

**THE RELATIVE AND COMBINED EFFICACY OF THE HOMOEOPATHIC
SIMILIMUM (TAKEN ORALLY) AND THE TOPICAL APPLICATION OF A
LOTION (PREPARED FROM THE HOMOEOPATHIC MOTHER TINCTURES OF
HYPERICUM PERFORATUM AND CALENDULA OFFICINALIS) IN THE
TREATMENT OF VENOUS LEG ULCERS.**

By

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Mini dissertation submitted in compliance with the requirements of the Master's Degree in Technology: Homoeopathy, in the Faculty of Health Sciences at the Durban University of Technology.

I, Delia Hoffmann, declare that this mini-dissertation is representative of my own work, both in conception and execution.

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ABSTRACT

The purpose of this double-blind placebo-controlled study was to evaluate the relative and combined efficacy of the homoeopathic similimum, taken orally, and the topical application of a lotion made from the homoeopathic mother tinctures of *Hypericum perforatum* and *Calendula officinalis* in the treatment of venous leg ulcers.

Venous hypertension in the lower limb, occurring from a variety of causes, leads to microcirculatory abnormalities which may permit the formation of a chronic ulcer (Zimmet, 1998). Venous leg ulcers are a cause of much debility, social isolation, depression, fears of loss of employment and income (Royal College of Nursing Institute, 1998).

The mainstay of treatment at present is compression bandaging to reduce the venous pressure in the lower limb. Eighty percent of venous leg ulcers will heal within eight to twelve weeks with compression bandaging (Thomas, 1997).

Homoeopathy is a system of medicine based on natural laws of healing, and recognizes the biophysical energy of an individual (also known as the vital force) as that which provides the normal protective defence mechanisms of the body, and is disturbed in disease, producing symptoms on the physical, mental and emotional levels (Vithoukias, 1980).

Many plants are known to have wound-healing properties (Curtis and Fraser, 2003).

Calendula officinalis and *Hypericum perforatum* were considered the best plants in a homoeopathic lotion to be used on chronic venous leg ulcers, as they cover all the common problems associated with this type of wound, providing pain relief and anti-microbial activity (Lawless, 1995). In this study, homoeopathic mother tinctures of the herbs were used to make the lotion for topical application to the wounds.

Thirty-six patients were recruited from the leg-ulcer clinic at Addington Hospital on the basis of inclusion and exclusion criteria, and randomly assigned to three groups. Patients assigned to the first group received both their homoeopathic similimum (drops to be taken daily as prescribed), and the lotion (applied to the wound by the researcher at each visit).

Patients assigned to the second and third groups received similimum and placebo lotion, or lotion and placebo similimum. Each patient was interviewed on recruitment to determine the homoeopathic similimum. All groups received compression bandaging following assessment of their lower limb circulation by means of a Doppler Ankle-Brachial Pressure Index (ABPI). The Profore (Smith & Nephew) three- or four-layer compression bandaging system was used, or alternatively, Tensopress (BSN Medical) bandages. Suitable non-medicated dressings were applied to the ulcer after the application of the active lotion or placebo lotion. The bandages and dressings were changed weekly in most cases, but where necessary, more frequently.

The rate of healing was assessed by means of wound mapping with a Visitrak grid (Smith & Nephew ©), and electronic recording of the wound area in cm², and maximum length and breadth. The percentage reduction in wound area over time was noted, and used for statistical purposes.

On completion of eight weeks of treatment, or on healing of the ulcer if prior to this, patients who were on placebo similimum were offered homoeopathic treatment free of charge.

The outcome of this study showed that there was no significant difference between the lotion and similimum together compared to the either used alone.

