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THE PRECLINICAL AND CLINICAL ASSESSMENT OF THE PHYSICAL CHARACTERISTICS OF BURN WOUND DRESSINGS.

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Degree of

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"to JAN - her courage and strength

are an inspiration to others"

Dedication

I dedicate this thesis to the memory of MRS. JANET PARK who died in April 1983 as a result of her extensive burn injuries. Jan was a very good personal friend and her death not only shocked her family but our whole community.

At the time of her death we were deeply saddened, but had great admiration for her courage.

Her courage and cheerful nature encouraged me to enter the field of "burn care" in the hope that some day my research may help others.

Douglas Queen, Sanquhar.

Abstract

Preclinical assessment procedures for wound dressings have been established with the clinical situation in mind, taking into account the important parameters of tensile mechanical properties, conformability to body surfaces, water vapour transmission rate (WVTR) and gaseous transmission (GTR) to O_2 and CO_2.

The mechanical (tensile) properties, the WVTR and the GTR's are measured by modified international standards. These are ASTM D882-81, ASTM E96-81 and BS 2782 respectively. The mechanical test is basically a uniaxial test taken to failure, from which the stress-strain characteristics and the ultimate strength of the material are determined.

The WVTR is determined by measuring the rate of water loss from a container, covered with the dressing being evaluated, under controlled humidity conditions.

Gaseous transmission, to both oxygen and carbon dioxide, is determined by the British Standard Vacuum technique. This method was used only for the assessment of the hydrophobic dressings. A liquid to gas technique was employed to assess the hydrophilic (water containing) dressings in respect to their transmission characteristics.

Conformability is measured by an inflation test. At a pressure of 40 mmHg, a radius of curvature is calculated from the incremental change in height of the central point of a disc of the material under test.

Viscoelastic tests were carried out to determine if any of the materials showed viscoelastic behaviour. These properties are of importance in the application of pretensioned dressings.

A series of commercial and experimental materials were evaluated using the techniques described above. Some of the materials were assessed as a bi-laminate form, with a Mefix (adhesive bandage) top layer. Such a layer generally proved beneficial with regard to their possible clinical performance.

Clinical studies were carried out for both <u>in situ</u> water vapour transmission and conformability. Such studies were carried out to provide a correlation between the laboratory and clinical situations.

By providing an indication of possible clinical problems, preclinical assessment is of importance to clinicians and manufacturers.

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CHAPTER 1

Introduction

CHAPTER 1

1.1 Introduction.

Skin forms the major protective barrier of the human body. Damage to the skin, and hence the partial or complete loss of this protective barrier, can be induced in many ways. A wound occurs when energy is dissipated within the tissues of the body (Goode, 1984). Wounds may result from thermal, mechanical, chemical or electrical energy sources. The degree of injury is determined to some extent by the amount of energy dissipated.

Thermal injuries are among the most traumatic that can occur to the human body and can lead to death. Although the number of deaths due to burn injuries has been on the decrease since the early 1900's (when 2500 died/year), in the U.K. the annual mortality rate has stabilised at around 700 to 900 since the mid-1960's (Lawrence,1979). In the 1960's, about 100,000 burn injuries occurred in Great Britain; 10,000 of these required hospital admission and 800 were fatal (Batchelor, 1968). The decrease in deaths is a direct result of improved wound management and improved coverings. However, the number of recorded burn injuries in 1979 (Lawrence) was 150,000 of which

14,000 required hospitalisation, indicating a general rise in the number of accidents resulting in burn injuries. In the United States, these statistics are very much larger with 2,000,000 burn injuries per year; 10,000 of them being fatal. These figures make burn injuries one of the major causes of accidental death (Stewart, 1981).

Many clinicians regard burn victims as "the sickest patients you'll ever see" (Montgomery, 1979). After surviving the immediate injury many victims may die due to sepsis, respiratory disorders or cardiovascular problems.

Sepsis is a major problem, and 85% (who survive the initial 'shock', inhalation etc) of those who ultimately die from severe burns, die of sepsis. In the treatment of burn wounds, a wound covering, which can simulate the role of natural skin, is desirable (Park,1978). The purpose of the temporary dressing is to produce an environment conducive to the natural healing or the preparation of a granulation bed for autografting.

Many materials have been evaluated, with promising results, on small partial thickness burns. However, such wounds will heal promptly if kept clean regardless of the type of coverage or dressing, if

any. The real test is in the covering of severe burns both deep and extensive. In these cases, improved dressings are necessary to protect the wound from infection and fluid loss. Despite advances in polymer technology (Park, 1978), there is still a potential need for developing a superior temporary wound covering to protect and prepare the wound site for future autografting.

Allografts and xenografts are the most desirable and frequently used dressings, and their advantages have been well documented (Bromberg et al, 1965; Hackett and Bowen, 1974). However, these dressings have definite limitations, including supply, high cost of collection, storage and bacterial problems (Pruitt and Silverstein, 1971; Tavis et al, 1978). A suitable synthetic dressing could overcome these limitations.

1.2 Burn Injuries.

The depth of thermal injury is determined by a combination of the nature of the burning agent, temperature, time of exposure, and subsequent events initiated by the injury (Goode, 1984). The injury may extend through the entire thickness or only a part of the skin.

A consequence of the skin damage is the destruction of the barrier function of the skin, allowing bacterial invasion and the abnormal loss of body fluids (Pruitt and Silverstein, 1971). In severe burns, these problems may result in (the patient's) death (Yannas and Burke, 1980). It is therefore essential that the barrier function of skin is restored as quickly as possible, by either a synthetic dressing, an allograft or a xenograft. These measures are necessary to act firstly as a physical barrier to bacterial invasion and secondly as a controlling barrier for evaporative water loss and heat loss. The necessity becomes more urgent in extensive burns where a large skin area is destroyed and the chances of autografting are reduced or non-existent. Such dressings are immediate post burn wound dressings.

In the initial stage of full thickness burns, the wound bed is not sufficiently viable for granulation to occur. A number of treatment phases are necessary before granulation can take place. The initial phase is to stabilise the patient's condition and control shock using intravenous analgesia. The next phase is to clean and prepare the viable tissue area, by debridement, ready for autografting. This debridement procedure can be carried out by surgical or chemical means, using antibacterial agents and surgical

treatment to control infection. The most widely used antibacterial agent is silver sulphadiazine in the form of a cream (Flamazine, Smith and Nephew Pharmaceuticals Limited). A granulation bed can now develop in the clean wound. Once this phase is complete the condition of the granulating bed must be maintained in anticipation of autografting. The granulating bed can be kept in prime condition by the use of temporary wound dressings.

Some clinicians practice the exposed method of treatment (Wallace,1939), which renders wound coverings unnecessary. However, the eschar which forms during the exposure treatment is a fine growth medium for bacteria and may promote wound infection. Since infection control in burn patients is difficult, it is highly desirable to remove the eschar and to obtain closure of the wound. Surgical excision of eschar as early as possible is becoming normal practice (Riel,1984). Such practice necessitates the need for a wound covering which will allow wound closure to take place (post-excision coverings).

The requirements of both immediate post burn wound dressings and post excision dressings are basically similar. The ideal situation is that one dressing may be used for both purposes.

1.3 Wound Dressings.

At present, there is a large variety of wound dressings (discussed in detail in Chapter 3). Commercial companies are distributing and researching into novel dressings. In most cases, these dressings are receiving only limited clinical trials as clinicians tend to adopt a conservative approach.

Presently, allograft skin, xenograft skin or the repeated application of conventional gauze dressings represent the main methods used to protect the granulating bed.

The last-named technique is the most widely used, since allografts and xenografts are vastly more expensive than the conventional gauzes. The gauze dressings have one major drawback, in that they adhere to the wound surface, subsequently causing tissue trauma on removal.

The relevant clinical requirements of a successful burn wound dressing may be listed as follows (Park,1978; Lawrence,1979; Wong, 1980; Davies, 1983; Turner,1984; Quinn et al,1985) :

(a) Ready availability;

(b) Provision of an effective bacterial barrier;

(c) Ease of application and removal;

(d) Sufficient strength to be secured over the wound area without splitting or tearing;

(e) Capable of being sterilised and easily stored;

(f) No antigenic properties;

(g) Water vapour permeability which will maintain a satisfactory moisture balance in the repairing tissue;

(h) Cost of dressing must be low.

Dressings are available as films, foams, sprays, composites and hydrogels. The hydrogels are the most recent dressings to be introduced into the field of burn wound dressings. The term " hydrogel " refers to a broad class of polymeric materials which are swollen extensively in aqueous media, while remaining insoluble (Hoffman, 1975; Ratner, 1982). A major advantage of such materials is their good biocompatability.

The Pure and Applied Chemistry Department, University of Strathclyde is active in the field of " hydrogel chemistry ". Graham in 1980 developed a

polymeric hydrogel which has achieved success in the field of controlled drug release, and it is envisaged that this hydrogel can be modified to meet the requirements of a burn wound dressing. Recent developments have led to the production of thin hydrogel films which were assessed in this study.

Park in his review of 1978 suggested that hydrogels, as burn wound dressings, would offer the following advantages :

1. Incorporation of antibacterial drugs;

2. Controlled drug delivery;

3. Biocompatibility;

4. Minimal mechanical irritation to surrounding cells and tissues;

5. Availability in a variety of physical structures (Andrade, 1976).

1.4 Assessment of Dressings

At present the main method of screening existing wound dressings is by expensive clinical trials.

The expense, labour and extensive time periods involved in clinical trials have stimulated research into the field of preclinical assessment, i.e. laboratory techniques which will provide a screening mechanism, narrowing down the number of dressings being taken to clinical trial.

Many important parameters have to be evaluated by preclinical assessment procedures (1.3).

Several groups are currently working on techniques for the above evaluations (Tavis et al,1978; Turner,1984). Most emphasis has been placed on the evaluation of the WVTR of the dressing materials. However, the experimental conditions from centre to centre vary greatly.

Turner (1985) recently expressed concern on the possibility of protein adhesion which may occur to the dressing while in situ. He stated that such protein adhesion would alter the WVTR characteristics of the material rendering any preclinical assessment invalid.

It was for these reasons (i.e. variation in experimental conditions and the possibility of protein adhesion) that a short clinical investigation of evaporative water loss using three materials, was included in this thesis, to obtain clinical data which would allow the optimisation of our experimental set

up.

Information obtained from these techniques will be of assistance in dressing development by giving a comparison with the ideal dressing characteristics, once these have been established.

1.5 Objective of Thesis.

The principal objective of this study was to undertake a preclinical assessment of a variety of commercially available synthetic dressings and four novel materials which the manufacturers have indicated may be of use as dressing materials. The assessment protocol included three material controls, which had been studied previously (Wong, 1980; Rahman, 1982).

The assessment procedure was to evaluate the dressings with regard to their tensile properties, conformability, water vapour transmission rate and gaseous transmission characteristics (O_2 and CO_2). Some of the assessment procedures had to be established, while others were modifications of standard techniques.

A short clinical experimental programme was to be used to establish the significance of the protein adhesion phenomenon and to provide an indication of the clinical situation in respect of water vapour loss.

To obtain a correlation between the laboratory measurement of conformability and the clinical situation, a "pseudoclinical" trial was to be carried out. This "pseudoclinical" trial would employ "normal" individuals and allow the assessment of five body regions, giving an *in situ* assessment of conformability. The assessment procedure was to be purely observational and based upon any wrinkling or fluting which may or may not occur.

Many of the dressings to date are non-adhesive and therefore require some form of external fixation. Several fixation dressings are available. To assess the effect of such a top layer on the dressing's physical characteristics, the materials assessed were also to be studied with an adhesive top layer, Mefix.

In summary the objectives of this research were as follows :

1. The establishment of four preclinical assessment procedures (tensile parameters, water vapour loss, conformability and gaseous transmission).

2. To examine the physical effect of a top layer on an underlying dressing.

3. To examine clinically water vapour loss in order to optimise the laboratory technique.

4. To examine clinically dressings in respect of the possibility of protein adhesion.

5. To examine pseudoclinically in situ conformability providing a correlation with in vitro studies.

The above work was designed to provide a research programme which would provide a preclinical assessment package developed and modified with the clinical situation in mind.

The standard techniques utilised were modified, in this study, to give techniques which were applicable to the clinical situation. With respect to the gaseous transmission and conformability techniques, these were novel to the field of preclinical assessment. The conformability test was devised for and first implemented in this study.

To enable a correlation between the in vitro systems and the clinical situation, two clinical studies were devised and implemented in this study.

The test procedures were also utilised to assess the effect of top-layers on the physical characteristics of the under-lying dressing. This novel approach brings to light the importance of using such layers with certain of the commercial dressings available.

CHAPTER 2

The Skin and the Consequences of Thermal Injury.

CHAPTER 2

2.1 Introduction

The skin, the largest and most versatile organ of the body, is a complex structure consisting of various tissues which perform specific functions. It is normally under tension but as it is extensible and mobile it allows the free movement of the body.

These functions may be summarised as (Tortora and Anagnostakos, 1981) : protection against physical and chemical attack; prevention of bacterial invasion, tissue dehydration and penetration of harmful U.V. light rays; control of body temperature; prevention of excessive loss of organic and inorganic materials; incorporation of tactile and sensory receptors; excretion of water and salts via sweat production; synthesis and storage of important compounds; and the identification of the individual e.g. facial characteristics, finger prints.

The skin crowns all of the above properties by having the ability to regenerate, thereby healing wounds (Montagna, 1974), for example, after burn injury.

To obtain a better understanding of the effects of thermal injury and subsequent healing, a more detailed description of the skin and in particular its principal layers, the epidermis and the dermis, is necessary.

In this chapter, the structure and other properties of the principal layers of the skin are clearly defined in a condensed form. For more detailed information the author recommends the work of Montagna and Parakkal(1974) and Weiss(1983).

The particular properties and function of the layers which are relevant to the dressing (temporary skin substitutes) parameters assessed are detailed. These parameters (mechanical properties and gaseous permeability) are also discussed in context in Chapters 5,6,7 and 8.

2.2 Functions of Skin

One of the primary functions of skin is to afford protection, from the environment, to the underlying tissues. An important property is the prevention of tissue dehydration, while permitting the release of water from the sweat gland to the skin surface (Langley and Christensen, 1978). The subsequent evaporation of this water acts to cool down the blood

circulating within the skin (thermoregulation). Hence the skin is of a design which is between total isolation and selective permeability.

It is important that the skin remains permeable to all basic nourishing agents, to oxygen and to metabolic waste products in order, to maintain the overall internal, homeostatic, environment. Within skin there lies a dense network of small blood vessels, the capillary bed. The volume of blood carried by this network is greater than that required to nourish the skin. The capillary bed acts in two ways; in the maintenance of body temperature and in the regulation of blood pressure.

In a warm environment or on sustained muscular exertion, the arteriolar blood vessels dilate thereby reducing their flow resistance and allowing maximal blood flow through the capillary bed. This permits the release of heat to the surrounding environment. On the other hand a cold environment causes the blood vessels to contract rapidly, reducing the blood flow, to conserve heat. These blood vessels within the skin have sphincter-like passages which permit the closing of the capillary beds, giving an increased blood flow in the arteries going directly to the veins. This is called collateral circulation and it acts as a safety valve when the blood pressure rises to dangerous

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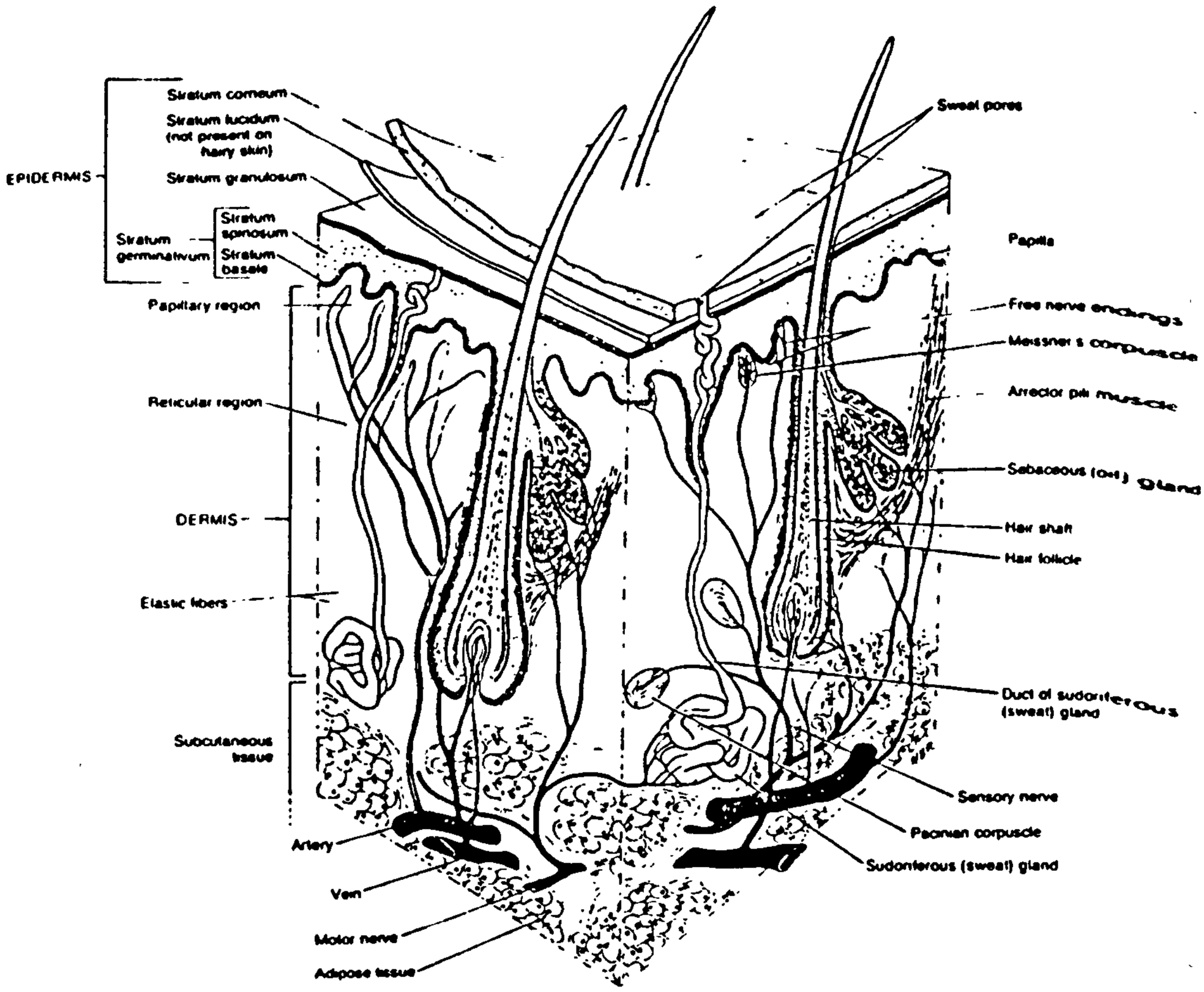

Figure 2.1

Diagram of the skin.

(Tortora and Anagnostakos, 1981)

Figure 2.2

Dermal Papillae

levels.

The skin is a highly compliant covering which accommodates any change in shape or size of the body within. The extent of this compliancy is dependent on regional, racial, age and genetic factors, hence varying from individual to individual.

Within the skin an extensive network of nerves can be found. The main function of this network is to control the glands, blood vessels and other organs within the skin. There is also a network of sensory endings on the skin surface, especially in places such as the finger tips, soles of the feet and the lips, which give the sensation of touch.

2.3 Structure of the Skin

Structurally, the skin consists of two principal parts (fig 2.1). The outer, thinner portion, which is composed of layers of epithelial cells, is called the epidermis. The epidermis is connected to the inner, thicker, connective tissue-layer called the dermis. Beneath the skin is a subcutaneous layer of tissue, the superficial fascia, which consists of areolar and adipose tissues. The superficial fascia is attached to the underlying tissues and organs.

The following sections detail the two main layers of the skin. They are orientated to show the relationship between layer structure and skin function.

2.3.1 Epidermis

The epidermis is an avascular layer, which is composed of stratified squamous epithelium comprised of four or five cell types, depending on its location in the body. These cell types can be stacked in varying depths. This layer covers the entire surface of the body. The epidermis extends down into the hair follicle capsules. Therefore, in the event of full thickness injuries when the epidermis is destroyed, re-epithelialisation can occur from the epithelial cells lining the hair follicles.

The outer layer, stratum corneum, consists of 25 to 30 laminae of flat, dead cells containing keratin, which are continously shed and replaced from beneath. It is this mantle of dead tissue in addition to the melanin present, called the horny layer, that serves as the principal shield of the body, protecting the underlying tissues from light and heat, bacteria, and many chemicals. This thin, flexible transparent membrane (7-16 μm thickness) provides the total

mechanical strength of the epidermis (Sheuplein and Blank, 1971). In protected areas of the body this layer is smooth and very supple; on surfaces which experience a great deal of abrasion, such as the palms of the hands or the soles of the feet, it is thickest and most rugged. In these areas the thick keratinous outer layer, in combination with the dermis, plays a major role in defining the mechanical properties of the skin (Kenedi et al,1975).

The layers below the horny layer; the stratum lucidum and stratum granulosum, contain eledin (translucent substance) and keratohyalin respectively. These compounds are the precursors of keratin, indicating the gradual death and keratinisation of the cells as they migrate to the surface. Degeneration of the nuclei of the cells, occurring in the stratum granulosum, prevents vital metabolic reactions from taking place and hence leads to subsequent cellular death.

The stratum corneum is steadily replenished by new cells originating from the deeper layers of the epidermis, the stratum spinosum and stratum basale (collectively called the stratum germinativum). As the cells ascend from these layers, they die as they become keratinised.

Melanocytes are evenly scattered within the epidermis and they produce a dark pigment, melanin. This pigment is injected into the surrounding epidermal cells, where it forms a protective cap over each cell nucleus. This cap is on the side which is towards the skin surface and thus provides a shield from the harmful rays of the sun, by absorbing the ultra-violet light.

The keratinocytes of the upper spinosum and granular layers contain granules in their peripheral cytoplasm. These granules are called lamellar granules. It is thought that they form the primary intercellular barrier to water. The epidermis is permeable to water in both its deeper and most superficial portions, but it is impermeable from either direction at the level of the granular layer. It is at the level of the granular layer that the functional barrier to water is found.

In view of the protective role of the epidermis, it is important that it remains intact to form a continuous covering of the body.

2.3.2 Dermis

The dermis is composed of fibrous connective tissue containing collagenous and elastin fibres. It is the major supporting layer of the skin and it is 0.5 - 2.5 mm thick, nourishing the epidermis above and merging with the subcutaneous tissue below. Numerous blood vessels, nerves, glands, and hair follicles are also embedded in the dermis. The dermis is divided broadly into two distinct areas.

The upper region of the dermis, about one fifth of the total thickness, is named the papillary region. Its surface area is greatly increased by small finger like projections called dermal papillae (fig 2.2), which interlock with similar undulations in the epidermis. This layer contains dense capillary networks. The ridges marking the external surface of the epidermis are caused in part by the size and arrangement of dermal papillae. The ridge patterns on the finger tips are responsible for the finger prints of each individual.

The remaining portion of the dermis which is termed the reticular layer is composed of dense, irregular collagenous connective tissue. It is the reticular dermis which gives skin its leather-like character. The irregularity of structure permits

flexibility and strength in all directions. The spaces between the connective tissue fibres are occupied by ground substance, hair follicles, nerves, blood vessels and sweat glands.

The dermis is made up predominantly of connective tissue - collagen, elastin tissue and ground substance, and to a lesser extent of cells and cellular structures.

The microstructure of skin shows that its elasticity is provided by this collagen - elastin rich network (Kenedi et al,1975). The elastic (elastin) fibre network of the dermis extends into both the reticular and papillary layers. In the papillary dermis, the elastic fibres are fine and extend directly toward the epidermis, splaying out under it. These fibres may serve to bind the epidermis to the dermis (MacKenzie, 1972).

Coarse elastic fibres entwine the thick collagen bundles of the reticular dermis. The unique mechanical properties of the dermis probably depend on the compliant elastin fibres interwoven in the mesh of rather inextensible collagen elements (Montagna et al, 1970, Weiss, 1983).

The inter-relationship between these elements allows the skin to conform to body contours. Although elastin fibres are deformed by small forces, they recover their original dimensions even after considerable stretch (Ayer,1964). The viscoelastic nature of collagen and its interaction with the gel-like ground substance renders the skin's mechanical properties time dependent.

The skin can thus accommodate the flexion and extension of joints. The skin stretches to allow movement but recovers after joint movement, returning to normal very quickly.

Beneath the dermis, the fibrous tissue branches out and merges with fat containing, subcutaneous tissue which insulates the underlying structures. The subcutaneous fat acts as a cushion for the dermis and epidermis, allowing lateral displacement.

Such mechanical properties would be ideal in a temporary wound covering as it would mimic the skin giving the flexibility of motion required in physiotherapeutic terms.

Active physiotherapy methods are essential for the well being of the extensively burned patient. Early mobilisation of all parts of the body, when this is possible, may prevent stiffness, and is

particularly important in burns of the hands and joints (Cason and Lowbury, 1980). For example, active hand exercises should be started immediately in the case of partial-skin loss burns and the 'hand bag' treatment (Reid,1974), using a polyethylene bag with an antibacterial cream inside, is an ideal method.

Therefore if dressings were to possess similar mechanical characteristics to the skin, injuries to other joints (e.g. elbow) may be successfully treated in the same manner, allowing early mobility to preserve joint function.

It is for these reasons that dressing conformability is very important. Non-conformability can lead to many clinical problems. Two main problems are the inhibition of joint movement when the material is non-elastic; and the tearing of the dressing due to the stresses initiated by joint movement, which leads to a breakdown in the barrier properties of the material.

2.4 Effects of Thermal Injury

Tissues may be damaged by physical, thermal (heat), electrical, radioactive or chemical agents. These agents can destroy the proteins in the affected cells, causing cell injury or death. Direct

convection of the heat energy from the injured site to the normal tissue around the wound site can also cause tissue damage. The cells are injured and destroyed by interference with vital metabolic processes, and by the denaturation of the cell membrane. The thermolabile enzymatic reactions are blocked due to enzyme denaturation, altering or abolishing cellular respiration, leading to cellular death (Railton, 1984).

Tissue thermal damage occurs when cells are raised to temperatures >44^{o}C for an extended period. Exposure of the skin to a temperature of 70^{o}C will cause epidermal necrosis in one second, while at 45^{o}C at least six hours is required to cause damage (Goode, 1984).

The degree of burning is therefore dependent on the temperature of the heat source and the length of time that the tissues are exposed to the heat. Burning can therefore be caused by a short quick exposure to a high temperature source or a prolonged exposure to a low temperature source. The depth of thermal injury (either partial-thickness or full-thickness) is therefore a combination of both exposure time and source temperature.

The identification of both burning parameters is not usually of great importance. However, the identification of the depth of the burn injury is of most importance. For example a full-thickness thermal injury results in an uncontrolled rate of water loss, from the injured site, by exudation. Most of this loss is accounted for by evaporation, which is an energy consuming process (Lamke et al, 1977). This rate of evaporation is dependent on the environmental temperature and relative humidity.

Since the latent heat of evaporation is high (Wenger,1972; Lamke et al,1977), a large water loss will cause a large heat loss and thus the basic metabolic rate will increase to try to maintain body temperature (Bittel et al,1977). Chao et al (1977) predicted the water losses expected from superficial, partial and full-thickness injuries, using mathematical modelling. They predicted that from superficial burns the water loss increased rapidly to about six times that of normal skin. A similar observation was noted for partial-thickness injuries. Full-thickness injuries, however, were predicted to give rise to a lower loss rate of around four times that of normal skin.

The differences observed between partial and full-thickness burns are most likely due to the increased vascular permeability observed in partial-thickness injuries as opposed to the total destruction of the vessels themselves, in full-thickness burns.

These predicted results have been experimentally substantiated using different methods. Lamke et al (1977) measured the evaporative loss from different types of wounds using an evaporimeter.

The fluid loss can also be measured by the change in body weight over a period of time (Moncrief and Mason, 1962; Davies et al, 1974), or by an estimation of the vapour pressure gradient of the air layer close to the injured surface (Nilsson, 1977). All of these techniques showed a similar trend.

The proteinaceous-lipid product of the epidermis, the stratum corneum, is tailored in every detail to protect the body against its environment (Montagna and Lobitz, 1964; MacKenzie, 1972; Elias and Friend, 1975). However one cannot refer to a single structure as the barrier layer, since the entire epidermis acts as a barrier against penetration.

The cutaneous surface is coated with a complex layer of lipids and organic salts, secreted by the sebaceous and sweat glands. This layer has a pH of between 4.5 and 6.0 and is called the "acid mantle". The "acid mantle" is said to have antifungal and antibacterial properties (Blank, 1959).

If agents do pass through the top layer, the stratum corneum acts as a filter mechanism. It does so, due to the interstices gradually reducing in size, with increasing depth. They probably serve as physical and chemical traps for large molecules and micro-organisms.

Breakdown of the intact skin barrier, due to damage of the lipo-protein layer in the stratum corneum allows the invasion of pathogenic micro-organisms from the environment. Full-thickness injuries abolish bacterial protection and systemic infection or septicaemia can result if this problem is not controlled (Jelenko, 1967; Scheuplein and Blank,1971).

The systemic effects of injury are complex and inter-related. They can be split into two main categories; the 'shock syndrome' and the metabolic responses to trauma.

The term "shock" is used to describe a group of conditions with broadly similar characteristics but a variety of causes. The beginning of shock may be metabolic events within critical cells. The cause of these early metabolic changes is ischemia (inadequate perfusion). Shock is often diagnosed in terms of low blood pressure or low cardiac output.

Burn injury results in capillary leakage within the wound site. If the area of injury is extensive such leakage can result in a sudden drop in systemic blood pressure, resulting in shock.

The major feature of the metabolic response to trauma is increased energy expenditure, and this is proportional to the severity and duration of the injury. In the healthy adult, tissue synthesis and breakdown are in essential equilibrium. Trauma and shock upset the equilibrium, tipping the balance in favour of catabolism. In severe burns (>50% of body surface) the resting metabolic rate is almost doubled, energy expenditure rising to 1190 kJ per day. Such sudden energy requirements rapidly utilise the body's energy stores, and exhaustion occurs unless replenished.

The blood supply to granulation tissue is itself critical. It is the first to be deprived of blood with diminishing blood pressure or blood volume. It is also the last to be restored when the

pressure or volume is restored.

Any factor which locally reduces blood flow in granulation tissue is likely to affect wound healing adversely. The amount of oxygen delivered to a healing wound depends on the oxygen partial pressure (PO_2), good tissue perfusion and normal haemoglobin levels.

Since the desired end point of an adequate circulation is to perfuse the tissues and supply them with the necessary nutrients, 'shock' may be defined as "a generalised state of severe circulatory inadequacy" (Goode,1984). It is therefore of vital importance that steps be taken to stabilise the patient using drugs, nutrients and blood where necessary.

2.5 Wound Healing

After injury, the body repairs damaged tissue to restore continuity and essential function to the injured area. Structure and function are restored by a series of complex cellular and biochemical events,

resulting in the formation of scar tissue. Granulation tissue is responsible for this and synthesises collagen and ground substance. When the injury to tissue is slight, fibrin seals the open tissue by hardening into a scab. If the tissue and cell damage is extensive, as in large open wounds, the connective tissue stroma and parenchymal cells are active in repair. Repair involves the rapid cell division of many fibroblasts which manufacture the collagenous fibres to provide strength within the new tissue. These cells also increase (by cell division) the number of small blood vessels within the growing area. All of these processes create an actively growing connective tissue called granulation tissue.

The process of wound healing occurs in three main stages;

Phase 1 - Inflammation

The trauma of injury induces clot formation by allowing platelet aggregation and the coagulation processes leading down to the formation of fibrin. Injury also triggers the kinin and complement systems which cause an inflammatory response to bacteria and to the necrotic tissue within the wound.

Phase 2 - Proliferation

By day five, the fibroblasts have begun to synthesise collagen and ground substance. The number of fibroblasts present increases as the healing proceeds and they move ahead of the advancing endothelial buds. These buds 'vacuolate' forming a continous lumen, and further differentiate into arterioles and venules. The earliest collagen fibres soon abound and are laid down haphazardly, giving the granulation tissue.

Phase 3 - Differentiation

There is no clear demarcation between proliferation and differentiation. Differentiation gradually gets underway in the proliferating granulation tissue and continues indefinitely. There is a reorganisation of the blood vessels, many of which occlude and disappear. The chief feature of the scar tissue which is formed is the haphazardly arranged collagen fibres.

In burns, the principal objective is to obtain epithelialisation. This occurs in the following way :

- the wound is plugged initially by a fibrin coagulum;

- the epidermis turns downwards over the edge of the underlying dermis;

- after 24 hours, large basal cells mobilise on the under surface of the epidermis;

- after 48 hours the advancing epithelial edge undergoes cellular hypertrophy and mitosis;

- the epithelial cells respond to the loss of contact by migrating until they meet other epithelium;

- the surface cells keratinise;

- the epidermis becomes thinner and attaches to the underlying dermis to gain strength.

Once epithelialisation has occurred the dermis can be repaired primarily by fibroblast proliferation and protein synthesis.

2.6 Depth and Area of Injury

A burn may extend through the entire thickness of the skin or it may damage or destroy only part of the skin. The depth of burn wounds is determined clinically by colour, presence or absence of sensation, blister formation, or the loss of elasticity. Many other techniques have been established which can differentiate between the different classes of burns. The pin-prick test and histology (taken from biopses) are examples of the invasive techniques. Non-invasive techniques include ultrasound; determination of heat destroyed

microcirculation using dyes, or radioisotopes; infrared photography; multispectral photographic analysis and thermography (Pauwels,1985).

The common classification of three degrees of burn depth is described below. However most surgeons are only concerned with a measure of depth which indicates whether skin grafting is required and hence burns are more simply and practically classified as partial-thickness or full-thickness skin losses.

A first degree burn is characterised by erythema (redness) and mild pain. This type of burn involves only the surface epithelium and it can generally heal in 2-3 days. Healing is usually accompanied by flaking or peeling of the dead skin layer. An example of such a burn is a typical sunburn.

Second degree burns involve the deeper layer of the epidermis and there is a characteristic erythema, blister formation, oedema and pain associated with such burns. These burn wounds take 7-10 days to heal and on healing mild scarring can occur.

Deep second degree burns are more serious and both the epidermis and the upper levels of the dermis are destroyed, epidermal derivatives such as hair follicles, sebaceous glands, and sweat glands are usually not injured. If there is no infection, deep

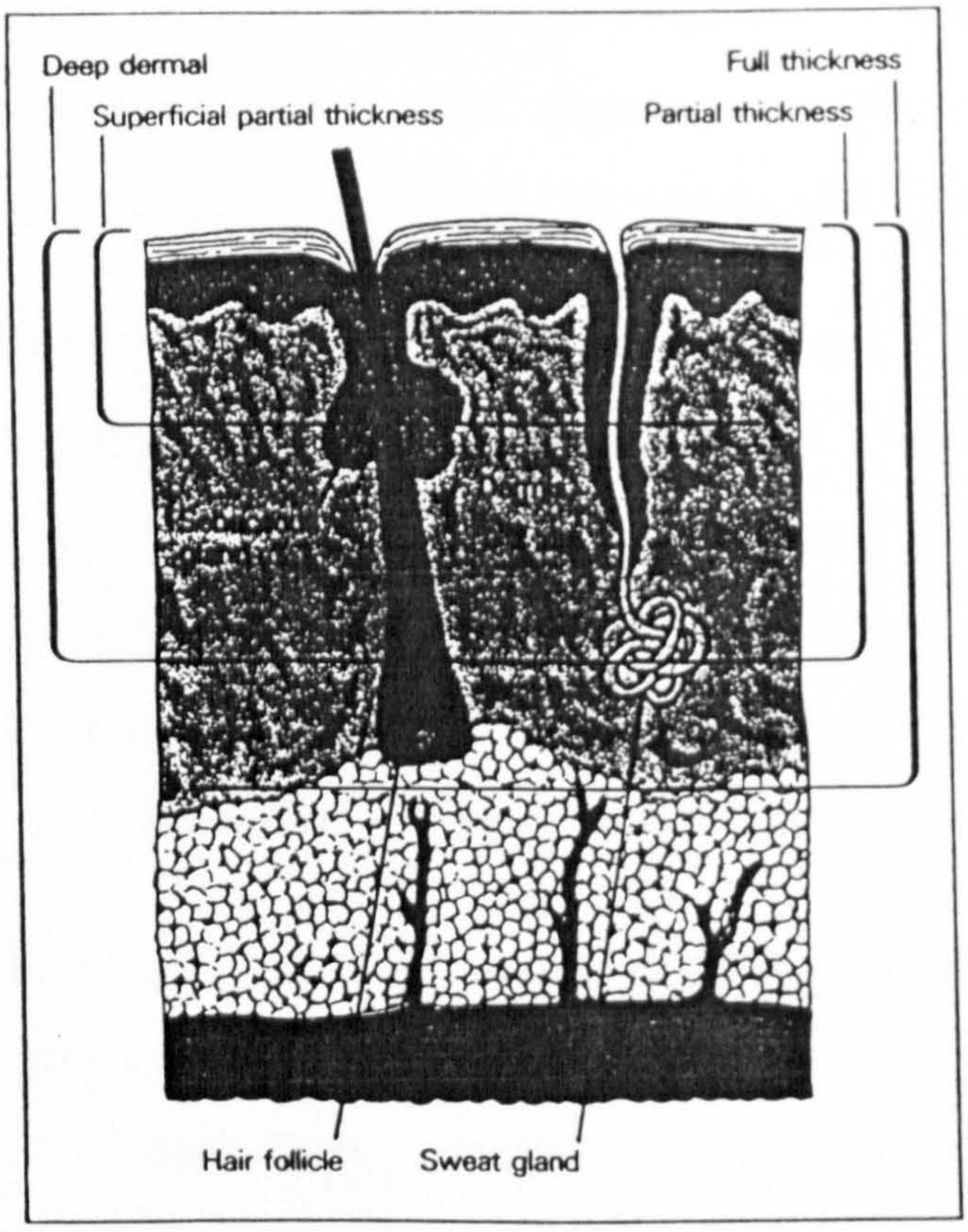

Figure 2.3

Diagram indicating the different degrees of burning.

(Goode, 1984)

second degree burns heal, without grafting in about 3-4 weeks. Scarring may result on healing. First degree and second degree burns are referred to as partial-thickness burns (Fig 2.3).

The most serious burns of all are the third degree burns. These burns are full-thickness burns, destroying the epidermis, dermis, and epidermal derivatives. Commonly there is a little oedema and no sensation of pain due to the destruction of nerve endings. In healing, the regeneration is slow and much granulation tissue forms before being covered by epithelium. Even after an extensive burn injury has finally healed, other complications, such as deep vein thrombosis and pulmonary embolus, may occur, and the disabilities due to contracture of the scarring. Scarring may even take place after grafting as third degree burns contract.

Contractures of the face may involve repeated operations for several years afterwards, especially when extensive reconstruction, for example of the ears, is required. Likewise, deformities of the hands may require corrective, reconstructive surgery to allow reasonable hand mobility and function.

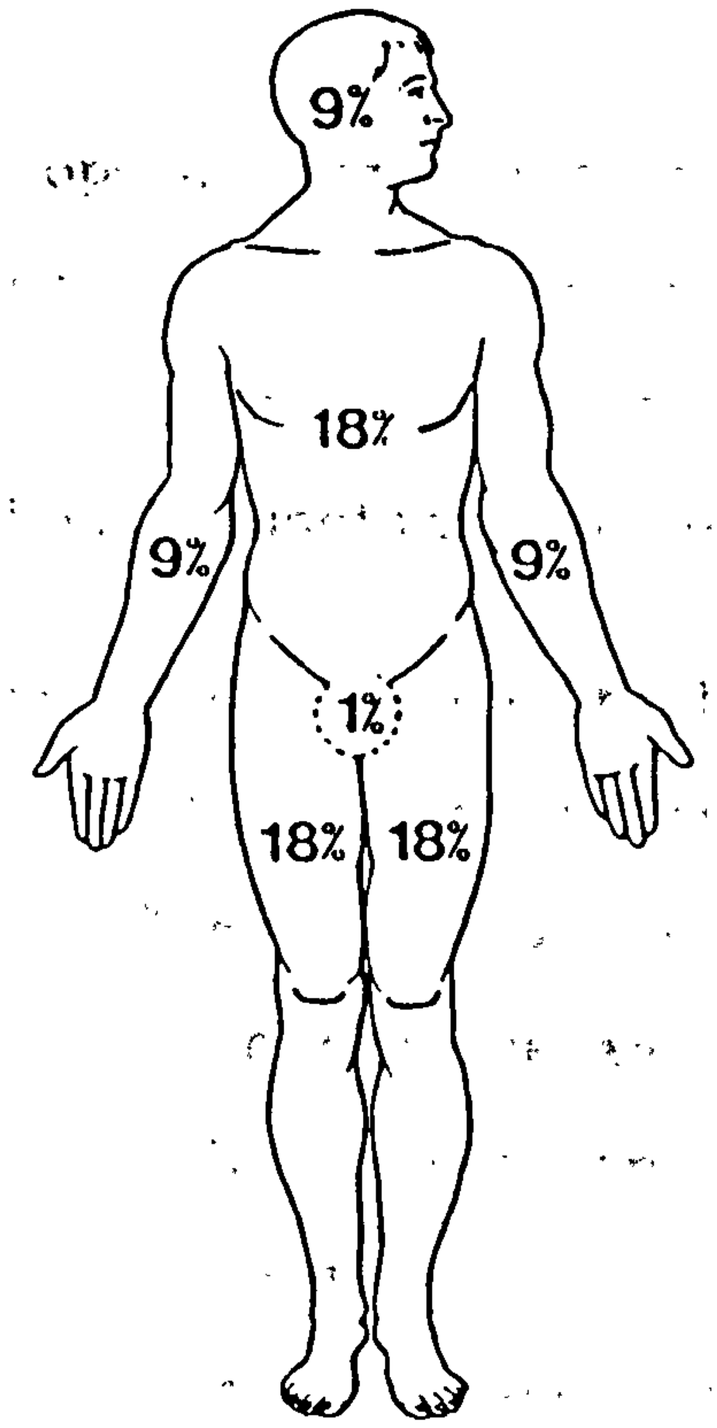

Figure 2.4

"Rule of Nines"

(Cason and Lowbury, 1983)

Figure 2.5

Lund and Browder Chart.

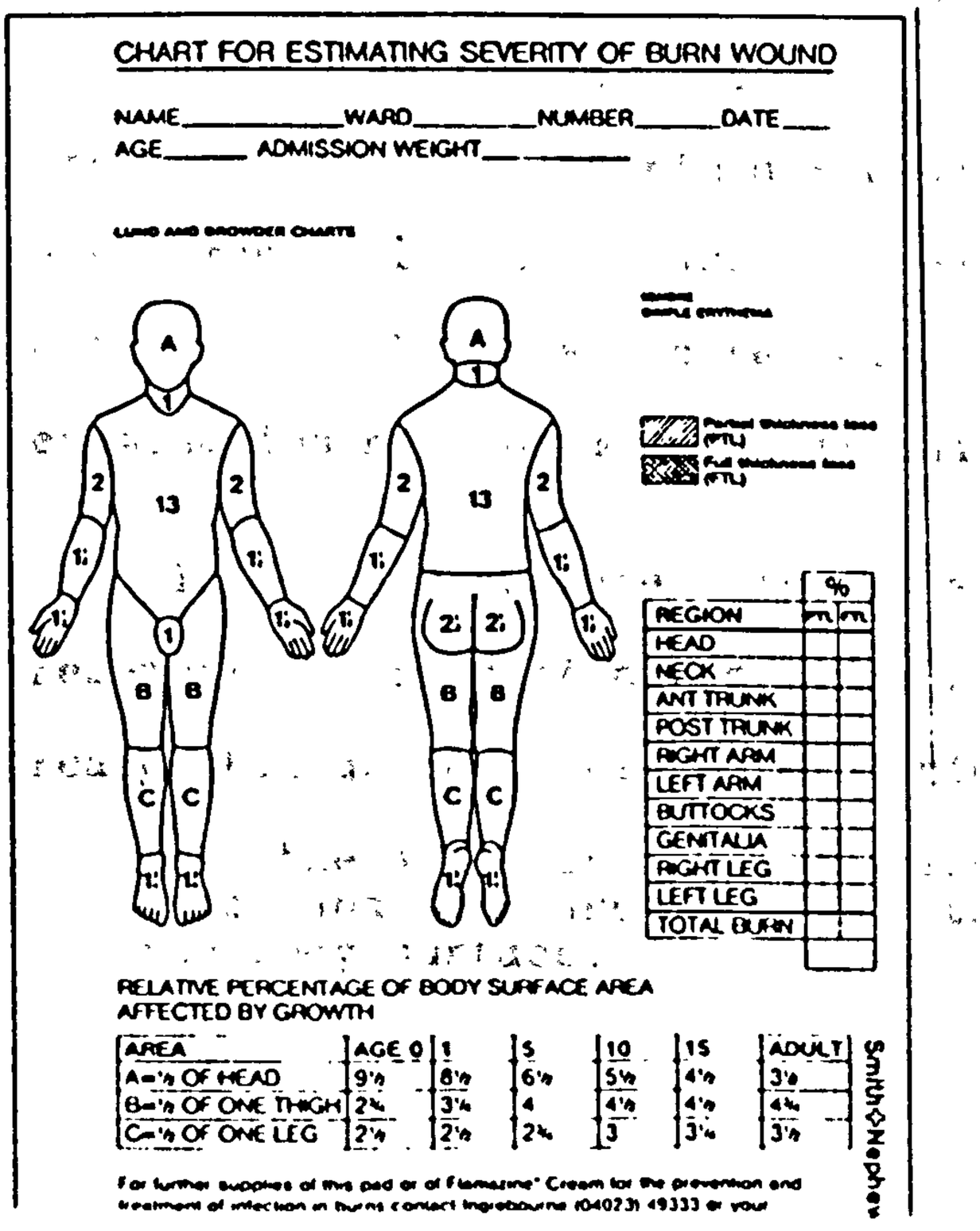
CHART FOR ESTIMATING SEVERITY OF BURN WOUND

NAME_____WARD_____NUMBER_____DATE___
AGE_____ ADMISSION WEIGHT_____

LUND AND BROWDER CHARTS

REGION	%
HEAD	
NECK	
ANT TRUNK	
POST TRUNK	
RIGHT ARM	
LEFT ARM	
BUTTOCKS	
GENITALIA	
RIGHT LEG	
LEFT LEG	
TOTAL BURN	

RELATIVE PERCENTAGE OF BODY SURFACE AREA AFFECTED BY GROWTH

AREA	AGE 0	1	5	10	15	ADULT
A=½ OF HEAD	9½	8½	6½	5½	4½	3½
B=½ OF ONE THIGH	2¾	3¼	4	4½	4½	4¾
C=½ OF ONE LEG	2½	2½	2¾	3	3¼	3½

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Smith&Nephew

These operations are tedious and more severe for the patient, and even after many operations there may still be obvious scarring and unsatisfactory cosmetic results, though function can usually be improved.

The use of dressings which are viscoelastic and conformable will allow active physiotherapy to be carried out. The mobilisation of joints will lessen the risk of contracture and as this is the ultimate aim of both the clinican and physiotherapist, dressings when chosen correctly can prevent or lessen such disfigurements and lessen the risk of contractures.

In the treatment of burns, the depth of the burn is not the only important factor, as the clinician, in determining the course of treatment, has also to take area of the burn into consideration. The percentage of the body surface area burned is needed to calculate the necessary rate of fluid replacement. The accurate assessment of the injured area is surprisingly difficult. Burns are often patchy and irregular, and examination must be methodical and detailed.

If no body surface chart is available, the easily remembered "rule of nines" (fig 2.4) can be used as a reasonable guide. The "rule of nines" is as follows :

- if the anterior and posterior surfaces of the head and neck are affected, the burn covers 9% of the body surface;

- if the anterior and posterior surfaces of each shoulder, arm, forearm and hand are affected, this constitutes another 9% of body surface;

- the anterior and posterior surfaces of the trunk, including the buttocks, constitute 36% (4 X 9);

- the anterior and posterior surfaces of each foot, leg and thigh as far up as the buttocks total 18% (2 X 9);

- the perineum constitutes 1%. The perineum includes the anal and urogenital regions.

A more accurate method is to use the chart of Lund and Browder (1944)(fig 2.5). The patient's age is taken into consideration and the percentage area, of the head and legs, is modified accordingly. The patient is examined methodically and an estimate is made of what fraction of each of the thirty-three charted regions is burned. These fractions are totalled to give an overall area value.

2.7 Requirements of Wound Coverings

In the design of a covering or dressing for burn wounds many of the functions of skin have to be effectively restored.

The main role of dressings can be summarised as : the protection of wounds from physical damage; the prevention of micro-organisms from entering or leaving the wound; the improvement of patient comfort.

Modern dressings should possess a number of properties (Lawrence, 1982; Turner, 1985; Quinn et al, 1985) :

- non-toxicity;
- be non-allergenic towards skin or wound surface;
- strong, giving mechanical protection without inhibiting movement or irritating the wound;
- bacteria proof;
- conformable to body contours;
- have absorptive capability;
- provide an environment conducive to wound healing;
- provide a controlling barrier for water vapour transmission;
- remove excessive exudate and toxic components;
- maintain a satisfactory humidity at the wound site;
- provide thermal insulation;
- allow gaseous exchange (O_2 and CO_2);
- non-adherent;
- removal without trauma;
- simple to apply;
- compatible with topical therapeutic agents;
- free of material which may be shed in to the wound e.g. fibres;
- inexpensive.

Many of these characteristics can profitably be examined in the laboratory. Laboratory tests are therefore important for the characterisation of the dressing with regard to many of these points before clinical usage.

2.8 Summary

Burn wounds are amongst the most traumatic injuries and they present a highly complex pathological state due to the skin loss. As skin is a multi-layer organ, the pathological effects of skin loss are dependent on the skin layers lost. For example, full-thickness burns take longer to heal, than partial-thickness burns as all skin layers are lost and therefore have to be replaced by autografts or heal by contracture.

When damaged, the skin loses its very important barrier role. Injury therefore causes serious clinical problems, particularly with shock and infection. The severe physiological disturbances give greater risk of infection. Bacteria can enter and proliferate in the warm, humid atmosphere of the wound site, resulting in severe infection. This can be a major problem if the infection becomes systemic.

The barrier breakdown promotes severe metabolic disturbances. Coupled with shock these disturbances can sufficiently endanger life. The first course of action is therefore to stabilise the patient. As evaporative water loss becomes a significant caloric expenditure the second course of action is therefore to control the evaporative loss from the wound site. The loss should be controlled in such a manner that the dressing also maintains a satisfactory moisture balance within the repairing wound.

If dressings were "ideal" they would replace all the barrier and functional properties of the skin. To aid research in the field of dressing evaluation and design, the burn wound has still to be comprehensively defined.

At present, the characteristics of burn wounds can be defined as the following :

- colonisation by potentially pathogenic bacteria;
- the presence of necrotic tissue;
- the exudation of large quantities of intra-cellular fluid;
- the loss of bacterial protection;
- requirement of immediate temporary covering i.e. dressings;
- the possible requirement of permanent covering i.e. grafting.

CHAPTER 3

Burn Wound Coverings

A Review.

CHAPTER 3

3.1 Introduction

The following quotation of Bishop made in 1960 remains pertinent to the current treatment of burn wounds using dressings.

"One of the first things that a wounded man would do whatever the injury, would be to protect it from the influence of external forces or agents. For this there was, and is to this day, only one means - the application of a dressing. From amongst the great variety of substances available in his immediate surroundings, the injured man was rapidly led to exercise a choice. The first dressing ever used may have been the leaf of a tree or shrub. Some substances were found to be less painful when applied than others, some gave better results and more secure protection. Many observations were made, many things tried, and in time a body of experience was accumulated. The first results were modified by daily use and experiment and a considerable body of inherited knowledge gradually came into being. The art of dressing wounds long constituted the whole of medicine."

3.1.1 Historical Aspects of Dressings

In the "Ebers and Smith" papyri (1500-1600 BC), are descriptions of a variety of dressing materials used in ancient Egypt, including bandages with grease (Bryan 1930; Ebell, 1937) which can be seen as the precursors of tulle gras. This close-meshed cotton dressing (impregnated with soft paraffin) was introduced during the 1914-1918 World War by Lumiere (Lawrence, 1982). In the intervening years many materials have been used as wound dressings. As cited by Wong (1980) these dressings include : tinctures and extracts (600 BC); warm-vinegar soaked dressings (430 BC); greasy dressings (1596); pressure dressings (1797); dry cotton wool dressings (1827); allografts (1869); skin autografts (1870); boric lint and carbolic dressings (1871); skin grafts from cadavers (1881); and cutaneous xenografts (1880).

In 1947 A.B. Wallace of Edinburgh advocated the open treatment of burn wounds (i.e. no dressing applied).

During the last twenty years, major advances in the production of synthetic dressings have occurred leading to a large variety of suitable polymeric materials. These materials come in the form of films, sprays, foams and gels. However, there is minor

progress in the clinical acceptance and usage of these dressings as clinicians tend to be relatively conservative. Biological dressings in this period have become established as temporary (allografts and xenografts) and permanent (autograft) wound coverings (Bromberg et al, 1965; Rappaport et al, 1970; Wood and Hale, 1972).

Recent research has led to a clearer indication of the required properties of a dressing (Section 2.7)(Park, 1978; Tavis et al, 1978; Chvapil, 1982; Lawrence, 1982; Spector et al, 1982; May, 1983; Davies, 1983; Pruitt and Levine, 1984; Quinn et al, 1985).

3.2 Classification and Terminology

3.2.1 Classification of Dressings

Burn wound dressings can be conveniently divided into two main categories, according to usage (Tavis et al, 1978; Bartlett, 1981; Rahman, 1982; Quinn et al, 1985) :

(i) Short term application - Dressings. Replacement at regular intervals is required;

(ii) Long term application - Skin substitutes

(a) Temporary - used on fresh partial thickness wounds until healing is complete.

(b) Semi permanent - used on full thickness wounds until autografting can be carried out.

The above functional classification is seldom used, with dressings more commonly being considered to fall into one of the following material categories :- conventional, biological and synthetic.

Such a classification has been used in recent, comprehensive reviews (Park, 1978; Tavis et al, 1978; Quinn et al, 1985) and in comparative reports on a selection of burn wound coverings (Guldalian et al, 1973; Schwope et al, 1974; Norton and Chvapil, 1981; Chvapil, 1982; Wong, 1980; Rahman, 1982; Pruitt and Levine, 1984).

3.2.2 Terminology for burn dressings

Due to the recent extensive research and development related to wound dressings, many terms have come into use. These include : burn covering (Schwope et al, 1974); wound covering (Schwope et al, 1977); burn wound covering (Park, 1978); skin substitutes (Tavis et al, 1978; Bartlett, 1981; May,

1983); artificial skin (Hall et al, 1970; Yannas and Burke, 1980); synthetic skin (Lin et al, 1981); wound dressing (Norton and Chvapil, 1981; Griffith and Clark, 1982; Myers, 1983); and burn dressing (Chvapil, 1982; Browne, 1982; Quinn et al, 1985).

In this thesis all of the above terms will be referred to as burn wound dressings (or coverings).

Before discussing burn wound coverings in detail it is important to define some of the terms used (Wong, 1980) :

Dressings - a general term referring to those materials which are removed and replaced at regular intervals (Section 3.2.1).

1. Burn Wound Dressings - refers to materials that may be of biological or synthetic origin.

2. Conventional Dressings - refers to fabric-type materials.

   These can be divided into two basic groups :

   (a) Simple - one material fulfilling all functions.

   (b) Compound - a number of different materials (usually two), each with a specific function to perform.

3. <u>Biological Dressings</u> - the material is skin which comprises an adherent collagenous dermal surface and a partially keratinized epidermis.
There are three main categories :

(a) Allograft (Homograft) - a human graft from living or recently deceased donors.

(b) Xenograft (Heterograft) - tissue obtained from animals.

4. <u>Synthetic Dressings</u> : refers to man-made materials.

3.3 <u>Conventional Dressings</u>

Conventional dressings are still the most widely used for all types of wounds. These dressings require a high absorptive capacity, and a structure that prevents pooling thereby distributing the absorbed fluid evenly throughout its substance. The material

which best meets these criteria is gauze (Muir and Barclay, 1962) which is commonly regarded as the most satisfactory absorbent dressing presently available.

Due to the low cost of gauze the most widely used absorptive dressings are gauze-cotton wool composites. The Gamgee tissue pad is a typical example. This dressing consists of a layer of cotton wool which is sandwiched between two sheets of gauze. Its absorptive capacity is determined by the volume (thickness) of the cotton wool layer.

The inner layer of composite dressings should be non-adherent to prevent the pain and trauma associated with the removal of an adherent dressing. Tulle gras is a paraffin impregnated, wide-mesh gauze which is rendered non-adherent by depending on its greasiness. Other greasy materials have been tried on similar mesh networks (Norton and Chvapil, 1981; Spector et al, 1982). However excessive grease will interfere with the absorption of fluid by the absorbent dressing above.

Infection due to the contamination of exudate through the open network of the gauze can be a problem with these dressings. To overcome this problem many clinicans use the above materials in combination with a layer of antibacterial cream (Wong, 1980). The

TYPE	MATERIAL	TRADE NAME	REFERENCE
Films	Chlorhexidine Tulle Gras	Bactigras	Smith and Nephew Ltd. Lawrence (1977)
	Paraffin Tulle Gras	Jelonet	Smith and Nephew Ltd. Lawrence (1980)
	Framycetin	-	Wicks and Paterson (1972)
	Vaseline Petrolatum Gauze	Vaseline	Chesebrough-Ponds Ltd.
	Xeroform Petrolatum Gauze	Xeroform	Chesebrough-Ponds Ltd.
	Scarlet Red Ointment Dressing	Scarlet Red	Chesebrough-Ponds Ltd.
	Xeroflo Gauze Dressing	Xeroflo	Chesebrough-Ponds Ltd.
	Ointment/Gauze Dressing	Kalfalan	Kalff Ltd.

Table 3.1 (a) - Conventional Dressings

TYPE	MATERIAL	TRADE NAME	REFERENCE
Films	Aquaphor Cream + Gauze	Aquaphor	Beiersdorf AG Ltd. Waymack et al (1986)
	Adaptic Cream + Gauze	Adaptic	Johnson and Johnson Ltd.
	Zinc Textile Film	Mefix	Molnlycke Ltd. Gang (1981) Queen et al (1986)
	Zinc Textile Film	Hypafix	Smith and Nephew Ltd.
Composites	Gamgee Tissue Pads	-	Bailey and Bishop (1972) Lawrence (1980)
	Cotton Wool	-	Lawrence (1980)
	Dry Gauze Dressing	Telfa	Kendall Company Ltd.
	Paper based + Telfa Films	Exu-dry	Caceres et al (1986)
	Tulle gras + polyvinyl alcohol sheet	-	Smith and Nephew Ltd. Hart and Lawrence (1984)

Table 3.1 (b) - Conventional Dressings

incorporation of antibacterial agents into dressings has been practised for over a century. In the 17th century some clinicans used carbolic acid and mercuric chloride in combination with absorbent dressings (Lawrence, 1982). Trials were carried out in the 1950's by several centres. However the first controlled clinical trials, assessing the performance of penicillin and Polymixin creams, were only recently carried out by Lowbury (1978 and 1979).

The outer layer is required to be porous to permit the evaporation of water from the absorptive component of the dressing. If the dressing prevents fluid evaporation, it may become soggy and may encourage bacterial growth.

The aim of dressings, when used to prepare the wound surface for autografting, is to provide a healthy granulation tissue bed. Conventional dressings partially achieve this by the control of infection using antibacterial agents. However these agents can result in adherence and subsequent tissue trauma can result from the changing of the dressing.

A detailed survey of commercially available conventional dressings was not undertaken in this thesis, as none were evaluated. Table 3.1 however lists several of the more important dressings and indicates the large range of compositions available.

TYPE	MATERIAL	TRADE NAME	REFERENCE
Allograft	Scalp Tissue	-	Barnett et al (1984)
Xenograft	Porcine Tissue	Mediskin	Genetic Laboratories Ltd. May (1982)
	Silver Impregnated Porcine Xenograft	SIPX	Genetic Laboratories Ltd. Ersek and Denton (1983)
Allograft	Foetal Membranes	-	Redmond (1983)
	Amnion	-	Peters (1980) del Mundo (1986)
Tissue Derivatives	Regenerated Beef collagen	-	Alder et al (1962)
	Formalinized Skin	-	Parvish et al (1964)
Films	Collagen Film	Cutycol	Schwope et al (1974) Lamke (1971)
Foams	Collagen Sponge	-	Chvapil (1982) Park (1978)
	Collagen non-woven fibre mat	-	Gourlay et al (1975)
Natural	Potato peel Dressing	-	Keswani et al (1985) Keswani et al (1986)

Table 3.2 - Biological Dressings

3.4 Biological Dressings

Biological dressings are natural tissues, usually skin, consisting basically of collagen sheets containing elastin and lipid (Bartlett, 1981).

A number of beneficial effects has been attributed to biological dressings (Pruitt and Levine, 1984). These include : reduction in population density of bacteria on the wound surface; reduction of desiccation, evaporative water loss and heat loss of an open wound; prevention of further contamination of the wound; and prevention of physical damage to the newly developing granulation tissue (Pruitt and Levine, 1984).

3.4.1. Allografts

The most superior graft method used in the covering of burn wounds is an autograft (i.e. taken from the recipient)(Park, 1978; Yannas and Burke, 1980). However in extensive burns (greater than 50% body surface) the supply of "split" skin graft is inadequate and other tissue sources are sought (Park, 1978; Yannas and Burke, 1980; Pruitt and

Levine, 1984).

Allograft skin can be obtained from a family member or another living volunteer, but it is most commonly harvested from cadavers. The use of fresh, frozen or lyophilised (freeze dried) allografts is most effective in thermal injuries, especially for extensive full-thickness burns (Hackett, 1975).

One distinct advantage of an allograft is that it can be used as a test material to determine the likelihood of autograft take. When allograft skin shows general adherence to a burn wound and evidence of graft vascularisation within 48-72 hours of application, it can be anticipated that an excellent take of autograft skin to the wound surface will occur. The "test" allograft will of course be removed. Such a preparation of a "receptive" wound bed is important in the treatment of patients with extensive burns and paucity of donor sites, to prevent the unnecessary loss of autograft skin (Pruitt and Levine, 1984).

In spite of favourable reports, allografts have limitations as burn wound coverings. They become vascularised (Kim et al, 1970) and if immunosuppresive drugs are employed, preventing rejection (Yannas et al, 1981) they then have to be removed. The use of

immunosuppresion permits the application of allografts until autografting can be carried out (Burke et al, 1975, 1981). A consequence of such treatment is the increased risk of infection due to a depressed immune response. Allograft usage is severely limited by inadequate supply, the expense and difficulty of collection and preparation (lyophilised specimens) and a restricted shelf-life (Pruitt and Levine, 1984).

Amniotic membranes have been used as allografts (Robson et al, 1973; Unger and Roberts, 1976). Amnion is readily available from the maternity delivery room and is inexpensive to prepare. However this approach has limited use as it has been reported that these materials are very ineffective in the prevention of evaporative water loss, which may lead to wound dehydration (Lamke, 1971).

The most recent line of development has been the tissue culturing of epidermal cells obtained from the prospective recipient of the graft material. Epidermal cells can be cultured into confluent sheets in around 14 - 21 days and can then be applied to full-thickness burns (Bell et al, 1981). The major disadvantage of this technique is the length of time required to culture the cell sheets, during which time, synthetic dressings will be used.

3.4.2 Xenograft

As an alternative to autografts or allografts, grafts from animal sources have been investigated (Bromberg et al, 1965). Studies on the use of skin grafts from cats, rats, rabbits, chickens and pigeons gave disappointing results (as reviewed by Park, 1978). At present the xenograft in common use is pigskin (porcine xenograft). It provides a readily available, easily stored and sterilised dressing in contrast to allograft skin (Tavis et al, 1978).

Porcine skin on the microscopic level is unlike human skin. However in respect to texture, adherence and collagen content it is very similar. In addition, the presence of a "foreign" surface would trigger the native immunological defence mechanisms, thereby helping to sterilise a contaminated wound (Tavis et al, 1976). The use of immunosuppressive drugs counteracts the natural rejection response and thus the advantage of wound sterilisation by the natural immune response is lost.

Lyophilised porcine xenografts have been used by many workers in the treatment of both partial and full thickness burns (Lamke, 1971), with variable results (Lee, 1972; MacDowall and Hackett, 1976).

One major drawback with lyophilised porcine xenograft is the need to reconstitute it before use by soaking in sterile saline or Ringers solution. This procedure takes around thirty minutes (@ 30°C) which causes a serious delay in the treatment of burn wounds. It is therefore essential that an accurate assessment of the amount of material required to cover the injured area is carried out before reconstitution. Xenografts suffer from the same disadvantages as allografts in respect of the bacterial infection of the granulating bed. In addition, porcine xenografts have poor mechanical properties and tend to split into separate layers, inhibiting the intake of autograft skin (Chatterjee, 1978).

3.4.3 Tissue Derivatives

Collagen offers many advantages as a biological wound dressing. It can be isolated and purified easily in large quantities and its antigenicity and water vapour permeability can be altered (Tavis et al, 1978). Such dressings have been reported by Tavis et al (1978) to stimulate the vascularised granulating bed in preparation for future autografting. The main drawback of collagen dressings in the long term application is the control of infection. Collagen has been used in a variety of forms.

A comprehensive list of biological dressings and their associated references can be found in Table 3.2.

3.5 Synthetic Dressings

The need for a relatively inexpensive, effective and easily stored wound dressing has led to the development of numerous synthetic materials.

Comprehenisive reviews of synthetic dressings have recently been published (Park, 1978; Tavis et al, 1978; Wong, 1980; Rahman, 1982; Davies, 1983; Quinn et al, 1985). Due to the extensive interest in this area, commercially available and prototype (research associated) dressings are ever increasing in number. Hence such reviews are very quickly out of date. An updated list of synthetic burn wound coverings is presented in Table 3.3.

For the purposes of this review, the forms in which these materials have been manufactured have been classified as follows (Rahman, 1982) :

(i) Films - homogeneous structures with uniform properties, including homopolymers, copolymers and plasticised polymers.

(ii) Foams - structures with a large fluid-binding capacity, processed in the form of a foam or a sponge.

(iii) Composites - laminates of two or more materials. These materials may be of synthetic or have components of biological origin.

(iv) Sprays - conventional aerosol containers, which propel the polymer and solvent directly onto the wound surface, where the film is formed by solvent evaporation.

(v) Gels - polymeric structures which have the ability to swell extensively in aqueous media while remaining insoluble.

