1. Introduction

1.1 Introduction and Aims of the Research

The research aims to evaluate the reliability and validity of differential electrical potentials measured from the skin surface as an objective indicator of the soft tissue state following injury.

The project has three main components - (a) the development of a novel instrumentation and software system for recording the potentials, (b) the investigation of differential surface skin potentials (DSSP's) in non injured subjects and (c) the investigation of the potentials in subjects who have recently experienced a soft tissue lesion, following these subjects through to recovery where possible.

The skin potential is the measured potential (voltage) between two skin electrodes when no current is applied (Leonesio and Chen 1987). Skin potential recording techniques in the literature almost exclusively involve measurement of the potential difference across the skin (i.e. from the external surface of the skin to the internal environment of the body - the transcutaneous potential). This work uses differential skin potential measurements from pairs of surface electrodes on both lower limbs, limited to the DC or ultra-low frequency range. The characteristics of these signals from injured or uninjured subjects are largely unreported in the literature.

Electrical correlates of physiological function have been investigated widely though spasmodically for more than 100 years. Several reports have suggested that the skin and musculoskeletal tissues (in addition to muscle and nerve, the accepted 'excitable tissues') are not only electrically sensitive but appear to be capable of generating specific electrical potentials - usually referred to as endogenous bioelectric potentials in that they arise from within the body. Changes in these endogenous potentials following injury or pathology have been reported (e.g. Foulds and Barker 1983, Chakkalakal 1988, Lokietek 1974).

Electrical potentials recorded from the skin surface may arise from a number of generator mechanisms which include the skin and the underlying musculoskeletal tissues. These are reviewed in Chapter 2. The experimental work reported concentrates on the relationship between the magnitude, polarity and characteristics of the potentials and the physiological state of the individual in both the non injured and injured conditions. This research does not specifically investigate the source of the measured potentials or attempt to ascribe any cause-effect relationship between skin potentials, injury and recovery, although the published research which has considered these complex issues is reviewed. The primary aim of the work is to establish whether there is a valid and reliable relationship between differential potentials recorded from the skin surface and the progress of a soft tissue lesion from injury to recovery. Correlation with environmental, physiological and psychological variables is reported in an attempt to establish which factors could be associated with skin potential behaviour.

1.2 Previous Work

Elements of the work had been investigated prior to commencement of the experimental components of the PhD. Firstly, the author, as a part of his BSc project (Watson 1988) had made a preliminary investigation of the surface skin potentials in non injured subjects using a commercial bench multimeter Section 4.1.2). Secondly, Wood (1990) had designed and tested a prototype dedicated skin potential measuring device in accordance with the hypotheses proposed by the author in the initial phase of this research. This system was developed by Wood during an MSc project and continued as a part of his PhD, taking it from a single channel instrument to a computer interfaced dual channel system as used in the main non injured and injured trials (Section 4.2).

1.3 Reason for conducting the research

The evaluation of treatment efficiency (functioning with the least waste of effort) and efficacy (being capable of producing an intended result) using objective methods enables practitioners to make reasoned choices regarding the treatment technique(s) which are most likely to achieve the optimum results for a patient.

The primary interest of the author is the use of electrotherapy in clinical medicine in order to alter or enhance physiological function (e.g. the use of Pulsed High Frequency Energy to promote soft tissue repair, the use of Interferential Therapy to enhance resolution of oedema). Many treatment techniques are claimed to 'speed the rate of tissue healing' yet there is limited supportive evidence for some modalities.

One of the problems in clinical research regarding treatment efficiency and efficacy is the apparent lack of appropriate research tools which can be used for outcome measurement. The purpose of this study therefore is not necessarily to create a new measurement tool for daily clinical use, but to provide a research tool which can be used to fill some of the knowledge gaps and consequently enhance clinical decision making.

1.4 General Hypotheses

A general hypothesis for the project can be formulated thus:

> The electrical activity of musculoskeletal tissues following injury will vary from 'normal', and by measuring the changes in the differential skin potential from the skin surface, it will be possible to objectively assess the rate and extent of the repair process.