TABLE OF CONTENTS

	Page
<u>DECLARATION</u>	i
<u>ACKNOWLEDGEMENTS</u>	ii
<u>ABSTRACT</u>	iv
<u>TABLE OF CONTENTS</u>	vi
<u>LIST OF FIGURES</u>	xi
<u>LIST OF TABLES</u>	xiii
<u>DEFINITION OF TERMS</u>	xvi
<u>CHAPTER 1</u>	
1.1 <u>INTRODUCTION</u>	1
1.2 <u>PROBLEM STATEMENT</u>	1
1.3 <u>ASSUMPTIONS</u>	2
1.4 <u>HYPOTHESES</u>	3
<u>CHAPTER 2</u> <u>REVIEW OF RELATED LITERATURE</u>	4
2.1 <u>INTRODUCTION</u>	4
2.2 <u>INCIDENCE</u>	4
2.3 <u>ANATOMY OF THE VENOUS SYSTEM</u>	5
2.3.1 <u>Deep and superficial veins and their valves</u>	6
2.3.2 <u>The superficial veins</u>	6
2.3.3 <u>The deep veins</u>	6

2.4	<u>NORMAL PHYSIOLOGY OF THE VENOUS SYSTEM</u>	8
	2.4.1 <u>The calf muscle pump</u>	8
2.5	<u>PATHOPHYSIOLOGY OF THE VENOUS SYSTEM</u>	8
2.6	<u>DEEP VEIN PATHOLOGY</u>	9
2.7	<u>SUPERFICIAL VEIN PATHOLOGY</u>	10
	2.7.1 <u>Perforator vein pathology</u>	10
	2.7.2 <u>Effects of chronic venous hypertension</u>	11
	2.7.3 <u>Skin changes due to chronic venous hypertension</u>	12
2.8	<u>CLASSIFICATION OF LEG ULCERS</u>	13
2.9	<u>WOUND HEALING</u>	16
	2.9.1 <u>Anatomy of the skin</u>	17
	2.9.1.1 <u>The Epidermis</u>	18
	2.9.1.2 <u>The Dermis</u>	19
	2.9.1.3 <u>The subcutaneous layer</u>	20
	2.9.2 <u>The phases of wound repair</u>	20
	2.9.2.1 <u>The inflammatory phase</u>	20
	2.9.2.2 <u>The proliferation phase</u>	22
	2.9.2.3 <u>The maturation phase</u>	22
	2.9.3 <u>Factors impeding the healing of chronic wounds</u>	24
	2.9.3.1 <u>Local problems</u>	24
	2.9.3.2 <u>Systemic problems</u>	25
2.10	<u>TREATMENT BY MEANS OF BANDAGING</u>	26
	2.10.1 <u>Bandage pressure</u>	27
	2.10.2 <u>Types of compression bandages</u>	28
	2.10.2.1 <u>Profore multi-layer bandage system</u>	28
	2.10.2.2 <u>Tensopress high compression bandaging</u>	28

2.10.3	<u>Dressings</u>	29
2.11	<u>MEASUREMENT OF THE ULCER AND MEASUREMENT TOOLS</u>	30
2.12	<u>USE OF MEDICATIONS AND OTHER NON-HOMOEOPATHIC MODALITIES IN THE TREATMENT OF VENOUS LEG ULCERS</u>	32
2.12.1	<u>Mineral deficiencies</u>	33
2.12.2	<u>Local applications</u>	36
2.12.3	<u>Other medical treatments available</u>	37
2.12.3.1	<u>Hyperbaric oxygen therapy</u>	37
2.12.3.2	<u>Jet therapy</u>	38
2.12.3.3	<u>Skin grafting</u>	38
2.12.3.4	<u>Bio-engineered tissue</u>	38
2.12.3.5	<u>Wound modulating products</u>	39
2.13	<u>HOMOEOPATHIC TREATMENT</u>	40
2.13.1	<u>Principles of homoeopathy</u>	40
2.13.2	<u>The Vital Force</u>	44
2.13.3	<u>Homoeopathic potencies</u>	45
2.13.3.1	<u>The Plussed potency</u>	46
2.13.4	<u>Tinctures</u>	47
2.13.5	<u>Drug pictures</u>	47
2.13.5.1	<u>Calendula officinalis</u>	48
2.13.5.1.1	<u>Classification</u>	48
2.13.5.1.2	<u>Description</u>	48
2.13.5.2	<u>Hypericum perforatum</u>	49
2.13.5.2.1	<u>Classification</u>	49
2.13.5.2.2	<u>Description</u>	49
2.13.6	<u>Combined herbs</u>	50