3.5.1 Films

In the search for a suitable synthetic burn wound dressing various commercially available materials have been investigated. One example is plasticised PVC food wrapping film (e.g Clingfilm, Stretch 'n' Seal) (Lendrum and Bowen - Jones, 1975; Townsend, 1977).

Silicone elastomeric films have been widely used (Park, 1978; Quinn et al, 1985) and the results obtained have been favourable (Bartlett, 1981; Tavis

et al, 1978).

Many other polymeric films have been investigated for the purpose of wound covering. These materials include : polyurethane; polyethylene; polycaprolactone; poly (lactic acid); poly (amino-acids) and polytetrafluoroethylene (PTFE). A co-polymer of acrylonitrile (AN) and dimethylaminoethyl methacrylate (DMAEMA) developed within the Bioengineering Unit, Strathclyde University has also been suggested as having a possible application (Park et al, 1978).

Aware of the retention of exudate by some film materials, manufacturers are producing second generation products to cope with this problem. For example, 3M Health Care the manufacturers of Tegaderm have produced a new product named Tegaderm Pouch Dressing which has a pouch to accommodate the excess exudate and to allow it to be lost at a faster rate than the normal dressing.

3.5.2 Foams and Sprays

Poly (vinyl alcohol) and polyurethane foams are commonly in use at the present time (Chardack et al, 1962). Other variations are acrylic, and polysiloxane foams, however so far none have been clinically

successful.

The spray on dressings have two major advantages in that they are totally conformable to the wound surface and they are totally portable and ready for use in any circumstances. One major drawback is that some of the early types of sprays proved to have a toxic effect on superficial blood vessels. Many of these sprays are copolymers, for example Aeroplast is a copolymer of hydroxyvinyl chloride-acetate sebacic acid and modified maleic resin ester. More recently a combination of a spray and a foam has been developed, a gelatin based sprayable foam, by Neumann et al (1981).

3.5.3 Composites

In this category, the dressing consists of laminates of two or more materials. The outer layer is designed for durability and elasticity, and possibly to act as a rate controller (e.g. for water vapour) while the inner layer is designed for maximum adherence and elasticity (Tavis et al, 1978). Current reports emphasise the double layer construction based on the anatomy of a natural skin graft (Pruitt and Silverstein, 1971). Split-thickness skin grafts comprise two functionally different parts.

Firstly, the epidermis which functions as a barrier layer and secondly, the dermis which functions as an attachment surface. Fibroblasts and capillaries from the wound surface can grow into the dermis, thereby anchoring the graft to the wound.

Several bi-layer synthetic dressings have been developed along this bilaminar ideal. The more important examples are :

1. Epigard - a composite of an inner layer of reticulated polyurethane which has been laminated to an outer sheet of microporous polytetrafluoro-ethylene (PTFE)(Alexander et al, 1973). Adherence, availability, sterility, long shelf-life and low cost are its major advantages (Park, 1978).

2. Biobrane - a composite of an ultra-thin, porous membrane of polydimethylsiloxane bonded to an inner nylon mesh. Tavis et al (1981) reported its successful use on both superficial and deep donor sites. Several groups recently backed this successful treatment using Biobrane (Stein, 1986; Roberts et al, 1986). On the other hand, Lin et al (1981) reported that bacterial infection was a major problem in the clinical usage of Biobrane.

3. Synthetic Skin (IP-758, International Paper Company) - this is composed of a silicone elastomer on a nylon 66-looped velour. No satisfactory clinical findings have been reported to date.

4. Artificial Skin - this is a bilaminar polymeric membrane comprising a silicone elastomeric epidermis and a porous, crosslinked network of collagen and a glycosaminoglycan (GAG) dermis, developed by Yannas and Burke (1980). At present, the epidermal portion can be replaced with a thin layer of autoepidermal cells in sheet or mesh form. A further development is aimed at eliminating the need for an epidermal graft (Yannas et al, 1981).

5. Vigilon - this is a reinforced PEO hydrogel sandwiched between two polyethylene films. The patent for this material indicates the these films can be of other polymeric structures. This composite dressing has been characterised by Rahman (1982) and it is used as a control in this study.

6. Granuflex - this consists essentially of two layers; an outer protective layer of polyurethane foam and an inner layer consisting of a hydrocolloid/polymer complex (Hermans and Hermans,

1984).

3.5.4 Gels

In 1960, Wichterlie and Lim, produced a hydroxyethyl methacrylate (HEMA) based hydrogel and demonstrated that it was biocompatible and non-toxic.

A commercially available hydrogel material, Vigilon (C.R. Bard Inc.), consisting of a polyethylene oxide (PEO) hydrogel, reinforced by a polyethylene supporting web, has recently been used as a burn wound covering (U.S. Patent, 1968)

The main thrust in hydrogel development has occurred in the last decade. Nathan et al (1976), developed a PHEMA-PEG (Hydron) hydrogel, which is formed directly on the wound surface, by mixing a powder and solvent. In 1979, an entirely new type of wound covering, Geliperm, was developed by Wokalek et al. Geliperm gel results from the polymerisation of a mixture of agar and acrylamide. It consists of two interwoven molecular networks containing 96 to 97% water.

The Pure and Applied Chemistry Department of University of Strathclyde are active in the field of hydrogels. A cross-linked poly(ethylene oxide)(PEO) hydrogel has been developed by Graham et al (1980). This gel was devised primarily as a carrier matrix for drug delivery. Its potential as a burn wound covering was assessed by Wong (1980) and Rahman (1982). At the time of Wong's study a suitable technique was not available to produce uniformly thin films of the PEO hydrogel. Rahman had the advantage of having uniformly thin films to assess (1mm thick).

Graham, McNeill and Moran (1984) have produced a novel non-crosslinked polyurethane (linear) hydrogel which is sheet cast. Further details can be found in Chapter 4. The gels evaluated in this study (cross-linked and non-crosslinked hydrogels) were very much thinner than in both of the previous two studies.

A highly absorbent, biodegradable (alginate) gel, Sorbsan, derived from seaweed has been descirbed by Gilchrist and Martin (1983). Wound secretions and bacterial contamination are controlled by strong hydrophilic gel formation (from a fibrous film) on the uptake of wound exudate. This dressing has the advantage that the fibres entrapped in the wound are biodegradable.

Another biodegradable dressing, Kaltostat (Cair Ltd.) is also derived from seaweed. The manufacturers indicate that this material is particularly useful for bleeding wounds, due to its haemostatic properties (Oliver and Blaine, 1950).

One of the most recent dressings developed is a thin, transparent gel named Omniderm (Omikron Scientific Ltd.). The manufacturers advocate that the gel is secured in place and allowed to remain on the wound until sloughed off by the progression of healing. This material is a thin membrane of about 40 microns in thickness which is made of polyacrylamide grafted to a polyurethane film (Golan et al, 1985).

3.6 State of the Art

Conventional dressings are still widely used in conjunction with topical agents to control wound infection. The disadvantages associated with these dressings are the requirement of frequent changing with associated pain, immobility (due to joint movement being restricted) and bacterial contamination.

Porcine xenografts and human allografts have proved effective. However these dressings are not widely used in the United Kingdom (Hackett and Bowen, 1974). The main factors restricting their usage are supply, expense and handling difficulties (Roberts, 1976).

Many synthetic materials have been developed and assessed, and a set of wound dressing criteria has evolved from this extensive research (discussed in Chapter 2). Further research is required in the field of synthetic dressings to produce the "ideal" dressing or a range of "ideal" dressings. It may be that such dressings could be produced by combining several of the dressings presently available.

TYPE	MATERIAL	TRADE NAME	REFERENCE
Films	Poly caprolactone	PLC 700	Schwope et al (1974) Union Carbide Corp.
	Poly (amino acids)	-	Pruitt and Levine (1984) Walder et al (1969)
	Poly(hydroxyethyl methacrylate-silver sulphadiazine	-	Fox et al (1979)
	Methyl cellulose	-	Pickrell (1942)
	Nylon Velour (nylon 6-looped film)	Capran 77C	Allied Chemical Co. Hall et al (1967)
	Silicone rubber	-	Kornberg et al (1972) Dow Corning Company
	Vinylidene chloride copolymer	Saran Wrap	Schwope et al (1974)
	Polyurethane Hydrocolloid	Granuflex	Squibb Surgicare Ltd.

Table 3.3 (b) - Synthetic Dressings

TYPE	MATERIAL	TRADE NAME	REFERENCE
Films	Polyurethane	Opsite	Smith and Nephew Ltd. Myers (1982) Barnett et al (1984)
		Bioclusive	Johnson and Johnson Ltd.
		MP 2080	Moulded Plastic Co.
		Tegaderm	3M Health Care Ltd. Barnett et al (1984)
	Poly (vinyl chloride)	Stretch 'n' Seal	Colgate-Palmolive Ltd. Lendrum et al (1975) Townsend (1975)
	Poly-ethylene	-	Reid (1974)
	Polyacrylonitrile (AN-DMAEMA)	-	Park et al (1978)
	Polypropylene	-	Bierenbaum et al (1971)
	Polytetrafluoro ethylene	-	Pruitt and Silverstein (1971)
	Poly(lactic acid)	-	Schwope et al (1974)

Table 3.3 (a) - Synthetic Dressings

TYPE	MATERIAL	TRADE NAME	REFERENCE
Films	Polyamide Mesh	Surfasoft	Mediprof Ltd.
	Synthetic Fibre + Aluminized Pad	Aluderm	W. Sohngen GMBH
	Synthetic fibre + Metal Coating	Scantape	Norgesplaster Ltd.
	Activated Charcoal Cloth	Carbopad	Charcoal Cloth Ltd.
Foams	Poly(vinyl alcohol) sponge	Ivalon	Chardack et al (1962) Taylor et al (1963)
	Polyurethane foam	Lyofoam	Winter (1975) Ultra Labs Ltd. Lawrence (1975)
		Synthaderm	Revlon Health Ltd. Myers (1982)
		Coraderm	Revlon Health Ltd.
	Polysiloxane foam	Silastic	Dow Corning Ltd. Gourlay et al (1975) Myers (1982)

Table 3.3 (c) - Synthetic Dressings

TYPE	MATERIAL	TRADE NAME	REFERENCE
Foams	Polyesterurethane	-	
	Polyetherurethane and Acrylic Foams	-	
	Poly(vinylalcohol) formaldehyde foam	-	Mutschler et al (1980)
Gels	Calcium Alginate Gel	Kaltostat	NI Med.Ltd., Cair Ltd.
	Polyacrylamide-poly urethane Gel	Omniderm	Omikron Scientific Ltd.
	Water Based Gel	Waterjel	Trilling Resources Ltd.
	Poly (ethylene glycol) 1,2,6 - hexane triol and diisocyanate.	-	Wong (1980) Rahman (1982)

Table 3.3 (d) - Synthetic Dressings

TYPE	MATERIAL	TRADE NAME	REFERENCE
Composites	Polyurethane foam laminated to a polypropylene film	Epigard	Alexander et al (1973) Parke-Davis and Co.
	Polydimethylsiloxane membrane laminated to nylon fabric.	Biobrane	Bartlett (1981) Hall-Woodroof Inc.
	Silastic epidermis and collagen glycosamino-glycan dermis.	Artificial Skin	Yannas and Burke (1980)
	Silicone rubber laminated to medical grade nylon velour.	IP - 758	Lin et al (1981) International Paper Company
	Polycaprolactone foam laminated to polycaprolactone film.	-	Schwope et al (1977)

Table 3.3 (e) - Synthetic Dressings

TYPE	MATERIAL	TRADE NAME	REFERENCE
Composites	Soft cotton covered with perforated plastic film.	Telfa	Kendall Co. Winter (1963)
	Collagen poly (E capro-lactone) film laminate.	-	Schwope et al (1977)
	Acrylic copolymer (60%)-gelatin (30%)-glycerol(10%).	Cynthaskin	Walliczek (1983)
	Melonin film on cotton(85%) and acrylic (15%) fabric.	Astroplast	Dalmuir Trading
Sprays	Hydroxy vinyl chloride-acetate, sebacic acid and modified maleic rosin ester (copolymer).	Aeroplast	Choy and Wendt (1952)
	Poly(-2-ethoxyethyl methacrylate) with ethyl acetate as carrier solvent poly hydroxyethyl methacrylate.	Nobecutane Rezifilm Opsite	Rob and Eastcott (1954) Ellerker (1955) Smith and Nephew

Table 3.3 (f)- Synthetic Dressings

TYPE	MATERIAL	TRADE NAME	REFERENCE
Sprays	Poly (1-hydroxyethyl methacrylate) powder and polyethylene glycol 400 solvent.	Hydron	Nathan et al (1974) Hydron Laboratory
	-	Astroplast Spray	Dalmuir Trading Company
	Gelatin-based Foam	-	Neumann et al (1981)

Table 3.3 (g) - Synthetic Dressings

CHAPTER 4

Materials Selection

CHAPTER 4

4.1 Introduction

Many factors have to be considered in the design of a burn wound covering. An ideal burn wound covering should function by providing total protection to the injured site, thereby optimising the processes of wound healing. Ideally, such materials should afford complete protection from bacterial invasion and from the total dehydration of the granulating epithelial bed.

The degree to which these materials can provide the desired environment is dependent on the mechanical properties of the dressing material, its resistance to wear and tear and the retention of pliability. A practical burn wound covering requires to be pliant to allow it to conform to the body, especially at the joints. However, the material also requires sufficient toughness to allow the handling of the dressing during application and the subsequent trauma in situ.

A suitable material requires the above properties. However, these properties alone are not sufficient. The prevention of wound surface dehydration is of equal importance. The total

dehydration of the wound site causes scab formation which in turn would probably cause adherence of the dressing to the wound site. This would lead to the disturbance of the newly formed epithelial layer on removal of the dressing.

On the other hand, a totally impervious dressing causes fluid build up and subsequently maceration of the healthy tissue surrounding the wound. Thus, an intermediate water evaporation and/or absorption rate is desirable.

Considering all of the required factors, an experimental programme was designed to assess burn wound coverings by an in vitro procedure. Several of the procedures adopted have been the subject of previous research (Wong 1980; Rahman 1982; Turner 1984).

Clinical studies have also been carried out using some of the materials described below. These studies were intended to provide a correlation between the in vivo performance and the in vitro evaluation of dressing parameters.

The materials chosen for in vitro assessment were to be evaluated against known material standards (serving as controls). Detailed descriptions of these materials are given below.

The conjugates chosen are as follows :

(1) Geliperm Dry + Mefix

(2) Linear Polyurethane Hydrogel + Mefix

(3) Non-Linear PEO Hydrogel + Mefix

(4) Lyofoam + Mefix (WVTR only)

(5) Silicone Rubber Support + Mefix (Gas Transmission only)

A detailed study of the physical effect of Mefix on the above dressings is presented in Chapter 9.

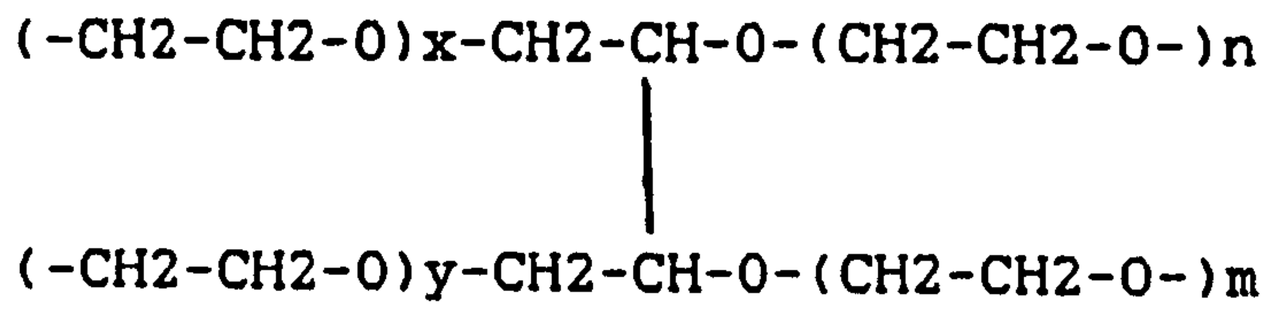
4.3 Plasticised P.V.C. film - Stretch 'n' Seal

The plasticised P.V.C. film assessed is marketed under the trade-name Stretch 'n' Seal by Colgate - Palmolive Ltd. for the wrapping of food products. Several researchers have used similar materials in the treatment of partial - thickness burn wounds (Lendrum and Bowen-Jones, 1975) and in the dressing of donor sites (Townsend, 1977). Lendrum and Bowen-Jones (1975) have also indicated that this material may be used in the desloughing of full-thickness burn wounds.

4.4 Poly(ethylene oxide) hydrogel - Vigilon

Vigilon is marketed by C.R. Bard Inc. The gel material is prepared as a colloidal suspension of radiation cross - linked poly(ethylene oxide) (structure below) and water on a polyethylene mesh support (Fig 4.3).

CHEMICAL STRUCTURE



It is collodial in gelatinous form with water as the dispersion medium, i.e. 96% water holding 4% insoluble cross - linked poly(ethylene oxide) in suspension. For the mesh, the manufacturers claim a pore size of 0.75mm with 16 pores per square centimetre.

The above hydrogel is sandwiched between two layers of film, with polyethylene normally being used. The manufacturers advocate that the material can be utilised with; both coverfilms in place, one coverfilm in place or both of the covers removed.

On the whole, this dressing is used clinically with one coverfilm removed. Therefore, for the purposes of this research only the Vigilon Coverfilm alone and Vigilon with one coverfilm in place were assessed.

4.5 Geliperm

Geliperm is a polyacrylamide agar gel which was evolved in 1977 at the Max Planck Institute for Immunobiology, Freiburg. The gel is marketed by Geistlich Sons Limited under the trade name Geliperm Dry. It is available in individual sheets, approximately 25cm x 11cm, which are sterile and ready for use.

Geliperm is manufactured in three physical forms viz : Geliperm Wet (a hydrated sheet, 96% water), Geliperm Dry (a hydrated sheet, 5% water) and Geliperm Granulate (a particulate form of the wet gel with a variable water content). For the purposes of this study, only the Geliperm Wet and Geliperm Dry gels were studied.

Geliperm Wet is manufactured by polymerising a mixture of agarose or agar-agar and acrylamide in varying proportions, with corresponding differences in physico - chemical properties (Wokalek et al,1979).

The degree of crosslinking of the structure allows the passage of secretions and proteins (e.g. antiseptics or antibacterial agents). The porosity of

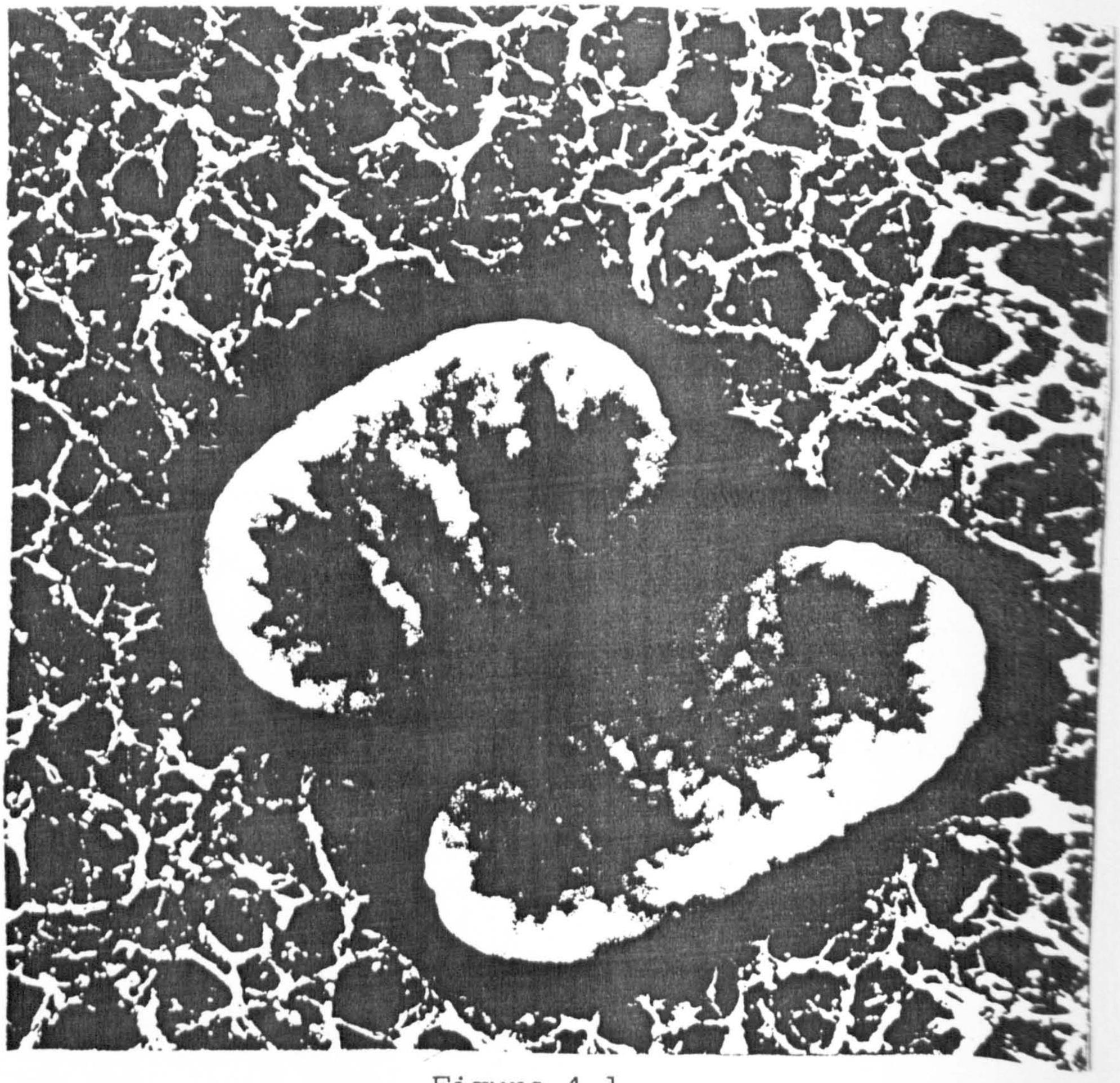


Figure 4.1

Electron microscope (SEM) photograph

of Geliperm at 55 000X enlargement

with superimposed diagramatic representation

of E. coli on the same scale.

(Geliperm Information)

Geliperm is adjusted to enable not only small molecules to pass through, but also protein molecules of molecular weights up to one million daltons (Wokalek et al, 1985). On the other hand, it is impermeable to bacteria (Fig 4.1).

Geliperm Dry has the same composition as the wet gel with the exception of water content. The dry gel contains around 5% water in the form of glycerol solution. The glycerol solution is present to give the dry gel a degree of flexibility preventing the normally rigid (glasslike) dry gel from fracturing.

For clinical use, the manufacturers suggest that the dry sheet should be soaked in an aqueous medium for a short period (30 seconds). On soaking, the gel swells up slightly and becomes highly elastic.

Due to the gel's low water content it is highly absorbent and it is claimed to be suitable for heavily exudating wounds. The dry gel can also be hydrated with topical antiseptics, anaesthetics or haemostatic agents to aid the healing of the wound.

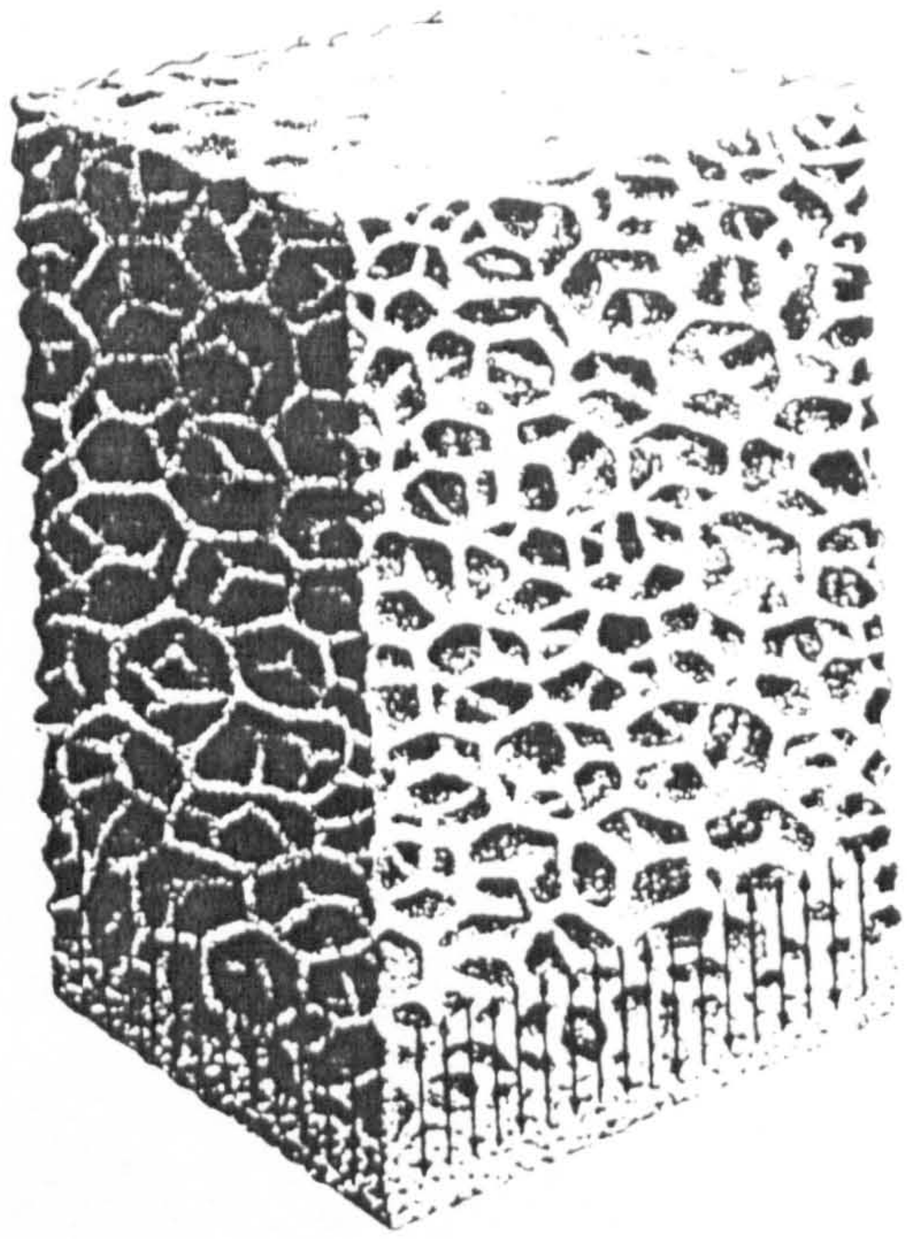


Figure 4.2

Diagram of Lyofoam Structure.

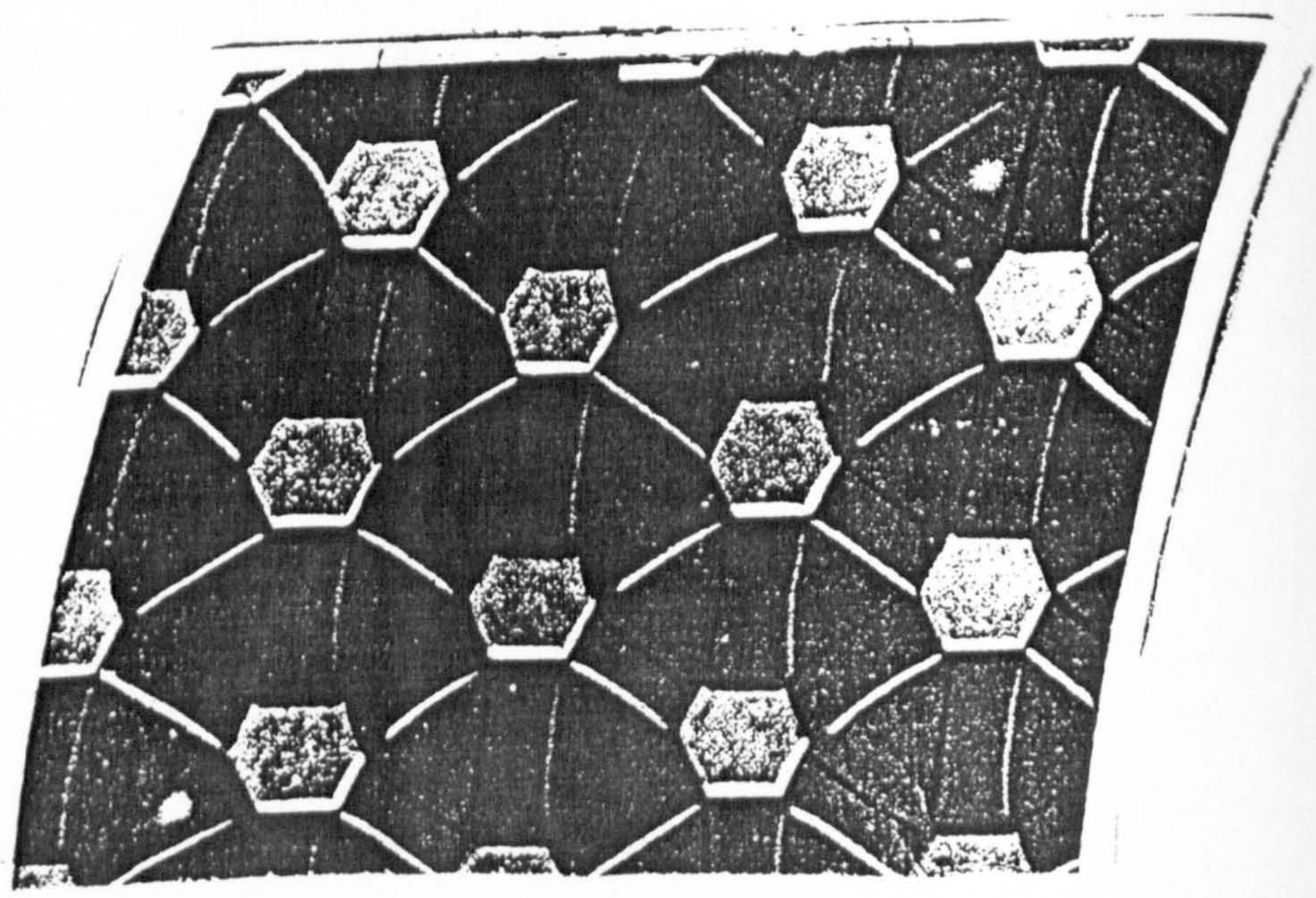


Figure 4.3

Diagram of the Vigilon Gel

with Reinforcing Mesh.

(Bard Information)

4.6 Lyofoam

Lyofoam is a microporous polyurethane foam, marketed by Ultra Laboratories Limited. The non - absorbent polyurethane is converted (on one surface of the dressing) by a heat process, to a smooth hydrophilic surface to allow the controlled absorption of excess wound fluids. Air will diffuse freely through the foam and around the wound surface (manufacturer's information)(Fig 4.2).

Lyofoam is supplied in various sizes, including a sheet large enough to be used as a base sheet for beds or stretchers, thereby providing an overall protection for the patient.

4.7 Tegaderm

Tegaderm is a continuous semi - permeable polyurethane membrane. It is completely devoid of pores, thereby preventing the penetration of water or bacteria (Fig 4.4). However, its molecular structure allows the passage of water vapour and oxygen (Fig 4.5)(manufacturer's information).

The Tegaderm dressing is a transparent film which is carried on a special applicator frame and backing that stabilises the dressing and makes it easier to

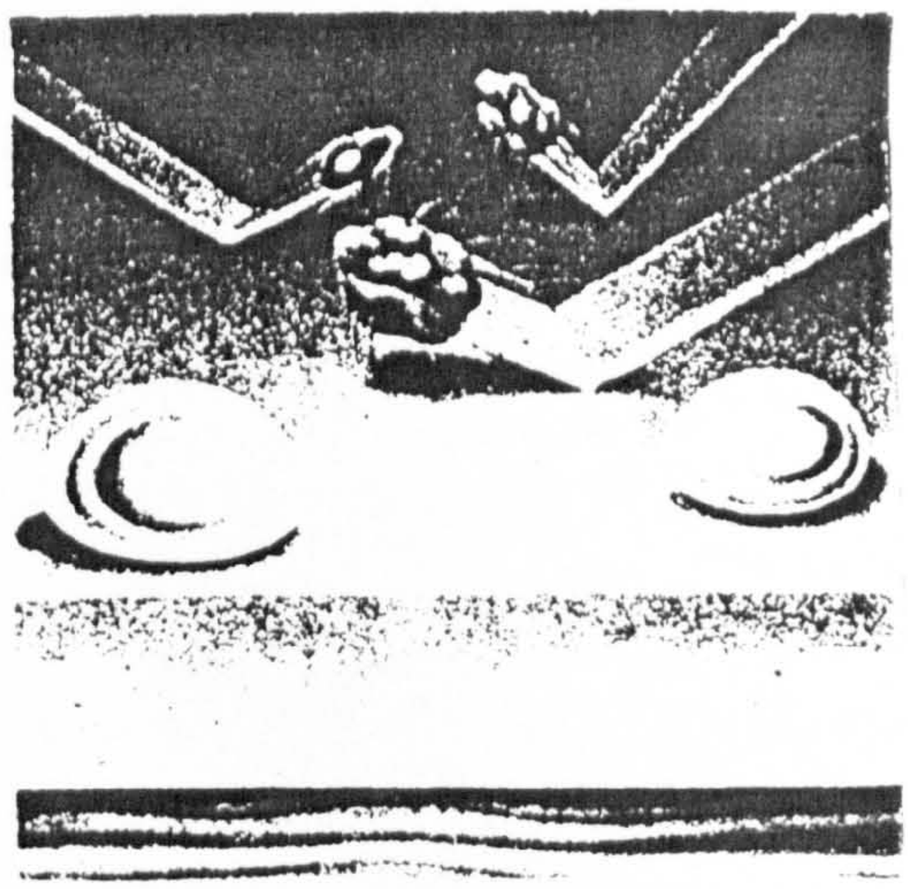


Figure 4.4

Diagram indicating the impermeability of Tegaderm to bacteria and water.

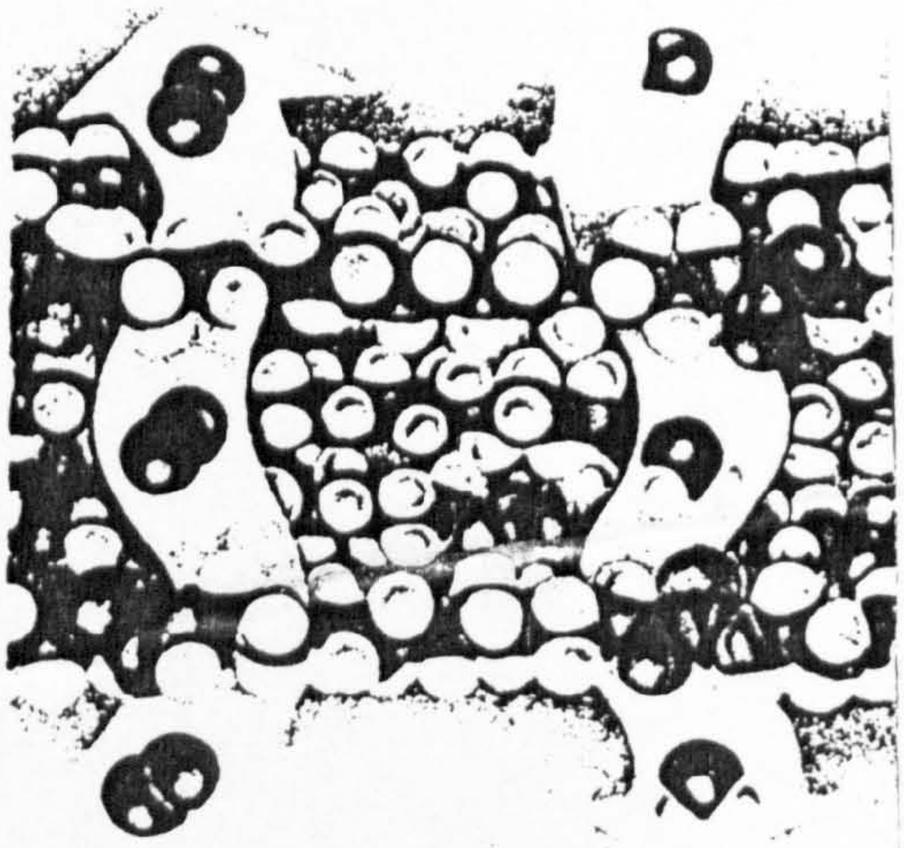


Figure 4.5

Diagram indicating the permeability of Tegaderm to water vapour and oxygen.

(3M Information)

apply, eliminating problems like bunching, wrinkling and self adherence. The frame allows the precise and secure placement of the dressing over the wound site. Its transparency allows the examination of the wound without the disturbance of the granulating tissue bed.

The dressing is supplied in varying sizes and it is marketed by 3M Health Care Limited (United Kingdom).

4.8 Mefix

Mefix is an adhesive fabric (whose nature is undefined) which is intended for the fixation of wound dressings and swabs. It is manufactured as a non - woven fabric, which is highly elastic and conforms to the body surface while accommodating body movement. The adhesive coating consists of synthetic components (polyacrylate) and is hypoallergenic.

Mefix was chosen for assessment in conjunction with other materials as it is often used as a fixation dressing for other materials such as Geliperm. It is supplied in 10m rolls of varying widths and it is marketed by Molnlyke Limited.

The structure and the effects of such a layer on underlying dressings were studied in detail. The results of this study are presented in Chapter 9.

4.9 Linear Polyurethane Hydrogel

The linear polyurethane hydrogel(Strathclyde Hydrogel 2) is a material which has been developed in the Department of Pure and Applied Chemistry of the University of Strathclyde. The intermolecular forces utilised in the gel structure are of such a nature that the polymer is soluble in organic solvents (Graham - personal communication).

The gel requires to be hydrated before testing. For testing this was carried out by soaking the gel overnight in distilled water. As with Geliperm, this material becomes elastic and swells up after a short soaking in an aqueous medium. The material is transparent which allows the examination of the injured site without the trauma of removal and as with all of the other hydrogels, this material is non - adherent. The hydrogel is cast in thin sheet form.

Due to a limitation of supply of this material, the full spectrum of tests could not be carried out.

4.10 Non - Linear PEO Hydrogel

The Non - linear PEO hydrogel [PEO/4360/2 Molar PPG 425/3 Molar HT/7.5 Molar Desmodur.](Strathclyde Hydrogel 1) is a cross - linked poly(ethylene oxide) hydrogel which has been developed in the Department of Pure and Applied Chemistry, University of Strathclyde. Information on the manufacturing process is given in Appendix 1.

The gel is thicker and more rigid than the linear hydrogel . The material is more opaque than the linear gel and required a similar hydration cycle to the other two hydrogels. Its rigidity changes only slightly after an overnight, or even longer, hydration.

Due to a limitation of supply of this material, the full spectrum of tests could not be carried out.

4.11 Porvair 232013

This material is a microporous polyurethane sheet. The manufacturing process involves the mixing of the monomer with a salt solution produced from extremely fine NaCl. The resultant paste is then extruded, in sheet form, into water. The polymer

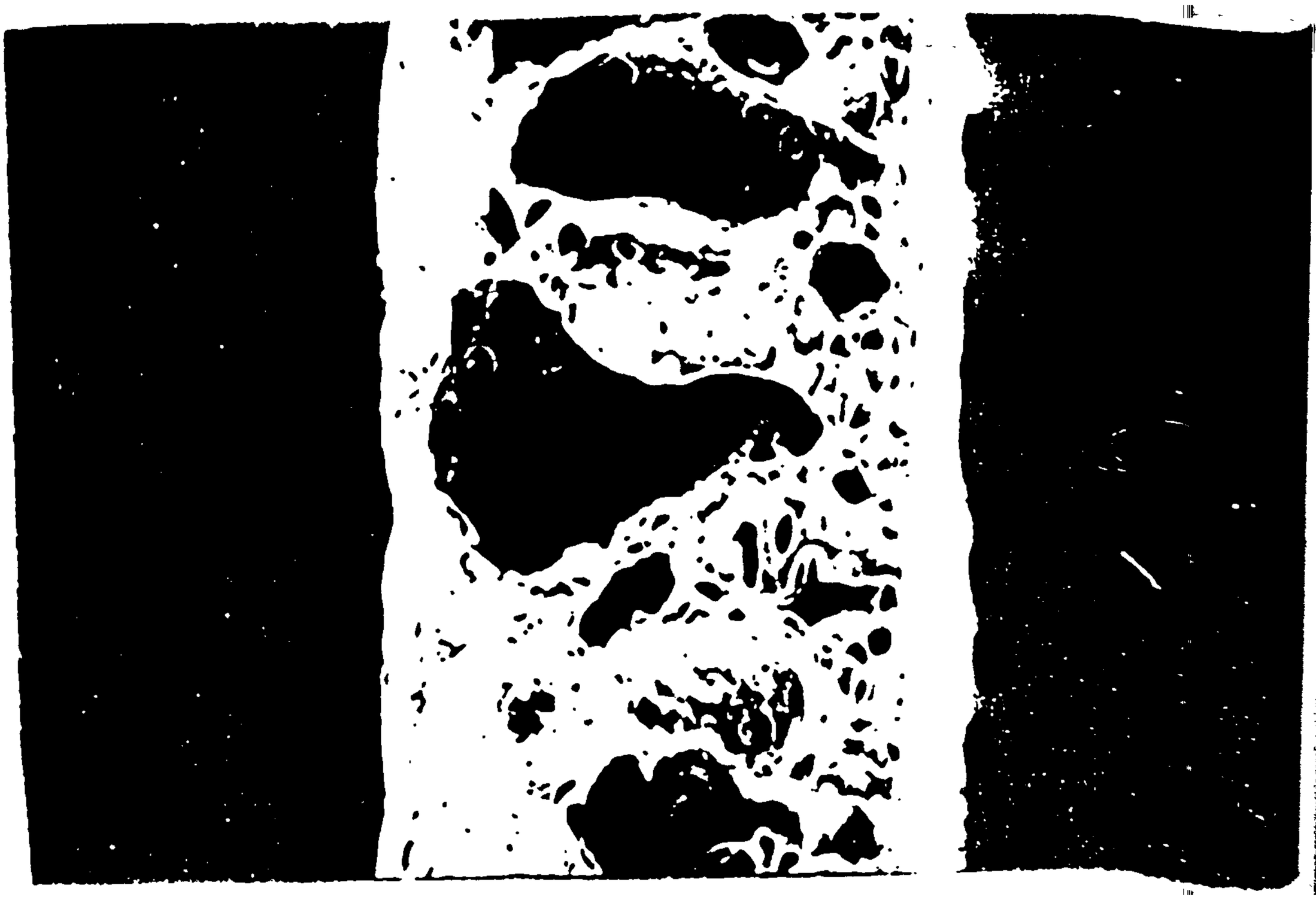


Figure 4.6

Scanning Electron Micrograph of the Porvair 232013 Material - complete cross-section.

(Mag X600)

(Porvair Information)

coagulates and the water, solvent and salt are removed. The leaching of the salt particles facilitates a control over the material's porosity. The porosity of the material is shown in figure 4.6. The polyurethane structure is such that the material is hydrophobic.

Porvair 232013 was supplied in rolls of about 6m x 0.5m.

4.12 Porvair 32/5/1

Porvair 32/5/1 is an earlier version of Porvair 232013. It is a microporous polyurethane sheet, which is not hydrophobic. The manufacturing process is as above and the manufacturers supplied this material in rolls of 6m x 0.5m.

4.13 Synthaderm

Synthaderm is a modified polyurethane foam. It is a similar product to Lyofoam. However, it is very much thinner than Lyofoam. This material is supplied in various sizes by Revlon Health Care Limited. Synthaderm is supported by a backing paper, which has to be removed before use.

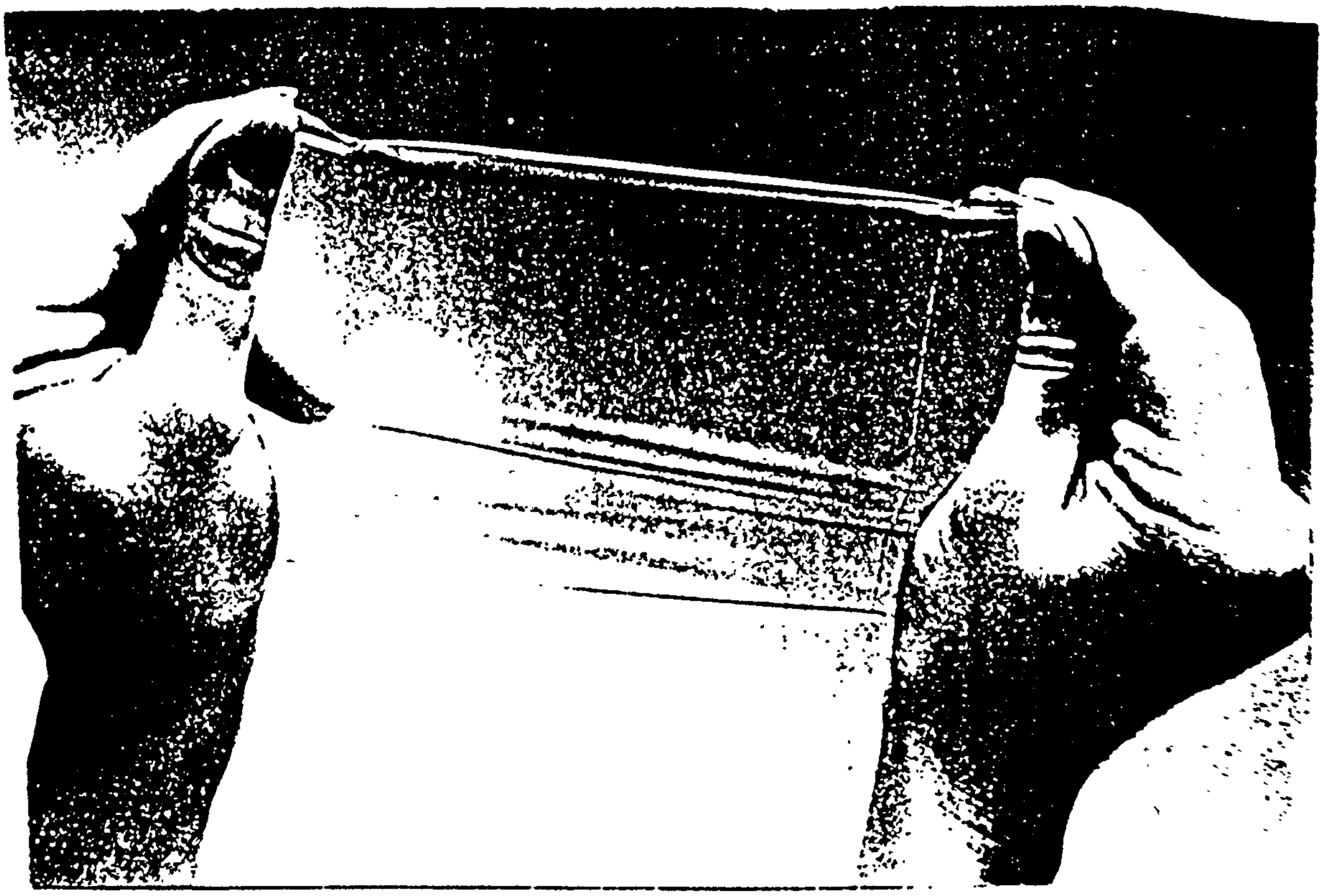


Figure 4.7

Bioclusive Transparent Wound Dressing.

(Johnson and Johnson Information)

4.14 Coraderm

Coraderm is a similar product to both Synthaderm and Lyofoam in that it is a modified polyurethane foam. The manufacturers, Revlon Health Care Limited, claim that this material is a more conformable example of Synthaderm. It appears to be more plasticised than the other two products. Coraderm is also supported by a backing paper which has to be removed before use.

4.15 Bioclusive

Bioclusive is a thin polyurethane film coated with a hypoallergenic adhesive. The material is transparent allowing wound examination without dressing removal (Fig 4.7).

Removal of the adhesive dressing from its backing paper is facilitated by a centre tab and two side tabs which allow the positioning of the dressing on the wound surface without wrinkling or fluting (manufacturers information).

Bioclusive is supplied in varying sizes by Johnson and Johnson Limited.

4.16 Corethium 1

Corethium 1 is lyophilised porcine skin. It consists of porcine epidermis which is freeze dried to give a long shelf life. This material requires to be reconstituted in normal saline before use.

Corethium 1 was chosen, for assessment , as an example of the biological type dressings. It is supplied in varying sizes by Johnson and Johnson Limited.

4.17 Composites

In clinical practice, many of the materials described above, especially the hydrogels, are non - adherent and therefore require some means of fixation to remain in place. Most clinicans use some form of adhesive tape. One such adhesive tape is Mefix (4.8).

Therefore, to obtain a true assessment of the performance of some of these materials, several of the samples were assessed both on their own and with a Mefix top layer.

The following materials were assessed with a Mefix top layer :

(1) Geliperm

(2) Linear Polyurethane Hydrogel

(3) Non - Linear Hydrogel

(4) Lyofoam

This utilisation of Mefix is reported in Chapter9.

CHAPTER 5

Evaluation of the Water Vapour Transmission Rate Through Dressings.

CHAPTER 5

5.1 Introduction.

One of the major problems, arising in the treatment of burn wounds, is the prevention of total wound surface dehydration. Water loss by evaporation is an important factor in the maintenance of body homeostasis. Thermal injury to the skin destroys the semi-permeable membrane associated with the lipoprotein layer in the stratum corneum (Moyer and Butcher, 1967; Jelenko et al,1968; Jelenko,1969). The damage caused allows excessive water to be lost through the injured skin.

After thermal injury, the evaporative water loss from the wound surface can be some twenty times greater than normal skin (Lamke et al,1977). Insensible water loss can place unacceptable demands on body metabolism especially if the area of injury is extensive. Wenger (1972) calculated that 2.43 MJ of energy are lost upon the evaporation of one litre of water and hence substantial evaporative water loss is associated with an abundant heat loss.

Factors such as the above indicate the importance of limiting the water loss and hence heat loss during treatment. Heat loss can be reduced by maintaining a warm treatment environment (Barr et al 1968). Insensible water loss can be reduced by the application of a temporary wound covering or a permanent graft (Lamke,1971; Lawrence,1977; Park,1978; Wong,1980; Rahman,1982; Davies,1983; Quinn et al,1985). Additionally, wound dressings may also limit bacterial invasion and growth within the wound. The ability to transport water vapour is therefore an important function of the dressing and hence a valuable preclinical assessment is the measurement of the water vapour transmission rate (WVTR) of the dressing.

The in vitro study of the WVTR has been the subject of research in recent years (Gourlay et al,1975; Schwope et al,1977; Lamke et al,1977; Park et al,1978; Schwope et al,1978; Tavis et al,1980; Wong,1980; Rahman,1982; Aiba et al,1985). Most of this research has dwelt on the American Society for the Testing of Materials (ASTM E96-80) procedures. Some have used the desiccant method, others the water-cup and inverted methods. A vast variety of test conditions has been utilised, with the relative humidity driving force ranging from 13% to 100% and

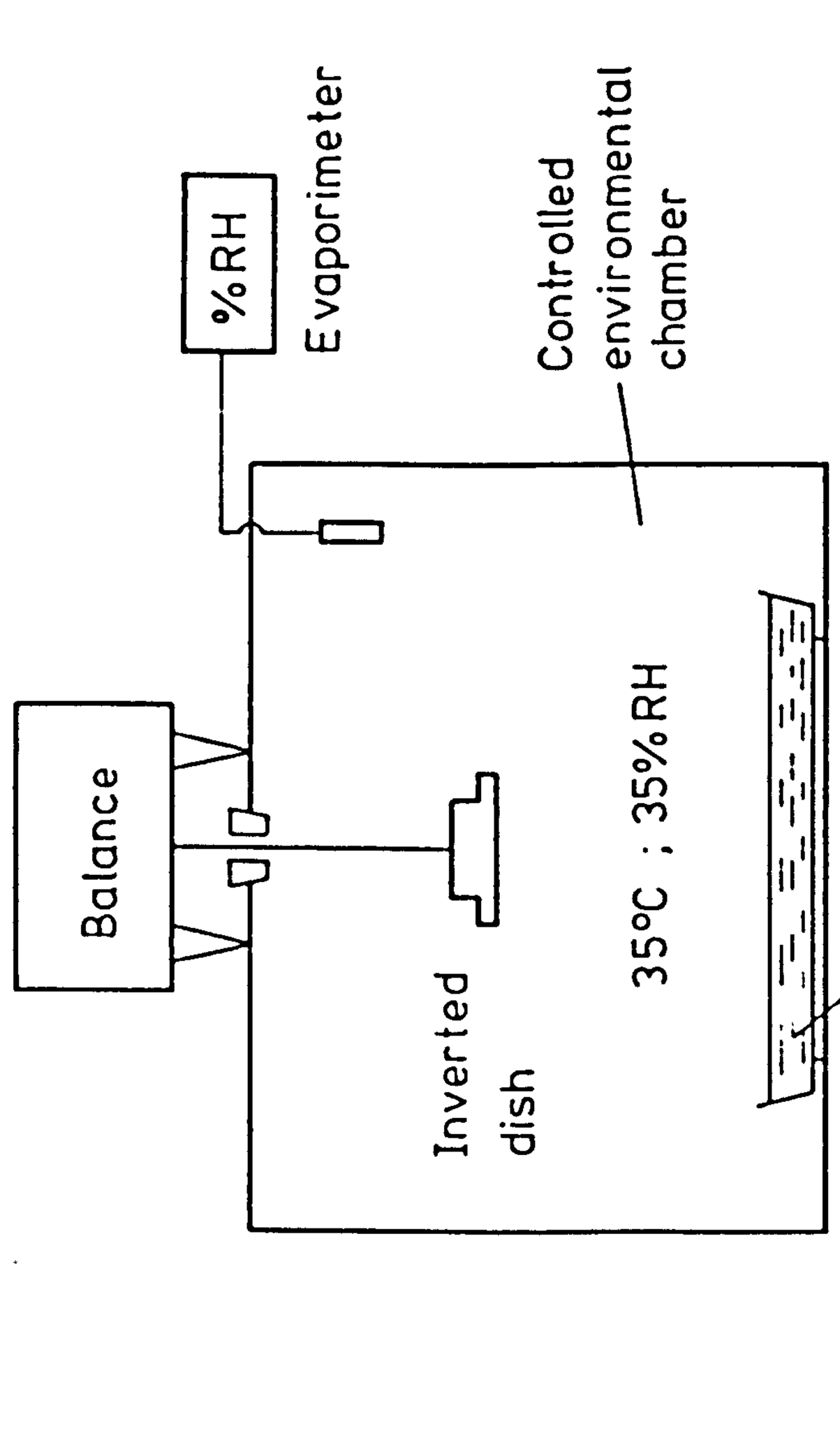


Figure 5.1

Diagramatic Representation of the WVTR Experimental System.

the temperature of test from 28°C to 40°C.

This study has been geared towards *in vitro* evaluation of the WVTR and the comparative evaluation with *in vivo* clinical WVTR observations. The aims of the study were twofold. Firstly, to determine the relevance of the *in vitro* test conditions with those occurring clinically. Secondly, to suggest modifications, if required, off the *in vitro* test in order to simulate the clinical situation more accurately. Concern has also been expressed on the possible effect of protein adhesion (adsorption) on the WVTR of dressings while *in situ* (Turner,1985). *In vitro* and clinical experiments have been used to determine the possibility of such an effect.

The materials tested in this thesis are marketed or manufactured in sheet form and therefore to determine their WVTR, a modified ASTM Standard Method E96 (Wong,1980; Rahman,1982) was used. In this method, a disc of the material being assessed is mounted on a metal cup which contains water. The cup is placed in a controlled air environment of lower relative humidity than that within the cup (Fig 5.1). From periodic weighing of the cup, the water loss may be determined and hence the WVTR of the material.

All of the materials described in Chapter Four were assessed in this way.

5.2 Experimental Apparatus.

A humidity incubator, (Gallenkamp Incubator, Model IM 100) illustrated in Fig. 5.1, with internal dimensions of 50cm x 50cm x 60cm, was used to provide the controlled air environment.

To provide a water vapour driving force, the relative humidity of the incubator interior was maintained nominally at 35% by the use of saturated solutions of magnesium chloride. The incubator temperature was held at 35^{o}C for all WVTR evaluations.

The work of Lamke et al has shown that the average surface temperature of the injured skin is 35^{o}C and hence the water vapour transmission experiments were carried out at this temperature.

It is essential that the weighing is carried out with the minimum disturbance to the environment in order to avoid fluctuation in relative humidity and hence water vapour driving force. For this reason, the weighing was carried out remotely by means of a Gallenkamp Mettler Balance P163, which was placed above the incubator (Fig 5.1). The balance was

connected to the cup via a hooked rigid wire rod which passed through an aperture in the incubator roof. A platform, capable of holding five cups, permitted each cup to be weighed in turn. The platform was rotated by a stepping motor, using an external control switch, so that a cup could be positioned under the hooked rod. To attach the cup to the rod, the latter can be manually detached from the balance and hooked onto a pick-up lug on the cup; the rod was subsequently attached to the balance for weighing. An inner glass door within the chamber allowed the manipulations of rod and platform to be observed without environmental disturbance.

The cups were circular dishes made from aluminium. The test specimen was fixed between a threaded locking ring and a mating flange on the cup perimeter. A Mylar ring gasket placed between the locking ring and the specimens ensured that the specimens did not crease during clamping. To obtain a water tight seal a Neoprene O - ring was mounted on the threaded flange. A pick-up ring can be attached to the bottom of the cups to allow weighing of the cup with the specimen face downwards (Inverted Water Cup method)(Fig 5.2). Alternatively a strap can be attached to the locking ring to allow the cup to be weighed with the specimen face upwards (Water Cup

Figure 5.2

The cups used to measure WVTR.

Method)(Fig 5.2).

5.2.1 Environmental Control.

As indicated previously, Section 5.2 the control of the internal environment is of major importance in the assessment of the water vapour transmission rate of any material, since the control of the internal environment determines the driving force for the transmission of water vapour across the membrane.

In the above procedure, the relative humidity of the oven was maintained at 35% using a saturated salt solution. Many researchers (Powell and Griffiths, 1935; Burcham, 1953; Young, 1967) have shown that a saturated salt solution at a given temperature produces a fixed partial pressure of water vapour and hence relative humidity when in equilibrium with a gaseous environment. It was also shown that in setting up a constant humidity chamber using saturated salt solutions certain criteria have to be adhered to, viz :-

1. The chamber should be leak-proof;

2. The chamber should have a non-hygroscopic lining to prevent the adsorption of water vapour thus ensuring that equilibrium is achieved as rapidly

as possible;

3. A porcelain or plastic tray should be used to hold the salt solution thus preventing any alteration of humidity via corrosion;

4. It is essential that only a saturated solution is present and there must be no droplets or films of water on the sides of the tray. Hence the tray should be dry initially;

5. Thermal equilibrium within the chamber should be maintained by keeping the chamber and its contents at a constant temperature;

6. The surface area of the salt solution should be as large as is practically possible. An external fan motor provides a means of circulating air within the oven to provide a uniform humidity.

5.2.2. Measurement of the Relative Humidity.

In this study, the saturated salt solution used was magnesium chloride which should produce a relative humidity of 32% at 35°C (Hickman,1970).

The relative humidity during the experimental procedure was continuously monitored using an Evaporimeter EP 1, Servo Med AB, Stockholm, Sweden. This instrument gives a digital display of relative humidity as measured by thin film capacitive type sensors which were placed in the incubator (Appendix 2).

As a check on the measured value obtained from the Evaporimeter, the relative humidity was also measured using a ventilated psychrometer (Delta-T Devices, Cambridgeshire)(Appendix 2).

Preliminary data showed that no difference was observed between the two measuring techniques, both giving a value of 35% +/- 2%. Although this value was slightly higher than the literature value, it remained relatively constant from test to test.

5.3 Preparation of the Test Materials.

The test specimens consisted of circular sheets of uniform thickness with an overall diameter of 8.5 cm. Due to the opening in the cup locking ring, the exposed diameter of the specimen was 7.5 cm, giving an effective transfer area of 4.5×10^{-3} m^2.

5.3.1 Tegaderm.

The Tegaderm wound dressing was supplied in pre-sterilised sheets (10cm x 15cm). The procedure used to mount the dressing onto the cup without any pre-tensioning was as follows;

1. Remove the Tegaderm from its packing;

2. Peel away the inner window of protective paper and then the protective backing paper;

3. By means of the protective frame apply the adhesive side of the Tegaderm to the cup;

4. Gently remove the cardboard protection frame;

5. Cut around the edge of the cup to remove the excess;

6. Position the gaskets and clamp down the specimen via the cup locking ring.

5.3.2 Bioclusive.

Bioclusive was supplied as pre-sterilised sheets in varying sizes (e.g. 10cm x 10cm or 10cm x 15cm). The mounting procedure was as follows :

1. Remove the centre portion of the protective backing paper;

2. Place the adhesive side on the cup and remove the other protective tabs;

3. Cut around the edge of the cup to remove the excess;

4. Position the gaskets and clamp down the specimen via the locking ring.

5.3.3 Stretch 'n' Seal.

Stretch 'n' Seal was available in rolls of 14m x 0.3m. The specimens were cut from the centre of the width of the roll using a metallic, circular template and a scalpel.

5.3.4 Porvair 232013 and Porvair 32/5/1.

The manufacturers supplied this material in rolls of approximately 2m x 0.6m. The specimens were cut from the centre of the width of the roll using the template and scalpel.

5.3.5 Vigilon and Vigilon Coverfilm.

The Vigilon dressing was supplied in pre-sterilised sheets of dimensions 10cm x 10cm. From each sheet, a Vigilon and a Vigilon Coverfilm specimen could be obtained, since the Vigilon dressing is supplied with two coverfilms and it is tested with one removed. The specimens were cut using the template and scalpel.

5.3.6 Geliperm Dry.

Since the Geliperm material was supplied in the dry state, the material required hydration before the test. Preliminary studies indicated that maximum adsorption of distilled water occurred after several hours.

A cut disc was hydrated overnight in distilled water. As the lateral swelling of this material is only about 5% (the hydration volume is primarily taken up by the increase of the specimen thickness), only slight trimming of the disc was required before use.

5.3.7 Linear Polyurethane Hydrogel.

The linear polyurethane hydrogel is supplied in the dry state and hence it requires an overnight hydration before use. A disc of the material was removed from the sheet, as above, and hydrated in distilled water. The lateral swelling characteristics of this material are such that a new disc has to be prepared, from the swollen disc, using the template and scalpel.

5.3.8 Cross-linked PEO Hydrogel.

As with the other hydrogels, this material required to be soaked in distilled water (overnight) before use. A similar trimming as in 5.3.7 was required for this material.

5.3.9 Lyofoam.

The Lyofoam dressing was supplied in sheets of 10cm x 10cm in size. The specimens were obtained using the template and scalpel.

5.3.10 Synthaderm.

Synthaderm was supplied in pre-sterilised sheets of 10cm x 10cm in size. The dressing was removed from its backing paper and the specimens prepared as in 5.3.9.

5.3.11 Coraderm.

Coraderm wound dressing was supplied and prepared as in 5.3.10.

5.3.12 Corethium.

The Corethium pig skin dressing was supplied in pre-sterilised sheets of 10cm x 10cm. The dressing was reconstituted in sterile saline, for 15-30 minutes, before use. A disc of the material was prepared using the template and scalpel.

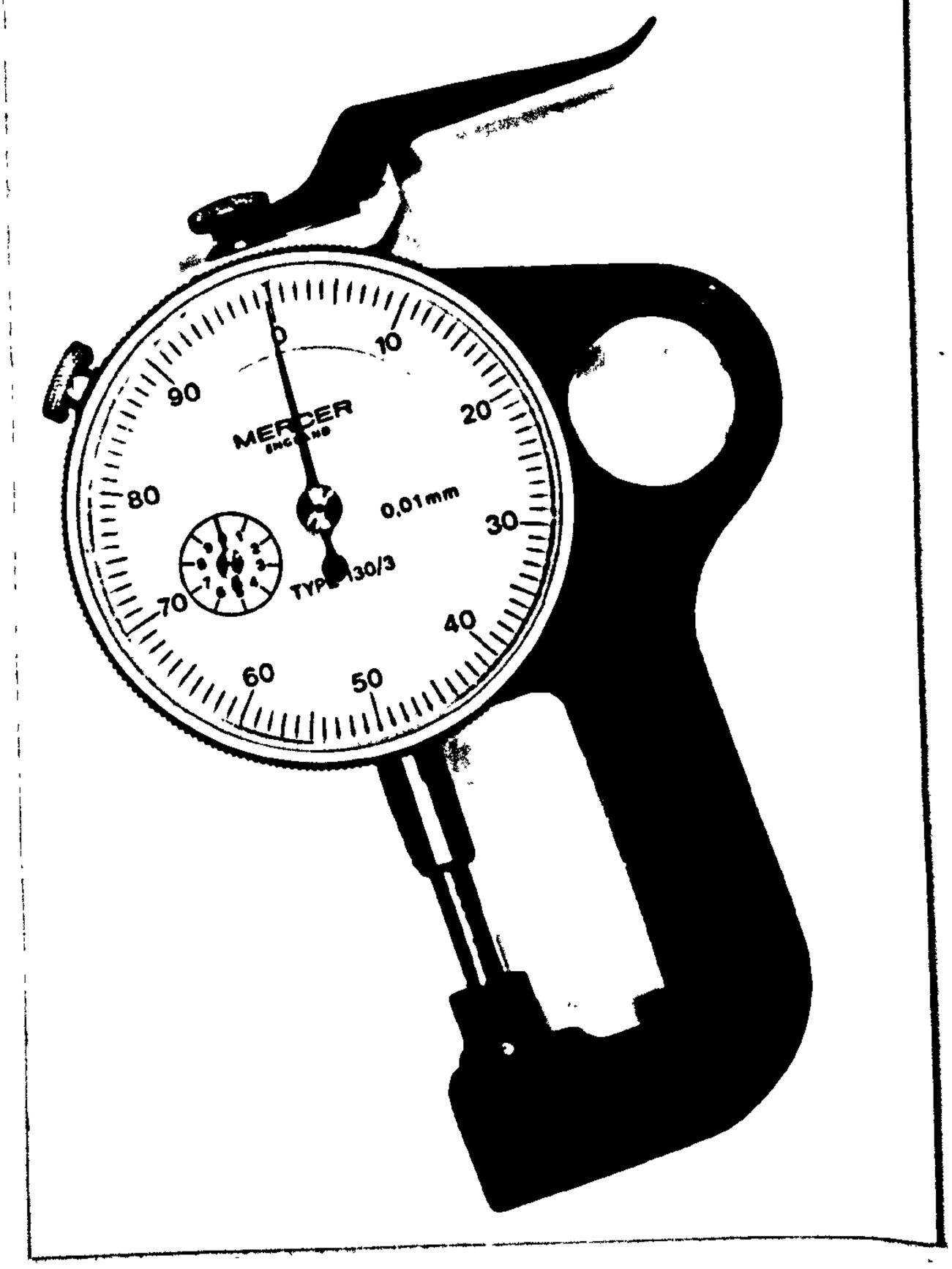


Figure 5.3

Dial gauge micrometer used to measure thickness.