The hypotheses for the experimental work reflects the subdivision of the research into its elements:

a) that there will be a measurable DC potential from the skin surface in non injured and injured subjects.

b) that the potentials measured from the left and right limbs of a non injured subject will be similar on the same occasion.

c) that the potentials from the limbs of a non injured subject will be similar when measured on subsequent occasions.

d) that following injury, the measured potentials will show a significant difference from those recorded from non injured subjects.

e) that there will be a progressive change in the potentials recorded from injured subjects as clinical recovery occurs.

f) that skin potentials from injured subjects, some time after the insult (related to tissue repair), will be indistinguishable from those recorded from non injured subjects.

1.5 Context of the Research

Within physiotherapy practice, there is a need for objective measurement systems which can be used as a research tool to evaluate the effectiveness of various treatment modalities (Bohannon 1989). It has been suggested by Rothstein (1985) that 'Without a scientific basis for the assessment (and measurement) process, we face the future as independent practitioners unable to communicate with one another, unable to document treatment efficacy, and unable to claim scientific credibility for our profession.'

In the current clinical climate where audit has become an important factor in decision making, improved performance is being carefully considered by many practitioners. Beyond current political trends, improving treatment outcomes is part of the ethos of clinical professionals. Clinical decision making is a complex topic, but essentially has several components, including identification of the problem, developing a hypothesis as to why the problem exists, and generation of a treatment plan (Rothstein 1985, Balla et al 1989). This is based both on the knowledge base of the profession combined with experience. Even with adequate knowledge, decision making can be very difficult in the early stages of practice (Abercrombie 1979). An increasing awareness of research through the basic education of clinicians has resulted in a change of emphasis in the decision making process in therapists. Gaps in the background knowledge have become more evident over the last ten years. In Borks' introduction to research in physical therapy, he identifies the problem as a combination of a relatively small knowledge base and a largely anecdotal basis for treatment (Bork 1993).

At the present time, treatment effectiveness is primarily measured or assessed by using subjective or quasi-objective measurements. Examples include the Visual Analogue Scale for pain, circumferential tape measurements for oedema, manual muscle testing to assess muscle function. Although some of the methods employed have been shown to be valid within specified criteria, the inter-rater reliability is often poor, leading to limited acceptance of research results (Rothstein 1985, Lamb 1985, Miller 1985).

Additionally, it is often very difficult to establish with any degree of certainty whether the effect of treatment constitutes an alteration of the disease state (an objective modification) or a perceived improvement/change from the patients or therapists viewpoint (a subjective modification).

Several researchers have evaluated aspects of clinical practice and have concluded that the placebo effect of treatment and intervention is responsible for much if not all of the change in the patients condition (e.g. Grant et al 1989). Within the profession, many treatment modalities are used which are applied with the intention of modifying the 'disease process'. Modes of action and treatment selection rationales are largely based on clinical findings, empirical and anecdotal evidence (Bork 1993). The placebo effect of any therapeutic intervention can be important in relation to the treatment programme as a whole, but it would be advantageous to be able to separate the placebo effects from the physiological/pathological changes that occur.

The electrical activity of the body has been extensively investigated in the last 100 years, leading to the development of numerous clinical investigation techniques which have established a place in medical practice e.g. ECG, EEG, EMG.

The endogenous electrical activity of the body arises from a variety of sources, some of which are well documented whilst others remain more obscure in their origins and control mechanisms (Offner 1984, Leonesio and Chen 1987). The relationship between endogenous electrical activity (not exclusively potentials), injury and healing have been researched in several areas of clinical practice. These investigations appear to follow three main themes:

1) that the endogenous electrical activity of the body can be used as an indicator of a particular pathological process without necessarily attributing a cause/effect relationship. (Edelberg 1971,1977, Marino 1989, Woodrough et al 1975).

2) that the endogenous electrical activity of the body acts as an initiator, control mechanism or modulator of the post embryonic growth and healing processes. (Becker et al 1962a,b,1967,1974, Borgens 1982, Foulds and Barker 1983, Hinkle et al 1981, Illingworth and Barker 1980, Patel and Poo 1982).

3) that by enhancing the endogenous electrical activity of the damaged tissues, the growth and/or healing processes can be stimulated or enhanced. (Brighton et al 1981, Brown et al 1988, Carley and Wainapel 1985, Kincaid 1989, Kloth and Feedar 1988, Reed 1988, Rowley et al 1974, Wheeler et al 1971).