2.13.7	<u>Studies using topical homoeopathic applications for wound healing</u>	50
2.13.8	<u>Conclusion</u>	51
<u>CHAPTER 3</u>	<u>METHODOLOGY</u>	53
3.1	<u>GROUP DESIGN</u>	53
3.2	<u>RECRUITMENT PROCEDURE</u>	53
3.3	<u>DISPENSING OF MEDICATION</u>	54
3.4	<u>HOMOEOPATHIC REMEDIES</u>	55
3.4.1	<u>Preparation of the similimum remedy</u>	56
3.4.2	<u>Preparation of the placebo remedy</u>	56
3.5	<u>LOTIONS</u>	57
3.5.1	<u>Active lotion</u>	57
3.5.2	<u>Placebo lotion</u>	57
3.6	<u>WEEKLY DRESSING PROCEDURE</u>	57
3.7	<u>MEASUREMENT TOOLS</u>	59
3.7.1	<u>Visitrak</u>	59
3.7.2	<u>Ankle-brachial pressure index</u>	60
3.8	<u>DATA COLLECTION</u>	60
3.8.1	<u>Friedman intra-group test</u>	61
3.8.2	<u>Wilcoxon Signed-Rank test</u>	61
3.8.3	<u>Kruskal-Wallis test</u>	61
<u>CHAPTER 4</u>	<u>RESULTS</u>	62
4.1	<u>CRITERIA FOR ADMISSIBILITY OF DATA</u>	62
4.2	<u>DEMOGRAPHIC DATA</u>	62

4.2.1	<u>Gender</u>	62
4.2.2	<u>Age</u>	63
4.2.3	<u>Allocation of patients to each group</u>	64
4.3	<u>PROCEDURE 1 (INTRA-GROUP): FRIEDMAN TEST</u>	65
4.4	<u>PROCEDURE 2: WILCOXON SIGNED RANK TEST</u>	66
4.5	<u>PROCEDURE 3: KRUSKAL-WALLIS TEST</u>	68
4.6	<u>DESCRIPTIVE STATISTICS</u>	69
4.7	<u>HOMOEOPATHIC REMEDIES PRESCRIBED</u>	76
4.7.1	<u>Total remedies prescribed in the study</u>	76
4.7.1.1	<u>The most frequently prescribed remedies</u>	77
4.7.2	<u>Treatment groups – remedies received</u>	77
4.7.3	<u>Placebo group – remedies prescribed</u>	78
CHAPTER 5	<u>DISCUSSION</u>	79
CHAPTER 6	<u>CONCLUSION AND RECOMMENDATIONS</u>	85
6.1	<u>CONCLUSION</u>	85
6.2	<u>RECOMMENDATION</u>	86
	LIST OF REFERENCES	87
	APPENDICES	99

LIST OF FIGURES

	Page
Figure 2.1	5
Diagram of the arterial and venous circulation of the legs.	
Figure 2.2	8
Flow diagram of the venous circulation in the right lower extremity.	
Figure 2.3	13
Venous leg ulcer.	
Figure 2.4	14
Arterial leg ulcer.	
Figure 2.5	15
Diabetic ulcer.	
Figure 2.6	16
Malignant ulcer.	
Figure 2.7	17
Diagram of the layers of the skin.	
Figure 2.8	23
Diagram showing the phases of wound healing	