5.3.13 Mefix.

A disc of Mefix was prepared using the template and scalpel. Since this material was only assessed for water vapour transmission in conjunction with other materials the preparation procedure for each was as above, with the additional step of removing the protective backing from the Mefix disc and placing the adhesive dressing on top of the other specimen.

5.4 Test Procedure.

Before the test, the materials were prepared as described in Section 5.3. The thickness of each disc specimen was measured at four locations using a spring-loaded dial-gauge micrometer (Fig 5.3) and the mean was calculated to give an overall thickness measurement.

For the compressible hydrogels and Vigilon materials, the micrometer anvil force was distributed over a large surface area by sandwiching the material between two glass slides, the combined thickness of the slides being subtracted from the overall value.

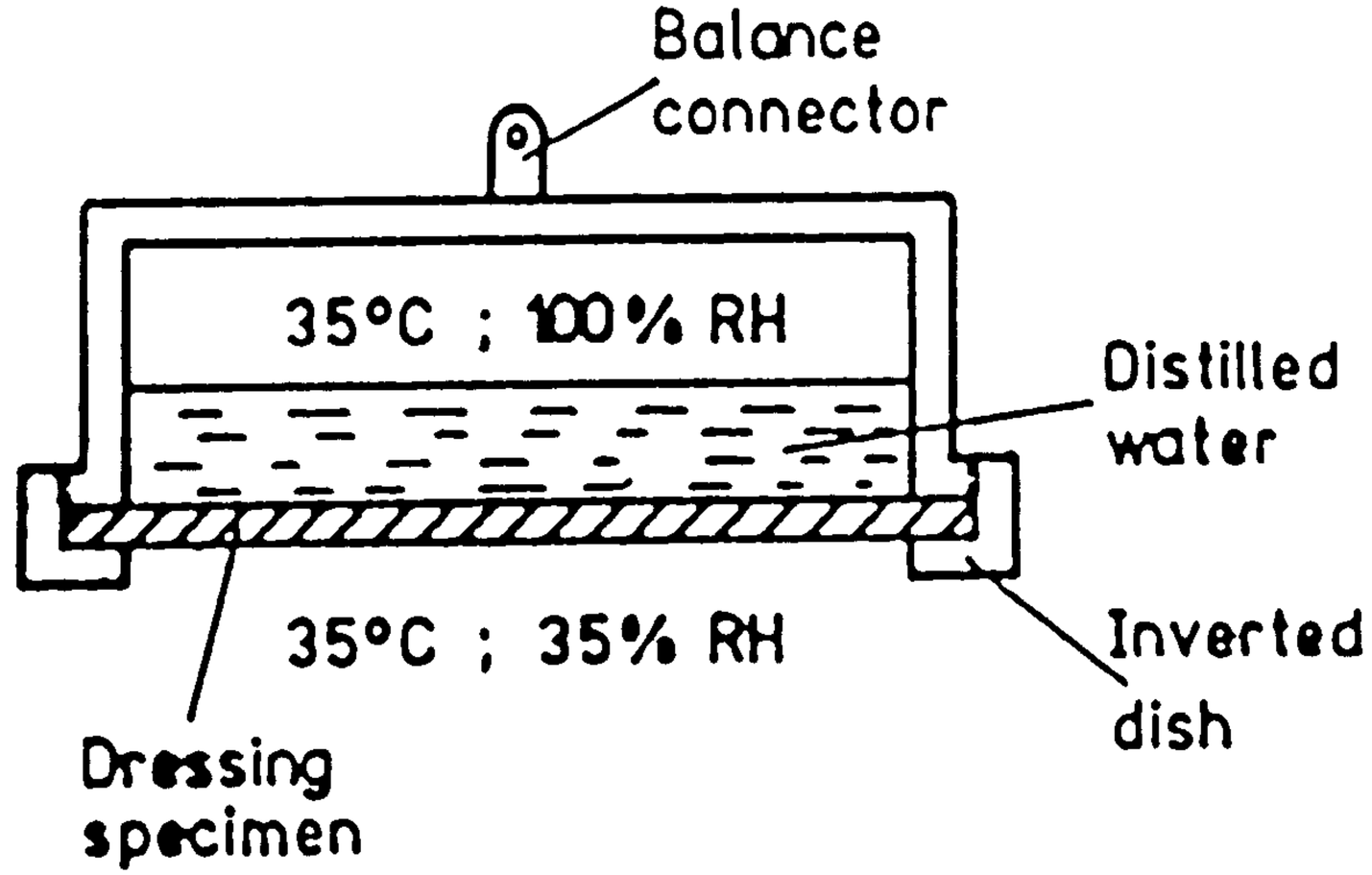


Figure 5.4

Diagram of Assembled Dish

and Environmental Conditions.

The Evaporimeter sensor probe was placed within the incubator to allow equilibration to the chamber environment. Once it was established that the relative humidity was of the desired level the cups were prepared for either the Inverted Water Cup or Water Cup procedures.

5.4.1 Inverted Water Cup Method.

In this method, the cup is inverted to provide physical contact between the distilled water within the test cell and the test specimen, thus ensuring that the relative humidity on the inner side of the specimen is 100% (Fig 5.4). For this reason this is the most commonly used procedure.

Distilled water is placed in the cup to a depth of 5-10mm (around 30ml of distilled water). The upper 10mm limit is strictly adhered to as any excess could cause distortion of the specimen due to the mass of the water. There should also be a sufficiency of water present such that the WVTR of the specimen will not completely empty the reservoir over the test period.

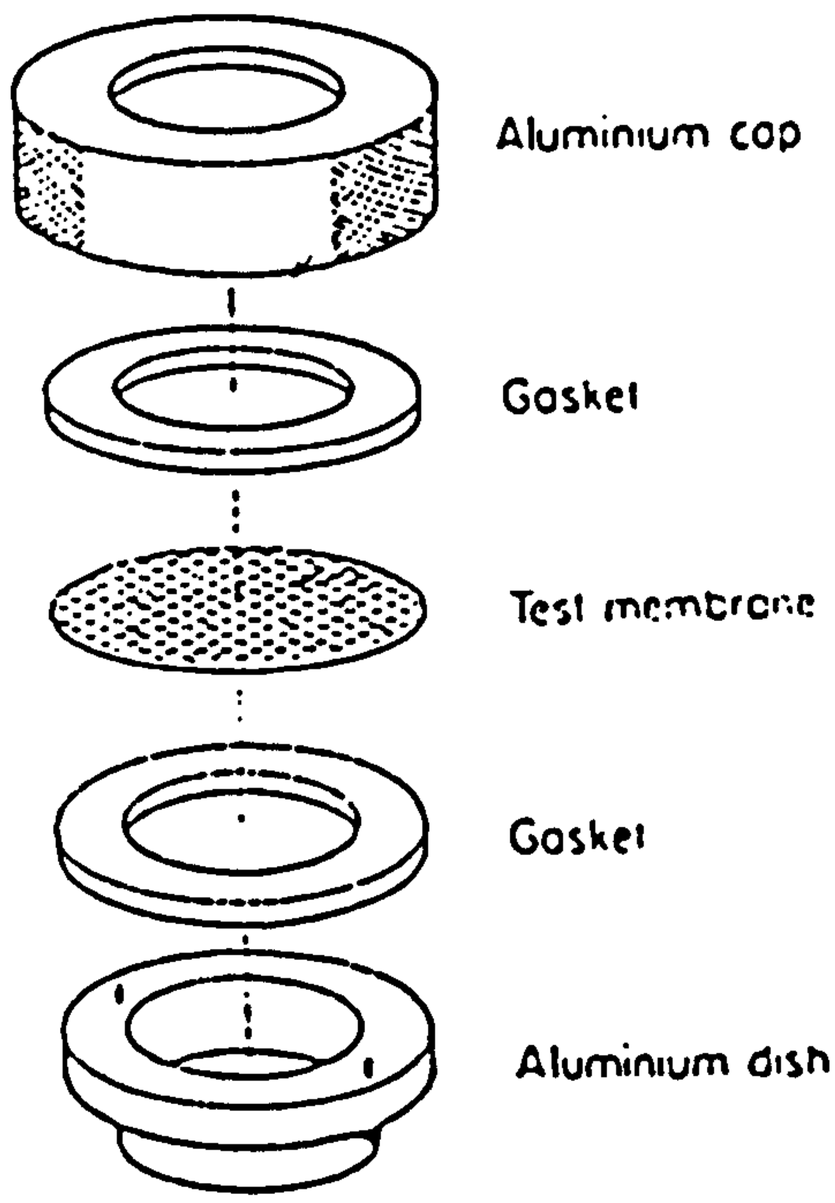


Figure 5.5

Aluminium Cup with Test Membrane in Position.

(Park et al, 1978)

The specimens are clamped onto the cups as shown in Fig 5.5. The cups were inverted and placed on absorbent paper to determine if any leakage was present. If leakage was absent, the pick-up rings were attached to the base of the cups and the cups were placed, inverted, on the rotating platform within the chamber. An acclimatisation period of one hour was allowed before taking the initial weight measurements. Successive weight measurements were taken and recorded every thirty minutes.

5.4.2 Water Cup Method.

The only difference between this procedure and the Inverted Procedure above is that the cups are kept in the upright position. Hence the water is not in contact with the specimen and the water level within the cup has to be such to allow the maintenance of an internal relative humidity of approximately 100% (i.e. the air phase has to be small enough to be totally saturated with water vapour).

Only the foams and Corethium were assessed by this method since, in the inverted position, the water flows by gravity through these materials which possess porous structures.

Previous workers (Wong 1980; Rahman 1982) have found that the WVTR values for Opsite and Clingfilm, obtained via this procedure are lower than those obtained by the Inverted method. This may be explained by the creation of a relative humidity gradient at the air/dressing interface within the cup. The magnitude of this gradient or boundary layer will depend on the WVTR of the dressing. Also with hydrophilic materials, the material structure may be altered, with change from a liquid interface to a gaseous interface. The Inverted method was the preferred method of evaluation since it simulates the clinical situation more closely.

The above methods give a measure of the overall transmission rate, with no account taken of boundary layer resistances. The WVTR will also eventually be limited by that due to evaporation from a free water surface.

With dressings which have low WVTR's, the limitation of WVTR by the above evaporation is not important as it occurs to a minor extent. Such resistances are more significant for dressings with high WVTR's.

The resistance offered by the boundary layers is influenced by the velocity of air circulated over the dressing surface. In accordance with ASTM E96-80 the air within the chamber is circulated in order to maintain uniform conditions next to the material under assessment. A small boundary layer may however exist depending on the permeability of the material. However boundary layers will be present in actual clinical usage and hence no attempt has been made to correct for it here.

If there is a necessity to define the absolute transmission arises, this can be done by studying films of different thicknesses (Park et al, 1978).

5.5 Results.

Weight loss measurements were recorded at specific times allowing a weight loss versus time plot to be constructed. Examples of typical plots are shown in figure 5.6.

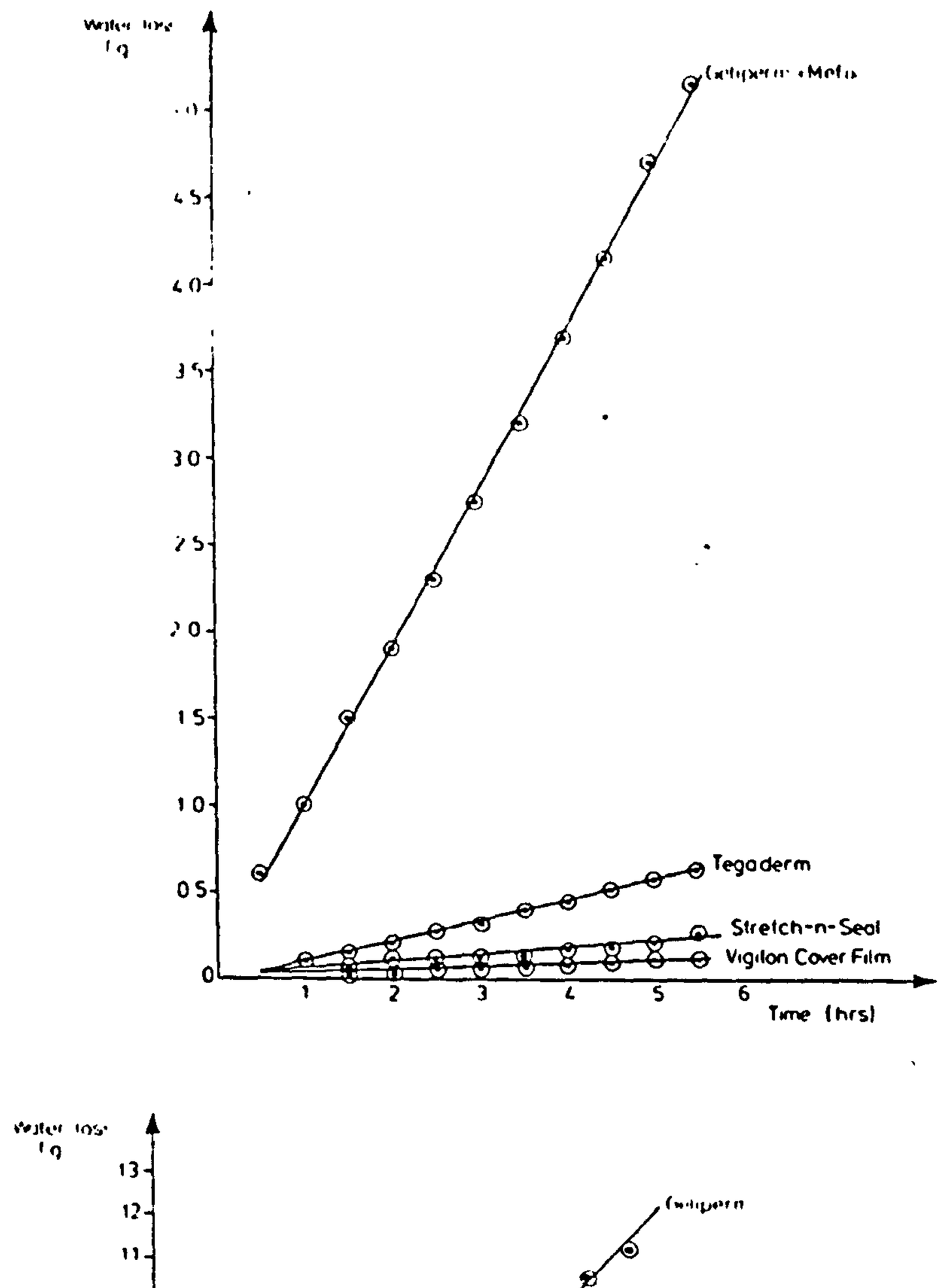
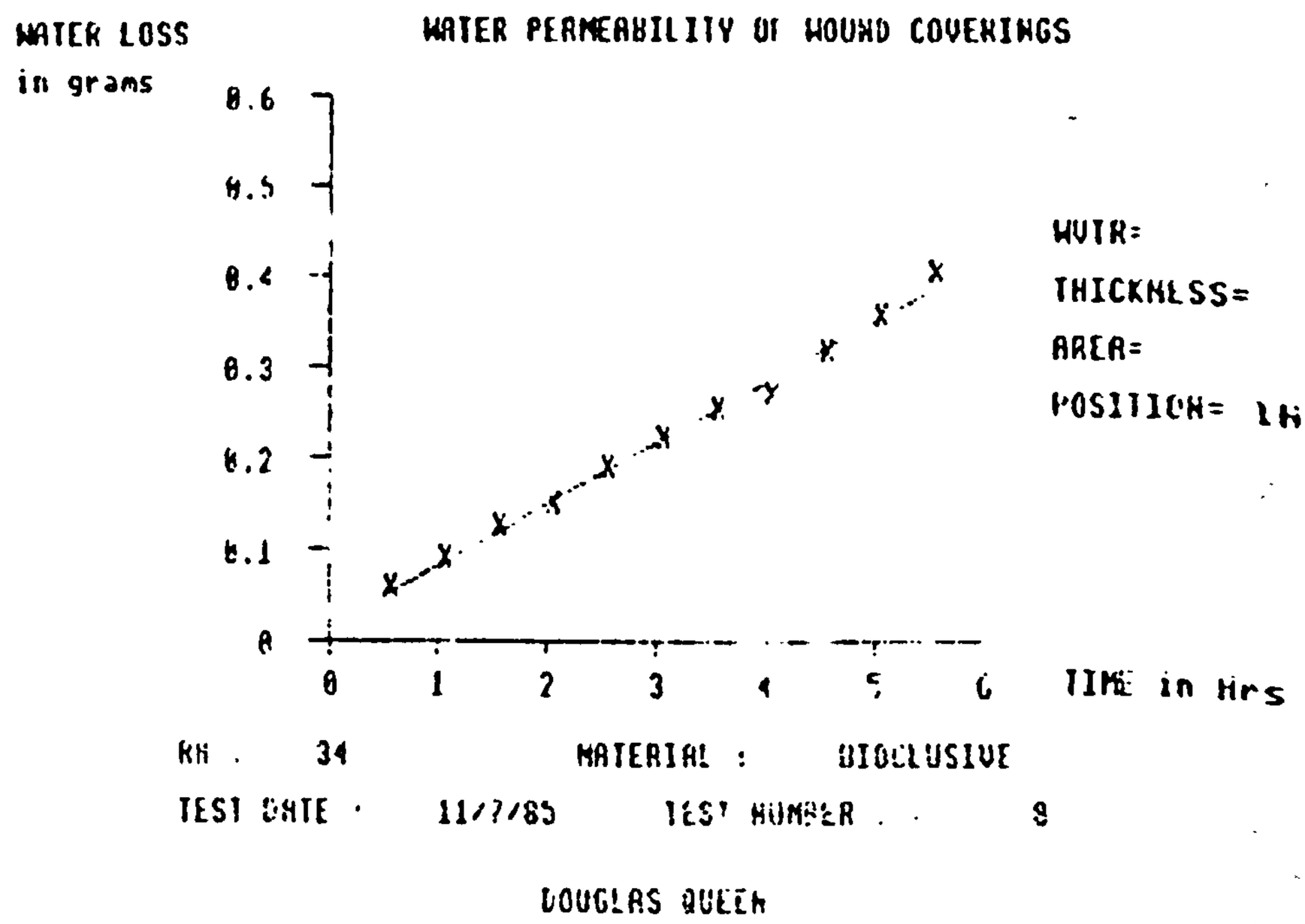


Figure 5.6

Examples of WVTR plots.



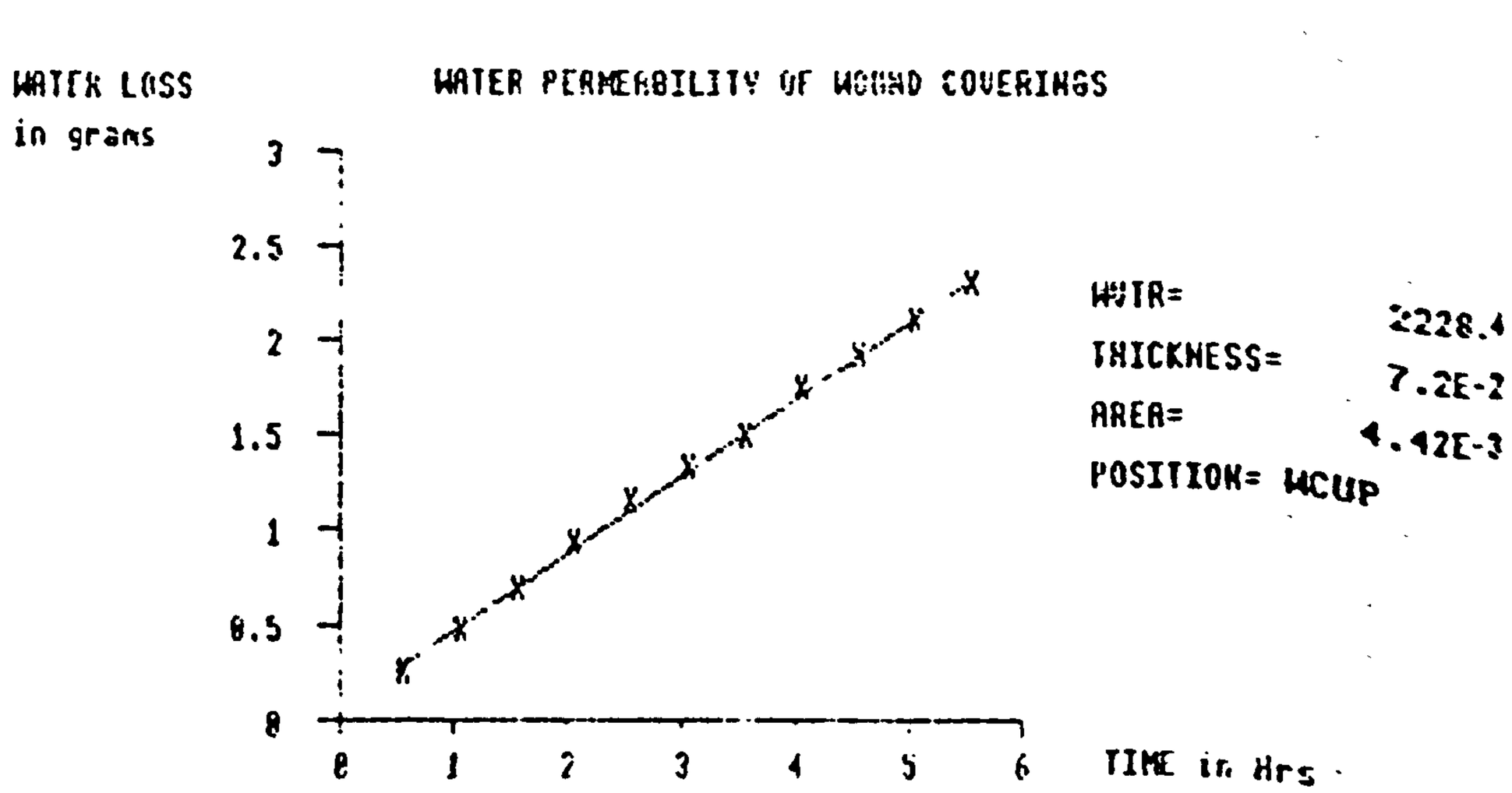


Figure 5.7

Examples of the computer printout.

WVTR in g/(m^2.24h)

As can be seen from these examples, the plots are essentially linear indicating the attainment of steady-state operating conditions. The gradient of this line gives a rate of water transport, m, in grams per hour (gh^{-1}). These values can be converted to WVTR by the following formula:

$$WVTR = \frac{m \times 24}{A} \quad g/(m2.24h)$$

where A = the exposed area of the cup in m^2.

The results of individual tests are given in Tables 5.1 to 5.4 listing WVTR, specimen thickness and relative humidity measurement.

In the latter tests, a computer program was written (Appendix 3) which plotted the best fit line to the experimental data and calculated the WVTR of the dressing tested. Examples of the computer printout (hardcopy) are given in Fig 5.7.

Material (n)	Thickness (mm)	RH (%)	WVTR g/(m2.24h)	Mean WVTR +/- 1 S.D.
Plasticised P.V.C. (7)	0.01	34	326	
	0.01	34	366	
	0.01	34	317	
	0.01	34	316	
	0.01	34	233	
	0.01	34	362	
	0.01	34	362	362+/-44
Vigilon Coverfilm (7)	0.03	34	139	
	0.03	34	118	
	0.03	34	125	
	0.03	34	121	
	0.03	35	184	
	0.03	34	156	
	0.03	34	127	139+/-23
Vigilon (+1 cover) (7)	1.03	34	153	
	1.02	34	174	
	1.08	35	174	
	1.06	36	137	
	1.14	36	223	
	1.41	36	187	
	1.39	36	130	168+/-32

Table 5.1

Water Vapour Transmission Rates

for the Control Materials.

Material (n)	Thickness (mm)	RH (%)	WVTR g/(m2.24h)	Mean WVTR +/- 1 S.D.
Tegaderm (7)	0.03	35	499	
	0.03	35	510	
	0.03	35	467	
	0.03	35	404	
	0.03	35	528	
	0.03	35	527	
	0.03	35	502	491+/-44
Bioclusive (7)	0.10	35	403	
	0.10	35	374	
	0.10	34	431	
	0.10	34	363	
	0.10	35	361	
	0.10	34	365	
	0.10	34	380	382+/-26
Porvair 232013 (7)	0.10	35	3661	
	0.10	35	3563	
	0.10	35	3371	
	0.10	35	3379	
	0.10	35	3388	
	0.10	35	3491	
	0.10	35	3447	3472+/-109
Porvair 32/5/1 (7)	0.08	35	3235	
	0.08	35	3323	
	0.08	35	3199	
	0.08	36	3296	
	0.08	36	3640	
	0.08	36	3298	
	0.08	36	3120	3302+/-165

Table 5.2

Water Vapour Transmission Rates

for the Film Type Dressings.

Material (n)	Thickness (mm)	RH (%)	WVTR g/(m2.24h)	Mean WVTR +/- 1 S.D.
Lyofoam (7)	12.0	35	2623	
	11.0	35	2686	
	10.0	35	1929	
	11.0	35	3859	
	11.0	35	3083	
	8.2	35	3601	
	9.1	35	3579	3052+/-684
Synthaderm (7)	0.65	35	2222	
	0.65	35	1953	
	0.75	35	1654	
	0.75	34	2017	
	0.80	34	2090	
	0.72	35	2228	
	0.80	35	1874	2005+/-203
Coraderm (7)	0.69	34	2822	
	0.80	34	2915	
	0.70	34	2411	
	0.74	34	2639	
	0.79	35	3330	
	0.79	35	3085	
	0.80	35	2809	2859+/-296

Table 5.3

Water Vapour Transmission Rates

for the Foam Type Materials.

Material (n)	Thickness (mm)	RH (%)	WVTR g/(m2.24h)	Mean WVTR +/- 1 S.D.
Geliperm (7)	1.20	34	11,643	
	1.23	34	11,689	
	1.21	35	11,907	
	1.15	34	11,512	
	1.21	36	10,353	
	1.20	36	10,546	
	0.69	35	9,161	10,973+/-998
Linear Polyurethane Hydrogel (7)	0.14	34	10,912	
	0.13	34	7,887	
	0.13	35	8,845	
	0.11	37	8,733	
	0.13	37	10,369	
	0.19	36	10,847	
	0.22	36	11,357	9,850+/-1240
Cross-linked PEO hydrogel	- Gel contracted within the oven indicating a very high WVTR			
Corethium (7)	0.34	36	2254	
	0.38	35	2281	
	0.30	35	2054	
	0.35	35	1250	
	0.33	35	1563	
	0.44	35	1697	
	0.40	35	1653	1822+/-385
Free Water Surface (6)	-	33-36	11,063	
	-	33-36	10,892	
	-	33-38	10,699	
	-	33-38	9,269	
	-	33-38	9,671	
	-	33-35	10,917	10,419+/-689

Table 5.4

Water Vapour Transmission Rates

for the Hydrophilic Dressings

and a Free Water Surface.

Studied Area	n	Evaporative Water Loss g/(m^2. 24h)	Surface Temperature ^{O}C
Normal Skin	60	204.0 +/- 12.0	35.8 +/- 0.2
First Degree	12	278.4 +/- 26.4	35.3 +/- 0.1
Second Degree	30	4274.4 +/- 132.0	35.3 +/- 0.4
Third Degree	20	3436.8 +/- 108.0	34.5 +/- 0.4
Granulating Wound	21	5138.4 +/- 201.6	34.7 +/- 0.2
Donor Site	35	3590.4 +/- 180.0	35.3 +/- 0.2

Table 5.5

The Evaporative Water Loss and Skin Temperature values obtained by Lamke et al, 1977.

(n = no. of observations)

5.6 Discussion.

Fluid retention behind a burn wound dressing or the dehydration of the granulating wound bed are serious problems in the treatment of burn injuries.

It is therefore essential that the water vapour transmittivity of a burn wound dressing should be such that it maintains a satisfactory moisture balance within the repairing wound.

Lamke et al (1977) investigated the water vapour transmission across normal and injured skin. They reported the evaporative water loss for burns, granulating wounds and donor sites along with the average surface temperature (Table 5.5). This work has helped the study of burn wound dressings by laying down some guidelines as to the required WVTR of a dressing for a particular injury.

From the table, it can be seen that the granulating wound has the highest evaporative water loss (some 20 times that of normal skin). Courtney et al (1976) suggested that a covering should have a similar WVTR as skin. However due to the findings of Lamke et al it can be said that such a covering would allow the build up of exudate to occur due to the high evaporative water loss from the wound.

A similar outcome would arise if the suggestion of a range 500-1700 $g.m^{-2}.24hr^{-1}$; by McKnight and Guldalian (1974) was followed.

It was for these reasons that Wong (1980) suggested a level of 2000-2500 $g.m^{-2}.24h^{-1}$ which is half of the loss in a granulating wound. This 50% level will be sufficient to give adequate moisture and prevent wound dehydration.

Sensibly one can suggest that dressings should not have WVTR's which exceed 2000 - 2500 $g.m^{-2}.24h^{-1}$ but should have a rate which is close to the lower limits of this range. This assumes that the production of water will remain unchanged once the dressing is in place. As yet we do not know if this will be the case.

5.6.1 Control Materials.

Vigilon, Vigilon coverfilm and Stretch'n'Seal were used as control materials, to check on experimental technique, since they have been the subject of recent research (Wong 1980; Rahman 1982). The respective WVTR of 168 +/- 32, 139 +/- 23 and 326 +/- 44 $g.m^{-2}.24h^{-1}$ found here are consistent with the results of previous workers. The Vigilon values differ slightly and this may have occurred due to the

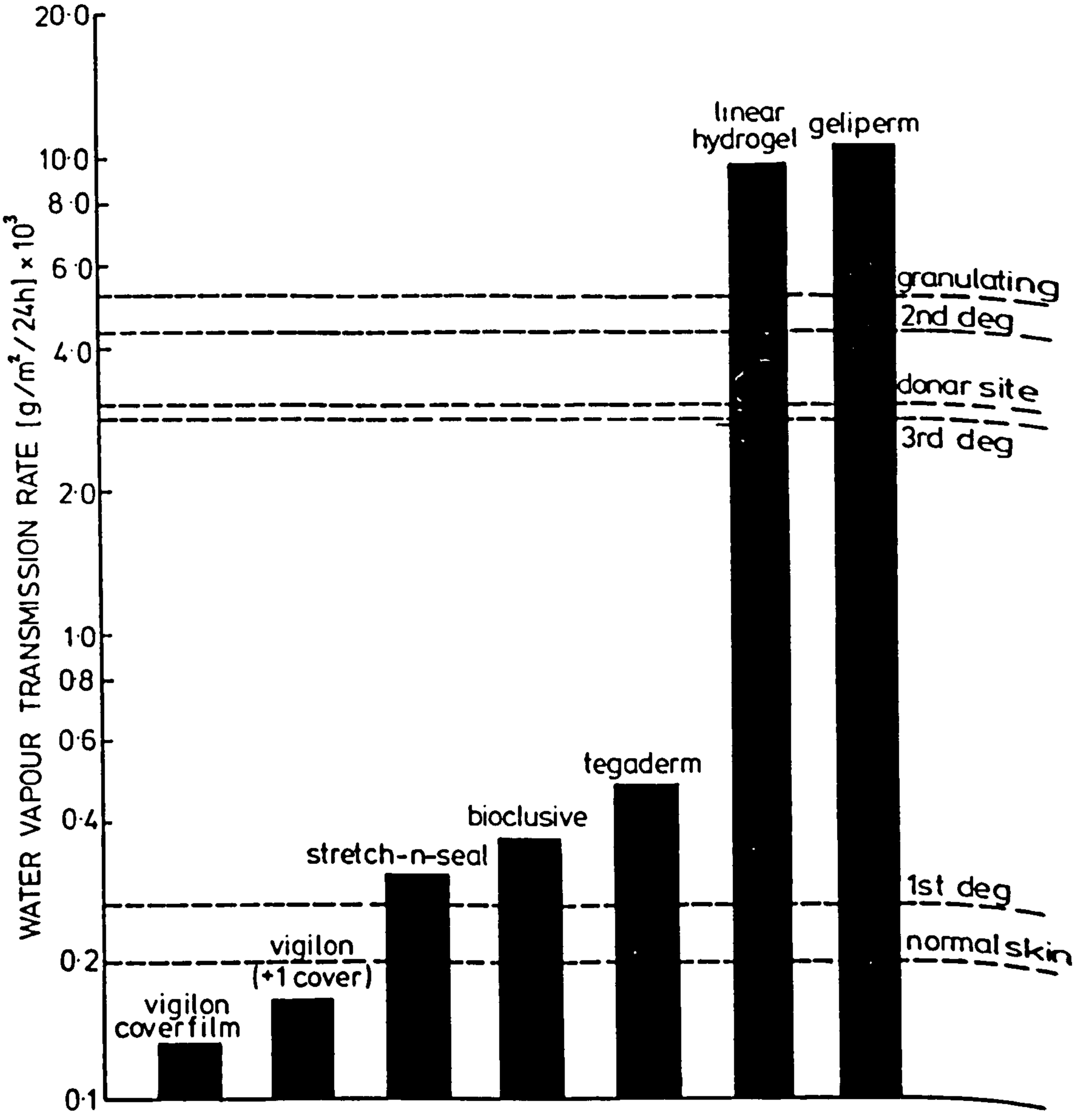


Figure 5.8

The Water Vapour Transmission Results.

very small incremental change in weight per unit time observed for this material. Other differences between materials are due to the test conditions employed or different specimen thicknesses (Table 5.6).

All of the above materials have very low water vapour transmission rates (Fig 5.8) which can lead to clinical problems due to the build-up of exudate below the wound dressing. Such a buildup can create three main clinical problems. The first is that of a back pressure effect on the wound due to the material resistance to transmit water in the liquid form. This would cause considerable pain to the patient especially if the wound was partial thickness. Secondly, leakage from the edge of the dressing may be associated with certain types of dressing. Edge leakage may be encouraged by an exudate pocket, in a bid to relieve the pressure associated with exudate buildup. This exudate accumulation can result in the maceration of the healthy surrounding tissue, causing pain and discomfort to the patient. Lastly, wound edge exposure may be a problem due to the movement of the dressing in accommodation of the fluid build-up. Thus the wound edges would be open to dehydration and the bacterial barrier provided by the wound covering would be broken.

Material	Thickness (mm)	RH (%)	WVTR ($g.m^{-2}.24h^{-1}$)	Method
Stretch'n'Seal (this study)	0.01	35	326 +/- 44	Inverted
Stretch'n'Seal (Rahman,1982)	0.01	35	330 +/- 28	Inverted
Clingfilm (Wong, 1980)	0.0141	38	266 +/- 6	Inverted
Stretch'n'Seal (Park et al,1978)	-	40	307 +/- 32	Water Cup
Vigilon (+cover (this study)	1.15	35	168 +/- 32	Inverted
Vigilon (+cover (Rahman,1982)	-	34	24	Inverted
Vigilon Cover (this study)	0.03	35	139 +/- 23	Inverted
Vigilon Cover	0.03	34	24	Inverted
Tegaderm (this study)	0.03	35	470 +/- 41	Inverted
Opsite (Wong,1980)	0.07	38	533 +/- 21	Inverted
Opsite (Park et al,1978)	-	40	417 +/- 25	Water Cup

Table 5.6

Comparison of results with previous workers.

The Tegaderm wound covering assessed could also be regarded as a control as the manufacturers claim that the material is similar to Opsite (Smith and Nephew, Ltd.). The WVTR obtained for this material was 491 +/- 44 $g.m^{-2}.24h^{-1}$ which is about 4% less than the value for Opsite obtained in Wong's (1980) study (Table 5.6). The Tegaderm dressing would however be prone to the same clinical problems as the dressings above, since the WVTR of this dressing is low. One would expect Tegaderm to have half the transmission rate exhibited by Opsite since the latter material is over twice as thick as Tegaderm. As this was not observed it would suggest the presence of a rate controlling boundary layer on the chamber side next to the dressing. Given the low WVTR of both materials this hypothesis is unlikely and the claimed similarity in composition of the materials should be questioned.

5.6.2 Film Materials.

Bioclusive proved to have a low WVTR as observed with many of the adhesive type film dressings (5.6.1). Its measured WVTR was 382 +/- 26 $g.m^{-2}.24h^{-1}$ (Fig 5.8) and hence the problems associated with low WVTR's, i.e. fluid accumulation, may be experienced in its clinical use.

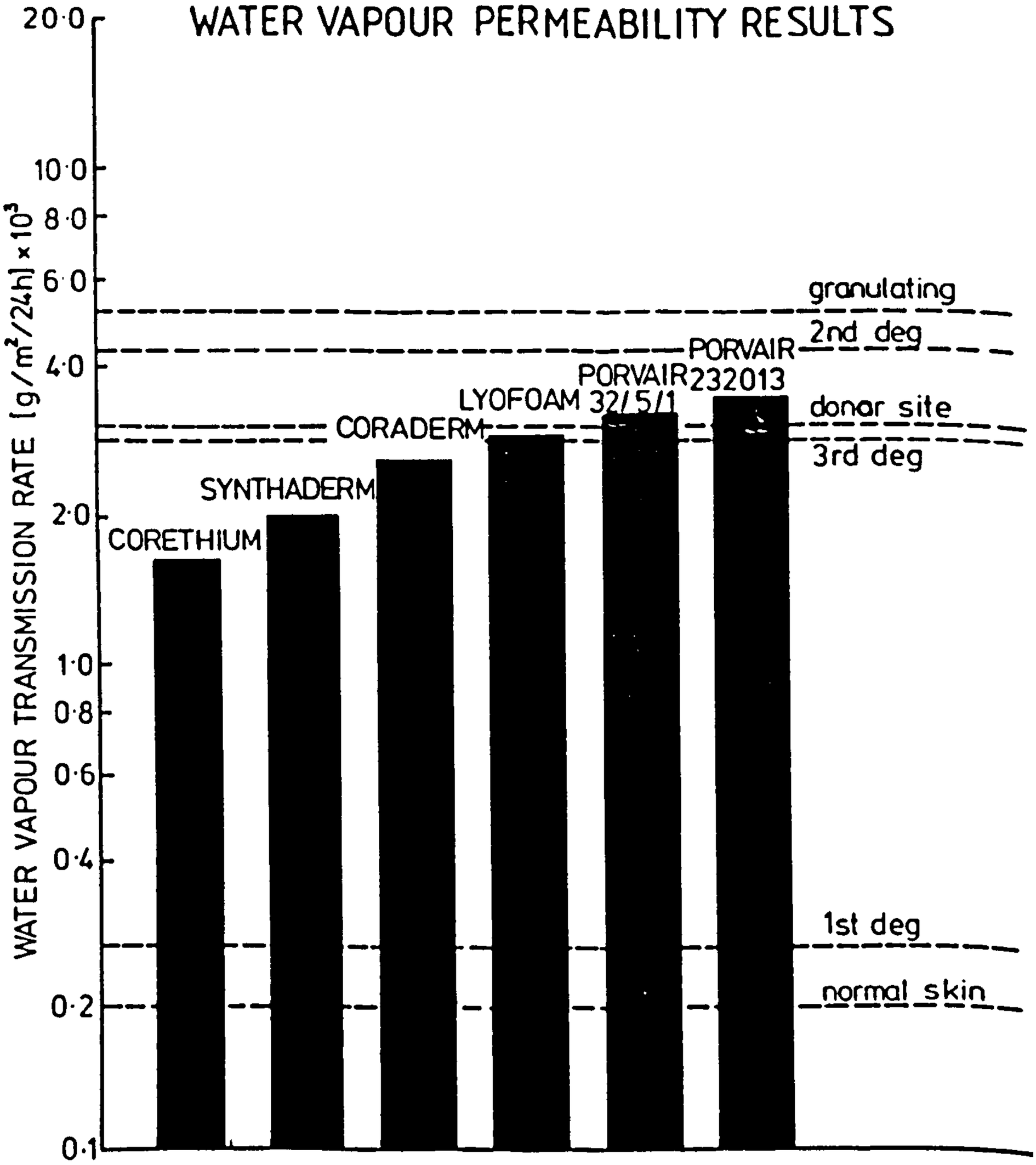


Figure 5.9

The Water Vapour Transmission Results.

Porvair 232013 and Porvair 32/5/1, unlike the other film dressings, have intermediate WVTR's with 3472 +/- 109 and 3302 +/- 165 $g.m^{-2}.24h^{-1}$ respectively (Fig 5.9). One reason for this may be due to the fact that neither has an adhesive backing. It is envisaged that few of the clinical problems associated with high and low WVTR's may be experienced. Since these materials are not commercially manufactured or sold as wound coverings, it can only be suggested that they may be suitable materials.

5.6.3 Hydrophilic Type Materials.

In this study, the hydrogels proved to have very high WVTR's e.g.the Non-linear (crosslinked) PEO hydrogel (Strathclyde PEO/4360/2 Molar PPG 425/3 Molar HT/7.5 Molar Desmodur). This leads to problems with the contraction of the membrane due to dehydration. The assessment of this hydrogel on its own could not be carried out.

Geliperm has a slightly lower WVTR (10,973 +/- 995 $g.m^{-2}.24h^{-1}$) (Fig 5.8) and no problems due to membrane contraction were experienced. The value obtained was similar to that which was obtained for a free water surface (10,419 +/- 689). A student 't'-test showed no significant difference (at 2.5%

level) between the two values. It can also be shown that the increase in relative humidity observed during the free water tests will give rise to a lower WVTR. Therefore the values obtained can be considered as similar WVTR's.

The linear polyurethane hydrogel had a lower value 9850 +/- 1240 (Fig 5.8). However the value is still much greater than the required level of 2000-2500 $g.m^{-2}.24h^{-1}$.

The clinical problems experienced with each material would be very similar due to the nature of their WVTR characteristics. The very high values may lead to the total dehydration of the wound surface. Gel dehydration may also occur and in this case the dressing would adhere to the wound surface. Due to the gel dehydration, the dressing would probably shrink and wound edge exposure would occur, breaking down the bacterial barrier.

In the literature, it was found that many clinicians fix the hydrogels on to the wound using a two way stretch adhesive bandage (Browne 1984). The material used in this study was Mefix. Since this material generally covers the surface of the gel, the WVTR in such circumstances is due to a combination of both the Mefix and the hydrogel. Therefore, the

hydrogels were also assessed in combination with a Mefix top layer. The physical effects of this adhesive top layer on the burn wound dressings are discussed in Chapter 9.

5.6.4 Foams.

Lyofoam was found to have a WVTR of 3052 +/- 684 $g.m^{-2}.24h^{-1}$ which is close to the desired range of 2000-2500 $g.m^{-2}.24h^{-1}$ (Wong 1980).

Coraderm had a similar transmission rate, having a value of 2859 +/- 296 $g.m^{-2}.24h^{-1}$, to Lyofoam being slightly higher than the desired range.

Synthaderm the third foam material tested had a WVTR (2005 +/- 203 $g.m^{-2}.24h^{-1}$) which was at the lower end of the desired range.

Thus all the foam type materials have WVTR's (Fig 5.9) around the desired range. In all probability, the clinical problems associated with the dressings having high and low WVTR's (i.e. dehydration and accumulation) may not be experienced with the clinical use of the foam materials.

5.7 In Vitro Determination of WVTR using Human Plasma

This set of experiments was designed to determine the difference, if any, between the WVTR using plasma rather than water, since in the clinical environment the dressing is in contact with plasma. Human Plamsa (Australian Antigen screened) was supplied by the Blood Bank, Glasgow Royal Infirmary.

The procedure followed was virtually identical to that given in Section 5.4. However due to the fact that the plasma was of human origin several safety precautions were instituted.

These precautions were as follows :

1. on all occasions when handling plasma disposable gloves were worn;

2. the cups were filled with plasma and the wound dressing placed in to position to give a sealed system. This operation took place in a designated biological tissue handling area;

3. the outside of the cups were swabbed down with Cidex or an equivalent;

4. the cups were carried to the oven chamber in a spill tray;

5. the cups were placed in the humidity chamber and the experiment performed as in Section 5.4, with the rotating platform placed on the spill tray to catch any plasma released due to cup leakage;

6. the cups were carried back to the designated handling area as in (4); all glassware, cups etc., were washed with Cidex or an equivalent after use;

7. the plasma was disposed of by the addition of chloros (10% solution) and subsequent flushing to a designated waste pipe.

5.7.1 Results

The results for the above experiments were derived in exactly the same manner as in Section 5.5. The calculated results can be found in Table 5.7 and sample graphs in Figure 5.8.

To determine the difference, if any, between the values obtained using water and those using plasma, a student 't' test was performed and the results derived can be found in Table 5.8.

Material (n)	Thickness (mm)	RH (%)	WVTR ($g.m^{-2}.day^{-1}$)	Mean +/- 1SD
Stretch	0.01	35	282	
'n'	0.01	35	307	
Seal	0.01	34	280	
(4)	0.01	34	318	297 +/- 16
Geliperm	1.40	34	4434	
+	1.77	34	4173	
Mefix	1.42	34	3964	
(4)	1.42	33	5000	4393 +/- 388
Tegaderm	0.03	33	504	
(4)	0.03	34	465	
	0.03	34	460	
	0.03	34	400	457 +/- 37
Vigilon	0.03	34	96	
Cover	0.03	34	111	
Film	0.03	33	82	
(4)	0.03	33	81	93 +/- 12

Table 5.7

Water Vapour Transmission Rates using plasma in place of water.

Material (n)	WVTR (water) ($g.m^{-2}.day^{-1}$)	WVTR (plasma) ($g.m^{-2}.day^{-1}$)	Significance Level
Stretch 'n' Seal (4)	326 +/- 44	297 +/- 16	No sig dif at 5% level
Geliperm + Mefix (4)	3897 +/- 464	4393 +/- 388	No sig dif at 5% level
Tegaderm (4)	470 +/- 41	457 +/- 37	No sig dif at 5% level
Vigilon Coverfilm(4)	139 +/- 23	93 +/- 12	Sig dif at 5% level

Table 5.8

Comparison of the WVTR's of the materials using water or plasma.

5.7.2 Discussion

The statistical tests have shown that there is no significant difference between the water vapour transmission rate of a dressing when in contact with plasma rather than water (Table 5.8).

However the result for Vigilon Coverfilm shows a significant difference at the 5% level. This difference is probably due to inaccuracies in the weighing of the cup as the incremental change is small for this dressing, rather than a property of the material.

Since the results obtained are not significantly different from those using water, this indicates that the test can be performed using either. Hence the problems associated with each material as described in Section 5.6 hold for the clinical situation when the material is in contact with plasma.

5.8 A Clinical Investigation of Evaporative Water Loss.

5.8.1 Introduction.

Several researchers are studying the preclinical assessment of wound coverings (Park, 1978; Wong, 1980; Rahman, 1982; Lawrence, 1984; Turner, 1984; Thomas, 1984 and Turner, 1985). The experimental conditions for evaporative water loss vary quite markedly from group to group. A clinical trial was undertaken to determine if the *in vitro* test conditions of this study were representative of those found *in vivo*.

Turner (1985) has expressed concern that protein adhesion, during the first six hours of treatment, will reduce the WVTR of the dressing being utilised. He expressed particular concern on the use of adhesive dressings as protein deposits may adhere to the adhesive layer. Several reports have shown that protein adhesion (adsorption) to artificial surfaces is rapid from protein solutions (Brash and Lyman, 1969; Berger and Salzmann, 1974; Bagnall, 1978; Chan and Brash, 1981), plasma (Vroman et al, 1972) or whole blood (Gendreau et al, 1981). However the effect of the protein layer on the transmission characteristics has not been reported and hence was studied.

After a preliminary study, using a plasma reservoir in place of the distilled water reservoir (Section 5.7), a short clinical study was undertaken to establish the significance of protein adhesion. The dressings utilised in this study were subsequently assessed for protein adhesion.

The assessment method used was scanning electron microscopy. On comparison with control micrographs (water contact), it was hoped that it could be determined if protein had or had not adhered to the dressing material. However this technique is insensitive with regards to the detection of protein deposits. With regards to the Tegaderm dressing however this technique gave some useful information on the role of necrotic skin adhesion.

The clinical study undertaken should provide a correlation between the *in vitro* and *in vivo* measurement of evaporative water loss through the dressing materials.

5.8.2 Materials.

Due to the limitations of patient availability only three of the dressings described in Chapter Four were evaluated clinically.

The materials chosen for assessment were Geliperm (Section 4.5), Lyofoam (4.6) and Tegaderm (4.7). The selection of these materials was based on the following :

(a) they have high, intermediate and low WVTR's respectively;

(b) they belong to different material classes;

(c) Tegaderm is adhesive whilst the others are non-adhesive.

5.8.3 Experimental Procedure.

(a) Clinical Protocol.

(i) The medical staff applied the dressings according to the protocol detailed by the manufacturers. In the case of the non-adherent dressings, these were secured by perimeter fixation (i.e. around the edges) using the adhesive dressing, Mefix.

(ii) The dressings were only left in place for the duration of test, minimising the disturbance to normal nursing procedure.

(iii) Upon daily examination the following tasks were carried out by the investigator with the assistance of the medical staff when ethically required.

1. While in situ the dressing was photographed.

2. The evaporative water loss through the dressing was measured over a period of four hours, every thirty minutes.

3. A brief description of the general state of the wound, the patient's health and the causes of injury were provided by the clinician in charge.

4. In addition to the injured areas being dressed, an area of intact skin was also dressed with the wound covering, providing a control site.

(b) Measurement Procedure.

(i) The patient was assessed in the shock room or screened from the general ward environment to prevent any air fluctuations.

(ii) The evaporimeter (Section 5.2.2) was switched on and allowed to stabilise for a period of 15 minutes. The apparatus remained on for the duration of the test.

(iii) The evaporimeter was placed on an area of open wound (in the case of the transparent dressings) or on a premarked spot (in the case of the non-transparent dressings).

(iv) The WE switch was depressed and then the range button, giving an effective range of 0 to 100 $g.m^{-2}.h^{-1}$. After the digital reading had stabilised (about 10 s), time averaging of the reading was selected (by electronic filtering) and the evaporative water loss reading recorded.

(v) The RH was then measured by depressing the RH button and after a 10 second stabilisation period a value of RH was recorded.

(vi) The temperature was determined by depressing the CAL and P (partial pressure) buttons which, by means of a conversion chart, gave a temperature measurement.

(vii) Dependent on the number of test sites per patient, procedures (iii)-(vii) were repeated.

(viii) The above procedures were carried out every thirty minutes.

(c) Preparation and Examination by Scanning

Electron Microscopy.

The dressings once removed from the patient were cut into small pieces (lcm x lcm) and placed in formaldehyde to fix any tissue matter which might be present. After a minimum period of 24 h, the specimens were dehydrated by using a series of alcohols (i.e. from distilled water to 75% alcohol to 100% alcohol). The specimens were allowed to air dry and then prepared in the following manner :

1. The specimens were secured to the microscope stubs, right side up (i.e. surface to be studied), by means of double sided adhesive tape.

2. The edges of the stubs and the dressing were coated with conducting cement.

3. The stubs and specimen were given a fine coating of gold.

The specimens were examined by a scanning electron microscope. Magnifications of 20X and 320X were chosen. The results of these studies are presented and discussed in the following sections. Results are presented only for Tegaderm as the test generally proved insensitive with regards to the

detection of protein layers.

5.8.4 Results

The results obtained during the clinical study were generally derived by direct measurement. The evaporimeter reading of the WVTR was multiplied by 24 to give the same units for both the laboratory and clinical studies. The temperature values were obtained by means of the conversion chart given in Appendix 14.

The clinical values obtained are presented in Table 5.9. Three patients were studied and on each burn area eight different spots were chosen for measurement (Table 5.13).

Material (n)		WVTR ($g.m^{-2}day^{-1}$)	Room Temp (oC)	Room RH (%)
Geliperm (8)	Day 1	1938 +/- 67	25 +/- 1.3	28.8 +/- 4.6
	Day 2	1827 +/- 139	24 +/- 2.1	26.7 +/- 1.9
Lyofoam (8)	Day 1	1546 +/- 91	24 +/- 2.4	22.5 +/- 2.5
	Day 2	1367 +/- 199	23 +/- 2.0	21.8 +/- 2.0
Tegaderm (8)	Day 1	127 +/- 36	-	-
	Day 2	214 +/- 86	-	-

Table 5.9

Clinical Data Obtained for Three Dressings

Material	WVTR (clin)* ($g.m^{-2}.day^{-1}$)	WVTR (lab) ($g.m^{-2}.day^{-1}$)	% Diff
Geliperm	1883 +/- 78	3543**	47
Lyofoam	1457 +/- 127	3052 +/- 684	52
Tegaderm	171 +/- 61	491 +/- 44	65

Table 5.10

Comparison of the Clinical and Laboratory Data

* mean of Day 1 and Day 2 as in Table 5.9

** calculated value from the rate for Geliperm Dry.

5.8.5 Discussion

The object of the clinical study was to establish clinical criteria and to correlate the laboratory and clinical findings. The comparative results are presented in Table 5.10.

WVTR Results

As can be seen from this table the percentage difference between the *in vitro* and the *in vivo* values range from 47 - 65%.

The difference observed arises in part from the differing air velocity conditions adjacent to the dressing surfaces. For the *in vitro* testing a fan stirs the internal environment of the chamber to prevent the build-up of water vapour around the open area of the test dish (i.e the dressing surface). There will be small convection currents around the patient in the clinical situation. However to the author's knowledge, no research group has studied local air flows (stirring motions) within a typical Burns Unit ward, and hence a comparison between the velocities in both situations cannot be drawn.

The use of the Evaporimeter probe also predisposes the WVTR measurement to the situation where local stirring is very small. It is most likely that velocities within the chamber are much higher accounting for some of the differences observed clinically. Another factor having an influence, on the WVTR measurements, is the local air temperature. If the material obeys an Arrhenius type relation for water vapour transport then :

$$WVTR \propto \exp\left(\frac{k}{T}\right)$$

The local temperature is very much lower in the clinical situation and subsequently the WVTR measured is lower (provided that the RH driving force is similar).

Other findings during this clinical study will allow further optimisation of the <u>in vitro</u> test. The room temperature and humidity found during these studies were between 23°C and 25°C and 21% to 29% respectively (Table 5.9). These are different to the <u>in vitro</u> test conditions and hence these should be changed to accommodate the clinical values observed.

During the clinical studies temperature and humidity values were also measured at the dressing surface. These values are presented in Table 5.11. They are presented to show how the local temperature and

MATERIAL (n)	DAY	TEMPERATURE (°C)	R.H. (%)
Lyofoam (8)	1	25 +/- 0.4	71 +/- 3
	2	24 +/- 0.4	71 +/- 5
Geliperm (8)	1	25 +/- 0.2	83 +/- 2
	2	23 +/- 0.6	78 +/- 3
Tegaderm (8)	1	-	33 +/- 2
	2	-	35 +/- 3

Table 5.11

Temperature and Humidity Measurements

at the Dressing Surface.

relative humidity at the wound dressing surface are higher than the room values. In the case of temperature these differences were small. However when considering humidity they are quite large in some cases, particularly with the hydrogel material. This concurs with the concept of reduced local air flow adjacent to the dressing surface.

Effect of Protein Adhesion

The other aim of the clinical studies was to establish the significance of protein adhesion (absorption) on the WVTR of a dressing material when used clinically. As previously discussed some protein adhesion is inevitable with many polymeric materials. However the effect of such adhesion on the transmittivity of these materials is unknown.

The preliminary study (Section 5.7) indicated that protein adhesion does not have an effect on the water vapour transmission characteristics of a dressing material, at least for the four dressings tested.

It may be that some of the differences observed between the clinical and laboratory values may be due to the limitation of transmission by protein adhesion. However the preliminary studies indicate otherwise and

MEASURING SITE	EVAPORATIVE WATER LOSS g/(m2.day)	
	DAY 1	DAY 2
1	144	110
2	110	72
3	118*	264
4	84*	283
5	91*	274
6	180*	240
7	161*	254
CONTROL	77	50
MEAN	121	193

Table 5.12

Clinical results for Tegaderm showing the differences observed between the two days of measurement.

* - obvious necrotic skin adhesion resulting in lower readings.

it seems unlikely.

The SEM technique employed proved insensitive in the detection of the adhered protein layer. This technique however provided an insight into the reason behind the differences seen between the two tests carried out using Tegaderm (Table 5.12).

With Tegaderm a great difference is observed between the measurements taken on Day 1 and those taken on Day 2. Clinical and SEM studies, subsequent to their removal, have shown that this difference was due to the presence of necrotic tissue.

During Day 1 it was observed that the values obtained on open areas, necrotic skin covered areas and intact skin areas were greatly different (Fig 5.11). Removal of the Tegaderm gave a debriding action by removing most of the necrotic tissue present. Hence on Day 2 most of the wound area was open and the measurement values were much higher.

The SEM studies backed this up by showing that on some areas of the dressings taken from Day 1, necrotic tissue had adhered to the surface. From comparison with "normal" controls and those from Day 2 it is clear that necrotic tissue can adhere to the dressing material (Figures 5.12 to 5.16).

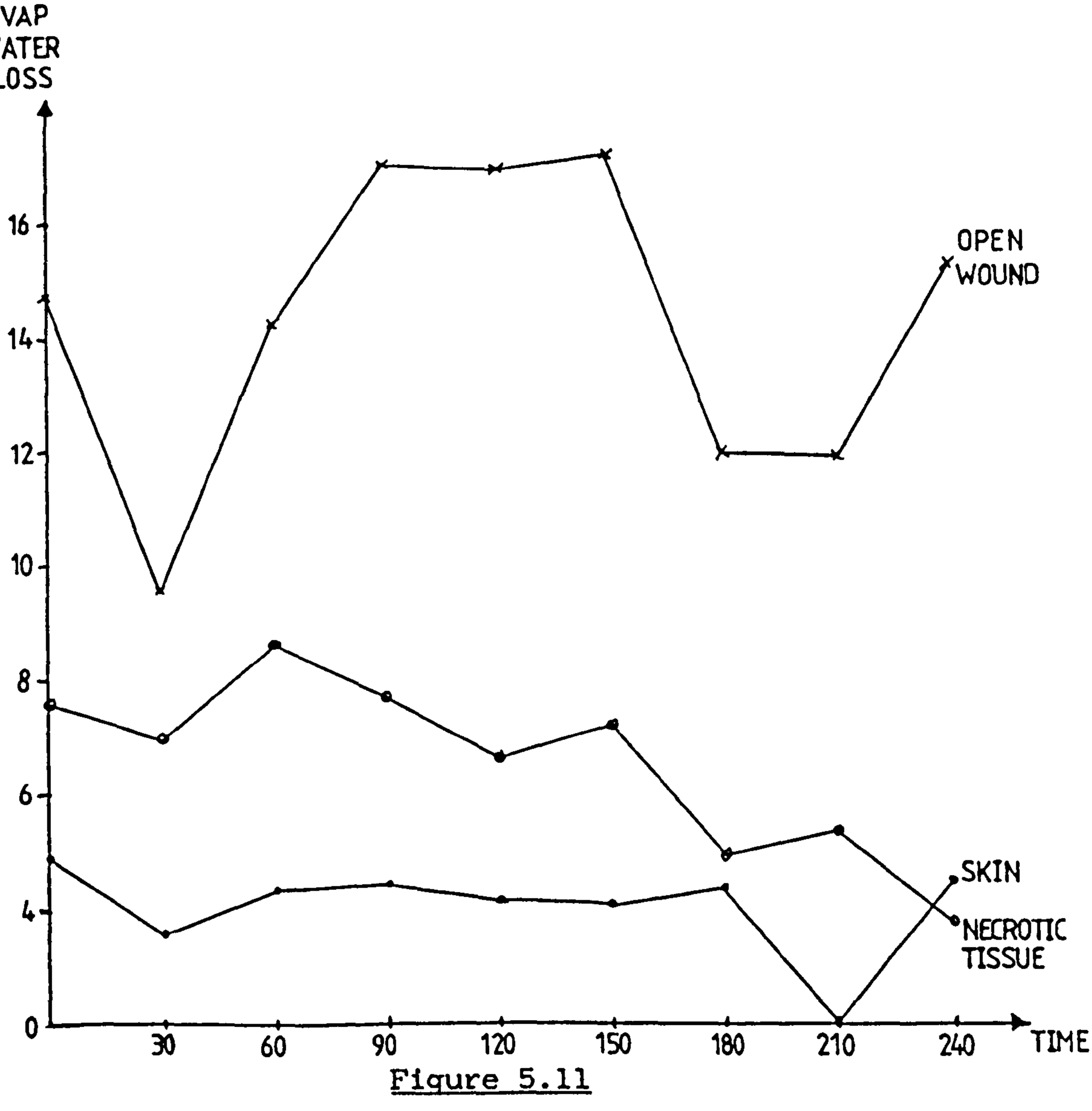


Figure 5.11

Graph showing the shielding effect of adhered necrotic tissue.

From this study it is apparent that this necrotic skin has a shielding effect reducing the transmission through the dressing material.

One advantageous point offered by such adhesion is as a rapid method of debridement (although not in respect of reepithelialisation).

5.8.6 Conclusions

One can conclude from these findings that the *in vitro* evaluation has to be modified to allow any correlation to be drawn between the two situations. One possible improvement would be to adjust local air flow conditions in the environmental chamber to levels typically found in the ward or shock room. Also the Evaporimeter could be employed within the environmental chamber to measure WVTR of the dressing. A comparison could be made with the gravimetric method for WVTR and that given by the Evaporimeter. A further modification would be the imposition of differential temperatures between the test dishes and the chamber environment. This could be achieved by incorporating heating elements in the test dishes.

Patient (Age,Sex)	Type of Burn(s)	Depth of Burn(s)	Total Area of Burning (Region Studied)
1 (16, F)	Second Degree	Mixed	10 % B.S.A. (Upper Back)
2 (23, M)	Second Degree	Mixed	30 % B.S.A. (Right Forearm)
3 (30, M)	Second Degree	Mixed	40 % B.S.A. (Chest)

Table 5.13

Patient Details.

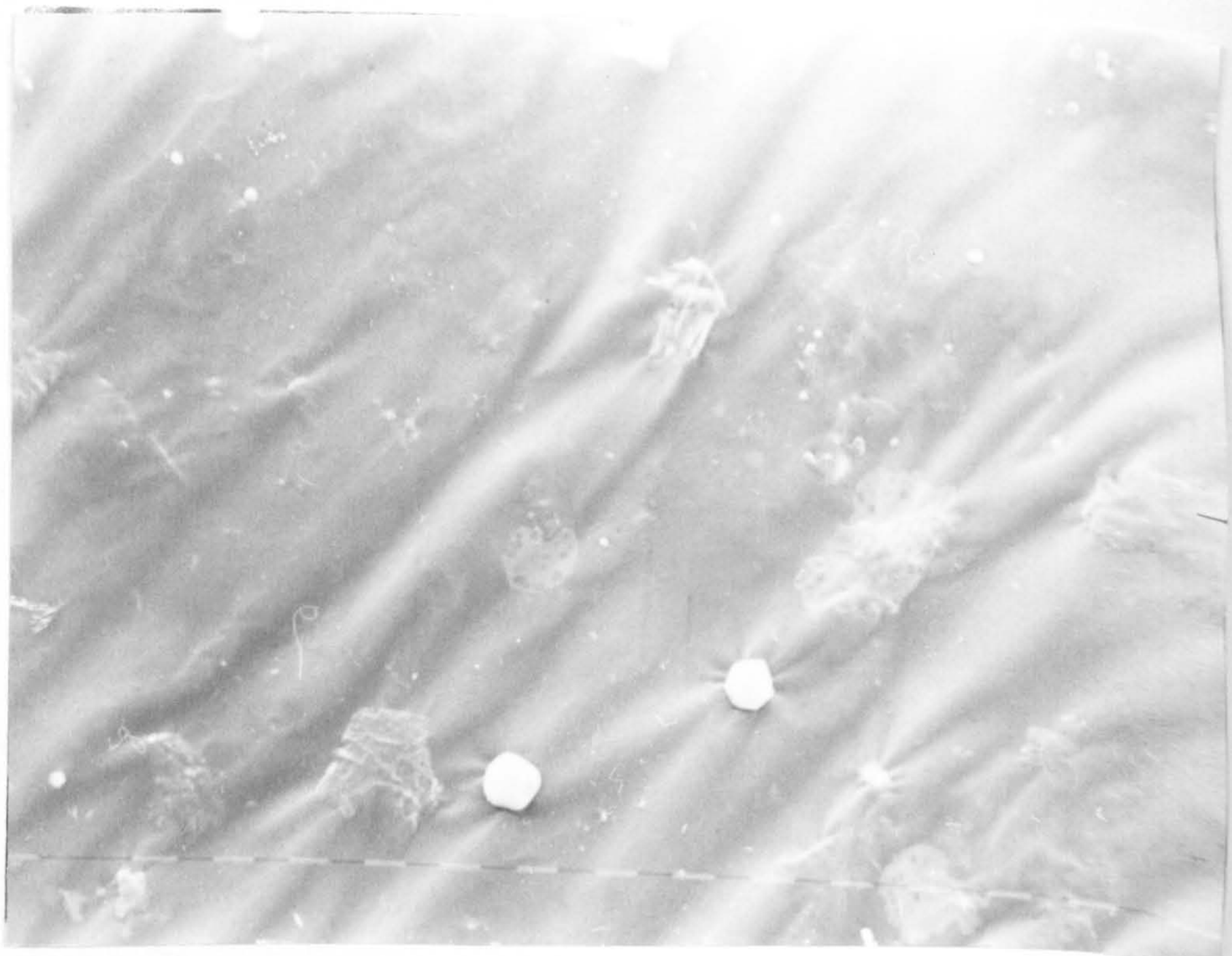


Figure 5.12

Micrograph showing adhesion of dead skin cells from normal, control patch of skin.

(Mag X320)

Figure 5.13

Micrograph of Tegaderm with no obvious skin adhesion. Tracks caused by hairs on skin.

(Mag X320)

Figure 5.14

Micrograph showing obvious necrotic skin adhesion (Day 1).