In the course of the literature search, no research has been identified which has used endogenous potentials, measured from the skin surface as an indicator of the healing state of the tissues following soft tissue injury, although fracture healing and nerve regeneration processes have been investigated. In the context of the current research, the 'soft tissues' constitute muscle, ligament, tendon, fascia, bursa etc.

From the hypothetical concepts and experimental evidence studied, living tissue systems manifest a particular level of endogenous electrical activity, most likely arising from a series of batteries and membrane potentials (Chapter 2). These potentials can be expected to undergo a degree of change following injury (Becker 1962,1967, Dunn et al 1988, Konikoff 1976, Leonesio and Chen 1987) and a progressive return to the `normal' state as the damaged tissue returns to its pre-injured condition (Becker 1967, Chakkalakal et al 1988, Rowley et al 1974).

Following the literature review, a rationale is presented for the use of differential surface potentials as opposed to the more traditional transcutaneous skin potential measurement systems (Chapter 3). The instrument design and experimental work for the project was considered to follow three main phases:

<u>STAGE 1</u> The development of a system to measure the differential skin potential from surface electrodes, development of the computer interface and software together with testing and evaluation of the system. (Chapters 4 and 5)

<u>STAGE 2</u> Establishing the magnitude, polarity and characteristics of the potentials from non injured subjects (over time periods of 1 - 3 weeks), comparing equivalent tissue masses from opposite lower limbs. (Chapters 6-9)

<u>STAGE 3</u> Establishing the magnitude of the change in skin surface potential behaviour following soft tissue injury and the behaviour of the potentials over an appropriate time period for healing/repair (Chapters 9-10).

Stage 1 of the work also involved the development of appropriate subject testing procedures for the second and third phases. Physiological, anthropometric and environmental tests were incorporated alongside the skin potential measurements to allow a more extensive consideration of the relationships between the measured skin potentials and variables which might exert an influence on them in addition to soft tissue injury (Chapter 7).

The tests with non injured subjects included students and staff at the University and at the authors workplace (Physiotherapy Section at the West London Institute). Thirty non injured subjects were investigated during these tests (Chapters 8 and 9), and it was anticipated that simultaneous testing could be performed on students who had recently experienced a soft tissue lesion. The numbers of injured subjects at the second location were much smaller than had been expected (15), and an extended third phase was conducted in the Orthopaedic Unit at Ashford Hospital, where a further population of subjects (5) with musculoskeletal trauma were investigated (Chapter 10). The total injured subject sample remained small even with the additional tests in the clinical setting, giving 20 injured subjects altogether.

The non injured subject trial at the University is referred to as the A Series, the combined non injured and injured subject trial at the West London Institute the B Series and the Clinical trial at Ashford Hospital, the C Series.

1.6 The need for an objective measurement system in clinical electrotherapy research

In electrotherapy, clinical judgement is confounded by the rapid changes that have taken place over the last few years. Many new (or modified) treatment techniques have become available with a limited research base for their use. There are few research publications which compare the efficacy of one treatment with another (e.g. Quirk et al 1985, Vasseljen 1992) and not many more which consider the basic physiological effects of the modality itself.

In the light of these rapid advances, there is a need for published research which not only identifies the mechanism of action of the new modalities, but also provides comparative results with the treatments already in existence and with control groups. The selection of a treatment modality for a particular clinical problem is largely based on anecdotal and empirical evidence together with information provided by the companies manufacturing and selling the equipment. A recent publication concerning clinical laser therapy in Northern Ireland (Baxter et al 1991) used a survey to consider a wide range of laser use issues. One section deals with the source of formal and informal instruction on laser therapy for the 116 respondents. Almost 70% of these practitioners gained their formal information from manufacturers' seminars whilst almost 90% used the suppliers' literature for their informal training. These are not exclusive groups as some therapists also attended courses or attempted to search the literature for further information. The salient point is that for many practitioners, laser therapy would not have been included in the core training, and the reliance on manufacturers information for determining methods of application in clinical practice raises issues of professional ethics. The clinician should not have to rely on manufacturers information as the primary source of training in a new method, yet adequate investigative and comparative trials have not been published.

An example from electrotherapy research highlights the need for adequate objective outcome measurements when conducting comparative trials. Vasseljen (1992) compared laser therapy with ultrasound and transverse frictions (established techniques in treating tennis elbow) in a randomised trial. The method of evaluating which treatment produced the greater effect was divided into two parts - assessment of the subjective and the objective changes. The subjective tests constituted a Visual Analogue Scale (to assess current pain state) and completion of a scale relating to the patients' own judgement of progress (choice of 4 categories). The objective measurements constituted a test for grip strength, a weight test (the ability to extend the wrist with a weight in the hand and without pain) and a goniometric measurement of wrist flexion before pain onset.

