascular disease. *Brit Med J*; 1: 478-81.

Burgess B, Robinson B (1993) Comparative benefits. *Nursing Times*; 89(13): 90-2.

Burnand KG, Layer GT (1986) Graduated elastic stockings. *Br Med J*; 293: 224-5.

Burnand KG, Pattison M, Layer GT (1986) How effective and long lasting are elastic stockings. In *Phlebology '85* D. Negus, G. Jantet (Eds) John Libbey Co Ltd.

Callam MJ, Ruckley CV, Harper DR, Dale JJ (1985) Chronic ulceration of the leg: extent of the problem and provision of care. *Br Med J*; 290(6485): 1855-6.

Callam MJ, Dale JJ, Ruckley CV, Harper DR (1986) Trial of ultrasound in the treatment of chronic leg ulceration. In: *Phlebology '85.* Negus D, Jantet G (eds) London. John Libbey. 625-6.

Callam MJ, Ruckley CV, Dale JJ, Harper DR (1987) Hazards of compression treatment of the leg: an estimate from Scottish surgeons. *Br Med J*; 295(6610):1382.

Callam MJ (1992) Prevalence of chronic leg ulceration and severe chronic venous disease in western countries. *Phlebology*; Suppl 1. 6-12.

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

Callam MJ, Harper DR, Dale JJ, Brown D, Gibson B, Prescott RJ, Ruckley CV (1992) Lothian and Forth Valley Leg Ulcer Healing Trial, Part 1: Elastic versus non-elastic bandaging in the treatment of chronic leg ulceration. *Phlebology*; **7** (4): 136-41.

Cameron J (1990) Patch testing for leg ulcer patients. *Nurs Times*; 86 (25): 63-64.

Cameron J (1995) Contact sensitivity and eczema in leg ulcer patients. In: Cullum N and Roe B (eds) *Leg Ulcers: Nursing Management.* London, Balliere Tindall. p 101-112.

Cameron J (1998) Contact sensitivity in relation to allergen exposure in leg ulcer patients. M.Phil. Thesis, University of Liverpool, Department of Nursing.

Caprio B, Murgiano GA, Ricci E, Siciliano G, Zurleni G (1995) The cost effectiveness of modern dressings in leg ulcer care. In Harding KG, Dealey C, Cherry GW, Gottrup F (eds) *Proceedings of the 4th European Conference on Advances in Wound Management.* London, Macmillan Magazines. p199.

Caro CG, Pedley TJ, Schroter RC, Seed WA (1978) *The Mechanics Of The Circulation.* Oxford. Oxford University Press.

Carter AJ, Davies M, Jackson AP et al (1992). A new controlled tension compression bandage. In Proceedings of the 11th World Congress of the Union Internationale de Phlebologie. P291.

Chant ADB (1990) Tissue pressure, posture and ulceration. *Lancet*; 336: 1050-1.

Charles H (1991) Compression healing of ulcers. *J District Nursing*; 4: 6-7.

Christopoulous D, Nicolaides A, Belcaro G, Duffy P (1990) The effect of elastic compression on calf muscle pump function. *Phlebology*; 5: 13-19.

Christopoulous D, Nicolaides A, Szendro G, Irvine A, Bull M, Eastcott H (1987) Air-plethysmography and the effect of elastic compression on venous haemodynamics of the leg. *J Vasc Surg*; 5: 148-159.

Clark C, Cotton LT (1968) Blood-flow in deep veins of the leg. *Br J Surg*; 55(3): 211-214.

Coleridge-Smith PD, Thomas P, Scurr JH, Dormandy JA (1988) Causes of venous ulceration: a new hypothesis. *Brit Med J*; 296: 1726-1727.

Coleridge-Smith P, Sarin S, Hasty J, Scurr JH (1990) Sequential gradient pneumatic compression enhances venous ulcer healing: A randomised trial. *Surgery*; 108(5): 871-875.

Coleridge-Smith PD (1997) The micro-circulation in venous hypertension. *Vascular Medicine*; 2: 203-213.

Colgan MP, Dormandy JA, Jones PW, Schraibman IG, Shanik DG, Young RAL (1990) Oxpentifylline treatment of venous ulcers of the leg. *Br Med J*; 300: 972-5.

Colgan MP, Teevan M, McBride C et al (1995) Cost comparisons in the management of venous ulceration. In Cherry GW, Gottrup F, Lawrence JC, Moffatt CJ, Turner TD (eds). *Proceedings of the 5th European Conference on Advances in Wound Management*, London. Macmillan Magazines. p103.

Contini R (1970) *Body segment parameters (pathological).* Technical report no 1584.03. New York. New York University School of Engineering and Science.

Cook NHR, Rabinowicz E (1963) *Physical measurement and analysis.* Reading, Mass. Addison-Wesley Publishing Co.

Cornwall J, Dore C, Lewis J (1987) Graduated compression and its relation to venous refilling time. *Brit Med J*; 295: 1087-90.

Cornwall JV, Dore CJ, Lewis JD (1986) Leg ulcers; epidemiology and aetiology. *British Journal of Surgery*; 73: 693-6.

Cullum NA, Last S (1991) The prevalence, characteristics and management of leg ulcers in Wirral HA. Unpublished report. University of Liverpool, Department of Nursing.

Cullum NA, Last S (1993) The prevalence, characteristics and management of leg ulcers in a UK community. In Harding KG, et al (eds) *Proceedings of 2nd European Conference on Advances in Wound Management.* London. Macmillan Magazines.

Cullum NA, Roe BH (1995) *Leg Ulcers; Nursing management, a research based guide.* London. Scutari Press.

Cullum N, Deeks JJ, Fletcher A, Sheldon TA, Song F (1995) Beds and mattresses in pressure sore prevention. *Quality in Health Care.*

Cullum N, Fletcher AW, Nelson EA, Sheldon TA (1999) Compression bandages and stockings for patients with venous leg ulcers (Cochrane Review). Cochrane Library; 1999 (4). Oxford, Update Software.

CRC Handbook of Chemistry and Physics (1988) Boca Raton, CRC Press.

Dahn I, Lessen NA, Westling H (1967) Blood flow in human muscles during external pressure or venous stasis. *Clin Sci*; 32: 467-73.

Dale JJ, Callam MJ, Ruckley CV, Harper DR, Berrey PN (1983) Chronic ulcers of the leg: A study of prevalence in a Scottish community. *Health Bull (Edin)*; 41: 310-314.

Dale JJ, Callam M, Ruckley CV (1983) How efficient is a compression bandage? *Nursing Times*; 79(46): 49-51.

Dale JJ, Gibson B (1986) Treatment of leg ulcers. *Prof Nurs*; Sept: 321-324.

Dale JJ, Gibson B (1989) Which compression stocking. *Prof Nurs*; 4(7): 550-556.

Dale JJ, Gibson B (1990) Back-up for the venous pump. *Prof Nurs*; 5: 481-4.

Dale JJ, Gibson B (1992) Leg ulcer management. *Prof Nurs*; 7(Suppl. Nov): 9.

Dale JJ, Ruckley CV, Harper DR, Gibson B, Nelson EA, Prescott RJ (1999) Randomised, double blind placebo controlled trial of pentoxifylline in the treatment of venous leg ulcers. *Brit Med J*; 319(7214):875-8.

Danielsen L, Madsen SM, Henriksen L, Sindrup J, Petersen LJ (1998) Subbandage pressure measurements comparing a long-stretch with a short-stretch compression bandage. *Acta Derm Venereol (Stockh)*; 78:201-4.

Duby T, Hoffman D, Cameron J, Doblhoff-Brown D, Cherry G, Ryan T (1993) A randomised trial in the treatment of venous leg ulcers comparing short stretch bandages, four layer bandage system, and a long stretch-paste bandage system. *Wounds*; 5(6): 276-279.

Dyson M, Franks C, Suckling J (1976) Stimulation of healing of varicose ulcers by ultrasound. *Ultrasonics ;*14:232-6.

Editorial (1986) *J District Nurs*; 4(9): 3.

Eriksson G, Eklund AE, Lidén S, Zetterquist S (1984) Comparison of different treatments of venous leg ulcers : A controlled study using stereophotogrammetry. *Current Therapeutic Research*; 35: 678-84.

Eriksson SV, Lundeberg T, Malm M (1991) A placebo controlled trial of ultrasound therapy in chronic leg ulceration. *Scand J Rehabil Med*; 23:211=213.

Ertl P (1992) A recipe for assessment. *Journal of District Nursing*; July:10-14.

Evans CJ, Fowkes FGR, Ruckley CV, Allan PL, Carson MN, Kerracher EMG, Lee AJ (1997) Edinburgh Vein Study: Methods and response in a survey of venous disease in the general population. *Phlebology*; 12: 127-135.

Fentem PH (1988) Observations on the performance of elastane fibres used in compression bandages and hosiery. *Swiss Med*; 10(4a): 87-90.