Figure 2.9	
Diagram to illustrate the law of the infinitesimal dose:	42
Kotschau's Biphasic response Curve.	
Figure 2.10	48
<i>Calendula officinalis</i>	
Figure 2.11	49
<i>Hypericum perforatum.</i>	
Figure 4.1	62
Pie chart: percentage of male and female participants	
Figure 4.2	63
Number of patients in each age group	
Figure 4.3	64
Pie chart: number of patients allocated to each group	
Figure 4.4	74
Comparison of mean wound area reduction in cm² between combined, similitum and lotion groups	
Figure 4.5	75
Pie chart: patients whose wounds healed completely within 8 weeks	
Figure 4.6	75
Patients in each group whose ulcers healed in eight weeks	

LIST OF TABLES

	Page
Table 4.1	63
Ages of patients in the study	
Table 4.2	65
Results of the Friedman Test: summary in p-values for length, width, and area within each group	
Table 4.3	66
Wilcoxon test: group 1 wound width reduction between baseline and second measurements, and third to second measurements and third to baseline measurements	
Table 4.4	66
Wilcoxon test: Group 3 wound length reduction between baseline and second, second to third, and third to baseline measurements	
Table 4.5	67
Wilcoxon test: Group 3 wound width reduction between baseline and second, second to third, and third to baseline measurements	
Table 4.6	67
Wilcoxon test: Group 3 wound area reduction between baseline and second, second to third, and third to baseline measurements	

Table 4.7	68
Kruskal-Wallis test: comparison of length between all three groups	
Table 4.8	68
Kruskal-Wallis test: comparison of width between all three groups	
Table 4.9	69
Kruskal-Wallis test: comparison of area between all three groups	
Table 4.10	69
Group 1: descriptive statistics – length of ulcer in cm	
Table 4.11	70
Group 1: descriptive statistics – width of ulcer in cm	
Table 4.12	70
Group 1: descriptive statistics – area of ulcer in cm²	
Table 4.13	71
Group 2: descriptive statistics – length of ulcer in cm	
Table 4.14	71
Group 2: descriptive statistics – width of ulcer in cm	

Table 4.15	72
Group 2: descriptive statistics – area of ulcer in cm²	
Table 4.16	72
Group 3: descriptive statistics – length of ulcer in cm	
Table 4.17	73
Group 3: descriptive statistics – width of ulcer in cm	
Table 4.18	73
Group 3: descriptive statistics – area of ulcer in cm²	
Table 4.19	76
Total remedies prescribed during the study	
Table 4.20	77
Remedies prescribed and received in the treatment groups	
Table 4.21	78
Remedies prescribed in the placebo group, but not received	

DEFINITION OF TERMS

Alkaloids

Nitrogen-containing natural products, mostly found in actively growing young tissues (van Wyk and Wink, 2004).

Allantoin

Helps to destroy necrotic tissue and enhances tissue proliferation and formation of new skin (van Wyk and Wink, 2004).

Allografts

Skin for grafting onto a wound, taken from cadavers (Jones and Nelson, 2006).

Allopathic

A term coined by Hahnemann to describe conventional medicine, from the Greek *allo* meaning other, and *pathos*, meaning suffering or disease, in other words 'other therapy'.

Angiogenesis

Formation of new capillary networks (Mazzotta, 1994).

Ankle-brachial pressure index

A ratio between the ankle and brachial systolic blood pressure, used to determine the safety of pressure bandaging (Leng, Fowkes, Lee, Dunbar, Housely, Ruckley, 1996).

Ankle flare

Redness of the skin in the ankle area caused by chronic venous hypertension (Cullum, 1994).

Antigen-antibody response

Activation of the defence mechanisms of the body when antibodies combine with one or more antigens on the surface of foreign pathogens (Solomon and Davis, 1983).

Anti-oxidant

Substances which neutralize free radicals (abnormal oxygen molecules), rendering them harmless (van der Merwe, 2002).

Arndt-Schultz Law

This states that small doses of drugs encourage life, large doses impede life activity, and very large doses destroy life (Wilcher, 1996).

Atopic dermatitis

Chronic, itchy, superficial inflammation of the skin, frequently associated with a family history of allergy (Beers and Berkow, 1999).