Correspondence has been published in the professional journal questioning the trial methodology (e.g. that no control group was included and that one treatment was blind whilst the other was not), but the testing procedures involved generated no comment. The overall conclusion of the trial was that both treatment groups improved significantly but that laser therapy was no more effective in relieving the symptoms than traditional therapy. The pertinent issue to the current research is the testing procedure used to evaluate treatment effectiveness. Some of the tests were acknowledged to be subjective (questionnaire and VAS pain scale) whilst others were purported to be objective (grip strength, free weight test and range of movement). The problem with these objective tests is that at least 2 of the 3 tests relied on the patients' perception of pain to achieve a result. Pain perception is clearly a complex issue (Wall and Melzack 1984) and the tests are not strictly objective (existing independently of perception) but quasi-objective.

The question is raised (and this paper provides but one example) as to how one might objectively evaluate the changes that take place in the tissues following injury and subsequent treatment without invoking patient perceptions or subjective bias. A measurement tool which was capable of reflecting physiological change in the tissues without relying on patient perception of pain, improvement or well being, could be used in research. Elimination of subjective information from clinical practice or research is not advocated in this context. Over-reliance on 'measurement information' is at least as bad as not measuring anything. The subjective information provided by the patient is very important in taking the 'holistic' approach to treatment. The need for objective measurement in the context proposed here is primarily for the clinical research programme - a necessary process to provide evaluation and comparison of treatment techniques to allow future development within the profession.

1.7 Rationale for using skin potentials as the objective indicator

Electrical intervention as a form of treatment (electrotherapy) is common in clinical practice, using a wide range of energy forms from interrupted DC, through a variety of low and middle frequency AC stimulations through to higher frequency EM waves in MHz and GHz bands, including Laser therapy. Current practice suggests that very low levels of these stimulations are capable of exerting strong physiological effects (e.g. Bentall et al 1985, Karu 1987). If the body is capable of both responding to low level external stimuli and generating its own electrical potentials, the measurement of some aspect of the internal electrical activity could provide an insight into the physiological processes which are predominant at a particular moment in time.

The literature review (Chapter 2) considers the generation and behaviour of the endogenous electrical signals. Measurement of skin potentials as an indicator of the physiological processes associated with tissue damage at depth has only been reported in a few instances (e.g. Marino 1989, Woodrough et al 1974) and none of these relate specifically to soft tissue injury.

The choice of electrical potentials rather than other forms of measurement (e.g. resistance, impedance, admittance) was made on the basis that if low energy inputs are capable of modifying physiological processes, it would be inappropriate to utilise any form of energy input into the body in order to make such a measurement - a situation where the measurement device may interfere with the system being evaluated. Measurement of resistance, capacitance, impedance, conductance and admittance all require energy introduction into the tissues although often on a small scale. Suggestions have been made in the literature that there are changes in some of these parameters associated with healing (e.g. Adam et al 1983). Measurement of potentials can be made from the skin ostensibly with no energy input and therefore are the technique of choice in this context and was therefore selected as the measurement parameter of choice.

1.8 Organisation of the thesis

Following the literature review (Chapter 2) and the rationale for the new measurement system (Chapter 3), the design of the system and associated software are considered in Chapter 4. The initial system tests and evaluation are described in Chapter 5 and the subsequent pilot studies on non injured subjects and a small injured subject population are reviewed in Chapter 6.

Following these initial tests, there was a need for a more detailed consideration of the environmental, physiological and psychological factors which may influence the skin potential measurement as several unexpected results had been recorded. This resulted in the construction and evaluation of a basic environmental test chamber and hence to the development of the full test protocol. These elements are described in Chapter 7.

The A, B and C test series are presented in Chapters 8, 9 and 10. The discussion is largely considered throughout the thesis due to the multi faceted nature of the work. Chapter 11 draws on the conclusions from each element and relates the results to the original hypotheses. The possible future work and implications for clinical practice are also considered in this chapter.

The detailed results from each of the test series are included in the Appendices together with software listings and detailed test procedures.