(Mag X320)

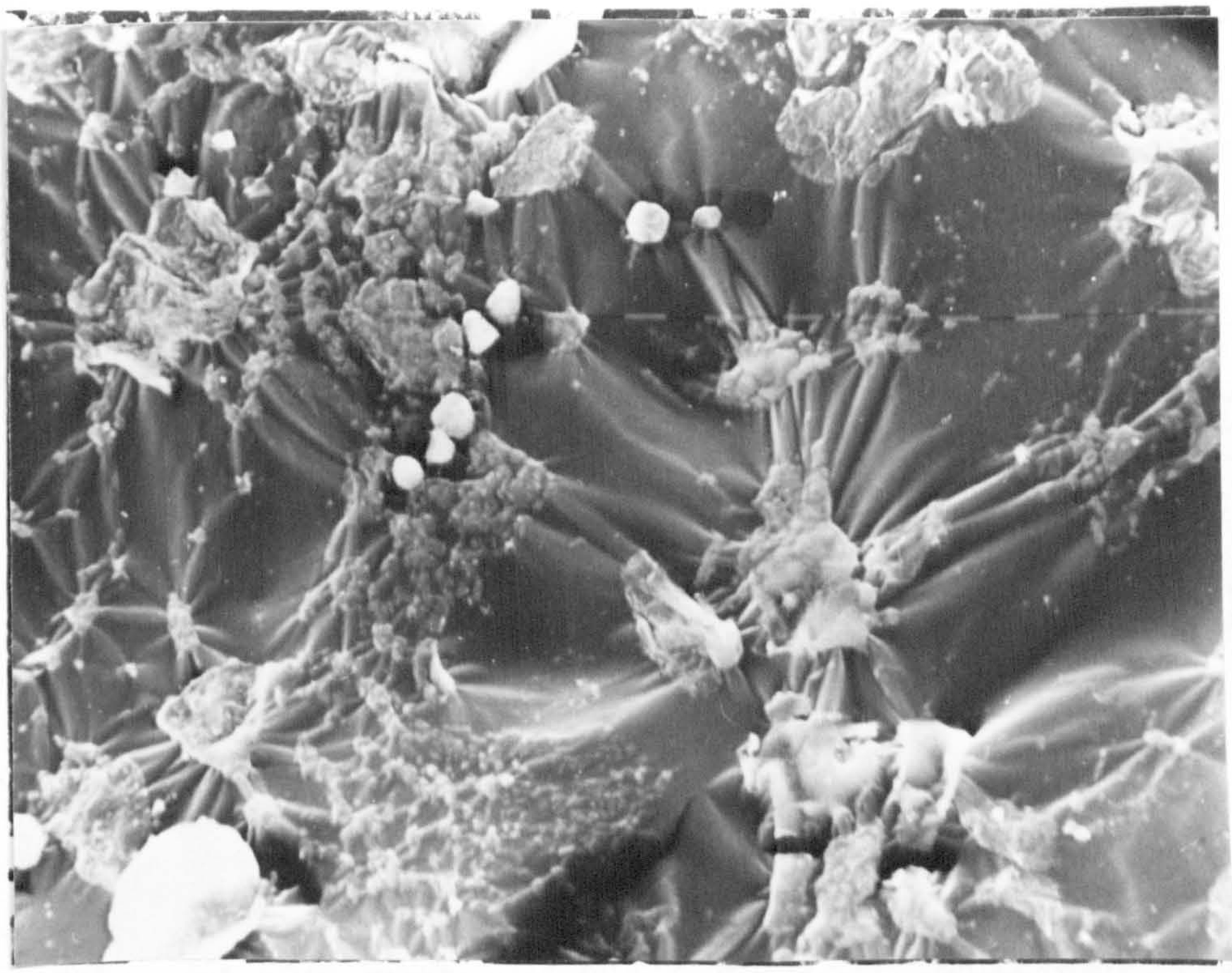


Figure 5.15

Micrograph showing obvious necrotic skin adhesion (Day 2).

(Mag X320)

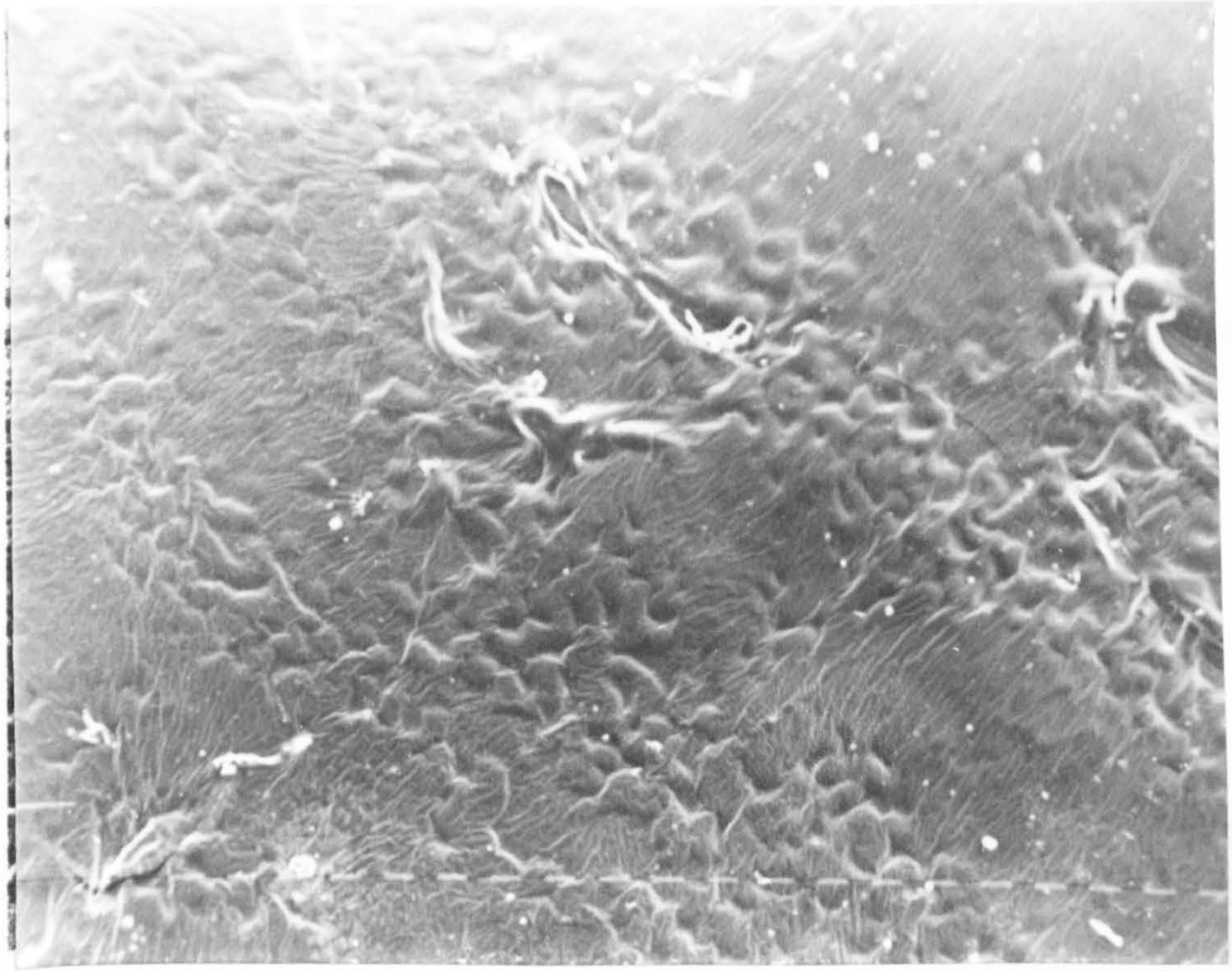


Figure 5.16

Micrograph of control (unused) Tegaderm.

(Mag X20)

CHAPTER 6

Evaluation of Gaseous Transmission (O_2 and CO_2) Through Dressings.

CHAPTER 6

6.1 Introduction

The role of oxygen in wound healing remains a controversial subject. However, several research groups have shown that oxygen is beneficial to epidermal wound healing (Niinikoski and Kulonen, 1970; Hunt and Pai, 1972; Kivisaari and Niinikoski, 1975; Hinmann et al, 1963; Winter, 1972; Silver, 1972 and 1984; May, 1982).

Many groups have also observed that wounds heal poorly at high altitudes where the oxygen tension (P_{O2})is low (Monge and Lui, 1983) and conversely they are difficult to infect, and heal quickly in oxygen enriched environments.

Starr (1932) was probably the first person to apply oxygen-enriched therapy to the treatment of wounds. He introduced an "oxygen boot" for the treatment of gangrene of the feet. It is only recently however that oxygen has been used systematically in the treatment of simple wounds. Hunt and his colleagues (1980 and 1984) found that some wounds heal more rapidly by raising the P_{O2} of the wound as measured by an oxygen electrode.

It appears to be due partly to the enhancing effect of raised P_{O_2} on the ability of phagocytes to destroy invading organisms and partly to the improved energy supply provided by oxidative as opposed to glycolytic metabolism in the synthesis of ATP. Another factor is the requirement of molecular oxygen in collagen synthesis. It has been demonstrated that wound strength and collagen accumulation in experimental (animal) wounds was accelerated when the wound P_{O_2} is raised (Hunt and Pai, 1972; Kivisaari and Niinikoski, 1975).

Silver (1984) recently added to the controversy by publishing work which indicated that increased oxygen may be detrimental to wound healing by inhibiting connective tissue synthesis. Although he has reservations about his results he was inclined to the belief that oxygen enrichment speeds up epidermal healing.

Winter (1972) showed in experimental wounds that if they were covered with a moisture retaining but oxygen permeable covering, the mitotic rate of regenerating epidermal cells is increased by 5 to 10 fold. These findings paved the way for the treatment of wounds, using dressings, while treating the patient in an oxygen enriched environment. Winter (1972) while using the "occlusive type dressings" described

above, artificially raised the oxygen tension around the wound surface by applying pure oxygen to the outside of the dressing. He observed that the rate of healing was greatly improved with the combination therapy. This was confirmed by the work of Silver in 1972 using both clinical and other experimental (animal) wounds. Silver outlined some practical problems with the use of the "occlusive dressings". He proposed that the rapidly regenerating epithelial cells may migrate along the surface of any exudate that might be present, covering the wound, rather than become attached to the surface of the exposed dermis. He concluded that this is due to the characteristic of the migrating cells taking the line of least resistance (Silver, 1984).

While the studies of Winter (1972) seem to indicate that the oxygen enrichment therapy increases the rate of healing, experience with different forms of occlusive dressings in the treatment of indolent ulcers indicated that some wounds can heal more quickly under oxygen impermeable dressings (Silver, 1984). Silver (1972,1984) concluded that where the surface of a wound is moist and relatively free of exudate, epidermal healing is quicker under oxygen permeable occlusive dressings in the presence of oxygen. When large amounts of oxygen consuming

exudate are present, bacteria within this exudate can utilise any free oxygen which passes through the dressing and the epidermis must derive its oxygen supply almost exclusively from the underlying blood vessels.

The repair of connective tissue appears to be a more complicated process when compared to epidermal regeneration. Many factors are important for the repair of connective tissue and although oxygen is certainly one of them, its exact role is unknown. Collagen synthesis and consequently the development of early wound strength has been shown to be critically dependent on oxygen supply (Hunt and Pai, 1972). However, unlike epidermis, fibroblast activity (and subsequent collagen synthesis) is stimulated by moderately elevated P_{O2} only and reduced if the tension is increased further in a wound (Silver, 1984). However Silver (1984) concluded that this may be associated with reduced blood supply, and therefore substrate limitation that occurs in hyperoxygenated tissue, rather than a direct effect of the oxygen on the fibroblasts.

Silver (1984) recently summarised the current situation regarding the use of increased oxygen tension in wound healing as "oxygen access to wounds is biologically normal but it is also normal to have

complex gradients across the surface of the wounds. Occlusive dressings that grossly disturb such gradients are likely to retard healing while those that retain or slightly enhance them have a better chance of being clinically useful".

While extensive research has been carried out on the effects of oxygen on wound healing, very little if any, has been carried out on the effects of carbon dioxide on wound healing.

The author personally feels that the retardation of carbon dioxide loss from a wound bed, may cause a buildup which would result in an acidic environment around the wound site.

In 1973 Leveen et al studied the effect of acidification on wounds. This led an Israeli group (Kaufman et al, 1982,1984 and 1985) to study the effect of topical acidification on the healing of deep partial thickness skin burns. Previous research by this group had indicated that the pH of some local therapeutic agents might effect the healing processes of experimental wounds (Kaufman et al, 1984). Susequently a randomised double-blind study was performed by Kaufman et al, 1985 to determine the effect of pH on wound healing at pH values of 3.5, 7.42 and 8.5.

From this study they concluded that acidification promoted epithelialization and closure of the wounds, without the adversely affecting scar formation. On the other hand alkalinisation hindered epithelialisation and delayed wound closure.

One can therefore say that at least for deep partial thickness skin burns an acidic environment around the wound site is beneficial to the healing of the wound. Therefore it may be that dressings which have low carbon dioxide transmission rates will provide an environment which is conducive to more rapid healing.

It was for the above reasons (i.e. the importance of O_2 and CO_2 in wound healing) that several of the series of dressings studied were assessed in respect to their transmission characteristics.

6.2 Experimental Methods

6.2.1 Materials and their Preparation

Due to the porous nature of some of the dressing materials, several of the dressings described in Chapter 4 were excluded from this part of the study.

The materials excluded were as follows :

1. Foams - Lyofoam, Synthaderm and Coraderm

2. Porcine Xenograft - Corethium

3. Porvair Microporous Materials - Porvair 232013 and 32/5/1

4. The hydrogels supplied by the Pure and Applied Chemistry Department - Linear and Non-linear.

Those materials in 1 to 3 were porous by nature and as such were assumed to permit the free passage of oxygen and carbon dioxide in either direction. To verify this assumption tests were carried out on Lyofoam, alone, and Lyofoam in series with a silicone rubber support (Section 6.4).

The materials assessed in respect of their transmission rates to both oxygen and carbon dioxide were as follows : Tegaderm (Section 4.7); Bioclusive (Section 4.15); Stretch 'n' Seal (Section 4.3); Vigilon Coverfilm (Section 4.4); Lyofoam (Section 4.6); Geliperm (Section 4.5) and silicone rubber support.

The silicone rubber membrane was used as a support to enable adequate sealing in the test system described in Section 6.2.2. It is a Silastic^{R} non-reinforced medical grade sheet membrane (0.25 mm thick) manufactured by Dow Corning Ltd.

The materials were prepared using the metallic, circular template as in Sections 5.3 and 8.3. In the case of adhesive dressings, the dressing was placed on top of the silicone support and the template was used to prepare a disc of the composite material. The other dressings were prepared and then placed on top of the silicone support before sealing of the system.

The hydrogel was prepared by soaking over-night in distilled water and then cutting to size using a scalpel.

6.2.2 Measurement Procedure for Hydrophobic Dressings

The gas transmission rates of the hydrophobic dressings were assessed using the British Standard Method (BS 2782, 1979)(James, 1969). This technique is a gas-gas vacuum method.

The experimental apparatus used is shown in figure 6.1 (a and b). The test gas (O_2 or CO_2) is dried before being passed at atmospheric pressure and

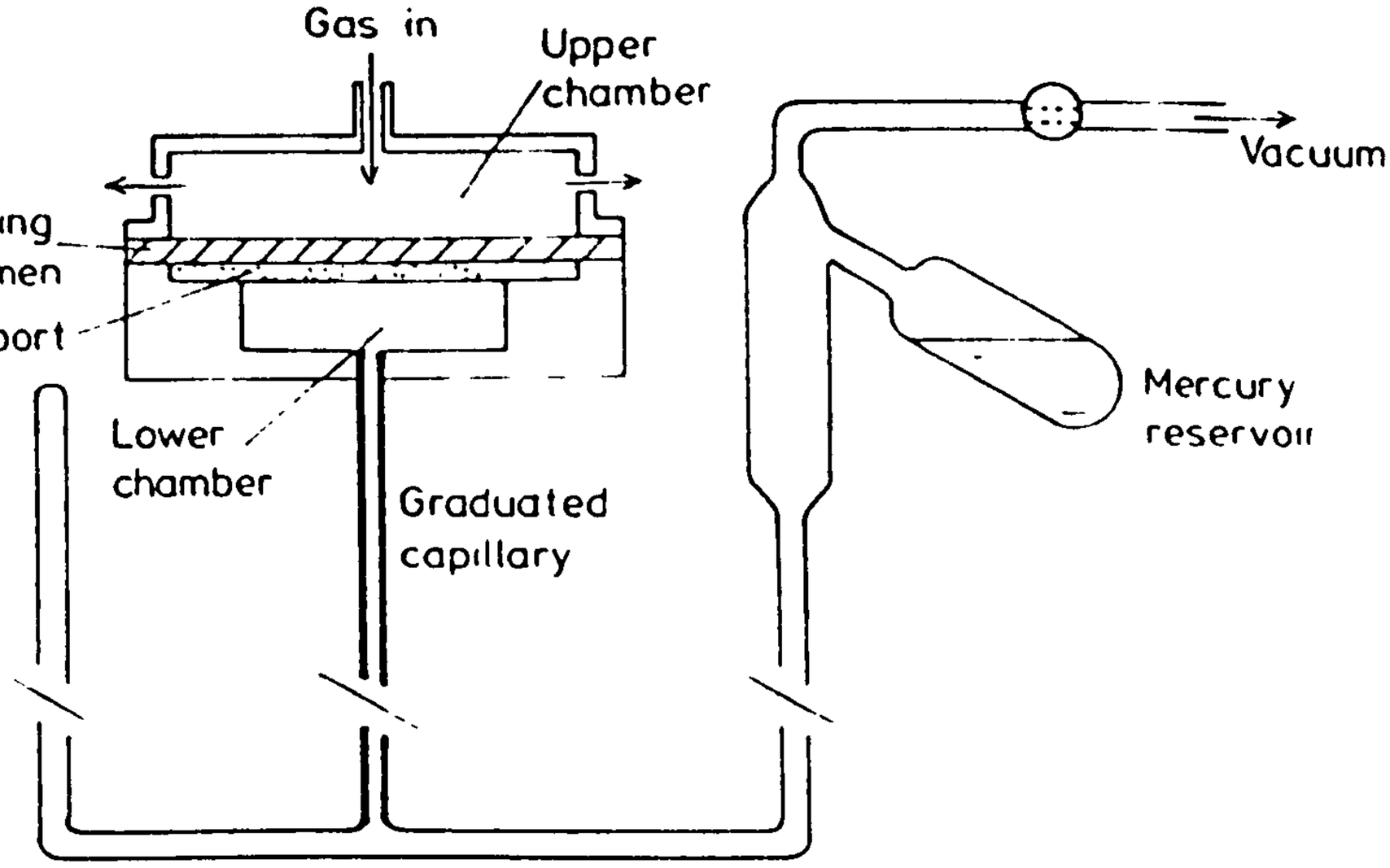


Figure 6.1(a)

Apparatus used for the BS Method of determining Gaseous Transmission.

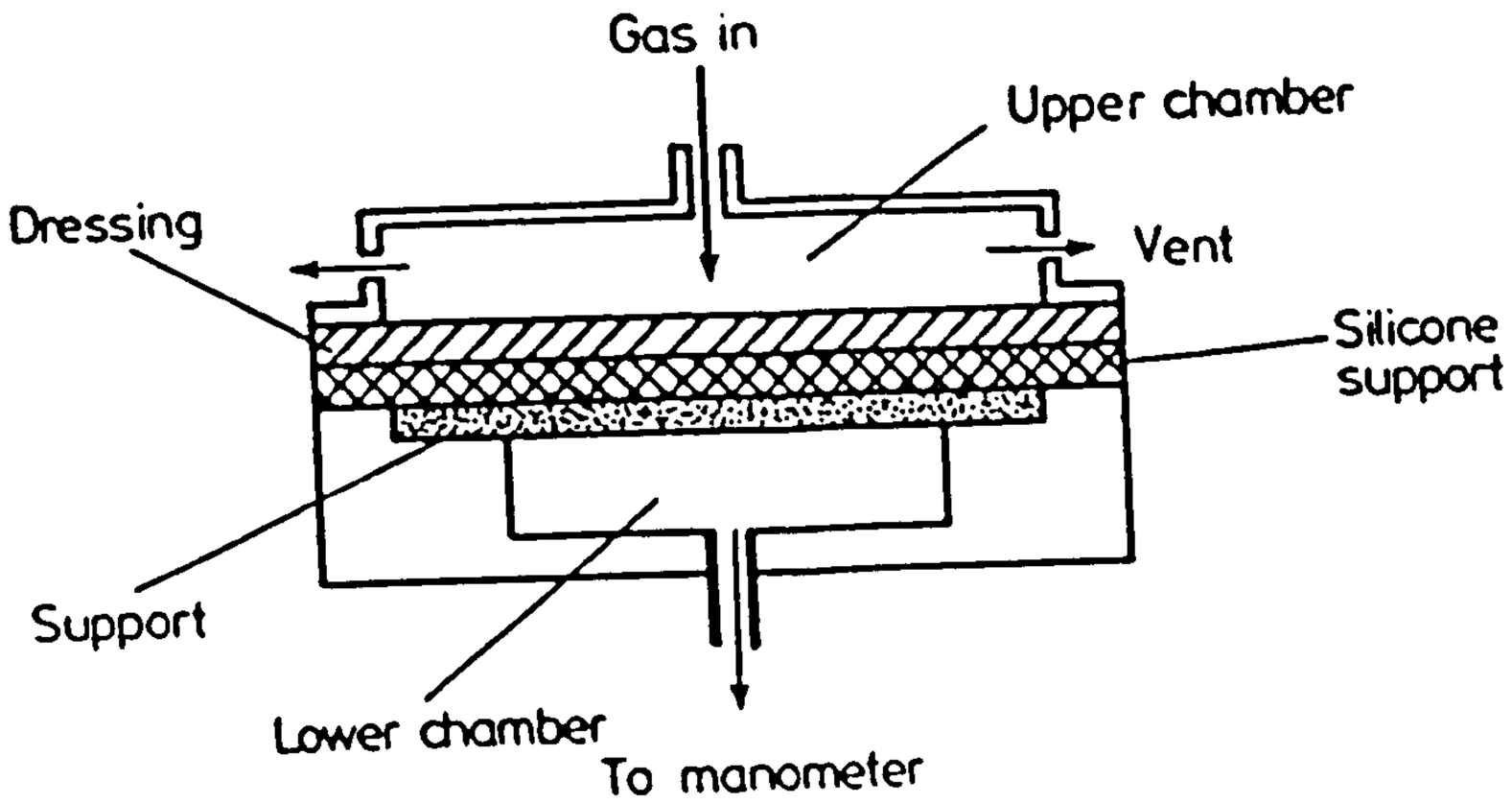


Figure 6.1(b)

Test cell showing the Silicone Rubber Support in position.

room temperature into the upper chamber and allowed to vent freely from this chamber. The test membrane is placed over the silicone support and the composite is supported in the lower chamber by means of a sintered metallic support (either brass or nickel in this study). The composite therefore separates the upper and lower chambers. The lower chamber is evacuated to a pressure of approximately 0.5 mmHg by means of a vacuum pump. The pressure in the vacuum chamber was measured using a McLeod gauge. On attaining the required pressure in the lower chamber the stopcock was closed and the vacuum pump was vented to air and switched off. The apparatus was tilted until the mercury filled both the side tubes and central capillary tube. The apparatus was returned to the upright position and the mercury level within the central capillary noted. An arbitrary zero time was noted about fifteen seconds after the instant when the stop clock was started and the mercury level (h_o) recorded. The mercury level in the central capillary tube was recorded at suitable time intervals, depending on the transmission rate of the material. The time values chosen ranged from 15s to 3min intervals. After recording approximately 10-12 values, the mercury in the system was returned to the reservoir and the system vented to the atmosphere.

6.2.3 Experimental Procedures for Hydrophilic Dressings

Due to the material nature of the dressings in this category (mainly hydrogels) the gas-gas vacuum method cannot be utilised to determine the gas transmission rate. The fact that these materials are hydrated excludes them from vacuum analysis. Instead methods using liquid in contact with one side of the material and gas on the other side were employed. These techniques have been developed by Keller and Shultis (1979) and Wong (1984).

Keller and Shultis measured oxygen transmission through homogeneous and microporous type membranes. They used a combination of high speed stirring and a catalysed sodium sulphite reaction in the liquid phase to reduce the liquid boundary layer resistance to a minimum. The transmission rate was determined by a manometric system, measuring the decrease in pressure in a closed volume of the gas phase at regular time intervals. Further information on this method is given by Shultis (1979). The method of Keller and Shultis depends on the scavenging reaction taking place. This sulphite reaction is very easily contaminated. Problems arising due to contamination prevented the oxygen transmission characteristics of

Geliperm from being measured.

As part of his Ph.D. research in the Bioengineering Unit, Wong (1984) developed a gas-membrane-liquid method for assessing the carbon dioxide transmission through membranes for blood-oxygenator applications. A modification of Wong's technique was used in this study and is described below.

The test system (Figure 6.2) employs a dynamic test cell (Gaylor, 1970) which is commonly used for measuring the diffusion resistances of haemodialysis membranes. The cell consists of two compartments which are separated by the dressing or membrane under test. Each compartment is filled with a 95% void volume open pore nickel foam. This acts as a membrane support and as a turbulence generator for the NaOH solution which is circulated at 4 l/min through one of the compartments. The other compartment contains CO_2 gas. Liquid boundary layer resistance is negligible due to the NaOH reaction with CO_2 coupled with the flow turbulence. The rate of CO_2 transmission across the membrane is measured by the rate of change in volume of CO_2 gas supplied to the cell from a calibrated glass cylinder. The change in gas volume is determined by the rise in level of water within the cylinder. A gas impermeable pipe conects the other

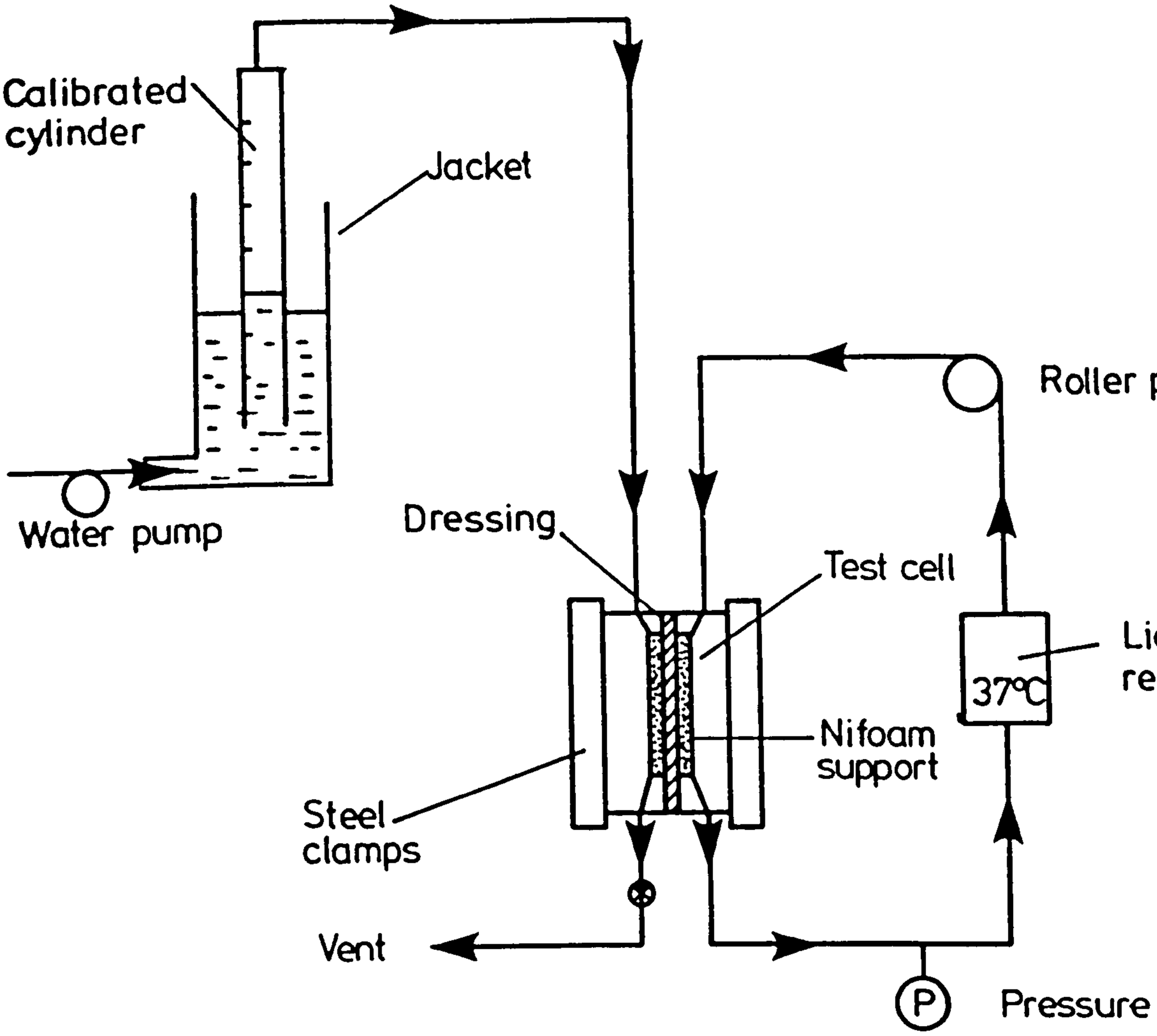


Figure 6.2

Liquid/Gas Experimental Set-up.

end of the cylinder to the test cell. The CO_2 partial pressure in the cylinder is maintained at atmospheric by pumping water into the jacket which surrounds the cylinder such that the water levels inside and outside the cylinder are equal.

In the initial tests the NaOH had an effect on the structure of the hydrogel. Subsequent tests utilised a Celgard microporous hydrophobic membrane placed between the hydrogel and NaOH solution. From studies with the Celgard membrane alone (Wong, 1984), the resistance to CO_2 transfer it imposes is negligible compared to that of the hydrogel.

The duration of the experiment is about 20 minutes. The procedure for each test can be summarised as follows :

1. Prepare 1.0 l of 1.0 M solution of NaOH using distilled water and vacuum to remove dissolved gases.

2. Assemble the circuit with the membrane positioned in the test cell.

3. Introduce the reaction solution into the test cell and check for leakage.

4. Flush the calibrated cylinder and gas side of the test cell with CO_2.

5. Close the gas vent on the test cell and start circulation of NaOH solution at 4.0 l/min.

6. Adjust water pump speed to maintain equal levels of water in the cylinder and in jacket annulus.

7. Measure the water level in the cylinder at regular time intervals.

6.3 Theoretical Derivation of Results

6.3.1 Theory and the Calculation of the GTR Determined by the Vacuum Method (James, 1969).

The quantity of gas present in the lower chamber at time, t expressed as a volume in cm^3 at Standard, Temperature and Pressure (273°K, 76 cmHg) is given by:

$$q = V \times \frac{P}{76} \times \frac{273}{T} \quad cm^3(STP) \qquad 6.1$$

where V, P and T are the volume (cm^3), pressure (cmHg)

and absolute temperature of the gas (^{o}K) in the lower chamber.

Thus the rate (dq/dt) at which the quantity of gas in the lower chamber is increasing with time t (hours) is given by :

$$\frac{dq}{dt} = \frac{273}{76T}\left[P\left(\frac{dV}{dt}\right) + V\left(\frac{dP}{dt}\right)\right] \quad cm^3(STP)/hour \qquad 6.2$$

The gas transmission rate of a film, GTR, is defined as the volume of gas at STP which would pass through 1 m^2 of the membrane in one day under steady-state conditions, with a pressure difference of one atmosphere (76 cmHg) across the film. If the rate of transfer (dq/dt) is proportional to the pressure difference between the upper and the lower chambers, S cmHg, it then follows that for A cm^2 of the membrane.

$$\frac{dq}{dt} = \frac{S \times A \times GTR}{76 \times 10^4 \times 24} \quad \frac{cm^3(STP)}{hour} \qquad 6.3$$

Thus combining equations 6.2 and 6.3

$$GTR = \frac{k}{S}\left[P\left(\frac{dV}{dt}\right) + V\left(\frac{dP}{dt}\right)\right] \quad \frac{cm^3(STP)}{m^2.d.atm} \qquad 6.4$$

where

$$k = \frac{273 \times 10^4 \times 24}{T \times A} \qquad \frac{hour}{m^2.d.atm}$$

An arbitrary zero of time, $t=t_o$ is chosen when uniform gas flow has been established and the pressure at this instant is P_o (cmHg)and the volume of the chamber V_o (cm^3). At time t=t, the mercury in the capillary has been depressed by a distance h cm from $t=t_o$ and if A_c is the cross-sectional area (cm^2) of this capillary then equation 6.4 becomes :

$$GTR = \frac{k}{S}\left[(P_o + h)\, A_c\left(\frac{dh}{dt}\right) + (V_o + A_c h)\left(\frac{dh}{dt}\right)\right]$$

which simplifies to :

$$GTR = \frac{k}{S}\left[V_o + A_c P_o + 2A_c h\right]\left(\frac{dh}{dt}\right) \qquad 6.5$$

$S = (P_A - P_o - h)$ cmHg where P_A is the atmospheric pressure (in the upper chamber). Substituting for S in equation 6.5 and integrating over a time interval $t=t_o$ to $t=t_t$, with corresponding values of h given by h_o and h_t cm, it may be shown that :-

$$GTR = \frac{k}{t_t - t_o}\left[-2A_c(h_t - h_o) - \left\{V_o + A_c(2P_A - P_o)\right\}\log_e\left(1 - \frac{(h_t - h_o)}{S_o}\right)\right]\frac{cm^3(STP)}{m^2.d.atm} \qquad 6.6$$

where $S_o = P_A - P_o$ i.e. the driving pressure at time $t=t_o$.

The Gas Transmission Rate (GTR) is then calculated using equation 6.6 by the following method. It is important to record the pressure indicated by the McLeod gauge at the start of the experiment, P_{vac} and the level of mercury in the central capillary, h_{vac} corresponding to P_{vac}. The rate of fall of the

mercury level reading versus time is constructed. The best fit line is drawn through the data points.

Appropriate values for the parameters given in equation 6.6 are as follows :-

P_o = pressure in the lower chamber at t_o

= $P_{vac} + (h_o - h_{vac})$ cm Hg

$V_o = 15.784 + A_c \times h_o$

= $15.784 + 0.0175 \times h_o$ cm^3

$A = 37.39$ cm^2

$A_c = 0.0175$ cm^2

Note : In SI units the GTR is expressed as $fm.Pa^{-1}.s^{-1}$. In terms of the units of GTR used above : 1 cm^3 (STP).$m^{-2}.d^{-1}.atm^{-1}$ = 0.1143 $fm.Pa^{-1}.s^{-1}$

6.3.2 Theory and the Calculation of GTR for the Gas-Liquid Method

The calibrated cylinder has a known cross-sectional area (4.14 cm^2) and therefore the linear displacement of the water level in the cylinder can be related to a gas volume change (provided the cross-sectional area remains constant with length).

From a volume versus time plot, the gradient will give the rate of change of volume. For a transfer area, A and a CO_2 partial pressure driving force ΔP_{CO2}, the GTR is given as :

$$GTR = \frac{V}{A \cdot \Delta P_{CO_2}} \qquad \frac{cm^3(STP)}{m^2 \cdot atm \cdot d}$$

where V is the gradient corrected to STP, cm^3 (STP)/d

$$A = 4.18 \times 10^{-3} \ m^2$$

$$\Delta P_{CO2} = P_{atmospheric}, \ atm.$$

It is assumed that the P_{CO2} of the reaction fluid is zero.

6.4 Results

The results for the series of materials assessed were obtained using methods 6.2.2 and 6.2.3. From the raw data obtained the Gas Transmission Rates (GTR's) for both oxygen and carbon dioxide were calculated using procedures 6.3.1 and 6.3.2.

Due to the large number of tests carried out and the lengthy mathematical derivation of the GTR for the vacuum method a computer program was written to assist with the calculations. The program calculated the GTR from the experimental raw data values, by fitting the best straight line and subsequently using this line to calculate the GTR of the material under test. A copy of this program can be found in Appendix 4. The program is in two sections, the first files and stores the data, (for future reference if required) and the second analyses the data.

In the experimental setup the gas transmission has to take place through two materials, with different transmission resistances in series with each other. By analogy with electrical resistances in series (Squires and Deason, 1974), the overall resistance of the bi-laminate to gaseous transmission is the sum of the individual resistances of the layers. In this context the resistance is equal to the reciprocal of the GTR.

According to this theory one can predict the GTR of the dressing alone with knowledge of the GTR of the underlying support.

$$\frac{1}{GTR_c} = \frac{1}{GTR_s} + \frac{1}{GTR_d}$$

$$GTR_s = \frac{GTR_d \times GTR_c}{GTR_d - GTR_c} \qquad 6.7$$

Subscripts :-

c = composite

s = silicone rubber support

d = dressing

Using equation 6.7 the "true" transmission characteristics of the dressing materials were calculated.

The results obtained for those dressing materials tested can be found in Tables 6.1 and 6.2. These tables give the mean values with their corresponding standard deviation. The raw data values from which these values were obtained are presented in Appendix 5.

MATERIAL	GTR cm3(STP)/(m2.day.atm)*	
	OXYGEN	CARBON DIOXIDE
Silicone Rubber**	67552 +/- 792	339649 +/- 3588
Tegaderm	8012 +/- 1809	55276 +/- 3774
Bioclusive	3297 +/- 350	39022 +/- 2484
Stretch 'n' Seal	9758 +/- 2064	107568 +/- 11273
Vigilon Coverfilm	8088 +/- 1391	29671 +/- 2761
Lyofoam + Silicone	66,737 +/- 4,322	336,598 +/- 5,428
Mean +/- 1 S.D. (n = 9)		

* measurement at 20 +/- 2 ^{o}C

** thickness = 0.56mm

MATERIAL (thickness,mm)	GTR(CARBON DIOXIDE) (cm (STP)/(m2.day.atm))
Geliperm (0.98)	245727 +/- 32529

Table 6.2

Gas Transmission Rate

For the Hydrophilic Material.

(n=9)

6.5 Discussion

As detailed in the introduction (Section 6.1) at the present time there is controversy as to whether the oxygen and carbon dioxide transmission characteristics of dressing materials are of importance to wound healing.

Research has shown (Winter, 1972; Silver, 1972) that an enriched oxygen environment around the wound site is of great benefit in the rapid re-epithelialisation of the injured site. However Silver (1984) has shown that such an environment reduces the speed with which collagen is laid down in the reformation of connective tissue within the wound.

Kaufman et al (1985) have recently shown that the topical acidification of a wound site can be of great benefit to the healing of the wound. Such an environment may be created if a build-up of CO_2 within the wound site were to occur due to the impermeability of the dressing covering the wound to carbon dioxide.

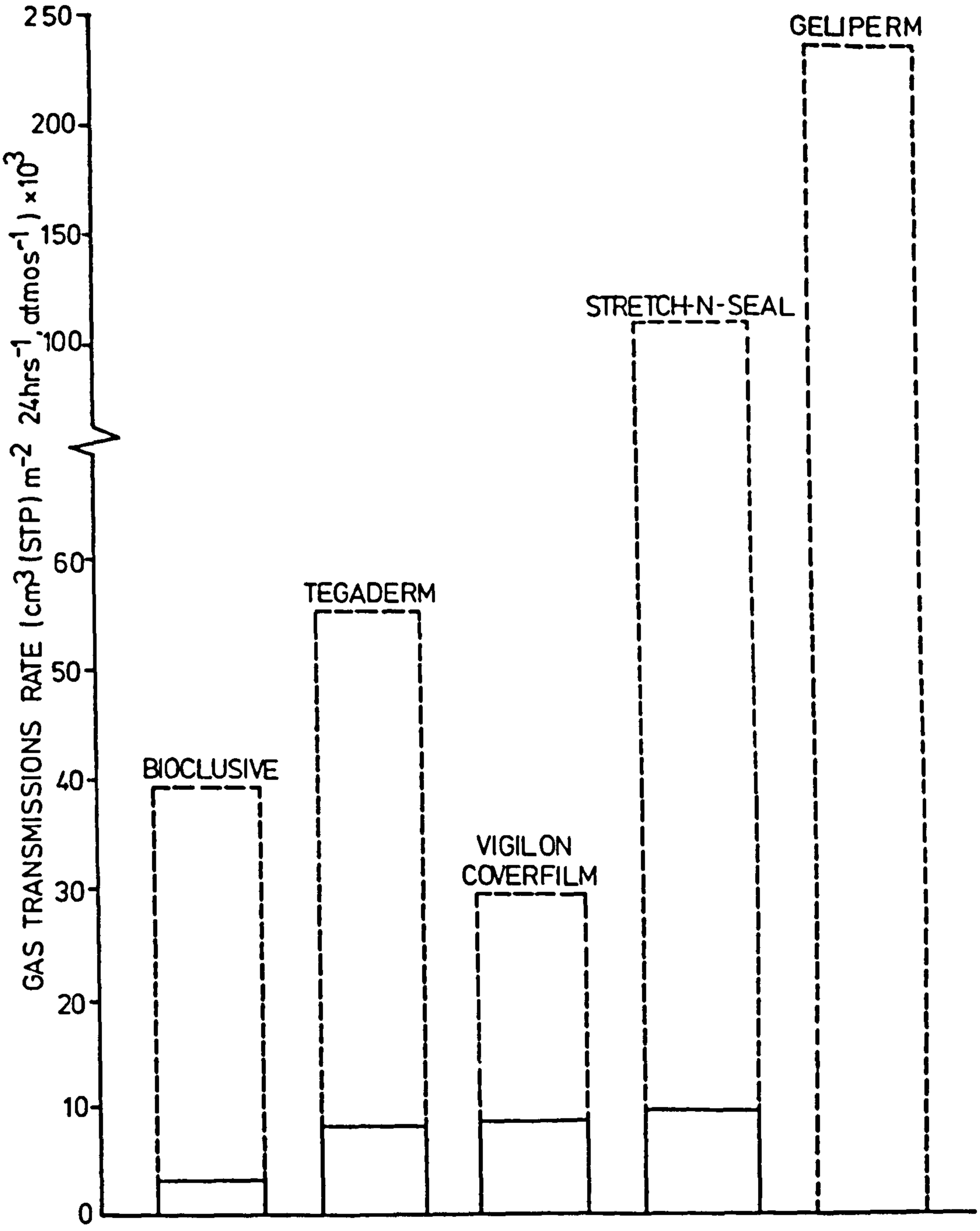
From these research findings it would appear that the "ideal" material may have to be permeable to oxygen whilst impermeable to carbon dioxide. In reality however for most materials the GTR for carbon dioxide is generally 2 - 10 times greater than that for oxygen. Hence if the above situation were "ideal"

then none of the existent dressings could be termed "ideal" with respect to their GTR's.

The information obtained from test methods 6.2.2 and 6.2.3 will be of more consequence clinically once the "desirable" levels of oxygen and carbon dioxide required in wound healing have been established. However at the present time for the purposes of this discussion these tests allow the materials assessed to be compared against each other.

From the results (Tables 6.1 and 6.2) it appears that the film-type and the hydrogels studied, when compared to the silicone rubber, have low oxygen and carbon dioxide rates (Figure 6.3).

In all cases the transmission rates for carbon dioxide were greater than those for oxygen. The adhesive backed dressings (Tegaderm and Bioclusive) proved to be in general less transmissible than the non-adhesive materials (Stretch 'n' Seal and Vigilon Coverfilm). Geliperm had a high carbon dioxide transmission rate in comparison to the film type dressings. If the permeation process through Geliperm is likened to passive diffusion through a stagnant layer of water then one could expect that the O_2 transmission rate will be 20-25 times lower than that for CO_2. This selectivity arises from the fact that



GAS TRANSMISSION RESULTS
(OXYGEN AND CARBON DIOXIDE)

Figure 6.3

the material permeability is the product of the gas diffusivity and solubility in the material. For similar diffusivities the selectivity is explained by the 20-25 fold higher solubility of CO_2 compared to O_2 in an aqueous phase.

As mentioned in Section 6.2.1 only a limited series of materials were assessed in respect of their gas transmission rates. Some of the commercially available dressing materials are porous and therefore are totally permeable to both oxygen and carbon dioxide. The materials falling into this category are the foam materials (Lyofoam, Synthaderm and Coraderm), the porcine xenograft (Corethium) and the microporous films supplied by Porvair Ltd (Porvair 232013 and 32/5/1).

Foam dressings cannot be evaluated alone by the BS vacuum method due to their porous structure. Provided that the pore structure remains unwetted these dressings should be highly permeable to both oxygen and carbon dioxide.

To verify this, the assessment procedure was carried out for one of these foam materials, Lyofoam, as a composite with the silicone rubber support. On comparison with the transmission rate of silicone rubber alone, there is no significant difference

between the gas transmission of the composite and of the silicone support.

Others not tested were the two hydrogels supplied by the Pure and Applied Chemistry Department (Linear and Non-linear) due to the limitation of supply.

In general it appears that all of the dressings have adequate transmission characteristics. This can be concluded from the successful clinical data available. One factor not covered in this theory is the speed with which they heal. Without a controlled trial, utilising animals with the same area and degree of burning, these questions remain unanswered.

CHAPTER 7

Mechanical Properties

Tensile Parameters.

CHAPTER 7

7.1 Introduction

One of the major requirements of a burn wound dressing is that it exhibits a certain toughness to withstand handling and the subsequent trauma *in situ*.

Resistance to tearing is also a requirement as any break in the dressing would cause a breakdown in the control barrier for water vapour transmission and bacterial protection. However this problem can be compounded into a laminate structure.

It is therefore necessary to include an examination of the mechanical properties in the preclinical testing of dressings.

The principal test, adopted from international standards, the uniaxial test is performed by pulling a material specimen at a constant deformation rate while recording force.

The biaxial tensile test is a constrained tensile test. The width of the specimen is constrained within the grips, fixing the strain (90^{o} to axis of test) to zero. This results in a biaxial test where the strain is fixed in one axis while recorded in the other.

Figure 7.1(a)

Instron TTCM Material Testing

Machine with pneumatic grips.

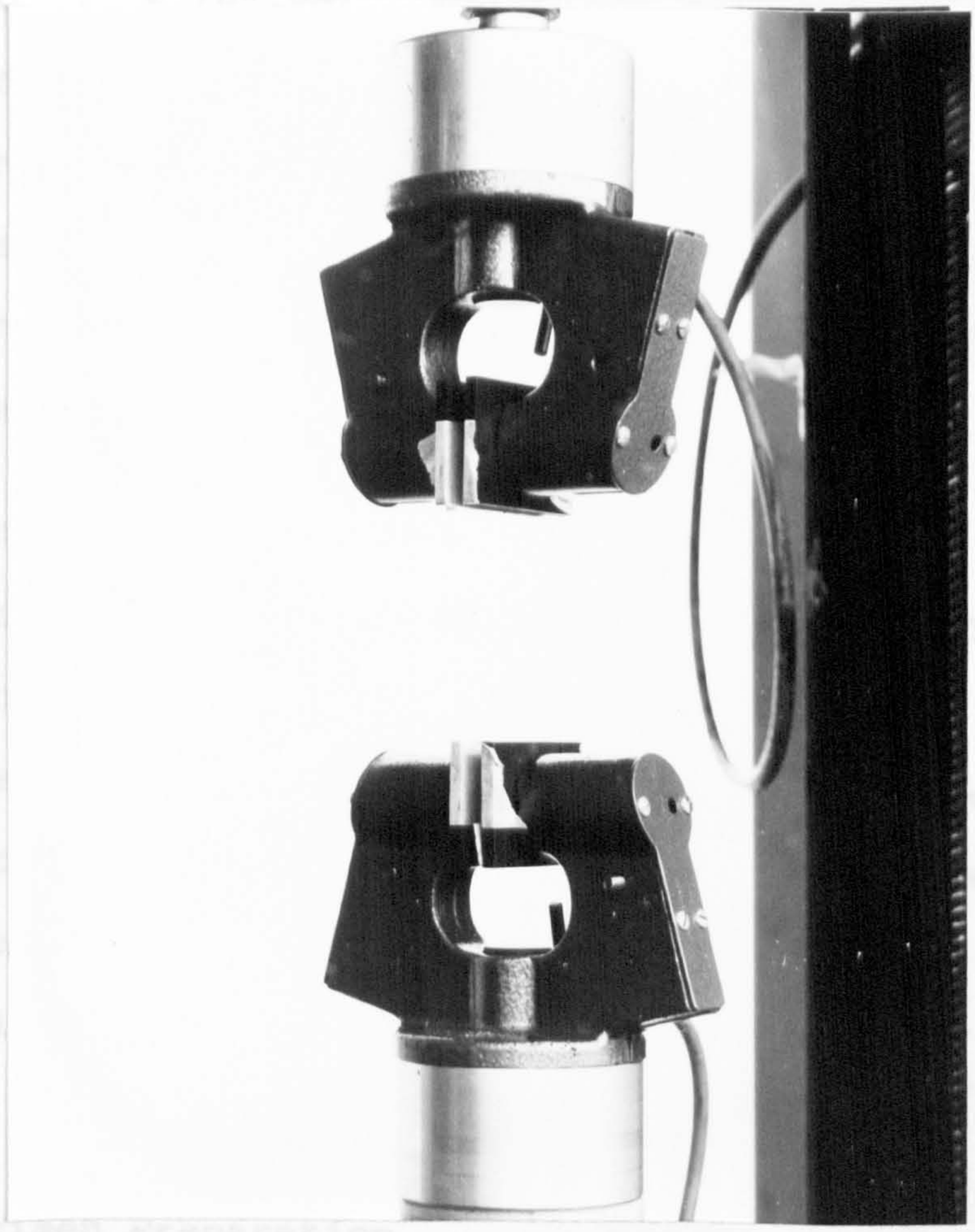


Figure 7.1(b)

Pneumatic grips used to grip the test specimen.

7.2 Experimental Apparatus

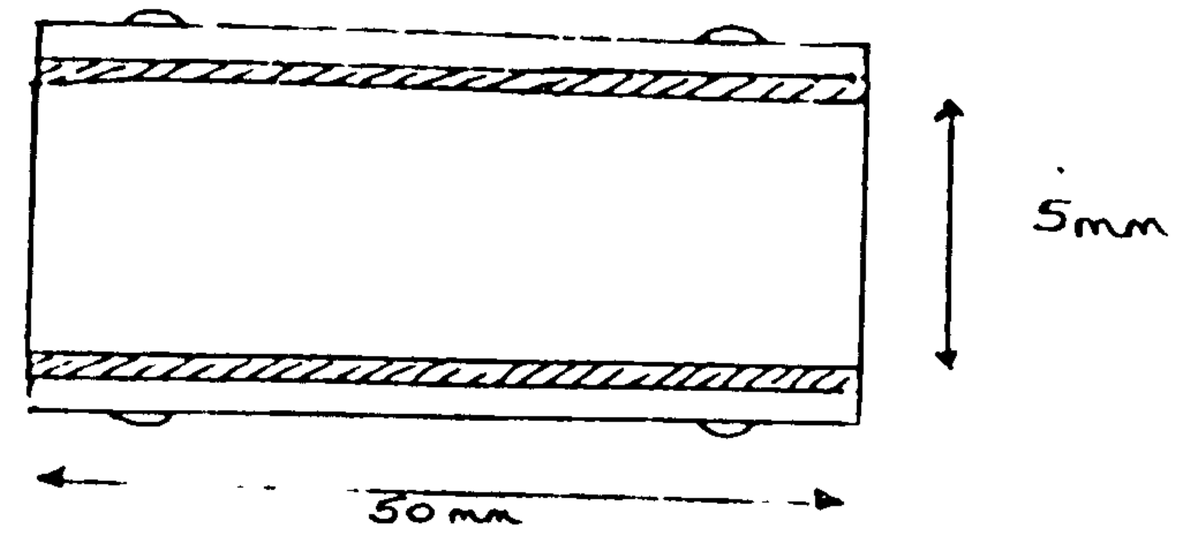
An Instron TTCM Machine (Fig 7.1) was used to measure the mechanical properties of both wet and dry specimens. This model has full scale load ranges of 2kgf to 2 x 10^3 kgf. These can be converted to the S.I. units of force, the newton - (i.e. 1 kgf = 9.81 N). However for convenience, allowing a direct comparison with previous research, the load values in this thesis are given in kg. The crosshead speed can be varied from 0.05 cm/min to 50 cm/min.

The machine has interchangeable load cells based on electrical resistance strain gauges. Signals corresponding to load variations, are recorded on a high speed X-Y recorder. The recorder chart speed may be selected at fixed ratios of the crosshead speed so that the deformation of the material under test may be obtained (Section 7.5).

7.3 Specimen Preparation

7.3.1 Uniaxial Test

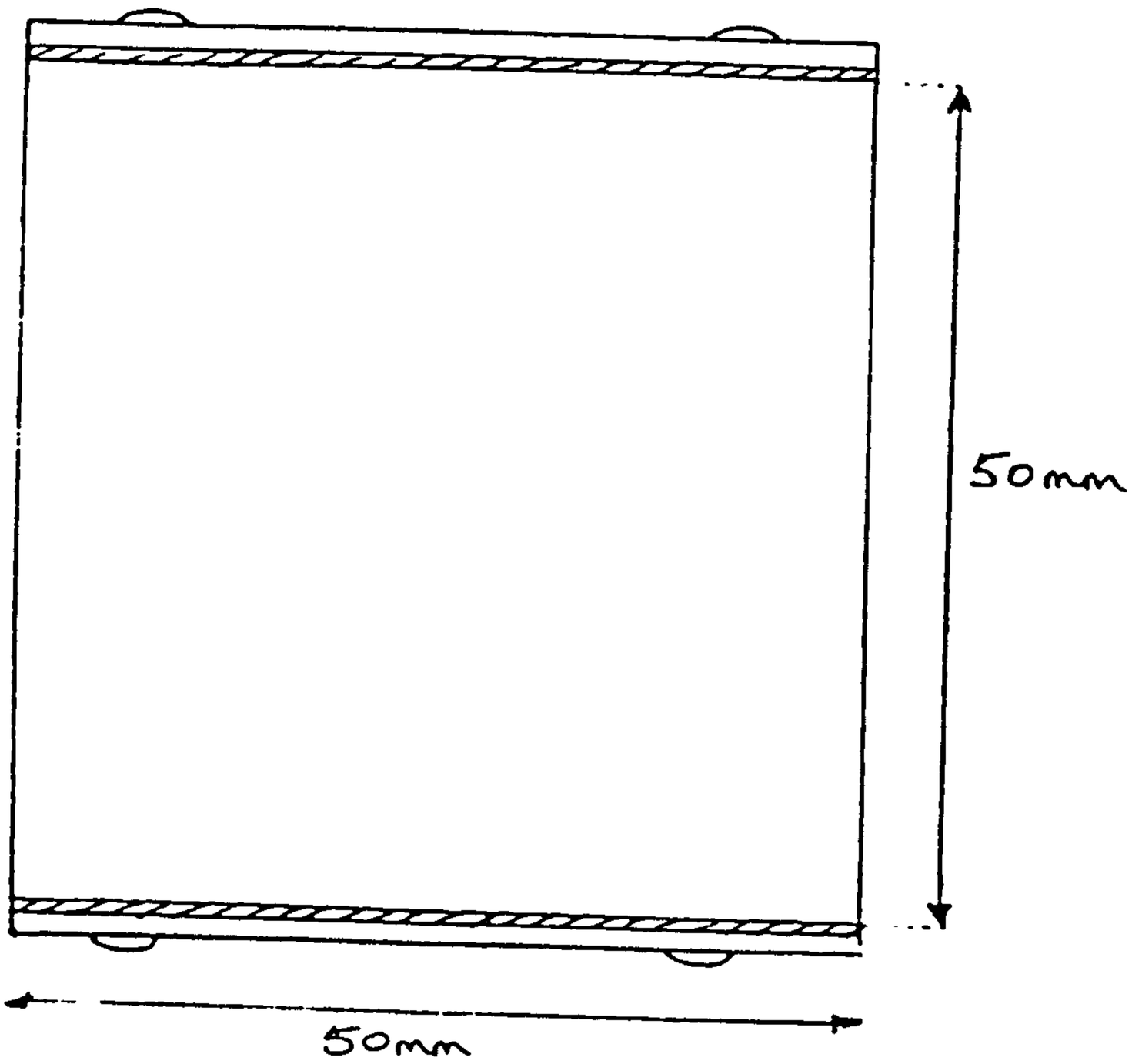
The specimens were prepared in the form of a strip of a uniform width, 5mm. The gauge length (actual free specimen test length) was 25mm; and the



▨ - Dermatome Blade

Figure 7.2 (a)

Dermatomes used for cutting the uniaxial test specimens.



▨ - Dermatome Blade

Figure 7.2 (b)

Dermatomes used for cutting the biaxial test specimens.

specimens had a total strip length of 50mm to allow for adequate end gripping. The specimens were cut from sheet form using dermatome blades which were held rigidly, at a set distance (5mm), in a Perspex frame (Fig 7.2).

Specimens of each material were cut in two directions; longitudinal (machining direction) and transverse (normal to longitudinal) directions, as shown in Fig 7.3. With some of the materials it was not obvious which direction was that of machining. It was therefore assumed and subsequently demonstrated, that upon opening the packaging, in a set orientation, that the directional parameters were constant for each material. This two-directional test was carried out to demonstrate any mechanical anisotropy within the test specimens.

7.3.2 Biaxial Test

The specimens for the biaxial test (sometimes known as 'constrained biaxial' or 'pure shear') were prepared to give a 10:1 aspect ratio, in favour of the biaxial specimen, over the uniaxial specimens. A width of 50mm, was chosen for this test and a gauge length of 10mm. The total specimen length was 40mm to allow adequate gripping within the pneumatic grips.

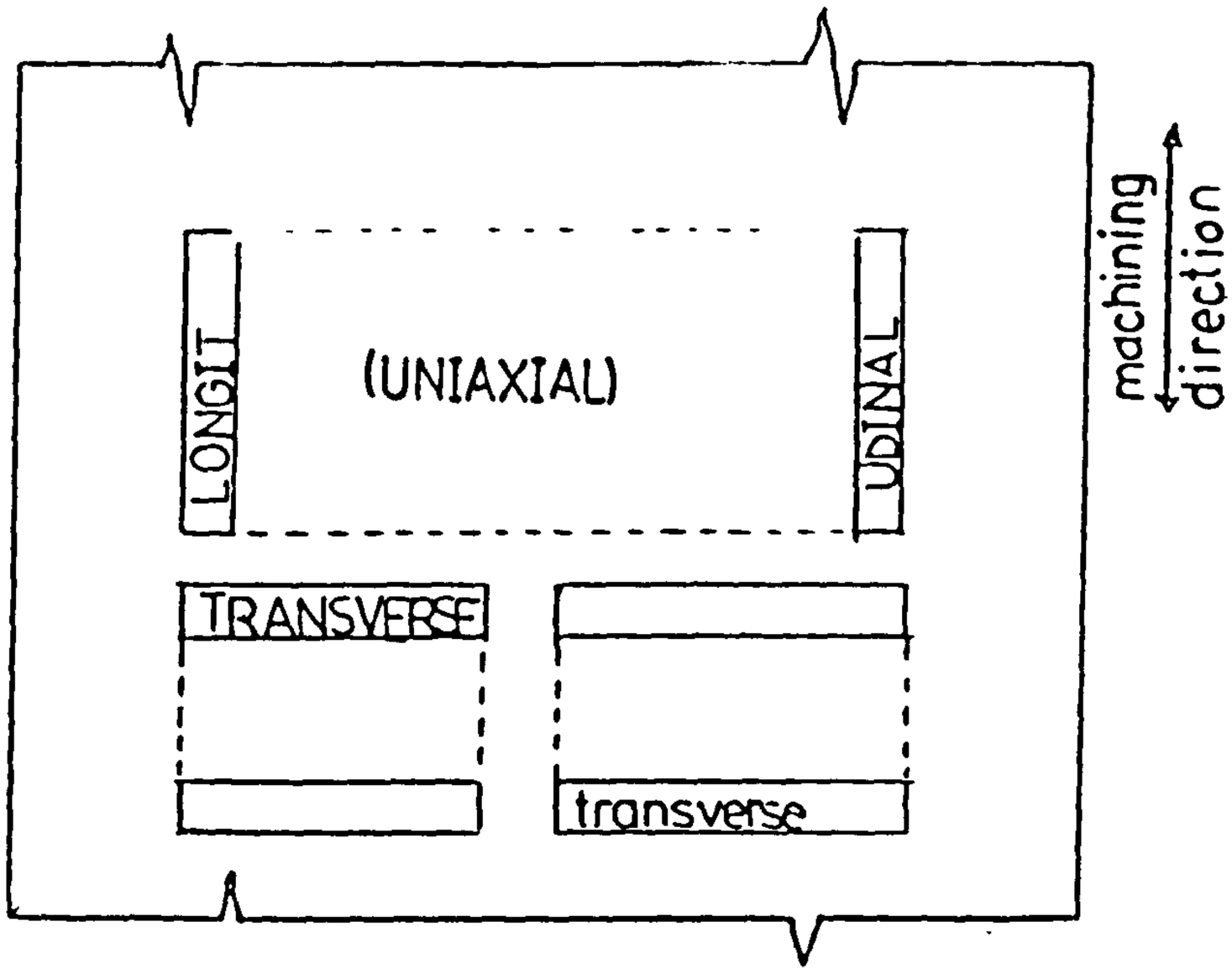


Figure 7.3

Orientations used.

The cutting blades were held in a larger frame to give a blade separation of 50mm (Fig 7.2). As in section 7.3.1, the specimens were assessed in the longitudinal and transverse directions.

In this test and the uniaxial test the material specimens were placed on a cardboard backing, to improve grippage and to reduce any inadvertent tensioning during handling. The backing was cut with scissors and removed from the gauge length before the test was carried out.

7.3.3 Thickness Measurement

The thickness of each specimen sheet was determined by multiple measurements of a trial sample before preparation as in Sections 5.3 and 8.3 using a dial-gauge micrometer. This value was assumed to be representative of the (assumed) uniform thickness for each test specimen. This procedure was adopted to prevent any distortion of the test specimens (small strips) due to compressive stress imposed by the dial gauge.

7.4 Test Procedure

The following procedure is common to both the uniaxial and biaxial tests.

The test machine was prepared as follows :

1. the Instron machine was switched on for at least one hour before the tests were carried out, allowing the system to stabilise;

2. the load cell was zeroed and calibrated using a 1kg weight;

3. the appropriate load scale was selected;

4. the cross-head speed appropriate to the test was selected i.e. 5 cm/min (uniaxial) or 2 cm/min (biaxial), to give the same nominal strain axial rate;

5. the chart speed was selected to obtain a satisfactory graphical output;

6. the grips were set to the appropriate gauge length i.e. 25 mm (uniaxial) or 10 mm (biaxial). This length is the minimum distance between the jaws of the upper and lower pneumatic grips.

7.4.1 Uniaxial Test (Dry) (ASTM method D882-67)

The test specimen was aligned within the centre of the grips and the pneumatic grips were closed via a foot switch. This alignment is facilitated by the cardboard backing (Section 7.3.2). The backing also aids in the gripping of the thinner materials, and in preventing distortion of the material.

Before beginning the test, the cardboard support was cut to render it non-load bearing. The cross-head downward movement switch and the chart movement switch were pressed simultaneously. The test was continued until specimen rupture.

7.4.2 Uniaxial and Biaxial Tests (Wet)

The procedures adopted for the uniaxial (wet) and the biaxial (wet) are similar to that of Section 7.4.1. The only difference being that all the test specimens were soaked in distilled water for 2-3 minutes (hydrogels - overnight soaking) before testing and a moisture spray was used to keep the specimen moist through-out the period of the testing.

7.4.3 Conformability (Equibiaxial) Test

Conformability was assessed by an equibiaxial inflation technique, at a fixed transmural pressure of 40mmHg. A detailed presentation of this technique can be found in Chapter 8, where it is more appropriate.

7.4.4 Definitions of the Terms Used

(Ref. ASTM D638 and D882)

Gauge Length - is the original length of that portion of the specimen over which strain or change in length is determined (in this thesis - the free length between the grips).

Elongation - is the increase in length produced in the gauge length of the test specimen by a tensile load. In this thesis elongation was expressed as a percentage of the gauge length.

Tensile Stress - is the tensile load per unit area of the minimum original cross-section, within the gauge boundaries, carried by the specimens at any given instant.

The above parameters were used to calculate the following :

Breaking Load - is the tensile load at which the specimen breaks.

Tensile Strength - is the maximum tensile stress sustained by the specimen during a tension test. Dividing the maximum load by the original cross-sectional area of the specimen, gives a value of the tensile strength (this is nominal stress). In this thesis these values are expressed in kg/cm^2. These values can be expressed in S.I. units, pascals (Pa) by the following conversion : 1 kg/cm^2 = 9.81×10^4 Pa. However for the convenience of comparison they are given in the above units (kg/cm^2).

If the maximum tensile stress occurs at the yield point it should be designated the Tensile Strength at Yield. When it occurs at the breaking point, it is designated the Tensile Strength at

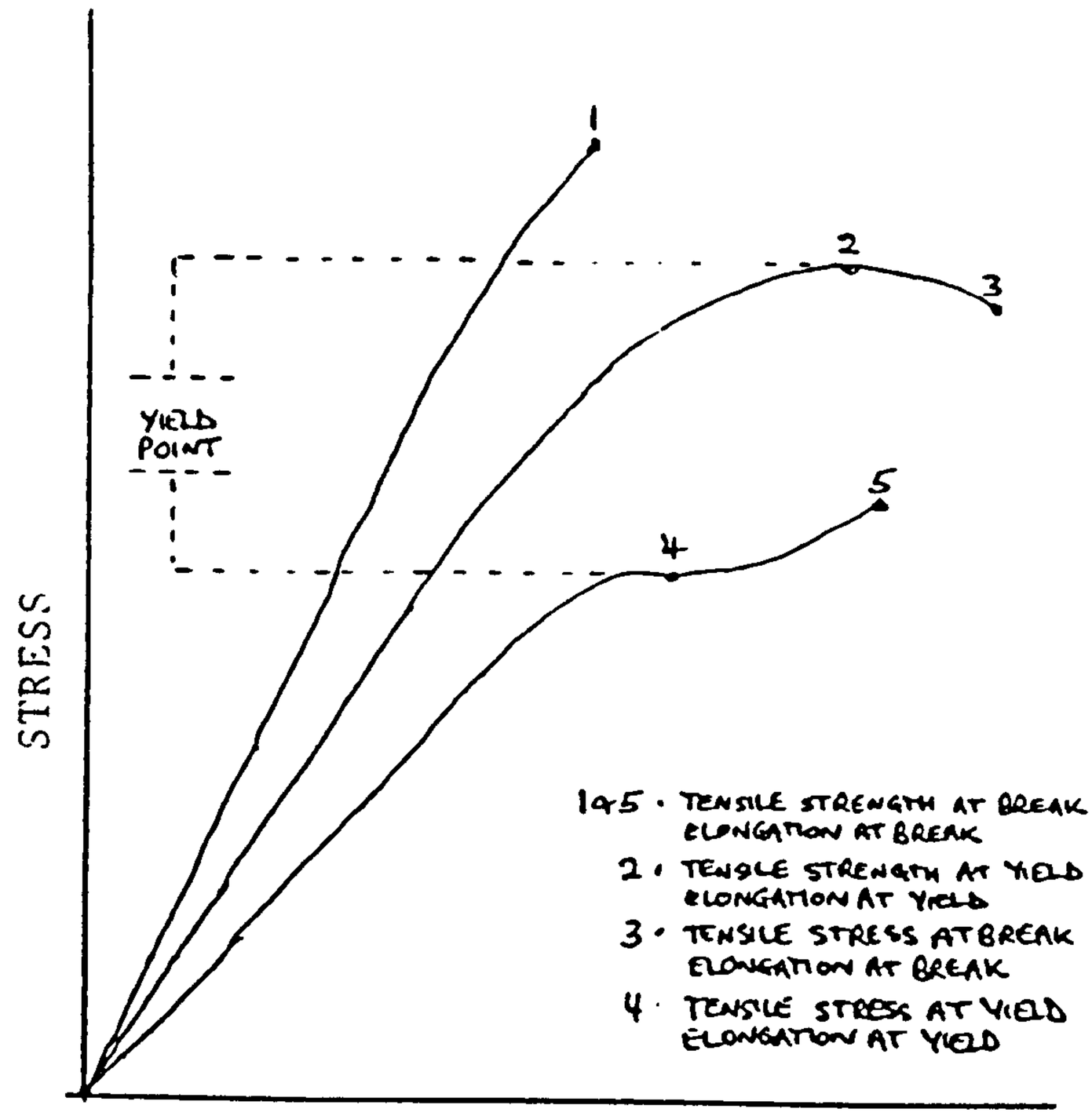


Figure 7.4

Tensile Designations.

