An Integrated Evaluation of Compression Devices with a focus on Ambulatory Monitoring of Sub-bandage Pressure and Posture

by

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The Activity Sensor described in Chapter Seven and referred to in this thesis is filed for patent protection. British Patent Application Number 9304571.4.

ABSTRACT

This thesis describes an investigation on the performance of compression bandages and elastic stockings used in the treatment of venous ulcers. It examines the magnitude and distribution of pressures beneath these devices and the factors that influence the generation of compression.

An electro-hydraulic interface pressure measuring device was specifically designed and developed to measure pressure beneath these compression devices.

An integrated short term evaluation of the performance of twelve routinely used bandages and elastic stockings was carried out. Two techniques of bandaging and the effects of laundering on stockings were also examined. In vivo tests revealed that the majority of the compression devices failed to produce appropriate compression at the ankle and favourable pressure gradients over the leg. The tests also indicated that posture, technique of bandaging and the duration of use were important influencing factors. These factors have previously not been considered in the classification of bandages and stockings. Mechanical properties of the devices relevant to the generation of compression were also examined. In vitro tests on specimen materials showed non-linear and non-elastic load deformation behaviour and stress relaxation by all the devices. A subjective assessment based on the personal experiences of the bandager and the volunteer subjects yielded useful information on the compression devices. The findings of the integrated evaluation suggested a need for long term ambulatory monitoring of pressure and posture.

A novel ambulatory pressure and posture monitoring device comprising a pressure transducer and sensor, a flexible goniometer and pocket sized data logger was developed. This device was used to the monitor sub-bandage pressure and posture on subjects in three controlled postures during activities of daily living.

The long term performance of five commonly used compression bandages (Granuflex, Elastocrêpe, Coban Wrap, Lestreflex and Low Tack) applied by the same physiotherapist, was investigated on a single subject. The Granuflex bandage was further investigated on nine subjects. With the exception of the Elastocrêpe bandage, the pressures fell significantly over the first six hours after which the pressures progressively became independent of time. Superimposed on the decreasing trends were cyclic daily variations in pressure for all five bandages. The magnitude and

gradient of sub-bandage pressures were influenced by posture. The Granuflex bandage produced the highest pressures with relatively small standard deviations after the first day. The Coban Wrap performed well in maintaining pressure with low standard deviations. The performances of the Low Tack and Lestreflex bandages were average while that of the Elastocrêpe bandage was poor. The findings in this investigation warranted a more comprehensive study on venous ulcer patients.

The ambulatory device was further miniaturised and the goniometer replaced with the activity sensor which measured posture unambiguously and was conducive for prolonged use on patients.

A preliminary analysis of the data for three patient tests is reported in this thesis. The time course of the ambulatory sub-bandage pressure over the seven days had no discernible trend. Cyclic daily variations of pressure were observed and its association with the fall in pressure during periods of sleep were confirmed. The pressures generated during continuous ambulation varied considerably for each day, patient, bandage and site, and were influenced by posture. Favourable pressure gradients achieved during ambulation were generally low. The results indicate that the pressures in the lower section of the leg predominately dictates the profile of the pressure gradient. Analysis of daily activities revealed that the patients spent a majority of their time in the upright posture, often continuously during the hours of work. Further, the patients did not regularly spend time with their legs elevated. This lifestyle may have a direct bearing to venous ulceration. The preliminary analysis has highlighted the multiplicity and complexity of factors governing sub-bandage pressures during activities of daily living.

The ambulatory pressure and posture monitoring device has proven to be a powerful investigative tool. This research has unveiled new long term characteristics of pressure generated by bandages and has also provided confirmation of many previous findings. The measurement of patient activity should provide additional information on venous ulceration and its reoccurrence. The investigation has confirmed the limitations of short term measurement of interface pressure beneath compression devices on non-ambulatory subjects. The knowledge acquired from this research should prove useful in the ongoing effort to improve compression therapy used in the treatment of venous ulcers.

I dedicate this thesis to
the woman behind this success,
my best friend and wife,
SIV

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....with you all, I share this thesis

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PREFACE

The Objectives of this Study

Compression bandages and elastic stockings are routinely used in the treatment of venous ulcers. However, little is known of the functional properties and efficacy of these compression devices.

The primary objective of this study was to conduct an integrated assessment of the performance and the biomechanical properties of a selected number of compression bandages and elastic stockings. To accomplish this, a suitable device capable of measuring interface pressure reliably was designed and developed.

Several factors governing the nature of the pressures beneath these compression devices emerged from the integrated assessment. In order to examine these factors, in more detail, an ambulatory device capable of monitoring interface pressure and posture over prolonged periods was designed and developed.

Ultimately, the objective of the ambulatory studies on subjects and patients was to enable a fundamental understanding of the properties of interface pressure beneath compression devices used during activities of daily living and their effect on the treatment of venous ulcers.

CHAPTER 1

INTRODUCTION

1.1 A Historical Perspective

1.2 Venous Ulcers - The Ailment

1.3 The Prevalence of Venous Ulcers

1.4 The Cost Implications of Venous Ulcers

1.5 Venous Anatomy and Physiology

1.6 Diagnostic Approaches to Venous Dysfunction

1.7 The Pathogenesis of Venous Ulcers

1.8 Therapeutic Management of Venous Ulsers

Figure 1.1 Votive tablet of leg with varicose veins (reproduced from Browse et al., 1988).

1.1 A HISTORICAL PERSPECTIVE

The accumulation of our knowledge and understanding of venous disorders, has its roots and humble beginnings in ancient Egypt. History reveals that man has had a considerable empirical understanding of the treatment of venous disorders for at least 2000 years but the course of advancement has had to await many corner-stones of science. Some of these great works are unveiled as an attempt is made to review the history of venous disorders.

If interpretations have it right, then the first known "venous publication" is contained in the Ebers Papyrus (1550 BC) advocating that incision should not be used on varicose veins as it would prove fatal (Major, 1954; Majno 1975). At the Acropolis in Athens lies a votive tablet, dedicated to Doctor Amynos, showing the medial side of a large leg with swellings characteristic of varicose veins (Figure 1.1). It dates to sometime in the 4th century BC and probably symbolises the beginning of phlebology.

In De Carnibus and De Ulceribus (460-377 BC), Hippocrates describes the artery and the vein as vessels arising from the heart, the effects of tourniquets as causes of gangrene and bleeding, the causes of venous ulcers and its treatment. It is possible that the Hippocratic text holds the first, faintest, suggestion of compression therapy for the treatment of venous ulcers (Adams, 1949; Chadwick and Mann, 1950; Majno, 1975). In contemporary times in China, the Yellow Emperor's Classic of Internal Medicine (400 BC) describes the treatment of ulcers but clarity in the interpretation of this ancient text is somewhat uncertain (Veith, 1966). Meanwhile, in another ancient civilisation, the practice of medicine was developing rapidly. The textbook of Indian surgery, The Sushruta Samhita (200 BC), describes the treatment of ulcers with maggots to clear away necrotic material, curettage and dressing made of leaves. Interestingly, it also describes the use of Chinese cloth bandages for the treatment of these ulcers. These cloth bandages could have been the earliest ancestor of the modern day compression bandage.

Over the centuries that followed other significant contributions were made, from the dispelling of "evil humours" by the use of bandages to the masterly anatomical drawings of the veins by Leonardo da Vinci (1452). Leonardo's drawings

Figure 1.2 Leonardo's drawing of the superficial veins of the lower limb (reproduced from Browse et al., 1988).

(Figure 1.2), however, did not show valves in the veins. It was a century later that Amatus Lusitanus and J B Canano first identified valves in the veins (Withington, 1894). The first recorded drawing of a valve in the vein was published by Saloman Alberti in 1585 (Alberti, 1585). Possibly, one of the greatest contributions to physiology since the beginning of medicine was the revelation, by Harvey (1628), that blood circulated. He also illustrated the function of valves in the veins to ensure unidirectional blood flow. Another significant contribution to physiology came from Lower in 1669, who showed a clear role for the limb muscles on blood flow, in his book "Tractatus de corde item de motu et colore sanguinis et chyli in eum transitu", and so gave the first description of the peripheral muscle venous pump. Wiseman (1676), whilst working at St Thomas's Hospital revealed a deep understanding of venous diseases in his book, "Several Chirurgical Treatises". He was also the inventor of the "leather lace-up stocking" which was used in the treatment of venous disorders of the lower limb and was to become the forerunner of the modern day elastic stocking.

Seventy one years after Sir Issac Newton described his Laws of Gravity, Sharp (1758) in his book, "A Treatise on the Operations of Surgery", indicated an appreciation of the effects of gravity on blood and interstitial fluid within the lower limb. Perhaps the first reference to "stasis" as a cause of thrombosis, was made in 1793 by Ballie when he stated that a reduction in the rate of blood flow leads to thrombus formation. The fact that hydrostatic forces were important for venous flow was soon realised by Home in 1797, when he stated that the patient's height and weight affected pressures in the veins and hence the risk of venous ulcers. He also mentioned that venous diseases varied with the weather. In a book on the management of all forms of leg ulcers, Baynton (1799) reported that ulcers were situated on the distal part of the limb because they were remote from the "foundation of life and heat" and were at a disadvantage for the return of blood and lymph. He also introduced a primitive form of paste bandage. Bandages and stockings to provide compression therapy was, by this time, a popular theme. The first physiological explanation for such a therapy came from Cooper in 1824, who stated that compression of varicose veins restored the competence of the valves in the veins.

In 1845 the invention of the hypodermic needle, by Francis Rynd,

revolutionised medical science. It led to the development of sclerotherapy, the measurement of intravascular pressures and the analysis of blood samples. This invaluable tool provided scientists with a means of unravelling factors related to the better understanding of venous diseases in the centuries that followed.

The use of medicated compression bandages for the treatment of ulcers was introduced by Unna in 1854, and has become better known as the "Unna Boot". Virchow in 1859 published the well known "Virchow's triad", in which he described the three predisposing causes of thrombosis; changes in the vessel wall, the blood flow and blood. By this time the understanding of venous diseases had significantly improved. Gay (1866) and Spender (1868) clarified that the use of the term "varicose ulcers" was misleading and used the term "venous ulcers" instead. The success of compression therapy was reiterated when Martin (1878), in his letter to the British Medical Journal, gave a detailed description of India-rubber bandages for the treatment of leg ulcers and how they produced elastic compression.

The twentieth century marked the beginning of quantification and classification of physiological measurements. Hooker (1911) noticed that exercise affected pressure in the veins of the lower limb. Homan (1916) classified varicose veins as primary, if the deep veins were normal and secondary if the deep veins showed evidence of post-thrombotic damage. Berberich and Hirsch (1923) described their first attempt at venography using strontium bromide.

The term "Gravitational ulcer" was first used by Wright (1930), who also described the use of local dressings and adhesive bandages (Elastoplast) for the treatment of venous ulcers. In the same year, Ratschow (1930) introduced the first water-soluble x-ray contrast material, a di-iodinated pyridine derivative, for safer phlebography.

From the 1930's up to the present day, studies on venous related diseases, have been a subject of continuing interest. The knowledge accumulated thus far, has highlighted the complex nature of the disease process and the need for a multi-disciplinary approach in treatment. It would not be possible to comprehensively review the numerous works here, and it would be invidious to single out any one piece of work for a special mention. However, the more detailed sub-sections of this thesis do bear reference to some of these important works.

1.2 VENOUS ULCERS - THE AILMENT

Ulcers of the lower limb have been a therapeutic problem for centuries, causing immense suffering to patients and despair to those treating them. Many in the health care profession consider the problem of leg ulcers as insoluble and intractable. Harding (1991) pointed out that leg ulcers have received such scant attention that many of the treatments prescribed are at best probably not beneficial and at worst potentially harmful. The treatment of leg ulcers has even been described as "an unpleasant and inglorious task where much labour must be bestowed, and little honour gained" (Edinburgh Medical and Surgical Journal, 1805).

An ulcer can range from a superficial erosion of the epidermis to massive tissue damage involving the entire dermis and subcutaneous layers (Rook and Wilkinson, 1979; Ryan, 1987). The term "Leg Ulcers" is often used inter-changeably to describe a variety of ulcers occurring in the lower limb. These ulcers differ in aetiology and distinguishing one from another is often a formidable task even in the hands of experienced clinicians (Dale, 1986; Callam, 1986). In 1982, the Lothian and Forth Valley Leg Ulcer Study revealed that venous ulcers were the most common form of leg ulcers, occurring in the order of seventy percent of all leg ulcers. Also recorded in this study were arterial ulcers, diagnosed in twenty two percent of the leg ulcer patients. Ulcers of mixed aetiology, rheumatoid arthritic ulcers, diabetic ulcers and ulcers associated with vasculitis, hypertension, burns, haematological disorders, infections and lymphoedema were less common (Callam et al., 1986). Others, Anning (1956), Kappert (1971) Haeger (1977), and Ryan (1983) had previously established that between seventy and ninety seven percent of ulcers were of venous origin.

The term "venous ulcers" is preferred to varicose ulcers, postphlebitic ulcers, stasis ulcers, gravitational ulcers or hypostatic ulcers, since the exact pathogenetic mechanisms for venous ulcers have still not been fully elucidated. Venous ulcers are most commonly situated on the lower third of the leg, along the medial aspect, above the malleolus and seldom on the foot. This ulceration is the final event in a well recognised series of changes in the skin and subcutaneous tissue. The first changes are cutaneous pigmentation, mild ankle oedema, and the appearance of dilated subdermal venules. Later the skin and subcutaneous fat become thickened and hard. Since the tissues are often red and tender they are sometimes mistakenly thought to

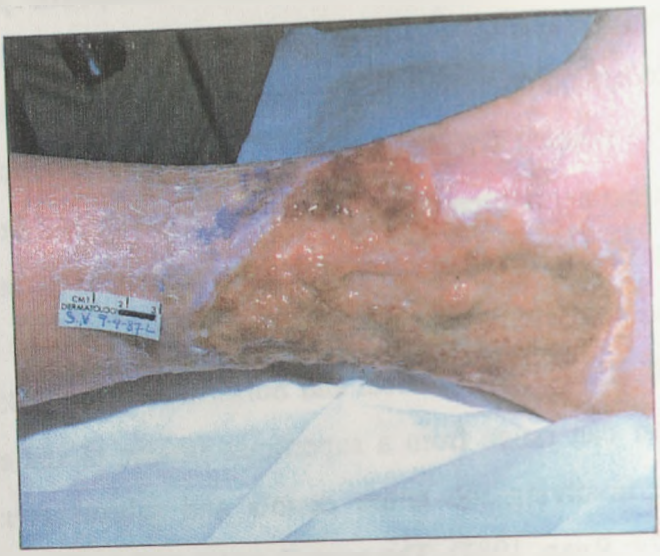


Figure 1.3 A typical venous ulcer.
(from Cherry et al., 1987)

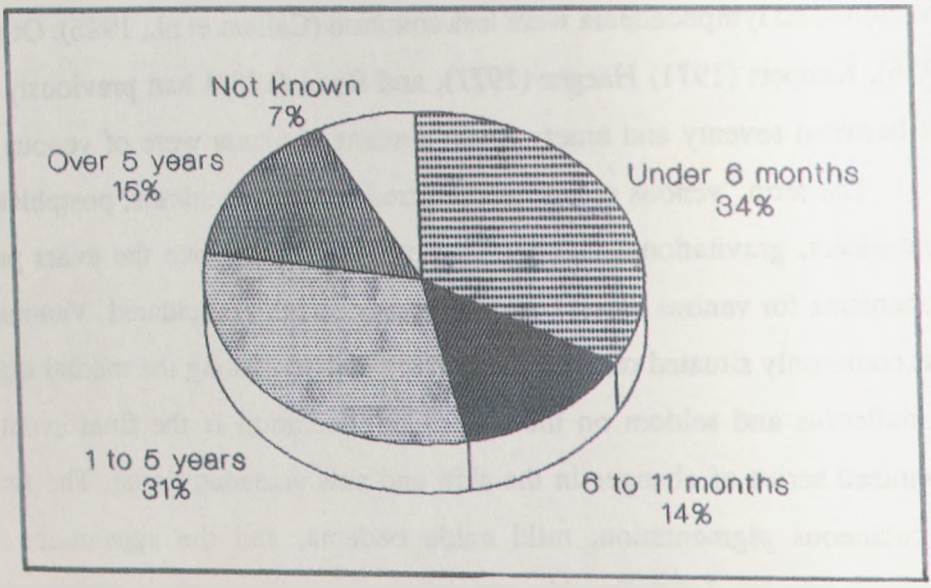


Figure 1.4 Durations of venous ulcers (reproduced from Nicholls, 1990).

be infected or to be the site of superficial thrombophlebitis. At this stage minor trauma will cause an ulcer. If ulceration does not occur the skin and fat contract and the patient develops a tight narrow gaiter of hard skin. This whole process is termed lipodermatosclerosis (Burnand et al., 1982).

A typical venous ulcer does not have raised margins like malignant ulcers and is irregular in shape. It is usually superficial, although the depth of the lesion may often be masked by the presence of eschar or necrotic debris. Occasionally penetration into the deep fascia may occur through infection. The ulcer bed is often painless, cyanotic and oedematous, and the edges tend to bleed easily through the granulated tissue. The surrounding leg area frequently presents indurated skin with shiny texture, loss of hair, hyperpigmentation and oedema (Hill, 1989; Dale, 1986; Dealey, 1991; Levine, 1990). A typical venous ulcer is illustrated in figure 1.3.

The unfortunate sufferers of this disease tend to be the old and the frail, often obese and immobile. The disease, often long-standing (Figure 1.4) when compounded with other health complications, not only makes the suffering intolerable but treatment highly problematic (Stevens and Ball, 1964). Finally, even when ulcers heal, much care is required as recurrence within a short period is common (Monk and Sarkany, 1982).

1.3 THE PREVALENCE OF VENOUS ULCERS

The exact prevalence of leg ulcers is uncertain, let alone that of venous ulcers (Callam et al., 1985; Callam, 1992). It is regrettable that epidemiological studies of this age-old condition only began late this century. None of these studies was conducted on any large scale. In the developed world where such studies exist, the number is small and can, at best, be described as sporadic.

In 1929 Dickson-Wright ventured on an estimate, suggesting that 0.5% of the British population suffered from venous ulceration. Boyd et al., arrived at a similar British figure in 1951 based on the returns of patients registered as off work due to leg ulceration. It is dubious if this figure reflects the entire cross-section of the population, and besides it is inclusive of the entire spectrum of leg ulcer ailments. Elsewhere, in Europe several similar isolated attempts at estimating the magnitude

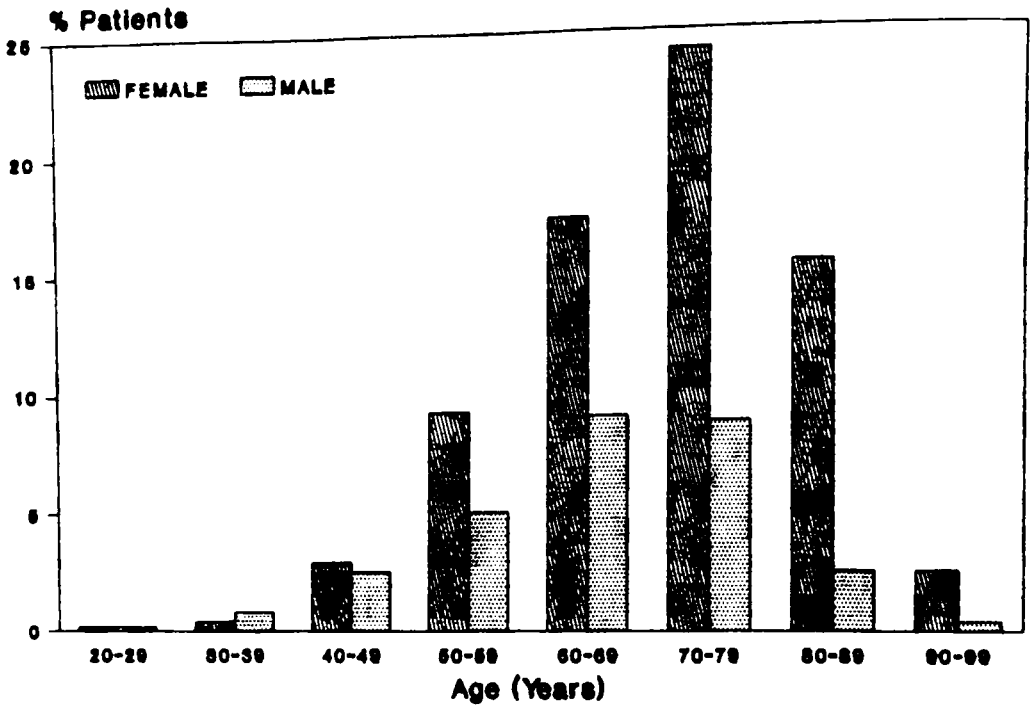


Figure 1.5 Age and sex distribution of leg ulcer patients (reproduced from Dale, 1984).

of the problem were carried out. A Swedish study conducted in Göteborg, based on medical records from 1980 to 1982 on leg and foot ulcers, estimated the prevalence to be about 0.3% (Hansson, 1988). A more limited Danish investigation (Christophersen, 1984) revealed that 24% of the in-patient capacity of dermatological departments were occupied by leg ulcer patients. Two other studies, one in Czechoslovakia (Bobek et al., 1966) and the other in Switzerland (Widmer et al., 1978) present a figure of 1% of the adult population, as suffering from leg ulcers. Across the Atlantic, the prevalence of leg ulcers or venous ulcers is unknown. It is thought that some 500 thousand adult Americans have or have had venous disorders (Coon et al., 1973; Dalen et al., 1986).

Between 1980 and 1982 the Forth Valley Ulcer Group carried out a postal survey in Southern Scotland comprising a mixed urban and rural population of about one million people. The objective of the survey was to identify all the patients receiving treatment for chronic leg ulceration from any branch of the National Health Service at that time (Dale et al., 1983; Dale, 1984; Callam et al., 1985). This is the most comprehensive study available to date on the prevalence of leg ulcers, including venous ulcers. The study also highlighted the difficulties encountered in obtaining accurate and reliable information, and has endeavoured to make the appropriate corrections.

Results from this study reveal that 1% of the adult population and 3.6% of those over sixty five years of age suffered from leg ulcers, of which 70% were venous ulcers. The survey also confirmed that leg ulcers of vascular origin increased in both incidence and prevalence with age (Figure 1.5), as was also shown in the Swedish study. Höhn et al. (1990) also reported increased prevalence as a result of reduction in the efficacy of venous function associated with ageing. Another revelation of the study was that females outnumbered males in the incidence of leg ulcers and this progressively increased with age (Figure 1.5). Obesity was observed in nearly half the patients and over three quarters of the overweight were females.

Mobility was a point of particular interest to this study and 45% of those suffering from ulcers had some limitation of activity while in 20% walking was reported as being difficult. Limitation of the ankle joint movement was found in 83%

of ulcerated legs compared with 57% of the unulcerated legs in the same group of patients (Dale, 1984).

Having established that the incidence of these ulcers was high, it was observed that the problem was further aggravated by the fact that healing was slow and recurrence common (Dale, 1984; Monk et al., 1982; Cherry et al., 1985). The Forth Valley study reveals that only 21% of ulcers healed within three months, 40% took more than a year, and 10% were open for more than five years. A few had never healed from onset. Recurrence was rife, two thirds of the patients had more than one episode and over a third of these had at least five episodes. The survey showed that only about one ulcer in ten was likely to heal and never recur. Meanwhile, approximately 100 limbs are amputated every year in the United Kingdom as a result of venous diseases (Browse et al., 1988).

1.4 THE COST IMPLICATIONS OF VENOUS ULCERS

The costs incurred in the treatment and caring for venous ulcer patients are immense. In Britain, a recent estimate of cost to the National Health Service provided at a Department of Health and Social Security Seminar (1989) on venous ulceration was £300 to £600 million per annum. Similar high costs of caring for venous ulcer patients have been reported in America. Wood and Margolis (1992) have estimated an average cost of $1951 (range $784 - $6449) for healing a single leg ulcer in the USA.

The primary cost of treatment, wound dressings, bandages, elastic stockings, drugs and sometimes surgery can, in itself, be very expensive. Furthermore, there are large underlying costs in diagnosis, equipment and evaluation, community nursing care, patient transport and rehabilitation (Sartain, 1985; Bloom, 1987).

Much of these costs are probably an inevitable aspect of health care but many in the profession (Moffatt, 1991; Sartain, 1985; Eagle, 1990) argue that some of the current practices in venous ulcer management are not cost effective. Moffatt (1991), claims that few Health Authority premises are ideal for ulcer treatment as they lack adequate space and resources. She advocates the setting up of Community leg ulcer clinics which offer the advantages of collective resources, expertise, in-house training and education, and an atmosphere that is caring and warm. The latter is particularly

important as links between social isolation and recurrence of ulcers have been previously established (Wise, 1986). These clinics run by community nurses would alleviate bed shortage problems at hospitals, economise the community nursing time and would have a better opportunity of providing an informed quality of care which in the long run may help arrest the costly problem of recurring ulcers. These community leg ulcer clinics offer a viable alternative to the current practice of treating venous ulcers in the community and in hospitals both of which are reported to be costly (Dale, 1984; Eagle, 1990; Sartain, 1985).

Sartain (1985) relates unnecessary expenditures to poorly informed selection of treatment material and the lack of skills in applying compression therapy which contributes to low healing rates and recurrence. Often patients wash their bandages in a commendable effort to economise. Dale (1984) and Sartain (1985) both question this practice as it has been shown in some instances to reduce the functional properties of the bandages (Callam et al., 1983) and this may lead to higher cost implications in the longer term. Eagle (1990) compared and contrasted the different regimes in the nursing of venous ulcers, and highlighted the role of the model nurse in being cost effective.

The lack of proper comprehensive standardization of materials used in venous ulcer treatment, the scarcity of documentation on the performance characteristics of compression bandages and stockings collectively, the limitations of the Drug Tariff and the difficulties in estimating and comparing unit costs of each item, are all considered as contributory factors to the high cost of treatment (David, 1990; Dunford, 1989; Eagle, 1990; Sartain, 1985; Dale, 1990; Corbett, 1988).

Demographic changes indicate that by the year 2000 there will be a 43% increase in the number of people aged over 85 years, many of whom will suffer from ulcers, thus further increasing the demand for treatment (Bosanquet, 1989). With the current restructuring of the National Health Service it may be necessary for enterprising managers to reconsider the limitations and cost implications of the existing framework within which ulcers are cared for in Britian, and possibly the European Community from 1992 onwards.

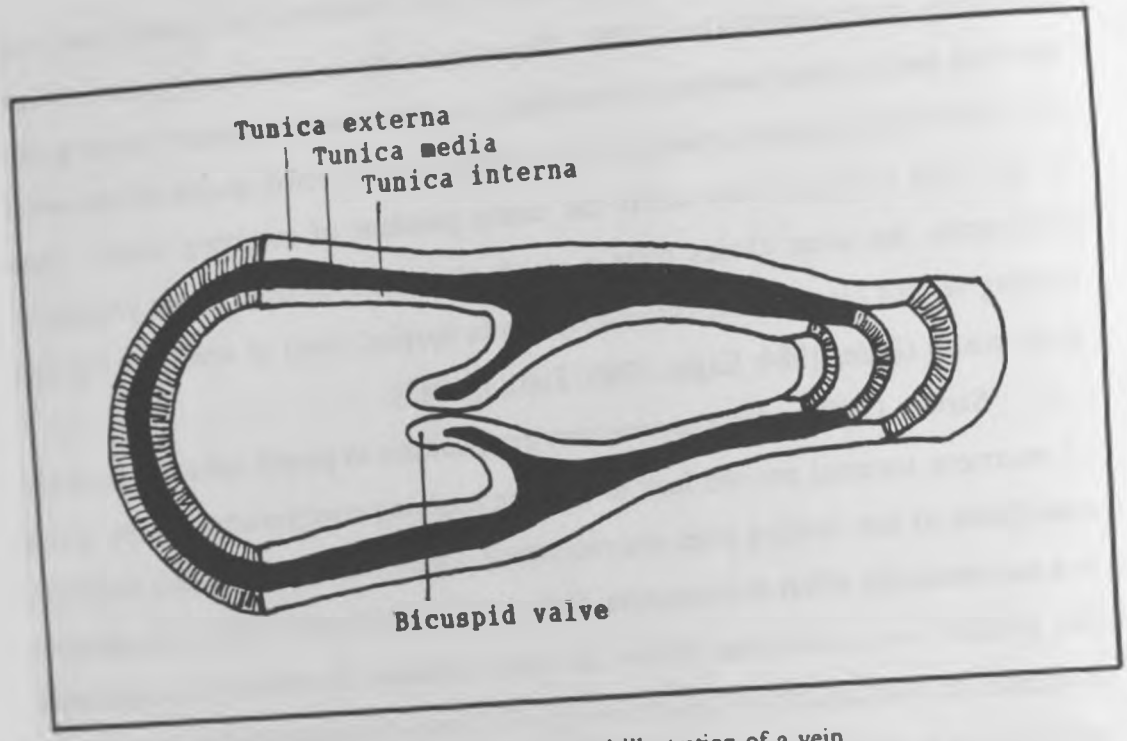


Figure 1.6 Cross-sectional illustration of a vein.

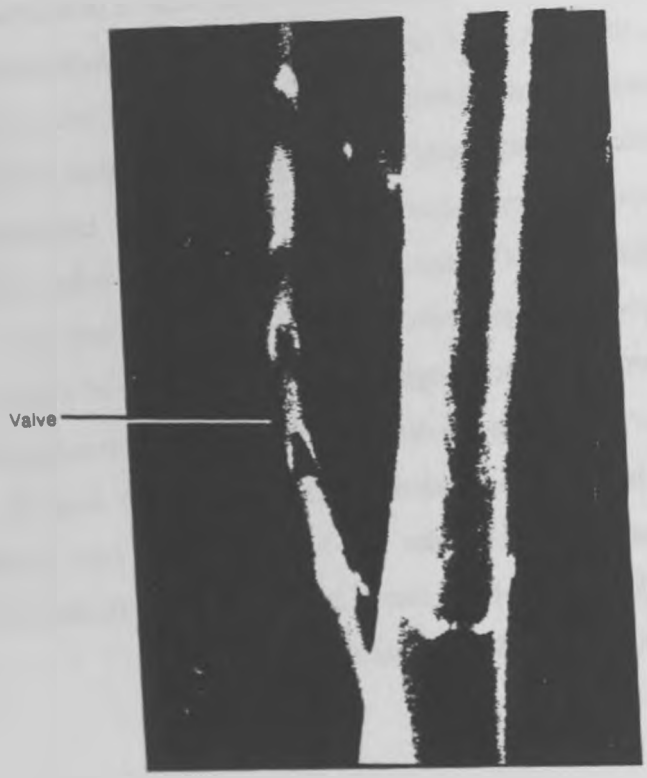


Figure 1.7 A one-way bicuspid venous valve.

1.5 VENOUS ANATOMY AND PHYSIOLOGY

1.5.1 Venous Anatomy of the Lower Limb

The human body contains a network of blood vessels, the vessels of the arterial system carrying blood from the heart to tissues of the body and the vessels of the venous system returning blood to the heart. It is through this network that blood transports oxygen, nutrients, hormones, enzymes, carbon dioxide and wastes in the body (Tortora and Anagnostakos, 1984).

The venous system comprises vessels called venules and veins. Venules are small vessels that continue from the capillaries in the tissues and progressively merge into larger vessels, the veins. The anatomical structure of these vessels consists basically of three coats which make up its wall. The inner coat, called the tunica interna is composed of endothelium; the middle coat, tunica media is composed of elastic fibres, smooth muscles and white fibrous tissue; the outer coat, tunica externa is composed of connective tissue. The venules closest to the capillaries consist of only two coats, tunica interna and tunica externa. A structural illustration of these coats are shown in figure 1.6. These vessels are capable of distension and are functionally adapted to cope with variations in volume and pressure of blood passing through them although, they are not quite as elastic and muscular as arterial vessels.

Blood that leaves the capillaries and enters the veins has lost much of its pressure, and flows sluggishly. Further, as flow is directed against the force of gravity, there is a risk that backflow of blood may occur, especially in the limbs. However, the anatomical structure of the veins incorporates one-way bicuspid valves which ensure unidirectional flow of blood towards the heart (Figure 1.7).

The venous system of the lower limb comprises essentially three categories of veins, the deep, the superficial and the communicating veins. The femoral vein, the popliteal vein and the tibial vein, collectively make up the deep veins. These veins are surrounded and supported by muscle and lie within the tough muscle sheath, the deep fascia. The deep veins carry around 90% of the venous return. The long and short saphenous veins are known as the superficial veins, and lie outwith the fascia. Shorter veins, called communicating veins connect the superficial and the deep venous systems. They perforate the deep fascia at various points and are sometimes referred to as perforating veins. They are greatest in number at the

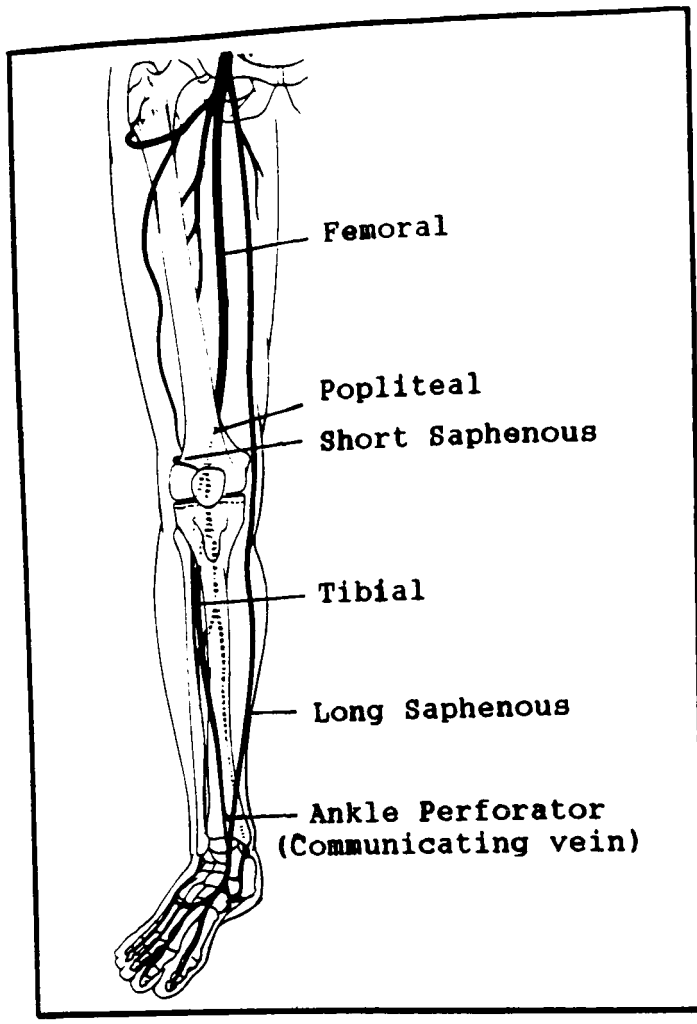


Figure 1.8 Venous system of the lower limb.

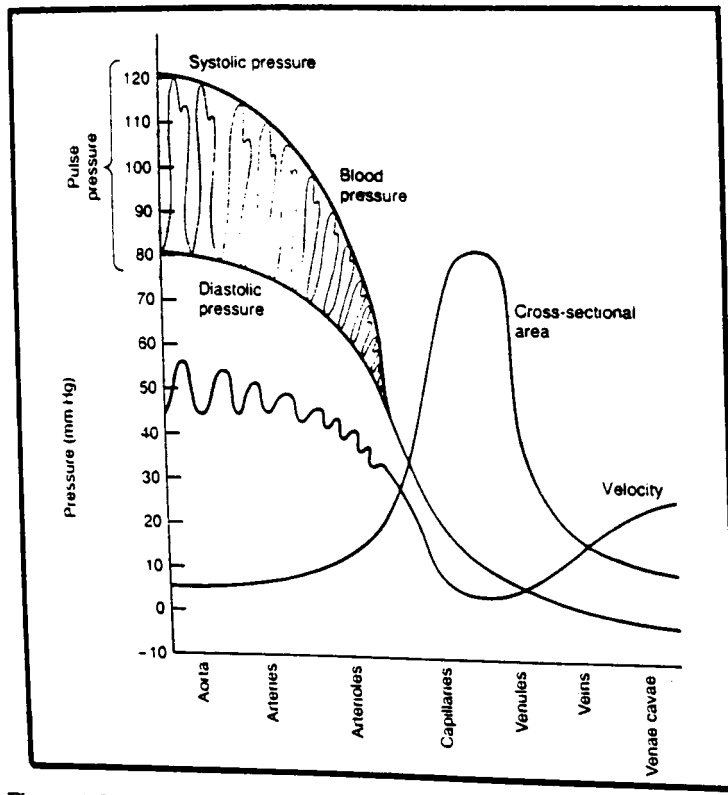


Figure 1.9 Blood pressure (from Tortora and Anagnostoko, 1984).

posterior edge of the tibia above the ankle and also occur above and below the knee (Figure 1.8). All three categories of veins contribute in returning venous blood from the lower limb to the heart (Gray, 1973).

1.5.2 The Physiology of Venous Blood Flow

Blood flows through the closed circulatory system of vessels as a result of pressure gradients within it. Blood is pumped out of the heart through the aorta with a mean pressure of 100mmHg (13.3kPa) and by the time it reaches the capillaries the pressure has dropped to between 25 and 12 mmHg (3.3-1.6kPa). Blood enters the venous system with pressures between 12 and 8 mmHg (1.6-1kPa) in the venules and the pressure further drops to between 10 and 5 mmHg (1.3-0.7kPa) in the veins before returning to the right atrium of the heart (Figure 1.9).

In the venous system where blood pressure is lower, there are other mechanisms which enhance venous return. The exact level to which some of these mechanisms contribute to venous return in the lower limb is still controversial (Gardner and Fox, 1986).

One established means of improving venous return is based on the anatomical structure of the vessels. The velocity of blood flow is inversely related to the cross-sectional area of the vessel. Thus, as blood vessels leave the capillaries and approach the heart, their total cross-sectional area decreases. As a result, the velocity of blood increases as it flows from the capillaries to venules, and to veins (Tortora and Anagnostakos, 1984).

Breathing is an important factor in maintaining venous circulation. During inspiration the diaphragm moves downward. This causes a decrease in pressure in the chest cavity and an increase in pressure in the abdominal cavity. Once the pressure difference is established, blood is squeezed from the abdominal veins into the thoracic veins. When the pressure is reversed during expiration, backflow of blood in the veins is prevented by the unidirectional mechanism of the valves (Gray, 1973).

First described by Harvey (1628) as the muscle pump, the combined complimentary action of skeletal muscle contraction and the venous valves offer a pump mechanism which assists venous return (Gray, 1973). This type of pump action is particularly important in the veins of the extremities such as the lower limb, where

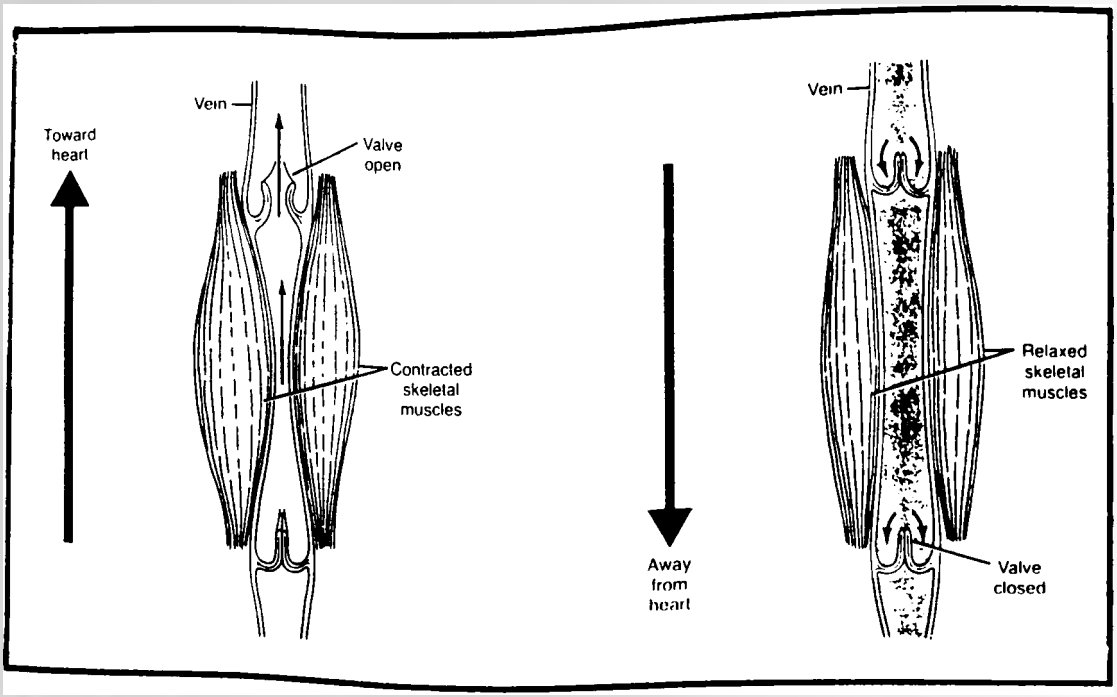


Figure 1.10 The calf pump and "milking" process (reproduced from Tortora and Anagnostakos, 1984).

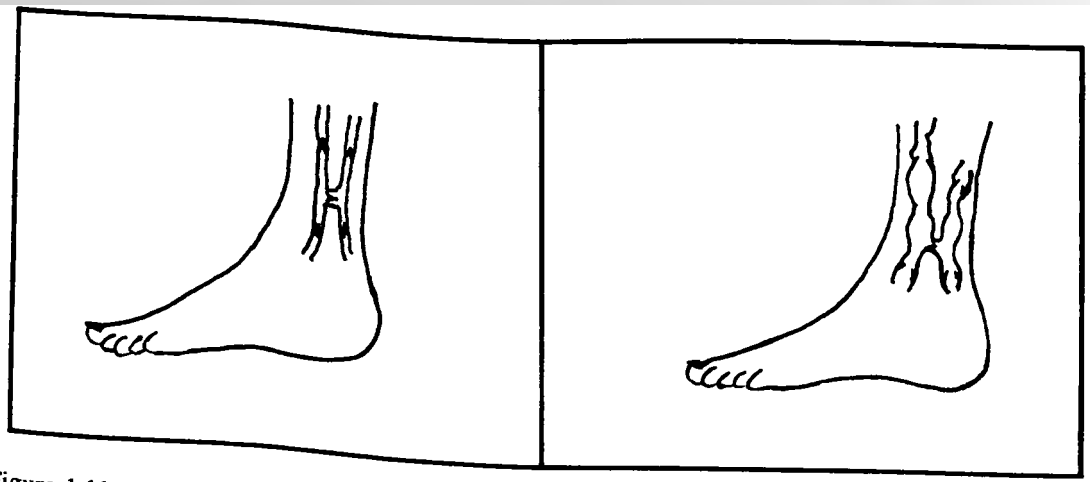


Figure 1.11 (a) Normal venous system (b) Distended veins, damaged valves and venous stasis.

it is frequently referred to as the calf pump. When the muscles in the lower limb contract, they tighten around the veins running through them and the valves open. The pressure derived from the contraction squeezes the blood in the direction of the heart. This process is called milking and is illustrated in figure 1.10. When the muscles relax, the valves close and prevent backflow of blood. Lewis et al. (1972) reported that the veins of the leg emptied at a much slower rate in patients under anaesthesia than those awake. They believe that this was because the leg muscles were relaxed under anaesthesia and the muscle pumps were not functional.

Another variation of the muscle pump is the venous pump in the foot, first suggested by Le Dentu in 1868. Later, Fegan (1967) and Bassi (1962) have described the foot pump mechanism in aiding venous return during walking. Fox and Gardner (1986) claim that the footpump improved venous return during weight-bearing. Their studies also showed that the footpump not only emptied the deep veins but also emptied through the long and short saphenous veins.

Van Der Molen et al. (1979), have described a different type of venous pumping system, the skin-tendon pump as a supplement to the muscle pump. This mechanism is based on the passive distention of the skin, in the supramalleolar region during contraction of the extensor muscles of the foot, thus enabling venous flow in the proximal direction.

There is a less powerful venous pump, first described by John Hunter (1794), resulting from the compressive action of the arterial pulse on the veins enclosed within the vascular bundles. Rose (1986) suggested that the tone of the venous vessel walls provided by the smooth muscles has a physiological function in assisting venous return.

It is clear that all these mechanisms depend on competent valves in the veins to aid venous flow in the right direction towards the heart. In people with weak venous valves, large quantities of blood are forced by gravity back down into the distal parts of the vein (Figure 1.11). Here the excessive pooling of blood, referred to as venous stasis, creates abnormally high pressures on the walls of the vein thus causing venous hypertension. Over longer periods, the walls of the veins become stretched and flabby, losing their elasticity. Veins damaged in this way are called varicose veins (Tortora and Anagnostakos, 1984). This condition can lead to further

Figure 1.12 Venographs showing damaged valves (a) and normal bicuspid valves (b) (reproduced from Browse et al., 1988).

complications such as deep venous thrombosis, lipodermatosclerosis and eventually venous ulceration (Burnand et al., 1982).

Venous insufficiency causing venous stasis and hypertension can be brought about by congenital or acquired incompetence of the venous vascular system. Congenital defects include absence of valves, connective tissue defects and arteriovenous aneurysm. Acquired incompetence may be secondary to lack of physical activity, increased abdominal pressures from a tumour or pregnancy, prolonged periods of standing, anaemia and deep venous thrombosis. The majority of leg ulcers are due to chronic venous stasis (Hill and Pogue, 1989).

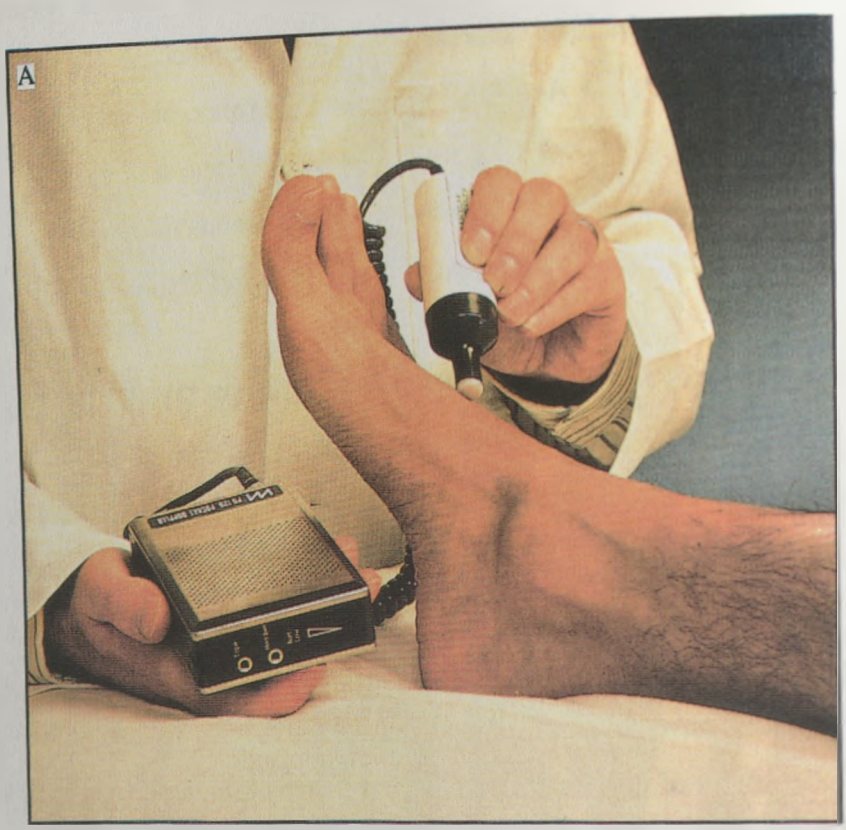
1.6 DIAGNOSTIC APPROACHES TO VENOUS DYSFUNCTION

The first measurement of venous pressure was carried out by the Reverend Stephen Hale in 1733, on conscious animals. Further progress in this area had to await developments in science and technology. From about the middle of the twentieth century there has been a keen interest in diagnostic tools and techniques for the qualitative and quantitative assessment of the haemodynamics of the human body. Several devices have been developed and are currently in use, some in routine clinical assessment of venous diseases while others are limited to research work only.

1.6.1 Venography (Phlebography)

Venography was the earliest technique used to define the state of veins (Berberich and Hirst, 1923) and has been the standard by which other diagnostic methods are assessed (Nicolaides, 1978). This technique offers direct visualization of the venous system and is often used to confirm the extent of deep vein obstruction and valvular damage. This valuable tool (Figure 1.12) is also used in locating the site of perforator veins and in assisting examinations prior to surgery or sclerotherapy.

The clarity of venography is enhanced by the use of image intensifiers or contrast medium such as meglumine diatrizoate. This type of venography is also known as ascending phlebography. The contrast medium is injected into a vein in the dorsum of the foot. Tourniques at the ankle and the knee may be used for preferential direction and visualization of the contrast material. Serial pictures are taken with



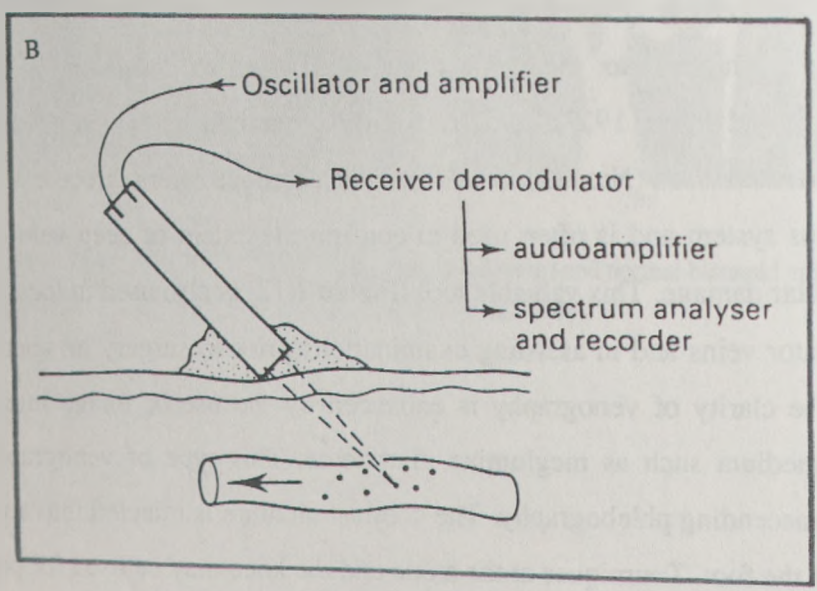


Figure 1.13 The Doppler ultrasound.

consecutive rotation and tilting of the table and patient to obtain a comprehensive view of the venous anatomy of the lower limb.

Although this is a valuable examination technique with no significant complications, it is an invasive procedure and only offers transitory images. However, based on the principles of venography, more advanced devices have evolved such as computerised digital radiography, which may become common place in the future.

1.6.2 The Doppler Ultrasound Flowmeter

The Doppler ultrasound flowmeter is extensively used for both clinical and research purposes (Figure 1.13a). It offers a noninvasive means of measuring the direction and velocity of blood flow. In experienced hands, this device is a valuable diagnostic tool and has been used to define patency and incompetence of deep veins, superficial veins (Barnes et al., 1975) and even the communicating veins (Folse and Alexander, 1970).

The Doppler ultrasound detector contains a crystal that directs an ultrasonic beam percutaneously to an underlying vein, where it is reflected by the cells of the blood. When blood in the vein is stationary, the frequency of the reflected beam is identical to that of the incident beam, however, when blood is moving in the vein, part of the reflected beam is at a changed frequency proportional to the velocity of blood flow. The difference in frequency is detected by a sound crystal in the probe and processed into useful information by the conditioning unit (Figure 1.13b).

In some clinics, a portable version of this device is use by community nurses to measure systolic blood pressure in the posterior tibialis artery near the medial malleolus. The ratio of this ankle systolic pressure and the brachial systolic pressure, known as the "ankle pressure index" is used in the early differential diagnosis of venous ulcers (Cornwall, 1985; Dale, 1986).

More recent versions of the Doppler ultrasound are the Duplex and Triplex scanners. These scanners combine the Doppler ultrasound with real-time (B-mode) and provide colour coded haemodynamic images (Corbett, 1988).

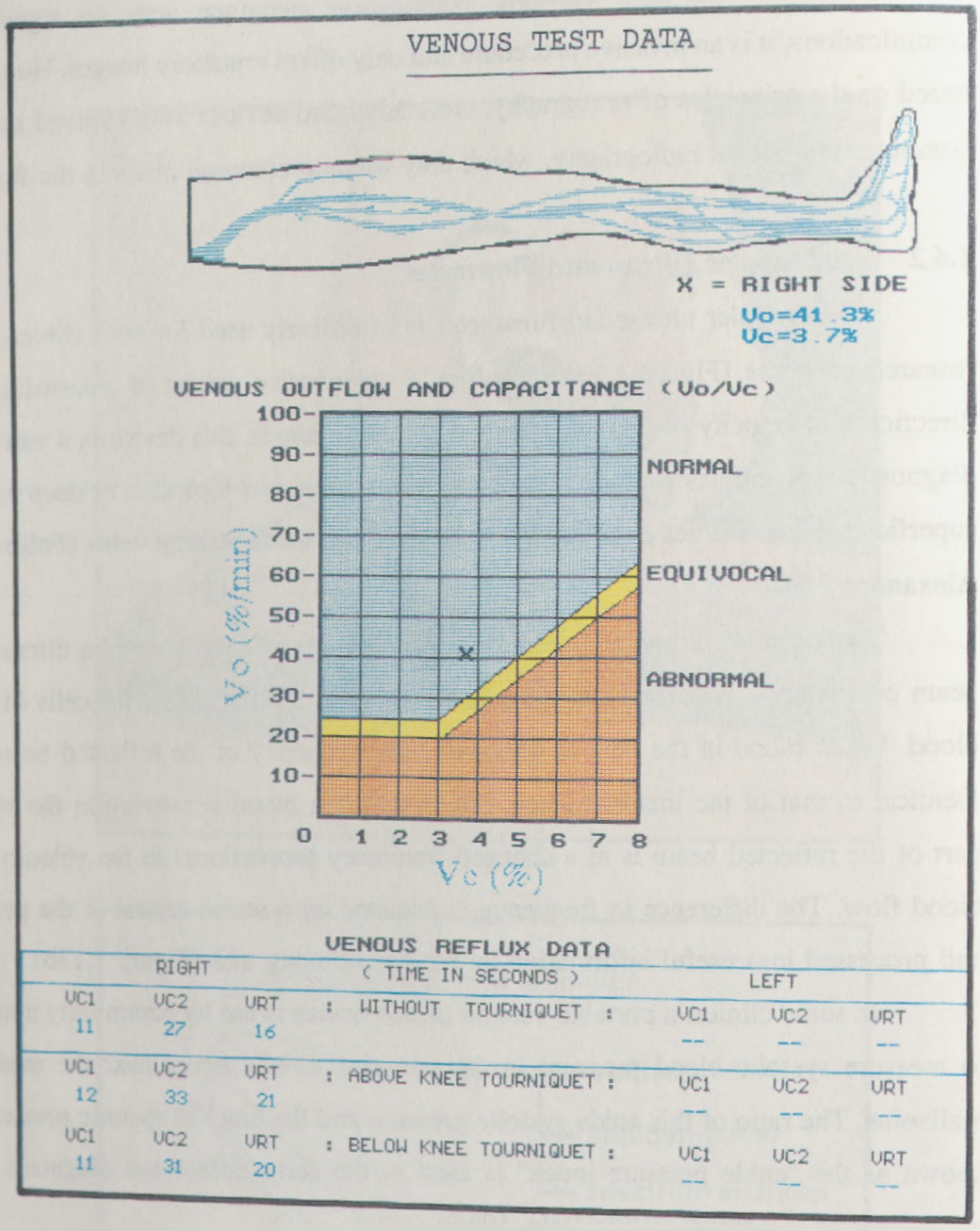


Figure 1.14 Specimen output from Photo-plethysmography

1.6.3 Plethysmography

Plethysmographic techniques are also widely used in research involving haemodynamics and venous incompetence. Plethysmography offers a noninvasive technique and it is relatively easy to use. There are several variations of this device; Air-plethysmography (Cranley et al., 1973), Water-plethysmography (Dahn and Eiriksson, 1968), Impedance-plethysmography (Wheeler et al., 1972), Strain gauge-plethysmography (Barnes et al., 1972) and Photo-plethysmography (Abramowitz et al., 1979).

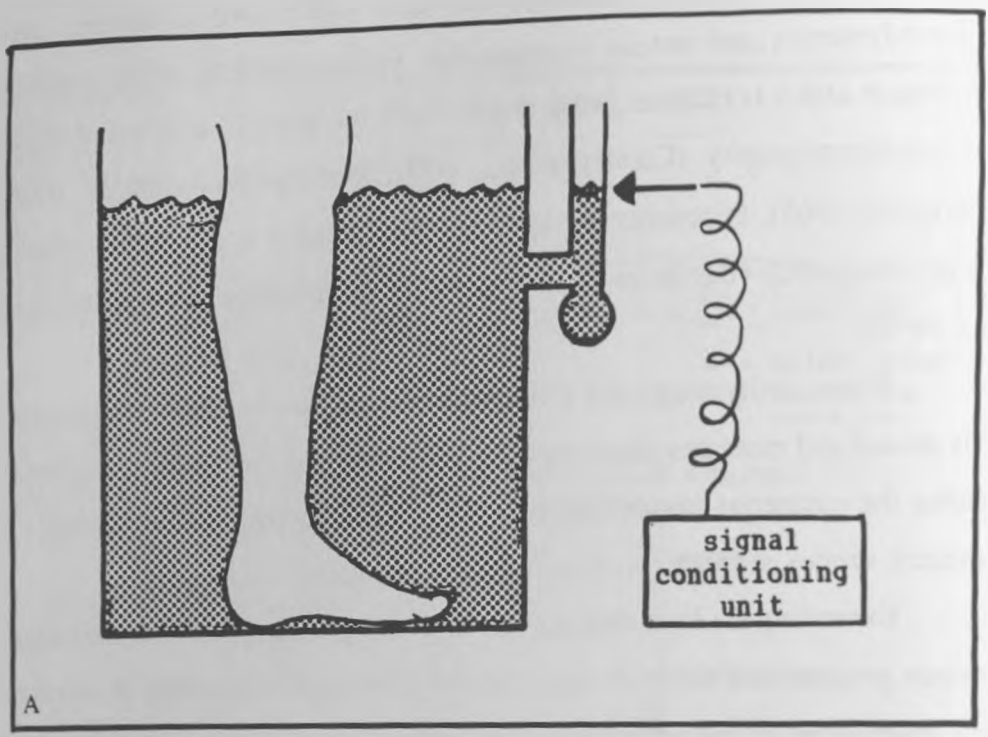
Photo-plethysmography (Figure 1.14) is the most extensively used version of this device and measures photoelectrically the degree of congestion of red blood cells within the cutaneous microcirculation. This is directly responsive to changes in the ambient venous pressure which can then be estimated.

Exercising the limb causes a fall in venous pressure, known as the ambulatory venous pressure and the time taken for this pressure level to return to normal is the key observation in this procedure. A full normal recovery time indicates satisfactory deep vein and valve function. A very short recovery time often indicates venous insufficiency. Improvement to the recovery time with temporary occlusion of the superficial vein under suspicion indicates the presence of superficial incompetence. If there is no improvement in the recovery time then it is possible that there is a deep vein dysfunction.

The technique is frequently used for assessing the performances of compression therapy devices, such as bandages and stockings used in the treatment of venous ulcers. However, this technique has a limitation in that it is difficult to place the probe on the skin without removing the bandage or stocking (Nicolaides, 1987). For this reason, other plethysmographic techniques such as the strain gauge version are sometimes preferred (McIrvine et al., 1986).

1.6.4 The Light Reflection Rheography

Shepard et al. (1984), described a technique of measuring venous emptying and refilling times using the light reflection rheography. This device consists of an electronic sensor head and a combined amplifier recorder. The sensor head contains three light-emitting diodes which transilluminate the skin to a depth of 0.5 to 1.5 mm.



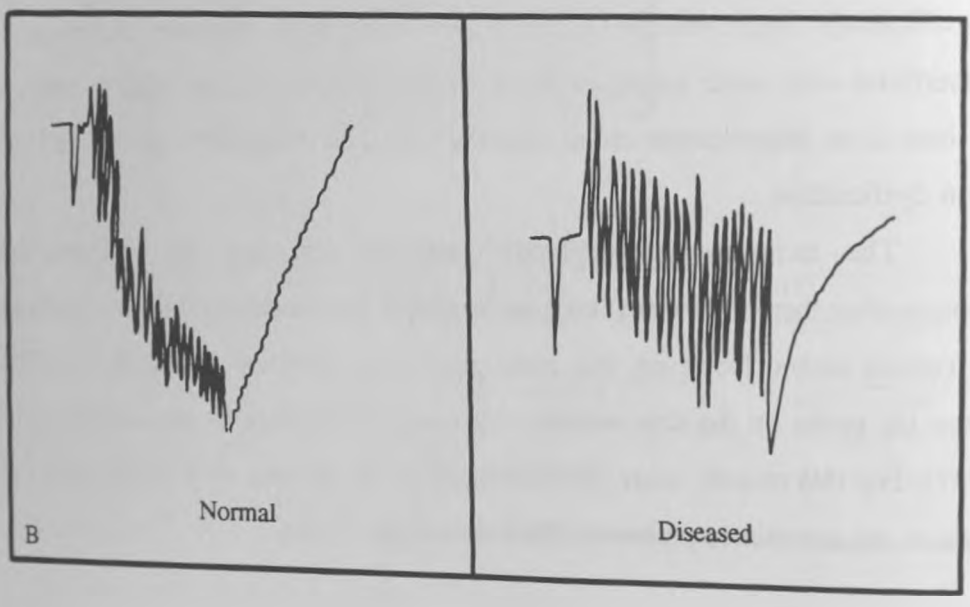


Figure 1.15 Foot volumetry

The light is either absorbed primarily by red blood cells within the dermal microcirculation or reflected back to the photodetector on the sensor. The intensity of reflected light is translated into an electrical signal which is recorded on a strip chart. The light reflection rheography curve thus provides a continuous display of dermal blood content. This technique is similar to photo-plethysmography but has the advantage of being able to quantify both venous emptying and venous refill times.

1.6.5 The Direct Cannulation Method

This is an invasive technique of measuring venous pressure directly, by cannulating the dorsal foot vein (Somerville et al., 1974; Hoare et al., 1981; Runchman and Rowland, 1986). Such measurements performed in the upright posture during exercise and at rest were used to investigate chronic venous insufficiency (Bjordal, 1973). The results of this method produced poor correlation between recorded vein pressures and the degree of chronic venous insufficiency (Lawrence and Kakkar, 1980). An explanation for this poor correlation was suggested by Stranden et al. (1986) who claimed that venous pressures should be measured not only at the foot but also at the calf.

1.6.6 Foot Volumetry

Foot Volumetry (Figure 1.15a) is a simple, non-invasive technique used in the assessment of superficial and deep venous competence (Thulesius et al., 1973). It has also been used for the evaluation of prophylactic devices, such as compression bandages and stockings (Gjöres and Thulesius, 1977; Pierson et al., 1983).

The method involves placing the foot in an open, temperature controlled, water bath, filled to a constant level. A photoelectric float sensor continuously registers changes in the level of water while the foot is placed in the bath and exercised. With exercise, blood is translocated from the dependent venous reservoirs of the foot up to the calf and thigh. Inferences on the state of the venous system can then be drawn based on the measurements of expelled volume (Norgren et al., 1974). Figure 1.15b depicts an example of a foot volumetry trace for a normal leg and a leg with venous insufficiency showing the reduction in expelled volume and rapid reflux

at the end of exercise. Gjöres and Thulesius (1977) claim that this is an easy and useful method of investigating venous flow.

1.6.7 Transcutaneous Oxygen Pressure ($TcPO_2$)

Non-invasive methods of measurement of transcutaneous oxygen pressure have been previously used to assess arterial insufficiency (White et al., 1982; Wyss et al., 1982). Partsch et al. (1984) have reported low transcutaneous oxygen pressure adjacent to venous ulcers. It was suggested that the low $TcPO_2$ values in venous diseases may reflect a barrier to oxygen diffusion from dermal pericapillary fibrin as previously demonstrated (Browse and Burnand, 1982). Thus, it has been suggested that these values may have prognostic significance (Nemeth et al., 1989). More recently, Falanga et al. (1991), have reported on an ongoing study for the usefulness of this approach in the prognosis and management of venous ulcers.

1.6.8 Radioactive Isotope Labelling

The use of ^{125}I-fibrinogen tracer in the investigation of venous thrombosis was discovered by Atkins and Hawkins (1965). This test is now relatively simple to perform and suitable for routine screening of a large number of patients. However, it is an invasive procedure and carries a small but definite risk of serum hepatitis.

Radioactive ^{125}I-fibrinogen is injected into the blood circulation and the rate of clearance is measured using a scintillation counter or a ratemeter. The information derived can then be used for investigation or diagnosis of venous related diseases and in the assessment of prophylatic devices (Sabri et al., 1971; Nicolaides et al., 1980).

Other tracer materials commonly used are Technetium-99, the inert gas Xenon-133 and Sodium-24. The choice of tracer material depends on the nature of the investigation.

There are numerous other diagnostic tools and techniques available, such as Thermography, Infra-red photography, Fluorescein testing, Computerized tomography, Magnetic resonance imaging and so on. It would be outwith the main context of this thesis to discuss these in detail.

1.7 THE PATHOGENESIS OF VENOUS ULCERS

The precise nature of the pathogenesis of lipodermatosclerosis leading to venous ulceration, still remains uncertain. Its association with venous disorders has been known for over 2000 years (Adams, 1949). It is now thought that venous insufficiency and hypertension are the primary factors which eventually lead to venous ulceration. The exact mechanism of the ulcerating process has been poorly understood and is open to much controversy. There are three main theories that attempt to offer an explanation to the underlying mechanism of venous ulceration (Browse et al., 1988).

1.7.1 The Underlying Mechanism of Venous Ulceration.

Homans (1917) was the first person to suggest that defective venous return from the lower limb caused by deep vein damage or varicose veins, could result in "venous stasis". His theory was that the resulting stagnant anoxia was responsible for the tissue death seen as cutaneous ulceration. This concept of stasis causing ulceration was widely accepted until measurements of oxygen content of the venous blood, capillary blood and tissues of ulcerated limbs were carried out. It was found that venous blood leaving an ulcerated limb had a high oxygen content and an increased flow (Blalock, 1929; Blumoff et al., 1977). However, venous stasis as a cause of ulceration has not been entirely discredited. Videomicroscopy has provided some evidence that there is local slowing of blood flow through the cutaneous capillary bed of the peri-ulcer skin compared to other areas of the limb (Bollinger et al., 1982).

Holling et al (1938) suggested that it was possible that a shunt of blood directly from the arterioles to the venules, largely avoiding the capillary bed might explain their findings of high oxygen levels in the venous blood of the ulcerated limbs. This lead to Pratt (1949) and Brewer (1950) suggesting that the arteriovenous communication beneath the skin resulted in the death of the overlying tissues by anaemic anoxia. This concept received support from a number of indirect observations (Brewer, 1950; Haimovici, 1966). However the validity of this theory is still treated with caution as direct evidence for the existence of these arteriovenous shunts is limited and its concept is open to criticism (Lindemayr et al., 1972; Gius, 1960; Hehne et al., 1974).

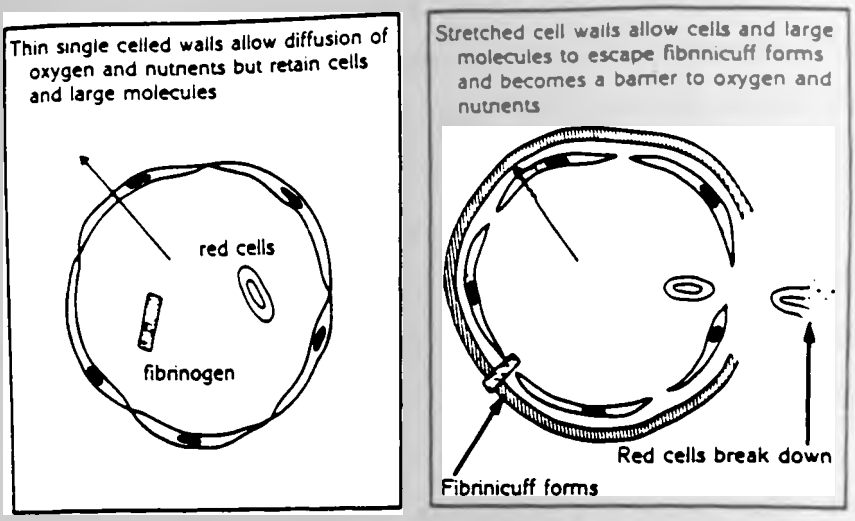


Figure 1.16 Fibrin cuff barrier to oxygen (reproduced from Dale and Gibson, 1986).

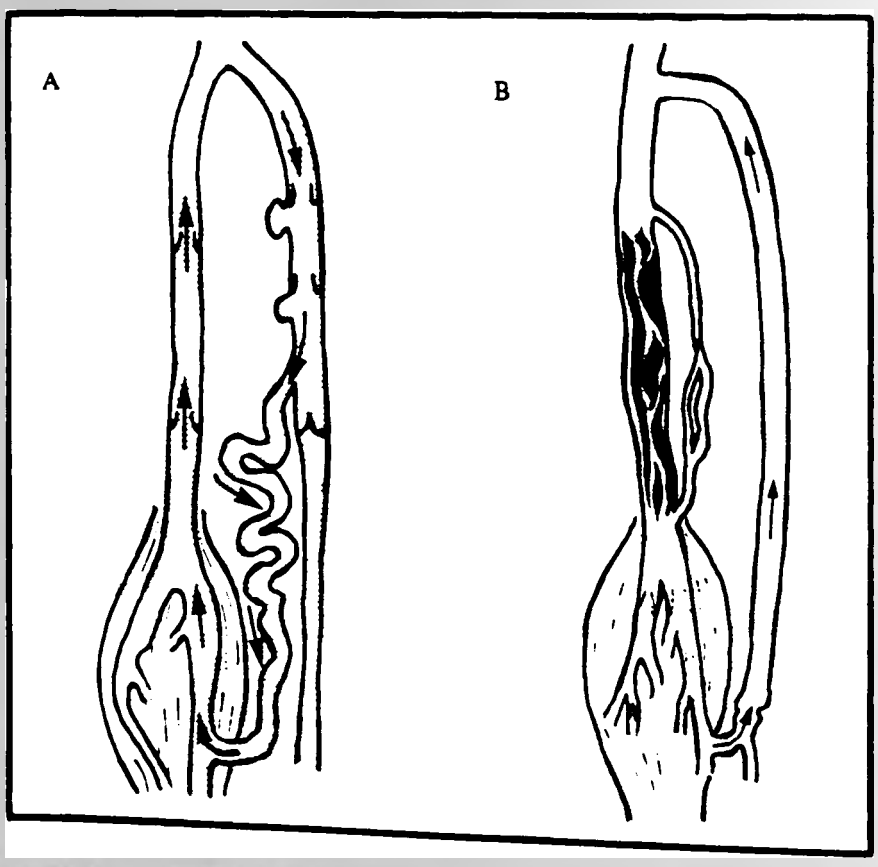


Figure 1.17 (a) Valvular incompetence and retrograde venous flow, (b) superficial collateral vein.

The third theory which has received much popular support was proposed by Browse and Burnand (1982). They suggested that chronic venous hypertension leads to leakage of fibrinogen from capillary venules into the perivascular interstitial space. This fibrinogen is then polymerized and deposited as a "cuff" of fibrin around the blood vessel. The fibrin cuff is believed to prevent diffusion of oxygen from affected vessels which leads to tissue necrosis and cell death (Figure 1.16). The high oxygen tension often found in venous blood of ulcerated limbs could be accounted for by this theory and has been supported by Falanga and Eaglstein (1986), Lotti et al. (1987) and Falanga et al. (1987). However, Cheatle et al. (1990) failed to yield evidence suggesting that an oxygen diffusion barrier existed in lipodermatosclerosis.

1.7.2 Secondary Causes of Venous Ulcers

There are a host of secondary disorders, abnormalities and acquired conditions that are predisposing factors to chronic venous insufficiency and hypertension. Often the problem is exacerbated as several of these conditions may present concurrently.

(i) Simple valvular incompetence of the superficial veins usually in the saphenous veins leads to retrograde flow causing stasis and hypertension (Figure 1.17a). The condition can be severe enough to overwhelm the venous muscle pump (Browse et al., 1988).

(ii) Patients with a history of deep vein thrombosis often present with impaired deep veins. In these patients the deep veins are deformed, occluded to varying degrees and usually have extensive valvular damage (Edwards and Edwards, 1937). As shown in figure 1.17b, sometimes the superficial veins act as collaterals in the upward flow of blood.

(iii) Communicating vein incompetence often as a result of valvular dysfunction leads to retrograde flow and disruption of the muscle pump, resulting in venous insufficiency (Lawrence and Kakkar, 1980).

(iv) An ineffective calf pump mechanism, which is central to venous blood flow, will result in venous insufficiency. This can be caused by muscular atrophy resulting from injury, disease or lack of physical activity, or a combination of the above factors (Browse et al., 1988)

(v) Obstruction of venous outflow caused by thrombosis leads to venous insufficiency (Sevitt, 1974).

(vi) Patients with reduced levels of blood and tissue fibrinolytic activity have been shown to be predisposed to thrombosis and varicose veins, and consequently venous dysfunction (Clayton et al., 1976; Pandolfi et al., 1969).

(vii) Congenital venous abnormalities such as absence of valves (valveless syndrome), connective tissue defects affecting collagen and elastin fibres, and arteriovenous aneurysm are predisposing factors to poor venous function (Plate et al., 1983).

(viii) Ageing has been associated with reduced efficiency of venous function (Höhn et al., 1990) and this has been supported by prevalence surveys (Dale, 1984).

(ix) Acquired conditions resulting in venous insufficiency may be secondary to lack of physical activity, obesity, prolonged standing or sitting, prolonged wearing of constrictive clothing and high heeled shoes, abdominal pressures from a tumour or during pregnancy (Demis, 1986; Jacques, 1987) and poor nutrition (Cheatle et al., 1991).

These theories and predisposing factors based on clinical and experimental evidence provide some clues to the pathogenesis of venous ulcers. Unfortunately, as Burnand and Browse (1988) have commented, the mechanism by which the cutaneuos changes of lipodermatosclerosis and ulceration develop in response to prolonged venous hypertension remains open to speculation.

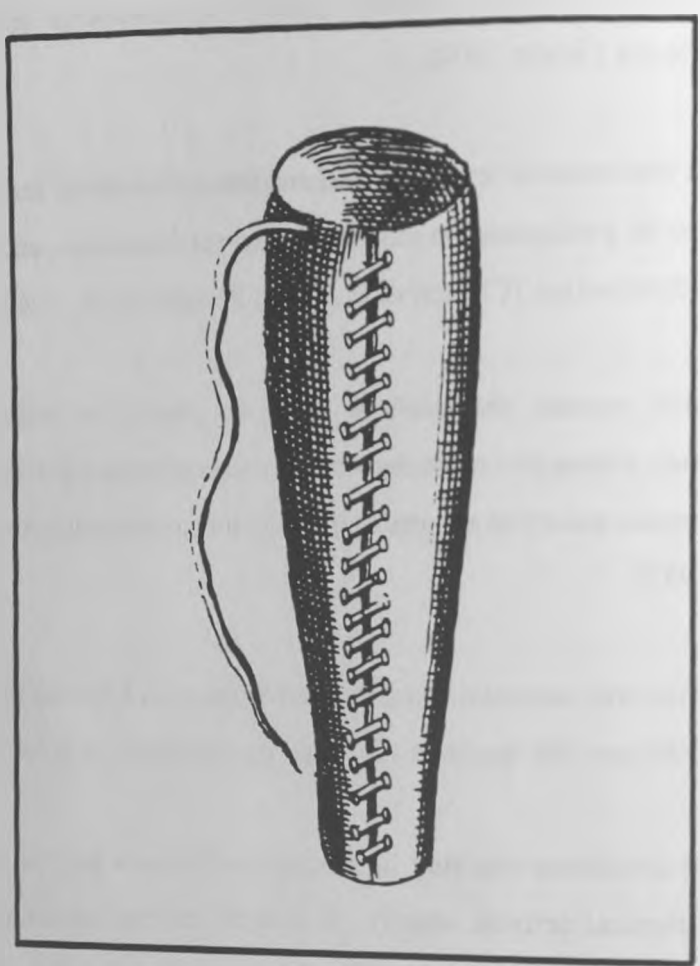


Figure 1.18 Wiseman's laced leather stocking (reproduced from Browse et al., 1988).

1.8 THERAPEUTIC MANAGEMENTS OF VENOUS ULCERS

The treatment of venous ulcers has posed such a great challenge that numerous forms of treatment have evolved with mixed results. The use of compression therapy to treat venous ulcers was first recognised by Hippocrates, although his objective was to let out the "evil humours" (Majno, 1975). Compression therapy and leg elevation are still, by far, the most widely used forms of treatment, despite advances in medicine and surgery. The present day management of venous ulcers relies to a large extent on conservative methods which are non-invasive and most successful, although the results of treatment can be varied. Other categories of treatment include invasive techniques and therapies that focus on local aspects of the ulceration.

1.8.1 Conservative Therapies

(i) Compression Therapy

Graduated external compression applied to the lower limb can be of therapeutic benefit in treating venous ulcers. The compression is achieved by the use of devices such as bandages, elastic stockings and inflatable pneumatic leggings. The therapeutic value of compression bandages and stockings has been recognized since very early times. The Indians used cloth bandages to treat venous ulcers in 200 BC. Later, Celsus described the use of plasters and linen roller bandages in 25 AD. The first alternative means of compression in the form of a laced leather stocking was introduced by Wiseman in 1676 and was the forerunner of the modern elastic stocking (Figure 1.18).

Compression therapy is the most acceptable and probably the most effective means of treatment currently available (Cherry, 1992; Dale, 1990; Myers et al., 1972; Lewis et al., 1976). The external compression provided by bandages and elastic stockings give support to the tissues and superficial veins of the lower leg, control oedema and venous hypertension, and assist in improving venous return. Elastic stockings are also widely used along with other modes of treatment and are particularly favoured in post healing therapy (Stacey et al., 1988).

(ii) Bedrest with Leg Elevation

Like compression therapy, the benefits of bedrest with leg elevation were recognised during the time of Hippocrates who stated that "in the case of an ulcer it is not expedient to stand, more especially if the ulcer be situated in the leg". Bedrest with leg elevation is now an integral part of the routine management of venous ulcers. It is also regarded as an essential preliminary to non conservative regimes of treatment (Dodd and Cockett, 1976). Browse et al. (1988) whilst echoing the opinions of numerous clinicians claimed that a period of bed rest with leg elevation was beneficial for ulcer healing. Prolonged in-patient treatment with bedrest may, however, have social and economic disadvantages (Cottonot et al., 1979).

1.8.2 Invasive Techniques

(i) Surgical Techniques

Surgical ligation and reconstruction have been more frequently used in recent times to improve calf pump function, in an attempt to address the underlying causes of venous insufficiency. Ligation is usually performed on the incompetent communicating veins of the lower limb and incompetent superficial veins are either ligated or removed (Linton, 1948). Surgical reconstruction is used in rectifying valvular damage and to bypass damaged deep veins (Husni, 1971; Raju, 1983). Both ligation and surgical reconstruction are generally advocated only after the ulcers have healed by conservative methods of treatment. The success of these approaches in improving ulcer healing or in preventing recurrence is difficult to assess and requires further evaluation (Ackroyd and Browse, 1986). There may be a place for these corrective procedures in the prevention of ulcer recurrence but they do not as yet have a role in accelerating ulcer healing (Browse et al., 1988).

(ii) Skin Grafting

The option of skin grafting is often only used after conservative methods have failed to heal the venous ulcer. There are several techniques of skin grafting frequently advocated, however, the two most widely used techniques are, the Split skin graft or the Thiersch graft (Negus and Friedgood, 1983) and the Pinch graft (Monk and Sarkany, 1982). Both techniques involve removing sections of healthy

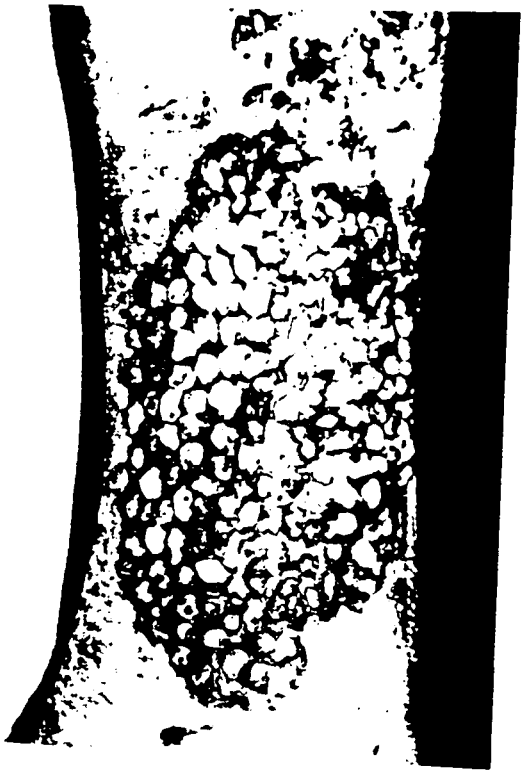


Figure 1.19 Ulcer covered with pinch grafts (reproduced from Browse et al., 1988).

skin, usually from the thigh, which are then applied onto the ulcer bed. In the split graft technique, larger sections of healthy skin are cut to the shape of the ulcer or sometimes into small squares (postage stamps) which are then applied to the ulcer bed. This is usually done under general anaesthetic. In the pinch graft technique, one centimetre discs of healthy skin are closely placed to cover the whole ulcer (Figure 1.19). There are mixed reports on the success of skin grafting. Monk and Sarkany (1982) found that 80% of ulcers, treated by the pinch graft technique, recurred within one year.

(iii) Systemic Medication

The use of systemic drugs in the treatment of venous ulcers has been of little benefit and until very recently, of minor importance (Cheatle, 1991). With progress in the understanding of the pathological mechanisms of ulceration, more rational pharmacotherapeutic methods may become common place in the future. Some of the medicaments that have been tried include, zinc supplements, fibrinolytic enhancing agents, vasodilators, diuretics and systemic antibiotics (Browse et al., 1988).

1.8.3 Local Ulcer Treatments

(i) Topical Medication

An assortment of topical medications is available and is often used in conjunction with conservative methods of treatment, in an attempt to improve the healing of venous ulcers. These drugs can be broadly categorised into antiseptics, antibiotics and cleansing agents.

Antiseptics have been shown to have harmful effects on the ulcer micro-environment in animal experiments (Niedner and Schöpf, 1886). Osmundsen (1982) has reported that antiseptics have never been shown to promote venous ulcer healing and can cause allergic skin reactions.

Several antibiotics have been applied to the surface of ulcers but there is little justification for their use because there are few controlled trials which show that they are beneficial. Bacterial resistance and skin sensitivity reactions are real risks. Browse et al. (1988) and Hansson (1988) have recommended that topical antibiotics should be abandoned as a mode of treatment for venous ulceration. Some topical antibiotics,

such as neomycin and gramicidin (Graneodin - Squibb) and silver sulphadiazine (Flamazine - Smith and Nephew) have, at best, received anecdotal support in the treatment of ulcers.

Possibly the most encouraging of the topical applications are the cleansing agents. These substances are mainly chemicals or naturally derived enzymes that are proteolytic or fibrinolytic. Although these agents have not been shown to accelerate ulcer healing, their contribution to ulcer cleansing has been notable (Morrison, 1979 and Coopwood, 1976). These preparations have a place in the use of desloughing dirty ulcers, particularly when surgical cleansing cannot be tolerated because of pain.

(ii) Ulcer Dressing

Although the treatment of the underlying causes of venous ulcers is paramount, the local management of the ulcers should not be disregarded. According to Scales (1963) and Turner (1985), an ideal local dressing for ulcers should protect the wound, absorb wound exudate, remove bacteria, allow some fluid evaporation (in order to allow concentration of the exudate, which retards bacterial growth), offer thermal insulation, be impermeable to bacteria and should be easy to remove without destroying the new epithelium.

A wide variety of dressings are now available and the main types include, absorbent dressings, impregnated dressings, absorbent and occlusive or semi occlusive dressings, and impregnated bandages. Absorbent dressings made from linen, cotton wool, open weaved gauze (often moistened with saline), melolin and gamgee pads serve to absorb ulcer exudate. Impregnated dressings are made of gauze coated with vaseline and often with an antibacterial agent. This is a popular form of dressing although there are doubts about the use of antibacterial agents (Browse et al., 1988). The semi-occlusive and occlusive dressings may include, hydrogels, foams, polyurethane films and hydrocolloids which offer varying degrees of permeability and absorption. The majority of these dressings have been developed recently and there has been no large scale clinical trials conducted to evaluate their performance. However, the introduction of the occlusive hydrocolloid dressing (Granuflex) has been shown to have made a significant contribution to the process of wound healing (Alvarez et al., 1983; Cherry and Ryan, 1985). Impregnated bandages with

medicament have been a very popular form of ulcer dressing (Kikta et al., 1988). Its forerunner was the famous "Unna Boot" (Unna, 1854). There has been much doubt about the actual benefits of the medicament which can often cause sensitivity reactions, although many have reported reasonable success in treating venous ulcers (Munro-Ashman and Wells, 1968). It is the belief of some that, impregnated bandages work because they set into a semi-hard cast which acts as an effective form of external compression.

1.8.4 Other Miscellaneous forms of Treatment

In an attempt to find an alternative, successful, method of treatment, many less effective techniques were experimented with. Even herbal remedies have been tried in desperation (Dale, 1985). Some of the lesser known treatments include the use of hyperbaric oxygen (Bass, 1970; Zelikovski et al., 1985), lumbar sympathectomy (Patman, 1982), pulsing electromagnetic fields (Cadossi, 1991) and electrical stimulation (Doran and White, 1967). None of these methods has been widely accepted and the success of these treatments has been dubious.

1.9 THE LYMPHATIC SYSTEM

A review of venous physiology is not complete without reference to the lymphatic system which functions alongside the venous system. It is made up of the lymphatic vessels, lymph nodes, lymph organs and lymph (fluid within the vessels). The fine network of lymphatic vessels are responsible primarily for the drainage of excess interstitial fluid that is not returned to the blood at the capillaries.

Lymph within the lymphatic circulation flows as a result of skeletal muscle contractions and respiratory movement, aided by valves in the vessels similar to mechanisms associated with venous flow. Lymphatic drainage when disrupted leads to lymphoedema and a host of ailments as a consequence.

Conservative treatment of peripheral lymphoedema is similar to that of venous oedema. As such, elevation of the oedematous leg, external compression and exercise are the normal modes of treatment (Yamazaki et al., 1988).

CHAPTER 2

PROGRESS IN COMPRESSION THERAPY

2.1 Compression Devices used on the Lower Limb

2.2 Principles of Compression Therapy

2.3 Evaluation and Classification of Compression Devices

2.4 The Art of Applying Compression Devices

2.5 The Hazards of Compression Therapy

Figure 2.1 Inflatable pneumatic legging

2 PROGRESS IN COMPRESSION THERAPY

Compression therapy refers to the deliberate application of graduated compression on the lower limb with the aim to produce a desirable clinical effect (Thomas, 1990). The use of compression is a well established modality for the treatment and management of venous ulcers, oedema, venous hypertension, varicose veins, lymphoedema, amputee-stumps, hypertrophic scars, and for the prevention of deep vein thrombosis. External compression applied on the skin surface of the leg, is usually achieved by the use of elasticated stockings or bandages. Little is known of the nature of pressures generated by the very early devices. Richard Wiseman, in 1676, had shaped his laced leather stocking narrower at the ankle and wider at the calf but it is not clear if it was designed to produce graduated compression.

It was Sigg (1963) who formally introduced the idea of graduated compression, with highest pressures at the ankle decreasing progressively towards the knee or thigh. It is becoming increasingly obvious that graduated compression has beneficial effects in improving venous return and may play a significant role in the healing process of venous ulcers (Backhouse et al., 1987; Dale and Gibson, 1990). The exact magnitude of pressure required for the treatment of venous disorders still remains uncertain. Reports on optimal pressures necessary at the ankle for healing venous ulcers, range from 18mmHg (Sigel et al., 1975) to 40mmHg (Blair et al., 1988). Even higher pressures (40-60mmHg) are frequently quoted as suitable, in many European countries (Partsch, 1984). In the United Kingdom, the present consensus is that a pressure of about 30 to 40mmHg at the ankle with a gradual reduction to about 15 to 20mmHg at the calf, is adequate for the treatment of venous ulcers (Dale, 1990).

2.1 COMPRESSION DEVICES USED ON THE LOWER LIMB

Compression devices used on the lower limb to treat venous disorders fall into three main categories, bandages, elastic stockings and inflatable pneumatic leggings. There are many versions of the inflatable pneumatic leggings (Figure 2.1) most of which provide graduated, rhythmic, external compression and encourage venous blood flow. These devices are not readily portable and cab be expensive, and consequently are not suitable for regular use in the treatment of venous ulcers. However, pneumatic

devices have a place in the prevention of deep venous thrombosis and are used in both pre and post operative treatment regimes (Rithalia, 1991). The use of bandages and elastic stockings in the treatment of venous ulcers is equally widespread, although there may be preferential variation between the two devices from one medical practitioner to another. Elastic stockings which are easier to apply, are generally prescribed for patients whose ulcers have healed and who are capable of applying the devices themselves.

2.1.1 Bandages

Most bandages are manufactured from large pieces of fabric which are cut to finished widths, although a few are made directly to standard widths. Typical bandages measure between 7.5 and 15 cm in width and come packed in rolls of varying lengths. The fabric of a bandage is either woven or warp knitted and is often coloured in shades of brown, simulating skin. Bandages can be categorised as extensible, crepe and inextensible according to their fabric content and ability to stretch.

The majority of modern day bandages are extensible and stretch to varying degrees. The compression generated by these bandages is provided by elastomeric threads which run along the length of the bandage. These elastomeric threads are made of either elastadiene (natural rubber) or elastane (polyurethane such as lycra). Extensible bandages are knitted or woven whilst the fabric is in a fully stretched state, hence the extension of the bandage is actually developed as a result of contraction after manufacture. The magnitude of compression exerted by these bandages depends on the type of elastomeric yarn, the thread thickness (gauge or decitex), the density of elastic threads in the fabric (number of threads per cm) and the extension (draft) of the elastomer in the extended fabric. By varying these parameters, a large selection of bandages with different compressional capabilities is available, each designed to suit a particular regime of treatment (Thomas et al., 1986). In most instances, the elastic yarns have a covering consisting of two spirals of inelastic textile yarn (either polyamide or cotton) in opposite directions around the stretched elastomeric core. This covering facilitates the knitting and weaving process, prevents thread slippage and provides protection to the elastic core from perspiration

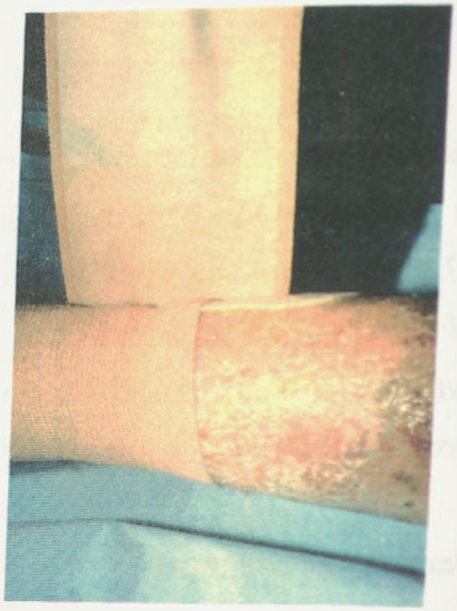


Figure 2.2 An adhesive hydrocolloid compression bandage

and laundering (Reicher, 1990). Recent attempts to overcome the common problem of slippage in bandages during use have resulted in the development of adhesive, semi-adhesive and cohesive types of bandages. The adhesive bandages have a sticky inner surface which helps the bandage to remain in place. Some bandages have partial adhesive surfaces such as Lestreflex (Seton, UK), which has strips of tack on its inner surface. Cohesive bandages like Coban Wrap (3M, USA) have the advantage in that it only adheres to itself and not to the skin or hair. A further advancement in bandage design was made with the introduction of hydrocolloid coated adhesive bandages. Figure 2.2 illustrates the Granuflex bandage (ConvaTec, UK), incorporating an adhesive hydrocolloid inner surface which dresses the ulcer and surrounding skin whilst applying compression.

Another type of extensible bandages which have been used frequently in the past, for the treatment of venous ulcers are crêpe bandages. These bandages like Elastocrêpe (Smith and Nephew, UK) do not contain elastomeric threads, instead their elasticity is generated by highly twisted crêpe warp yarns (Reicher, 1990). The crêpe fabric is usually made of crimped cotton, wool or rayon threads. It is now known that these bandages do not sustain prolonged compression and their recommended use is limited to providing light support in the treatment of cramps, pains and mild joint injuries (Thomas, 1980).

Circular support or tubular bandages such as Tubigrip (Seton, UK) have been frequently used in the treatment of venous disorders (Makin, 1969). These devices are referred to as bandages although they bear much resemblance to footless hosieries. They can be tubular or leg shaped, with the elastic yarns running circumferentially in the knitted fabric. Circular support bandages are available in a range of circumferential sizes and the levels of pressure generated by these bandages are dependent on the size and number of layers applied (Thomas, 1980). For patients with an open ulcer, different sizes and number of layers are used to produce a gradual build up compression to ease the initial pain. However, some controversy exists regarding the pressure gradients produced by tubular bandages and its benefits to ulcer healing (Cornwall, 1991 and 1987).

Until recently, the most common type of bandage used in the United Kingdom for treatment of venous ulcers was inextensible bandages, impregnated with

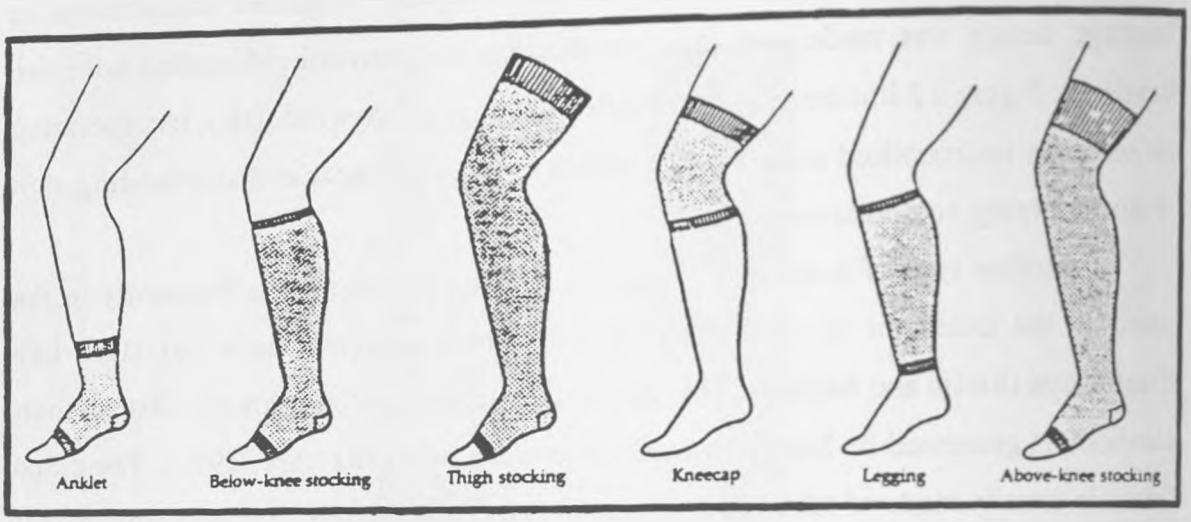


Figure 2.3 Types of elastic hosiery

medicament paste containing various zinc oxide mixtures (Kikta et al., 1988). This type of bandage is referred to as the "Unna's boot", otherwise known as rigid bandages or non-elastic bandages. These bandages such as Viscopaste (Smith and Nephew) are normally made from woven cotton and do not contain elastomeric threads and hence are not able to stretch. Upon application, the paste in the bandage, which is wrapped snugly around the leg, hardens to form a firm fitting boot. Over this boot, elastic stockings or low compression bandages have frequently been used. The sub-bandage pressures generated by these non-elastic devices are often much higher than that of the elastic bandages and have been shown to provide better differential compression, (i.e., more pronounced variations), especially during walking (van der Molen, 1982; Thomas, 1990). Although inextensible bandages are gradually being displaced by modern extensible bandages, many still believe that treatment with non-elastic bandages is superior and results in a higher rate of healing (Kikta et al., 1988; Schmitz, 1987; van der Molen, 1982). Inextensible cotton bandages, such as those manufactured by Lohmann and Comprilan are the main type of bandages used in Switzerland, Austria and Germany (Cornwall, 1988).

2.1.2 Elastic Stockings

Elastic hosiery are used on the lower limb for a variety of therapeutic reasons, and as such many different types are available (Gent, 1986). Figure 2.3 illustrates some of the commonly available elastic hosiery. The below-knee, the thigh and the above-knee elastic stockings are used in the treatment of venous disorders including venous ulcers. Below knee elastic stockings are by far the most popular elastic hosiery used for providing graduated compression on the lower limb. Previous studies have shown that the above-knee and thigh stockings can be hazardous as they can cause a tourniquet effect around the knee (Husni et al., 1968). Further, it is understood that the pathological changes relating to venous ulceration take place below the knee and it has been shown that below knee stockings are as effective as the above-knee devices (Partsch, 1984).

Like the extensible elastic bandages, elastic stockings are made of fabric containing covered elastomeric yarns and the properties of these yarns dictate the magnitude of compression. The fabric used in elastic stockings, however, can be

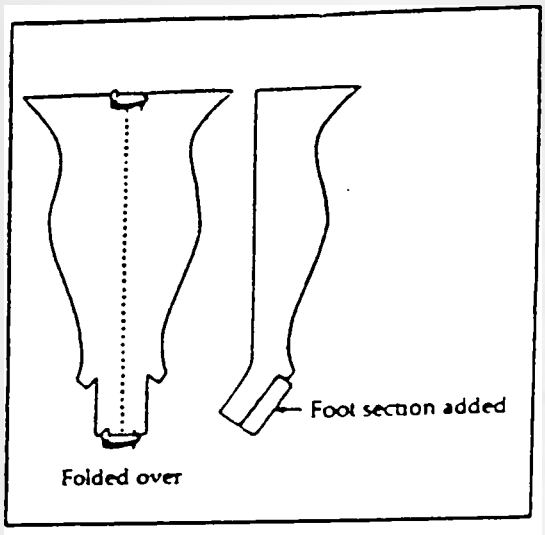


Figure 2.4 Cut to shape

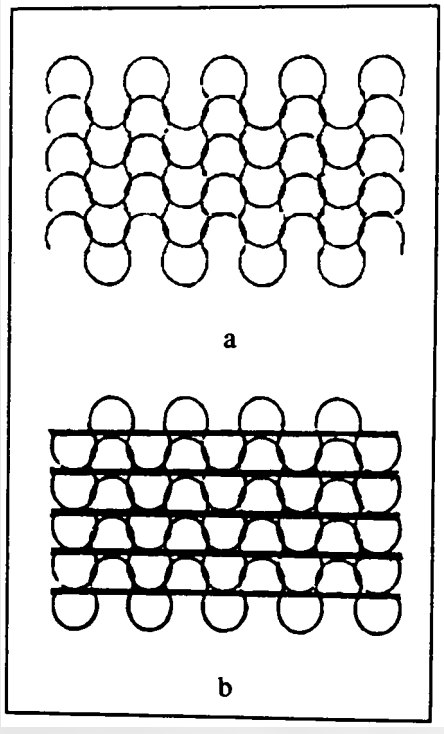


Figure 2.5 (a) Knitted only (b) knitted with weft inlay

either one way stretch or two way stretch, although elasticity in the longitudinal direction is not necessarily an advantage. The modern day elastic stockings are manufactured on weft knitting machines which can be circular or flat bed. Elastic stockings made from fabric knitted on the flat bed machines are shaped to fit the leg, by controlling the number of needles in the machine and these stockings can be made with or without seams. In the case of the circular bed knitting machines, stockings are shaped by using cylinders of different diameters and these elastic stockings are seam free.

In the past, elastic fabrics were woven or bobbinnet fabrics which were cut to shape from a roll of material, folded down the middle and seamed along its edges, with the foot section added on later (Figure 2.4). Present day, elastic fabrics may be knitted or knitted with weft inlay, as illustrated in figure 2.5. Elastic stockings, such as Venosan 3000 (Salzmann, Switzerland) which are designed to generate higher compression are normally knitted on the circular machines with weft inlay. Specialised machines are now used to control the tension in the inlay yarn during manufacture. The inlay yarns may be covered elastomers or just bare yarns, not all of which within a fabric are required to be elastic. Further, the number of the inlay yarns can be varied and do not have to be laid in every course. By varying the type and number of inlay yarns, along with the factors considered in the case of extensible bandage, a variety of elastic stockings, providing a range of compression, can be manufactured (Reicher, 1990). In the knitted fabrics where inlay yarns are not used, the threads are normally covered elastomers and the compression generated is relatively lower.

Elastic stockings are required to provide graduated compression, maximum at the ankle and decreasing proximally. Typically, pressures are defined at the ankle and it has to be 30% lower at the calf, and 50% lower at the thigh (Reicher, 1990). This pressure profile is achieved by varying the tension in the elastic yarn along the stocking during manufacture.

Commercially available elastic stockings come in a range of standard sizes measured according to calf circumferences, typically, from small (circumference less than 30.5cm) to extra large (circumference greater than 44.5cm). Most manufacturers also provide a further choice of leg length to improve the fit of the garment. Many

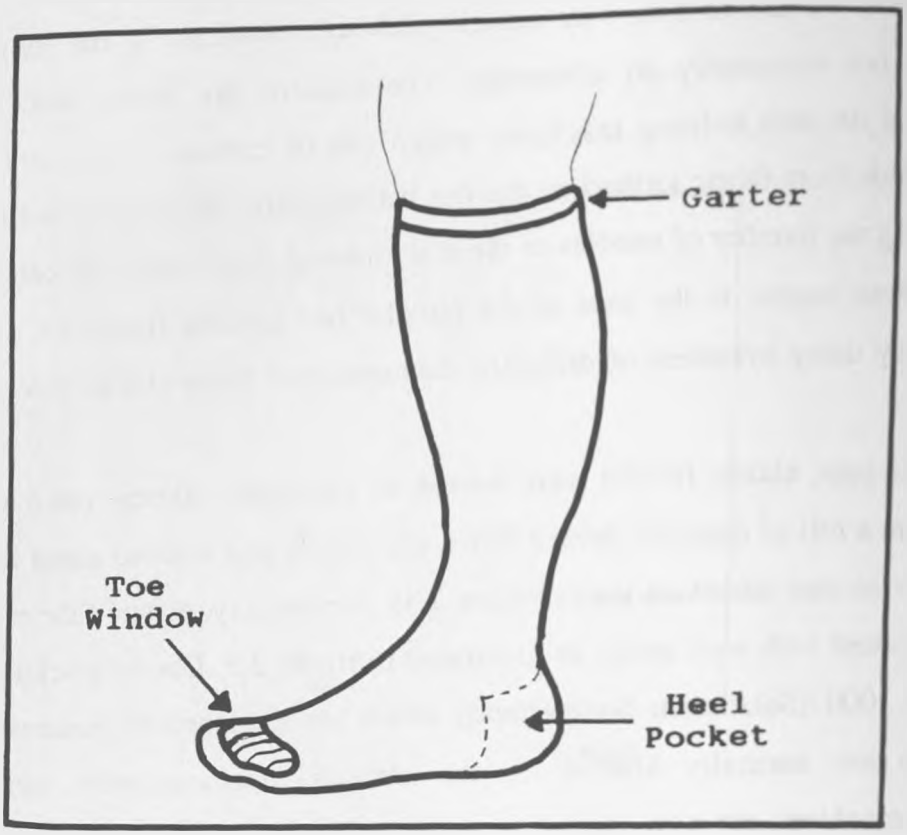


Figure 2.6 An elastic stocking

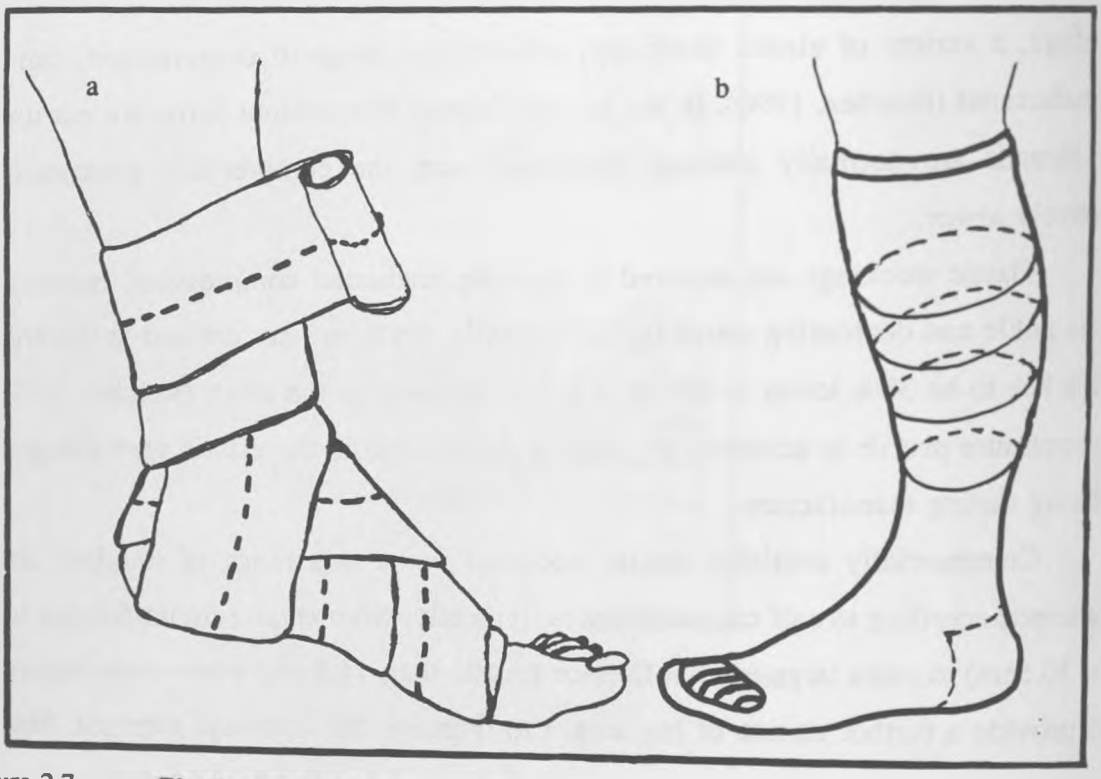


Figure 2.7 Elastic yarns running along the length of the bandage (a) and circumferentially in the stocking (b).

elastic stockings have a toe window which can prevent discomfort of the toes especially if they are squeezed together by the stocking. The toe window also makes it easier to apply the elastic stocking correctly with the heel pocket in place (Dale and Gibson, 1990). Some elastic stockings have a garter around the top edge (Figure 2.6) to hold it in position, however, this can act as a tourniquet and restrict blood flood (Lewis et al., 1976). Modern elastic stockings are made cosmetically more appealing to encourage patient compliance, however there still exists the problem of poor fit, especially in patients with atypical leg shapes (Partsch, 1984). In extreme cases, customised stockings are made available but as they are more expensive such a service is highly selective.

2.2 PRINCIPLES OF COMPRESSION THERAPY

2.2.1 Theoretical Considerations of Compression Therapy

External compression on the lower limb produced by elastic stockings and bandages is derived from the tension in the elastic yarns within the fabric of these compression devices. These elastic yarns, whilst necessary in the radial direction, do not particularly have an advantage in the longitudinal direction (Reicher, 1990). Therefore, bandages have elastic yarns running along its length while elastic stockings have elastic yarns running circumferentially (Figure 2.7). In the following sub-sections, theoretical approaches to the calculation of radial and longitudinal pressures generated by these devices are described. Further, theoretical observations made on the mechanism of blood flow in a model vein, under different modes of external compression, and the effect of the changes in cross sectional area of the vein, are examined.

(a) Radial Pressure Profile

Ideally, compression produced by bandages or elastic stockings, should generate uniform radial pressures around the whole perimeter of the leg, for any given height. This radial pressure is produced by the radial tension in the elastic fibres of the stocking fabric. The degree to which this tension is transformed into radial pressure is dependent on the curvature of the leg surface (de Bruyne and Dvorák, 1976).

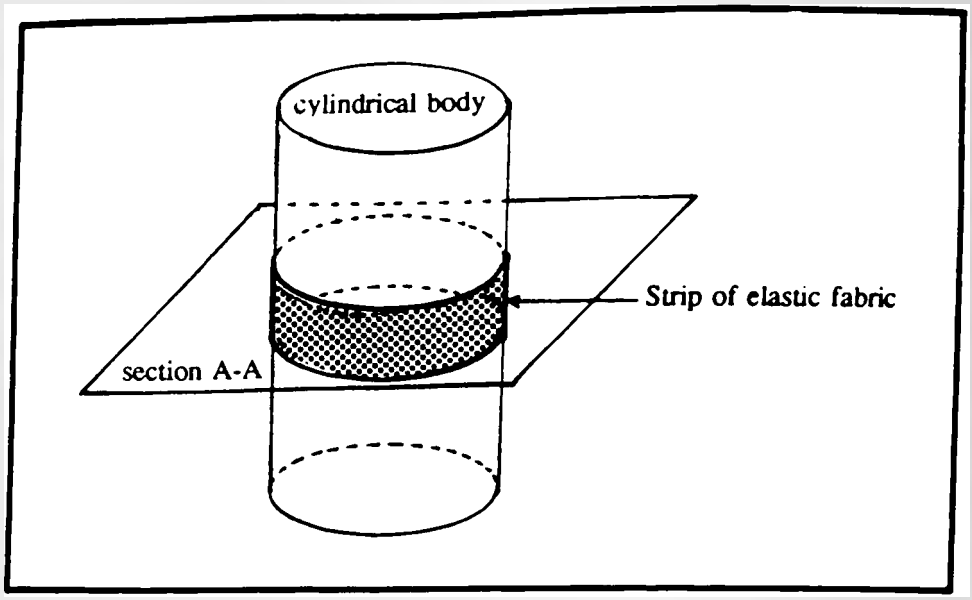


Figure 2.8 A cylindrical model (reproduced from Bruyne and Dvorák, 1976)

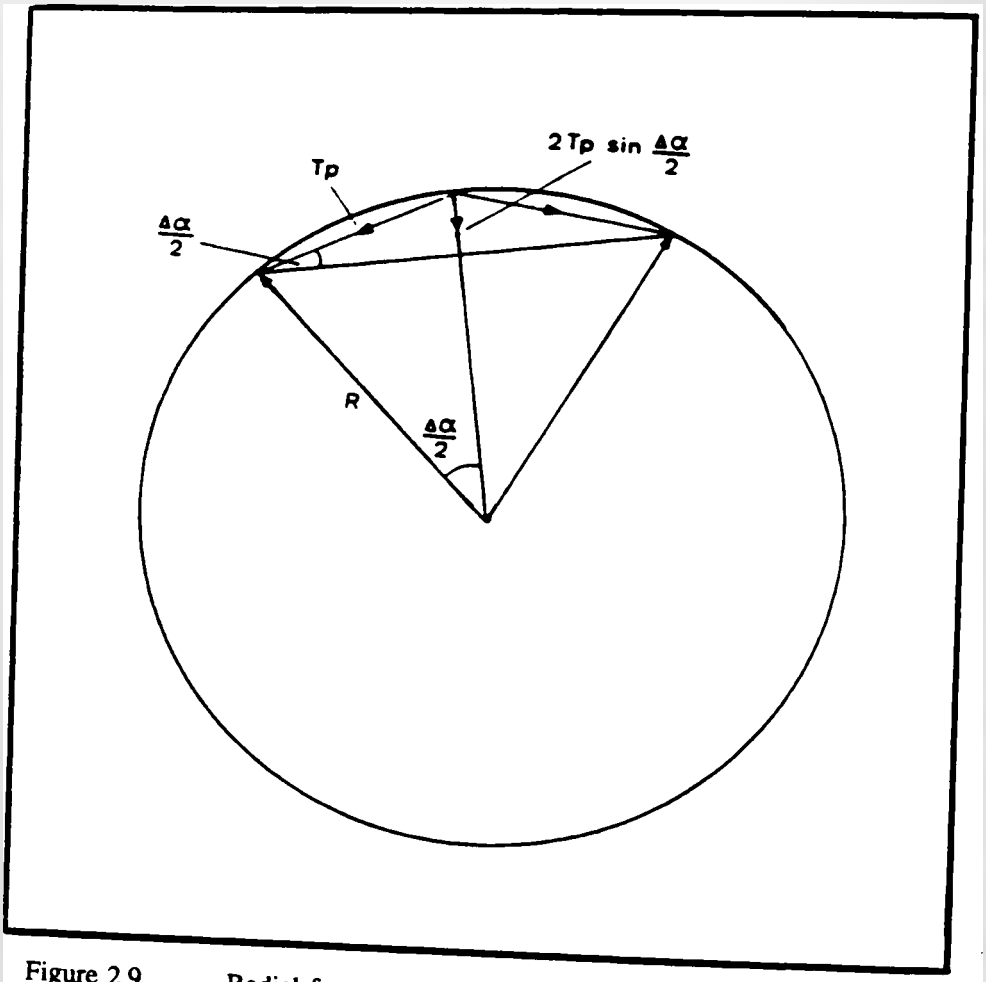


Figure 2.9 Radial forces at section A-A (reproduced from Bruyne and Dvorák, 1976)

de Bruyne and Dvorák offered a theoretical explanation of such an elastic compression based on a simplified model of the leg. The model was assumed to have an uniform circular cross-section with no longitudinal curvature. A further assumption was that, there was no friction between the stocking and the surface of the cylindrical model (Figure 2.8).

Based on this model and the illustration in figure 2.9, de Bruyne and Dvorák calculated the radial component of force F_r exerted by a one cm wide strip of fabric as;

$$F_r = 2T_p \sin\frac{(\Delta\alpha)}{2}$$

and the pressure p_r per square centimetre as;

$$p_r = \frac{F_r}{S} = 2T_p \frac{\sin(\Delta\alpha/2)}{\Delta\alpha R}$$

where,

$S = \Delta\alpha R \times 1$ cm is the area of the one cm wide strip subtended by the angle $\Delta\alpha$

For small angles of $\Delta\alpha$

$$\sin\frac{\Delta\alpha}{2} \approx \frac{\Delta\alpha}{2}$$

and hence;

$$p_r \approx \frac{T_p}{R} \qquad \text{.....(1)}$$

They concluded that, "the radial pressure profile per square centimetre exerted by an elastic stocking on the surface of a cylindrical body is proportional to the peripheral tension of a 1cm wide strip of fabric divided by the radius in centimetres

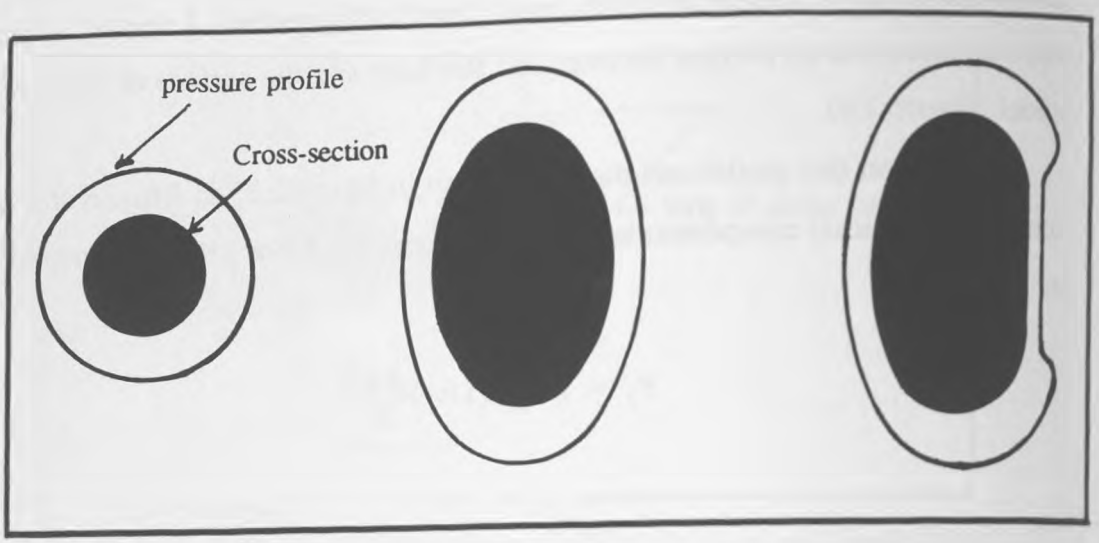


Figure 2.10 Pressure profiles at the cross-sections of different shapes (reproduced from Bruyne and Dvorák, 1976)

$$P = \frac{K.10}{b.r.133}$$

P	= pressure (mmHg)
K	= pull force (N)
b	= bandage width (cm)
r	= radius of the cylinder (cm)

Figure 2.11 Laplace's equation as modified by Hansson and Swanbeck (1988)

$$P = \frac{T.N \times 4630}{C.W}$$

P	= pressure (mmHg)
T	= bandage tension (kg)
C	= circumference of the limb (cm)
W	= bandage width (cm)
N	= number of layers applied

Figure 2.12 Laplace's equation as modified by Thomas (1990)

of the curvature at the area considered." Based on this, the relative pressure profiles for three differently shaped cross-sectional areas are illustrated in figure 2.10.