Atrophy

Acquired decrease in size in a part of the body due to a reduction in the number or size of the cells (Rippey, 1994).

Argyria

Toxic state caused by excessive ingestion of silver (Barrett, 1996).

Auto-immune vasculitis

Inflammation of the small blood vessels ultimately leading to tissue damage and the possibility of ulceration (Mitchell and Kumar, 2003).

Avogadro

Italian physicist who postulated that equal volumes of substances contain equal numbers of molecules (Cook, 2000).

Basal cell carcinoma

A superficial eroding ulcer that derives from epidermal basal cells (Beers and Berkow, 1999).

Bio-engineered tissue

Tissue closely resembling human skin, manufactured in the laboratory (Badylak, 2004).

Biofilm

A film over a wound produced by micro-organisms on its surface (Percival and Bowler, 2004).

Biophysical energy

Biophysics applies the theories and methods of physics to questions of biology. These sciences are useful in understanding the therapeutic efficacy of homoeopathy, as opposed to bio-chemical energy (Schulte and Endler, 1998).

Biphasic response curve

Produced by Kotschau, following the principle of the Arndt-Schultz Law, this effectively validates the Law of the Infinitesimal dose (Wilcher, 1996).

Calamine lotion

A lotion including zinc used topically for inflammation, it has a soothing effect on irritated skin (Mazzotta, 1994).

Calf muscle pump

Compression of the veins running through or adjacent to the calf muscles when the muscles contract. The blood is forced upwards in the direction of the heart (Guyton and Hall, 1997).

Capillary hydrostatic pressure

Pressure exerted by the volume of fluid in the capillary (Zimmet, 1998).

Chronic venous insufficiency

A condition arising out of increased pressure of blood in the veins of the lower limbs leading to poor nutrition of the tissues (Thomas, 1998).

Clathrates

Small water clusters which occur and multiply during the preparation of homoeopathic potencies (Anagnostatos, 1994).

Collagen

A fibrous protein found in connective tissues (Solomon and Davis, 1983).

Colloidal silver

A mixture in which the large molecules of silver are suspended (Lansdown, 2002).

Deep vein thrombosis

Venous stasis leading to a clot completely or partially occluding a vein (Schoen and Cotran, 2003).

Diabetes mellitus

A syndrome caused by a complete or relative impairment in insulin secretion or action (Beers and Berkow, 1999).

Eczema

Dermatitis; superficial skin inflammation characterized by oedema, vesicles, redness with oozing, crusting and scaling (Beers and Berkow, 1999).

Fibrinogen

Plasma-protein, precursor to fibrin, an insoluble fibrous protein (Zimmet, 1998).

Fibroblast

A large cell that produces the fibres of connective tissue (Solomon and Davis, 1983).

Friedman test

Test for intra-group analysis of data (Crichton, 1998).

Gaiter

Covering for lower leg and ankle (The Pocket Oxford Dictionary, 1999).

Growth factors

Substances produced by participants in the inflammatory phase of wound healing, which

attract and stimulate cell division of fibroblasts and endothelial cells (Rippey, 1994).

Hallux

The bony prominence over the joint between the distal end of the first metatarsal bone with the proximal end of the proximal phalanx of the foot (Solomon and Davis, 1983).

Hemosiderin

Red-brown pigment released with the breakdown of red blood cells in the tissues (Thomas, 1998).

Herbalism

The art of using herbal remedies to support the body in its natural healing process (Curtis and Fraser, 2003).

Homoeopathy

A system of medicine which stimulates the body's ability to heal itself. Formulated by Samuel Hahnemann (1755 – 1843) (Vithoukas, 1980).

Hyperbaric oxygen therapy

Oxygen supplied under high pressure to the tissues to encourage healing (Wright, 2001).

Hypothyroid state

A characteristic clinical response to thyroid hormone deficiency (Beers and Berkow, 1999).

Hypoxia

Oxygen deficiency (Solomon and Davis, 1983).