(Wong, 1980)

Break (Fig 7.4).

<u>Elongation at Break</u> - is the percentage elongation at the moment of rupture of the specimen.

It was calculated as follows :

$$\frac{\text{Elongation at rupture}}{\text{Original Gauge Length}} \times 100\%$$

7.5 <u>Calculation of Results</u>

The load being applied was recorded on a chart which was driven at a rate which was directly related to the rate of movement of the cross-head. Chart movement thus provided a measurement of the extension of the specimen. Thus graphical output was a record of the load (kg) versus elongation (cm) curve of the test specimen. From this curve the stress-strain characteristics can be calculated as follows :

$$\text{Stress} = \frac{\text{load}}{\text{area}}$$

where Load = chart displacement (cm) X F.S.D. (kg)

24.15

Area = original width x original thickness (cm^2)

Stress = kg/cm (units chosen to allow comparison)

F.S.D.= Full Scale Deflection = 24.15 cm of chart.

$$\text{Strain} = \frac{\text{change in length}}{\text{original length}}$$

(Note : The elongation values obtained assume no grip slippage.)

7.6 Results

Five specimens of each material, in each orientation, were tested, both uniaxially and biaxially. Examples of the load versus deformation characteristics of each material are shown in Figures 7.5 and 7.6.

The breaking load, tensile strength and elongation at break of each material were calculated by the procedures detailed in Sections 7.4 and 7.5. These values can be found in Tables 7.1 to 7.7.

Sample (Thickness) (n = 5)	Orientation	Breaking Load kg (N)	Elongation at break (%)	Tensile Strength kg/cm2 (MPa)
Vigilon Web (0.55mm)	Transverse	0.368 +/- 0.050 (3.610 +/- 0.491)	29.6+/- 3.9	13.31 +/- 1.68 (1.36 +/- 0.17)
	Longitudinal	0.232 +/- 0.054 (2.276 +/- 0.530)	26 +/- 8.9	8.40 +/- 2.06 (0.86 +/- 0.21)
Vigilon Cover (0.03mm)	Transverse	0.130 +/- 0.020 (1.275 +/- 0.196)	188 +/- 82	262 +/- 32 (26.7 +/- 3.26)
	Longitudinal	0.224 +/- 0.010 (2.197 +/- 0.098)	132 +/- 36	450 +/- 25 (45.9 +/- 2.55)
Stretch 'n' Seal(0.01mm)	Transverse	0.096 +/- 0.050 (0.942 +/- 0.491)	86 +/- 35	192 +/- 10 (19.6 +/- 1.02)
	Longitudinal	0.136 +/- 0.010 (1.334 +/- 0.098)	108 +/- 22	275 +/- 22 (28.0 +/- 2.24)
Mean +/- 1 s.d.				

Table 7.1

Results for Uniaxial Test (Dry)

using Control Materials.

Sample (Thickness) (n = 5)	Orientation	Breaking Load kg (N)	Elongation at break (%)	Tensile Strength kg/cm2 (MPa)
Vigilon Web (0.55mm)	Transverse	0.138 +/- 0.030 (1.354 +/- 0.294)	79 +/- 32	4.97 +/- 0.86 (0.51 +/- 0.09)
	Longitudinal	0.340 +/- 0.100 (3.335 +/- 0.981)	26 +/- 5	12.3 +/- 3.6 (1.25 +/- 0.37)
Vigilon Cover (0.03mm)	Transverse	0.170 +/- 0.020 (1.668 +/- 0.196)	441 +/- 38	338 +/- 38 (34.4 +/- 3.87)
	Longitudinal	0.236 +/- 0.020 (2.315 +/- 0.196)	152 +/- 38	470 +/- 41 (47.9 +/- 4.18)
Stretch 'n' Seal(0.01mm)	Transverse	0.128 +/- 0.030 (1.256 +/- 0.294)	180 +/- 66	252 +/- 54 (25.7 +/- 5.50)
	Longitudinal	0.202 +/- 0.030 (1.982 +/- 0.294)	262 +/- 15	401 +/- 53 (40.9 +/- 5.40)
Mean +/- 1 s.d.				

Table 7.2

Results for Uniaxial Test (Wet)

using Control Materials.

Sample (Thickness) (n = 5)	Orientation	Breaking Load kg (N)	Elongation at break (%)	Tensile Strength kg/cm2 (MPa)
Tegaderm (0.03mm)	Transverse	0.252 +/- 0.043 (2.472 +/- 0.422)	559 +/- 119	167 +/- 29 (17.0 +/- 3.0)
	Longitudinal	0.170 +/- 0.050 (1.668 +/- 0.491)	774 +/- 173	120 +/- 36 (12.2 +/- 3.7)
Bioclusive (0.10mm)	Transverse	0.338 +/- 0.064 (3.316 +/- 0.628)	608 +/- 81	68 +/- 13 (6.93 +/- 1.32)
	Longitudinal	0.333 +/- 0.070 (3.267 +/- 0.689)	528 +/- 57	67 +/- 13 (6.83 +/- 1.32)
Porvair 232013 (0.10mm)	Transverse	0.320 +/- 0.021 (3.139 +/- 0.206)	344 +/- 22	64 +/- 4 (6.52 +/- 0.41)
	Longitudinal	0.293 +/- 0.057 (2.874 +/- 0.559)	395 +/- 114	59 +/- 11 (6.01 +/- 1.12)
Porvair 32/5/1 (0.08mm)	Transverse	0.229 +/- 0.033 (2.246 +/- 0.324)	251 +/- 34	57 +/- 8 (5.81 +/- 0.82)
	Longitudinal	0.207 +/- 0.023 (2.031 +/- 0.226)	276 +/- 28	52 +/- 6 (5.30 +/- 0.61)
Mefix (0.3mm)	Transverse	0.195 +/- 0.03 (1.913 +/- 0.294)	116 +/- 5	130 +/- 17 (13.25 +/- 1.73)
	Longitudinal	1.370 +/- 0.16 (13.440 +/- 1.570)	55 +/- 5	913 +/- 109 (91.30 +/- 11.11)
Mean +/- 1 s.d.				

Table 7.3

Results for Uniaxial Test (Dry)

using the Film Type Dressings.

Sample (Thickness) (n = 5)	Orientation	Breaking Load kg (N)	Elongation at break (%)	Tensile Strength kg/cm2 (MPa)
Lyofoam (11mm)	Transverse	0.426 +/- 0.020 (4.179 +/- 0.196)	236 +/- 26	0.776 +/- 0.03 (0.079 +/- 0.003)
	Longitudinal	0.440 +/- 0.020 (4.316 +/- 0.196)	274 +/- 16	0.080 +/- 0.04 (0.008 +/- 0.004)
Synthaderm (0.75mm)	Transverse	0.262 +/- 0.033 (2.571 +/- 0.324)	214 +/- 45	7 +/- 0.9 (0.713 +/- 0.090)
	Longitudinal	0.208 +/- 0.026 (2.040 +/- 0.255)	171 +/- 33	6 +/- 0.7 (0.611 +/- 0.070)
Coraderm (0.78mm)	Transverse	0.190 +/- 0.012 (1.864 +/- 0.118)	410 +/- 66	5 +/- 0.3 (0.510 +/- 0.031)
	Longitudinal	0.144 +/- 0.013 (1.413 +/- 0.128)	268 +/- 67	4 +/- 0.3 (0.408 +/- 0.031)
Mean +/ 1 s.d.				

Table 7.4

Results for Uniaxial Test (Dry)

using the Foam Dressings.

Sample (Thickness) (n = 5)	Orientation	Breaking Load kg (N)	Elongation at break (%)	Tensile Strength kg/cm2 (MPa)
Tegaderm (0.03mm)	Transverse	0.214 +/- 0.070 (2.100 +/- 0.687)	692 +/- 119	143 +/- 45 (14.57 +/- 4.58)
	Longitudinal	0.256 +/- 0.070 (2.511 +/- 0.687)	846 +/- 148	170 +/- 44 (17.32 +/- 4.48)
Bioclusive (0.10mm)	Transverse	0.351 +/- 0.050 (3.443 +/- 0.491)	699 +/- 193	70 +/- 11 (7.13 +/- 1.12)
	Longitudinal	0.427 +/- 0.100 (4.189 +/- 0.981)	687 +/- 147	86 +/- 20 (8.76 +/- 2.04)
Porvair 232013 (0.10mm)	Transverse	0.268 +/- 0.053 (2.629 +/- 0.520)	205 +/- 74	54 +/- 11 (5.50 +/- 1.12)
	Longitudinal	0.232 +/- 0.017 (2.276 +/- 0.167)	307 +/- 43	46 +/- 3 (4.69 +/- 0.31)
Porvair 32/5/1 (0.08mm)	Transverse	0.192 +/- 0.040 (1.884 +/- 0.392)	205 +/- 74	48 +/- 11 (4.89 +/- 1.12)
	Longitudinal	0.169 +/- 0.050 (1.658 +/- 0.491)	281 +/- 78	42 +/- 13 (4.28 +/- 1.32)
Mefix (0.3mm)	Transverse	0.158 +/- 0.030 (1.550 +/- 0.294)	154 +/- 26	10 +/- 2 (1.02 +/- 0.20)
	Longitudinal	1.120 +/- 0.100 (10.987 +/- 0.981)	86 +/- 16	75 +/- 6 (7.64 +/- 0.61)
Mean +/- 1 s.d.				

Table 7.5

Results for Uniaxial Test (Wet)

using the Film Type Materials.

Sample (Thickness) (n = 5)	Orientation	Breaking Load kg (N)	Elongation at break (%)	Tensile Strength kg/cm2 (MPa)
Lyofoam (11mm)	Transverse	0.330 +/- 0.010 (3.237 +/- 0.098)	235 +/- 19	0.602 +/- 0.02 (0.061 +/- 0.002)
	Longitudinal	0.330 +/- 0.030 (3.237 +/- 0.294)	235 +/- 7	0.602 +/- 0.06 (0.061 +/- 0.006)
Synthaderm (0.75mm)	Transverse	0.113 +/- 0.020 (1.109 +/- 0.196)	74 +/- 28	3 +/- 0.5 (0.306 +/- 0.051)
	Longitudinal	0.109 +/- 0.010 (1.069 +/- 0.098)	62 +/- 12	3 +/- 0.3 (0.306 +/- 0.031)
Coraderm (0.78mm)	Transverse	0.085 +/- 0.011 (0.834 +/- 0.108)	182 +/- 39	2 +/- 0.2 (0.204 +/- 0.020)
	Longitudinal	0.080 +/- 0.010 (0.785 +/- 0.098)	183 +/- 33	2 +/- 0.3 (0.204 +/- 0.031)
Mean +/- 1 s.d.				

Table 7.6

Results for Uniaxial Test (Wet)

using Foam Dressings

Sample (Thickness) (n = 5)	Orientation	Breaking Load kg (N)	Elongation at break (%)	Tensile Strength kg/cm2 (MPa)
Geliperm	Transverse	0.070 +/- 0.007 (0.687 +/- 0.069)	139 +/- 43	1.46 +/- 0.19 (1.488 +/- 0.019)
(0.95mm)	Longitudinal	0.060 +/- 0.007 (0.589 +/- 0.069)	102 +/- 23	1.20 +/- 0.14 (1.223 +/- 0.014)
Non-Linear	Transverse	1.366 +/- 0.197 (13.400 +/- 1.933)	86 +/- 23	30 +/- 4 (3.057 +/- 0.408)
PEO Hydrogel (0.92mm)	Longitudinal	1.964 +/- 0.357 (19.267 +/- 3.502)	60 +/- 20	43 +/- 8 (4.382 +/- 0.820)
Linear	Transverse	0.026 +/- 0.005 (0.255 +/- 0.049)	223 +/- 73	4 +/- 0.6 (0.408 +/- 0.061)
Polyurethane Hydrogel (0.15mm)	Longitudinal	0.030 +/- 0 (0.294 +/- 0)	318 +/- 50	4 +/- 0.1 (0.408 +/- 0.010)
Corethium	Transverse	0.376 +/- 0.093 (3.689 +/- 0.912)	30 +/- 5	19 +/- 5 (1.936 +/- 0.510)
(0.40mm)	Longitudinal	0.131 +/- 0.048 (1.285 +/- 0.471)	28 +/- 5	7 +/- 2 (0.713 +/- 0.204)
Mean +/- 1 s.d.				

Table 7.7

Results for Uniaxial Test (Wet)
using Hydrophilic Materials

7.7 Discussion

Burn wound dressings should be pliant (relatively easily deformed and elongated) to enable conformation between the dressing and the body surface. Although this pliancy is desirable, the dressing should also be sufficiently strong to withstand the handling during application and any subsequent trauma *in situ*.

It is very important that the dressing possesses strength and resistance to tearing, to prevent the breakdown of the bacterial barrier and the water vapour transmission control barrier.

7.7.1 Control Materials (Those previously studied by Wong and Rahman)

Stretch 'n' Seal (Plasticised P.V.C.) has a reasonable extensibilty (to break)(86 - 108%) giving it a good pliancy. Its tensile strength (192 - 275 kg/cm^2) is adequate and no handling problems are envisaged.

The Vigilon Coverfilm, a polyethylene film, has a greater extensibility with a value of 132 - 188% elongation. This material has a tensile strength of 262 - 450 kg/cm^2, which is stronger than any of the other materials tested. No handling problems are

envisaged. The Vigilon Web has a very poor tensile strength and it is very inextensible. Hence the mechanical strength of the Vigilon composite dressing is provided by the coverfilm.

Tegaderm can also be considered as a control material as this material is similar to Opsite (Smith and Nephew Ltd.). The Tegaderm dressing was found to be the most pliant of all the dressing materials tested (Tables 7.3 and 7.5). The dressing is anisotropic, having the greatest elongation capability in the longitudinal direction (774%). Its tensile strength is sufficient (120 - 167 kg/cm^2) to withstand handling. Tables 7.8 - 7.10 compare the results obtained for the control materials with the findings of previous research. These tables show that many of the results are comparable to previous research. From the tables, it can be seen that some variation exists in the results for the Stretch 'n' Seal material, which may be due to differences within the different commercial materials. The discrepancy between the Vigilon Web values may be due to better grippage of the specimen (in this study).

State and Orientation	Parameter	Wong (1980)	Rahman (1982)	This Study
DRY Longitudinal	B.L.	0.21 +/- 0.02	0.158 +/- 0.016	0.136 +/- 0.01
	E.L.B.	177 +/- 16	159 +/- 15	108 +/- 22
	T.S.	415 +/- 39	310 +/- 31	275 +/- 22
WET Transverse	B.L.	0.17 +/- 0.01	0.184 +/- 0.015	0.096 +/- 0.05
	E.L.B.	164 +/- 13	261 +/- 21	86 +/- 35
	T.S.	345 +/- 22	361 +/- 29	192 +/- 10
WET Longitudinal	B.L.	0.195 +/- 0.004	-	0.202 +/- 0.03
	E.L.B	196 +/- 8	-	262 +/- 15
	T.S.	384 +/- 8	-	401 +/- 43
DRY Transverse	B.L.	0.155 +/- 0.01	-	0.128 +/- 0.03
	E.L.B.	180 +/- 9	-	180 +/- 66
	T.S.	305 +/- 20	-	252 +/- 54

NB B.L. - Breaking Load (kg)
E.L.B. - Elongation at Break (%)
T.S. - Tensile Strength (kg/cm^2)

Table 7.8

Comparison of Previous Research with this study. (Stretch 'n' Seal)

State and Orientation	Parameter	Wong (1980)	This Study
DRY Longitudinal	B.L.	0.648 +/- 0.037	0.170 +/- 0.05
	E.L.B.	824 +/- 37	774 +/- 173
	T.S.	190 +/- 11	120 +/- 36
WET Transverse	B.L.	0.434 +/- 0.01	0.214 +/- 0.07
	E.L.B.	1064 +/- 54	692 +/- 119
	T.S.	127 +/- 9	143 +/- 45
WET Longitudinal	B.L.	0.458 +/- 0.009	0.256 +/- 0.07
	E.L.B	1110 +/- 30	846 +/- 148
	T.S.	134 +/- 3	170 +/- 44
DRY Transverse	B.L.	0.618 +/- 0.05	0.252 +/- 0.043
	E.L.B.	784 +/- 35	559 +/- 119
	T.S.	176 +/- 21	167 +/- 29

NB B.L. - Breaking Load (kg)
E.L.B. - Elongation at Break (%)
T.S. - Tensile Strength (kg/cm^2)

Table 7.9

Comparison of Previous Research with this study.

(Tegaderm/Opsite)

State and Orientation	Parameter	Wong (1980)	This Study	Material
WET Transverse	B.L.	0.484 +/- 0.025	0.138 +/- 0.03	Vigilon Web
	E.L.B.	47 +/- 21	79 +/- 32	
	T.S.	40 +/- 3	5 +/- 0.9	
WET Longitudinal	B.L.	0.137 +/- 0.027	0.340 +/- 0.10	Vigilon Web
	E.L.B	9 +/- 2	26 +/- 5	
	T.S.	11 +/- 2	12 +/- 4	
DRY Transverse	B.L.	0.199 +/- 0.054	0.130 +/- 0.02	Vigilon Cover Film
	E.L.B.	401 +/- 146	188 +/- 82	
	T.S.	124 +/- 30	262 +/- 32	
DRY Longitudinal	B.L.	0.277 +/- 0.022	0.224 +/- 0.01	Vigilon Cover Film
	E.L.B.	185 +/- 29	132 +/- 36	
	T.S.	181 +/- 14	450 +/- 25	

NB B.L. - Breaking Load (kg)
E.L.B. - Elongation at Break (%)
T.S. - Tensile Strength (kg/cm^2)

Table 7.10

Comparison of Previous Research with this study.

(Vigilon Cover and Web)

7.7.2. Film Type Materials (Tables 7.3 and 7.5)

Bioclusive, like many of the film type materials has good elongation capabilities (528 - 608%) and a reasonable tensile strength (67 - 68 kg/cm^2). Its good degree of pliancy should give reasonable conformability. No handling problems are envisaged with this material.

Both the Porvair materials (232013 and 32/5/1) have good extensibility ranges (344 - 395% and 251 - 276% respectively). Their tensile strengths were almost identical, being around 58 kg/cm^2. Due to their strength no handling problems are envisaged with the clinical use of either.

Upon wetting the above materials show very little difference in their strength or elongation capabilities, this probably being due to their hydrophobic nature.

The "two-way stretch" dressing, Mefix, is a very anisotropic material being considerably more extensible in the transverse direction (Tables 7.3 and 7.5). The extensibilities of the transverse and the longitudinal directions were 116% and 55% respectively. The tensile strengths in each direction are also different, having the greatest value in the longitudinal direction, (913 kg/cm^2) as opposed to the transverse direction (130 kg/cm^2). These values are strength values. Therefore study

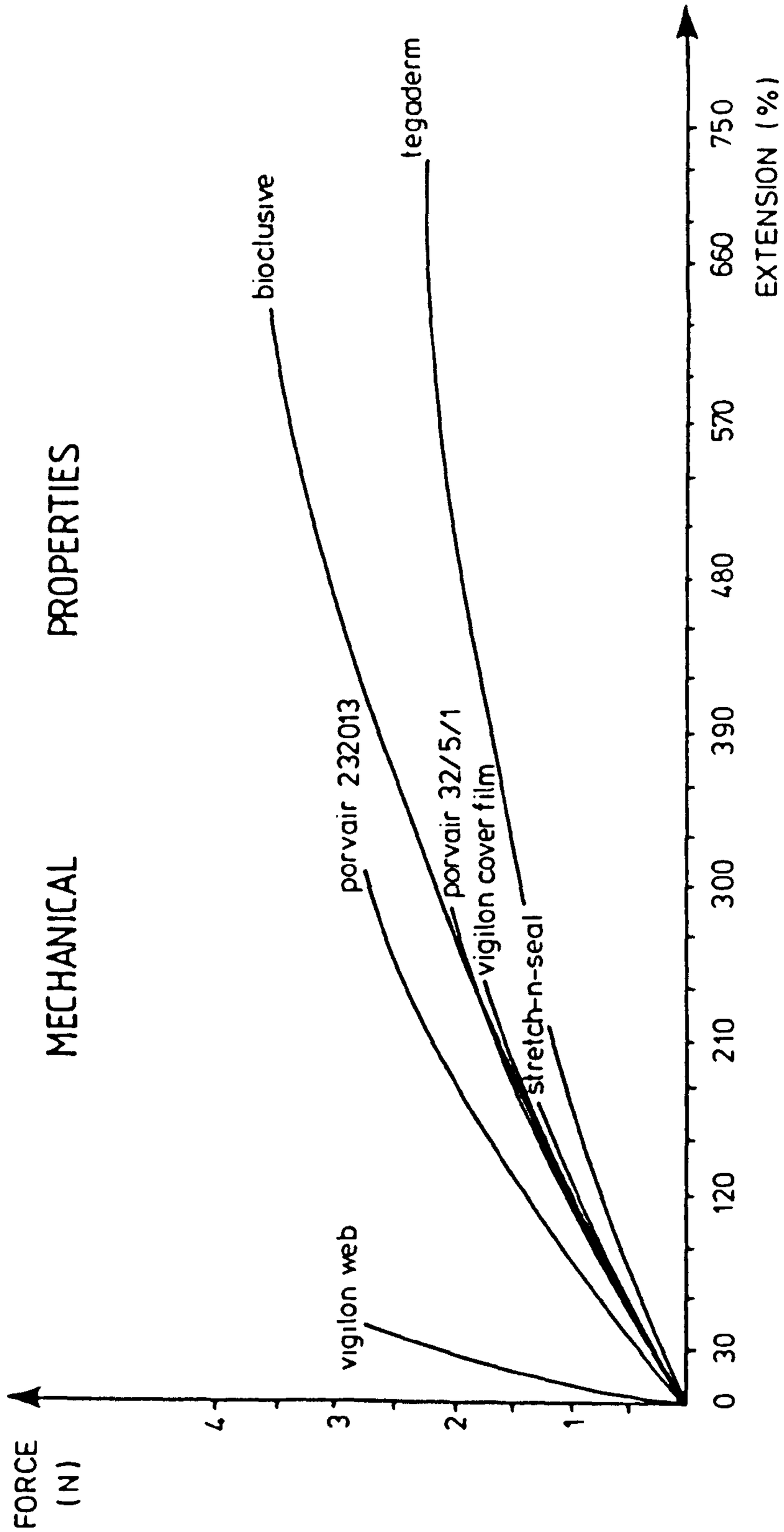


Figure 7.8

Examples of Load Deformation Curves.

of the force at rupture and the useable elongation indicates that no handling or <u>in situ</u> (trauma) problems can be envisaged. Mefix is more extensible and very much weaker in the wet state (Table 7.5).

7.7.3 <u>Foam Type Materials (Tables 7.4 and 7.6)</u>

Lyofoam proved to be an isotropic material which is quite extensible. This dressing has an elongation of 236 - 274%. However due to the thickness of the material (since thickness is used in the calculation of the tensile strength) and its foam structure, this material has a very poor tensile strength (0.6 - 0.8 kg/cm^2). Although this material has a good degree of pliancy, according to the test it is suggested that handling problems could be experienced in its clinical use, particularly when wet. However successful clinical use indicates that this is not a problem. It can therefore be said that due to the foam nature of the material, a large percentage of the thick dressing is air and subsequently this results in an apparent poor tensile strength.

Synthaderm was the strongest of the foam type materials having a tensile strength of 6 - 7 kg/cm^2. However handling problems may be experienced in clinical use. This material is the least extensible of the three foams having an extensibility of 171 -

214%. These elongation qualities are however reasonable giving this material a certain degree of pliancy.

Coraderm has the greatest elongation range (268 - 410%) making this material anisotropic having its largest elongation in the transverse direction. This material is stronger than Lyofoam but slightly weaker than Synthaderm, having a tensile strength of 4 - 5 kg/cm^2. Coraderm is an anisotropic material.

With the Synthaderm and Coraderm materials, wetting of the foam material considerably decreases the tensile strength and elongation capabilities. However, Lyofoam being considerably thicker than both of the other foams, only a slight decrease in these properties upon wetting, was observed during testing.

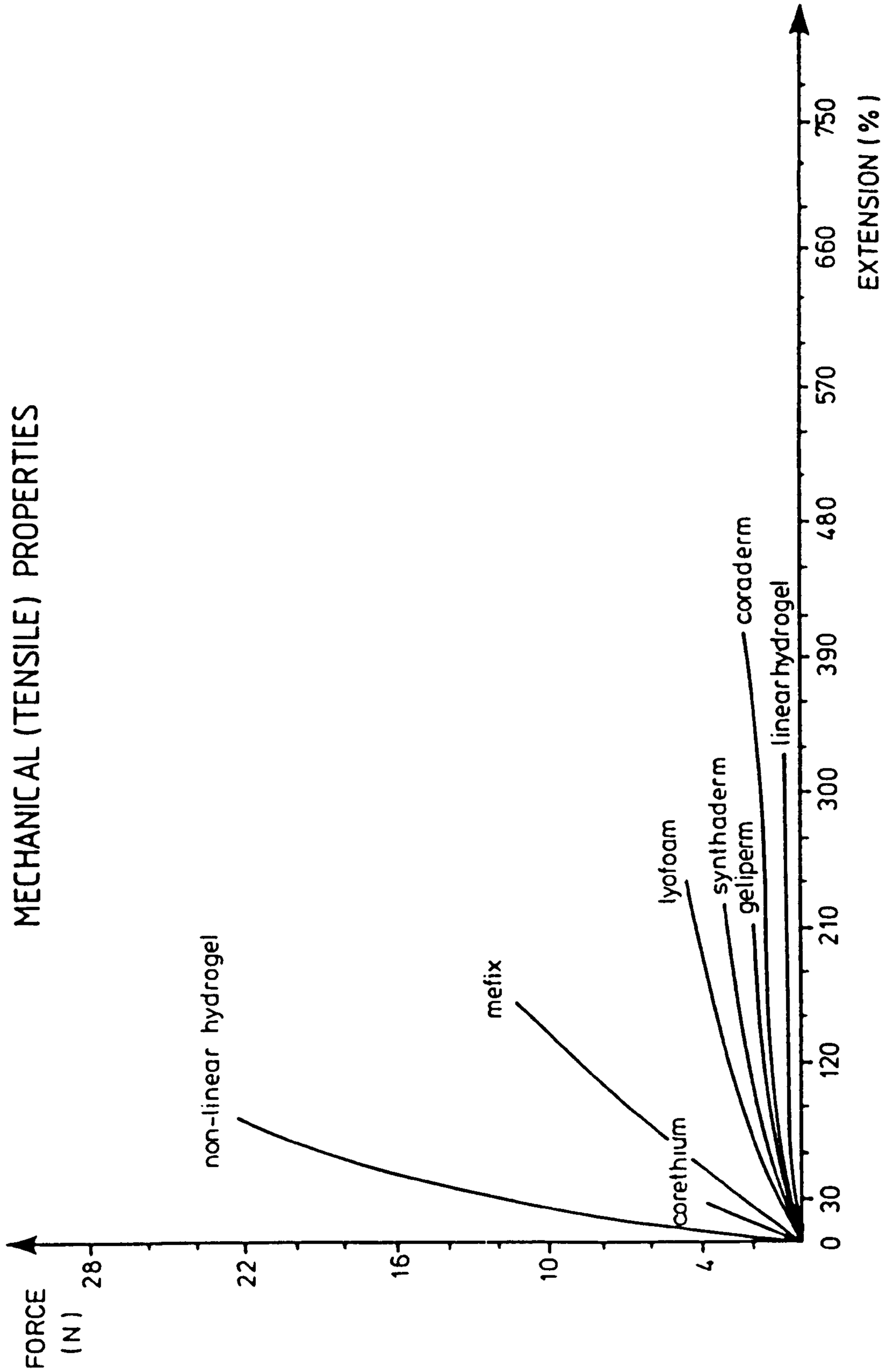


Figure 7.9

Examples of Load Deformation Curves.

7.7.4 Hydrophilic Materials (Table 7.7)

The main materials belonging to this class are the hydrogels. The other material in this class is Corethium, which requires reconstitution in saline before use and hence it is water containing. These materials were only assessed in the wet state, as indicated by their clinical use.

The Linear PEO Hydrogel had an elongation of 223 - 318%. This material proved to be isotropic. Its pliancy will allow conformability, however its low tensile strength (3.96 - 4.35 kg/cm^2) may cause some handling problems. Tearing was found to be a problem with this material, in that, once a tear was initiated, the tear propagates with considerable ease.

The other hydrogels assessed were less pliant than the linear hydrogel. Geliperm had an elongation of 102 - 139% and the Non-linear hydrogel, was considerably less extensible, having an elongation of 60 - 86%. Both of these hydrogels also proved to be isotropic. As with the linear hydrogel, both of these gels had low tensile strengths (1.2 - 1.5 kg/cm^2 and 29.7 - 42.8 kg/cm^2 respectively). These materials were prone to the handling problems and to the tearing problems exhibited by the linear hydrogel.

Corethium was very inextensible having an elongation of 28 - 30% which might lead to problems with dressing conformability. Its poor tensile strength (7 - 19 kg/cm^2) may cause handling problems. This material is anisotropic having its greatest tensile strength in the transverse direction.

7.8 Calculation of Stress-Strain Moduli

Stress-strain moduli were calculated for each test to give an indication of the stiffness of each material.

For the biaxial tests these values were calculated by obtaining the gradient of the linear portion (around 2% strain level) of the stress-strain curves. The calculated values can be found in Tables 7.11 to 7.14.

The conformability stress-strain moduli were calculated using the following two formulae.

The stress values were calculated using :

$$\text{Stress} = \frac{p\, a^2 \left(1 + \frac{x^2}{a^2}\right)}{4xd} \times \frac{10^5}{760} \text{ Pa} \quad (1)$$

and the corresponding strain values were calculated using :

$$\text{Strain} = \frac{2\, x^2}{3a^2 \left(1 + 2\frac{x^2}{a^2}\right)} \quad (2)$$

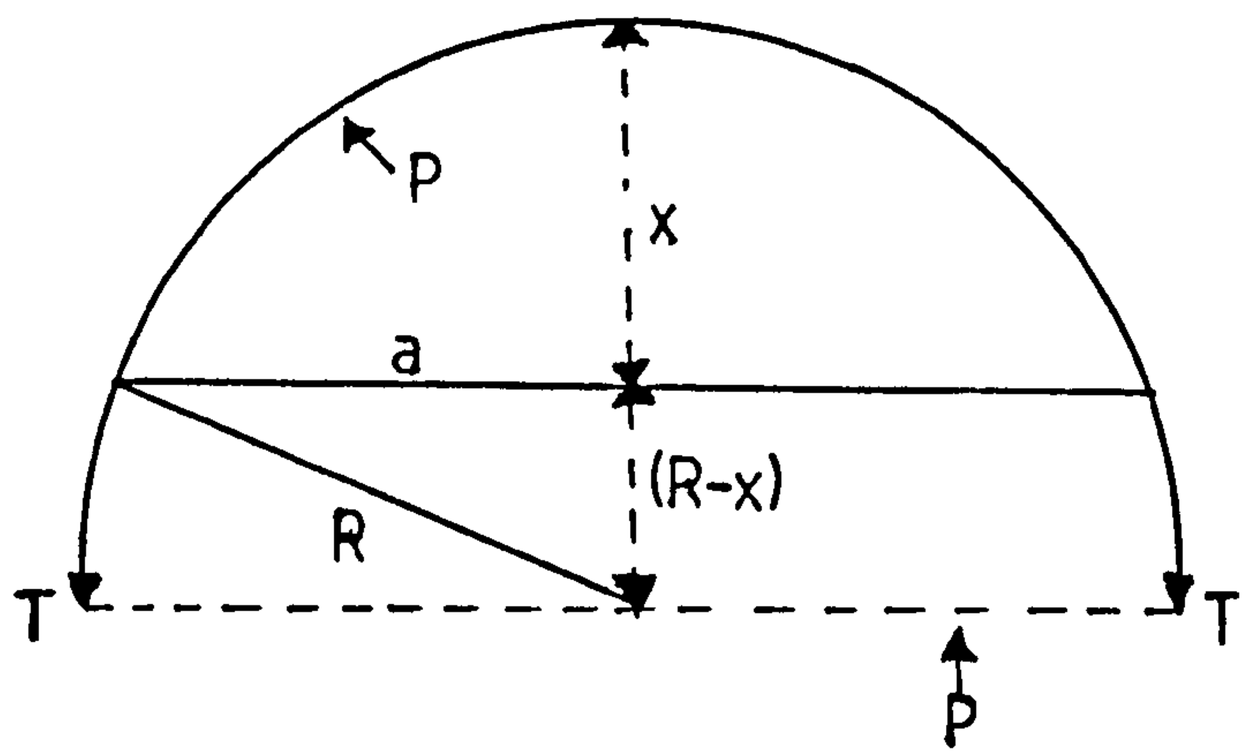
Where p = pressure (mm Hg)

a = radius of diaphragm (cm)

x = height of the dome (cm)

d = thickness of the membrane (cm)

The above formulae were derived in the following way :



Where T = circumferential tension (per unit length) in the dressing

p = radial pressure on the dressing

R = radius of curvature

$$\leq Fv = 0 = - T \pi 2 R + p \pi R^2$$

$$T\ 2 \pi R = p \pi R^2$$

$$T = \frac{p \pi R^2}{2 \pi R}$$

$$T = 0.5\ p\ R$$

obtaining R in terms of a and x :-

$$R^2 = a^2 + (R - x)^2$$

$$R^2 = a^2 + R^2 - 2Rx + x^2$$

$$R = \frac{a^2 + x^2}{2x}$$

substituting for R :-

$$T = 0.5\ p\ R$$

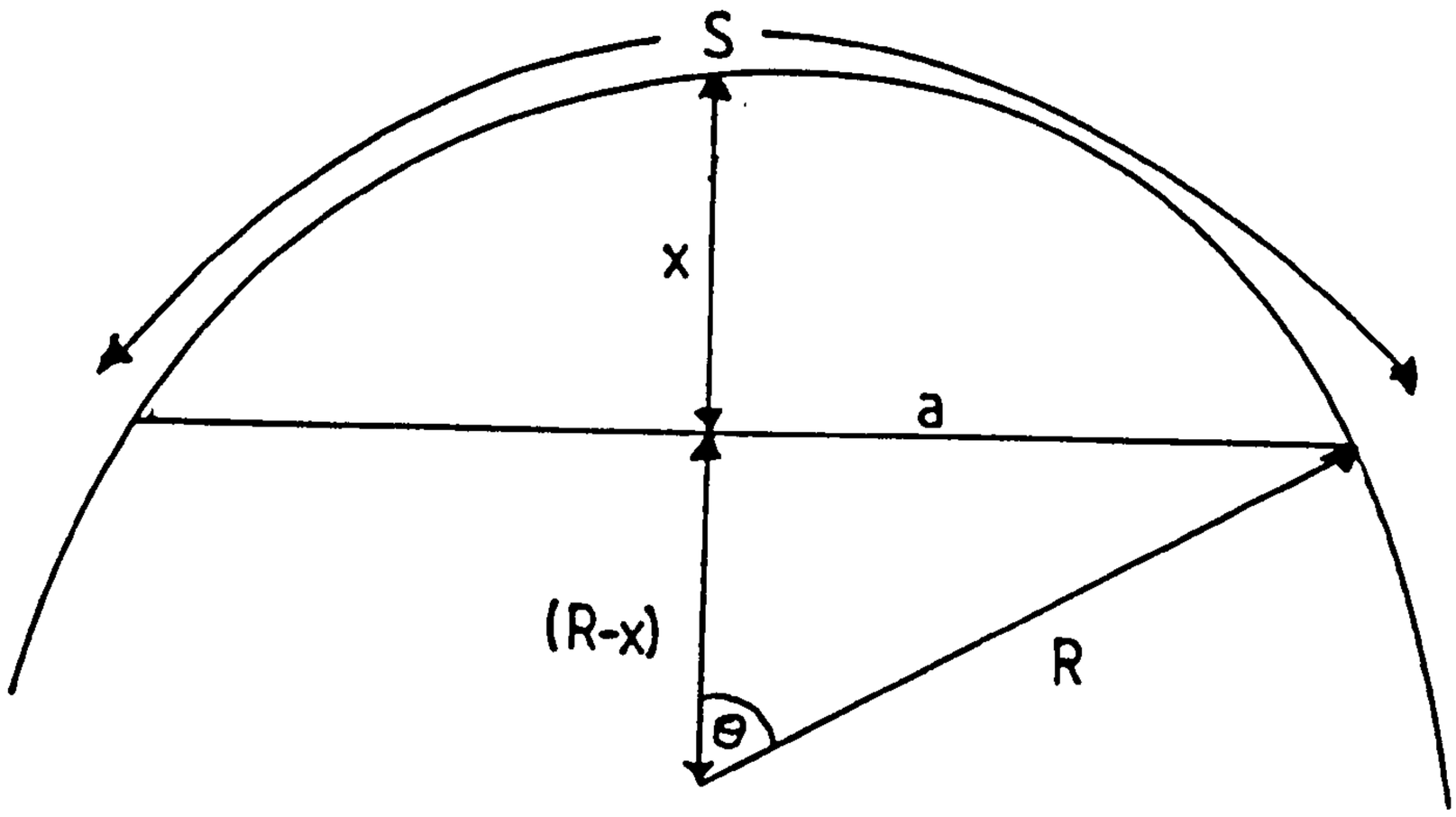
$$T = 0.5\ p\ \frac{(a^2 + x^2)}{2x}$$

$$\sigma = \frac{T}{d}$$

$$\sigma = \frac{0.5\ p\ \frac{(a^2 + x^2)}{2x}}{d}$$

$$\sigma = \frac{p\ a^2 (1 + \frac{x^2}{a^2})}{4\ xd}$$

the strain values were derived as follows :



$$a = R \sin\Theta$$

$$\Theta = \sin^{-1} \frac{a}{R}$$

Substituting $R = \dfrac{a^2 + x^2}{2x}$

Therefore $\Theta = \sin^{-1} \dfrac{2 \times a}{a^2 + x^2}$

$$S = 2\Theta \frac{a^2 + x^2}{2x}$$

Arc length, $S = 2 \Theta R$

$$S = \Theta \frac{a^2 + x^2}{x}$$

Using the approximation :

$$\sin^{-1} x = x + \frac{1}{6} x^3 + \ldots\ldots$$

taking the first two terms only,

$$\ominus = \sin^{-1} \frac{2xa}{a^2+x^2} = \frac{2xa}{a^2+x^2} + \frac{1}{6}\left[\frac{2xa}{a^2+x^2}\right]^3$$

Substituting for $\ominus$

$$S = \frac{a^2+x^2}{x}\left[\frac{2xa}{a^2+x^2} + \frac{1}{6}\left(\frac{8x^3a^3}{(a^2+x^2)^3}\right)\right]$$

$$S = 2a + \frac{4}{3}\frac{x^2a^3}{(a^2+x^2)^2}$$

$$\text{Strain} = \frac{\text{change in length}}{\text{original length}} = \frac{S-2a}{2a}$$

$$\text{Strain} = \frac{2a + 4x^2a^3 - 2a}{\frac{3(a^2+x^2)}{2a}}$$

$$\text{Strain} = \frac{2}{3a^2}\frac{x^2}{(1+\frac{x^2}{a^2})^2}$$

due to the ratio of x to a the $\frac{x^4}{a^4}$ term becomes negligible.

Giving strain as a percentage value :

$$\text{Strain} = \frac{2\,x^2}{3\,a^2\,\left(1 + \frac{2\,x^2}{a^2}\right)} \times 100 \quad \%$$

Since the conformability test was only carried out at one pressure to determine the gradient of an imaginary stress-strain curve, it has to be assumed that the curve passes through the origin. Hence the stress-strain moduli were calculated by dividing the values calculated in the first formula by those in the second. These results are shown in Tables 7.11 to 7.14

Specimen (Orientation)	Biaxial (WET) Modulus (k Pa)	Conformability (k Pa)
Vigilon Coverfilm (Transverse)	255913 +/- 30592	-
Vigilon Coverfilm (Longitudinal)	246773 +/- 34551	5945 +/- 2790
Stretch 'n' Seal (Transverse)	55000 +/- 5500	-
Stretch 'n' Seal (Longitudinal)	47000 +/- 990	19200 +/- 19700
Tegaderm (Transverse)	6138 +/- 1233	-
Tegaderm (Longitudinal)	5597 +/- 1157	1200 +/- 350

Table 7.11

Stress-Strain Moduli for the Control Materials.

Specimen (Orientation)	Biaxial (WET) Modulus (k Pa)	Conformability (k Pa)
Bioclusive (Transverse)	1360 +/- 114	-
Bioclusive (Longitudinal)	1420 +/- 175	224 +/- 16
Porvair 232013 (Transverse)	3420 +/- 1755	-
Porvair 232013 (Longitudinal)	3600 +/- 510	250 +/- 60
Porvair 32/5/1 (Transverse)	1552 +/- 948	-
Porvair 32/5/1 (Longitudinal)	2054 +/- 808	610 +/- 70

Table 7.12

Stress-Strain Moduli for the Film Type Dressings.

Specimen (Orientation)	Biaxial (WET) Modulus (k Pa)	Conformability (k Pa)
Geliperm (Transverse)	28 +/- 8	-
Geliperm (Longitudinal)	25 +/- 16	90 +/- 40
Linear Hydrogel (Transverse)	555 +/- 100	-
Linear Hydrogel (Longitudinal)	622 +/- 154	240 +/- 10
Non-linear Hydrogel (Transverse)	78629 +/- 5780	-
Non-linear Hydrogel (Longitudinal)	86000 +/- 11000	2450 +/- 410
Corethium (Transverse)	600 +/- 300	-
Corethium (Longitudinal)	400 +/- 60	2574 +/- 1294

Table 7.13

Stress-Strain Moduli for the Hydrophilic Dressings.

Specimen (Orientation)	Biaxial (WET) Modulus (k Pa)	Conformability (k Pa)
Lyofoam (Transverse)	30 +/- 5	-
Lyofoam (Longitudinal)	40 +/- 4	3989 +/- 1780
Synthaderm (Transverse)	300 +/- 100	-
Synthaderm (Longitudinal)	348 +/- 188	32 +/- 3
Coraderm (Transverse)	144 +/- 23	-
Coraderm (Longitudinal)	146 +/- 30	39 +/- 10

Table 7.14

Stress-Strain Moduli for the Foam Type Dressings.

7.9 Discussion

The stiffness of each specimen, in both test procedures, was determined from the initial stiffer region of the stress-strain curves and the formulae in section 7.8 (conformability). These values denote the possibility of each test giving the required conformability measurements. Such a coordination of these results would permit the future testing of materials, via the simplest test procedure, resulting in a measurement of conformability (radii of curvature).

In most cases, there are small discrepancies between the two test values. This is due to the low strain levels (0.1 to 5%) observed in the conformability test. In the biaxial test this level is very low and corresponds to the initial stiffer region of the stress-strain curves. The determination of the gradient line here may be inaccurate, resulting in the small discrepancies between most of the values.

It was observed that in those tests which differed greatly (in excess of ten times) the materials did not exhibit viscoelastic behaviour. It may therefore be that in many of the conformability tests, these types of materials may reach their maximum radius of curvature before the one minute

reading period. The others therefore would have a greater time to reach a greater radius of curvature giving better results.

The largest discrepancy was observed for Lyofoam. The conformability modulus was some 80 times the biaxial modulus in the case of Lyofoam. This may be due to the factors mentioned above (i.e. non-viscoelasticity) and also to the collapse of the foam structure at the central point (conformation test, Section 8.3), which is caused by the tension developed due to the pressure head. The material would therefore have a much greater experimentally derived stiffness, than the material would actually possess.

The high standard deviation values in relation to the mean were due to the mathematical manipulation, in Section 7.8, of the raw data. The errors in the raw data were squared and multiplied many times resulting in a continuous increase in the error figure. For materials where the central deviation is small the test can be insensitive as slippage from the edges of the grips can be exaggerated.

It can be seen from the results that the two tests can be tied together. However at the present time some further modifications have to be made to allow a more accurate measurement of stiffness, at the low levels of strain, for the biaxial tests.

CHAPTER 8

The Conformability

Of

Wound Dressings

CHAPTER 8

8.1 Introduction

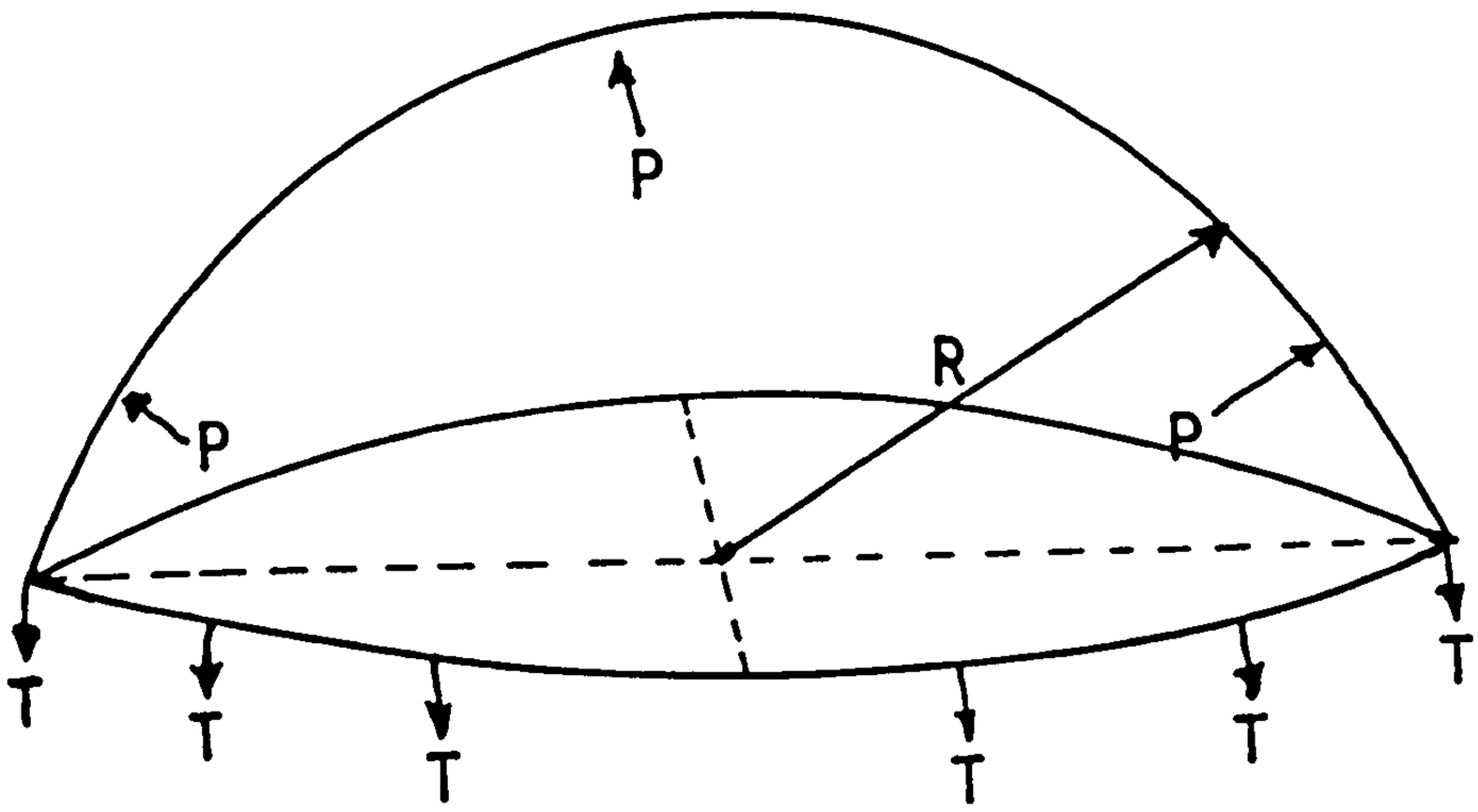
In affording the barrier function of bacterial protection and moisture control to a burn wound it is important that the wound covering remains intact and conforms to the body and to the wound surface. The conformability of a covering is therefore an essential parameter to be considered in its design. For the purposes of this thesis conformability is defined as the continuous apposition to the body surface without the dressing wrinkling or fluting, in the area covering the wound. Wrinkling or fluting may occur at the edges of the dressing however these are usually of little importance.

Wound coverings are applied under tension to make them conform to the body surface. It is important that this tension must not produce a sustained interface pressure which is greater than 40 mmHg, as this has been shown to be the limiting value in terms of tissue viability in normal skin (Scales, 1975). At lower pressures more wrinkling or fluting may be seen, as said above, 40 mmHg pressure is the maximal value for tissue viability and hence no increase in pressure, to smooth out any residual wrinkling, is

tolerable.

It has been shown both experimentally and clinically that it is essential that this 40 mmHg pressure should not be exceeded for prolonged periods. The corresponding tensile forces within the dressing, can be calculated using an elastic garment model (membrane theory). This model relates the tensile forces to transmural pressure for a surface of fixed geometry. The worst case, giving the highest pressures, corresponds to a spherical surface under uniform tension (equibiaxial).

A formula can be derived for spherical surfaces



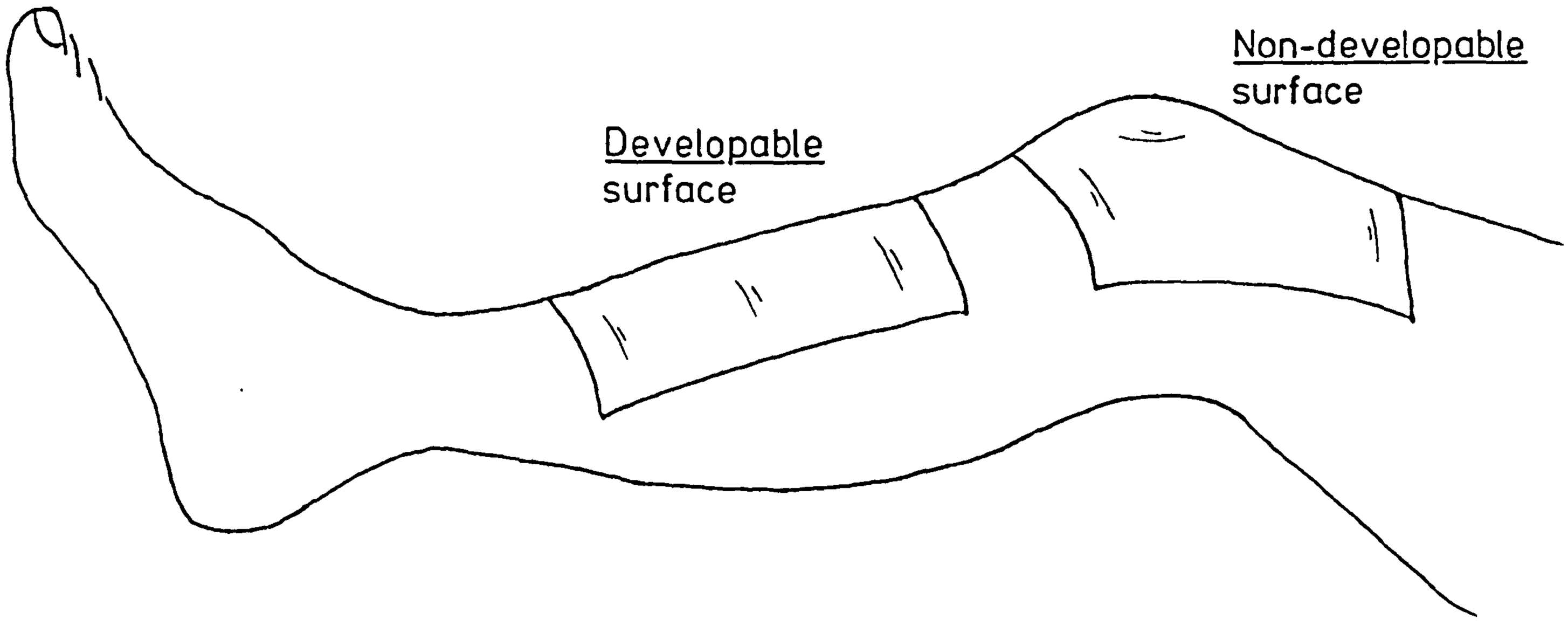


Figure 8.1

Conformability to Body Surfaces.

$$\Sigma F = 0 = - T\ 2\pi R + p\pi R^2$$

$$\therefore T\ 2\pi R = p\ \pi\ R^2$$

$$\therefore T = p\ \frac{\pi\ R^2}{2\pi R}$$

$$\therefore T = 0.5\ p\ R$$

Where T = circumferential tension in the dressing;

p = transmural pressure (pressure on the skin);

R = radius of curvature of the dressing.

On application of a transmural pressure (40 mmHg maximum) a wound dressing will adopt a curvature and to ensure total conformability this value must equal or exceed that of the appropriate body joint surface.

Dressings are required to meet two different conformability criteria. They must conform to 1) developable surfaces of fixed geometry e.g. curvature of the torso; and 2) non-developable surfaces, mainly the joints (Fig 8.1), which are examples of mobile surfaces and, the chin which is an example of a non-dynamic surface.

In the first category many of these developable surfaces are cylindrical or conical and to conform the dressing merely requires flexibility and not necessarily extensibility. However in the second, conformability has to be obtained to three dimensional

surfaces and this has to be maintained during motion of these sufaces e.g. elbow joint. Such a conformation for non-developable surfaces requires dressing flexibility and biaxial extensibility.

Dressing conformability is very important in the treatment of burn wounds over the body joints. It is essential that the joints are kept mobile during the healing process to obtain satisfactory joint mobility after healing is complete. For this reason, the use of a totally conformable and preferably elastic dressing provides the ideal environment for the protection of the wound and for the maintanence of joint mobility.

Non-conformability could lead to pocket formation due to the wrinkling of the dressing or to the blanching of the healthy and injured skin. The effect of such pressures on the wound surface is unknown but it is unlikely to be less than normal skin. The wrinkling of a dressing may lead to the build-up of exudate in the space between the wound surface and the wound dressing. This hot, humid fluid-filled space would provide the ideal conditions for bacterial growth and the tracking of bacteria from the dressing margins leading to serious infection problems.

A major problem with non-conformability is the blanching effect caused by the pressure of the dressing. This pressure effect will almost certainly cause tissue breakdown due to ischemia.

It is therefore very important that a dressing has the ability to adapt to the body surfaces. The importance of conformability has indicated the requirement of a preclinical assessment method to provide a measure of the conformability of a wound covering.

A preclinical assessment technique was designed on the basis of a simple inflation test, under a fixed pressure corresponding to the maximal pressure tolerable, a persistent interface pressure of 40 mmHg.

8.2 Experimental Apparatus

Test specimens were assessed using a water vapour transmission test cell (Chapter 5) modified to include outlet and inlet ports (Fig 8.2). The dressing was inflated by water delivered to the cell interior by a roller pump (Travenol, Inc.). To counteract any sagging by providing buoyancy and, in the case of the hydrogels, any dehydration, the cell was immersed in a water bath. A transmural pressure of 40 mmHg was maintained by the pump by allowing water to overflow from a standpipe whose outlet was 54.4cm above the bath free water surface. Since the pump feed is taken

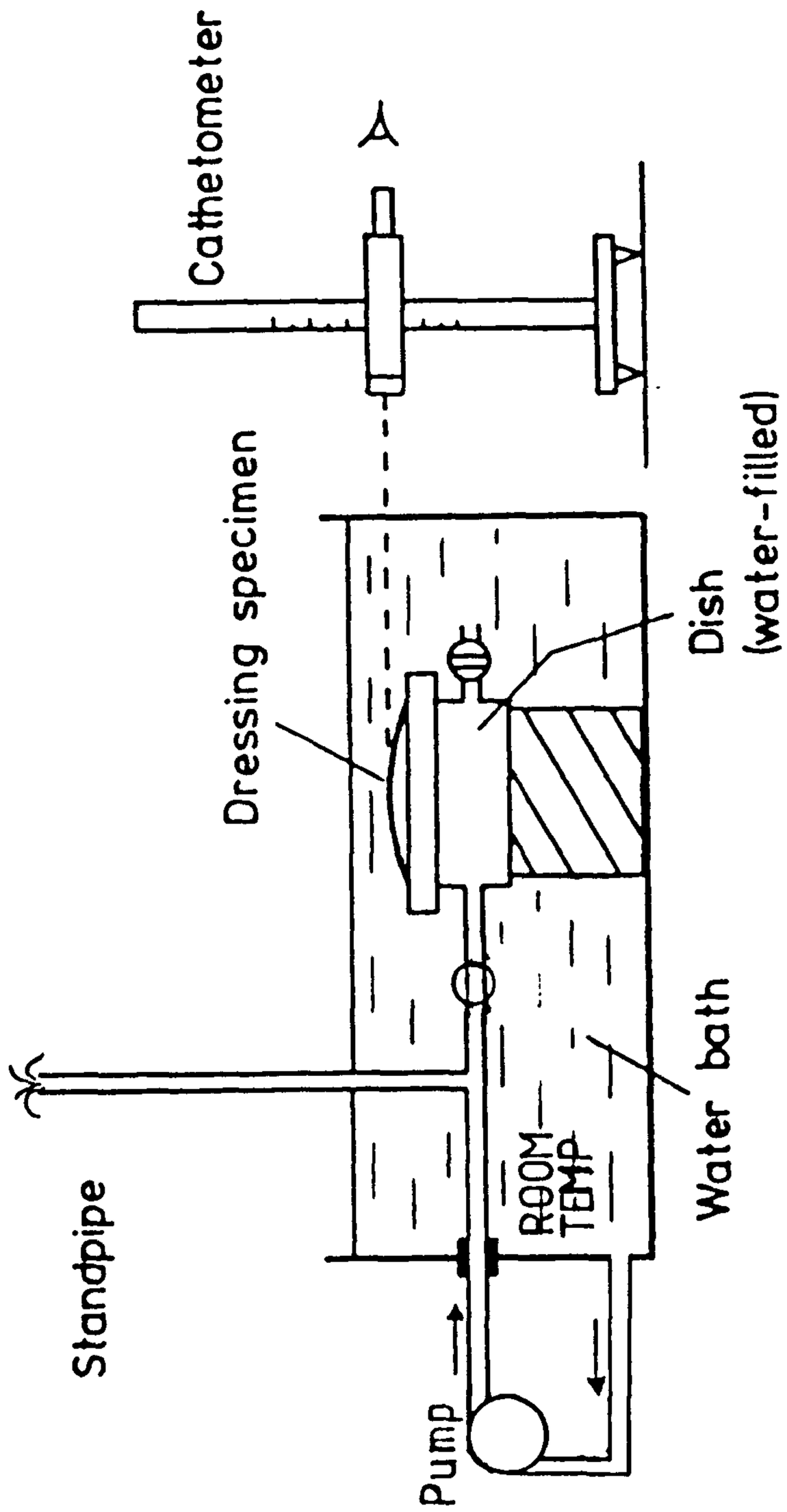


Figure 8.2

Test Equipment for the
Assessment of Conformability

from the water bath the pressure head is maintained constant. The neoprene and mylar gaskets present in the water vapour transmission test-cells were replaced with coarse, wet/dry emery cloth (grade P150C) gaskets, to give a more secure fixation against the pulling-out of the membrane under the tension induced by the pressure (Fig 8.3). Sealing was not important as modest water leaks did not effect the pressure head.

The materials were not deliberately prestressed although a small tension was applied to the flexible dressings to ensure that the specimens were not slack and wrinkled.

The change in height of the central point of the deformed sample was measured using a free standing travelling microscope [Griffin and George Ltd.]. Measurements were taken and recorded before and after the application of the pressure, the difference being the change in height (central deviation).

Figure 8.3

The test cell used to measure conformability.

8.3 Experimental Procedure

The membranes were prepared exactly as in Section 5.3 and the thickness of each test specimen was determined as in 5.4.1.

8.3.1 Inflation Procedure

The test cell was filled with distilled water and the lower cloth gasket was placed on the test cell rim. The prepared dressing was carefully placed on top of the water surface and the test cell cap was screwed down to clamp the membrane in position.

Any residual air which was trapped below the membrane was removed, via the outlet port, using a syringe. This was done by tilting the test cell and evacuating the air. Additional water may be added, via the inlet port, to bring the dressing into its neutral position (i.e. flat). Both the inlet and outlet ports are closed.

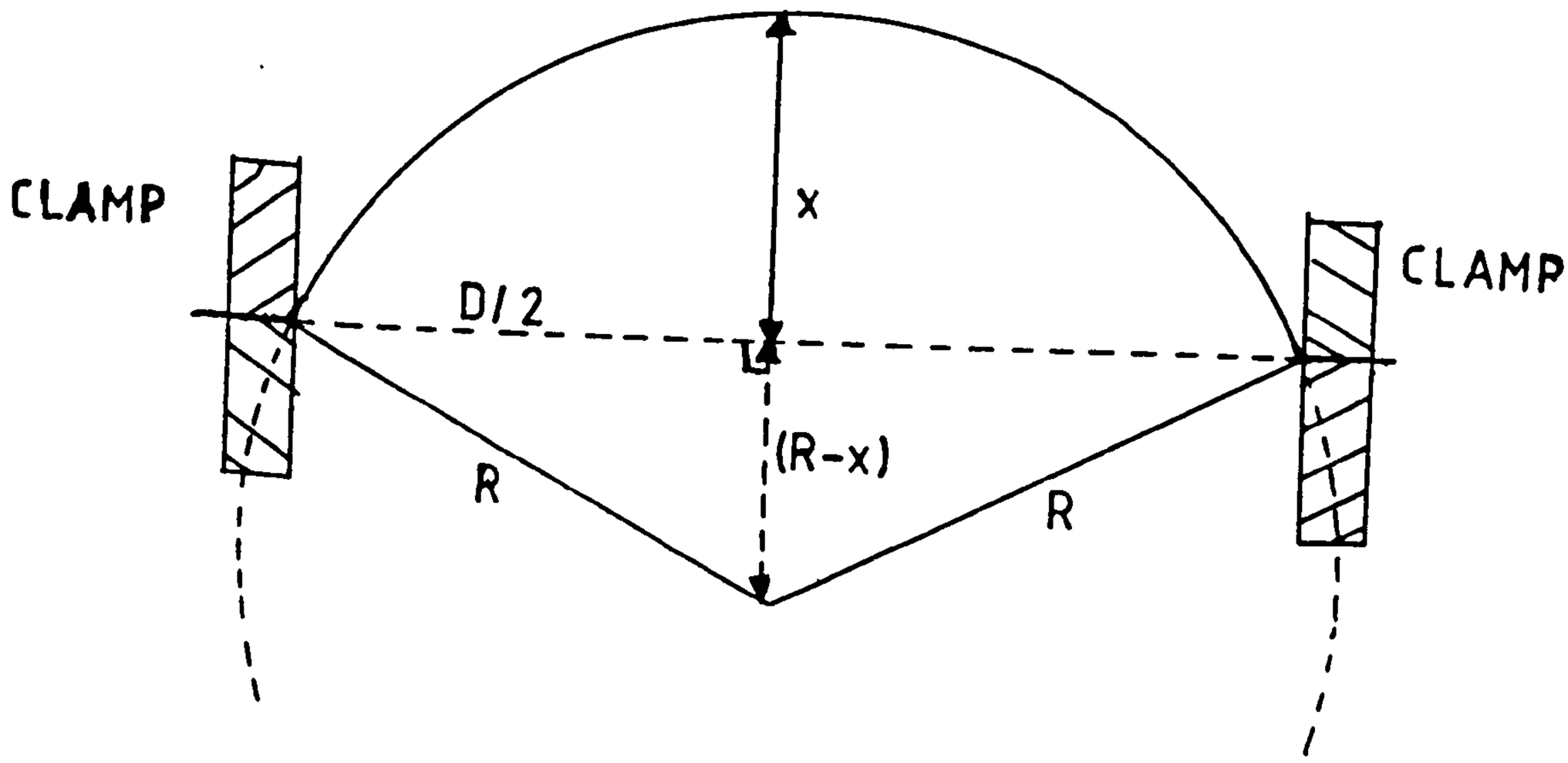
The test cell was placed in the water tank and connected to the pressure head via tubing. It was essential that the inlet port remains closed until the height measurement has been recorded at zero pressure.

The inlet tap was opened to allow the water to enter the test cell and it was closed one minute later. This time interval was chosen as it is long enough for equilibration. It was convenient and provided an immediate elastic response with the long term viscoelastic test in mind. Once the inlet tap had been securely closed, the height of the resulting dome was measured and recorded.

8.4 Theoretical Derivation and Results

A zero pressure height (reference) measurement and a maximum height measurement were recorded. The change in height was therefore given by subtracting one from the other, giving a value, x, in cm.

To calculate the radius of curvature values the following formula was derived :



The shape of the test specimen is assumed to be spherical giving a dome shape in the test cell (small defections allow this approximation). This approximation is justified for small deflections in flexible materials which are sensibly isotropic.

$$R^2 = \frac{D^2}{4} + (R - x)^2$$

$$R^2 = \frac{D^2}{4} + R^2 - 2Rx + x^2$$

$$R = \frac{D}{8x} + \frac{x}{2}$$

Where R = radius of curvature (cm)

D = diameter of the exposed area of dressing (cm)

x = change in height of the central point of the disc of specimen (cm)

[assumed to be planar, at zero pressure x = 0].

The conformability measurements calculated in the above manner can be found in Tables 8.1 and 8.3 and are expressed as the minimum radius.

Specimen (n = 8)	Height (cm)	Thickness (cm)	Radius of Curvature (cm)
Tegaderm	1.2 +/- 0.12	0.003	6.73 +/- 0.65
Bioclusive	1.4 +/- 0.04	0.010	5.90 +/- 0.14
Porvair (232013)	1.3 +/- 0.11	0.010	6.08 +/- 0.43
Porvair (32/5/1)	1.0 +/- 0.04	0.008	7.59 +/- 0.28
Vigilon Coverfilm	0.6 +/- 0.10	0.003	12.4 +/- 1.99
Stretch 'n' Seal	0.7 +/- 0.15	0.001	11.2 +/- 3.12
Mean +/- 1 S.D.			