This relationship better known as Laplace's law is frequently quoted in the literature pertaining to compression therapy. It should be pointed out that the relationship implicated by this law is highly simplified and based on many assumptions. Apart from the assumptions outlined earlier, the law assumes homogeneity of the material within the "cylindrical body". The human leg, composed of soft and hard tissues, fibres, muscles and fluids, is non homogeneous and this should be taken into account when applying the law.

Attempts have been made to modify Laplace's law to derive specific equations for use in the study of compression devices (Hansson and Swanbeck, 1988; Thomas, 1990). However, caution must be exercised when using such modified equations. Hansson and Swanbeck (1988) compared a cohesive bandage and a non adhesive elastic bandage using the same, modified, equation (Figure 2.11). These bandages have different frictional characteristics and must be accounted for. Thomas (1990) appears to have overlooked this point when presenting a general equation for sub-bandage pressures (Figure 2.12). Similarly, such equations would fail in a multi-layer bandaging system where different types of bandages are used.

Laplace's law may be a useful tool in providing a general understanding of the distribution of pressures beneath compression devices but extending the principles for specific applications should be viewed with caution until more detailed investigations are carried out. Further, the behaviour of elastic tension outside the recommended limits of stretch, which are easily exceeded when applying a bandage, has not been fully understood as yet (Hansson and Swanbeck, 1988).

(b) Longitudinal (Vertical) Pressure Profile

de Bruyne and Dvorák (1976) used the previously derived expression (1) to describe the nature of the longitudinal pressure profile resulting from the longitudinal component of tension in the fabric. The pressure p_L was calculated as;

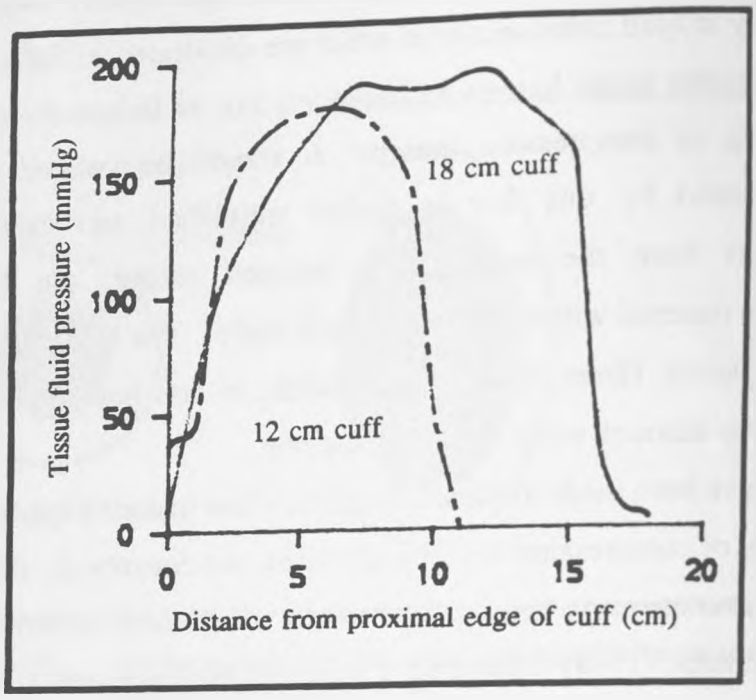


Figure 2.13 Transverse pressure variation beneath cuffs (reproduced from Cranshaw et al., 1988)

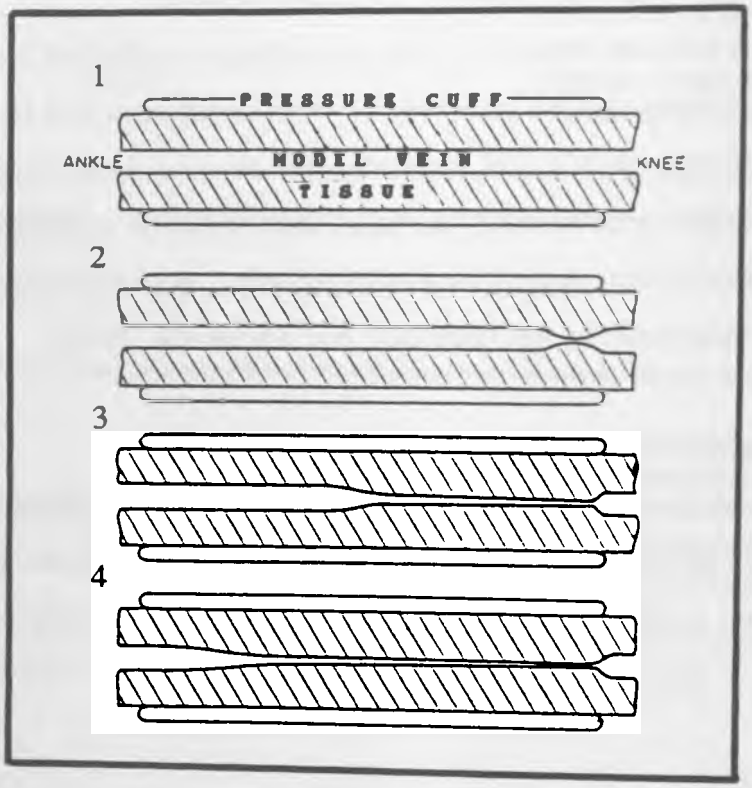


Figure 2.14 Geometric changes in a vein during the collapse process (from Kamm, 1982)

$$p_L \approx \frac{T_L}{R_L}$$

(In practice, with the exception of the area around the ankle and shin, the radius of longitudinal curvature R_L is very large)
Therefore,

$$p_L \to 0 , \quad as \quad R_L \to \infty$$

Hence, the pressure resulting from the longitudinal component of tension is generally less significant than the radial component and as such longitudinal elastic yarns are not usually used within the fabric of compression devices.

In bandages, however, a local distribution of pressure within its width is likely. Crenshaw et al. (1988) investigated tourniquet cuffs of different sizes and have shown that the pressure transmitted varied transversely across the cuffs. The pressure was greatest at the centre of the cuff and least at the edges (Figure 2.13). A bandage could be expected to produce similar local pressure profiles. Crenshaw et al. (1988) also showed that broader cuffs were more efficient in transmitting pressure than narrower cuffs and that the pressure profile was dependent on the width of the cuffs. Therefore it would seem reasonable to assume that the longitudinal pressure profile generated by a bandage would depend on its width and further, would be influenced by the degree of overlap of the bandage material (Raj et al.,1980).

(c) External Compression and Flow

Kamm et al. (1979) observed the geometrical changes in a model vein, of a single compliant tube, subjected to uniform external compression. They observed that the model vein was emptied by a sequential process of vein collapses. Figure 2.14 is an exaggerated schematic representation of this sequence. In this representation the final configuration is one in which the collapse is maximal at the proximal (knee) end and minimal at the distal (ankle) end. Thus, uniform compression, as seen by this model, may compromise flow, especially at the proximal end, as a result of a flow-limiting throat.

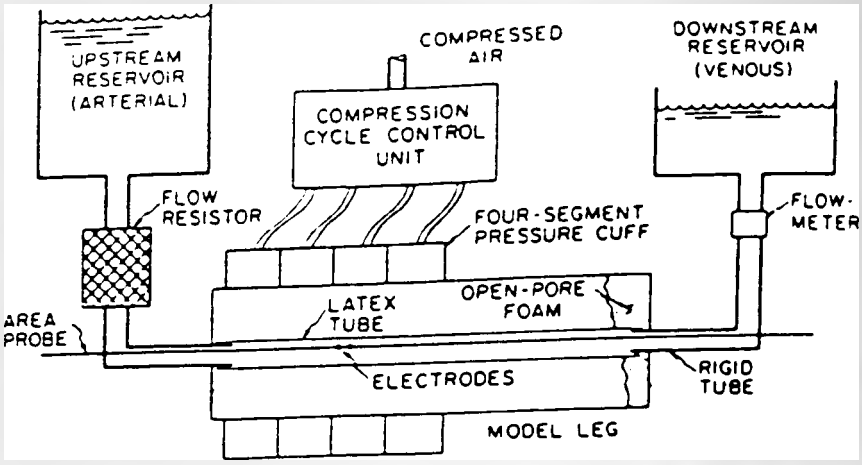


Figure 2.15 A simplified model of a leg and vein (reproduced from Olson et al., 1982)

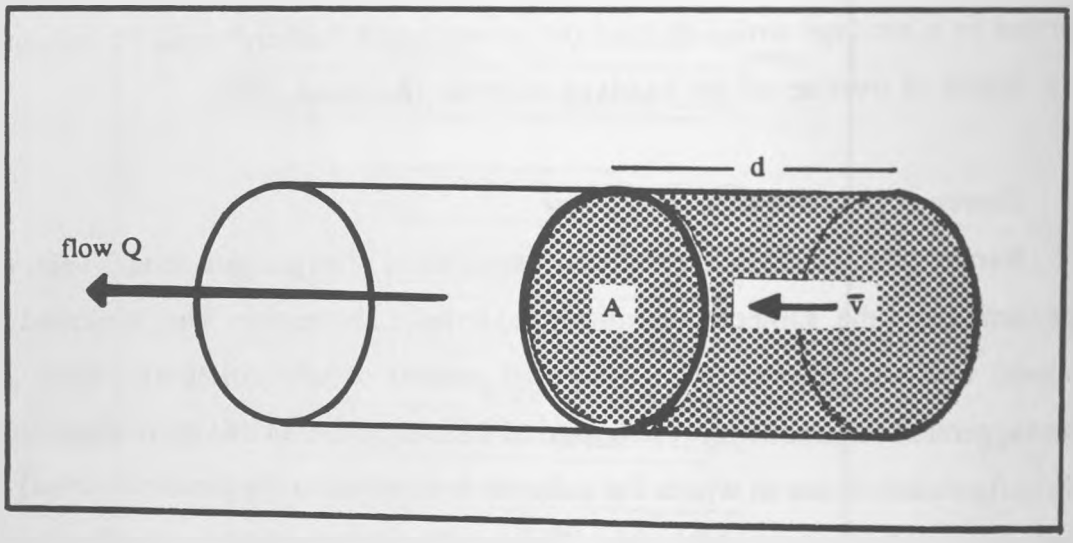


Figure 2.16 Cylindrical flow model

As a follow up to the above study, Kamm (1982) and Olson et al. (1982) conducted a numerical study on the effects of different types of external compression on flow rate, flow velocity and shear stress. This theoretical study was based on a highly simplified model of a leg and vein, with simple flow conditions (Figure 2.15). The authors reported that sequential or graduated compression was significantly more effective in promoting flow than uniform compression, and that optimum compression was around 4 kPa.

(d) Flow and Cross-Sectional Area of Vein

The volume (V) of fluid that passes through a vessel per second and the fluid flow rate (Q) are related to the mean velocity of flow ($\bar{v}$) and the cross-sectional area (A) of the vessel by the equation of continuity;

$$Q = \frac{V}{t} = \frac{Ad}{d/\bar{v}} = A\bar{v}$$

(where t is the time and d the distance travelled by the fluid as illustrated in figure 2.16)

It follows that a reduction in the cross-sectional area of a vein as a result of external compression will increase the mean velocity but not necessarily the flow rate (Stanton et al., 1949 and Yamaguchi and Yamaguchi, 1986). Perhaps, for this reason venous flow velocity is often measured at a distant point, typically at the femoral vein, well away from the point of compression (Stanton et al., 1949, Sigel et al., 1975, Lawrence and Kakkar, 1980 and Spiro et al., 1970). At this distant point it may be assumed that the cross-sectional area is unaffected by compression, hence an increased venous velocity would reflect increased flow rate and therefore increased venous return.

A practical point of interest is that, to-date, there is no reliable, non invasive means of measuring blood flow rate. The measurement of venous blood flow rate is particularly difficult because of the highly complex and variable nature of the blood flow pattern and the cross-sectional profiles of the veins (Fisher, 1992). Spiro et al.

(1970) and Roberts et al. (1972) have measured flow rate in the femoral vein invasively using an electromagnetic flowmeter, initially on dogs then on a limited number of patients under general anaesthesia and have reported that external compression of leg increases the flow rate.

2.2.2 The Effect of Compression on Venous Haemodynamics

Graduated compression of the leg can have favourable effects on venous haemodynamics by alleviating the aetiological factors of impaired venous function. External compression in the first instance, provides support to the weakened musculature and underlying tissues. Further, such a support can assist the muscle pump mechanism in "milking" the venous blood upwards against the force of gravity, by providing a firm "skin" for the muscles to counteract against (Fentem, 1990 and Cornwall, 1988).

Graduated external compression may also oppose the reflux of venous blood from incompetent perforating veins and encourage unidirectional flow from the superficial veins to the deep veins and thereafter towards the heart (Somerville et al., 1974 and Sigel et al., 1975). Meyerowitz et al. (1964) and Makin et al. (1969) using ^{125}I-fibrinogen tracer and venographic techniques reported improved venous flow as a result of compression therapy. A similar observation was also reported by Jones et al. (1980) using foot volumetry and Na-24 subcutaneous tissue clearance techniques.

Stanton et al. (1949) using Evans blue dye tracer technique, observed that local compression of the leg accelerated the venous blood flow velocity. Sigel et al. (1975) reiterated this when they reported that graduated compression produced maximum increase in venous flow velocity. Further, Lawrence and Kakkar (1980), using technetium-99 tracer also reported that for external pressures between 18 and 8 mmHg (2.4 and 1kPa) there was a significant increase in the mean deep vein blood velocity. Similar findings were also reported by Wilkins et al. (1952), Spiro et al. (1970) and Sabri et al. (1971). The increased venous velocity is seen by clinicians as improved venous return (Burnand and Layer, 1986).

Lewis et al. (1976) using venographic techniques have reported that external compression of the leg significantly improved clearance of stagnant blood from behind venous valves. Browse et al. (1974) had previously reported similar findings.

Blood propelled in the deep veins by compression from surrounding muscles travels in the direction of least resistance. The application of external support, compresses the superficial veins and hence, increases the resistance to retrograde flow from the communicating veins. As a result more blood is returned in the normal centripetal fashion in the deep venous system (Keely et al., 1962). Somerville et al. (1974) substantiated this claim by reporting that external compression helped to restore competence and reduce retrograde flow.

Lawrence and Kakkar (1980), using sodium-24 tracer clearance in subcutaneous tissues reported increased blood flow in the tissues when suitable levels of compression were applied.

The equilibrium that exists between the intra and extravascular fluid compartments is a delicate balance (Starling's Law). Among several factors influencing this equilibrium, intravascular, osmotic and hydrostatic pressures are of paramount importance. Prolonged venous hypertension can easily upset this delicate balance. External compression may contribute to the redressing of this imbalance, preventing capillary transudation and oedema in the leg (Keeley, 1962 and Backhouse, 1987).

2.2.3 The Influence of Compression on Venous Ulcers

It has been previously established that compression therapy plays an important role in improving venous return (Section 1.8). As such, it directly addresses the aetiology of venous ulceration.

Prolonged venous hypertension is a primary factor in the process leading to lipodermatosclerosis and eventually venous ulceration. The value of supportive, graduated, compression of the leg in overcoming the effects of prolonged venous hypertension has been widely proven (Sigg, 1963; Fentem et al., 1976; Gjöres and Thulesius, 1977 and Somerville et al., 1974). External compression alleviates venous hypertension by reducing the distension of the superficial veins and by counteracting the excessive intra-venous pressures (Fentem et al., 1976).

Compression therapy is also widely used in the control of oedema implicated in venous ulceration. External compression discourages swelling by reducing the pressure difference between the capillaries and tissues, thereby restoring normal rate

of tissue fluid formation (Heather, 1969).

The persistently raised venous pressure distends the dermal capillary bed and encourages large macromolecules, particularly fibrinogen, which are normally held within the vascular compartment, to escape into the tissues. This initiates the mechanism leading to lipodermatosclerosis and eventually venous ulceration (Burnand et al., 1981; Burnand et al., 1982). External compression applied to the leg, raises the local interstitial pressure and decreases the superficial venous pressure thereby reducing the leakage of solutes and fluid into the interstitial space, and thus preventing the onset of lipodermatosclerosis (Burnand and Layer, 1986).

External compression enhances the local release of plasminogen activators (Clarke, 1960; Burnand et al., 1982), which initiates extravascular dissolution of fibrin. This may have potential benefits in restoring defective fibrinolysis and stimulating the breakdown of pericapillary fibrin deposits responsible for the onset of lipodermatosclerosis (Burnand et al., 1980).

Low transcutaneous oxygen tension adjacent to venous ulcers has been previously reported (Partsch et al., 1984). Burnand and Browse (1982) have suggested that low oxygen tension values in venous diseases may reflect a barrier to oxygen diffusion from the dermal pericapillary fibrin. External compression of the leg has been shown to increase tissue oxygenation (Kolari et al., 1987 and Okoye, 1984). Kolari et al. (1987) have suggested that a decrease in oedema, resulting from compression therapy, augments oxygen diffusion. Further, a decrease in venous stasis, as a result of such therapy, can enhance capillary and arterial inflow which, in turn, can increase tissue oxygen content. The reversal of the low oxygen content in the tissues can prevent tissue necrosis and promote ulcer healing.

2.3 EVALUATION AND CLASSIFICATION OF COMPRESSION DEVICES

The first official standard for bandages appeared in a supplement to the 1911 British Pharmaceutical Codex (BPC) which included a specification for crêpe bandages, and monographs for simple non-extensible bandages, used mainly to provide warmth and protection. As new products were developed, additional monographs were introduced, but when the publication of the BPC ceased, many of these standards were transferred to the British Pharmacopoeia (Thomas, 1990). These

specifications were based on the construction rather than the performance of the device, and as such had little relevance to compression therapy. Furthermore, there were no specifications for elastic stockings.

2.3.1. The Standard BS6612 For Compression Hosiery

A committee of the British Standards Institute (BSI) was first convened in 1970, to produce the standard BS6612 for compression hosiery but this was not published until 1985. Progress in producing a standard based on performance was particularly slow because methods of measuring compression had to be sufficiently developed so that monitoring standards were possible (Fentem, 1990).

The intention of the standard was to provide a description of the devices in terms of their compressional ability. Each elastic stocking was labelled with a specific range of compression values that would be exerted at the ankle when the stocking was worn on a leg of the size for which it was manufactured. The standard also required the elastic stocking to provide graduated compression along the limb within predefined compression profiles. Further, it was necessary to demonstrate that the elastic stocking retained its compression with simulated wear, and its "stiffness" was within stated limits. The desired effect of such classification was to assist clinicians in selecting suitable elastic stockings according to levels of compression, to ensure that these devices were manufactured to performance specifications, to create a nationally acceptable standard, and to form a basis for future research and development of compression devices (Fentem, 1990).

In order to achieve this classification, the performance of elastic stockings had to be measured, either by using direct or indirect methods. Direct measurement of compression involved placing sensors between the elastic stocking and the patient's leg. Indirect compression measurement was based on the theoretical considerations previously discussed in section 2.2.1. Measurements of fabric tension and leg circumference are used to estimate the stocking compression. The Instron tester, the NAHM tester (National Association of Hosiery Manufacturers'tester), and the HATRA tester (Hosiery and Allied Trades Research Association) are commonly used indirect measuring instruments. The committee of the BSI on compression hosiery had selected the HATRA tester to be the instrument by which all elastic stockings are

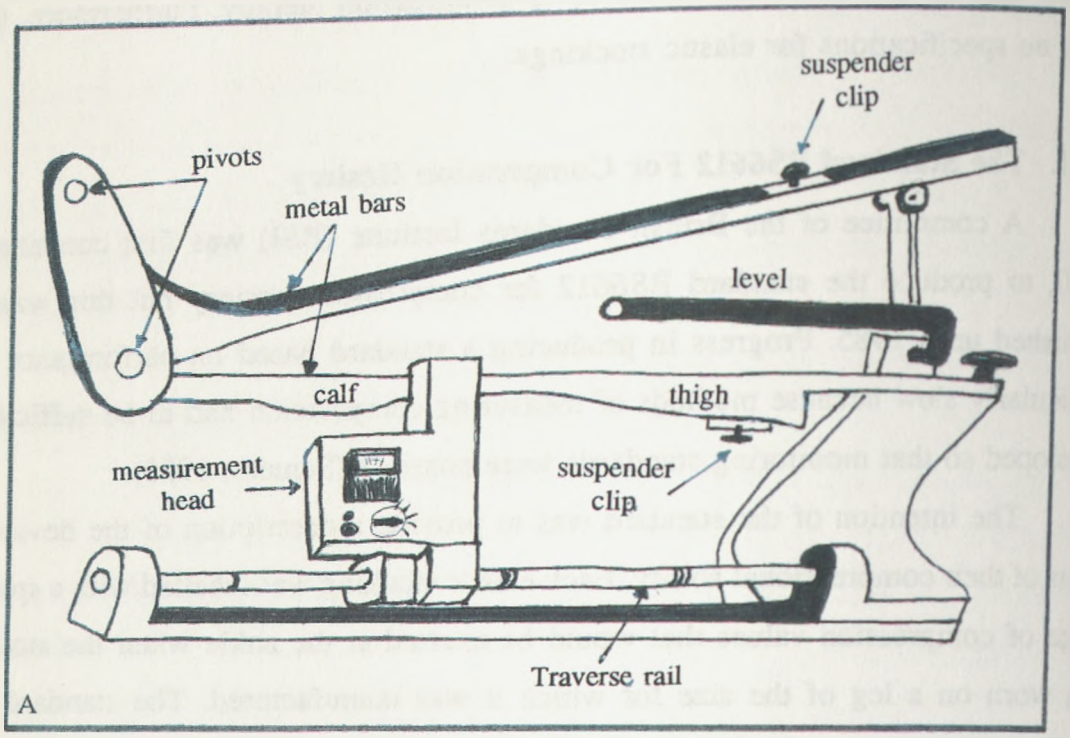


Figure 2.17 The HATRA hosiery tester

to be tested in accordance with the standard BS6612.

The HATRA hosiery tester is illustrated in figures 2.17a and b, (Peat, 1977). This instrument essentially comprises of two main parts, the "garment former" and the "measurement head". The former consists of two metal bars constructed to simulate a simple leg shape. The upper bar is movable by an operating lever to facilitate the positioning of the stocking. Pivots at both ends enable the former to be adapted to accommodate seven standard girth settings. The fixed lower section is provided with two curved areas representing the calf and thigh. Conventional suspender type clips are incorporated on the upper bar to hold the stocking in place. These clips are movable to adjust to different garment sizes. The tension in the stocking is measured by sliding the measurement head along a traverse rail to any of the three marked measuring positions representing ankle, calf and thigh. The measurement head has an electronic display showing readings of fabric tension. These readings are then converted to compression values in mmHg by using a previously calculated chart.

Based on the HATRA tester, a system of classification as described in figure 2.18 was formulated for elastic stockings in accordance with BS6612. This system of classification is quoted in the Drug Tariff and routinely used within the National Health Service. Further, manufacturers are obliged to conform to the test and mark the appropriate class on their products.

CLASS	STOCKING DESCRIPTION
1	These are the lightest, producing pressures of 14-17 mmHg at the ankle. Recommended for the treatment of mild varicose veins and varicose veins during pregnancy.
2	These give medium support in the range of 18-24 mmHg at the ankle. Recommended for the treatment of severe varicosities and prevention of venous ulcers in smaller, lighter patients.
3	These provide 25-35 mmHg at the ankle. Recommended prescription for severe chronic venous insufficiency, severe varicose veins and for ulcer prevention in patients with large, heavy legs.

Figure 2.18 Classification of elastic stockings.

CLASS	BANDAGE DESCRIPTION
1	**Lightweight conforming stretch bandages.** These bandages do not exert any significant compression and are used for retention of dressings.
2	**Light support bandages.** These bandages are intended to give firm support without exerting any significant compression. They may be used in the prevention of oedema, and in the management of mild sprains and strains.
3a	**Light compression bandages.** These bandages are intended to provide low levels of pressure in the order of 14-17mmHg at the ankle. Recommended for the management of mild varicose veins and varicosis formed during pregnancy.
3b	**Moderate compression bandages.** These bandages are intended to provide moderate to high levels of pressure in the order of 18-24mmHg at the ankle. Recommended for the treatment of severe varicosities, and the management of venous ulcers and treatment of oedema in limbs of average circumference.
3c	**High performance compression bandages.** These bandages are capable of providing pressures in the order of 25-35mmHg at the ankle. Recommended for the treatment of severe chronic venous insufficiency, severe varicose veins and for ulcer prevention in patients with large, heavy legs.
3d	**Extra high performance compression bandages.** These bandages are capable of providing pressures in the order of 36-60mmHg at the ankle, the highest levels which are likely to be required clinically. These powerful bandages can apply and retain the pressure on even the largest and most oedematous limbs.

Figure 2.19 Classification of Extensible bandages

2.3.2 The SDPT1 Test For Extensible Bandages

There is no British standard for compression bandages, as yet. The surgical dressings performance test (SDPT1) for extensible bandages was drafted in 1989 and is the only test available at present (Thomas, 1989). This test method was jointly developed by representatives of the regional quality control pharmacists and members of surgical dressings manufacturing industry. It is a laboratory test method, designed to measure the elastic properties of extensible bandages. These measurements are then used to predict the performance of extensible bandages and to classify them.

The test is carried out on a tensile testing device, such as the Instron tester, using samples of 20cm sections of extensible bandages. The resulting stress-strain parameters are measured and used in a predetermined tabulation of test limits to classify bandages into six "types". Figure 2.19 describes the classification according to the types and their relevance to medical applications. Manufacturers are obliged to test and mark the class of their bandages accordingly.

2.3.3 Future Standards

The introduction of the BS6612 for elastic stockings and the SDPT1 test for bandages provides a useful standardisation of compression devices but much controversy still surrounds the efficacy of these test methods and the resulting compression levels within the classification.

Discontent with the British standards for hosiery was first voiced by Burnand and Layer (1986). Swain et al. (1986) endorsed this dissatisfaction when they claimed that graduated compression was not achieved despite the manufacturers' use of the BS6612 test procedures. They strongly suggested the need for direct interface pressure measurement at a clinical level. Meanwhile, Westlake and Hasty (1986), compared the performance of a direct measuring device, the medical stocking tester and two indirect measuring devices, the HATRA and the Instron tester, and reported significant differences in the recorded compression values. Cornwall et al. (1987) upon reporting unsatisfactory performance of ten out of fifteen elastic stockings evaluated, reiterated the need for functional testing of compression devices as part of future British standard specifications. Schraibman et al. (1982) have previously stated that compression stockings should be tested in two stages, first by the manufacturer

BRITISH BANDAGE	BRITISH STOCKING	EUROPEAN STOCKING
Class 3a 14-17mmHg	Class I 14-17mmHg	Class I 18-21mmHg
Class 3b 18-24mmHg	Class II 18-24mmHg	Class II 25-32mmHg
Class 3c 25-35mmHg	Class III 25-35mmHg	Class III 36-46mmHg
Class 3d 36-60mmHg		Class IV > 59mmHg

Figure 2.20 A comparison of British and European Classifications

and then in the clinical situation.

There is dissatisfaction with the performance of compression bandages as well, although no direct reference has been made to the SDPT1 test method. Tennant et al. (1988) upon completing a study of some commonly used bandages, concluded that bandages available on the U.K. drug tariff were in the main unsatisfactory for the treatment of chronic venous diseases.

The need for clinical evaluation as part of the tests leading to standard specifications and classification is clearly recognised. At present, very few clinical evaluations of compression bandages and elastic stockings exist (Burnand and Layer, 1986). These isolated studies often focus only on a limited selection of compression devices. Further, as different interface pressure measuring devices are used in each study, an overall comparison is not possible. This highlights the need for a standard, interface pressure measuring system which can be readily used in the clinical environment.

The recommended compression levels put forth by the BSI for elastic stockings and that suggested by the SDPT1 draft (1989) for compression bandages are notably lower than the equivalent European specifications (Figure 2.20), which have aroused some concern (Burnand and Layer, 1986). However, such differences would have to be carefully considered, along with other factors such as the need for clinical evaluation and the use of multi-layer bandages, when the European standards are formulated. The European standards committee (CEN/TC 205) dealing with non-active medical devices has been appointed to produce an European standard on compression devices that will apply to eighteen member countries by 1992.

2.4 THE ART OF APPLYING COMPRESSION DEVICES

2.4.1 Bandaging

Compression bandaging of the lower limb for the treatment of venous ulcers not only requires skill, but also a sound knowledge of the principles of compression therapy and familiarity with the type of bandage (Dale, 1990; Thomas, 1991; Cornwall, 1991). The effectiveness of a bandage in improving venous return is dependent on the bandaging ability of the operator (Callam et al., 1987; Fentem et al., 1976). Eighty percent of compression bandaging for the treatment of venous

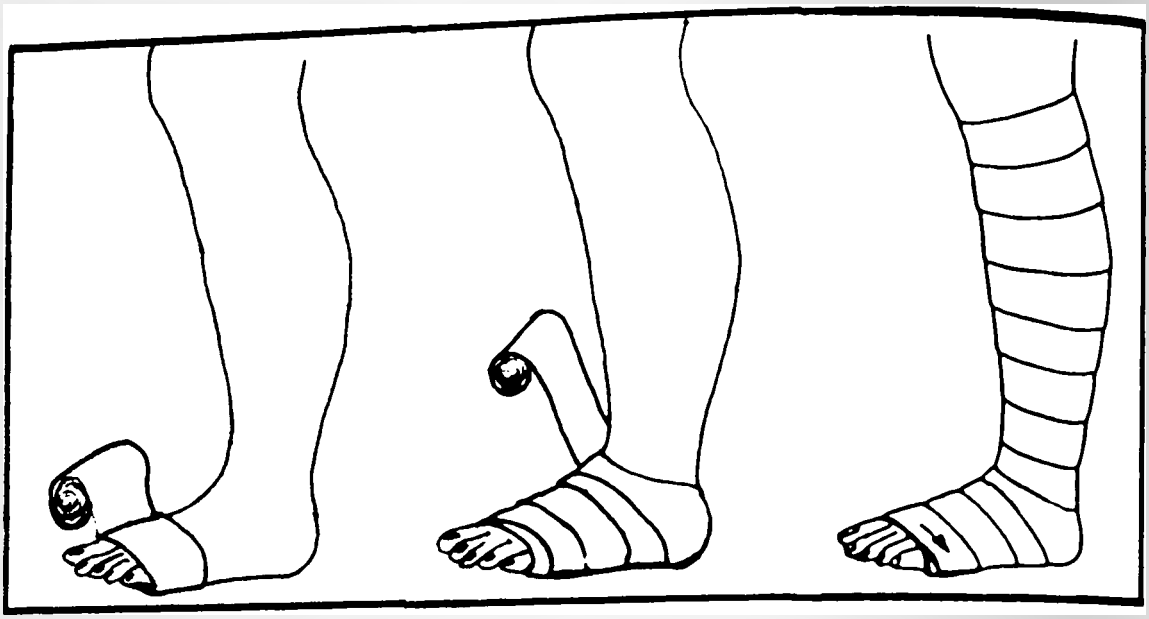


Figure 2.21 The spiral technique of bandaging

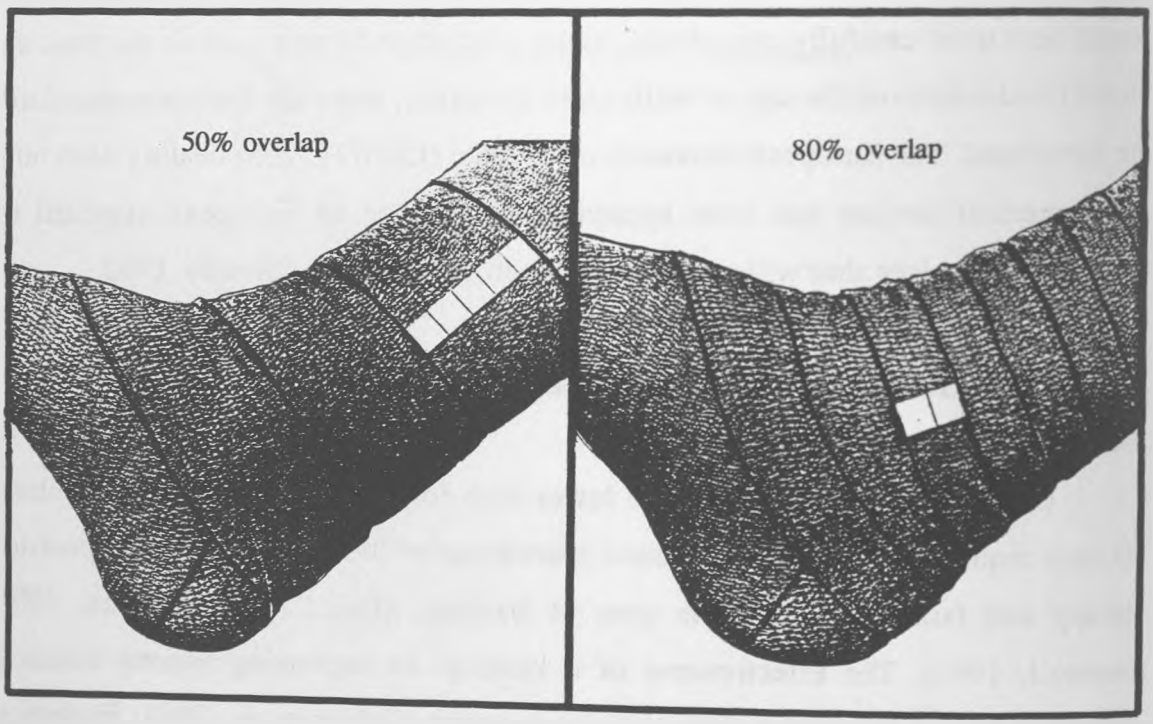


Figure 2.22 Varying degrees of overlap

ulcers are carried out by district nurses. The importance of good bandaging is now recognised and emphasis is placed on training and educating district nurses and others in the profession, on the art of bandaging.

An ulcerated leg should be bandaged only after the vascular status of the patient has been investigated (Dale and Gibson, 1986; Cornwall, 1985). Usually the distal pulses are palpated but in excessively edematous legs a Doppler ultrasound may be used to establish the Ankle Pressure Index (Kulozik et al., 1986; Johnson, 1990). This precaution is taken to exclude arterial disorders. Further, it is recommended practice that a patch test be carried out to exclude possible skin allergies such as contact dermatitis. This is particularly important when paste bandages are used (Kulozik et al., 1988).

Most bandages are accompanied with the manufacturers' brochures which provide instructions and information regarding the bandage. Prior to the actual bandaging, the bandager is expected to gain some familiarity with the bandage, a feel for its stretch and elasticity (Gibson, 1990). In order to be able to reproduce the recommended percentage of stretch, the bandager may need to practise unrolling a length of the bandage and stretching it to varying degrees. Many bandages have lines or patterns printed on them to assist the bandager in estimating the required percentage of stretch (Thomas, 1990; Parpex, 1984).

Bandaging of the leg starts at the foot and finishes just below the knee, with the primary objective of producing an uniformly graduated compression which decreases proximally. If excessive oedema is present, a period of leg elevation prior to bandaging is advantageous. In the United Kingdom, the two most popular techniques of bandaging are the "simple spiral" and the "criss-cross" also referred to as the "figure of eight" technique. The spiral technique starts with a double turn of the bandage at the base of the toes, usually on the medial side of the foot, forming an anchor. The stretched bandage is then wrapped around in consecutive spirals to cover the foot including the heel and the leg up to just below the knee. Each new turn of the bandage overlaps the previous turn as illustrated in figure 2.21. The degree of overlap, as seen in figure 2.22, can be varied according to the manufacturer's instructions and is an important factor in determining the level of compression (Raj et al., 1980; Hansson and Swanbeck, 1988). The criss-cross

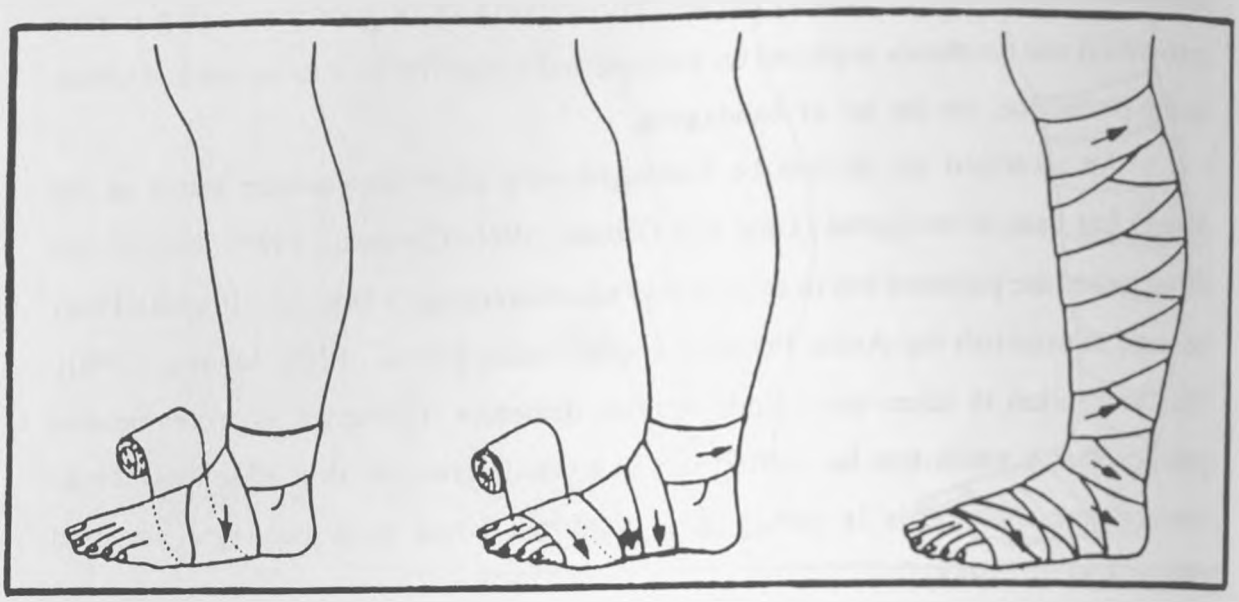


Figure 2.23 The criss-cross technique of bandaging

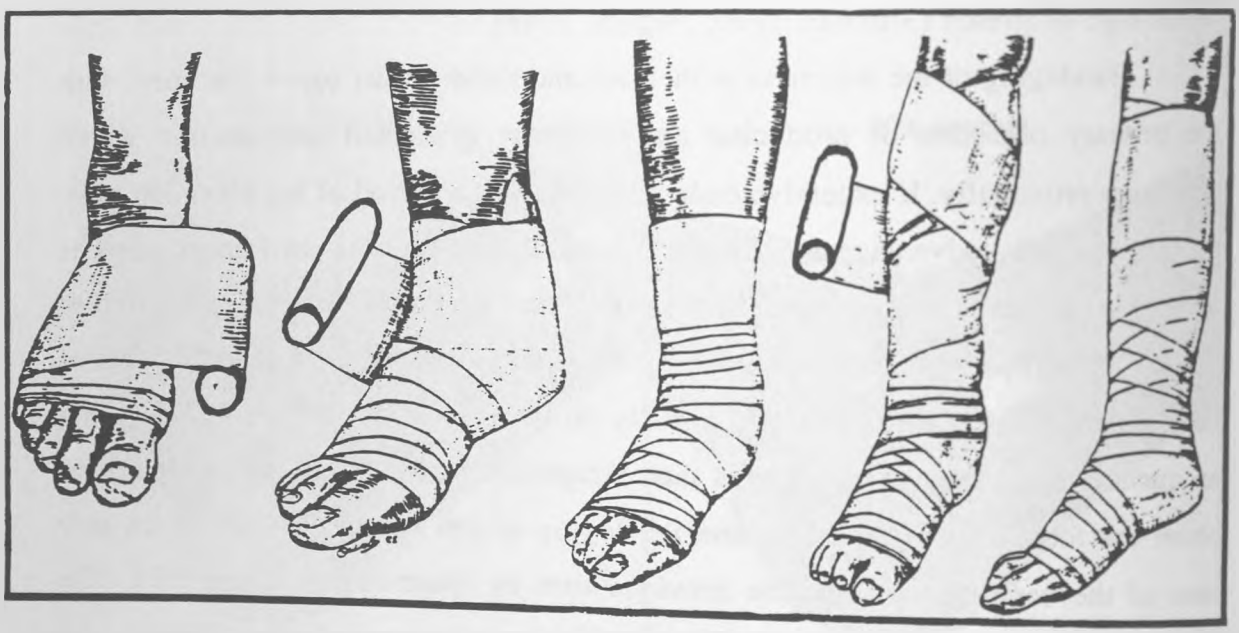


Figure 2.24 Technique of bandaging used in Europe

technique starts with a turn at the ankle which anchors the bandage. The bandage is then carried distally in simple spirals to the base of the toes where the criss-cross sequence of bandaging starts. The stretched bandage is wrapped around the leg in alternate ascending and descending turns which form a criss-cross pattern and this proceeds to cover the foot, heel and eventually the leg up to the knee (Figure 2.23). With both techniques there may be small variations in the anchoring process but the overall bandaging technique remains the same.

In many European countries, however, a different technique of bandaging is used. This technique illustrated in figure 2.24 incorporates both the simple spiral and the criss-cross (Cornwall, 1988).

Recent practices in bandaging include foam padding of bony prominences and the ulceration itself, to improve the local pressure distribution. When paste bandages are used, a similar effect is achieved at these sites by folding the bandage back over area and then proceeding forward, as illustrated in figure 2.25. Good bandaging includes ensuring that each turn is smoothly and neatly laid without creases, at every stage. At the last turn just below the knee, the bandage is cut and taped. Occasionally, bandages are not long enough especially if the criss-cross technique is used and may have to be joined. Care must be taken to minimise the overlap at the joins to prevent a tourniquet forming (Raj et al., 1980). A check with the patient for overall comfort and an examination of the toes and the toe nails ensures that excessively high compression is not applied. Finally, the bandaging should not restrict ankle movement and the use of foot wear, particularly when paste bandages are used.

In 1988, a four layer bandaging system was reported to produce favourable results (Blair et al., 1988). The concept of multi layer bandaging is not new and each bandage in the system is still applied using either the simple spiral or the criss-cross technique.

2.4.2 Applying Elastic Stockings

Elastic stockings used in the treatment of venous ulcers require less skill to apply and are less user dependent than bandages (Callam et al., 1987). For these reasons they are more suited for out-patients who are expected to apply elastic stockings by themselves and who may not have the necessary skills required for

Figure 2.25 Folding the paste bandage

SELECTION OF CORRECT SIZE:

a) Measure the ankle, taking the circumference around the narrowest point (usually about 2 inches above the ankle bone).

b) Select size of garment by referring to Column 1 in the chart below.

c) For knee length stockings take one more measurement around the calf (the widest point below the knee) and check that this measurement falls within the range shown against the selected size in column 2 to ensure that the selected size will fit the patient.

d) For Thigh Stockings take the calf measurement as referred to in (c) above and also a thigh measurement. Check that both these measurements fall within the ranges shown in columns 2 and 3 to ensure that the selected size will fit the patient.

TYPE	Mean Ankle Circum-ference	Column ① Will Fit Ankle	Column ② Will Fit Calf	Column ③ Will Fit Thigh
Small	20 cms	19 – 21 cms (7½ – 8½ ins)	28 – 34 cms (11 – 13½ ins)	42 – 56 cms (16½ – 22½ ins)
Medium	23 cms	22 – 24 cms (8¾ – 9½ ins)	32 – 38 cms (12¾ – 15¼ ins)	48 – 62 cms (19¼ – 24 ¾ ins)
Large	26 cms	25 – 27 cms (9¾ – 10¾ ins)	36 – 42 cms (14½ – 16¾ ins)	54 – 68 cms (21½ – 27¼ ins)
Extra large	29 cms	28 – 30 cms (11 – 12 ins)	40 – 46 cms (16 – 18½ ins)	60 – 74 cms (24 – 29½ ins)

Figure 2.26 Manufacturer's information chart

bandaging. However, an elastic stocking will only be effective in providing appropriate compression if the type and size of the device are correctly selected (Dale and Gibson, 1990).

As in bandaging, elastic stockings should only be applied on a patient's leg after the vascular status of the patient has been examined. Manufacturers of elastic stockings provide varying levels of information on the overall size, calf and ankle circumference, length and type or classification of the stocking. Figure 2.26 illustrates an information chart supplied by the manufacturer. Many also provide instructions on application and include devices such as foot slips to assist application. Elastic stockings are designed to provide the appropriate compression, for its class, with the desired pressure gradient, but its performance is dependent on a good fit (Lewis et al., 1976; Whitley, 1988).

When applying for the first time, the circumference at the widest section of the calf, the circumference at the narrowest section of the ankle and the length of the leg must be recorded. These measurements are used along with the chart provided by the manufacturer to select the best fit elastic stocking within the prescribed class.

Application of an elastic stocking is best done in the morning when the leg is least likely to be oedematous. The leg should be dry, as perspiration can make application difficult. Light powdering of the leg often helps application by reducing the skin surface friction. An elastic stocking can be applied in one of two ways, as recommended by the manufacturer. The most common method is to reach into the stocking and pull the heel pocket out whilst turning the stocking inside out. The stocking is then placed onto the foot and the material worked on, until the heel pocket is positioned over the heel. The loose material at the toe end is gathered and slid over the heel. Then by a gentle rocking motion, the material is evenly smoothed out over the leg, removing any creases. This sequence is illustrated in figure 2.27. Final adjustments include, positioning the toe window, heel pocket, garter and ensuring that there are no tight bands or unevenness.

The other method sometimes recommended by the manufacturers does not involve turning the stocking inside out, instead a silk foot slip is used over the foot and the stocking is worked up the foot by gently spreading the material until the toe window and heel pocket are in place. The remaining material is then slid over the

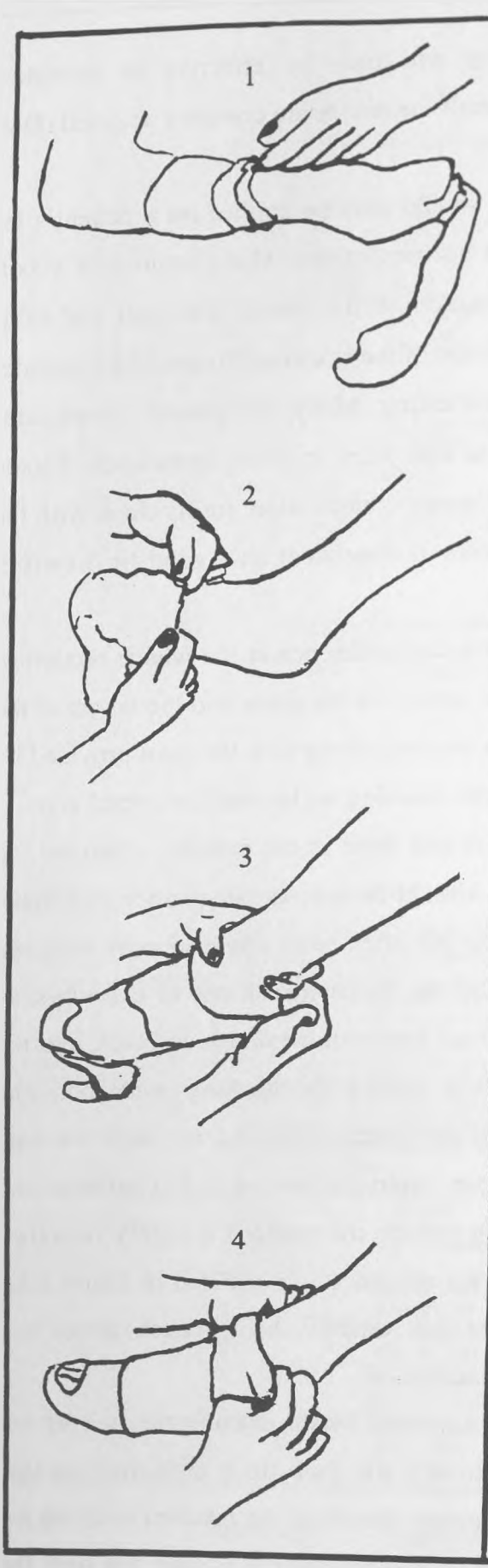


Figure 2.27 Applying an elastic stocking

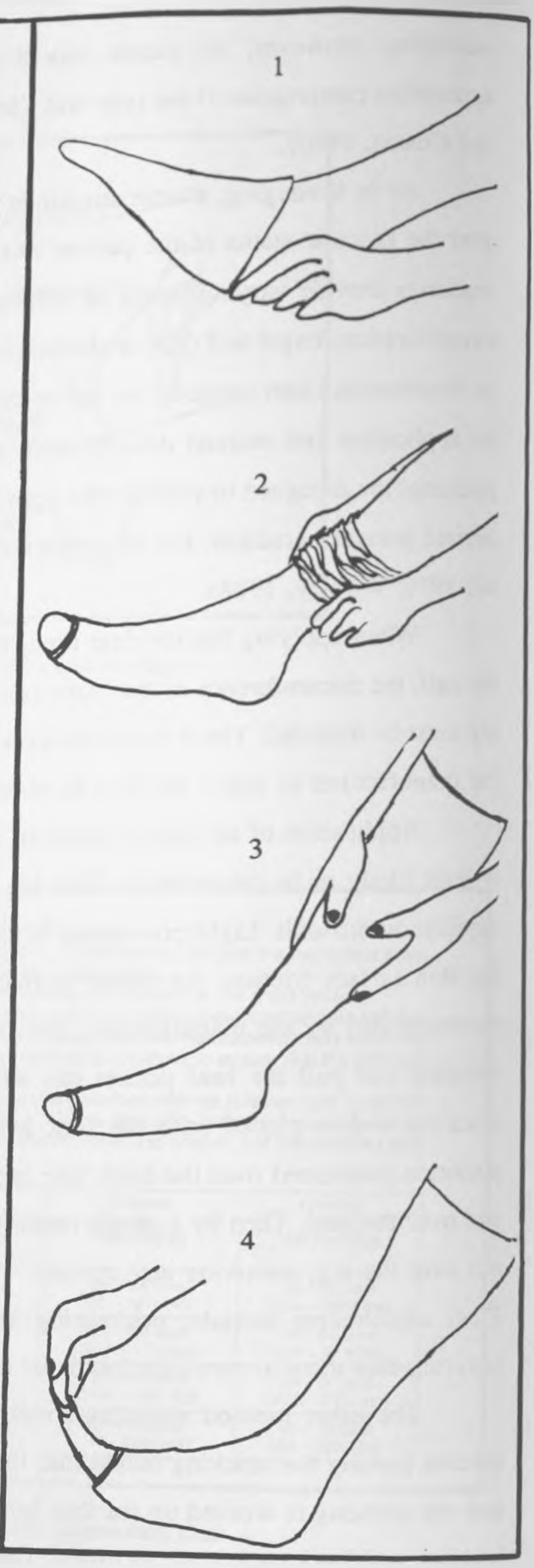


Figure 2.28 Applying an elastic stocking

heel and gradually spread out, in a similar fashion, over the leg with the palm of the hand. Once the stocking is in place, the foot slip is then withdrawn. This method is illustrated in figure 2.28.

When highly compressive elastic stockings are prescribed, especially for the infirm and elderly, simple aids may not be sufficient for patients to apply the devices themselves (Whitley, 1988; Partsch, 1985). The problem can be made worse by the presence of a fresh, open ulcer which can be very painful. Various devices have been introduced to assist application in these awkward circumstances, like the simple wire frame (Figure 2.29) by Cornu-Thenard et al. (1983), but none have been particularly popular.

Like bandaging, it is necessary precaution to examine the toes for colour and warmth to ensure that blood flow is not occluded. Ankle mobility, foot wear and overall comfort must be checked. It is good practice to regularly examine the fit of the elastic stocking by re-measuring the necessary dimensions as these tend to change when the oedema subsides.

2.5 THE HAZARDS OF COMPRESSION THERAPY

Compression therapy, like any other treatment, involves certain risks. These can range from simple skin allergies to severe tissue necrosis and, in a few instances, to amputation. Very high compression can easily be produced and sustained by the improved modern day bandage and elastic stocking, consequently narrowing the margin between benefit and hazard. A survey conducted in Scotland over a five year period, revealed that 32% of the surgeons who took part in the study had experienced at least one case of damage induced by compression therapy and there were twelve cases of amputations (Callum et al., 1987).

i. Improper Diagnosis

The injudicious use of compression therapy on a leg with arterial disease, as a result of improper diagnosis, is a danger with the gravest consequence. The effect of such an action would lead to impairment of arterial circulation, tissue necrosis and if the pressure is prolonged, irreversible damage of the leg (Dale and Gibson, 1987). Arterial impairment is normally diagnosed by palpation of the pedal pulses but

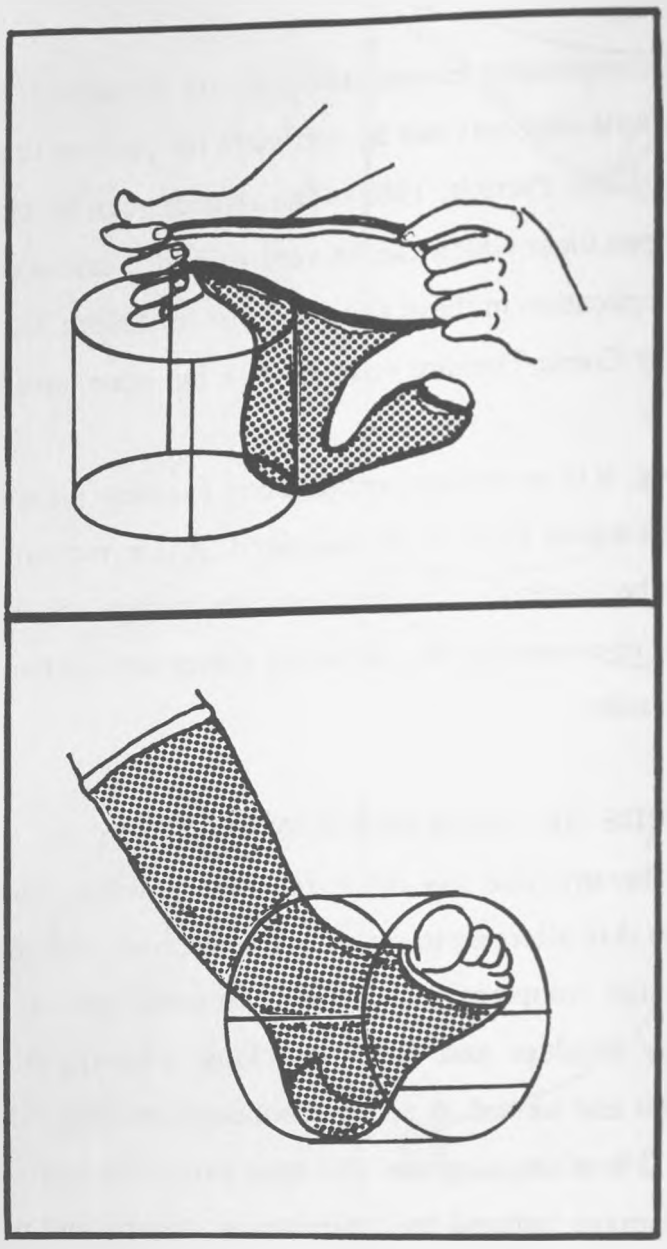


Figure 2.29 The wire frame application aid (Cornu-Thenard et al., 1983)

Ruckley et al. (1986) have highlighted that the correlation of such a condition with palpation of the pedal pulses is poor and emphasized the importance of the use of Doppler ultrasound for conclusive diagnosis, especially if the legs were oedematous.

ii. Dangers Inherent To Device

Some compression devices, especially paste bandages, can cause skin irritation and allergic reactions (Thomas, 1991). This is a minor side-effect and precautionary, patch-tests are usually carried out.

Many bandages and elastic stockings slip as the material works loose from the leg during ambulation and as a result creases accumulate at the ankle. The slippage not only disrupts the desired pressure distribution but could also result in a tourniquet, particularly around the ankle, and can have dangerous effects on the blood circulation (Raj et al., 1980). Adhesive and cohesive bandages have been designed to secure the bandage in place and resolve the problem of slippage (Battle, 1973). Unfortunately, some adhesive bandages can damage fragile skin during removal (Thomas, 1991) and cohesive bandages can be dangerous in inexperienced hands as they can produce bands of high pressure if not correctly applied (Dale and Gibson, 1987). Most elastic stockings have an elastic garter around the top edge of the stocking, to prevent the stocking from slipping down. Lewis et al. (1976), have reported that some of these garters behave like tourniquets and should, preferably, be avoided when selecting an elastic stocking.

Occasionally, bandages need to be joined as they may not be long enough and this can be potentially dangerous, especially in inexperienced hands. The extra layers at the join can disrupt the pressure distribution and also produce a band of high pressure (Raj et al., 1980; Dale et al., 1983).

Husni et al. (1968) have reported that bandaging the knee joint retards venous circulation and should be abandoned. Similarly, Dale and Gibson (1990) have reported that, above knee elastic stockings tend to gather in folds behind the knee which can lead to obstruction of blood flow and recommend the use of below knee stockings.

Cornwall et al. (1987) conducted an investigation on fifteen types of elastic stockings using photoplethysmography and reported that only five of these devices

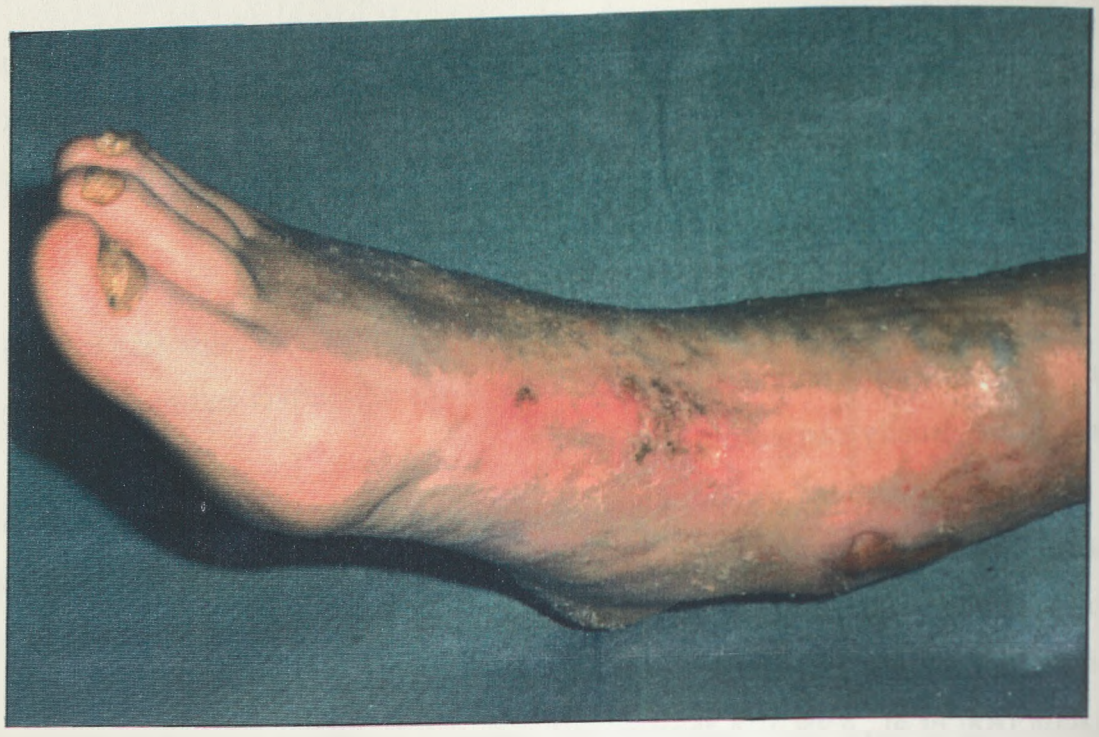


Figure 2.30 Sores caused by poor bandaging

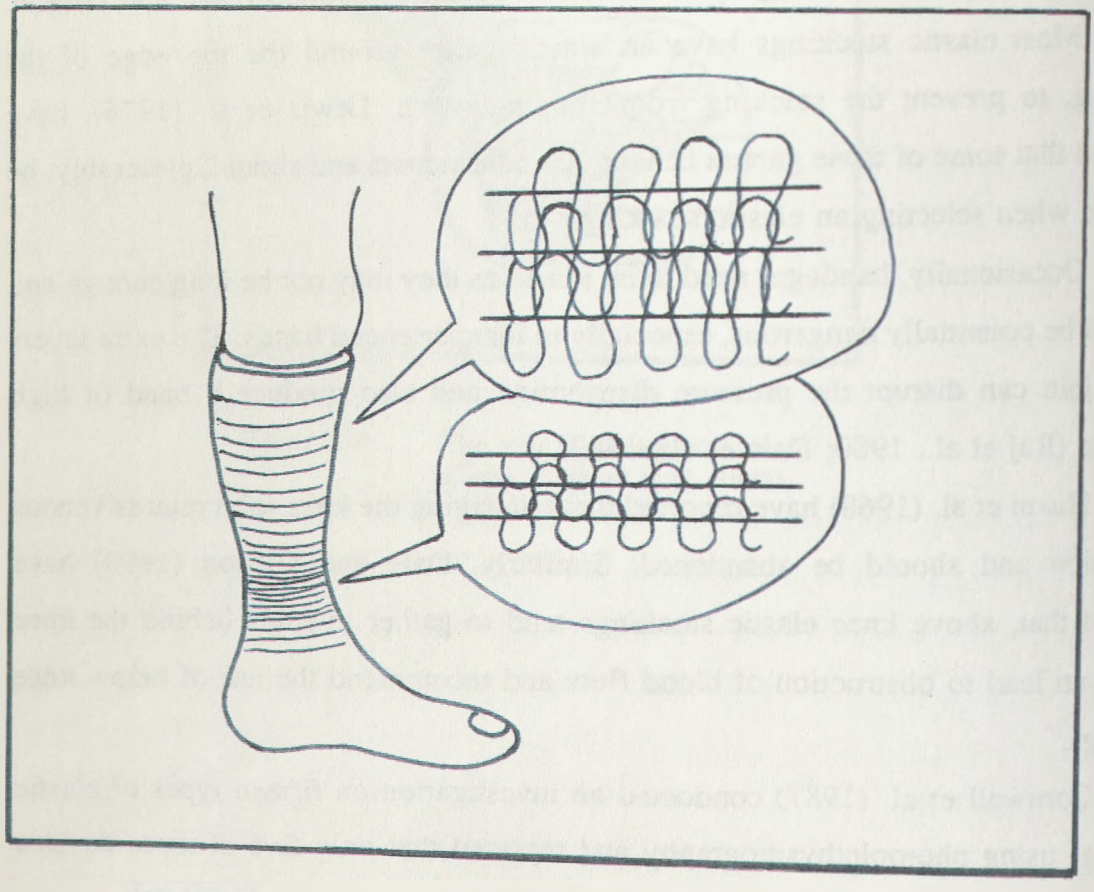


Figure 2.31 Variation in the concentration of elastomeric yarns

were functionally satisfactory. This draws attention to the fact that despite rigorous tests carried out by the manufacturers and controls imposed by the British Standards Institution, there are inherent risks involved in the use of these devices.

iii. Improper Application of Compression Device

Improper application of compression devices can be potentially harmful or even dangerous. If the appropriate compression and pressure gradient is not achieved by skilful application of the device, then the device could cause more harm than if not treated at all (Cornwall, 1991).

Bands of high compression may develop as a result of poor application of compression devices and lead to local pressure sores, as shown in figure 2.30, or in more severe cases, impede blood circulation (Thomas 1991). In the case of elastic stockings, such dangers often arise from devices that are poorly selected and fitted (Pierson et al., 1983; Lewis et al., 1976; Dale and Gibson, 1990). Peat (1988), describes how the intended compression of an elastic stocking can be distorted if the stocking is not correctly stretched and positioned. If the stretch of the stocking is uneven, then the distribution of elastomeric fibres may concentrate at a particular area and result in a dangerous band of high compression as illustrated in figure 2.31.

Poor bandaging can restrict ankle movement, particularly when paste bandages are used and can disrupt the calf muscle pump (Dale et al., 1986). Uneven creases or folds, especially at the foot and ankle, can cause blistering and further trauma which may be difficult to heal, in patients already suffering from venous insufficiency (Cornwall, 1985; Smith et al., 1986).

CHAPTER 3

A FOCUS ON AMBULATION AND INTERFACE PRESSURE MEASUREMENT

3.1 The Influence of Ambulation on Ulcer Healing

3.2 The Effect of Ambulation on External Compression

3.3 The Long-Term Monitoring of Ambulation

3.4 Pressure Measuring Systems Commonly Used in Evaluating Compression Therapy

3.5 The Choice of an Interface Pressure Measuring System

3 A FOCUS ON AMBULATION AND INTERFACE PRESSURE MEASUREMENT

3.1 THE INFLUENCE OF AMBULATION ON VENOUS ULCER HEALING

Ambulation is an integral part of the normal activities of daily living. The constant change of posture and activity during ambulation is an essential component in promoting venous return (Van Der Molen et al., 1979). The importance of the leg muscle pump mechanism and improved venous return in venous ulcer healing has been previously established (Section 1.5.2). For the muscle pump to function effectively the patient needs to be ambulant, unfortunately this can be difficult for the frail, the elderly and for those who suffer from diseases like arthritis (Jarrett, 1984; Gaylarde et al., 1990). It is therefore not surprising that an association between venous ulcers of the leg and loss of mobility, typically due to restriction of the ankle joint, has been noted (Gaylarde et al., 1990; Ruckley et al., 1982). Sadly, for these sufferers the lack of ambulation can lead to muscular atrophy and further impairment of venous return. The importance of ambulation as an integral part of venous ulcer treatment was pointed out by Hordegen (1989) when he reported that complete healing of venous ulcers was achieved in 96% of the 75 patients who received ambulatory treatment along with compression therapy. Gardner and Fox (1985) have measured improved venous flow using a Doppler velocimeter during ambulation and described the importance of foot movement in improving venous return. Sabri et al. (1971) using the I^{125} fibrinogen uptake test, found that femoral venous flow improved even with just passive dorsi-plantar flexion of the foot. Wright and Osborn (1952), reported that venous flow velocity in the unparalysed legs of hemiplegics was within normal limits but the flow velocity in the paralysed legs was greatly retarded. In adducing a reason for the retardation of venous flow, Wright and Osborn mentioned immobility, lack of muscular tone and muscle atrophy.

Oedema of the lower extremities is a common feature in patients with incompetent venous function and has undesirable effects on ulcer healing. Posture has a significant role in the management and control of oedema. This is the basis of the already established "leg elevation" treatment to reduce oedema (Section 1.8). Conversely, the lack of ambulation as in prolonged standing or sitting by patients

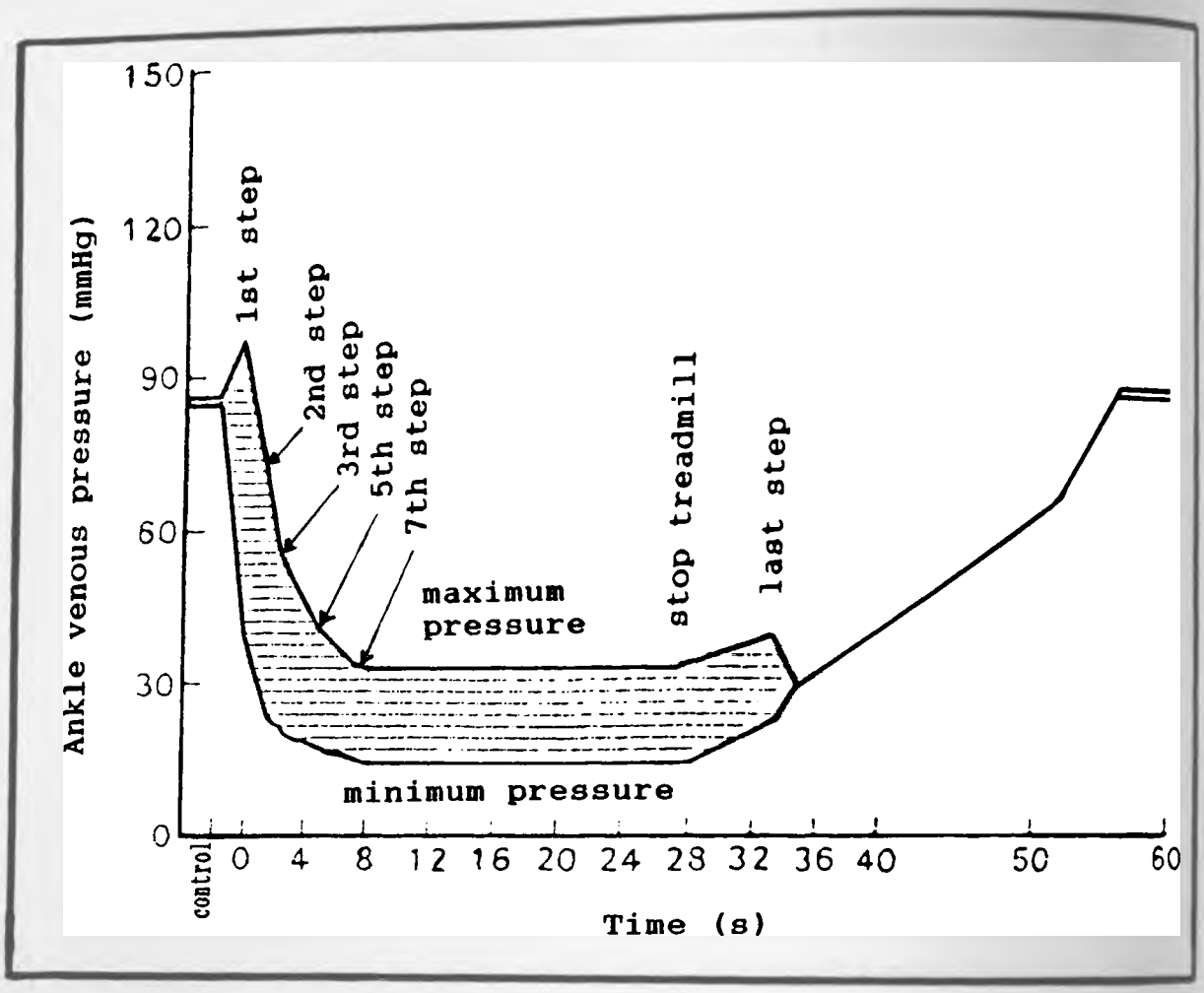


Figure 3.1 Ambulatory venous pressure (reproduced from Pollack and Wood, 1949)

with venous dysfunction can further aggravate oedema and can hinder the ulcer healing process (Stemmer, 1982; Demis, 1986; Jacques, 1987). Chant (1972) noted a reduction in Na^{24} clearance when the leg was lowered and deduced that it was due to the pooling which was clinically observed in the form of oedema. Keeley et al. (1962) have observed walking by patients undergoing compression therapy to be an effective means of controlling oedema.

The hydrostatic component of venous pressure arising as a result of gravitational effects is dependent on posture especially at the lower extremities. Pollack and Wood (1949) measured variations in the resulting venous pressure in the dorsal vein of the foot brought about by postural changes. They reported that average venous pressures at the ankle were 11.7mmHg (1.6kPa) in the recumbent posture, 56.0mmHg (7.5kPa) in the sitting posture and 86.8mmHg (11.6kPa) in the standing posture. It has been previously pointed out (Section 1.7) that venous hypertension is a primary factor in the process leading to venous ulceration and that restoring normal venous pressure is vital to ulcer healing.

During ambulation and exercise such as in walking there is a significant drop in venous pressure which has been measured using plethysmographic and foot cannulation techniques (Somerville et al., 1974; Horner et al., 1980; Norris et al., 1984). Figure 3.1 illustrates the ambulatory venous pressure measured by Pollack and Wood (1949) showing the pressure drop as the subject walked. Ambulation may therefore have a role in reducing venous hypertension at the lower extremities and favour ulcer healing as reported by Hordegen (1989). Chant (1990) also voiced a similar opinion when he stated that a reduction of venous pressure in the lower extremities by any means including postural changes will promote healing of venous ulcers.

3.2 THE EFFECT OF AMBULATION ON EXTERNAL COMPRESSION

Very little is known about the long term characteristics of pressures generated beneath compression devices and the effect of ambulation on external compression of the leg. However, from very early times it had been recognised that both ambulation and external compression of the leg had favourable effects on the healing of venous ulcers. Such ambulation may simply be periodic changes in posture, short

walks interrupting prolonged periods of standing or sitting, simple dorsiflexion of the foot or periodic leg elevation (Keeley et al., 1962).

The idea that the performance of a compression bandage or an elastic stocking is enhanced by ambulation has received much support (Georgiev, 1985; Christopoulos et al., 1987 and Keeley et al., 1962). Christopoulos et al. (1987) using air-plethysmographic technique found that external compression produced by elastic stockings reduced venous reflux and improved the ejecting ability of the calf muscle during the rhythmic exercise brought about by ambulation. Van der Molen et al. (1979) have observed that pressure beneath compression devices fluctuated during walking and concluded that such variations in compression were favourable for controlling oedema during ambulation. Keeley et al. (1962) reported that compression bandages help control oedema in recumbency, sitting or standing but were most effective when the patient was walking. They explain that the muscle and skin supported by the bandage improves the efficiency of the muscle pump which is active during walking. It is generally accepted that ambulation and exercise have favourable effects on venous pressure at the lower extremites. Christopoulos et al. (1987) using the foot vein canulation technique have shown that external compression along with ambulation can further reduce ambulatory venous pressure and have beneficial effects on venous function. Van der Molen et al. (1979) demonstrated that non-elastic external compression produced greater fluctuations in interface pressure during ambulation than elastic compression which they believe is useful in improving venous return.

The relationship between interface pressure beneath compression devices and changes in posture has not been fully examined as yet. Barbenel et al. (1990) have suggested that small postural changes such as dorsiflexion of the foot and large postural changes such as sitting or standing, can produce significant alterations in the interface pressures generated beneath bandages and elastic stockings. They account these changes to the contracture and activity of different muscle groups. Van der Molen et al. (1979) have previously shown that different types of external compression produce fluctuations in pressure generated even with small postural changes such as flexion-extension of the foot. Ruckley (1992) demonstrated a significant drop in interface pressure when the patient changed posture from standing

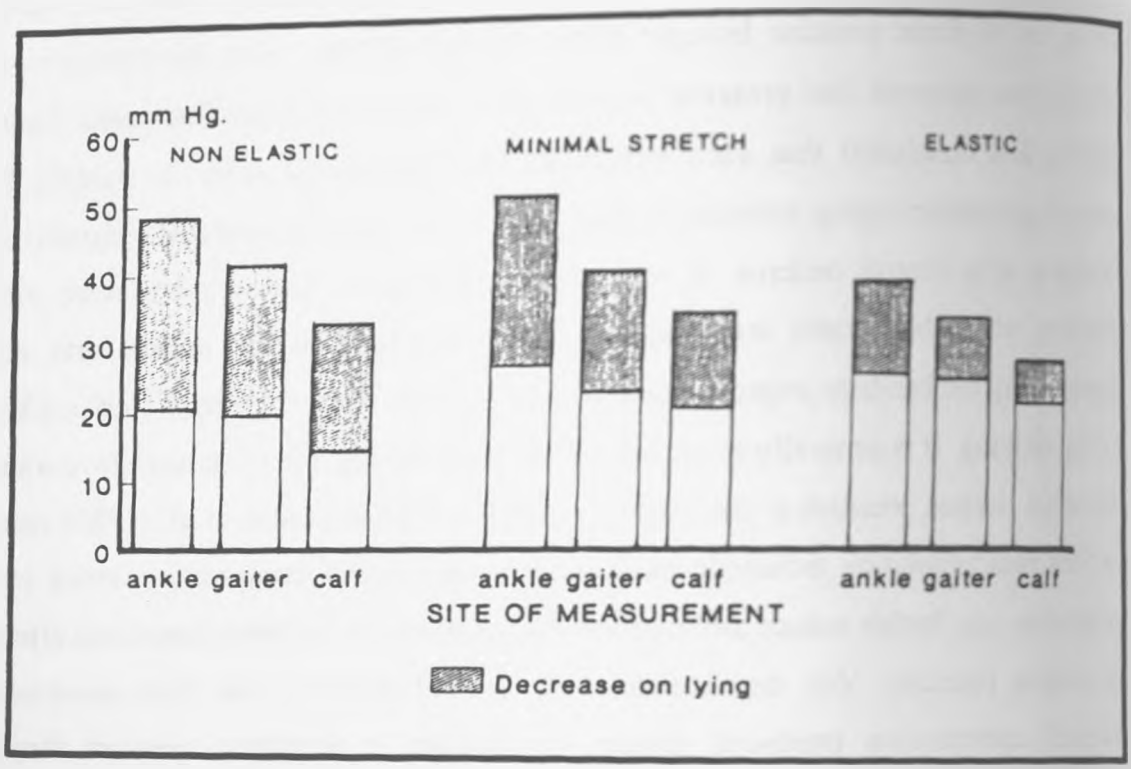


Figure 3.2 The effect of posture on compression (reproduced from Ruckley, 1992)

to lying, using three different types of external compression devices (Figure 3.2). Burnand et al. (1985) whilst investigating the performance of elastic stockings reported significant increases in the interface pressures when the patients changed from the lying to the standing posture. Fentem et al. (1976) suggested that movements of the leg during walking will produce variations in pressure as a result of changes in tension within the fabric of the compression device.

It has been pointed out that during recumbency a much lighter compression is optimal (Sigel et al., 1975; Arnoldi, 1976). Sigel et al. (1975) pointed out that hospitalised patients receiving "leg elevation" treatment may require even lesser compression. Conversely, patients who work in the upright posture for long periods of time would need high levels of compression to conteract the hydrostatic pressures and thus preventing distension of veins. This opinion was also voiced by Stemmer (1982), who stated that these patients should be prescribed with elastic stockings of a higher compression class.

Blecher et al. (1985) have mentioned that during leg movement there is a constant change of shape and dimension of the leg. This could significantly interfere with the interface pressure beneath the compression device. Further, such changes also lead to the problem of the device slipping during ambulation. Adhesive bandages were developed to overcome the problem of slippage but the characteristics and sustenance of the resulting interface pressure can only be verified by long term monitoring of pressure and ambulation.

Despite claims that ambulation coupled with compression therapy has favourable effects on venous function and ulcer healing, Fox and Gardner (1985) pointed out that ambulation could adversely affect superficial varices by pressurising them via incompetent perforator veins. Norris et al. (1984) whilst measuring ambulatory venous pressure demonstrated worsening ambulatory hypertension following the application of elastic stockings. Schraibman et al. (1982) did not note any significant changes in interface pressure beneath elastic stockings that related to postural changes or exercise. Chant (1972) reported that when external compression was maintained at intravascular hydrostatic pressure the effect of posture on Na^{24} clearance was removed.

Clearly, the influence of ambulation on venous function, compression therapy

and interface pressure requires further investigation. Monitoring interface pressure and ambulation during activities of daily living should provide the much needed additional information to shape future compression devices and therapeutic regimes.

3.3 THE LONG-TERM MONITORING OF AMBULATION

Early measurements of motion evolved around the desire to understand the biomechanics of human locomotion. With the development of technology, interests soon extended to studies involving human joint functions, and levels of energy expenditure associated with the intensity of body movements. In more recent times, with the advent of micro-electronics, data logging units and miniaturised physiological measuring devices, interests in monitoring ambulation have expanded to incorporate multiple parameters over prolonged periods of time. In order to achieve this, such a monitoring device has to be miniature in size, lightweight, robust, inconspicuous and socially acceptable, and have a large memory and battery capacity. A multitude of devices are available, which measure short term movement, locomotion, posture and activity, with varying levels of success.

(i) Pedometers

One of the earliest mechanical physical activity sensor is the pedometer, a stepcounter that consists of an arm balanced by a delicate spring (Stunkard, 1960). It is worn at the ankle or at the waist and with each step the impulse of the foot when landing will result in the swinging of the balance arm which, through a series of gears, is registered in a counting mechanism. However, the validity and reliability of this instrument are rather poor (Kemper, 1977). In addition it cannot identify activities other than walking or running and as such it has not been extensively used.

(ii) Actometers

The actometer, described by Schulman and Reisman (1959), is a modified wristwatch in which the escape mechanism has been removed, whereby any rotation of the rotor will be directly transduced to its hands. Activity can be interpreted from the resulting time displayed on the watch face. This device is only reliable when used in standardised movements (Massey, 1971) and has very large inter-instrument

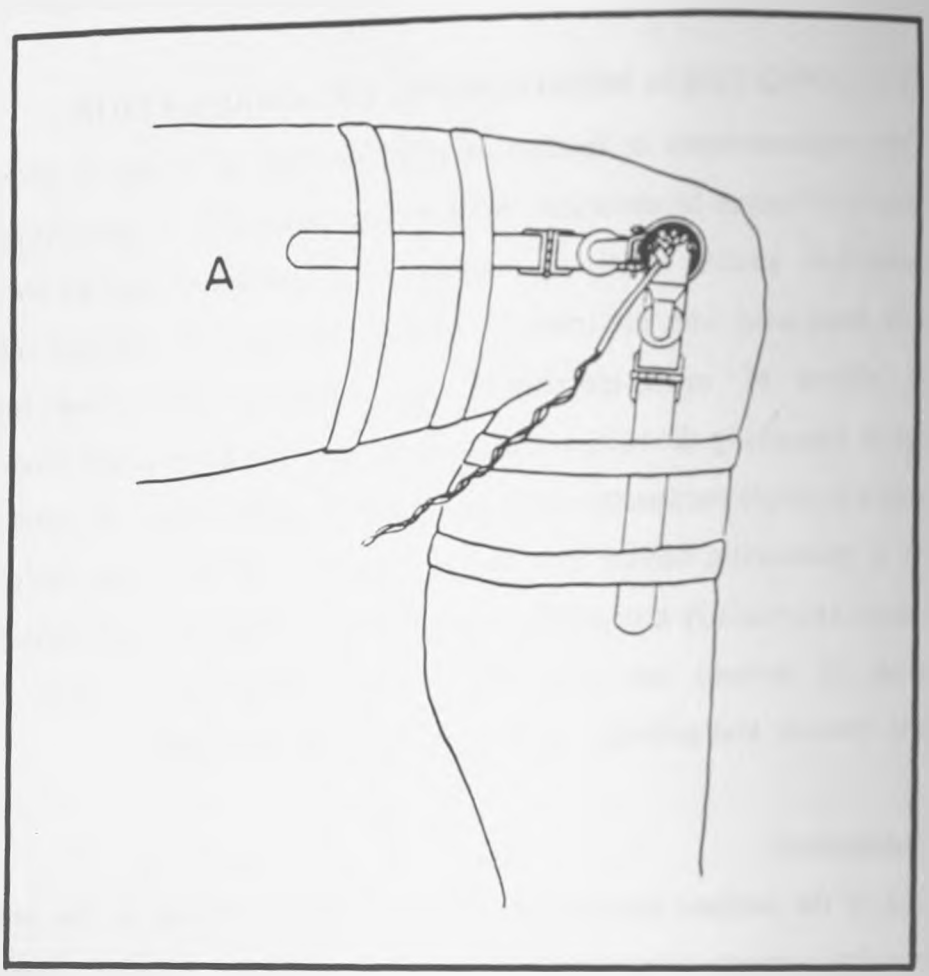


Figure 3.3 A potentiometer device (reproduced from Karpovich and Sinning, 1971)

variability making individual calibration essential (Saris and Binkhorst, 1977). As this device was essentially intended to reflect the amount and intensity of body movement, its use in monitoring ambulation is limited.

(iii) Accelerometers

Commercially available miniature accelerometers can be used to measure linear acceleration of any object. The mechanism is based on the measurement of deformation (strain) in a small beam or electro-active crystal as a result of the inertial force of a mass attached to the beam or crystal. By locating several such devices, in orthogonal orientations, on the human body, linear and angular accelerations can be measured. Numerical integration of the acceleration data is then performed to estimate velocity and displacement. Morris (1973) described the use of accelerometry for the measurement of human body movements. Meijer et al. (1991) in a study on the performance of this device, under standardized laboratory conditions, reported inter-instrumentation variation, decline in response with time, repeatability errors and the influence of the mode of attachment, on performance. The need for multiple devices, and complex electronics requiring charge amplifiers, to make this instrumentation feasible is not conducive for monitoring ambulation. Further, it is highly probable that such a device may output ambiguous data of activity during sleep.

(iv) Potentiometer Devices

This device uses a central rotational potentiometer with two long arms pivoted within it (Karpovich and Sinning, 1971). Upon the rotation of these arms, a potential difference is created which is proportional to angular displacement. Thus when the device is aligned with the anatomical joint axis it can be used to measure movement. This device requires a framework of straps to hold the protruding arms of the device in place, as illustrated in figure 3.3. Apart from being cumbersome and invariably restrictive to the patient's movement, the potentiometer has a fixed axis of rotation which must coincide with that of the joint. This becomes complicated as the axis of rotation of a human anatomical joint is not fixed and often non co-planar. It was not possible to adapt this system to monitor long term ambulation.

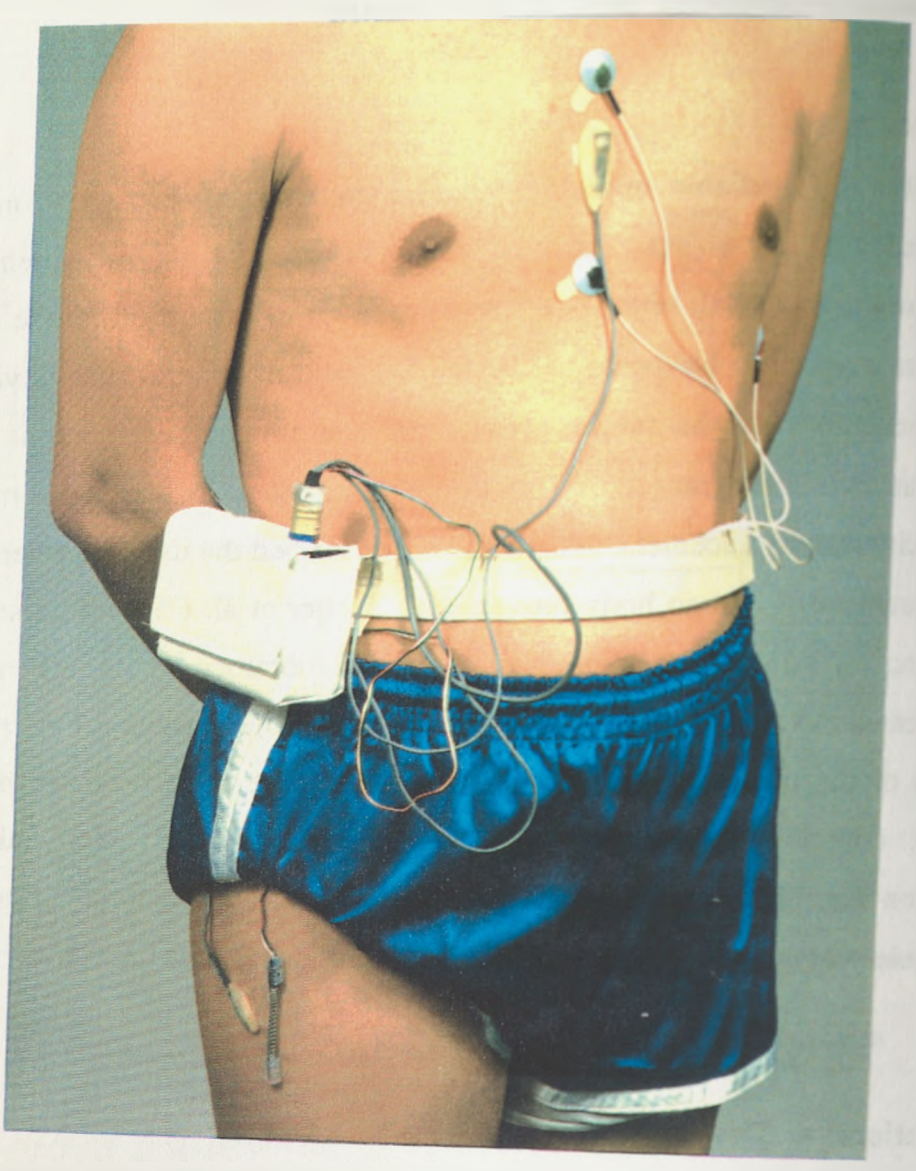


Figure 3.4 Mercury tiltswitch device (reproduced from Mulvey, 1986)

(v) Sonic Emitters

Engin et al. (1984) used a sonic emitter on the wrist and microphone receivers to locate and measure movement. This system requires multiple, orthogonally positioned microphones and complex geometric relationships to configure movements. It is further restricted by the available working volume of the microphone, as such its use was limited to the laboratory only.

(vi) Optical Switch Devices

This device employs a light emitter and detector placed at close proximity over a joint. The switching mechanism is activated by normal light when the emitter and detector are aligned. Grieve (1969) reported the use of such a device for determining changes in joint angles. Its use in monitoring ambulation is seriously limited by the working angular range, need for multiple devices and complex logic operations, and the inability to function in non co-planar movements.

(vii) Mercury Tilt Switches

When a small amount of mercury is encapsulated in a miniature cylindrical tube with electrical contacts on either side, it offers an ON/OFF switch mechanism upon the cylinder being tilted through 90 degrees. Several such tilt switches when placed on the trunk, thigh and leg of a human body could be used to describe human posture and movement with the aid of a logic system. Mulvey (1986) described the use of such a system employing two tilt switches (Figure 3.4). This method of measuring and recording human posture has gross limitations. Although modern housing of mercury tilt switches may be robust and claimed to be relatively safe, when used next to skin, one runs the potential risk of accidental spillage of this toxic substance. The maximum angular working range of these switches is at best ± 20 degrees from the "just ON" position and typical angular hysteresis is 15 degrees (R S Components Ltd., 1991). This imposes a major restriction in the complicated analysis of an in-between stance in posture. The nature of the tilt switch mechanism provides a poor frequency response to the "ON/OFF" change. This accompanied by "splashing" within the capsule gives rise to ambiguous outputs especially in rapid postural changes such as walking. Further, these switches respond to tilts in any plane

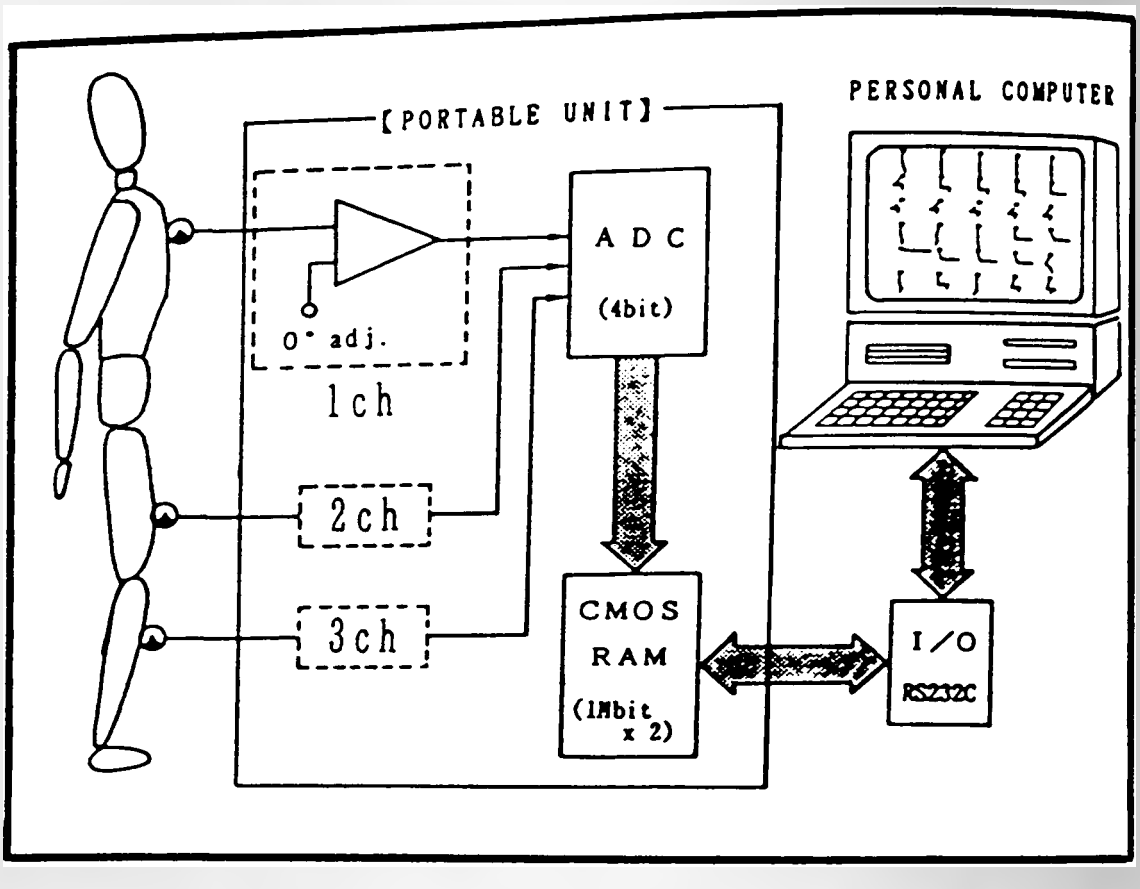


Figure 3.5 Electro-magnetic inclinometer (reproduced from Tanaka, 1990)

thus making precise analysis of posture very cumbersome. The need for major post analysis involving complex logic operations to produce even moderately detailed information on posture makes this device unattractive.

(viii) Electro-Magnetic Inclinometers

A freely swirling miniature plumb-line pendulum in the presence of a magnetic field can be used to provide a simple angle measuring mechanism based on the Hall effect. As the plumb-line is sensitive to gravitational force, angular deviations from the vertical can be measured using a Hall effect integrated circuit. Several such devices may be interlinked to provide a system to monitor posture. Tanaka (1990) described the use of a miniature electro-magnetic inclinometer to monitor ambulation. Three devices, 13mm in diameter and 30 mm in length each, are attached to the chest, thigh and leg of a patient and linked to a portable data recording unit via three separate channels (Figure 3.5). This system has been used to record human posture over a period of twenty four hours. However, little is known of its reliability and performance characteristics.

This is the most applicable device available to date that has been designed for the purpose of monitoring long term human posture. Unlike the mercury tilt switch system it is fairly safe, possibly less sensitive to bounce and has the full angular working range. Unfortunately, this system requires at least three input channels in the data logging unit. This is a major drawback in any long term monitoring as it is a drain on both the memory capacity and power supply thus limiting the duration of use. Further, it limits the number of input channels available for other useful parameters, such as pressure. The devices when operational are attached onto skin which readily slides over the skeletal structure beneath. It appears that a small shift in the position of attachment will constitute a large datum error in the angular output because of its relatively small size compared to the human body. The likelihood of such an event happening during sleep, does call for concern.

(ix) Flexible Goniometers

This is the state of the art device for angular measurement in joint movement. There are several varieties of flexible goniometers ranging from mercury-in-rubber

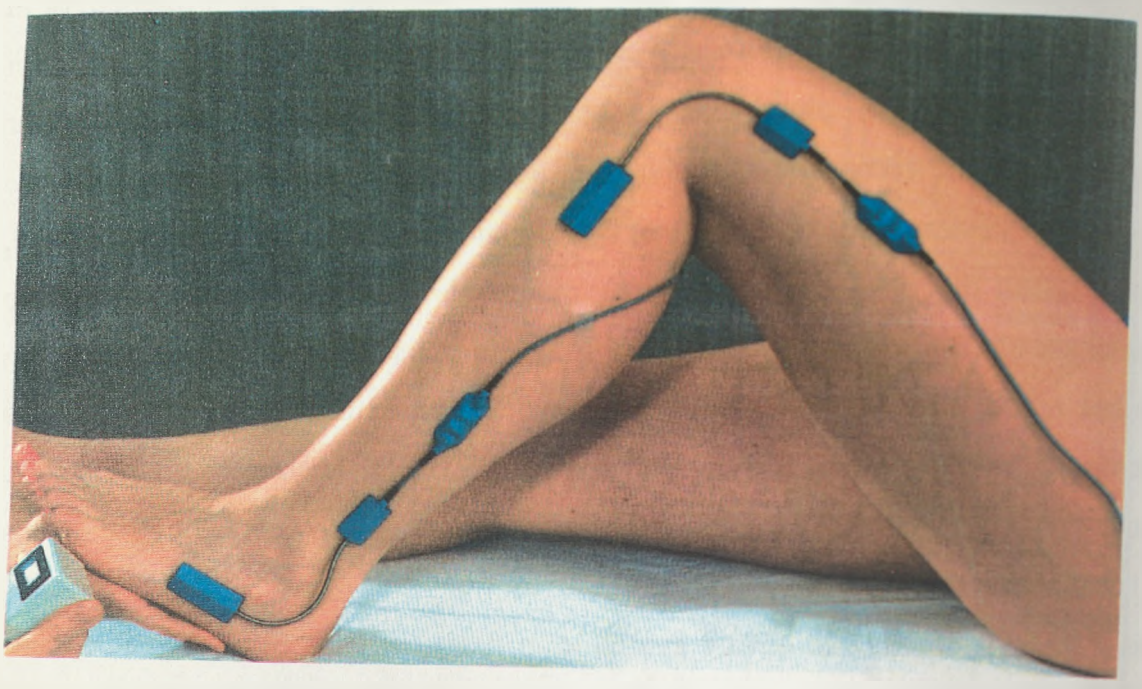


Figure 3.6 Flexible electro-goniometer

(Crosbie, 1982) to strain gauged types. However, the flexible, strain gauged, electrogoniometer developed by Nicol (1987), has been highly successful and is currently used in clinical work (Figure 3.6). It is a device based on a narrow steel foil fitted with long strain gauges. The device is capable of very high resolution (0.02 degrees) and produces a linear relationship between electrical output and the angle subtended between the two encapsulated ends. A feature of this instrument is that the measured angle is independent of the precise shape of the bend along the length of the foil hence it does not require alignment with the axis of rotation of the joint. An attempt was made to use this device to monitor posture over a duration of a week by securing the goniometer along the lateral side of the knee joint (Sockalingham et al., 1990). The instrument has several drawbacks when used for long term posture monitoring. The measurement of joint angle cannot unequivocally identify posture particularly when trying to distinguish between standing upright and lying horizontal with the legs extended. In another circumstance, when the patient is recumbent with the knee flexed 90 degrees the posture could be mistaken for sitting. These problems cannot be solved even if multiple devices were used at various joints. Further, the very fine hair line instrumentation within this device proved too fragile for prolonged use. Finally, the encapsulated blocks at either end of the device are too bulky for continuous long term clinical use and often give rise to pressure sores in the underlying skin.

It is apparent from this review that a more suitable device has to be developed for monitoring ambulation, which would better satisfy the required criteria. Such a device would ideally utilise only one channel in the data logger, thus allowing for multiple recording of interface pressures.

3.4 A REVIEW OF PRESSURE MEASURING SYSTEMS COMMONLY USED IN EVALUATING COMPRESSION THERAPY

The application of pressure to the skin surface for a prolonged period of time may influence the physiology of the skin and subcutaneous tissue. Excessively high pressures may produce damage leading to pressure sores (Barbenel, 1983). More moderate or graduated pressures may have favourable effects such as the acceleration of the resolution of hypertrophic scars or in improving venous return (Kischer et al.,

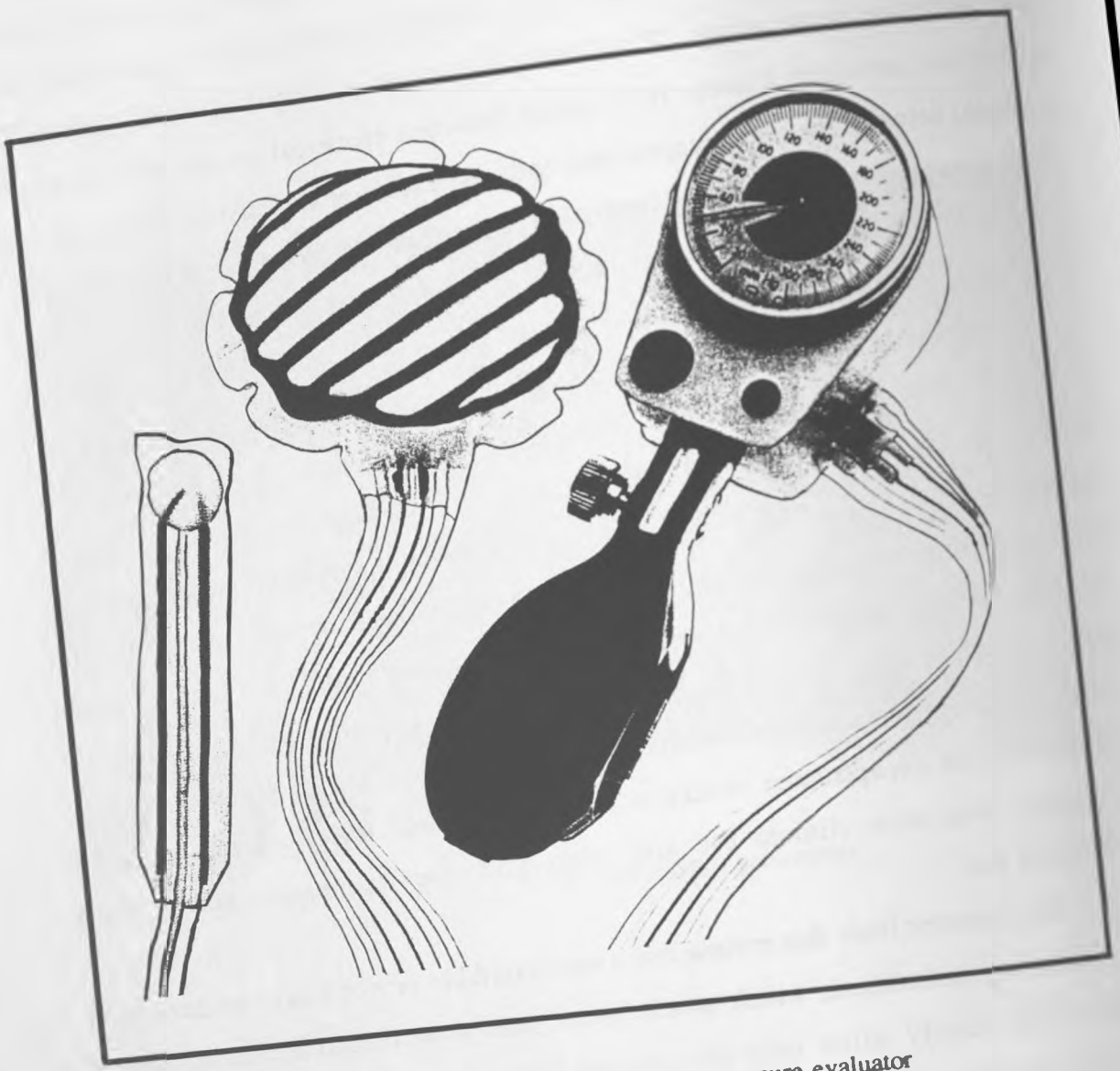


Figure 3.7 The Talley-Scimedic pressure evaluator

1975). The desire to measure the resulting interface pressure has posed formidable challenges and it would be accurate to say the an ideal means of measurement still does not exist (Grant, 1985). As a consequence, there exist numerous pressure mesuring devices and transducers that perform to varying levels of success (Wytch et al., 1989; Grant, 1985; Crenshaw and Vistnes, 1989). Some of these pressure measuring systems have been regularly used in the study of compression therapy and in the evaluation of elastic stockings and bandages.

(i) Talley-Scimedic Pressure Evaluator

The Talley-Scimedic Pressure Evaluator (Talley Medical Equipment, U.K.), developed by Reswick and Rogers (1976), is an electro-pneumatic device that has been used for investigating interface pressures (Figure 3.7). This device, a derivative of the pneumatic system first described by Hendry et al. (1946), had been very popular but is now superceded by more automated systems. In its simplest form it consists of a polyvinyl chloride (PVC) "bladder" sensor with metal strips bounded to the upper and lower inside surfaces. When the deflated sensor is placed at the interface, the metal strips are in contact and this completes an electrical circuit which switches on a light emitting diode or an electrical bulb. The sensor cell is then inflated by a standard, hand-held, sphygmomanometer which also indicates pressure. When the pressure inside the sensor cell exceeds the externally applied interface pressure the capsule inflates, the contacts break and the light goes out. By releasing the screw on the sphygmomanometer the sensor cell is allowed to deflate slowly until the light re-illuminates, at which point the interface pressure is taken as equal to the pressure within the capsule as indicated on the sphygmomanometer gauge. Variations of this device include a larger sensor pad which has a metallic grid covering the entire inner surface instead of a single pair of metal strips.

As one of the pioneer devices, this instrument has enjoyed many favourable reports (Wytch et al., 1989; Palmieri et al., 1980; Reddy et al., 1984). The device is easy to use, simple to manufacture, and relatively inexpensive, although caution should be exercised when interpreting the results. The sensor in the deflated mode is thin, flexible and contours well around anatomical features. The inflated sensor, however, is considerably less flexible and the inflation also increases the thickness

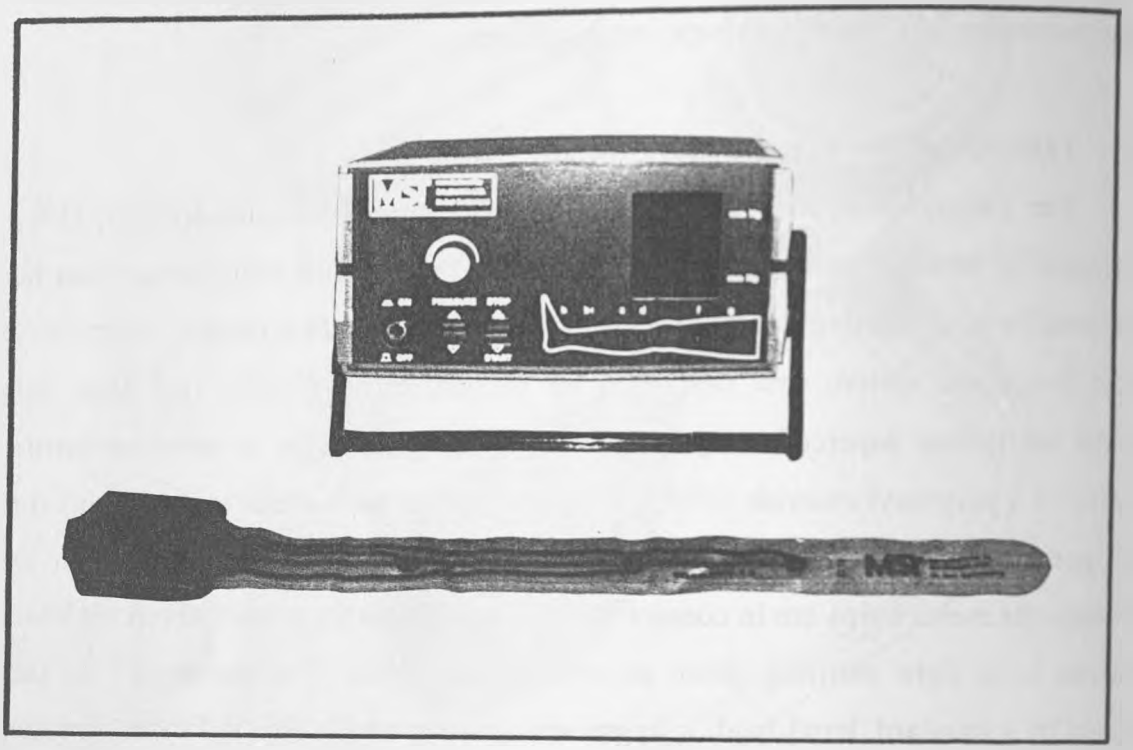


Figure 3.8 Medical stocking tester

of the sensor which results in some averaging effect of the pressures measured (Barbenel,1983; Ferguson-Pell et al., 1985). The sensor with the single point contacts appeared to respond to the pressure in the area of contact only (Barbenel, 1983). The precise point of pressure measurement cannot be determined when the larger sensor pad, with the metallic grid contacts, is used (Reswick and Rogers 1976). This device, like the other pneumatic devices is only capable of providing intermittent pressure measurement and as such is limited to static applications only. Nevertheless, it has formed the basis of more complex systems such as the Borgnis medical stocking tester.

(ii) Borgnis Medical Stocking Tester (MST)

The Borgnis medical stocking tester (Saltzman Limited, Switzerland) developed by Borgnis et al. (1978) is the most extensively used pressure measuring system in the evaluation of pressures generated by compression devices. The Borgnis instrument (Figure 3.8) consists of "bladder" sensors connected to pressure transducers. Within each sensor cell, there are two very thin metal discs bounded to the upper and lower inside surfaces. These metal discs are connected to leads running within the connecting air tube to an electronic conditioning and display unit. Initially when the sensor cell is placed at the interface between the compression device and the skin, it is deflated and the disc contacts are together. Air is then automatically pumped into the sensor cell until the pressure within it is just sufficient to break the contact between the two metal discs. The pressure at the point is taken to be equal to the interface pressure which is recorded and displayed.

The Borgnis instrument offers an advantage over other electro-pneumatic systems in its more compact sensor cells. Van Den Berg et al. (1982) have reported that such a small sensor cell with a relatively large radius of curvature does not bulge under the compression device nor does it unduly lift up the textile. These sensor cells, normally in a set of four or six, are layed out in a row at regular intervals, on a PVC strip and are designed for easy use on the limb. Van Den Berg et al. (1982) have tested this system against plethysmography techniques and have reported high accuracy and reliability based on their measurement of relative coefficient of variation (4.2% at the calf).

Figure 3.9 The Oxford pressure monitor

Regular users of the Borgnis medical stocking tester, however, have expressed less favourable reports. The most common practical problem was the fixed layout of the sensor cells which limits its effective use to a narrow range of leg sizes (Cornwall et al., 1987; Dale et al., 1983). Even when used on a suitable leg size, the measurements just below the knee were not included because the readings were not reproducible. This was because the device's bulky connecting box was too near the sensor and disturbed its performance. Tennant et al. (1988) had found that the first two readings of each measurement, using Borgnis device, were inconsistent and they had to allow the sensor cells to be inflated twice before a reading was taken. Blair et al. (1988) have reported that the Borgnis device was both more cumbersome and less accurate over prolonged periods than the Oxford pressure monitor.

(iii) The Oxford Pressure Monitor

The Oxford pressure monitor (Talley Medical Equipment, U.K.) described by Bader and Hawken (1986) is a pneumatic device which is a modification of a previous device, the Denne gauge (Bader, 1982). The Oxford monitor (Figure 3.9) was primarily developed to measure interface pressure at support surfaces but it has also been used to measure pressure beneath compression devices (Blair et al., 1988). The instrument operates on a pressure sensing cycle which is controlled by a microprocessor. At the start of the cycle the PVC "bladder" sensor cell is placed at the interface and held in a deflated condition by a vacuum pump. In the following stage of the cycle, the pump mechanism is reversed and air is forced into the sensor cell. When the pressure in the cell becomes equal to the interface pressure, the cell begins to inflate causing a change in volume. This change in volume is detected by the microprocessor and the pressure at that instant is recorded. At the end of the cycle the sensor cell is returned to the deflated state.

As pointed out by inventors, Bader and Hawken (1986), the Oxford pressure monitor is not ideal but it may be suitable for clinical and research use provided that its limitations are recognised. It is easy to use, has a working range of 0-250 mmHg, offers up to twelve sensors and unlike other pneumatic devices has the advantage of not having metal inserts in the sensor cell. However, this device is relatively expensive, has a deviation from linearity of 3%, and has a stated accuracy of

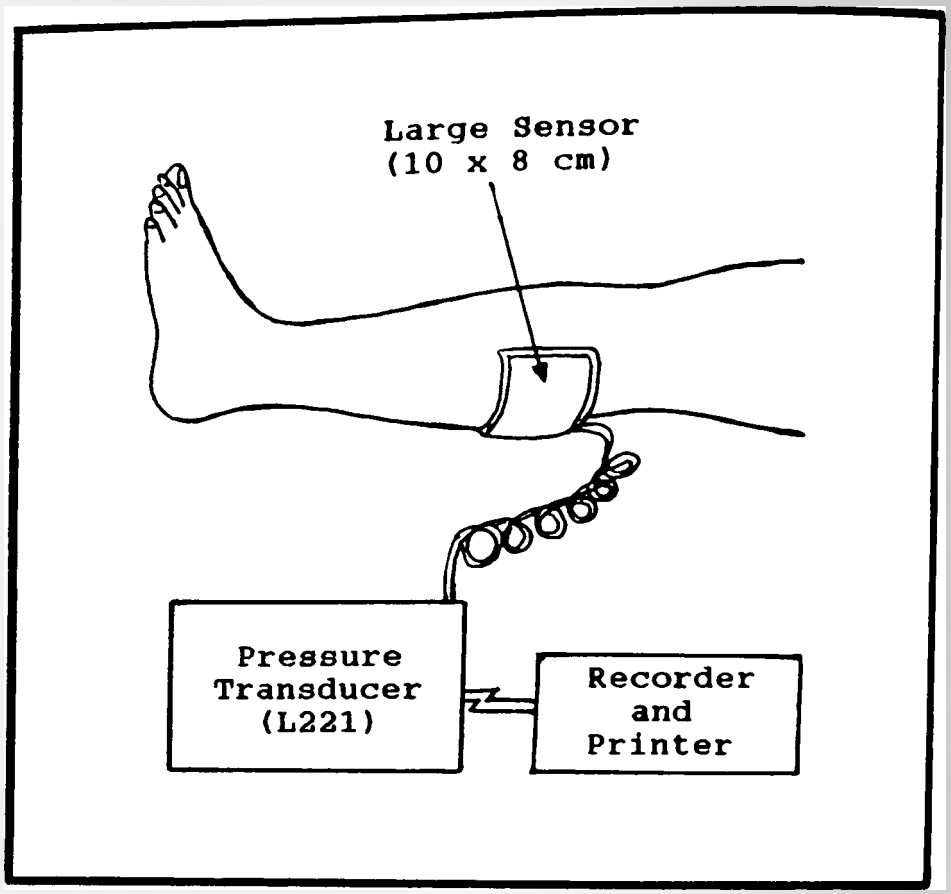


Figure 3.10 An Electro-hydraulic pressure measuring device (reproduced from Fentem et al., 1976)

±4mmHg (0.5kPa) which is not particularly suitable for evaluating compression devices (Wytch et al., 1989). An intrinsic disadvantage of the device is the delay, between the instant pressure is applied and equilibrium of the system reached, before pressure is recorded (Torres-Moreno, 1991). The sampling frequency of the Oxford monitor is quoted to be in excess of 2 Hz by the inventors but this can vary as it is dependent on the applied pressure and pump characteristics of the device.

(iv) An Electro-hydraulic System (Nottingham)

An electro-hydraulic system was described by Fentem et al., in 1976 and was popularly used for evaluating compression devices for several years that followed. The device (Figure 3.10) was not commercially developed but a review is in order as many important research works on compression therapy were based on the device (Raj et al., 1980; Schraibman et al., 1982; Fentem et al., 1976; Gandhi et al., 1984).

The system utilises a large PVC bag (10x8 cm), containing a small amount of water (5ml), as the sensor. This bag is connected by a fine nylon tube to a pressure transducer (Bell and Howell L221) which is linked to a recording device. Prior to use, the sensor bag is taped to the site of measurement and the base-line reading is recorded, which is then subtracted from the pressure reading when the compression device is applied, to give the interface pressure.