Ferguson-Pell MW (1977) *Critical assessment of the effects of pressure with special reference to the development of pressure sores.* Ph.D. Thesis. University of Strathclyde, Glasgow.

Fletcher A, Cullum N, Sheldon TA. (1997) A systematic review of compression treatment for venous leg ulcers. *Brit Med J* ; 315: 576-80.

Franks PJ, Moffat CJ, Connolly M, Bosanquet N, Oldroyd M, O'Malley MK, Greenhalgh RM, McCollum CN (1992) Quality of life during leg ulcer treatment. In Raymond-Martimbeau P, Prescott R and Zummo M (eds) *Phlebology '92.* Paris, Libbey Eurotext. pp 275-77.

Franks PJ, Moffatt CJ, Oldroyd M, Greenhalgh RM. (1993) Acceptability of surgery in patients with leg ulceration. *J Epidemiol Community Health*; 47: 418.

Franks PJ, Moffatt CJ, Connolly M, Bosanquet N, Oldroyd MI, Greenhalgh RM, McCollum (1995) Factors associated with healing leg ulceration with high compression. *Age and Ageing*; 24: 407-410.

Gaylarde PM, Dodd HJ, Sarkany I (1990) Venous ulcers and arthropathy. *British Journal of Rheumatology*; 29:142-4.

Gaylarde PM, Sarkany I, Dodd HJ (1993) The effect of compression on venous stasis. *Br J Dermatol*; 128: 255-58.

Gebhardt K, Bliss M, Winwright P. A randomised controlled trial to compare the efficacy of alternating and constant low pressure supports for preventing pressure sores in and intensive care unit. Cited in Effective Health Care (1995) The prevention and treatment of pressure sores. 2:1.

Gjores J, Thulesius O (1977) Compression treatment in venous insufficiency evaluated with foot volumetry. *VASA*; 6(4): 364-368.

Gorin DR, Cordts PR, LaMorte WW, Menzoian JP (1996) The influence of wound geometry on the measurement of wound healing rates in clinical trials. *J Vasc Surg*; 23(3): 524-8.

Gould DJ, Campbell S, Harding EF (1992) A clinical evaluation of Setopress high compression bandage with Elastocrepe in the management of chronic venous ulceration. In Harding KG et al (eds) *Proceedings of the 2nd European Conference on Advances in Wound Management.* London , Macmillan Magazines.

Gray DG, Campbell M (1994) A randomised clinical trial of two types of foam mattress. *Journal of Tissue Viability*; 4: 128-32.

Groenewald JH (1984) Comparative effects of HCD and conventional treatment on the healing of venous stasis ulcers. In Ryan T (ed.) *An environment for healing: The role of occlusion.* London. Royal Society of Medicine International Congress and Symposium Series; v(88): 105-9.

Guilhou JJ, Dereure O, Marzin L et al (1997) Efficacy of Daflon in venous leg ulcer healing: a double-blind, randomized, controlled versus placebo trial in 107 patients. *Angiology*; 48: 77-85.

Hamer C, Cullum N, Roe BH (1993) Patients' perceptions of chronic leg ulceration. In Harding KG et al (eds.) *Proceedings of the 2nd European Conference on Advances in Wound Management*. London, Macmillan Magazines. pp178-180.

Harper DR, Ruckley CV, Dale JJ, Callam MJ, Allan P, Brown D, Gibson B, Nelson A, Prescott RJ (1995) A prospective randomised trial of class 2 and class 3 compression in the prevention of venous ulceration. In: Negus D, Jantet G, Coleridge-Smith PD (eds) *Phlebology* (Suppl 1), 872-3. London, Springer-Verlag.

Heatley JP (1991) A simple recipe for success with leg ulcers. *Care of the Elderly*; June: 294.

Hedman TP. A new transducer for facet force measurement in the lumbar spine: benchmark and *in vitro* test results. *J Biomechanics* 1992; 25(1): 69-80.

Hendricks WM, Swallow RT (1985) Management of stasis leg ulcers with Unna's boots versus elastic support stockings. *J Amer Acad Derm*; 12:90-98.

Henry M (1986) Incidence of varicose ulcers in Ireland. *Irish Medical Journal*; 79: 65-67.

Holford CP (1976) Graded compression in preventing deep venous thrombosis. *Brit Med J*; 2: 969-70.

Horácová M, Partsch H (1994) Venous leg ulcers: are compression bandages indicated? *Phlebologie* ; 47(1): 53-7.

Horner J, Lowth L, Nicolaides A (1980) A pressure profile for elastic stockings. *Brit Med J*; 280: 818-20.

Johnson G, Kupper C, Farrar D, Swallow R (1982) Graded compression stockings, custom vs. non-custom. *Arch. Surg*; 117: 69-72.

Jones JE, Nelson EA (1997) Evaluation of an education package in leg ulcer management. *Journal of Wound Care*; 6(7): 342-343.

Jones N, Webb P, Rees R, Kakkar V (1980) A physiological study of elastic compression stockings in venous disorders of the leg. *Brit J Surg*; 67: 569-72.

Journal of District Nursing (1987) Your data on leg ulcers. *Journal of District Nursing*; March:4-6.

Kellner R (1986) The symptom rating test. In: Sartorius N, Ban T (eds) *Assessment of Depression*. New York, Springer.

Kikta MJ, Schuler JJ, Meyer JP, Durham JR, Eldrup-Jorgensen J, Schwarcz TH, Flanigan DP (1988) A prospective, randomized trial of Unna's boots versus hydroactive dressing in the treatment of venous stasis ulcers. *Journal of Vascular Surgery*; 7: 478-83.

Knight CA, McCulloch J (1996) A comparative study between two compression systems in the treatment of venous insufficiency leg ulcers. 1996 Symposium on Advanced Wound Care and Medical Research Forum on Wound Repair. 117.

Kosiak M (1959) Etiology and pathology of ischaemic ulcers. *Arch Phys Med Rehab*; 40: 62-69.

Kralj B, Kosicek M. (1996) A randomised comparative trial of single-layer and multi-layer bandages in the treatment of venous leg ulcers. In Leaper DJ, Cherry GW, Dealey C, Lawrence JC, Turner TD (eds) *Proceedings of the 6th European Conference on Advances in Wound Management*. London, Macmillan Magazines. pp158-160.

Lagatolla NRF, Burnand KG, Eastham D (1995) A comparison of perforating vein ligation, stanozolol, and stockings in the prevention of recurrent venous ulceration. *Phlebology*; 10: 79-85.

Laing W (1992) *Chronic venous diseases of the leg*. London. Office of Health Economics.

Lawrence D, Kakkar V (1980) Graduated, static, external compression of the lower limb: a physiological assessment. *Brit J Surg*; 67: 119-121.

Lees TA, Lambert D (1992) Prevalence of lower limb ulceration in an urban health district. *Br J Surg*; 79:1032-1034.

Lewis C, Antoine J, Mueller C, Talbot W, Swaroop R, Edwards W (1976) Elastic compression in the prevention of venous stasis. *Am J Surg*; 132: 739-742.

Lewis CE, Mueller C, Edwards WS (1972) Venous stasis on the operating table. *Am J Surg*; 124: 780-784.

Lindan O, Greenway RM, Piazza JM (1965) Pressure distribution on the surface of the human body, evaluation in lying and sitting positions using a bed of springs and nails. *Arch Phys Med Rehab*; 46: 378-385.

Lindholm C, Larsson K, Holmgren T, Moller M, Ohlsson P (1993) Leg ulcer treatment in primary care – comparison of gauze and Duoderm in a prospective randomised study. In Harding KG et al (eds) *Proceedings of the 2nd European Conference on Advances in Wound Management*. London. Macmillan Magazines. p131.

Lindholm C (1997) What is the evidence for the rational use of wound cleansers in wound management? In Leaper DJ, Cherry GW, Dealey C, Lawrence JC, Turner TD (eds) *Proceedings of the 6th European Conference on Advances in Wound Management*. London. Macmillan Magazines. pp 8-10.

Lineaweaver W, Howard R, Soucy D, McMorris S, Freeman J, Crain C, Robertson J, Rumley T (1985) Topical antimicrobial toxicity. *Archives of Surgery*; 120: 267-70.

Logan RA, Thomas S, Harding EF, Collyer G (1991) Bandage design and bandager experience: the effect on sub-bandage pressures. RSM Venous Forum, Oct 23.

Logan RA, Thomas S, Harding EF, Collyer G (1992) A comparison of sub-bandage pressures produced by experienced and inexperienced bandagers. *J Wound Care*; **1**(3): 23-26.

London N, Scriven JM. Unpublished data from Department of Surgery, University of Leicester. Cited in Cullum N, Fletcher AW, Nelson EA, Sheldon TA (1999) Compression bandages and stockings for patients with venous leg ulcers. In: Cochrane Library; 1999 (4). Oxford, Update Software.

Loudon ISL (1981) Leg ulcers in the eighteenth and early nineteenth centuries. *J Royal Coll of General Practitioners*; 31: 263-73.