Table 8.1

Conformability Characteristics of

Film Type (Thin) Dressings.

Specimen (n = 8)	Height (cm)	Thickness (cm)	Radius of Curvature (cm)
Lyofoam	0.1 +/- 0.02	1.1 +/- 0.08	66 +/- 12
Synthaderm	1.4 +/- 0.06	0.71 +/- 0.05	5.86 +/- 0.21
Coraderm	1.2 +/- 0.16	0.79 +/- 0.07	6.46 +/- 0.64
Mean +/- 1 S.D.			

Table 8.2

Conformability Characteristics of the Foam Type Dressings.

Specimen (n = 8)	Height (cm)	Thickness (cm)	Radius of Curvature (cm)
Geliperm	0.8 +/- 0.18	0.1 +/- 0.02	9.3 +/- 1.4
Non-linear PEO Hydrogel	0.6 +/- 0.05	0.09 +/- 0.009	12.4 +/- 0.9
Linear Polyurethane Hydrogel	1.1 +/- 0.12	0.02 +/- 0.002	7.0 +/- 0.8
Corethium	0.4 +/- 0.06	0.37 +/- 0.04	19.7 +/- 2.8
Mean +/- 1 S.D.			

Table 8.3

Conformability Characteristics of the Hydrophilic (fully hydrated) Wound Dressings.

8.5 Linear Viscoelastic Behaviour and Conformability

8.5.1 Introduction

Dressings are normally applied under tension to obtain conformation with wounded body surfaces. They may conform with an applied tension which is less than that required to produce the limiting interface pressure (40 mmHg).

However, conformation may sometimes require the dressing to be plastically deformed. This is acceptable if subsequent joint motion is small. Large surface strains, which cannot be accommodated by elastic deformation will produce wrinkling or compression buckling of the dressing, which may be unacceptable.

If the dressing material is viscoelastic (time dependent mechanical properties) initial surface pressures greater than 40 mmHg may be tolerated as, with fixed dressing boundaries (e.g. taped) the tension, and thus pressure, will relax with time. Thus long term conformability can be significantly increased above the immediate values based on elastic calculations. The advantage over plastic conformation is that subsequent joint motion is less likely to induce wrinkling as time dependent deformations are

recoverable.

8.5.2 Experimental Procedure

The experimental procedure was identical to that described in 8.3, except that the test was carried out for a period of five minutes. The incremental change in height was recorded at minute intervals.

8.5.3 Theoretical Derivation and Results

The results from the viscoelastic experiments were calculated as described in 8.4.

However, rather than expressing the height and radii measurements, only as finite values over the five minute period, they were also expressed as the average rate of change per minute (Tables 8.4 and 8.5). These rate values were calculated as follows :

$$\frac{\text{Height at 5 mins} - \text{Height at 1 min}}{5 - 1} = \text{Rate / Min}$$

The results calculated above are average values indicating creep. A more conventional analysis of such data would be to calculate, time constants, R_∞ and

other material parameters. However for the purposes of this research it was only necessary initially to obtain an indication of viscoelastic behaviour.

Specimen (n = 4)	Height (Final) (cm)	Rate of Change in Height (cm/min)	Thick-ness (cm)	Radius of Curvature (ROC)(Final) (cm)	Rate of Change in ROC (cm/min)
Stretch 'n' Seal	2.0 +/- 0.8	0.2 +/- 0.1	0.001	4.6 +/- 0.4	1 +/- 0.9
Tegaderm	3.3 +/- 0.4	0.5 +/- 0.05	0.003	3.8 +/- 0.1	0.6 +/- 0.25
Vigilon Coverfilm	NO SIGNIFICANT VISCOELASTIC BEHAVIOUR				
*Linear Hydrogel	1.6 +/- 0.1	0.5 +/- 0.08	0.02+/- 0.002	5.3 +/- 0.3	3.6 +/- 1.3
**Geliperm	2.3 +/- 0.1	0.6 +/- 0.39	0.09+/- 0.004	4.2 +/- 0.1	0.8 +/- 0.69
Non-linear Hydrogel	NO SIGNIFICANT VISCOELASTIC BEHAVIOUR				
Mean +/- 1 S.D.					

Note : * - test over 3 mins - pin hole formation

** - test over 2 mins - grip slippage

Table 8.4

Viscoelastic Characteristics.

Specimen (n = 4)	Height (Final) (cm)	Rate of Change in Height (cm/min)	Thick -ness (cm)	Radius of Curvature (ROC)(Final) (cm)	Rate of Change in ROC (cm/min)
Bioclusive	2.7 +/- 0.1	0.4 +/- 0.01	0.10	4.0 +/- 0.06	0.5 +/- 0.06
*Synthaderm	2.2 +/- 0.2	0.7 +/- 0.17	0.74+/- 0.05	4.3 +/- 0.20	1.3 +/- 0.3
Coraderm	4.6 +/- 0.02	0.9 +/- 0.03	0.80+/- 0.07	3.8 +/- 0.01	1.4 +/- 0.3
Lyofoam	NO SIGNIFICANT VISCOELASTIC BEHAVIOUR				
Porvair 232013	4.0 +/- 0.2	0.7 +/- 0.04	0.10	3.75	0.5 +/- 0.08
Porvair 32/5/1	1.6 +/- 0.2	0.3 +/- 0.1	0.08	5.2 +/- 0.4	1.0 +/- 0.3
Corethium	NO SIGNIFICANT VISCOELASTIC BEHAVIOUR				
Mean +/- 1 S.D.					

Note : * - test over 2.5 mins - specimen rupture.

Table 8.5

Viscoelastic Characteristics.

8.6 Discussion

Conformability is an important parameter which has to be taken into account in the design or assessment of a burn wound dressing.

In a bid to compare the experimentally derived radii of curvature with the natural radii of the non-developable surfaces of the body, the latter had to be measured. These natural radii values were determined, in a short "pseudoclinical" trial (Section 8.7), by the use of a "flexi-curve". The curve was placed around the body surface and a corresponding curve was drawn using the "flexi-curve". From these curves a radius of curvature was calculated as detailed in section 8.4.1. The values calculated in this manner are found in Table 8.6.

The range of radii of curvature for the various body regions was 1 - 14.5 cm, representing the minimum to the maximum measured. From Tables 8.1 to 8.3 and Figures 8.5 to 8.8 it can be seen that no dressing is totally conformable to all body regions, without wrinkling or folding occuring, at the 40 mmHg interface pressure limit.

BODY REGION	RADIUS OF CURVATURE (cm)
Buttocks	14.5
Head	10.2
Shoulder*	7.8
Knee*	5.7
Heel	5.0
Chin*	4.1
Elbow*	3.9
Knuckle	1.5
Finger-joint	1.0

*Derived from pseudoclinical trial

Table 8.6

Natural Radii of Curvature.

(Mean values for an adult)

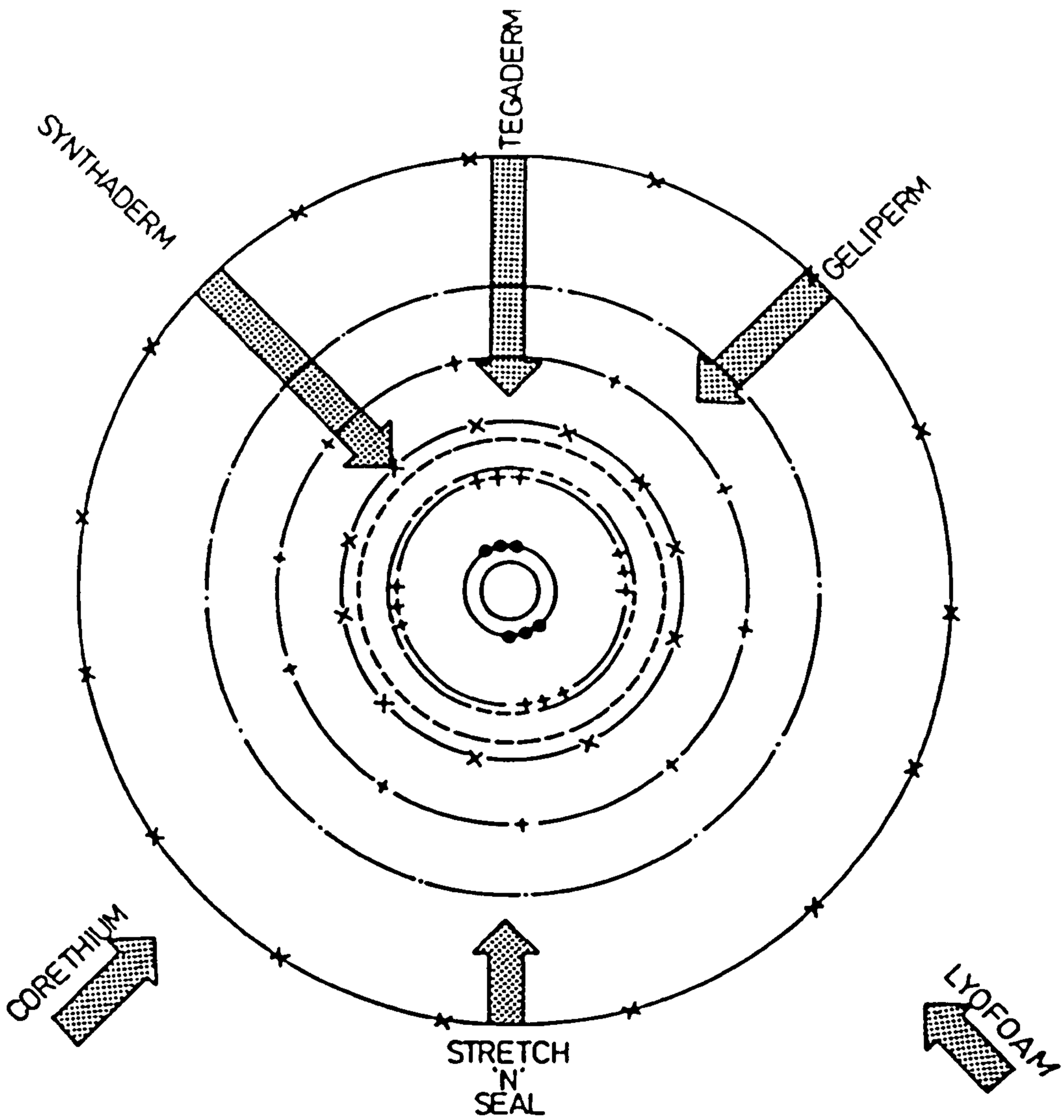
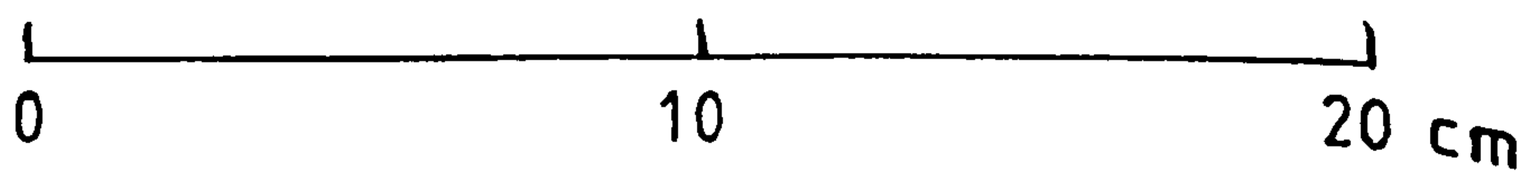


Figure 8.5

Conformability Results.



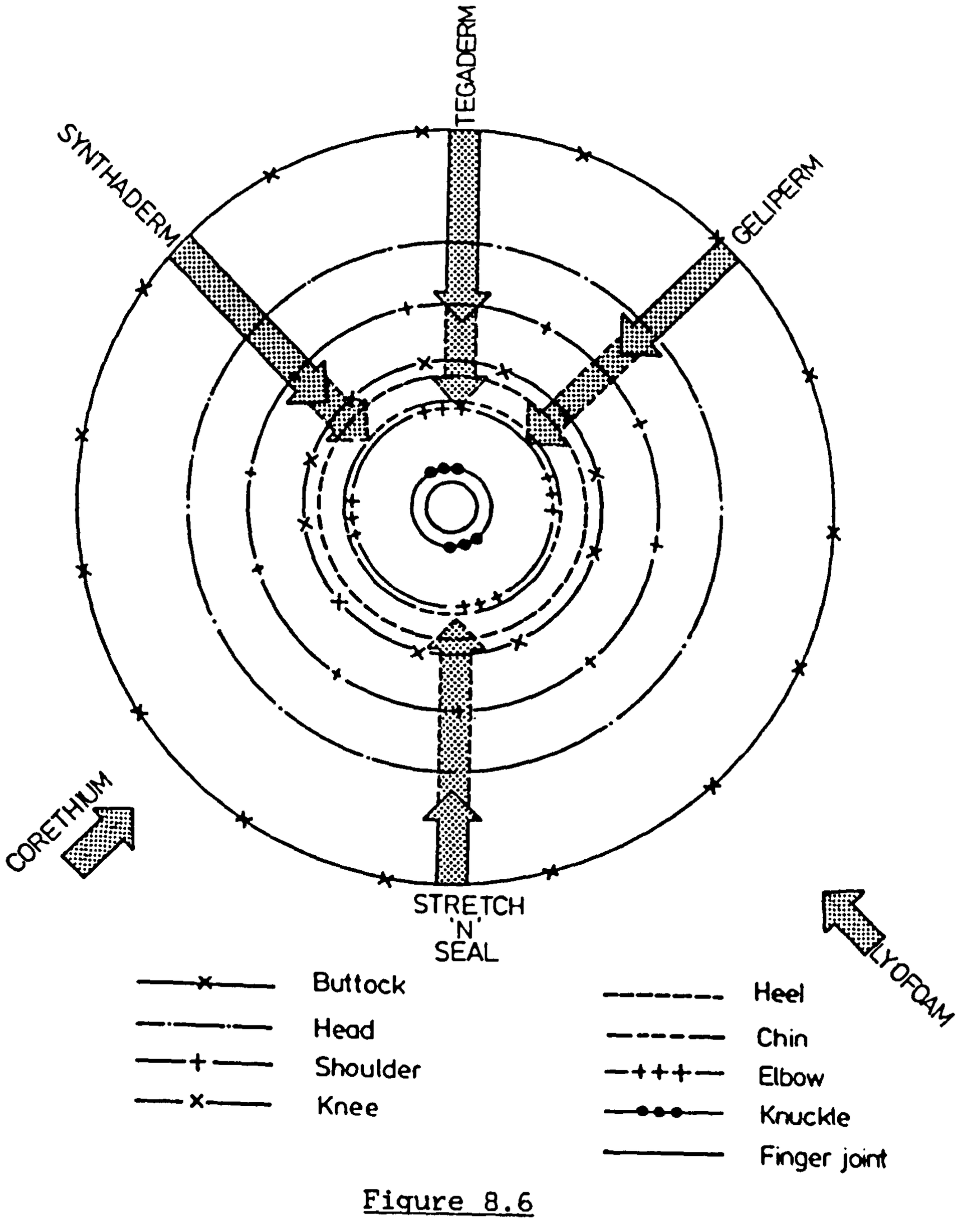
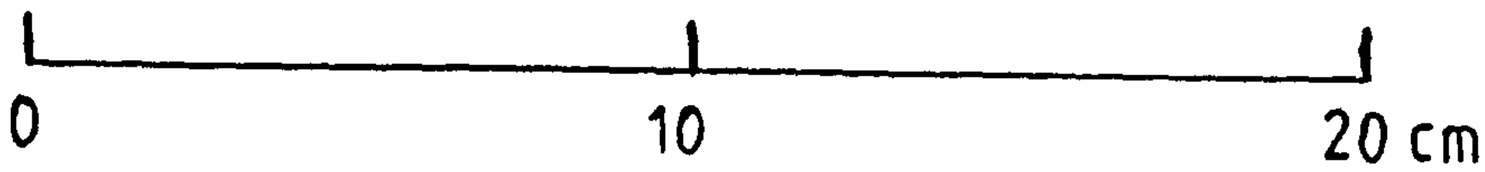


Figure 8.6

Viscoelastic Enhancement.



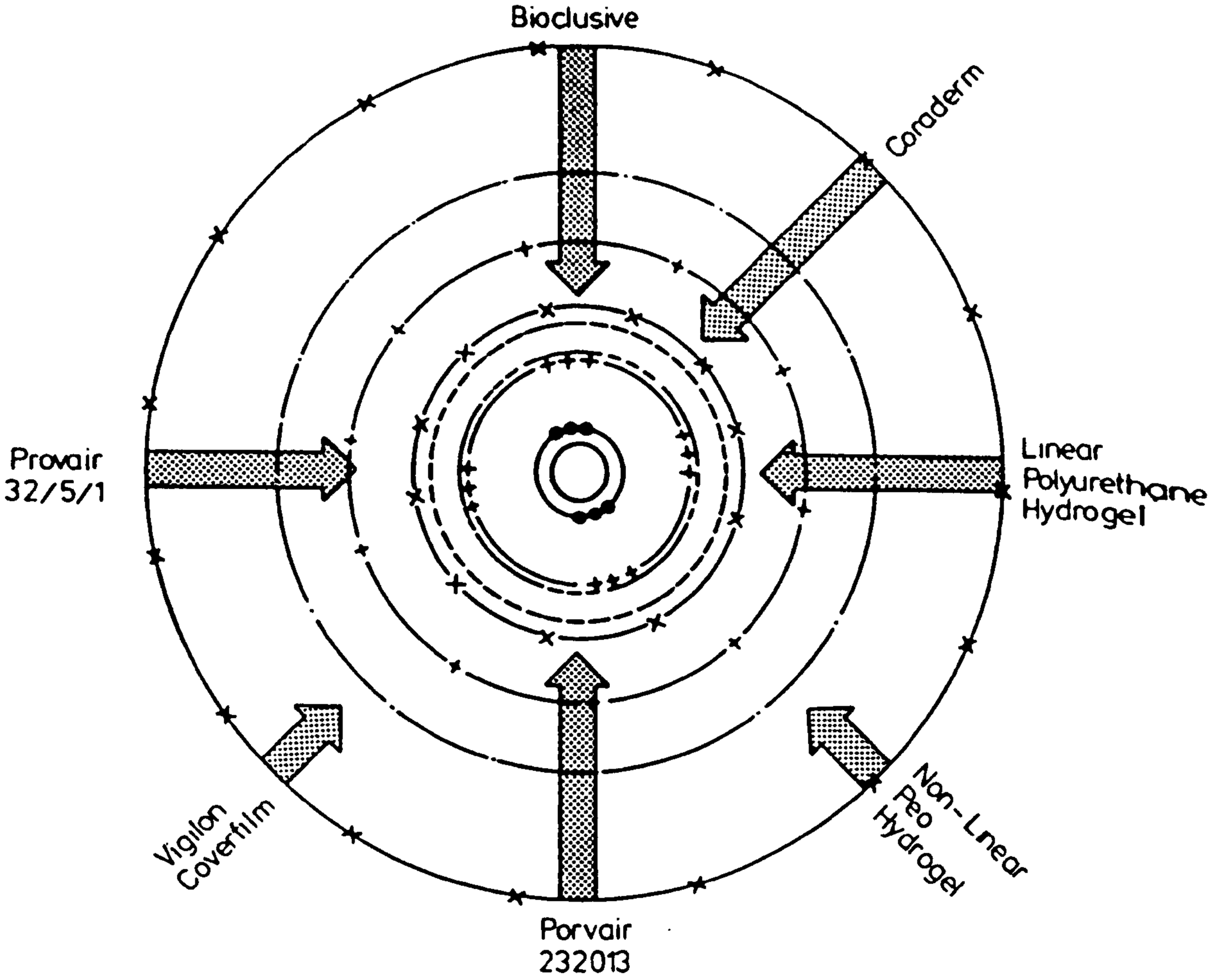
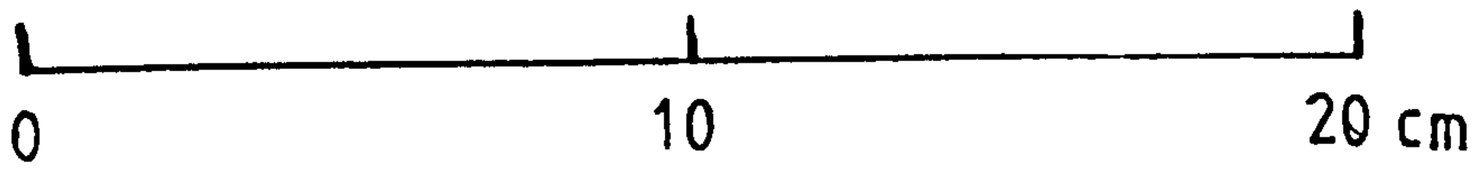


Figure 8.7

Conformability Results.



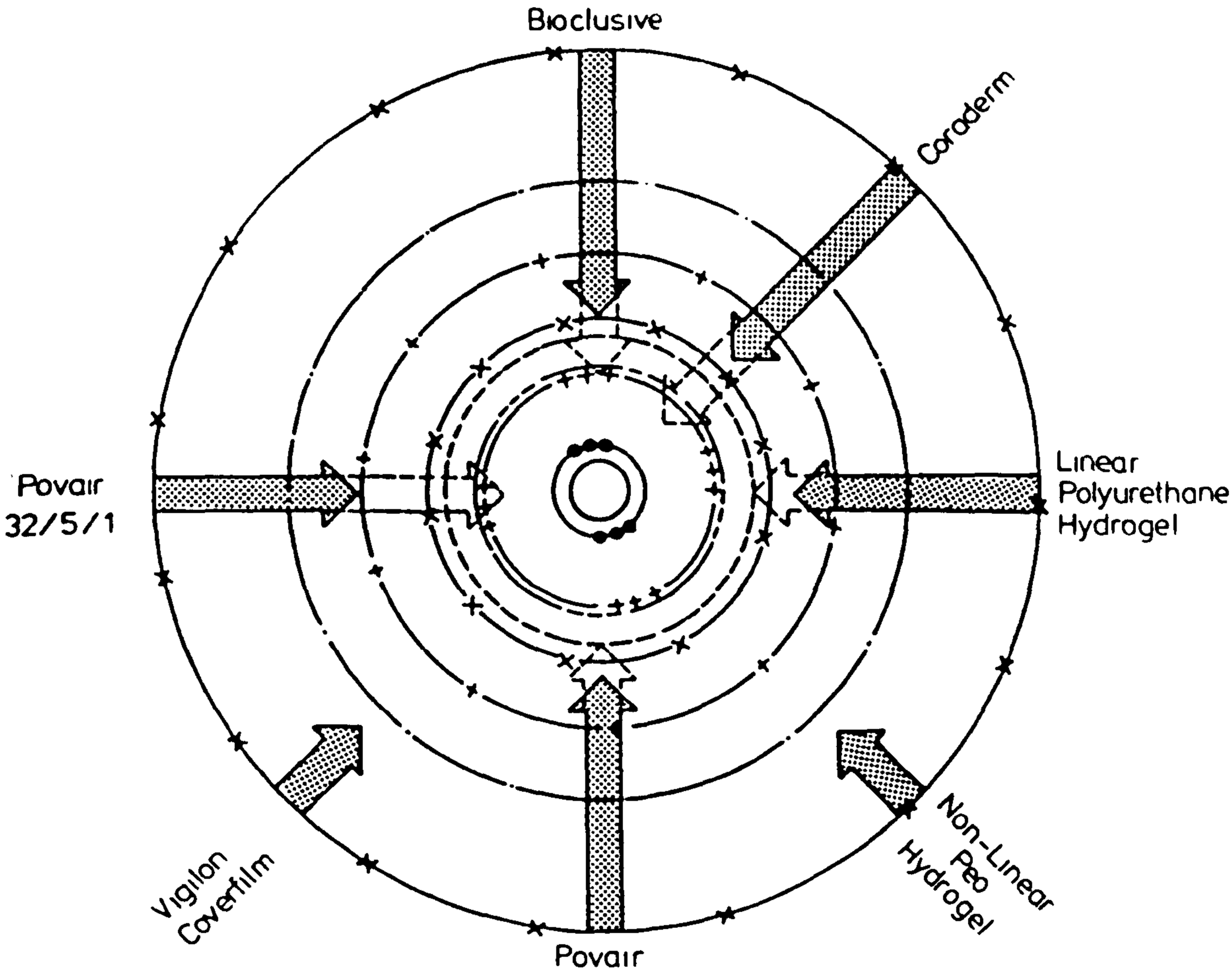
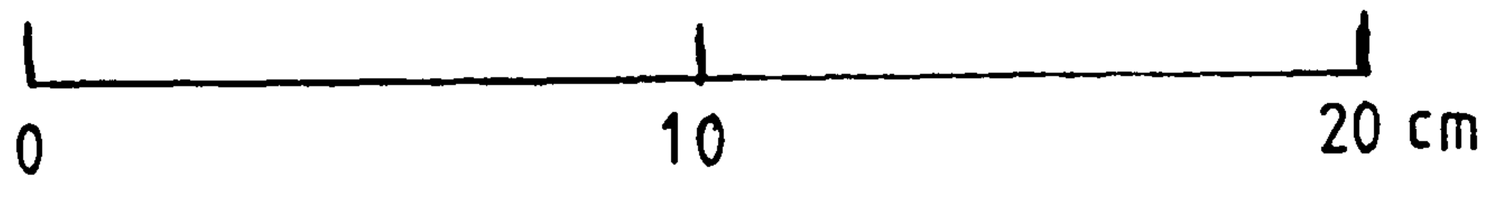


Figure 8.8

Viscoelastic Enhancement.



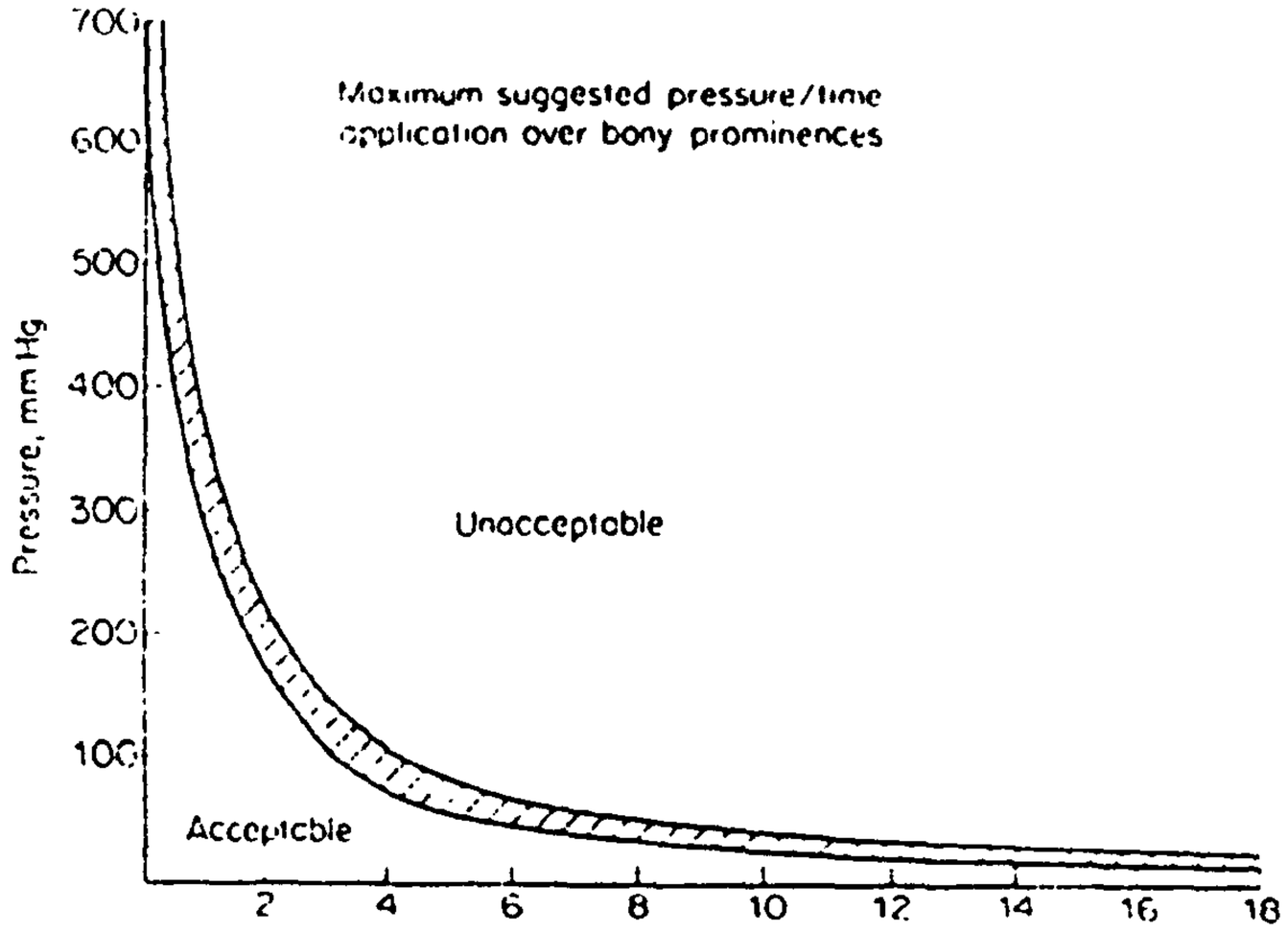


Fig 8.4 Pressure tolerance curve
(Reswick and Rogers, 1975)

It is important to point out that in the case of adhesive dressings any wrinkles or folds which appear will be self-sealing due to their adhesive backing. Therefore the problems associated with bacterial tracking along such folds should not be experienced with these dressings.

The viscoelastic properties (Tables 8.4 and 8.5) of a dressing are very important as the dressing once applied under tension can conform to the smaller joints. The initial blanching effect caused by the dressing lessens with time and an increased conformability, without wrinkling, is achieved. Blanching of the skin can only be tolerated for short periods. Reswick and Rogers (1975) constructed a pressure (mmHg) versus time (hrs of continuous pressure) plot from clinical data. From this curve guidelines can be obtained to the tolerable time of application, of a given pressure (Fig 8.4).

If a dressing is applied under significant tension to attain conformability, with initial blanching of the surrounding tissue resulting from the pressure, then the viscoelastic relaxation can reduce the pressure to acceptable levels after a period of time. From clinical data obtained in pressure sore therapy the time period for continuous application of pressure is generally limited to two hours and hence

this would be the maximum time for which these dressings should exert any pressure.

In general the film type dressings were the most conformable tested. Of the film dressings; Bioclusive, Tegaderm, Porvair 232013 and Porvair 32/5/1 had similar elastic conformability ranges, conforming down to the shoulder. Stretch 'n' Seal and the Vigilon Coverfilm were less conformable only conforming down to the buttocks. The viscoelastic behaviour exhibited by all of the film type dressings, excluding the Vigilon Coverfilm, enhances their conformability considerably (Figures 8.7 and 8.8). Based on viscoelastic data most of the dressings can accommodate regions down to the elbow. Stretch 'n' Seal (plastic deformation also) shows a marked improvement by conforming down to the heel.

Two of the foams tested, Synthaderm and Coraderm, had conformability characteristics which were similar to those of the film dressings. Both these dressings conform down to the shoulder. The third foam material tested, Lyofoam, is considerably thicker (some 10 times) than the other two materials. For this reason its conformability range was poor, as this material did not conform to any body region which was studied. From table 8.3 it can be seen that this value is very high in comparison to the others, indicating its poor

conformability. Lyofoam is probably more conformable than the calculated value. Due to the gripping technique in the test cell this material had to be tested with the foam-side up (according to dressing technique). It is likely that due to the tension, caused by the pressure, on the dressing, that the upper foam structure collapses. This will result in a thickness change at the central point and hence a lower height value is observed experimentally than occurs at the lower surface.

The hydrogels tested were slightly less conformable (without folding) than four of the film type dressings (Tegaderm, Bioclusive, Porvair 232013 and Porvair 32/5/1) and two of the foam dressings (Synthaderm and Coraderm). The Linear Polyurethane Hydrogel was more conformable than Geliperm, which in turn has a greater conformability than the Non-linear PEO Hydrogel. The Linear Hydrogel has the capability of conforming, without wrinkling, down to the shoulder (Table 8.2). This hydrogel also possesses viscoelastic properties. However the viscoelastic test for this material was carried out over a period of three minutes, as a longer period led to the formation of pinholes within the material (due to dust particles at casting).

The viscoelastic nature of this material allows conformability, without wrinkling, to be reached in body regions down to the knee.

Geliperm is less conformable and only satisfies the radii of curvature down to the head. Its viscoelasticity was recorded over a period of two minutes as the material slipped from the grips when the pressure was applied for prolonged periods. This slippage incidentally increases the apparent conformability measurement. The viscoelastic properties of this material allows conformability to be reached in surfaces down to the elbow.

The non-linear PEO hydrogel is the least conformable hydrogel, being only conformable, without wrinkling, to the buttocks. No viscoelastic test was carried out for this material as incidental observations showed that no height change occurred in the latter stages of the one minute test.

The pigskin dressing, Corethium, proved to be very non-conformable. This material did not conform to any joint region studied and it showed no viscoelastic behaviour which could have enhanced its conformability characteristics.

Dressing	Body Regions to which the Dressing Conforms
Tegaderm	Buttocks, Head, Shoulder, KNEE, HEEL, CHIN, ELBOW.
Bioclusive	Buttocks, Head, Shoulder, KNEE, HEEL, CHIN, ELBOW.
Porvair (232013)	Buttocks, Head, Shoulder, KNEE, HEEL, CHIN, ELBOW.
Porvair (32/5/1)	Buttocks, Head, Shoulder, KNEE, HEEL, CHIN, ELBOW.
Vigilon Coverfilm	Buttocks
Stretch 'n' Seal	Buttocks, HEAD, SHOULDER, KNEE, HEEL.
Lyofoam	No body region studied.
Synthaderm	Buttocks, Head, Shoulder, KNEE, HEEL, CHIN, ELBOW.
Coraderm	Buttocks, Head, Shoulder, KNEE, HEEL, CHIN, ELBOW.
Geliperm	Buttocks, Head, SHOULDER, KNEE, HEEL, CHIN, ELBOW.
Non-linear Hydrogel	Buttocks
Linear Hydrogel	Buttocks, Head, Shoulder, KNEE.
Corethium	No body region studied.

Table 8.7

Regions of Conformation (l.c.) and the Viscoelastic Improvement (U.C.).

The conformability test has proved to be a very useful preclinical assessment tool and the information obtained has given some indication of the necessary conformability values required in situ and of how well the materials meet these requirements (Table 8.9). To substantiate the in vitro findings a short clinical study was to be carried out (Section 8.7).

8.7 A Pseudoclinical Measurement Of Conformability

8.7.1 Introduction

If a dressing material accommodates body surfaces, by folding and wrinkling this may lead to wound infection by bacterial tracking. One research group, Eaglstein (1984), published data showing how with a series of dressings, in which wrinkling occurred, bacterial infection of the underlying wound was observed after several days. It was assumed by this group that bacteria entered the wound via the wrinkles which formed in the material, when accommodating the injured surface.

To relate the *in vitro* conformability measurement with the real body surfaces a pseudoclinical study was undertaken. Normal, uninjured individuals were used in this study of the *in situ* evaluation of dressing conformability to "normal" body surfaces.

In this study seven commercial dressings were evaluated on five body regions, namely the elbow, knee, shoulder, shin and chin.

In a bid to relate the *in vitro* measurement of conformability with body surfaces the radii of curvature of the body regions being studied had to be

assessed. This was necessary as a literature survey showed that such anatomical data had not been studied in any great detail.

8.7.2 Experimental Procedure

The procedure adopted was such that a minimum radius of curvature for each individual's body regions was determined and then the *in situ* conformability of a selected dressing was assessed. The assessment of dressing conformability was observational and based on the degree of folding and/or wrinkling which may or may not have occurred in accommodating the body region.

The observations and measured parameters were recorded on data sheets examples of which appear in Appendix 12.

The assessment procedure followed was :

1. Determination of the parameters required for data sheet one (i.e. personal details e.g. body weight).

2. Measurement of the radii of curvature of the body surfaces to be studied. In the case of joints this was done at maximum flexion.

3. The dressing was secured in place, by perimeter fixation if required, without the application of tension.

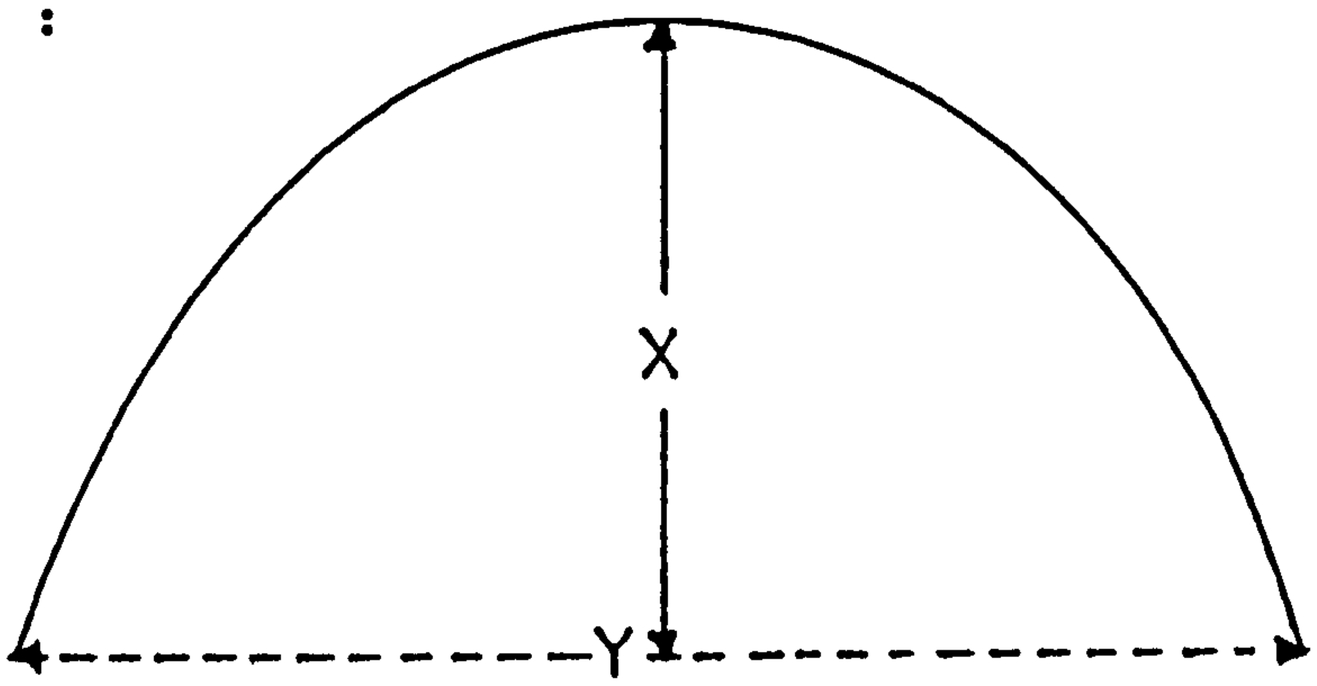
4. The dressing was photographed *in situ*.

5. The observations were recorded on the data sheets.

8.7.3 Theoretical Derivation and Results

The radii of the body surfaces were obtained by measuring the degree of curvature of the region by means of a "flexi-curve". The shape of the curve was transposed to a sheet of paper and a subsequent radii of curvature assigned by a similar method to the *in vitro* test.

The method of assessment is shown in the example below :



The height X is determined from the horizontal line Y. This Y-line is the horizontal line taken when the two

Radii of Curvature for Body Region (cm)					
Subject	Chin	Shoulder	Elbow	Knee	Shin
1	3.95	7.35	3.80	5.44	3.80
2	4.06	6.25	4.03	4.99	3.84
3	3.79	4.99	6.06	3.95	4.00
4	4.00	6.46	3.84	6.46	3.91
5	3.76	7.88	3.75	5.57	3.80
6	4.30	9.19	4.13	6.06	5.19
7	3.91	7.53	3.76	4.81	4.06
8	3.75	10.39	3.86	6.06	4.06
9	3.91	7.53	3.77	5.19	4.06
10	3.82	6.69	3.75	5.44	4.00
11	3.81	7.53	3.76	5.19	3.84
*12	4.45	5.44	3.75	5.72	4.06
Mean	3.96	7.28	4.02	5.41	4.05
+/-	+/-	+/-	+/-	+/-	+/-
1 S.D.	0.22	1.50	0.65	0.66	0.38

Table 8.8

The Measured Radii for the Male Population

(including the shin - developable)

* - subject not taken to trial.

Radii of Curvature for Body Region (cm)					
Subject	Chin	Shoulder	Elbow	Knee	Shin
1	3.91	6.46	3.77	6.25	3.75
2	4.03	14.30	3.79	5.72	5.72
3	4.13	8.26	3.84	5.72	4.65
4	3.95	9.19	3.79	6.06	4.21
5	4.52	14.31	3.83	5.72	3.91
6	3.98	4.81	3.76	5.72	5.72
7	3.76	6.46	3.75	5.72	3.78
8	4.13	6.69	3.84	6.94	4.00
9	4.30	6.94	3.75	6.06	4.17
10	4.81	7.53	3.80	6.06	4.35
Mean	4.15	8.50	3.79	6.00	4.43
+/-	+/-	+/-	+/-	+/-	+/-
1 S.D.	0.31	3.27	0.04	0.39	0.73

Table 8.9

The Measured Radii for the Female Population

parts of the curve are 7.5 cm apart. Once established the height X is used in the method described in Section 8.4 and a subsequent radius of curvature is calculated.

Using this method one assumes that as a first approximation the arc of the joint profile is circular. It is recognised that this will be in error where the curve is not a circle e.g. a parabola or sine wave (alternative equations can be derived for these surfaces). However as a first indicator of in situ conformability this method is adequate for the preliminary study presented here.

Twenty one individuals were assessed in the above manner and the physiological data obtained for the five body surfaces studied is presented in Tables 8.8 and 8.9. This data allowed the calculation of an average radius of curvature for each body region studied and for the different sexes, since 11 males and 10 females were studied.

The author is aware of the secondary curvature in the case of joint measurements. The curvature measured in these cases was that plane in which the curvature altered greatly with joint movement.

Body Region	Radius of Curvature (cm)
Shoulder	7.83 +/- 2.48
Knee	5.68 +/- 0.62
Shin	4.22 +/- 0.58
Elbow	3.92 +/- 0.49
Chin	4.05 +/- 0.28

Table 8.10

Examples of the Radii of the Curvature Values for all Individuals Studied.

(n = 21)

Band	Scaling Factor (cm)
A	Radius of Curvature +/- 0.5
B	Radius of Curvature +/- 1.0
C	Radius of Curvature +/- 2.0
D	Radius of Curvature +/- 5.0

Table 8.11

Ranking System Utilised in the In Vitro Tests to Allow A Correlation with the In Situ Tests

The study showed very little difference between the measured radii of curvature for males compared to females. The slight differences observed may be due to differences in fat distribution between the two sexes. Both populations were combined to give overall mean values (Table 8.10).The data obtained during the in vitro work utilised these average values giving a conformability range for each dressing material.

The observations recorded in the data sheets comprised an approximate number of wrinkles or folds. A number was not stated when these folds/wrinkles exceeded twenty. In these cases they were noted as "many". From these observations and from the photographic records a conformability grading was given for each dressing when used on each body region. These gradings are shown in Table 8.13.

Several examples of the photographic records from which these gradings were assessed are shown in Figures 8.10 to 8.15.

In a bid to correlate the in vitro and the in vivo studies one had to grade the findings of the laboratory experiments.

The experimental findings using the laboratory test procedure were therefore given a grading corresponding to how well they performed during testing. The gradings were given in a ranking fashion. The banding system used is shown in Table 8.11.

The band was assigned by matching the experimentally derived radius of curvature with the "pseudoclinically" derived radius of curvature for each particular joint region studied. The values given can be found in Table 8.12.

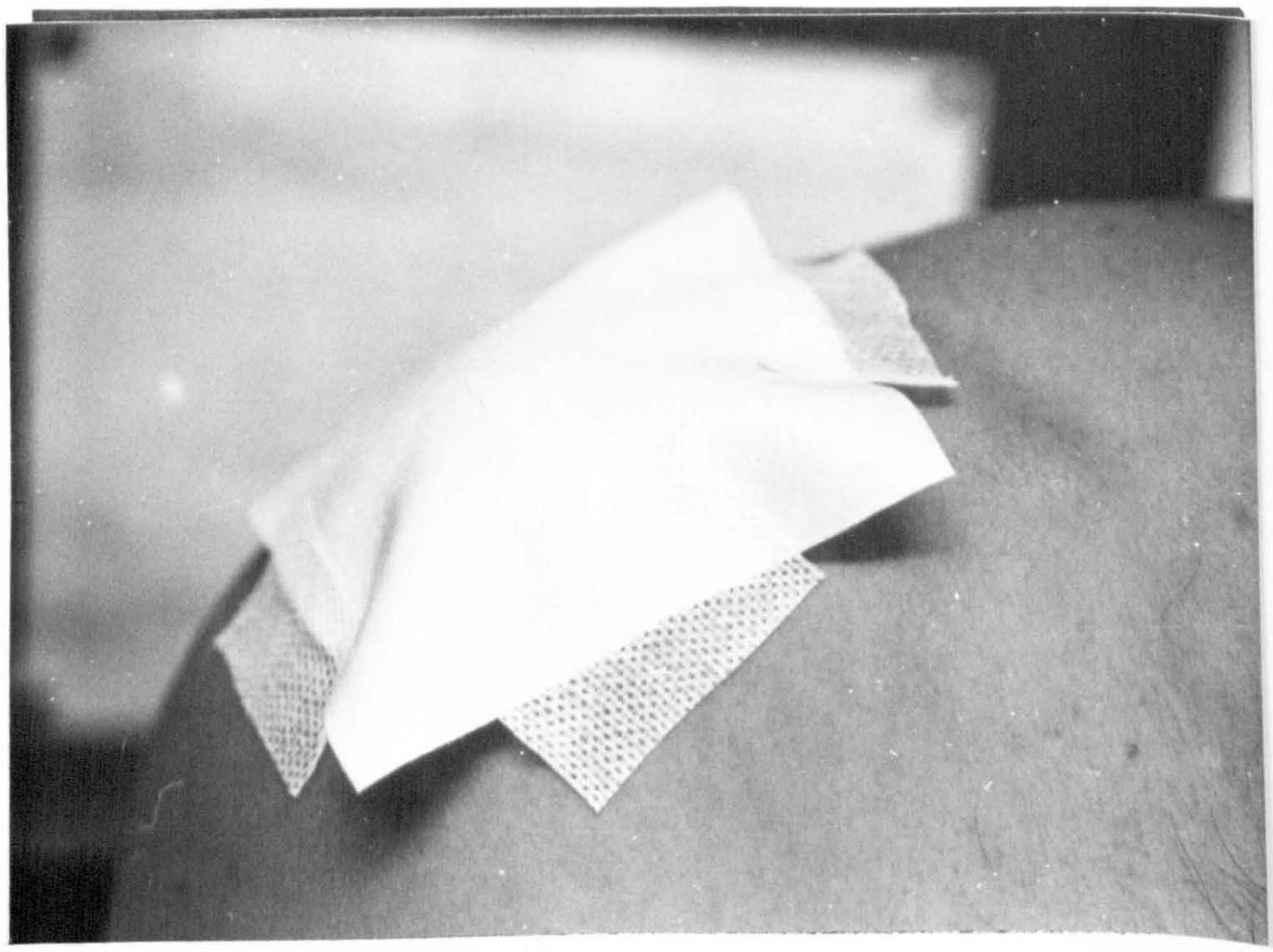


Figure 8.10

Example of a dressing which was given a rating of C due to the flutes which formed.

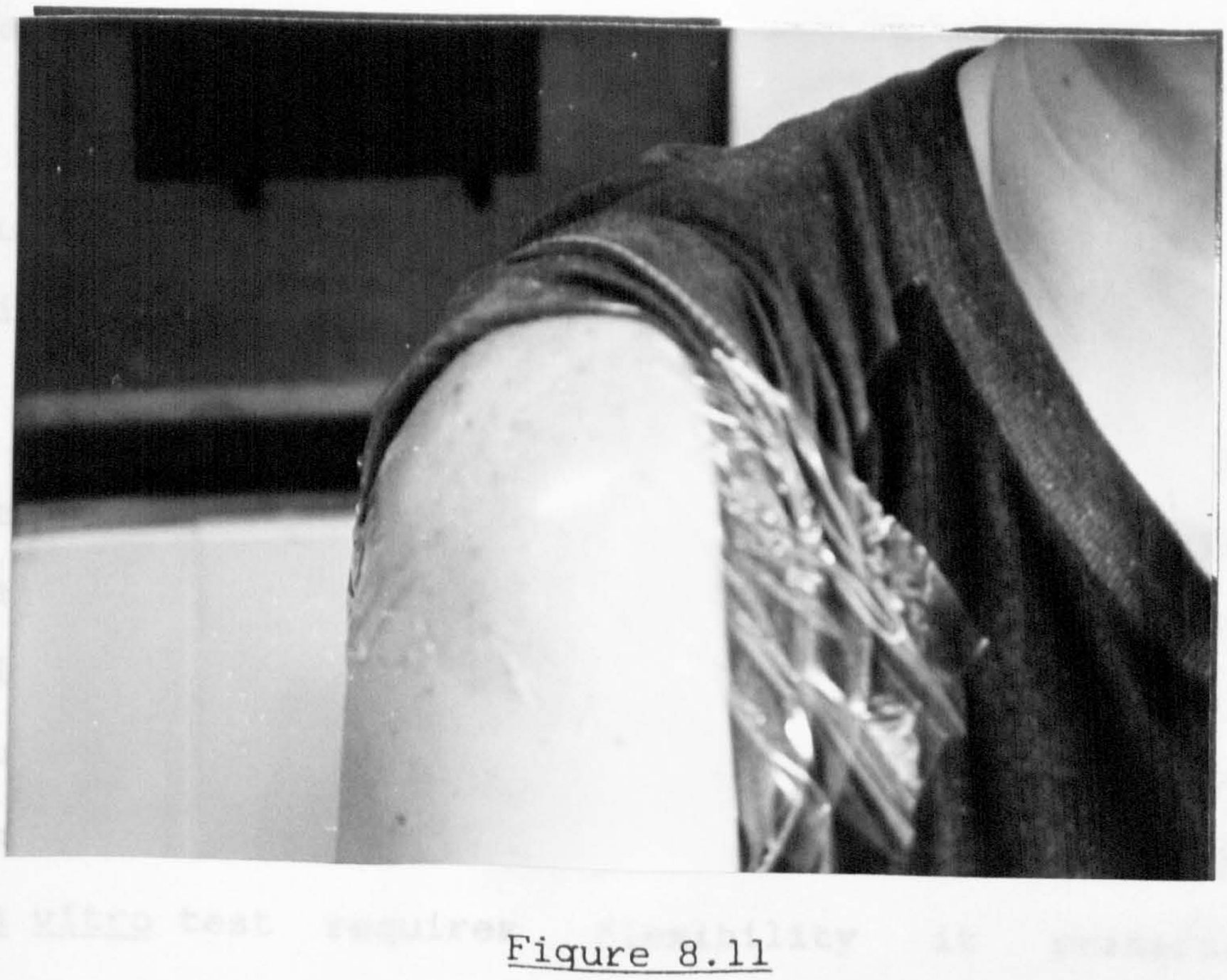


Figure 8.11

Example of an adhesive dressing which was given a rating of B due to the wrinkling.

8.7.4 Clinical Discussion

In general most of the conformability characteristics found either preclinically or "pseudoclinically" are similar, as can be seen in Tables 8.12 and 8.13.

However in some cases the gradings are different but an explanation of this difference can often be given.

One of the main groups of values differing between tests are the values obtained for the materials when used on the shin. The reason for this difference is due to the shin being a developable surface and hence the materials when used on the shin only require flexibility to conform. Since the *in vitro* test requires flexibility it primarily assesses biaxial extensibility, the estimation of the conformability in respect to developable surfaces is grossly under-estimated.

The conformability of Synthaderm and Coraderm indicated by the *in vitro* test is an over-estimation of the true clinical conformability. This is due to the inflation test taking place under water. The dressings therefore become saturated and in such a state become more pliant resulting in a greater apparent conformability than that indicated *in*

Dressing	Elbow	Knee	Shoulder	Shin	Chin
Bioclusive	B	B	A	B	B
Tegaderm	C	A	A	C	C
Stretch'n'Seal	D	D	C	D	D
Lyofoam	D	D	D	D	D
Synthaderm	B	A	A	B	B
Coraderm	C	A	A	C	C
Geliperm	D	C	B	D	D

Table 8.12

Gradings given for In Vitro Testing.

Dressing	Elbow	Knee	Shoulder	Shin	Chin
Bioclusive	B	B	B	B	C
Tegaderm	C	B	B	B	C
Stretch'n'Seal	D	D	C	B	D
Lyofoam	D	D	C	A	D
Synthaderm	C	C	C	A	D
Coraderm	C	C	C	A	D
Geliperm	D	B	A	A	D

Table 8.13

Gradings given for In Vivo Testing.

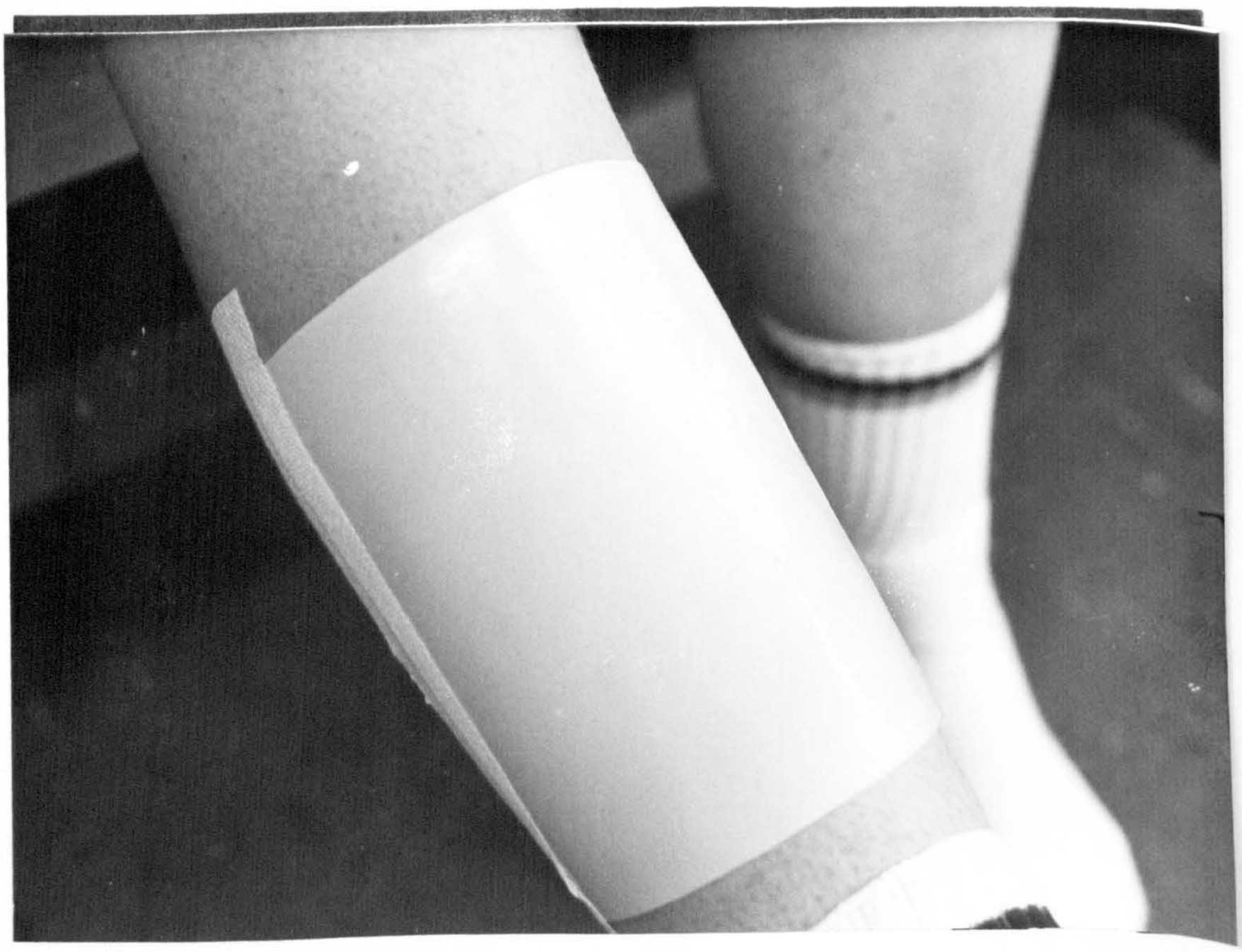


Figure 8.12

Example of a dressing on the shin (a developable surface) which was given a rating of A.

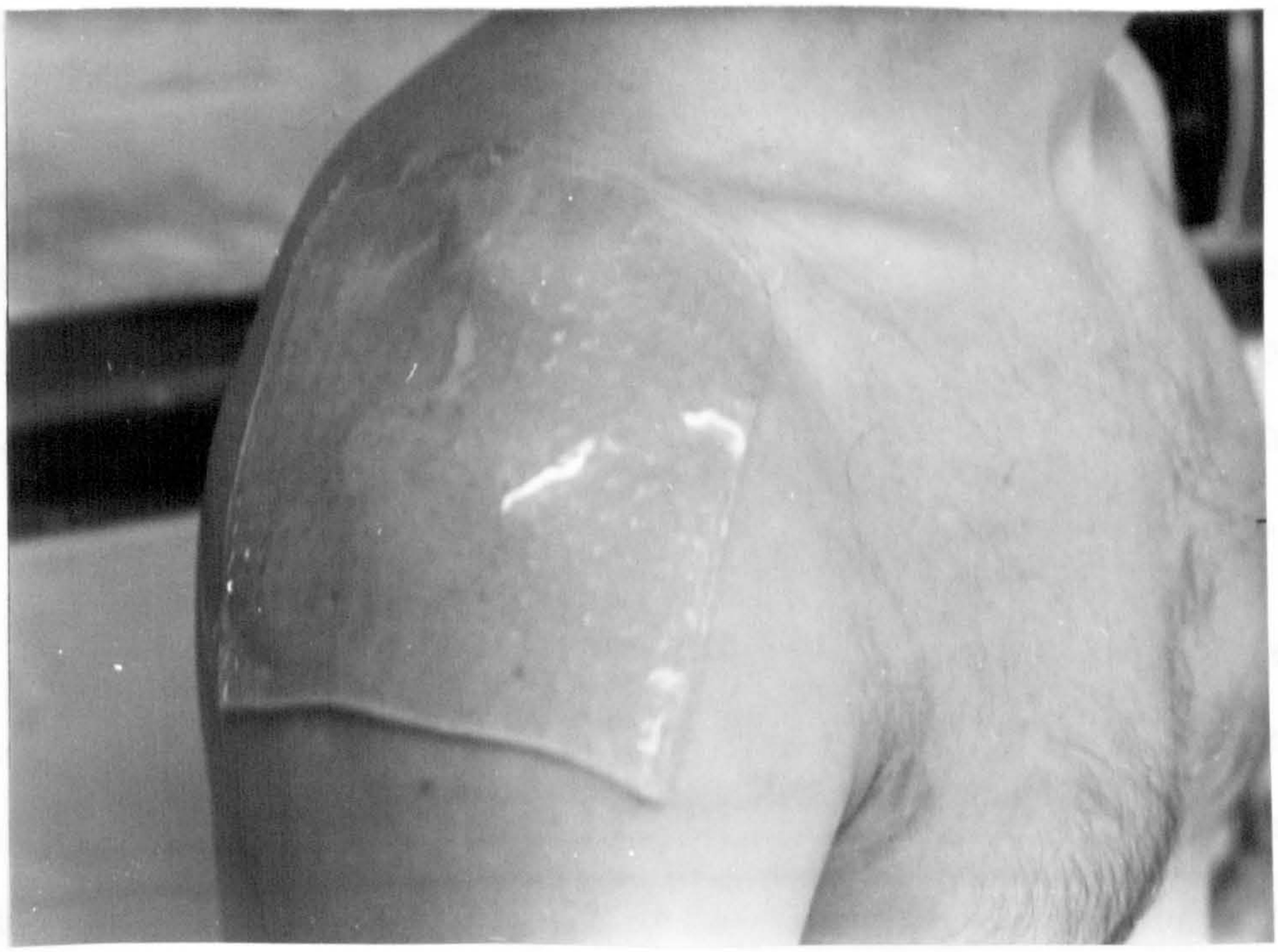


Figure 8.13

Example of a dressing on a broad shoulder which was given a rating of A.

vivo when exposed to air.

In some cases the values obtained for the knee and the elbow joint are slightly under estimated by the laboratory test. However this arises due to the different physical characteristics between males and females. Males tend to have broad flat shoulders and females broad flat knees. These characteristics create a slightly better surface for conformation on some individuals and hence this causes the discrepancies between the two measuring techniques.

The adhesive dressings may be given a lower conformability rating *in situ* than deserved. with these dressings the wrinkles which may form close due to the adhesive backing and the associated problems of bacterial tracking are therefore reduced.

Overall the *in vitro* test gives an objective and fair indication as to the potential conformability characteristics of any dressing material. The findings of the clinical study substantiate the laboratory findings in most cases and also allow other conclusions to be drawn in respect of the other material characteristics which lead to acceptable conformability.

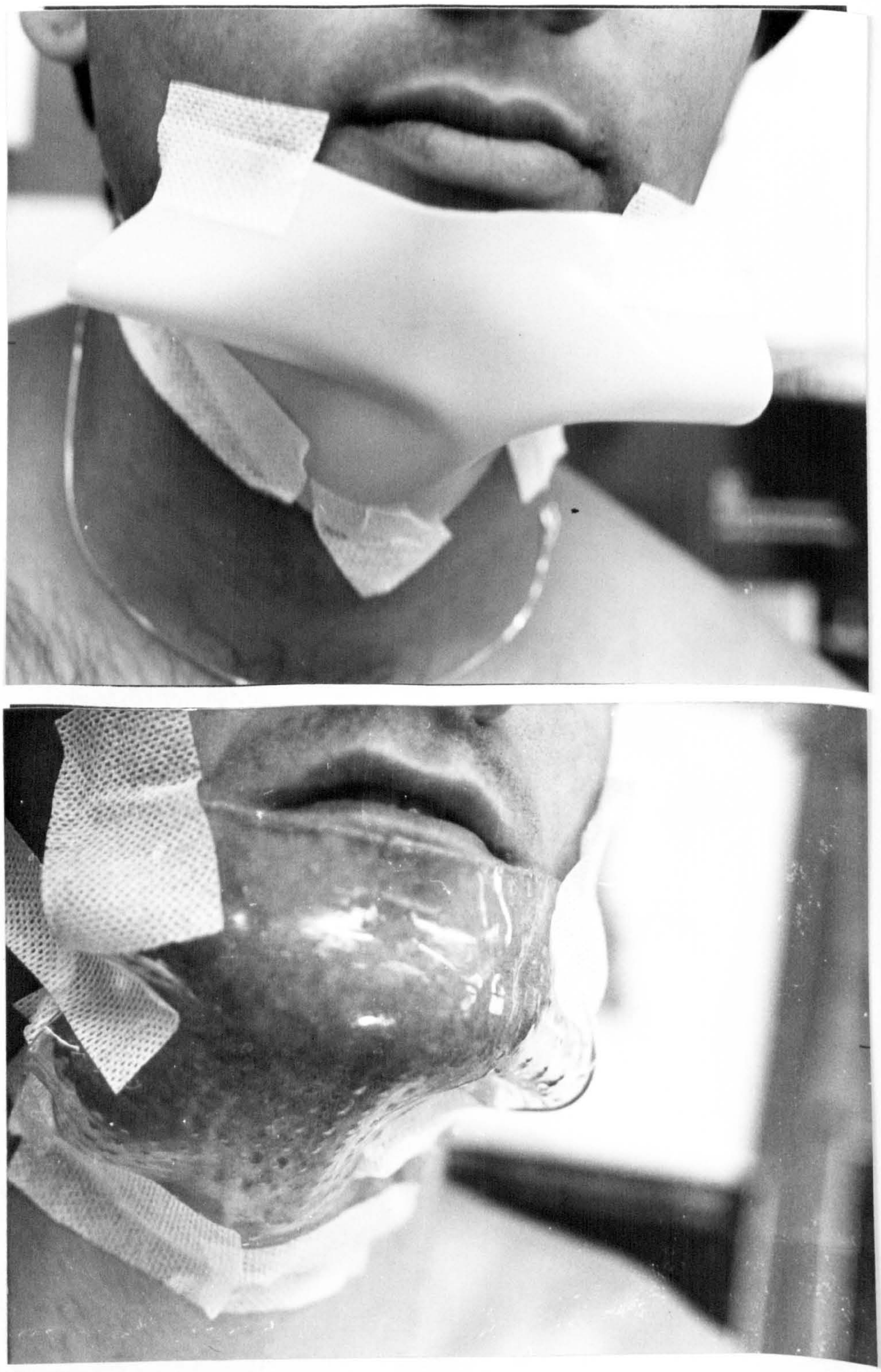


Figure 8.14

Examples of dressings on the chin. Both were very non-conformable due to the fluting and were therefore given a rating of D.