Unlike the pneumatic devices, this hydraulic device is capable of continuous pressure measurement. Its partially filled, large sensor bag conforms well over the anatomical curvatures and is a prominent feature of the system but not without controversy. Fentem et al. (1976) claim that such a large sensor would avoid over estimates of pressure, locally, because of its larger radius of curvature. Shaw (1979) on the other hand, has pointed out that a large sensor is a source of a multitude of errors. Disappointingly, the performance characteristics of this system were never fully investigated despite extensive use.

Numerous other pressure mesuring devices have been developed with less than satisfactory performance (Patel et al., 1989; Patterson and Fisher, 1979; Sachs et al., 1974). Nevertheless many of these less sucessful devices have contributed to the better understanding of the properties required of an interface pressure measuring device.

3.5 THE CHOICE OF AN INTERFACE PRESSURE MEASURING SYSTEM

There exists a dilemma of choice when selecting an appropriate interface pressure measuring system. As an ideal pressure measuring system is still not available, suitable selection or development of a device usually involves compromise in some aspects of measurement. A closer look at some of these aspects, would reveal the difficulties and limitations of interface pressure measurement.

3.5.1 The Ideal Pressure Measuring System

The properties required of an ideal pressure measuring device have been understood, in general terms, for a considerable time. A number of attempts have been made to establish general guidelines describing the characteristics and parameters of an ideal pressure measuring system (N.A.S.W., 1968; Fernie, 1973; Ferguson-Pell, 1976; Mott, 1973; Bader, 1982). Quantitative estimates of some of these parameters were also suggested by Ferguson-Pell (1977). However, it has proved extremely difficult to incorporate these guidelines into a single effective pressure measuring system. Such a system would normally consist of the sensor, pressure transducer and conditioning unit.

The ideal sensor would not interfere with the pressure that is being measured nor alter the surrounding interface at the site of measurement. In order to achieve this, the presence of the sensor at the site of measurement ought to be as inconspicuous as possible and preferably distant from the pressure transducer. Such a sensor must be non-invasive, relatively small, thin, compliant, flexible, insensitive to shear and yet robust. Its compliance and flexibility would accommodate the anatomical contours without distorting the interface, whilst its small size would be capable of measuring localised pressures.

The ideal pressure transducer would be distant from the site of measurement and as such not influenced by factors such as perspiration or body temperature, although most modern transducers are independent of such variables. Pressure transducers may be either static or continuous measuring devices and their suitability would depend on nature of measurement. In general, static devices tend to be less versatile in their application. An ideal continuous device would have an appropriate

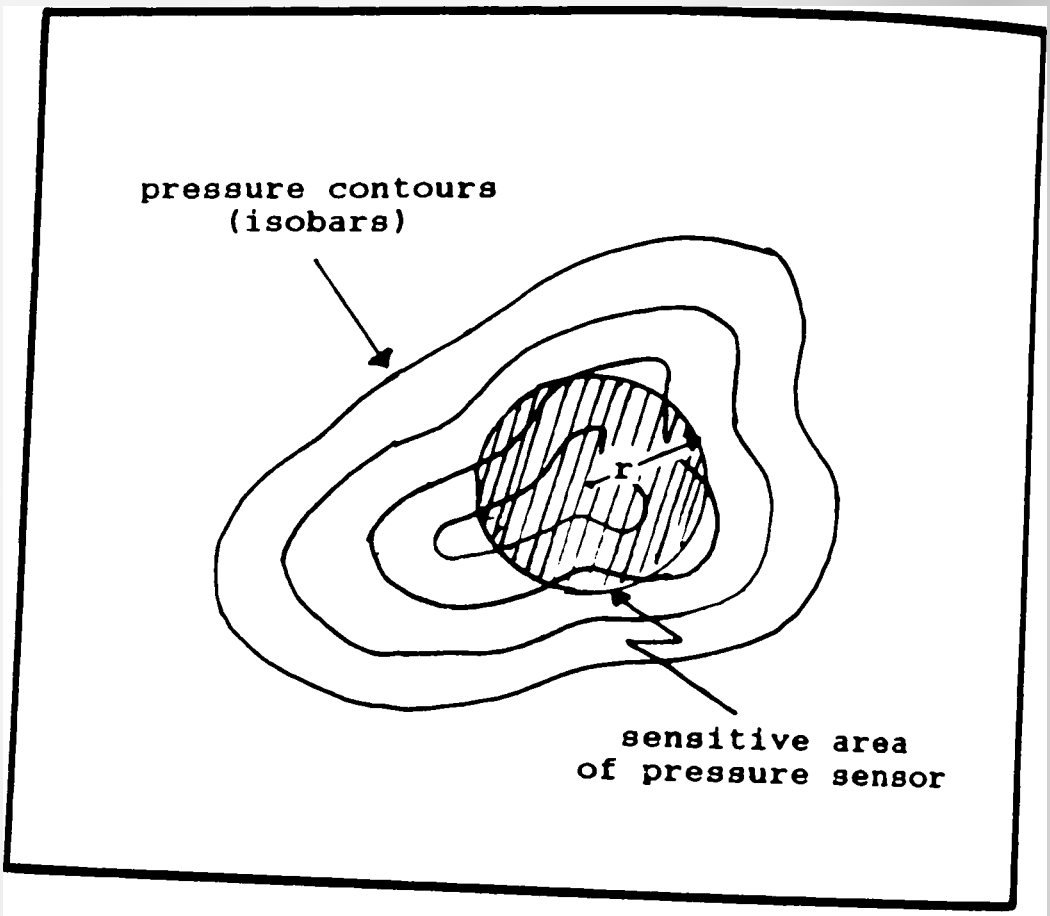


Figure 3.11 Pressure contours and sensitive area

frequency response to suit a particular dynamic measurement. The precision and accuracy of the resulting pressure measurement depend on the performance of the transducer. Ideally, the performance characteristics would include high sensitivity, good linearity, negligible hysterisis and long term drift, independance of temperature and humidity, and a suitable working range.

With the advent of micro-electronics, the development of conditioning units does not pose serious difficulties. Miniaturised units offering a wide range of data storage, display and printing facilities are readily available. Finally, the ideal pressure measuring system would meet these requirements at an affordable cost and must be easy to use in routine work.

3.5.2 The Pressure Sensor

The sensor of an interface pressure measuring system is probably the weakest link in such an apparatus. Upon resigning to the fact that the sensor in reality cannot be a mathematical point, several factors such as the sensitive area, the thickness and the stiffness of the sensor, the nature of the interface and the type of loading have to be considered.

(i) The sensitive area of sensor

Sensors, generally, have a sensitive surface area which ideally would be uniformly sensitive and the output would reflect the mean pressure on this surface (Fernie 1977). If the sensitive area or the contact area is too large then it will not be able to resolve local pressures and if the area is too small relative to the thickness of the sensor then its presence at the interface may interfere with the measurement. Ferguson-Pell (1977) conducted a theoretical analysis to determine the optimum radius of a circular sensor that would measure peak pressure, within an acceptable percentage error of measurement. The analysis was based on the assumption that the pressure distribution at the interface was radially uniform with a constant pressure gradient (Figure 3.11) and that the sensitivity of the sensor was uniform across its area. This analysis led to the conclusion that the radius (r) of a sensor may be described as follows;

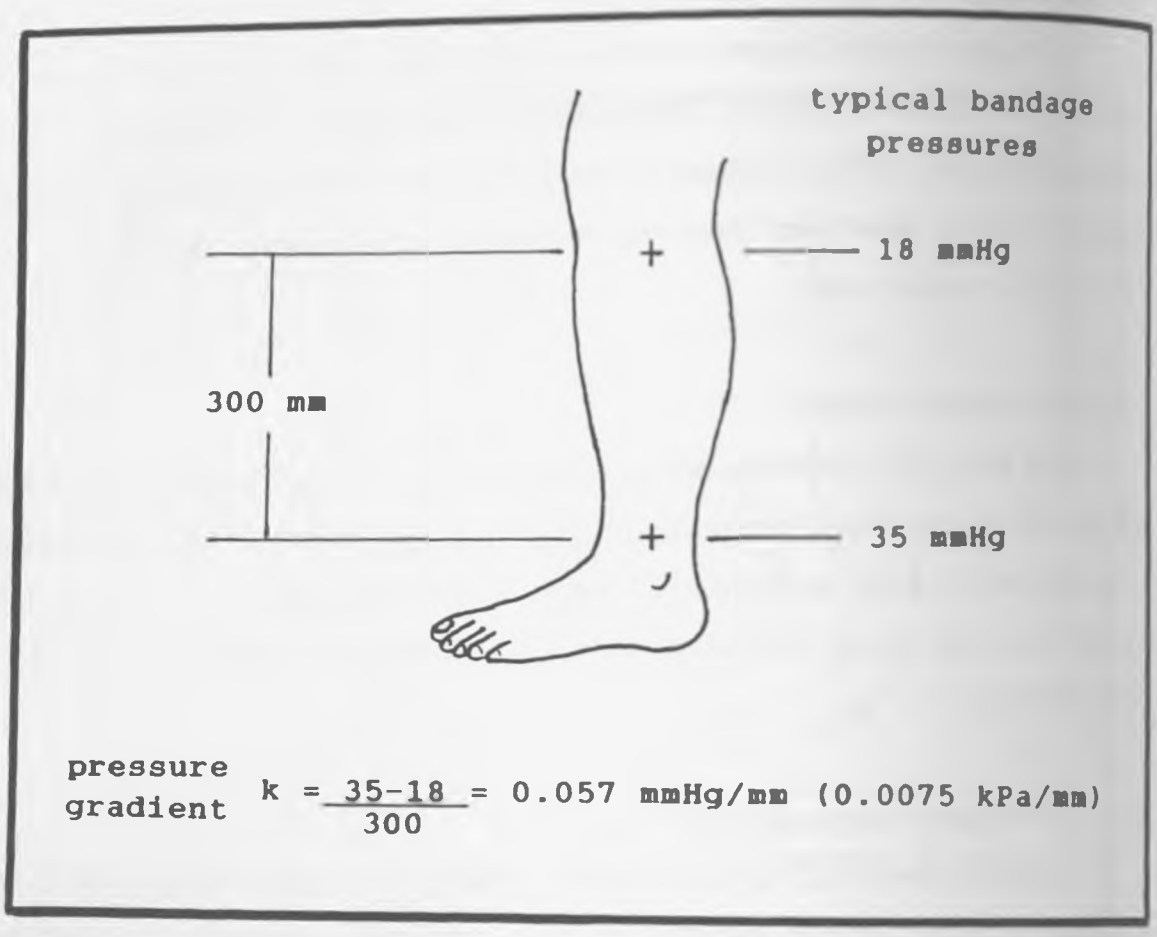


Figure 3.12 A typical pressure gradient

$$r < eP_o /200k$$

where, e .... is the percentage error
P_o .... is the local peak pressure
k .... is the pressure gradient

Furthermore, Ferguson-Pell (1977) used estimates for the peak pressure (P_o) and the pressure gradient (k), derived from previous work (Kosiak et al., 1958; Lindan, 1961; Houle, 1969) to provide a "ball-park" figure for the radius of a pressure sensor. Based on this, he concluded that the radius had to be smaller than 2.5mm to resolve the pressure distribution to an accuracy of 5% of the local peak pressure. Such a requirement would impose serious technical difficulties in developing pressure sensors by virtue of its very small size. More importantly, it casts alarming doubts on the accuracy of interface pressure measurements as a whole which generally relies on considerably larger sensors.

Fortunately, this problem is less critical in the measurement of interface pressures beneath compression devices. This is because the sensors are placed over smooth surfaces on the lateral or medial side of the leg, carefully avoiding bony prominences and at these sites the local pressure gradient is very small. Following the relationship suggested by Ferguson-Pell, for a given percentage accuracy (e) and peak pressure (P_o), the radius (r) is inversely proportional to the pressure gradient (k).

$$r \propto (1/k)$$

This implies that a larger sensor may still be suitable for pressure measurement at an interface where the pressure gradient is small and is illustrated in the example below using typical estimates. Dale and Gibson (1987) have suggested that typical pressures at the ankle and just below the knee to be around 35mmHg and 18mmHg respectively, and a tolerable a peak pressure is normally about 60mmHg. Assuming that the average distance between the ankle and the tibial plateau is 300mm (Figure 3.12), then the radius of a suitable pressure sensor may be estimated as follows;

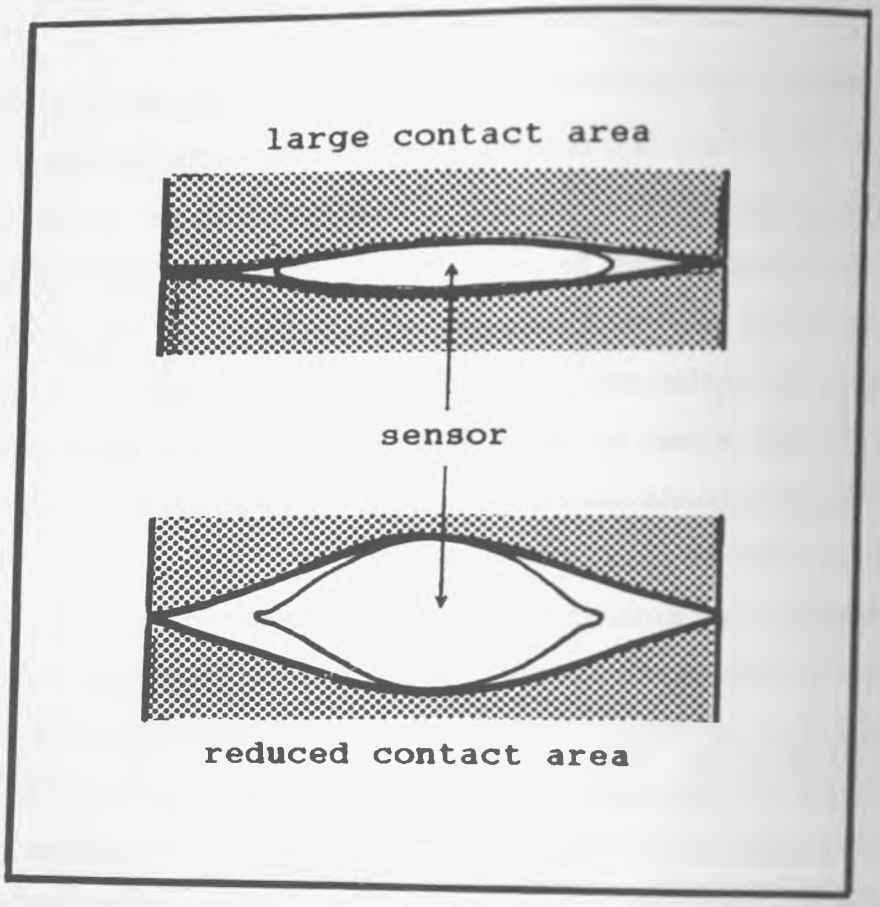


Figure 3.13 Inflated and deflated sensor at interface

percentage error (e) 2.5%

local peak pressure (P_o)... 8 kPa (60mmHg)

pressure gradient (k) ..... 0.0075 kPa/mm (0.057mmHg/mm)

Therefore,

$r < (2.5 \times 8) / (200 \times 0.0075)$ mm

$r < 13$ mm

The philosophy behind Ferguson-Pell's calculations appears sound and should serve as a reasonable guideline but caution is required for more precise applications, in view of the many assumptions involved.

The inflatable sensors used in pneumatic pressure measuring devices tend to have a varying area of sensitivity according to the volume of air that is pumped into the sensor. Figure 3.13 exaggerates this variation of the sensitive area, with the sensor deflated and inflated (Chow, 1974; O'Leary and Lyddy, 1978). If this variation in size of the sensitive area of the sensor is an important contributory factor to error in measurement, as implied by Ferguson-Pell, then most pneumatic devices including the Talley-Scimedic and Oxford monitor would have an identified source of error. Van Den Berg et al. (1982) claim that such variations are minimised in the Borgnis device by limiting the volume of the sensor cell. Further, Robertson et al. (1980) have reported that, the "switch pressure" required to make and break the contact in sensors with metallic inserts varied with the radius of sensor. Perhaps conductive paint contacts as suggested by Krouskop et al. (1981) may help overcome this irregularity and also minimise the variation in stiffness within the sensor wall.

Liquid filled sensor cells used in a hydraulic measuring device, similar to the that used by Van Pijkeren et al. (1980), have a constant volume within the sensor and do not experience the problem of varing sensitive contact area. In principle this device is similar to the device described by Fentem et al. (1976) but they insist that compression beneath bandages and elastic stockings should be measured with very large sensors, typically 100 x 80mm. This would proportionally increase the error in the pressure measured, according to Ferguson-Pell (1977) and Shaw (1979).

Capacitive, inductive and resistive types of pressure measuring devices can

have the advantage of smaller sensors. Unfortunately, these sensors tend to be less compliant at the interface and are often of higher stiffness than the soft tissue or bandage. A compromise is difficult to achieve as sensors made of more complaint material tend to be predisposed to "creep", exhibit hysteresis and drift with time (Grant, 1985; Ferguson-Pell, 1976; Barbenel, 1983).

(ii) Thickness of sensor

A pressure sensor when placed at an interface will produce some perturbation of the pressure at that site. The thickness of the sensor is an important factor and may contribute to irregularities in the interface pressure measurement. Some form of quantification was necessary to establish an acceptable thickness of sensors. Early attempts were less scientific in their approaches. A maximum limit of 1.25mm for the thickness of a sensor, 6.3mm in radius, was proposed during the National Academy of Sciences Workshop (1968), based on general consensus. Later, Mott (1973) deduced that the thickness of a sensor should be 10% of the thickness of the skin at the site of measurement. Mathematical expressions for sensor thickness derived from theoretical models, were first put forth by Dhaliwal and Rau (1970) and, later, Bennett (1971). These models assumed that Poissons's ratio for skin to be less than one but Ferguson-Pell (1977) pointed out that this was not necessarily so, rendering these expressions invalid.

Ferguson-Pell (1977) pioneered the concept that the perturbation of a soft tissue interface by a pressure sensor is a function of both the sensor's thickness and diameter. The ratio of the sensor's thickness to its diameter known as the "aspect ratio" soon became a more satisfactory measure of the devices' capacity for perturbation rather than just the thickness or sensitive area.

In order to provide a crude estimation for the thickness of a pressure sensor beneath a bandage, Ferguson-Pell (1980) derived a mathematical expression;

$$d \approx \frac{1}{2}\sqrt{\frac{1p}{2ET}}$$

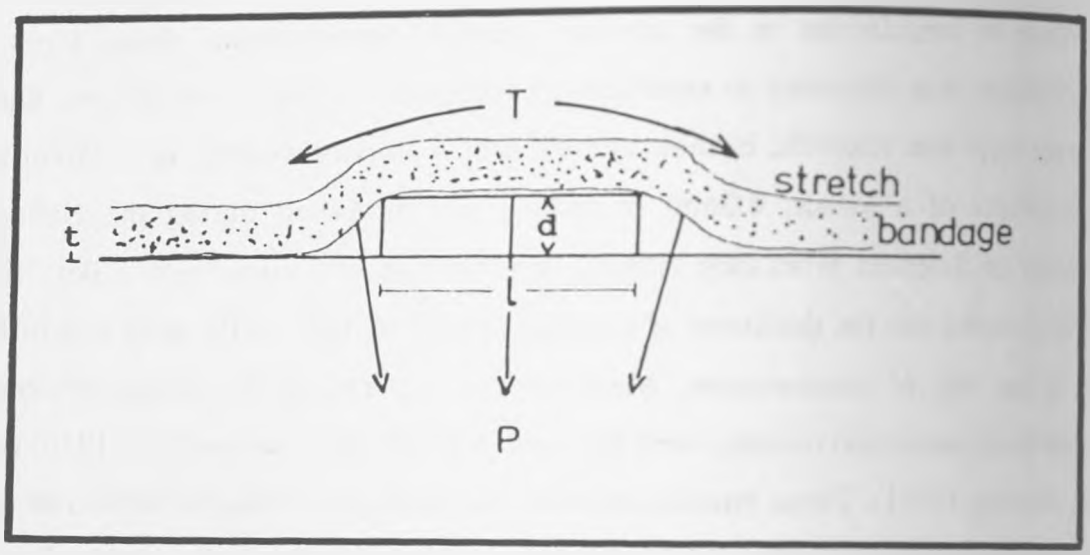


Figure 3.14 The interface perturbation effect of a sensor (reproduced from Ferguson-Pell, 1980)

where; p = perturbation pressure (% error x pressure)

r = radius of curvature

l = diameter of sensor

t = thickness of bandage

d = thickness of sensor

E = stiffness of bandage

(as shown in figure 3.14)

This expression was based on the assumption that the interface representing skin and bandage was linear, elastic, homogeneous, isotropic and not time dependent; clearly a rash assumption for skin (Barbenel, 1978).

Based on Ferguson-Pell's expression the following calculation was carried out using typical values; Typical pressure was taken to be 30 mmHg (4kPa) (Dale and Gibson, 1987); An error of ±1 % and sensor diameter of 28mm (Barbenel and Sockalingham, 1990); Stiffness of Tubigrip bandage, E = 30 kPa and thickness t = 1.3mm (Ferguson-Pell, 1980).

$$p = 2 \times 4$$

$$d \approx \frac{28}{2}\sqrt{\frac{28 \times 0.08}{2 \times 30 \times 1.3}}$$

therefore,

$$d \approx 2.4mm$$

It follows that the aspect ratio (2.4:28.0) for the pressure sensor in the above estimation is in the same order of magnitude as the minimum aspect ratio (1:10) recommended by Ferguson-Pell (1980).

As there is no current research available on the ideal dimensions of a pressure sensor, the aspect ratio is the only satisfactory guideline.

(iii) The Interface

Any interface involving body tissue is predisposed to a multitude of factors such as pressure gradients, shear stresses, frictional forces, temperature and humidity (Barbenel, 1978; Appoldt et al, 1968; Lowthian 1976). The significance of each of these factors is dependent on the physical properties of the interface, the nature of the applied pressure, the geometry of the surfaces at the interface, and the degree of movement between the surfaces. Artefects in the interface pressure measurement as a result of these in-plane factors are difficult to assess. Ferguson-Pell (1977) was of the opinion that these artefacts were less than 10% of the normal pressure measured between body and support cushion. Therefore, it would seem reasonable to assume that such artefacts would be considerably less at the more benign bandage-soft tissue interface, especially at sites of small pressure gradients.

The choice of an appropriate pressure sensor is dependent on the nature of the interface (Reddy et al., 1984). Some interface materials do not exhibit good "envelope properties" and as such do not readily accommodate the presence of a sensor (Reddy et al, 1984; Chow, 1974). In such circumstances non compliant, rigid or thick sensors like the strain gauged diaphragm or inflatable air cell types may prove less suitable. The frequent change in volume during inflation and deflation of the pneumatic sensor does not conveniently allow the interface to "wrap" around the sensor (Reddy et al., 1984).

The compliance of the underlying material at the interface may also affect the performance of a pressure sensor. Barbenel (1983) reported that inflatable pneumatic and capacitive sensors show good agreement for medium density mattresses but displayed much poorer correlation on the more compliant interfaces. Patterson and Fisher (1979) have reported that Sensotec (strain gauged diaphragm) sensors performed better at a soft tissue interface than over hard underlying surfaces.

If the pressure gradient at the interface is relatively small as in the flat areas of the bandage-soft tissue interface then useful results may be obtained by using simple sensors like the inflatable electro-pneumatic types (Barbenel, 1983). Conversely, these sensors are not suited for pressure measurement at highly curved interfaces like the amputee stump-socket interface. Over such harsh contours these

sensors are prone to a build up of stresses within the sensor cell (Barbenel, 1992). At such an interface, very small and thin resistive, capacitive or strain gauged sensors would be more applicable by virtue of their size.

Little is known of the characteristics of in-plane forces at an interface with body tissue but it appears that some pressure sensors are affected more than others. Fernie (1973) had shown that the "Katie beam" (strain gauged sensor) is highly proned to distortion from in-plane forces at the interface. Similar sensors like the Entran EPL series do not conform well to curvatures and have been reported to be susceptable to bending stresses (Wytch et al., 1989). Palmieri et al. (1980) and Bader (1982) have made claims that the pneumatic sensors cells are inherently less sensitive to the shear stresses that develops at an interface.

The suitability of a sensor to measure pressure is also dependent on the type of loading that is transmitted through the interface. Patterson and Fisher (1979) have reported that strain gauged diaphragm sensors are not suitable at interfaces where the diaphragm may be unevenly loaded. An interface subjected to temporal variations in loading would require a sensor capable of continuous measurement such as the liquid filled hydraulic sensors. For this requirement, devices with pneumatic sensors like the Oxford pressure monitor, the Talley-Scimedic or the Borgnis stocking tester are not suitable because of their intermittent nature of measurement.

Clearly, the choice of an appropriate sensor rests on a multitude of factors and requires careful consideration of the limitations involved within a particular application.

3.5.3 The Pressure Transducer

The pressure transducer can either be an integral part of the sensor as in the capacitive device or be located at a distant point from the sensor as in the hydraulic device. The remote transducer has the advantage of being independent of the prevailing conditions at the site of measurement. Upon overcoming the difficulties posed by the sensor and the interface, the quality of the pressure measurement then rests on the type of transducer and its operating characteristics. There is a large variety of commercial and custom-made pressure transducers available. Each of these

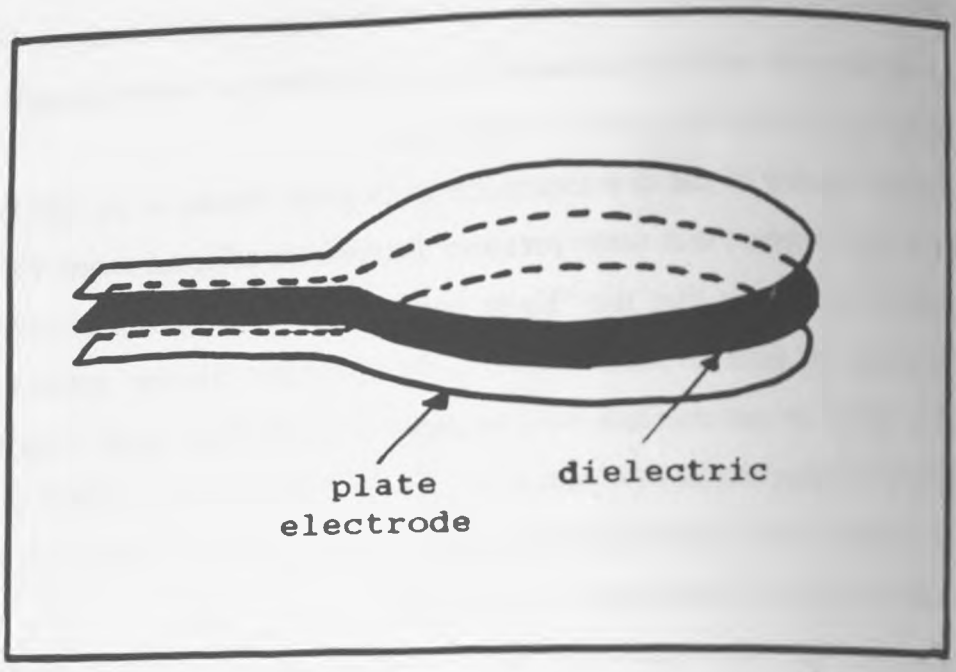


Figure 3.15 A capacitive pressure transducer

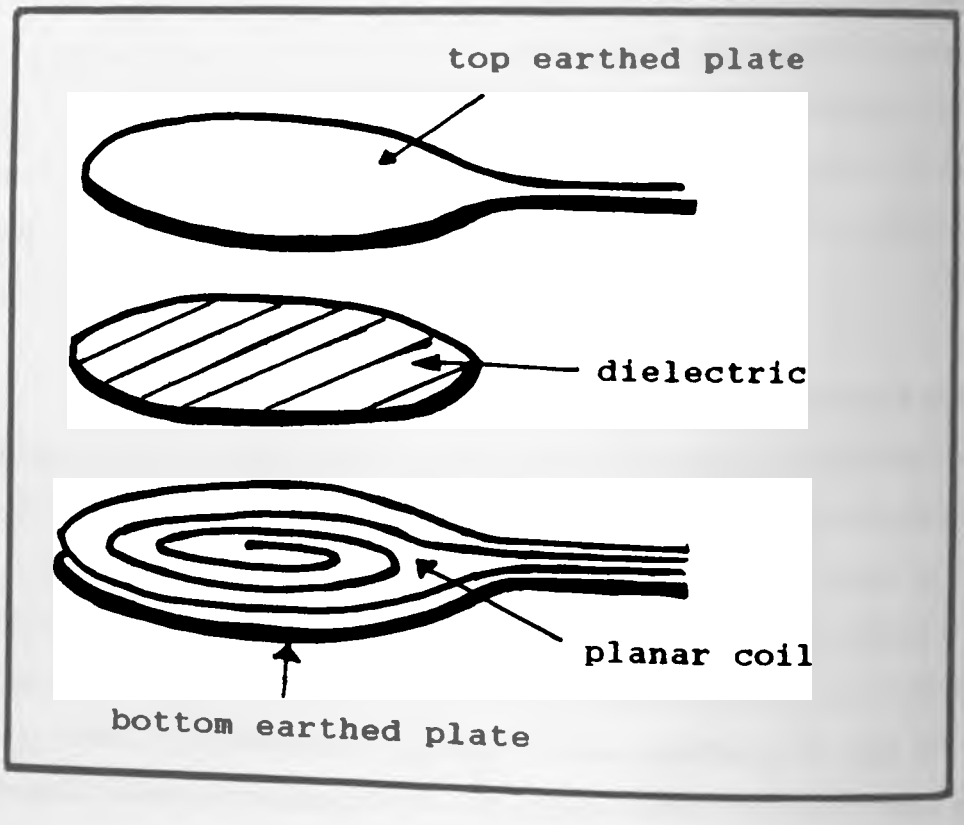


Figure 3.16 An inductive pressure transducer

transducers relies on different properities of the transducing element such as strain, resistance, capacitance or chemical reactance and vary greatly in their performance.

(i) Common Types of Pressure Transducers

The capacitive transducer comprises a compliant dielectric material which is sandwiched between two thin flexible plate electrodes (Figure 3.15). As pressure is applied on the sensing surface, the dielectric is compressed and this changes the distance between the electrodes resulting in a change in the capacitance. With suitable electronic conditioning the change in capacitance can be used to measure the corresponding applied pressure. Capacitive transducers were previously developed and used for interface pressure measurement with varying success (Frank and Gibson, 1954; Knapp and Bradley, 1970; Ferguson-Pell, 1977).

The inductive transducer has a thin flexible conducting planar coil and a compliant dielectric material sandwiched between two earthed plates as illustrated in figure 3.16. When pressure is applied to the sensing surface, the dielectric is compressed reducing the distance between the coil and plate leading to a change in mutual inductance. This change in inductance can be electronically processed to produce signals that correspond to the applied pressure. Inductive pressure tranducers have been used by Fernie (1973) and Mott (1973), and later investigated by Ferguson-Pell (1976) who reported that the problems relating to this device were still not resolved.

The resistive transducer utilises conductive material which changes in electrical resistance when subjected to pressure. In its simplest form the sensing element is wired in a Wheatstone bridge configuration which produces an imbalance in the bridge proportional to applied pressure. Other variations of resistive transducers include pressure sensitive paint (Elab Ltd, California, USA) and conductive carbon impregnated foam. These materials are impregnated with conductive particles during manufacture. When pressure is applied on the material, the conductive pathways increase and the resistance decreases proportionally thus providing a means of measuring pressure.

The most common version of the strain gauged transducer is the strain gauged diaphragm device which comprises of a thin diaphragm with strain gauges mounted

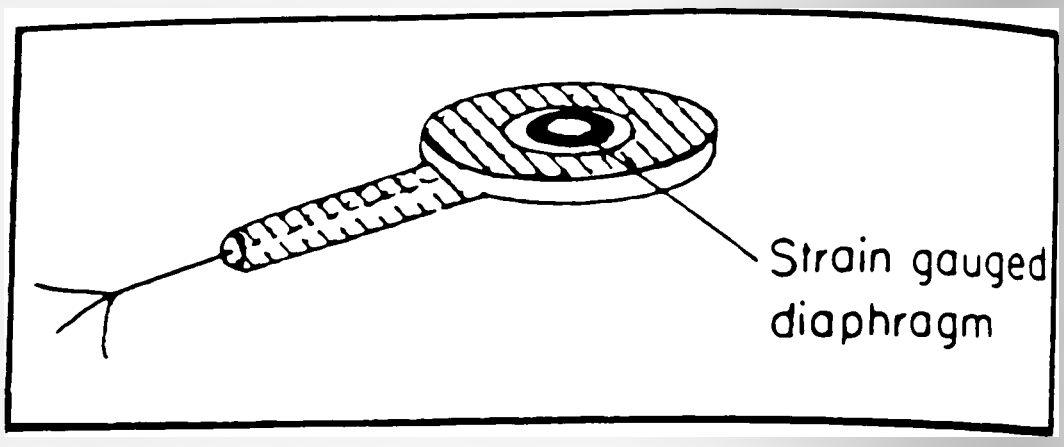


Figure 3.17 A strain gauged diaphragm pressure transducer

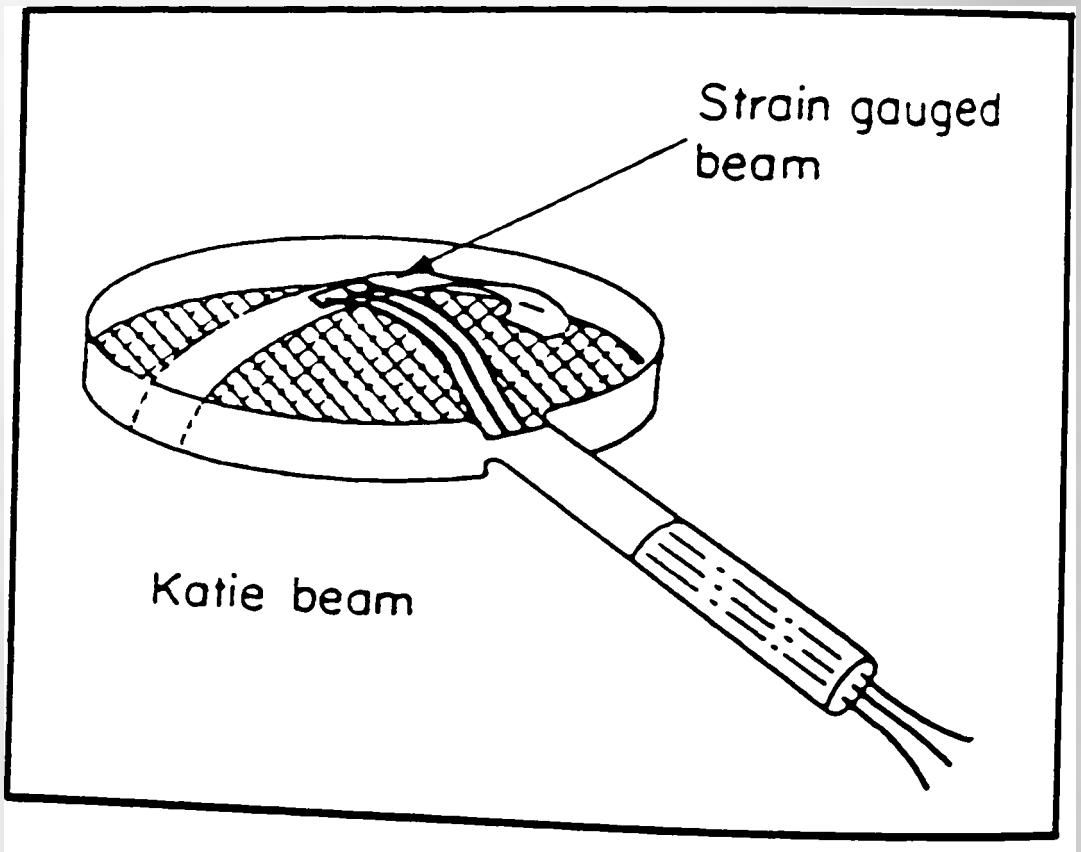


Figure 3.18 A strain gauged beam pressure transducer

on it, as illustrated in figure 3.17. When a pressure difference occurs across its active surface, the diaphragm deforms and generates membrane forces which are detected by the strain gauges. With appropriate electrical conditioning the output from the strain gauges can be used to measure pressure differences across the membrane. There are many variations of this type of transducer such as the strain gauged beam device described in figure 3.18 (Maslin, 1969). Modern strain gauged devices have semiconductor strain gauges diffused into silicon diaphragms and perform to high specifications. These transducers can be either part of the sensor or be entirely separate. Many commercially available strain gauged devices are particularly suited for the measurement of fluid pressure and are regularly use in hydraulic, pneumatic and electro-pneumatic pressure measuring sytems (Raj et al., 1980; Bader et al.,1985).

The piezo-electric transducer uses piezoelectric materials to convert pressure to electrical signals. In the past, various ceramic based materials were used which were brittle and could not be made with large surface areas, as such not particularly suitable for pressure measurement. The introduction of a new piezoelectric material, polyvinylidene fluoride, holds new promise for this type of transducer (Carlisle, 1986). This film material is flexible and thin but its application is limited as steady state or very slow changes cannot be detected without specialised electrical circuitary. Gross and Bunch (1988), however, have reported the successful use of this type of transducer for monitoring pressure in the shoe during gait.

Nornes and Serck-Hanssen (1970) described a device which utilised the piezo-resistive properties of silicon. Resistors were diffused onto silicon rod to form part of a Wheatstone bridge circuit. A pressure sensitive diaphragm was linked mechanically to the piezo-resistive rod resulting in an output voltage from the bridge which corresponded to the applied pressure. This early version had problems with the zero level drift but the modern piezo-resistive pressure transducer is designed to perform to very high standards. The device uses ion implanted resistors in an integral silicon diaphragm to convert the shear stress due to pressure into electrical signals via an integrated circuit. Commercially available piezo-resistive transducers are relatively inexpensive and have a wide range of applications where high precision pressure measurement is required.

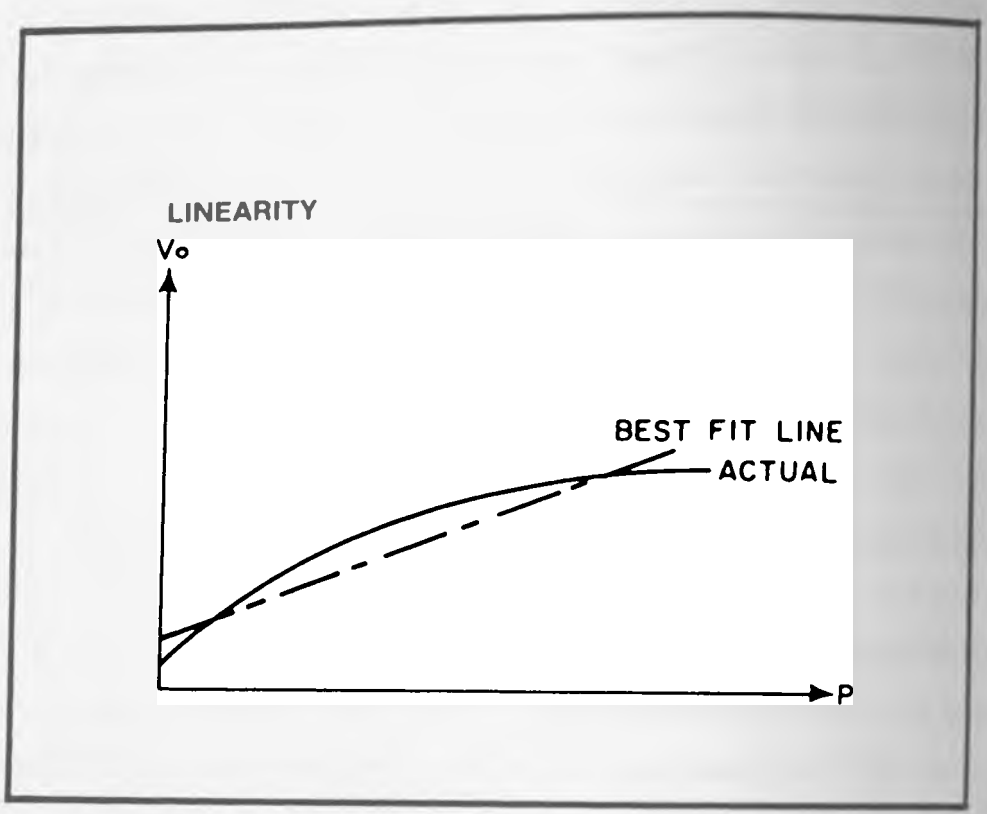


Figure 3.19 Best fit straight line calculated by least squares

(ii) Operating Characteristics of a Pressure Transducer

The operating characteristics of a pressure transducer provide useful guidelines when selecting or developing such a device. The transducer's performance and suitability to a particular application may be assessed by examining some of the following characteristics.

The operating range specifies the maximum and minimum pressures within which the transducer is designed to function effectively. Selection of a transducer with a suitable operating range is required for optimising the sensitivity and resolution of the pressure measurement. This is particularly important in the measurement of interface pressures beneath bandages and elastic stockings as the pressures generated are relatively small (typically below 60mmHg or 8kPa). Pressure transducers operating in the absolute mode have a minimum operating range of 0 to 103kPa which would severely compromise the sensitivity of measurement if used at the bandage-skin interface. A differential mode pressure transducer with a choice of a lower operating range would be more suitable for this type of application.

The sensitivity describes the ratio of the change in output voltage signal to the corresponding change in input pressure. The sensitivity of a pressure measuring device may be optimised by selecting an appropriate operating range. In interface pressure measurements beneath bandages and elastic stockings it is particularly important to have high sensitivity because of the very low pressures generated within a low pressure range. For this reason the Talley-Scimedic pressure evaluator which has a large operating range of 0 to 300mmHg (0-40kPa) and poor sensitivity below 20mmHg (2.7kPa), is not suitable for such pressure measurement. The semiconductor strain gauged transducers (Honeywell, UK) and the piezo-resistive silicon diaphragm transducers (Sensor Technics, UK) both offer a good selection of operating ranges with very high sensitivities.

The linearity of a transducer decribes the maximum deviation of the measured output from the best fit straight line, usually calculated by the least square method (Figure 3.19). Problems relating to poor linearity are often present in transducers which depend on the compressibility of the sensing material. Brown and Muratori (1979) have reported poor linearity of the resistive transducers which use pressure sensitive paints and foams. Other transducers that use dielectric materials such as the

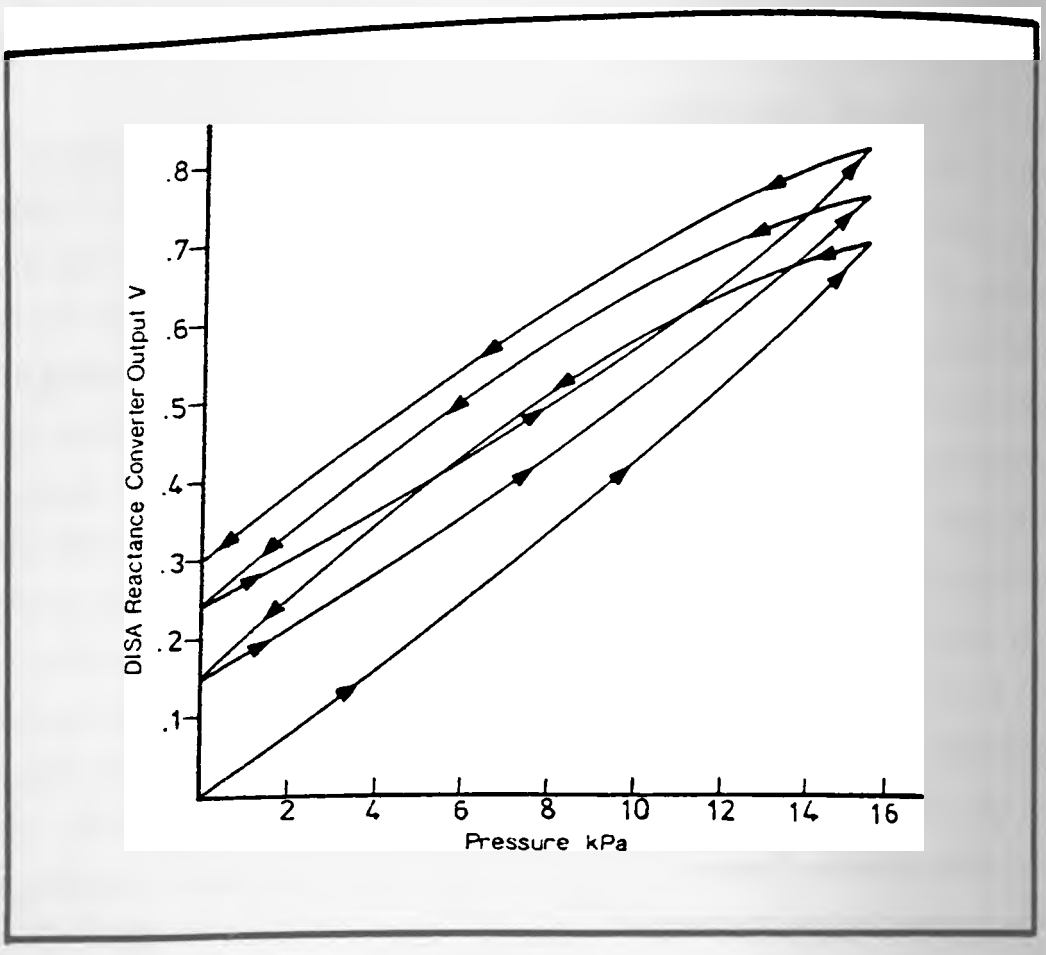


Figure 3.20 Hysteresis produced by a 3-plate capacitive transducer

capacitive and inductive devices often have poor linearity (Patel et al., 1989; Ferguson-Pell, 1976). Linearity no longer poses a problem with the modern pressure transducers as the output from these devices are linearised using compensatory circuitry or microprocessors.

Hysteresis is the maximum deviation in the transducer output for any given input pressure when the input is approached first with an increasing pressure and then with decreasing pressure or vice versa. Transducers that utilise elastic material for the detection of changes in pressure may be more prone to exhibit hysteresis as a result of creep, stress relaxation or time dependency of the sensing material. Capacitive, inductive, pressure sensitive paint and resistive foam transducers generally exhibit noticeable hysteresis. Figure 3.20 illustrates hysteresis in a capacitive transducer with unsuitable dielectric material (Ferguson-Pell, 1977). Early versions of strain gauged diaphragm transducers were also prone to hysteresis of the diaphragm material (Sachs et al., 1974). However, advances in silicon technology have lead to the development of strain gauged diaphragm and piezo-resistive transducers which have negligible hysteresis.

A transducer has good repeatability when successive applications of any given input pressure do not yield large deviations in the output signal, with other conditions remaining constant. Good repeatability is particularly important in continuous pressure measurement when frequent calibration checks are not possible. Transducers such as the capacitive and inductive devices that utilise dielectric materials which exhibit creep or drift with age and use, often have poor repeatability (Grant, 1985; Patel et al., 1989). Most modern transducers, however, perform with a high level of repeatability.

Long term stability of a pressure transducer expresses the ability of the devices to maintain the value of an output signal for a given input pressure, over prolonged periods of time whist other conditions remain constant. Good long term stability is essential when monitoring dynamic pressures over prolonged periods of time which are more difficult to correct for time dependent drift. Modern solid state pressure transducers such as the strain gauged diaphragm and piezo-resistive silicon diaphragm devices have very high stability over periods of a year.

Frequency response relates to the time required by the transducer to respond to a change in input pressure from zero to full scale. The level of frequency response required would depend entirely on the nature of the pressure measurement. Applications with rapid dynamic changes in pressure would require a high frequency response and for such measurements slower devices such as the Talley-Scimedic pressure evaluator or the Oxford pressure monitor would be not suitable (Torres-Moreno, 1991). The frequency response required for interface pressure measurement beneath compression devices does not pose any technical difficulties on most modern transducers.

The temperature coefficient describes the maximum deviation of the transducer output signal as a result of temperature variation from 25 degrees Celsius, within a specified pressure range. This coefficient is virtually negligible for most modern pressure transducers which are temperature compensated. Such temperature compensation also rectifies any temperature hysteresis that may be exhibited by the transducer.

3.5.4 The Calibration of a Pressure Transducer

Meaningful interpretation of pressure measurements carried out at an interface can only be achieved if the pressure measuring device is suitably calibrated. The technique of calibration is particularly important if a high degree of accuracy is expected and if the measurements are absolute rather than relative. Ferguson-Pell (1980) and Bader (1982) have correctly pointed out that a suitable technique of calibration should simulate the conditions encountered in the clinical situation. Attempts to simulate these conditions have led to a variety of calibration rigs and techniques.

(i) Hydrostatic Calibration

Hydrostatic calibration is probably the simplest method of calibration. It involves immersing the sensor into a column of water, the height of water column above the sensor then provides an accurate measure of the hydrostatic pressure acting on the sensor. Shaw (1979) successfully used this technique to calibrate a pneumatic pressure measuring device. The suitability of this technique for calibrating capacitive,

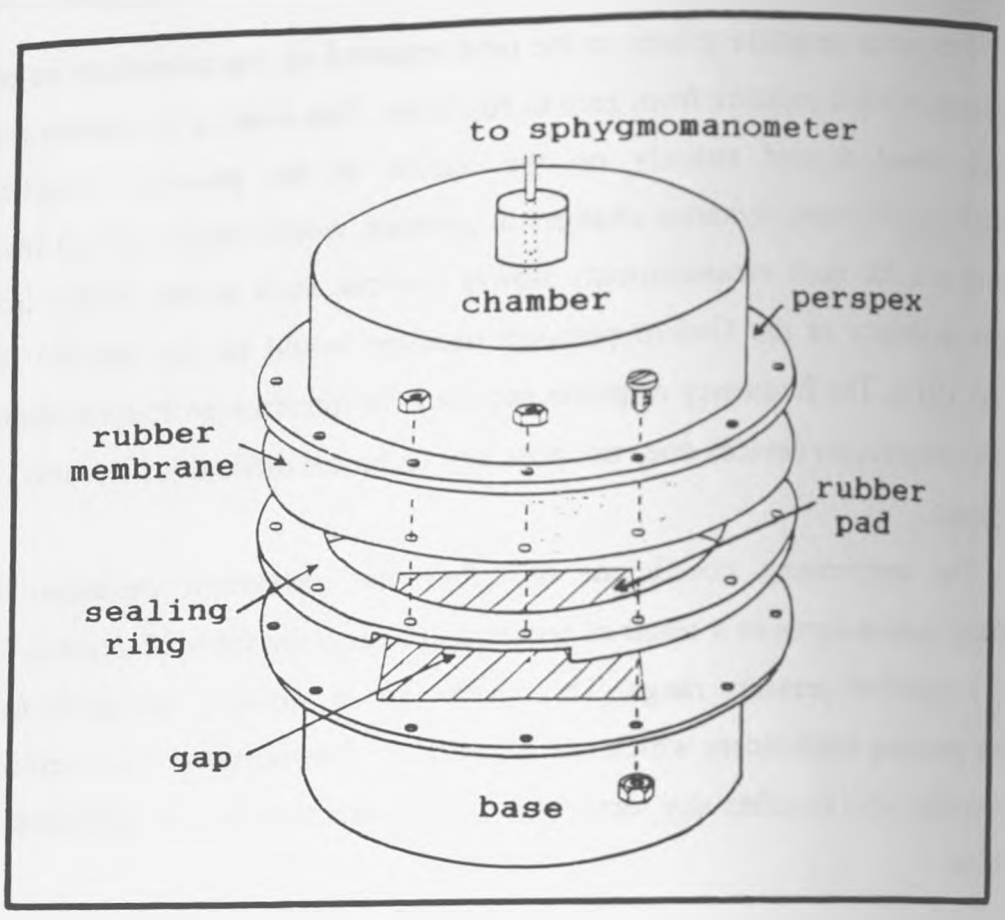


Figure 3.21 Pneumatic calibration (reproduced from Sach et al., 1974)

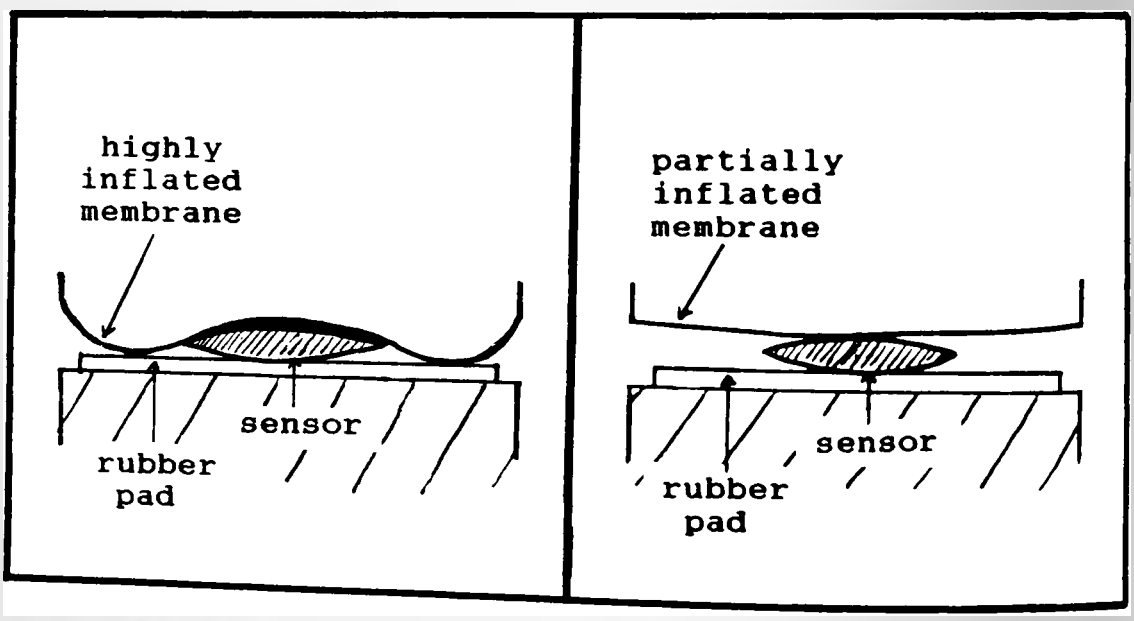


Figure 3.22 The different contact areas between membrane and sensor

inductive or resistive devices is limited as it involves getting the sensors wet which may interfere with the performance of these devices. This mode of calibration does not physically simulate the interface encountered in the clinical situation but when applicable it serves as a useful "bench-mark" and convenient counter-check. Hydrostatic calibration has its limitations and is not practical when calibrating to high pressures because the height of water column required would be too great.

(ii) Rubber Membrane - Pneumatic Calibration

Sachs et al. (1974) developed a pneumatic calibration rig which consists of a Perspex pressure chamber sealed with a rubber membrane on one face. The chamber is mounted onto a solid Perspex block with a small gap as illustrated in figure 3.21. The upper surface of the gap comprises the rubber membrane and the lower surface has a rubber pad glued onto the Perspex block. The gap at this interface is just sufficient to place a pressure sensor and was designed to simulate the skin-support interface. A sphygmomanometer attached to the chamber is used to inflate the rubber membrane which then loads the pressure sensor. The applied pressure at any instant is read directly from the sphygmomanometer dial.

This rig was originally designed for calibrating devices used in the measurement of seating pressures and as such the simulated interface does not resemble the bandage-skin interface, nor the skin-support interface. Major modifications of the rig would be required to simulate the bandage-skin interface. A further drawback of this calibration system is that the contact area between the membrane and sensor is not constant. The curvature of the stretched membrane increases with the level of inflation in the chamber thus varying its envelope property and the area of contact between the membrane and sensor. An exaggeration of this is illustrated in figure 3.22. It appears that this variation in contact area is more pronounced in the lower pressure range and therefore not suitable for calibrating devices used in pressure measurement beneath bandages or elastic stockings.

A simpler version of this method of calibration was used by Talley Medical Equipment Ltd., to calibrate the Oxford pressure monitor. The calibration technique was based on the inflation of a PVC bag which was folded into two and enclosed

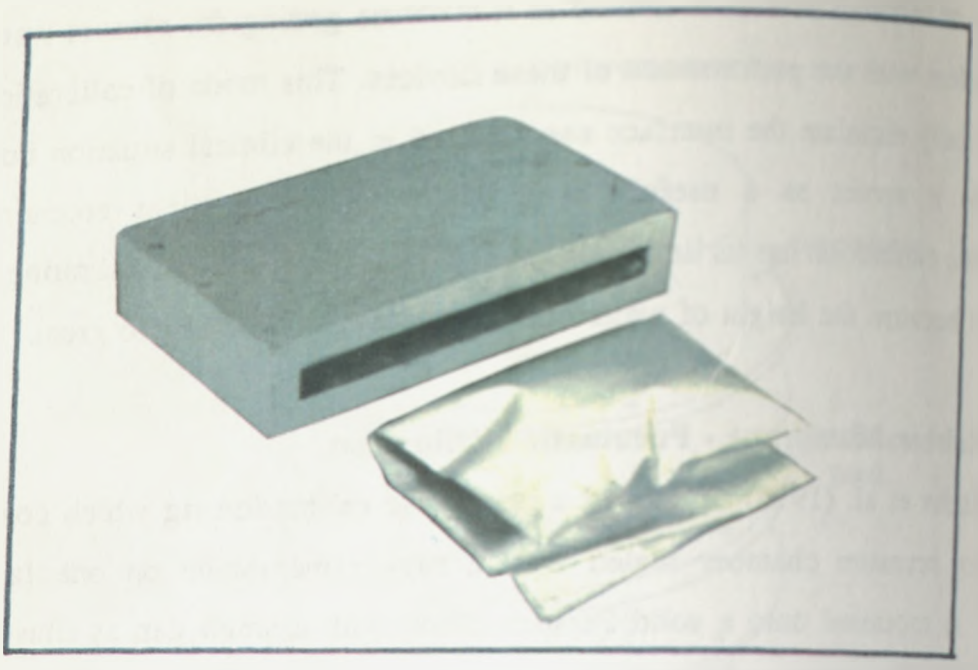


Figure 3.23 Calibration device for the Oxford Pressure Monitor

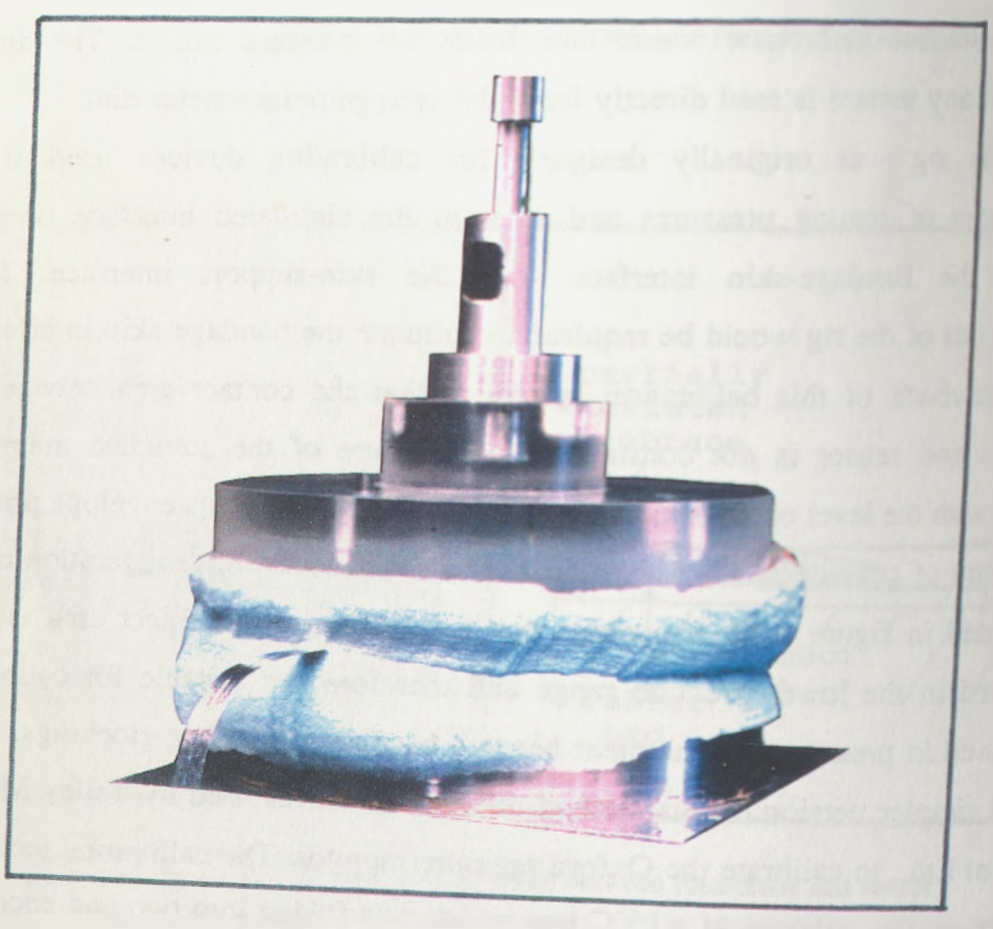


Figure 3.24 Calibration device incorporating polyurethane foam (reproduced from Ferguson-Pell, 1977)

within a rigid wooden box (Figure 3.23). The pressure sensor was placed between the folds of the bag and upon inflation of the bag, pressure is applied to the sensor. The applied pressure is recorded directly from the sphygmomanometer pump used for inflating the bag. The surfaces of the inflated PVC bag may provide a reasonable simulation of the bandage-skin interface.

Patterson and Fisher (1979) used another crude version of this method to test a range of pressure measuring devices. Their apparatus consisted of a rubber condom placed within a small (3cm diameter) tube with the pressure sensor inserted between the condom and tube. As the rubber condom was inflated it exerted pressure on the sensor and this applied pressure was read directly from the sphygmomanometer dial. The curved rigid surface of the small tube was a poor attempt in simulating any patient-support interface.

(iii) The Load Calibration Method

This calibration method attempts to simulate the loading conditions at the patient-support interface by using two blocks of polyurethane foam to represent soft tissue and support cushion (Ferguson-Pell (1977); Reddy et al., (1984). The pressure sensor is then sandwiched between the foam blocks which is loaded uniaxially in the Instron load machine (Figure 3.24). The pressure exerted on the sensor is then calculated by dividing the applied load by the active area. This technique, however, cannot be readily adapted to suit the calibration of pressure measuring devices used at the bandage-skin interface.

Knapp and Bradley (1970) reported earlier use of a load calibration rig illustrated in figure 3.25. The rig had a central axle upon which known loads were placed. The load was transmitted via the axle onto the pressure sensor which was sandwiched between the base of the axle and a hard wooden block. This crude device had no provisions to simulate the patient-support interface and the linearity of the resulting calibration curves were poor.

(iv) Sphygmomanometer Cuff Method

Patterson and Fisher (1979) reported the use of a sphygmomanometer cuff wrapped around the calf of the leg with the pressure sensor placed between the cuff

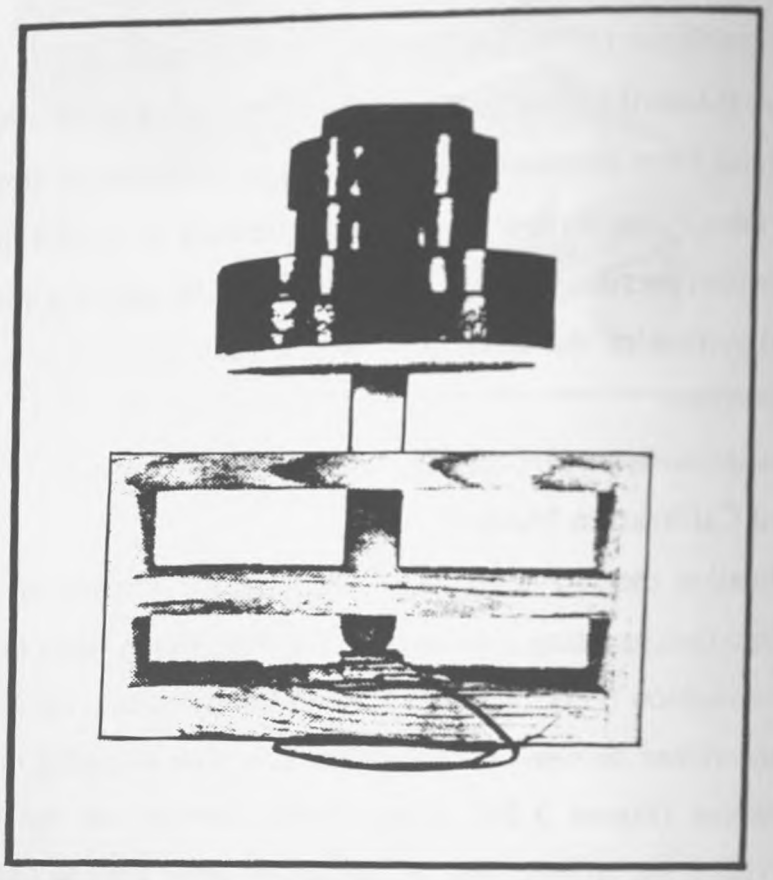


Figure 3.25 Load calibration rig (reproduced from Knapp and Bradley, 1970)

and skin. Pressure was applied on the sensor by inflating the sphygmomanometer cuff and was directly read from its dial. This simple method of calibration provides a good means of simulating the bandage-skin interface. Further, it can be readily used over the actual site of measurement to study its effect on the pressure measurement.

The selection of a suitable technique for calibrating a pressure measuring device used in a clinical situation would largely depend on its application. The simulation of an interface for the purpose of calibration can at best be only a close approximation and is subject to various factors such as the properities of materials used, the type of loading and the load-transfer characteristics (Bennett, 1971). In view of the complexities involved some degree of compromise is required which can be kept to a minimum by selecting an appropriate method of calibration.

The choice of an interface pressure measuring system rests on the sound knowledge of both the quantitative and qualitative aspects of the various factors that influence the measurement and most importantly an appreciation of the limitations involved (Barbenel, 1983).

3.5.5 The Need for an Improved System

At present, interface pressure measurement is severely restricted by the lack of a suitable measuring device despite the numerous devices commonly available. A number of extensive evaluations have shown that these devices are largely unsatisfactory (Crenshaw and Vistnes, 1989; Wytch et al., 1989; Crant, 1985 and Barbenel, 1983). A review of the more popularly used pressure measuring systems in section 3.4 confirmed that none of the systems is particularly suitable for measuring pressure beneath bandages and stockings. This is not surprising as a suitable pressure measuring device has to meet many difficult and stringent demands (Section 3.5). Successful interface pressure measurement in the future would therefore depend on an improved measuring system. Chapter four describes the design and development of such a pressure measuring system, custom built to meet the needs of interface pressure measurement beneath bandages and stockings.

CHAPTER 4

THE DESIGN AND DEVELOPMENT OF A PRESSURE MEASURING DEVICE

4.1 The Pressure Measuring Device

4.2 The Pressure Transducer

4.3 The Signal Conditioning Unit

4.4 The Pressure Sensor and Tubing

4.5 The Assembly of the Pressure Measuring Device

4.6 Calibration of the Pressure Measuring Device

4.7 Simulation of Conditions During Use

4.8 Evaluation of Operational Characteristics

4.9 Discussion

4 THE DESIGN AND DEVELOPMENT OF A PRESSURE MEASURING DEVICE

Interface pressure measurement to date has had only limited success, largely due to the lack of suitable measuring devices as reviewed in Chapter three. The construction of a suitable interface pressure measuring device has to satisfy several stringent design criteria (Section 3.5). Successful application is also dependent on appropriate calibration simulating the conditions of the interface at the site of measurement (Ferguson-Pell, 1980). Further, a thorough knowledge of its limitations is vital in interpreting the resulting pressure measurements (Barbenel, 1983).

The ability to quantify the magnitude of pressure applied to the skin is pivotal in deciding between its therapeutic value and its hazardous effects. As such, efforts in producing a suitable device have been relentless. Numerous devices of various descriptions and performance characteristics are available. Although none of these devices has fully satisfied the requirements of a suitable interface pressure measuring device, they have made invaluable contribution to the improved understanding of this difficult measurement. General guidelines on the properties of an ideal interface pressure measuring device have been established and over the last decade useful quantitative estimates of design parameters have also been introduced.

Despite these efforts, the development and construction of a satisfactory device remain formidable. The measurement of relatively low interface pressures beneath compression bandages and stockings poses additional challenges requiring a highly sensitive, accurate and stable device in order to minimise the errors in measurement.

With the benefit of the accumulated knowledge and by taking advantage of the recent piezo-resistive silicon technology, a simple electro-hydraulic pressure measuring device was developed to measure interface pressure beneath bandages and stockings. The design, development, calibration and evaluation of this device are described in this chapter.

4.1 The Pressure Measuring Device

The "Strathclyde Pressure Monitor", is an electro-hydraulic pressure measuring device which was specifically designed to measure interface pressure beneath

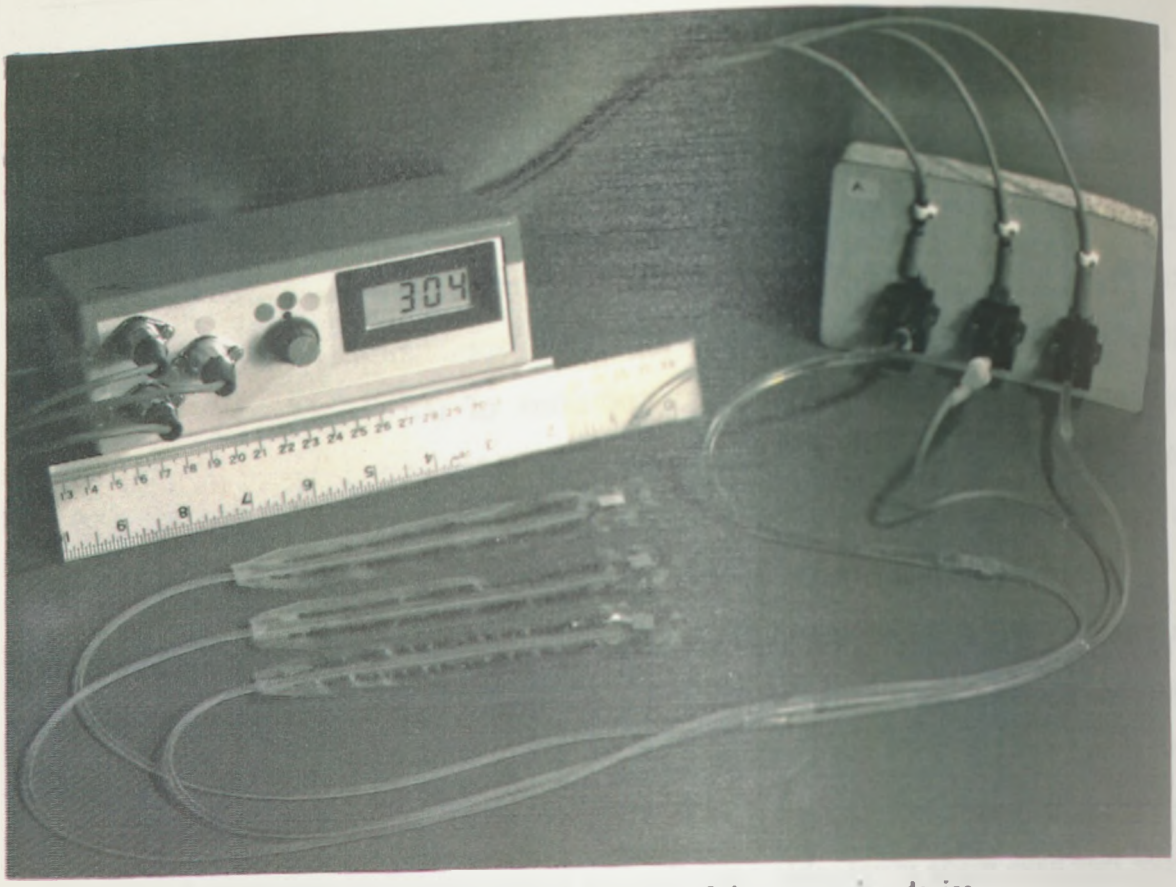


Figure 4.1 The early version of the measuring device

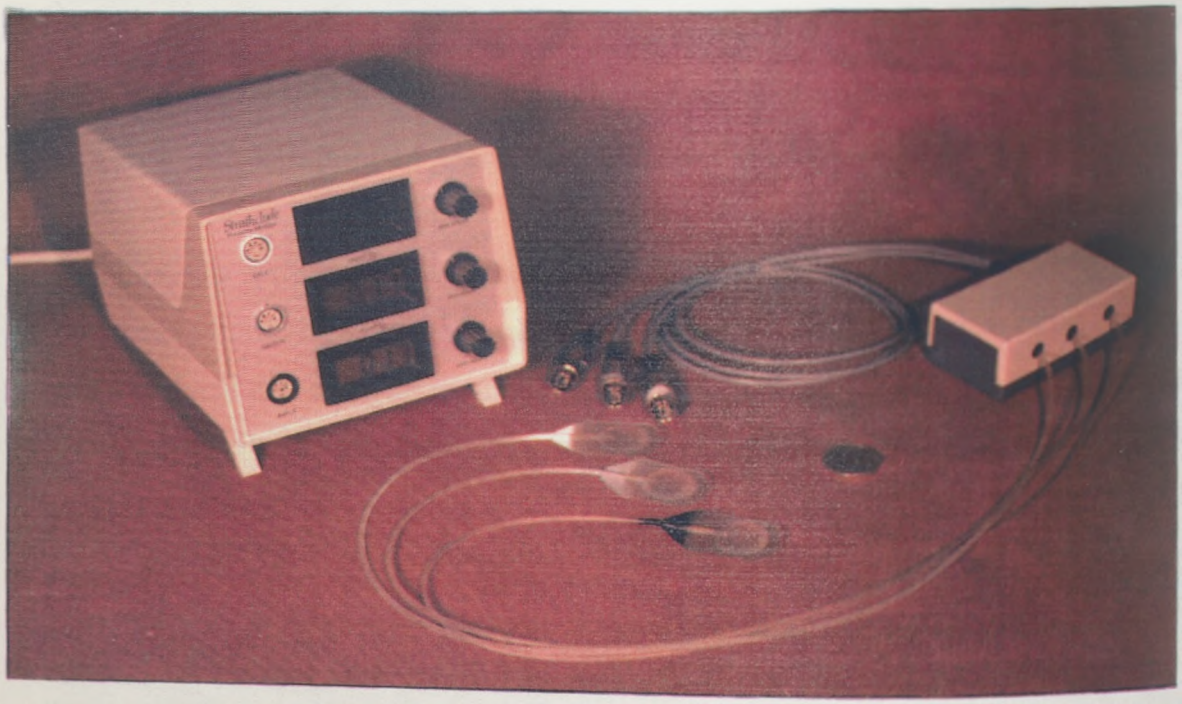


Figure 4.2 The Strathclyde pressure monitor (later version of the measuring device)

compression bandages and elastic stockings. Its general application, however, is more widespread and has been successfully used to measure seating pressures in paraplegics (Ferguson, 1992).

The device comprises four essential components, the pressure transducer, the signal conditioning unit, the fluid filled sensor and the tube that connects the sensor and transducer. Later versions of this device had additional features such as multiple calibrated displays, zero adjustment and a facility for printing data. Figures 4.1 and 4.2 illustrate the two versions of the device.

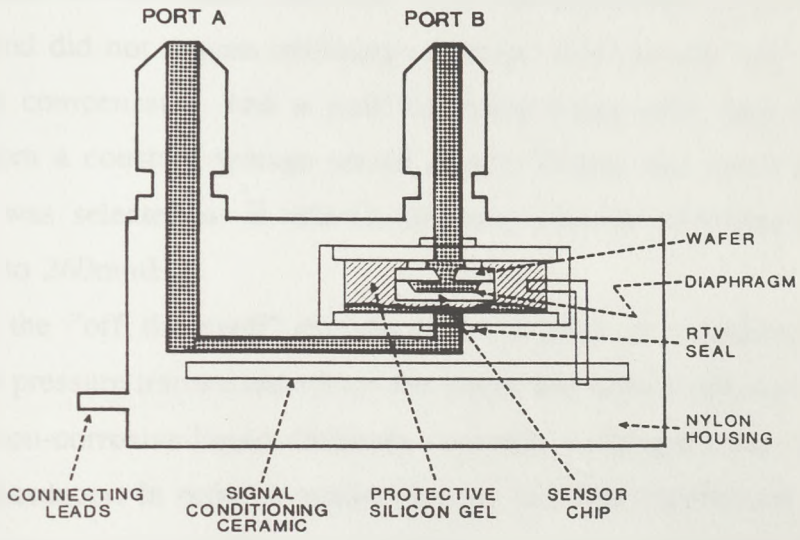


Figure 4.3 Cross-sectional view of the transducer

4.2 The Pressure Transducer

The transducer illustrated in figure 4.3, is a miniaturised, high precision, low cost, commercially available device (Sensor Technics, U.K.) and utilises piezo-resistive silicon technology in pressure sensing. The sensing element is an integral silicon diaphragm with four ion implanted resistors in a Wheatstone bridge configuration which transduces the applied pressure into an electrical signal via an integrated circuit. The ion implanted silicon based sensing element allows very high precision and long term stability in output.

The entire device is housed in a compact nylon casing (22 X 18 X 9 mm) with two protruding nozzles, ports "A" and "B", and has four small connecting pins along one edge. The pressure sensitive diaphragm operates on a differential basis with each surface connected to a separate port. While port B is sensitive to the applied pressure, port A serves as the reference port. The housing also carries convenient mounting facilities.

4.2.1 Selection and Preparation of Transducer

A range of piezo-resistive pressure transducers with different performance capabilities are now available. The SCX series was selected because it was internally calibrated and did not require trimming networks. Additionally, the transducer was temperature compensated, had a good operating range with very low noise and operated from a constant voltage power supply. Within this series the SCX05DN transducer was selected as it offered the most suitable operating range of 0 to 34.5kPa (0 to 260mmHg).

For the "off the shelf" transducer to be used as a hydraulic device, the medium for pressure transmission from the sensor had to be a non-ionic, non-silicone based and non-corrosive liquid. Ordinary vegetable cooking oil was used to fill port B of the transducer. In order to ensure that the hair-line channel and cavity in port B were completely filled without air bubbles, a special vacuum chamber (described in Section 4.6) was constructed and used. This chamber permitted the transducer within it to be connected to a multi-meter outside via connecting pins through its wall. A small container with oil was attached to port B of the transducer and placed inside the chamber. An electrical vacuum pump was then used to reduce the pressure in the chamber by about 50 kPa. With both ports of the transducer exposed to the same pressure there were no net stresses on the diaphragm. As the pressure outside the cavity in port B fell bubbles of air progressively worked their way out through the tube and the small container of oil thus allowing the oil to trickle down into the cavity. During this period a close watch was kept on the multi-meter readings to ensure that high differential pressures were not generated. The low pressure was maintained until no further air bubbles appeared, at which point the transducer was completely filled with oil.

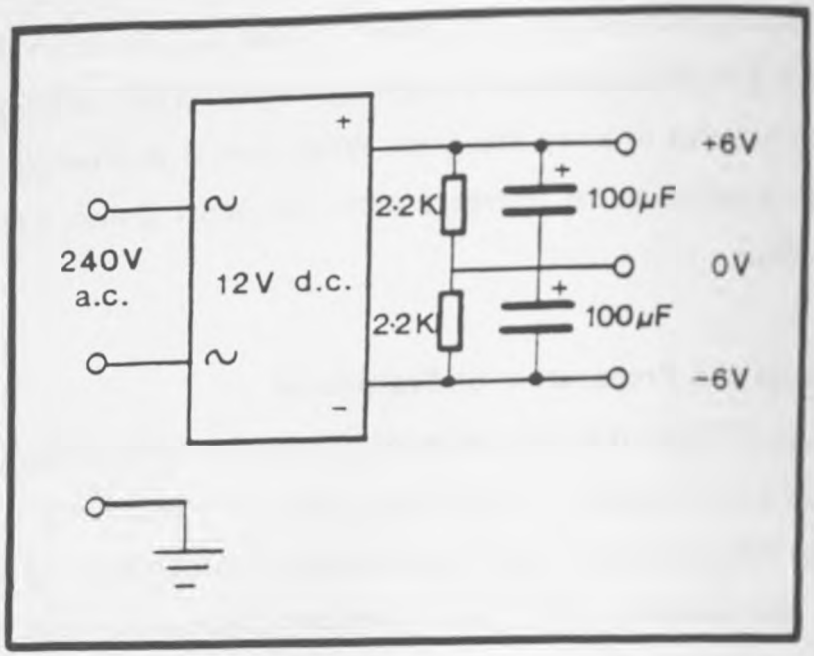


Figure 4.4 The power supply

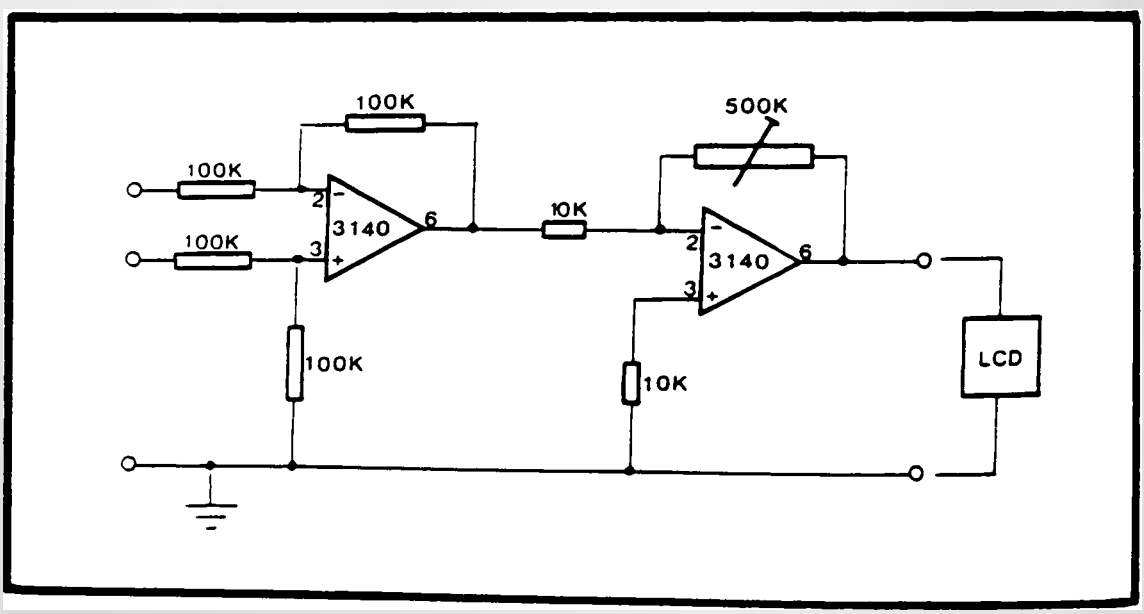


Figure 4.5 The amplifying circuit

4.3 The Signal Conditioning Unit

This unit consisted of two components, the power supply and the instrumentation amplifying circuits. The constant voltage power supply circuit illustrated in figure 4.4 is mains driven to deliver ± 6 volts. Figure 4.5 describes the basic amplifying circuit for the one channel used in the earlier version of the device. The use of three channels in this device was facilitated by a switch mechanism. The circuit diagrams of the improved version incorporating, zero controls (fine and coarse), variable gain settings, external printer port and multiple display boards (LCD) mounted on a printed circuit board are illustrated in Appendix A.

The variable gain setting was used to calibrate the pressure readings to display in millimetres of mercury (mmHg). The zero controls enabled the zero datum to be set after placing the sensor in position, an important requirement of the system. Finally the multiple liquid crystal display (LCD) facilitated simultaneous observations of measurements made in the three channels.

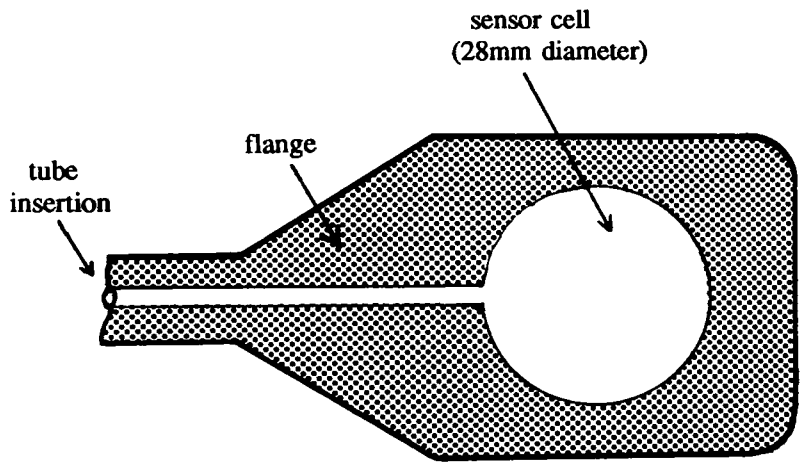


Figure 4.6 The P.V.C. sensor

4.4 The Pressure Sensor and Tubing

The sensor was a disc shaped cell constructed of two sheets of polyvinyl chloride (PVC), each 0.25mm thick. It had a central circular area (28mm diameter) and a narrow slot for the insertion of the connecting tube where the layers of PVC were not bonded (Figure 4.6). The surrounding layers PVC were bonded forming a flange which was ideal for taping the sensor in place. The sensor was commercially

available (Diastron Ltd., U.K.) and was manufactured by heat sealing the two PVC sheets in a mould with a central rim. The mould also had a parallel channel which was used to connect the metre long nylon tube. The tube with an internal diameter of 1mm and a wall thickness of 1mm was sealed to the sensor and was sufficiently stiff not to be sensitive to the applied pressure.

4.4.1 Sensor and Tube Preparation

The cell and attached tube had to be filled with a suitable liquid for the sensor to be used in the hydraulic mode. Vegetable cooking oil was preferred as it met the requirements of the transducer and would not be harmful in the event of accidental leakage. An ordinary syringe half filled with the oil was attached to the connecting tube and used to draw air out of the cell. When most of the air was drawn out, the syringe was gradually released while it was held vertically along with the connecting tube and sensor cell. The oil at the bottom of the syringe rapidly flowed into the tube and partially filled the sensor. The syringe was then detached and the sensor cell was gently massaged to remove the trapped air bubbles while the tube was still held vertically. The procedure was repeated until the sensor was completely filled. The sensor was always filled with more oil than required thus enabling suitable adjustments to be made during final assembly.

4.5 The Assembly of the Pressure Measuring Device

The pressure transducer already filled with oil up to the brim of nozzle B had a bulging meniscus and was connected to the signal conditioning unit with its output adjusted to zero. An adaptor piece to fit the size of nozzle B was then attached to the free end of the connecting tube. The oil in the sensor cell and tube was then drained gradually by holding them at an inclined angle, until the thickness of the sensor at the centre of the cell was about 2 mm. At this point, the bulging meniscus of oil at the adaptor end of the tube was fused into the meniscus of oil at the transducer nozzle and the adaptor was firmly fitted to the nozzle. While fitting the adaptor to the nozzle the signal output was observed to ensure that excessive pressure was not exerted. The three components of the pressure measuring device were now connected and ready for calibration.

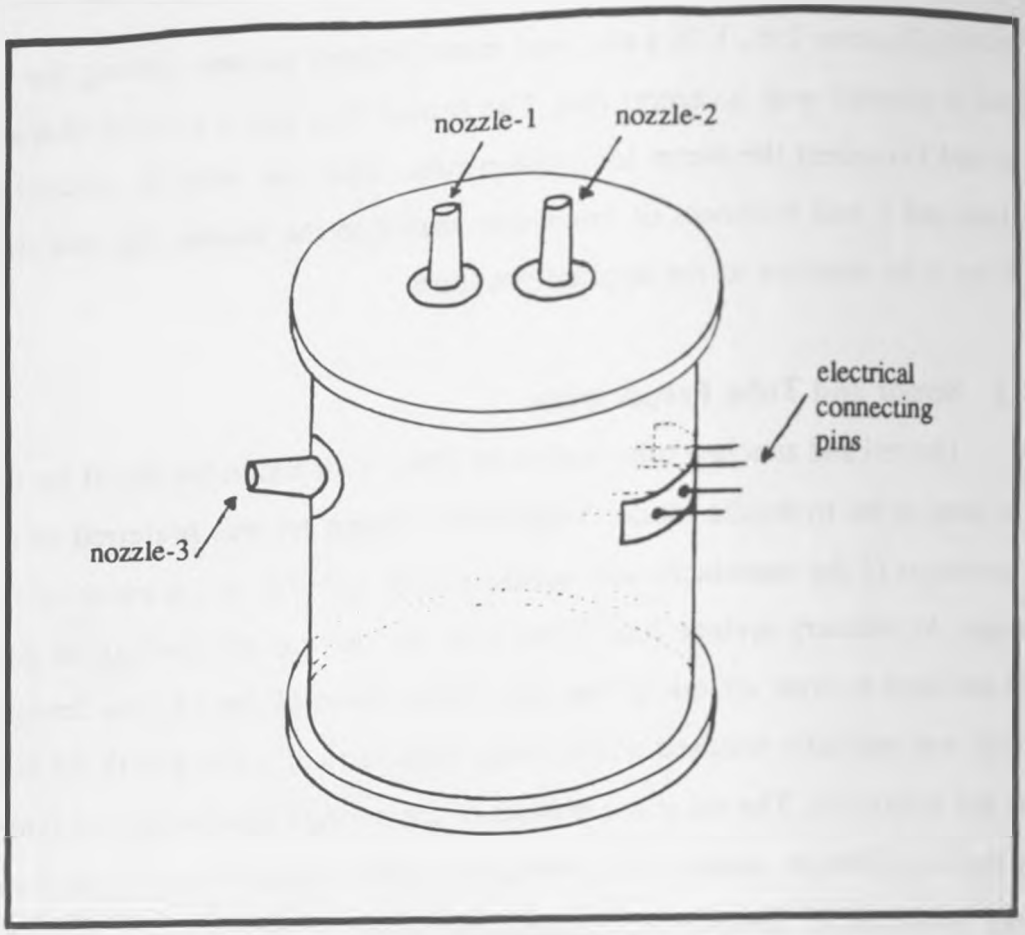


Figure 4.7 The pneumatic calibration chamber

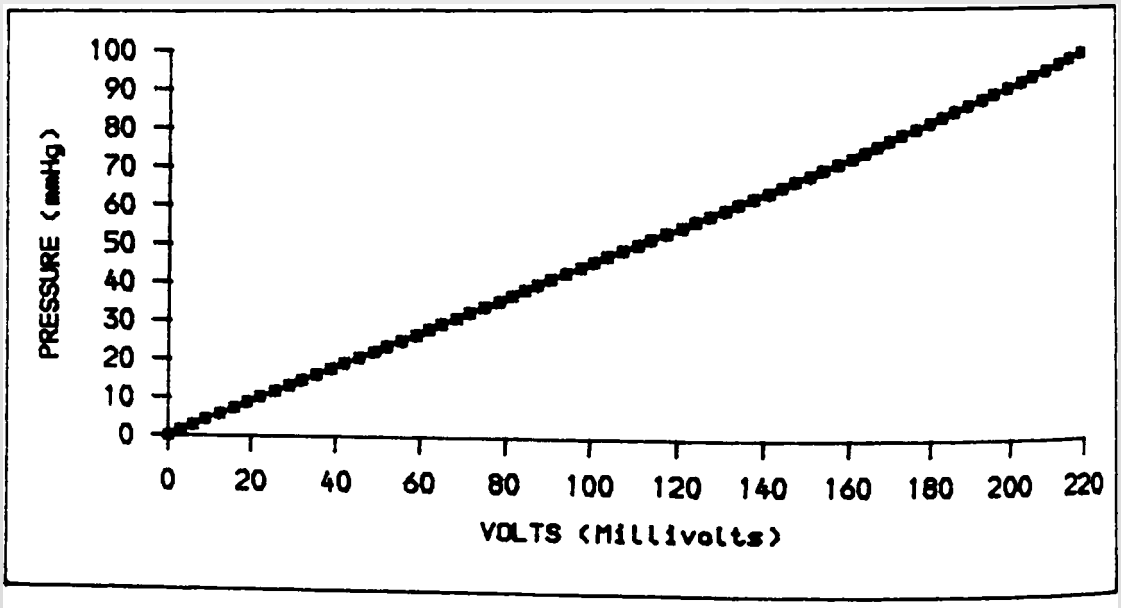


Figure 4.8 Calibration curve

4.6 Calibration of the Pressure Measuring Device

A calibration chamber was constructed from Perspex with three outlet nozzles and four electrical connecting pins through its wall as illustrated in figure 4.7. The first outlet nozzle was connected to a U-tube water manometer which was 1.5m high and the second outlet nozzle was attached to a simple hand pump. The transducer connected to the sensor via the tubing was placed inside the chamber and attached to the signal conditioning unit via pins in the chamber wall. A short piece of tube connected to port A was exposed to atmospheric (reference) pressure through the third nozzle in the chamber.

As the pressure in the chamber was increased in equal steps by working the hand pump, the output voltage from the conditioning unit was recorded together with the corresponding manometer reading. The pressure in the chamber was increased until the manometer reading was 100mmHg (13.33kPa) after which the system was gradually vented to the atmosphere while readings were obtained during the unloading phase. The output voltages were then plotted against the manometer readings for both the loading and unloading phases. The resulting graph (Figure 4.8) was always linear and its gradient was used as the calibration factor. This calibration factor was later used in pressure measurements to convert the output voltage to either millimetres of mercury or kilo-pascal. The above procedure was repeated three times for each device and periodically during use to ensure reproducibility.

4.7 Simulation of Conditions During Use

The pneumatic calibration described in the previous section, however, does not simulate the conditions of the skin-bandage interface during use. A skin-bandage interface was simulated using a cloth covered sphygmomanometer cuff representing the bandage and the flat area of skin beneath the forearm. With the pressure sensor at the interface, the pressure in the sphygmomanometer was gradually increased while the voltage output from the conditioning unit and the manometer readings were recorded. Similar to the previous calibration, readings were taken for both the loading and unloading cycles and plots of the output voltages against the manometer readings

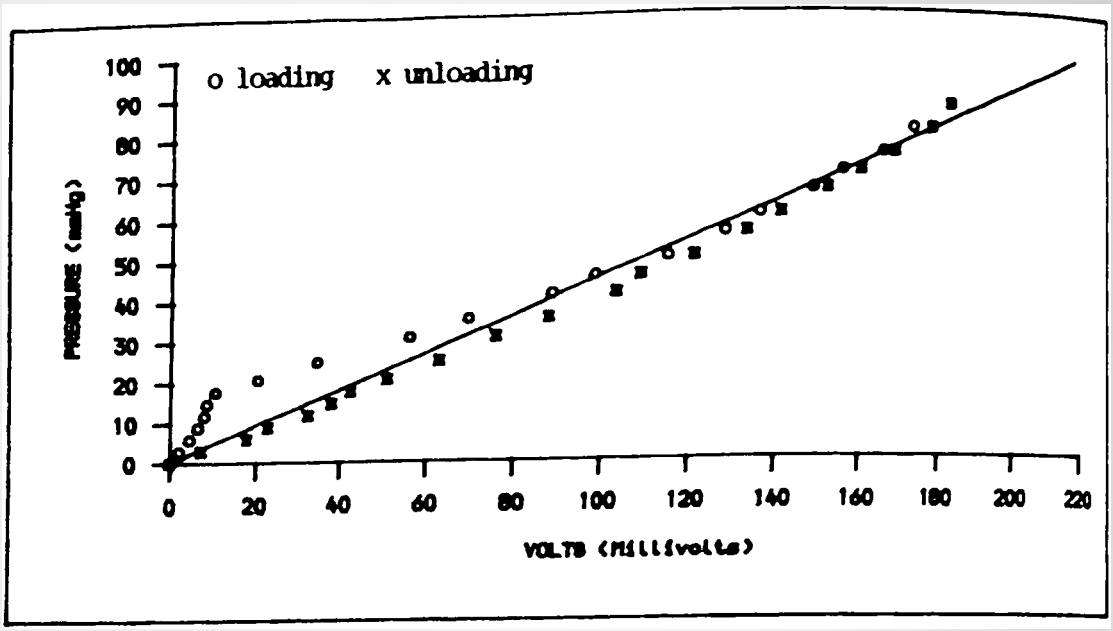


Figure 4.9 Simulated data and calibration line

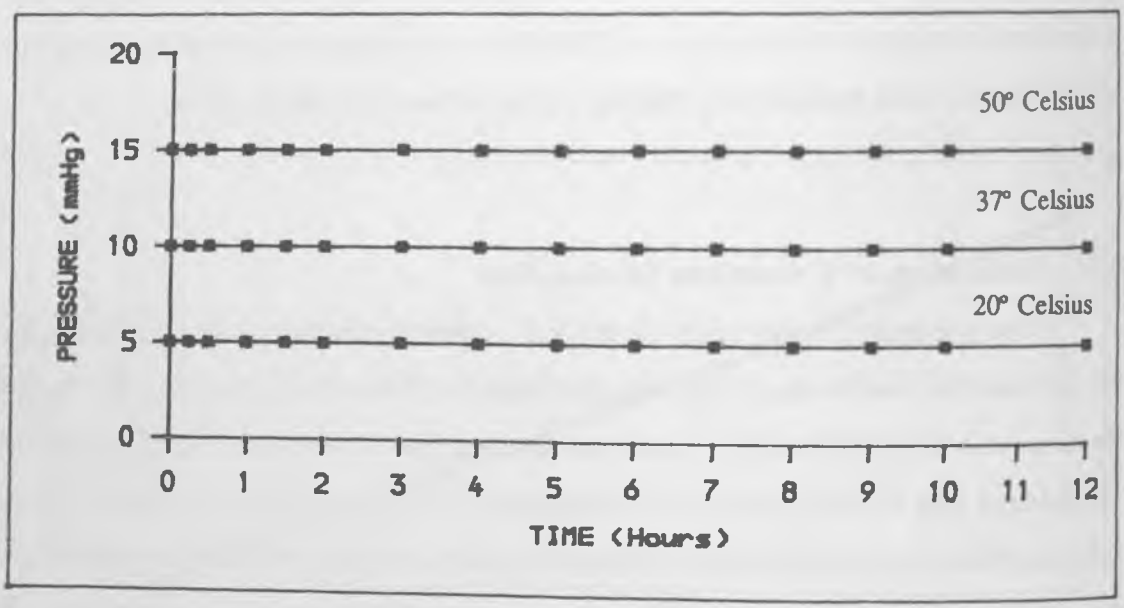


Figure 4.10 The influence of changes in temperature

were produced (Figure 4.9). The Pearson Correlation test on the resulting linear relationship showed good agreement with the results obtained from the pneumatic calibration (Loading curve, r = 0.991; Unloading curve, r = 0.997).

4.8 Evaluation of Operational Characteristics

The pressure measuring device was evaluated for an operating range of 0 to 13.33 kPa (0 to 100mmHg), although the transducer was capable of measuring pressures up to 34.5kPa (260mmHg).

The sensitivity of the measuring device over the operating range was obtained by periodically comparing the output voltage with the applied pressure. The sensitivity was found to be greater than 15mV per kPa (2mV per mmHg).

The linearity of the output voltage signal was computed by least squares linear regression and was found to be less than 0.5% of the operating range. (The maximum deviation from the best fit straight line was calculated as a percentage of the operating range).

Hysteresis was investigated by gradually increasing and decreasing the applied pressure using the pneumatic chamber. The maximum hysteresis was 0.5% of the operating range.

Repeatability of the measuring device was investigated by performing periodic measurements while maintaining a constant applied pressure on the sensor within the pressure chamber. The maximum difference between repeated measurements was 1mV (0.5 mmHg) which is 0.5% of the operating range.

The pressure sensor was placed in a temperature controlled water bath for twelve hours to investigate the effects of temperature on the device. The depth of water in the bath conveniently served to hydrostatically pre-load the sensor during the test. Three temperature levels including core body temperate were examined as illustrated in figure 4.10. The device was insensitive to changes in temperature from 20°C to 50°C.

The above test also served to examine the long term stability of the device and a maximum of 1mV difference was occasionally observed. This is 0.5% of the operating range and is within the inherent level of accuracy of the device. Additionally, regular measurements of the calibration factor over a period of one year

showed that it varied by less than 2%. The variation was random rather than as a result of ageing.

As the pressure measuring device was not intended for dynamic use, the frequency response was not specifically investigated. However, pilot studies (Nelson, 1991) indicate that the response time of the device is less than 100 ms with 48% glycerine solution and less than 500 ms with cooking oil.

The sensor cell had a diameter of 28mm and a maximum central thickness of 2mm, thus the aspect ratio of the sensor was less than 0.07.

Finally, the device was sensitive to any vertical displacement of the sensor relative to the transducer. It was therefore necessary to fix the positions of these components prior to used.

4.9 Discussion

The "Strathclyde Pressure Monitor" was built specifically to measure interface pressure beneath compression bandages and elastic stockings, although it can be used for many other applications. It was designed to meet the stringent requirements of an interface pressure measuring device, outlined in Section 3.5 and features improvements in many aspects of existing devices. The performance of this easy to use and robust device has been highly satisfactory both under laboratory conditions and during clinical use.

4.9.1 The electro-hydraulic system

The choice of an electro-hydraulic pressure measuring system was preferred as it offered a range of advantages. Unlike the resistive, inductive and capacitive devices, it is possible to have the sensor distant from the transducing element, thereby protecting it from being exposed to the conditions at the interface such as perspiration or changes in body temperature. The system permits the use of fluid filled PVC sensors which have low stiffness and which are flexible and pliable over the contours of the interface. Further, the electro-hydraulic system is best suited for the use of the more advanced piezo-resistive, silicon technology transducer which is highly regarded for its precision and low cost.

A disadvantage of the electro-hydraulic pressure measuring system is that the device is sensitive to the vertical displacement of the sensor relative to the transducer. Any change in the vertical separation of the two components will produce a change in the hydrostatic pressure resulting from the column of fluid in the tube and is recorded by the transducer. This effect is eliminated by fixing the vertical separation of the sensor and transducer prior to use.

During postural changes the vertical separation of the two components cannot be easily fixed. However, recording and subtracting the zero datum from the pressure measurements for each posture would resolve the problem.

In the longer term, the effect may be eliminated by either using a very low density fluid or by using the transducer in a differential mode. The most suitable low density fluid is air but it is not a viable option because it is highly compressible. Further research on the differential mode of operation of the transducer, with a "dummy" fluid filled tube connected to port A, to counteract this effect is underway (Nelson, 1991).

4.9.2 The Transducer

The SCX series transducers have performance characteristics that are only matched by devices which are at least twenty times more expensive such as those produced by Entran International (France). The SCX transducers are internally calibrated and temperature compensated to provide accurate and stable output. It has a wide selection of operating ranges and is particularly useful for the measurement of very low pressures as in the case of sub-bandage pressures. The sensing element is well housed in a ceramic case and is distant from the site of measurement. It is therefore not directly exposed to any abrupt pressure gradients, shear and frictional forces, excessive temperature and humidity that may be present at the interface. Such factors have often produced large hysteresis and drift in the capacitive, resistive and strain-gauged transducers. The hysteresis, linearity and long term stability for the SCX series transducers are 0.1% of full scale output (Sensor Technics Handbook, 1992) which is negligible. Unlike the intermittent measurements produced by the Oxford Pressure Monitor and the Medical Stocking Tester, the SCX transducer is capable of continuous measurement and output, with a sampling frequency of 100

micro-seconds. Finally the SCX transducer is relatively easy to assemble, requires only very basic electronic circuitry and operates from a constant voltage power supply which offers good stability.

4.9.3 The Sensor

The PVC fluid filled sensor has several advantages over other sensors. It has low stiffness and once in place it is virtually insensitive to minor bending or shear stresses. Unlike capacitive or inductive sensors it does not undergo significant material creep which can cause hysteresis and drift in the output. The fluid filled sensor cell has a fixed volume which does not changes during use. In contrast, the air sensors of the pneumatic devices inflate and deflate during use which constantly disrupt the interface thus producing distortions in the measurement. The fluid filled sensor inherently responds to the average pressure within the sensor area and is not affected by small changes in the contact surface area. In contrast, the capacity or resistive sensors may produce disproportionate measurements as the contact area changes. These sensors are also likely to be affected by an abrupt pressure gradient such as a point "peak" load. The fluid acting as the medium of pressure transmission from the PVC sensor ensures an even loading of the pressure sensitive diaphragm thus avoiding differential stresses and ambiguous outputs. An additional feature of the PVC sensor is that it is not limited to the flat disc shape and has the potential to be pre-shaped to fit any awkward anatomical feature.

4.9.4 Assembly and Calibration of the Device

The connecting tubes used initially were made of PVC but as they were too soft and sensitive to pressure, they were replaced by the more rigid polytetrafluoroethylene (PTFE) tubes. These tubes although hard and insensitive to pressure did not adhere well to the PVC sensor and frequently leaked at the joints. A compromise was achieved with nylon tubes which glued well to the PVC sensor with a PVC adhesive (Strathbond Ltd.) and was insensitive to any applied pressure.

The choice of fluid used in the system was limited because of the silicon based material in the transducer. The fluid had to be non-ionic, non-corrosive and non-silicon based. This restricted the use of most hydraulic fluids. A further

constraint was safety in the event of accidental spillage on the skin. A variety of aromatic, mineral, immersion and vegetable cooking oils were considered. However, these oils reacted with the PVC material of the sensor, extracting the plasticiser and causing it to become stiff or even brittle. As an alternative, glycerine solution with a suitable viscosity was prepared and tested. Unfortunately, over a short period the water in the solution permeated through the PVC material of the sensor.

Vegetable cooking oil was selected because it satisfied all the requirements and was slowest in extracting the plasticiser from the PVC. A sensor filled with cooking oil typically remained soft and pliable for about six months and this was sufficient time to use the device after which the sensor was replaced. The long term solution to the problem is to either use a material with non-extractable plasticiser for the sensor or a fluid that does not react with the plasticiser. This would require further research and is not within the scope of this thesis.

Filling the sensor cell and tube with oil without trapping air bubbles required some skill and experience. Small air bubbles were occasionally held within the tube by capillary forces and required gentle tapping of the tube to encourage movement which eventually forced the bubble out.

The hydrostatic method of calibration was used initially. This involved systematically lowering the sensor into a column of water while recording the output. The maximum level of pressure attained by this method of calibration was limited by the length of the tube. Further, the sensor had to be kept horizontal in the column of water to avoid a pressure gradient on its surface. For these reasons the pneumatic calibration method was later adopted.

4.9.5 The Pressure Measuring Device

The Strathclyde Pressure Monitor has provided a means of measuring interface pressure accurately and reliably. Careful consideration of its design has helped to resolve many of the common problems encountered in the use of other pressure measuring devices. Its operational characteristics are superior to those of existing devices and match the ideal characteristics listed in Chapter three. Several teething problems were identified in the earlier model and solved. Future improvements will focus on eliminating the effect of change in hydrostatic pressure caused by vertical

displacement and on selecting a suitable transmission fluid. In the meantime the device has been successfully used to measure interface pressure beneath bandages and elastic stockings in studies described in the following chapter.

CHAPTER 5

THE EVALUATION OF COMPRESSION BANDAGES AND ELASTIC STOCKINGS

5.1 An In Vivo Assessment of Compression Bandages

5.2 An In Vivo Assessment of Elastic Stockings

5.3 An In Vitro Investigation of Bandages and Stockings

5.4 A Subjective Assessment of Compression Devices

5.5 Discussion

5 THE EVALUATION OF BANDAGES AND ELASTIC STOCKINGS

As reported in Chapters One and Two, compression bandages and elastic stockings are widely used in the treatment of venous ulcers, yet little is known of the precise magnitude and distribution of compression provided by these devices. Evaluating the performance of these compression devices either clinically or in the laboratory is often very demanding. Consequently, only a few comprehensive studies have been reported (Burnand and Layer, 1986). Amongst the many difficulties faced in the clinical evaluation of the performance of these devices, the lack of a suitable interface pressure measuring equipment is predominant. In this study, the difficulty was resolved by using a custom built device which was specifically designed for interface pressure measurement beneath compression devices.

The aim of this section of the study was two fold, firstly to assess the performance of some routinely used bandages and elastic stockings, and secondly to identify the various parameters which could influence their functional properties. The study therefore focused on the evaluation of a selected number of compression bandages and elastic stockings which are commercially available both in the United Kingdom and in America. In order to provide a balanced comparison, a few of these compression devices were also selected from the United Kingdom Drug Tariff.

In vivo and in vitro tests were conducted on these compression bandages and elastic stockings separately, to establish a comprehensive understanding of the factors that influenced the compression generated by these devices. Statistical analyses were performed on the data obtained from these tests to examine the influence of each factor in detail. The study also incorporated a subjective questionnaire which investigated the qualitative aspects of these bandages and elastic stockings.

5.1 In Vivo Assessment of Compression Bandages

For a bandage to be successfully used in the treatment of venous ulcers, it must generate graduated compression of sufficient magnitude. The mechanism behind graduated compression and its role in ulcer healing have been discussed in Chapters One and Two. The graduation in compression must be proximal from the ankle to just below the knee. The required magnitude of compression is usually predetermined by the class of bandage selected.

Age (sex)	Weight kg	Height cm	Circumference Calf (cm)	Gaiter (cm)	Ankle (cm)
29 (M)	70.2	169.5	36.6	28.0	21.6
24 (M)	77.0	180.5	37.5	28.1	23.5
22 (F)	69.6	169.5	39.2	31.0	22.6
24 (M)	79.0	178.0	36.6	27.0	23.3
23 (F)	64.4	161.5	40.2	29.5	22.0
30 (M)	74.2	170.0	37.9	28.6	20.9
26 (F)	68.4	180.0	39.6	30.2	22.4
28 (M)	79.7	167.0	40.6	30.5	24.1
28 (F)	92.5	160.0	44.5	34.7	25.0
25 (F)	66.5	160.0	40.0	32.5	23.5

TABLE 5.1 Details of the volunteer subjects

This in vivo study was aimed at assessing the performance of six selected bandages in meeting their functional requirements. In addition, the study examined the influence of related factors such as bandage type, technique of application, duration of use, inter-subject variability and change in posture on the pressures generated.

5.1.1 Instrumentation

Pressures beneath the compression bandages were measured using an earlier version of the Strathclyde pressure monitor. This continuous pressure measuring device used oil filled sensor cells (28mm diameter and 2mm thickness) and a piezo resistive pressure transducer. It featured all the standard operational characteristics of the more recent models, but unfortunately its recording facilities were not automated and its use required pressure readings to be recorded manually. The calibration and working order of the instrumentation were regularly checked prior to the start of each test. Detailed description of the design, development, operational characteristics and calibration of this pressure measuring device is presented in Chapter Four.

5.1.2 Subject Selection and Preparation

Ten volunteer subjects (five males and five females) were selected from within the student population of the Bioengineering Unit. In an effort to avoid extremes, the subjects selected were between 23 and 30 years of age and were of average stature. (The average weight and height was 74kg and 170cm respectively, as shown in table 5.1).

The nature of the study and the protocol involved were briefed and each subject was then required to fill a form consenting to their participation in the study. The subjects were questioned on their general well being and were reported as generally healthy and normal. The foot pulse was checked for each subject as a matter of routine, rather than a necessity, as the volunteers were young and healthy. Also for the purpose of documentation, blood pressures at the left arm were measured for each subject.

Three specific sites on the right leg were previously chosen to represent pressures measured at the ankle, gaiter and calf. The sites were then located and

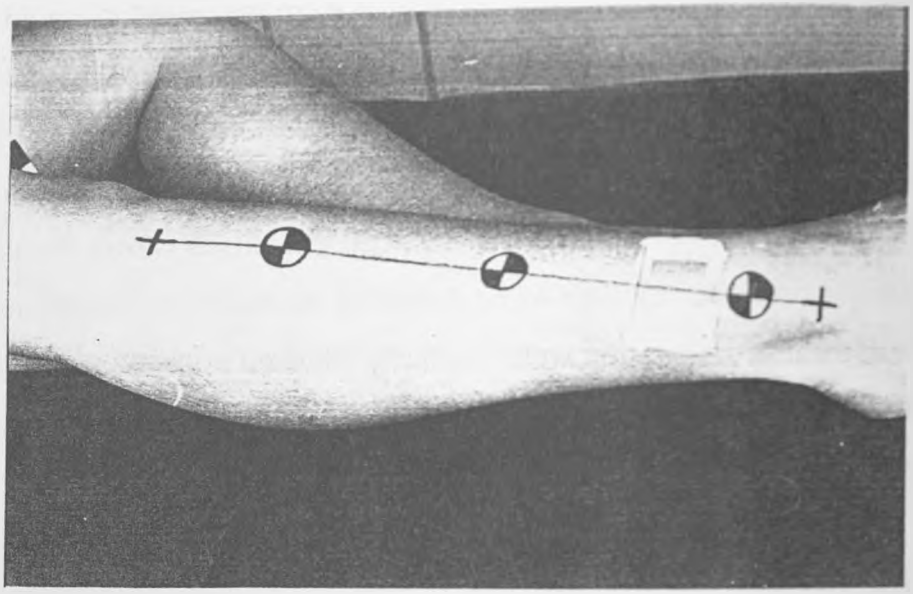


Figure 5.1 Sensor sites and reference points on the leg

marked on the leg of each subject using a body marker pen. The markings ensured reproducible placement of the sensor throughout the study. In order to ensure uniformity within the ten subjects, the head of fibula, the lateral malleolus and the line joining the two points were selected as reference markings (Figure 5.1). The sensor site at the ankle was located 40mm above the lateral malleolus on the reference line. The calf sensor site was located on the reference line at the point of maximum calf circumference. The sensor site at the gaiter was then located at the mid-point between the two previously marked sites. Leg circumferences at each of these sites were then recorded as shown in table 5.1. Finally, as each test lasted for a duration of one hour, the subjects were advised to bring along some reading material to keep themselves occupied.

5.1.3 Materials Tested

The description of the six compression bandages tested in the in vivo study is presented in the table 5.2.

BANDAGE	WIDTH	COLOUR	TYPE	CLASS	MANUFACTURER
SURGICOT	75mm	brown	elastic	-	ConvaTec
ELASTOCREPE*	75mm	brown	crêpe	2	Smith & Nephew
COBAN WRAP	75mm	white	cohesive	-	3M
BLUE LINE*	100mm	white	elastic	3d	Seton
ACE	75mm	brown	elastic	-	Becton Dickinson
GRANUFLEX	100mm	brown	adhesive	3b	ConvaTec

TABLE 5.2 Description of the bandages tested (* Available on the Drug Tariff)

5.1.4 Method

The tests were conducted in the clinical measurement room of the Bioengineering Unit which was centrally heated to a comfortable room temperature. Each subject sat on a chair in a natural comfortable posture with the feet on the floor which was covered with a mat to prevent the feet from getting cold. The location of the feet on the mat was marked to ensure that subsequent standing and sitting manoeuvres were reproducible. The subjects were then required to check that they were able to rise to a standing posture without any discomfort. They were also reminded to place equal weight on both feet when standing.

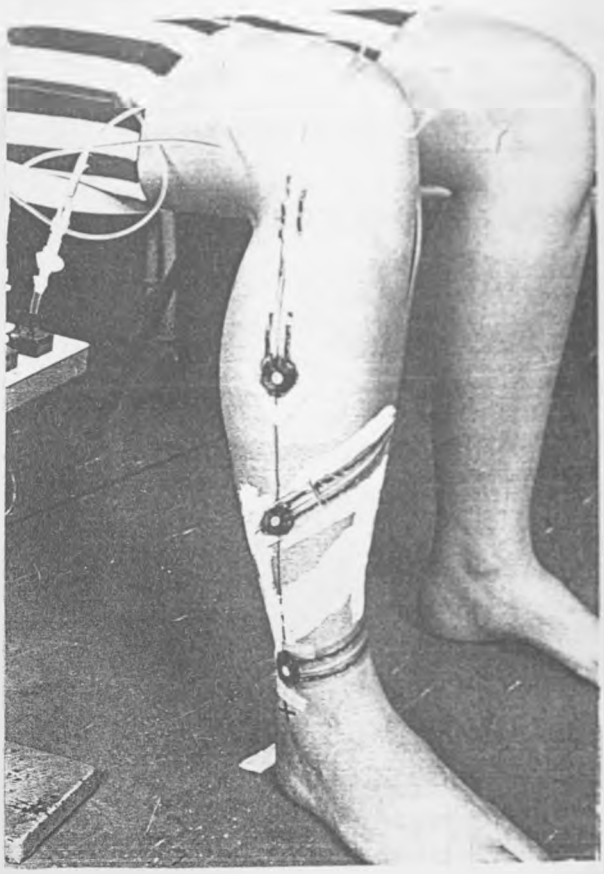


Figure 5.2 Sensors taped in position

Once the subjects were ready, the sensors were placed at each of the three marked sites on the leg and the flanged PVC edges of the sensor were taped onto the skin with micropore tape (3M, UK) as illustrated in figure 5.2. The tubes leading from the sensors were neatly taped along the limb to ensure that they did not interfere with the bandaging. The transducers and electronic conditioning unit attached to the tubes from the sensors were placed adjacently on a stool.