Luker K, Kenrick M (1995) Towards knowledge based practice: evaluating a model of dissemination. *International Journal of Nursing Studies*; 32(1): 59-67.

Luker KA, Kenrick M (1992) An exploratory study of the sources of influence on the clinical decisions of community nurses. *J Adv Nurs*; 17: 457-466.

Lundeberg T, Nordstrom F, Brodda-Jansen G, Eriksson SV, Kjartansson J, Samuelson UE (1990) Pulsed ultrasound does not improve healing of venous ulcers. *Scand J Rehabil Med*; 22:195-7.

Lydon MJ, Hutchinson JJ, Rippon M, Johnson E et al (1989) Dissolution of wound coagulum and promotion of granulation tissue under DuoDerm. *Wounds*; 1: 95-106.

Lyon RT, Veith FJ, Bolton L, Machado F (1998) Clinical benchmark for healing of chronic venous ulcers. Venous Ulcer Study Collaborators. *Am J Surg*; 136:172-175.

Magazinovic N, Phillip S, Turner J, Wilson GV (1993) Assessing nurses knowledge of bandages and bandaging. *Journal of Wound Care*; 2(2): 97-101.

Majno G (1975) *The Healing Hand.* Cambridge. Harvard University Press. p153.

Maklebust J, Magnan MA (1994) Risk factors associated with having a pressure ulcer: a secondary data analysis. *Adv Wound Care* ;7(6):25, 27-8, 31-4.

Mann R, Yeong EK, Moore ML, Engrav LH. A new tool to measure pressure under burn garments. *Journal of Burn Care and Rehabilitation* 1997; 18(2): 160-163.

Mansson T (1996) Effect of Iodosorb dressing, Duoderm E, and Jelonet on symptomatic parameters in exudative venous leg ulcers. In Cherry GW, Gottrup F, Lawrence JC, Moffatt CJ, Turner TD. (eds) *Proceedings of the 5th European Conference on Advances in Wound Management.* London, Macmillan Magazines. pp160-2.

Mayberry J, Moneta G, Taylor L, Porter J (1991) The influence of elastic compression stockings on deep venous haemodynamics. *J Vasc Surg*; 13 (1): 91-100.

McCollum CN, Ellison DA, Groarke L et al (1997) Randomised trial comparing Profore and the original four layer bandage. Proceedings of the Conference of the European Wound Management Association. Milan 27-29 April 1997; p97. London. EMAP Healthcare.

McCulloch J, Marler K, Neal M et al (1994) Intermittent pneumatic compression improves venous ulcer healing. *Advances in Wound Care*; 7: 22-26.

McGough A (1998) The effectiveness of pressure sore risk indicators in preventing pressure sores. Oral presentation; Leeds.

McMullin GM, Watkin GT, Coleridge Smith PD, Scurr JH (1991) The efficacy of fibrinolytic enhancement with stanozolol in the treatment of venous insufficiency. *Phlebology*; 6: 233-9.

Meredith K, Gray E (1988) Dressed to heal. *Journal of District Nursing*; 7(3): 8-10.

Millard LG, Blecher A, Fentem PH (1986) The pressure at which nursing staff apply compression bandages when treating patients with varicose ulcers. In *Phlebology '85.* Eds. Negus D, Jantet G. London, John Libbey Co. Ltd.

Milward P (1988) Comparing treatments for leg ulcers. *Nursing Times* 87(13), 70-72. 91.

Moffatt CJ, Oldroyd MI, Dickson D (1992) A trial of hydrocolloid dressing in the management of indolent ulceration. *Journal of Wound Care*; 1(3): 20-2.

Moffatt CJ, Franks PJ, Bosanquet N, Oldroyd M, Connolly M, Brown P, O'Malley MK, Greenhalgh R, McCollum CN (1991) *The provision of innovation in venous ulcer*

management to the elderly population in the community. Report to the King Edward's Hospital Fund for London.

Moffatt CJ, Franks PJ, Oldroyd M, Bosanquet N, Brown P, Greenhalgh RM, McCollum CN (1992) Community clinics for leg ulcers and impact on healing. *Br Med J*; 305: 1389-92.

Moffatt CJ, Oldroyd MI (1994) A pioneering service to the community. The Riverside Community Leg Ulcer Project. *Professional Nurse*; 10: 486-97.

Mondeville H de (1893) *Chirurgie de Maitre Henri Mondeville composee de 1306 a 1320.* Translated by Nicaise E. Paris. Alcan.

Monk BE, Sarkany I (1982) Outcome of treatment of venous stasis ulcers. *Clinical and Experimental Dermatology*; 7: 397-400.

Moody M (1984) A new lease of life. *Nursing Times*; July 4: 46.

Moyses C, Cederholm-Williams S A, Michel C C (1987) Haemoconcentration and accumulation of white cells in the feet during venous stasis. *Int J Microcirc Clin Exp*; 5: 311-320.

Muir-Gray JA, Wilcock G (1981) *Our Elders.* Oxford. Oxford University Press.

Naismith RS (1980) *Hypertrophic therapy: pressure induced modelling and its determinants.* Ph.D. Thesis, University of Strathclyde, Glasgow.

Nehler MR, Moneta GL, Woodard DM et al (1993) Perimalleolar subcutaneous tissue pressure effects of elastic compression stockings. *J Vasc Surg*; 18: 783-88.

Nelson EA (1995) Compression bandaging. In Cullum, N and Roe BH (eds) *Leg Ulcers; Nursing management, a research based guide.* London. Scutari Press.

Nelson EA, Barbenel JC (1992) Patient powered dynamic compression. Poster at *1st European Conference on Advances in Wound Management.* Cardiff, 4-6 September 1991.

Nelson EA, Barbenel JC, Ruckley CV (1995) Improvements in bandaging technique following training. *Journal of Wound Care*; 4(4): 181-4.

Nelson EA, Cullum N, Jones JE (2000) Venous leg ulcers. *Clinical Evidence*;3: 987-996..

Nelson EA, Harper DR, Ruckley CV, Prescott RJ, Gibson B, Dale JJ (1995) A randomised trial of single-layer and multi-layer bandages in the treatment of chronic venous ulceration. In: Negus D, Jantet G, Coleridge-Smith PD (eds) *Phlebology.* London. Springer-Verlag. pp915-6.

Nelson EA, Harper DR, Ruckley CV, Prescott RJ, Gibson B, Dale JJ (1995) A randomised trial of dressings in the treatment of chronic venous ulceration. In: Negus D, Jantet G, Coleridge-Smith PD (eds) *Phlebology.* London. Springer-Verlag. pp.

Nelzen O, Bergqvist D, Lindhagen A (1991) Leg ulcer aetiology- a cross sectional population study. *J Vasc Surg*; 14(4): 557-64.

Nelzen O, Bergqvist D, Lindhagen A (1994) Venous and non-venous leg ulcers: clinical history and appearance in a population study. *British Journal of Surgery*; 81: 182-187.

NHS Executive (1992) *The nursing skill mix in the district nursing service.* HMSO.

Nicolaides AN, Hobbs JT, Vasdekis S, Tonnison GH (1987) Graduated compression and its relation to venous refilling time. *Br Med J*; 295: 1484-5.

Northeast ADR, Layer GT, Wilson NM, Browse NL, Burnand KG (1990) Increased compression expedites venous ulcer healing. Royal Society of Medicine Venous Forum.

Norton D (1975) Research and the problem of pressure sores. *Nurs Mirr*; 140(7): 65-67.

O'Donnell T, Rosentahl D, Callow A, Ledig B (1979) Effect of elastic compression on venous haemodynamics in post-phlebitic limbs. *JAMA*; 242(25): 2766-68.

OPCS Monitor (1989) *Population Projections*. HMSO. London

Pare A (1649) *The works of that famous surgeon Ambrose Pare*. Trans by Johnson T. London. Cotes and du Gard.

Partsch H (1984) Do we need firm compression stockings exerting high pressure? *VASA*; 13:52-7

Patel A, Kothari M, Webster JG, Tompkins WJ, Wertsch JJ (1989) A capacitance pressure sensor using a phase locked loop. *J Rehab Res Dev*; 26(2): 55-62.

Patterson RP, Fisher SV (1979) The accuracy of electrical transducers for the measurement of pressure applied to the skin. *IEEE trans BME* ;26: 450-456.

Peat D (1988) Variability of the pressure exerted upon the leg by a stocking, *Swiss Med*; 10(4a): 82-84.

Peschen M, Vanscheidt W (1996) Low frequency ultrasound of chronic venous leg ulcers as part of out-patient treatment. In Cherry GW, Gottrup F, Lawrence JC (eds). Proceedings of the 5th European Conference on Advances in Wound Management. London. Macmillan Magazines. p271.

Phillips ED (1987) *Aspects of Greek Medicine*. The Charles Press. Philadelphia.

Pierson S, Pierson D, Swallow R, Johnson G (1983) Efficacy of graded elastic compression in the lower leg. *JAMA*; 249(2): 242-3.