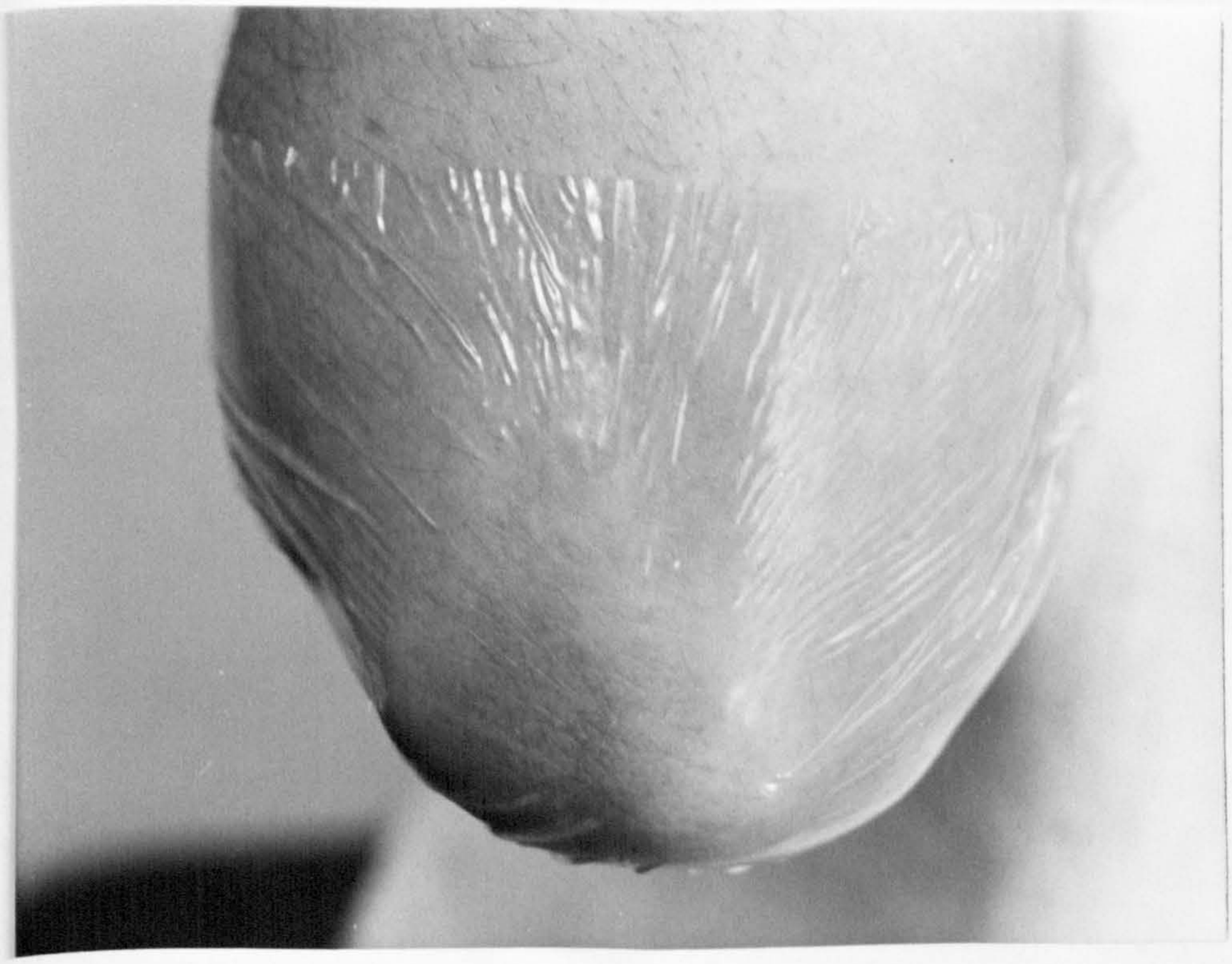


Figure 8.15

Example of an adhesive dressing on the elbow which was given a low rating of C due to the wrinkles. Subsequently a higher ranking should be given as the problem of bacterial tracking is not valid due to the adhesive sealing the wrinkles.

Chapter 9

The Physical Effects of an Adhesive Dressing Top Layer on Burn Wound Dressings

CHAPTER 9

9.1 Introduction

Browne (1982) studied the bacteriological and physical properties of a hydrogel dressing (Geliperm, Geistlich and Sons Ltd.) and its application to wounds, burns and grafts. One difficulty encountered was how to secure the slippy, non-stick hydrogel on the body surface. The best method found was to secure the Geliperm in place using a compliant, adhesive dressing (Mefix, Molnlycke Ltd.). It was shown that Mefix fixation was sufficiently secure to allow the patient to be ambulant. Such mobility permits the patient to be at home and to be treated on an outpatient basis thereby reducing hospitalisation costs.

The dressing technique employed by Browne(1982) is illustrated in Figures 9.1 and 9.2. The Geliperm is first placed on the wound surface and then totally covered, together with a region of the surrounding skin, with Mefix.

Geliperm has been the subject of recent preclinical and clinical studies (Wokalek et al, 1979; Griffith and Clark, 1982; Browne, 1982; Turner,1984). A major problem experienced was gel dehydration and

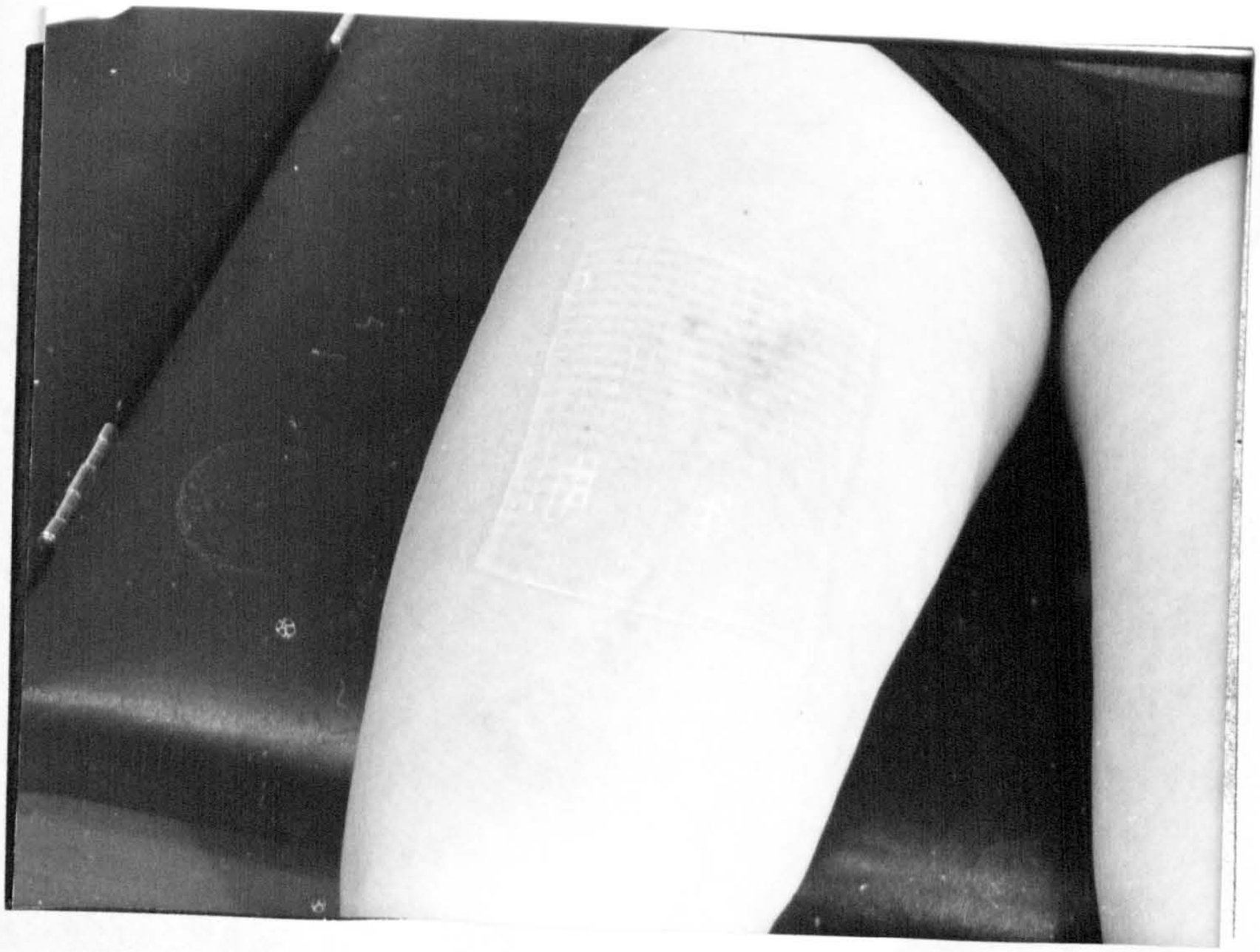


Figure 9.1

First stage of the dressing procedure.

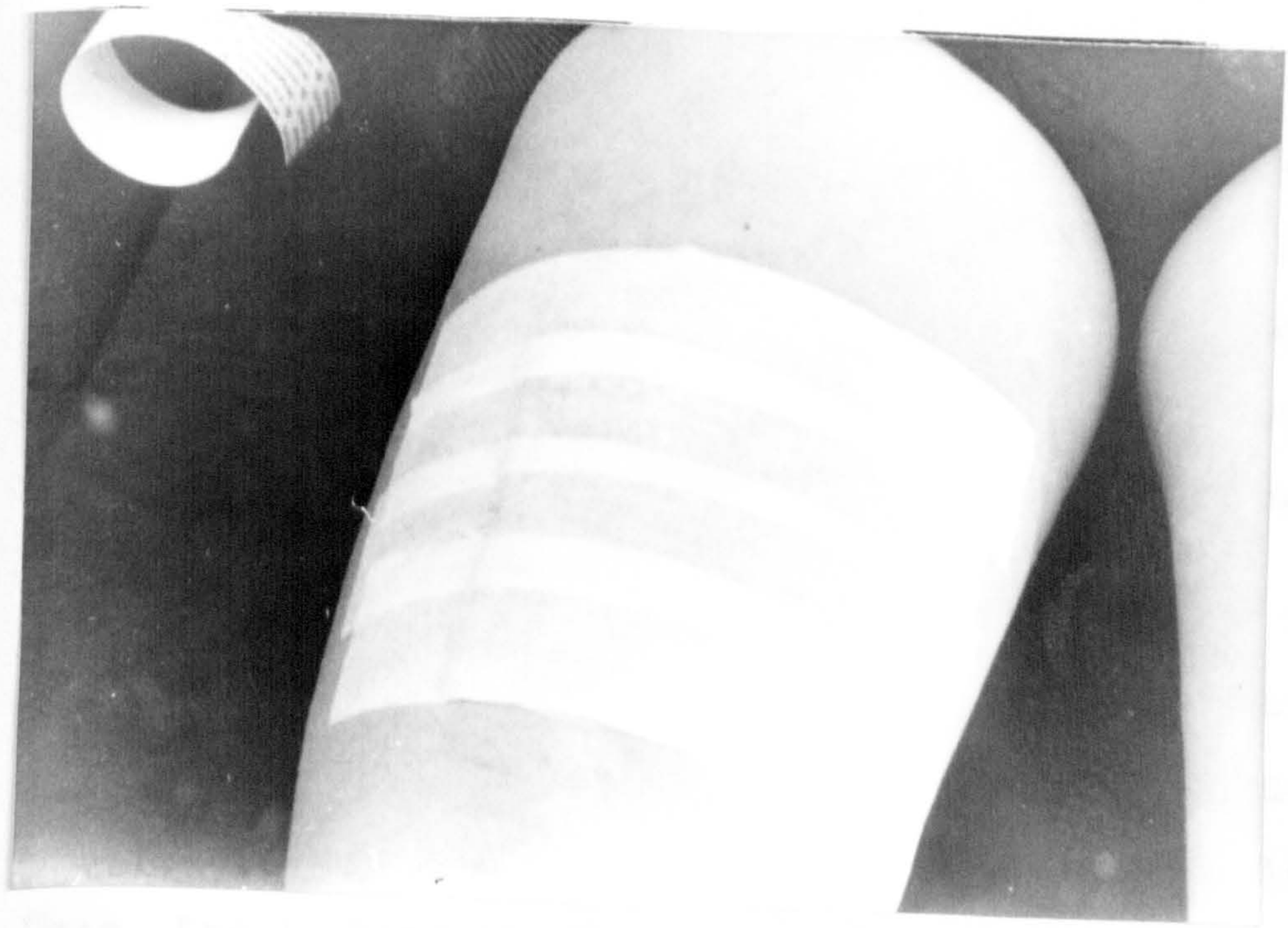


Figure 9.2

The finished bilaminate dressing.

subsequent adherence to the wound surface. This could be overcome by saline irrigation, which rehydrated the gel and facilitated its removal without disturbing the newly formed epithelium.

From the results presented by Browne(1982), it appears that gel dehydration was delayed until towards the end of the treatment without the need for irrigation. These observations only occurred when the gel was covered with a Mefix top layer, indicating that the rate of gel dehydration was altered by the presence of the Mefix.

Many types of wound dressing are currently available (Park, 1978; Davies, 1983; Wise, 1984; Quinn et al,1985). Some (e.g. Tegaderm, 3M Health Care Ltd.) have their own adhesive layer and hence do not require a securing layer. However, in general most wound dressings require a securing layer(s). Conventional bandages (e.g. crepe bandages) are the most common retaining layer and these will have an effect on the physical properties of the under-lying dressings. An upper layer will affect the rate of dehydration by limiting the water vapour transmission rate of the composite dressing. It also alters the dressing's conformability. The WVTR of a dressing is important to wound healing. As discussed in Chapter 5, it should control the evaporative water loss in order to maintain adequate moisture at the wound dressing interface, thereby

allowing re-epithelialisation without dressing adherence. Conformability is important in maintaining the integrity of the bacterial barrier function of the dressing (Queen et al,1986). It is necessary therefore to quantify such effects to provide information relevant to the clinical use of the retaining layers.

A series of experiments was carried out in the laboratory to determine the effect that Mefix has on the physical properties of Geliperm and other candidate hydrogels. Assessment was made of the water vapour transmission and the conformability of the bilaminates.

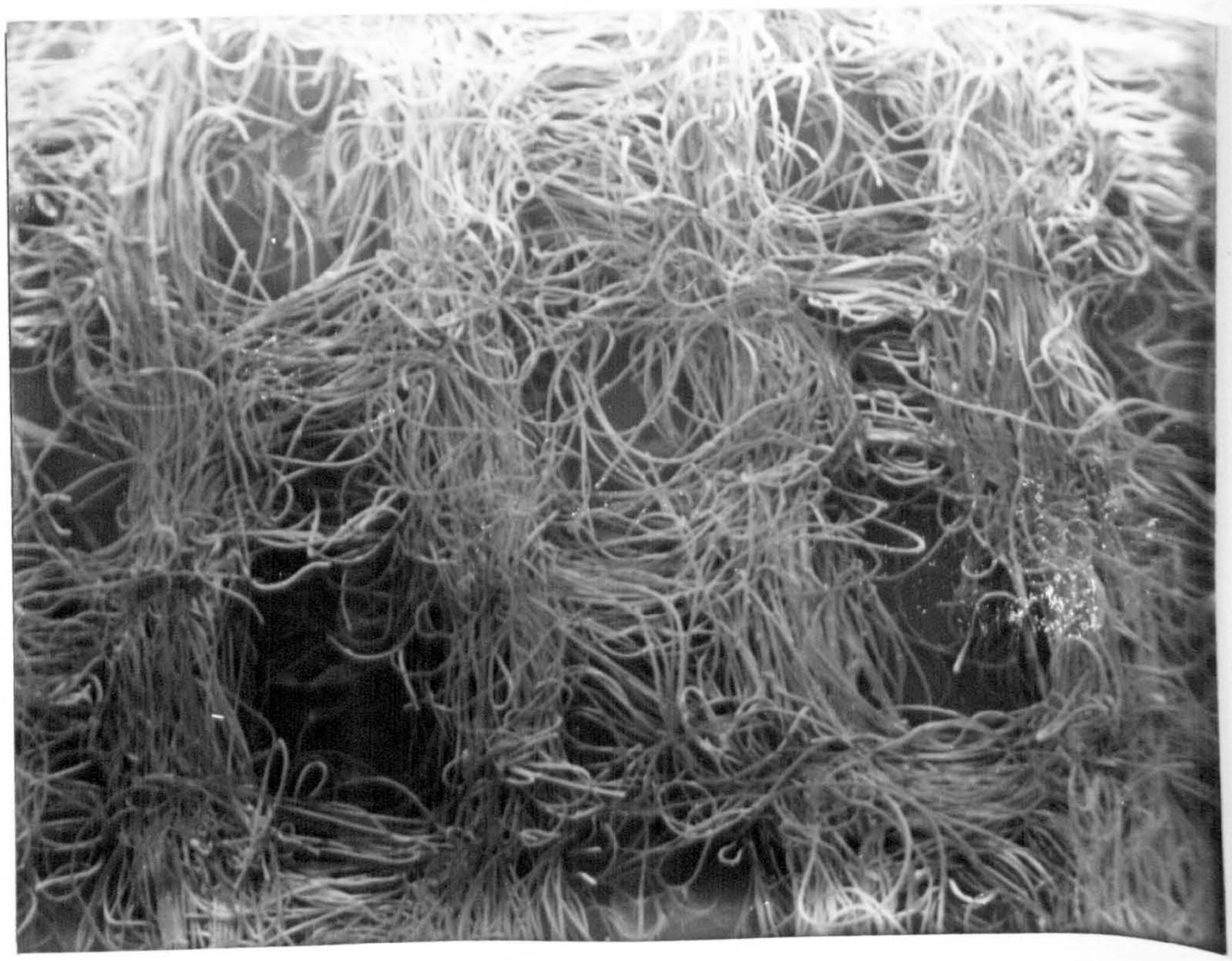


Figure 9.3

Micrograph showing the non-woven fibres of the Mefix fabric.

(Mag X20, Markers 100 microns)

9.2 Experimental description

9.2.1 Materials

The materials used for these studies were Mefix, Geliperm and the two novel hydrogels (Linear and Non-linear Hydrogels) developed in the Department of Pure and Applied Chemistry, University of Strathclyde. Detailed descriptions of the materials above can be found in Chapter Four.

A detailed study was carried out on the adhesive dressing Mefix to gain a better understanding of the structure and its effect on the physical properties of the underlying dressing.

Mefix is an adhesive coated fabric, which is intended for the fixation of wound dressings and swabs. It is made of a non-woven fabric (Figure 9.3), with the fibres held together by the adhesive coating (Figure 9.4). It is highly compliant and conforms to the body surface allowing body movement. The adhesive is described by the manufacturer as a polyacrylate and is hypoallergenic. As shown in Figure 9.5, the adhesive coating is discontinuous due to the presence of small open pores, which are randomly distributed.

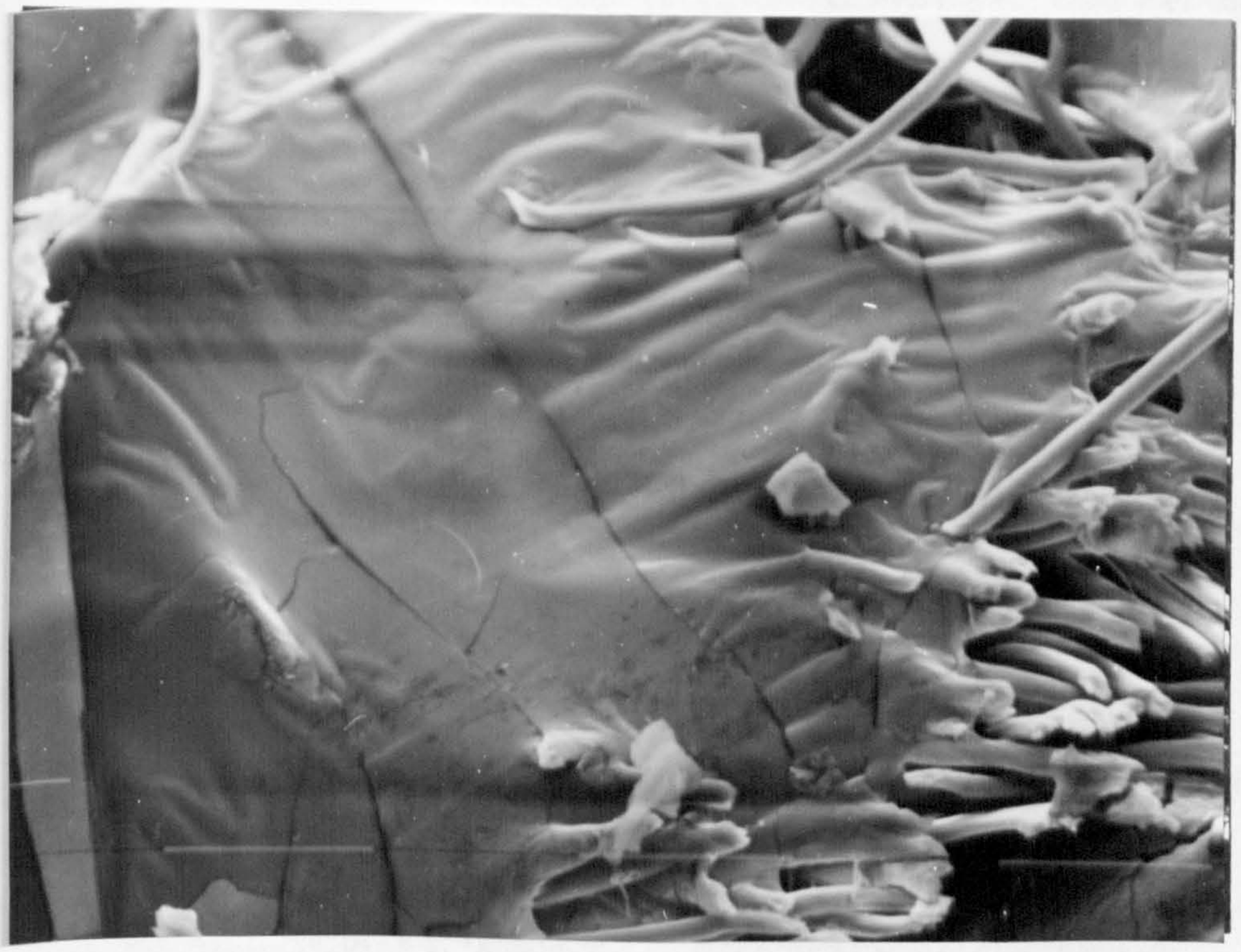


Figure 9.4

Micrograph showing how the adhesive coating binds the fibres together.

(Mag X160, Markers 100 microns)

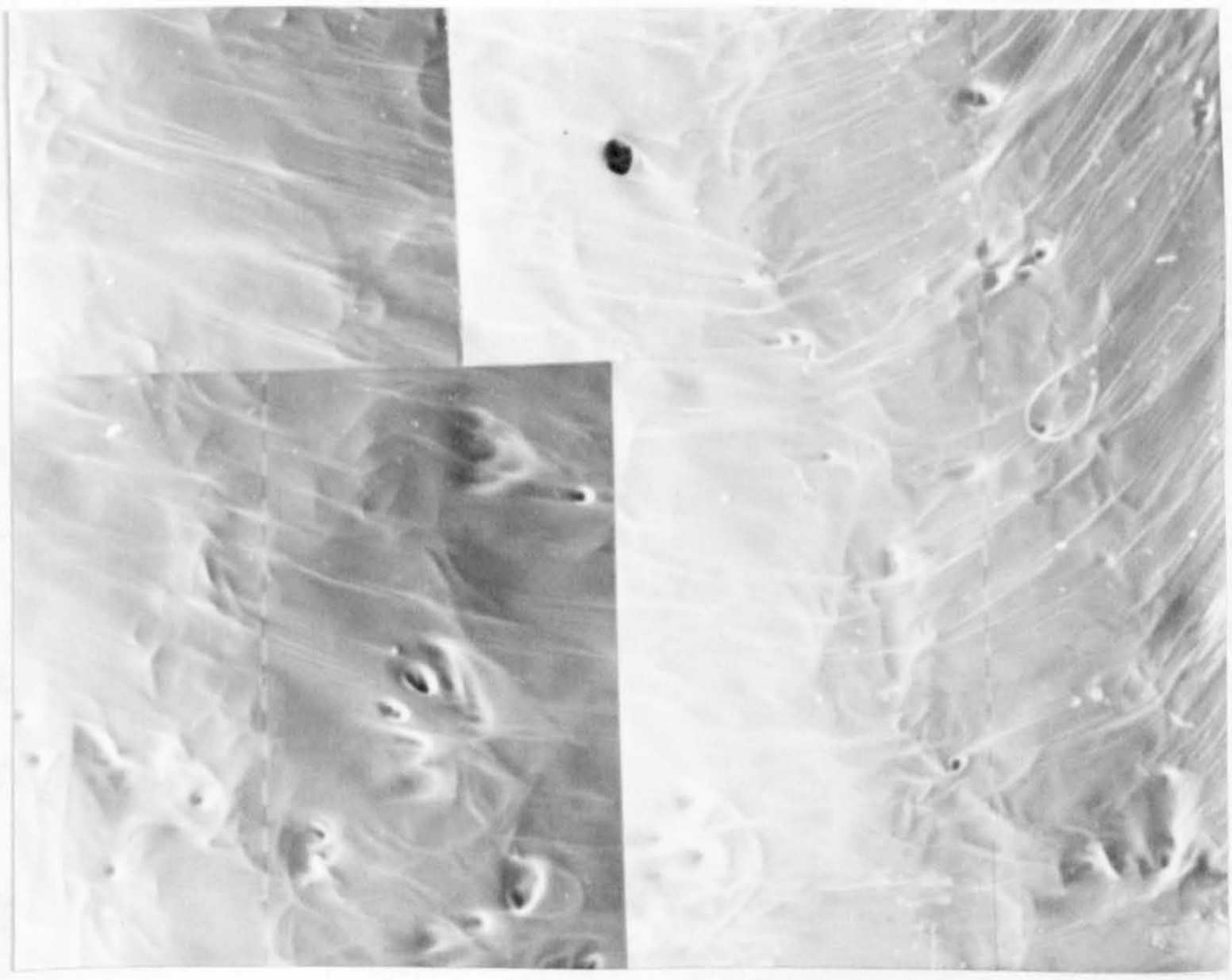


Figure 9.5

Micrograph showing the discontinuity of the adhesive (small pores in adhesive layer).

(Mag X20, Markers 100 microns)

9.2.2 Methods

The materials above were assessed as the hydrogel dressing alone and in the bi-laminate form. The parameters determined were the water vapour transmission rate and the conformability.

The water vapour transmission rate was determined using the modified international standard (ASTM E96-81) method described in Chapter Five. When testing the bi-laminate the test dish was assembled with the Mefix covering on top of the dressing as shown in Figure 9.6.

Conformability was assessed, using 40mmHg transmural pressure, by the inflation technique described in Chapter Eight.

9.3 Results

The results obtained in this study are presented in Tables 9.1 and 9.2. These results were calculated by the methods described in 5.5 and 8.4.

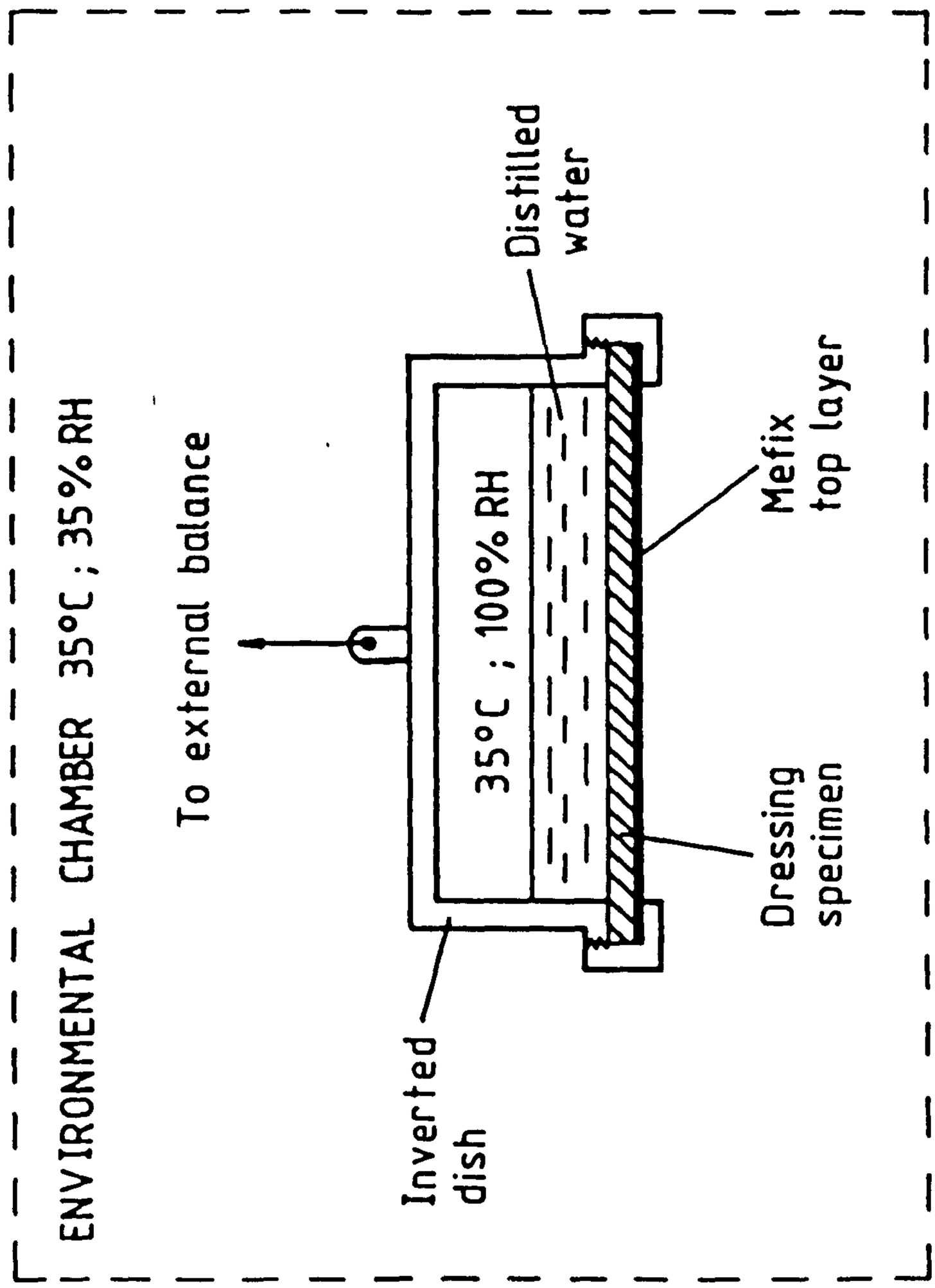


Figure 9.6

Assembled Dish with Mefix/Dressing Bilaminate in Position.

MATERIAL (n)	THICKNESS (mm)	RH (%)	WVTR (g/m2/24 h)
Geliperm (7)	1.13 +/- 0.2	34	10,973 +/- 998
Geliperm + Mefix (7)	1.57 +/- 0.3	35	3,907 +/- 464
Non-linear PEO Hydrogel	WVTR very high as the gel contracted due to dehydration in the oven.		
Non-linear PEO Hydrogel + Mefix (6)	1.08 +/- 0.06	36	3,140 +/- 393
Linear Polyurethane Hydrogel (7)	0.15 +/- 0.04	36	9850 +/- 1240
Linear Polyurethane Hydrogel + Mefix (5)	0.46 +/- 0.05	36	3673 +/- 726
Mean +/- 1 S.D.			

Table 9.1

Water Vapour Transmission Results

for the Dressings and Composites.

MATERIAL (n)	THICKNESS (mm)	RADIUS OF CURVATURE (cm)
Geliperm (8)	1.105 +/- 0.159	9.275 +/- 1.396
Geliperm + Mefix (8)	1.359 +/- 0.187	9.223 +/- 0.664
Non-linear PEO Hydrogel (8)	0.880 +/- 0.092	12.408 +/- 0.934
Non-linear PEO Hydrogel + Mefix (8)	1.096 +/- 0.089	13.266 +/- 1.101
Linear Polyurethane Hydrogel (8)	0.169 +/- 0.024	6.960 +/- 0.747
Linear Polyurethane Hydrogel + Mefix (8)	0.431 +/- 0.026	10.914 +/- 1.410
Mean +/- 1 S.D.		

Table 9.2

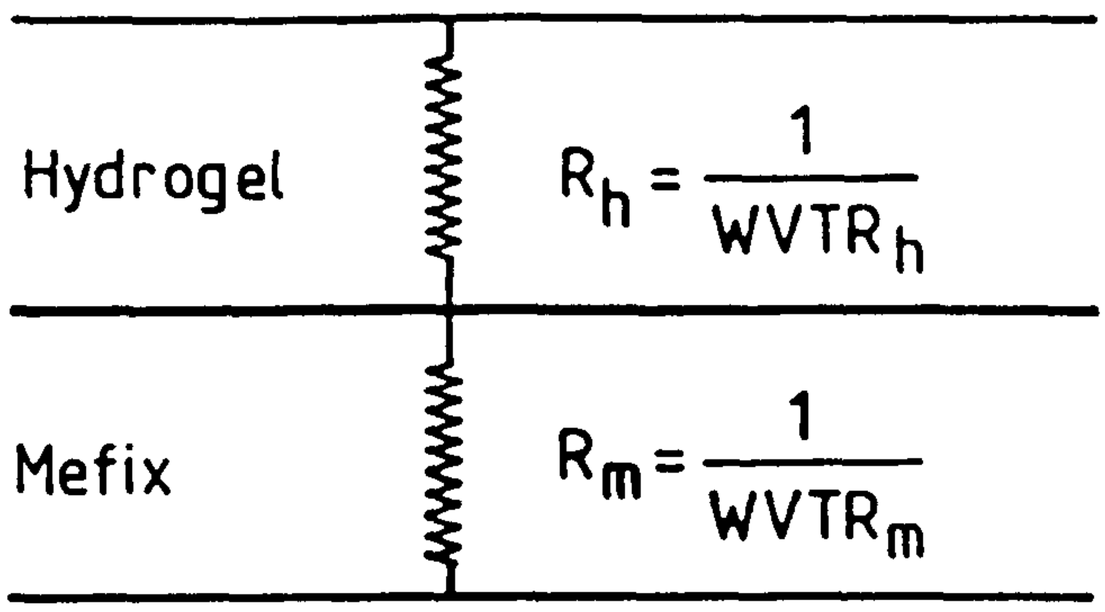
Conformability Results for the Dressings and Composites.

9.4 Discussion

As suggested in Chapter Five, a dressing should have a WVTR not exceeding 2000-2500 g $.m^{-2}$ $.day^{-1}$. This level will be sufficient to retain adequate moisture, thereby avoiding both dehydration and excessive fluid accumulation.

It can be seen from Table 9.1 that the hydrogels have very high WVTR's, being comparable to free water surface evaporation under the conditions of test. Such dressings may cause the wound to dehydrate and cause dressing adherence, while the latent heat loss occurring on evaporation could place unacceptable demands on body metabolism if the area of injury is extensive.

Therefore, any mechanism which can lower the WVTR's of such dressings to clinically more acceptable levels will be clinically advantageous. From Table 9.1, it can be seen that a Mefix top layer dramatically reduces the WVTR's of the underlying hydrogels. The 60-65 percent reductions observed bring the WVTR's of the hydrogels down to more clinically acceptable levels. This is due to the evaporative water loss having to be transmitted through two materials, with different WVTR's in series with each other (Figure 9.7). By analogy with



Resistance of composite, $R_c = R_h + R_m$

Figure 9.7

Diagramatic Representation of the Analogy to Electrical Resistances in series.

electrical resistances in series, the overall resistance of the bilaminate to water vapour transmission is the sum of the individual resistances of the layers. In this context, the resistance is equal to the reciprocal of the WVTR.

According to this theory, one can predict the WVTR of the composite (WVTRc) from knowledge of the WVTR's of the hydrogel and the Mefix, WVTRh and WVTRm respectively, hence :-

$$\frac{1}{WVTRc} = \frac{1}{WVTRh} + \frac{1}{WVTRm} \qquad (1)$$

WVTRm is therefore given by :-

$$WVTRm = \frac{WVTRh * WVTRc}{WVTRh - WVTRc} \qquad (2)$$

For each of the hydrogels assessed, a WVTR for Mefix was calculated using equation (2). The values obtained were 6067 $g.m^{-2}.day^{-1}$ (Geliperm data) and

5857 $g.m^{-2}.day^{-1}$ (Linear Polyurethane Hydrogel data) giving a mean value of 5962 $g.m^{-2}.day^{-1}$. [It should be noted that the value of WVTRh will include any additional resistance due to boundary layer effects.]

In a bid to validate this theory, the results of tests carried out for a polyurethane foam dressing, Lyofoam (Ultra Laboratories Ltd.), are presented in Table 9.3. These results show that there is no significant difference between predicted (by the equation above) and experimentally determined values.

It seems probable that Mefix would have the same effect on gaseous transmission i.e. on O_2 and CO_2 transmission. Therefore, this was tested by utilising the silicone rubber support used in the gas transmission experiments. The support was assessed, alone and with a Mefix top layer for O_2 transmission. The results are presented in Table 9.4, and they show that there is a 44% reduction in the transmission of O_2, indicating the influence of Mefix on O_2 transmission is similar to the influence on water vapour transmission. The effect of such a reduction of gaseous transmission on wound healing is unknown. As expressed in Chapter 6, at present, there is controversy as to whether an enhanced oxygen environment is beneficial or detrimental to wound healing. Therefore, one cannot conclude as to whether

Material (n)	Thickness (mm)	RH (%)	WVTR (g/m2/24 h)
Lyofoam (7)	10.33 +/- 1.31	35	3052 +/- 684
Lyofoam + Mefix	PREDICTED VALUE		2019
Lyofoam + Mefix (7) (EXPERIMENTAL)	11.56 +/- 0.73	35	2187 +/- 223
Mean +/- 1 S.D.			

Table 9.3

Water Vapour Data for Lyofoam supporting the Resistance Analogy.

(predicted value calculated from equation (1) using Lyofoam WVTR = 3052 g/m^2/24h and Mefix WVTR = 5962 g/m^2/24h).

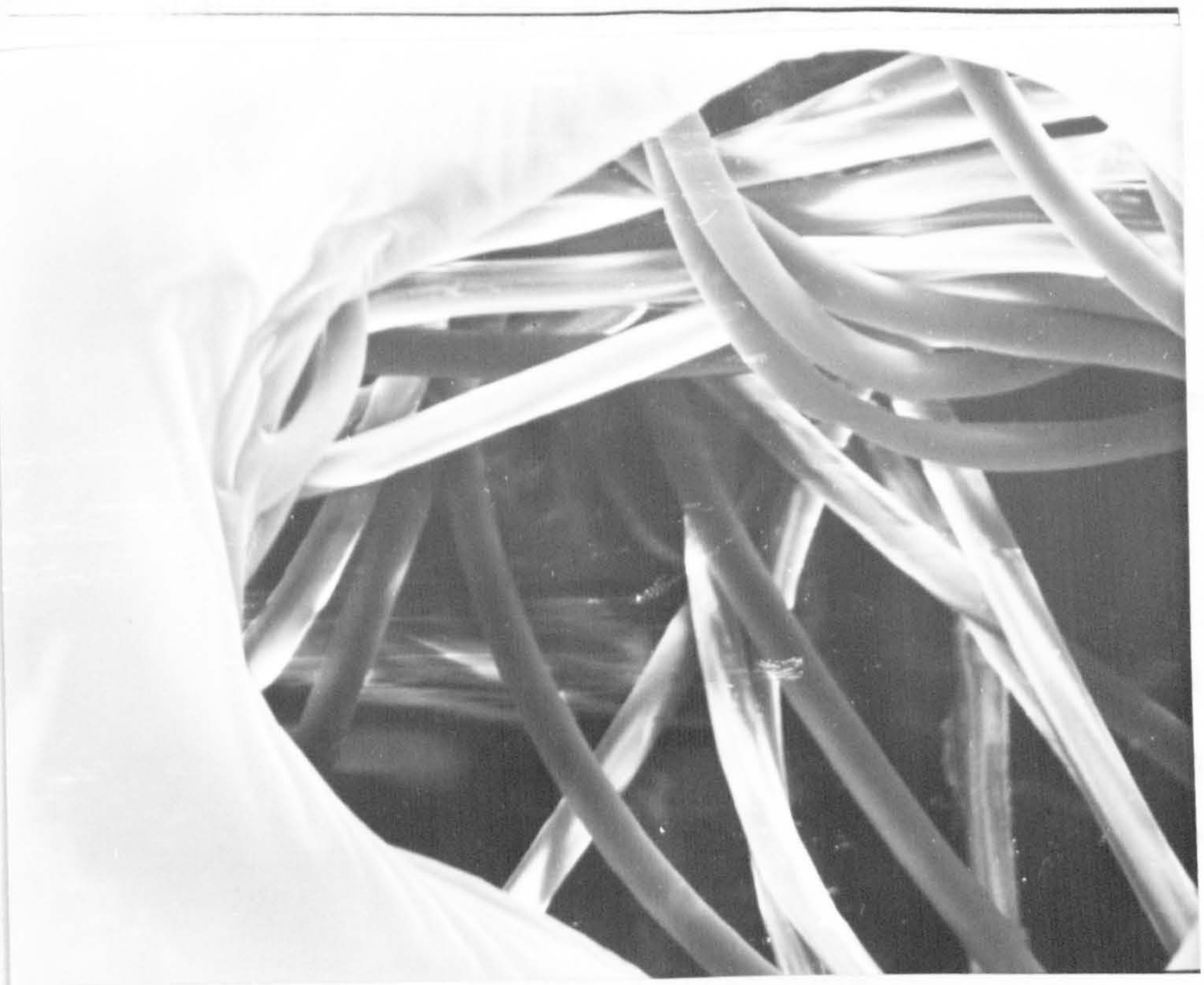


Figure 9.8

Micrograph showing the orientation of the fibres in the pores.

(Mag X320, Markers 10 microns)

this layer would be of benefit clinically on consideration of O_2 and CO_2 transmission. A similar relationship to that described in equations (1) and (2) can be applied to gaseous transmission.

Scanning electron microscopic studies provide further information as to the physical nature of the resistances offered by the Mefix dressing. From the micrographs in Figure 9.5, it can be seen that the adhesive layer is almost continuous but that the small pores which are present are randomly distributed.

The pores which are present, are about 100 μm in diameter (Figure 9.5) and are probably caused by air bubbles entrainment during manufacture. These pores contain fibres which lie randomly (Figure 9.8) and some of the fibres are not bound together by adhesive. It was experimentally observed that water did not leak through Mefix until the top surface was indented or brushed against breaking down the surface tension at the adhesive-water interface. Such mechanical disturbances could align or remove the fibres in such a way that the pores become opened up. Provided that such 'leak through' does not occur, as in the laboratory tests performed here, the resistance of the Mefix to water vapour transport is primarily that due to diffusion through the adhesive coating.

A Mefix covering provides a strengthening support to the relatively weak hydrogel. Such support is desirable for this class of materials. However, as shown in Table 9.2, a general decrease in comformability by elastic restraint will occur. The restraining effect is more evident in the thinner materials, as they are more conformable initially.

In conclusion, the use of Mefix (or an equivalent) in conjunction with hydrogel type materials (with high WVTR's) may be, according to the in vitro tests, advantageous to the healing of the wound. Clinically, the 60-65 percent reduction in the WVTR's may more than compensate for the 5-35 percent reduction in conformability. The use of Mefix offers control over the evaporative water loss and mechanical protection to the underlying hydrogel, without the use of other types of securing layer.

Material (n)	Thickness (mm)	Gas Transmission for 02 cm3(STP)/(m2.24h.atm)
Silicone Rubber Support (9)	0.025	123,550 +/- 2153
Silicone Rubber Support + Mefix (9)	0.054	68,872 +/- 2023
Mean +/- 1 S.D.		

Table 9.4

Gas Transmission Results

CHAPTER 10

Conclusions and Recommendations for Future Work

CHAPTER 10

10.1 General Conclusions

Currently many dressings are available presenting the clinician with the problem of choice. There is therefore a need for a preclinical assessment programme which would confine the choice to those dressings of most use clinically.

Preclinical assessment techniques allow materials to be assessed particularly in respect of their physical characteristics. These can provide the information necessary to modify or compound the dressings currently available or any candidate materials. For example, the Mefix top covering (Chapter 9) modified several of the physical characteristics of the hydrogel materials. In the case of water vapour transport and mechanical protection this effect appears to be of benefit clinically.

Of the large number of desirable properties (Chapter 1) a potentially successful wound dressing should possess, non-toxicity must take first priority with non-antigenicity next. No dressing, regardless of any desirable physical and transport properties is

of potential clinical use if it is toxic to the newly formed epithelial cells or if it induces an immune response.

Next in order of importance are the mechanical properties and the barrier functions against bacteria and of limiting water vapour transport. Ranking these parameters, the ability to withstand handling and subsequent trauma (i.e. mechanical strength) is of major importance since the barrier functions of a dressing are dependent on the maintenance of dressing integrity. Subsequently bacterial impermeability and control of water vapour transport can be ranked as the next most important physical properties.

With respect to obtaining the "ideal" burn wound dressing it is important that a burn wound can be defined. For example, the volume of exudate released by different degrees of burning should be quantified so that the water vapour transmittivity level of the dressing can be specified for each type of burn. Similar arguments can be made to assign critical values for the different physical parameters.

At present the author has suggested (Queen et al,1986 and Chapter 5) that a suitable level for water vapour transmission might be 2000-2500 $g.m^{-2}.day^{-1}$, which is half that found in a granulating wound (Lamke

et al, 1977). With respect to the mechanical properties it seems appropriate that the critical value for extensibility and conformability (biaxial extensibility) should be equivalent to that of normal skin, since the latter extends and conforms adequately to the human frame accommodating its motion.

The principal aim of this study was therefore to establish preclinical assessment techniques for the quantitative evaluation of candidate materials for dressings against rational criteria based on clinical usage. Most of the parameters assessed are of a physical nature and relate to producing a suitable environment for wound healing in a fashion which is clinically acceptable.

Of the techniques used, those for water vapour transmission, oxygen/carbon dioxide transmission and tensile parameters are well established. In contrast, the conformability test is at an early stage of development and was first implemented in this thesis.

The water vapour transmission rates (WVTR's) found for the series of materials evaluated ranged from around 140 to 11,000 $g.m^{-2}.24h^{-1}$. Such differences result in different clinical problems as explained in Chapter 5 (i.e. exudate accumulation or wound surface dehydration).

The major requirement of any dressing is an adequate strength to maintain its barrier role while in situ. In general the mechanical properties of many of the dressings were adequate. Linked to the elongation properties of these materials is their capacity to conform to body surfaces, the two parameters being related.

To date the oxygen and carbon dioxide environment required to give rapid and successful wound healing has not been quantified. Until such times, one can only suggest that for many of the dressings tested their transmission characteristics to carbon dioxide and oxygen must be adequate as many have been used successfully in the clinical environment.

The following are the general conclusions drawn for each dressing tested with regard to their physical parameters.

The WVTR's of the control materials (Chapter 4) were found to be very low and hence exudate accumulation under these materials if used as a dressing may be a problem. The Vigilon Coverfilm and Stretch 'n' Seal materials have good mechanical strength and extensibility, but they were not very conformable only adapting to the buttocks. However the Stretch 'n' Seal material showed viscoelastic

behaviour, allowing greater conformability to be achieved, when the dressing is applied under tension. This material also exhibits great plasticity and it can be made to adapt to joints. However it will not accommodate the underlying motion of joints without wrinkling.

The adhesive film type dressings exhibited low WVTR's and would be prone to the problems associated with low transmission values. Tegaderm and Bioclusive have excellent tensile and conformability properties. One possible added advantage of the adhesive layer is as a possible agent for debridement. Observations during the clinical study indicated that during the early post-burn phase, these adhesive dressings, gave adequate and rapid debridement upon removal. However, consideration should be given to the application of an anaesthetic to reduce the pain to the patient. On this basis their use for epithelialised wounds may be contraindicated.

The other film type dressings (Porvair 232013 and 32/5/1) were experimental materials. Their WVTR's were very good, being close to the desired range. The mechanical properties and conformability characteristics of these materials were excellent. Recently (Milner et al, 1986)) several groups have advocated Stretch 'n' Seal as an excellent temporary

first aid dressing. One disadvantage reported, by members of the fire and ambulance services, was that its transparency allowed the wound to be seen by both the first aid personnel and patients.

Therefore, it is suggested that the Porvair materials which are non-transparent may be ideal for this application and therefore they have a potential use in the field of dressing wounds. The transmission characteristics in respect to both water vapour and atmospheric gases (O_2 and CO_2) are excellent due to the microporous nature of the materials.

All of the film type dressings discussed above have shown viscoelastic capabilities and pretensioning during application to body regions improves their conformability range.

The foam type dressings (Lyofoam, Synthaderm and Coraderm) had poor tensile properties but had excellent transmission characteristics. All three foam dressings are porous materials and, provided their structure remains unsaturated, oxygen and carbon dioxide should be freely transmitted. With respect to their WVTR's, for all three materials the values measured fall close to or within the desired range of 2000-2500 $g.m^{-2}.24h^{-1}$. In all cases the mechanical strength of the material was poor, particularly when

the material is wetted. Their elongation qualities however were reasonable. The conformability characteristics of both Synthaderm and Coraderm were excellent, particularly when these materials were wet (as indicated by the in vitro test, Section 8.4). Lyofoam on the other hand, mainly due to the thickness of the material, was very non-conformable.

The hydrogel materials have extremely high WVTR's, corresponding to a free water surface. The Mefix/Hydrogel laminates, however have much lower WVTR's, which are clinically more acceptable. Although these values were lower they are still slightly higher than the desired range.

The tensile properties of the hydrogels were generally poor and all of these materials were observed to have poor tearing strengths. The linear polyurethane hydrogel showed good extensibility characteristics. Geliperm and the linear hydrogel were reasonably conformable. The non-linear PEO hydrogel however proved to be very non-conformable, only adapting to the buttocks. With the Vigilon dressing the results specifically show that the mechanical and water vapour transmission properties of the composite dressing are a direct consequence of the polyethylene top layer.

Corethium was chosen as an example of the biological dressings. Its WVTR characteristics were reasonable as was its tensile strength. The elongation qualities possessed by this material are very poor and this contributes to the non-conformability observed for this material.

The two clinical studies were undertaken to give an insight into the in vivo situation. Two main factors influenced such studies; that of the significance of the in vitro measurements and that of optimising the test systems to give a close correlation with the clinical situation.

The evaporative water loss study, carried out in the Burns Unit of Glasgow Royal Infirmary, provided the clinical information to optimise and correlate the water vapour transmission studies. It seems feasible that our in vitro measurement and the clinically measured values will be comparable. However, further work will have to be carried out to establish the "true" experimental values required to evaluate against the clinical data. Air convection within the chamber was observed to have a dramatic effect on the WVTR of the dressing being assessed. Since in the in vitro set up a stirring fan is used to give an even humidity within the chamber, the area over which this acts has to be comparable in both measurement

procedures.

The "pseudoclinical" study carried out to assess in vivo conformability showed reasonably that our in vitro measurement procedure gives a close approximation of what is actually observed in the clinical situation.

The in vitro experiments have shown that viscoelastic behaviour was exhibited by some of the materials evaluated (Section 8.5). Such behaviour would allow the dressing to be applied in a pretensioned state allowing adaptaion to surfaces with small radii of curvature (i.e. increasing conformability). It is necessary however to establish a link between the pressure applied by the pretensioned dressing and the time of tissue tolerance to this pressure, before any suggestions as to the amount of pretensioning required can be made. Further "pseudoclinical" experimentation may provide some of the answers to these problems.

The problem of protein adhesion (adsorption) onto wound dressings was addressed in this study since it was claimed (Turner, 1985) that this would influence the WVTR of dressings while in situ and protein adsorption is inevitable with polymeric materials. Both in vitro and in vivo experiments were carried out

to establish the significance of such a problem. Water vapour experiments using human plasma as the fluid reservoir, on several of the materials, showed no significant difference between the plasma values and the distilled water values. Since the in vivo experiments show that a correlation between the laboratory and clinical measurement of WVTR is possible this indicates that the protein layer adhered to the surface has no or little effect on the WVTR of any dressing material. Thus, at least for the materials tested, the presence of the main plasma constituents (e.g. proteins and salts) would not appear to alter the transmission characteristics of the material.

Generally it can be concluded that at present, no dressing material has all of the desired properties.

A Mefix layer may lower the WVTR of a dressing, but it was shown that such an elastic restraint reduced the conformability of the dressing material which it covers. The Mefix layer also provides mechanical protection due to its high tensile strength and marked extensibility at rupture, giving tear resistance to the dressing below. It is therefore recommended that for the hydrogel materials some form of controlling layer (e.g. Mefix, Hypafix,Smith and Nephew Ltd.) should be incorporated to give more

desirable properties.

10.2 Recommendations for Future Work

There is an economic and clinical need for a preclinical assessment programme based on techniques which can be carried out *in vitro*. Such an assessment should not be considered a suitable substitute for thorough clinical trials of those dressings which appear satisfactory from the preclinical assessement programme. However they do provide an excellent screening mechanism. There is also a clear need for more comprehensive data on the necessary or desirable conditions for healing. These include the dependence on the time after burning, burn depth and area. However in relation to the methods of assessment (techniques and analysis) the following are of importance.

10.2.1 Materials

It would be beneficial to future work if well characterised materials (e.g. hydrogels) could be provided to give a controlled series which would permit a direct comparison of the different parameters for the same material composition. This would allow a determination of the sensitivity of the preclinical

assessment techniques.

Since many of the hydrogels offer the possibility of drug release, it could be important to have a series of materials with different anti-bacterial drugs incorporated to determine (a) the immediate effect on the WVTR, gas, conformability and tensile properties; (b) the long term effect as the drug is released (i.e. how the properties change with the amount of drug released) and vice-versa.

10.2.2 Mechanical Properties

Future work on the tensile and conformability properties of the dressings should involve a more positive tying together of the two *in vitro* tests.

Once definite correlation is obtained, either test (tensile or conformability) could be used to derive a measure of conformability and subsequently the tensile parameters or vice-versa.

It is important, with respect to the conformability of a dressing, that in the case of anisotropic materials the most extensible axis can be positioned such that the dressing allows maximal joint flexion and extension. Therefore the tensile tests should provide such information and in future those

materials which exhibit marked anisotropy (e.g Mefix - Chapter 7) may be labelled to allow for 'correct' positioning. This is particularly important for the knitted or woven materials which will almost certainly be anisotropic. The correct positioning of these dressings is of particular importance in physiotherapy to allow mobility of the dressed, injured joint.

Another modification which may allow a more accurate determination of the moduli from the conformability measurements, would involve the testing of the materials at different pressures. Such an experimental programme would enable the determination of creep parameters. Either the effect, on conformability, of using different pressures or the effect of the pressure generated under different radii of curvature. Both should give the same result and since the former is the easier test, it should the method chosen.

As shown in Chapter 8 the viscoelastic behaviour of a dressing is a very important parameter in its application as a wound covering. Therefore future work could be aimed at a more technical creep/relaxation analysis to determine the numerical viscoelastic characteristics of these materials (e.g. time constants).

Further work is also necessary with respect to the shape of actual body surfaces. An extensive study of the radii of curvature of all the body surfaces is required to give average values to enable conformabilty ranges to be assigned to a dressing via the *in vitro* assessment technique. This could be done using plaster casts of the body regions to be studied and curve fitting carried out to determine the radius of curvature. Both a maximum (extended) and minimum (flexed) radius of curvature could be determined, since many of the body's surfaces will change with skeletal position. Further tests could also be carried out to assess the *in vivo* significance of pretensioning. Pretensioned dressings could be applied and tissue blanching taken as a measure of excessive pressure. An indication of such blanching can be measured using techniques such as laser doppler, thermography and pressure transducers. The use of several techniques is likely as a mixture of 'transparent' and 'non-transparent' dressing exists. Time dependance could also be assessed with respect to the relaxation of these pretensioned dressings preventing the breakdown of tissue due to excessive pressure. It is also important in the recovery of conformability after joint movement. However better data on the effects of pressure on the wound surface and subsequent healing

are necessary to allow the level of pretensioning to be addressed.

10.2.3 Water Vapour Transmission

The fluid losses from different degrees of burning need to be quantified to allow the correct choice of dressing for a particular burn injury. This is of particular importance when the degree of burning is extensive and energy losses have to be considered. Dressings which limit the loss of water vapour can reduce and stabilise such energy losses.

However at present there is still some work necessary to allow a correlation between the *in vitro* and *in vivo* tests. The stirring effects within the chamber and those in the clinical situation are dissimilar.

It is necessary firstly to measure the local air velocities in both the laboratory and clinical situations. The WVTR of the dressing should be evaluated *in vitro* for different air velocities which may be achieved by varying the chamber fan speed. This would permit the comparison of the dressing WVTR *in vitro* with that measured *in vivo* for similar air velocities.

The clinical tests also provided the clinical parameters to enable the optimisation of the in vitro assessment chamber (i.e. room temperature and humidity). However at present, the WVTR tests are carried out in isothermal conditions. In future studies such tests could be carried out at differential temperatures as this would be more representative of the clinical situation, where the skin has a temperature of 35^{o}C and the clinical (shock room) environment is at 27 +/- 2.5 ^{o}C (Pollock, 1981 and Section 5.8) and the subsequent ward environment is at 23^{o}C, giving a problem in that there is a temperature differential during the various stages of treatment. This could be achieved by maintaining the chamber at the environment temperature (27^{o}C) and the inside of the test cup at skin temperature (35^{o}C). The test cup would have to be insulated and the most practical form of heating would be with flexible foils with resistive heating elements.

Automation of the WVTR test procedure is desirable since the present manual method is laborious and time consuming. The weighing procedure could be centrally controlled by a micro-computer, which would also control the cycling of the sample tray and an electromagnetic pick-up mechanism, to permit the weighing of each cup in turn. The balance used would

be one capable of giving a digital output of the weight measurements for subsequent processing by the microcomputer.

10.2.4 Gas Transmission

The test used to assess the hydrophobic materials is adequate for the assessment of their gas transmission rates to oxygen and carbon dioxide.

The tests used for the hydrophilic materials require long preparation procedures particularly that for oxygen. The O_2 method requires the preparation of a complicated and easily poisoned scavenging solution which requires lengthy autoclaving and cleansing of the test system. It would therefore be more satisfactory to have a simpler test method.

Such a system could be based on the rate of oxygen uptake in a stirred cell arrangement such as that utilised to assess the gaseous permeability of contact lenses (Tighe, 1976). It would however only be suitable for materials with relatively low gas transmission rates.

The final conclusion is that a preclinical assessment package has been established with the clinical situation in mind. Such a package is of

major importance for the reduction of clinical trials, the screening of new and existing dressings and for the development of improved dressing materials. The assessment of these materials may allow the combination of two or more of those exhibiting desirable characteristics to give an improved dressing. For example the author recommends that Mefix and Geliperm are used as a bilaminate dressing. Justification for such a statement can be found in Chapter 9.

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APPENDICES

APPENDIX 1

EXAMPLE OF HYDROGEL PREPARATION.

Appendix 1

Example of Hydrogel Preparation

Composition reference :- PEO/4360/2 Molar PPG 425/ 3 Molar HT/7.5 Molar Desmodur

	Molar Ratio	M.Wt	Weight (g)
Polyethylene glycol	1	4,360	50
1,2,6 hexane triol	3	134	4.610
Polypropylene glycol	2	425	9.748
Desmodur W.	7.5	262.5	22.577
Dicyclohexyl methane diisocyanate			21.10 ml
Ferric chloride catalyst			0.0225

The PEG is melted down and dried for 3 hours under vacuum at 100^{o}C while bleeding with nitrogen to agitate and assist water removal. 0.0225g of Ferric chloride is dissolved in 4.610g 1,2,6 hexane triol; 50g PEG 4360 are added, then 9.748g PPG 425 and the mixture is stirred and heated to 95^{o}C. A reaction takes place as soon as the isocyanate is mixed with the polyol. The Desmodur is run in from a burette, 21.10ml are added to the hot mixture, working in a ventillated fume cupboard, then the beaker is returned

to the oven to degas for 3 minutes.

While the PEG is being dried, the moulds for the films were prepared. Aluminium sheets approximately 28cm square and lcm thick are lined with polyester laminated aluminium foil and 2 sheets are bolted together, but kept 0.5mm apart by a strip of shim 0.5mm thick. A ribbon of Silastic adhesive just inside the shim acts as a sealant and good contact and a smooth surface are achieved by rolling the polyester laminated foil onto the mould. The prepared moulds are heated to 95^{o}C.

The prepolymer is then drawn up into a syringe and injected into the mould through an inlet hole at the bottom. The polymer is cured at 95^{o}C fo 4 hours. After cooling, the two halves of the mould are separated and the foil is peeled back from the polymer film.

APPENDIX 2

RELATIVE HUMIDITY

MEASUREMENT.

Figure (a)

Evaporimeter.

Appendix 2

Measurement of Relative Humidity

(a) using the ServoMed Evaporimeter (Fig A)

Operation

1. plug the probe into the main unit. When not actually measuring, leave the cylindrical protection cap on the measuring head.

2. connect the Evaporimeter to the mains and switch on the power by pressing the button marked on. Allow a 15 minute warming period.

3. when the warming period has elapsed, zero the instrument. For the two channel model Ep 1D, the two channels have to be zeroed separately. Press the "WE" button and throw the toggle switch underneath it to the desired position (i.e. 1 or 2). Leave the cylindrical protection cap in place during the zeroing procedure. Use the "offset" potentiometer, at the right on the display, to balance the + and - signs to equal intensity. The instrument is now zeroed.

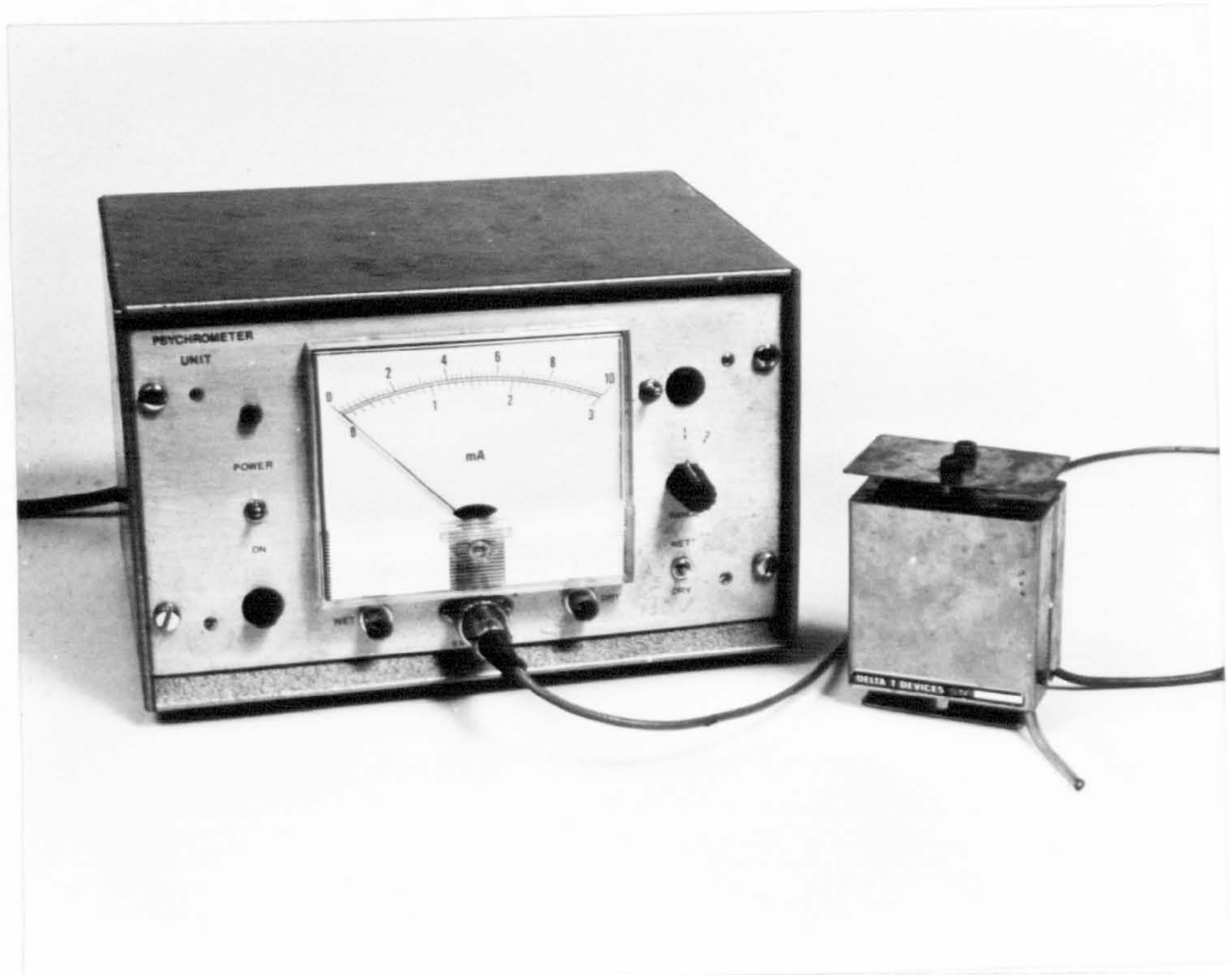


Figure (b)

Psychrometer.

4. place the probe in the oven and allow a 30 minute stabilisation time, for the sensor unit to attain the ambient temperature of the oven.

5. select the RH channel corresponding to the position of the toggle switch in 3.

6. the instrument will now be measuring the RH of the oven environment. This value is displayed on the digital read out.

(b) <u>using the Aspirated Psychrometer (Fig B)</u>

<u>Operation</u>

1. connect the Psychrometer unit to the mains.

2. ensure that the wet bulb distilled water reservoir has sufficient volume for the length of the test.

3. place the sensor unit within the oven environment.

4. allow an acclimatisation period of 30 minutes.

5. record the dry bulb and the wet bulb temperature, and calculate relative humidity by means of a slide rule calculator with these values as the input.

(c) Calculation of Relative Humidity by Slide Rule

Blundell Harling Humidity Slide Rule MK 6A

1. set cursor over wet bulb reading on scale (1).

2. move slide to bring depression (i.e. difference between wet and dry bulb temperatures) of wet bulb on scale (2B) under cursor.

3. read DEW POINT on scale (1) under $0^{o}C$ index of scale (2B).

4. set relative humidity index (R H) on scale (3) to read 100 on scale (4).

5. set cursor over DEW POINT on scale (3).

6. move slide until dry bulb reading on scale (3) is under cursor.

7. read relative humidity on scale (4) against relative humidity index (R H).