The test procedure commenced with the recording of the initial zero datum readings from the display panel of the conditioning unit. The zero readings were taken with the subjects in both standing and sitting postures to eliminate any interference caused by a possible hydrostatic difference between the sensor and transducer as a result of the change in posture. A bandage selected at random was then applied on the subject by a qualified physiotherapist, following the instructions supplied by the manufacturer. The same physiotherapist applied all the bandages in the study. The bandages were applied with a fifty percent overlap but the degree of stretch varied according to the manufacturer's instructions. (The art of bandaging is reviewed in depth in Chapter Two). The spiral and criss-cross techniques of application were used in random order with at least 24 hours between each application. The time taken for the application of each bandage was recorded and later used in the qualitative study as an index of the ease of application. Immediately after the bandage was applied, the subject was required to stand whilst the first readings were taken. This was then repeated in the sitting posture. Readings were taken for a total period of sixty minutes, at five minute intervals for the first fifteen minutes, and at fifteen minute intervals thereafter. Each pressure reading was recorded in triplicate with a fifteen second interval between each reading. The subjects were required to remain seated without undue movement during the periods between measurements. After recording the last pressure reading, a five centimetre line was marked on the bandage at the level of maximum circumference along the length of the stretched bandage. The bandage was then removed and the zero datum readings were once again recorded to ensure the long term stability of the pressure measuring device. Finally, the previously marked line along the length of the bandage was re-measured with the bandage unextended. This difference in the length of the

Source of Variation	Sum of Squares	D.F.	Mean Square	F	Sig. of F
Main Effects	156801570	15	10453438.0	962.8	0.000
POSTURE	5533929	1	5533929.4	509.7	0.000
TIME	1257503	6	209583.9	19.3	0.000
SITE	156454	2	78226.9	7.2	0.000
TECHNIQ	67342087	1	67342086.7	6206.3	0.000
BANDAGE	82511597	5	16502319.4	1519.9	0.000
2-Way Interactions	19689247	79	249231.0	23.0	0.000
POSTURE TIME	29827	6	4971.2	0.5	0.840
POSTURE SITE	136631	2	68315.4	6.3	0.000
POSTURE TECHNIQ	368608	1	368607.6	34.0	0.000
POSTURE BANDAGE	621114	5	124222.7	11.4	0.000
TIME SITE	32126	12	2677.2	0.3	0.996
TIME TECHNIQ	402632	6	67105.3	6.2	0.000
TIME BANDAGE	349053	30	11635.1	1.1	0.361
SITE TECHNIQ	3887860	2	1943929.8	179.0	0.000
SITE BANDAGE	5077655	10	507765.5	46.8	0.000
TECHNIQ BANDAGE	8783742	5	1756748.4	161.8	0.000
Explained	176490817	94	1877561.9	172.9	0.000
Residual	53690943	4945	10857.6		
Total	230181760	5039	45680.1		

TABLE 5.3 Results of the first analysis of variance (excluding SUBJECT)

marked line was later used (Section 5.3) to estimate the in situ extension of the bandage.

5.1.5 Data Processing

The pressure readings were recorded in units of volts which served as a control in eliminating observer bias. The data were entered into the Strathclyde University mainframe (VMS) system which had the capacity to handle very large data files. A pascal computer program called "Convert.pas" (Appendix B1) was written to convert the pressure readings from units of volts to millimetres of mercury (mmHg) using the calibration equations obtained prior to each test. This program also restructured the format of the data layout to suit the input requirements of a powerful statistical computer package, "Statistical Package for Social Sciences" (SPSS). This statistical package was selected because it offered a wide range of statistical techniques and more importantly was capable of handling large volumes of data.

The next phase of data processing required a reduction in the bulk volume of data to enable ease of analysis and was done by averaging each pressure reading recorded in triplicate. In order to justify such an averaging, a knowledge of the triplicate pressure readings was required. For this purpose, a pascal computer program called "Getrange.pas" (Appendix B2) was written which calculated the maximum difference between the three readings taken for each measurement and the percentage of the pressure readings that were within 1 mmHg of the median was obtained. The triplicate readings were found to be in very good agreement with an average of 96% within 1 mmHg of the median (Appendix C). A fortran computer program called "Dataverage.for" (Appendix B3) was then written to calculate the average of the triplicate data thus reducing the bulk volume of the data to a third.

Upon completing the initial preparation of the data, the SPSS program was used to produce two sets of five-way analysis of variance (ANOVA) to assess the significance and level of interaction of the factors involved. The first five-way ANOVA examined pressure by **POSTURE** (standing or sitting), **TIME** (0 to 60 minutes), **SITE** (calf, gaiter and ankle), **TECHNIQUE** (spiral or criss-cross), and **BANDAGE** (six types). The results of the analysis (Table 5.3) showed that all five factors were highly significant (p=0). The two way interaction indicated that with the

Source of Variation	Sum of Squares	D.F.	Mean Square	F	Sig. of F
Main Effects	162150439	23	7050019.1	941.5	0.000
TIME	1257503	6	209583.9	28.0	0.000
SITE	156454	2	78226.9	10.5	0.000
SUBJECT	10882799	9	1209199.9	161.5	0.000
TECHNIQ	67342087	1	67342086.7	8993.3	0.000
BANDAGE	82511597	5	16502319.4	2203.8	0.000
2-Way Interactions	31901493	191	167023.5	22.3	0.000
TIME SITE	32126	12	2677.2	0.4	0.978
TIME SUBJECT	161771	54	2995.8	0.4	1.000
TIME TECHNIQ	402632	6	67105.3	9.0	0.000
TIME BANDAGE	349053	30	11635.1	1.6	0.028
SITE SUBJECT	3234072	18	179670.7	24.0	0.000
SITE TECHNIQ	3887860	2	1943929.8	259.6	0.000
SITE BANDAGE	5077655	10	507765.5	67.8	0.000
SUBJECT TECHNIQ	732731	9	81414.6	10.9	0.000
SUBJECT BANDAGE	9239851	45	205330.0	27.4	0.000
TECHNIQ BANDAGE	8783742	5	1756748.4	234.6	0.000
Explained	194051933	214	906784.7	121.1	0.000
Residual	36129827	4825	7488.1		
Total	230181760	5039	45680.1		

TABLE 5.4 Results of the second analysis of variance (excluding POSTURE)

exception of TIME-POSTURE (p=0.840), TIME-SITE (p=0.996) and TIME-BANDAGE (p=0.361), all factors influenced each other significantly (p=0). The second five-way ANOVA examined pressure by **SUBJECT** (ten volunteers), **SITE, TIME, TECHNIQUE,** and **BANDAGE**. The results of the second ANOVA (Table 5.4) also showed that all five factors were highly significant (p=0) and the two way interactions indicate that with the exception of TIME-SUBJECT (p=1), TIME-SITE (p=0.978) and TIME-BANDAGE (p=0.028), all factors influenced each other significantly (p=0).

In view of the complexity of the data, the multiplicity of significant factors and their interactions, it was necessary to simplify the approach to subsequent analysis by adopting the following criteria;

(1) analysis of data was based on standing POSTURE.

(2) analysis of data was at a specific moment of TIME (30 minutes after application).

(3) each SUBJECT was used as their own control (in order to compare the performance of the different bandages on the same subject).

(4) the effects of POSTURE, TIME and SUBJECT were examined separately

The data were analyzed using non parametric statistical techniques. Non parametric statistics were used as the data were not normally distributed, obtained experimentally and for the specific comparison tests, the sample size was small. The Friedman's test (Linton and Gallo, 1975), Nemenyi's test (Linton and Gallo, 1975) and the non parametric Paired test (Ryan et al., 1985) were used. The Friedman's test is a non-parametric analogue of two-way analysis and one factor was always SUBJECT thus allowing for within subject comparisons. The Nemenyi's test and the Paired test were used for specific comparisons. For each analysis, a null hypothesis was set up in the form of a statement, question or comparison and then tested using a 95% confidence limit (p=0.05). Three versions of a fortran computer program called "Sortformat.for" (Appendix B4) were produced to create suitable matrixes of input data required for performing the statistical tests.

Finally, the influence of POSTURE, TIME and SUBJECT on the pressures generated by the bandages at each site of measurement was analyzed separately.

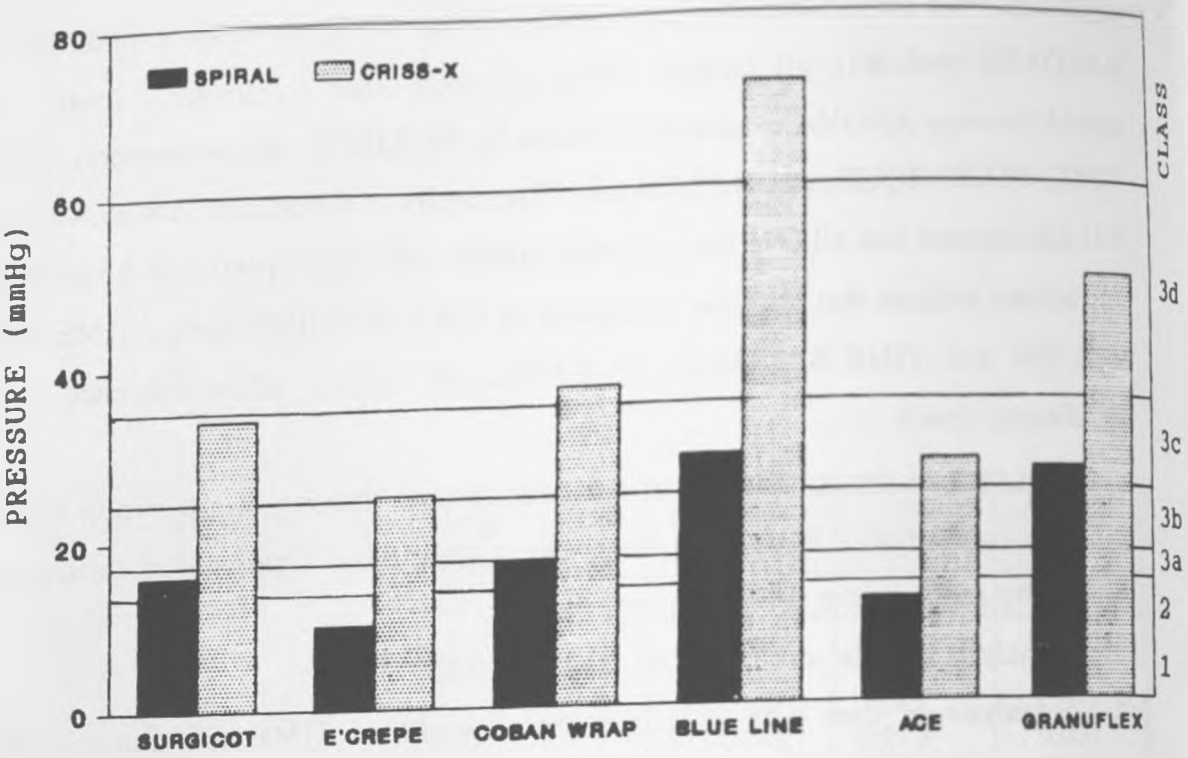


Figure 5.3 Average ankle pressures and corresponding classifications

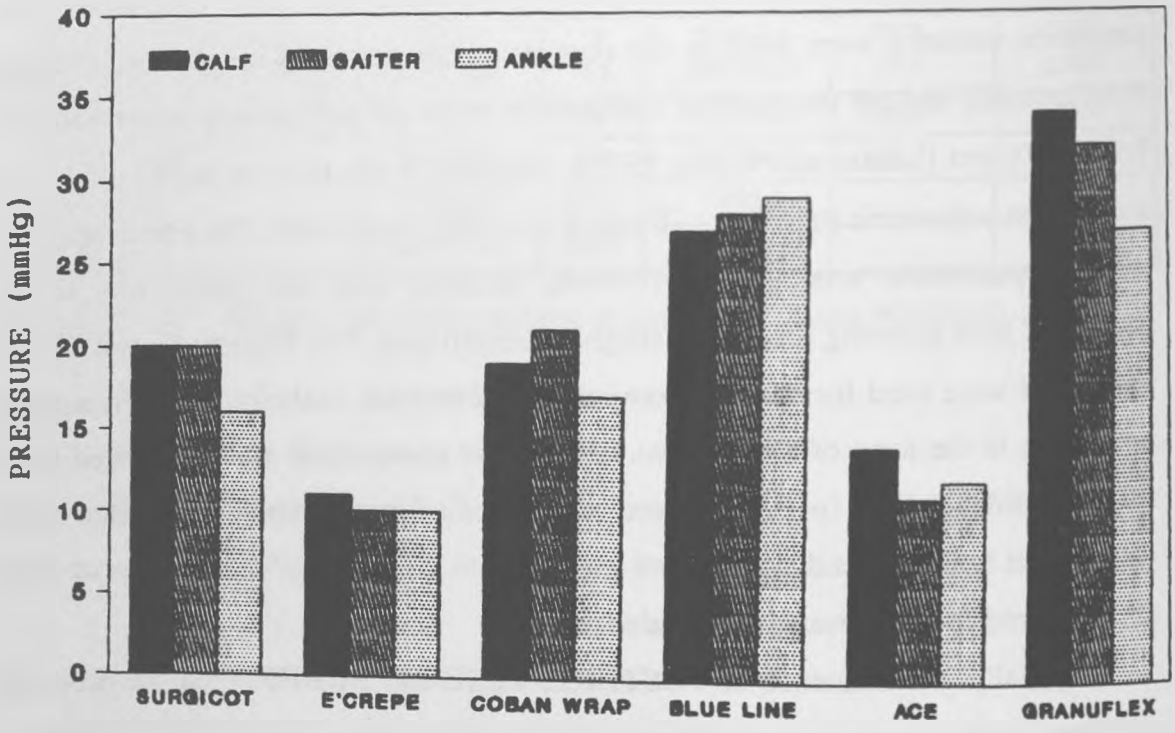


Figure 5.4 Typical average pressure gradients produced by the spiral technique of bandaging

5.1.6 Results

(a) Magnitude of Compression

Bandages are expected to produce a predetermined magnitude of compression at the ankle and in the U.K. they are classified according to their ability to produce this compression. Figure 5.3 illustrates the average ankle pressure produced by each bandage used in both techniques and the corresponding bandage classification.

Mean values and standard deviations were obtained for the pressures at the ankle produced by each bandage applied using both techniques. The bandages were then classified according to the magnitude of pressure recommended by the SDPT1 Test, 1989 (described in section 2.3.2) and were compared with the assigned classifications (Table 5.5). The results indicated that for bandages that were assigned a class, only Elastocrêpe bandage used in the spiral technique produced a magnitude of compression at the ankle that corresponded to its classification. More importantly, the results revealed that the magnitude and therefore the classification of bandages is dependent on the technique of application. In contrast the classification assigned in the SDPT1 Test did not discriminate the technique of application.

BANDAGE	TECHNIQ	PRESSURE AT ANKLE MEAN (SD) (mmHg)	CLASS MEASURED	CLASS ASSIGNED	WAS ASSIGNED PRESSURE ACHIEVED?
SURGICOT	Spiral	16 (5)	3a	none	unknown
	Criss-X	34 (6)	3c	none	unknown
ELASTOCRÊPE	Spiral	10 (3)	2	2	YES
	Criss-X	25 (7)	3c	2	NO
COBAN WRAP	Spiral	17 (7)	3a	none	unknown
	Criss-X	37 (8)	3d	none	unknown
BLUE LINE	Spiral	29 (7)	3c	3d	NO
	Criss-X	72 (11)	out of scale	3d	NO
ACE	Spiral	12 (4)	2	none	unknown
	Criss-X	28 (8)	3c	none	unknown
GRANUFLEX	Spiral	27 (10)	3c	3b	NO
	Criss-X	49 (10)	3d	3b	NO

TABLE 5.5 A comparison of the class measured with the class assigned

(b) Graduated Compression

As discussed in Chapter Two, the compression produced by a bandage must be graduated decreasingly towards the calf. The graph in figure 5.4 illustrates typical

BANDAGE	TECHNIQUE	ARE THE PRESSURES DIFFERENT AT EACH SITE? (P Value)	SPECIFIC COMPARISON	WAS GRADIENT ACHIEVED?
SURGICOT	Spiral	No (0.301)	Calf>ankle	No
	Criss-X	No (0.123)	Gaiter>ankle	No
ELASTOCRÊPE	Spiral	No (0.497)	Calf>ankle	No
	Criss-X	No (0.123)	Calf>gaiter	No
COBAN WRAP	Spiral	No (0.670)	Calf>ankle	No
	Criss-X	No (0.294)	Gaiter>ankle	No
BLUE LINE	Spiral	No (0.905)	Gaiter>ankle	No
	Criss-X	Yes (0.006)	Calf<gaiter<ankle	Yes
ACE	Spiral	No (0.273)	Calf>ankle	No
	Criss-X	No (0.407)	Calf>gaiter	No
GRANUFLEX	Spiral	No (0.270)	Calf>ankle	No
	Criss-X	No (0.900)	Gaiter>ankle	No

TABLE 5.6 The pressure profile and gradient

BANDAGE	SITE	DID TECHNIQUE INFLUENCE COMPRESSION?	SPECIFIC COMPARISON
SURGICOT	Calf	No P = 0.058	None
	Gaiter	Yes P < 0.002	Criss-X > Spiral
	Ankle	Yes P < 0.002	Criss-X > Spiral
ELASTOCRÊPE	Calf	Yes P < 0.002	Criss-X > Spiral
	Gaiter	Yes P < 0.002	Criss-X > Spiral
	Ankle	Yes P < 0.002	Criss-x > Spiral
COBAN WRAP	Calf	Yes P < 0.002	Criss-X > Spiral
	Gaiter	Yes P < 0.002	Criss-X > Spiral
	Ankle	Yes P < 0.002	Criss-x > Spiral
BLUE LINE	Calf	Yes P < 0.002	Criss-X > Spiral
	Gaiter	Yes P < 0.002	Criss-X > Spiral
	Ankle	Yes P < 0.002	Criss-x > Spiral
ACE	Calf	Yes P < 0.002	Criss-X > Spiral
	Gaiter	Yes P < 0.002	Criss-X > Spiral
	Ankle	Yes P < 0.002	Criss-x > Spiral
GRANUFLEX	Calf	No P = 0.058	None
	Gaiter	Yes P < 0.002	Criss-X > Spiral
	Ankle	Yes P < 0.002	Criss-x > Spiral

TABLE 5.7 The influence of the technique of application on compression

average pressure gradients produced by each bandage using the spiral technique.

The data was analyzed for all three sites of measurement, for each bandage used in both the spiral and criss-cross techniques. Specific comparisons between the sites were carried out to identify the compression profile produced by each bandage. The results in table 5.6 indicated that only the Blue Line bandage used in the criss-cross technique provided suitable graduated compression. This bandage used in the spiral technique and all the other bandages used in either technique failed to provide adequate graduated compression.

(c) Technique of Application

The compression generated at the three measuring sites by each bandage, using both the Spiral and Criss-cross techniques was analyzed and compared. A specimen graph illustrated in figure 5.5 displays the ankle pressures produced by each bandage applied in the two techniques.

The results of the analysis (Table 5.7) indicated that with the exception of compression generated at the calf by Surgicot and Granuflex bandages, the Criss-cross technique generated significantly ($p<0.002$) higher compression than the Spiral technique.

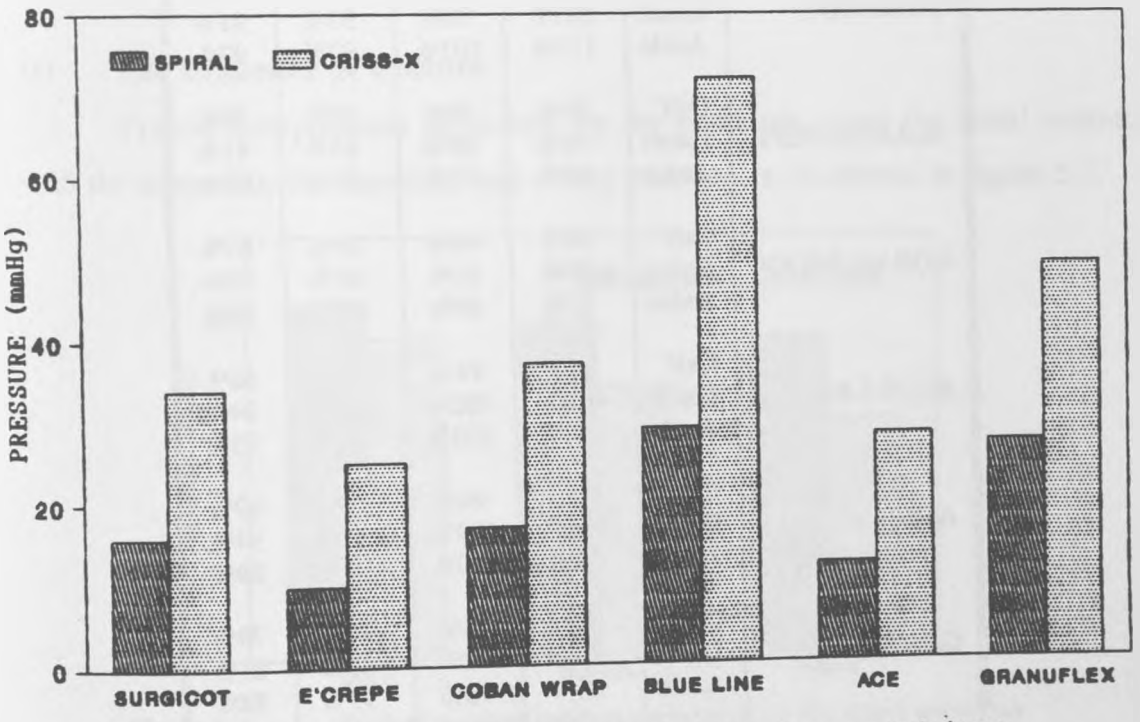


Figure 5.5 Ankle pressures produced by spiral and criss-cross techniques

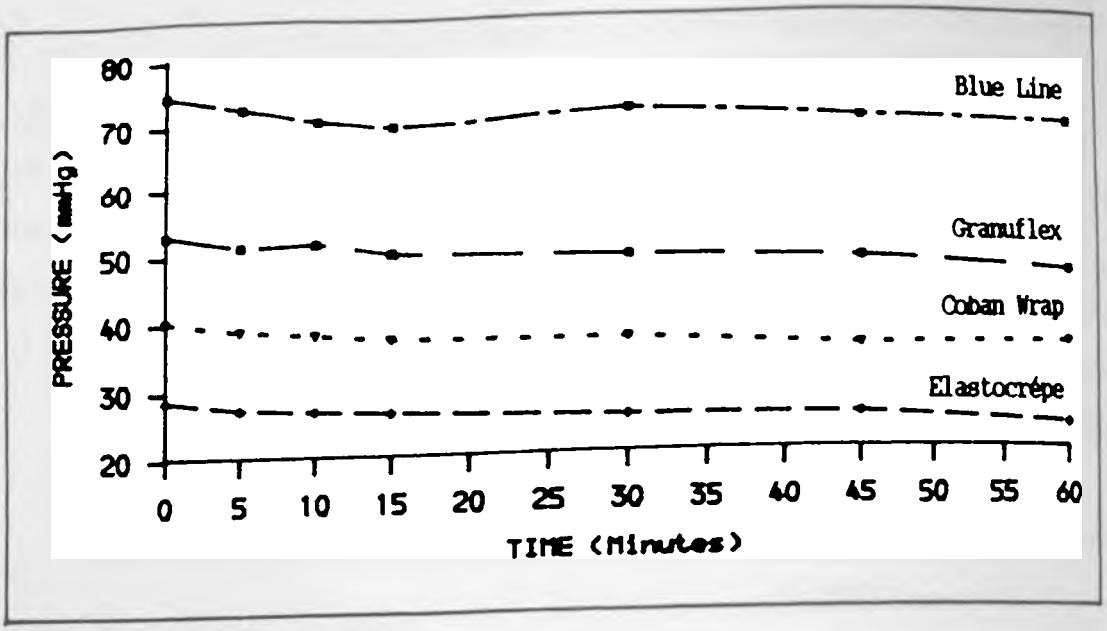


Figure 5.6 The influence of time on compression generated at the ankle by the spiral technique of bandaging

BANDAGE	SITE	SPIRAL		CRISS-X	
		30min	60min	30min	60min
SURGICOT	Calf	95%	94%	92%	87%
	Gaiter	103%	99%	93%	91%
	Ankle	110%	103%	97%	97%
ELASTOCRÉPE	Calf	86%	79%	79%	78%
	Gaiter	98%	96%	85%	81%
	Ankle	91%	91%	88%	83%
COBAN WRAP	Calf	88%	86%	85%	83%
	Gaiter	93%	91%	92%	90%
	Ankle	92%	89%	92%	89%
BLUE LINE	Calf	96%	94%	90%	88%
	Gaiter	103%	102%	96%	94%
	Ankle	100%	100%	96%	93%
ACE	Calf	98%	94%	93%	89%
	Gaiter	106%	103%	95%	94%
	Ankle	100%	100%	93%	89%
GRANUFLEX	Calf	89%	84%	85%	79%
	Gaiter	96%	92%	89%	85%
	Ankle	96%	93%	93%	88%

TABLE 5.8 The percentage change in compression at 30 and 60 minutes

(d) The Influence of Time

The magnitude of compression sustained by a bandage during the period of use is important if the bandage is to function effectively. Figure 5.6 illustrates the influence of time on the compression produced at the ankle by bandages applied in the spiral technique.

In order to examine the trend in the compression produced over the duration of the test, the compression data at 30 minutes and 60 minutes were analyzed as a percentage of the datum at the start of the tests, for each bandage, site and technique.

The results (Table 5.8) indicates that the level of compression at 60 minutes is lower than that at 30 minutes for all the bandages and at all sites of measurement. Statistical comparisons showed that the difference was significant ($p<0.0001$ for Spiral technique; $p=0$ for Criss-cross technique). The analysis at 60 minutes also indicate that the drop in the magnitude of compression for all bandages and at all sites was significantly ($p=0$) greater for the Criss-cross technique than the Spiral technique. However, a further comparison of percentage drop in pressure between 30 and 60 minutes for both techniques of bandaging reveal no significant difference. Over the 60 minute duration the Elastocrêpe bandage exhibited the greatest percentage drop in compression for both techniques and at all sites of measurement.

(e) The Influence of Posture

Typical compression generated by the bandages using the spiral technique with the subject in the standing and sitting postures is illustrated in figure 5.7.

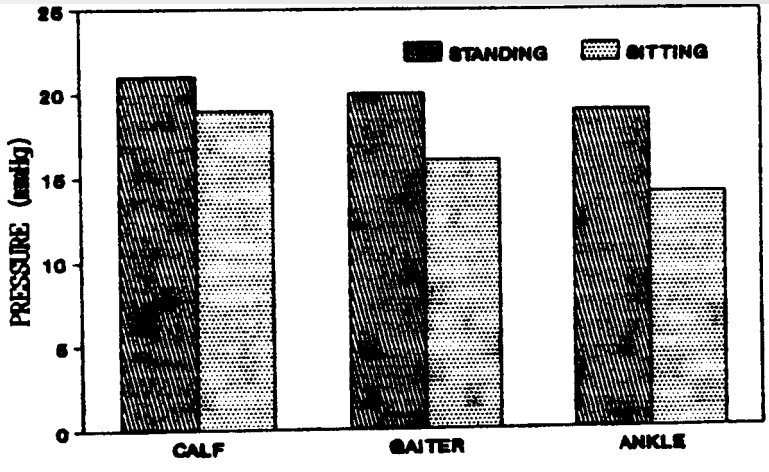


Figure 5.7 Typical average pressures produced by the spiral technique during standing and sitting

BANDAGE	SITE	SPIRAL		CRISS-X	
		STAND	SIT	STAND	SIT
SURGICOT	Calf	20	17	28	23
	Gaiter	20	16	38	31
	Ankle	16	11	34	27
ELASTOCRÉPE	Calf	11	12	21	19
	Gaiter	10	8	22	18
	Ankle	18	8	25	18
COBAN WRAP	Calf	19	18	34	29
	Gaiter	21	16	37	31
	Ankle	17	12	37	30
BLUE LINE	Calf	27	24	48	39
	Gaiter	28	23	59	50
	Ankle	29	23	72	62
ACE	Calf	14	12	24	19
	Gaiter	11	8	23	18
	Ankle	12	10	28	23
GRANUFLEX	Calf	34	31	46	38
	Gaiter	32	24	51	42
	Ankle	27	19	49	38

TABLE 5.9 A comparison of average pressures produced during standing and sitting

BANDAGE	SITE	INTER-SUBJECT VARIABILITY	
		SPIRAL	CRISS-X
SURGICOT	Calf	± 37%	± 30%
	Gaiter	± 37%	± 26%
	Ankle	± 32%	± 17%
ELASTOCRÉPE	Calf	± 31%	± 37%
	Gaiter	± 49%	± 24%
	Ankle	± 34%	± 29%
COBAN WRAP	Calf	± 32%	± 27%
	Gaiter	± 40%	± 29%
	Ankle	± 40%	± 22%
BLUE LINE	Calf	± 27%	± 29%
	Gaiter	± 30%	± 20%
	Ankle	± 25%	± 16%
ACE	Calf	± 31%	± 29%
	Gaiter	± 30%	± 20%
	Ankle	± 37%	± 30%
GRANUFLEX	Calf	± 19%	± 30%
	Gaiter	± 38%	± 25%
	Ankle	± 35%	± 20%

TABLE 5.10 Percentage inter-subject variability of measurement

Analysis of the data produced in the two postures (Table 5.9) revealed that, with the exception of the compression produced by the Elastocrêpe bandage at the calf, the compression generated in the standing posture was significantly greater than in the sitting posture for both techniques of application. ($p<0.0001$ for the spiral technique; $p=0$ for criss-cross technique). The criss-cross technique produced higher compression than the spiral technique for both standing and sitting postures.

Specific comparisons between the two postures at each site of measurement also revealed that compression during standing was significantly greater than during sitting. ($p=0.0063$ for Calf; $p=0.0005$ for Gaiter; $p=0.0005$ for Ankle).

(f) Inter-Subject Variability

As the statistical analyses were based on within subject comparisons, it was necessary for completeness that the inter-subject variability be examined.

Table 5.10 shows the percentage inter-subject variability of the measurement recorded after 30 minutes of commencing each test. The criss-cross technique produced less inter-subject variability than the spiral technique for all the bandages. The Blue Line bandage exhibited least inter-subject variability for both techniques of application while the Elastocrêpe bandage exhibited greatest variability. Inter-subject variability was recorded at all sites of measurement.

5.2 In Vivo Assessment of Elastic Stockings

An in vivo assessment of six routinely used elastic stockings was carried out, similar to the previous in vivo study on bandages. The aim of the study was to assess the functional properties of these elastic stockings in providing suitable compression for the treatment or the prevention of recurrence of venous ulcers. As elastic stockings are normally washed and reused, it was also the purpose of this study to examine if washing these stockings altered their functional properties.

5.2.1 Instrumentation and Subjects

The instrumentation used for measuring interface pressures and the procedure adopted in preparing the subjects for the tests were similar to that in the in vivo bandage study and are detailed in sections 5.1.1 and 5.1.2.

STOCKING	COLOUR	STYLE	PRESCRIBED CLASS	MANUFACTURER
HARCOURT	white	below knee open toe	none	Harcourt Knitting Co.
T.E.D.	white	below knee open toe	1	Kendal Company
VENOSAN (2002)	brown	below knee	2	Salzmann
SIGVARIS (601)	brown	below knee	1	Ganzoni & Cie
JOBST	white	below knee open toe	1	Jobst Inst. Inc.
TUBIGRIP	creme	tubular (doubled)	1	Seton Ltd.

TABLE 5.11 Description of the elastic stockings tested

5.2.2 Materials Tested

The description of the six elastic stockings tested is presented in table 5.11.

5.2.3 Method

The procedures involved in setting up the pressure measuring device, positioning the pressure sensors at the three selected sites and subsequent recording of data were identical to that followed in the in vivo bandage study (Section 5.1.4).

New elastic stockings were selected for each subject according to the subject's calf and ankle circumferences, and the length of the leg. As the subjects were of average stature, the size of the elastic stockings required were generally "large/regular". The elastic stockings were applied by a qualified physiotherapist in accordance with the manufacturers' instructions. The same physiotherapist applied all the stockings in the study. The two methods of application that were used are reviewed in detail in section 2.4. Application of the elastic stockings was relatively straightforward as the legs of the subjects were not oedematous and their skins were supple. The time required for the application of each elastic stocking was recorded for later use in the qualitative study as an index of the ease of application. Upon completing the pressure measurements over the sixty minutes duration, an estimation of the in situ extension of the garment was made as described in the previous bandage study for later use in the in vitro study (Section 5.3).

The elastic stockings were then hand washed with a non bleaching, mild detergent in luke warm water and spun dried. The laundering of each elastic stocking was repeated thirty times after which it was re-applied on the subjects and the above tests were repeated.

5.2.4 Data Processing

The initial preparation of the data was carried out according to the procedure described in the in vivo bandage study (Section 5.1.5).

The influence of six factors, the type of STOCKING, the SITE of pressure measurement, the SUBJECT, the duration of use (TIME), the condition of the stockings (NEW/WASHED), and the POSTURE of the subjects (standing or sitting) were examined. To investigate this, the SPSS statistical computer program was used

Source of Variation	Sum of Squares	D.F.	Mean Square	F	Sig. of F
Main Effects	18386858	15	1225790.6	382.3	0.000
POSTURE	2337099	1	2337098.8	729.0	0.000
TIME	141279	6	23546.5	7.3	0.000
SITE	9838593	2	4919296.3	1534.4	0.000
NEW-WASHED	165	1	164.7	0.1	0.821
STOCKING	6069723	5	1213944.6	378.6	0.000
2-Way Interactions	3541438	79	44828.3	14.0	0.000
POSTURE TIME	11619	6	1936.5	0.6	0.727
POSTURE SITE	83356	2	41678.2	13.0	0.000
POSTURE NEW-WASH	140	1	140.3	0.0	0.834
POSTURE STOCKING	92861	5	18572.3	5.8	0.000
TIME SITE	31271	12	2606.0	0.8	0.637
TIME NEW-WASHED	2295	6	382.5	0.1	0.994
TIME STOCKING	15246	30	508.2	0.2	1.000
SITE NEW-WASHED	10967	2	5483.7	1.7	0.181
SITE STOCKING	3215460	10	321546.0	100.3	0.000
NEW-WASH STOCKING	78221	5	15644.2	4.9	0.000
Explained	21928296	94	233279.8	72.8	0.000
Residual	15853833	4945	3206.0		
Total	37782129	5039	7497.9		

TABLE 5.12 Results of the first analysis of variance (excluding SUBJECT)

Source of Variation	Sum of Squares	D.F.	Mean Square	F	Sig. of F
Main Effects	18558766	23	806902.9	354.8	0.000
TIME	141279	6	23546.5	10.4	0.000
SITE	9838593	2	4919296.3	2163.3	0.000
SUBJECT	2509007	9	278778.5	122.6	0.000
NEW-WASHED	165	1	164.7	0.1	0.788
STOCKING	6069723	5	1213944.6	533.8	0.000
2-Way Interactions	8251205	191	43200.0	19.0	0.000
TIME SITE	31271	12	2606.0	1.2	0.317
TIME SUBJECT	51678	54	957.0	0.4	1.000
TIME NEW-WASHED	2295	6	382.5	0.2	0.985
TIME STOCKING	15246	30	508.2	0.2	1.000
SITE SUBJECT	2088784	18	116043.6	51.0	0.000
SITE NEW-WASHED	10967	2	5483.7	2.4	0.090
SITE STOCKING	3215460	10	321546.0	141.4	0.000
SUBJECT NEW-WASH	714479	9	79386.6	34.9	0.000
SUBJECT STOCKING	2042803	45	45395.6	20.0	0.000
NEW-WASH STOCKING	78221	5	15644.2	6.9	0.000
Explained	26809972	214	125280.2	55.1	0.000
Residual	10972158	4825	2274.0		
Total	37782129	5039	7497.9		

TABLE 5.13 Results of the second analysis of variance (excluding POSTURE)

to produce two sets of five-way analysis of variance (ANOVA). The first five-way ANOVA examined pressure by **POSTURE, TIME, SITE, NEW/WASHED** and **STOCKING**. The results of the analysis (Table 5.12) showed that, with the exception of NEW/WASHED (p=0.821) all other factors were highly significant (p=0). The second five-way ANOVA examined pressure by **SUBJECT, TIME, SITE, NEW/WASHED** and **STOCKING**. The results of this ANOVA (Table 5.13) also showed that, with the exception of NEW/WASHED (p=0.788) all other factors were highly significant (p=0). The two-way interactions in both these ANOVA tests revealed that the data was highly complex with multiple interacting factors which were significant.

Some simplification of the approach to subsequent analysis of the data was necessary. The four criteria previously developed in the in vivo bandage study (Section 5.1.5) were also applied to this study to facilitate analysis of the data. Non parametric statistical techniques were then used as described in section 5.1.5.

5.2.5 Results

(a) Magnitude of Compression

Elastic stockings, like bandages, are expected to produced a predetermined magnitude of compression at the ankle and are classified according to their ability to produce such a compression. Figure 5.8 illustrates the average magnitude of compression produced by each stocking at the ankle and its corresponding classification.

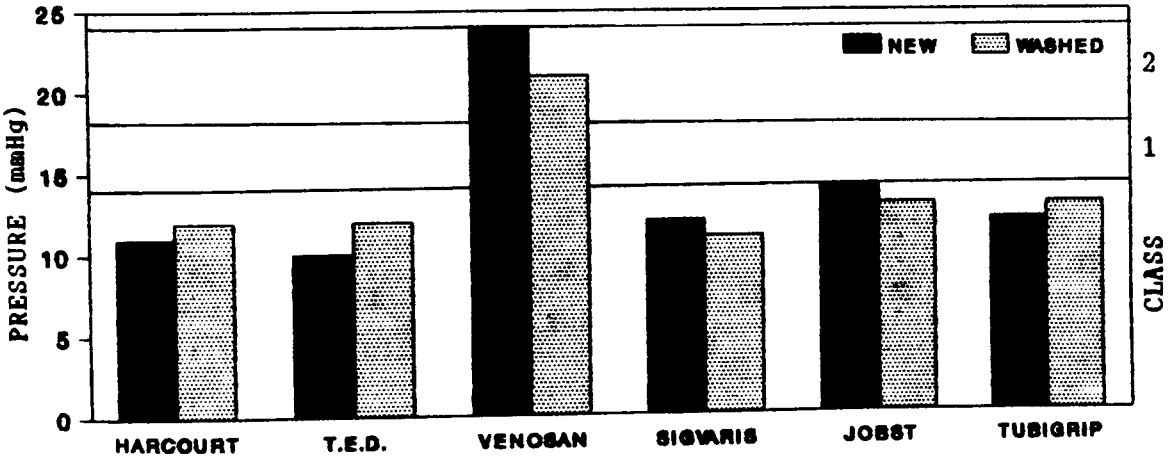


Figure 5.8 Average ankle pressures and corresponding classifications

STOCKING	STATE	PRESSURE AT ANKLE MEAN (SD) (mmHg)	CLASS MEASURED	CLASS ASSIGNED	WAS ASSIGNED PRESSURE ACHIEVED?
HARCOURT	NEW	11 (3)	Too low	none	NO
	WASH	12 (4)	Too low	none	NO
T.E.D.	NEW	10 (3)	Too low	1	NO
	WASH	12 (4)	Too low	1	NO
VENOSAN (2002)	NEW	24 (8)	2	2	YES
	WASH	21 (8)	2	2	YES
SIGVARIS (601)	NEW	12 (4)	Too low	1	NO
	WASH	11 (4)	Too low	1	NO
JOBST	NEW	14 (4)	1	1	marginal
	WASH	13 (2)	Too low	1	NO
TUBIGRIP	NEW	12 (2)	Too low	1	NO
	WASH	13 (4)	Too low	1	NO

TABLE 5.14 A comparison of the class measured with the class assigned

With the exception of Venosan stocking, the compression produced by these elastic stockings at the ankle was too low to be classified. Mean values and standard deviations of the pressures at the ankle were obtained for each new and washed elastic stockings as shown in table 5.14. Based on these measured pressures at the ankle, the stockings were then classified in accordance with the system of classification described in BS6612 (Section 2.3.3). This classification was then compared with the classification assigned for each device. Only Venosan stocking had generated the magnitude of compression that was in accordance with its assigned classification. The compression produced by the new Jobst stocking was marginally within its assigned classification. All other elastic stockings used in the test failed to produce the appropriate prescribed magnitude of compression at the ankle.

(b) Graduated Compression

Graduated compression decreasing towards the calf is a necessary requirement of compression devices as discussed in Chapter Two. The average pressures produced at the calf, gaiter and ankle by each elastic stocking were used to examine if suitable gradients in compression were produced as illustrated in figure 5.9. With the exception of Venosan stocking, all the elastic stockings tested produced inverse gradients with the highest pressures at the calf.

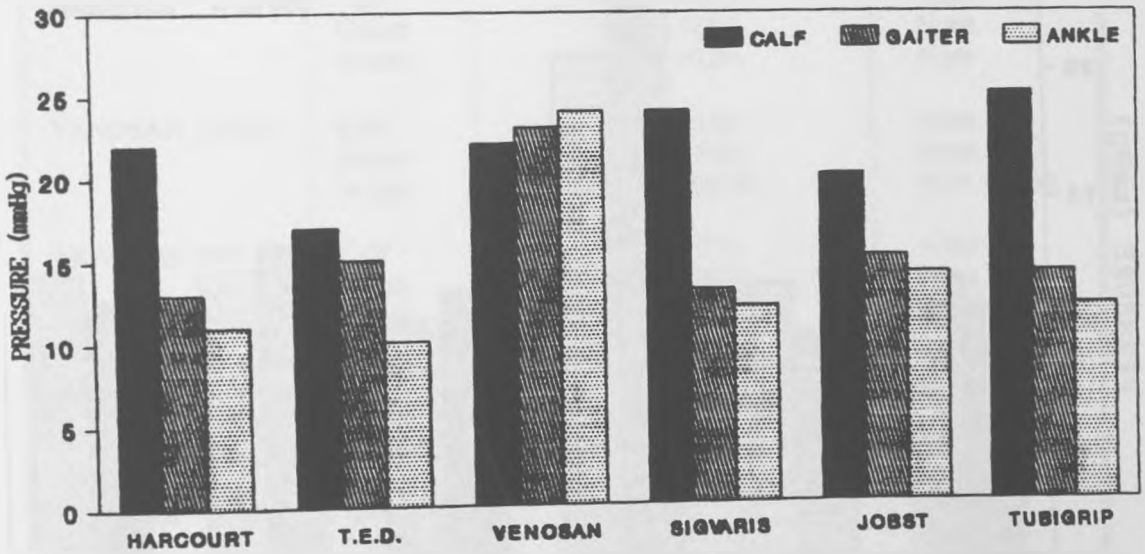


Figure 5.9 Typical average pressure gradients produced by new stockings

STOCKING	STATE	ARE THE PRESSURES DIFFERENT AT EACH SITE? (P Value)	SPECIFIC COMPARISON	WAS GRADIENT ACHIEVED?
HARCOURT	NEW	YES (0.0005)	Calf > gaiter Calf > ankle	NO
	WASH	YES (0.0003)	Calf > gaiter Calf > ankle	NO
T.E.D.	NEW	YES (0.0136)	Calf > ankle Gaiter > ankle	NO
	WASH	YES (0.0136)	Calf > ankle Gaiter > ankle	NO
VENOSAN (2002)	NEW	NO (0.4966)	none	NO
	WASH	NO (0.7985)	none	NO
SIGVARIS (601)	NEW	YES (0.0005)	Calf > gaiter Calf > ankle	NO
	WASH	YES (0.0004)	Calf > gaiter Calf > ankle	NO
JOBST	NEW	YES (0.0202)	Calf > gaiter Calf > ankle	NO
	WASH	NO (0.0821)	none	NO
TUBIGRIP	NEW	YES (0.0004)	Calf > gaiter Calf > ankle	NO
	WASH	YES (0.0006)	Calf > gaiter Calf > ankle	NO

TABLE 5.15 The pressure profile and gradient

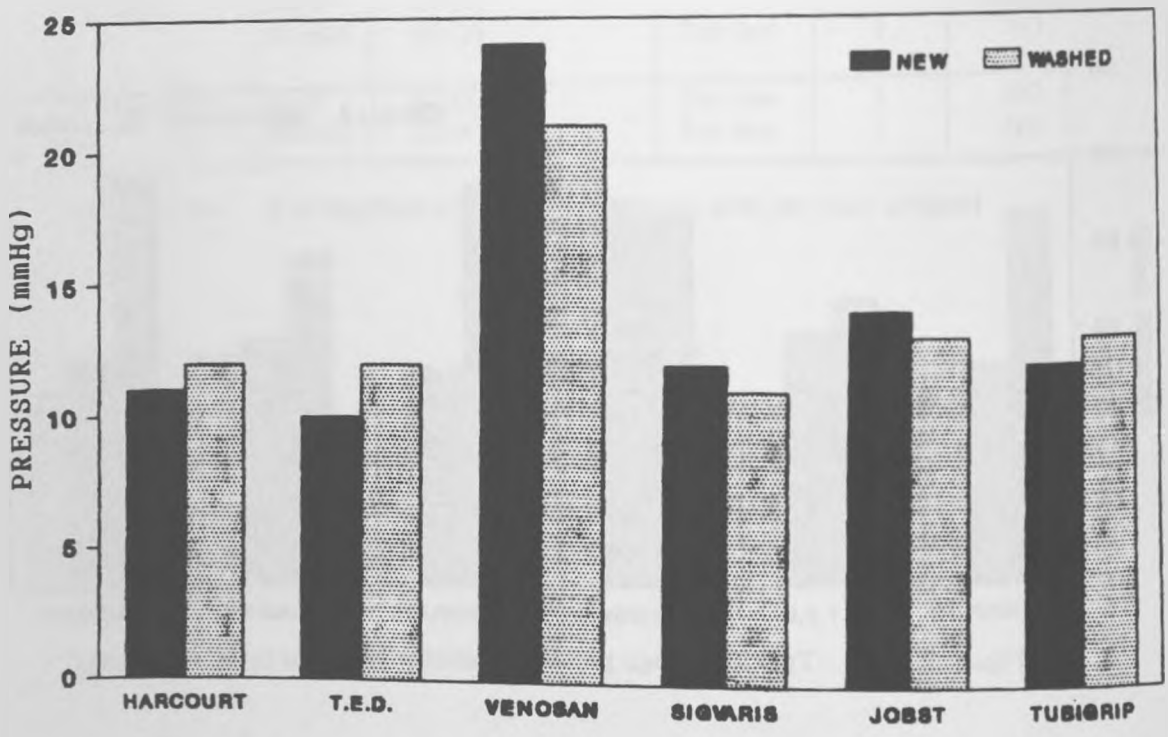


Figure 5.10 Ankle pressures produced by new and washed stockings

The data for all three sites were analyzed, for each stocking under both new and washed conditions. With exception of Venosan stocking, the pressures produced by all other stockings were significantly ($p<0.0202$) different at each site. None of the six elastic stockings tested produced the required compression gradient as shown in table 5.15. Specific comparisons between each site of measurement revealed that pressures generated at the calf were frequently higher than that at the gaiter or ankle.

(c) The Influence of Washing

The influence of laundering on each stocking at all sites was investigated. The average compression produced by each elastic stocking in the new and washed conditions is illustrated in figure 5.10. Analysis of the data revealed that laundering the stockings did not significantly alter the compression produced by the devices (Table 5.16). Although the new Venosan stockings have marginally ($p=0.0578$) higher pressures at the ankle than the washed stockings.

STOCKING	SITE	DID WASHING INFLUENCE COMPRESSION? (P-VALUE)	SPECIFIC COMPARISON
HARCOURT	Calf	NO (0.5271)	None
	Gaiter	NO (0.7518)	None
	Ankle	NO (0.5271)	None
T.E.D.	Calf	NO (0.2059)	None
	Gaiter	NO (0.5271)	None
	Ankle	NO (0.2059)	None
VENOSAN (2002)	Calf	NO (0.7518)	None
	Gaiter	NO (0.7518)	None
	Ankle	YES (0.0578)	New > wash
SIGVARIS (601)	Calf	NO (0.5271)	None
	Gaiter	NO (0.9991)	None
	Ankle	NO (0.5271)	None
JOBST	Calf	NO (0.9991)	None
	Gaiter	NO (0.5271)	None
	Ankle	NO (0.5271)	None
TUBIGRIP	Calf	NO (0.9991)	None
	Gaiter	NO (0.5271)	None
	Ankle	NO (0.5271)	None

TABLE 5.16 The influence of laundering stockings on compression

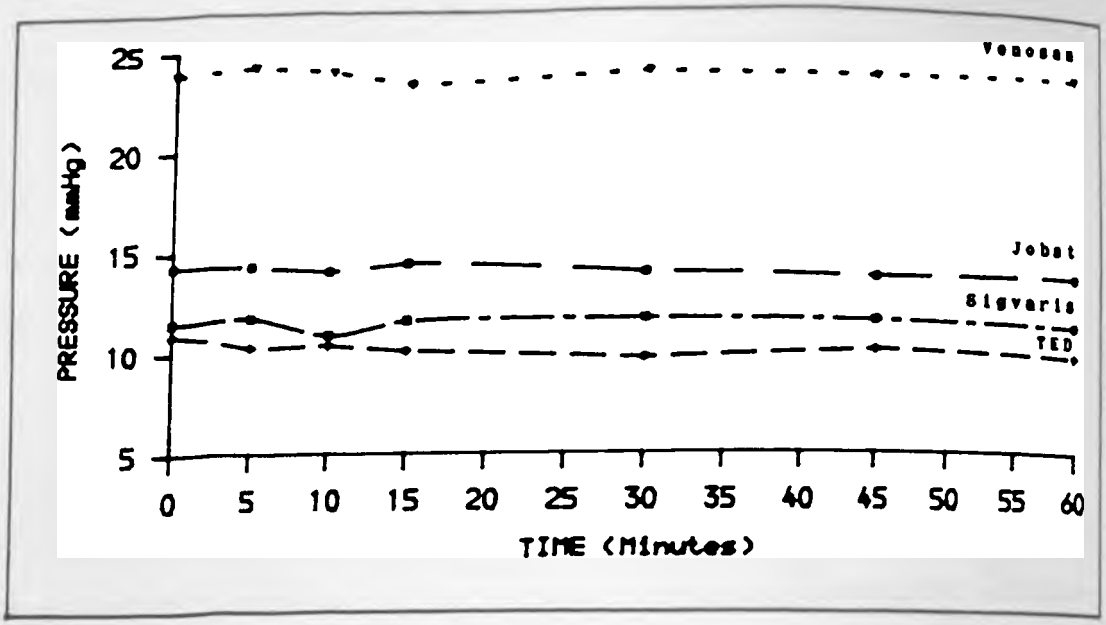


Figure 5.11 The influence of time on compression generated at the ankle by new elastic stockings

STOCKING	SITE	NEW		WASHED	
		30min	60min	30min	60min
HARCOURT	Calf	94%	91%	90%	88%
	Gaiter	103%	104%	97%	97%
	Ankle	104%	107%	99%	99%
T.E.D.	Calf	94%	93%	86%	85%
	Gaiter	97%	95%	96%	95%
	Ankle	89%	90%	113%	110%
VENOSAN (2002)	Calf	96%	95%	96%	93%
	Gaiter	102%	94%	101%	102%
	Ankle	100%	100%	94%	94%
SIGVARIS (601)	Calf	95%	92%	92%	88%
	Gaiter	102%	104%	102%	100%
	Ankle	100%	98%	103%	101%
JOBST	Calf	94%	91%	91%	87%
	Gaiter	94%	90%	96%	94%
	Ankle	97%	96%	96%	83%
TUBIGRIP	Calf	94%	91%	94%	64%
	Gaiter	98%	98%	94%	93%
	Ankle	105%	107%	101%	102%

TABLE 5.17 The percentage change in compression at 30 and 60 minutes

(d) The Influence of Time

Elastic stockings are normally used for prolonged periods of time and it would be necessary for these devices to sustain their compression during use. The overall maintenance of compression produced at the ankle by new stockings is illustrated in figure 5.11.

In order to examine the trend in compression produced by the stockings over the duration of the test, the compression data at 30 and 60 minutes were calculated as a percentage of the datum at the start of the test. The percentage compression is presented in table 5.17 for new and washed stockings at each site of measurement.

Analysis of the data indicates that the difference in compression at 30 and 60 minutes for new stockings is not significant ($p=0.1435$). However, there was a significant ($p=0.0075$) drop in compression between 30 and 60 minutes when the stockings were washed.

(e) The Influence of Posture

The compression produced by elastic stockings was affected by the subjects' posture. Figure 5.12 shows average pressures produced by new elastic stockings at each site during standing and sitting.

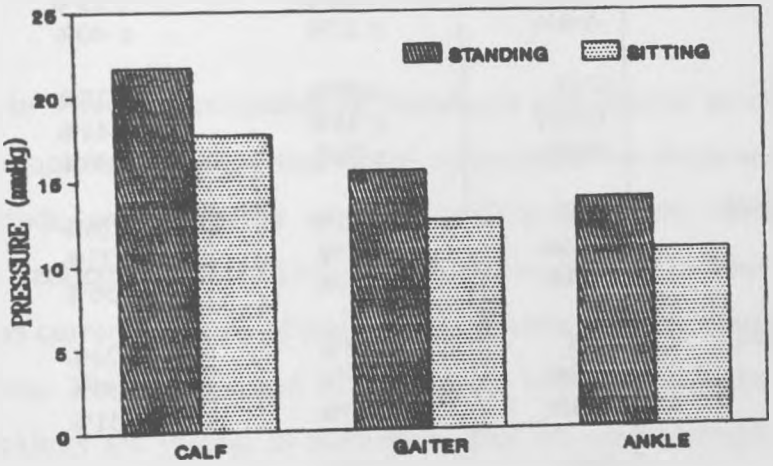


Figure 5.12 Typical average pressures produced by new stockings during standing and sitting

STOCKING	SITE	NEW		WASHED	
		STAND	SIT	STAND	SIT
HARCOURT	Calf	22	20	22	21
	Gaiter	13	22	13	12
	Ankle	11	8	11	9
T.E.D.	Calf	17	13	15	13
	Gaiter	15	11	15	11
	Ankle	10	7	11	8
VENOSAN	Calf	22	19	23	20
	Gaiter	23	18	21	18
	Ankle	24	19	21	17
SIGVARIS	Calf	24	20	23	20
	Gaiter	13	11	14	12
	Ankle	12	9	11	9
JOBST	Calf	20	16	19	15
	Gaiter	15	13	16	12
	Ankle	14	11	13	9
TUBIGRIP	Calf	25	18	26	18
	Gaiter	14	11	15	11
	Ankle	12	10	13	11

TABLE 5.18 A comparison of average pressures produced during standing and sitting

STOCKING	SITE	INTER-SUBJECT VARIABILITY NEW	WASHED
HARCOURT	Calf	± 22%	± 26%
	Gaiter	± 20%	± 29%
	Ankle	± 23%	± 40%
T.E.D.	Calf	± 32%	± 28%
	Gaiter	± 35%	± 44%
	Ankle	± 33%	± 36%
VENOSAN	Calf	± 26%	± 26%
	Gaiter	± 20%	± 23%
	Ankle	± 33%	± 36%
SIGVARIS	Calf	± 33%	± 24%
	Gaiter	± 23%	± 30%
	Ankle	± 30%	± 31%
JOBST	Calf	± 30%	± 25%
	Gaiter	± 25%	± 36%
	Ankle	± 27%	± 17%
TUBIGRIP	Calf	± 16%	± 17%
	Gaiter	± 33%	± 36%
	Ankle	± 18%	± 33%

TABLE 5.19 Percentage inter-subject variability of measurement

The data illustrated in table 5.18 was analyzed for each new and washed stocking at all three sites of measurement in the standing and sitting postures. The compression generated by all the stockings in the standing posture was significantly greater than in the sitting posture (p=0 for both new and washed stockings). Specific comparisons revealed that compression generated during standing was also significantly greater at all three sites than during sitting (p=0.0010 for calf; p=0.0005 for gaiter; p=0.0005 for ankle).

(f) Inter-Subject Variability

For the reasons outlined in Section 5.1.6f an investigation of the inter-subject variability was carried out. The inter-subject variability presented in table 5.19 was calculated as a percentage of the mean pressure produced by both new and washed stockings at all three sites. All stockings exhibited inter-subject variability at every site.

Analysis of the data indicated that washed elastic stockings produced significantly (p=0.049) greater inter-subject variability than new stockings. Specific comparisons showed no significant difference in inter-subject variability between the three sites of measurement (p=0.1460 for calf/ankle; p=0.7744 for gaiter/ankle; p=0.7744 for calf/gaiter). The T.E.D. stockings exhibited greatest inter-subject variability for both new and washed conditions.

5.3 An in Vitro Investigation of Bandages and Elastic stockings

A comprehensive investigation of compression bandages and elastic stockings should include an evaluation of their performance both clinically and in the laboratory. Laboratory tests of performance and mechanical properties are particularly important as current systems of bandage and elastic stocking classification are based on such tests. The SDPT1 test for extensible bandages and the HATRA test for elastic stockings are typical in vitro tests used for classification. These tests have been reviewed in section 2.3.

Laboratory tests were conducted on six bandages and six elastic stockings to investigate the load deformation behaviour and mechanical properties of the materials. A cyclic extension-retraction test and a stress relaxation test were carried out. For the

BANDAGE/ STOCKING	WIDTH mm	CLASS	MANUFACTURER
SURGICOT	75mm	-	ConvaTec
ELASTOCRÉPE	75mm	2	Smith & Nephew
COBAN WRAP	75mm	-	3M
BLUE LINE	100mm	3d	Seton
ACE	75mm	-	Becton Dickinson
GRANUFLEX	100mm	3b	ConvaTec
HARCOURT	-	-	Harcourt Knitting
T.E.D.	-	1	Kendal
VENOSAN	-	2	Salzmann
SIGVARIS	-	1	Ganzoni & Cie
JOBST	-	1	Jobst
TUBIGRIP	-	1	Seton

TABLE 5.20 Materials used in the in vitro tests

bandage materials, the resulting stress-strain curves were used in accordance with the SPDT1 test procedure to estimate their classification which was then compared with the assigned classification. For the stocking materials, however, such comparison was not possible because the method of this investigation differed from that of the HATRA test. The stress relaxation produced in the in vitro tests were compared with that produced in the in vivo tests.

5.3.1 Materials Tested

The bandage and stocking materials used in the laboratory tests are described in table 5.20.

5.3.2 Instrumentation

The in vitro tests were carried out on an Instron (model 95) servo-hydraulic universal test machine (UTM). The UTM is equipped with pneumatic grips for holding the specimen under test firmly at each end. These grips can move axially whilst stretching or relaxing the specimen under test at any predetermined rate. The device outputs amplified analogue voltage signals of load and displacement which were fed to a BBC micro computer for digital data collection.

The UTM also offers facilities such as automatic extension and retraction between predetermined load or displacement limits. It has a on-line two pen chart recorder which provides graphical output whilst the test is underway, thus enabling immediate observations to be made.

5.3.3 Preparation of Test Specimen

As it was not possible to test an entire bandage or elastic stocking in the UTM, a suitable specimen size of the material had to be ascertained. It was necessary to confirm that the selected dimension of the specimen or the cutting process itself did not produce any artifacts. For this purpose a pilot test was conducted using four sample specimens of each bandage. The specimens used were 10mm, 20mm, 50mm and full width, which was either 75mm or 100mm. For the pilot test the specimens were cut along the length of bandage (primary direction) using a jig consisting of

parallel dermatone blades separated by a spacer. The length of all the specimens was set at 50mm with an allowance of 30mm on either side for placement between the grips.

The four specimens of each bandage were then individually mounted on the UTM. The gauge length was set at 50mm and a cross head speed of 100mm per minute was used. The stress-strain relationship was produced for each specimen over an extension of 0 to 35mm. The resulting stress-strain graphs illustrated in Appendix D, revealed that cutting the specimens along the primary direction influenced their mechanical properties. Observations made during the tests also showed that the cut edges of the specimens frayed progressively with increased extension.

Based on this finding, full widths were used for all the bandage specimens. For the specimens from the stocking material, cutting to size was inevitable and dimensions identical to that of the bandage specimens were chosen to maintain uniformity through the study.

The samples were prepared under normal laboratory conditions. Each specimen was produced from a different packet of unused bandage and elastic stocking. The first and last 25cm from each roll of bandage were not used. Similarly, the specimens from the stocking material were obtained from the central portion clearly avoiding the edges and seams. Throughout the preparation of the specimens care was taken not to pre-stretch the material.

The structure of the bandages and stockings suggested that their mechanical behaviour would be directionally dependent and therefore two sets of specimens were prepared. One set of specimens was taken in the primary direction which was along the length of the roll for bandages and along the circumference for stockings. The other set of specimens were taken in the secondary direction which was along the width of bandage and along the vertical length of the stocking.

As the cyclic extension-retraction test and the stress relaxation test were conducted on five specimens for each material obtained in two directions, a total of two hundred and forty specimens were prepared from the bandage and stocking materials.

BANDAGE	WORKING EXTENSION (mm)	STOCKING	WORKING EXTENSION (mm)
SURGICOT	50	HARCOURT	65
ELASTOCRÉPE	25	T.E.D.	40
COBAN WRAP	30	VENOSAN	20
BLUE LINE	15	SIGVARIS	25
ACE	30	JOBST	40
GRANUFLEX	60	TUBIGRIP	75

TABLE 5.21 Average working extensions measured in situ

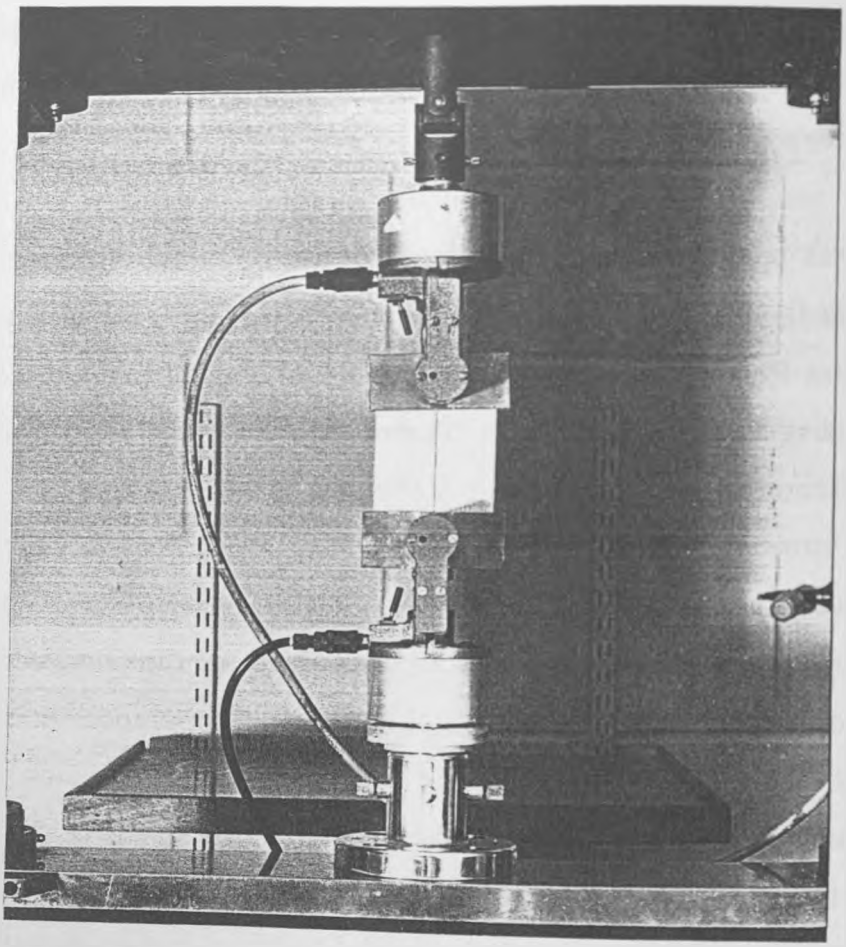


Figure 5.13 Test specimen gripped in the Instron machine

5.3.4 Method

(a) Cyclic Extension-Retraction Test

Estimates of the average working extension for each bandage and stocking were calculated, based on the in situ extensions previously measured in the in vivo studies (Sections 5.1 and 5.2). The average working extensions are shown in table 5.21.

The specimen under test was placed with one end within the upper jaw and the other end within the lower jaw of the pneumatic grips of the UTM, as illustrated in figure 5.13. The gage length was set at 50mm such that the specimen was neither slack nor under load. The jaws for the pneumatic grips were specially fabricated to match the width of the specimen.

The cross head speed of the UTM was set at 100mm per minute for the majority of tests. For specimens which were highly extensible, a higher rate of 200mm per minute was used to avoid excessive data collection. The specimens were tested under extension control. The maximum extension limits were set at the working extension of each material as tabulated in table 5.21. The cross head was driven by a triangular waveform cycling between zero and maximum extension for five cycles. The load and extension data were collected using a BBC micro computer.

The entire process was repeated five times for each specimen. However additional replicates were tested for the specimens from the Elastocrêpe bandage as the chart recorded output suggested inconsistent behaviour.

(b) Stress Relaxation Test

The specimen was placed within the jaws of the pneumatic grips of the UTM in accordance with the procedure previously described. The maximum extension limits were set at the working extension of each material as measured in the in vivo study. The UTM was programmed to extend to the maximum limit for each specimen at a cross head speed of 100mm per minute. The specimen was then held at maximum extension for the duration of the test, while the tension generated in the material was recorded using the BBC micro computer.

The chart recorded output was used to decide the duration of each test. For all the specimens a duration of fifteen minutes was deemed sufficient. The change

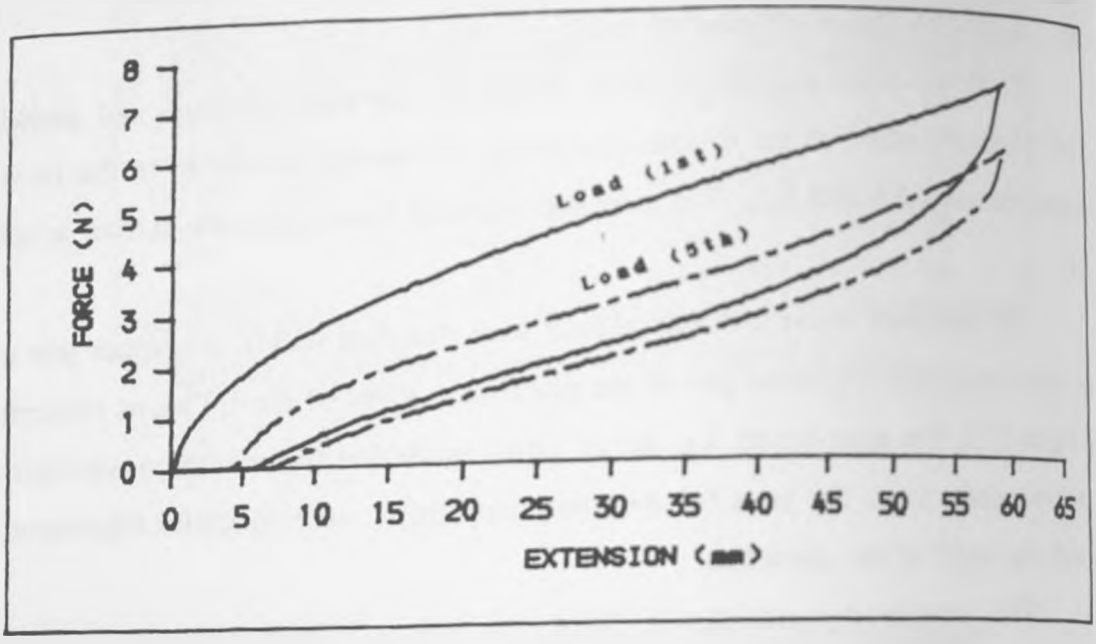


Figure 5.14 Typical force-extension relationship for the first and fifth cycles (Granuflex bandage)

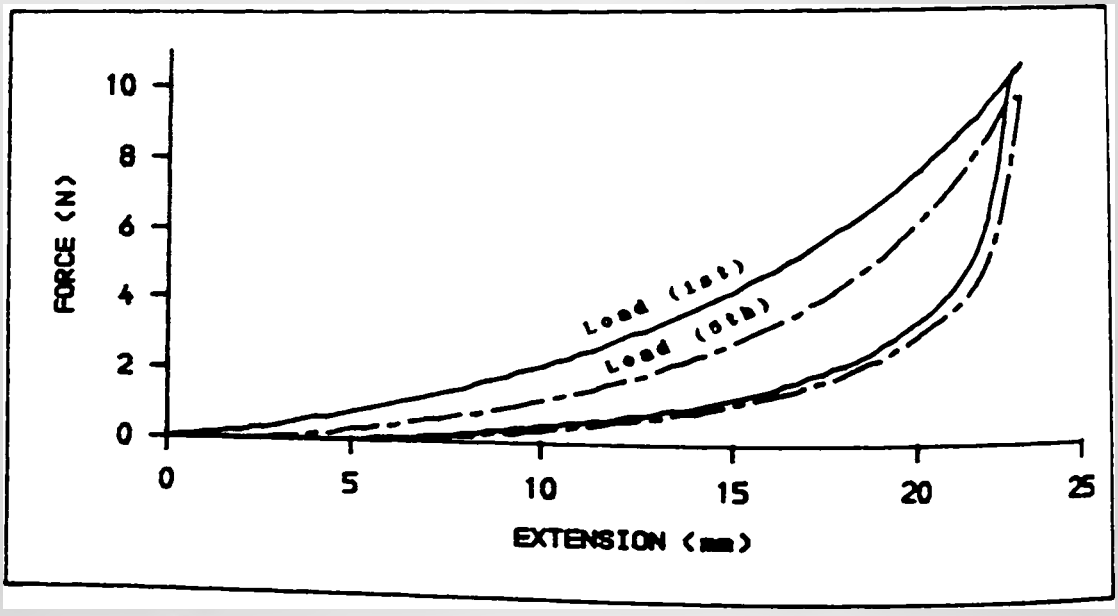


Figure 5.15 Force-extension relationship produced by the Elastocrêpe bandage (first and fifth cycles)

in stress relaxation beyond fifteen minutes was not significant. The entire process was repeated for all the specimens.

5.3.5 Data Processing

The data collected using the BBC micro computer was then transferred to the VAX mainframe VMS system (Version 5.5, Digital Equipment Corporation, UK) via the Kermit program (Version 3.3, University of Lancaster, UK). The mainframe system offered better data handling and graphics facilities.

Initial stress-strain plots revealed that the bandages were effectively inextensible in the secondary direction. The stockings, however, were extensible in both directions. In order to keep the analyses manageable subsequent analysis were carried out only for the primary direction.

For each bandage and stocking, a force-extension graph for the first and fifth cycles of the extension-retraction test was produced (Appendix E). The peak force for each of the five specimens from the first cycle was recorded and compared.

The data from the stress relaxation test is presented as a force-time graph for each compression device (Appendix F). In order to facilitate direct comparisons between the force-time graphs produced for each device, the graphs were normalised with respect to the peak force attained. The percentage drop in tension over the duration of the stress relaxation test was also calculated.

5.3.6 Results

(a) Force-Extension Behaviour

The force-extension graphs revealed that all the bandages and stockings exhibited non-linear load-deformation behaviour. Figure 5.14 illustrates a typical force-extension graph. The graphs were sigmoid shaped with significant hysteresis, limit strain, and residual strain. The majority of the materials showed a decrease in stiffness with increasing extension. The notable exception was Elastocrêpe, which exhibited increasing stiffness with increasing extension as illustrated in figure 5.15.

For all the materials the peak forces generated were highest in the first cycle and progressively decreased with repeated cycling. There was a striking range of peak force produced by each of the five specimens for all the materials. The range of peak

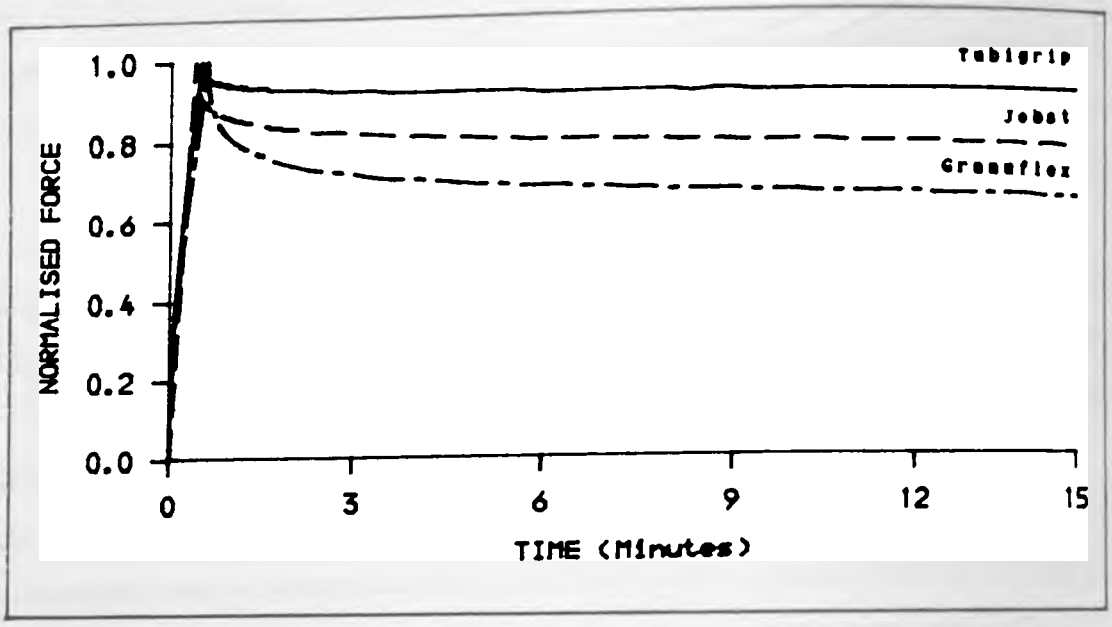


Figure 5.16 Typical stress relaxation curves

BANDAGE	DROP IN LOAD	STOCKING	DROP IN LOAD
SURGICOT	12.6%	HARCOURT	21.9%
ELASTOCRÉPE	29.8%	T.E.D.	28.6%
COBAN WRAP	26.3%	VENOSAN	16.5%
BLUE LINE	9.8%	SIGVARIS	25.7%
ACE	14.2%	JOBST	23.5%
GRANUFLEX	36.0%	TUBIGRIP	9.0%

TABLE 5.23 Percentage drop in load due to stress relaxation (after 15 minutes)

force calculated as a percentage of the mean is shown in table 5.22. The Elastocrêpe bandage exhibited exceptionally inconsistent behaviour and had a large range of 67%. Results from additional tests confirmed this inconsistency.

BANDAGE	MEAN PEAK LOAD	RANGE (% of mean)
SURGICOT	3.6N	(13.0)
ELASTOCRÉPE	11.9N	(67.0)
COBAN WRAP	2.9N	(4.8)
BLUE LINE	6.9N	(9.8)
ACE	2.4N	(9.9)
GRANUFLEX	7.5N	(4.8)
HARCOURT	16.3N	(15.0)
T.E.D.	7.9N	(7.6)
VENOSAN	13.3N	(3.0)
SIGVARIS	9.7N	(11.5)
JOBST	9.2N	(8.2)
TUBIGRIP	3.5N	(13.0)

TABLE 5.22 The range of peak load (1st cycle) as a percentage of mean

(b) Stress-Relaxation Behaviour

All the materials tested showed some stress relaxation at constant extension as illustrated in figure 5.16. The majority of stress relaxation occurred within the first three minutes for all the materials and after fifteen minutes the rate of relaxation was negligible. The percentage drop of the peak load after fifteen minutes is tabulated in table 5.23. The greatest stress relaxation was exhibited by the Granuflex bandage (36%) and the least by Tubigrip (9%).

(c) Comparison Between In Vivo and In Vitro Tests

(i) Cyclic Extension-Retraction Test

For elastic stockings there is no suitable means of directly relating the results of the cyclic extension-retraction test with that of the in vivo test. For the bandages, however, the approach described in the SPDT1 test was adopted to classify the devices thus providing a means of comparison with the in vivo test. Although the SPDT1 test is based on repeated cyclic loading and differs slightly from this test, the approach could still be used for bandage classification.

BANDAGE	CLASSIFICATION	
	IN VIVO	IN VITRO
SURGICOT	3a	3a
ELASTOCRÉPE	2	2
COBAN WRAP	3a	3a
BLUE LINE	3c	3b or 3c
ACE	2	2
GRANUFLEX	3c	3a

TABLE 5.24 A comparison of in vivo and in vitro classification of bandages

BANDAGE/ STOCKING	PRESSURE RELAXATION IN VIVO	PRESSURE RELAXATION IN VITRO
SURGICOT	none	13%
ELASTOCRÉPE	7%	30%
COBAN WRAP	7%	26%
BLUE LINE	6%	10%
ACE	4%	14%
GRANUFLEX	6%	36%
HARCOURT	none	22%
T.E.D.	7%	29%
VENOSAN	2%	16%
SIGVARIS	none	26%
JOBST	none	23%
TUBIGRIP	none	9%

TABLE 5.25 A comparison of in vivo and in vitro relaxation

Detailed calculations following the SPDT1 test procedure are included in Appendix G. The bandage classification calculated following the SPDT1 test procedure and the classification measured in the in vivo test with the bandage applied in the spiral technique, are tabulated in table 5.24.

The results of classification obtained by the in vivo and in vitro methods are in good agreement with the exception of the Granuflex bandage. The in vivo test classified the Granuflex bandage as a "High Performance Compression Bandage" but the in vitro test classified it as a "Light Compression Bandage".

(ii) Stress-Relaxation Test

Ideally it would be useful to compare the stress relaxation produced in the laboratory with the pressure relaxation measured in the in vivo study. At present, such a comparison is not possible because the relationship between pressure beneath a compression device and the tension in the device is still not fully understood. However, the percentage pressure relaxation measured in the in vivo study and the percentage stress relaxation obtained in the in vitro study over the initial fifteen minute duration are illustrated in table 5.25. In vivo relaxation was always less than in vitro relation but, for the reason mentioned above, no firm quantitative conclusion could be drawn.

5.4 A Subjective Assessment of Compression Devices

The effectiveness of a compression bandage or an elastic stocking used in the treatment of venous ulcers is dependent on the acceptance and conformity of the patient wearing it. Further, the choice of a particular device is also affected to some extent by the personal preferences of the carer. Therefore, an assessment of these devices in relation to the patients' and bandagers' personal and social preferences is paramount.

A survey on the subjective aspects relating to compression devices was conducted on ten subjects and the bandager by means of a questionnaire. The questionnaire focused on issues that would supplement the objective studies already carried out.

DEVICE BANDAGE/STOCKING	COLOUR	TYPE	CLASS	MANUFACTURER
SURGICOT	brown	elastic	-	ConvaTec
ELASTOCRÉPE	brown	crépe	2	Smith & Nephew
COBAN WRAP	white	cohesive	-	3M
BLUE LINE	white	elastic	3d	Seton
ACE	brown	elastic	-	Becton Dickinson
GRANUFLEX	brown	adhesive	3b	ConvaTec
HARCOURT	white	open-toe	-	Harcourt Knitting
T.E.D.	white	open-toe	1	Kendal
VENOSAN	brown	open-toe	2	Salzmann
SIGVARIS	brown	open-toe	1	Ganzoni & Cie
JOBST	white	open-toe	1	Jobst
TUBIGRIP	creme	tubular	1	Seton

TABLE 5.26 Devices used in the subjective assessment

BANDAGE	TECH	EASE/ APPLY	FIT BANDAGER	FIT SUBJECT	ACCEPTANCE HOSP	ACCEPTANCE HOME	CONFORM-ABILITY	SLIP
SURGICOT	Spiral	2.7	2.5	2.5	2.3	2.5	2.6	2.4
	Cris-X	2.9	1.9	2.5	2.3	2.4	2.6	2.4
ELASTO-CRÉPE	Spiral	3.0	3.1	3.9	2.7	3.4	4.4	3.2
	Cris-X	3.0	3.1	3.9	2.7	3.2	4.4	3.2
COBAN WRAP	Spiral	3.4	2.2	1.8	2.2	2.3	1.6	1.0
	Cris-X	4.1	2.3	1.8	2.5	2.6	1.6	1.0
BLUE-LINE	Spiral	3.1	3.4	4.0	3.4	3.5	4.6	3.6
	Cris-X	3.0	4.0	4.0	3.8	3.5	4.7	3.6
ACE	Spiral	2.2	2.5	2.8	2.2	2.5	2.3	2.1
	Cris-X	2.2	2.5	2.3	2.2	2.6	2.4	2.1
GRANU-FLEX	Spiral	3.0	2.6	2.0	3.0	3.3	1.0	1.0
	Cris-X	3.0	2.9	2.0	3.2	3.4	1.0	1.0

TABLE 5.27 Mean grades of the subjective bandage assessment (1 for excellent and 5 for poor)

5.4.1 Materials Used in the Study

Six compression bandages and six elastic stockings, described in table 5.26, were used in the survey to provide a subjective analysis of preferences.

5.4.2 Method

A questionnaire was designed to incorporate the opinions of each subject and the bandager on several issues relating to the devices in the study. A specimen of the questionnaire is illustrated in appendix H. The "acceptance" of the device both in the home and hospital environment, the comfort of wearing the device with regards to its "fit", the "conformability" of the device over the leg and the "slippage" during use, were assessed as experienced by each subject. Further, the "ease of application" and the "fit" of each device were also assessed by the bandager. The questionnaire had additional provisions for other individual comments, which were taken into account in the overall assessment. The questionnaire also discriminated the two techniques of application of each bandage, and the new and washed conditions of each elastic stocking.

The ten subjects and bandager who participated in the in vivo study were requested to complete the questionnaire immediately after each compression device was applied and tested. The participants were briefed on the questionnaire which was based on a rating system. The devices were graded on a point system from 1 to 5 for each issue separately. A grading of "1" was given for excellent, 2 for good, 3 for average, 4 for below average and 5 for poor. As the devices were applied on each subject separately, no precaution was necessary to prevent them from conferring with each other. After the twelve devices were graded by all ten subjects and the bandager, the overall data were compiled. Mean values of the grades were produced and analyzed subjectively.

5.4.3 Results

(a) Compression Bandages

The mean grades for the compression bandages relating to each issue in the questionnaire are tabulated in table 5.27.

Ease of application

With the exception of Coban Wrap, the technique of application had no notable influence on the ease of application of the bandages. Coban Wrap was rated easier to apply in the spiral technique than in the criss-cross technique.

The majority of bandages were rated "average" in the ease of application with the exception of the Ace bandage which was rated "good" and Coban Wrap which was rated "below average".

Fit as assessed by bandager

For the Granuflex and Blue Line bandages, the spiral technique of bandaging produced better fit than the criss-cross technique. However, the converse was true for the Surgicot bandage. For all other bandages the technique of application had no notable influence on the fit of the device.

The Coban Wrap bandage had the best fit regardless of the technique of application, while Blue Line used in the criss-cross technique had the worst fit.

Fit as experienced by the subjects

With the exception of the Ace bandage, the technique of application had no influence on the nature of fit experienced by the subjects. The Ace bandage used in the criss-cross technique produced a better fit than in the spiral technique.

The Coban Wrap bandage had the best fit regardless of the technique of application, while Blue Line in both techniques had the worst fit.

Acceptance in the hospital environment

For the majority of bandages, the technique of application did not influence the acceptability of the device. However, Coban Wrap, Blue Line and Granuflex used in the criss-cross technique were less favoured.

The acceptability of the bandages in general was "good" to "average" with the exception of Blue Line used in the criss-cross technique which was rated "below average".

STOCKING	COND.	EASE/ APPLY	FIT BANDAGER	FIT SUBJECT	ACCEPTANCE HOSP	HOME	CONFORM -ABILITY	SLIP
HARCOURT	New	4.0	2.2	3.0	2.2	2.3	2.0	2.0
	Washed	3.0	3.1	3.0	2.4	2.5	2.0	2.0
T.E.D	New	2.0	2.1	2.0	2.4	2.3	2.0	2.0
	Washed	2.0	2.5	2.0	2.5	2.3	2.0	2.0
VENOSAN	New	4.0	3.0	4.0	2.8	3.2	3.0	2.0
	Washed	4.0	3.6	4.0	3.2	3.5	3.0	2.0
SIGVARIS	New	3.0	2.6	3.0	2.8	2.9	3.0	2.0
	Washed	3.0	3.1	3.0	2.7	2.8	3.0	2.0
JOBST	New	2.0	1.9	2.0	2.2	2.4	2.0	2.0
	Washed	2.0	2.3	2.0	2.2	2.4	2.0	2.0
TUBIGRIP	New	2.0	2.7	2.0	2.4	2.9	2.0	3.0
	Washed	2.0	2.8	2.0	2.6	2.9	2.0	3.0

TABLE 5.28 Mean grades of the subjective stocking assessment (1 for excellent and 5 for poor)

Acceptance in the home environment

With the exception of Coban Wrap, there was no notable preference for the technique of application. Coban Wrap used in the criss-cross technique was less favoured.

All the bandages were "averagely" acceptable in the home environment. Blue Line was least acceptable.

Conformability of the bandages

The conformability of the bandages was not influenced by the technique of application.

The Granuflex bandage was rated "excellent" while Coban Wrap was rated "good". The Elastocrêpe and Blue Line bandages were rated "below average" and "poor" respectively.

Slippage of the bandage during use

The technique of application did not influence the slippage of the device. The Coban Wrap and Granuflex bandages were rated "excellent".

(b) Elastic Stockings

The mean grades for the elastic stockings relating to each issue in the questionnaire are tabulated in table 5.28.

Ease of application

Generally, the ease of application was not affected by the new or washed conditions of the stockings.

The T.E.D., Jobst and Tubigrip stockings were rated easier to apply than the Harcourt or Venosan stockings.

Fit as assessed by bandager

The influence of the new or washed conditions of the stockings on the "fit" of all the devices was clearly evident. Consistently, new stockings produced better fit than washed stockings. The fit of the Harcourt stocking was worst affected by

washing. The effect of washing on Tubigrip was minimal.

There were no significant differences in the fit of the devices, all of which were rated between "good" and "average".

Fit as experienced by the subjects

The new or washed conditions of the stockings did not influence the fit of the device as experienced by the subjects. This result was consistent for all the stockings.

The T.E.D., Jobst and Tubigrip stockings were rated "good" in terms of fit whilst the Venosan stocking was only rated "below average".

Acceptance in the hospital environment

With the exception of the Venosan stocking, there was no notable difference in the influence of the new or washed conditions on acceptance. The washed Venosan stocking was rated less acceptable than the new stocking.

All the stockings were rated between "good" and "average" in terms of acceptability.

Acceptance in the home environment

Apart from the Harcourt and Venosan stockings, there was no notable difference in the influence of the new or washed conditions on acceptance. Washed Harcourt and Venosan stockings were rated less acceptable than new stockings.

The acceptability of all the stockings were rated between "good" and "average".

Conformability of the stockings

The new or washed conditions of the stockings did not influence the conformability of the device. The ratings for all the devices were precisely the same for each condition.

The Venosan and Sigvaris stockings were rated "average" while the rest were rated "good" for conformability.

BANDAGE/ STOCKING	FAVOURABLE	UNFAVOURABLE
SURGICOT	Good tension in stretch.	Too short and requires an inner core.
ELASTOCRÊPE		Wrinkles whilst applying, no tension in stretch, too short, no grip when joining.
COBAN WRAP		Wrinkles during application difficult to remove, risk of applying too tightly, feels tight, itchy and uncomfortable, colour not appealing.
BLUE LINE	Central line useful in application, no joints required, does not feel warm.	Bulky to apply, difficult to control tension, packaging too big, feels tight, heavy and uncomfortable, colour not appealing.
ACE	Good tension in stretch.	Too short and requires an inner core.
GRANUFLEX	Good width and length for application.	Bandage rolled on the wrong way, needs tubinet to protect skin from adhesion, too warm, heavy, tight, sticky and itchy, irritates skin and pulls hair during removal.
HARCOURT		Wrinkles at ankle, feels tight especially after wash, label too conspicuous.
T.E.D.		Restrictive at ankle, label too conspicuous.
VENOSAN		Material too stiff particularly after wash, difficult to stretch, too restrictive, wrinkles at ankle.
SIGVARIS	Material has good feel, easy to stretch.	Feels tight.
JOBST	Easy to remove wrinkles.	Restrictive at ankle, label too conspicuous.
TUBIGRIP	Easy to stretch and remove wrinkles.	Clumsy, fraying edges can be cumbersome.

TABLE 5.29 Summary of the additional comments

Slippage of the stocking during use

Slippage was not influenced by the new or washed conditions of the stockings. The ratings for both conditions were identical.

With the exception of Tubigrip, all other stockings were rated "good" in terms of slippage. Tubigrip had an "average" rating.

(c) Additional Comments

Additional comments contributed by the participants which are not already covered in the questionnaire are summarised in the table 5.29.

5.5 Discussion

5.5.1 In Situ Pressure Measurement

Interface pressure measurement is difficult and it is not surprising that Burnand and Layer (1986) have reported a scarcity of in vivo pressure studies on compression devices. However, such measurements are important and useful in the study of compression therapy. The technical difficulties of this measurement are often related to the instrumentation. The presence of any pressure sensor at the interface will inevitably produce some degree of interference. However, this interference can be minimised by choosing a suitable pressure measuring system. In this study a pressure measuring device was custom built to satisfactorily meet the needs of pressure measurement beneath compression devices. Additionally, as pointed out by Barbenel (1983), the success of any interface pressure measurement is also dependent on a sound appreciation of its limitations. Throughout this study the limitations of the measurements were carefully considered.

The tests in this in vivo study were carried out under closely controlled conditions to enable the investigation to focus on several important factors. This imposed some additional constraints which required selective data acquisition and controlled data analysis in order to optimise useful information.

The interface pressure was only measured at three specific sites on the lateral aspect of the leg, at discrete times and over a relatively short duration. The lateral aspect of the leg was preferred because it allowed future studies on venous ulcer patients who frequently have ulcers on the medial aspect. These controlled

measurements provided useful snap shots of the nature of the compression generated. A more comprehensive spatial and temporal investigation of compression would require a large number of sensors at the interface used over prolonged periods. The use of a large number of sensors would severely distort the interface and result in ambiguous measurements. Further, an excessive number of sensors would generate large volumes of data which would be unmanageable and counter productive. Prolonged pressure measurement over the entire duration of treatment would be desirable. This would serve best as a follow up to the initial short term study as it would require more specialised instrumentation and data handling facilities.

The study was limited to two postures and based on young, healthy subjects whose supple skin and non oedematous legs do not typify those of venous ulcer suffers. This facilitated the measurement of interface pressures by avoiding the more subtle difficulties such as the effect of pressure sensors on the already fragile skin of venous ulcer patients. As a result of this simplification the influence of the activities of daily living were not investigated. Consequently, the influence of ambulation, muscular activity, or body perspiration on the pressures beneath bandages and stockings were not included in the measurement. Although the intention of this study was only to provide an initial understanding of compression beneath the devices, these limitations must be appreciated. Like most other tests involving the measurement of biomechanical properties, these tests yield large volumes of highly complex data with multiple interacting factors. Specific controls on selected parameters at each stage of the analysis were necessary to simplify the process. The data which were obtained experimentally were not normally distributed and in some instances, for specific comparison tests, the sample size was small. This difficulty was resolved by the use of non parametric statistical techniques.

Despite the limitations of interface pressure measurement and the controlled nature of the study, valuable information on the compression generated by bandages and elastic stockings was obtained.

5.5.2 The In Vivo Assessment of Compression Bandages

Several important aspects of compression therapy were investigated in this study: the magnitude of compression at the ankle; the graduation of pressure over the

leg; the influence of the technique of application; the maintenance of pressure over the duration of the test; the effect of standing and sitting; and the inter subject variability.

The expected magnitude of compression at the ankle produced by the bandages was frequently not achieved or a classification was not assigned (Table 5.5). As the medical provider relies on the assigned classification of the device to ensure that the magnitude of compression appropriate for a specific treatment is produced, any discrepancy is potentially dangerous. It is difficult to isolate a single contributory factor to this anomaly as the generation of pressure beneath bandages is complex. The failure of the bandages to produce the appropriate magnitude of compression could be due to an intrinsic design fault of the devices or a result of the lack of specific familiarity required for the application of each device as suggested by Stemmer (1982). Similar unsatisfactory performance of bandages available in the United Kingdom has also been reported by Tennant et al. (1988).

Only the Blue Line bandage used in the criss-cross technique produced the pressure gradient required to enhance venous flow. Blue Line used in the spiral technique and all other bandages used in either technique failed in this aspect (Table 5.6). Some bandages even produced inverse gradients. This is an alarming situation as the use of these bandages on leg ulcer patients is potentially dangerous. It creates a tourniquet effect, restricting the already poor venous return.

It is outwith the scope of this study to isolate the precise reasons for the failure of these bandages in producing appropriate pressure gradients. As in the case of failing to produce the appropriate magnitude of compression, it is possible that the fault is inherent to the bandages themselves. On the other hand, if the effectiveness of a bandage is dependant on the skills of the operator as suggested by Callam et al. (1987) then it appears that the skills of the qualified physiotherapist are inadequate. This raises other issues such as the adequacy of training programmes available for the medical providers. Alternatively, future bandage designs should be tailored to be less user dependent if bandages are to be widely used.

The two techniques of application produced markedly different compressions (Table 5.7). The criss-cross technique of application, consistently, produced higher compression than the spiral technique, often more than double. More bandage

material was used for application in the criss-cross technique and the greater material bulk could explain the higher compression. Hansson and Swanbeck (1988) have previously shown the direct relationship between material bulk and compression. This is further substantiated by the fact that the bulkier Blue Line bandage consistently produced higher compression. Additionally, the application of stretch in diagonally opposing directions may also contribute to reinforcing each turn of the bandage. In contrast, the spiral technique only relies on a simple fifty percent overlap.

An important revelation of this study is that the magnitude of compression produced by each bandage was also dependent on the technique of application (Table 5.5). The classification of bandages assigned in accordance with the SPDT1 test does not discriminate between techniques when quoting the magnitude of compression at the ankle. As a result Elastrocrepe bandage when used in the spiral technique produced a magnitude of compression at the ankle in accordance with its assigned classification but when the criss-cross technique was used it failed. If future classification of bandages were to be precise then it should also specify the technique of application.

The influence of the bandaging technique on generating the desired pressure gradient was difficult to assess because of the overwhelming failure of the bandages in this respect (Table 5.6). Although the Blue Line bandage when applied in the criss-cross technique did produce a suitable pressure gradient. It would be of interest in the future to determine if a specific technique of bandaging is more likely to generate the appropriate pressure gradient.

For a bandage to function effectively it must sustain continuous compression adequately throughout the course of the treatment. Normally the duration of compression therapy can vary from a day to a week depending on the state of the venous ulcer. This aspect of treatment could not be investigated in this study because of the limited duration of the tests. However, it was possible to examine the nature of pressure variation within the sixty minutes whilst appreciating that the limited data cannot be extrapolated.

At the end of the sixty minute test all the bandages exhibited a drop in pressure at all sites of measurement. This could be due to stress relaxation of the bandage material, the time dependence of the underlying soft tissue and/or the

relaxation of the application itself as a result of body movement. Raj et al. (1980) have previously recorded a similar drop in compression generated by bandages over a four hour period. Some bandages when applied in the spiral technique, however, exhibited an initial rise in pressure over the first thirty minutes which eventually fell at the end of the test. Presumably this was a result of variations in muscle tone as the subjects settled with the bandage in place.

When the drop in compression was compared at the end of the test, the spiral technique of bandaging sustained compression better than the criss-cross technique. It could be argued that the spiral technique had initially produced a rise in compression for the first thirty minutes and therefore the net fall in compression was less. A further comparison of percentage drop in compression between 30 minutes and 60 minutes for both techniques of bandaging revealed no significant difference. This not only supports the previous argument but also indicates that no firm conclusion can be drawn based on a sixty minute test. A more complete understanding of the sustainment of pressure can only be achieved by long term pressure monitoring.

The Elastocrêpe bandage applied in either technique was least able to sustain compression. This result is a useful bench mark as it is consistent with the expectations of a light support, class two bandage.

Variability in the compression produced by bandages even when a single operator is used has always been a concern as pointed out by Raj et al. (1980). All the bandages in this study exhibited some degree of variation between the ten subjects as illustrated in table 5.10. It was interesting to note that the criss-cross technique of bandaging produced less inter-subject variation than the spiral technique. Blue Line the bulkiest bandage produced least inter-subject variation while Elastocrêpe the lightest bandage produced most. Further, the criss-cross technique also produced greater material bulk. Perhaps there may be an inverse relationship between bandage material bulk and variability in compression generated.

Another important finding of this study was that changes in posture significantly altered the pressures beneath bandages. The pressures generated by all the bandages, at all the sites of measurement, were greater in the standing posture than in the sitting posture (Table 5.9). Presumably this change in interface pressure

is related to the contracture and activity of the different muscle groups in the leg. It is of immediate concern to examine the influence of posture on the performance of bandages if the therapeutic value of these devices used on ambulant patients are to be relied upon. This would necessitate the simultaneous monitoring of pressure beneath bandages and posture during normal ambulation. The additional information obtained would be vital in characterising the performance of bandages as they are normally used.

5.5.3 The In Vivo Assessment of Elastic Stockings

The features investigated in this study were similar to that in the bandage study. The influence of the technique of application was not relevant and was omitted. Instead, the influence of repeated laundering of the stockings was assessed.

The magnitude of compression at the ankle produced by the Venosan stocking was within the limits of its assigned classification, in accordance with BS6612 (Figure 5.8). In this respect, all other stockings failed to produce the appropriate magnitude of compression. Fortunately, the failure was due to inadequate compression at the ankle thus causing no harm to the patient although rendering the treatment ineffective. Cornwall et al. (1987) have previously reported unsatisfactory performance of many elastic stockings but found the performance of the Venosan (2002) stocking satisfactory. Interestingly, their measurement of compression at the ankle produced by the Venosan stocking was identical to that obtained in this study. Medical providers rely on the classification of elastic stockings to ensure that the appropriate compression is delivered. Cornwall et al. (1987) were justified in suggesting that the classification of elastic stockings should not be only based on the HATRA test but should also incorporate in vivo tests to ensure clinical performance.

With the exception of Venosan, all the stockings failed to produce a suitable pressure gradient that would encourage venous return, as illustrated in figure 5.9. Even the pressure gradient generated by the Venosan stocking was very marginal and not statistically significant (Table 5.15). Alarmingly, the stockings consistently produced inverse pressure gradients. These unsatisfactory findings are similar to that reported by Cornwall et al. (1987). The implications of these findings are grave to the leg ulcer sufferer who is undergoing compression therapy. The absence of a

suitable pressure gradient can further aggravate their already poor venous return and hinder the ulcer healing process.

It is outwith the scope of this study to isolate the precise reasons for the failure of these stockings in producing appropriate pressure gradients. Unlike compression bandages, elastic stockings are user independent therefore the skills of the operator are not in question. However, these stockings are not custom made and the best fitting standard devices are selected for application. Small anatomical differences can therefore contribute to large irregularities in pressure. Further, elastic stockings have never been aggressively tested for their functional performance during ambulation or for their effectiveness when applied over tissues of different texture and density such as underlying bone or adipose. This, coupled with the inability of these devices to produce the appropriate pressure gradient, casts doubts on the routine prescription and use of elastic stockings.

The laundering of elastic stockings has always been a commendable practice, at least for economical reasons. Most manufacturers recommend laundering and often provide detailed guidelines. This investigation revealed that laundering had no significant effect on the magnitude of pressures produced by the stockings (Table 5.16). However, in retrospect, the approach taken in this aspect of the investigation had a limitation. The stockings were merely washed and dried thirty times. It would have been more realistic to simulate the repeated use of stockings by cyclically stretching and relaxing the devices in a machine prior to each laundering. Perhaps the effect of sweat could have also been simulated. In the knowledge of this limitation, the influence of laundering on the magnitude of pressures produced by stockings still remains unanswered.

Elastic stockings, like compression bandages, must sustain adequate compression for the duration of use for the treatment to be effective. The investigation in this study on elastic stockings is limited by the short duration of the tests. However, it is possible to examine the variation of pressure within the sixty minute period.

At the end of the test, the pressures measured beneath elastic stockings were varied, with some pressures greater than the initial value whilst others had dropped. These variations were relatively small with the exception of the pressures produced

by the Tubigrip stocking (Table 5.17). It would require long term monitoring of pressure to confirm if these variations were merely local fluctuations or part of a long term trend. A comparison between the pressure at 30 minutes and 60 minutes indicated that there was no significant difference when new stockings were used, suggesting that the pressures were sustained over the period. However, the washed stockings did produce a drop in compression over this period (Table 5.17). The information available from this study is insufficient to confirm if laundering affects the ability of elastic stockings to sustain compression.

The variation in pressure produced between the ten subjects for each stocking was also examined. All the stockings exhibited inter subject variability at every site of measurement as illustrated in table 5.19. It is possible that small discrepancies in the fit of standard sized stockings could have contributed to the variability. Alternatively, as the degree of variability was comparable to that of bandages, it is also possible that subtle anatomical variation in the leg of each individual subject may have contributed to the inter subject variability.

Washed stockings produced greater inter subject variability than new stockings. As the same subject, stocking and operator were used throughout the study, the issue of the effect of laundering on stockings surfaces again. In practice, Dale (1990) recommend regular washing of elastic stockings to help restore its shape. Perhaps the laundering and the restoring of the shape does influence the fabric of the stocking material, giving rise to greater inter subject variability. It is out with the scope of this study to examine this issue in detail.

This study also revealed that changes in posture significantly altered the pressures beneath elastic stockings similar to that found in the in vivo bandage study. The pressures generated by all the stockings were greater in the standing posture than in the sitting posture, at all the sites of measurement for both new and washed stockings (Table 5.18). The proposed underlying reasons and recommendations for further investigation on this finding are similar to that discussed for bandages.

5.5.4 The In Vitro Assessment of Compression Devices

Specimens of the bandages and elastic stockings were investigated in the laboratory. The results of the force extension tests showed non-linear and non-elastic

load deformation behaviour by all the materials. This type of load deformation behaviour is more akin to biological materials. Such a behaviour implies that an increase in the stretch of the material will not necessarily produce a proportionate increase in compression. Therefore, the manufacturer's recommendations on the stretch required for a specific magnitude of compression should be based on a sound understanding of the material's stress-strain properties. More importantly, the user should be aware that a small additional stretch of the material can cause a disproportionate increase in compression. In stockings small variations in the shape, size and fit, which ultimately determine the in situ stretch, can produce significant variations in the magnitude of compression.

With the exception of the Elastocrêpe all the materials showed a decrease in stiffness with an increase in extension. Further, the load deformation behaviour of the Elastocrêpe bandage was not readily reproducible. It is possible that the bandage material has limited elasticity and the elastomeric fibres reach their elastic limit at very low extensions. This would account for its ambiguous load deformation behaviour and if so the bandage should not be used for generating compression. This is supported by Thomas (1990) who described the bandage as a class two device suitable for support but not for generating pressure.

All the bandage and stocking materials exhibited non-elastic response with significant hysteresis, limit strain and residual strain. Repeated extension-retraction cycles produced a progressively altered load extension response with reduced peak loads. If these results were translated to compression generated during use, then each time a bandage or a stocking is reused, or excessively stretched prior to use, it would not only lose some of its ability to produce compression but would do so disproportionately. The load deformation behaviour of these materials with the large hysteresis and residual strain implies that they are inefficient in storing energy. Therefore, as the materials lose some stretch during use, the drop in compression would be more severe as suggested by the retraction curves. This is not favourable for the sustainment of long term compression or during ambulation when loosening due to slippage is likely to occur. Interestingly, for all the materials tested, the hysteresis and residual strain in the extension-retraction cycle progressively reduced. Perhaps pre-conditioning the materials would be advantageous.

The materials also exhibited variation within the five samples used. The percentage variation of the mean peak load was calculated to serve as an index of variability as shown in table 5.22. With the exception of the Elastocrêpe bandage which was highly variable, the other materials had peak loads ranging from 3% to 15% of the mean. Since the smallest range in the magnitude of compression allowed within the classifications of bandages and stockings is 20%, these variations based on peak load are therefore acceptable. The smallest range within the classification is for class 1 stockings and class 3a bandages which is between 14 to 17 mmHg.

For the elastic stockings it was not possible to link the in vivo tests with the in vitro tests. The HATRA test which is normally used for evaluating stockings differs notably with the in vitro test carried out in this investigation. However, for bandages the SPDT1 test procedure was used to calculate the classification based on the in vitro tests results which were then compared to that obtained in the in vivo tests. The two classifications were in good agreement with the exception of the Granuflex bandage. According to the in vivo test the Granuflex bandage used in the spiral technique was categorised class 3c and when used in the criss-cross technique it was class 3d. However, according to the in vitro test classification the bandage was in class 3a. To further complicate matters, Thomas (1990) has classified the Granuflex bandage as 3b. The incompatibility of the in vivo and in vitro results may be a result of the adhesive property of the bandage. This property while enhancing the in situ performance of the bandage is not accounted for in the in vitro tests. The need to specify the technique of application is again highlighted.

The laboratory tests also showed that all the materials exhibited stress relaxation at constant extension to varying degrees. The level of stress relaxation produced by some materials was high and may call for concern. It would be useful to translate the impact of the stress relaxation obtained in the laboratory to in situ pressure measurement beneath the devices. Laplace's equation has been used in the past to provide a relationship between in situ pressure and the tension in the device, although the use of this equation within compression therapy remains dubious. Hasson and Swanbeck (1988), and Thomas (1990) have produced modified versions of this equation which are very dissimilar. A reluctant application of these modified equations to convert the tension in the device (Stress on unit area) to pressure

produced ambiguous results. If Laplace's equation were applicable then in its simplest form pressure must be directly related to tension, given that all other variables such as leg circumference, bandage width and number of layers remain unaltered.

$$P = k \times T$$

(where P is pressure, k is a constant and T is tension)

This implies that there ought to be a simple proportional relationship between in vivo pressure relaxation and in vitro stress relaxation. The data in table 5.25 fail to show any relationship between the two parameters. Presumably, the control variables changed during the course of the measurement which is probable when dealing with soft tissues. Alternatively, Laplace's equation is not directly applicable or there is no relationship between in vivo pressure relaxation and in vitro stress relaxation. Unfortunately, these questions cannot be answered in this study and would require a more detailed investigation.

5.5.5 The subjective Assessment of Compression Devices

The opinions gathered from the physiotherapist and the volunteer subjects in the subjective assessment yield useful information based on their experience of applying and wearing the devices.

The subjects were primarily concerned with comfort and cosmetic appearance, and had no firm preference for either technique of bandage application. Although there were occasional marginal preferences expressed, these were more related to a specific property of the bandage itself. The Coban Wrap and Blue Line applied in the criss-cross technique were less acceptable in both the hospital and home environment. These bandages had unfavourable comments such as itchy, uncomfortable, heavy and tight, which were aggravated by the higher pressures of the criss-cross technique and hence were less preferred.

The bandager, however, expressed a preference for the spiral technique when applying certain bandages. The Coban Wrap bandage was found to be more difficult to apply in the criss-cross technique. This cohesive bandage wrinkled easily during application which was more difficult to remove in the criss-cross technique. Also in

this technique more care was required as it was easy to apply this bandage tightly. The bandager also felt that the Granuflex and Blue Line bandages produced a better fit when applied in the spiral technique. These were the only two bandages that were ten centimetres wide. Perhaps, the broader bandages are better suited for application in the simple spiral technique rather than the more elaborate criss-cross technique, especially around the ankle.

The Coban Wrap and Granuflex were rated as the best fitting and most conformable bandages respectively, by both the bandager and subjects. Presumably, the cohesive property of Coban Wrap and the adhesive property of Granuflex enhanced the ability of each layer of the bandage to remain securely in place thus producing a good fit and ensuring conformability. This argument is further supported by the fact that both these bandages were rated excellent for not slipping.

The Blue Line and Elastocrêpe bandages were considered least conformable and also the Blue Line bandage had the poorest fit. The crepe material in the Elastocrêpe bandage has poor conformability and therefore it is not surprising that the bandage was rated poorly in this respect. The typical comments about the Blue Line bandage were bulky, heavy and difficult to control tension during application. These comments suggest good reasons for the poor fit and conformability of the bandage.

Some useful general comments were also gathered from the study. The brown colour was preferred to white for bandages presumably because it was less conspicuous. The central line in the Blue Line bandage was a useful guide during application. The cohesive and adhesive bandages caused itching of the skin. In addition, the adhesive bandage pulled hairs during removal. It was suggested that a tubinet protection would help solve this problem. The inner core in the roll of a bandage makes application easier. Many bandages were too short and required joining which was not only cumbersome but also raised concern about the level of compression at that point.

The results from the subjective assessment of stockings were equally informative. Generally, the subjects were not influenced by the new or washed conditions of the elastic stockings. However, the washed Harcourt and Venosan stockings were marginally less popular. The overall opinion was that washing did not alter the cosmetic appearance of the devices and therefore no particular preference

was indicated. In the case of the Harcourt and Venosan stockings, comments such as too tight and too stiff especially after washing, suggested that the lack of preference was a result of reduced comfort. The physiotherapist on the other hand consistently felt the washed stockings produced a poorer fit. Dale (1990) suggested that washing the stockings restored its shape and the subjects in this study felt that washing made some stockings stiffer and tighter. Perhaps there is a subtle link between these reactions to washing and the poorer fit assessed by the physiotherapist.

The assessments of the elastic stockings in most of the aspects considered were very neutral. With the exception of the Venosan stocking the ratings were generally between good and average. The Venosan stocking was unpopular with both the physiotherapist and subjects. It was considered the most difficult to apply by the physiotherapist and produced the worst fit as assessed by the subjects. It was interesting to note that the Venosan stocking was the only class two stocking in the study, all the other stockings were class one and the Harcourt stocking was not classified. Perhaps the Venosan stocking which is designed for higher compression did stand out in contrast with the other lighter stockings. For this reason it may have been relatively less comfortable and more difficult to apply.

The subjective assessment carried out in this study was by no means comprehensive. Slippage for example was not fully examined because the subjects were not ambulant during the tests. The selection of compression devices assessed was also limited when compared with the wide range available in the market. However, the subjective assessment was only intended to provide a general overview and was successful in raising many important issues.

The overall evaluation of bandages and elastic stockings described in this chapter was a necessary preliminary phase in the study of compression devices. It served as the basis for identifying the significance and importance of the numerous factors that influenced the generation of compression by these devices. The evaluation also provided the means by which the complex interaction between these influencing factors could be collectively examined. The results of this overall evaluation have provided an improved appreciation of the highly complex nature of pressure beneath compression devices. Further, it has been useful in assessing the functional properties and therefore the therapeutic value of these devices. Perhaps more importantly, the

results of this evaluation have dictated the course of future investigations. The need for long term monitoring of pressures beneath compression devices, including the postural changes incurred during activities of daily living, has been repeatedly highlighted throughout the analysis. The design and development of a long term ambulatory pressure and posture monitoring system would be an invaluable sequel to this evaluation and are described in the following chapter.

CHAPTER 6

DESIGN AND DEVELOPMENT OF AN AMBULATORY PRESSURE AND POSTURE MONITORING SYSTEM

6.1 The Early Ambulatory Device (Version-1)

6.1.1 The Pressure Measuring Device

6.1.2 The Goniometer

6.1.3 The Data Logger

6.1.4 The Assembly and Operation

6.2 The Revised Ambulatory Device (Version-2)

6.1.1 The Pressure Measuring Device

6.1.2 The Activity Sensor

6.1.3 The Data Logger

6.1.4 The Assembly and Operation

6.3 Discussion

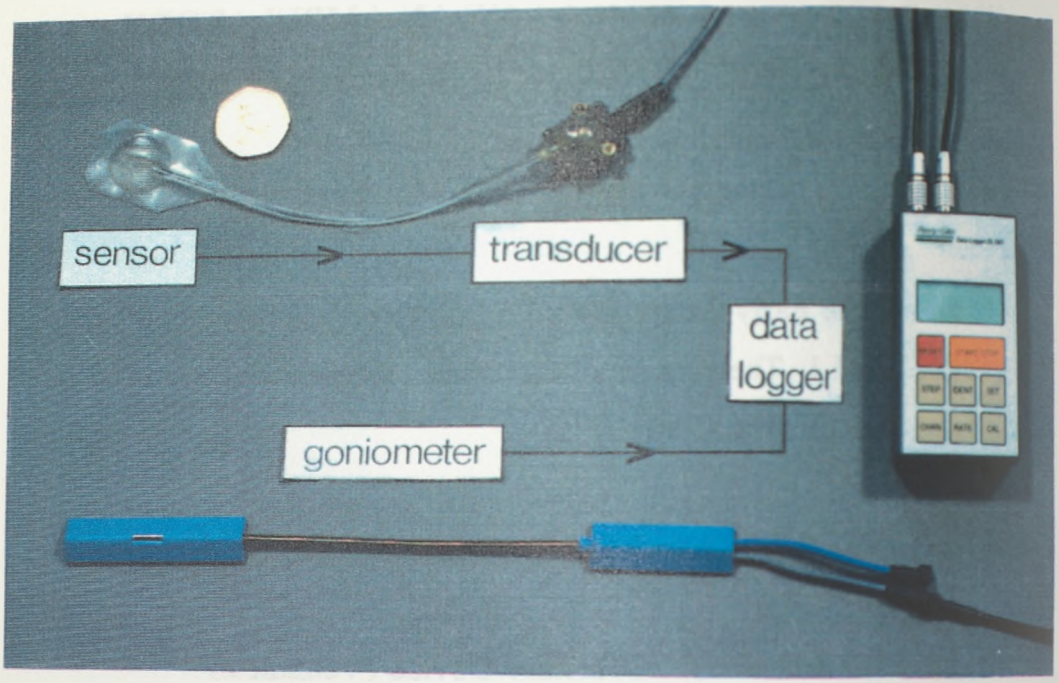


Figure 6.1 The Ambulatory device (version-1)

6 DESIGN AND DEVELOPMENT OF AN AMBULATORY PRESSURE AND POSTURE MONITORING SYSTEM

Compression therapy in conjunction with postural changes during ambulation is known to be beneficial in the treatment of venous ulcers (van der Molen et al., 1979). Higher healing rates of venous ulcers in patients who received both ambulatory and compression therapy have been reported (Hordegen, 1989). The association between the incidence of venous ulcers and loss of mobility is also well documented (Gaylarde et al., 1990).

Despite the keen interest in the effect of compression therapy and ambulation on ulcer healing, no previous attempts have been made to monitor the influence of these parameters. Progress in ambulatory monitoring of interface pressure and posture has been restricted by the lack of suitable instrumentation. A suitable device, not only had to incorporate two traditionally difficult areas of measurement but also had to be compact and portable.

A realistic prospect of developing an ambulatory monitoring system emerged with the advent of the miniaturised, portable, data logger unit. With the successful development of the miniaturised pressure transducers described in Chapter four, with coupled the commercially available goniometer it was possible to uniquely measure ambulatory interface pressure and posture.

A novel ambulatory monitoring device, consisting of these three essential components, was designed and developed. As the device was developed in progressive stages, two distinct versions were produced and are described separately in this chapter.

6.1 The Early Ambulatory Device (Version-1)

This prototype version of the ambulatory pressure and posture monitoring device was developed in order to investigate sub-bandage pressures and the influence of posture on volunteer subjects. The system consisted of a pressure measuring device, a strain-gauged goniometer and a portable data logger as illustrated in figure 6.1.