Raj TB, Goddard M, Makin GS (1980) How long do compression bandages maintain their pressure during ambulatory treatment of varicose veins? *Br J Surg*; 67: 122-4.

Reddy NP, Palmieri V, Cochran GVB (1984) Evaluation of transducer performance for buttock-cushion interface pressure measurements. *J Rehab Res Dev*; 21(1): 43-50.

Rigby AJ, Anand SC, Miraftab M, Collyer GJ.(1996) Development of novel structures for wound care. *Medical Textiles* '96. Cambridge, Woodhead. pp35-41.

Roberts VC, Sabri S, Beeley AH, Cotton LT (1972) The effect of intermittently applied external pressure on the haemodynamics of the lower limb in man. *Br J Surg*; 59(3): 223-226.

Roche C, West J (1984) A controlled trial investigating the effect of ultrasound on venous ulcers referred from general practitioners. *Physiotherapy*; 70:475-477.

Roe B, Cullum N, Hamer C (1995) Patients' perceptions. In Cullum N and Roe B (eds) *Leg Ulcers: Nursing Management*. London. Balliere Tindall.

Rubin JR, Alexander J, Plecha EJ, Marman C. (1990) Unna's boot vs polyurethane foam dressings for the treatment of venous ulceration. A randomized prospective study. *Archives of Surgery*; 125(4): 489-90.

Ruckley CV (1992) Treatment of venous ulceration - compression therapy. *Phlebology*; 7(Suppl 1): 22-26.

Scurr J, Coleridge-Smith PD (1992) Pathogenesis of venous ulceration. *Phlebology*; 7(Suppl 1): 13-16.

Scurr J, Ibrahim S, Faber R. Le Quesne L (1977) The efficacy of graduated compression stockings in the prevention of deep vein thrombosis. *Brit J Surg*; 64: 371-4.

Sibley JC, Sackett DL, Neufeld V, Gerrard B, Rudnick KV, Fraser W. A randomized trial of continuing medical education. *New England Journal of Medicine* 1982 ; 306(9) : 511-5.

Sigel B, Edelstein A, Felix W, Menhardt C (1973) Compression of the deep venous system of the leg during inactive recumbency. *Arch Surg*; 106: 38-43.

Sigel B, Edelstein A, Savitsch L, Hasty J, Felix W (1975) Type of compression for reducing venous stasis. *Arch Surg*; 110: 171-5.

Sikes E. (1985) Evaluation of a transparent dressing in the treatment of stasis ulcers of the lower limb. *Journal of Enterostomal Therapy*; 12: 116-20.

Smith BA (1994) The dressing makes the difference: trial of two modern dressings on venous ulcers. *Professional Nurse*; 9(5): 348-352.

Smith BP. Hudson WB. The use of force sensing resistors for muscle force measurements. *Biomed Sci Instrum* 1994; 301: 153-8.

Smith JM, Dore CJ, Charlett A, Lewis DJ (1992) A randomised trial of Biofilm dressings for venous leg ulcers. *Phlebology*; 7: 108-113.

Sockalingham S, Barbenel JC, Queen D (1990) Ambulatory monitoring of the pressures beneath compression bandages. *Care Sci Prac*; 6(2): 75-9.

Sockalingham S (1993) An integrated evaluation of compression devices with a focus on ambulatory monitoring of sub-bandage pressure and posture. Ph.D. Thesis, Bioengineering Unit. University of Strathclyde.

Somerville JJ, Brow GO, Byrne PJ, Quill RD, Fegan WG (1974) The effect of elastic stockings on superficial venous pressures in patients with venous insufficiency. *Brit J Surg*; 61(12): 979-81

Spiro M, Roberts VC, Richards JB (1970) Effect of externally applied pressure on femoral vein blood flow. *Br Med J*; 21 Mar (1): 719-23.

Stacey M, Burnand KG, Layer G et al (1988) calf pump function in patients with healed venous ulcers is not improved by surgery to the communicating veins or by elastic stockings. *Br J Surg*; 75: 436-39.

Stacey M, Burnand K, Layer G (1990) Transcutaneous oxygen tension in assessing the treatment of healed venous ulcers. *Br J Surg*; 77: 1050-54.

Stemmer R, Marescaux J, Furderer C. (1980) Compression treatment of the lower extremities particularly with compression stockings. *The Dermatologist*; 31: 355-65.

Stockport JC, Groarke L, Ellison DA, McCollum C (1997) Single layer and multi layer bandaging in the treatment of venous leg ulcers. *J Wound Care*; 6 (10): 485-488.

Strandness-DE Jr, Langlois Y, Cramer M, Randlett A, Thiele BL (1983) Long-term sequelae of acute venous thrombosis. *JAMA*; 250(10): 1289-92.

Struckman J (1986) Compression stockings and their effect on the venous pump – a comparative study. *Phlebology*; 1: 37-45.

Taylor AD, Taylor RJ, Marcuson RW. Prospective comparison of healing rates and therapy costs for conventional and four layer high compression bandaging of venous leg ulcers. Unpublished. Cited in Effective Health Care: Compression therapy for venous leg ulcers. August 1997. 3: 4. Financial Times Healthcare.

Tennant WG, Park KGM, Ruckley CV (1988) Testing compression bandages. *Phlebology*; 3: 55-61.

Thomas PRS, Nash GB, Dormandy JA (1988) White cell accumulation in dependent legs of patients with venous hypertension: a possible mechanism for trophic changes in the skin. *Brit Med J* ; 296: 1693-1695.

Thomas S (1990) Bandages and bandaging: The science behind the art. *Care Science & Practice*; 8(2): 56-60.

Thomas S (1990) *Wound management and dressings.* London. The Pharmaceutical Press.

Thomas S, Jones M, Shutler S, Jones S (1996) Using larvae in modern wound management. *J Wound Care*; 5(2): 60-9.

Thulesius O, Norgren L, Gjores JE (1973) Foot volumetry, a new method for objective assessment of edema and venous function. *VASA*; 3: 325.

Travers JP, Dalziel KL, Makin GS (1992) Assessment of a new one-layer adhesive bandaging method in maintaining prolonged limb compression and effects on venous ulcer healing. *Phlebology*; 7: 59-63.

Turner TD (1979) Hospital use of absorbent dressings. *Pharm J*; 22 :421-422.

Underwood M (1783) *A treatise upon ulcers of the legs.* London. Mathews.

Van Gerwen HJL (1994) *Pressure gradient tolerance in compression hosiery.* Doctoral thesis; Catholic University of Nijmegen.

Van-Pijkeren T, Naff M, Kwee HH (1980) A new method for the measurement of normal pressure between amputation residual limb and socket. *Bulletin of Prosthetics and Research*; 17: 31-34.

Veraart JCJM, Neumann HAM, Hulsmans RFHJ, van den Broek MBJ (1994) A comparative study of the characteristics of Comfeel Extra Absorbing Dressings in terms of healing, effects of periulcer skin, and patient comfort in care of leg ulcers. Poster *at 4th European Tissue Repair Society Meeting.*

Vinckx L, Boeckx W, Berghmans J (1990) Analysis of the pressure perturbation due to the introduction of a measuring probe under an elastic garment. *Med Biol Eng Comput*; 28(2): 133-138.

Vowden P, Vowden K (1998) Anatomy, physiology and venous ulceration. In:Compression therapy – a complete guide. The philosophy of compression therapy. London. Emap Healthcare. P1-5.

Walker N, Rodgers A, Norton R, Birchall N, and MacMahon S. Venous thrombosis and related risk factors for leg ulcers: results from the Auckland Leg Ulcer Study. First World Wound Healing Congress. 46. Sydney, 2000.

Warburg FE, Danielsen L, Madsen SM et al (1994) Vein surgery with or without skin grafting versus conservative treatment for leg ulcers. *Acta Derm Venereol;* 74:307-309.

Waterlow J (1988) The Waterlow card for the prevention and management of pressure sores: towards a pocket policy. *Care Science and Practice*; 6:8-12.

Weichenthal M, Mohr P, Stegmann W, Eckhard W et al (1997) Low frequency ultrasound treatment of chronic venous leg ulcers. *Wound Repair and Regeneration*; 5:18-22.

Wertheim D, Melhuish J, Trenary K, Williams R, Harding KG (1997) Assessment of changes in forces under compression stockings associated with movement. In: Leaper DJ, Cherry GW, Dealey C, Lawrence JC, Turner TD (eds*) Proceedings of the 6th European Conference on Advances in Wound Management*. London, Macmillan Magazines. p89.

Widmer LK (1978) *Venenkrankheiten. Haufigkeit und sozialmedizinische Bedetung*. Huber, Bern/Stuttgart/Wien.

Wilkinson E, Buttfield S, Cooper S, Young, E (1997) Trial of two bandaging systems for chronic venous leg ulcers. *J Wound Care*; 6(7), 339-340. 97.