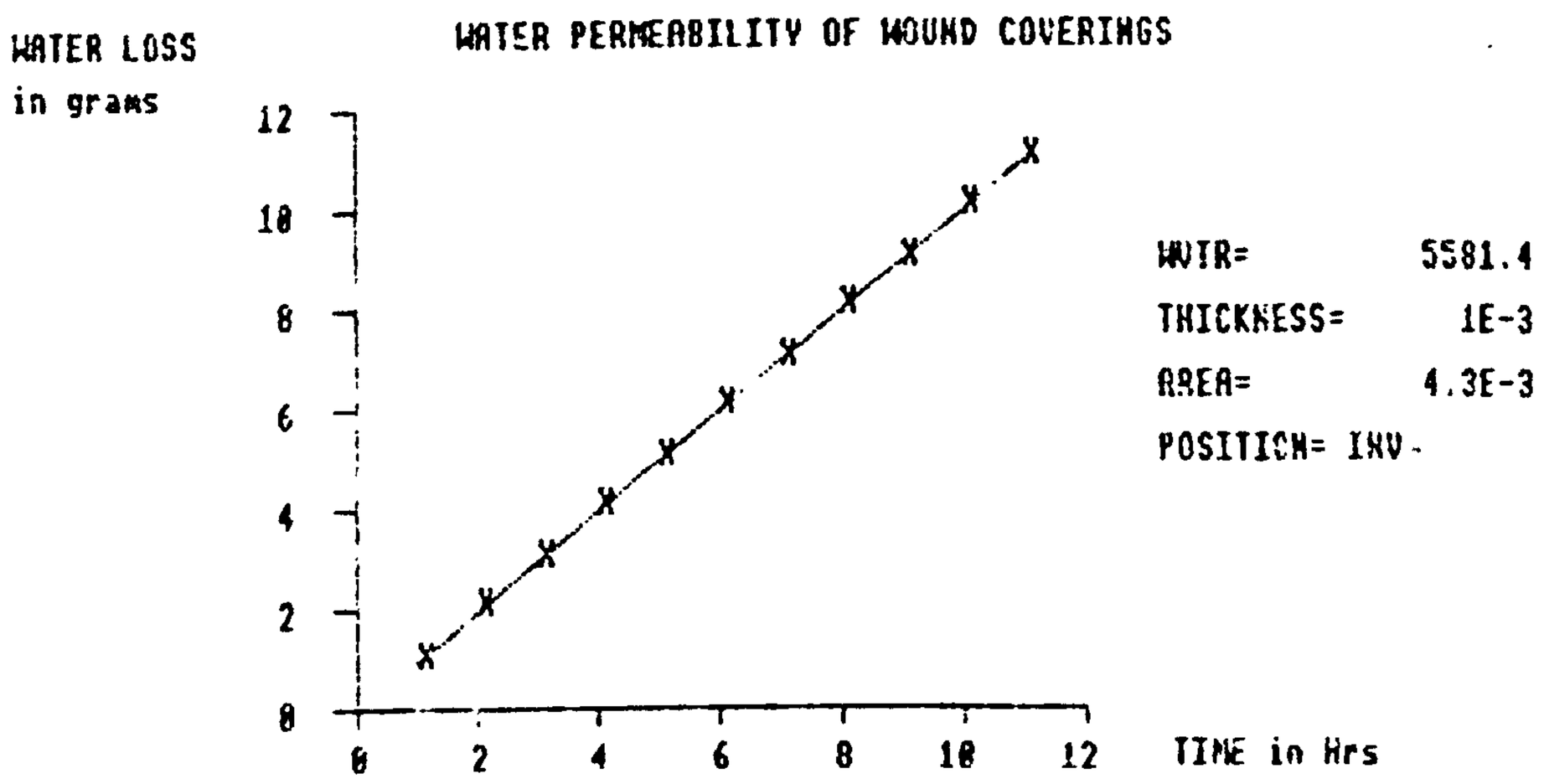
APPENDIX 3

COMPUTER PROGRAMS USED TO ANALYSE THE WATER VAPOUR DATA.

331A

TIME POINTS AND WEIGHT LOSS VALUES FOR EXAMPLE 1 12/4/85

POINT NO.1	1	1
POINT NO.2	2	2
POINT NO.3	3	3
POINT NO.4	4	4
POINT NO.5	5	5
POINT NO.6	6	6
POINT NO.7	7	7
POINT NO.8	8	8
POINT NO.9	9	9
POINT NO.10	10	10
POINT NO.11	11	11



$$WVTR = \frac{m \times 24}{A} = \frac{1 \times 24}{4{\cdot}3 \times 10^{-3}} = 5581\ g.m^{-2}.24h^{-1}$$

```
 10 REM FILENAME "WATERF"
 20 REM VERSION NO.1 WHICH FILES DATA
 30 REM STATUS : DEVELOPMENT
 40 REM DATE :12 FEB 85
 50 REM PROGRAMMER :D.QUEEN
 60   NPTS%=11
 70 DIM X(NPTS%) : DIM R(NPTS%)
 80 MODE 7 :CLOSE#0
 90   *FX200,1
100  REM DISABLE THE ESCAPE KEY
110  *FX6,0
120  CLS
130  M$=STRING$(15," ")
140  D$=M$:G$=M$
150  PRINT TAB(1,6) "ENTER THE NAME OF THE NEW DATA FILE (7 characte
rs maximum)"
160  INPUT TAB(25,9)F$
170  F$=LEFT$(F$,7)
180  CH1=OPENUP(F$)
190  IF CH1<>0 PRINT"FILE ALREADY EXISTS":PRINT TAB(1,6)"          ":G
OTO 150
200  CH1=OPENOUT(F$)
210  REPEAT
220    PROC_data_input
230    PROC_store
240    UNTIL TA$="Y"
250  CLOSE#0
260  *FX200,0
270 END
280
290 DEF PROC_data_input
300  CLS
310 PRINT TAB(1,3) "MATERIAL?":INPUT TAB(25,3)M$
320 PRINT TAB(1,4) "TEST DATE?":INPUT TAB(25,4)D$
330  PRINT TAB(1,5) "TEST NUMBER?":INPUT TAB(25,5)TN%
340  PRINT TAB(1,6) "RELATIVE HUMIDITY?":INPUT TAB(25,6)RH
350   PRINT TAB(1,8) "TEST POSITION?":INPUT TAB(30,8)N$
360  PRINT TAB(1,10) "INITIAL WEIGHT READING?":INPUT TAB(30,10)WSTAR
T
370  PRINT TAB(1,12) "THICKNESS(cm)?":INPUT TAB(30,12)Z
380  PRINT TAB(1,14) "MEMBRANE AREA (m2)?":INPUT TAB(30,14)A
390  PRINT TAB(1,18)"IS THIS DATA CORRECT ?"," (Y/N)":INPUT TAB(39,1
8)A$
400  IF A$="N" CLS: GOTO 310
410  CLS : PRINT''
420  REM choice_of_X_values
430  PRINT TAB(1,1)"ENTER THE RANGE BY INPUTING MAXIMUM VALUE","XMAX
=":INPUT XMAX
440  CLS:PRINT''
450  PRINT "ENTER RAW DATA EXCLUDING THE INITIAL READING":PRINT
460  Xstep=XMAX/12
470  FOR I% = 1 TO NPTS%
480    X(I%)=I%*Xstep
490    PRINT "POINT NO.",I%,X(I%),"   ";
500   INPUT R(I%)
510    PRINT
520    NEXT I%
530  PRINT TAB(1,23) "IS THIS DATA CORRECT ?"," (Y/N)":INPUT TAB(38.
23)A$
540  IF A$ = "N" GOTO 410
550  CLS:PRINT TAB(1,15) "IS THIS THE LAST TEST?","(Y/N)"
```

```
560   INPUT TAB(38,15)TA$
570   ENDPROC
580
590   DEF PROC_store
600   PRINT#CH1,M$:PRINT#CH1,D$:PRINT#CH1,TN%
610   PRINT#CH1,RH:PRINT#CH1,N$:PRINT#CH1,WSTART:PRINT#CH1,Z
620   PRINT#CH1,A
630   FOR I%=1 TO NPTS%
640     PRINT#CH1,X(I%):PRINT#CH1,R(I%)
650     NEXT I%
660   ENDPROC
```

```
  10 REM FILENAME "WATERA"
  20 REM VERSION NO.1 WHICH ANALYSES STORED DATA
  30 REM STATUS : DEVELOPMENT
  40 REM DATE :12 FEB 85
  50 REM PROGRAMMER :D.QUEEN
  60  NPTS%=11
  70 DIM X(NPTS%) : DIM R(NPTS%) :DIM Y(NPTS%)
  80 MODE 7 :CLOSE#0
  90  REM *FX200,1
 100  REM DISABLE THE ESCAPE KEY
 120  REG%=0
 130  CLS
 140  M$=STRING$(15," ")
 150  D$=M$:G$=M$
 160  PRINT TAB(1,6)"ENTER THE NAME OF THE DATA FILE FOR ANALYSIS" :I
NPUT TAB(1,8)F$
 170  CH1=OPENUP(F$)
 180  IF CH1=0 PRINT "FILE NOT FOUND":PRINT TAB(1,6)"     ":GOTO 160
 190  PRINT TAB(1,8) "ENTER THE TEST NUMBER REQUIRED":INPUT TAB(1,9)t
est%
 200  PTR#CH1=0
 210  REPEAT
 220    PROC read file
 230    UNTIL TN%=test% OR EOF#CH1
 240  IF TN%<>test% PRINT "TEST NOT ON FILE" :PRINT TAB(1,9)"      ":
GOTO 190
 250  CLS
 260  PROC_data_display
 270  MODE 0
 280  PROC_processing_of_raw_data
 290  DUM=GET
 300  INPUT "HARDCOPY REQUIRED(Y/N)",B$
 310  IF B$="Y" HCOPY%=1 ELSE HCOPY%=0
 320  CLS
 330  PROC_processing_of_raw_data
 340  IF HCOPY%=1 THEN *SDUMP
 350  CLS
 360  PROC_choice_of_Y_axis
 370  PROC_choice_of_X_axis
 380 PROC_plot
 390 PRINT TAB(27,28)"PRESS SPACEBAR TO CONTINUE"
 400 DUM=GET
 410 MODE 7
 420 PROC_regression
 430 MODE 0
 440 PROC_calculate
 450 INPUT"HARDCOPY REQUIRED(Y/N)",H$
 460 IF H$="Y" HCOPY%=1 ELSE HCOPY%=0
 470 CLS
 480 PROC_plot
 490  PROC_results
 500 IF HCOPY%=1 THEN *SDUMP
 510  CLOSE#0
 520  @%=10
 530 END
 540
 550  DEF PROC_choice_of_Y_axis
 560  REM this chooses the desired Y axis scale
 570  REM this program uses data line 510
 580  RESTORE630
 590  REPEAT
```

```
600     READ YMAX
610     UNTIL YMAX>=Y(NPTS%) OR YMAX=24
620   stepY=YMAX/6
630   DATA 0.06,0.18,0.6,3,6,12,18,24
640   REM SFY=scaling factor for the Y_axis
650   SFY=600/(6*stepY)
660   ENDPROC
670
680   DEF PROC_choice_of_X_axis
690   REM this repeat chooses the X_axis scale
700   REM this program uses data statement 620.
710   RESTORE760
720   REPEAT
730     READ XMAX
740     UNTIL XMAX>=X(NPTS%) OR XMAX=30
750   stepX=XMAX/6
760   DATA 3,6,9,12
770   REM SFX=scaling factor for X_axis
780   SFX=600/(6*stepX)
790   ENDPROC
800
810   DEF PROC_plot
815 @%=&50A
820   VDU5
830   REM PLOTS PRESSURE VS TIME
840   FOR I% = 1 TO NPTS%
850     MOVE X(I%)*SFX+300,Y(I%)*SFY+320
860     PRINT"X"
870     NEXT I%
880   IF REG%=1 THEN MOVE X(1)*SFX+300,YSTART*SFY+300 :DRAW X(NPTS%)*
SFX+300,YEND*SFY+300
900   REM DRAW X AXIS
910   MOVE 300,300
920   FOR J%=0 TO 6
930     A%= 300+J%*100
940     DRAW A%,300
950     DRAW A%,285
960     MOVE A%-150,265
970     PRINT J%*stepX
980     MOVE A%,300
990     NEXT J%
1000  MOVE 970,270
1010  PRINT "TIME in Hrs"
1020  REM DRAW Y AXIS
1030  MOVE 300,300
1040  FOR J% =0 TO 6
1050    A%= 300 + J%*100
1060    DRAW 300,A%
1070    DRAW 280,A%
1080    MOVE 90,A%+8
1090    PRINT J%*stepY
1100    MOVE 300,A%
1110    NEXT J%
1120  MOVE 10,980
1130  PRINT "WATER LOSS"
1140  MOVE 10,930
1150  PRINT "in grams"
1160  VDU4
1170  PRINT TAB(24,1) "WATER PERMEABILITY OF WOUND COVERINGS"
1180  ENDPROC
1190
1200  DEF PROC regression
```

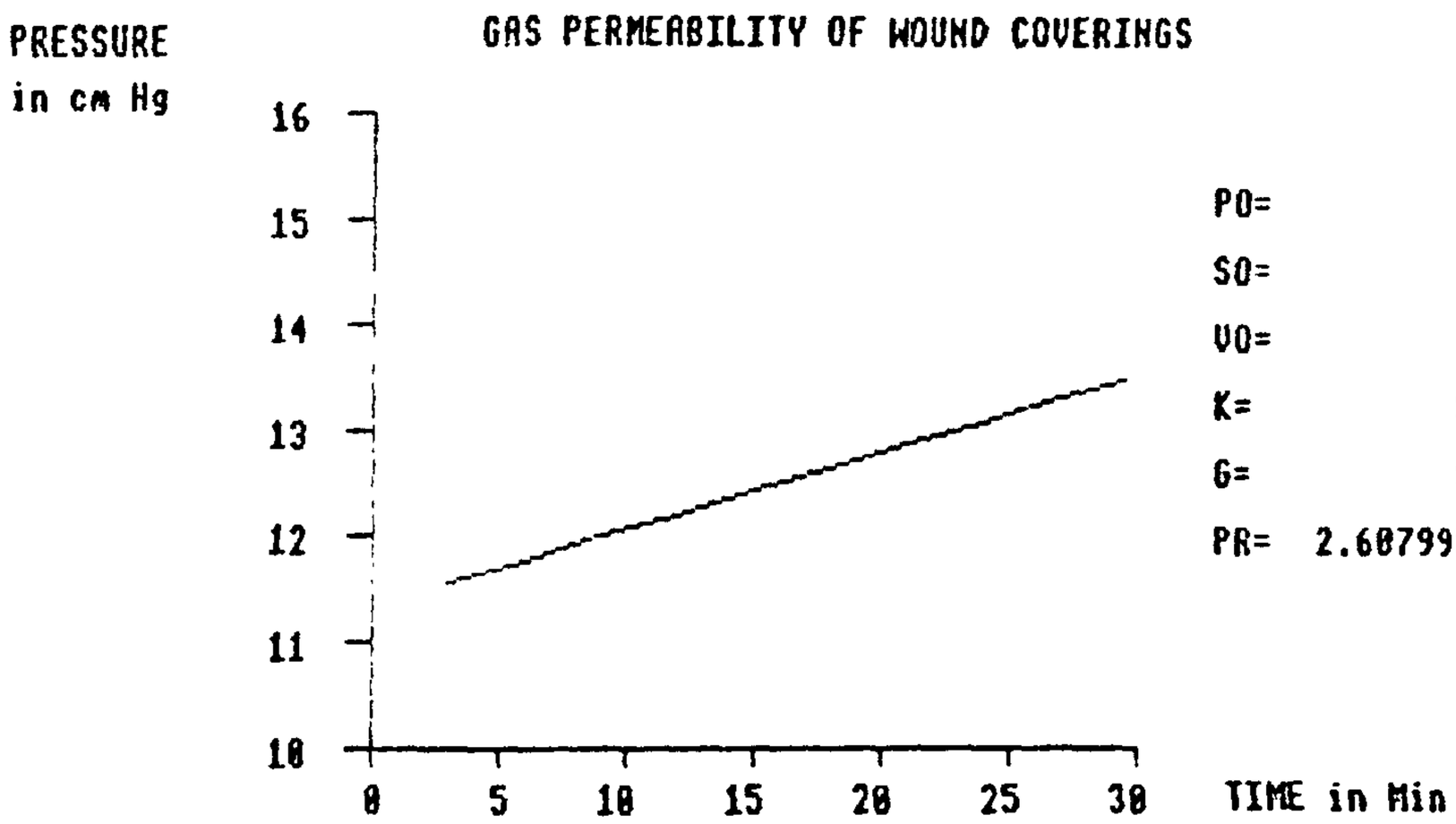
```
 1210  REG%=1
 1220  PRINT TAB(1,3)"ENTER NUMBER OF POINTS TO BE"
 1230  PRINT TAB(1,4)CHR$(129)"EXCLUDED"CHR$(135)"FROM THE REGRESSION
":INPUT TAB(38,4)N%
 1240  IF N%>9 OR N%<0 PRINT "INVALID DATA":GOTO 1220
 1250 @%=131850
 1260  XSUM=0:X2SUM=0:YSUM=0:Y2SUM=0:CROSS=0:M%=NPTS%-N%
 1270  FOR K%=N%+1 TO NPTS%
 1280    XSUM = XSUM + X(K%)
 1290    X2SUM = X2SUM + X(K%)*X(K%)
 1300    YSUM = YSUM +Y(K%)
 1310     Y2SUM =Y2SUM +Y(K%)*Y(K%)
 1320    CROSS = X(K%)*Y(K%)+CROSS
 1330    NEXT K%
 1340  X2=X2SUM-XSUM*XSUM/M%
 1350  Y2=Y2SUM-YSUM*YSUM/M%
 1360  C2=CROSS-XSUM*YSUM/M%
 1370  GRAD =C2/X2
 1380  inter=YSUM/M%-GRAD*XSUM/M%
 1390 R=C2/SQR(X2*Y2)
 1400  PRINT "GRADIENT    ",GRAD
 1410  PRINT "INTERCEPT   ",inter
 1420  PRINT "CORRELATION COEFF    ",R
 1430 PRINT
 1440  PRINT TAB(1,15)CHR$(134)"REGRESSION  OK ?",CHR$(129),"(Y/N) " :
INPUT TAB(37,15)A$
 1450   IF A$="N" CLS :GOTO 1220
 1460  YSTART=X(1)*GRAD+inter
 1470  YEND=X(NPTS%)*GRAD+inter
 1480  HO=Y(N%+1):HT=Y(NPTS%)
 1490  @%=10
 1500  ENDPROC
 1510
 1520  DEF PROC_calculate
 1530  @%=&50A
 1540  WVTR=(GRAD*24)/A
 1550  @%=10
 1560  ENDPROC
 1570
 1580  DEF PROC_processing_of_raw_data
 1590 CLS:PRINT''
 1600  PRINT"TIME POINTS AND WEIGHT LOSS VALUES FOR",M$"  ",TN%"  ",D$
 1610  PRINT''
 1620  FOR I%=1 TO NPTS%
 1630    @%=&50A
 1640    Y(I%)=WSTART-R(I%)
 1650    PRINT "POINT NO.":I%"    ",X(I%)"    ",Y(I%)
 1660    PRINT
 1670    NEXT I%
 1680  ENDPROC
 1690
 1700  DEF PROC_read_file
 1710  INPUT#CH1,M$:INPUT#CH1,D$:INPUT#CH1,TN%
 1720  INPUT#CH1,RH:INPUT#CH1,N$:INPUT#CH1,WSTART
 1730  INPUT#CH1,Z:INPUT#CH1,A
 1740  FOR I%=1 TO NPTS%
 1750    INPUT#CH1,X(I%):INPUT#CH1,R(I%)
 1760    NEXT I%
 1770  ENDPROC
 1780
 1790  DEF PROC_data_display
 1800  @%=&50A
```

```
1810  PRINT TAB(1,3) "MATERIAL":PRINT TAB(25,3)M$
1820  PRINT TAB(1,4) "TEST DATE":PRINT TAB(25,4)D$
1830  PRINT TAB(1,5) "TEST NUMBER":PRINT TAB(25,5)TN%
1840  PRINT TAB(1,6) "RELATIVE HUMIDITY":PRINT TAB(25,6)RH
1850  PRINT TAB(1,8) "TEST POSITION":PRINT TAB(30,8)N$
1860  PRINT TAB(1,10) "INITIAL WEIGHT READING":PRINT TAB(30,10)WSTART
1870  PRINT TAB(1,12) "THICKNESS(cm)":PRINT TAB(30,12)Z
1880  PRINT TAB(1,14) "MEMBRANE AREA (m2)":PRINT TAB(30,14)A
1890  DUM=GET
1900  @%=131850
1910  CLS : PRINT''
1920  PRINT CHR$(134)"THE COORDINATES ARE AS FOLLOWS" :PRINT
1930  FOR I% = 1 TO NPTS%
1940    PRINT "POINT NO.",I%,X(I%),R(I%)
1950    NEXT I%
1960  DUM=GET
1970  ENDPROC
1980
1990 DEF PROC_results
2000  @%=&50A
2010  PRINT TAB(60,8) "WVTR=",WVTR
2020  PRINT TAB(60,10) "THICKNESS=",Z
2030  PRINT TAB(60,12) "AREA=",A
2040  PRINT TAB(60,14)"POSITION=",N$
2050  @%=5
2060  PRINT TAB(33,26) "MATERIAL : ",M$
2070 PRINT TAB(10,28) "TEST DATE : ",D$,"    TEST NUMBER : ",TN%
2080  PRINT TAB(10,26) "RH : ",RH
2090  PRINT TAB(28,31)"   DOUGLAS QUEEN"
2100  @%=10
2110  ENDPROC
```

APPENDIX 4

COMPUTER PROGRAMS USED TO ANALYSE THE GAS TRANSMISSION DATA.

338 A



$$GTR = \frac{6816}{0{\cdot}25}\left[-2\times 0{\cdot}0175\times 1{\cdot}08+\left\{15{\cdot}9+0{\cdot}0175\left(2\times 74{\cdot}1-0{\cdot}2\right)\right\}\times \ln\left(1-\frac{1{\cdot}08}{73{\cdot}92}\right)\right]$$

$$= 5{,}241$$

```
 10 REM FILENAME "DQF"
 20 REM VERSION NO.1 WHICH FILES DATA
 30 REM STATUS : DEVELOPMENT
 40 REM DATE :1 FEB 85
 50 REM PROGRAMMER : N. MULVEY & D.QUEEN
 60   NPTS%=10
 70 DIM X(NPTS%) : DIM Y(NPTS%)
 80 MODE 7 :CLOSE#0
 90   *FX200,1
100  REM DISABLE THE ESCAPE KEY
110  *FX6,0
120  CLS
130  M$=STRING$(15," ")
140  D$=M$:G$=M$
150  PRINT TAB(1,6) "ENTER THE NAME OF THE NEW DATA FILE (7 characte
rs maximum)"
  160  INPUT TAB(25,9)F$
  170  F$=LEFT$(F$,7)
  180  CH1=OPENUP(F$)
  190  IF CH1<>0 PRINT"FILE ALREADY EXISTS":PRINT TAB(1,6)"          ":G
OTO 150
  200  CH1=OPENOUT(F$)
  210  REPEAT
  220    PROC_data_input
  230    PROC_store
  240    UNTIL TA$="Y"
  250  CLOSE#0
  260  *FX200,0
  270 END
  280
  290 DEF PROC_data_input
  300  CLS
  310 PRINT TAB(1,3) "MATERIAL?":INPUT TAB(25,3)M$
  320 PRINT TAB(1,4) "TEST DATE?":INPUT TAB(25,4)D$
  330  PRINT TAB(1,5) "TEST NUMBER?":INPUT TAB(25,5)TN%
  340  PRINT TAB(1,6) "GAS?":INPUT TAB(25,6)G$
  350  PRINT TAB(1,8) "INITIAL Hg HEIGHT(cm Hg)?":INPUT TAB(30,8)HVAC
  360  PRINT TAB(1,10) "ATMOSPHERIC PRESSURE(cm Hg)?":INPUT TAB(30,10)
PA
  370  PRINT TAB(1,12) "ROOM TEMPERATURE(DEG C)?":INPUT TAB(30,12)TO
  380  PRINT TAB(1,14) "MCLEOD GAUGE READING (cm Hg)?":INPUT TAB(30,14
)PVAC
  390  PRINT TAB(1,16) "THICKNESS(cm)?":INPUT TAB(30,16)Z
  400   PRINT TAB(1,18) "CHAMBER VOLUME(cm3)?":INPUT TAB(30,18)VC
  410  PRINT TAB(1,20) "VOID VOLUME(cm3)?":INPUT TAB(30,20)VS
  420  PRINT TAB(1,22) "MEMBRANE AREA (cm2)?":INPUT TAB(30,22)AT
  430  PRINT TAB(1,24) "VOID FRACTION?":INPUT TAB(30,24)F
  440  PRINT TAB(1,1)CHR$(129)"IS THIS DATA CORRECT ?",CHR$(129)" (Y/N
)":INPUT TAB(39,1)A$
  450  IF A$="N" CLS: GOTO 310
  460  CLS : PRINT''
  470  REM choice_of_X_values
  480  PRINT TAB(1,1)CHR$(129)"ENTER THE RANGE BY INPUTING MAXIMUM VAL
UE",CHR$(129) "XMAX=":INPUT XMAX
  490  CLS:PRINT''
  500  PRINT CHR$(134)"ENTER Y_COORDINATES " :PRINT
  510  Xstep=XMAX/NPTS%
  520  FOR I% = 1 TO NPTS%
  530    X(I%)=I%*Xstep
  540    PRINT "POINT NO.",I%,X(I%),"   ";
  550   INPUT Y(I%)
```

```
560     PRINT
570     NEXT I%
580  PRINT TAB(1,23) CHR$(134)"IS THIS DATA CORRECT ?",CHR$(129)" (Y
/N)":INPUT TAB(38,23)A$
590  IF A$ = "N" GOTO 460
600  CLS:PRINT TAB(1,15) CHR$(134) "IS THIS THE LAST TEST?",CHR$(129
)"(Y/N)"
610  INPUT TAB(38,15)TA$
620  ENDPROC
630
640  DEF PROC_store
650  PRINT#CH1,M$:PRINT#CH1,D$:PRINT#CH1,TN%
660  PRINT#CH1,G$:PRINT#CH1,HVAC:PRINT#CH1,PA
670  PRINT#CH1,TO:PRINT#CH1,PVAC:PRINT#CH1,Z
680  PRINT#CH1,VC:PRINT#CH1,VS:PRINT#CH1,AT:PRINT#CH1,F
690  FOR I%=1 TO NPTS%
700     PRINT#CH1,X(I%):PRINT#CH1,Y(I%)
710     NEXT I%
720  ENDPROC
```

```
 10 REM FILENAME "DQA"
 20 REM VERSION NO.1 WHICH ANALYSES STORED DATA
 30 REM STATUS : DEVELOPMENT
 40 REM DATE :1 FEB 85
 50 REM PROGRAMMER : N. MULVEY  & D.QUEEN
 60  NPTS%=10
 70 DIM X(NPTS%) : DIM Y(NPTS%)
 80 MODE 7 :CLOSE#0
 90  REM *FX200,1
100  REM DISABLE THE ESCAPE KEY
110   *FX6,0
120  REG%=0
130  CLS
140  M$=STRING$(15," ")
150  D$=M$:G$=M$
160  PRINT TAB(1,6)"ENTER THE NAME OF THE DATA FILE FOR ANALYSIS" :I
NPUT TAB(1,8)F$
170  CH1=OPENUP(F$)
180  IF CH1=0 PRINT "FILE NOT FOUND":PRINT TAB(1,6)"     ":GOTO 160
190  PRINT TAB(1,8) "ENTER THE TEST NUMBER REQUIRED":INPUT TAB(1,9)t
est%
200  PTR#CH1=0
210  REPEAT
220    PROC_read_file
230    UNTIL TN%=test% OR EOF#CH1
240  IF TN%<>test% PRINT "TEST NOT ON FILE" :PRINT TAB(1,9)"      ":
GOTO 190
250  CLS
260  PROC_data_display
270  MODE 0
280  PROC_choice_of_Y_axis
290  PROC_choice_of_X_axis
300 PROC_plot
310 PRINT TAB(27,28)"PRESS SPACEBAR TO CONTINUE"
320 DUM=GET
330 MODE 7
340 PROC_regression
350 MODE 0
360 PROC_calculate
370 INPUT"HARDCOPY REQUIRED(Y/N)",H$
380 IF H$="Y" HCOPY%=1 ELSE HCOPY%=0
390 CLS
400 PROC_plot
410  PROC_results
420 IF HCOPY%=1 THEN *SDUMP
430  CLOSE#0
440 END
450
460  DEF PROC_choice_of_Y_axis
470  REM this chooses the desired Y axis scale
480  REM this program uses data line 510
490  RESTORE540
500  REPEAT
510    READ YMAX
520    UNTIL YMAX>=Y(NPTS%) OR YMAX=40
530  stepY=(YMAX-10)/6
540    DATA 13,16,19,22,25,28,31,34,37
550  REM SFY=scaling factor for the Y_axis
560  SFY=600/(6*stepY)
570  ENDPROC
580
```

```
590  DEF PROC_choice_of_X_axis
600  REM this repeat chooses the X_axis scale
610  REM this program uses data statement 620.
620  RESTORE670
630  REPEAT
640    READ XMAX
650    UNTIL XMAX>=X(NPTS%) OR XMAX=30
660  stepX=XMAX/6
670  DATA 6,12,24,30
680  REM SFX=scaling factor for X_axis
690  SFX=600/(6*stepX)
700  ENDPROC
710
720  DEF PROC_plot
730  VDU5
740  REM PLOTS PRESSURE VS TIME
750  FOR I% = 1 TO NPTS%
760    MOVE X(I%)*SFX+300,(Y(I%)-10)*SFY+320
770    PRINT"X"
780    NEXT I%
790  IF REG%=1 THEN MOVE X(1)*SFX+300,(YSTART-10)*SFY+300 : DRAW X(N
PTS%)*SFX+300,(YEND-10)*SFY+300
800  REM DRAW X AXIS
810  MOVE 300,300
820  FOR J%=0 TO 6
830    A%= 300+J%*100
840    DRAW A%,300
850    DRAW A%,285
860    MOVE A%-150,265
870    PRINT J%*stepX
880    MOVE A%,300
890    NEXT J%
900  MOVE 970,270
910  PRINT "TIME in Min"
920  REM DRAW Y AXIS
930  MOVE 300,300
940  FOR J% =0 TO 6
950    A%= 300 + J%*100
960    DRAW 300,A%
970    DRAW 280,A%
980    MOVE 90,A%+8
990    PRINT J%*stepY+10
1000   MOVE 300,A%
1010   NEXT J%
1020 MOVE 10,980
1030 PRINT "PRESSURE"
1040 MOVE 10,930
1050 PRINT "in cm Hg"
1060 VDU4
1070 PRINT TAB(24,1) "GAS PERMEABILITY OF WOUND COVERINGS"
1080 ENDPROC
1090
1100 DEF PROC_regression
1110 REG%=1
1120 PRINT TAB(1,3)"ENTER NUMBER OF POINTS TO BE"
1130 PRINT TAB(1,4)CHR$(129)"EXCLUDED"CHR$(135)"FROM THE REGRESSION
":INPUT TAB(38,4)N%
1140 IF N%>9 OR N%<0 PRINT "INVALID DATA":GOTO 1120
1150 @%=131850
1160 XSUM=0:X2SUM=0:YSUM=0:Y2SUM=0:CROSS=0:M%=NPTS%-N%
1170 FOR K%=N%+1 TO NPTS%
1180   XSUM = XSUM + X(K%)
```

```
1190     X2SUM = X2SUM + X(K%)*X(K%)
1200     YSUM = YSUM +Y(K%)
1210      Y2SUM =Y2SUM +Y(K%)*Y(K%)
1220     CROSS = X(K%)*Y(K%)+CROSS
1230     NEXT K%
1240   X2=X2SUM-XSUM*XSUM/M%
1250   Y2=Y2SUM-YSUM*YSUM/M%
1260   C2=CROSS-XSUM*YSUM/M%
1270   GRAD =C2/X2
1280   inter=YSUM/M%-GRAD*XSUM/M%
1290 R=C2/SQR(X2*Y2)
1300   PRINT "GRADIENT    ",GRAD
1310   PRINT "INTERCEPT   ",inter
1320   PRINT "CORRELATION COEFF    ",R
1330 PRINT
1340   PRINT TAB(1,15)CHR$(134)"REGRESSION  OK ?",CHR$(129),"(Y/N) " :
INPUT TAB(37,15)A$
 1350    IF A$="N" CLS :GOTO 1120
 1360   YSTART=X(1)*GRAD+inter
 1370   YEND=X(NPTS%)*GRAD+inter
 1380   HO=Y(N%+1):HT=Y(NPTS%)
 1390   @%=10
 1400   ENDPROC
 1410
 1420   DEF PROC_calculate
 1430   @%=131850
 1440   PO=PVAC+(HO-HVAC)
 1450   SO=PA-PO
 1460   VO=(VC+VS)+(HO*0.0175)
 1470   TI=(X(NPTS%)-X(N%+1))/60
 1480   T=TO+273
 1490   A=AT
 1500   H=HT-HO
 1510   K=(273*10000*24)/(T*A)
 1520   TEMP1=LN(1-H/SO)
 1530   TEMP2=(2*PA-PO)*0.0175+VO
 1540   TEMP3=TEMP2*TEMP1
 1550   TEMP4=(-2*0.0175*H)-TEMP3
 1560   G=(K*TEMP4)/TI
 1570   PR =(G*Z)/6.5664E10
 1580   @%=10
 1590   ENDPROC
 1600
 1610   DEF PROC_read_file
 1620   INPUT#CH1,M$:INPUT#CH1,D$:INPUT#CH1,TN%
 1630   INPUT#CH1,G$:INPUT#CH1,HVAC:INPUT#CH1,PA
 1640   INPUT#CH1,TO:INPUT#CH1,PVAC:INPUT#CH1,Z
 1650   INPUT#CH1,VC:INPUT#CH1,VS:INPUT#CH1,AT:INPUT#CH1,F
 1660   FOR I%=1 TO NPTS%
 1670     INPUT#CH1,X(I%):INPUT#CH1,Y(I%)
 1680     NEXT I%
 1690   ENDPROC
 1700
 1710   DEF PROC_data display
 1720   @%=131850
 1730   PRINT TAB(1,3) "MATERIAL":PRINT TAB(25,3)M$
 1740   PRINT TAB(1,4) "TEST DATE":PRINT TAB(25,4)D$
 1750   PRINT TAB(1,5) "TEST NUMBER":PRINT TAB(25,5)TN%
 1760   PRINT TAB(1,6) "GAS":PRINT TAB(25,6)G$
 1770   PRINT TAB(1,8) "INITIAL Hg HEIGHT(cm Hg)":PRINT TAB(30,8)HVAC
 1780   PRINT TAB(1,10) "ATMOSPHERIC PRESSURE(cm Hg)":PRINT TAB(30,10)P
A
```

```
 1790  PRINT TAB(1,12) "ROOM TEMPERATURE(DEG C)":PRINT TAB(30,12)TO
 1800  PRINT TAB(1,14) "MCLEOD GAUGE READING (cm Hg)":PRINT TAB(30,14)
PVAC
 1810  PRINT TAB(1,16) "THICKNESS(cm)":PRINT TAB(30,16)Z
 1820   PRINT TAB(1,18) "CHAMBER VOLUME(cm3)":PRINT TAB(30,18)VC
 1830  PRINT TAB(1,20) "VOID VOLUME(cm3)":PRINT TAB(30,20)VS
 1840  PRINT TAB(1,22) "MEMBRANE AREA (cm2)":PRINT TAB(30,22)AT
 1850  PRINT TAB(1,24) "VOID FRACTION":PRINT TAB(30,24)F
 1860  DUM=GET
 1870  @%=10
 1880  CLS : PRINT''
 1890  PRINT CHR$(134)"THE COORDINATES ARE AS FOLLOWS" :PRINT
 1900  FOR I% = 1 TO NPTS%
 1910    PRINT "POINT NO.",I%,X(I%),Y(I%)
 1920    NEXT I%
 1930  DUM=GET
 1940   ENDPROC
 1950
 1960 DEF PROC_results
 1970   @%=131850
 1980   PRINT TAB(60,6) "PO=",PO
 1990   PRINT TAB(60,8) "SO=",SO
 2000   PRINT TAB(60,10) "VO=",VO
 2010   PRINT TAB(60,12) "K=",K
 2020   PRINT TAB(60,14) "G=",G
 2030   @%=5
 2040   PRINT TAB(60,16) "PR=",PR
 2050   PRINT TAB(33,26) "MATERIAL : ",M$
 2060 PRINT TAB(10,28) "TEST DATE : ",D$,"    TEST NUMBER : ",TN%
 2070 PRINT TAB(10,26) "GAS : ",G$
 2080   PRINT TAB(28,31)"    DOUGLAS QUEEN"
 2090   @%=10
 2100   ENDPROC
```

APPENDIX 5

GAS TRANSMISSION TESTS

RAW DATA.

MATERIAL	GAS TRANSMISSION (OXYGEN) cm (STP).m^{-2}.day^{-1}.atm^{-1}	GAS TRANSMISSION (CARBON DIOXIDE) cm (STP).m^{-2}.day^{-1}.atm^{-1}
SILICONE	67 635	334 449
	69 532	334 449
	67 625	343 041
	67 532	342 448
RUBBER	67 510	342 856
	66 964	342 374
SUPPORT	67 084	337 657
	67 055	337 803
	67 029	341 767
TEGADERM	9 165	54 899
	6 514	55 089
	10 657	55 089
	6 562	57 452
	11 047	45 670
	7 591	57 369
	7 087	57 313
	6 907	57 314
	6 574	57 288

MATERIAL	GAS TRANSMISSION (OXYGEN) cm (STP).m^{-2}.day^{-1}.atm^{-1}	GAS TRANSMISSION (CARBON DIOXIDE) cm (STP).m^{-2}.day^{-1}.atm^{-1}
BIOCLUSIVE	2 790	41 902
	3 151	40 925
	3 058	38 620
	2 894	43 159
	3 524	38 637
	3 675	36 521
	3 512	38 605
	3 278	36 442
	3 789	36 391
STRETCH 'N' SEAL	12 100	114 664
	10 442	115 165
	11 553	115 110
	12 020	114 904
	10 759	92 369
	7 978	96 672
	7 655	90 778
	8 747	120 455
	6 566	107 995

MATERIAL	GAS TRANSMISSION (OXYGEN) cm (STP).m^{-2}.day^{-1}.atm^{-1}	GAS TRANSMISSION (CARBON DIOXIDE) cm (STP).m^{-2}.day^{-1}.atm^{-1}
VIGILON	10 573	29 449
	8 505	31 474
	7 159	31 470
	6 327	33 520
COVERFILM	9 515	27 434
	8 808	27 452
	7 663	27 423
	7 650	27 397
	6 592	29 418
SILICONE + MEFIX	68 899	-
	66 984	-
	70 609	-
	70 599	-
	65 266	-
	67 106	-
	70 868	-
	70 625	-
	68 896	-

APPENDIX 6

DATA SHEETS USED IN EVAPORATIVE WATER LOSS CLINICAL STUDY.

ASSESSMENT OF BURN WOUND DRESSINGS FOR IN SITU EVAPORATIVE WATER LOSS.

DRESSING ..... HOSPITAL .....

WARD ..... CONSULTANT .....

PATIENT DETAILS

INITIALS..... AGE.....years SEX M.... F....

BRIEF HISTORY OF INJURY .....

TYPE OF BURN First Deg .... Second Deg .... Third Deg ....

DEPTH OF BURN Full Thickness .... Partial ..... Mixed .....

EXUDATION RATE Heavy ..... Light .....

PREVIOUS TREATMENT/S (if any) .....

GENERAL HEALTH OF PATIENT V.Good .... Good .... Poor .... V.Poor ....

DATE OF INJURY ..... TIME OF INJURY .....

TIME OF ADMISSION ..... TIME TREATMENT WAS STARTED .....

DATE TREATMENT COMMENCED ..... LENGTH OF TIME USED .....

TIME OF DRESSING CHANGES 1 ..... 5 .....

2 ..... 6 .....

3 ..... 7 .....

4 ..... 8 .....

.....

RESULTS

.....

DATE ..... PATIENTS INITIALS .....

PAIN ON APPLYING Nil..... Some..... Painful.....

PAIN ON REMOVING Nil..... Some..... Painful.....

SURROUNDING SKIN BEFORE USE Healthy .... Red .... Hard ....

SURROUNDING SKIN AFTER USE Healthy .... Red .... Hard ....

EASY TO APPLY Yes ..... No ..... Comment .....

EASY TO REMOVE Yes ..... No ..... Comment .....

PATIENT ACCEPTANCE Excellent .... Good .... Average .... Poor ....

NURSING ACCEPTANCE Excellent .... Good .... Average .... Poor ....

.....

EVAPORATION MEASUREMENTS

.....

DRESSING (i.e. First, second etc.) .....

TIME EVAPORATION DETERMINATION WAS STARTED .....

TIME WHEN WOUND WAS DRESSED ..... LOCATION OF AREA .....

TIME (mins)	EVAP. RATE.	ROOM TEMP.	ROOM RH.
0	.....	.....	.....
30	.....	.....	.....
60	.....	.....	.....
90	.....	.....	.....
120	.....	.....	.....
150	.....	.....	.....
180	.....	.....	.....
210	.....	.....	.....
240	.....	.....	.....

APPENDIX 7

UNIAXIAL TENSILE TESTS

RAW DATA.

MATERIAL (ORIENTATION)	BREAKING LOAD (kg)	ELONGATION AT BREAK (%)	TENSILE STRENGTH (kg/cm^2)
TEGADERM (TRANSVERSE) DRY	0.21	396	140
	0.29	554	193
	0.30	674	200
	0.21	674	178
	0.25	500	166
TEGADERM (TRANSVERSE) WET	0.14	544	94
	0.28	820	188
	0.25	640	166
	0.14	632	94
	0.26	814	171
TEGADERM (LONGITUDINAL) DRY	0.19	960	127
	0.24	960	160
	0.12	646	83
	0.12	606	83
	0.18	696	149
TEGADERM (LONGITUDINAL) WET	0.25	714	166
	0.29	1010	193
	0.19	684	127
	0.35	976	232
	0.20	844	133

MATERIAL (ORIENTATION)	BREAKING LOAD (kg)	ELONGATION AT BREAK (%)	TENSILE STRENGTH (kg/cm^2)
VIGILON WEB (TRANSVERSE) DRY	0.45	34	16.26
	0.36	32	12.95
	0.35	30	12.65
	0.35	24	12.65
	0.33	28	12.05
VIGILON WEB (TRANSVERSE) WET	0.10	32	3.76
	0.17	76	6.02
	0.15	94	5.27
	0.12	120	4.52
	0.15	72	5.27
VIGILON WEB (LONGITUDINAL) DRY	0.25	20	9.03
	0.28	28	10.24
	0.28	14	10.24
	0.16	36	5.72
	0.19	32	6.78
VIGILON WEB (LONGITUDINAL) WET	0.31	24	11.29
	0.25	20	9.03
	0.27	26	9.79
	0.37	32	13.55
	0.50	30	18.07

MATERIAL (ORIENTATION)	BREAKING LOAD (kg)	ELONGATION AT BREAK (%)	TENSILE STRENGTH (kg/cm^2)
VIGILON COVER (TRANSVERSE) DRY	0.14	160	282
	0.11	120	215
	0.13	162	265
	0.12	170	248
	0.15	330	298
VIGILON COVER (TRANSVERSE) WET	0.17	410	331
	0.14	416	282
	0.18	420	364
	0.19	500	381
	0.17	460	331
VIGILON COVER (LONGITUDINAL) DRY	0.21	88	414
	0.22	100	447
	0.24	162	480
	0.23	166	464
	0.22	146	447
VIGILON COVER (LONGITUDINAL) WET	0.20	98	398
	0.25	200	497
	0.24	164	480
	0.25	164	497
	0.24	136	480

MATERIAL (ORIENTATION)	BREAKING LOAD (kg)	ELONGATION AT BREAK (%)	TENSILE STRENGTH (kg/cm^2)
	0.13	118	265
STRETCH	0.12	72	248
'N' SEAL	0.13	108	265
(TRANSVERSE)	0.15	112	298
DRY	0.15	132	298
	0.09	140	182
STRETCH	0.15	120	298
'N' SEAL	0.12	168	232
(TRANSVERSE)	0.12	180	232
WET	0.16	290	315
	0.06	78	116
STRETCH	0.14	72	282
'N' SEAL	0.04	44	83
(LONGITUDINAL)	0.08	100	166
DRY	0.16	138	315
	0.23	272	464
STRETCH	0.17	270	331
'N' SEAL	0.22	272	431
(LONGITUDINAL)	0.18	238	364
WET	0.21	260	414

MATERIAL (ORIENTATION)	BREAKING LOAD (kg)	ELONGATION AT BREAK (%)	TENSILE STRENGTH (kg/cm^2)
LYOFOAM (TRANSVERSE) DRY	0.41	258	0.75
	0.42	198	0.77
	0.41	254	0.75
	0.46	248	0.83
	0.43	220	0.78
LYOFOAM (TRANSVERSE) WET	0.33	262	0.60
	0.31	226	0.57
	0.33	220	0.60
	0.34	218	0.62
	0.34	248	0.62
LYOFOAM (LONGITUDINAL) DRY	0.46	274	0.83
	0.41	250	0.75
	0.43	286	0.78
	0.47	268	0.86
	0.43	292	0.78
LYOFOAM (LONGITUDINAL) WET	0.38	238	0.69
	0.33	232	0.60
	0.29	224	0.53
	0.34	236	0.62
	0.31	244	0.57

MATERIAL (ORIENTATION)	BREAKING LOAD (kg)	ELONGATION AT BREAK (%)	TENSILE STRENGTH (kg/cm^2)
BIOCLUSIVE (TRANSVERSE) DRY	0.257	514	514
	0.398	716	795
	0.373	602	745
	0.282	552	563
	0.381	656	762
BIOCLUSIVE (TRANSVERSE) WET	0.348	500	696
	0.331	910	663
	0.389	594	779
	0.414	904	828
	0.273	588	547
BIOCLUSIVE (LONGITUDINAL) DRY	0.439	618	878
	0.282	482	563
	0.356	536	712
	0.298	526	596
	0.290	476	580
BIOCLUSIVE (LONGITUDINAL) WET	0.381	600	762
	0.381	646	762
	0.480	728	961
	0.571	920	1143
	0.323	540	646

MATERIAL (ORIENTATION)	BREAKING LOAD (kg)	ELONGATION AT BREAK (%)	TENSILE STRENGTH (kg/cm^2)
CORADERM (TRANSVERSE) DRY	0.182	374	4.67
	0.207	510	5.31
	0.182	386	4.67
	0.182	340	4.67
	0.199	440	5.10
CORADERM (TRANSVERSE) WET	0.075	166	1.91
	0.091	212	2.34
	0.083	146	2.12
	0.091	234	2.34
	0.083	154	2.12
CORADERM (LONGITUDINAL) DRY	0.149	280	3.82
	0.124	150	3.19
	0.157	308	4.03
	0.149	310	3.82
	0.141	294	3.61
CORADERM (LONGITUDINAL) WET	0.066	146	1.70
	0.083	200	2.12
	0.091	178	2.34
	0.083	230	2.12
	0.091	160	2.34

MATERIAL (ORIENTATION)	BREAKING LOAD (kg)	ELONGATION AT BREAK (%)	TENSILE STRENGTH (kg/cm^2)
	0.306	266	8.17
SYNTHADERM	0.273	160	7.29
(TRANSVERSE)	0.215	180	5.74
DRY	0.257	252	6.85
	0.257	210	6.85
	0.124	96	3.31
SYNTHADERM	0.133	110	3.53
(TRANSVERSE)	0.091	54	2.43
WET	0.116	60	3.09
	0.099	48	2.65
	0.248	216	6.63
SYNTHADERM	0.190	124	5.08
(LONGITUDINAL)	0.182	164	4.86
DRY	0.207	166	5.52
	0.215	184	5.74
	0.108	56	2.87
SYNTHADERM	0.116	82	3.09
(LONGITUDINAL)	0.116	56	3.09
WET	0.091	50	2.43
	0.116	64	3.09

MATERIAL (ORIENTATION)	BREAKING LOAD (kg)	ELONGATION AT BREAK (%)	TENSILE STRENGTH (kg/cm^2)
PORVAIR 232013 (TRANSVERSE) DRY	0.215	274	43.06
	0.356	376	71.22
	0.290	354	57.97
	0.340	390	67.91
	0.265	382	53.00
PORVAIR 232013 (TRANSVERSE) WET	0.232	280	46.38
	0.298	156	59.63
	0.232	134	46.38
	0.348	290	69.57
	0.232	166	46.38
PORVAIR 232013 (LONGITUDINAL) DRY	0.331	334	66.25
	0.340	370	67.91
	0.290	312	57.97
	0.331	348	66.25
	0.306	356	61.28
PORVAIR 232013 (LONGITUDINAL) WET	0.257	368	51.35
	0.215	296	43.06
	0.240	288	48.03
	0.224	254	44.72
	0.224	330	44.72

MATERIAL (ORIENTATION)	BREAKING LOAD (kg)	ELONGATION AT BREAK (%)	TENSILE STRENGTH (kg/cm^2)
	0.282	210	70.39
PORVAIR	0.207	258	51.76
32/5/1	0.232	272	57.97
(TRANSVERSE)	0.224	292	55.90
DRY	0.199	224	49.69
	0.190	280	47.62
PORVAIR	0.157	156	39.34
32/5/1	0.190	134	47.62
(TRANSVERSE)	0.265	290	66.25
WET	0.157	166	39.34
	0.240	264	60.04
PORVAIR	0.182	274	45.55
32/5/1	0.215	320	53.83
(LONGITUDINAL)	0.190	280	47.62
DRY	0.207	244	51.76
	0.166	264	41.41
PORVAIR	0.224	326	55.90
32/5/1	0.215	372	53.83
(LONGITUDINAL)	0.149	278	37.27
WET	0.091	164	22.77

MATERIAL (ORIENTATION)	BREAKING LOAD (kg)	ELONGATION AT BREAK (%)	TENSILE STRENGTH (kg/cm^2)
NON-LINEAR HYDROGEL (TRANSVERSE) WET	1.33 1.55 1.10 1.57 1.28	84 100 54 114 80	28.8 33.8 23.9 34.2 27.9
NON-LINEAR HYDROGEL (LONGITUDINAL) WET	1.65 1.66 2.48 1.86 2.17	42 44 88 52 74	35.8 36.2 54.0 40.5 47.3
LINEAR HYDROGEL (TRANSVERSE) WET	0.03 0.03 0.02 0.03 0.02	180 350 176 190 220	4.4 4.4 3.3 4.4 3.3
LINEAR HYDROGEL (LONGITUDINAL) WET	0.03 0.03 0.03 0.03 0.03	296 284 402 324 284	4.4 4.4 4.4 4.4 4.4

MATERIAL (ORIENTATION)	BREAKING LOAD (kg)	ELONGATION AT BREAK (%)	TENSILE STRENGTH (kg/cm^2)
GELIPERM (TRANSVERSE) WET	0.06	106	1.2
	0.07	132	1.4
	0.07	124	1.4
	0.08	214	1.7
	0.07	120	1.6
GELIPERM (LONGITUDINAL) WET	0.06	98	1.2
	0.06	98	1.2
	0.05	76	1.0
	0.07	140	1.4
	0.06	98	1.2
CORETHIUM (TRANSVERSE) WET	0.38	24	19.1
	0.32	26	16.2
	0.47	34	23.6
	0.25	28	12.4
	0.46	36	22.8
CORETHIUM (LONGITUDINAL) WET	0.09	28	4.6
	0.27	32	10.4
	0.14	28	7.4
	0.09	21	4.6
	0.12	33	6.2

APPENDIX 8

STRENGTH MODULI

RAW DATA.

MATERIAL (ORIENTATION)	BIAXIAL MODULUS (k Pa)	CONFORMABILITY MODULUS (k Pa)
LYOFOAM	30	2378
(TRANSVERSE)	39	7928
WET	33	3269
	41	4511
	29	2732
LYOFOAM	43	3269
(LONGITUDINAL)	43	4738
WET	33	3087
	39	-
	37	-
TEGADERM	7222	880
(TRANSVERSE)	6620	1763
WET	4814	945
	4814	972
	7222	1630
TEGADERM	6018	1282
(LONGITUDINAL)	4213	864
WET	7222	978
	5717	-
	4814	-

MATERIAL (ORIENTATION)	BIAXIAL MODULUS (k Pa)	CONFORMABILITY MODULUS (k Pa)
GELIPERM	43	51
(TRANSVERSE)	21	25
WET	21	97
	-	58
	-	118
GELIPERM	43	109
(LONGITUDINAL)	11	143
WET	21	116
	-	-
	-	-
STRETCH 'N'	46940	27957
SEAL	55967	65419
(TRANSVERSE)	55967	12057
WET	54162	9321
	62286	8154
STRETCH 'N'	36108	10200
SEAL	45135	9033
(LONGITUDINAL)	40621	11333
WET	54162	-
	60480	-

MATERIAL (ORIENTATION)	BIAXIAL MODULUS (k Pa)	CONFORMABILITY MODULUS (k Pa)
PORVAIR 232013 (TRANSVERSE) WET	3600	199
	2300	226
	1600	205
	6200	230
	3400	279
PORVAIR 232013 (LONGITUDINAL) WET	4100	244
	4100	257
	3400	378
	2900	-
	3500	-
PORVAIR 32/5/1 (TRANSVERSE) WET	2130	582
	1250	647
	500	611
	2880	500
	1000	592
PORVAIR 32/5/1 (LONGITUDINAL) WET	1880	579
	3130	699
	880	705
	2250	-
	2130	-

MATERIAL (ORIENTATION)	BIAXIAL MODULUS (k Pa)	CONFORMABILITY MODULUS (k Pa)
CORADERM (TRANSVERSE) WET	140	27
	170	53
	160	46
	110	40
	140	26
CORADERM (LONGITUDINAL) WET	160	49
	120	46
	140	25
	120	-
	190	-
CORETHIUM (TRANSVERSE) WET	300	1190
	580	1362
	780	4632
	900	2762
	280	2641
CORETHIUM (LONGITUDINAL) WET	430	1285
	300	2594
	430	4126
	400	-
	350	-

MATERIAL (ORIENTATION)	BIAXIAL MODULUS (k Pa)	CONFORMABILITY MODULUS (k Pa)
BIOCLUSIVE (TRANSVERSE) WET	1400	259
	1300	229
	1200	222
	1500	229
	1400	207
BIOCLUSIVE (LONGITUDINAL) WET	1100	216
	1000	216
	700	211
	3100	-
	1200	-
SYNTHADERM (TRANSVERSE) WET	400	32
	340	28
	140	34
	350	29
	340	33
SYNTHADERM (LONGITUDINAL) WET	280	30
	70	28
	560	36
	470	-
	360	-

MATERIAL (ORIENTATION)	BIAXIAL MODULUS (k Pa)	CONFORMABILITY MODULUS (k Pa)
NON-LINEAR HYDROGEL (TRANSVERSE)	109296	2394
	114628	2006
	111962	1948
WET	-	2394
	-	2766
NON-LINEAR HYDROGEL (LONGITUDINAL)	95967	2212
	87970	2891
	74641	3058
WET	-	-
	-	-
VIGILON COVER (TRANSVERSE)	264037	1499
	304658	9020
WET	233571	5754
	228494	2970
	248804	8927
VIGILON COVER (LONGITUDINAL)	233571	8554
	258960	5085
WET	299581	5754
	233571	-
	208183	-

MATERIAL (ORIENTATION)	BIAXIAL MODULUS (k Pa)	CONFORMABILITY MODULUS (k Pa)
LINEAR HYDROGEL (TRANSVERSE) WET	609 677 406 542	184 462 157 187
LINEAR HYDROGEL (LONGITUDINAL) WET	677 812 542 677 406	307 182 231 - -

APPENDIX 9

CONFORMABILITY ASSESSMENT

RAW DATA.

MATERIAL	HEIGHT (cm)	THICKNESS (mm)	RADIUS OF CURVATURE (cm)
GELIPERM	0.858	1.42	8.62
	1.225	1.15	6.35
	0.740	1.12	9.87
	0.865	1.22	8.56
	0.713	1.01	10.22
	0.741	0.99	9.86
	0.680	0.95	10.68
	0.727	0.98	10.04
STRETCH 'N' SEAL	0.529	0.01	13.56
	0.395	0.01	18.00
	0.711	0.01	10.24
	0.780	0.01	9.40
	0.819	0.01	8.99
	0.755	0.01	9.69
	0.789	0.01	9.31
	0.727	0.01	10.04
LINEAR HYDROGEL	1.152	0.18	6.68
	1.110	0.21	6.89
	0.849	0.16	8.71
	1.243	0.18	6.28
	1.146	0.18	6.71
	1.071	0.13	7.10
	1.184	0.17	6.53
	1.132	0.15	6.78
NON-LINEAR HYDROGEL	0.609	0.78	11.85
	0.634	0.83	11.41
	0.649	0.80	11.16
	0.591	0.85	12.19
	0.522	1.05	13.73
	0.578	0.98	12.45
	0.551	0.86	13.04
	0.534	0.89	13.43

MATERIAL	HEIGHT (cm)	THICKNESS (mm)	RADIUS OF CURVATURE (cm)
VIGILON	0.449	0.03	15.88
	0.535	0.03	13.41
	0.626	0.03	11.55
	0.793	0.03	9.26
	0.537	0.03	13.36
	0.545	0.03	13.17
	0.654	0.03	11.08
	0.626	0.03	11.55
LYOFOAM	0.118	10	59.60
	0.165	11	42.70
	0.103	11	68.32
	0.090	12	78.17
	0.113	10	62.28
	0.103	11	68.32
	0.088	12	79.94
	0.102	12	68.98
TEGADERM	1.264	0.03	6.19
	0.962	0.03	7.79
	1.228	0.03	6.34
	1.214	0.03	6.40
	0.991	0.03	7.59
	1.087	0.03	7.01
	1.274	0.03	6.16
	1.211	0.03	6.41
BIOCLUSIVE	1.275	0.10	6.15
	1.340	0.10	5.92
	1.360	0.10	5.85
	1.341	0.10	5.91
	1.400	0.10	5.72
	1.376	0.10	5.80
	1.374	0.10	5.80
	1.390	0.10	6.06

MATERIAL	HEIGHT (cm)	THICKNESS (mm)	RADIUS OF CURVATURE (cm)
SYNTHADERM	1.389	0.65	5.76
	1.423	0.71	5.65
	1.248	0.80	6.26
	1.390	0.72	5.75
	1.366	0.65	5.83
	1.389	0.70	5.76
	1.389	0.75	5.76
	1.291	0.69	6.09
PORVAIR 232013	1.425	0.10	5.65
	1.348	0.10	5.89
	1.407	0.10	5.70
	1.340	0.10	5.92
	1.235	0.10	6.31
	1.307	0.10	6.03
	1.269	0.10	6.18
	1.095	0.10	6.97
PORVAIR 32/5/1	1.010	0.08	7.47
	0.970	0.08	7.73
	0.991	0.08	7.59
	1.071	0.08	7.10
	1.003	0.08	7.51
	1.012	0.08	7.45
	0.942	0.08	7.94
	0.939	0.08	7.96
CORADERM	1.463	0.69	5.54
	1.071	0.75	7.10
	1.106	0.80	6.91
	1.225	0.70	6.35
	1.362	0.85	5.84
	1.086	0.78	7.02
	1.079	0.84	7.06
	1.351	0.87	5.88

MATERIAL	HEIGHT (cm)	THICKNESS (mm)	RADIUS OF CURVATURE (cm)
CORETHIUM	0.429	0.40	16.60
	0.433	0.42	16.46
	0.348	0.36	20.38
	0.428	0.38	16.64
	0.306	0.30	23.13
	0.346	0.35	20.50
	0.302	0.35	23.43
	0.350	0.36	20.26
GELIPERM + MEFIX	0.836	1.40	8.83
	0.885	1.71	8.39
	0.784	1.35	9.36
	0.740	1.51	9.87
	0.797	1.32	9.22
	0.697	1.13	10.44
	0.846	1.16	8.73
	0.825	1.29	8.94
LINEAR HYDROGEL + MEFIX	0.635	0.42	11.39
	0.669	0.42	10.84
	0.746	0.45	9.80
	0.721	0.39	10.11
	0.758	0.48	9.66
	0.744	0.42	9.82
	0.603	0.43	11.96
	0.522	0.44	13.73
NON-LINEAR HYDROGEL + MEFIX	0.492	1.10	14.54
	0.582	1.05	12.37
	0.571	1.21	12.60
	0.604	1.11	11.94
	0.541	0.99	13.27
	0.470	0.98	15.20
	0.556	1.22	12.92
	0.540	1.11	13.29

APPENDIX 10

LINEAR VISCOELASTICITY TESTS

RAW DATA.

MATERIAL (time for test)	RATE OF CHANGE OF	
	HEIGHT (cm/min)	RADIUS OF CURVATURE (cm/min)
STRETCH 'N' SEAL (5 mins)	0.33	0.74
	0.32	2.43
	0.14	0.27
	0.19	0.67
TEGADERM (5 mins)	0.53	0.53
	0.54	0.76
	0.48	0.23
	0.42	0.74
LINEAR HYDROGEL (3 mins)	0.46	4.64
	0.47	2.69
	0.47	2.43
	0.61	4.80
GELIPERM (2 mins)	0.55	0.64
	0.22	0.26
	1.14	1.79
	0.39	0.41
BIOCLUSIVE (5 mins)	0.37	0.54
	0.34	0.63
	0.35	0.49
	0.35	0.51

MATERIAL (time for test)	RATE OF CHANGE OF	
	HEIGHT (cm/min)	RADIUS OF CURVATURE (cm/min)
SYNTHADERM (2.5 mins)	0.48	1.15
	0.65	1.07
	0.87	1.56
	0.81	1.58
PORVAIR 232013 (5 mins)	0.67	0.46
	0.70	0.53
	0.71	0.36
	0.62	0.54
PORVAIR 32/5/1 (5 mins)	0.15	0.65
	0.30	1.23
	0.27	1.12
	0.39	1.19
CORADERM (5 mins)	0.85	1.29
	0.82	1.03
	0.87	1.64
	0.88	1.55

APPENDIX 11

DATA SHEETS USED IN THE PSEUDOCLINICAL CONFORMABILITY STUDY.

DATA SHEET ONE : CONFORMABILITY ASSESSMENT SUBJECT DATA SHEET

SUBJECT ..... AGE .....

BODY WEIGHT ..... BUILD ..... HEIGHT ....

RADII DATA

ELBOW JOINT .....

KNEE JOINT .....

SHOULDER .....

SHIN .....

CHIN .....

	DRESSINGS TESTED	BODY SURFACE
1.	.....	.....
2.	.....	.....
3.	.....	.....
4.	.....	.....
5.	.....	.....

DATA SHEET TWO : CONFORMABILITY ASSESSMENT RESULTS SHEET

SUBJECT REFERENCE .....

DRESSING TEST NUMBER .....

OBSERVATIONAL ASSESSMENT

PHOTOGRAPH TAKEN ..... REFERENCE CARD NUMBER .....

NO. OF WRINKLES/FLUTES .....

LOCATION OF WRINKLES/FLUTES .....

CONFORMABILTY RATING .....
(A - V. Good B - Average C - Poor D - V. Poor)

COMPARISON TO IN VITRO ASSESSMENT

* BODY SURFACE(S) TO WHICH THE IN VITRO TEST INDICATED THAT THE DRESSING CONFORMS .....

RADII OF THE SURFACE ABOVE * .....

ACCORDING TO THE IN VITRO TEST SHOULD THE DRESSING UTILISED CONFORM TO THE SURFACE STUDIED .....

WAS THIS OBSERVED IN THE TRIAL .....

ADDITIONAL COMMENTS .....

.....

.....

APPENDIX 12

PSEUDOCLINICAL CONFORMABILITY TRIAL

RAW DATA.

	DRESSING	JOINT : ELBOW					
	BIOCLUSIVE	TEGADERM	STRETCH 'N' SEAL	LYOFOAM	SYNTHADERM	CORADERM	GELIPERM
JS	B				C		D
RF						C	
PM							
JL							
KM			D				
NM			D				
MI				D			
HP							D
KS		C					
PR		C					
KT						C	
SG					D		
JF					C		
CV	C						
KO							C
LM			D				
MH				C			
KB		B					
BC				D			
JN						C	
JP	B						
AVERAGE	B	C	D	D	C	C	D

DRESSING	JOINT : KNEE						
	BIOCLUSIVE	TEGADERM	STRETCH 'N' SEAL	LYOFOAM	SYNTHADERM	CORADERM	GELIPERM
JS				C			
RF						C	
PM		B					
JL			D				
KM							C
NM							B
MI					C		
HP		B					
KS	B						
PR	B						
KT			D				
SG						C	
JF						C	
CV				D			
KO		C					
LM							A
MH					C		
KB	B						
BC					D		
JN			D				
JP				D			
AVERAGE	B	B	D	D	C	C	B

DRESSING	JOINT : SHOULDER						
	BIOCLUSIVE	TEGADERM	STRETCH 'N' SEAL	LYOFOAM	SYNTHADERM	CORADERM	GELIPERM
JS					C		
RF			C				
PM	B						
JL							A
KM		B					
NM		B					
MI						C	
HP	B						
KS					B		
PR				C			
KT							A
SG			B				
JF			D				
CV					D		
KO	B						
LM		B					
MH						C	
KB				C			
BC						C	
JN							A
JP					C		
AVERAGE	B	B	C	C	C	C	A

	DRESSING	JOINT : SHIN					
	BIOCLUSIVE	TEGADERM	STRETCH 'N' SEAL	LYOFOAM	SYNTHADERM	CORADERM	GELIPERM
JS						A	
RF							A
PM				A			
JL		B					
KM	B						
NM	B						
MI			C				
HP				A			
KS				A			
PR					A		
KT		B					
SG							A
JF							A
CV						A	
KO				A			
LM	A						
MH			B				
KB					A		
BC			B				
JN		B					
JP						A	
AVERAGE	B	B	B	A	A	A	A

DRESSING	JOINT : CHIN						
	BIOCLUSIVE	TEGADERM	STRETCH 'N' SEAL	LYOFOAM	SYNTHADERM	CORADERM	GELIPERM
JS			D				
RF		B					
PM					D		
JL	C						
KM				D			
NM				D			
MI							D
HP					D		
KS						D	
PR						C	
KT	C						
SG		C					
JF		C					
CV			D				
KO					D		
LM				D			
MH						D	C
KB							D
BC							
JN	C						
JP			D				
AVERAGE	C	C	D	D	D	D	D

APPENDIX 13

TEMPERATURE AND HUMIDITY MEASUREMENTS DURING THE CLINICAL STUDY - RAW DATA.

MATERIAL	TEMPERATURE		RELATIVE HUMIDITY	
	DAY 1	DAY2	DAY1	DAY2
LYOFOAM	24.3	23.5	72	79
	24.5	23.5	71	73
	24.6	23.4	70	74
	24.9	23.8	71	68
	24.6	23.8	66	64
	24.8	23.9	67	68
	25.2	24.2	74	71
	25.3	24.4	73	73
GELIPERM	24.1	22.5	82	75
	24.5	22.5	86	76
	24.4	22.5	84	77
	24.5	23.1	83	77
	24.6	23.5	82	83
	24.9	23.8	83	79
	24.6	23.8	80	74
	24.8	23.8	84	81
TEGADERM	-	-	35	35
	-	-	33	33
	-	-	34	37
	-	-	32	36
	-	-	34	37
	-	-	34	35
	-	-	33	35
	-	-	30	29

APPENDIX 14

TEMPERATURE STANDARDISATION SHEET

FOR THE EVAPORIMETER.

Figure 6

Saturation vapour pressure of water between 5 and 40°C

Temperature	Pressure	Temperature	Pressure
5°C	6.5 mm Hg	33°C	37.7 mm Hg
10	9.2	34	39.9
11	9.8	35	42.2
12	10.5	36	44.5
13	11.2	37	47.0
14	12.0	38	49.6
15	12.8	39	52.4
16	13.6	40	55.3
17	14.5		
18	15.5		
19	16.5		
20	17.5		
21	18.7		
22	19.8		
23	21.1		
24	22.4		
25	23.8		
26	25.2		
27	26.7		
28	28.3		
29	30.0		
30	31.8		
31	33.7		
32	35.6		