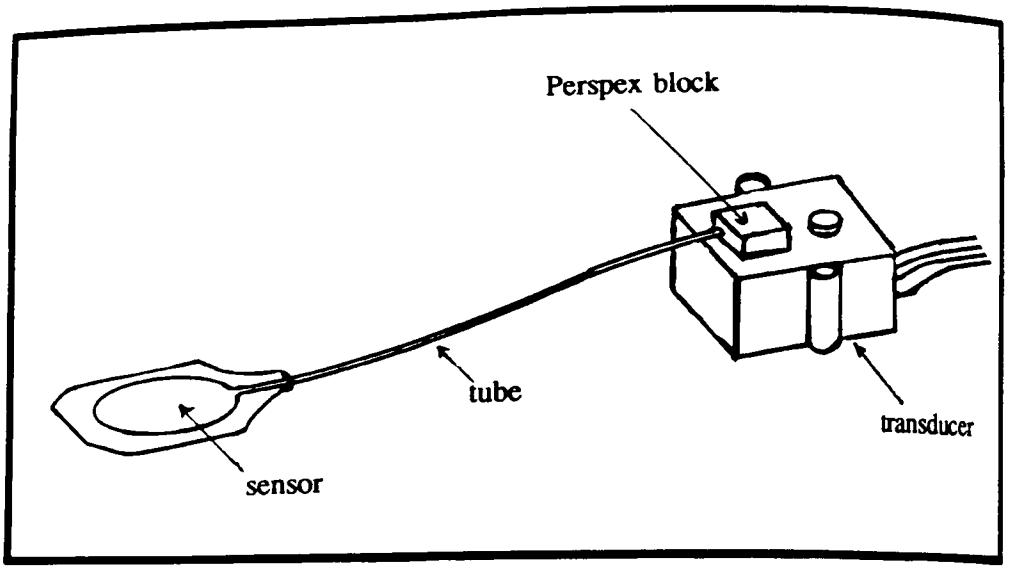


Figure 6.2 The device streamlined

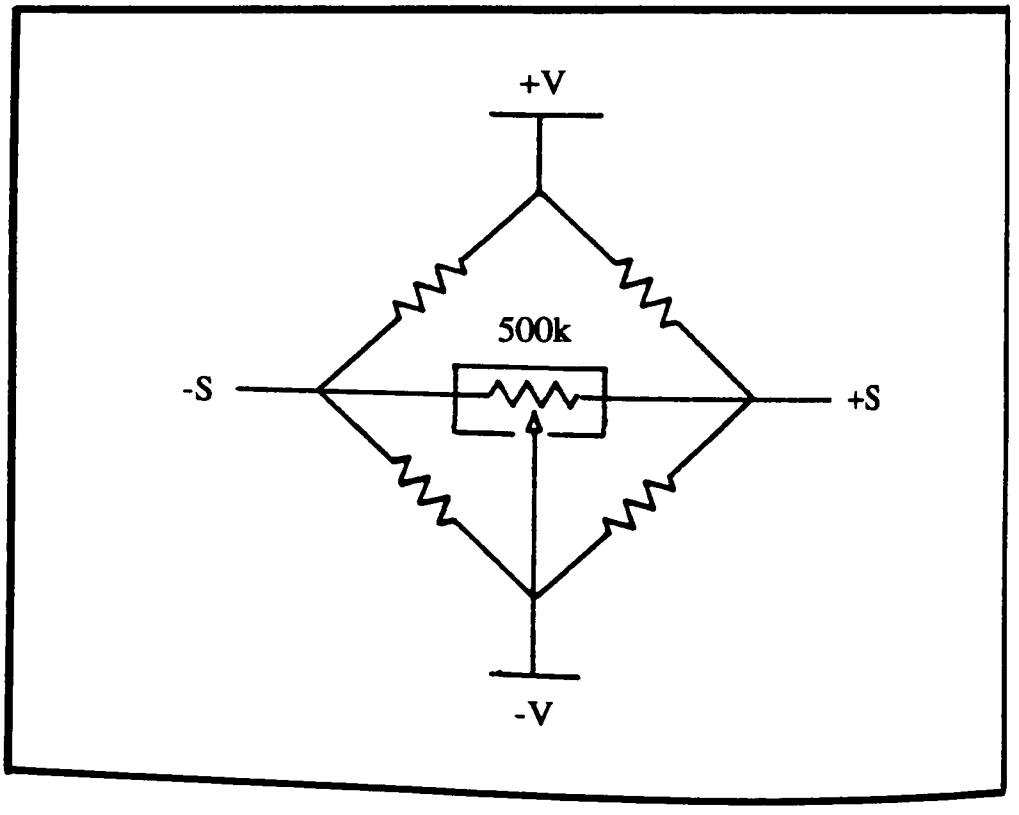


Figure 6.3 The additional resistive trim-pot

6.1.1 The Pressure Measuring Device

The pressure measuring device described in Chapter four was adapted to be more compact and compatible with the data logger unit thus rendering it portable and conducive for use during ambulation. The protruding nozzles of the piezo-resistive pressure transducer were removed and at port B, it was replaced with a small Perspex block. This block had a hair-line channel machined within it to redirect the outlet horizontally in order to streamline the transducer, the connecting tube and the sensor as shown in figure 6.2. Also built into this block was a "bleeder vent" which facilitated the draining of excess oil during construction of the pressure measuring device. A circular lip was machined at one end of the channel within the tiny Perspex block (8 x 8 x 6mm) which fitted snugly into the remaining stem of the nozzle and was glued with cyano-acrylate adhesive. A 1cm metal tube was partially screwed into the other end of the channel and provided the attachment for the connecting tube. The transducer, connecting tube and sensor were otherwise assembled and calibrated as described in Chapter four.

The electronic circuitry of the transducer required an additional resistive trim-pot to shift its output to match the scale of the data logger input. Figure 6.3 illustrates this addition in a circuit diagram. The transducer was linked to the data logger via a length of co-axial cable which was better suited to withstand the continuous rocking during ambulation. The battery in the data logger provided the power supply to operate the pressure transducer.

In order to minimise the vertical displacement of the transducer relative to the sensor, the transducer was fixed onto a T-shaped plastic holder which was strapped just below the knee. The plastic holder was moulded to fit the shape of each individual subject's leg and served to hold the transducer at the same vertical level as the sensor. The length of the connecting tube was specifically tailored to link the transducer and sensor in a tidy fashion.

6.1.2 The Goniometer

A flexible strain-gauged goniometer (Model M180, Penny and Giles, U.K.) normally used to measure joint angles was taped alongside the knee joint to indicate posture. This device, reviewed in Chapter three, was selected to monitor posture

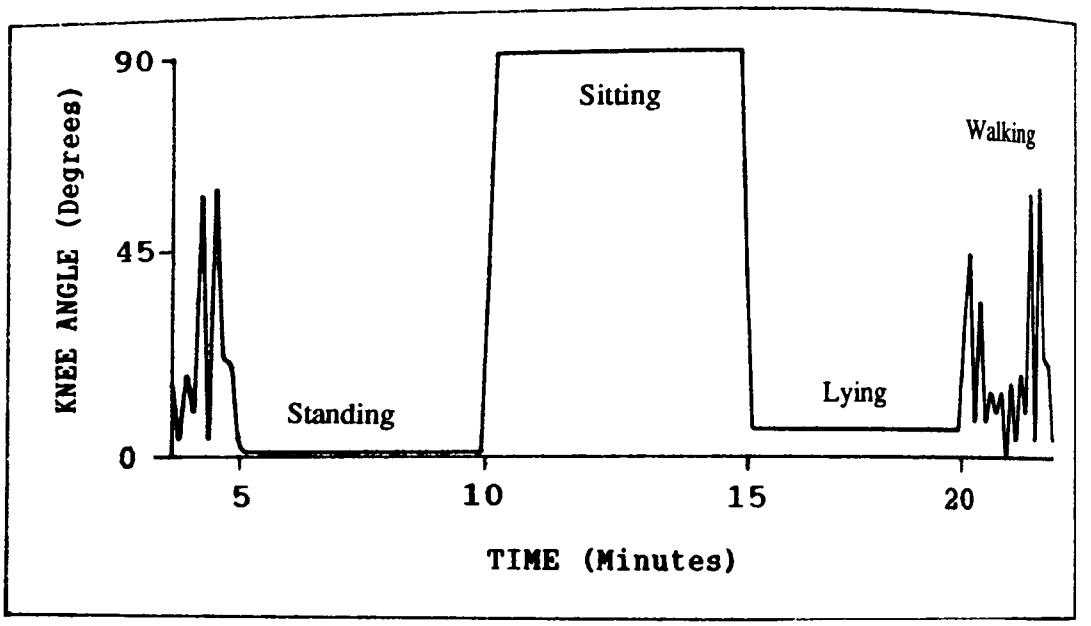


Figure 6.4 The strain-gauged goniometer output

because it was lightweight, portable and did not require alignment with the axis of rotation about the knee. Further, it was readily compatible with the data logger which powered the device.

The end blocks of the goniometer were padded with a layer of soft foam, prior to use, in order to prevent them from impinging on the skin during prolonged use. As in the case of the transducer, the goniometer was connected to the data logger via a length of co-axial cable. A typical output from the goniometer identifying posture is illustrated in figure 6.4

6.1.3 The Data Logger

Over the last decade, the use of data loggers for acquiring and storing information during prolonged use has increased dramatically. As a result there are numerous devices which are commercially available with a variety of operational features.

The DL 1001 (Penny and Giles, U.K.) was selected for its compact size (100 x 60 x 25mm) and light weight (0.2kg) which made it conveniently portable and conducive for long term ambulatory monitoring. Further, its technical specifications were sufficiently suitable for the needs of the ambulatory monitoring of pressure and posture. It had four input channels, a choice of sampling frequencies from 0.3 to 1000Hz, a memory capacity of 65kbytes, 8-bit resolution and required a standard PP3 battery.

This data logger was fully compatible with the goniometer and only required minimal electronic circuitry adaptation of the pressure transducer. Its casing though robust required an additional Perspex cover to protect its "soft touch" control buttons which could be easily disturbed during ambulation. It also had the secure Lemo plugs (Lemo Ltd, U.K.) as connecting pins which were an asset in long term use and particularly so when the subjects were asleep.

The information stored in the data logger could be easily unloaded onto any IBM compatible computer using the soft ware "Sivlog.pas" for further analysis.

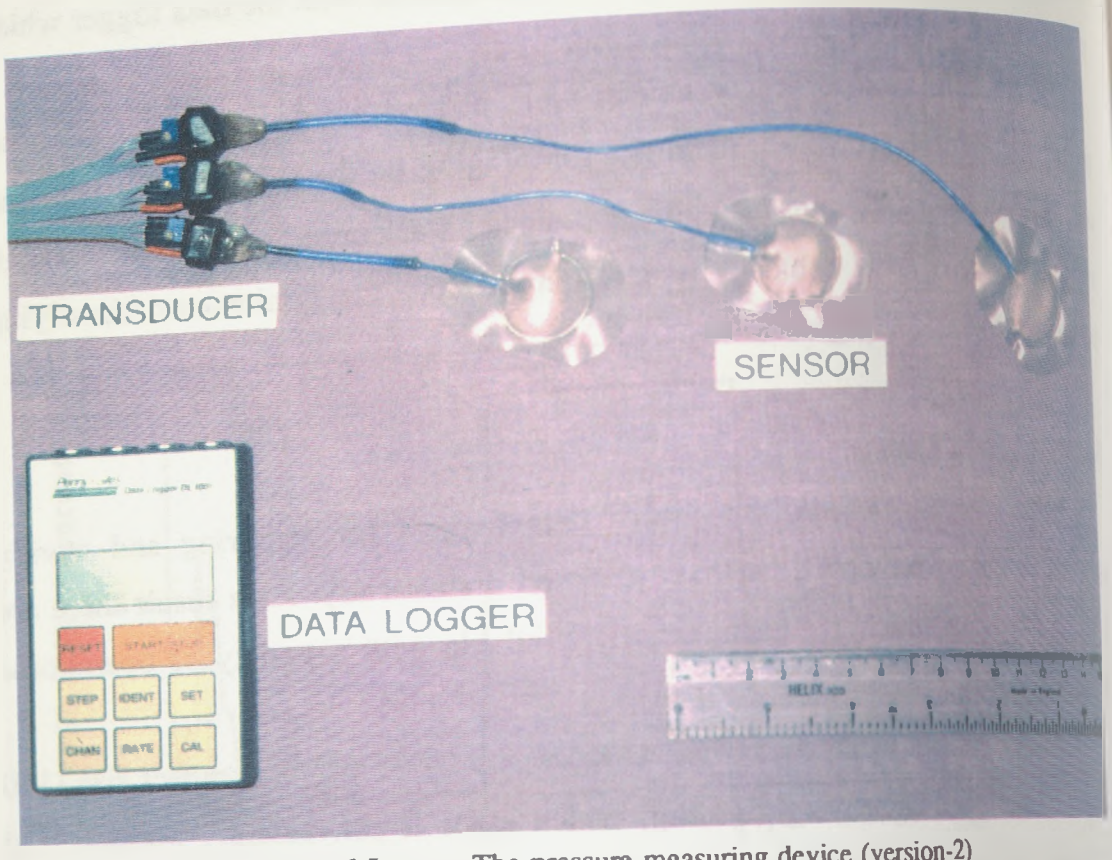


Figure 6.5 The pressure measuring device (version-2)

OPERATIONAL CHARACTERISTICS	SCX TRANSDUCER	16 PC TRANSDUCER
Operating range	103 kPa	103 kPa
Sensitivity	42 mV / kPa	46 mV / kPa
Linearity	0.1% FSO	0.5% FSO
Hysteresis	0.1% FSO	0.15% FSO
Repeatability	0.2% FSO	0.15% FSO
Temperature	0.2% FSO	1.5% FSO
Long term stability	0.1% FSO	1.5% FSO
Frequency response	100 micro sec	1 micro sec

TABLE 6.1 The transducer operational characteristics

6.1.4 The Assembly and Operation

The three components of the ambulatory device were assembled specifically for an individual volunteer participating in the long term investigation of sub-bandage pressure and posture. Although the tests were intended for a duration of seven days, the memory and battery capacities of the data logger only permitted continuous operation for a maximum of twenty four hours. This constraint was resolved by down loading the data logger on a daily basis, throughout the duration of use.

Details of the subject preparation, use of the instrumentation and the subsequent processing of data are described in Chapter seven.

6.2 The Revised Ambulatory Device (Version-2)

The prototype (version-1) ambulatory pressure and posture monitoring device was an important cornerstone in the development of the revised ambulatory device. With use it became clear that further modifications of the pressure measuring device and an alternative means of monitoring posture were necessary. A revised ambulatory device (Version-2) was designed incorporating these modifications. This version was further miniaturised, unobtrusive and durable for continuous use on leg ulcer patients. It comprised the three essential components but the goniometer was replaced with the activity sensor.

6.2.1 The Pressure Measuring Device

The pressure transducer used in the ambulatory device (Version-1) was replaced with the considerably smaller 16PC transducer (Honeywell, U.K.) as illustrated in figure 6.5. This differential transducer was also based on the piezo-resistive silicon technology. Its sensing element was an integral silicon diaphragm with four ion implanted resistors similar to that of the SCX05DN transducer. The operational characteristics of the 16PC transducer were comparable to that of the SCX transducer as illustrated in table 6.1.

The protruding nozzles of the transducer were removed and port-B was replaced with a small Perspex block which redirected the outlet horizontally to streamline the transducer, the connecting tube and the sensor. With this modification the dimensions of the transducer were 15 x 13 x 10mm and it was sufficiently small

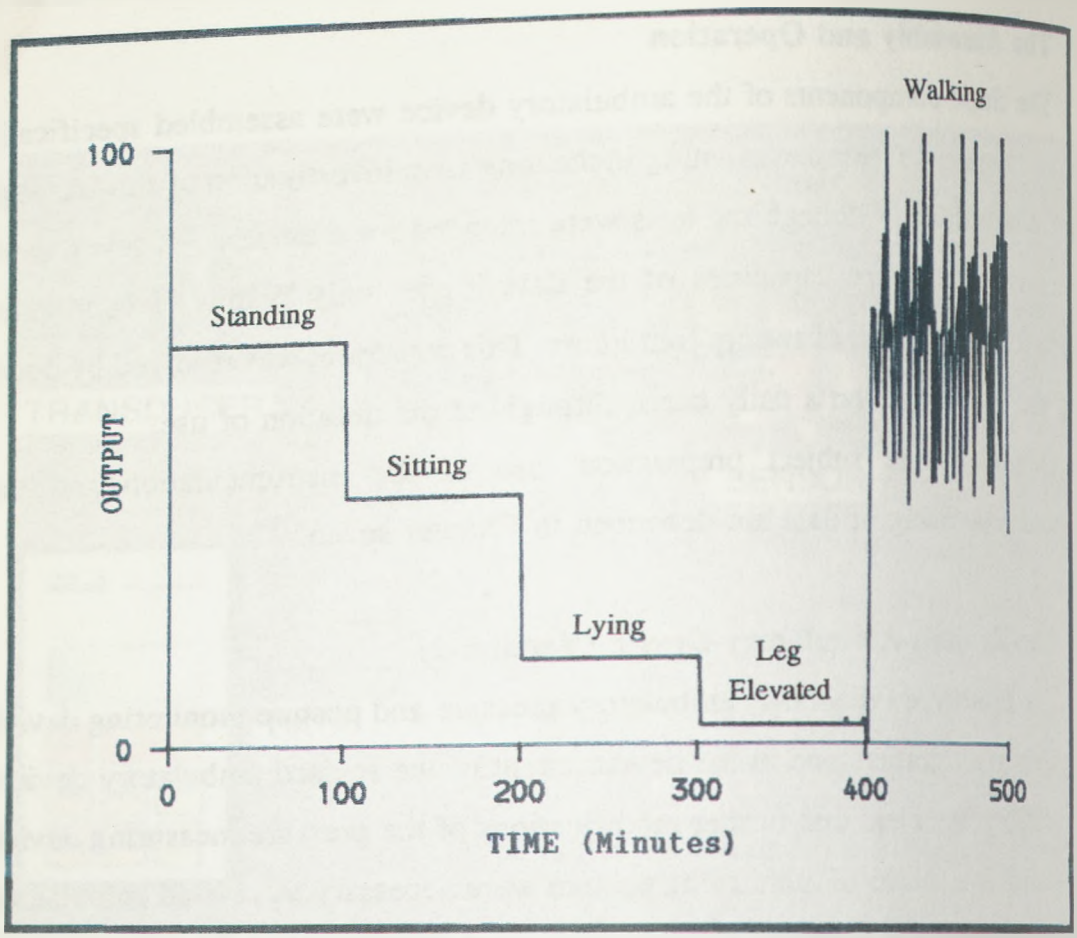


Figure 6.6 The Activity Sensor output

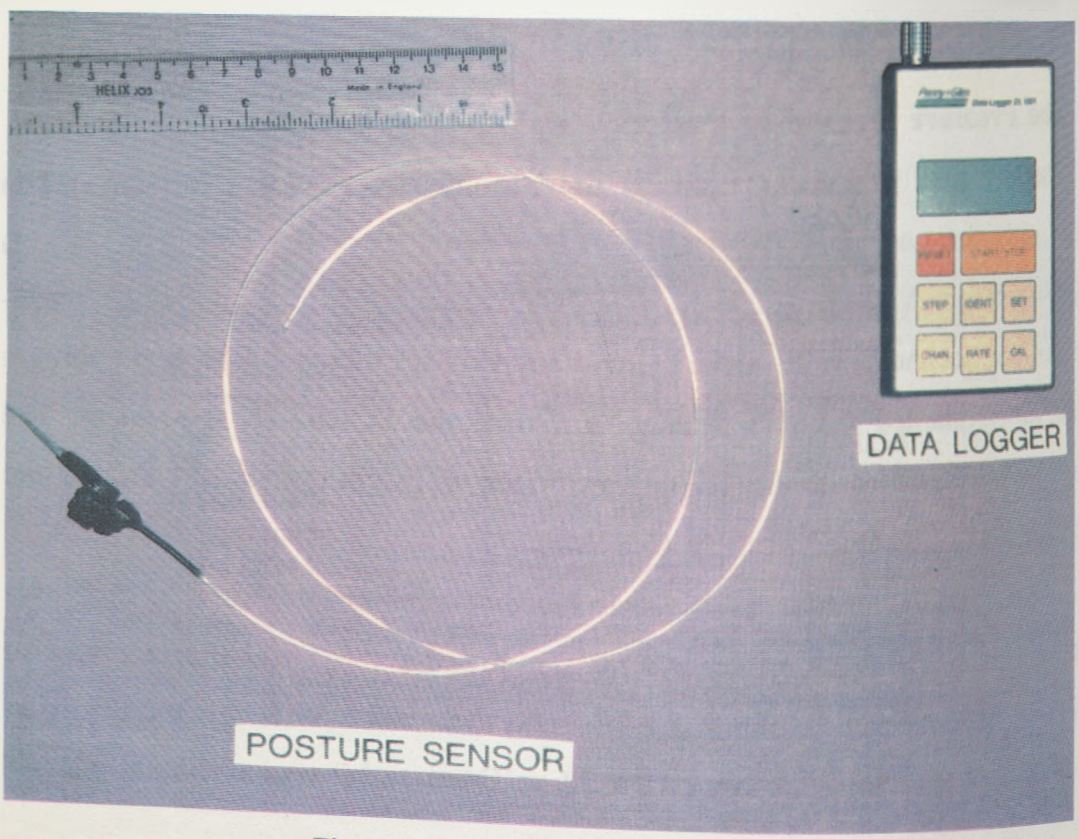


Figure 6.7 The Activity Sensor

to be tucked underneath the bandage. The cumbersome T-shaped transducer holder used in version-1 was now obsolete. This arrangement permitted the use of more transducers and was effective in concealing the measuring device within the bandage which would otherwise be obtrusive. The resulting difference in hydrostatic pressure as a consequence of having the transducer at a different level from the sensor was eliminated by recording and subtracting the baseline pressure for each posture.

The co-axial cable connecting the transducer and data logger in the earlier version was replaced with a twelve core ribbon cable. This flat, flexible cable was less prone to fracture from the constant rocking during ambulation and did not indent the skin. The transducer was mounted on a small piece of hard foam to protect the skin underneath and also to provided a base to secure the connecting ribbon cable.

The transducer, sensor and tube were otherwise assembled and calibrated as described in Chapter four.

6.2.2 The Activity Sensor

A novel miniaturised activity sensor capable of monitoring postural changes during ambulation was designed and developed. This highly miniaturised and simple to operate device, significantly improved the revised ambulatory system. The activity sensor was able to monitor the different postures during ambulation unambiguously as illustrated in its output (Figure 6.6). It did not require any calibration, was robust and withstood continuous prolonged use.

The activity sensor primarily consisted of the button sized 16PC transducer attached to a length of fine nylon tubing which was open at the free end, as illustrated in figure 6.7. The nozzles of the transducer were removed and port-B was replaced with a small Perspex block which redirected the outlet horizontally thereby, streamlining the transducer and attached tube.

Port-B of the transducer was primed with vegetable cooking oil using the apparatus and procedure described in Chapter four. Subsequently, the attached tube and port-B were filled with oil from a syringe connected at the free end of the tube. Upon flushing the air bubbles out through the "bleeding vent" in the Perspex block the system was sealed. Capillary forces and atmospheric pressure prevented the oil from leaking at the open free end of the tube.

Any displacement of the tube or sections of tube relative to the transducer would proportionally alter the hydrostatic pressure within the tube. As the diaphragm in the transducer was sensitive to changes in pressure it would produce a corresponding voltage output. Therefore, when the tube was taped along side the lower limb of the patient, any movement of the limb or sections of the limb would produce a similar effect. This allowed the movement of the limb to be quantified and consequently monitor posture. Further, as the data were sampled by the data logger at a known frequency, the rate of postural change or activity in general could also be deduced.

The construction of the activity sensor was versatile and allowed two shorter lengths of tube to be connected to each port of the transducer. Effectively, this placed the transducer centrally on the length tube as opposed to at one end. This configuration permitted the transducer to be concealed underneath the bandage whilst the tube was taped from the patient's hip to ankle. Consequently, the presence of the device was inconspicuous and unobtrusive.

Finally, the electronic circuitry of the transducer required a resistive trim-pot to suitably adjust its output to match the input of the data logger.

6.2.3 The Data Logger

The DL1001 data logger used in the previous ambulatory device (Version-1) proved robust and reliable and was reused in this device. However, a customised alteration of the minimum sampling frequency from 0.3 Hz to 0.03 Hz was undertaken by the manufacturers (Penny and Giles). This slower sampling frequency enabled a more economic use of the limited memory capacity and prolonged the period of continuous use.

The standard PP3 battery was also replaced with the long life, lithium battery (Kodak, U.K.). As a result of these measures the ambulatory device was able to measure pressure in three channels and posture on the fourth continuously for four days. This was particularly convenient when the device was used on leg ulcer patients.

6.2.4 The Assembly and Operation

The three components of the ambulatory device were assembled and used on leg ulcer patients in an investigation of sub-bandage pressure and posture. Detailed description of the assembly and the use of this device is presented in Chapter eight.

6.3 Discussion

The ambulatory pressure and posture monitoring device is an invaluable tool in the investigation of the long term effects of compression therapy and the influence of postural changes. The need for such a device in providing a comprehensive understanding of sub-bandage pressures generated during activities of daily living was firmly established in Chapter three. Progress in the development of this device was slow as it had to await the development of a suitable pressure measuring device. With the successful development and subsequent adaptation of the pressure measuring device described in Chapter four, it was then possible to produce the prototype (Version-1) of the ambulatory device.

6.3.1 Version-1

The success of the prototype ambulatory device was very encouraging and immediately highlighted the potentials of the device. However, like most prototype devices several teething problems soon became apparent which formed the basis for further improvement.

The pressure measuring device proved to be extremely versatile. The removal of the nozzles and construction of the Perspex block were fairly challenging. The nozzles were made of hard ceramic material and were difficult to saw off whilst ensuring that dust particles did not clog the hair-line channels. The construction and assembly of the tiny Perspex block required some dextrous workmanship.

The co-axial cable was selected because it was hardy and provided a protective covering for the fine leads within it. However, contrary to this assumption, the cable was too stiff and the leads within it occasionally fractured. Further, when the subjects were lying on the cable for prolonged periods it indented the skin. On the more fragile skin of a leg ulcer patient, the risk of pressures sores as a consequence was imminent.

The only significant modification required for the transducer to function with the data logger was an additional resistive trim-pot which was tidily concealed within the cable. However, the full potential of the sensitivity of the transducer was not realised. As this ambulatory device did not require an accuracy greater than ± 0.133kPa (±1mmHg) further modifications of the system were not necessary for the intended use. Such a modification would require an additional amplifying circuit which would be at the expense of the portability of the device and the trade-off was not justified at this stage.

The T-shaped polypropylene holder was a useful gadget for siting the pressure transducer but was aesthetically less pleasing. Despite its cumbersome appearance it held well in position even during sleep and ambulation. To attain the good fit, each holder had to be specifically moulded to shape an individual's leg, thus its construction was tedious. A serious disadvantage of this holder was that only a maximum of two transducers could be sited on it thus limiting the pressure measurement.

The flexible goniometer used to monitor posture was the best available device at the time of the development of the prototype ambulatory device. It offered many advantages over other devices such as the mercury tilt switch and the potentiometer device which were considered as alternatives. However, with progressive use of the prototype ambulatory device several limitations of the flexible goniometer emerged. The fine hair-line strain gauged wire in the device was too fragile for prolonged use. The goniometer output did not unequivocally identify posture. During standing and lying or sitting and lying with the leg flexed, the output did not differentiate the postures. The use of additional goniometers with complex logic operations would not be a feasible option. Although this was not a problem in the early use of the device as periodic standardised posture windows were created, subsequent non-standardised use would have been seriously limited. The encapsulated blocks at either end of the device were too bulky and the problem was further aggravated by the additional layer of protective foam. The device when placed alongside the knee joint protruded and was inconvenient for changing clothes. These limitations led to the flexible goniometer to be replaced in version-2 of the ambulatory device.

6.3.2 Version-2

The revised ambulatory device (Version-2) evolved from the prototype but was noticeably different. Its intended use on leg ulcer patients dictated its design criteria. Besides the technical and practical requirements, safety, convenience and comfort, and aesthetically acceptability were emphasised.

The adapted 16PC pressure transducer sufficiently reduced the size of the pressure measuring device enabling it to be concealed underneath the bandage. This made the device totally unobtrusive, inconspicuous and aesthetically acceptable. The bandage also provided protection for the device which was particularly useful when the patient was asleep. This arrangement of the pressure measuring device was also suitable for evaluating the compression generated by elastic stockings which was not possible with the previous siting of the transducer on the plastic holder. Further, with the plastic holder obsolete the application of the bandage became straight forward as intricate manoeuvring around the gadget was not necessary. As a result of the miniaturisation more transducers could be conveniently placed underneath the bandage than was previously possible. The increased number of pressure transducers and sensors would be an asset in evaluating pressure profiles.

As in the case of the SCX transducer a resistive trim-pot was required to make the transducer compatible with the data logger. Also the full potential of its sensitivity was not realised but for reasons previously discussed further modification was not justified at this stage. The connecting cable was replaced with the more flexible ribbon cable which was able to withstand the continuous rocking without fracturing because of its lower stiffness. This flat cable did not indent the skin under body weight and was much easier to tape onto the skin.

The development of the activity sensor for monitoring posture was perhaps the most significant improvement in version-2 of the ambulatory device. The activity sensor was highly miniaturised and extremely versatile in its design and application. With the transducer centrally sited on the tube, it was conveniently concealed beneath the bandage along with the lower section of the tube. The remaining section of the tube was inconspicuously taped on the thigh of the patient. The tube did not require alignment of the axis of rotation about the knee nor did it require any precise positioning except that the ends of the tube remained securely taped. Unlike the

goniometer, it did not obstruct the changing of clothes or impinge the skin under body weight.

The activity sensor was able to identify changes in posture unambiguously and with a suitable sampling frequency walking can be differentiated from running. Its output also identified leg elevation during sitting or lying which is an important feature in the venous ulcer treatment regime.

Technically it was simple to develop, easy to operate and did not require any calibration. The device required only one channel in the data logger thus, its memory and power consumption were minimal allowing multiple recordings of pressure in the remaining channels. Its components were not fragile and withstood repeated continuous use. Finally, it was safe for use on patients as it had no toxic material unlike the mercury tilt switch device and there was no imminent danger of seriously indenting the skin.

Perhaps the most crucial component in lending portability to the ambulatory device was the data logger. The pocket-size DL1001 data logger was a convenient means of accumulating and storing long term information. Its battery was an ideal source of power to operate the pressure transducer and activity sensor. During use it was conveniently and inconspicuously tucked in a pouch strapped around the waist.

The earlier data logger had a minimum sampling frequency of 0.3Hz which was unnecessarily high for monitoring sub-bandage pressure. As a result, the memory of the data logger was consumed quickly thereby reducing the period of continuous use. In version-2 this limitation was partially resolved by requesting the manufacturers to alter the sampling frequency to 0.03Hz which increased the duration of continuous use to four days. Correspondingly, the power supply had to be also increased and this was achieved by the use of long life lithium batteries. With the current pace of development in micro-electronic technology, data loggers in the future will have memory cards capable of storing several megabytes of data and operate on miniaturised battery cells with several years of life.

6.3.3 The Ambulatory Device

The ambulatory pressure and posture monitoring device is a new and powerful investigative tool in the study of compression therapy. Also its potential uses for

other applications are widespread.

The design and development of the device has successfully surmounted many obstacles in two difficult areas of measurement. Further, as the device is compact, miniaturised, highly portable and safe it is extremely conducive for clinical investigations involving leg ulcer patients.

Studies on the long term evaluation of compression generated by bandages and the effect of postural changes, using volunteer subjects and leg ulcer patients are described in the following two chapters.

CHAPTER 7

AMBULATORY MONITORING OF SUB-BANDAGE PRESSURE AND POSTURE ON NORMAL VOLUNTEER SUBJECTS

7.1 Instrumentation

7.2 Materials Tested

7.3 Subject Selection and Preparation

7.4 Method

7.5 Data Processing

7.6 Results

7.7 Discussion

7 AMBULATORY MONITORING OF SUB-BANDAGE PRESSURE AND POSTURE ON NORMAL VOLUNTEER SUBJECTS

The prolonged use of graduated compression is now a well established modality for the treatment of venous ulcers. It has been known for some time that the success of this treatment is dependent on an appropriate magnitude of compression being sustained for the duration of the treatment. Previous short term studies (Raj et al., 1980 and Tennant et al., 1988) to evaluate the performance of compression bandages have provided limited information, leaving the nature of long term compression generated by bandages open to speculation.

The importance of the influence of ambulation and postural change on sub-bandage pressure and the controversies surrounding it have been reviewed (Chapter Three). Confirmation of the influence of posture on the pressures generated by bandages in the short term emerged from the integrated evaluation of bandages and elastic stockings described in Chapter Five. The findings of the integrated evaluation suggested that further long term measurement of pressure beneath compression devices in conjunction with posture were required.

This pioneering study addresses the need to examine both the magnitude and time course of pressure generated by bandages over the duration of treatment. Unlike previous short term studies performed under controlled postures, this study investigates the influence of postural changes on sub-bandage pressure during activities of daily living. The measurement was made possible by the use of a custom built ambulatory pressure and posture monitoring system described in Chapter Six.

The ambulatory pressure and posture monitoring system generates large quantities of data. In order to optimise the acquisition of useful data, the tests were conducted in three trials. Each trial served to control different parameters thus enabling efficient use of the data whilst highlighting the important features.

Trial one investigates the pressures at mid-gaiter beneath the Granuflex bandage on five subjects. The pressures were recorded at three hourly intervals, in three standardised postures, over seven days. The aim of this section of the study was to provide an overview of the magnitude and time course of pressure, and the influence of posture. The test was limited to a single site of pressure measurement using a single bandage.

BANDAGE	WIDTH	COLOUR	TYPE	CLASS	MANUFACTURER
Granuflex	100 mm	brown	adhesive	3c	ConvaTec
Elastocrépe & Viscopaste	75 mm	brown	elastic	2	Smith & Nephew Smith & Nephew
Lestreflex & Viscopaste	75 mm	brown	partially adhesive	-	Seton Smith & Nephew
Granuflex (Low Tack)	100 mm	brown	low adhesive	3c	ConvaTec
Coban Wrap	75 mm	white	cohesive	-	3M

TABLE 7.1 The Compression Bandages Evaluated

Figure 7.1 The Ambulatory Device (Version 1)

Trial two investigates the pressures generated at mid-gaiter and ankle, beneath the Granuflex bandage, on four subjects. The pressures were recorded at three hourly intervals, in three standardised postures, over seven days. The aim of this section was to examine the graduation in compression and the long term influence of posture on the graduation.

Trial three investigates the pressures at mid-gaiter on a single subject wearing five different types of bandages (Table 7.1). The pressures were recorded at three hourly intervals, in three standardised postures, over seven days. The aim of this section was to examine and compare the long term characteristics of the five bandages.

Throughout the three trials, the bandages were applied by the same physiotherapist to avoid possible inter-bandager variation.

7.1 Instrumentation

The ambulatory pressure and posture monitoring system (Version 1) was used for the tests in all three trials. It features a pressure transducer attached to a plastic holder strapped to the leg, a fluid filled sensor, a goniometer and a data logging unit (Figure 7.1). Detailed descriptions of the design, development, operational characteristics and calibration of this system are presented in Chapter Six.

7.2 Materials

The general features of the compression bandages used in all three trials of the ambulatory study are presented in the table 7.1.

7.3 Subject Selection and Preparation

A total of nine volunteer subjects (six males and three females) selected from within the student population of the Bioengineering Unit participated in the three trials. The subjects selected were between 23 and 32 years of age and were of average stature. (The average weight and height was 69 kg and 170 cm respectively, as shown in table 7.2).

Subject preparation commenced with a general briefing on the prolonged nature of the study and the demanding protocol involving disrupted sleep, limited

SUBJECT	AGE (years)	SEX	WEIGHT (kg)	HEIGHT (cm)	CIRCUMFERENCE (cm)		
					CALF	GAITER	ANKLE
1	26	F	53.1	160	37	30	21
2	29	F	52.1	163	35	29	22
3	24	F	69.2	169	39	33	23
4	29	M	77.8	167	38	30	22
5	30	M	74.3	170	38	29	21
6	26	M	79.1	183	40	32	24
7	31	M	70.2	169	36	28	22
8	26	M	79.0	178	35	27	23
9	32	M	69.7	171	34	28	22

TABLE 7.2 Details of the volunteer subjects

washing for a week and abstinence from extreme physical activities such as sports. Further, the subjects were informed of the required three hourly routine, of standing with equal weight on each foot, sitting with the knee flexed at 90 degrees and lying without resting the weight of the leg on the sensor, with each stance lasting five minutes for an entire week. After agreement the subjects were then required to fill a form consenting to their participation in the study. The subjects were questioned on their general well being, including possible skin allergies. They were all reported as generally healthy and normal. The foot pulse was checked for each subject as a matter of routine, rather than a necessity, as the volunteers were young and healthy. Also for the purpose of documentation, blood pressures at the left arm were measured for each subject.

The leg of the subject selected for the test was opposite to the subject's preferred sleeping side in order to ensure that the equipment was not damaged during sleep. The head of fibula, the lateral malleolus and the line joining the two points were selected as standard reference markings, similar to that described in chapter five. The ankle site was located 40mm above the lateral malleolus on the reference line. The calf site was located on the reference line at the point of maximum calf circumference. The sensor site at the gaiter was then located at the mid-point between the ankle and calf sites. Finally the leg circumferences at each of these sites were then recorded and are shown in table 7.2.

7.4 Method

Pre-test preparation commenced with modification of the pressure measuring device to suit the leg of the selected subject and the calibration of the pressure transducer. A plastic holder which could be readily strapped around the leg and used for mounting the pressure transducer was developed for each subject. This T-shaped holder was moulded to snugly fit the leg of the individual subject and served to hold the transducer at the same level as the sensor (Figure 7.1). Details of these developments and calibration of the device are present in Chapter Six.

The test procedure began with the pressure sensor being placed at the predetermined site on the leg while the subject remained seated. A piece of absorbent

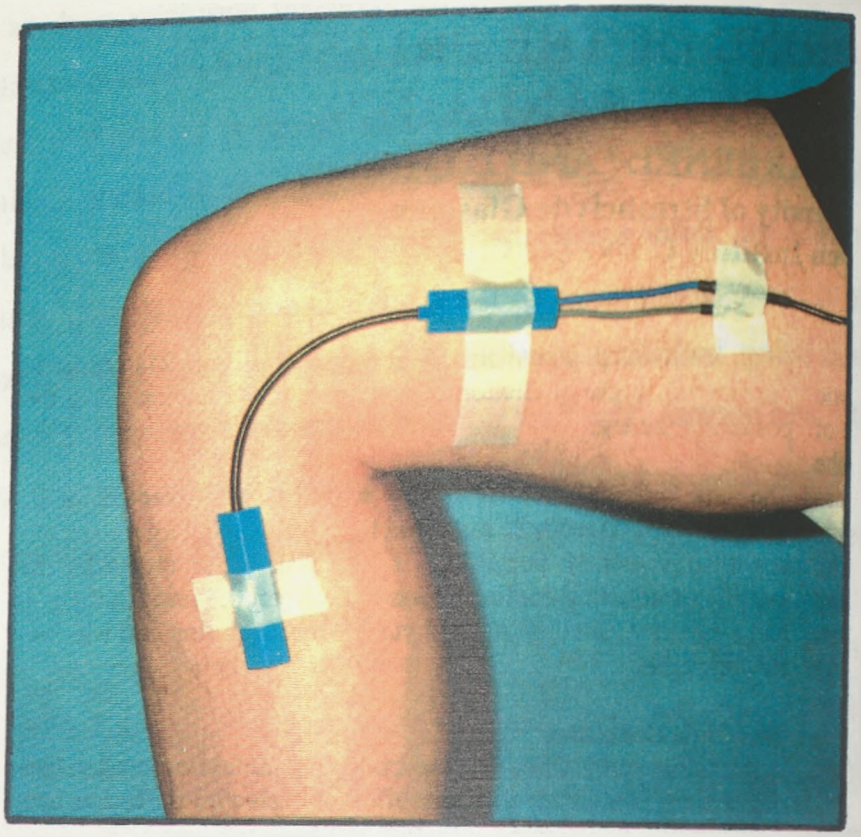


Figure 7.2 Flexible goniometer taped in place

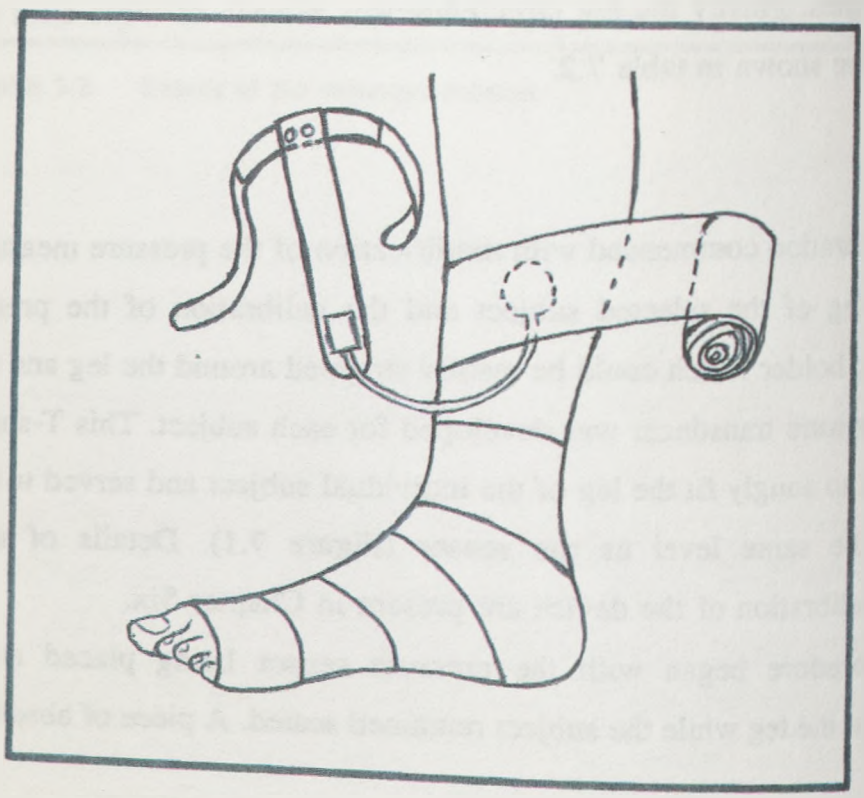


Figure 7.3 Sensor beneath bandage with connecting tube between two spiral layers

material cut to the shape of the sensor was placed immediately below the sensor to absorb sweat and to offer some protection against possible pressure sores. Upon securing the flanges of the sensor with micropore tape (3M, UK), the custom made plastic holder with the pre-mounted pressure transducer connected to the sensor was then temporarily fastened around the leg just below the knee. Following this, the goniometer was then secured using micropore tape across the knee joint on the medial side of the leg (Figure 7.2). The apparatus on the leg now resembled that of the final set up but without the bandage which allowed zero readings to be recorded. Leads from the sensor and the goniometer were then connected to the data logger which was set to sample at 1.67Hz (100 per minute). The zero readings were recorded with the subject standing, sitting and lying for five minutes in each stance, upon which the data were then down loaded onto an IBM compatible personal computer (PC) using a computer program, Sivlog.pas (Appendix I1).

The system was now suitably calibrated for the test. The plastic holder with the mounted pressure transducer was carefully unstrapped and held next to the sensor without tugging the short connecting tube. The physiotherapist then applied the bandage in a spiral technique starting from the toe covering the sensor but skilfully leaving the connecting tube out between two spiral layers of the bandage as shown in figure 7.3. The bandage was applied according to the manufacturer's instructions and in the case of the Granuflex bandage, a fifty percent over lap and stretch was used. For the Elastocrêpe and Lestreflex bandages an underlay of Viscopaste was used. The plastic holder with the mounted transducer was then re-fastened around the leg over the bandage while ensuring that it fitted snugly. The short connecting tube was gently taped in place. The goniometer was then replaced and firmly secured with micropore tape after checking that the leg was free to flex and extend. The leads from the transducer and goniometer were neatly taped along the lateral side of the limb passing underneath the under clothing to a pouch strapped around the waist (Figure 7.1). The data logger was then reset to sample at a slower frequency of 0.34Hz (20 per minute) and was neatly tucked in the pouch.

The test began with a posture routine which was repeated at three hourly intervals for twenty four hours whilst the subject kept a diary of major activities. At

the end of each twenty four hour period the data were down loaded onto a PC and the batteries renewed before restarting the data logger. This procedure was repeated for seven days after which the bandage was removed but the plastic holder and goniometer were replaced to record the zero readings again. The zero reading at the beginning and end of the test also served as a check on the performance of the device. Finally, the subjects' legs were checked for any adverse skin reactions.

7.5 Data Processing

At the end of each twenty four hour period, data from the logger were down loaded onto a PC via the RS232 port using a pascal program "Sivlog.pas". Data from the logger were in binary form and were converted to the ASCII form by using another pascal program "Sivtrans.pas" (Appendix I2). Since files in the ASCII form were very large (360 kBytes), they were transferred to the mainframe (VMS system) via the Kermit program (Version 2.31, 1988, Columbia University, USA) before analysis. Within each file the precise location of each three hourly pressure window was then manually flagged. A pascal program, "Process.pas" (Appendix I3), was then used to scan the data file and select blocks of data relating to each stand, sit and lie routine based on the goniometer readings. This program produced mean readings and standard deviations over the five minute period corresponding to each posture at the three hourly intervals.

The zero datum previously obtained was subtracted from the average data using the Minitab statistical package (Version 6.1.1, Minitab, Inc., 1987). Finally, the data were converted from data-logger units to millimetres of mercury (mmHg) using the calibration factor previously measured for each transducer prior to the test.

The data were then analyzed using non parametric statistical techniques for reasons discussed in Section 5.1.5. The Friedman's test (Linton and Gallo, 1975), Nemenyi's test (Linton and Gallo, 1975) and the non parametric paired test (Ryan et al., 1985) were used. The time course of pressure was analyzed using a one way analysis of variance. For all the statistical tests a 95% confidence limit was adopted. Finally, graphical presentations of the data were produced using Plotlib (University of Strathclyde, UK, 1987) and Harvard Graphics (Version 2.10, Software Publishing Corp., 1987).

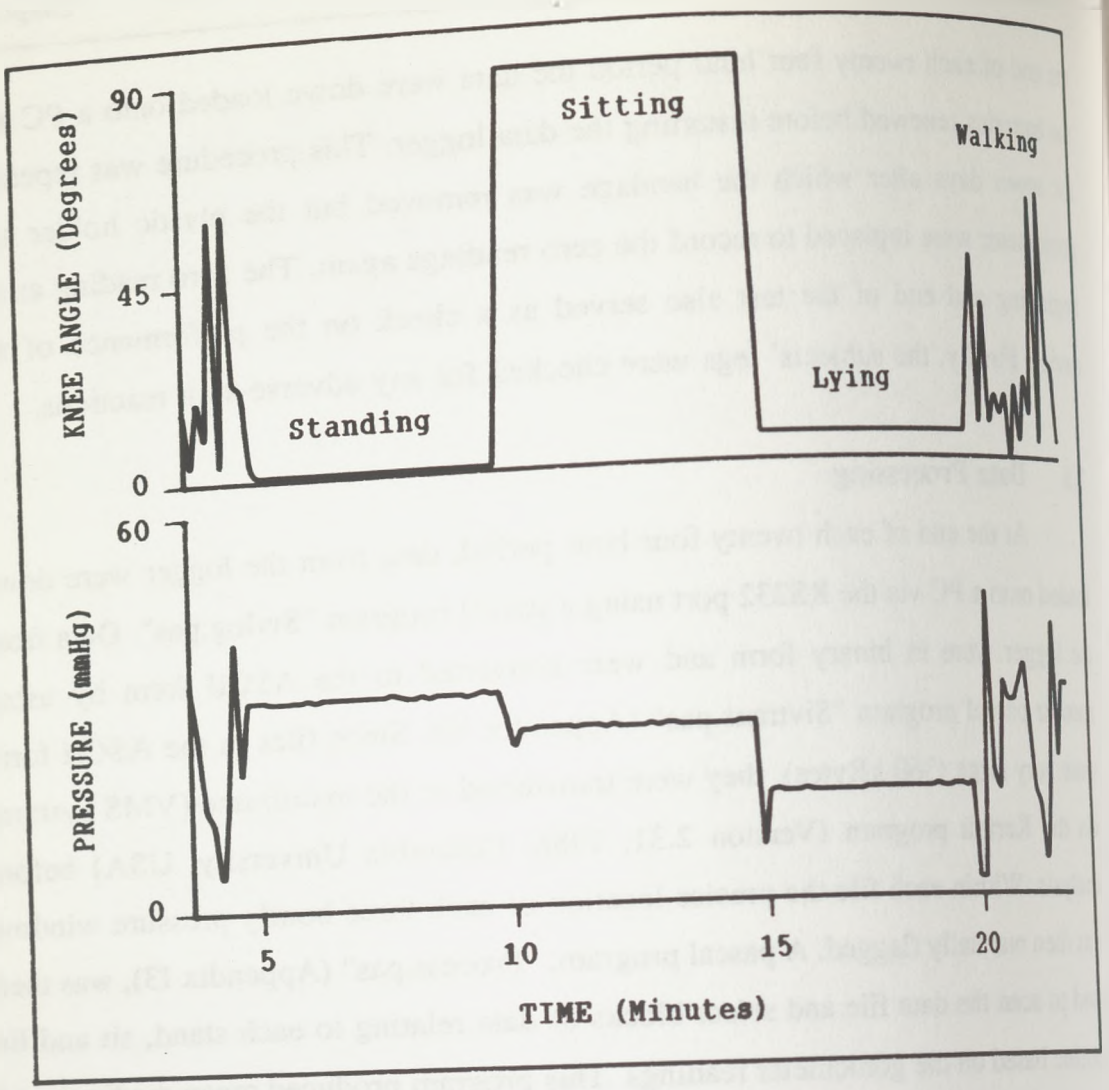


Figure 7.4 A typical stand, sit and lie routine

Posture	0 hrs	24 hrs	48 hrs	72 hrs	96 hrs	120 hrs	144 hrs	168 hrs
STD	45.2(0.7)	39.5(0.5)	39.1(0.7)	38.8(0.8)	39.0(0.4)	38.4(0.9)	38.2(0.6)	38.1(0.5)
SIT	42.0(0.4)	37.0(0.4)	37.7(0.7)	40.2(0.4)	38.0(0.5)	39.2(0.7)	39.6(0.5)	37.9(0.4)
LIE	37.7(0.9)	29.6(0.5)	33.0(0.6)	32.4(0.5)	31.4(0.6)	31.6(0.5)	31.5(0.5)	34.1(0.5)

TABLE 7.3 Typical average pressure and standard deviations for the five minute routines

7.6 Results

7.6.1 The Stand, Sit and Lie Routine

A typical graphical output from the stand, sit and lie routine is illustrated in figure 7.4. The knee angle demarks one posture from another and for each posture the corresponding pressure is displayed. The pressure within each five minute period remained relatively consistent for all the subjects. Periodic average pressures and the standard deviations over the five minute duration for subject-1 are shown in table 7.3. The maximum standard deviation was ±0.1 kPa (0.9 mmHg) which is smaller than the resolution of the measuring device and therefore was deemed not significant.

7.6.2 Results from Trial-1

(a) An Overview

Graphs of the average pressure, over five minutes, for each posture at every three hourly interval were produced for the five subjects (Appendix J1). Figure 7.5 illustrates such a graph for subject-5 and provides an overview of the magnitude and time course of pressure at the gaiter beneath the Granuflex bandage for each posture.

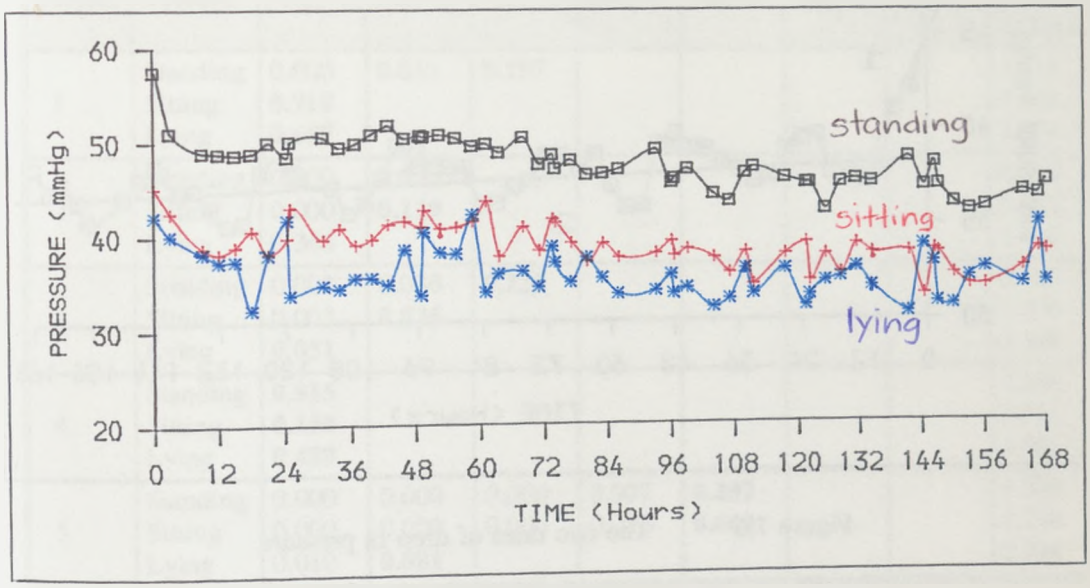


Figure 7.5 An overview of pressures produced at the gaiter (subject-5)

SUBJECT	POSTURE	ESTIMATED PERCENTAGE DROP IN PRESSURE (0-7 days)	RATES OF DROP IN PRESSURE (mmHg/hr)	
			0-6hrs	6-168hrs
1	Standing	18%	-0.7	-0.013
	Sitting	17%	-1.4	+0.004
	Lying	13%	-1.0	+0.008
2	Standing	21%	-0.9	-0.005
	Sitting	21%	-0.6	-0.005
	Lying	13%	-0.5	0.000
3	Standing	15%	-0.8	-0.009
	Sitting	16%	-0.5	-0.008
	Lying	12%	-0.3	-0.002
4	Standing	19%	-1.3	+0.007
	Sitting	23%	-1.2	+0.010
	Lying	14%	-1.3	0.000
5	Standing	22%	-0.9	-0.043
	Sitting	17%	-0.7	-0.032
	Lying	14%	-0.4	-0.012

TABLE 7.4 The overall percentage and rates of drop in pressure

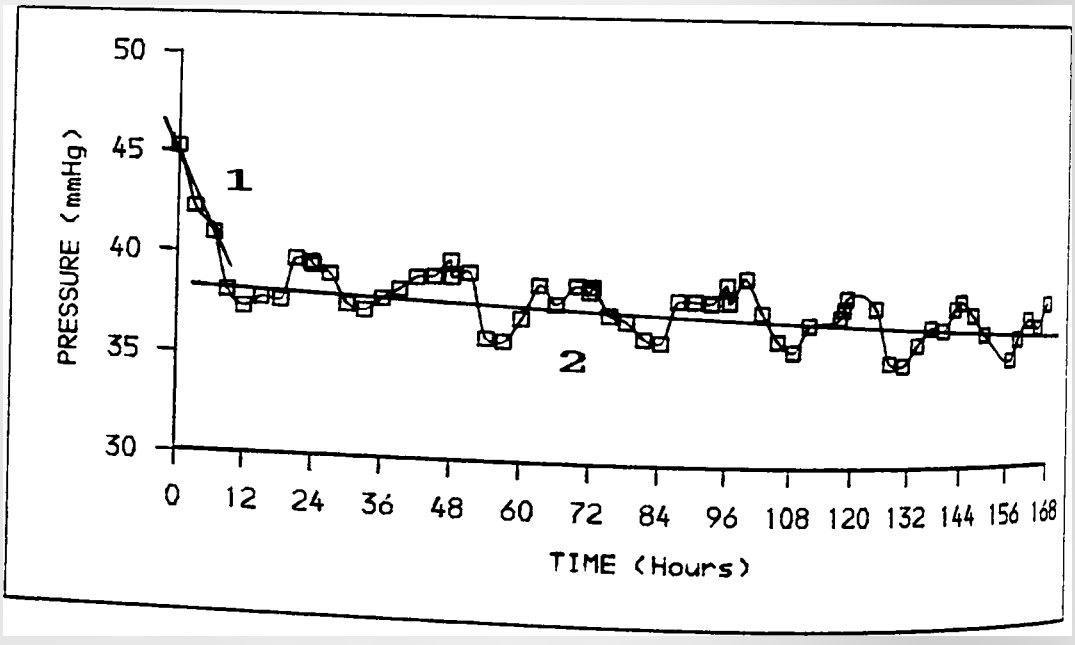


Figure 7.6 The two rates of drop in pressure

(b) The Time Course of Pressure

For each of the five subjects, the pressure beneath the bandage dropped over the seven day period. Table 7.4 provides an estimate of the percentage drop for each subject and posture.

The drop in pressure occurred at two rates. There was an initial rapid drop within the first six hours followed by a gradual drop over the remaining period. This was confirmed by a least squares linear regression over the two periods as demonstrated in figure 7.6. The rates of drop in pressure over the respective periods are shown in table 7.4. After the initial rapid drop, subjects 1 and 4 showed an increasing trend during sitting and lying and during standing and sitting respectively.

After the first day the average pressures progressively becomes less dependent on time. A one way analysis of variance of the average pressures was carried out to identify the period at which the pressure was independent of time. Table 7.5 illustrates the periods at which time ceased to be significant, the level of significance and the pooled standard deviation of pressures generated by the bandage for each posture. With the exception of pressures produced on subject-5, the average pressures were not significantly influenced by time after the second day.

Subject	Posture	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Pooled St.Dev
1	Standing	0.000	0.011	**0.197**					1.116
	Sitting	**0.918**							3.215
	Lying	**0.657**							2.394
2	Standing	0.000	**0.053**						0.775
	Sitting	0.000	**0.119**						1.061
	Lying	**0.348**							2.480
3	Standing	0.000	0.036	**0.239**					0.565
	Sitting	0.003	**0.835**						1.070
	Lying	**0.051**							2.349
4	Standing	**0.915**							2.108
	Sitting	**0.159**							2.371
	Lying	**0.489**							3.023
5	Standing	0.000	0.000	0.000	0.007	**0.253**			1.520
	Sitting	0.000	0.000	0.000	0.026	**0.663**			1.718
	Lying	0.010	**0.081**						2.214

TABLE 7.5 Results of the One Way Analysis of variance (significance)

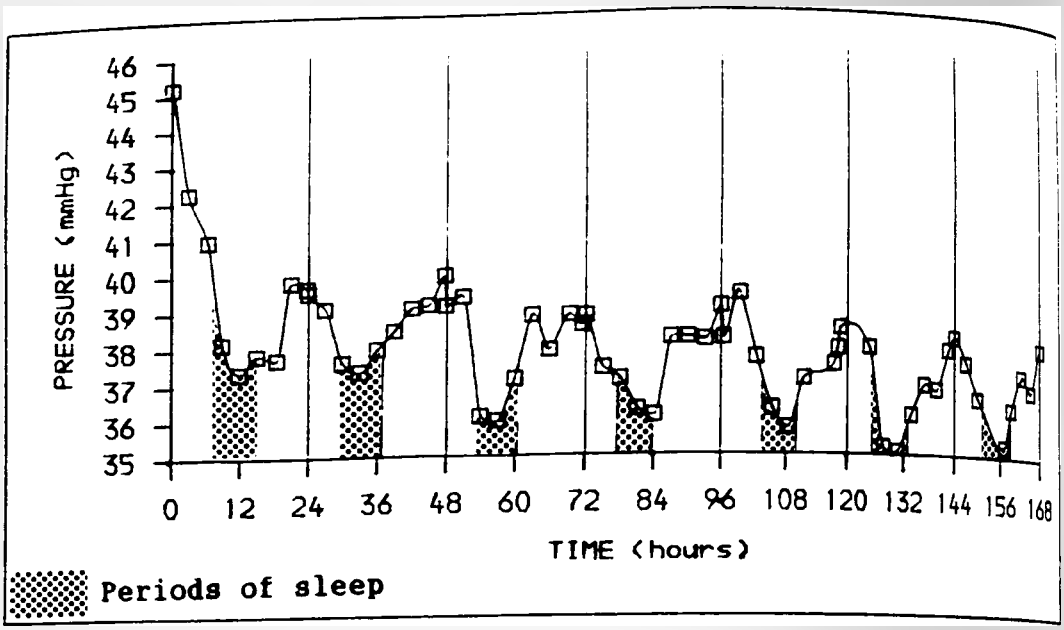


Figure 7.7 Daily variations in sub-bandage pressure

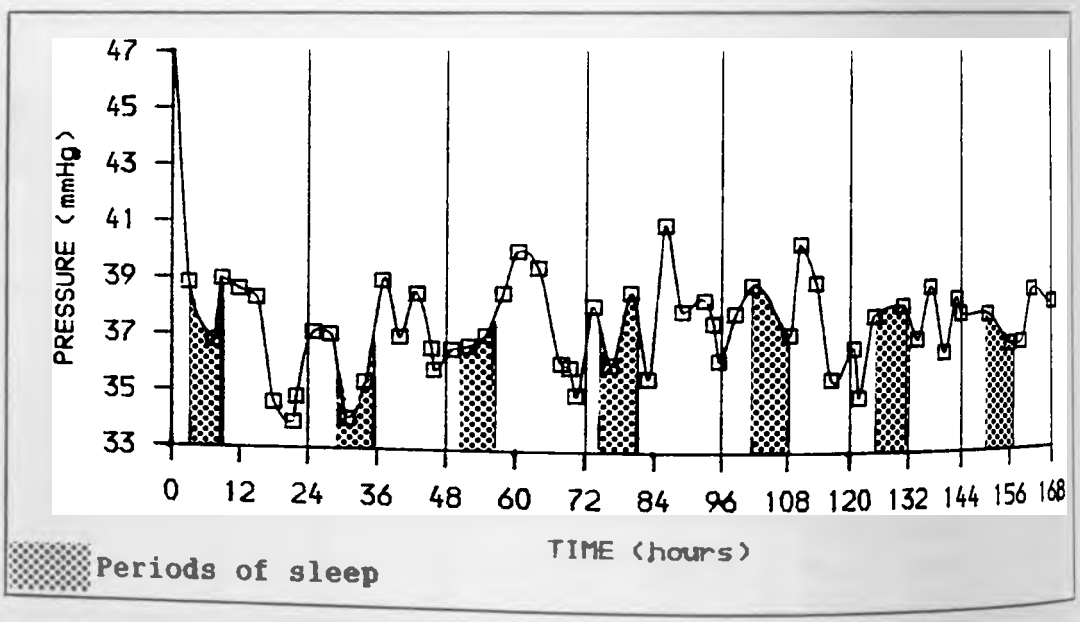


Figure 7.8 Daily variations not always symmetrical

Superimposed on the general decreasing trend were daily variations in the sub-bandage pressures as demonstrated in figures 7.6 and 7.7. These daily variations were, however, less obvious on some subjects and, in the sitting and lying postures as illustrated in figure 7.8. The time of the day and the periods of sleep, marked on the graphs do not always coincide with the daily variation (Appendix J2).

(c) The Magnitude of Average Daily Pressures

For each of the five subjects, the average daily magnitude and standard deviation of pressures generated at the gaiter in all three postures are shown in table 7.6. The average pressures during the first day are considered over two shorter periods of six hours and a further period of twelve hours to provide a better understanding of the change in magnitude of average pressures.

Subject	Posture	0-6hr	6-12hr	12-24hr	Day2	Day3	Day4	Day5	Day6	Day7
1	Stding	43(2)	39(2)	39(1)	39(1)	38(1)	38(1)	38(1)	37(1)	37(1)
	Sitting	36(5)	33(1)	35(3)	36(3)	36(4)	36(3)	37(3)	36(3)	35(3)
	Lying	34(3)	31(2)	31(2)	32(2)	33(3)	33(2)	32(3)	32(3)	33(1)
2	Standing	40(2)	36(4)	35(1)	34(1)	34(1)	35(1)	34(1)	34(1)	33(1)
	Sitting	30(2)	28(2)	27(1)	26(1)	25(1)	25(1)	25(1)	26(1)	26(1)
	Lying	29(3)	27(2)	28(1)	27(2)	26(2)	26(2)	27(2)	26(2)	28(4)
3	Standing	44(3)	42(1)	41(1)	41(1)	40(1)	40(1)	40(1)	40(1)	40(1)
	Sitting	43(2)	41(1)	39(2)	38(2)	38(1)	39(1)	38(1)	38(1)	38(1)
	Lying	43(1)	41(4)	38(1)	37(2)	37(3)	37(2)	36(2)	37(3)	38(1)
4	Standing	41(6)	39(1)	36(2)	37(2)	37(2)	38(2)	38(2)	38(1)	38(1)
	Sitting	34(5)	30(1)	31(2)	30(2)	31(1)	32(3)	33(2)	32(2)	30(2)
	Lying	30(5)	27(2)	31(8)	28(1)	27(2)	28(2)	28(1)	29(3)	30(2)
5	Standing	53(4)	49(1)	49(1)	51(1)	50(1)	47(1)	46(1)	46(2)	45(2)
	Sitting	43(2)	39(1)	39(1)	41(1)	41(2)	39(2)	37(2)	37(2)	37(2)
	Lying	40(2)	38(1)	37(4)	35(2)	38(3)	36(2)	34(2)	35(2)	36(3)

TABLE 7.6 The magnitude and standard deviation of pressures at the gaiter

With the exception of pressures produced at the gaiter for subject-5 in the standing posture, the average pressures within each posture were of the same order

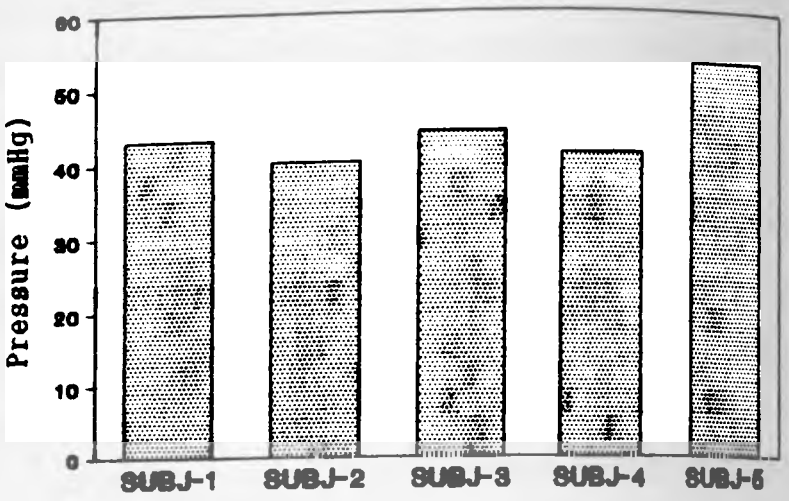


Figure 7.9 Average pressure at 6hrs in the standing posture

SUBJECT	POSTURE	RANGE OF AVERAGE PRESSURES (mmHg)	ESTIMATED CLASS OF BANDAGE
1	Standing	37 - 43	3d
	Sitting	33 - 36	3d
	Lying	31 - 34	3d
2	Standing	33 - 40	3d
	Sitting	25 - 30	3c(3d)
	Lying	26 - 29	3c(3d)
3	Standing	40 - 44	3d
	Sitting	38 - 43	3d
	Lying	36 - 43	3d
4	Standing	36 - 41	3d
	Sitting	30 - 34	3d
	Lying	27 - 31	3d
5	Standing	45 - 53	too high
	Sitting	37 - 43	3d
	Lying	34 - 40	3d

TABLE 7.7 Estimated class for the Granuflex bandage

of magnitude. The noticeably higher average pressure for subject-5 in the standing posture is illustrated in figure 7.9.

Bandages are normally classified according the magnitude of compression they generate at the ankle. According to Dale (1984) the pressure at the calf should be 50% of that at the ankle and if a linear relationship were assumed to provide an estimate then the pressure at mid gaiter should be about 75% of that at the ankle. Therefore, projecting the SPDT1 classification, class 3d bandages would exert pressures from 3.6 to 6.0 kPa (27 to 45 mmHg). The range of average pressure generated by the Granuflex bandage at the gaiter and the corresponding estimated classification are illustrated in table 7.7.

(d) The Influence of Posture

Pressures generated at the gaiter beneath the Granuflex bandage varied with posture throughout the seven days for all the subjects. Figure 7.10 demonstrates such a variation in average daily pressures for subject 1.

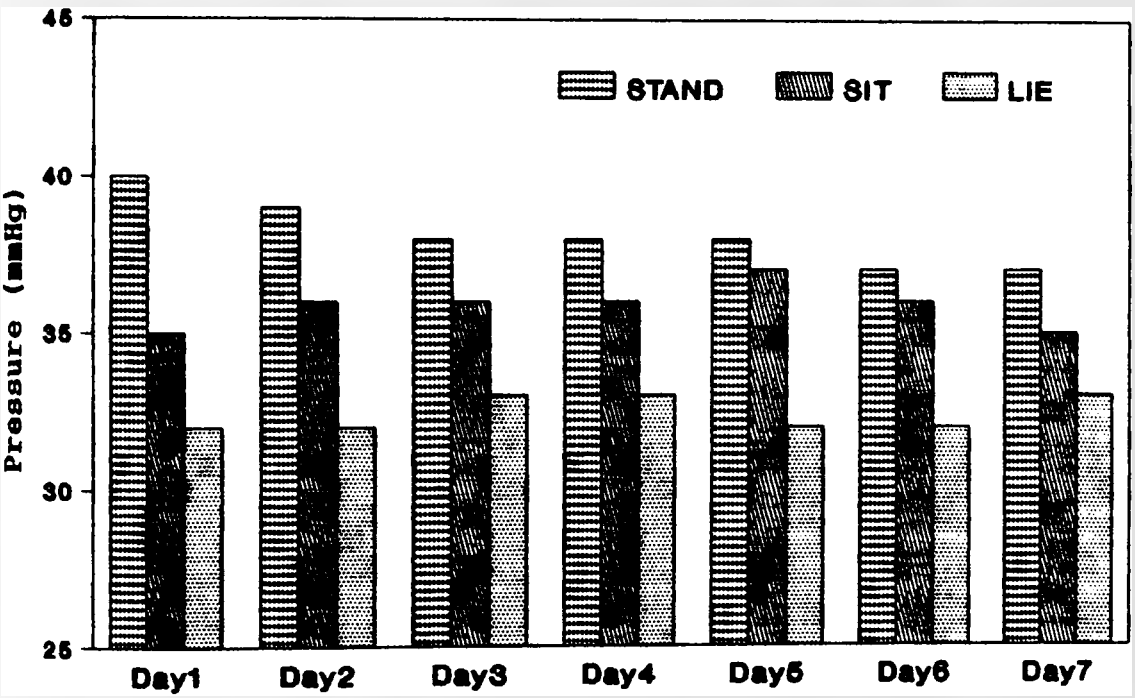


Figure 7.10 The influence of posture on average pressure

SUBJECT	Were the average pressures significantly different for each posture? (P-value)	Specific comparisons
1	Yes (0.000)	stand > sit > lie
2	Yes (0.000)	stand > lie > sit
3	Yes (0.000)	stand > sit > lie
4	Yes (0.000)	stand > sit > lie
5	Yes (0.000)	stand > sit > lie

TABLE 7.8 Results of the Friedman's and Nemenyi's tests

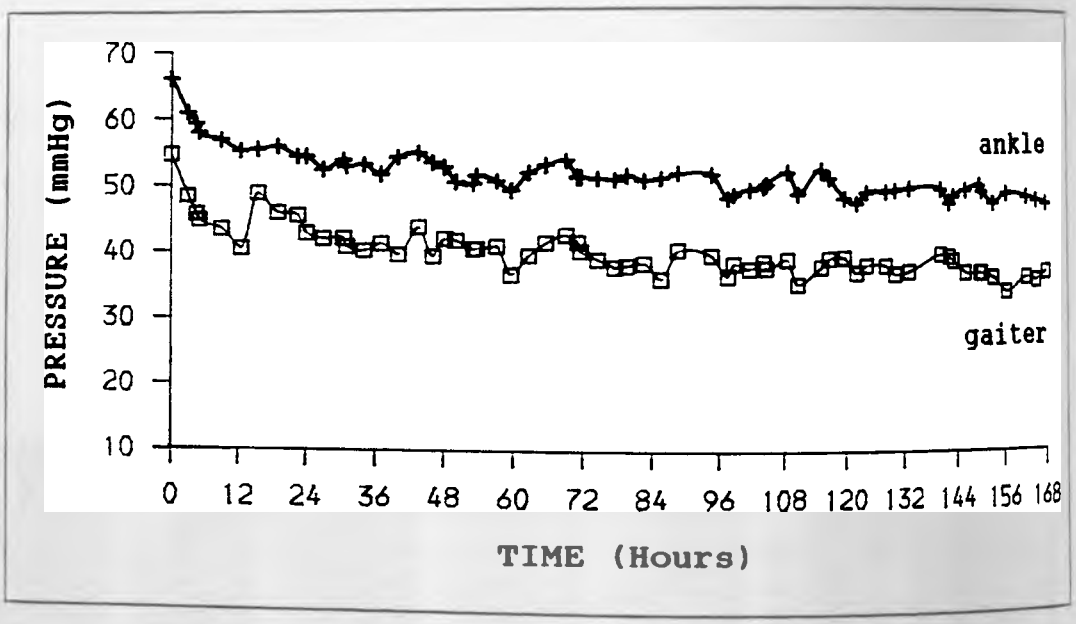


Figure 7.11 An overview of pressures at the gaiter and ankle (subject-1)

The Friedman's test indicated that the average pressures were significantly different for each posture throughout the seven days (Table 7.8). Specific comparison using Nemenyi's test showed that the standing posture consistently produced higher pressures than the sitting or lying postures.

7.6.3 Results from Trial-2

(a) An Overview

Graphs of the average pressure at the gaiter and ankle for each posture at the three hourly intervals were produced for the four subjects (Appendix K). Figure 7.11 illustrates such a graph for subject 1 in the standing posture which provides an overview of the magnitude, time course and gradient of pressure beneath the Granuflex bandage.

(b) The Time Course of Pressure

For all the four subjects the pressure beneath the bandage at the gaiter and ankle dropped over the seven day period. Table 7.9 provides an estimate of the percentage drop for each subject, posture and site of measurement.

SUBJECT	POSTURE	Estimated percentage drop in pressure over seven days	
		GAITER	ANKLE
1	Standing	34%	27%
	Sitting	36%	25%
	Lying	27%	25%
2	Standing	30%	21%
	Sitting	21%	14%
	Lying	31%	19%
3	Standing	31%	35%
	Sitting	35%	24%
	Lying	14%	25%
4	Standing	20%	24%
	Sitting	14%	17%
	Lying	21%	20%

TABLE 7.9 Estimated percentage drop in pressure

SUBJECT	POSTURE	Rates of drop in pressure at GAITER		Rates of drop in pressure at ANKLE	
		0-6hr	6-168hr	0-6hr	6-168hr
1	Standing	-2.0	-0.048	-1.6	-0.046
	Sitting	-1.4	-0.018	-1.1	-0.019
	Lying	-1.1	-0.019	-1.2	-0.023
2	Standing	-1.3	0.000	-0.9	-0.026
	Sitting	-0.8	-0.003	-0.2	-0.030
	Lying	-1.0	0.000	-0.2	-0.035
3	Standing	-1.1	-0.032	-2.4	-0.032
	Sitting	-2.1	-0.033	-3.4	-0.029
	Lying	-1.3	-0.026	-1.7	-0.041
4	Standing	-1.1	-0.024	-1.4	-0.029
	Sitting	-0.4	-0.008	-0.5	-0.012
	Lying	-0.5	-0.020	-0.6	-0.019

TABLE 7.10 Rates of drop in pressure at the gaiter and ankle

Subject	Posture	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Pooled St Dev
1	Standing	0.000	0.000	0.000	0.010	0.011	0.006	****	1.054
	Sitting	0.000	**0.375**						2.472
	Lying	0.000	**0.254**						1.605
2	Standing	0.012	**0.314**						0.938
	Sitting	0.096							1.719
	Lying	0.033	**0.315**						1.757
3	Standing	0.000	0.000	**0.671**					1.503
	Sitting	0.000	0.000	**0.252**					1.797
	Lying	0.000	**0.239**						2.639
4	Standing	0.000	0.000	**0.255**					0.945
	Sitting	0.000	**0.522**						1.443
	Lying	0.008	**0.706**						2.784

TABLE 7.11a Results of the One Way Analysis of variance (significance) for pressures at the GAITER

The drop in pressure at both sites occurred at two rates similar to that demonstrated in figure 7.6 (Section 7.6.2). There was an initial rapid drop within the first six hours followed by a gradual drop over the remaining period. Estimates of the rates of drop in pressure obtained by least squares linear regression over the respective periods are shown in table 7.10.

After the initial six hours the average pressures were progressively less influenced by time. A one way analysis of variance of the average pressures was carried out to identify the period at which pressure was independent of time. Table 7.11 (a&b) illustrates the periods at which time ceased to be significant, the levels of significance and the pooled standard deviation of pressures at the gaiter and ankle. With the exception of pressures produced on subject-1, the magnitude of average pressures at the gaiter are not significantly different after the second day. However, the fall in the magnitude of average pressures at the ankle remained significant over a longer period.

Subject	Posture	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Pooled St Dev
1	Standing	0.000	0.000	0.000	0.000	**0.073**			1.222
	Sitting	0.000	**0.131**						1.873
	Lying	0.000	0.007	0.030	**0.113**				1.425
2	Standing	0.000	0.001	**0.215**					2.127
	Sitting	0.000	0.000	0.019	0.018	**0.184**			1.771
	Lying	0.000	0.035	**0.057**					2.736
3	Standing	0.000	0.000	**0.270**					1.313
	Sitting	0.000	0.044	**0.451**					2.204
	Lying	0.000	**0.129**						2.962
4	Standing	0.000	0.000	0.000	0.004	0.034	0.022	****	1.014
	Sitting	0.000	**0.679**						1.505
	Lying	**0.068**							3.633

TABLE 7.11b Results of the One Way Analysis of variance (significance) for pressures at the ANKLE

Subject	Site	0-6hr	6-12hr	12-24hr	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	Gait	48(5)	43(2)	46(3)	41(1)	40(2)	38(1)	38(1)	38(1)	36(1)
	Ank	61(4)	57(1)	55(1)	53(1)	51(1)	51(0)	50(2)	48(1)	48(1)
2	Gait	32(4)	29(0)	26(1)	26(1)	26(1)	26(1)	26(1)	27(1)	26(1)
	Ank	49(3)	45(3)	43(1)	44(3)	40(2)	42(2)	40(1)	41(1)	41(3)
3	Gait	41(3)	38(1)	36(1)	36(1)	32(3)	32(1)	32(2)	32(1)	31(1)
	Ank	49(7)	44(2)	41(1)	40(2)	37(2)	37(1)	36(1)	36(1)	37(2)
4	Gait	41(3)	39(1)	37(1)	36(1)	34(2)	34(0)	34(1)	34(1)	33(1)
	Ank	46(4)	41(1)	40(2)	38(1)	38(1)	37(1)	36(1)	36(1)	35(1)

(a) Standing

Subject	Site	0-6hr	6-12hr	12-24hr	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	Gait	37(4)	29(6)	33(2)	29(3)	27(3)	27(2)	28(2)	25(3)	27(2)
	Ank	51(3)	44(5)	45(1)	43(1)	42(2)	42(2)	42(2)	40(2)	41(2)
2	Gait	26(3)	23(1)	22(1)	23(2)	21(1)	23(2)	21(1)	22(1)	22(1)
	Ank	37(1)	36(1)	36(1)	36(3)	32(1)	34(2)	32(2)	33(2)	32(2)
3	Gait	40(6)	36(2)	35(4)	34(2)	31(2)	32(2)	30(2)	31(1)	30(2)
	Ank	46(6)	39(3)	38(4)	38(4)	35(3)	36(2)	34(2)	34(2)	35(3)
4	Gait	36(2)	35(1)	33(1)	32(1)	31(2)	30(1)	31(2)	31(1)	31(1)
	Ank	36(2)	35(2)	32(2)	30(1)	31(2)	29(1)	30(2)	30(1)	30(2)

(b) Sitting

Subject	Site	0-6hr	6-12hr	12-24hr	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	Gait	37(3)	34(1)	33(1)	31(2)	31(1)	31(2)	30(2)	29(1)	30(2)
	Ank	50(3)	47(1)	44(1)	43(1)	43(1)	43(2)	41(1)	41(1)	41(1)
2	Gait	30(4)	25(3)	26(1)	24(2)	25(2)	23(2)	25(1)	25(1)	24(2)
	Ank	38(1)	35(3)	38(3)	35(4)	35(3)	32(2)	32(2)	33(2)	32(4)
3	Gait	37(5)	36(2)	35(1)	33(2)	31(4)	30(2)	31(3)	31(2)	32(2)
	Ank	49(6)	46(5)	43(4)	39(3)	37(4)	36(2)	36(2)	37(4)	37(2)
4	Gait	42(1)	39(1)	36(1)	35(1)	35(3)	35(3)	33(3)	35(4)	33(3)
	Ank	41(2)	37(1)	36(0)	35(2)	36(4)	36(5)	33(4)	36(5)	33(3)

(c) Lying

TABLE 7.12 Magnitude and Standard deviations of average daily pressures at the gaiter and ankle

Pressures at both the gaiter and ankle showed a daily variation which was superimposed on the overall decreasing trend. The variations at the gaiter and ankle had little resemblance to each other. As in trial one, the clarity of these variations differed for each subject and posture. Figure 7.12 illustrates the dissimilar variations in pressure at the gaiter and ankle.

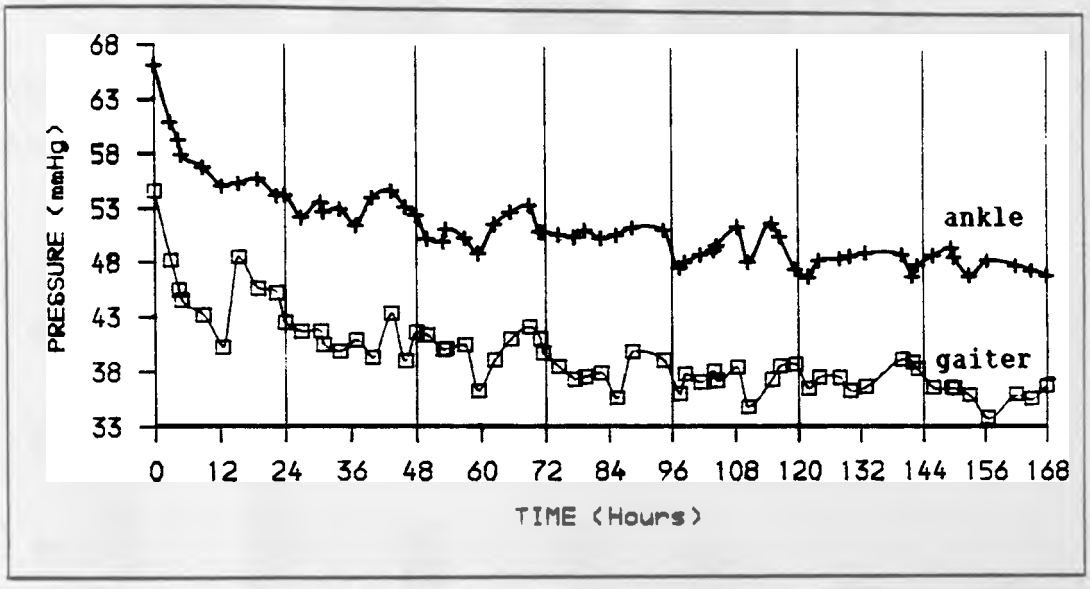


Figure 7.12 Dissimilar pressure variations at gaiter and ankle

(c) The Magnitude of Average Daily Pressures

The magnitude and standard deviation of the average daily pressures at the gaiter and ankle generated in all three postures for each subject are shown in table 7.12. The average pressures during the first day were considered over two shorter periods of six hours and a further period of twelve hours to provide a clearer understanding of the change in magnitude of average pressures.

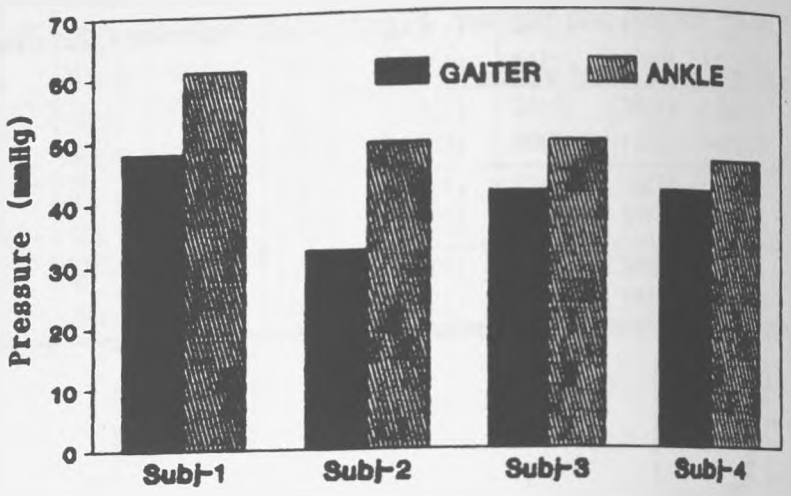


Figure 7.13 Average pressures (at 6hrs) in the standing posture

SUBJECT	POSTURE	RANGE OF ANKLE PRESSURES	CLASS OF BANDAGE
1	Standing	61-48	3d
	Sitting	51-40	3d
	Lying	50-41	3d
2	Standing	49-40	3d
	Sitting	37-32	3c(3d)
	Lying	38-32	3c(3d)
3	Standing	49-36	3d
	Sitting	46-34	3c(3d)
	Lying	49-36	3d
4	Standing	46-35	3c(3d)
	Sitting	36-29	3c(3d)
	Lying	41-33	3c(3d)

TABLE 7.13 Estimated class for the Granuflex bandage

With the exception of pressures produced at the gaiter and ankle of subject-1 in the standing posture, the average pressures within each posture were of the same order of magnitude. The noticeably higher average pressure for subject-1 is illustrated in figure 7.13.

The average daily pressures at the ankle were used to identify the class of bandage for each posture and subject in accordance with the values suggested by Thomas (1990) and are illustrated in table 7.13.

(d) The Influence of Posture

Pressures generated at both the gaiter and ankle for all the subjects varied with posture throughout the seven days. Figure 7.14 demonstrates such variation for subject-1.

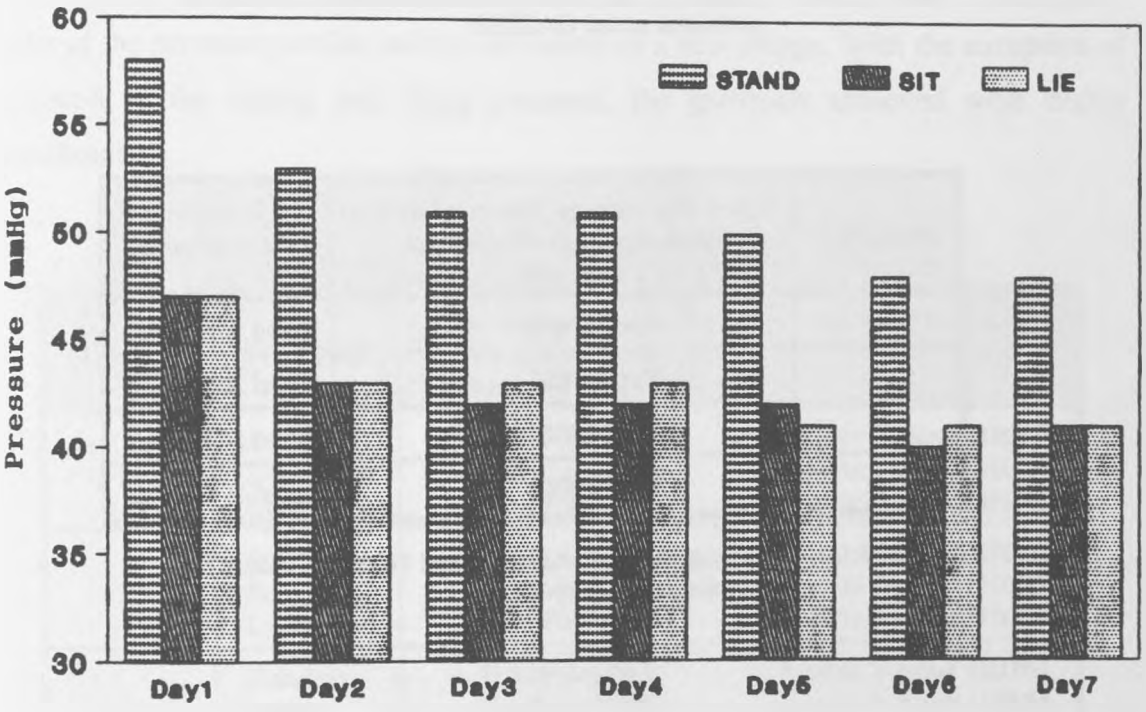


Figure 7.14 The influence of posture on ankle pressures

SUBJECT	Were the average pressures at the gaiter significantly different for each posture? (P-value)	Specific comparisons
1	Yes (0.000)	stand > lie > sit
2	Yes (0.000)	stand > lie > sit
3	Yes (0.000)	stand > sit > lie
4	Yes (0.000)	stand > lie > sit

TABLE 7.14a Results of the Friedman's and Nemenyi's tests for pressures at the GAITER

SUBJECT	Were the average pressures at the ankle significantly different for each posture? (P-value)	Specific comparisons
1	Yes (0.000)	stand > sit > lie
2	Yes (0.000)	stand > lie > sit
3	Yes (0.000)	stand > lie > sit
4	Yes (0.000)	stand > lie > sit

TABLE 7.14b Results of the Friedman's and Nemenyi's tests for pressures at the ANKLE

The Friedman's test indicated that the pressures generated, at the gaiter and ankle, for each posture were significantly different throughout the seven days (table 7.14). Specific comparisons using Nemenyi's test showed that the standing posture consistently produced higher pressures than the sitting or lying postures at both sites of pressure measurement.

(e) The Pressure Gradient

Graduated compression decreasing towards the calf is important if the bandage is to be successfully used in the treatment of venous ulcers. The measurement of pressures at both the ankle and gaiter provided a means of examining the pressure gradient. To detemine whether the pressure gradient was achieved at each three hourly measurement, the non-parametric paired test (Ryan et al., 1985) was used. This test provided a means of examining the pressure at the gaiter and ankle for each measurement throughout the seven days (table 7.15). The results also include the order of the pressure profile and its incidence as a percentage. With the exception of subject-4 in the sitting and lying postures, the gradients achieved were highly significant.

SUBJECT	POSTURE	Was the gradient achieved for each measurement over seven days? (significance)	Specific Comparison (incidence)
1	Standing	Yes (P = 0.000)	ankle > gaiter (100%)
	Sitting	Yes (P = 0.000)	ankle > gaiter (100%)
	Lying	Yes (P = 0.000)	ankle > gaiter (100%)
2	Standing	Yes (P = 0.000)	ankle > gaiter (100%)
	Siting	Yes (P = 0.000)	ankle > gaiter (100%)
	Lying	Yes (P = 0.000)	ankle > gaiter (100%)
3	Standing	Yes (P = 0.000)	ankle > gaiter (100%)
	Sitting	Yes (P = 0.000)	ankle > gaiter (100%)
	Lying	Yes (P = 0.000)	ankle > gaiter (100%)
4	Standing	Yes (P = 0.000)	ankle > gaiter (100%)
	Sitting	No	gaiter > ankle (90%) ankle > gaiter (10%)
	Lying	No	gaiter > ankle (58%) ankle > gaiter (42%)

TABLE 7.15 The pressure gradients

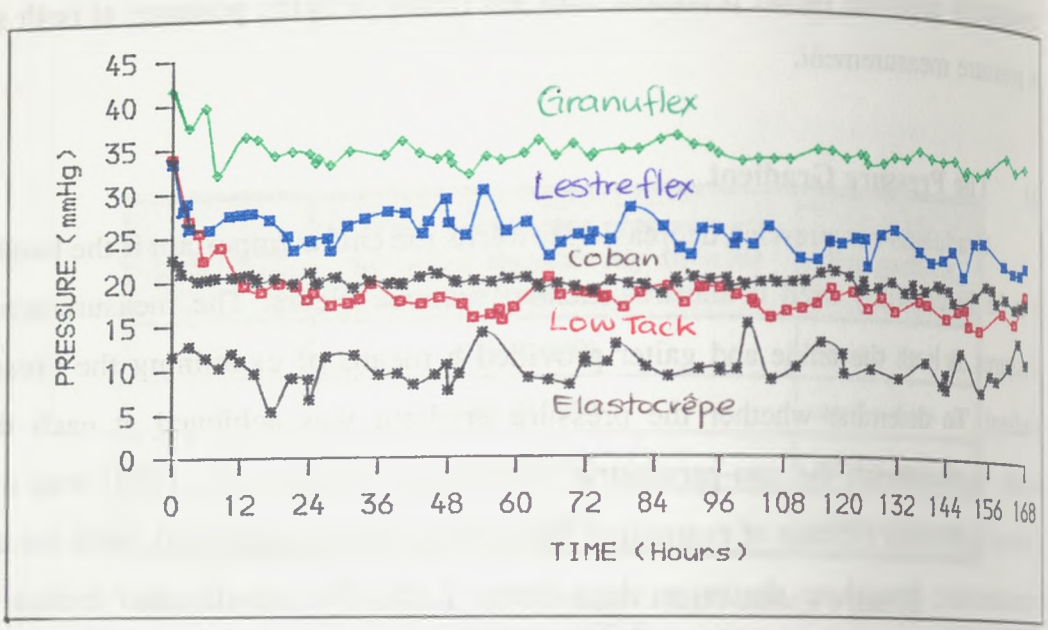


Figure 7.15 Typical pressures generated by the five bandages during standing

BANDAGE	POSTURE	ESTIMATED PERCENTAGE DROP IN PRESSURE (0-7 days)	RATES OF DROP IN PRESSURE (mmHg/hr)	
			0-6hrs	6-168hrs
Coban Wrap	Standing	16%	-0.38	-0.009
	Sitting	24%	-1.09	-0.006
	Lying	18%	-0.25	-0.013
Elastocrêpe	Standing	5%	-0.03	-0.006
	Sitting	29%	+0.45	-0.002
	Lying	79%	-2.47	-0.027
Low Tack	Standing	50%	-1.96	-0.014
	Sitting	47%	-1.36	-0.002
	Lying	47%	-1.57	-0.006
Lestreflex	Standing	31%	-1.06	-0.027
	Sitting	43%	-1.10	-0.041
	Lying	37%	-1.56	-0.016
Granuflex	Standing	21%	-0.93	-0.005
	Sitting	21%	-0.58	-0.005
	Lying	13%	-0.48	-0.000

TABLE 7.16 The overall percentage and rates of drop in pressure

7.6.4 Results from Trial-3

(a) An Overview

Graphs of the average pressure at the gaiter for each posture at the three hourly intervals were produced for the five bandages (Appendix L). Figure 7.15 illustrates typical pressures generated by the five bandages for the subject in the standing posture. It provides an overview of the magnitude and time course of pressure at the gaiter.

(b) The Time Course of Pressure

The pressures generated by the five bandages dropped during the seven day duration of the test. Table 7.16 provides estimates of the percentage drop in pressure produced by each bandage for the three postures.

With the exception of the Elastocrêpe bandage, the drop in pressure occurred at two rates as previously demonstrated in figure 7.6 (Section 7.6.2). There was an initial rapid drop within the first six hours followed by a gradual drop over the remaining period. Estimates of the two rates of drop in pressure were obtained by linear regression of pressure over the respective periods and are tabulated in table 7.16. The initial rate of drop in pressure was least for the Coban Wrap bandage in the standing and lying postures. For Elastocrêpe bandage, the percentage and initial rate of drop in pressure were irregular.

After the first day the average pressures for the five bandages progressively became less dependent upon time. A one way analysis of variance of the average pressures was carried out to determine the period at which the pressure became independent of time. The corresponding levels of significance and the pooled standard deviation of pressure generated by the bandages for each posture are illustrated in table 7.17. With the exception of pressures produced by the Coban Wrap bandage, the average pressures were not significantly different after the third day. However, this result must be viewed in conjunction with the pooled standard deviation. Pressures with large standard deviations, such as those produced by the Elastocrêpe bandage, are insensitive to time. The converse in the case of the Coban Wrap bandage makes its pressures highly sensitive to time.

Superimposed on the overall decreasing trends in pressure, were daily

Bandage	Posture	Day1	Day2	Day3	Day4	Day5	Day6	Day7	Pooled St Dev
Coban Wrap	Standing	0.000	0.000	0.001	0.001	0.000	0.027	****	(0.617)
	Sitting	0.036	0.023	**0.127**					(0.864)
	Lying	0.000	0.000	0.001	0.004	0.017	**0.273**		(0.711)
Elastocrêpe	Standing	**0.625**							(1.851)
	Sitting	**0.946**							(3.313)
	Lying	0.001	0.043	0.037	**0.192**				(3.422)
Low Tack	Standing	0.000	**0.122**						(1.130)
	Sitting	0.010	**0.922**						(1.311)
	Lying	0.000	0.015	0.041	**0.125**				(0.962)
Lestreflex	Standing	0.000	0.000	0.034	**0.059**				(1.437)
	Sitting	0.000	0.000	0.034	**0.113**				(2.301)
	Lying	0.000	0.023	**0.792**					(1.593)
Granuflex	Standing	0.000	**0.053**						(0.775)
	Sitting	0.000	**0.119**						(1.061)
	Lying	**0.348**							(2.480)

TABLE 7.17 The results of the one way analysis of variance (significance) on pressures produced by each bandage

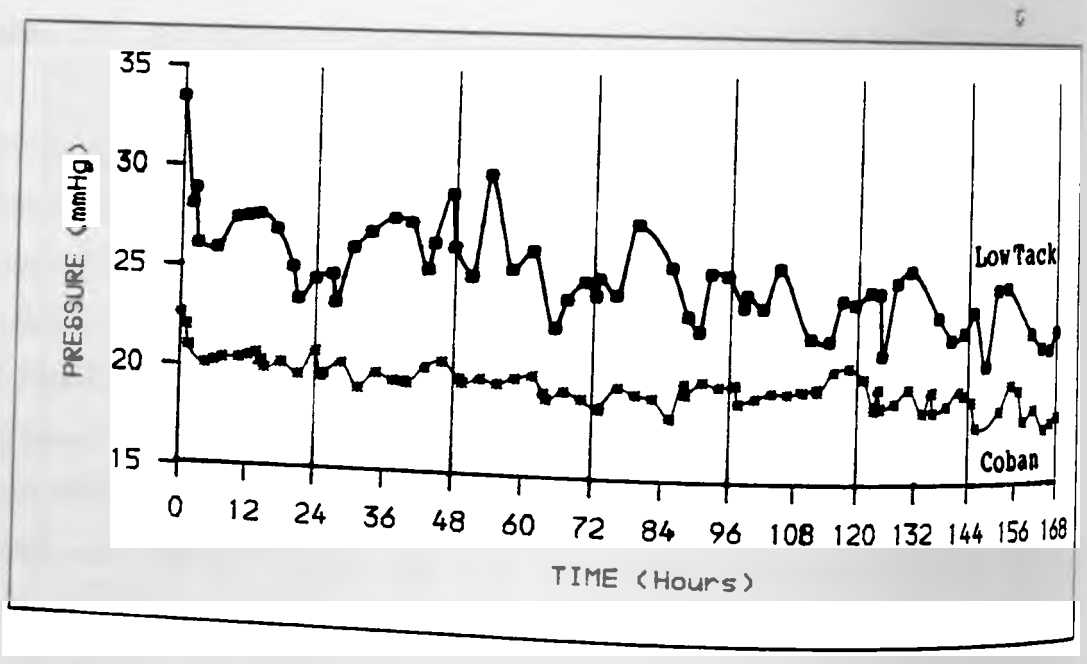


Figure 7.16 The variations in pressure were different for each bandage

variations for all the five bandages. This variations were in most cases asymmetrical bearing no relation to periods of sleep or the time of day, and were different for each bandage and posture. Figure 7.16 illustrates the difference in daily variation, showing the irregular peaks and troughs, for the Coban Wrap and Low Tack bandages.

(c) The Magnitude of Average Daily Pressure

The average daily magnitude and standard deviation of pressures at the gaiter for the five bandages with the subject in three postures are shown in table 7.18. The average pressures during the first day were considered over two shorter periods of six hours and a further period of twelve hours to provide a better understanding of the initial changes in magnitude of the pressures.

Bandage	Post	0-6hr	6-12hr	12-24hr	Day2	Day3	Day4	Day5	Day6	Day7
Coban Wrap	Std	21(1)	20(0)	20(1)	20(0)	19(1)	19(1)	20(1)	19(1)	19(1)
	Sit	18(3)	15(0)	17(1)	17(1)	16(1)	16(1)	16(1)	16(1)	15(1)
	Lie	19(1)	17(1)	19(1)	18(1)	17(1)	17(1)	17(1)	16(1)	16(1)
Elastocrêpe	Std	12(1)	11(1)	8(2)	10(1)	10(2)	10(1)	11(2)	9(1)	11(2)
	Sit	12(2)	11(2)	6(2)	8(3)	8(4)	8(3)	8(2)	8(3)	7(4)
	Lie	19(9)	9(2)	11(4)	8(4)	10(5)	5(3)	4(3)	8(5)	5(3)
Low Tack	Std	27(5)	22(2)	19(1)	18(1)	17(2)	18(1)	17(1)	17(1)	17(1)
	Sit	20(3)	15(2)	13(1)	13(2)	13(1)	13(1)	13(1)	13(1)	13(1)
	Lie	19(4)	15(3)	13(1)	13(1)	12(1)	12(1)	12(1)	12(1)	13(2)
Lestreflex	Std	29(3)	27(1)	26(2)	26(2)	25(2)	25(2)	24(1)	24(2)	23(1)
	Sit	25(3)	22(1)	22(3)	23(2)	20(2)	19(2)	19(3)	18(3)	17(2)
	Lie	22(4)	18(2)	19(2)	19(2)	17(2)	17(2)	17(2)	17(1)	17(1)
Granuflex	Std	40(2)	36(4)	35(1)	34(1)	34(1)	35(1)	34(1)	34(1)	33(1)
	Sit	30(2)	28(2)	27(1)	26(1)	25(1)	25(1)	25(1)	26(1)	26(1)
	Lie	29(3)	27(2)	28(1)	27(2)	26(2)	26(2)	27(2)	26(2)	28(4)

TABLE 7.18 Average daily pressure and standard deviations by each bandage

The magnitude of pressures produced by each of the five bandages was different. The lowest pressures were produced by the Elastocrêpe bandage and the highest pressures by the Granuflex bandage. The standard deviations of the average pressures generated by the Coban Wrap bandage were considerable lower than the other bandages, while the Elastocrêpe bandage produced pressures with high standard deviations.

Bandage	Posture	Range of average pressures at gaiter (mmHg)	Estimated class of bandage
Coban	Standing	19 - 21	3c
	Sitting	15 - 18	3b
	Lying	16 - 19	3b
Elastocrêpe	Standing	8 - 12	2(3a)
	Sitting	6 - 12	2(3a)
	Lying	5 - 19	2(3a)
Low Tack	Standing	17 - 27	3c
	Sitting	13 - 20	3b
	Lying	12 - 19	3b
Lestreflex	Standing	23 - 29	3c(3d)
	Sitting	17 - 25	3c
	Lying	17 - 22	3c
Granuflex	Standing	33 - 40	3d
	Sitting	25 - 30	3c(3d)
	Lying	26 - 29	3c(3d)

TABLE 7.19 The estimated class for each bandage

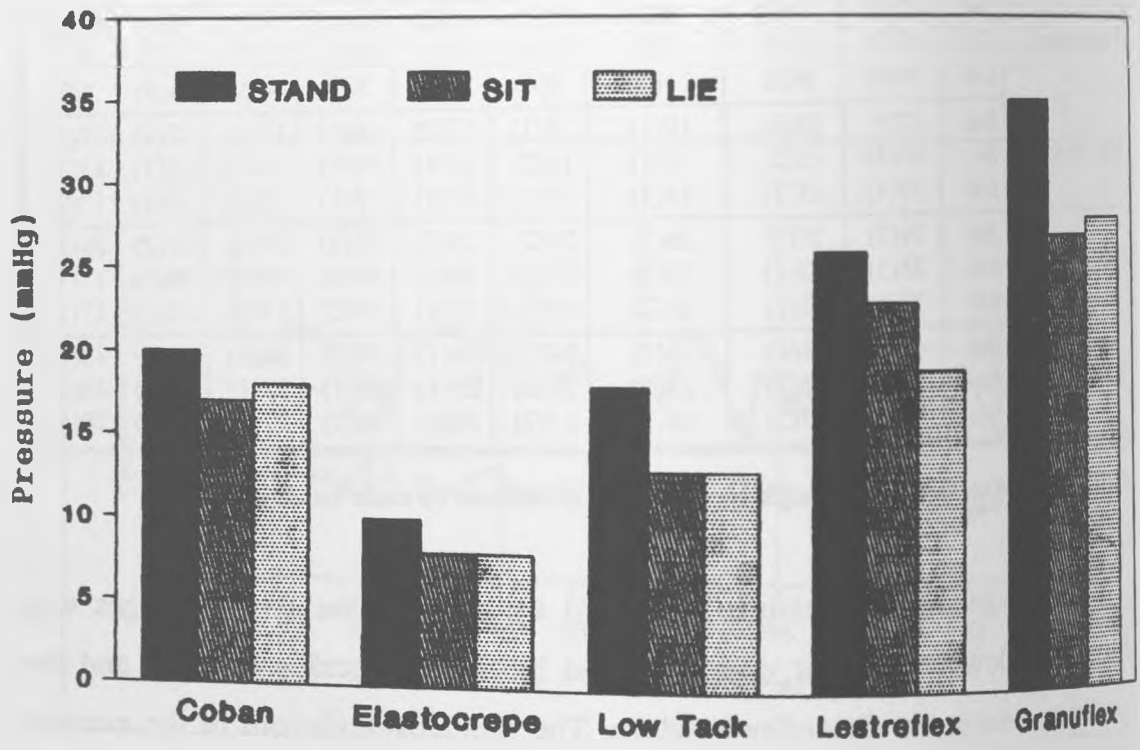


Figure 7.17 Influence of posture on the average pressures produced by each bandage (At day-2)

Bandages are normally classified according the magnitude of compression they generate at the ankle. In this trial pressures at the gaiter were used to estimate the class of the bandages based on the argument developed in Section 7.6.2c. The range of average pressure generated by each bandage at the gaiter and the corresponding estimated classification are illustrated in table 7.19.

(d) The Influence of Posture

Pressures generated at the gaiter beneath the five bandages varied with posture throughout the seven days. Figure 7.17 demonstrates typical variation in pressure as a result of postural changes for the five bandages.

The Friedman's test indicated that the difference in pressures generated for each posture was highly significant throughout the seven days (Table 7.20). Specific comparison using Nemenyi's test showed that the standing posture consistently produced higher pressures than the sitting or lying postures.

Bandage	Were the average pressures at the gaiter significantly different for each posture? (P-value)	Specific comparisons
Coban	Yes (0.000)	stand > lie > sit
Elastocrêpe	Yes (0.001)	stand > sit > lie
Low Tack	Yes (0.000)	stand > sit > lie
Lestreflex	Yes (0.000)	stand > sit > lie
Granuflex	Yes (0.000)	stand > lie > sit

TABLE 7.20 The difference in pressure generated in each posture

7.7 Discussion

7.7.1 Ambulatory Monitoring of Pressure and Posture

The importance of long term monitoring of pressure beneath bandages and the influence of postural changes on the pressures they generate has been a recurring theme throughout this thesis. In the past the main obstacle to pursuing such long term

measurement has been the technical difficulties of instrumentation. Expertise in long term monitoring of posture or mobility in humans during activities of daily living has been virtually non-existent. The introduction of the novel ambulatory pressure and posture monitoring system has provided an unique means of investigating the long term characteristics of pressure beneath bandages and the influence of posture. The pioneering ambulatory study described in this chapter, not only successfully addressed this issue but also served to confirm the reliability and satisfactory performance of the ambulatory device.

As a consequence of the continuous prolonged monitoring and measurement, the ambulatory device generates large volumes of data. Therefore, appropriate controls were adopted in this investigation to ensure acquisition of useful data. In this study only a limited number of pressure sensors were used. It allowed the tests to focus on important factors such as the magnitude and time course of pressure generated by the bandages. Additionally, the benefits of using fewer pressure sensors include more efficient use of data logger facilities such as memory capacity and battery power. Also, as previously mentioned in Section 5.5.1, the use of an excessive number of pressure sensors might distort the interface and result in ambiguous data.

The controlled standardised posture at three hourly intervals provided a convenient pressure window. This control was useful for containing the volume of relevant data and also for isolating the standardised postures. The standardised postures function as a convenient base upon which broad inter-bandage and inter-subject comparisons could be readily made. The earlier version of the ambulatory device used in this study relied on a strain-gauged goniometer to identify posture which was not capable of categorically differentiating between standing and lying. Thus, the pressure windows with the standardised postures were also a technical requirement and provided a check on posture.

As this study was the first of its kind, it was necessary that healthy volunteer subjects were used. The consequences of placing pressure sensors beneath compression bandages on the skin for prolonged periods had to be fully understood prior to testing on leg ulcer patients with fragile skin. The small piece of absorbent material place beneath the sensor functioned well in keeping the skin supple and free from pressure sores. The use of healthy subjects with non oedematous legs may not

typify possible sub-bandage pressure variations resulting from oedema in the leg of the ulcer patients. Further, the level of activity and therefore the influence of ambulation on sub-bandage pressure between subject and ulcer patients is also expected to differ. Despite these minor limitations the ambulatory study on subjects has yielded a wealth of information on the behaviour of sub-bandage pressures.

7.7.2 The Stand, Sit and Lie Routine

Figure 7.4 illustrates the graphical output from the three posture routine and the corresponding sub-bandage pressure at the gaiter. The difficulty in discriminating standing from the lying is obvious. However, this problem was resolved in the later version of the ambulatory device by use of the activity sensor. It was also possible to record walking as evident at either ends of the graphical output. The impact of walking on sub-bandage pressure is demonstrated in the corresponding graph as rapid fluctuation in pressure. This fluctuation in pressure could be a result of the calf muscle pump action which distends and contracts the enveloping bandage. A more detailed investigation on sub-bandage pressure during walking would require a separate study in the future.

The pressures produced during each stance were relatively consistent as shown in figure 7.4 and table 7.3. Although these controlled postures were necessary in this investigation, attention must be drawn to the fact that they were artificially created and the subjects were instructed to remain still in each posture. In reality, however, wider fluctuations in sub-bandage pressure could be expected, although the average pressure over each five minute period would have still been of the same order of magnitude. In venous ulcer patients the additional influence of oedema might have been reflected in the sub-bandage pressures. Finally, the standard deviations in pressure within each posture (over the five minutes stance) were smaller than the resolution of the measuring device and therefore deemed not significant.

7.7.3 Trial One

This section of the study focused on the pressure characteristics of a single bandage, the Granuflex, at the mid-gaiter using a single sensor. As a further control, all bandages in the entire study were applied by the same physiotherapist to eliminate

inter bandager variation.

Figure 7.5 is a typical graph of average pressures and highlights the time course and magnitude of pressure at the gaiter beneath the bandage for each posture. Contrary to previous speculation using other bandages (Raj et al., 1980; Tennant et al., 1988) the rapid drop in pressure ceases after the initial six hours as illustrated in figure 7.6. For the remaining duration of the test, although the pressure continued to drop in the majority of cases, the rate of drop is smaller than 0.067kPa/h (0.05 mmHg/h) as shown in table 7.4. Frequently, this rate of drop in pressure approached zero and occasionally there were small increasing trends. However, this behaviour may be unique to the Granuflex bandage. A comparison of several bandages is discussed in trial-3. This finding has an important consequence for the long term use of compression bandages. It provides reason to believe that bandages use for periods longer than six hours may have to be applied at a pressure higher than the recommended to counteract the initial rapid drop and to ensure that it still exerts beneficial pressures throughout the duration of use.

An examination of the magnitude of pressures for each subject and posture (Table 7.6) indicates that the differences in daily averages were very marginal, particularly after the first day. The one way analysis of variance of average pressures was used to determine the period at which the pressure became independent of time as shown in table 7.5. For the majority of subjects and postures, time ceased to be a significant factor after the second day. This substantiates the earlier observation that the drop in pressure is only significant initially (0-6h) during which period the bulk of the estimated pressure drop occurs (Table 7.4).

The pressures produced on subject-5 in the standing and sitting postures, however, remain significant up to the fourth day. Also the initial sub-bandage pressures on this subject in the standing and sitting postures were noticeably higher than the rest. Perhaps, there may be a trade off between the higher initial pressures and the longer duration over which the difference in average pressure remains significant. This is an investigation worth pursuing as a future exercise.

A unique finding emerged upon amplifying the scale of the graphs. Superimposed on the general decreasing trend there was a daily variation in the sub-bandage pressures as shown in figure 7.7. Such a variation was present for all the

subjects in the three postures. However, the daily variation was not always clear as shown in figure 7.8. Oedema in venous ulcer patients has been thought to wax and wane through a daily cycle particularly relating to periods before and after sleep. In normal subjects the interstitial fluid may behave similarly and could account for the daily variation in sub-bandage pressure. Attempts were made to correlate the periods of sleep with the variation in pressure for each of the subjects. Although an obvious link could be established in some subjects it could not be confirmed for all and this disparity is illustrated in figures 7.7 and 7.8. In figure 7.7 the daily troughs in the graph for subject-1 coincides with the periods of sleep but a more irregular sequence is seen for subject-4 in figure 7.8. However, it is likely that such a daily variation linked to periods of sleep may still exist because the periods of sleep in this investigation were regularly interrupted by the subject performing a standardised posture routine. This is supported by the fact that in many instances the troughs of the graphs occur in the middle of the period of sleep. An investigation with uninterrupted periods of sleep would help in confirming this relationship.

The importance of the magnitude of pressures generated by a compression bandage has been previously established in Chapter Two. Table 7.6 summarises the average pressures and corresponding standard deviations. The pressures obtained for the first four subjects were of the same order of magnitude but were higher for the fifth. This is most likely due to a variation in the application. Raj et al. (1980) have shown that such variations occur despite the fact that a single bandager was used throughout the study.

In order to translate the magnitude of pressure generated by the bandage at the gaiter to the widely used classification of bandages based on ankle pressures, a simple linear extrapolation was used. This projection was based on the fact that calf pressures ought to be 50% of that at the ankle (Dale, 1984) and assumed a linear graduation. The BS 6612 (1985) states that pressures at the calf should not exceed 70% of that at the ankle and therefore by adopting the 50% limit both conditions were satisfied.

The estimated classification of the Granuflex bandage was almost consistently class 3d which is an extra high performance bandage. In contrast the estimated classification of this bandage from the short term non-ambulatory study, described

in chapter 5, was class 3c which makes it a high compression bandage. This discrepancy in the range of average pressures and class raises the question of the influence of ambulation on interface pressure. The idea that the performance of a compression bandage is enhanced by ambulation has in the past received much support (Georgiev, 1985; Christopoulos et al., 1987; Keeley et al., 1962). Ideally, future bandage classifications might be based on ambulatory average pressures rather than static pressures.

The influence of posture on sub-bandage pressure has been frequently raised (Ruckley, 1992; Burnand et al., 1985) but never conclusively demonstrated over the entire duration of use. Figure 7.10 illustrates the influence of posture on average pressures over seven days. The Friedman's test was used to show that for all the subjects, the pressures differed significantly for each posture throughout the seven day duration. The Nemenyi's test confirmed that the sub-bandage pressure during standing was categorically higher than sitting or lying. Perhaps the pooling effect of interstitial fluids to the leg during standing increases the interface pressure within the enveloping bandage. Another possible explanation could be the fact that muscular activity during standing increases the calf diameter and therefore produces higher interface pressures.

The fact remains that if postural changes influence sub-bandage pressure then almost certainly ambulation would as well. This is supported by the rapid fluctuation in sub-bandage pressure observed during walking in figure 7.4 (Section 7.6.1). Van der Molen et al. (1979) and Keeley et al. (1962) have suggested that compression bandages coupled with ambulation were efficacious in controlling oedema and improving venous return because they improved the efficiency of the muscle pump. This, however, can only be verified by measuring venous flow in conjunction with ambulatory monitoring of sub-bandage pressure. For the moment, it is clear that any observation on sub-bandage pressure must specify the subject's posture.

7.7.4 Trial Two

This section of the study was similar to that of trial-1 but two pressure sensors were used. It enabled the investigation of the pressure characteristics of the Granuflex at both the mid-gaiter and ankle. More importantly it provided a means of examining

the pressure gradient generated by the bandage between the two sites.

Typical pressures illustrated in figure 7.11 show that the time course of average pressures at both the gaiter and ankle followed a similar pattern. The overall pattern at both sites over the seven day period was one of decreasing trend with a similar drop in pressures (Table 7.9).

Like the findings in trial-1, the pressures at the gaiter and ankle dropped rapidly within the first six hours followed by a very gradual rate of drop over the remaining period. With the exception of subject-1 the pressures at the gaiter ceased to be significantly different after the second day as shown in figure 7.11a. Pressures at the ankle, however, showed significant variation for a longer period (Figure 7.11b). Interestingly, the initial pressures at the gaiter and ankle for subject-1 were noticeably higher than that of the other subjects. This supports the argument discussed earlier that there may be a trade off between the higher initial pressures and the longer duration over which the difference in average pressures remain significant. Perhaps, there may be an optimum initial pressure that would ensure both sufficient magnitude and minimal variation after the initial six hours.