Williams R, Wertheim D, Shutler S, Melhuish J, Trenary K, Harding KG (1997) Sub bandage force measurements following application of compression bandages. In: Leaper DJ, Cherry GW, Dealey C, Lawrence JC, Turner TD (eds) *Proceedings of the 6th European Conference on Advances in Wound Management*. London, Macmillan Magazines. 163-4.

Wiseman R (1676) *Several chirurgical treatises*. London. Royston and Took.

Woodburn J, Helliwell PS. Observatiuons on the F-Scan in-shoe pressure measuring system. *Clinical Biomechanics* 1996; 11: 301-304.

Wright DDI, Franks PJ, Blair SD, Backhouse CM, Moffat C, McCollum CN (1991) Oxerutins in the prevention of recurrence in chronic venous ulceration: randomised control trial. *Br J Surg*; 78:1269-70.

Wytch R, Neil G, Kalisse C (1989) Skin-orthosis interface pressure transducers, a review. *Care Science and Practice*;7(4): 101-104.

Zucarelli F (1992) A comparative study of the hydrocellular dressing Allevyn and the hydrocolloid dressing Duoderm in the local treatment of leg ulcers. *Phlebologie*; 45(4); 529-33.

Appendix A: Raw data

Raw data for pressure change with movement of foot - both bandages in pilot study

	Site	medial		lateral	
	Subject	ankle	calf	ankle	calf
plantar flexion	1	6.7	-1.8	7.5	-3.6
	2	4.5	-2.3	4.3	-2.6
	3	4.1	-3.5	8.4	-4.0
	4	2.1	-0.5	7.0	-1.0
dorsi-flexion	1	4.6	-1.0	16	8.2
	2	3.5	-3.7	3.3	3.8
	3	7.5	0.7	3.3	3.8
	4	-0.1	2.4	-6.0	0.7
plantar eversion	1	0.4	1.6	14.5	-6.3
	2	3.0	-0.7	9.8	-0.7
	3	9.6	2.1	31.3	-7.5
	4	8.5	0.8	16.7	-0.4
plantar inversion	1	6.5	-0.8	-2.7	-2.3
	2	3.8	-2.6	0.1	-2.9
	3	11.4	-3.0	-7.4	-1.9
	4	10.7	4.7	16	-3.4

Table 1a Change in Granuflex ACB™ bandage pressure with foot movement

	Site	medial		lateral	
	Subject	ankle	calf	ankle	calf
Plantar flexion	1	8.7	0.5	11.1	-4.1
	2	0	-2.1	7.2	0.4
	3	1.5	-2.2	7.4	-3.7
	4	5.7	-0.4	24.8	-2.9
Dorsi-flexion	1	9.5	0.5	25.7	7.9
	2	20.8	-5.9	10.7	-4.5
	3	0.7	0	5.9	-0.7
	4	2.1	-1.5	14.7	-3.5
Plantar eversion	1	4.4	0.4	18.75	-6.5
	2	5.9	-4.8	16.25	-3.2
	3	1.5	-0.7	7.4	2.9
	4	5.3	0.7	35.7	-4.5
Plantar inversion	1	10.1	0.4	-2.1	-3.8
	2	5.3	-0.8	3.5	-10.7
	3	0.7	1.5	-2.2	-3.7
	4	7.3	4.7	10.9	-0.7

Table.1b Change in Elastocrepe™ bandage pressure with foot position

Measure	medial						lateral					
	ankle			calf			ankle			calf		
	Lie	Sit	Sta.	Lie	Sit	Sta.	Lie	Sit	Sta.	Lie	Sit	Sta.
1	13	15	16	14	13	10	15	10	21	16	11	17
2	39	45	50	17	21	21	34	32	40	29	20	24
3	29	39	40	19	19	17	25	36	40	19	14	24
4	38	44	46	31	29	31	32	27	29	40	34	40
5	15	17	15	20	13	14	31	18	24	15	14	18
6	15	15	14	19	12	16	31	18	21	15	13	15
7	22	22	21	20	16	18	35	14	29	17	13	16
8	20	19	20	15	14	15	35	17	35	21	17	19
9	25	27	25	22	18	22	35	17	30	21	16	17
10	25	27	25	22	18	22	37	16	31	21	13	18
11	74	64	74	14	32	16	34	20	38	27	17	32
12	72	64	69	12	11	27	30	21	37	27	17	28
13	*	69	86	*	13	29	*	21	38	*	17	30

Table 2a Granuflex ACB™: Sub- bandage pressure (mmHg) in 3 postures *(Sta =stand, *=missing data)*

	medial						lateral					
Measure	ankle			calf			ankle			calf		
	Lie	Sit	Sta.	Lie	Sit	Sta.	Lie	Sit	Sta.	Lie	Sit	Sta.
1	18	9	13	13	15	13	6	8	14	10	10	12
2	14	17	17	19	20	25	33	38	46	17	18	19
3	21	25	25	33	36	32	33	40	48	35	31	34
4	17	23	25	21	18	19	21	24	26	9	17	14
5	23	29	37	23	24	28	40	26	40	33	28	37
6	22	25	34	20	20	25	40	23	39	33	26	31
7	17	22	29	24	30	27	40	22	41	37	24	33
8	18	18	24	24	26	27	45	42	60	29	30	38
9	19	26	35	24	16	22	45	52	35	29	32	28
10	19	23	32	19	20	28	45	30	52	29	22	35
11	35	26	52	25	15	23	65	68	88	15	14	28
12	28	22	47	24	13	19	70	67	88	14	12	26
13	*	24	50	*	12	20	*	71	88	*	12	24

Sta. = standing "+" = missing data

Table 2 b Elastocrepe™: Sub- bandage pressure (mmHg) in 3 postures

Tensopress: pressures pre training (mmHg)			Tensopress: pressures after training (mmHg)	
Subject number	calf1	ankle1	calf2	ankle2
1	30	10	30	15
2	10	10	25	15
3			20	15
4	25	10	20	10
5	25	10	15	5
6	35	30	30	30
7	15	10	30	25
8	40	35	25	25
9	50	50	15	15
10	50	30	20	10
11			30	30
12	20	20	15	10
13	20	5	20	10
14	5	5	30	10
15	15	10	10	15
16	20	5		
17	15	15	15	15
18	40	20	20	10
19	0	5	25	20
20	15	5	5	10
21	35	30	20	35
22	45	15	30	5
23	30	15	20	25
24	15	10	30	5
25	35	40	30	30
26	15	10	20	15
27	15	10	25	20
28	20	25	20	15
29	30	15	25	20
30	35	20	30	20
31	25	30	40	30
32	20	15	15	15
33	30	25	40	30
34	20	20	15	15
35	40	30	30	15
36	15	5	15	25
37	25	25	25	30
38	25	20	15	15
39	30	25	25	15
40	30	10	15	10
41	20	10	20	15
42	10	10	15	10
43	15	5	20	20
44	15	5	20	10
45	30	15	20	25
46	20	5	10	0
47	10	15	35	15
48	10	20	15	5
49	10	5	35	35
50	10	5	15	10
51	5	5	15	10

Table 3 Pressures beneath single-layer bandage (Tensopress) pre and post training

52	20	5	30	25
53	10	5	25	15
54	25	15	20	5
55	15	10	15	15
56	50	35	20	15
57	15	5	15	5
58	20	20	30	15
59	25	25	15	15
60	0	20	20	15
61	20	10	15	25
62	20	20		
63	20	5	25	15
64	25	30	20	15
65	30	20	25	20
66	10	20	15	15
67	15	15	25	10
68	15	10	20	20
69	25	30	20	20
70	35	20	30	15
71	20	10	25	15
72	15	10	25	10
73	30	5	20	10
74	50	30	30	15
75	20	15	35	15
76	40	20	30	15
77	30	10	20	15
78	10	15	35	25
79	30	20	20	10
80	40	10		
81	5	10		
82	25	20	30	35
83	25	10	25	15
84	45	30		
85	20	15		
86	20	10	20	20
87	35	10	20	10
88	20	5	15	15
89	35	20	20	5
90	15	10	30	10
91	40	15	30	20
92	25	10	25	10
93	15	10	20	10
94	10	15		
95	20	15	10	10
96	30	15	30	10
97	30	15	30	30
98	20	20	25	15
99	25	15	15	5
100	40	15	10	10
101	20	5	10	10
102	30	5	15	10
103	30	15	25	20
104	25	10	15	5

Table 3 Pressures beneath single-layer bandage (Tensopress) pre and post training