Superimposed on the decreasing trend there were daily variations in average pressures at both the ankle and gaiter (Figure 7.12). However, these variations in pressures at the gaiter and ankle were not identical although occasional similarities were observed. The difference in variation of pressure at the two sites was expected as the underlying muscles and surface contours differ at these sites. As already suggested, a more controlled investigation is required to compare the daily variations and its link with periods of sleep.

With the exception of subject-1 in the standing posture, the pressures within each site were of the same order of magnitude as illustrated in table 7.12. The pressures at the gaiter produced in this trial were generally comparable to those produced in trial one. The higher pressures on subject-1 were probably due to a variation in the bandage application as pointed out earlier. The class of bandage based on the magnitude of ankle pressures in accordance with the SDPT1-test were predominantly class 3d although on occasions it drifted to class 3c. This result is in agreement with the previous classification of the Granuflex bandage in trial one.

The influence of posture on the pressures generated at both gaiter and ankle was significant throughout the seven days as shown in tables 7.14 a&b. Standing postures produced greater pressures than sitting or lying at both the gaiter and ankle. However, the difference in sub-bandage pressure between sitting and lying was marginal. If hydrostatic forces were an important factor in the differences in sub-bandage pressures then sitting would produce greater pressure than lying. The lack of difference tends to suggest that the relaxed state of the underlying muscles could be the predominant factor. However, this may be different with ulcer patients who suffer from oedema.

The generation of a pressure gradient, the pressure being highest at the ankle and decreasing proximally, is possibly the most important requirement in compression therapy. Failure to achieve the correct gradient would cause more harm than no treatment at all. The main purpose of using two sensors in this trial was to examine the gradient between the ankle and gaiter. The pressure gradient was examined at each three hourly measurement and the results are shown in table 7.15. For the first three subjects the pressure gradients were successfully achieved with the ankle pressures being greater than gaiter pressures throughout. In the fourth subject the desired pressure gradient was only produced when the subject was standing. In this particular case a suitable gradient was never achieved for the sitting and lying postures perhaps due to improper application of the bandage. Pressures in the sitting and lying postures tend to be lower than that of the standing posture. The difference in pressures between any two sites during sitting and lying also tend to be disproportionately smaller. This smaller difference in pressure between sites increases the likelihood of the gradient not being achieved. Therefore, it is essential that a significant pressure gradient is achieved in the sitting or lying postures to ensure that the gradient would be sustained for all other postures. Perhaps, applying a bandage with the patient in the lying posture would have the added advantage of reduced oedema. Future investigation examining the optimal posture for bandage application would seem worthwhile.

7.7.5 Trial Three

This section of the study was conducted using a single pressure sensor at the gaiter on the same subject to investigate the pressure characteristics of five different types of bandages applied by the same physiotherapist.

Figure 7.15 illustrates the typical time course and magnitude of pressures generated by the five bandages. It illustrates the diverse sequence and ranges of pressure that were produced by the bandages.

All the bandages produced a decreasing trend in average pressures, though to varying degrees. The overall percentage drop in pressure was least for the Coban Wrap and the Granuflex bandages, and greatest for the Low Tack bandage (Table 7.16). The percentage drop for the Elastocrêpe bandage, however, was irregular. The consistent maintenance of pressure by the Coban Wrap and the Granuflex bandages was expected. These cohesive and adhesive bandages are capable of holding each overlapping layer firmly together unlike the Low Tack which is only a semi-adhesive bandage. The Elastocrêpe on the other hand is only a support bandage, although it has been regularly used in the past as a compression bandage.

With the exception of the Elastocrêpe bandage the drop in pressure occurred at two rates, an initial rapid drop frequently within the first six hours followed by a very gradual drop as shown in table 7.16. This initial dramatic drop in pressure may be due to the time dependence of the bandage material and the underlying tissues, the latter related to the displacement of tissue fluids from the leg. The rate of rapid drop was least in the Coban Wrap bandage and greatest in the Low Tack and Lestreflex bandages. This implies that the Coban Wrap bandage is not only better at maintaining overall pressure, as discussed previously, but is also capable of sustaining minimal loses in the initial phase. The Elastocrêpe bandage showed no significant difference in the rate of drop for the standing posture but had an initial increasing trend in the sitting posture.

After the first day the average pressures for the five bandages progressively became less dependant on time. Table 7.17 illustrates the time at which the difference in pressure ceased to be significant, the level of significance and the pooled standard deviation. The pressures produced by the Elastocrêpe bandage in the standing and sitting postures ceased to vary with time within the first day. The pooled standard

deviations of the average pressures for this bandage were exceptionally high, thus the variation in pressure was insensitive to time. For the lying posture, the average pressures varied significantly for the first three days despite the high standard deviation. This could be accounted for by the influence of the first two very high readings (At time equals zero and three hours, Appendix L) which may have been caused by the weight of the subject's leg resting on the pressure sensor. If these two readings were discounted then the variation in average pressures produced by this bandage in all three postures, would have been insentive to time within the first day in view of the high pooled standard deviations.

On the other hand, the average pressures produced by the Coban Wrap bandage were highly sensitive to time, despite the very small differences over the seven days. This is because the standard deviations of average pressures were also very small, thus making the time course of pressure highly sensitive to even small variations. This implies that if the permissable standard deviations were set higher at ±1 mmHg (which is the resolution of the measurement) then the average pressures produced by this bandage would be independent of time within the first day.

The averages pressures generated by the Granuflex, Low-Tack and Lestreflex bandages had broadly the same order of pooled standard deviations. The pressures produced by the Granuflex ceased to vary with time after the first day, while the pressures produced by the latter two bandages were significantly time dependent up to the third day. Therefore, it appears that the time dependence of pressures generated by bandages is influenced by the type of bandage.

Daily variations for all the five bandages were superimposed on the overall decreasing trends in pressure. These variations were markedly different for each bandage, although occasional similarities were observed for the different postures with a single bandage. Figure 7.16 illustrates the difference in variation between two bandages for the standing posture. These daily variations were asymmetrical and bore no obvious relation to periods of sleep or the time of day. The amplitude of the variations, though irregular, were more pronounced in the partially and low adhesive bandages than the stronger cohesive bandage. Therefore, if such a variation had a desirable effect on improving venous return then a strong bandage with suppressed amplitude of daily variation might be less useful. Alternatively, it could simply imply

that a stronger bandage is more effective in containing any variation.

As previously discussed, the periods of sleep were disrupted in these tests and it is very likely that a clearer daily variation may emerge if a suitable test protocol designed to examine this effect were used.

The magnitude of the average daily pressures and standard deviations at the gaiter for the five bandages with the subject in three postures are shown in table 7.18. The range of pressures produced varied markedly for each bandage. The Granuflex which is a strongly adhesive bandage produced the highest pressures with a relatively small standard deviations after the first day. Its estimated class was appropriately 3d (Table 7.19), which was been consistent throughout the seven days for the standing posture. The Elastocrêpe bandage produced initial pressures within class 3a, but rapidly dropped to class 2 which was appropriate for a support bandage. Throughout the seven day the standard deviations of average pressures produced by this bandage were relatively high. It is quite certain that this bandage does not generate any elastic compression and the low pressures measured were a result of its bulk presence. This confirms the claim (Thomas, 1990) that the Elastocrêpe bandage is not a compression bandage but merely a support bandage.

The low adhesive Low-Tack and partially adhesive Lestreflex bandages were predominately class 3b and 3c, respectively. The Lestreflex bandage with strips of adhesive material appeared to produce average pressures with a higher standard deviations than the Low-Tack. Therefore, a bandage with an overall low adhesion may produce more stable average pressures than one with strips of adhesive material.

The Coban Wrap bandage produced average pressures with exceptionally low standard deviations, an effect probably due to its strong cohesive nature. The magnitude of pressures generated by this bandage can be deliberately varied during application depending on the nature of protective material beneath, especially at the ankle. In this investigation, no protective material was used and the bandage was applied ensuring that there was no discomfort to the subject. As such the pressures attained were therefore only within that of class 3c for the standing posture and 3b for sitting and lying. The Coban Wrap bandage is not categorised as an elastic bandage and therefore the bandage classifications do not strictly apply. However, a class was estimated for this bandage purely for comparative purposes.

The influence of posture on the pressures generated by all five bandages throughout the seven days was significant (Table 7.20). The standing posture consistently produced the higher pressures and the lower pressures in the sitting and lying postures were only marginal different for most bandages. The influence of posture on sub-bandage pressure has been discussed in depth in Section 7.7.2.

The three trials in this investigation produced remarkably consistent results in relation to the factors examined. The Granuflex bandage used in all three trials, performed comparably throughout the investigation. Similar daily variations in pressures and influence of posture on sub-bandage pressures were also observed in each trial.

The long term characteristics of pressures generated by compression bandages have been, for the first time, investigated in the three trials. The investigation had successfully addressed numerous issues on the functional properties of these bandages. On many occasions it has unveiled new long term characteristics of pressure generated by bandages and also provided confirmation of previous findings. Finally it has highlighted that comprehensive understanding of compression devices is still yet to be achieved and in the process, has left new unanswered questions. The investigation of the long term characteristics of pressure generated by compression bandages on venous ulcer patients, described in the next chapter, attempts to narrow these unanswered questions.

CHAPTER 8

AMBULATORY MONITORING OF SUB-BANDAGE PRESSURE AND POSTURE ON VENOUS ULCER PATIENTS

8.1 Instrumentation

8.2 Materials

8.3 Patient Screening, Selection and Preparation

8.4 Method

8.5 Data Processing

8.6 Results

8.7 Discussion

BANDAGE	COLOUR	WIDTH	CLASS	MANUFACTURER
Granuflex	Brown	100mm	3c	ConvaTec
4-Layer				
Velband	White	100mm	-	Johnson & Johnson
Crépe	Creme	100mm	-	Smith & Nephew
Elset	White	100mm	-	Seton
Coban	Brown	100mm	-	3M

TABLE 8.1 Description of the two bandages tested

8 AMBULATORY MONITORING OF SUB-BANDAGE PRESSURE AND POSTURE ON VENOUS ULCER PATIENTS

The ambulatory study on normal subjects described in the previous chapter was extended to a pilot study on venous ulcer patients in conjunction with the Forth Valley Ulcer Group, Scotland. This pilot study on the data collection and analysis of ambulatory sub-bandage pressure and posture is part of an on going study investigating several aspects of ulcer healing. The characteristics of pressure generated by two types of commonly used compression bandages over a typical seven day duration are being investigated. In addition the study also examines the influence of postural changes during activities of normal daily living on the sub-bandage pressures produced. A preliminary analysis of the pressure and posture measurements of the first three patients is reported in this chapter.

8.1 Instrumentation

The revised ambulatory pressure and posture monitoring system (Version-2) was used for these tests. It consisted of three miniaturised pressure measuring devices, an activity sensor and a data logger. This ambulatory system was specifically designed for long term use on venous ulcer patients. Detailed descriptions of its design, development, operational characteristics and calibration are presented in Chapter Six.

8.2 Materials

The description of the two compression bandages used in this study is summarised in table 8.1. The Four-Layer bandage is not a single bandage but is a system of bandaging comprising four bandages (Blair et al., 1988) each of which is individually described.

8.3 Patient Screening, Selection and Preparation

Patients attending the leg ulcer clinics at the Falkirk General Hospital and the Edinburgh Royal Infirmary were screened for suitability to participate in the study. The screening process was conducted by the nursing staff at these clinics based on the following criteria;

PATIENT	AGE	SEX	OCCUPATION	BANDAGE
1	55	Male	Factory worker	Granuflex
2*	65	Male	Chip-shop owner	Granuflex
3*	65	Male	Chip-shop owner	4-Layer

(* Same patient)

TABLE 8.2 Patient details

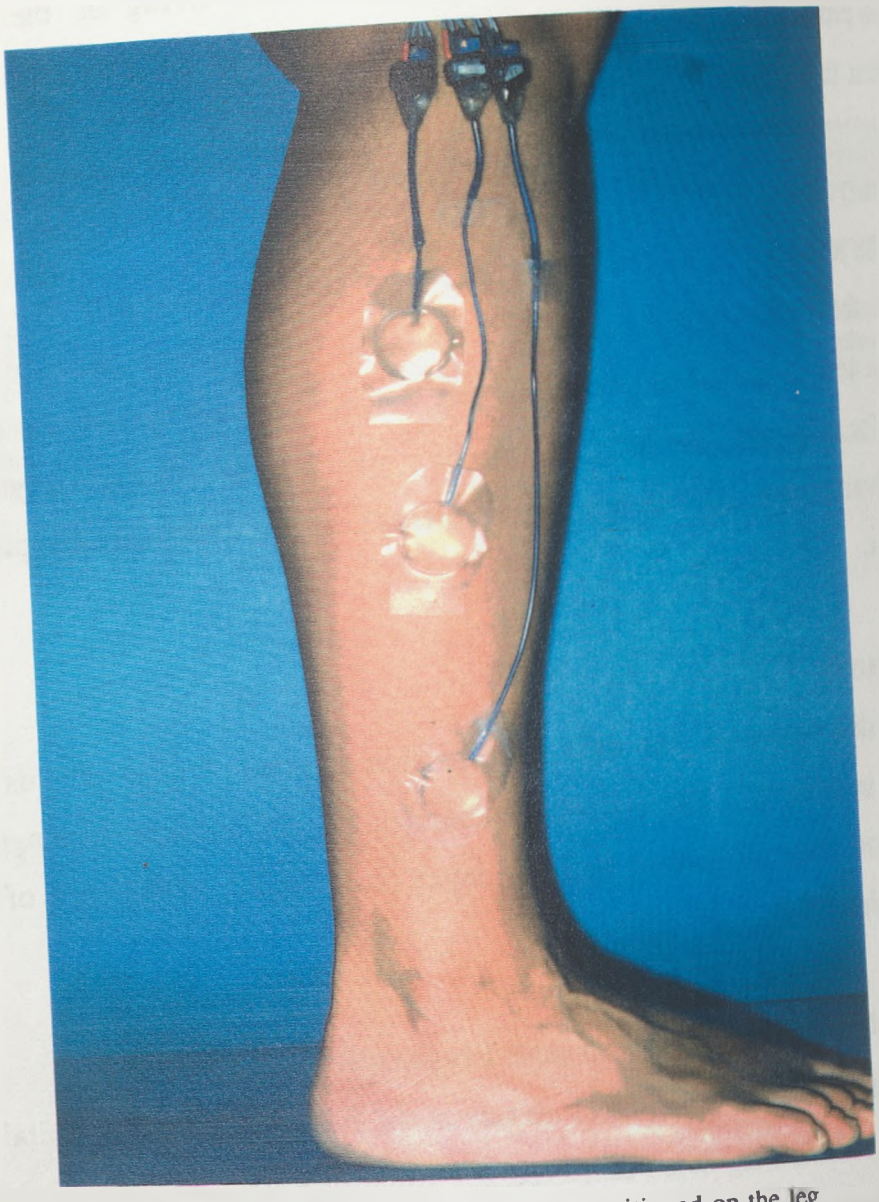


Figure 8.1 Transducer and sensor positioned on the leg

(a) Patient suffered from only venous ulceration.

(b) Patient was free of arterial disorders.

(c) Compression therapy was the prescribed mode of treatment.

(d) The patient was not on medication such as anticoagulants (Warfarin) or related drugs.

(e) Presence of clearly palpable pedis pulse.

(f) Absence of adverse skin reactions or allergies and negative skin patch test.

(g) Patient was mobile and relatively active.

(h) Patient was in sound mental health.

Patients who fulfilled the criteria outlined above were requested to participate and an informed written consent was obtained. These patients were informed in detail of the procedure involved in the seven day ambulatory test, were advised that they had the liberty to withdraw at any stage and were generally reassured. Detailed measurements of their leg, opposite to the patients' preferred sleeping side, were then recorded to enable a well fitting pressure measuring device to be fabricated. Finally, a convenient date for the test was arranged. Details of the three patients who participated in this pilot study and the type of bandage worn are shown in table 8.2.

8.4 Method

Pre-test preparation commenced with the construction of an individual pressure and posture sensing devices. The construction of these devices are described in Chapter Six. The pressure measuring device was tailored such that the three sensors could be sited at the calf, mid-gaiter and ankle of the patient as illustrated in figure 8.1. Similarly the activity sensor was constructed to match the length of the patient's lower limb.

The test procedure began with the pressure transducers being placed just below the knee on the lateral side while the sensors were placed at the three sites on the leg with the patient remaining seated. A piece of absorbent material cut to shape was placed immediately below the transducers, connecting tubes and sensors to absorb sweat and to offer protection against possible tissue damage. Once the devices were in place they were secured to the skin with micropore tape (3M, U.K.). The

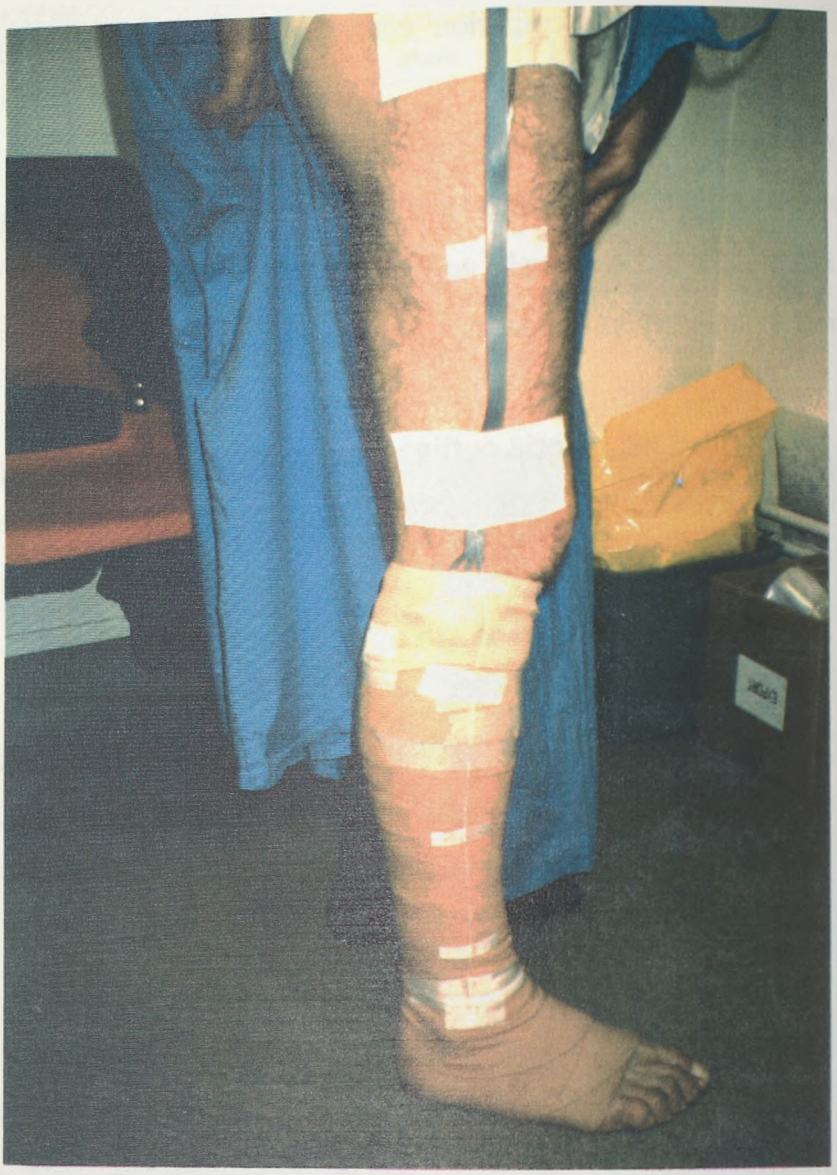


Figure 8.3 Patient with bandage and ambulatory device in place

transducer of the activity sensor was then taped adjacent to the pressure transducers and its tubes were neatly taped along the lateral side of the leg with one end on the thigh and the other at the ankle as illustrated in figure 8.2. At this point it was ensured that the tubes did not hinder comfortable extension and flexion of the leg. The apparatus on the leg now resembled that of the final set up but without the bandage which allowed zero readings to be recorded. Leads from the pressure transducer and the activity sensor were connected to the data logger which was set to sample at 1.67Hz (100 per minute). The zero readings were recorded with the patient standing, sitting, lying, elevating the leg (about 15 degrees) and walking for one minute in each stance, after which the data was down loaded onto an IBM compatible P.C. The data logger was then temporarily disconnected and a nursing sister applied the bandage.

The spiral technique of bandaging was used, starting from the toe and systematically covering the leg and sensors in accordance with the manufacturer's instructions. In the case of the Four-Layer bandaging system, the Velband bandage was applied next to the skin followed by a layer of crêpe, Elset and Coban bandages all applied with the spiral technique as described by Backhouse et al., (1987). The same nurse applied all the bandages in the study.

The bandage was applied to just below the knee and neatly covered the transducers while holding the devices beneath it firmly in place (Figure 8.3).

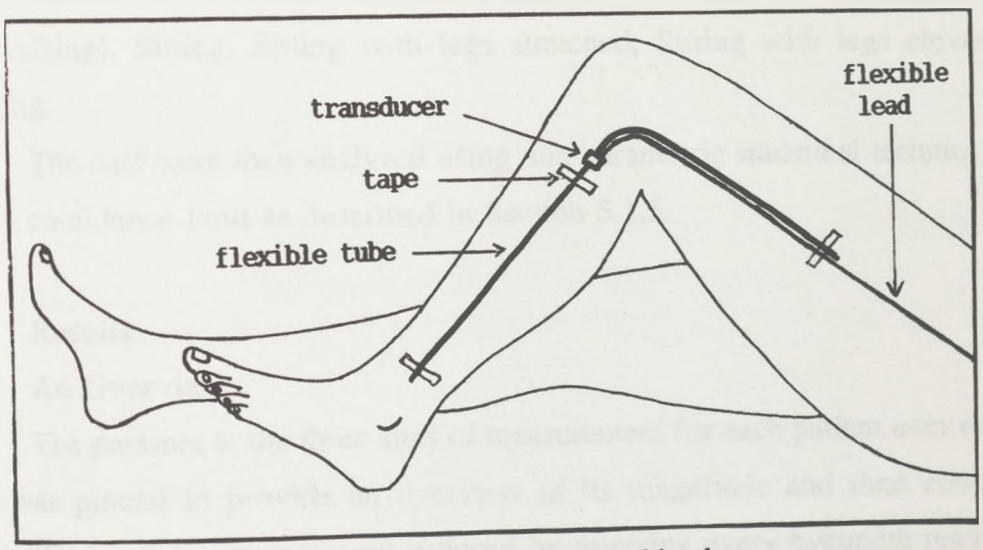


Figure 8.2 Activity sensor taped in place

The devices were now completely concealed and protected by the bandage. The flat ribbon cable from the transducer and activity sensor was neatly taped along the lateral side of the limb passing underneath the under clothing to a pouch strapped around the waist. The data logger was then set to sample at a low frequency of 0.034Hz (2 per minute) and was neatly tucked in the pouch. The patient now resumed normal daily activities but was requested not to wet the device or the bandage during body washing and to keep a simple diary of major activities.

The patient revisited the clinic four days later for the data logger to be down loaded onto a P.C. and for the batteries to be renewed. On the seventh day the data logger was down loaded again, the bandage removed and a final set of zero readings were recorded for each posture as previously described. Finally, the devices were removed and patient's leg was checked for any adverse skin reactions.

8.5 Data Processing

Data already down loaded from the logger were converted to the ASCII format and transferred to the mainframe as described in Chapter Seven. The zero readings, calibration factors and blocks relating to periods of sleep were then fed into a Pascal program (Posture1.pas, Appendix M1). The program processed the pressure data based on the activity sensor output into separate files. Each file contained pressure data converted to units of millimetres of mercury for each posture.

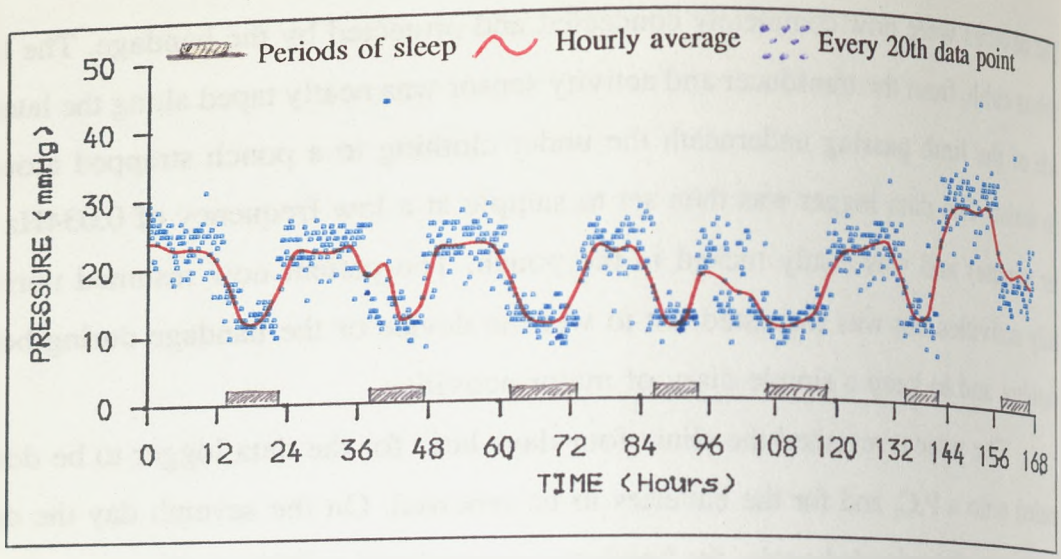
The five main postures considered in the data analysis were; Upright (standing and walking), Sitting, Sitting with legs stretched, Sitting with legs elevated and Sleeping.

The data were then analyzed using non parametric statistical techniques with a 95% confidence limit as described in Section 5.1.5.

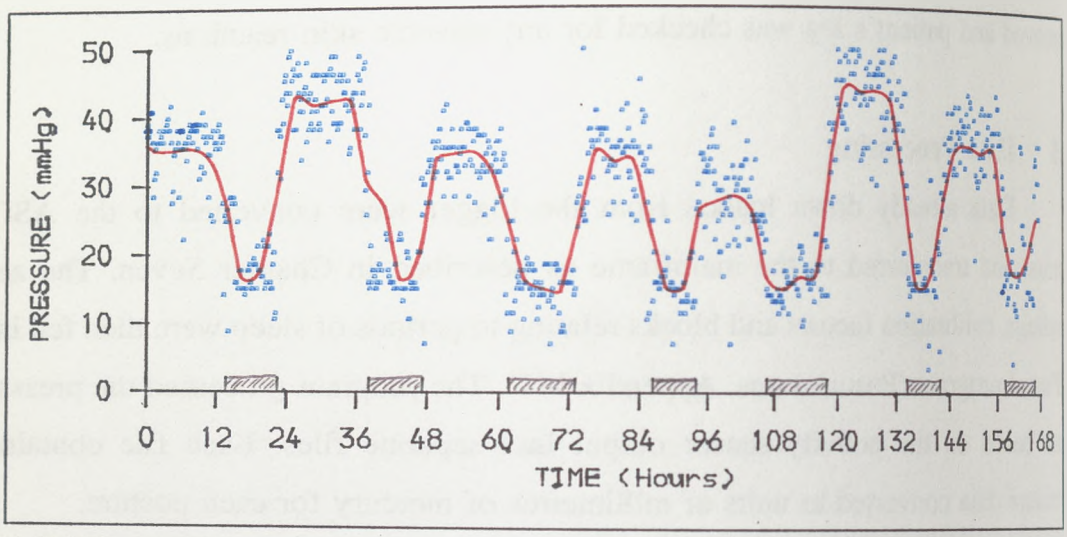
8.6 Results

8.6.1 An Overview

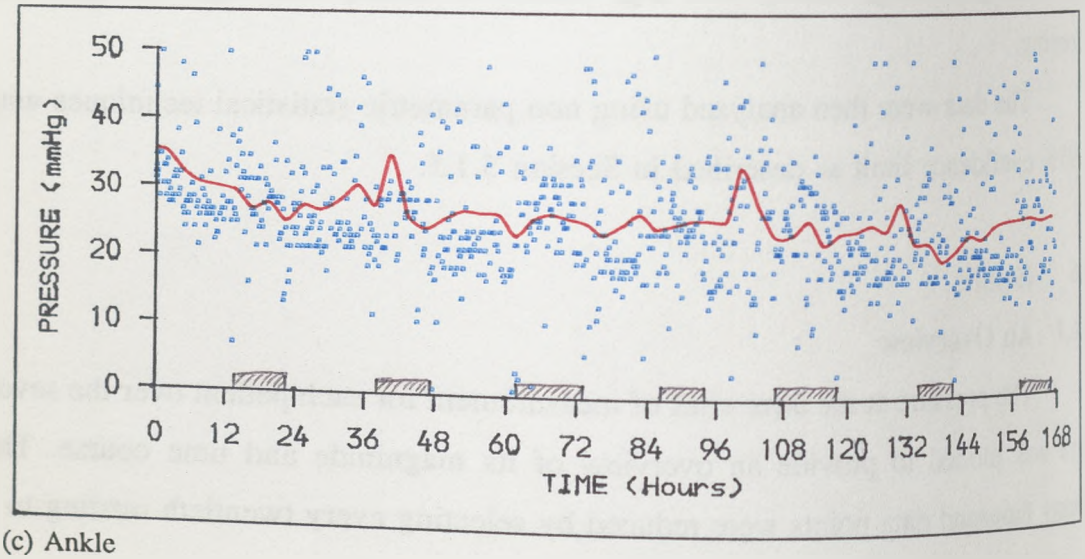
The pressure at the three sites of measurement for each patient over the seven days was plotted to provide an overview of its magnitude and time course. The twenty thousand data points were reduced by selecting every twentieth reading to



(a) Calf



(b) Gaiter



(c) Ankle

Figure 8.4 Overview of pressures for patient-2 (Granuflex Bandage)

enable an overall picture to be developed. Despite the reduction, the distribution and spread of pressure data were adequately represented as shown in figure 8.4. A second graph of hourly averages was superimposed to further illustrate the pressure profile over the seven days. (The complete set of graphs for the three patients are illustrated in Appendix N).

Figure 8.4 typically illustrates the daily variation as seen at the calf and gaiter sites with the troughs of the curves coinciding with the periods of sleep. However, these variations are not always present as illustrated by the graph of pressures at the ankle.

The distribution of pressure varied for each patient and site of measurement. As seen in figure 8.4 the pressures measured at the ankle have a greater spread than that at the calf or gaiter.

Figure 8.5 illustrates the pressure profile over a single daily cycle. The maintenance of pressure, its distribution and drop during the period of sleep are clearly shown.

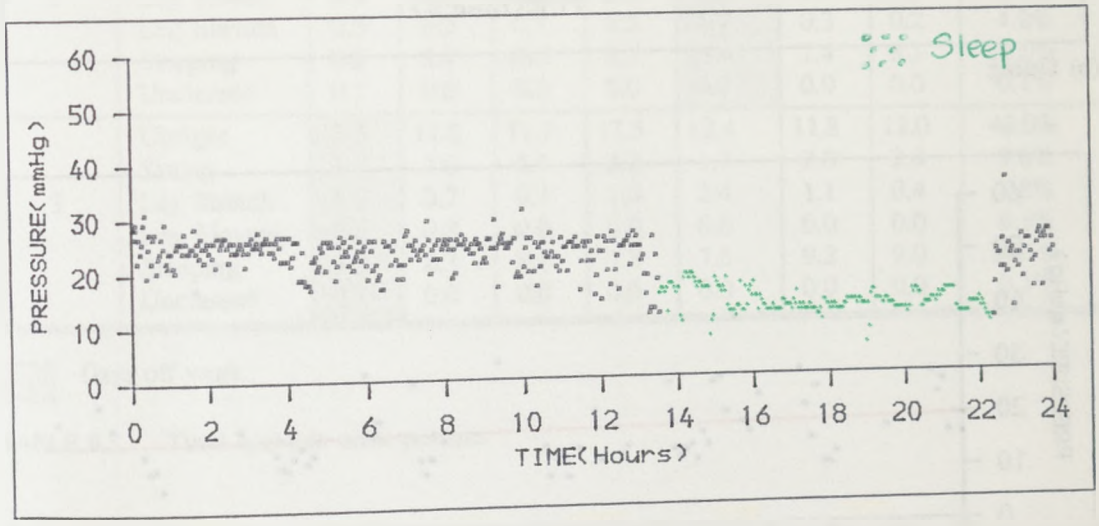
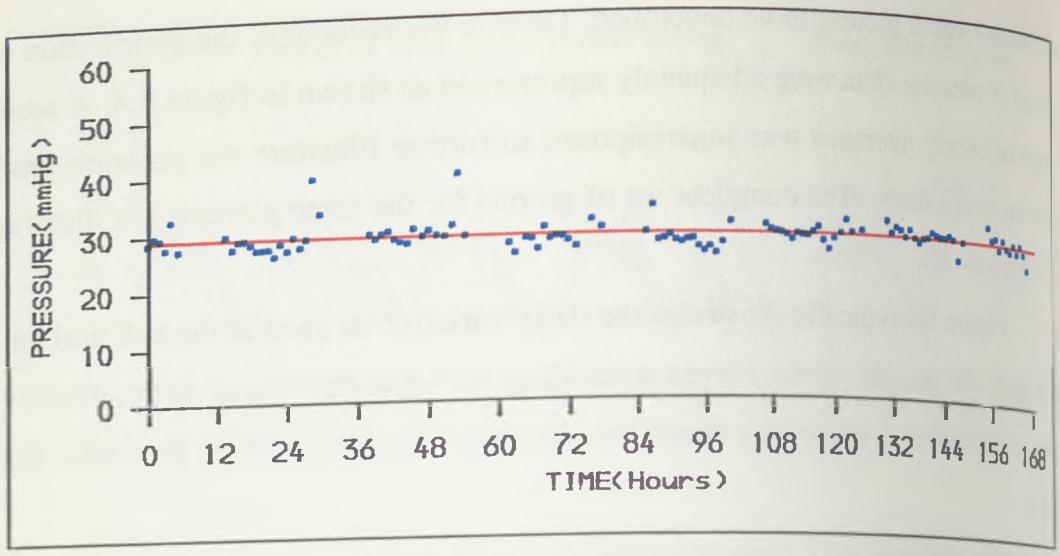
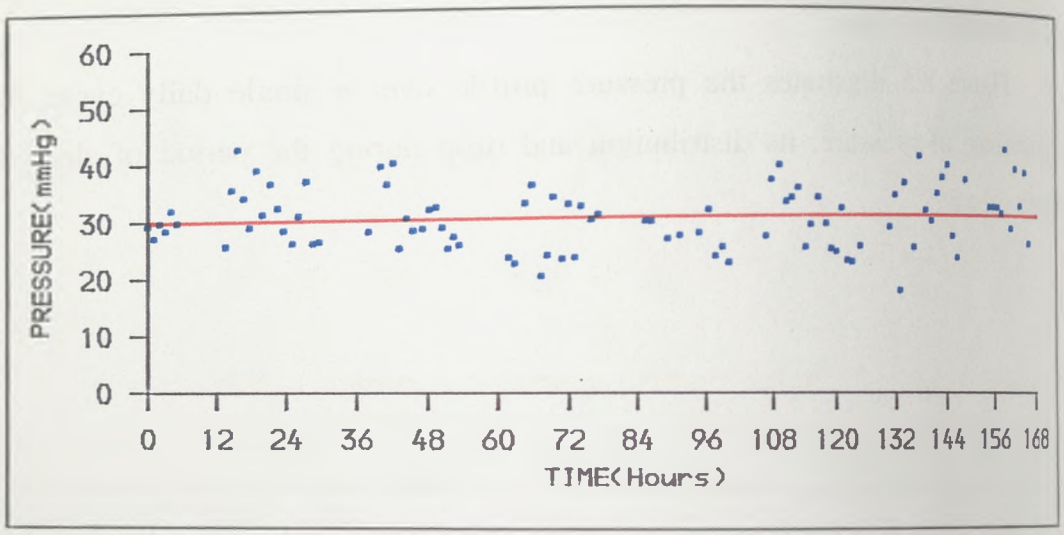


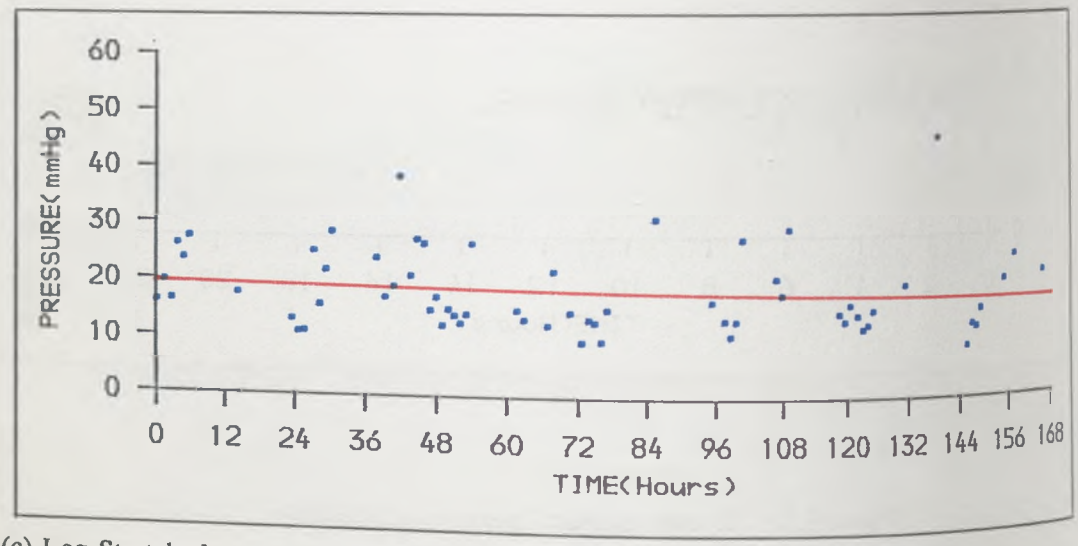
Figure 8.5 Overall pressure during a typical day



(a) Upright



(b) Sitting



(c) Leg Stretched

Figure 8.6 Hourly average pressures and regression line (Patient-1, Granuflex bandage, ankle)

8.6.2 Postural Changes

Specific analysis of the pressure required identification of postures within the activities of normal daily living. For each patient five main postures and the time spent in each posture were identified as illustrated in Table 8.3.

The time spent in the upright posture was noticeably higher for all three patients. On average the patients were in the upright posture for about 46% of the time. The average duration of sleep varied from 27% to 34%. Little or no time was spent with the leg in an elevated position, a requirement for the treatment of venous ulcers. For this reason the pressure data collected during periods of leg elevation were insufficient to perform detailed analysis. Table 8.3 also indicates that the patients spent a greater time sitting with the legs stretched rather than elevated.

Patient	Posture	TIME SPENT IN EACH POSTURE (Hours)							Overall Percentage
		Day1	Day2	Day3	Day4	Day5	Day6	Day7	
1	Upright	10.5	7.5	6.1	10.5	12.8	13.1	11.7	43.4%
	Sitting	3.4	2.4	3.2	1.9	1.9	2.1	1.7	10.0%
	Leg Stretch	3.0	5.0	5.9	4.0	3.0	3.7	2.6	16.3%
	Leg Elevate	0.2	1.6	1.4	0.0	0.1	0.2	0.3	2.3%
	Sleeping	6.7	7.4	7.3	7.6	6.0	4.8	5.8	27.4%
	Unclassed	0.2	0.1	0.1	0.0	0.2	0.1	0.3	0.6%
2	Upright	12.4	12.3	10.9	10.9	4.8	13.1	12.2	45.7%
	Sitting	1.9	2.0	1.9	3.1	2.0	2.3	2.4	9.3%
	Leg Stretch	0.3	0.6	0.1	0.8	1.1	0.9	0.8	2.7%
	Leg Elevate	0.5	0.2	0.7	0.5	4.7	0.3	0.2	4.2%
	Sleeping	8.8	8.9	10.5	8.7	11.4	7.4	8.1	38.0%
	Unclassed	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.1%
3	Upright	7.5	11.6	11.7	13.5	12.4	11.8	12.0	48.0%
	Sitting	1.7	2.6	3.5	2.2	1.7	2.0	2.4	9.6%
	Leg Stretch	6.8	0.7	0.7	1.0	2.4	1.1	0.4	7.8%
	Leg Elevate	0.0	0.8	0.0	0.0	0.0	0.0	0.0	0.5%
	Sleeping	7.9	8.3	8.1	7.3	7.5	9.2	9.0	34.1%
	Unclassed	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.1%

▒ Days off work

TABLE 8.3 Time spent in each posture

8.6.3 The Time Course of Pressure

The time course of pressure generated over seven days varied with each patient, posture and site. Figure 8.6 illustrates the distribution of hourly average

PATIENT	SITE	POSTURE	Estimated average change in pressure over seven days	Rate of change in pressure over seven days (mmHg/hr)
1	CALF	Upright	+ 34 %	+ 0.0309
		Sitting	+ 7 %	+ 0.0076
		Leg Stretch	- 52 %	- 0.0276
		Sleeping	+ 39 %	+ 0.0204
	GAITER	Upright	- 27 %	- 0.0455
		Sitting	- 25 %	- 0.0457
		Leg Stretch	- 60 %	- 0.0691
		Sleeping	- 38 %	- 0.0576
	ANKLE	Upright	+ 2 %	+ 0.0030
		Sitting	+ 3 %	+ 0.0044
		Leg Stretch	- 37 %	- 0.0486
		Sleeping	- 11 %	- 0.0211
2	CALF	Upright	+ 18 %	+ 0.0251
		Sitting	+ 9 %	+ 0.0115
		Leg Stretch	+ 22 %	+ 0.0192
		Sleeping	+ 28 %	+ 0.0215
	GAITER	Upright	- 1 %	- 0.0011
		Sitting	- 7 %	- 0.0155
		Leg Stretch	+ 1 %	+ 0.0009
		Sleeping	- 11 %	- 0.0120
	ANKLE	Upright	- 30 %	- 0.0530
		Sitting	- 12 %	- 0.0319
		Leg Stretch	+ 20 %	+ 0.0277
		Sleeping	- 19 %	- 0.0306
3	CALF	Upright	- 22 %	- 0.0298
		Sitting	- 17 %	- 0.0275
		Leg Stretch	+ 7 %	+ 0.0059
		Sleeping	- 19 %	- 0.0162
	GAITER	Upright	- 2 %	- 0.0025
		Sitting	+ 2 %	+ 0.0037
		Leg Stretch	+ 80 %	+ 0.0558
		Sleeping	- 6 %	- 0.0037
	ANKLE	Upright	+ 13 %	+ 0.0201
		Sitting	+ 11 %	+ 0.0197
		Leg Stretch	+ 83 %	+ 0.0659
		Sleeping	- 1 %	- 0.0010

TABLE 8.4 Summary of percentage change in pressure and overall trend

pressures and the corresponding least squares linear regression of pressure for three postures. The linear regression showed that the underlying trend in pressure could increase or decrease over the seven days. Further, the spread of pressure data was smaller in the upright posture than in sitting or sitting with legs stretched postures.

The average pressures on the first and seventh days were used to estimate the percentage change over the duration and the linear regression was used to calculate the rate of change. A summary showing the estimated percentage change and rate of change in pressure is illustrated in table 8.4 for each site, posture and patient. There were no obvious patterns in the increasing or decreasing trends. The estimated percentage change in pressure over the seven days varied from a 52% drop to an 83% rise.

A one way analysis of variance of average pressures for each site, posture and patient was carried out to further examine the time course of pressure. In the majority of cases the average pressures were not significantly influenced by time as illustrated in tables 8.5 (a,b & c). Levels of significance and the corresponding pooled standard deviation are also illustrated. This independence of time is despite the generally high pooled standard deviation and reflects the variable nature of the pressures generated.

Patient	Posture	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Pooled St Dev
1	Upright	0.000	0.000	0.000	0.000	0.000	0.000	*	5.421
	Sitting	0.000	0.000	0.000	0.000	0.000	0.030	*	6.319
	Leg Stretch	0.000	0.000	0.000	0.000	0.000	0.000	*	4.042
	Sleeping	0.000	0.000	0.000	0.000	0.000	0.000	*	2.623
2	Upright	0.000	0.000	0.000	0.000	0.000	0.000	*	3.327
	Sitting	0.000	0.000	0.000	0.000	0.000	0.000	*	4.359
	Leg Stretch	0.000	0.000	0.000	0.000	0.000	0.000	*	2.554
	Sleeping	0.000	0.000	0.000	0.000	0.000	0.000	*	6.664
3	Upright	0.000	0.000	0.000	0.000	0.000	0.000	*	5.629
	Sitting	0.000	0.000	0.000	0.000	0.000	0.000	*	5.401
	Leg Stretch	0.000	0.000	0.000	0.000	0.000	0.000	*	3.329
	Sleeping	0.000	0.000	0.000	0.000	0.000	0.000	*	6.686

TABLE 8.5 (a) One way analysis of variance of pressures at the CALF (significance)

Patient	Posture	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Pooled St Dev
1	Upright	0.000	0.000	0.000	0.000	0.000	0.000	*	5.435
	Sitting	0.000	0.000	0.000	0.000	0.000	**0.992**		6.302
	Leg Stretch	0.000	0.000	0.000	0.000	0.000	0.106	*	3.202
	Sleeping	0.000	0.000	0.000	0.000	0.000	0.000	*	2.817
2	Upright	0.000	0.000	0.000	0.000	0.000	0.000	*	5.197
	Sitting	0.000	0.000	0.000	0.000	0.000	0.000	*	5.997
	Leg Stretch	0.000	0.000	0.001	0.000	0.001	0.002	*	6.903
	Sleeping	0.000	0.000	0.000	0.000	0.000	0.000	*	5.732
3	Upright	0.000	0.000	0.000	0.000	0.000	0.000	*	5.876
	Sitting	0.000	0.001	0.001	0.000	0.002	0.001	*	8.697
	Leg Stretch	0.000	0.000	0.000	0.000	0.000	0.000	*	5.511
	Sleeping	0.000	0.000	0.000	0.000	0.000	0.002	*	7.256

TABLE 8.5 (b) One way analysis of variance of pressures at the GAITER (significance)

Patient	Posture	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Pooled St Dev
1	Upright	0.000	0.001	0.000	0.000	0.000	0.019	*	6.481
	Sitting	0.001	0.001	0.001	0.017	0.027	0.008	*	8.977
	Leg Stretch	0.000	0.000	0.000	0.001	**0.307**			7.333
	Sleeping	0.000	0.000	0.000	0.000	0.000	0.000	*	4.832
2	Upright	0.000	0.000	0.000	0.000	0.021	**0.085**		7.791
	Sitting	0.000	0.000	0.000	0.000	0.000	0.022	*	15.000
	Leg Stretch	0.000	0.000	0.000	0.000	0.000	0.000	*	11.890
	Sleeping	0.000	0.000	0.000	0.000	0.000	0.000	*	8.816
3	Upright	0.000	0.000	0.000	0.000	0.000	0.000	*	3.605
	Sitting	0.000	0.000	0.000	**0.458**				7.018
	Leg Stretch	0.000	0.000	0.000	0.000	0.000	0.040	*	5.331
	Sleeping	0.000	0.000	0.000	0.000	0.000	0.000	*	7.324

TABLE 8.5 (c) One way analysis of variance of pressures at the ANKLE (significance)

8.6.4 The Magnitude Average of Pressure

The magnitude and standard deviation of the average daily pressures at each site and for each posture for the three patients were tabulated as shown in table 8.6. The overall daily average pressures ranged from 11 to 46 mmHg (1.5 to 6kPa) with noticeable variations from day to day. The magnitude of pressures at the calf were generally lower than that at the gaiter and ankle. However, the magnitude of pressures at the ankle were not always higher than that at the gaiter.

Patient	Site	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	Calf	15(5)	11(4)	12(4)	13(5)	18(6)	18(6)	16(5)
	Gait	28(7)	24(6)	23(6)	24(7)	22(6)	21(6)	20(5)
	Ank	28(7)	29(8)	28(8)	28(8)	28(7)	29(7)	29(6)
2	Calf	24(3)	23(3)	23(3)	22(5)	22(3)	24(3)	29(4)
	Gait	37(4)	42(5)	35(3)	34(4)	34(7)	43(6)	36(4)
	Ank	30(9)	46(8)	24(8)	23(9)	21(10)	22(8)	22(8)
3	Calf	23(6)	26(6)	24(6)	23(6)	21(6)	22(6)	21(6)
	Gait	26(6)	28(6)	27(6)	28(6)	27(6)	28(6)	26(6)
	Ank	27(4)	27(3)	26(3)	30(3)	29(4)	30(3)	29(4)

(a) Upright

Patient	Site	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	Calf	19(5)	15(4)	15(5)	11(4)	20(9)	19(7)	17(6)
	Gait	31(7)	27(6)	24(6)	23(5)	25(6)	23(6)	23(7)
	Ank	30(9)	30(10)	28(8)	28(8)	29(9)	29(8)	31(10)
2	Calf	22(3)	22(2)	23(3)	20(3)	17(3)	23(4)	26(5)
	Gait	35(5)	42(7)	33(4)	32(5)	28(7)	41(7)	33(4)
	Ank	46(14)	45(14)	43(12)	40(15)	34(20)	45(17)	42(13)
3	Calf	27(5)	31(6)	30(6)	29(6)	27(6)	28(6)	26(5)
	Gait	29(5)	31(6)	31(11)	33(10)	31(7)	33(7)	30(10)
	Ank	31(6)	33(5)	33(6)	35(7)	35(8)	35(7)	34(7)

(b) Sitting

TABLE 8.6 Average daily pressures and standard deviations.

Patient	Site	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	Calf	9(3)	11(5)	13(7)	4(4)	10(5)	9(4)	6(4)
	Gait	19(4)	16(5)	13(5)	10(3)	11(5)	10(3)	9(3)
	Ank	22(9)	19(10)	15(8)	13(6)	14(7)	15(7)	14(8)
2	Calf	15(4)	15(3)	16(5)	14(4)	14(5)	15(3)	19(3)
	Gait	21(7)	24(9)	19(8)	19(7)	20(11)	24(6)	21(8)
	Ank	24(16)	20(12)	15(13)	24(20)	20(15)	19(11)	28(12)
3	Calf	14(5)	16(4)	18(4)	16(3)	13(3)	18(3)	15(3)
	Gait	12(7)	12(7)	11(7)	17(7)	17(5)	22(5)	16(8)
	Ank	13(7)	15(7)	11(3)	21(7)	22(6)	25(4)	23(9)

(c) Leg Stretched

Patient	Site	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	Calf	11(2)	16(8)	11(3)	none	18(3)	27(7)	14(2)
	Gait	23(3)	22(5)	21(3)	none	15(4)	18(4)	16(3)
	Ank	26(3)	21(13)	23(4)	none	14(4)	16(3)	19(8)
2	Calf	18(1)	18(2)	20(2)	19(2)	13(1)	18(1)	25(7)
	Gait	27(2)	35(4)	24(4)	30(6)	27(4)	38(9)	39(6)
	Ank	33(9)	28(6)	25(5)	23(9)	35(8)	26(5)	25(7)
3	Calf	none	15(1)	none	none	none	none	none
	Gait	none	18(2)	none	none	none	none	none
	Ank	none	34(28)	none	none	none	none	none

(d) Leg Elevated

Patient	Site	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	Calf	9(2)	10(3)	10(1)	10(2)	12(2)	11(3)	12(2)
	Gait	25(3)	20(3)	20(3)	21(5)	18(3)	17(3)	16(3)
	Ank	31(5)	29(5)	29(5)	30(6)	29(6)	30(5)	26(4)
2	Calf	13(2)	15(8)	12(2)	12(1)	12(2)	13(2)	20(9)
	Gait	19(5)	20(13)	16(4)	16(3)	17(3)	17(5)	18(6)
	Ank	27(7)	30(14)	26(7)	26(6)	24(6)	22(8)	26(9)
3	Calf	14(8)	15(9)	12(6)	14(7)	12(4)	12(5)	13(8)
	Gait	11(10)	10(8)	10(8)	12(5)	10(4)	10(6)	11(9)
	Ank	27(24)	19(7)	19(6)	22(5)	21(5)	21(5)	23(9)

(e) Sleeping

TABLE 8.6 Average daily pressures and standard deviations

There was a wide range of standard deviations from 1 to 28 mmHg (0.1 to 3.7kPa) with standard deviations in the upright and sleeping postures being lower than the sitting or sitting with leg stretched postures. The pressures produced by patient-2 had higher standard deviations than the others. Also the standard deviations in pressures at the ankle were greater than that at the gaiter which was in turn greater than that at the calf.

The magnitude of the pressures generated at the ankle for each patient and posture were used to estimate the class of the bandage applied in accordance with values recommended by Thomas (1990) and is illustrated in table 8.7.

Patient	Bandage	Posture	Range of average ankle pressures	Class of bandage
1	Granuflex	Upright Sitting Leg Stretch Sleeping	28 - 29 28 - 31 13 - 22 26 - 31	3c 3c 3a (3b) 3c
2	Granuflex	Upright Sitting Leg Stretch Sleeping	21 - 46 34 - 46 15 - 28 22 - 30	3b (3d) 3d 3b (3c) 3c (3b)
3	4 - Layer	Upright Sitting Leg Stretch Sleeping	26 - 30 31 - 35 11 - 25 19 - 27	3c 3c 3b (3a) 3b (3c)

TABLE 8.7 Estimated bandage classification

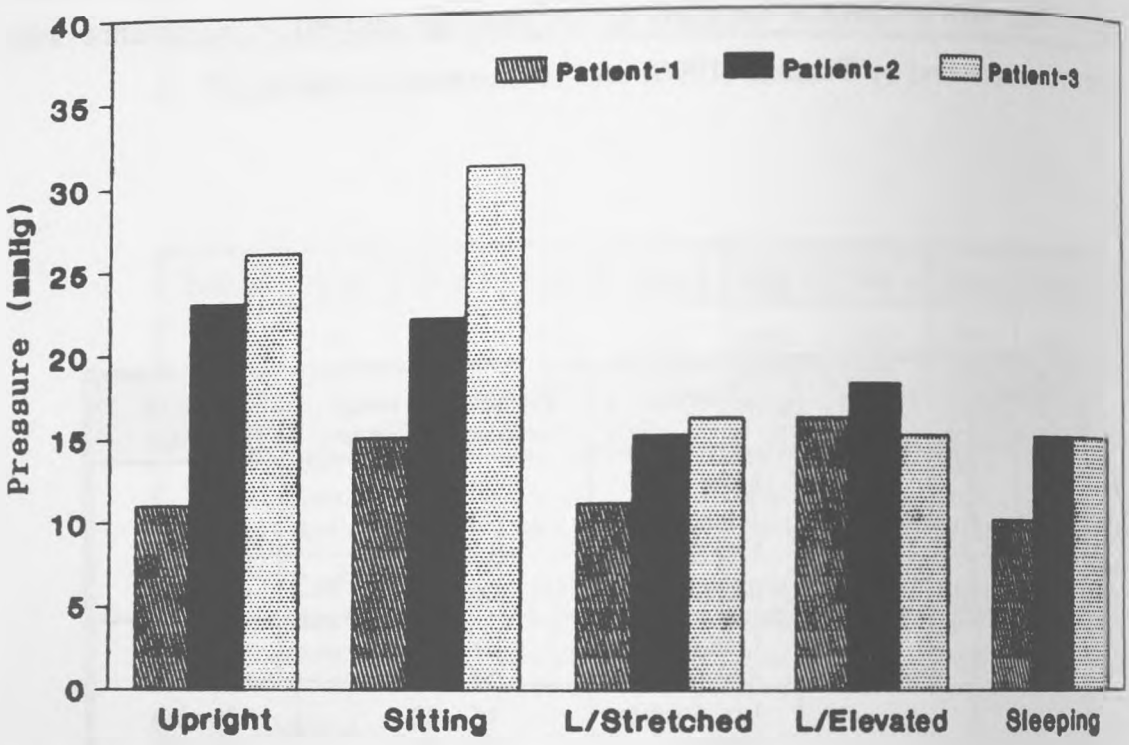


Figure 8.7 The influence of posture on sub-bandage pressure (Day-2, Calf)

8.6.5 The Influence of Posture

The pressures generated at all sites for the three patients were influenced by posture as demonstrated in figure 8.7. The Friedman's test showed that the pressures produced at each site were significantly different for each posture (Table 8.8). Specific comparison between each posture was carried using Nemenyi's test. The upright and sitting postures generally produced greater pressures than sitting with legs stretched or sleeping. The highest pressures were generally produced during sitting. Pressures produced during leg elevation were not considered due to insufficient data.

PATIENT	SITE	Were the pressures significantly different for each posture? (P-value)	Specific comparisons
1	Calf	Yes (0.0016)	sit > upright > lie > sleep
	Gaiter	Yes (0.0002)	sit > upright > sleep > lie
	Ankle	Yes (0.0032)	sit > upright > sleep > lie
2	Calf	Yes (0.0000)	upright > sit > lie > sleep
	Gaiter	Yes (0.0000)	upright > sit > lie > sleep
	Ankle	Yes (0.0016)	sit > sleep > upright > lie
3	Calf	Yes (0.0001)	sit > upright > lie > sleep
	Gaiter	Yes (0.0001)	sit > upright > lie > sleep
	Ankle	Yes (0.0003)	sit > upright > sleep > lie

TABLE 8.8 The influence of posture on sub-bandage pressures (significance)

8.6.6 The Pressure Gradient

The pressures measured at the calf, gaiter and ankle were used to gauge the gradient of compression over the leg. Figure 8.8 illustrates typical average pressures at the three sites for patient-1 on a single day. It also shows that suitable pressure gradients were not always achieved.

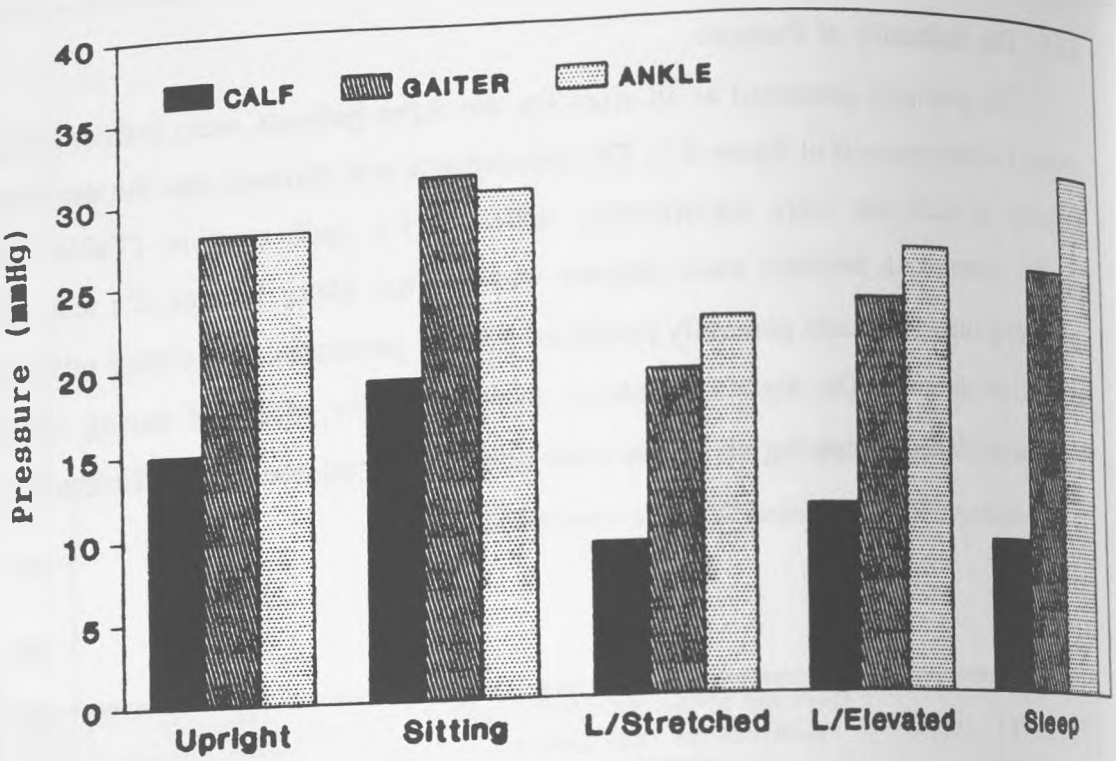


Figure 8.8 Typical pressure profile (Patient-1, Granuflex bandage)

PATIENT (Bandage)	POSTURE	Were pressures at each site different? (significance)	Suitable gradient (incidence)	Suitable gradient (weighted)
1 (Granuflex)	Upright	Yes (P = 0.000)	ankle > gaiter > calf (67.6%)	71%
	Sitting	Yes (P = 0.000)	ankle > gaiter > calf (59.6%)	
	Leg Stretch	Yes (P = 0.000)	ankle > gaiter > calf (48.5%)	
	Leg Elevate	Yes (P = 0.000)	ankle > gaiter > calf (55.8%)	
	Sleeping	Yes (P = 0.000)	ankle > gaiter > calf (94.1%)	
2 (Granuflex)	Upright	Yes (P = 0.000)	ankle > gaiter > calf (9.9%)	45%
	Sitting	Yes (P = 0.000)	ankle > gaiter > calf (64.6%)	
	Leg Stretch	Yes (P = 0.000)	ankle > gaiter > calf (27.9%)	
	Leg Elevate	Yes (P = 0.000)	ankle > gaiter > calf (68.3%)	
	Sleeping	Yes (P = 0.000)	ankle > gaiter > calf (81.0%)	
3 (4 - Layer)	Upright	Yes (P = 0.000)	ankle > gaiter > calf (40.2%)	32%
	Sitting	Yes (P = 0.000)	ankle > gaiter > calf (44.9%)	
	Leg Stretch	Yes (P = 0.000)	ankle > gaiter > calf (35.0%)	
	Leg Elevate	Yes (P = 0.000)	ankle > gaiter > calf (37.9%)	
	Sleeping	Yes (P = 0.000)	ankle > gaiter > calf (17.0%)	

TABLE 8.9 The difference in pressure at each site (significance) and suitable gradients

The Friedman's test conducted for each patient and posture showed that the pressures at each site were significantly different (Table 8.9). A pascal program (Gradient.pas, Appendix M2) was used to identify and calculate the percentage of pressure data that produced a suitable gradient. There were marked variation in the percentage of suitable pressure gradient produced for each patient and posture. Overall suitable gradients were achieved in 71% of the pressure data for patient-1, 45% in patient-2 and 32% in patient-3.

The pressure gradients obtained in this pilot study were based on three sites of measurement while the gradients obtained in the subject study were based on two sites. In order to compare the pressure gradients generated by the Granuflex bandage which was common to both tests, a further analysis using pressures only at the gaiter and ankle was carried out and the results shown in table 8.10. The percentage of suitable gradients achieved was higher in the subject study than the patient study. Further, the difference between gradients obtained using three sites and two sites in the pilot study was only marginal.

PATIENT OR SUBJECT	POSTURE	SUITABLE GRADIENT (percentage)		
		PATIENT STUDY		SUBJECT STUDY
		3 Sites	2 Sites	2 Sites
1	Upright Sitting Sleeping	67.6% 59.6% 94.1%	75.85% 62.07% 96.39%	100% 100% 100%
2	Upright Sitting Sleeping	9.9% 64.6% 81.0%	10.05% 65.37% 91.61%	100% 100% 100%
3	Upright Sitting Sleeping			100% 100% 100%
4	Upright Sitting Sleeping			100% 90% 58%

TABLE 8.10 A comparison of pressure gradients produced by the Granuflex bandage

8.7 Discussion

8.7.1 The pilot study on venous ulcer patients

The importance of monitoring compression beneath bandages and the influence of postural changes on the pressures generated have already been established in previous chapters. The revised ambulatory device has made it possible to extend the investigation to venous ulcer patients. Unlike previous studies under controlled conditions, this investigation has gathered a wealth of information on sub-bandage pressure during normal daily activities of leg ulcer patients. The measurement of posture has provided a good understanding of each patient's level of activity which is an important factor in the treatment and prevention of venous ulcers.

The revised ambulatory device (Version-2) was designed with prior knowledge of some of the difficulties experienced in the study on normal subjects. As such there were no serious problems with the use of the device in this study and the overall performance was satisfactory. In particular, the activity sensor proved highly robust and reliable. Its output describing posture was consistent with the activities recorded by the patients in their diaries. However, the ambulatory system did occasionally break down. It appeared that the durability of the device was dependant on the manner in which the patient cared for it. As the device was worn continuously for an entire week, some patients did become complacent. Problems that have lead to the device breaking down included patients accidentally sleeping on the data logger or fracturing the electrical leads whilst running the dog. A technical problem that requires further attention is fatigue at electrical connections resulting from the constant flexing during ambulation despite the additional precautions taken.

The pressure measuring device had to be custom made to precisely fit the leg of each patient. It is very time consuming to construct individual devices and further improvement in the design to standardise its application is required. The ambulatory device generally was well accepted by the patients as much of it was concealed beneath the bandage and it was relatively comfortable to wear.

Despite the large number of venous ulcer patients attending the clinics, the number of suitable patients available for participation in the study was very small. As most of the leg ulcer patients tend to be elderly and often suffer from other medical conditions they were frequently not eligible for the study. Further, elderly

patients who could otherwise be considered were often too frail and felt that participating in the study would be too strenuous. This only left a small group of potential patients available for the study. Of these, some were not keen on participating in the study. The poor availability of suitable patients has noticeably slowed down the progress of the study.

As the study was part of a wider investigation carried out by the Forth Valley Ulcer Group, the selection of bandages used in the ambulatory tests was limited to that used in the investigation. The newly launched Granuflex Adhesive bandage was tested against the highly acclaimed Four-Layer bandage (Blair et al.,1988). Both these bandages are at present widely used in many leg ulcer clinics throughout the U.K. Progress of the state of the ulcer of each patient remains confidential until the study is completed to ensure impartiality in the use of the bandages. For this reason, a detailed comparison of the two bandages in generating suitable compression and hence in healing ulcers was not possible at this stage.

8.7.2 Results of the pilot study

Only a preliminary analysis of the pressure and posture measurements of the first three patients has been presented in this chapter. The overview of pressures (Figure 8.4 and Appendix N) at the three sites of measurement for each patient over the seven day duration had highlighted several features.

The pressure generated by the bandages varied in a daily cycle. This cyclical variation is produced by the drop in sub-bandages pressure during periods of sleep. The clarity of this daily variation, however, differs for each patient and site of measurement. It appears that the clarity is sometimes lost when the scatter of the overall pressure data is high as illustrated in figure 8.4c for pressures at the ankle. Perhaps suitable filtering of the highly scattered pressure data may reveal the underlying variation although this procedure is outwith the scope of this study.

The drop in sub-bandage pressure during sleep over a single daily cycle is further illustrated in figure 8.5. This drop in pressure during sleep could be attributed to the reduced leg volume as a result of fluid drainage away from the leg. The increased drainage of fluids when the leg is in the horizontal position during sleep is expected as the effect of hydrostatic forces is reduced in this posture.

The initial pressures over the first six hours, for all three patients at each site of measurement did not show a sharp fall in pressure. This is in contrast with the initial pressures recorded on the normal volunteer subjects in controlled postures (Chapter Seven) and in previous controlled studies (Raj et al., 1980). In fact, the pressure appears to be sustained similarly over the seven day duration with the exception of the periods of sleep.

Further, the time course of the sub-bandage pressure over the seven days varied noticeably for each patient, posture and site. This is illustrated in figure 8.6 which shows an overall increasing trend in pressure at the ankle for patient-3 in the upright and sitting postures and a decreasing trend in the leg stretched posture. The summary of these trends shown in table 8.4, for each patient, posture and site, indicated that there was no discernible pattern. This is in contrast with the generally decreasing trend obtained with normal subjects in controlled postures (Chapter Seven).

The percentage change in average daily pressures over the seven day duration also varied unpredictably for each patient, posture and site ranging from a drop of 52% to a rise of 83% of the initial pressures. The one way analysis of variance of average daily pressures confirmed that the pressures were not influenced by time. Despite the large pooled standard deviations, time remained a significant factor in the majority of daily average pressures (Table 8.5).

It is clear that the time course of pressure measured during ambulation is quite different from that measured in controlled postures. The dynamic nature of ambulation would also continuously influence the leg volume and tone of the underlying tissues which could result in different levels of sub-bandage pressure. Such variations during ambulation could therefore be responsible for the unpredictable trends in pressure and its independence with time. The sub-bandage pressure is expected to vary with ambulation as its effects on leg volume, muscle tones and bandage tension vary for each patient, posture and site. The multiplicity of factors governing sub-bandage pressures during continuous ambulation is clearly evident and complex.

A striking feature of the magnitude of average hourly pressures seen in the overview (Figure 8.4) was that different levels are attained and frequently maintained

over each day. The overview also illustrates that the scatter in the pressure data varies for each patient and site of measurement.

The magnitude and standard deviation of average daily pressures for the three patients at each site and for each posture are shown in table 8.6. The average daily pressures ranged from 11 to 46 mmHg (1.5 to 6 kPa) which were within the order of magnitude required for the treatment of venous ulcers. The magnitude of pressures at the calf were generally lower than that at the gaiter or ankle but the pressures at the ankle were not always the highest.

The average daily pressures generated during continuous ambulation varied considerably even for a single patient, at each site and posture as compared to that of the controlled posture study (Chapter Seven). This is further substantiated by the results of the one way analysis of variance discussed earlier (Table 8.5). The variation in the magnitude of average daily pressures can be attributed to the influence of changing leg volume, muscle tone and bandage tension as pointed out earlier. It is possible that the levels of oedema in the venous ulcer patients vary significantly each day thus producing different levels of sub-bandage pressures. Alternatively, it is possible that the variation in daily average pressures may be a result of varying levels of creasing in the bandage caused by ambulation.

The range of average pressures generated at the ankle was also used to estimate the class of the bandages in accordance with the values suggested by Thomas (1990). The estimated classes for the bandages varied with posture as shown in table 8.7. As a result there were several possible classes for each bandage. Perhaps a different technique of categorising bandages is necessary particularly when its ambulatory performance is considered.

The standard deviations of average daily pressures (Table 8.6) for each patient and site of measurement in the ambulatory study were generally larger than that of the normal subject study (Chapter Seven). The standard deviations were smallest at the calf and greatest at the ankle. The standard deviations did not vary noticeably with posture.

The lower standard deviations of pressure at the calf were probably due to the nature of the underlying tissue. On the lateral side of the calf where the pressures were measured, the radius of curvature was larger and the tissue was generally softer

without any bony prominence. On the lateral side of the ankle, however, the converse was true. For reasons discussed in Chapter Two, pressures at the ankle are prone to greater fluctuations in pressure thus giving rise to higher standard deviations. Further, pressure at the ankle may also fluctuate along with foot movement during ambulation.

The pressures measured at the calf, gaiter and ankle were used to assess the gradient of compression produced over the leg. The example in figure 8.8 illustrates the gradients produced during each posture for patient-1. It shows that suitable gradients, with highest pressures at the ankle and lowest pressures at calf, were achieved when the legs were stretched and elevated, and during sleep but not in the upright or sitting postures.

The results of the Friedman's test indicated that the pressures measured at each site were significantly different (Table 8.9). However, the percentage of favourable gradients achieved, to enhance venous flow, were considerably low and varied for each patient and posture. At best an overall of 71% of the measurements produced a suitable gradient in patient-1 while only 32% in patient-3.

The pressure gradients based on two sites of measurement (Gaiter and Ankle), to facilitate direct comparison with the subject study, showed only marginal differences to that based on three sites (Calf, Gaiter and Ankle) as shown in table 8.10. This implies that the section between the gaiter and ankle predominantly dictates the nature of pressure gradients produced. As the contours change more abruptly in the lower section of the leg where there is less underlying soft tissue, unpredictable changes in pressure and pressure gradients are more likely as discussed in Chapter Two. Further, sub-bandage pressures in the lower section of the leg may also be influenced by the movement of the foot.

The controlled posture study (Chapter Seven) frequently yielded 100% favourable gradients in contrast with the much lower favourable gradients achieved in this continuous ambulatory study (Table 8.10). It is difficult to single out one specific reason for this difference but it is clear that ambulation does affect the pressure gradients produced by a bandage.

The percentage of favourable gradients achieved also varied with posture but no specific pattern was observed. It is clear that ambulation does affect the pressure gradients produced. Therefore a bandage applied with a favourable gradient in one

posture may not necessarily have favourable pressure gradients in other postures. Perhaps, in a dynamic continuous ambulatory state it may not be always possible to achieve the required gradient because of the multiplicity of factors involved. Provided that the pressures are not excessively high, it may be more appropriate to expect a bandage to produce favourable gradients only for the majority of the period of use.

The influence of posture on the various aspects of sub-bandage pressures has consistently arisen throughout this discussion. This influence is illustrated in the example in figure 8.7 which shows the different levels of sub-bandage pressure produced during each posture. The results of the Friedman's test for each patient and site of measurement showed that sub-bandage pressures were significantly different for each posture. Specific comparisons also show that the sitting and upright postures generally produced greater pressures than the sitting with legs stretched or sleeping postures.

In the sitting and upright postures the leg oedema may increase as a consequence of greater hydrostatic forces acting on them. Further, the muscles in the leg during standing and sitting are not relaxed. For these reasons, it is possible that the sub-bandage pressures during sitting and upright postures are greater. Similarly, the converse argument holds when the legs are stretched horizontally and during sleep thus producing lower sub-bandage pressures.

The measurement of postural changes has provided an unique opportunity to gather an overview of the patients' activities as illustrated in table 8.3. This has provided the means to examine the influence of patient activity on venous ulcers and compression therapy. On average the patients spend 46% of their time standing or walking (upright posture), mainly during the hours of work. This estimate included the days off work, therefore the time spent in the upright posture during working days was much greater. In one occasion patient-3 had spent as much as 13.5 hours in the upright posture. Further, as typical employment of these patients was serving food or attending to machines at a production line, the time spent in the upright posture was frequently long and continuous. This prolonged and continuous upright posture could probably explain the cause or the existence of venous ulcers in these patients as discussed in Chapters One and Three.

Table 8.3 also indicates that the patients do not regularly spend time with their legs elevated as advised therapy for their venous ulcers (Young, 1992). The little time spent in this posture is often concentrated on days off work and for the remaining working days of the week the leg is hardly elevated when it is most needed. In fact, there appears to be preference for sitting with the legs stretched rather than elevated. For six out of seven days patient three had not elevated the leg at all.

It would be useful to compare the activities of people in similar circumstances who do not suffer from venous ulcers with that of ulcer patients. This may reveal that people whose occupation requires prolonged standing such as waiters may be more prone to venous ulcers. Further, an investigation on the activities of patients with recurring ulcers may also reveal useful information.

Finally, this preliminary analysis has provided an insight to the results of this clinical pilot study. A more comprehensive analysis of the sub-bandage pressures, the many influencing factors and the efficacy of the bandages in healing venous ulcers can only be carried out upon completion of the entire study.

CHAPTER 9

FINAL DISCUSSION AND CONCLUSION

9.1 Venous Ulcers and Compression Therapy

9.2 The Pressure Measuring Device

9.3 An Evaluation of Bandages and Elastic Stockings

9.4 The Ambulatory Pressure and Posture Monitoring Device

9.5 Ambulatory Monitoring of Sub-bandage Pressure on Subjects

9.6 Pilot Ambulatory Study on Venous Ulcer Patients

9 GENERAL DISCUSSION AND CONCLUSION

9.1 Venous Ulcers and Compression Therapy

Venous ulceration has been a problem since ancient times. It has been estimated that 1% of population will suffer from leg ulceration at some point in their lives. Women are more prone to venous ulcers than men and the prevalence of chronic leg ulceration increases with age (Callum, 1992). The pathogenesis of venous ulceration is still not fully understood but it is clear that venous insufficiency and hypertension are central to the ulceration. Over the last few decades, advances in investigative techniques and physiological understanding of this disease have produced fresh impetus and concerted efforts to improve the treatment and management of venous ulcers. New regimens based on stringent care plans have been developed at hospital based practices and community clinics. Peripheral issues such as mobility, nutrition, lifestyle, social habits and education, and prevention of recurrence are also emphasised (Cherry, 1992). Treatment of venous ulcers predominantly relies on conservative techniques such as compression therapy and leg elevation.

Compression bandages and elastic stockings are widely used in the treatment of venous ulcers but little is known of the precise magnitude and distribution of pressure generated by these devices. At present there are many new compression devices commercially available with little or no information on their performance (Thomas, 1990). Although some basic quantitative guidelines on the magnitude and distribution of suitable pressure are available (Drug Tariff, 1989), clinical and laboratory tests on compression devices has been limited. This is largely due to the lack of a suitable interface pressure measuring device.

9.2 The Pressure Measuring Device

The "Strathclyde Pressure Monitor" was built specifically to measure interface pressure beneath compression bandages and elastic stockings. This electro-hydraulic device was designed to meet the stringent requirements of an interface pressure measuring device and featured improvements in many aspects of existing devices. Future improvements should focus on eliminating the effect of change in hydrostatic pressure caused by relative vertical displacement of the sensor and on selecting a

suitable transmission fluid for the device. The performance of this easy to use and robust device has been highly satisfactory both under laboratory conditions and during clinical use.

9.3 An Evaluation of Bandages and Elastic Stockings

In vivo and in vitro tests were conducted to assess the performance of twelve routinely used bandages and elastic stockings. The majority of bandages tested failed to produce the appropriate magnitude of compression at the ankle. With the exception of the Blue Line bandage used in the criss-cross technique the bandages also failed to produced favourable pressure gradients required to enhance venous flow. The failure may be attributed to either the device or the inadequate skills of the operator. As the bandages were applied by a qualified physiotherapist throughout the study, if the latter were true then it highlights the need for additional specialised training programmes in compression bandaging.

The criss-cross technique of application consistently produced much higher compression than the spiral technique. Perhaps future classification of bandages should specify the technique of application.

Similar unsatisfactory performance of elastic stockings were also obtained. With the exception of Venosan, the elastic stockings tested failed to produce appropriate compression at the ankle and suitable pressure gradients over the leg. Laundering the stockings did not significantly alter the compression produced by the device but washed stockings did produce greater variability in the pressures generated than new stockings.

The bandages and stockings exhibited a drop in pressure at all sites of measurement during the one hour test period. The pressures generated by both devices were greater during standing than sitting, perhaps due to the increased pooling of tissue fluids or change in muscle tone in the leg during standing.

The results of the force extension tests showed non-linear and non-elastic load deformation behaviour by all the materials. This implies that a small additional stretch of the material could cause a disproportionately high increase in compression. In standard sized stockings small variations in the shape, size and fit, can therefore produce significant variations in the compression. With repeated load cycling the

deformation behaviour progressively changed. Therefore, devices that are reused or excessively stretched prior to use can produce different levels of compression.

All the materials also exhibited stress relaxation to varying degrees and in vivo relaxation was always less than in vitro relaxation. The mechanical properties of the Elastocrêpe bandage were irregular with poor reproducibility.

The opinions gathered from the physiotherapist and the volunteer subjects in the subjective assessment yield useful information based on their personal experiences of applying and wearing the devices.

The results of this study suggested that further long term ambulatory monitoring of sub-bandage pressure and the influence of postural changes was necessary.

9.4 The Ambulatory Pressure and Posture Monitoring Device

A novel ambulatory pressure and posture monitoring device comprising a pressure transducer and sensor, a flexible goniometer and pocket sized data logger was developed. This miniaturised portable device was capable of prolonged continual measurement of sub-bandage pressure and posture. The pressure measuring device previously described was miniaturised and adapted for ambulatory use. Posture was monitored by use of a commercial flexible goniometer in the earlier version of the ambulatory device but it was later superseded by the activity sensor. The activity sensor identified posture unambiguously, was robust, unobtrusive and conducive for use on patients. Further, the device was easy to use and did not require calibration. Prolonged continuous use of the ambulatory device was achieved by use of a light weight data logger. The later version of the ambulatory device was also designed for safety, convenience and comfort, and aesthetic acceptability. The ambulatory pressure and posture monitoring device has proved to be a powerful investigative tool in the study of compression therapy and posture.

9.5 Ambulatory Monitoring of Sub-bandage Pressure on Subjects

The long term performance of five commonly used compression bandages was investigated on a single volunteer subject. The performance of the Granuflex bandage was further investigated on nine volunteer subjects. The ambulatory device (version-

1) was used to the monitor sub-bandage pressure and posture on these subjects during activities of daily living. Throughout the study the bandages were applied by a single qualified physiotherapist.

Pressures were measured at selected sites in three standardised postures at three hourly intervals over a period of seven days. The pressures produced by all five bandages decreased to varying degrees over the test period. With the exception of the Elastocrêpe bandage, the drop in average pressures over the first six hours were significant after which the pressures progressively became independent of time. This initial dramatic drop in pressure may be attributed to the time dependence of the bandage material and the underlying tissues, the latter related to the displacement of tissue fluids from the leg.

The Coban Wrap bandage performed well in maintaining pressure throughout the duration of use while the performance of the Low Tack and Lestreflex bandages were less impressive. This is because the Coban Wrap is a strongly cohesive bandage capable of holding each overlapping layer firmly together while the Lestreflex is only partially adhesive and Low-Tack is a low adhesion bandage. The time course of pressure produced by the Elastocrêpe bandage was irregular.

The Granuflex which is a strongly adhesive bandage produced the highest pressures with relatively small standard deviations after the first day. The Coban Wrap produced steady pressures over the seven days with low standard deviations. The pressures produced by the Elastocrêpe bandage were relatively low and inconsistent with high standard deviations. Although this bandage has been used for compression therapy in the past it should be strictly limited to a support bandage.

Pressures generated by the Granuflex bandage at the gaiter and ankle were used to examine the pressure gradients. Favourable pressure gradients, required to enhance venous flow, were always achieved in the standing posture but not in the sitting or lying postures. The difference in pressures between any two sites during sitting and lying tended to be smaller than during standing. This smaller difference in pressure between sites reduces the likelihood of the desired gradients being achieved. It is possible that a bandage applied with the patient in the lying posture may ensure a favourable gradient for all other postures. Perhaps a future investigation on the optimal posture for bandage application would be worthwhile.

Superimposed on the overall decreasing trends were cyclic daily variations in pressure for all five bandages. These variations were different for each bandage and were often asymmetrical. Such variations in the pressures produced by the Granuflex bandage were also present for all the subjects in the three postures. The clarity of the variations were however different for each subject. These variations may be related to periods of sleep as observed in a few cases but cannot be confirmed as the periods of sleep were disrupted every three hourly in these tests.

For all five bandages, the standing posture produced the highest pressures, while the difference in pressure between sitting and lying for most bandages were marginal. Perhaps the pooling effect of interstitial fluids in the leg during standing increases the interface pressure within the enveloping bandage. It is also possible that muscular activity during standing increases the calf diameter and therefore produces higher interface pressures.

This investigation provided an improved understanding of the long term characteristics of sub-bandage pressures and warranted a more comprehensive study on venous ulcer patients.

9.6 A Clinical Pilot Study

The ambulatory study on subjects was extended to a pilot study on venous ulcer patients as part of a wider investigation conducted in conjunction with the Forth Valley Ulcer Group, Scotland. Sub-bandage pressures and influence of postural changes incurred during activities of daily living were investigated using the Granuflex bandage and the Four-Layer bandaging system over a seven day duration. A preliminary analysis of the data for the first three patient tests was reported in this thesis.

The time course of the ambulatory sub-bandage pressure over the seven days had no discernible trend in contrast with the decreasing trend obtained on subjects in controlled postures. There was no initial drop in pressure instead, the pressure was sustained similarly over the entire duration with the exception of the periods of sleep.

Cyclic daily variations in pressure associated with the fall in pressure during periods of sleep were observed. The clarity of the variations were dependent on the scatter of the overall pressure data. The drop in pressure during sleep could be

attributed to the reduced leg volume caused by the displacement of tissue fluid from the leg and/or muscular relaxation.

The pressures generated during continuous ambulation varied considerably for each day even for a single patient, site and posture. It is possible that the levels of pressures attained each day are related to the daily varying levels of oedema in the patients.

The standard deviations of average daily pressures were considerably larger than that of the subject study. These fluctuations were smallest at the calf and greatest at the ankle, and did not vary noticeably with posture. These high standard deviations in pressure could be a result of ambulation which affects leg volume, muscle tones and bandage tension. The smaller fluctuations at the calf were probably related to the larger radius of curvature and the predominantly soft underlying tissue.

Favourable pressure gradients achieved during ambulation were generally low and varied from 32% to 71%. The percentage of favourable gradients achieved based on two sites of measurement (Gaiter and Ankle) was only marginally different from that based on three sites (Calf, Gaiter and Ankle). This implies that the lower section of the leg predominately dictates the profile of the pressure gradient. Perhaps, as the contours change more abruptly in the lower section of the leg where there is less underlying soft tissue, unpredictable changes in pressure and pressure gradients are more likely. Further, sub-bandage pressures in this section of the leg may also be influenced by movement of the foot and may therefore affect the pressure gradient.

The percentage of favourable gradients achieved in the ambulatory patient study was considerably lower than that in the controlled posture study (Chapter Seven). In view of the dynamic circumstances during ambulation, it may be more realistic to expect a bandage to produce favourable gradients only for the majority of the duration of use.

The sitting and upright postures generally produced greater pressures than the sitting with legs stretched or sleeping. This may be related to the oedema in the leg not being displaced and the muscles not being relaxed during the sitting and upright postures. The converse would be true when the legs are stretched and during sleep.

The measurement of posture has made it possible to examine patient activity. On average the patients spent 46% of their time in the upright posture, often

continuously during the hours of work. The results also indicate that the patients did not regularly spend time with their legs elevated and tended to concentrate this therapy on days off work. The patients showed a preference to sitting with their legs stretched rather than elevated. It is possible that people whose occupations require prolonged standing may be more prone to venous ulcers. Further investigation on the activities of healthy volunteers and patients with recurring ulcers may reveal useful information.

Further analysis of the sub-bandage pressure, the factors influencing it and the efficacy of the two bandages in healing venous ulcers can only be carried out upon completion of the entire study. However, it is clear that pressure measured during ambulation is quite different from that measured in controlled postures and multiplicity of factors governing sub-bandage pressures during continuous ambulation is evidently complex.

Finally, the investigation described in this thesis has successfully addressed numerous issues on compression therapy. The studies have unveiled new long term characteristics of pressure generated by bandages and have also provided confirmation of many previous findings. Further, the investigation has also highlighted the limitations of short term measurement of interface pressure beneath compression devices on non-ambulatory subjects. The knowledge acquired from this thesis should prove useful in the ongoing effort to improve compression therapy used in the treatment of venous ulcers.

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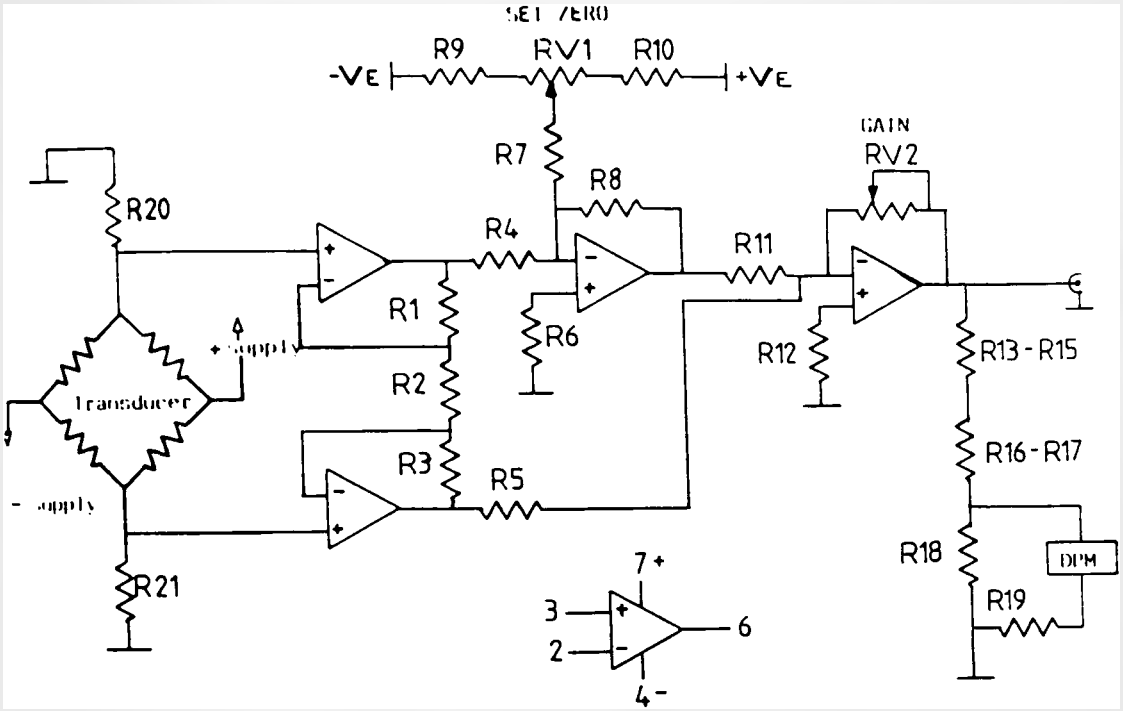
APPENDICES

STRATHCLYDE PRESSURE MONITOR

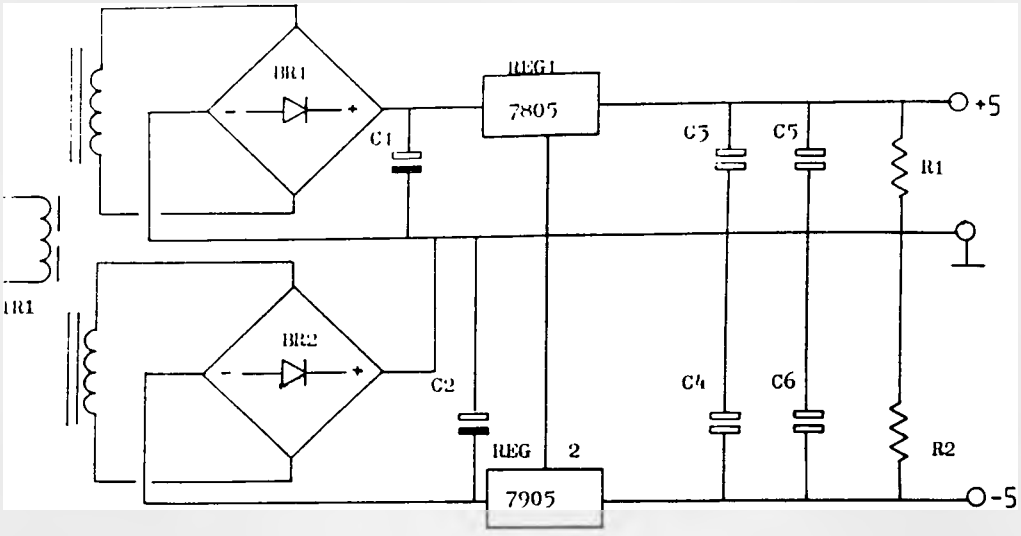


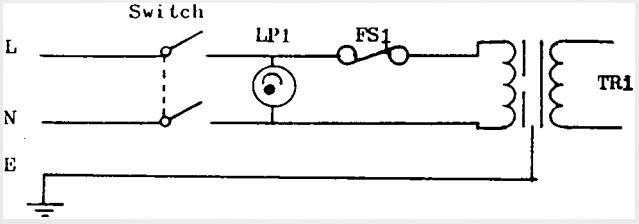
COMPONENT LIST

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		O.E.M. - 2 u
De-coupling capacitors		
0.1 u		
I.C.		3140

POWER SUPPLY





COMPONENT LIST

TR1	Toroidal	9 + 9 volt
BR1, BR2,	SIL. BRIDGE	2A 200v
REG1	7805	+ 5 volt
REG2	7905	- 5 volt
C1, C2	10,000 u	
C3, C4	0.47 u	
C5, C6	1 u	
R1, R2	4.7K	
D.P.D.T.	Mains Neon Switch	
FS1.	2 amp	

CONVERT.PAS
****

```
PROGRAM siv_volts_to_h2o(INPUT,OUTPUT,file1IN);

   {STRATHCLYDE UNIVERSITY
    BIOENGINEERING UNIT
    WOLFSON CENTRE

    Design : S Sockalingam
    Author : R Torres-Moreno
    Updated  on December 20, 1988}

CONST
  minnum     = 1;
  post1      = 1;  {standing position}
  post2      = 2;  {sitting  position}

                                                        {ARRAYS}
TYPE                                                    {CODES}
  raw_set_ray         =  ARRAY[1..126,1..7] of integer ; {1}
  raw_data_ray        =  ARRAY[1..21,1..6] of integer  ; {2}
  raw_base_ray        =  ARRAY[1..6,1..6]  of integer  ; {3}
  raw_base_real_ray   =  ARRAY[1..3,1..6]  of real     ; {4}
  raw_base_real_ave   =  ARRAY[1..3,1..2]  of real     ; {5}
  raw_data_ave_ray    =  ARRAY[1..21,1..2] of real     ; {6}
  h2o_data_ray        =  ARRAY[1..21,1..6] of integer  ; {7}
  h2o_data_ave        =  ARRAY[1..21,1..2] of integer  ; {8}

  fnames              =  packed array [1..18] of CHAR;
                         {INPUT AND OUTPUT FILEMANES}

VAR
  rawset       :  raw_set_ray        ; {1}
  rawdat       :  raw_data_ray       ; {2}
  rawbase      :  raw_base_ray       ; {3}
  rawbare      :  raw_base_real_ray  ; {4}
  rawbareave   :  raw_base_real_ave  ; {5}
  rawdatave    :  raw_data_ave_ray   ; {6}
  h2odat       :  h2o_data_ray       ; {7}
  h2odave      :  h2o_data_ave       ; {8}

  file1in                          : TEXT;
  MRED, MBLUE, MYELLOW             : real;
   {Slope values independent for each file, but remain
   the same within the active one. One for each transducer
   being used}

   file1, file2, file3  : fnames; {in and out filenames}
   AA, BB, X, T, T2,              {loop control variables}
   nextrow,
   timecode,                      {sample time code}
   counterlast,
   subjectcode,
   techniquecode,
   bandagecode                  : INTEGER;

   {-------------------------------------------------}
```

```
PROCEDURE read_data_in;

    {Reading input data '28x6' from the input file
    (file1)provided by the user, this data is loaded
    into an internal array with the CODE "1" '27x6'
    and three M's values representing the slopes}

VAR
  A, B, C, D, E, F  : integer;  {loop control variables}

BEGIN {read_data_in}
  OPEN(file1IN,file1,history := old);
  RESET(file1IN);
  FOR C := minnum TO 27 DO
    FOR D := minnum TO 6 DO
      READ(file1IN,rawset[C,D]);
  read(file1IN,MRED);
  read(file1IN,MBLUE);
  read(file1IN,MYELLOW);
  CLOSE(file1IN)

END;  {read_data_in}

{-------------------------------------------------------}

PROCEDURE separate_data_set;

    {Taking the data from the internal array "1" '27x6',
    this is separated into an array of BASE DATA
    representing the ZERO reading, CODE "3" '6x6"; and an
    array of all the data obtained within preset time
    schedule, CODE "2" '21x6'}

VAR
  G, H, I, J, K, L, M  : integer;

BEGIN {separate_data_set}
  FOR G := 1 TO 6 DO
    Begin {for G}
      rawbase[1,G] := rawset[1,G];
      rawbase[2,G] := rawset[3,G];
      rawbase[3,G] := rawset[5,G];
      rawbase[4,G] := rawset[22,G];
      rawbase[5,G] := rawset[24,G];
      rawbase[6,G] := rawset[26,G];
      rawdat[1,G]  := rawset[2,G];
      rawdat[2,G]  := rawset[4,G];
      rawdat[19,G] := rawset[23,G];
      rawdat[20,G] := rawset[25,G];
      rawdat[21,G] := rawset[27,G]
    End;  {for G}
  FOR H := 3 TO 18 DO     {related to newarray}
    FOR I := 1 TO 6 DO    {for the 6 columns}
      rawdat[H,I] := rawset[(H+3),I]

END;  {separate_data_set}

{-------------------------------------------------------}
```

```
PROCEDURE modify_base_data;

{Taking the array CODE "3" '6x6', we get the Start-End
average for each stand, sit positions and the 3
distintive M's. We create an array CODE "4" '3x6'. Then
we also take the original array CODE "3" '6x6' and
obtain the Universal average for thrre M's values but
differentiating between stand and sit position, this
action creats the other new array CODE "5" '3x2'}

VAR
    N, P, Q, R    : integer;

BEGIN {modify_base_data}
FOR N := 1 TO 6 DO
    Begin {for N}
    rawbare[1,N] := (rawbase[1,N] + rawbase[4,N])/2;
    rawbare[2,N] := (rawbase[2,N] + rawbase[5,N])/2;
    rawbare[3,N] := (rawbase[3,N] + rawbase[6,N])/2
    End;  {for N}
  FOR P := 1 TO 3 DO
  Begin {for P}
      rawbareave[P,1] := (rawbase[P,1] +
                         rawbase[P,2] +
                         rawbase[P,3] +
                         rawbase[(P+3),1] +
                         rawbase[(P+3),2] +
                         rawbase[(P+3),3])/6;
      rawbareave[P,2] := (rawbase[P,4] +
                         rawbase[P,5] +
                         rawbase[P,6] +
                         rawbase[(P+3),4] +
                         rawbase[(P+3),5] +
                         rawbase[(P+3),6])/6
   End   {for P}

 END;  {modify_base_data}

{-------------------------------------------------------}

PROCEDURE make_average_data;

{Taking the array CODE "2" '21x6', we obtain the
average by rows but distinguising between stand and
sit positions independently, in this manner, we
produce a new array CODE "6" '21x2' representing 21
different reading "7 times by 3 M's or transducers".

 [S,1] corresponde to stand data
 [S,2] corresponde to sit data}

VAR
  S : integer;  {loop control variable}
BEGIN {make average data}
FOR S := 1 TO 21 DO
```

```
    Begin {for S}
     rawdatave[S,1] := (rawdat[S,1] +
                        rawdat[S,2] +
                        rawdat[S,3])/3;
     rawdatave[S,2] := (rawdat[S,4] +
                        rawdat[S,5] +
                        rawdat[S,6])/3
    End   {for S}

END;  {make_average_data}

{-------------------------------------------------------}

PROCEDURE transform_into_H2O_system;

      {Taking array CODE "2" '21x6' and array CODE "4"
      '3x6' we create array CODE "7" '21x6' which contains
      the pressures in h2o system for 21 (rows) reading of
      the structure 7 times by 3 different transducers;
      and 6 (columns) indicating 3 stages by 2 positions.
       Taking array CODE "6" '21x2' and array CODE "5"
       '3x2' we create array CODE "8" '21x2' which
       contains the pressures in h2o system for 21 (rows)
       reading of the structure 7 times by 3 different
       tranducers; and 2 (columns) indicating
       the average of the 3 stages for each of the 2
       positions.}

VAR
    CC, DD, EE, FF    : integer;

BEGIN {transform_into_h2o_system}

  {--------  LOADING ARRAY 7 OF THE TOTAL SET OF DATA ---}

  FOR CC := 1 TO 21 DO
    FOR EE := 1 TO 6 DO
      Begin {for EE}
        IF CC MOD 3 = 1 THEN
          h2odat[CC,EE] := ROUND((rawdat[CC,EE] - rawbare
                           [1,EE])* MRED);{RED TRANSDUCER}
        IF CC MOD 3 = 2 THEN
          h2odat[CC,EE] := ROUND((rawdat[CC,EE] - rawbare
                           [2,EE])* MBLUE);{B-TRANSDUCER}
        IF CC MOD 3 = 0 THEN
           h2odat[CC,EE] := ROUND((rawdat[CC,EE] - rawbare
                           [3,EE])* MYELLOW){Y-TRANSDUCER}
      End;  {for EE}

  {---- LOADING ARRAY 8 OF TOTAL SET OF AVERAGE DATA ----}

  FOR DD := 1 TO 21 DO
    FOR FF := 1 TO 2 DO
      Begin {if FF}
        IF DD MOD 3 = 1 THEN
          h2odave[DD,FF] := ROUND((rawdatave[DD,FF] -
                            rawbareave[1,FF]) * MRED);
                            {RED TRANSDUCER}
```

```
IF DD MOD 3 = 2 THEN
  h2odave[DD,FF] := ROUND((rawdatave[DD,FF] -
                    rawbareave[2,FF]) * MBLUE);
                    {BLUE TRANSDUCER}
IF DD MOD 3 = 0 THEN
  h2odave[DD,FF] := ROUND((rawdatave[DD,FF] -
                    rawbareave[3,FF]) * MYELLOW)
                    {YELLOW TRANSDUCER}
End   {for FF}

END;  {transform_into_h2o_system}

{-------------------------------------------------------}

PROCEDURE read_data_out;

{Taking the arrays CODE "7" '21x6' and CODE "8" '21x2', we
create two output files "file2, and file3" given by the
user of the program. Those files maintain the same
structure than the array they have been loaded from.}

VAR
Y, Z     : integer;  {loop control variables}

BEGIN {read_data_out}

{-------------- TOTAL DATA TABLE -------------}

{All the data for the OUTPUT file is first loaded into the
array 1 in order to set all the complement data for the
statistycal analysis. This is done by loading columns with
the appropriate data as specified by the comments following
the command}

nextrow      := 0;      {initializing the variables}
timecode     := 1;      {time code goes from 1 to 7 only,
                         returns to 1 when = 8}
counterlast := 1;       {goes from 1 to 3 only, returns to
                        1 when = 4}
OPEN(file1IN,file2);   {Taking the array CODE "7"
                    COMPLETE TABLE}
REWRITE(file1IN);
FOR Y := 1 TO 21 DO
FOR Z := 1 TO 3 DO
 BEGIN (* for Z *)
 rawset[nextrow+1,1] := h2odat[Y,Z];
           { * load first column of final array for
            standing}
 nextrow := nextrow + 1
 END;  (* for Z *)
FOR Y := 1 TO 21 DO
FOR Z := 4 TO 6 DO
 BEGIN (* FOR Z *)
 RAWSET[NEXTROW+1,1] := h2odat[Y,Z];
           { * load first column of final array for
            sitting}
 nextrow := nextrow + 1
 END;  (* for Z *)
```

```
      FOR X := 1 TO 126 DO
       BEGIN (* for X *)
      rawset[X,7] := bandagecode;
                  { * loading the bandage code at column 7
                  of array}
     rawset[X,6] := techniquecode;
                  { * loading the technique code at column
                  6 of array}
     rawset[X,5] := subjectcode;
                  { * loading the subject code at column
                  5 of array}
     IF X <= 63 THEN
       rawset[X,2] := post1
                  { * loading posture code 1 if standing}
     ELSE
       rawset[X,2] := post2;
                  { * loading posture code 2 if sitting}
     rawset[X,3] := timecode;
                  { * loading time code at col 3 of array}
     IF X MOD 9 = 0 THEN
       timecode := timecode + 1;
     IF timecode = 8 THEN
       timecode := 1;
     rawset[X,4] := counterlast;
                  { * loading position code at column 4
                  of array}
     IF X MOD 3 = 0 THEN
       counterlast := counterlast + 1;
     IF counterlast = 4 THEN
       counterlast := 1
   END; (* for X *)

   {** OUTPUT FILE BEING CREATED BASED ON THE ARRAY 1 **}

FOR T := 1 TO 126 DO        {126 PRESSURE MEASUREMENTS}
  BEGIN  (* for T *)
    FOR T2 := 1 TO 7 DO     {7 COLUMN BASED ON:

                        1 = PRESSURE IN H2O
                        2 = SUBJECT STANDING SITTING 1..2
                        3 = TIME CODE OF MEASUREMENT 1..7
                        4 = POSITION OF TRANSDUCER 1..3
                        5 = CODE OF SUBJECT 1..10
                        6 = TECHNIQUE OF BANDAGING USED 1..2
                        7 = TYPE OF BANDAGE USED 1..5}
      write(file1IN,rawset[T,T2]:6);
    writeln(file1IN)
  END;   (* FOR T *)

writeln(file1IN);
writeln(file1IN);
CLOSE(file1IN);

    {--------------- AVERAGED DATA TABLE -----------}

OPEN(file1IN,File3);    {Taking the array CODE "8"
                         averaged values}
REWRITE(file1IN);
```

```
FOR Y := 1 TO 21 DO
Begin {for Y}
  FOR Z := 1 TO 2 DO
  write(file1IN,h2odave[Y,Z]:6);
  writeln(file1IN)
End;
writeln(file1IN);
CLOSE(file1IN)

END;  {read_data_out}

{-------------------------------------------------------}

BEGIN {main program}

MRED    := 0;       {Initializing the three SLOPES, red,
                     blue, yellow}
MBLUE   := 0;
MYELLOW := 0;
FOR AA := minnum TO 126 DO        {to initialize arrays}
FOR BB := 1 TO 7 DO
rawset[AA,BB] := 0;               {1}
FOR AA := minnum TO 28 DO
FOR BB := minnum TO 6 DO
Begin {for BB}
  IF AA <= 21 THEN
    Begin {if AA}
      rawdat[AA,BB] := 0;         {2}
      h2odat[AA,BB] := 0;         {7}
      IF BB <= 2 THEN
        Begin {if BB}
          rawdatave[AA,BB] := 0; {6}
          h2odave[AA,BB] := 0     {8}
        End {if BB}
    End; {if AA}
  IF AA <= 6 THEN
    rawbase[AA,BB] := 0;          {3}
  IF AA <= 3 THEN
    Begin {if AA, 3}
      rawbare[AA,BB] := 0;        {4}
      IF AA <= 2 THEN
        IF BB <= 2 THEN
          rawbareave[AA,BB] := 0 {5}
    End {if AA, 3}
 End; {for BB}
FOR AA := 1 TO 20 DO
writeln;
writeln;
writeln('                 ------------------------------');
writeln('                 **  WELCOME TO THE PROGRAM  **');
WRITELN('                 ------------------------------');
writeln; writeln;
writeln;
writeln;
writeln('          * TRANSFORMATION INTO H2O PRESSURE *');
WRITELN;
writeln('       **     INPUTS DATA INFORMATION      **');
writeln;
```

```
  write('* ENTER THE FILENAME OF THE INPUT DATA ------- ');
  READLN(file1);
  writeln;
  write('* ENTER CODE FOR  ... SUBJECT   FOR THE DATA --');
  READLN(subjectcode);
  writeln;
  write('* ENTER CODE FOR  ...TECHNIQUE  FOR THE DATA --');
  READLN(techniquecode);
  writeln;
  write('* ENTER CODE FOR  ... BANDAGE   FOR THE DATA - ');
  READLN(bandagecode);
  writeln;
  writeln('      ****   OUTPUT DATA INFORMATION    ****');
  writeln;
  write('* ENTER FILEMANE FOR THE SINGLE DATA IN H2O *');
  READLN(file2);
  writeln;
  write('* ENTER FILENAME FOR THE AVERAGE DATA IN H2O *');
  readln(file3);
  writeln;
  read_data_in; {reading raw data from the in file, file1}

  separate_data_set;  {separating into two arrays, one for
                       the ZERO reading, the other the data
                       based on TIME}

  modify_base_data;   {gets column average for red, blue
                       and yellow M's, also gets the
                       row-column average for each M's.}

  make_average_data;  {gets the row average, first of the
                       three columns for stand, the for
                       columns for seating}

  transform_into_H2O_system;  {Using all the array already
                              created, we use our equation
                              to transform the Volt's
                              reading into its equivalent
                              in cm of H2O}

  read_data_out;      {Once everything has being
                       transformed to our new
                       system, we create to output files.
                       One corresponding to pressures once
                       the average has being taken, the
                       second one, containing the pressures
                       of each measurement performed}

  writeln(' ********************************************');
  writeln(' *                                          *');
  writeln(' *       OUTPUT  FILES  CREATED             *');
  writeln(' *                                          *');
  writeln(' *                                          *');
  writeln(' * Complete Values Table ... ',file2,'.dat' * );
  writeln(' *                                          *');
  writeln(' * Averaged Values Table ... ',file3,'.dat' * );
  writeln(' *                                          *');
  writeln(' ********************************************');
  writeln; writeln;
  writeln('   ... E N D   O F   T H E   P R O G R A M ..');
END.  {main program}
```

GETRANGE.PAS
****

```
PROGRAM siv_getrange(input,output,infil,outfile);

   {This program gets sets of three
   consecutive number for the input file
   and firts order them from small to
   larger, then gets the range between
   the small and the largest and writes
   that range in the output file.

   Design : S.Sockalingam
   Author : R. Torres-Moreno,  110489}

CONST
   minnum         = 1;
   maxnumdata     = 7560;
   maxrowout      = 840;

TYPE
 fnames       = packed array[minnum..18]     of CHAR;
 dataarray2B = array[minnum..maxrowout,minnum..3]
               of integer;
 dataarray1A = array[minnum..maxnumdata]    of integer;

VAR
  A, B, E, F,
  datanum, counter1,
  number, row,
  num1, num2, num3          : integer;
  filein, fileout           : fnames;
  infil, outfile            : TEXT;
  datain                    : dataarray1A;
  dataout                   : dataarray2B;

 {-----------------------------------------------}

 PROCEDURE order(var X, Y : integer);

   {this procedure order the numbers given
   to X and Y inaccending order. If X > Y
   then their values are shifted, otherwise
   they remain the same}

 VAR
   temp : integer;

 Begin {order}
   IF X > Y THEN
   Begin {switch values}
    temp := X;
    X := Y;
    Y := temp
   End {switch values}

 End; {order}

 {-----------------------------------------------}
```

```
PROCEDURE read_data_out;

var
  numrowtoprint, C : integer;

 Begin
  OPEN(outfile,fileout);
  REWRITE(outfile);
  numrowtoprint := ROUND(datanum/9);
  FOR C := 1 to numrowtoprint DO
  writeln(outfile,dataout[C,1]:5,
         dataout[C,2]:5,dataout[C,3]:5);
  CLOSE(outfile)

End; {read data out}

{-----------------------------------------------}

BEGIN {main program}

 FOR A := 1 to maxnumdata DO    {initializing input
                                  data array}
 datain[A] := 0;

 FOR A := 1 to maxrowout DO    {initializing output
                                  data array}
 FOR B := 1 to 3 DO
  dataout[A,B] := 0;

  writeln;
  write('Enter the filename of input data  ... ');
  readln(filein);
  writeln;
  write('Enter the filename of output data ... ');
  readln(fileout);
  writeln;
  writeln('Enter the number of data in file  ');
  writeln('    ... maximum 7560, has to be   ');
  write('       multiple of 9 for now    ... ');
  readln(datanum);
  writeln;
  row := 1;

  OPEN(infil,filein,history := old);
  RESET(infil);
  FOR E := 1 to datanum DO      {reading the input data
                                  into datain array}
   begin
   readln(infil,number);
   datain[E] := number
   end;
  CLOSE(infil);

  counter1 := 1;          {limits the while loop top the
                           number of maximum input data}

  WHILE counter1 < datanum DO
    Begin {while}
```

```
    num1 := datain[counter1];
    num2 := datain[counter1 + 1];
    num3 := datain[counter1 + 2];
    order(num1,num2);
    order(num1,num3);
    order(num2,num3);
    dataout[row,1] := num3 - num1;

    num1 := datain[counter1 + 3];
    num2 := datain[counter1 + 4];
    num3 := datain[counter1 + 5];
    order(num1,num2);
    order(num1,num3);
    order(num2,num3);
    dataout[row,2] := num3 - num1;

    num1 := datain[counter1 + 6];
    num2 := datain[counter1 + 7];
    num3 := datain[counter1 + 8];
    order(num1,num2);
    order(num1,num3);
    order(num2,num3);
    dataout[row,3] := num3 - num1;

    row := row + 1;
    counter1 := counter1 + 9
    End; {while}

read_data_out

END. {main program}
```

DATAVERAGE.FOR
****

Author: S Nicol

```
C
      INTEGER INARR(3,7),OUTARR(1,7)
C
      DO 10 J=1,168
      DO 12 I=1,3
      READ (2,*)(INARR(I,K),K=1,7)
12    CONTINUE
C
      MEAN=(INARR(1,1)+INARR(2,1)+INARR(3,1))/3
C
      DO 14 K=1,7
      OUTARR(1,K)=INARR(1,K)
14    CONTINUE
C
      OUTARR(1,1)=MEAN
      WRITE(3,20)(OUTARR(1,K),K=1,7)
20    FORMAT(7I6)
C
10    CONTINUE
      STOP
      END
```

SORTFORMAT.FOR
****

Author: S Nicol

```
c program to create files of data for friedman test.
c subject by position.
c
      integer data(10,3)
c
      itime=5
      iposture=1
c
      do 130 itechnique=1,2
      do 140 ibandage=1,6
      open(20,file='DATASTOCK.dat',status='old',readonly)
      open(21,file='db5'//char(iposture+48)//
     *    char(itechnique+48)//char(ibandage+48),status='new',
     *    carriagecontrol='list')

     1     read(20,*,end=50) ivalue,jposture,jtime,jposition,
     *     jsubject,jtechnique,jbandage
           if (jtime.ne.itime) goto 1
           if (jposture.ne.iposture) goto 1
           if (jtechnique.ne.itechnique) goto 1
           if (jbandage.ne.ibandage) goto 1
           data(jsubject,jposition)=ivalue
           goto 1

50    continue

      do 60 isubject=1,10
60    write(21,700) isubject,(data(isubject,k),k=1,3)
700   format(4i6)
      close(unit=20)
      close(unit=21)
140   continue
130   continue
      end
```

HISTOGRAMS OF THE RANGE OF EACH TRIPLICATE PRESSURE MEASUREMENT FOR BANDAGES

Histogram of C1 N = 1680
Each * represents 15 obs.
1 Obs. above the last class

MEASUREMENTS AT THE CALF

midpoint (mmH20)	Count	
0.0	540	************************************
13.6	720	**
27.2	234	****************
40.8	103	*******
54.4	39	***
68.0	25	**
81.6	11	*
95.2	6	*
108.8	1	*

89% OF THE READINGS WERE WITHIN
1mm Hg (13.6mm H20) OF THE MEDIAN

Histogram of C2 N = 1680
Each * represents 20 obs.
1 Obs. above the last class

MEASUREMENTS AT THE GAITER

midpoint (mmH20)	Count	
0.0	557	****************************
13.6	839	**
27.2	210	**********
40.8	46	***
54.4	16	*
68.0	8	*
81.6	2	*
95.2	1	*

96% OF THE READINGS WERE WITHIN
1mm Hg (13.6mm H20) OF THE MEDIAN

Histogram of C3 N = 1680
Each * represents 20 obs.
1 Obs. above the last class

MEASUREMENTS AT THE ANKLE

midpoint (mmH20)	Count	
0.0	649	*********************************
13.6	772	**************************************
27.2	185	**********
40.8	47	***
54.4	13	*
68.0	6	*
81.6	4	*
95.2	0	
108.8	1	*
122.4	2	*

96% OF THE READINGS WERE WITHIN
1mm Hg (13.6mm H20) OF THE MEDIAN

HISTOGRAMS OF THE RANGE OF EACH TRIPLICATE PRESSURE MEASUREMENT FOR STOCKINGS

Histogram of C1 N = 1680
Each * represents 20 obs.

MEASUREMENTS AT THE CALF

midpoint (mmH20)	Count	
0.0	806	**
13.6	701	**********************************
27.2	146	********
40.8	23	**
54.4	3	*
68.0	0	
81.6	0	
95.2	0	
108.8	0	
122.4	0	
136.0	0	
149.6	0	
163.2	0	
176.8	0	
190.4	1	*

98% OF THE READINGS WERE WITHIN 1mm Hg (13.6mm H20) OF THE MEDIAN

Histogram of C2 N = 1680
Each * represents 20 obs.

MEASUREMENTS AT THE GAITER

midpoint (mmH20)	Count	
0.0	888	**
13.6	677	**********************************
27.2	101	******
40.8	10	*
54.4	3	*
68.0	1	*

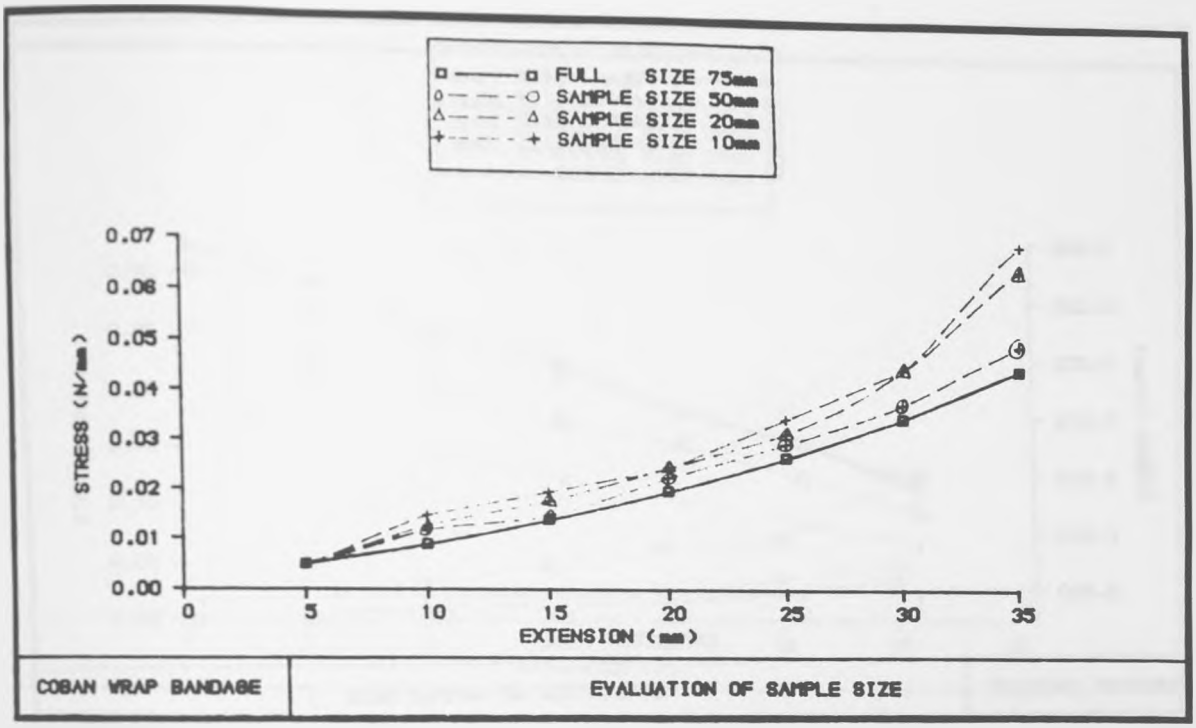
99% OF THE READINGS WERE WITHIN 1mm Hg (13.6mm H20) OF THE MEDIAN

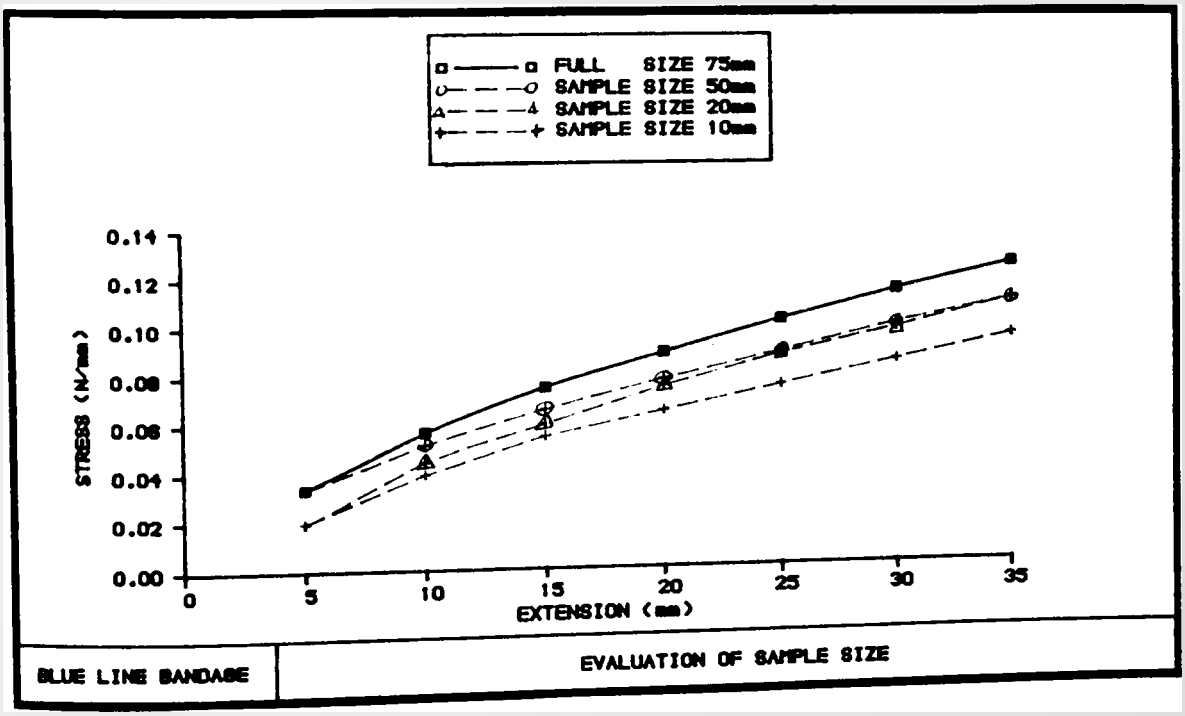
Histogram of C3 N = 1680
Each * represents 20 obs.

MEASUREMENTS AT THE ANKLE

midpoint (mmH20)	Count	
0.0	996	**
13.6	600	******************************
27.2	68	****
40.8	6	*
54.4	1	*
68.0	1	*
81.6	0	
95.2	0	
108.8	1	*
122.4	0	
136.0	0	
149.6	5	*
163.2	2	*

99% OF THE READINGS WERE WITHIN 1mm Hg (13.6mm H20) OF THE MEDIAN


FULL SIZE 75mm
SAMPLE SIZE 50mm
SAMPLE SIZE 20mm
SAMPLE SIZE 10mm
STRESS (N/mm)
0.07
0.06
0.05
0.04
0.03
0.02
0.01
0.00
0
5
10
15
20
25
30
35
EXTENSION (mm)
COBAN WRAP BANDAGE
EVALUATION OF SAMPLE SIZE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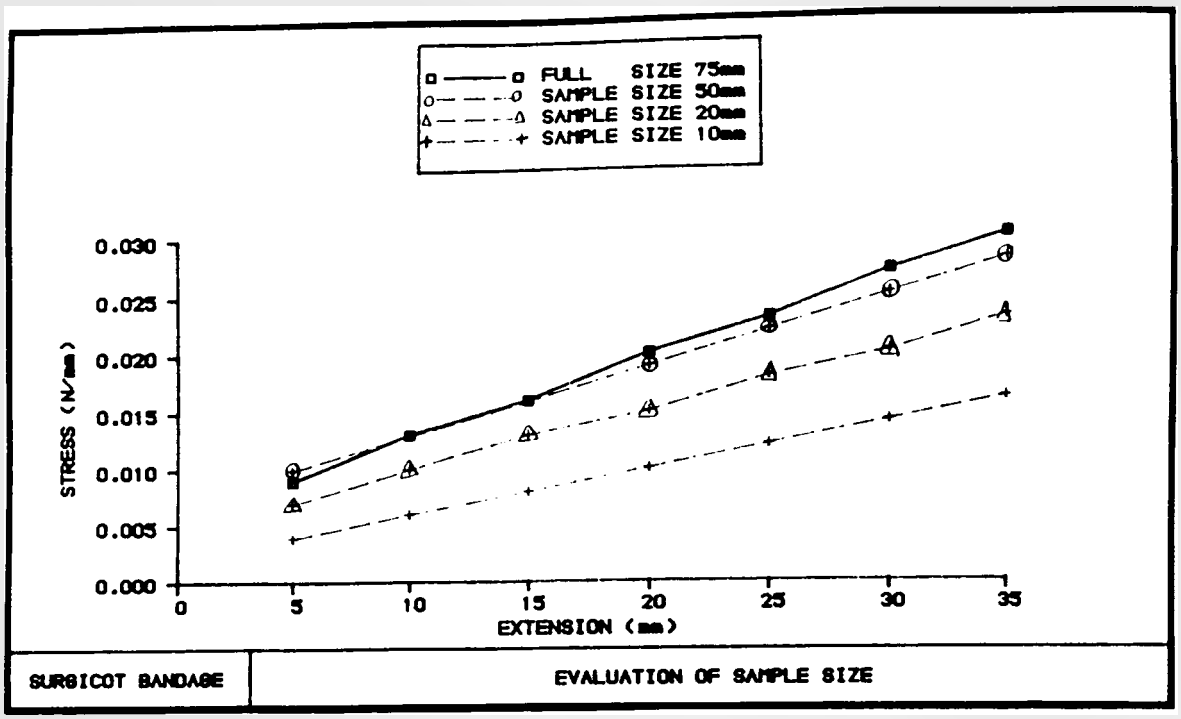
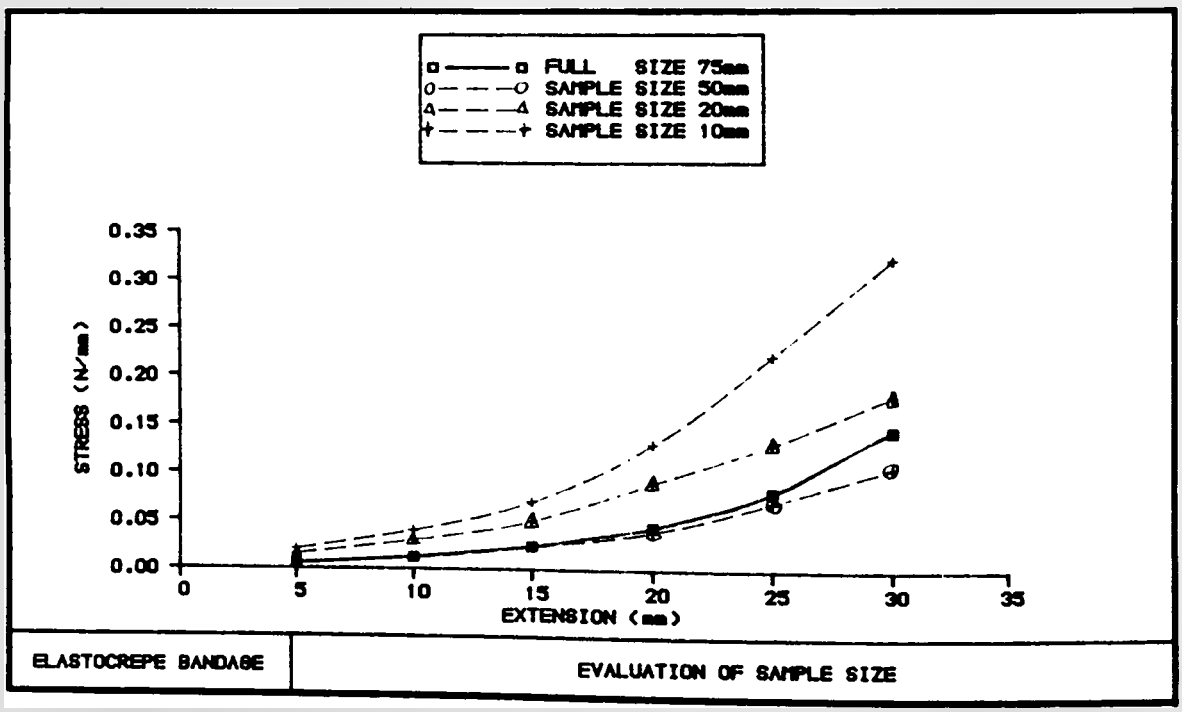
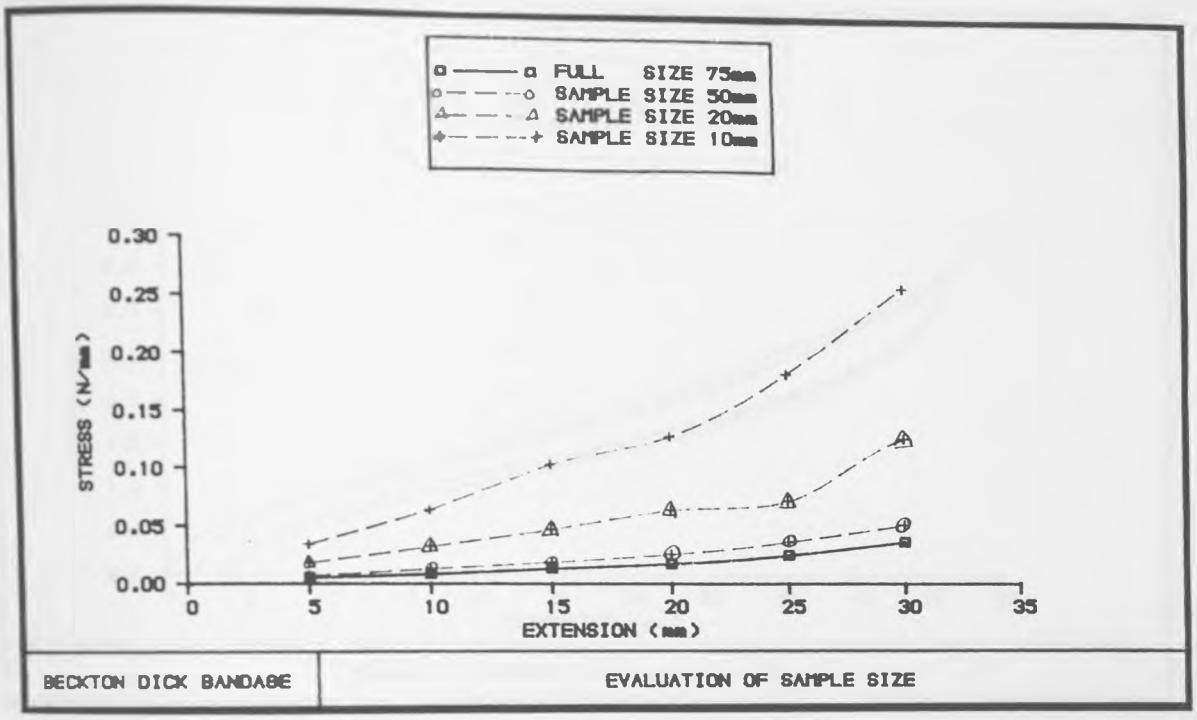
SAMPLE SIZE 20mm
SAMPLE SIZE 10mm
STRESS (N/mm)
0.14
0.12
0.10
0.08
0.06
0.04
0.02
0.00
0
5
10
15
20
25
30
35
EXTENSION (mm)
BLUE LINE BANDAGE
EVALUATION OF SAMPLE SIZE

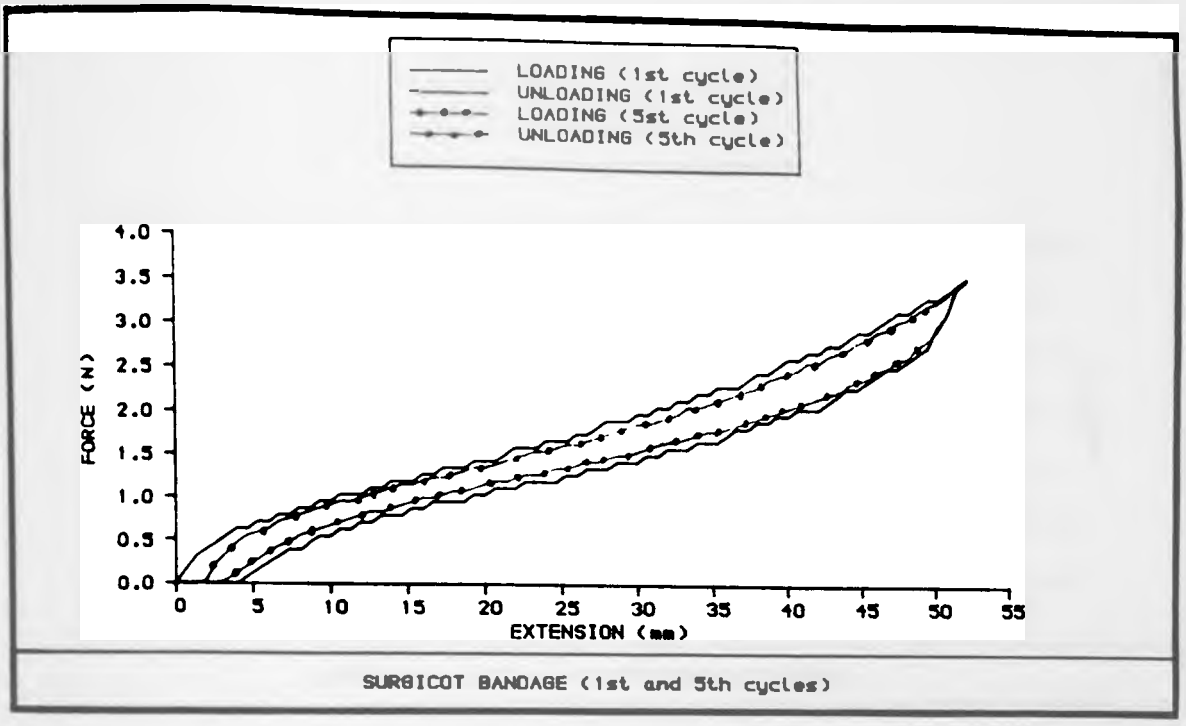


SURGICOT BANDAGE | EVALUATION OF SAMPLE SIZE

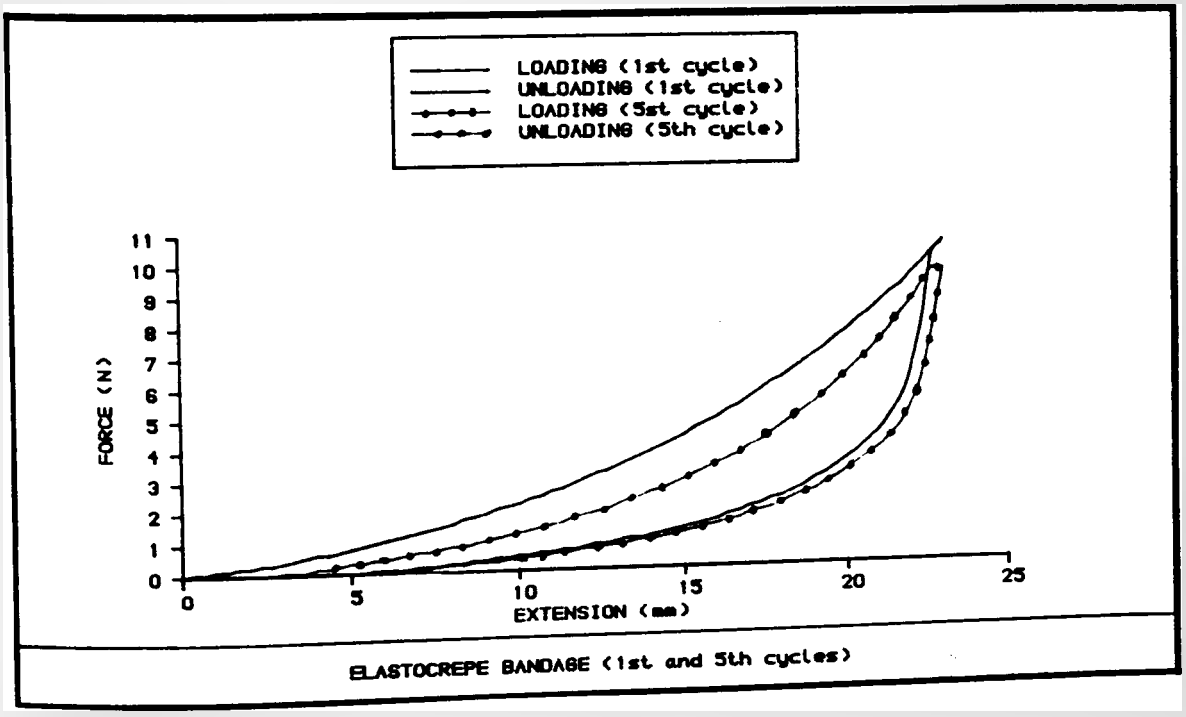


ELASTOCREPE BANDAGE | EVALUATION OF SAMPLE SIZE

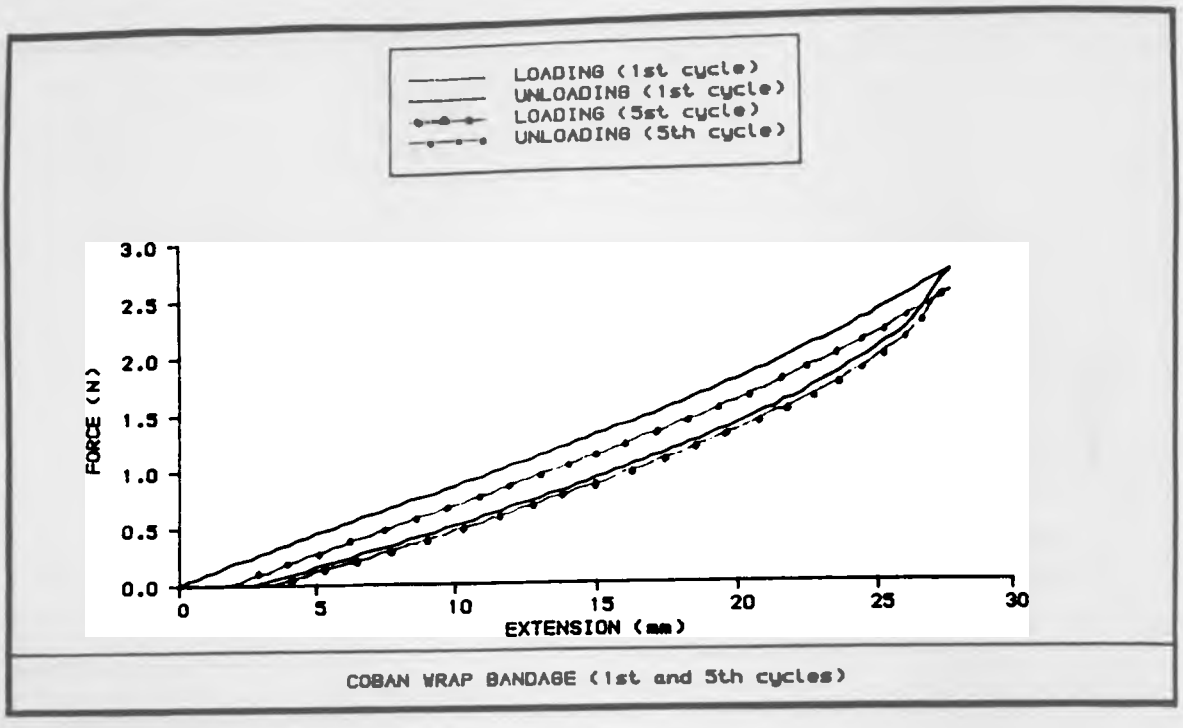

FULL SIZE 75mm
SAMPLE SIZE 50mm
SAMPLE SIZE 20mm
SAMPLE SIZE 10mm
STRESS (N/mm)
0.30
0.25
0.20
0.15
0.10
0.05
0.00
0
5
10
15
20
25
30
35
EXTENSION (mm)
BECKTON DICK BANDAGE
EVALUATION OF SAMPLE SIZE



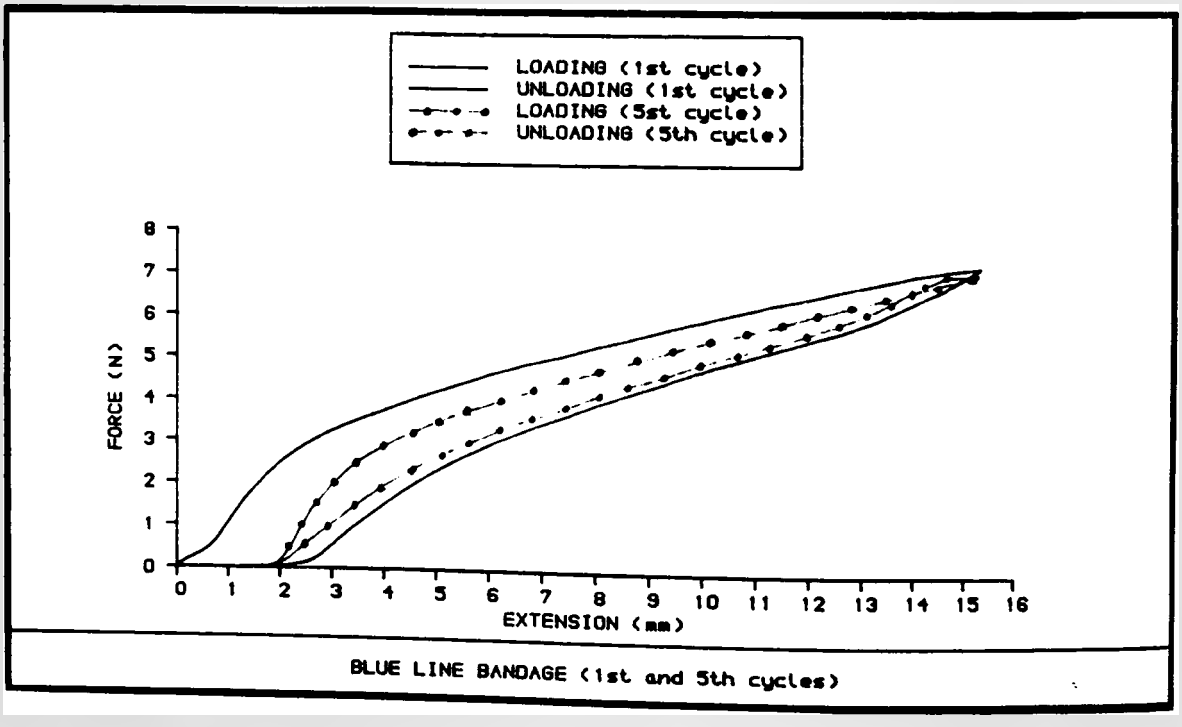
SURGICOT BANDAGE (1st and 5th cycles)



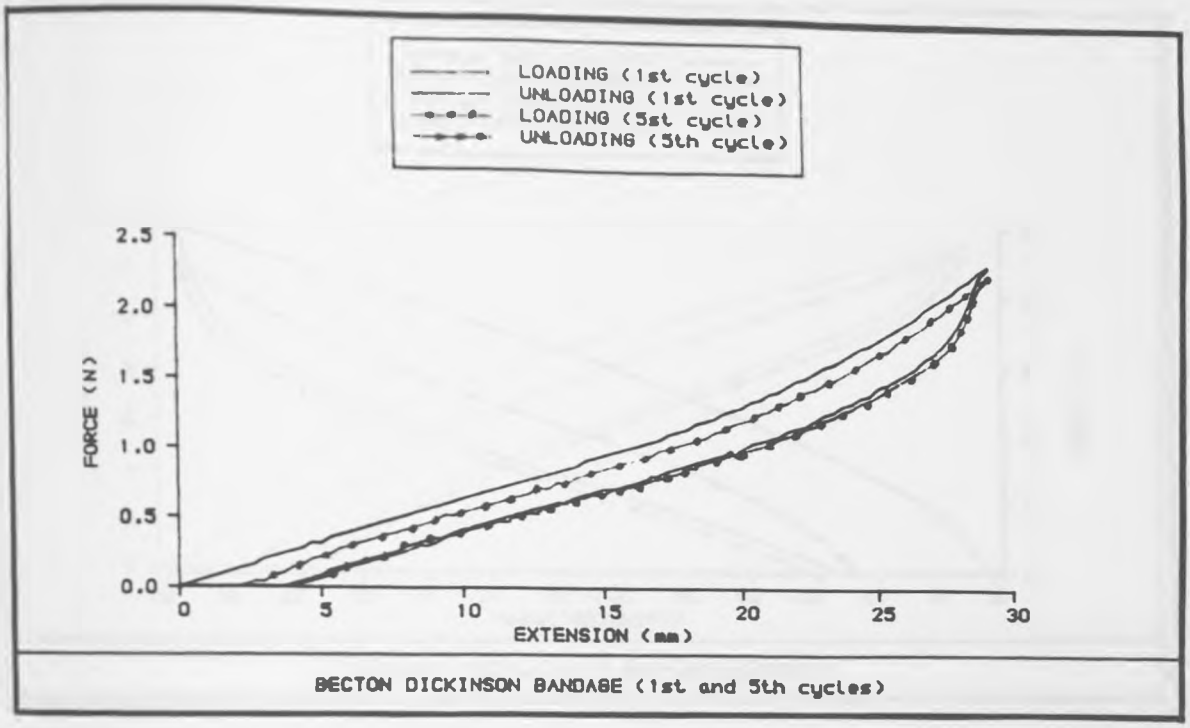
ELASTOCREPE BANDAGE (1st and 5th cycles)



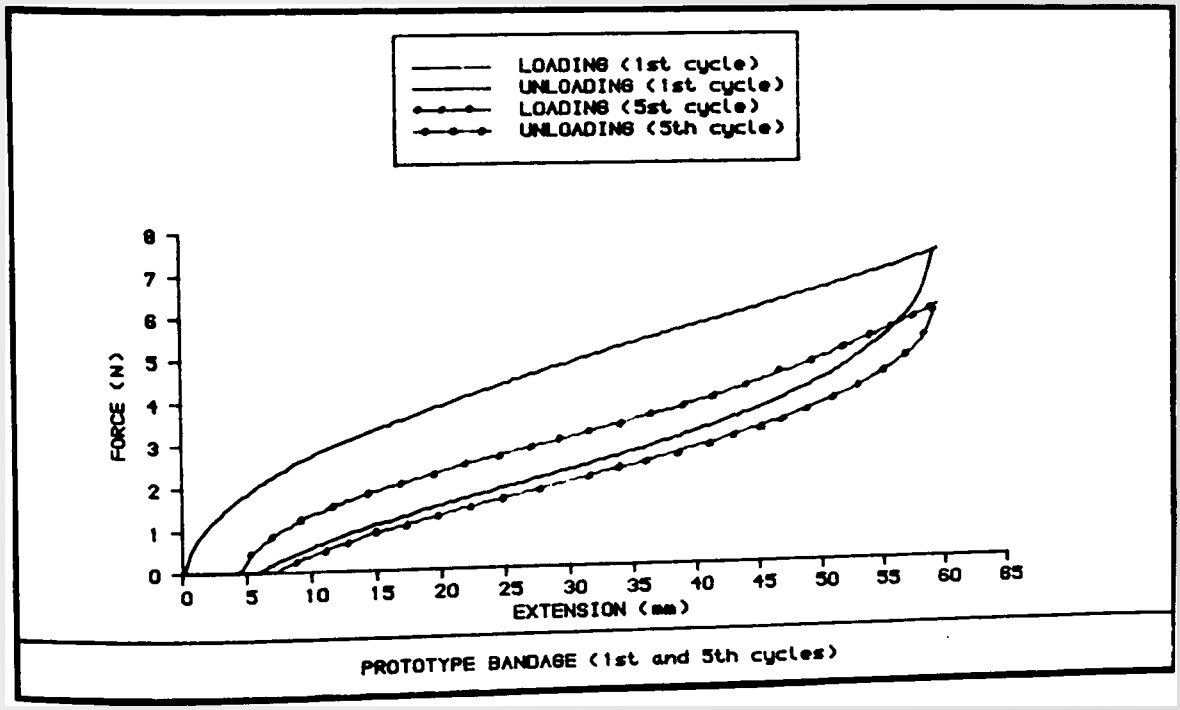
COBAN WRAP BANDAGE (1st and 5th cycles)



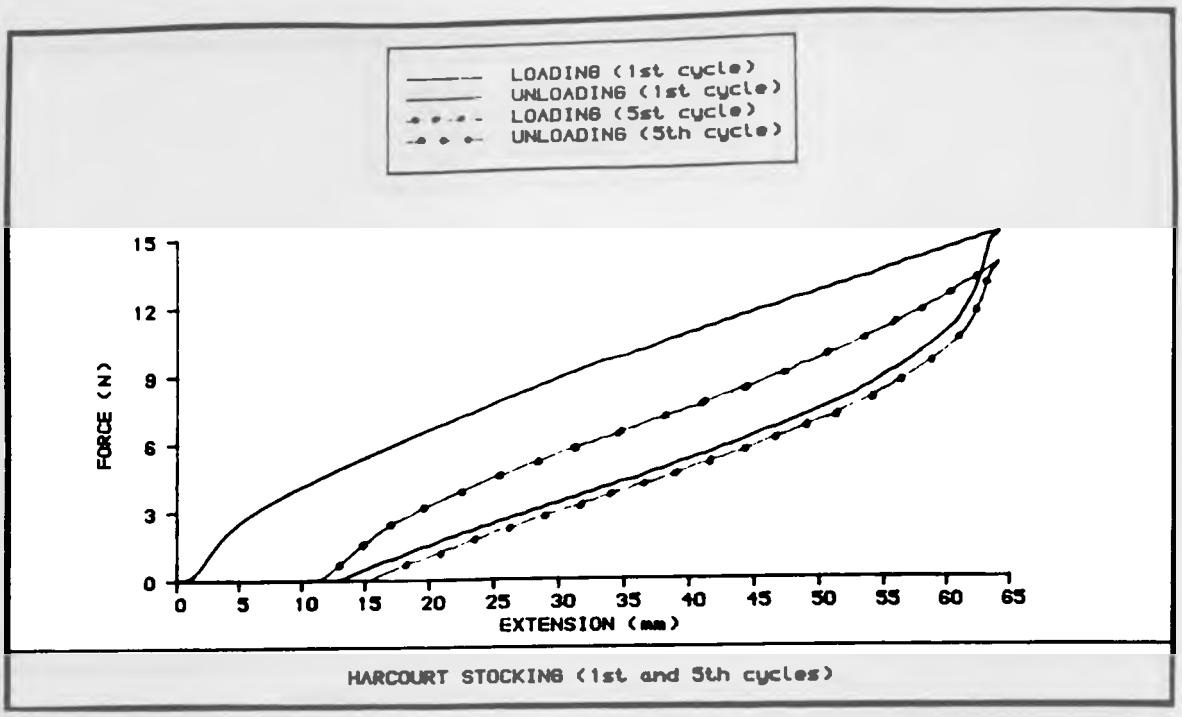
BLUE LINE BANDAGE (1st and 5th cycles)



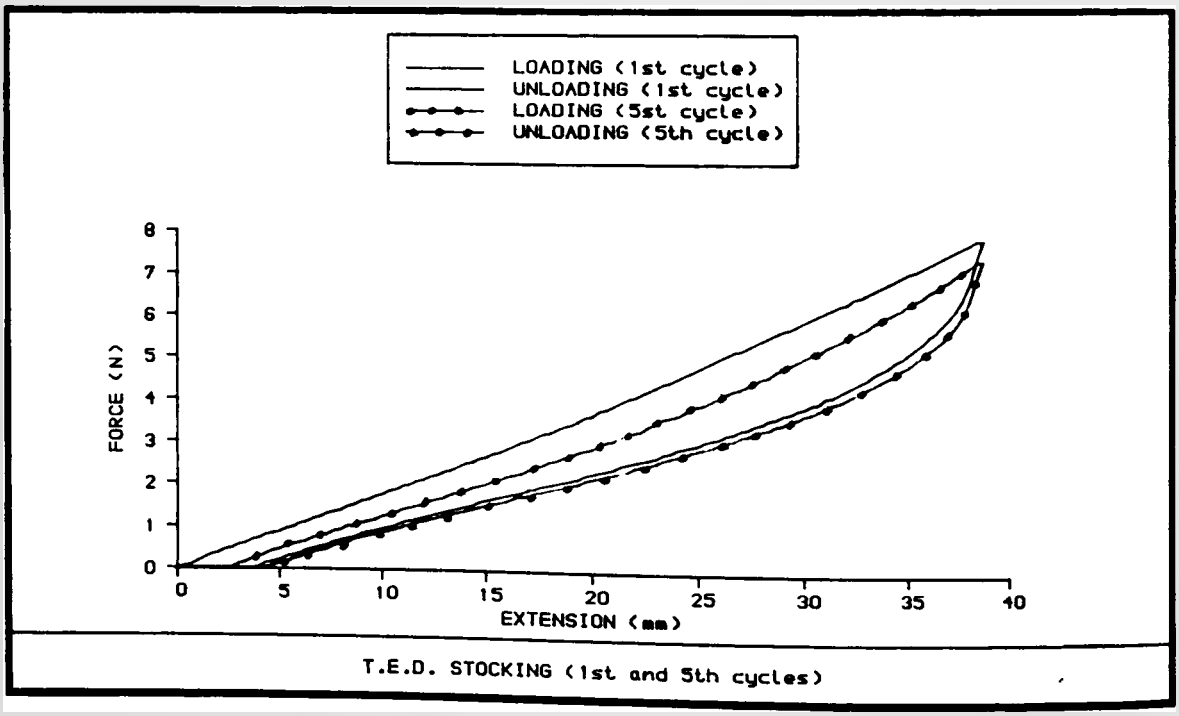
BECTON DICKINSON BANDAGE (1st and 5th cycles)



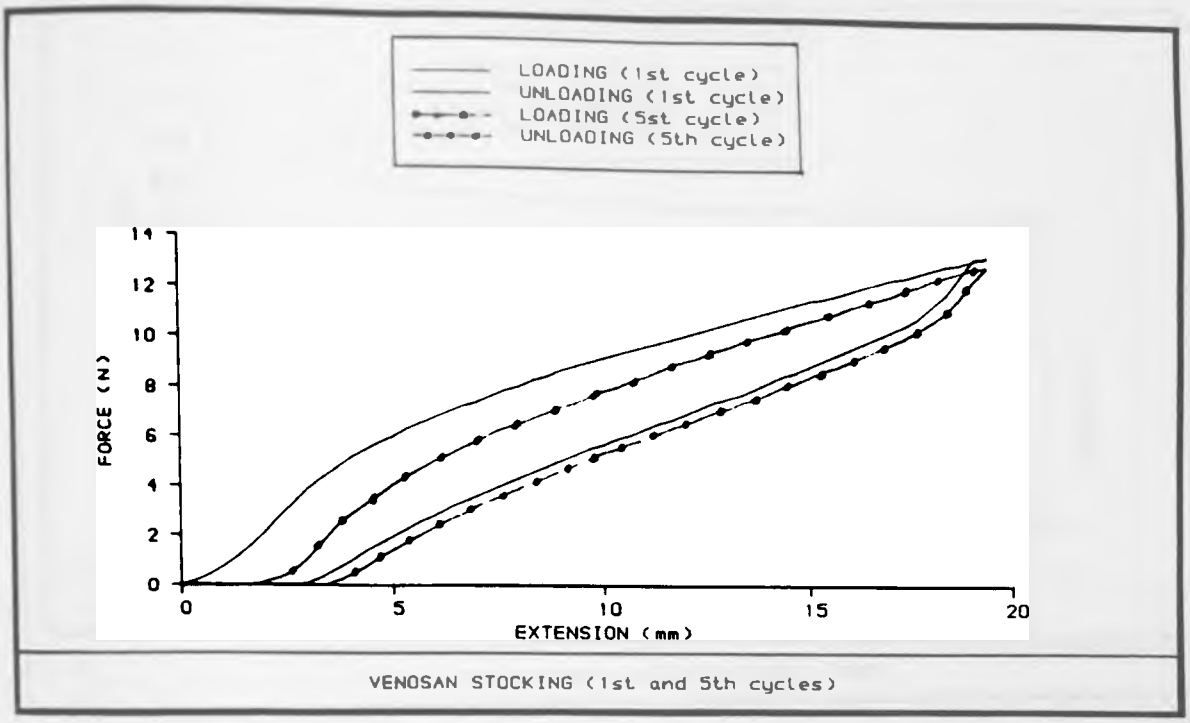
PROTOTYPE BANDAGE (1st and 5th cycles)



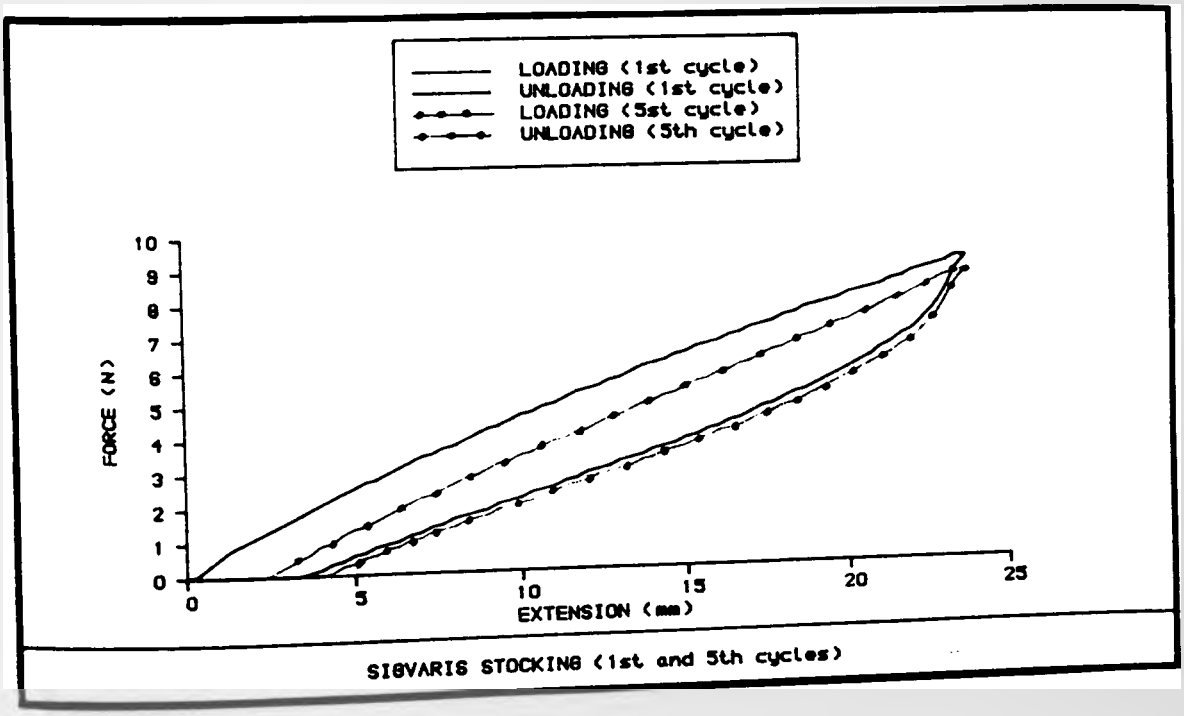
HARCOURT STOCKING (1st and 5th cycles)



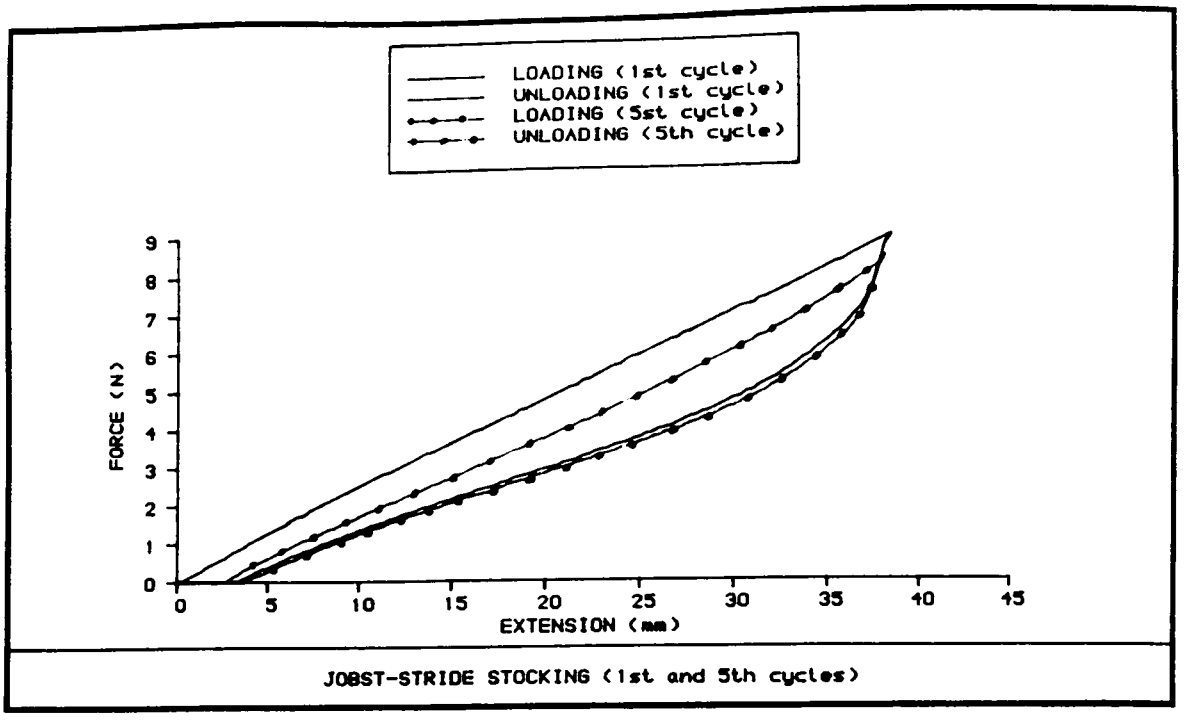
T.E.D. STOCKING (1st and 5th cycles)



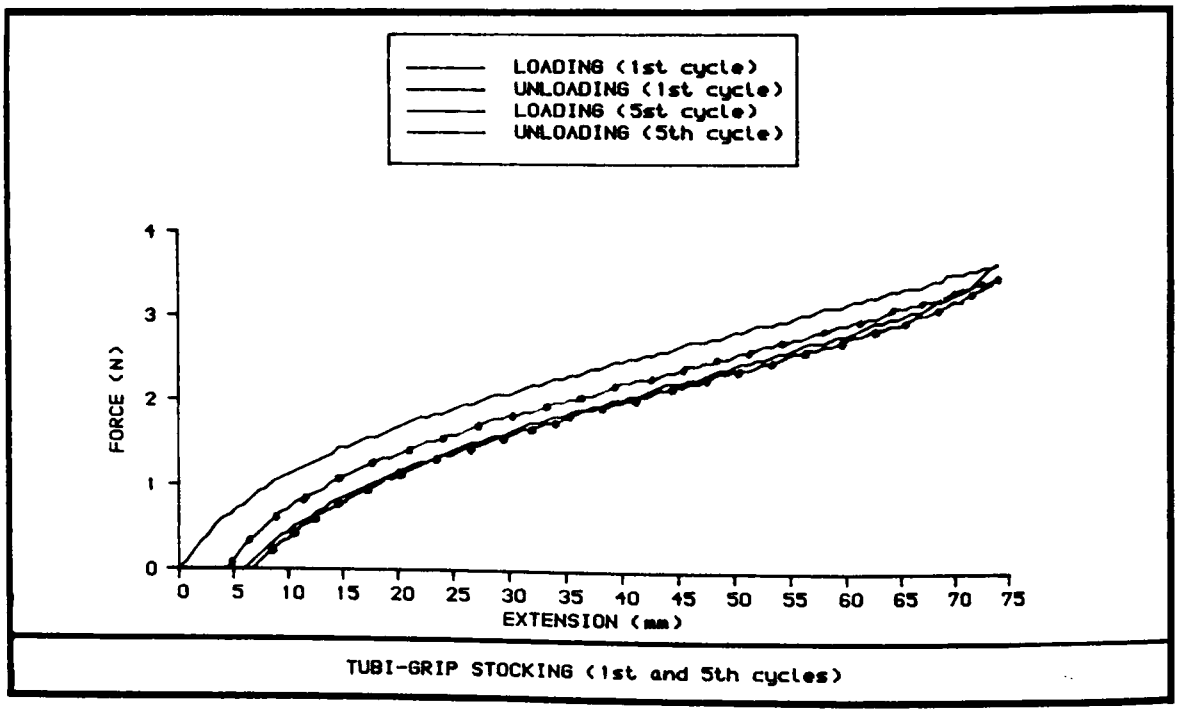
VENOSAN STOCKING (1st and 5th cycles)



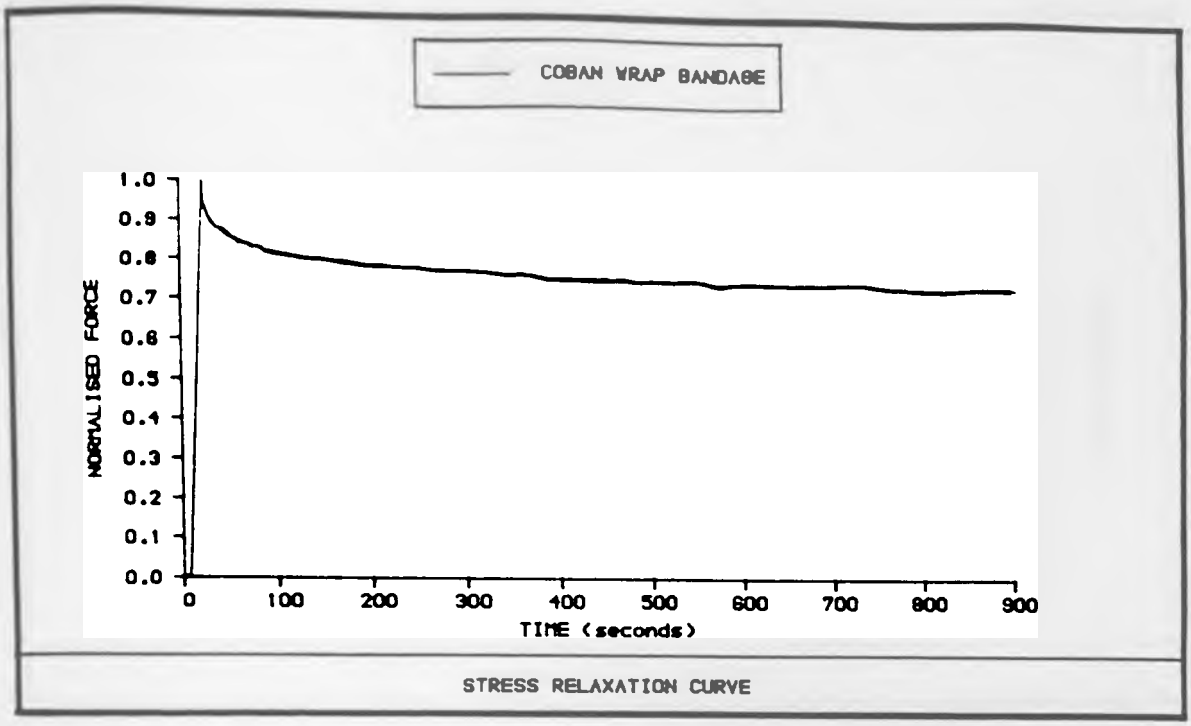
SIGVARIS STOCKING (1st and 5th cycles)



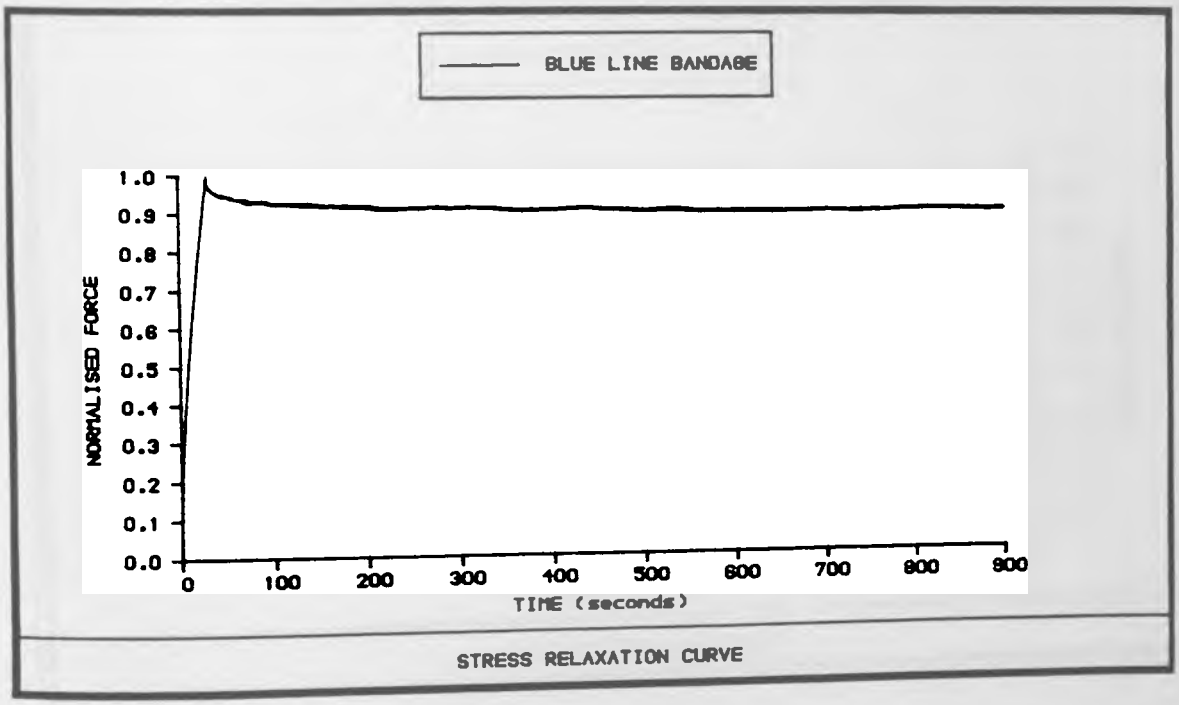
JOBST-STRIDE STOCKING (1st and 5th cycles)



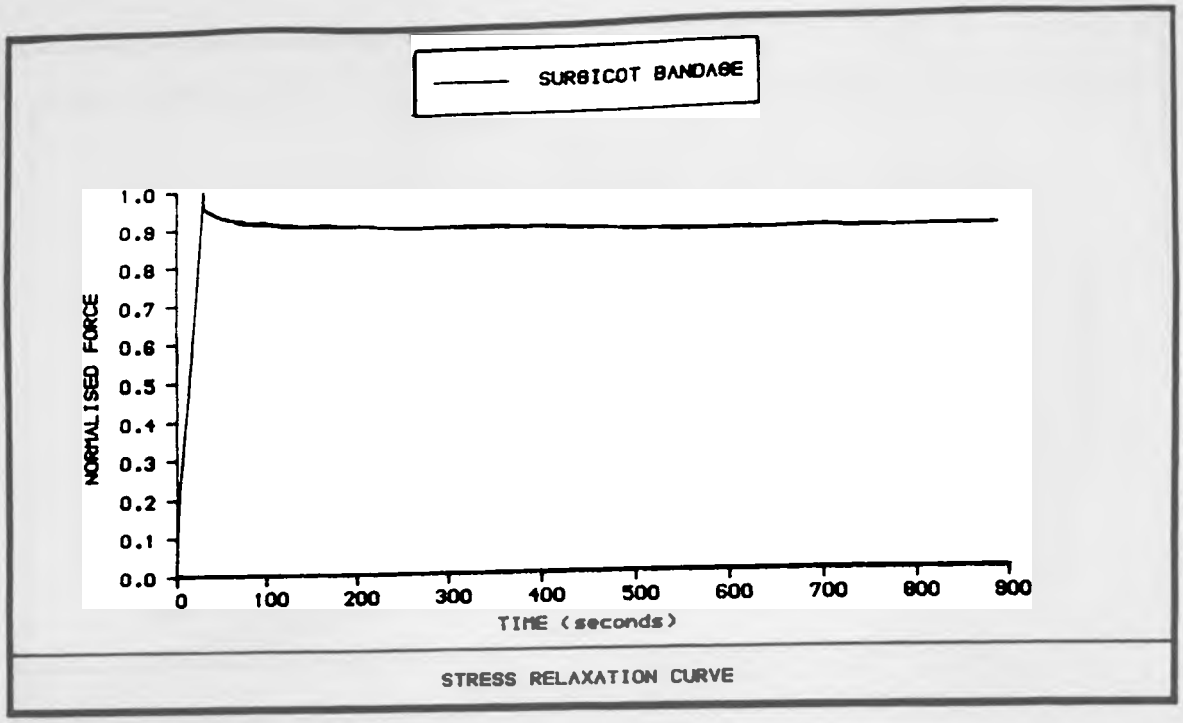
TUBI-GRIP STOCKING (1st and 5th cycles)



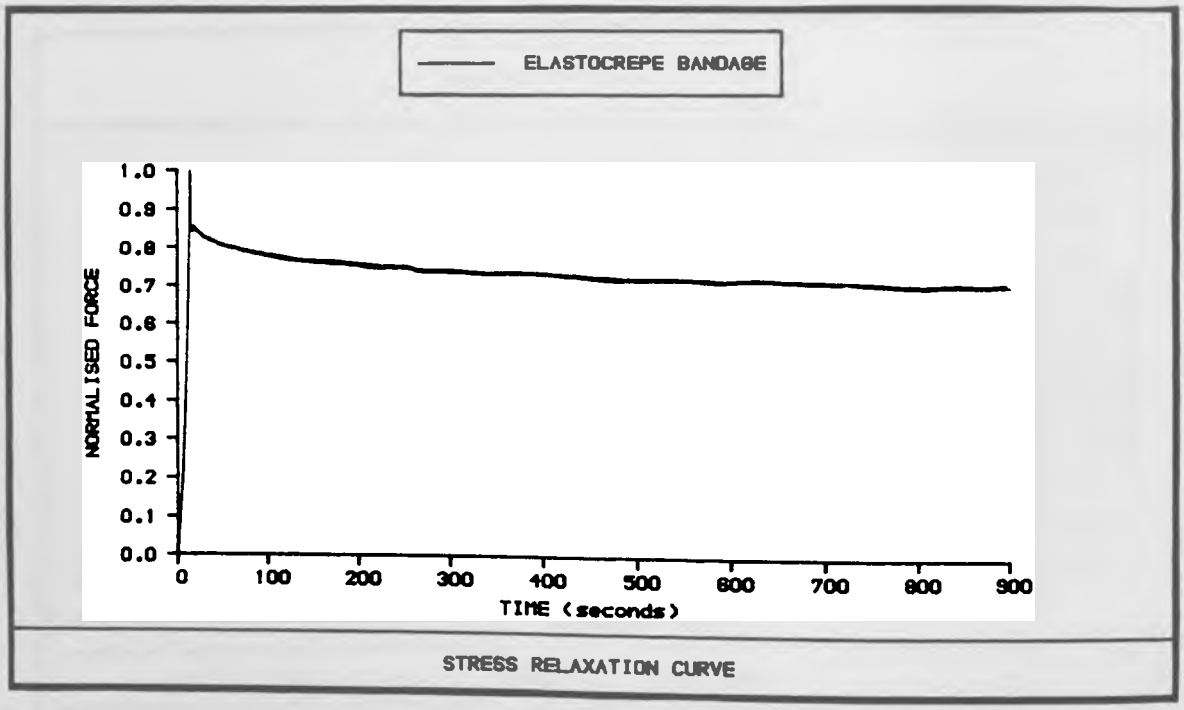
STRESS RELAXATION CURVE



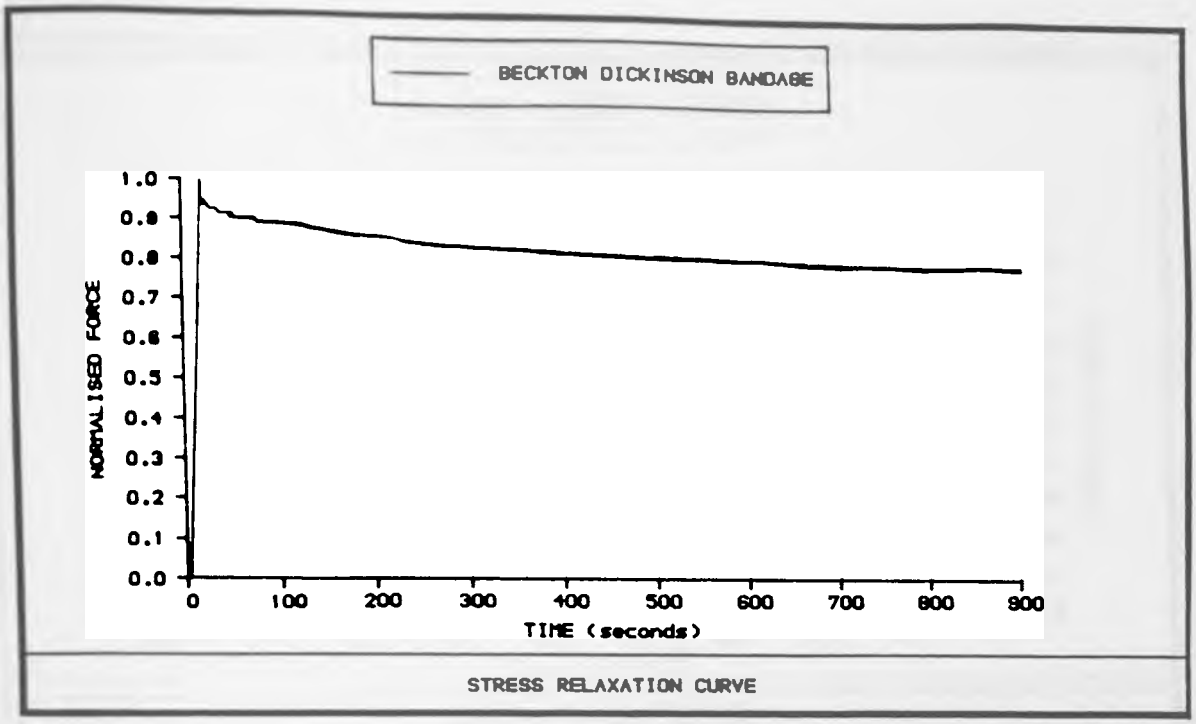
STRESS RELAXATION CURVE

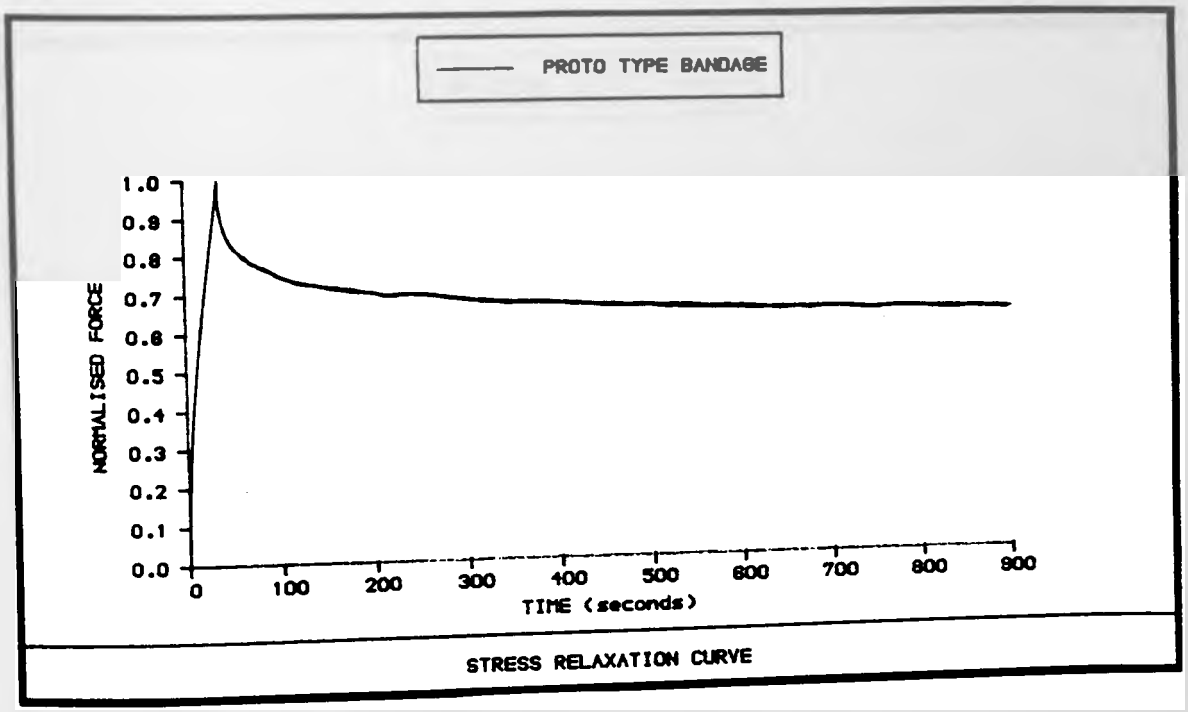


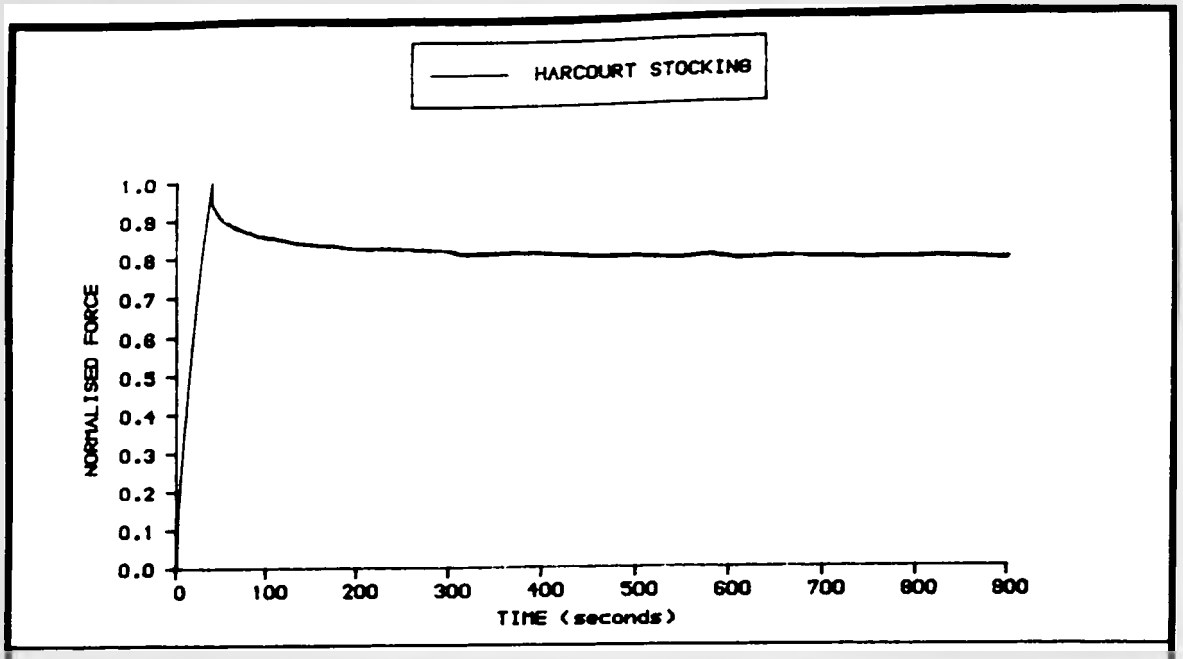
STRESS RELAXATION CURVE



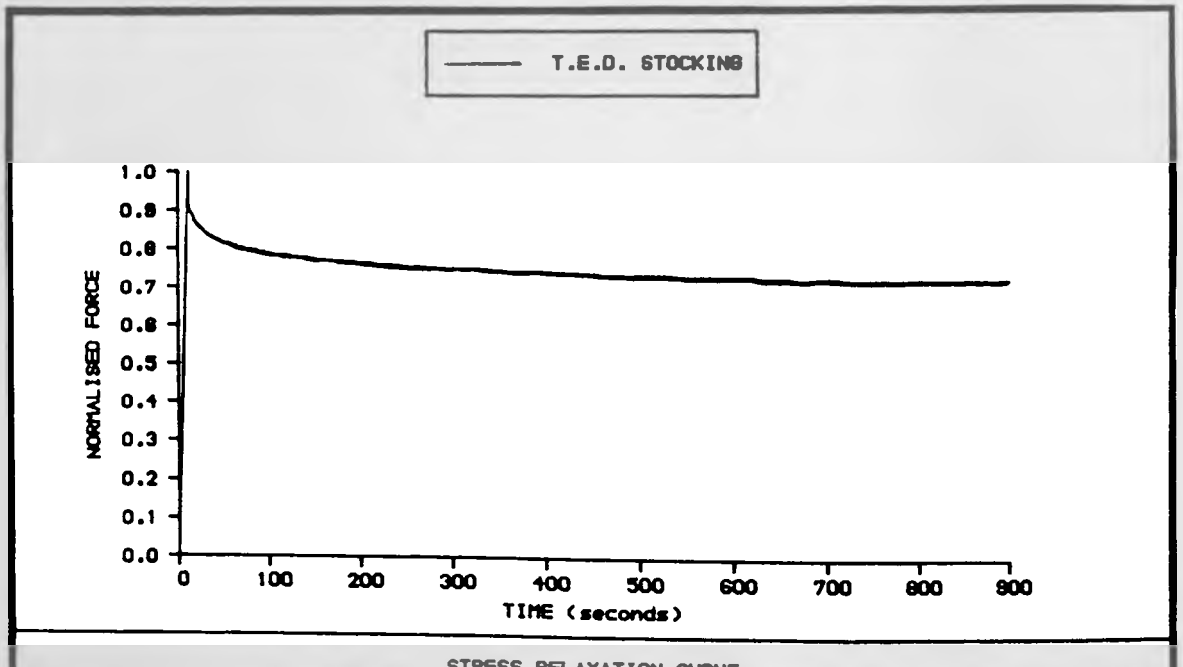
STRESS RELAXATION CURVE


BECKTON DICKINSON BANDAGE
NORMALISED FORCE
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
0
100
200
300
400
500
600
700
800
900
TIME (seconds)
STRESS RELAXATION CURVE

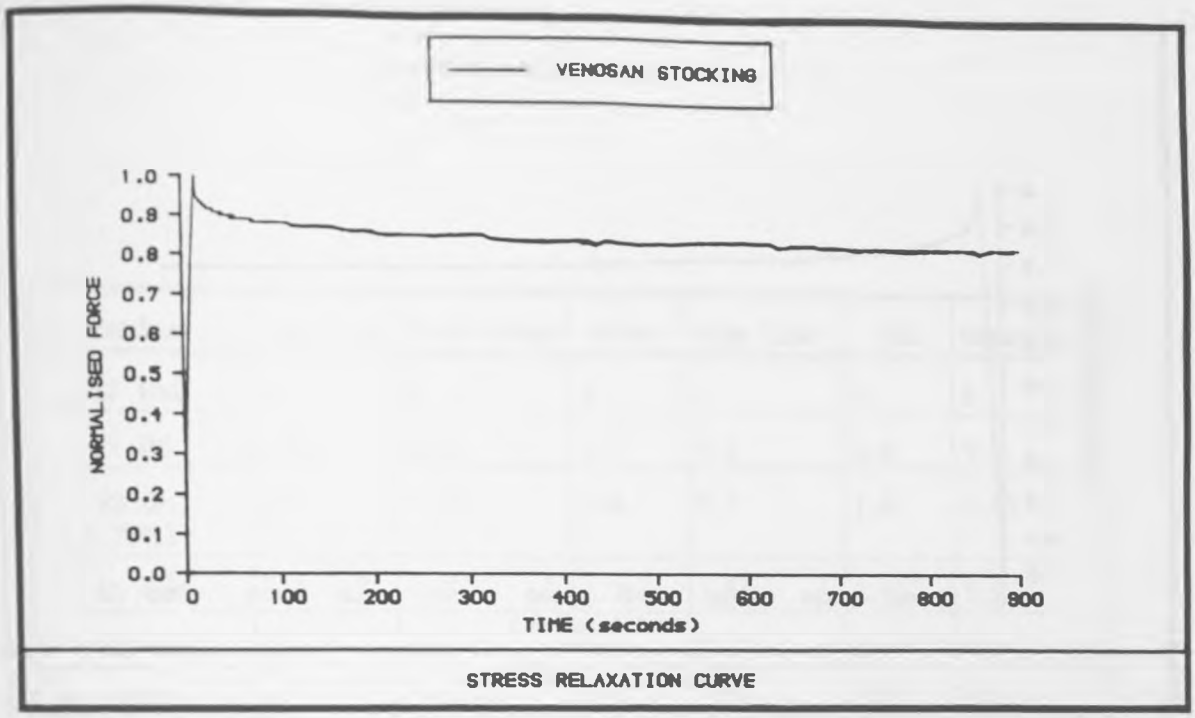

PROTO TYPE BANDAGE
NORMALISED FORCE
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
0
100
200
300
400
500
600
700
800
900
TIME (seconds)
STRESS RELAXATION CURVE

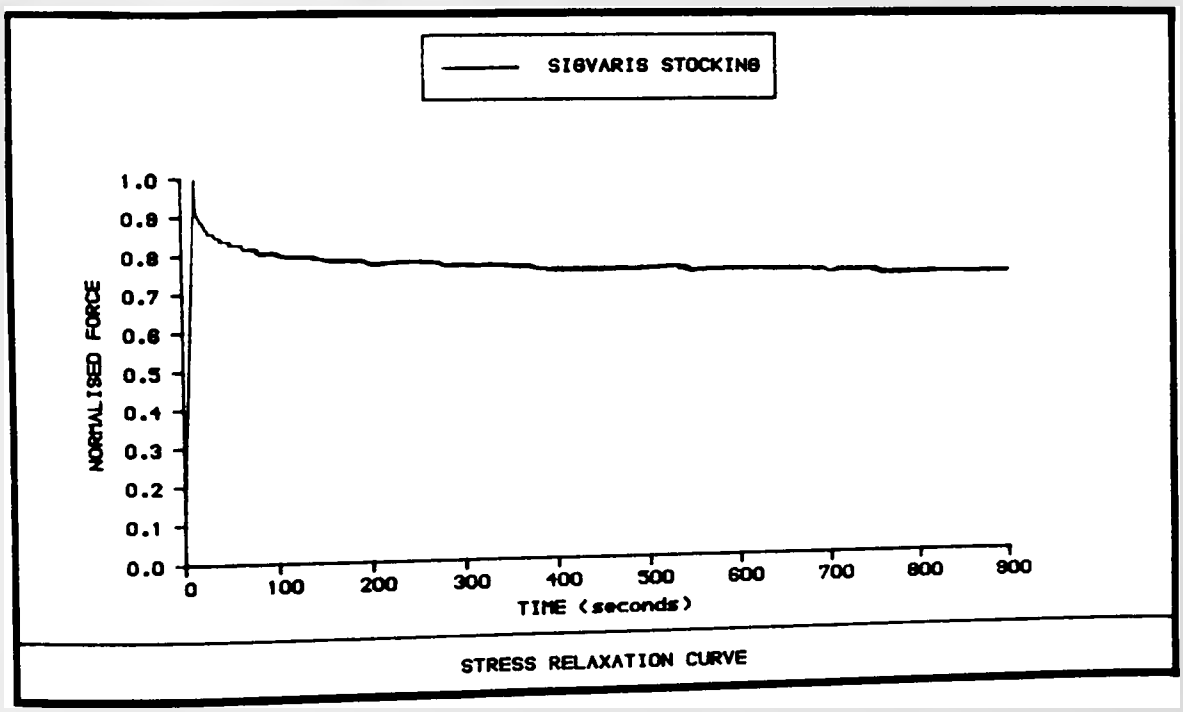


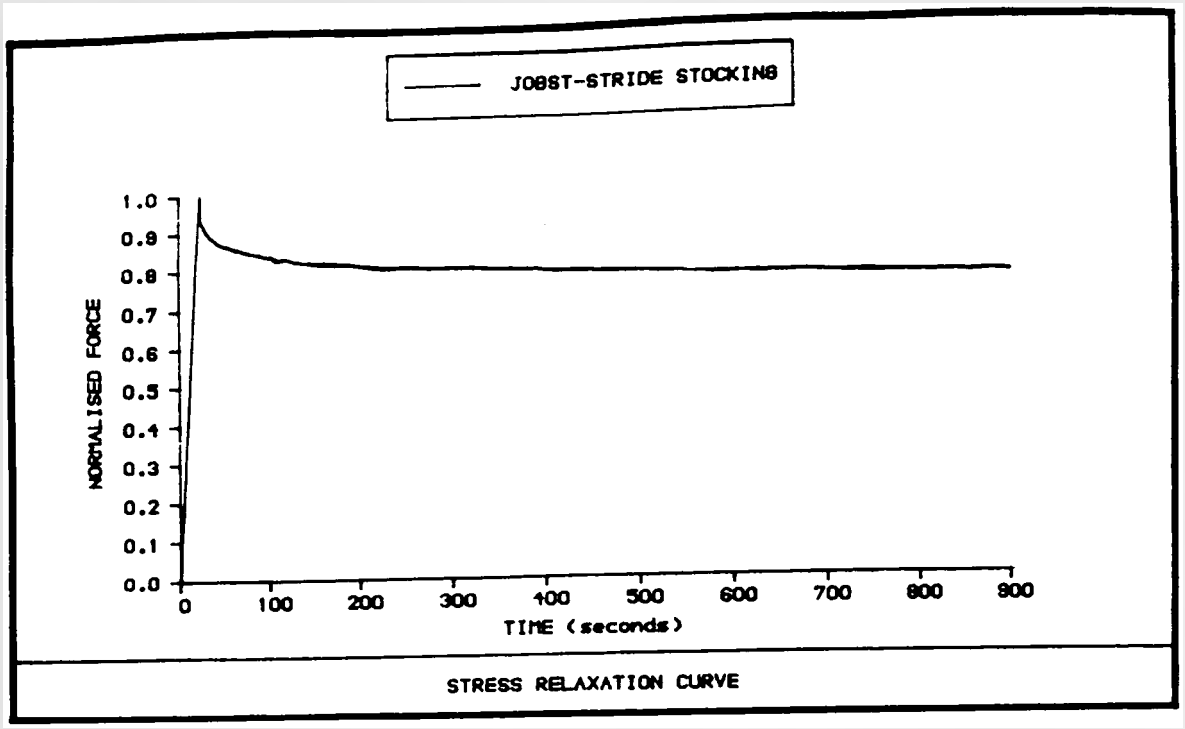
STRESS RELAXATION CURVE



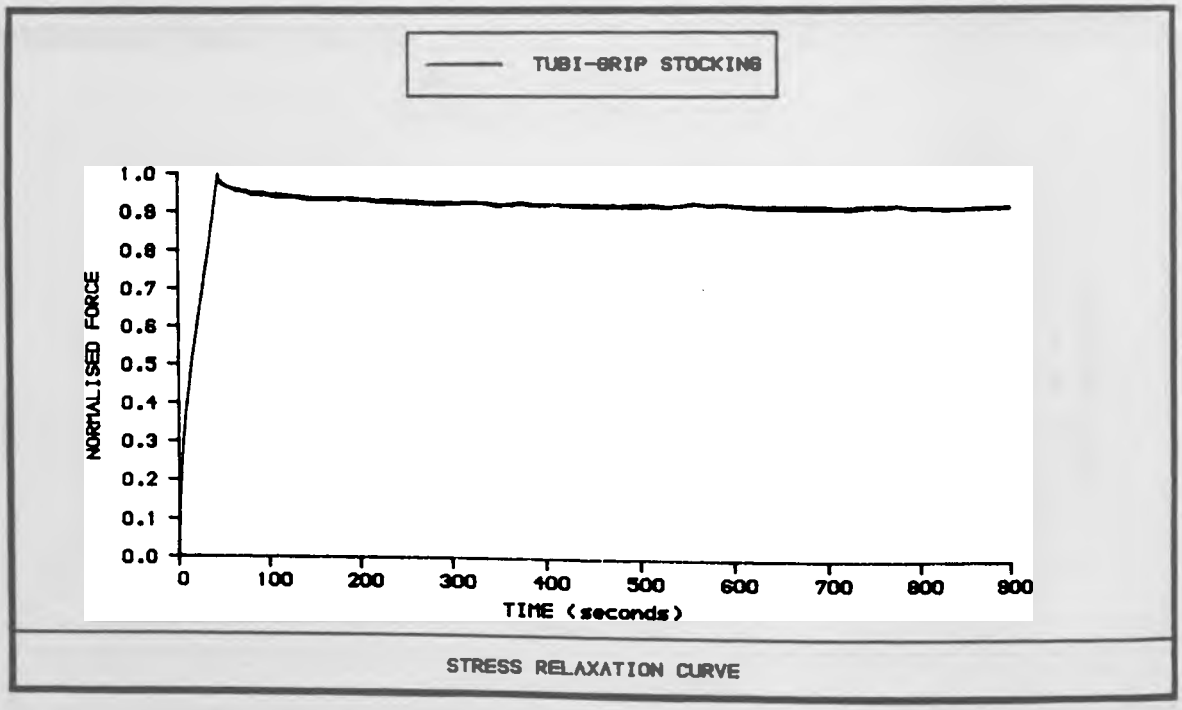
STRESS RELAXATION CURVE


VENOSAN STOCKING
NORMALISED FORCE
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
0
100
200
300
400
500
600
700
800
900
TIME (seconds)
STRESS RELAXATION CURVE


SIGVARIS STOCKING
NORMALISED FORCE
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
0
100
200
300
400
500
600
700
800
900
TIME (seconds)
STRESS RELAXATION CURVE



STRESS RELAXATION CURVE



STRESS RELAXATION CURVE

Bandage	Surgicot	Elastocrepe	Coban	Blue Line	ACE	Granuflex
L1 (cm)	5	5	5	5	5	5
T1 (N)	3.6	10.6	2.7	7.1	2.4	7.5
T2 (N) (=0.75T1)	2.7	7.95	2.0	5.3	1.8	5.63
E1 (cm)	5.2	2.3	2.75	1.54	2.9	5.9
E2 (cm)	4.9	2.2	2.5	1.2	2.75	5.6
L2(L1+E2) cm	9.9	7.2	7.5	6.2	7.75	10.6
R(0.03L2) cm	0.297	0.216	0.225	0.186	0.233	0.318
T3 (N)	2.5	3.6	1.75	5.2	1.5	4.75
(T3/T2)%	92.6	45	87.5	98	83	84
%E= (E2/L1)*100	98	44	50	24	55	112
F= (E1-E2)/L2*100	3	1	3	5.5	1.9	2.8
Classification	3a	2	3a	3b	2	3c

Detailed calculation using the SPDT1 procedure

Surgical Dressings Performance Test: SDPT 1

1. SAMPLE PREPARATION

1. Unroll the bandage and take five samples from along its length excluding the first and last 20 cm portions. Number these samples 1-5.
2. Place all the samples, loosely folded, on the bench in the standard atmosphere (20°C, 65% RH) for a minimum of 12 hours prior to testing. It is important that all samples are conditioned and tested under these conditions as it has been demonstated that changes in humidity can cause significant variations in the results.

2. TEST METHOD

1. Place an appropriate length of bandage in the jaws of a constant rate of extension machine set 20cm apart L_1 so that the material is neither slack or under significant tension.

   Using a cross head speed of 200mm/minute on both extension and retraction, cycle the sample twice without pause to the appropriate maximum tension T_1 selected from **Table 1**, recording the load extension curves produced.

2. By reference to the second retraction curve, record the following information.

   a. The extension of the samples E_1 at Tension T_1

   b. The extension of the sample E_2 at the Working Tension T_2

   c. The Working Length of the sample L_2 determined at the Working Tension. $(L_2 = L_1 + E_2)$

3. Calculate the value of R corresponding to 3% of L_2 (the Working Length)
4. Using this value of R determine the tension T_3 at a point on the graph corresponding to $(E_2 - R)$ cm.
5. Calculate;

   a. The value of; $\frac{T_3}{T_2} \times 100$

   b. The Percentage Extension, $E\%$, of the bandage calculated from; $\frac{E_2}{L_1} \times 100$

   c. The factor F using the formula; $F = \frac{E_1 - E_2}{L_2} \times 100$

6. Carry out the entire test 3 times on sample numbers 1, 3 and 5 using the appropriate values of tension calculated as described in Table 1 using in each case the *stated* width of the bandage.
7. From these results, calculate the mean values for; $E\%$, $\frac{T_3}{T_2} \times 100$ and F

   If these values fall within the limits shown in **Table 2**, the bandage may be considered to have met the requirements of the test. If these values fall *outside* the limits shown in **Table 2**, the remaining two samples (numbers 2 and 4) prepared previously should also be tested and the average of all five samples calculated. If these new values fall within the limits laid down in Table 2, the bandage will be considered to have met the requirements of the test.

TABLE 1. Levels of tension to be used in elasticity test.

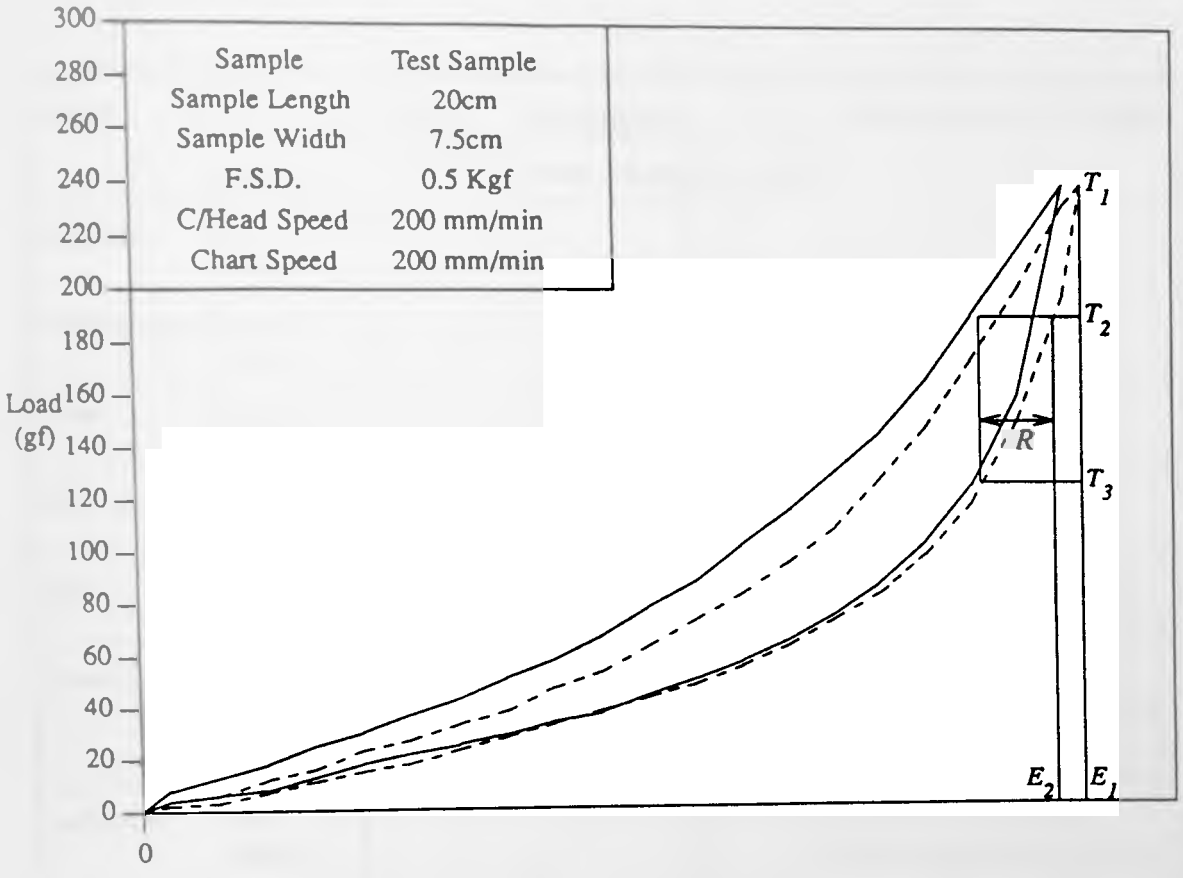
Bandage Type	Max Tension T_1(Kgf/cm)	Working Tension T_2(Kgf/cm)
1	0.032	0.025
2	0.067	0.050
3	0.067	0.050
4	0.133	0.100
5	0.200	0.150

TABLE 2. Test Limits

Bandage Type	$\frac{T_3}{T_2}$ %	% Extension	Factor F
1	≤ 40%	25-110	≤ 0.7
2	≤ 40%	25-75	≥ 1.5
3	≤ 70%	25-110	≤ 2
4	≤ 85%	25-110	≤ 4
5	≤ 85%	25-110	≤ 4

Surgical Dressings Performance Test SDPT 1

A curve typical of a type 1 bandage



Extension in cm

$L_1 = 20cm$

$T_1 = 0.24Kgf$

$T_2 = 0.19Kgf$

$E_1 = 11.6cm$

$E_2 = 11.3cm$

$L_2 = L_1 + E_2 = 31.3cm$

$R = 3\% \; x \; L_2 = 0.94cm$

$T_3 = 0.127Kgf$

$$\frac{T_3}{T_2} \; x \; 100 = 67\%$$

$$\%E = \frac{E_2}{L_1} \; x \; 100 = 57\%$$

$$F = \frac{L_1 - E_2}{L_2} \; x \; 100 = 0.96$$

Device	Technique or Condition	Ease of Application	Acceptance		Fit		Conformability	Slippage
			Hosp	Home	Hosp	Home		
Surgicot	Spiral Criss-x							
Elastocrepe	Spiral Criss-x							
Coban	Spiral Criss-x							
Blue Line	Spiral Criss-x							
ACE	Spiral Criss-x							
Granuflex	Spiral Criss-x							
Harcourt	New Washed							
T.E.D.	New Washed							
Venosan	New Washed							
Sigvaris	New Washed							
Jobst	New Washed							
Tubigrip	New Washed							

Specimen Questionnaire
(Grading: 1-excellent, 2-good, 3-average, 4-below average and 5-poor)

SIVLOG.PAS

is available on computer disk
from the author

SIVTRANS.PAS

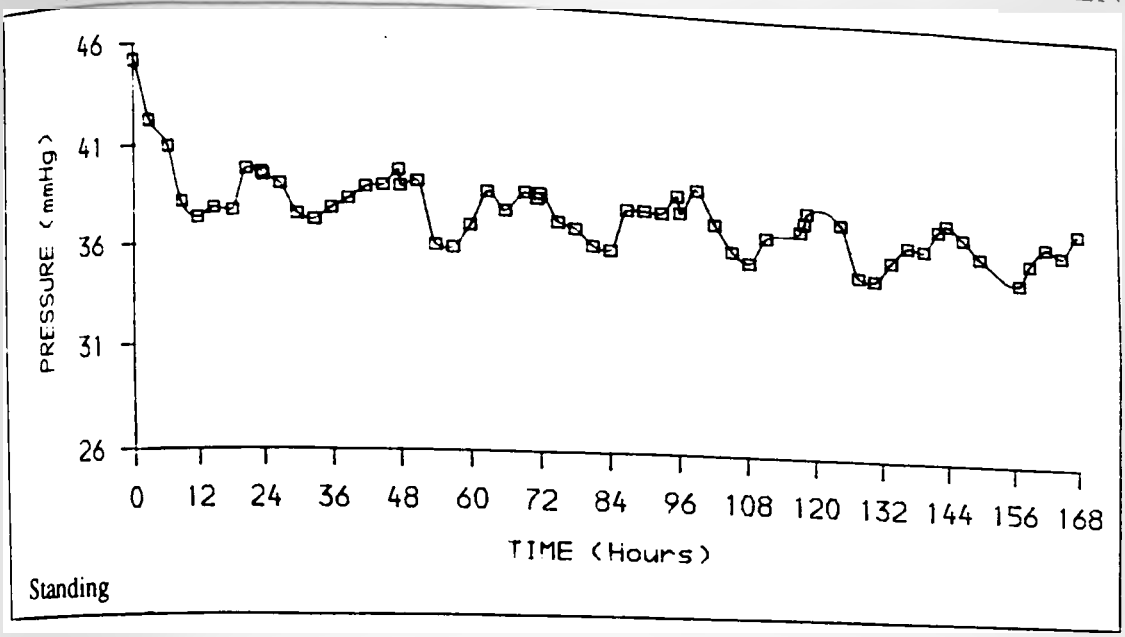
is available on computer disk
from the author

PROCESS.PAS
****

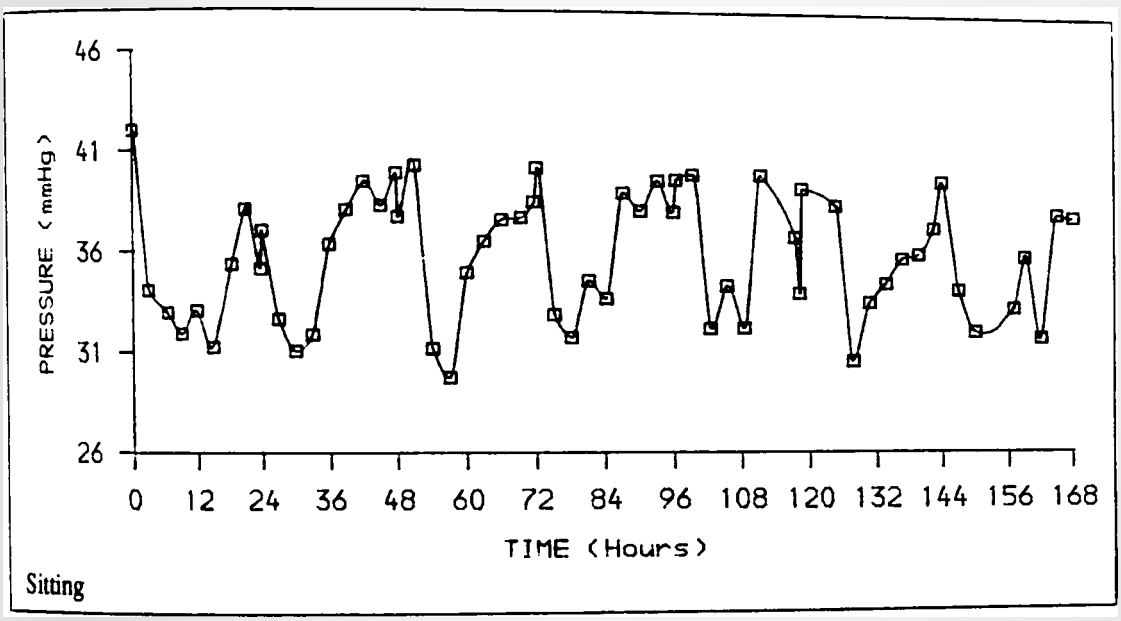
```
PROGRAM Process_siv(input,output);

 {Design : S Sockalingam
  Author : Ricardo Torres-Moreno
  Date       : 260490
  Updated    : 270490}

CONST
sentinel = -9; {marks the end of "start - stop" data file}

TYPE
fnames     = packed array [1..18] of char;
codefile   = packed array [1..4] of char;

VAR
fnam1,
fnam2            : fnames;
filecode         : codefile;
infile1,
infile2,
filetable,
outfile          : text;
AA,
BB,
counter,
sumpressure,
colnum,
goneodat,
pressdat,
laststopnum,
startnum,
stopnum,
num1,
num2,
numfiles,
numfiles1        : integer;
averagepress     : real;
countchar1,
countchar2           : char;


BEGIN {main program}

writeln;
writeln (' ************************************ ');
writeln (' *                                  * ');
writeln (' *                                  * ');
writeln (' *                                  * ');
writeln (' *    S I V  -  PROCESS             * ');
writeln (' *                                  * ');
writeln (' *                                  * ');
writeln (' ************************************ ');
writeln;
writeln;
writeln;
```

```
write ('Enter filename of raw data ..... ');
readln (fnam1); {file with 3 columns of data}
writeln;
write ('Enter filename of ranges data ..... ');
readln (fnam2); {file with filecode followed by 2 columns
                 of ranges start stop}
writeln;

OPEN (infile1,fnam1,history := old); {raw data file}
OPEN (infile2,fnam2,history := old); {filecode and start
                                      stop data file}

RESET (infile1);
RESET (infile2);
READLN (infile2,filecode);
READLN (infile2);
READLN (infile2,startnum,stopnum);
OPEN (filetable,filecode+'data.tab'); {file containing
                                       table of averages}
REWRITE (filetable);

counter := 1;
numfiles := 0;
laststopnum := 0;

WHILE startnum <> sentinel DO
  Begin {while startnum}

    numfiles := numfiles + 1; {counts the bnumber of
                               files created}
    numfiles1 := numfiles;

    IF (numfiles<10) THEN
      Begin
        countchar2 := CHR(numfiles1+48);
        countchar1 := '0';
      End;

    IF (numfiles>9) and (numfiles<20) THEN
      Begin
        countchar2 := CHR((numfiles1-10)+48);
        countchar1 := '1';
      End;

    IF (numfiles>19) and (numfiles<30) THEN
      Begin
        countchar2 := CHR((numfiles1-20)+48);
        countchar1 := '2';
      End;

    IF (numfiles>29) and (numfiles<40) THEN
      Begin
        countchar2 := CHR((numfiles1-30)+48);
        countchar1 := '3';
      End;
    IF (numfiles>39) and (numfiles<50) THEN
      Begin
        countchar2 := CHR((numfiles1-40)+48);
        countchar1 := '4';
      End;
```

```
IF counter = 1 THEN
  OPEN (outfile,filecode+countchar1+countchar2+'.std');

IF counter = 2 THEN
  OPEN (outfile,filecode+countchar1+countchar2+'.sit');

IF counter = 3 THEN
  OPEN (outfile,filecode+countchar1+countchar2+'.lie');

REWRITE (outfile);

FOR AA := (laststopnum + 1) TO (startnum - 1) DO
  READLN (infile1); {data not required for the analysis}

sumpressure := 0; {sumation of pressures to obtain mean}
FOR BB := startnum TO stopnum DO
  Begin {for bb}
    READLN (infile1,colnum,goneodat,pressdat);
    sumpressure := sumpressure + pressdat;
    writeln (outfile,goneodat:6,pressdat:6);
    writeln (colnum:6,goneodat:6,pressdat:6);
  End;

averagepress := sumpressure / ((stopnum+1) - startnum);
writeln (outfile);
writeln (outfile,' * Average pressure = ',averagepress:8:2);

CLOSE (outfile);

IF counter < 3 THEN
  write (filetable,averagepress:8:2)
ELSE
  writeln (filetable,averagepress:8:2);

IF counter < 3 THEN
  counter := counter + 1
ELSE
  counter := 1;

laststopnum := stopnum;
READLN (infile2,startnum,stopnum);

End;  {while startnum}

CLOSE (filetable);
writeln (' You have created ',numfiles:4,' files. ');
END.  {main program}
```



Standing



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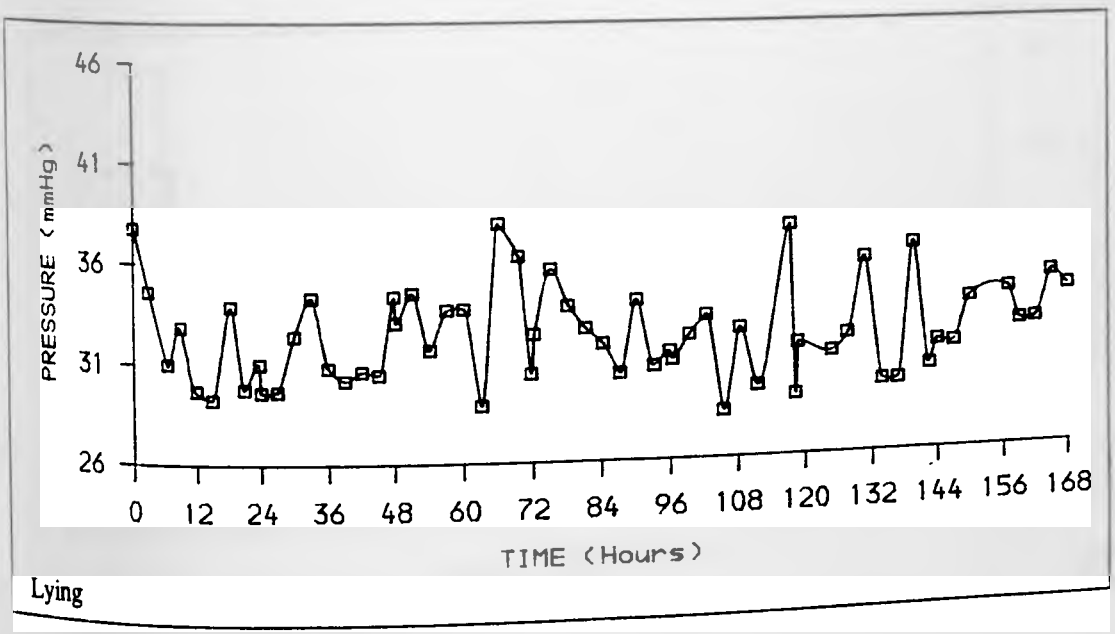
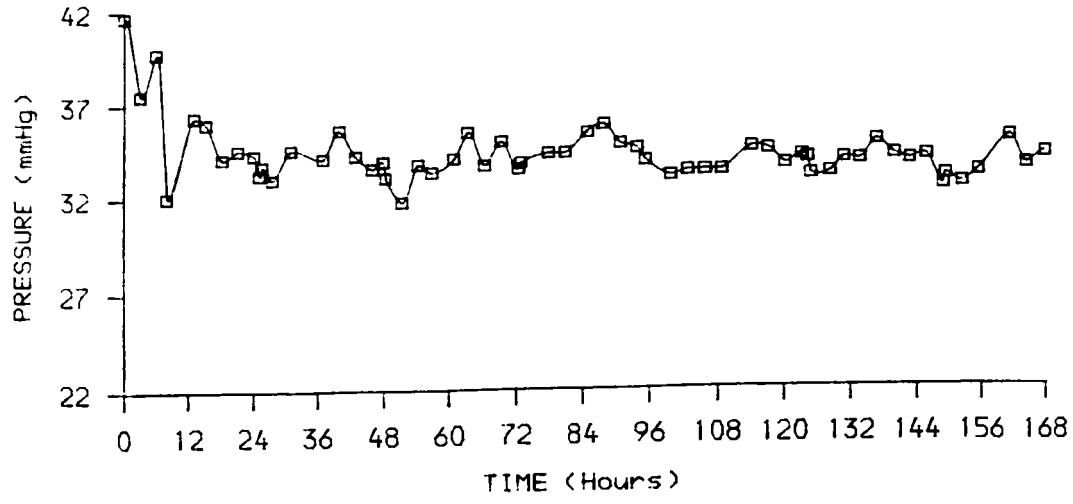


Lying

Subject-2



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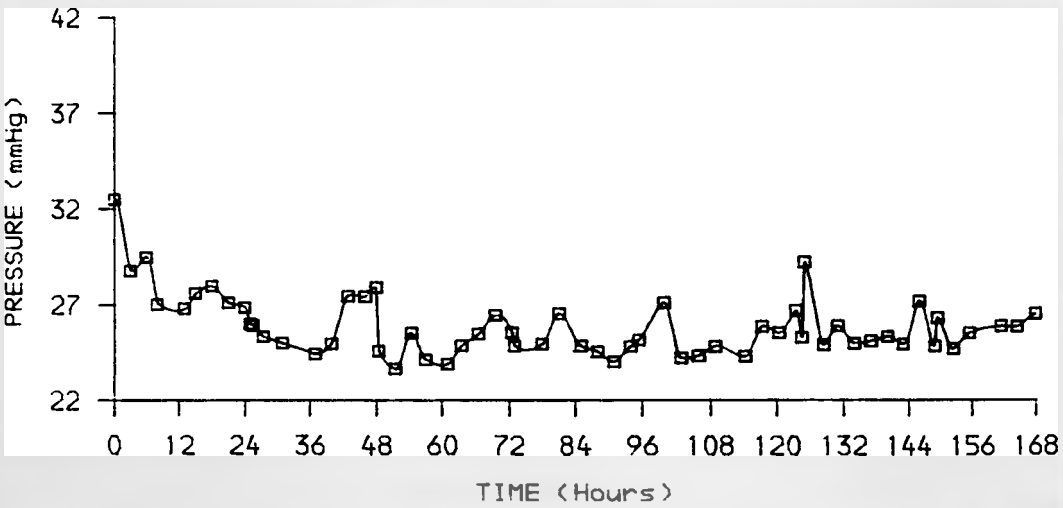

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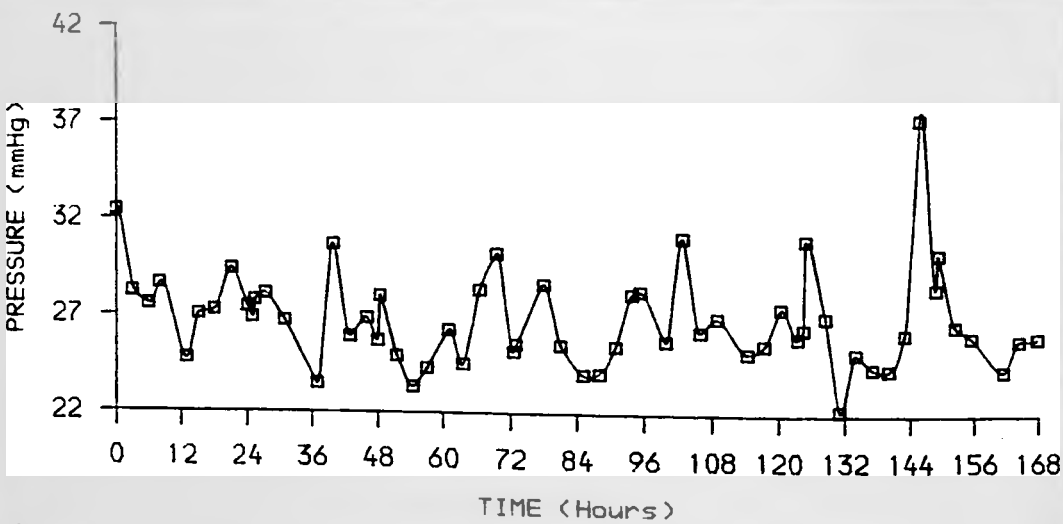

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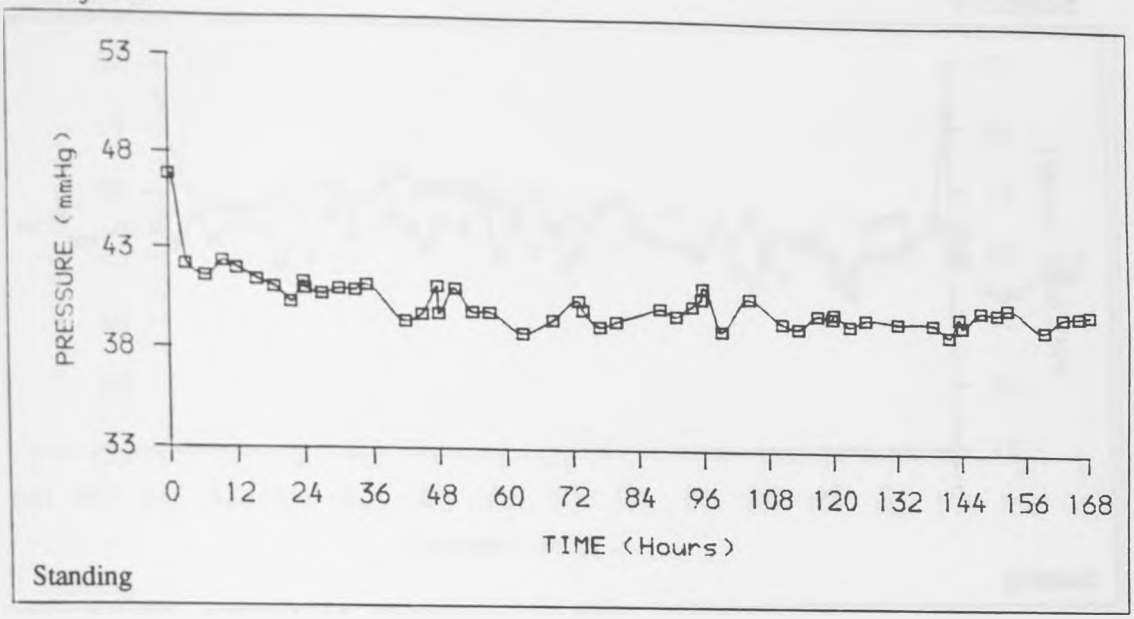

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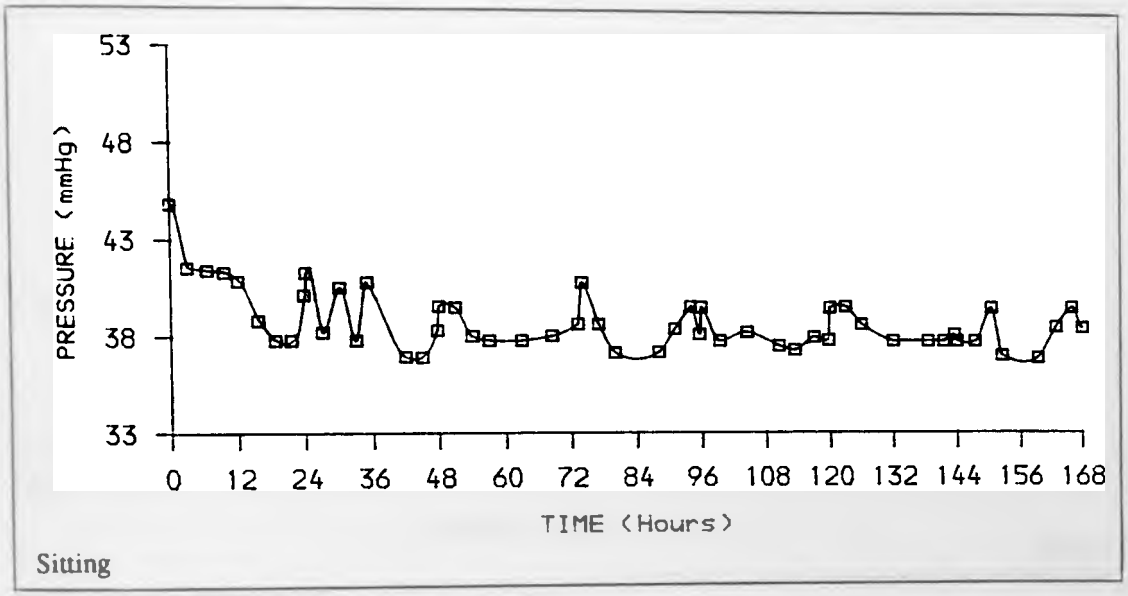

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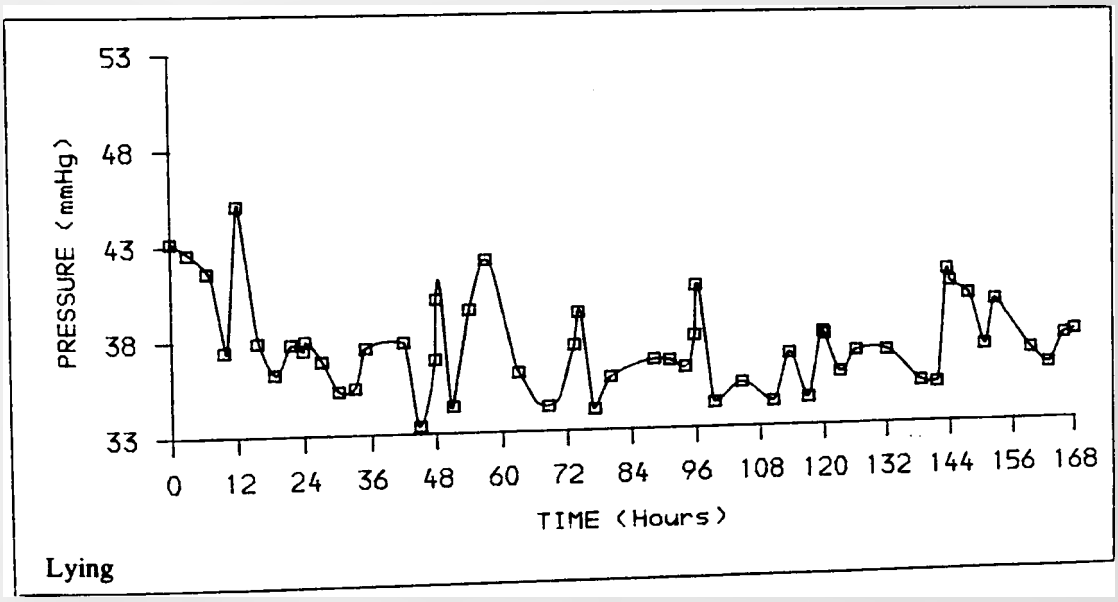

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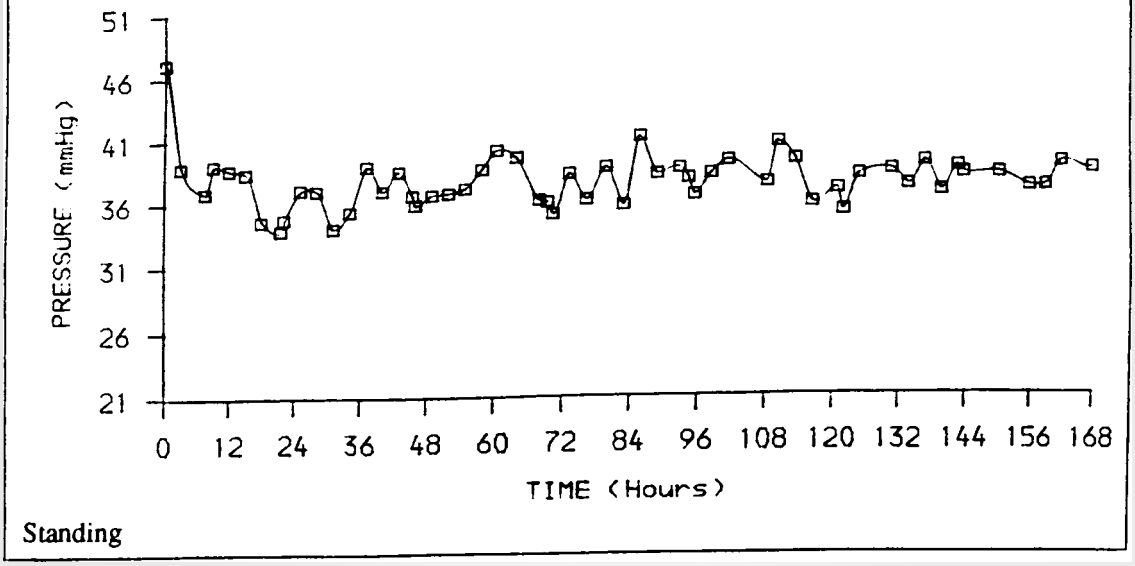

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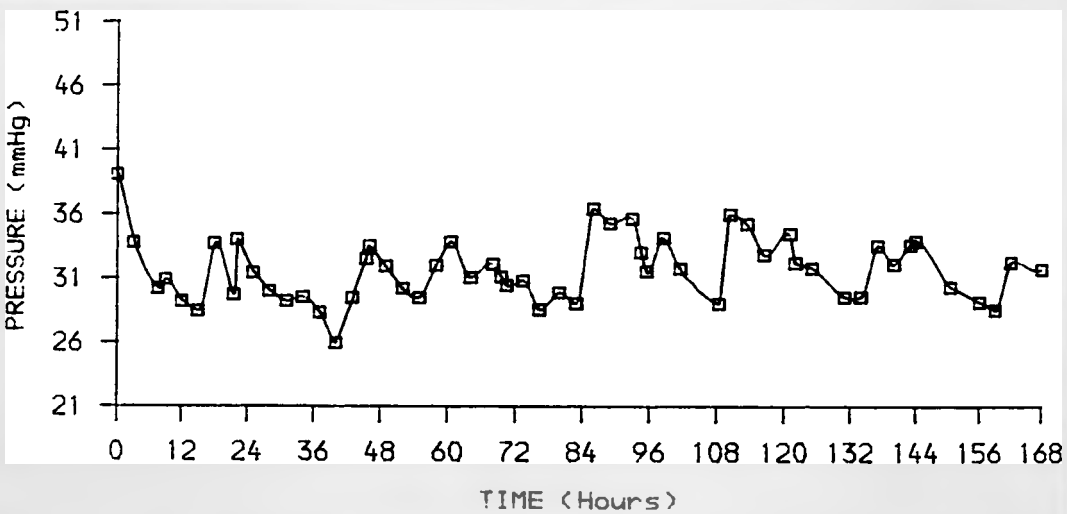

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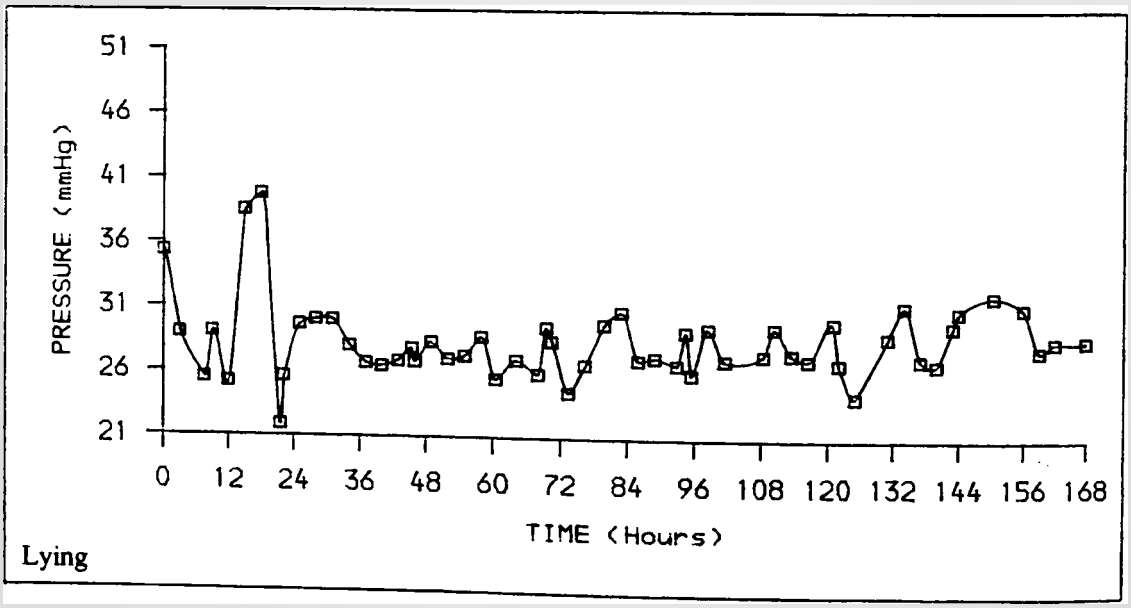