105	25	10	15	10
106	15	5	20	15
107	20	0	15	20
108	10	5	30	35
109	50	25	30	15
110				
111	30	20	30	15
112	25	30	25	25
113	40	20		
114	25	25	35	25
115	15	15	15	10
116	10	5	25	10
117	25	10	45	30
118	45	30	15	10
119	20	15	20	10
120	30	20	15	15
121	25	10	30	10
122	35	15	20	15
123	35	15	15	15
124	25	20	20	20
125	20	10	25	25
126	20	10	30	10
127	25	10	20	10
128	25	25		
129	25	10	30	25
130	35	50	20	15
131	50	50	20	20
132	35	30	15	5
133	50	50	20	10
134	50	40	25	20
135	50	45	25	10
136	20	10	10	10
137	30	45	30	15
138	25	15	15	20
139	25	10	20	15
140	30	25	10	10
141	35	35	15	10
142	50	30	20	15
143	35	45	20	20
144	50	35	50	35
145	20	10	10	5
146	50	20	15	10
147	50	30	20	15
148	30	20	25	20
149	20	10	30	15
150	15	25	20	15
151	35	20	15	10
152	35	20	15	10
153	10	5	20	15
154	35	10	10	10
155	25	25	15	10
156	30	10	20	10
157	25	20	15	10

Table 3 Pressures beneath single-layer bandage (Tensopress) pre and post training

158	30	10	25	15
159	15	10	15	20
160	35	15	25	20
161	35	10	15	15
162	35	10	15	10
163	30	10	25	25
164	20	10	20	25
165	20	20	15	15
166	20	15	15	25
167	30	20	30	20
168	20	20		
169	50	30	25	20
170	30	20	20	20
171	35	50	15	35
172	20	10	25	15
173	20	15	25	35
174	35	10	30	30
175	25	30		
176	20	5	20	5
177	30	10	25	20
178	35	20	30	30
179	20	20	20	10
180	30	15		
181	40	15	25	25
182	20	15	30	20
183	20	15	25	20
184	50	25		
185	30	35	20	20
186	25	5	30	30
187	20	10	15	15
188	15	15	25	30
189	30	15	30	25
190	10	10	20	10
191	20	15	15	10
192	15	10		
193	35	25	20	15
194	15	20	35	25
195	20	10	25	10
196	45	30	25	20
197	30	15	25	15
198	15	25	25	15
199	20	10	25	25
200	15	20	20	20
201	25	10	15	15
202	20	35	30	20
203	15	15	35	20
204	40	50	20	25
205	50	25	25	10
206	35	35	25	25
207	25	15	15	20
208	20	15	25	20
209	35	20	35	30
210	40	35	35	20

Table 3 Pressures beneath single-layer bandage (Tensopress) pre and post training

211	20	10	15	15
212	35	25		
213	50	35	35	20
214	30	15	20	10
215	20	10		
216	35	25	35	25
217	10	5	25	20
218	50	20	20	10
219	10	15	15	20
220	50	30	25	20
221	30	20		
222	20	15		
223	15	15	30	20
224	35	20		
225	45	20	30	20

Table 3 Pressures beneath single-layer bandage (Tensopress) pre and post training

ial numb	ankle press	calf pressu	pressure ra	ankle press	calf pressu	pressure ra
1	30	35	1.166667	50	50	1
2	20	25	1.25	25	35	1.4
3				30	35	1.166667
4	25	30	1.2	20	30	1.5
5	20	40	2	25	25	1
6	50	50	1	35	50	1.428571
7	30	35	1.166667	25	45	1.8
8	50	50	1	25	45	1.8
9	50	50	1	25	45	1.8
10	40	50	1.25	15	25	1.666667
11				35	50	1.428571
12						
13	25	40	1.6	20	20	1
14	20	30	1.5	5	10	2
15	30	40	1.333333	20	30	1.5
16	20	20	1	25	25	1
17	25	40	1.6	30	30	1
18	35	50	1.428571	25	25	1
19	10	25	2.5	40	50	1.25
20	10	25	2.5	25	20	0.8
21	40	50	1.25	45	25	0.555556
22	20	50	2.5	15	30	2
23	20	35	1.75	30	25	0.833333
24	30	50	1.666667	15	35	2.333333
25	50	50	1	40	50	1.25
26	30	50	1.666667	30	35	1.166667
27	15	40	2.666667	25	25	1
28	35	35	1	25	30	1.2
29	30	40	1.333333	20	35	1.75
30	30	40	1.333333	40	50	1.25
31	30	50	1.666667	50	50	1
32	30	30	1	35	35	1
33	25	45	1.8	35	50	1.428571
34	20	30	1.5	30	30	1
35	35	50	1.428571	20	30	1.5
36	20	35	1.75	40	35	0.875
37	30	50	1.666667	45	40	0.888889
38	35	45	1.285714	40	40	1
39	35	50	1.428571	25	20	0.8
40	30	45	1.5	15	20	1.333333
41	20	30	1.5	45	40	0.888889
42	15	30	2	10	25	2.5
43	25	35	1.4	25	30	1.2
44	25	35	1.4	25	30	1.2

Table 4- Pressures beneath 4 layer bandage pre and post training

	pre training			post training		
45	30	50	1.666667	35	50	1.428571
46	40	50	1.25	10	30	3
47	25	35	1.4	40	45	1.125
48	40	35	0.875	25	35	1.4
49	15	45	3	45	45	1
50	20	25	1.25	30	30	1
51	5	15	3	25	25	1
52	20	45	2.25	35	50	1.428571
53	10	20	2	35	30	0.857143
54	35	50	1.428571	20	25	1.25
55	25	30	1.2	30	35	1.166667
56	45	50	1.111111	45	40	0.888889
57	20	30	1.5	15	10	0.666667
58	25	30	1.2	40	50	1.25
59	35	50	1.428571	25	20	0.8
60	25	25	1	25	20	0.8
61	15	30	2	30	30	1
62	45	35	0.777778			
63	20	25	1.25	35	45	1.285714
64	45	30	0.666667	15	10	0.666667
65	30	40	1.333333	20	40	2
66	35	30	0.857143	25	25	1
67	30	40	1.333333	30	35	1.166667
68	30	30	1	40	40	1
69	45	50	1.111111	40	30	0.75
70	45	50	1.111111	30	45	1.5
71	20	50	2.5	25	30	1.2
72	20	20	1	10	30	3
73	35	50	1.428571	30	35	1.166667
74	50	50	1	30	35	1.166667
75	30	20	0.666667	30	45	1.5
76	50	50	1	20	45	2.25
77	20	25	1.25	25	25	1
78	25	45	1.8	45	35	0.777778
79	40	50	1.25	30	45	1.5
80	35	50	1.428571			
81	35	20	0.571429	30	25	0.833333
82	30	50	1.666667	35	35	1
83	30	50	1.666667	30	25	0.833333
84	35	50	1.428571			
85	35	50	1.428571			
86	25	50	2	25	25	1
87	20	45	2.25	30	25	0.833333
88	20	25	1.25	40	35	0.875
89	40	40	1	25	35	1.4

Table 4- Pressures beneath 4 layer bandage pre and post training

	pre training			post training		
90	40	50	1.25	35	30	0.857143
91	25	40	1.6	35	30	0.857143
92	30	30	1	45	35	0.777778
93	25	50	2	20	25	1.25
94	20	15	0.75	20	20	1
95	40	50	1.25	30	35	1.166667
96	30	40	1.333333	30	35	1.166667
97	15	35	2.333333	35	35	1
98	20	50	2.5	35	30	0.857143
99	25	35	1.4	25	20	0.8
100	30	50	1.666667	15	25	1.666667
101	20	30	1.5	20	15	0.75
102	40	40	1	30	25	0.833333
103	35	50	1.428571	20	30	1.5
104	15	45	3	15	20	1.333333
105	20	35	1.75	25	20	0.8
106	10	15	1.5	20	25	1.25
107	15	40	2.666667	25	25	1
108	10	20	2	30	25	0.833333
109	45	50	1.111111	20	35	1.75
110						
111	50	50	1	40	35	0.875
112	50	50	1	40	45	1.125
113	30	50	1.666667			
114	35	50	1.428571	40	40	1
115	30	50	1.666667	40	30	0.75
116	30	50	1.666667	50	30	0.6
117	30	40	1.333333	50	50	1
118	50	50	1	30	35	1.166667
119	35	50	1.428571	35	50	1.428571
120	30	35	1.166667	35	30	0.857143
121	20	40	2	30	35	1.166667
122	15	50	3.333333	40	45	1.125
123	25	50	2	20	30	1.5
124	25	30	1.2	25	25	1
125	25	50	2	30	50	1.666667
126	20	30	1.5			
127	40	40	1			
128	40	50	1.25			
129	25	45	1.8	45	40	0.888889
130	50	50	1	35	35	1
131	50	50	1	40	35	0.875
132	50	50	1	20	25	1.25
133	50	50	1	25	35	1.4
134	50	50	1	30	30	1