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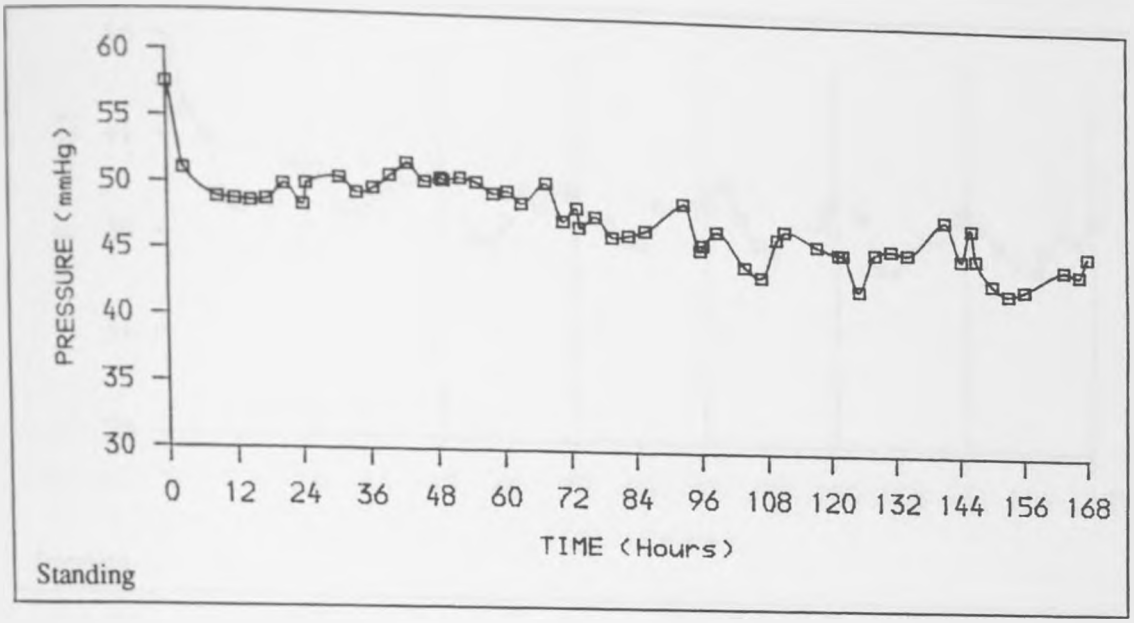

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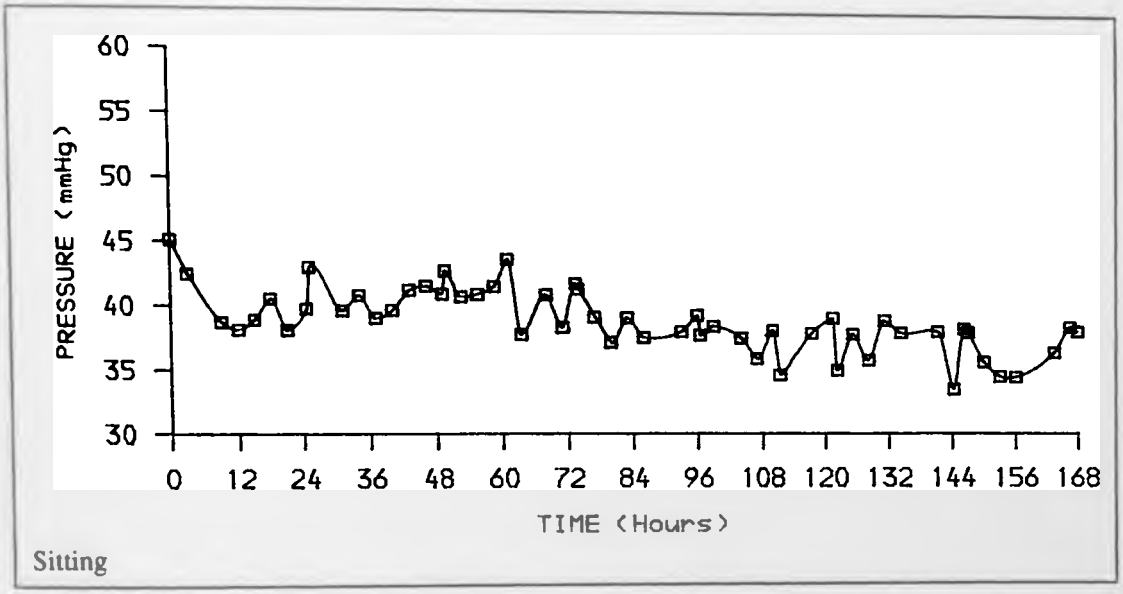

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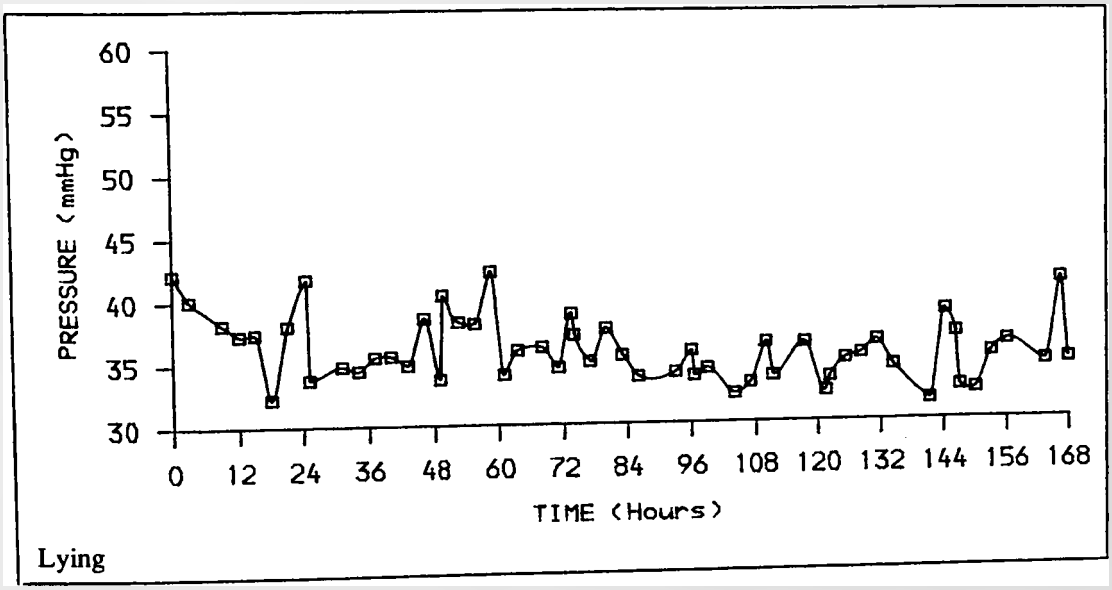

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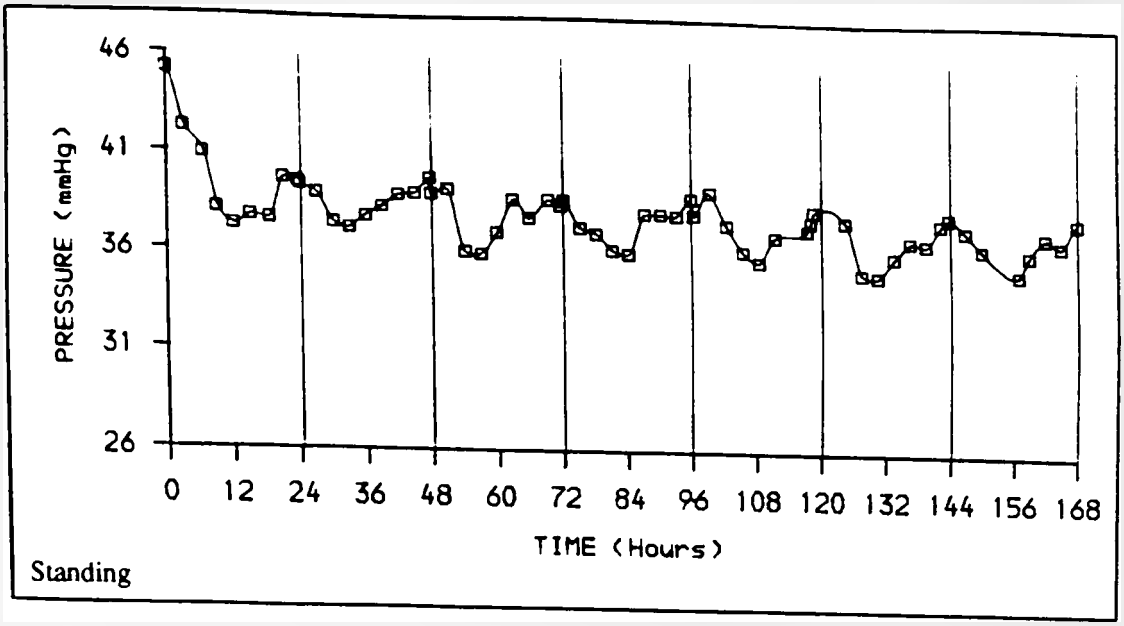

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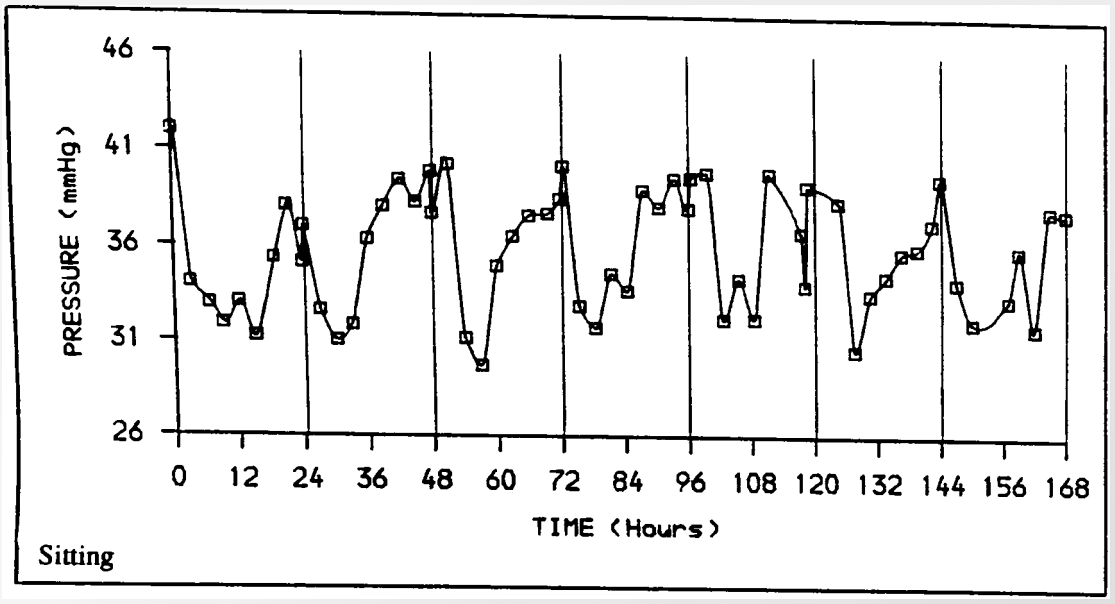

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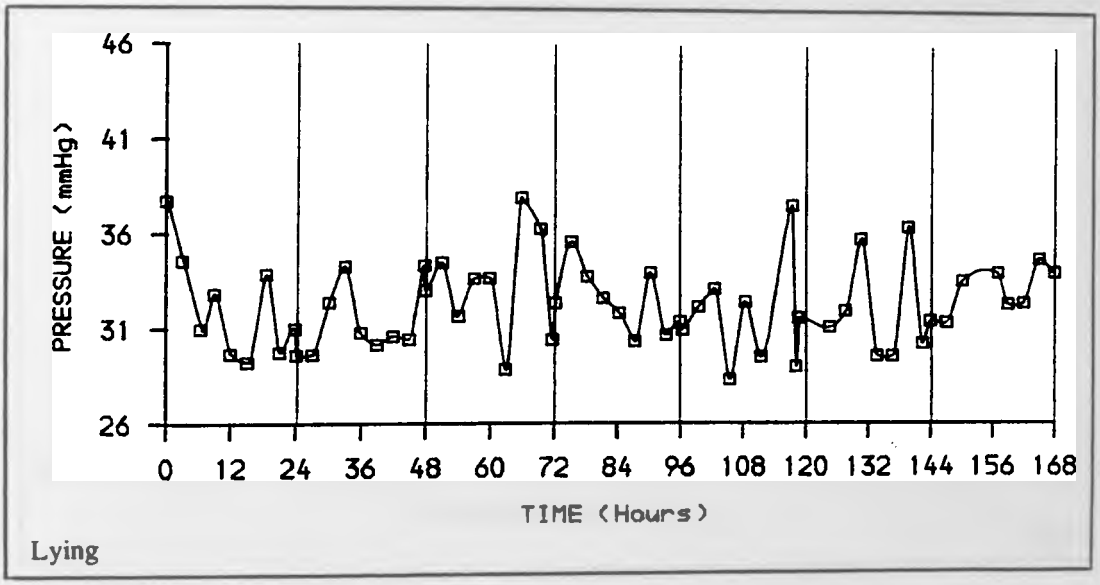

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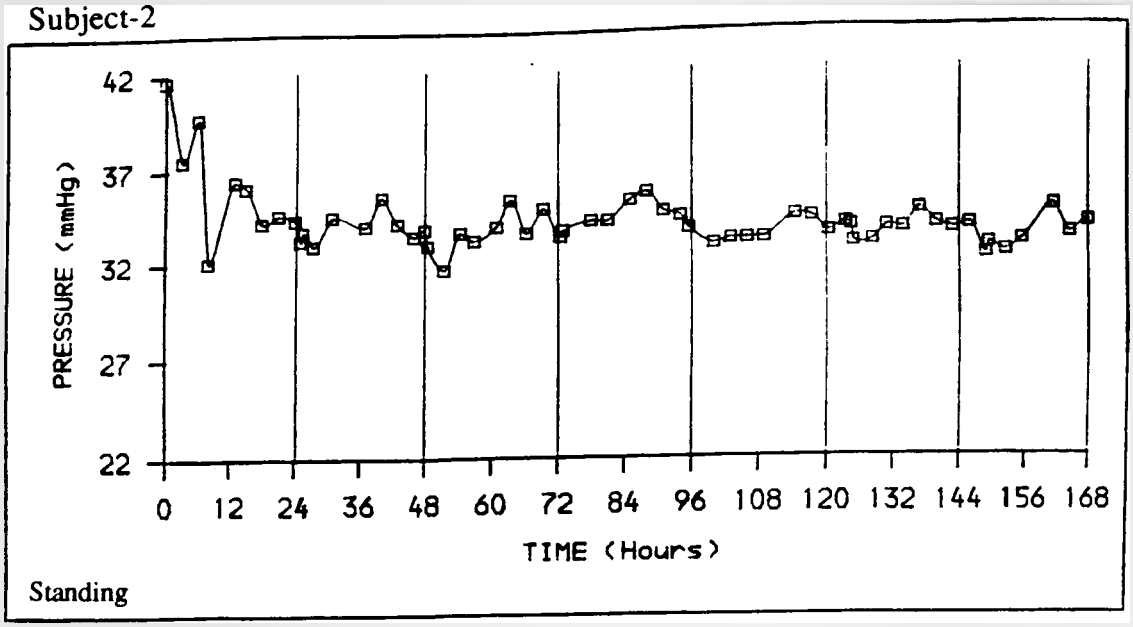

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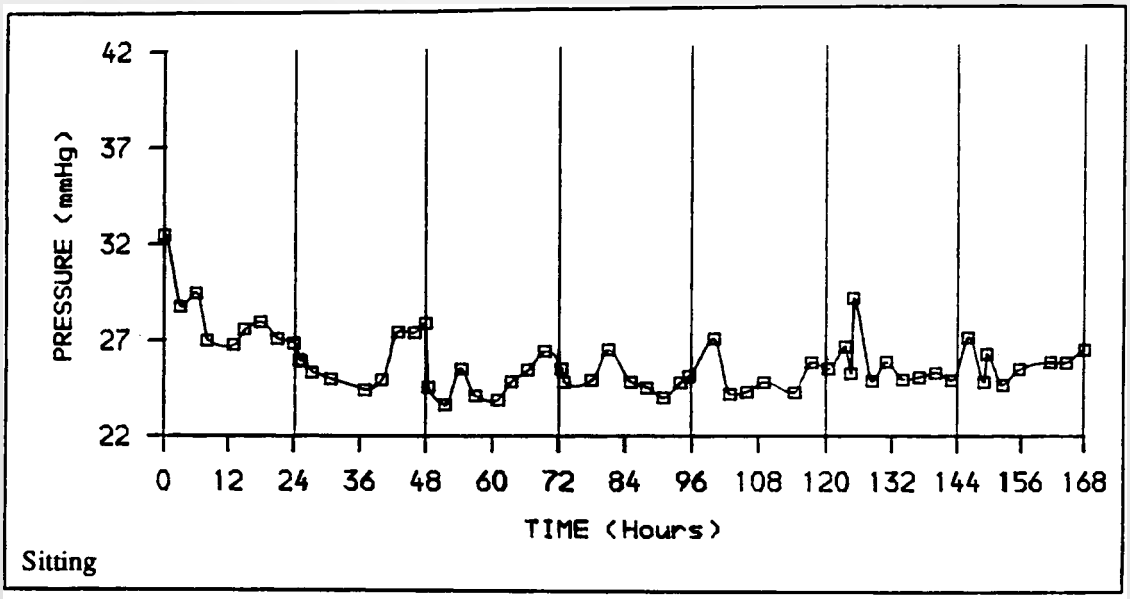

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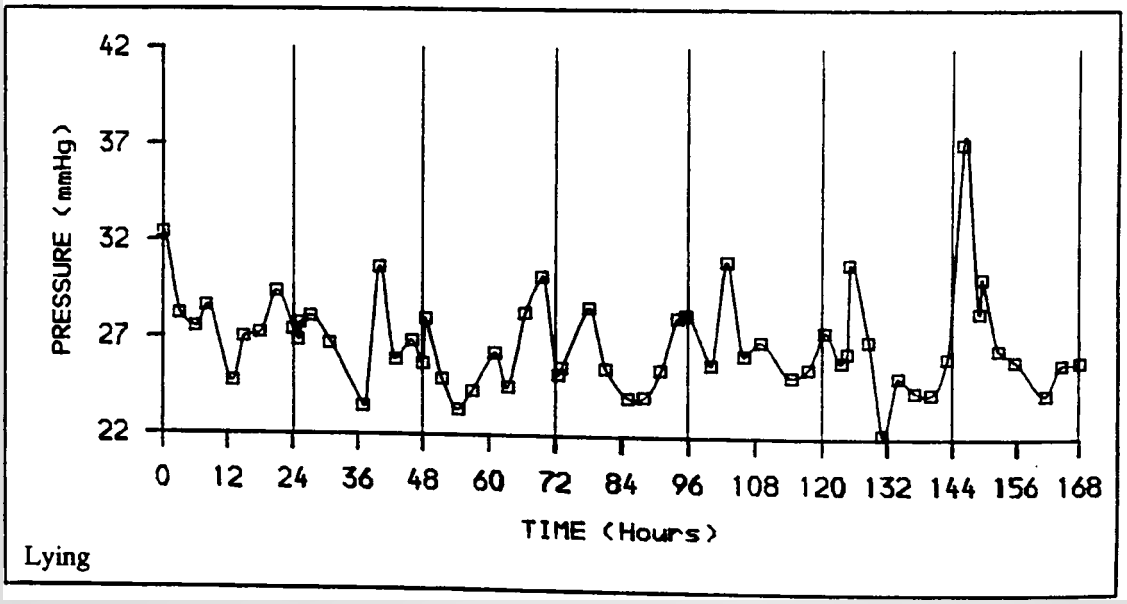

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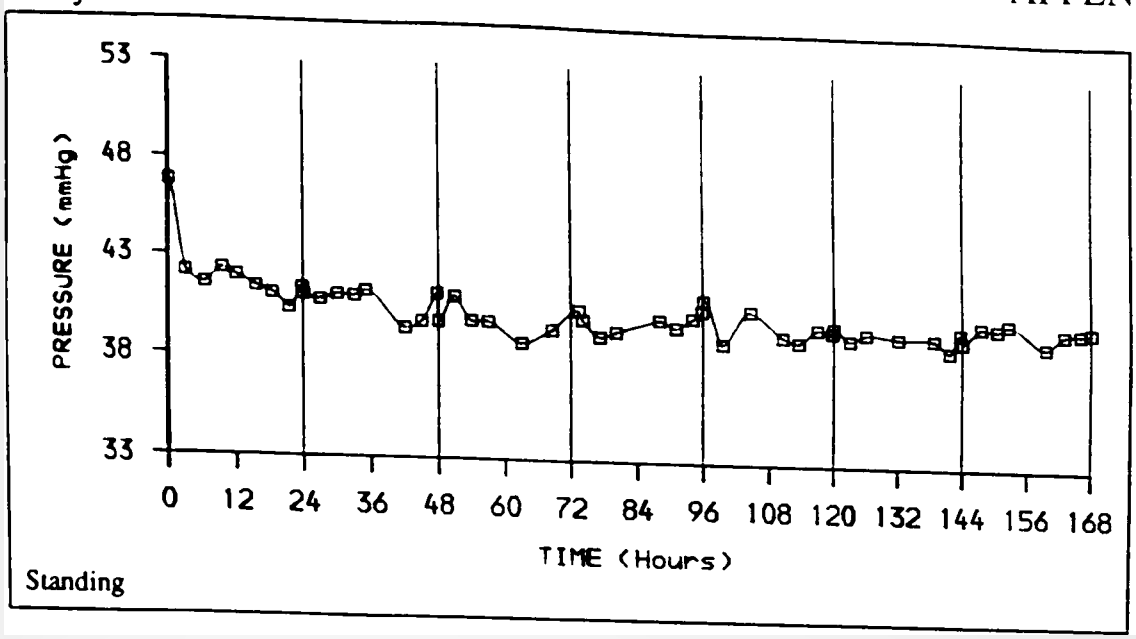

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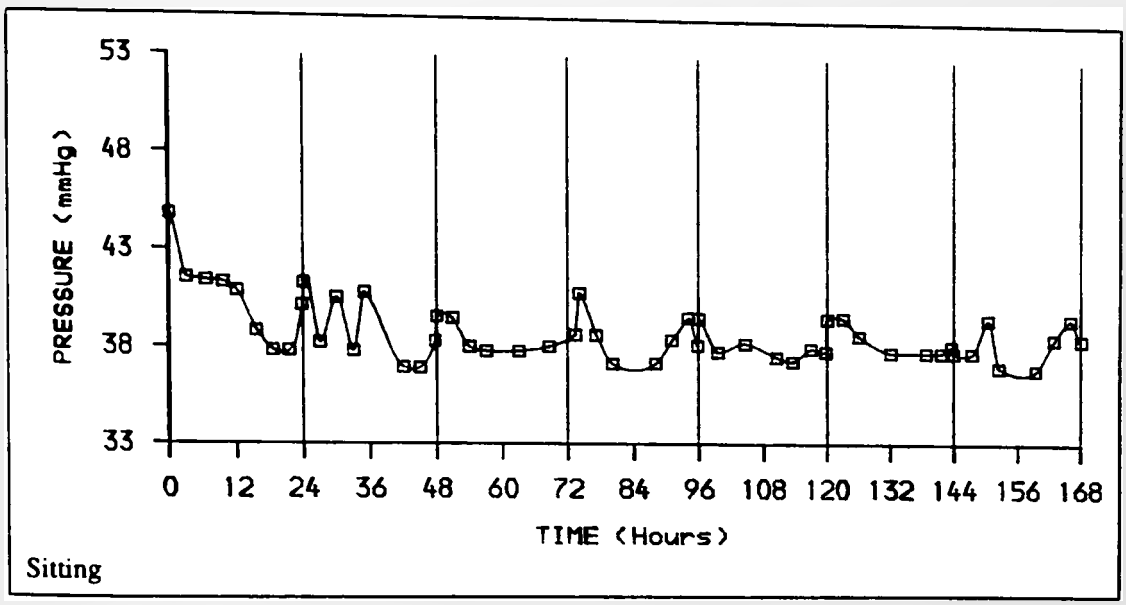

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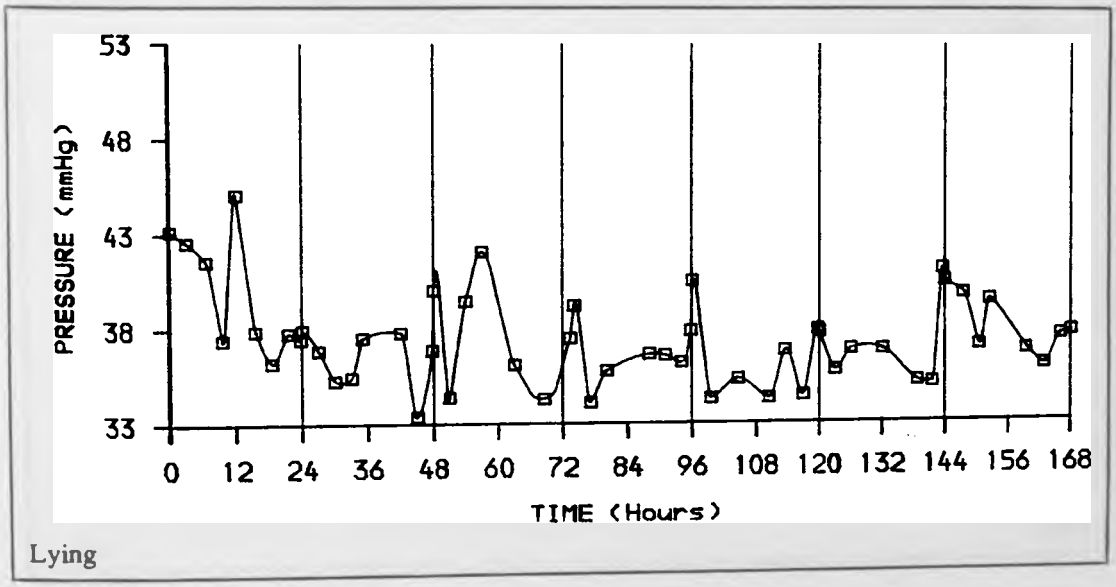

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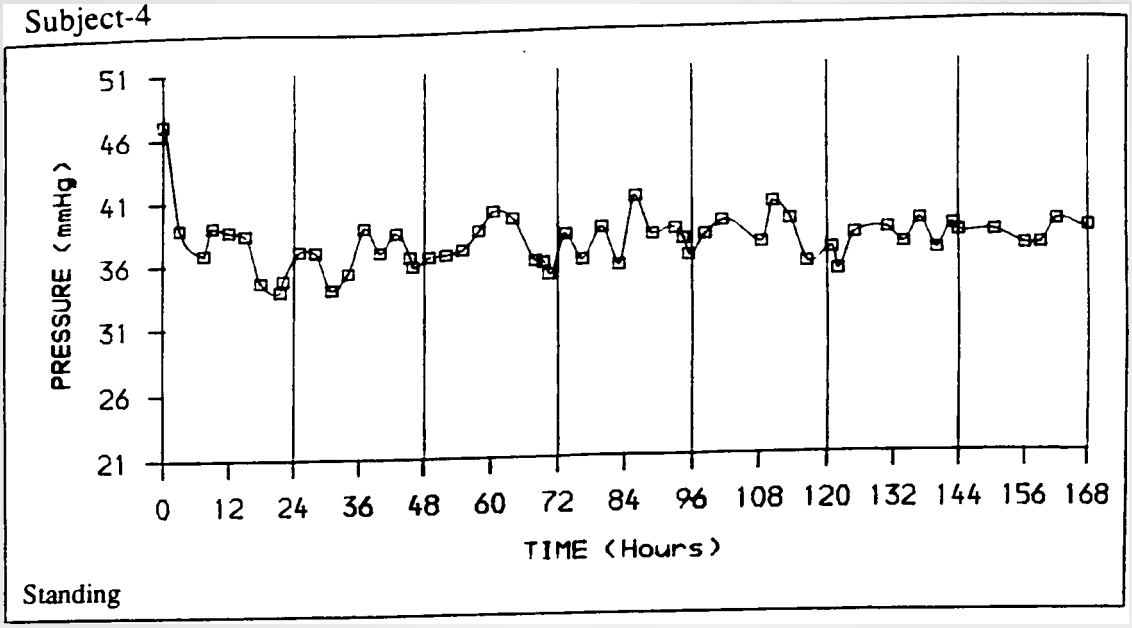

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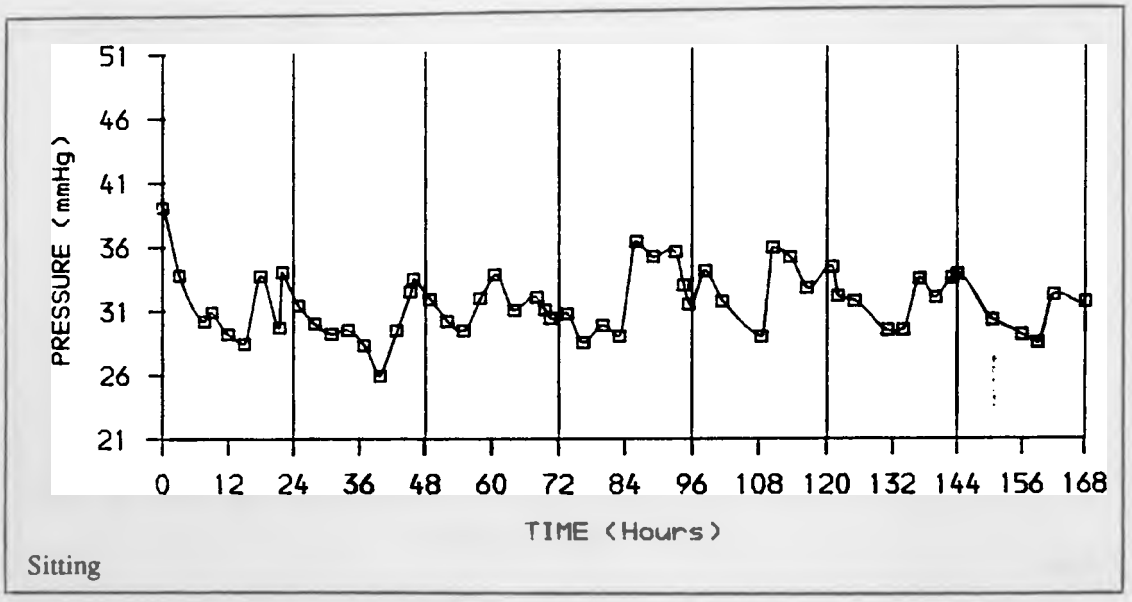

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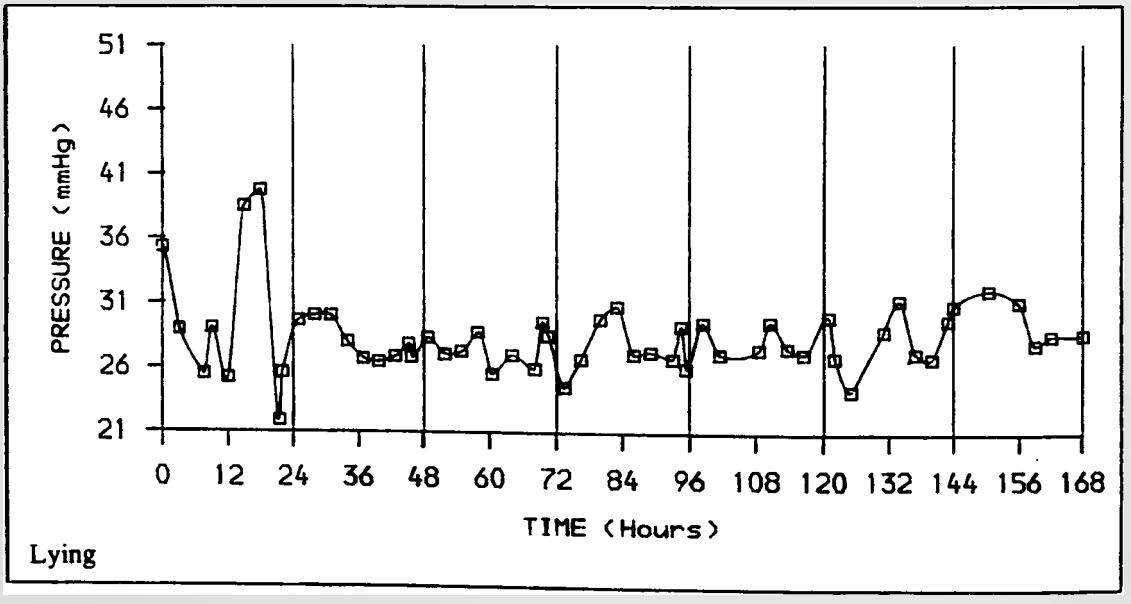

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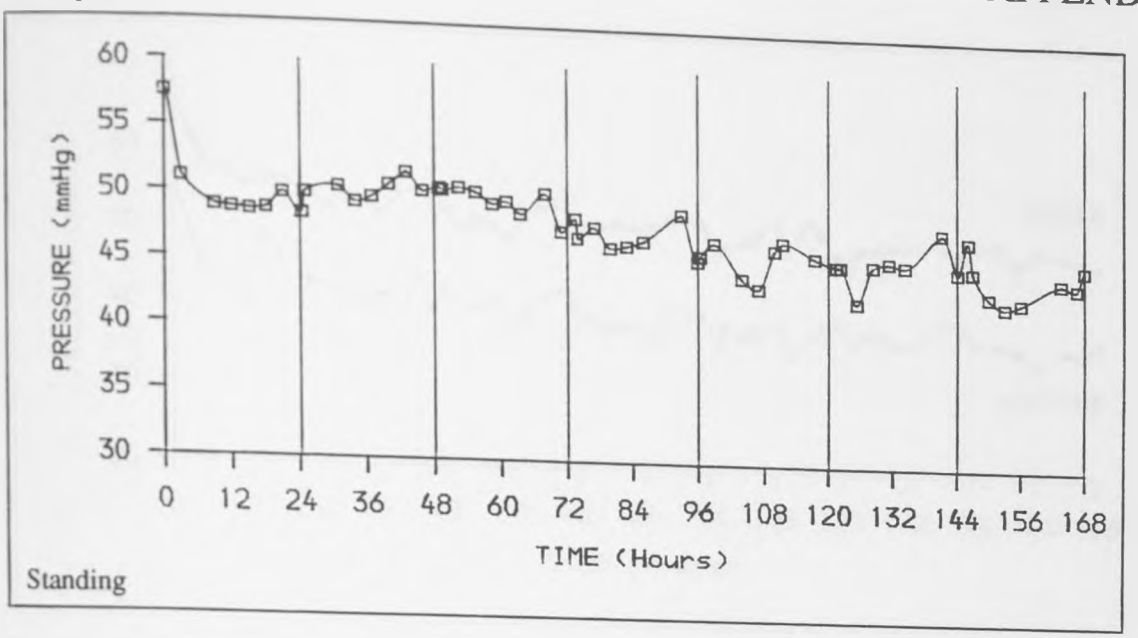

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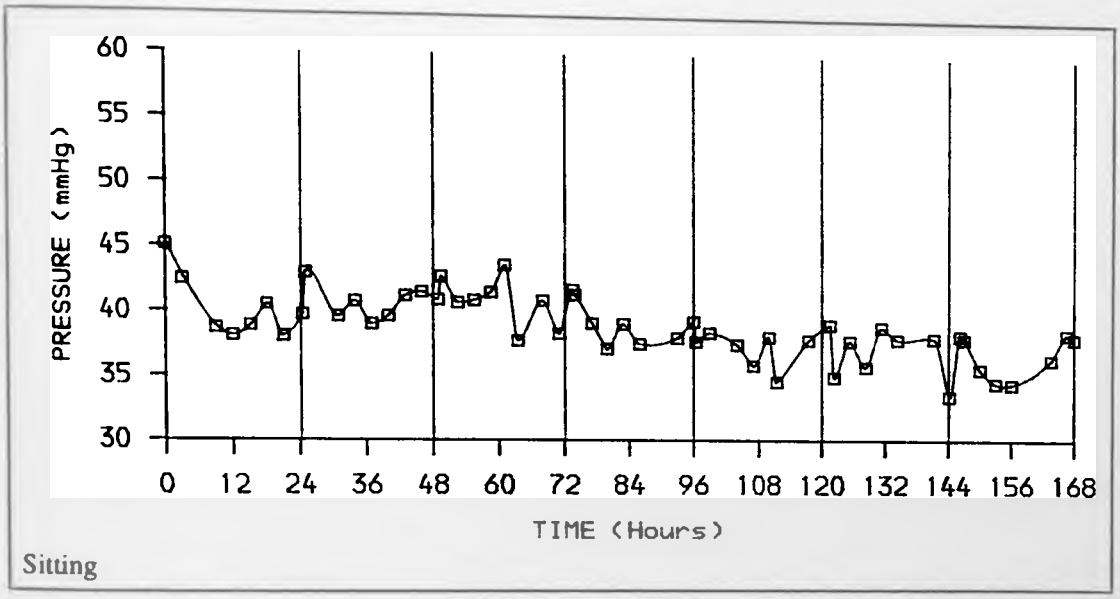

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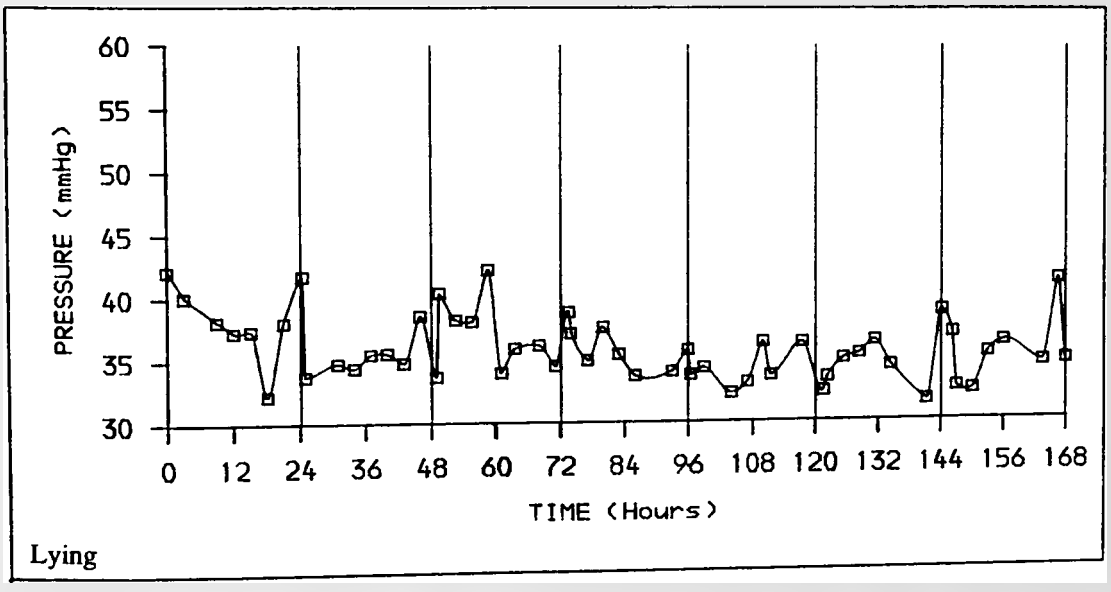

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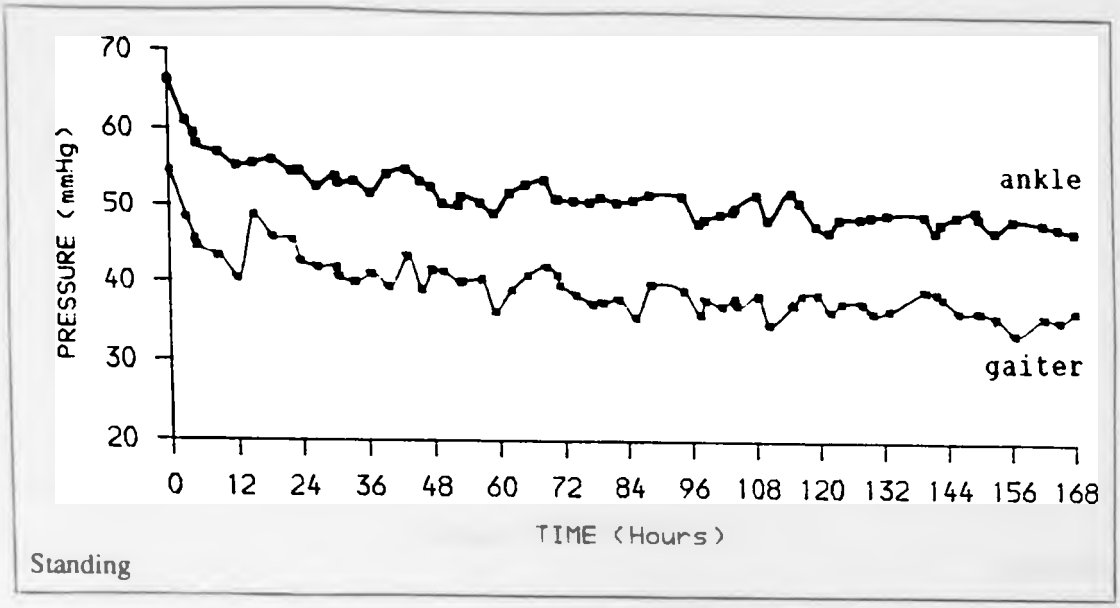

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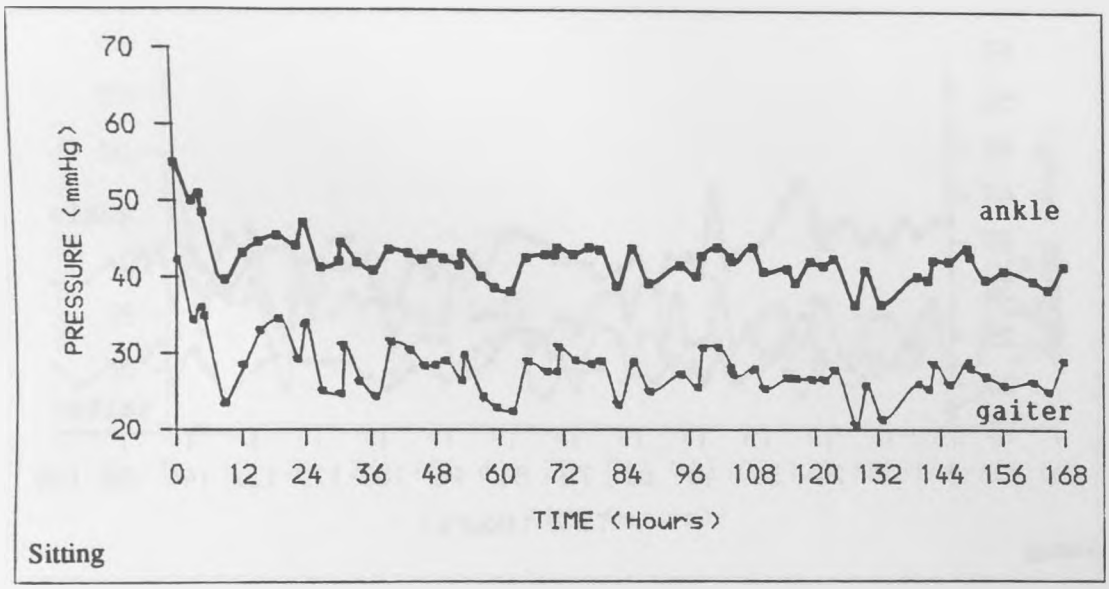

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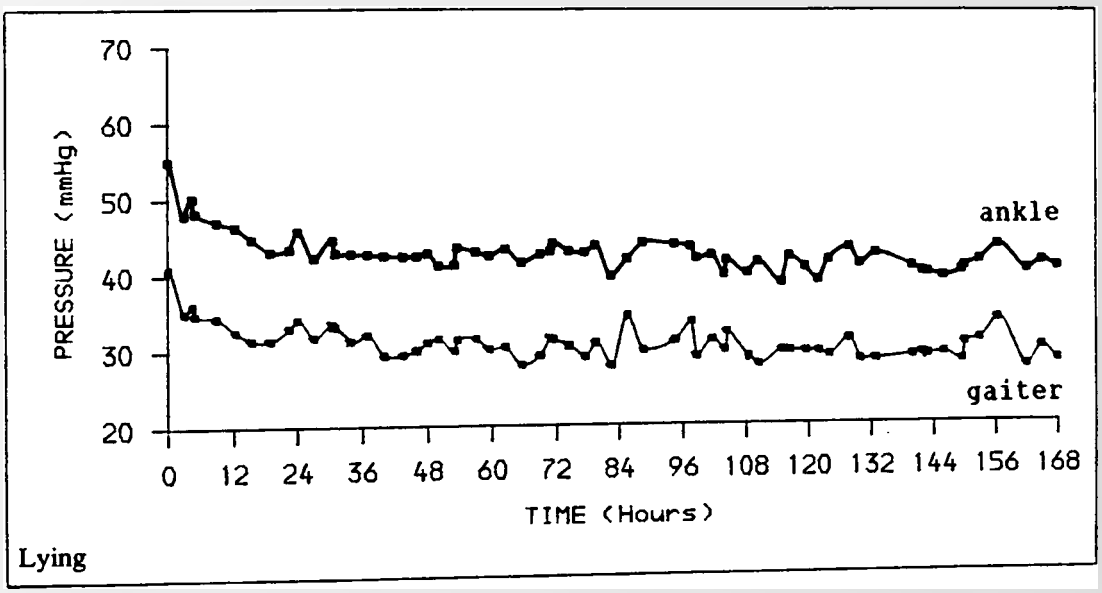
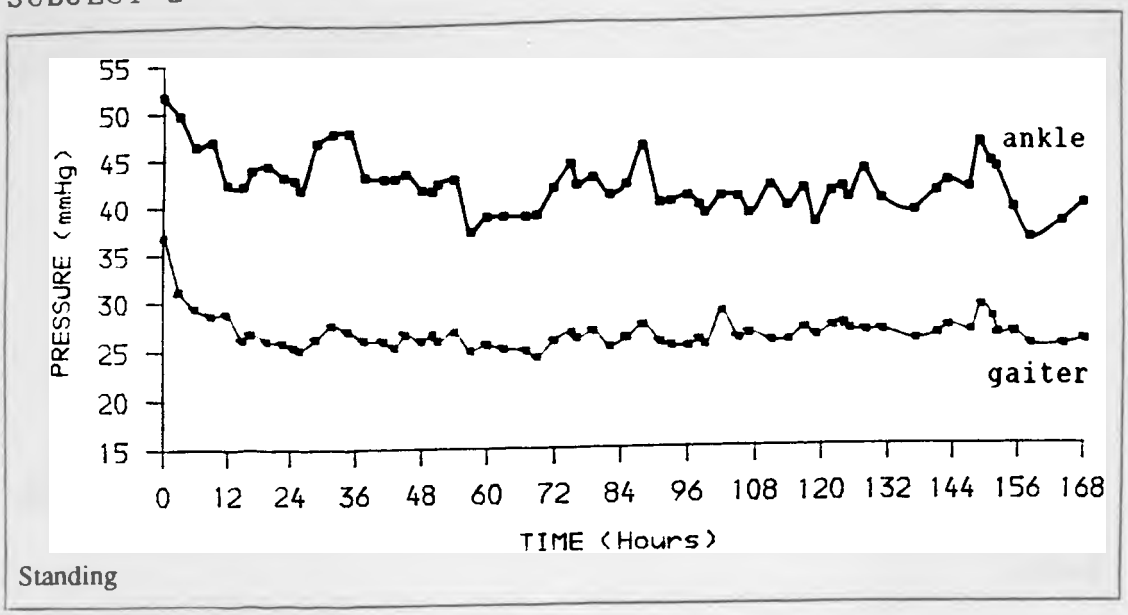


Lying

SUBJECT-2



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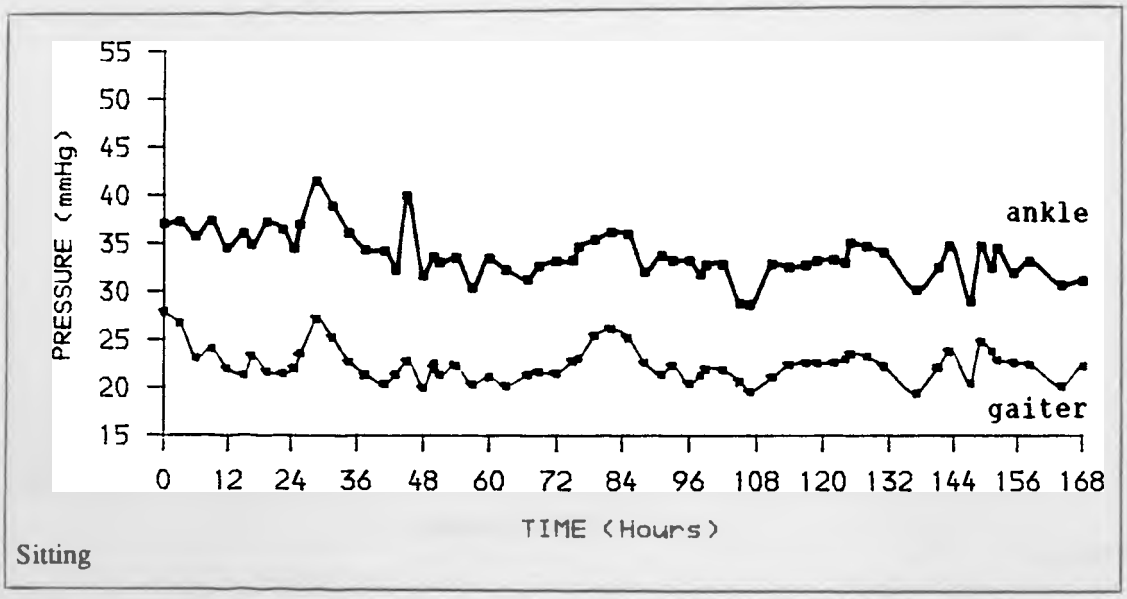

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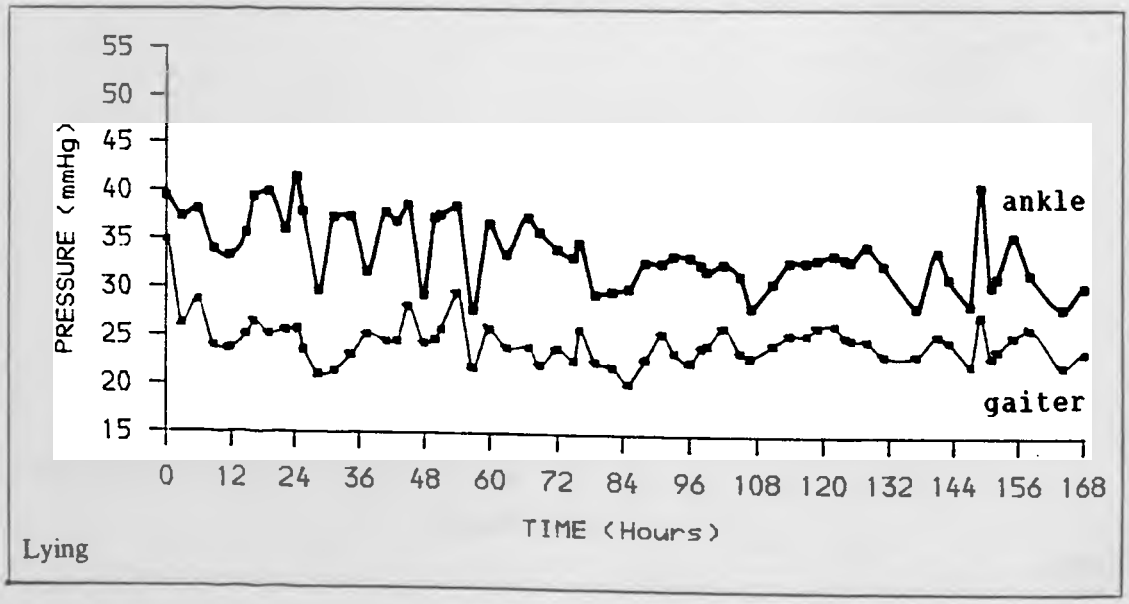

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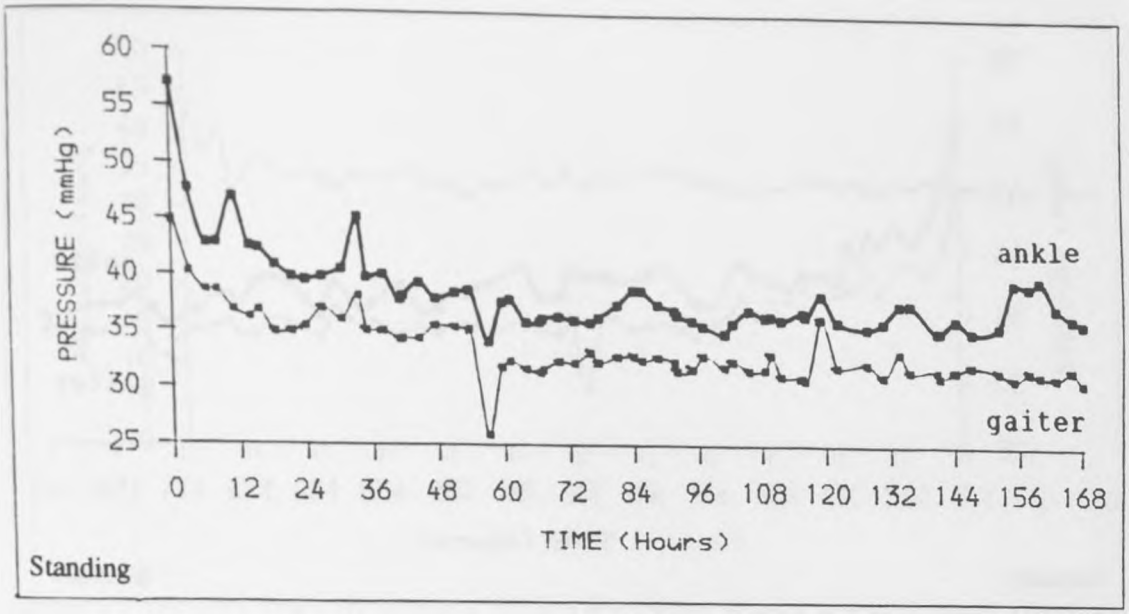

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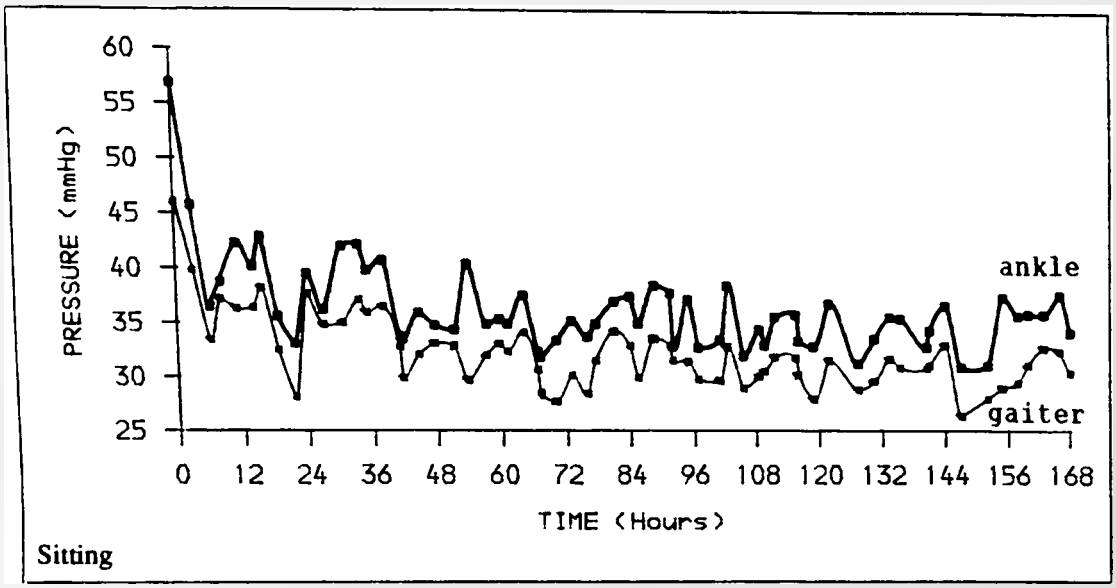

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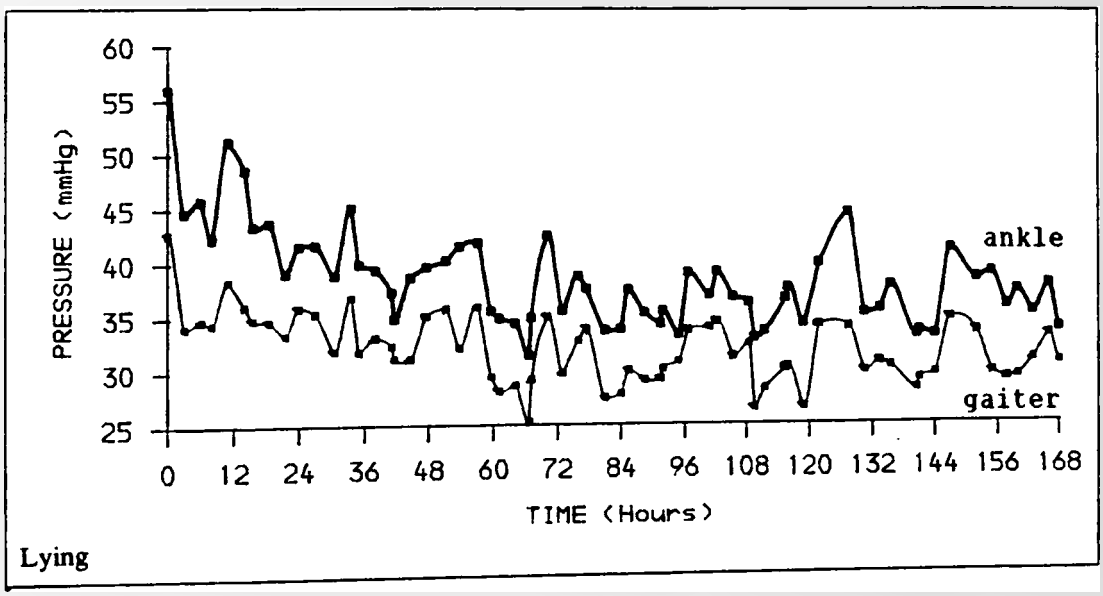
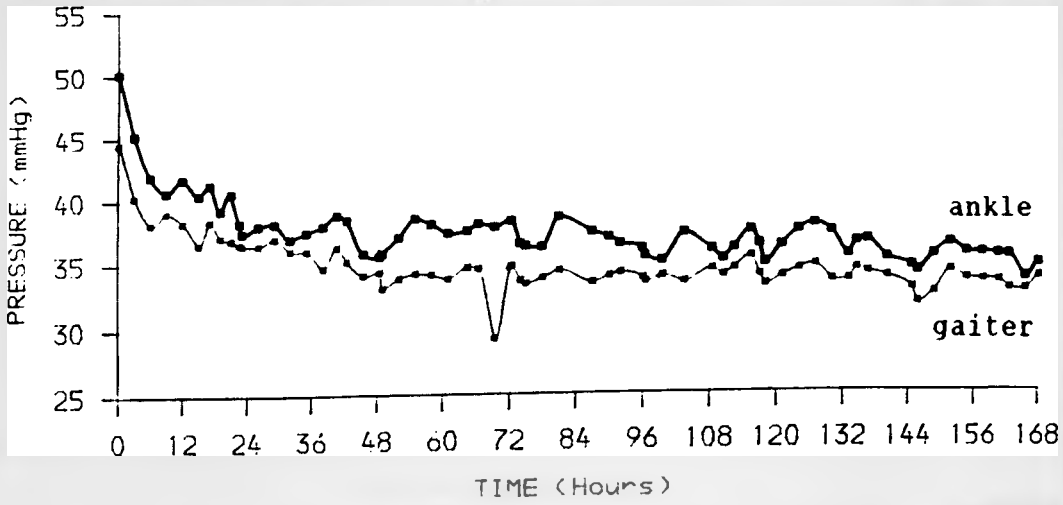


Lying

SUBJECT-4



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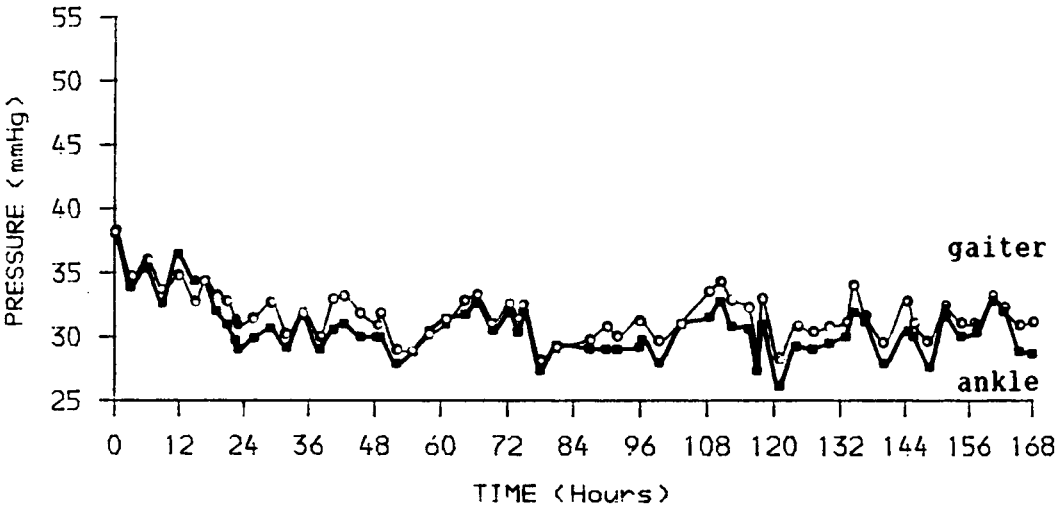

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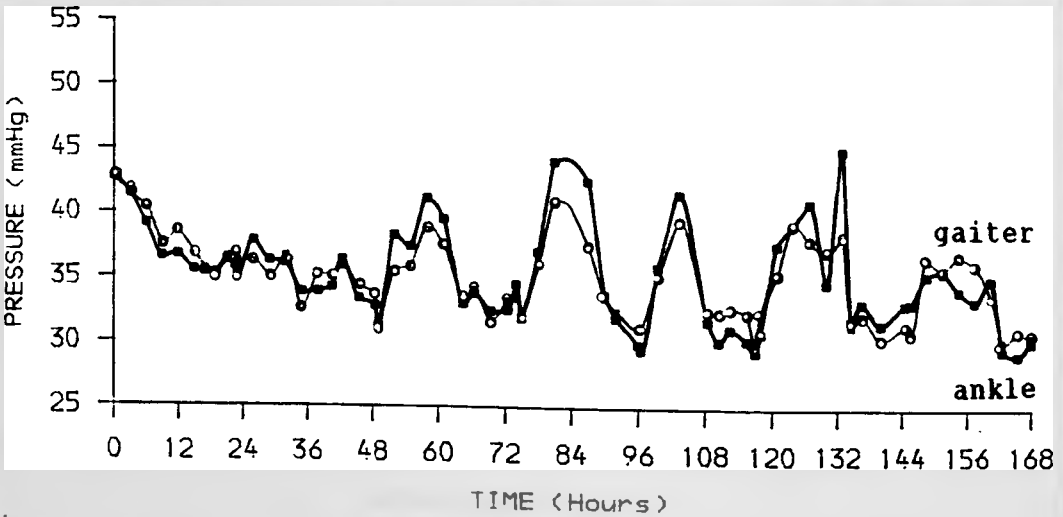
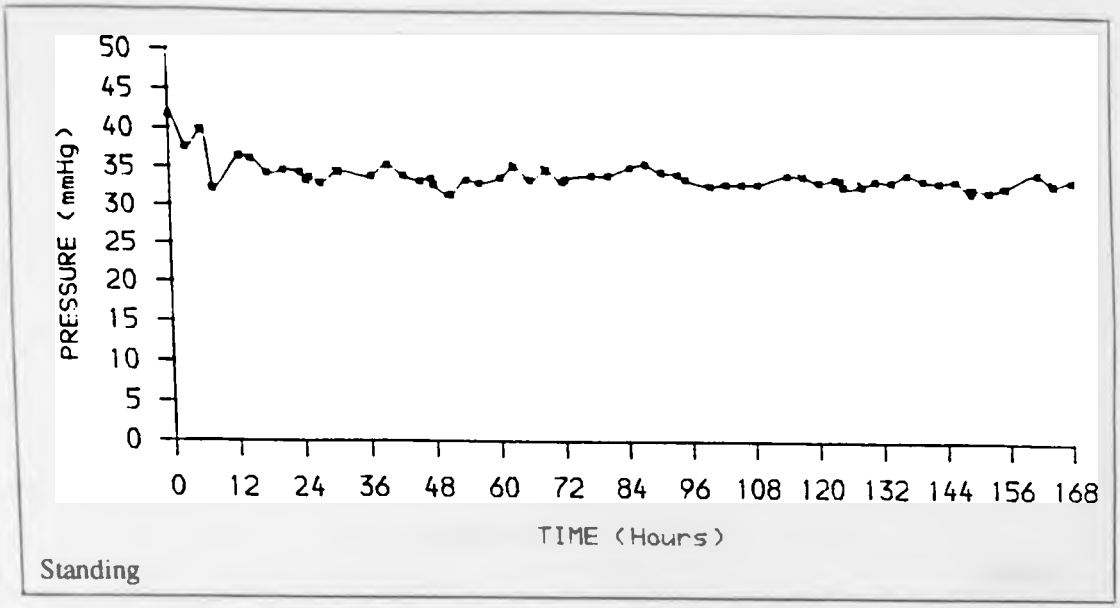
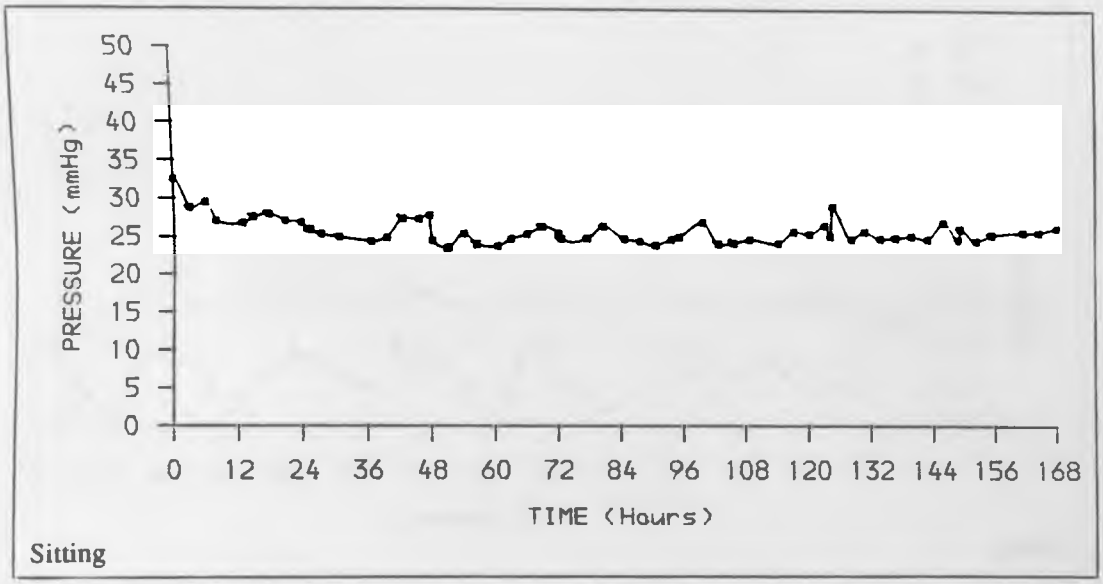


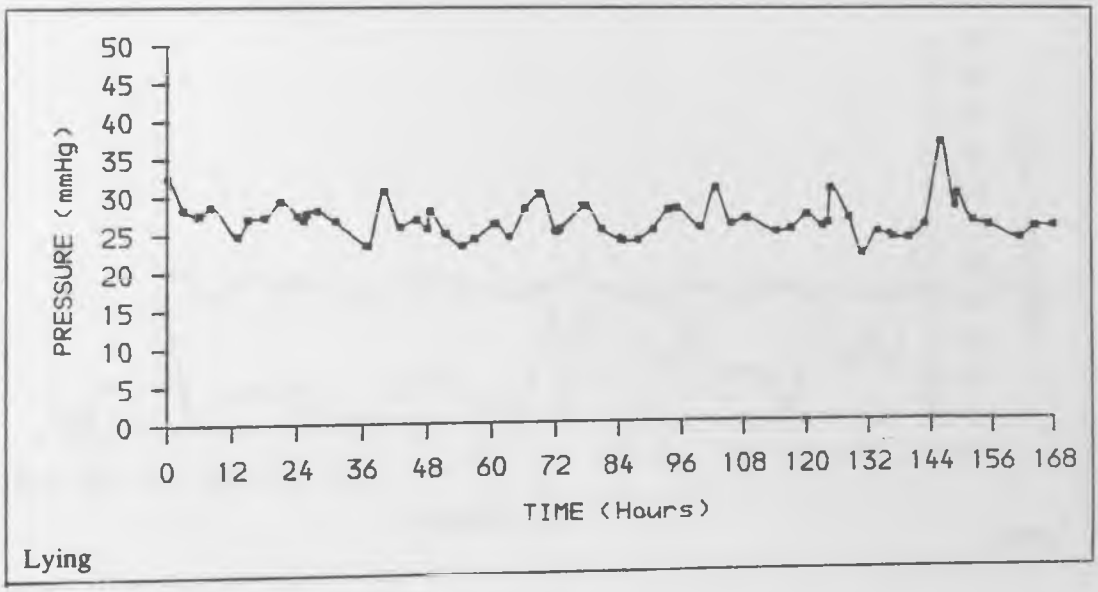
Lying



Standing

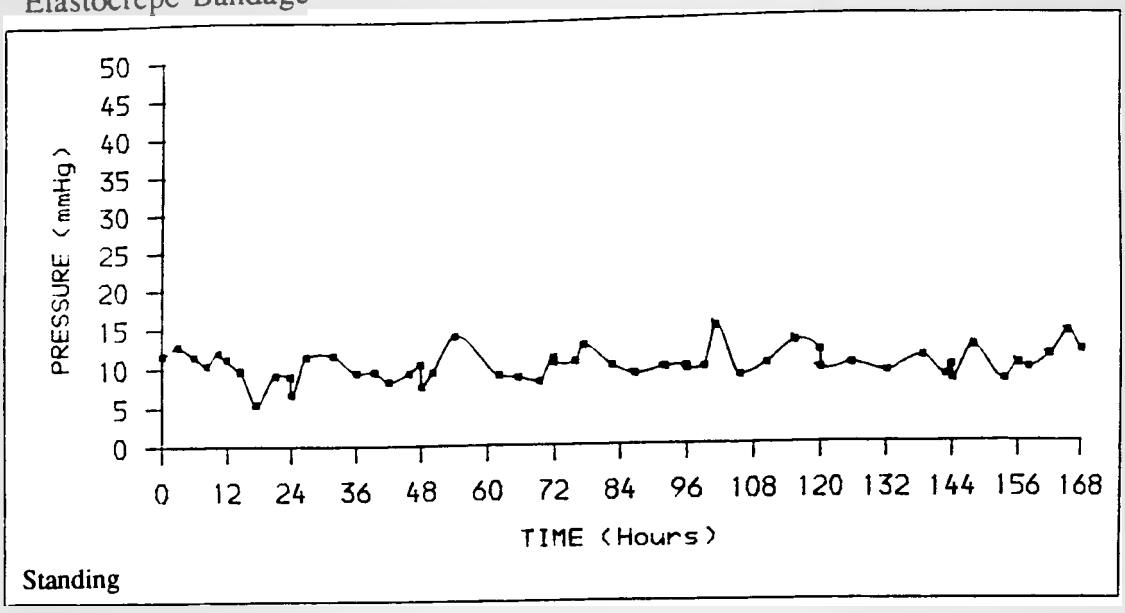


Sitting



Lying

Elastocrêpe Bandage



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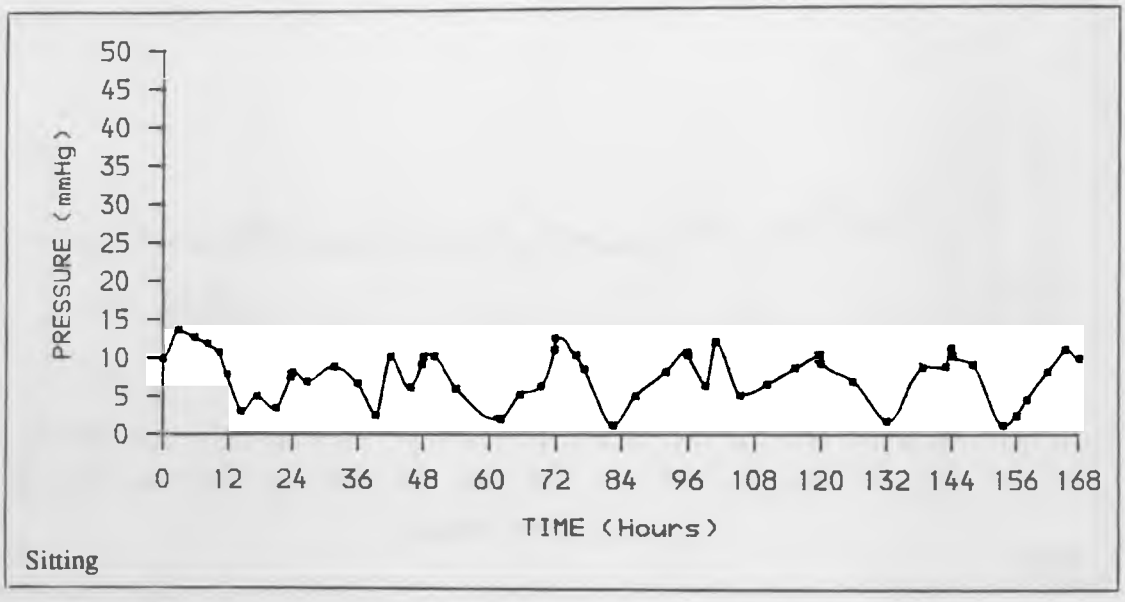

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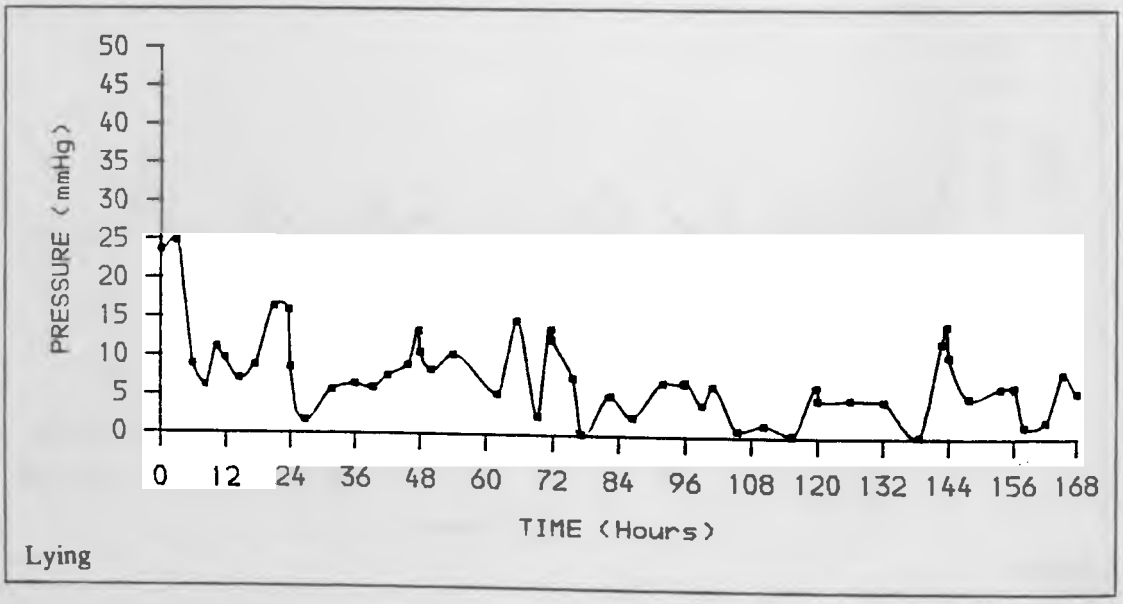
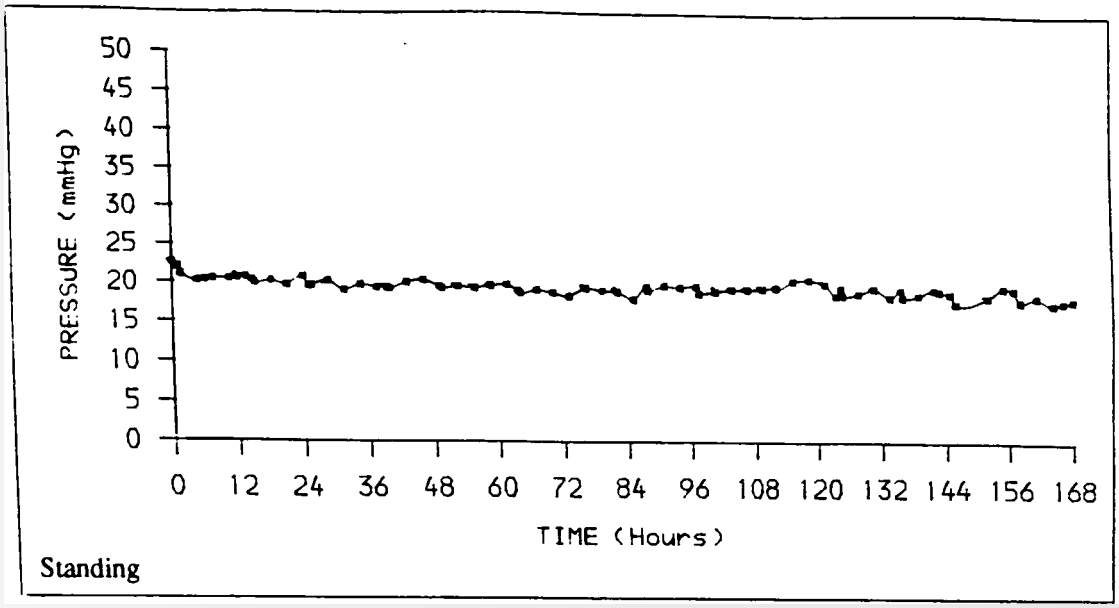


Lying

Coban Wrap Bandage



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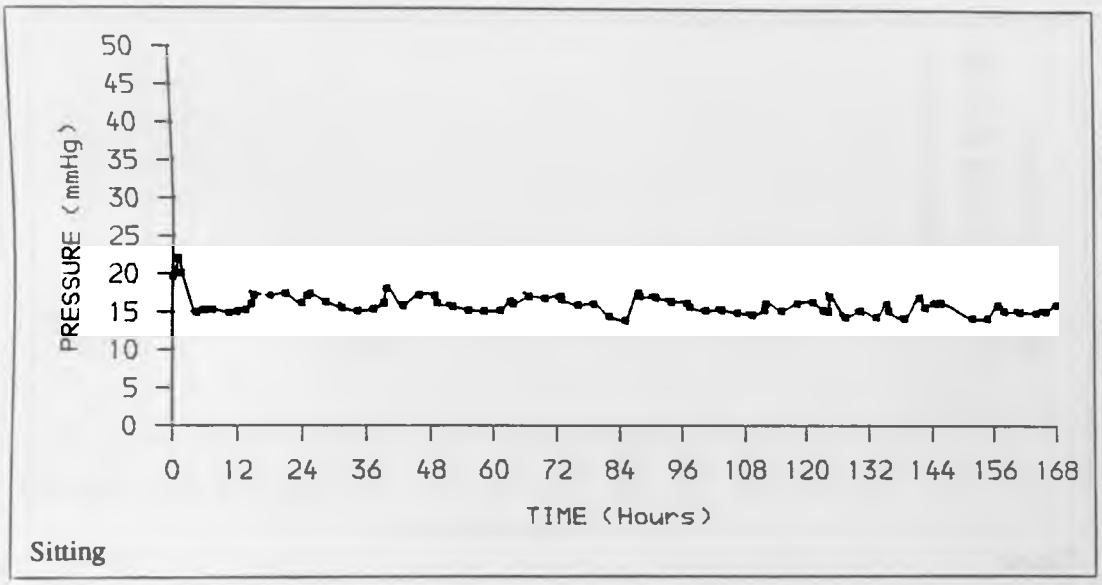

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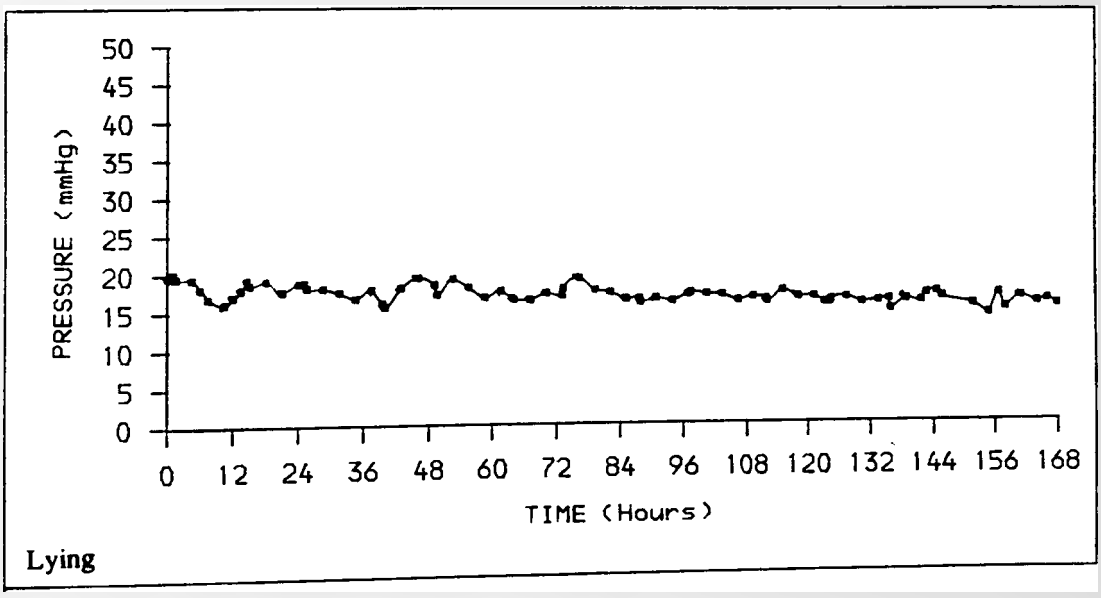
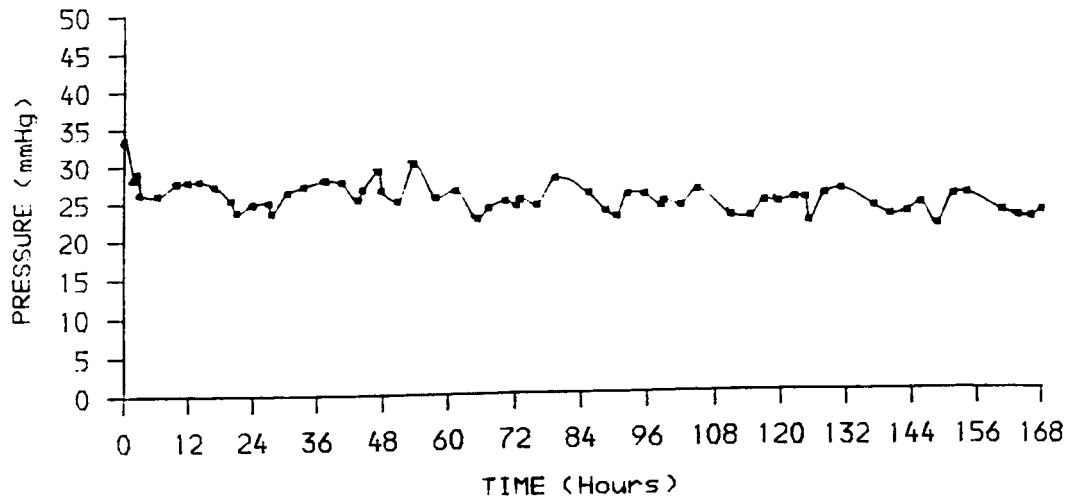


Lying

Lestreflex Bandage



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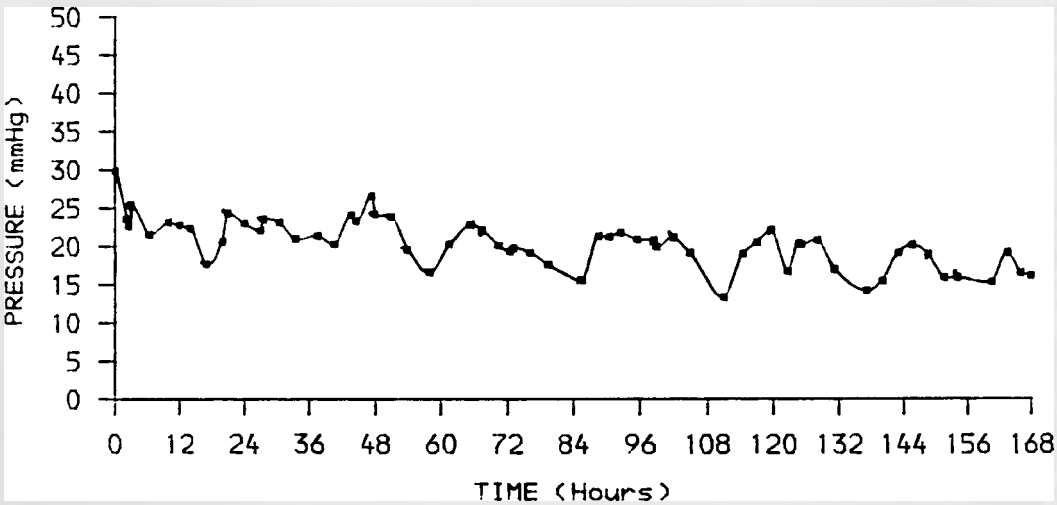

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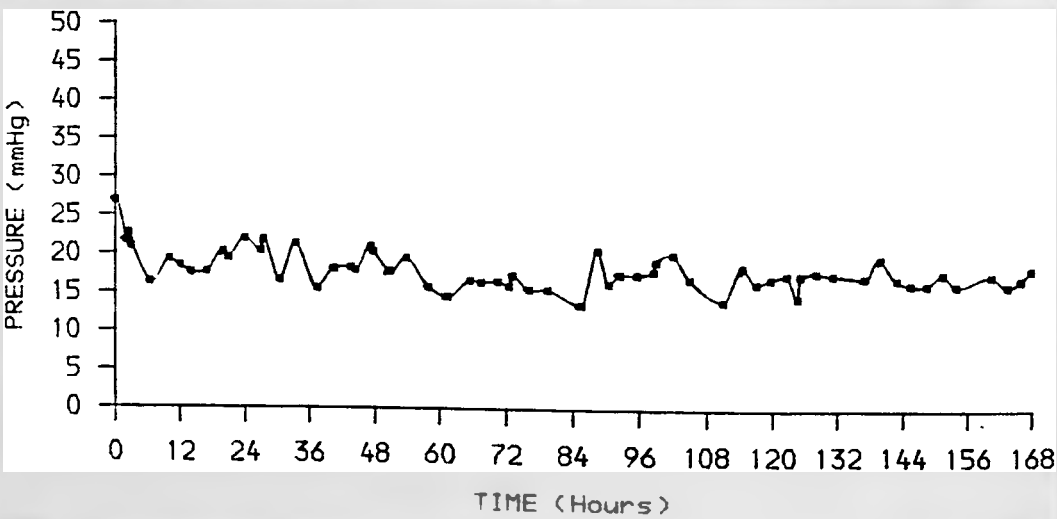

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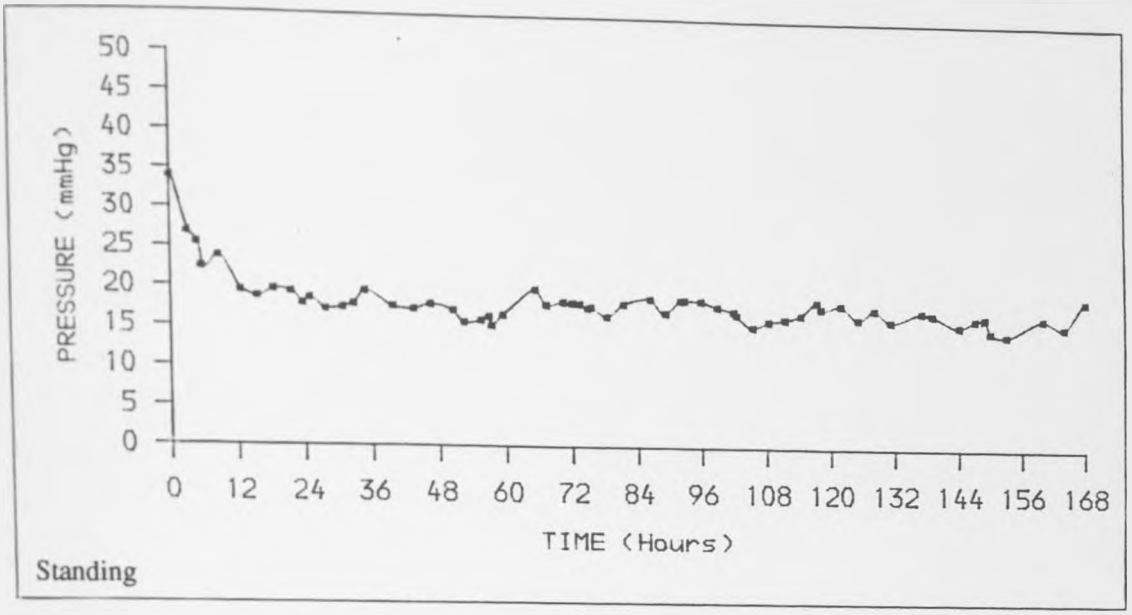

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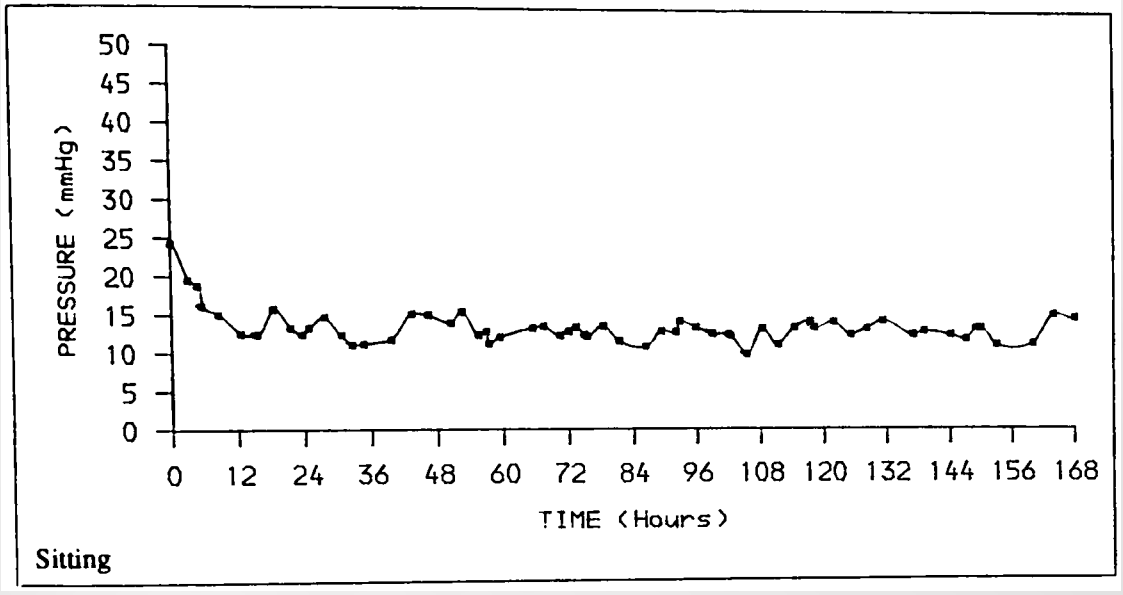

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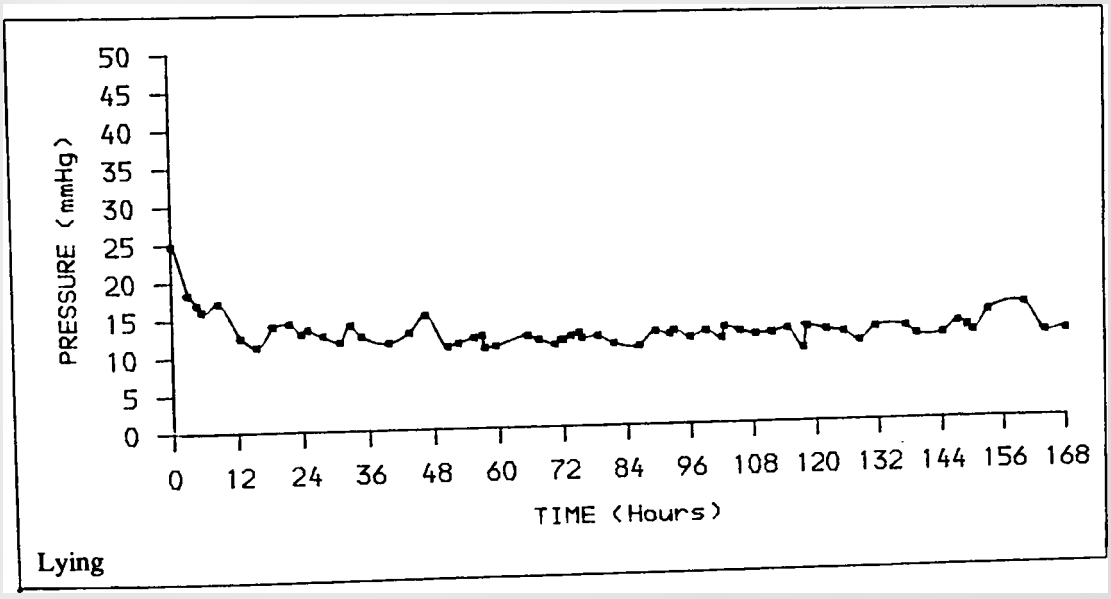


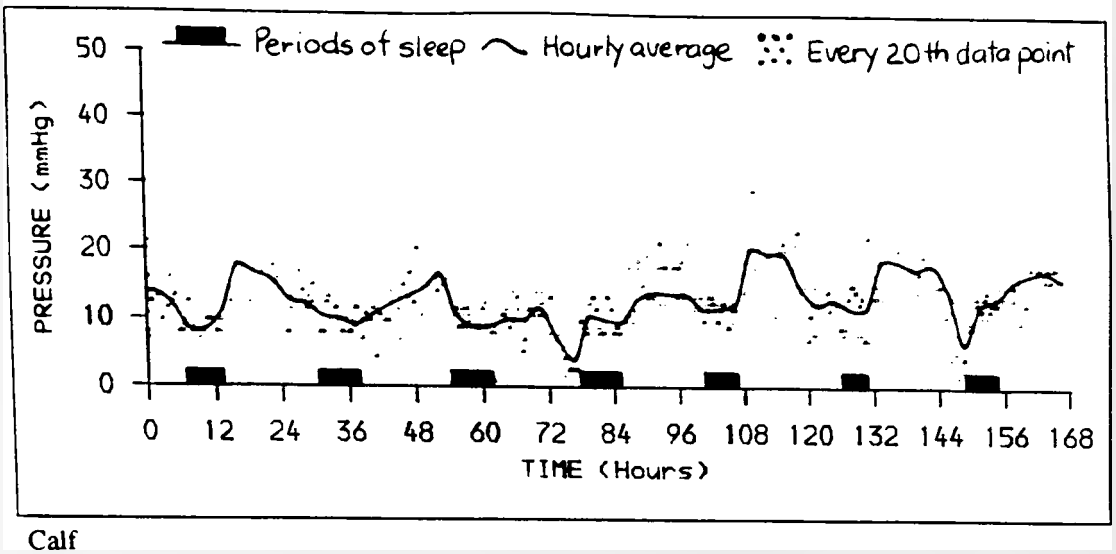
Lying

POSTURE1.PAS

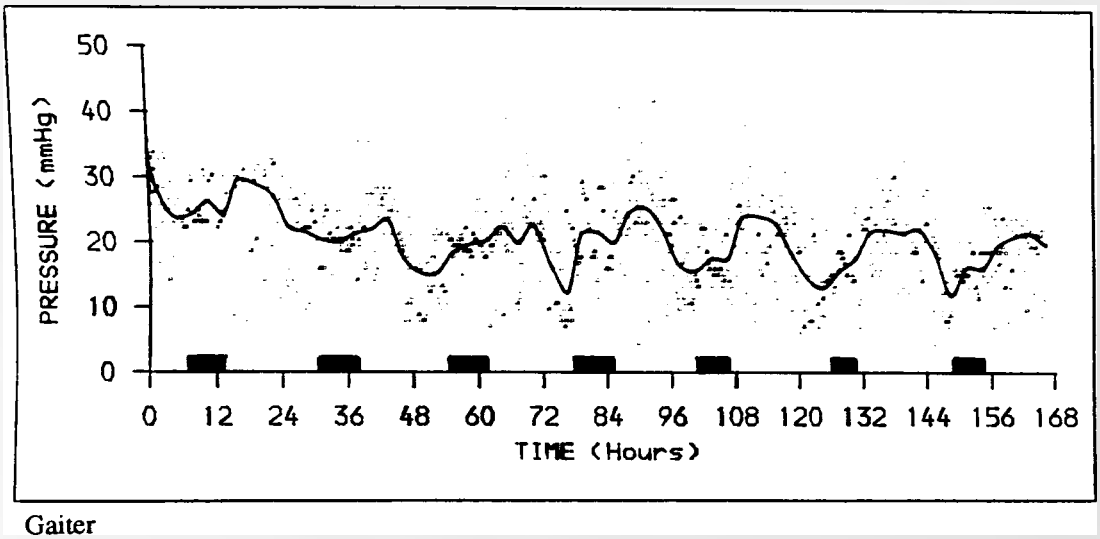
is available on computer disk
from the author

```
{THIS PROGRAM CHECKS IF A FAVOURABLR GRADIENT
WAS ACHIEVED.

Design: S Sockalingam
Date  : April 1993}


program CHECK_GRADIENT;
var
datafile, outfile : text;
time, calf, gait, ank, dummy : real;
c1, c2 : integer;
 BEGIN
  assign (datafile, 'C:\DATA\INFILENAME');
  reset (datafile);
  assign (outfile, 'C:\DATA\OUTFILENAME');
  rewrite (outfile);
  C1 := 0; C2 := 0;
  while not eof(datafile) do
  begin
  readln(datafile,calf, gait, ank, dummy, time);
  if (ank > gait) AND (GAIT > calf)  then
  c1 := c1 + 1
  else
  c2 := c2 + 1;
  WRITELN('TIME = ', TIME:6:2);
  end;
  WRITELN(' ');
  WRITELN('*********************************************');
  writeln('GRAIDENT ACHIEVED', ((c1)/(c1+c2))*100:6:2 ,'%');
  WRITELN('*********************************************');
  close (datafile);
  close (outfile);
  end.
 {END OF PROGRAM}
```

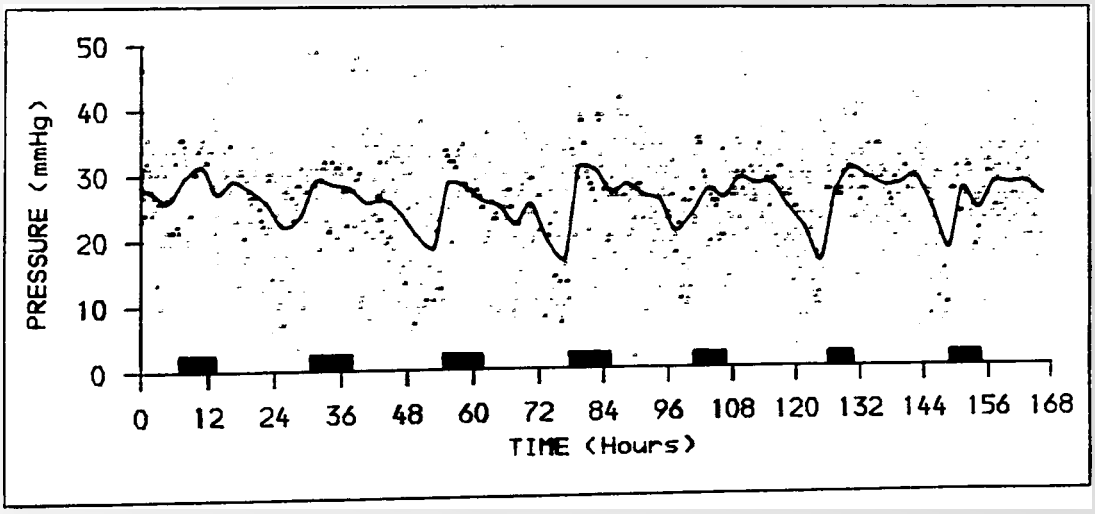
PATIENT-1



Calf

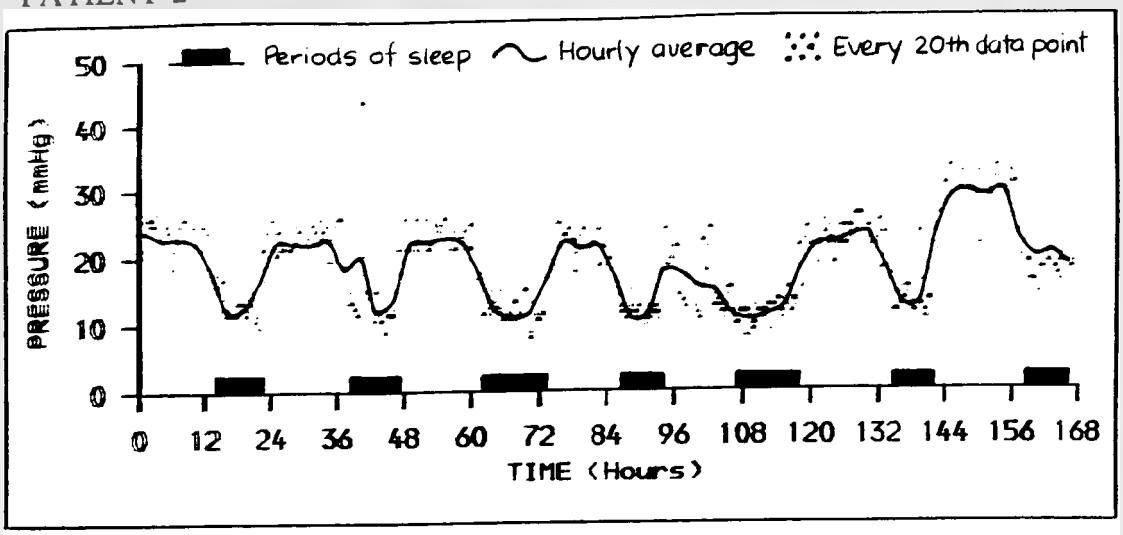


Gaiter



Ankle

PATIENT-2



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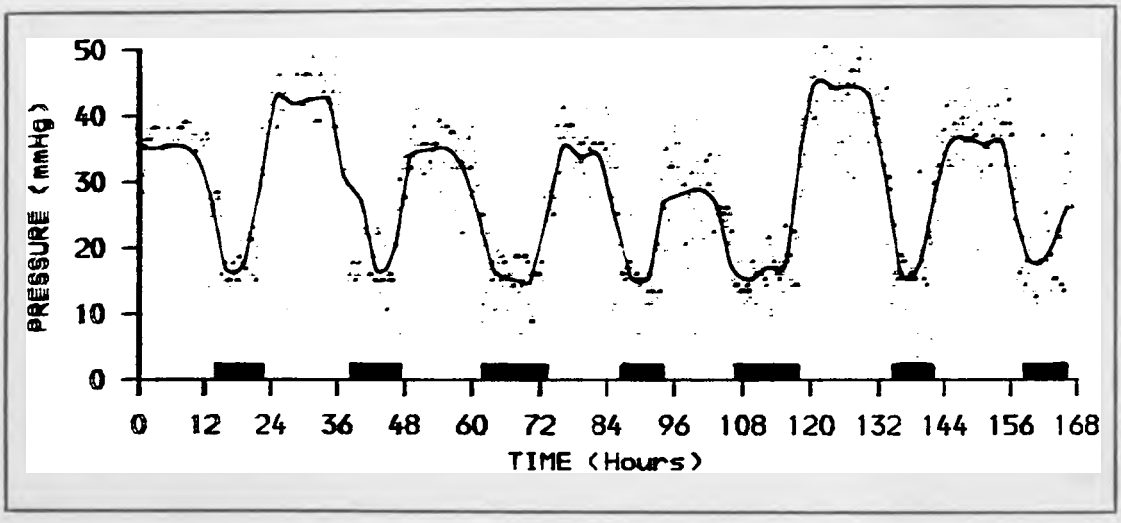

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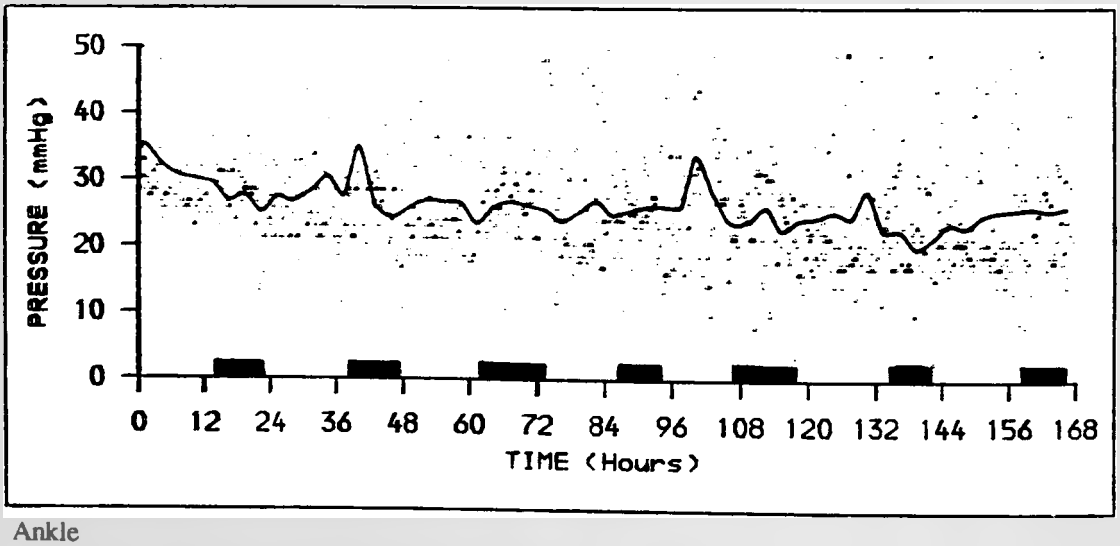

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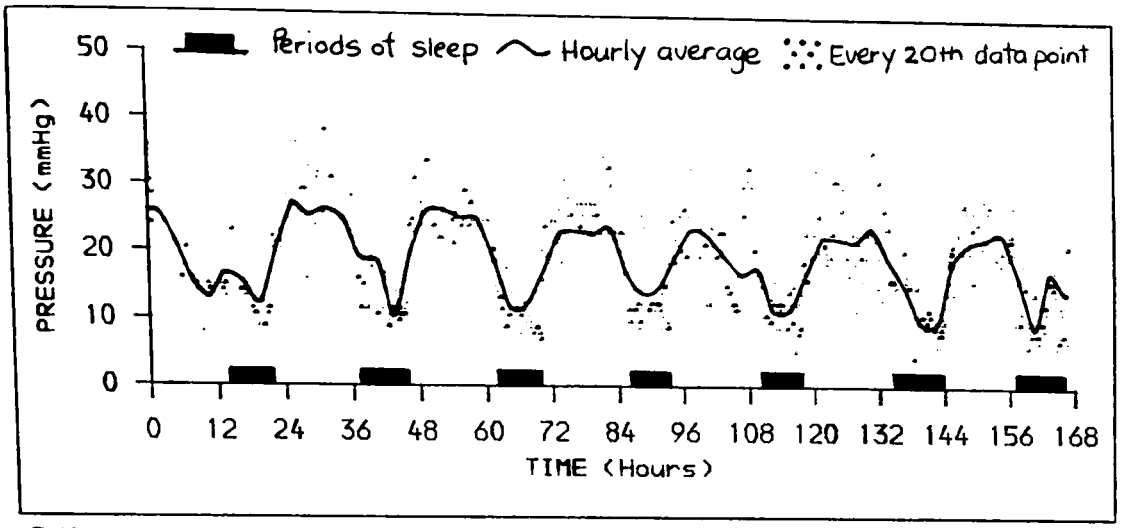
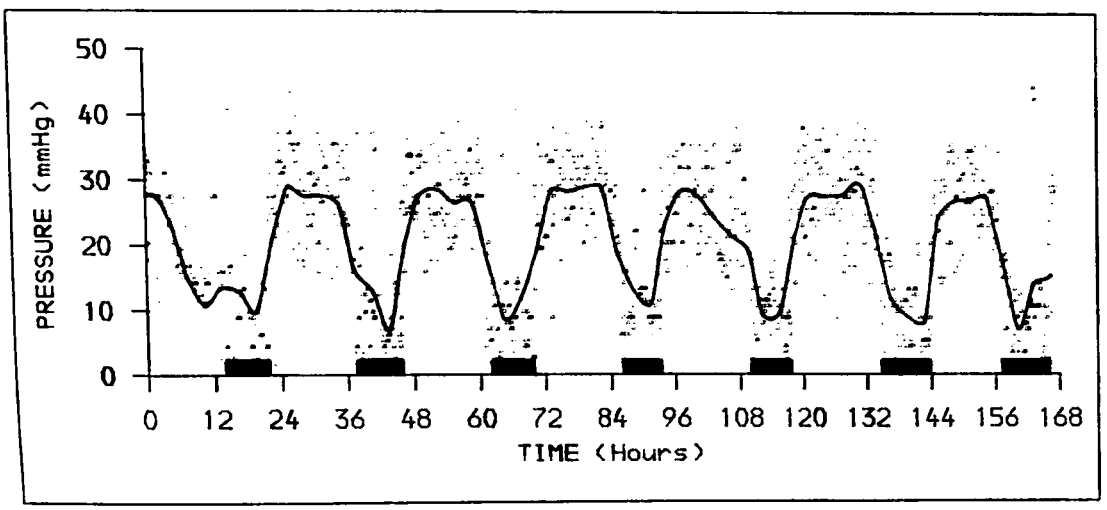


Calf



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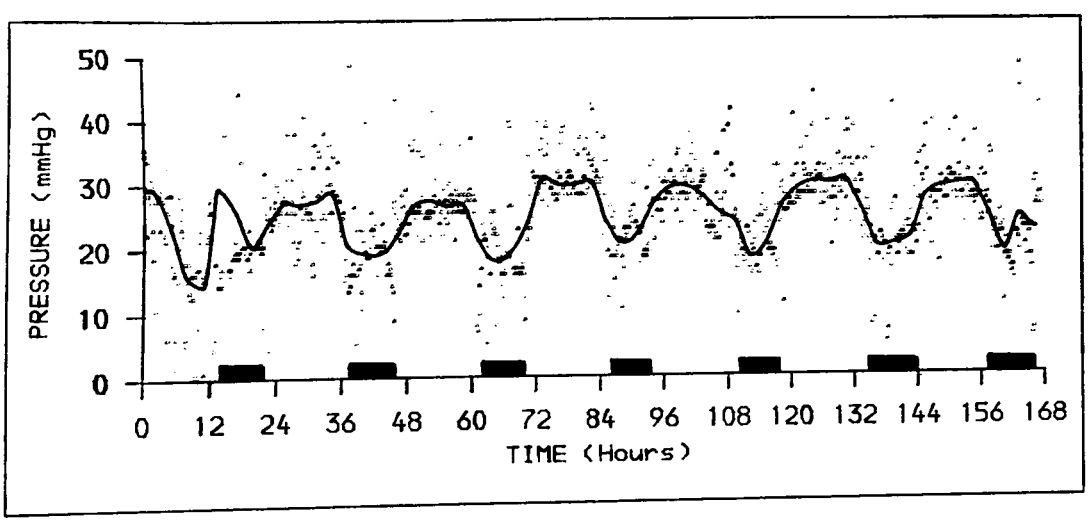

Ankle

Sections of this thesis have been published, presented and documented as listed in the following pages

PUBLICATIONS, PRESENTATIONS AND DOCUMENTATIONS

1 Sockalingam S, Barbenel J C and Queen D (1990), *Ambulatory monitoring of compression induced by bandages or stockings*. Society for Tissue Viability, Spring Conference, Bournemouth, UK

2 Barbenel J C, Sockalingam S and Queen D (1990), *Relationship between in vivo and in vivo measurements of forces induced by compression materials*. Society for Tissue Viability, Spring Conference, Bournemouth, UK

3 Cherry G, Queen D, Barbenel J C and Sockalingam S (1990), *Evaluation of a unique new compression bandage in the treatment of venous ulcers (Poster)*. Clinical Dermatology in the year 2000, May, London, UK

4 Barbenel J C, Sockalingam S and Queen D (1990), *In vivo and laboratory evaluation of elastic bandages*. CARE Science and Practice, June: 8,(2): 72-74

5 Sockalingam S, Barbenel J C and Queen D (1990), *Ambulatory monitoring of the pressures beneath compression bandages*. CARE Science and Practice, June: 8,(2): 75-79

6 Barbenel J C and Sockalingam S (1990), *Device for measuring soft tissue interface pressures*. Journal of Biomedical Engineering, Nov: 12: 519-522

7 Queen D, Barbenel J C and Sockalingam S (1990), *Ambulatory monitoring of the pressures beneath compression bandages*. European - American Symposium on Venous Diseases, Nov 8-10, Vienna, Austria

8 Sockalingam S, Barbenel J C and Queen D (1990), *Ambulatory monitoring of the pressures beneath compression bandages*. Proc of the 6th Int Con on Biomedical Engineering, Singapore, Dec, 439-442.

9 Queen D, Sockalingam S and Barbenel J C (1990), *Ambulatory monitoring of the pressures beneath compression bandages (Poster)*. American Academy of Dermatology, December, Atlanta, Georgia USA

10 Barbenel J C, Sockalingam S and Queen D (1991), *Measuring and recording of interface pressures*. Proc of the First European Conference on Biomedical Engineering, ed. Faust U, Feb 17-20, 200-201

11 Queen D, Sockalingam S and Barbenel J C (1991), *Ambulatory monitoring of the pressures beneath compression bandages (Poster)*. Symposium on Advanced Wound Care, April 7-10, San Francisco, USA

12 Queen D, Barbenel J C and Sockalingam S (1991), *Compression bandaging - Fact or fiction ?* Phlebology Society of America, May 8-12, Cincinatti, USA

13 Cherry G, Queen D, Sockalingam S and Barbenel J C (1991), *New compression bandage for the management of venous leg ulcers - Clinical and experimental studies (Poster)*. Society of Peripheral Vascular Nursing, June 2-5, Boston, USA

14 Sockalingam S, Barbenel J C and Queen D (1991), *Testing bandage pressures*. Journal of Wound Care Nursing, Nursing Times, June, 87(23): 78-83

15 Barbenel J C, Sockalingam S and Queen D (1991), *Continuous ambulatory monitoring of the pressures beneath compression bandages*. III International Congress of Phlebolymphology, Sept 18-21, Ferrara, Italy

16 Nelson E A, Sockalingam S and Ruckley C V (1993), *A pressure monitor for continuous measurement of sub-bandage pressure*. Joint American Venous Forum and United Kingdom Venous Forum Meeting. Orlando, Florida, U.S.A.

17 Sockalingam S and Barbenel J C (1992), *The Activity Sensor*. British Patent Application Number 9304571.4