Table 4- Pressures beneath 4 layer bandage pre and post training

135	50	50	1	35	45	1.285714
136	35	35	1	25	30	1.2
137	40	35	0.875	30	30	1
138	45	35	0.777778	40	25	0.625
139	40	35	0.875	35	35	1
140	35	50	1.428571	30	20	0.666667
141	50	35	0.7	35	25	0.714286
142	40	50	1.25	30	35	1.166667
143	50	50	1	40	30	0.75
144	50	50	1	55	50	0.909091
145	35	45	1.285714	25	20	0.8
146	45	50	1.111111	25	30	1.2
147	45	50	1.111111	35	35	1
148	30	30	1	40	25	0.625
149	35	35	1	25	25	1
150	40	25	0.625	35	30	0.857143
151	35	50	1.428571	25	15	0.6
152	35	45	1.285714	30	25	0.833333
153	25	20	0.8	20	20	1
154	40	50	1.25	20	20	1
155	30	35	1.166667	20	25	1.25
156	25	20	0.8	25	25	1
157	35	25	0.714286	20	30	1.5
158	35	25	0.714286	25	25	1
159	30	50	1.666667	40	25	0.625
160	35	25	0.714286	40	35	0.875
161	20	35	1.75	25	20	0.8
162	20	40	2	20	30	1.5
163	20	30	1.5	40	30	0.75
164	35	50	1.428571	45	35	0.777778
165	45	50	1.111111			
166	30	50	1.666667	40	25	0.625
167	25	50	2	30	35	1.166667
168	50	50	1			
169	40	50	1.25	50	50	1
170	45	50	1.111111	45	20	0.444444
171	45	45	1	30	30	1
172	30	40	1.333333	35	25	0.714286
173	25	30	1.2	30	35	1.166667
174	30	40	1.333333	15	30	2
175	25	50	2			
176	20	30	1.5	25	30	1.2
177	40	40	1	30	35	1.166667
178	40	50	1.25	30	50	1.666667
179	30	30	1	25	30	1.2

Table 4- Pressures beneath 4 layer bandage pre and post training

	pre training			post training		
180	30	50	1.666667			
181	25	40	1.6	30	45	1.5
182	30	25	0.833333	35	35	1
183	35	45	1.285714	40	50	1.25
184	30	50	1.666667			
185	35	30	0.857143	30	20	0.666667
186	15	35	2.333333	40	50	1.25
187	15	25	1.666667	25	20	0.8
188	15	35	2.333333	30	30	1
189	25	35	1.4	40	50	1.25
190	25	20	0.8	20	25	1.25
191	35	25	0.714286	25	25	1
192	20	25	1.25			
193	35	45	1.285714	25	30	1.2
194	20	25	1.25	40	40	1
195	30	50	1.666667	25	30	1.2
196	30	50	1.666667	30	35	1.166667
197	25	30	1.2	25	30	1.2
198	30	25	0.833333	20	20	1
199	30	35	1.166667	40	40	1
200	25	25	1	30	35	1.166667
201	25	25	1	35	30	0.857143
202	45	45	1	30	45	1.5
203						
204	50	45	0.9	30	25	0.833333
205	50	50	1	25	35	1.4
206	40	50	1.25	30	45	1.5
207	40	50	1.25	30	30	1
208	25	35	1.4	30	45	1.5
209	35	50	1.428571	40	45	1.125
210	45	50	1.111111	25	30	1.2
211	35	35	1	20	30	1.5
212	45	50	1.111111			
213	40	50	1.25	40	50	1.25
214	40	50	1.25	30	35	1.166667
215	45	50	1.111111			
216	45	30	0.666667	25	35	1.4
217	20	20	1	25	35	1.4
218	30	45	1.5	25	30	1.2
219	30	35	1.166667	40	30	0.75
220	35	50	1.428571	35	35	1
221	35	35	1			
222	40	50	1.25			
223	35	50	1.428571	35	35	1
224	35	50	1.428571			

Table 4- Pressures beneath 4 layer bandage pre and post trainin

	pre training			post training		
225	25	35	1.4	25	30	1.2

Table 4- Pressures beneath 4 layer bandage pre and post trainin

Appendix B

Timetables for Study Days

Study day 1 Programme

Time		
9:00 - 10:30	Evaluation of present skill and knowledge (Questionnaire)	Evaluation of present bandaging skill (pressure measurement)
10:30 - 10:45	**COFFEE**	
10:45 - 11:30	Aetiology, diagnosis and management of venous leg ulcers	
11:30 - 12:30	Theory of compression and its practical application	
12:30 - 13:15	**Lunch**	
13:15 - 15:15	Practical session on bandaging	Practical session on arterial Doppler + coffee
15:15 - 16:00	Distribution of learning package and video, clinic visits arranged and feedback on day.	

Timetable for second study day

9:00	Discussion of learning pack and video	EAN
9:30	Leg ulcer guidelines in Liverpool, referring patients and managing skin problems	EAN
10:30	**COFFEE**	
10:45	Case studies	KC + JJ
11:30	Bandaging practice	EAN, KC, JJ
12:30	**LUNCH**	
13:15	Evaluation of knowledge and bandaging skill + **COFFEE**	EAN, KC, JJ
15:15	Questions, feedback on days, plans for future	EAN
16:00	**DEPART**	

Appendix C

Pre test questionnaire for both groups

DEPARTMENT OF NURSING

The University of Liverpool

YOUR INITIALS =

As you are probably aware the management of patients with leg ulcers has been identified at a national level as an area where improvements in practise may be possible by improvements in knowledge, equipment, training and resources. National guidelines are being piloted locally in Wirral and this project will complement the guidelines and protocols. We are interested in how you actually care for your patients with leg ulcers, and how your practise is influenced and constrained. This information will help us identify barriers which prevent the optimal management of patients with leg ulcerations.

Most of the questions require you to tick a box, but the ones relating to your own practice are in two parts, these should be answered as follows'

In **PART a)** would you please write down briefly what you **ACTUALLY DO** in each clinical situation.

In **PART b)** please write down what you **WOULD DO DIFFERENTLY** (if anything) in an "ideal" situation whereyou had unlimited time and resources with which to do your work.

Please answer as fully as you can. The information you give us will be important in helping to determine whether more Clinical Information packs are produced. all your answers will be treated in the **strictest confidence** and will be used only for the purpose of this survey.

SECTION ONE;

THE FOLLOWING QUESTIONS ARE ABOUT YOURSELF AND YOUR WORK. PLEASE CONSIDER EACH ONE AND TICK THE APPROPRIATE ANSWER.

1. WHERE DO YOU WORK?

HEALTH AUTHORITY (NAME) _____

LOCALITY/WORK BASE _____

2. WHICH QUALIFICATIONS DO YOU HOLD?

S.R.N./R.G.N. ☐

Q.N./ D.N.CERTIFICATE ☐

P.W.T./C.P.T. ☐

E.N.B. COURSE(S) ☐

UNIVERSITY DEGREE(S) ☐

OTHER (PLEASE SPECIFY) ☐

_____

3. WHEN DID YOU QUALIFY AS A DISTRICT NURSE?

(YEAR) 19_____

4. DO YOU WORK FULL TIME OR PART TIME?

FULL TIME ☐

PART TIME (MORE THAN 20 HOURS) ☐

PART TIME (LESS THAN 20 HOURS) ☐

5. APPROXIMATELY HOW MANY OF YOUR PATIENTS HAVE LEG ULCERS?

NUMBER ☐

6. DO ANY OF THESE PATIENTS HAVE **VENOUS** ULCERS?

YES (INSERT NUMBER) ☐

NO ☐

DON'T KNOW ☐

7. DO ANY OF THESE PATIENTS HAVE **ARTERIAL** ULCERS?

YES (INSERT NUMBER) ☐

NO ☐

DON'T KNOW ☐

8. DO ANY OF THESE PATIENTS HAVE **MIXED** ULCERS?

YES (INSERT NUMBER) ☐

NO ☐

DON'T KNOW ☐

9. DO ANY OF THESE PATIENTS HAVE **DIABETIC** ULCERS?

YES (INSERT NUMBER) ☐

NO ☐

DON'T KNOW ☐

10. DO ANY OF THESE PATIENTS HAVE **RHEUMATOID** ULCERS?

YES (INSERT NUMBER) ☐

NO ☐

DON'T KNOW ☐

11. DO ANY OF THESE PATIENTS HAVE ULCERS OF UNKNOWN ORIGIN?

YES (INSERT NUMBER) ☐

NO ☐

DON'T KNOW ☐

12. WITHIN YOUR AREA WHO IS THE EXPERT IN LEG ULCER MANAGEMENT? (TICK ALL WHICH APPLY).

A LEG ULCER CLINIC ☐

A COMPANY REP WHO VISITS REGULARLY ☐

I HAVE A SPECIAL INTEREST IN LEG ULCERS ☐

MY G.P. HAS A SPECIAL INTEREST ☐

A COLLEAGUE HAS A SPECIAL INTEREST ☐

A SPECIALIST ULCER NURSE ☐

A HOSPITAL CONSULTANT ☐

THERE IS NO RECOGNISED EXPERT ☐

OTHER (PLEASE SPECIFY) _____ ☐

_____

13. IN THE LAST YEAR HAVE YOU READ ANYTHING ABOUT LEG ULCERS? (TICK ALL WHICH APPLY)

NO I HAVEN'T ☐

BOOKS ☐

JOURNAL ARTICLES ☐

INFORMATION FROM DRUG REPS ☐

OTHER (PLEASE SPECIFY) _____ ☐

_____

14. IN THE LAST YEAR HAVE YOU ATTENDED ANY COURSES ABOUT LEG ULCERS? (TICK ALL WHICH APPLY)

NO I HAVEN'T ☐

HEALTH AUTHORITY STUDY DAYS ☐

DRUG COMPANY DEMONSTRATIONS ☐

DRUG COMPANY LECTURES ☐

LEG ULCER ROADSHOW ☐

VISITS TO LEG ULCER CLINICS ☐

OTHER (PLEASE SPECIFY) ☐

_____

_____

15. IN CARING FOR YOUR PATIENTS WITH LEG ULCERS DO YOU EVER FEEL CONSTRAINED BY ANY OF THE FOLLOWING? (TICK ALL WHICH APPLY)

TOO BIG A CASELOAD	☐
UNDERSTAFFING	☐
PRESSURES FROM NURSE MANAGERS	☐
PATIENT NON-COMPLIANCE	☐
PATIENT'S LIFESTYLE	☐
PRESSURES FROM G.P.	☐
TOO FEW RESOURCES	☐
UNABLE TO GET SUPPLIES	☐
UNABLE TO GET PREFERRED PRODUCTS	☐
NOT ENOUGH INFORMATION AVAILABLE	☐
LACK OF EXPERIENCE IN LEG ULCER CARE	☐
NONE OF THESE	☐
OTHER (PLEASE SPECIFY)	☐

_____

_____

SECTION 2:

In **part a)** please write briefly what you **actually do** in each situation and in **part b)** what you **would do differently** (if anything) in an "ideal" situation.

QUESTION 1:

(a) WHEN A PATIENT WITH A LEG ULCER IS REFERRED TO YOUR CARE AND YOU ARE MAKING YOUR **GENERAL** NURSING ASSESSMENT, WHAT DO YOU LOOK FOR AND RECORD IN YOUR NOTES.

Boxes are for coding purposes only

_____ ☐a

_____ ☐b

_____ ☐c

_____ ☐d

_____ ☐e

_____ ☐f

_____ ☐g

(b) IF YOU HAD UNLIMITED TIME AND RESOURCES WOULD YOU DO ANYTHING DIFFERENTLY?

YES ☐

NO ☐

IF yes, please list below;

_____

_____

_____

_____

QUESTION 2;

(a) WHEN EXAMINING THE PATIENT'S **LEG(S)** WHAT DO YOU LOOK FOR AND RECORD IN YOUR NOTES?

Boxes are for coding purposes only.

_____ ☐ a

_____ ☐ b

_____ ☐ c

_____ ☐ d

_____ ☐ e

_____ ☐ f

_____ ☐ g

(b) IF YOU HAD UNLIMITED TIME AND RESOURCES WOULD YOU DO ANYTHING DIFFERENTLY?

YES ☐

NO ☐

If yes, please list below;

_____

_____

_____

_____

_____

_____

QUESTION 3;

(a) WHEN EXAMINING THE **ULCER ITSELF** WHAT DO YOU LOOK FOR AND RECORD IN YOUR NOTES?

Boxes are for coding purposes only.

_____ ☐ a

_____ ☐ b

_____ ☐ c

_____ ☐ d

_____ ☐ e

_____ ☐ f

_____ ☐ g

(b) IF YOU HAD UNLIMITED TIME AND RESOURCES WOULD YOU DO ANYTHING DIFFERENTLY?

YES ☐

NO ☐

If yes, please list below;

_____

_____

_____

_____

_____

_____

QUESTION 4;

(a) WHEN MAKING YOUR NURSING ASSESSMENT OF PATIENTS WITH LEG ULCERS WHICH CLINICAL INVESTIGATIONS DO YOU **ROUTINELY** CARRY OUT?

Boxes are for coding purposes only.

_____ ☐ a

_____ ☐ b

_____ ☐ c

_____ ☐ d

_____ ☐ e

_____ ☐ f

_____ ☐ g

(b) IF YOU HAD UNLIMITED TIME AND RESOURCES WOULD YOU DO ANYTHING DIFFERENTLY?

YES ☐

NO ☐

If yes, please list below;

_____

_____

_____

_____

_____

QUESTION 5;

DO YOU KNOW WHAT THE STAGES OF ULCER DEVELOPMENT AND HEALING ARE?

YES ☐

NO ☐

If yes, please state;

Boxes are for coding purposes only

_____ ☐a

_____ ☐b

_____ ☐c

_____ ☐d

_____ ☐e

_____ ☐f

QUESTION 6;

WHICH SOLUTION(S) DO YOU USUALLY USE TO CLEANSE ULCERS? (TICK ALL WHICH APPLY)

I DON'T USE SOLUTIONS ☐

SALINE ☐

TAP WATER ☐

CETRIMIDE ☐

HYPOCHLORITE ☐

HYDROGEN PEROXIDE ☐

CHLORHEXIDINE ☐

POTASSIUM PERMANGANATE ☐

OTHER (PLEASE SPECIFY) ☐

_____

QUESTION 7;

WHEN SELECTING THE DRESSING WHICH IS GOING TO BE IN **DIRECT CONTACT** WITH A LEG ULCER WHAT FEATURES DO YOU LOOK FOR IN THE PRODUCT?

Boxes are for coding purposes only.

_____ ☐ a

_____ ☐ b

_____ ☐ c

_____ ☐ d

_____ ☐ e

_____ ☐ f

QUESTION 8;

(a) HOW DO YOU DECIDE WHEN AN ULCER DRESSING NEEDS CHANGING?

Boxes are for coding purposes only.

_____ ☐ a

_____ ☐ b

_____ ☐ c

_____ ☐ d

_____ ☐ e

_____ ☐ f

_____ ☐ g

(b) IF YOU HAD UNLIMITED TIME AND RESOURCES WOULD YOU DO ANYTHING DIFFERENTLY?

YES ☐

NO ☐

If yes, please list below;

_____

_____

_____

_____

QUESTION 9;

ON WHICH TYPES OF ULCER DO YOU USE COMPRESSION BANDAGING?

- ALL ULCERS ☐
- VENOUS ULCERS ☐
- ARTERIAL ULCERS ☐
- MIXED ULCERS ☐
- DIABETIC ULCERS ☐
- RHEUMATOID ULCERS ☐
- I NEVER USE COMPRESSION ☐

QUESTION 10;

(a) IF YOU ARE TREATING A PATIENT WITH COMPRESSION WHICH PRODUCTS AND TECHNIQUES DO YOU USE? (PLEASE GIVE EXAMPLES)

Boxes are for coding purposes only.

_____ ☐ a

_____ ☐ b

_____ ☐ c

_____ ☐ d

_____ ☐ e

_____ ☐ f

_____ ☐ g

(b) IF YOU HAD UNLIMITED TIME AND RESOURCES WOULD YOU DO ANYTHING DIFFERENTLY?

YES ☐

NO ☐

If yes, please list below;

_____

_____

_____

_____

_____

_____

QUESTION 11;

(a) BESIDES THE DRESSINGS WHAT OTHER **GENERAL CARE AND ADVICE** DO YOU GIVE TO ALL YOUR PATIENTS WITH LEG ULCERS?

Boxes are for coding purposes only.

_____ ☐ a

_____ ☐ b

_____ ☐ c

_____ ☐ d

_____ ☐ e

_____ ☐ f

_____ ☐ g

(b) IF YOU HAD UNLIMITED TIME AND RESOURCES WOULD YOU DO ANYTHING DIFFERENTLY?

YES ☐

NO ☐

If yes, please list below;

_____

_____

_____

_____

_____

_____

_____

QUESTION 12;

(a) BESIDES THE DRESSINGS WHAT **SPECIFIC CARE AND ADVICE** DO YOU GIVE TO PATIENTS WITH **VENOUS** ULCERS?

Boxes are for coding purposes only.

_____ ☐a

_____ ☐b

_____ ☐c

_____ ☐d

_____ ☐e

_____ ☐f

_____ ☐g

(b) IF YOU HAD UNLIMITED TIME AND RESOURCES WOULD YOU DO ANYTHING DIFFERENTLY?

YES ☐

NO ☐

If yes, please list below;

_____

_____

_____

_____

_____

_____

QUESTION 13;

(a) BESIDES THE DRESSINGS WHAT SPECIFIC CARE AND ADVICE DO YOU GIVE TO PATIENTS WITH ARTERIAL AND MIXED ULCERS?

Boxes are for coding purposes only.

_____ ☐ a

_____ ☐ b

_____ ☐ c

_____ ☐ d

_____ ☐ e

_____ ☐ f

_____ ☐ g

(b) IF YOU HAD UNLIMITED TIME AND RESOURCES WOULD YOU DO ANYTHING DIFFERENTLY?

YES ☐

NO ☐

If yes, please list below;

_____

_____

_____

_____

_____

_____