Immunodeficiency

Diverse conditions caused by immune system defects, with increased susceptibility to infection (Beers and Berkow, 1999).

Intermittent claudication

Chronic occlusion of an artery in the lower limb, with symptoms of pain, or tiredness on walking (Beers and Berkow, 1999).

Iron-deficiency anaemia

A common type of anaemia, resulting in small, pale red blood cells, due to insufficient iron intake or absorption, or chronic loss of blood (Rippey, 1994).

Jet therapy

Purified air applied to the skin under pressure, with the aim of stimulating the circulation (Mars, Tufts, Naidu, Kleinfeldt and Robbs, 2000).

Kaposi sarcoma

A multifocal vascular neoplasm arising in the skin (Beers and Berkow, 1999).

Keloid formation

Excess production of collagen during the healing process, stretching the overlying skin (Rippey, 1994).

Kruskal-Wallis non-parametric test

Test for the comparison of treatment and placebo groups (Crichton, 1998).

Laplace Law

A principle used in calculating the pressure exerted by a bandage (Thomas, 2002).

Lipodermatosclerosis

Thickening and contraction of the skin and subcutaneous tissues due to chronic ulceration (Mitchell and Cotran, 2002).

Long-range electromagnetic fields

Electrically charged particles moving in a wave form (Wikipedia, 2006).

Lymphocytes

Small white blood cells which recognize foreign antigenic material in the body (Rippey, 1994).

Macrominerals

Minerals required in gram quantities by humans, daily (Beers and Berkow, 1999).

Macrophages

Mononuclear phagocytes, present in the tissues, with the responsibility of clearing foreign matter and the debris of inflammation (Rippey, 1994).

Malignant melanoma

A malignant tumour arising commonly in a pigmented mole (Beers and Berkow, 1999).

Mann-Whitney test

Test for inter-group analysis of data (Crichton, 1998).

Melanocytes

Cells of the skin whose function is to produce melanin, a brown pigment which helps to protect from the damaging effects of sunlight (Rippey, 1994).

Monocytes

Mononuclear phagocytes circulating in the blood (Rippey, 1994).

Mother tincture

The liquid produced during the first stage of preparation of homoeopathic remedies. A process of maceration, extraction, ageing and filtration of the substance provides the Mother tincture from which all other remedies are prepared (Cook, 2000).

Herbal treatment

Treatment which aims to enhance key body systems in a holistic manner, so establishing balanced health and wellness (van der Merwe, 2002).

Neuropathy

Sensory loss, muscle weakness and atrophy with vascular symptoms (Beers and Berkow, 1999).

Pericapillary cuff

Cuff surrounding the capillary preventing oxygen from diffusing into the tissues (Zimmet, 1998).

Pitting oedema

Abnormal accumulation of fluid in the body tissues; swelling which indents with pressure (Solomon and Davis, 1983).

Planimetry

Mapping onto a grid (Fette, 2006).

Platelet-derived growth factor

A growth factor produced by platelets in the healing process (Rippey, 1994).

Plussed potency

A remedy which is succussed before each dose to increase its potency slightly (de Schepper, 2001).

Polymorphonuclear neutrophils

Cells with a lobed nucleus and granules in the cytoplasm. They constitute 40-70 percent of the total white blood cells, and are intensely phagocytic, arriving first at the site of acute inflammation (Rippey, 1994).

Prostaglandins

A group of local hormones, released by many tissues which act as mediators of inflammation (Beers and Berkow, 1999).

Proteases

Substances which prevent healing by breaking down protein (Cullen, Smith and Silcock, 2002).

Proving

Homoeopathic method by which the effects of a substance upon a healthy human being can be discovered. The information is used when prescribing a homoeopathic remedy for a sick person (Digby, 1996).

Silver sulphadiazine

A preparation used topically to prevent infection in burns or wounds, containing sulfonamide drugs which are bacteriostatic and antibiotic (Beers and Berkow, 1999).

Similimum

Matching of all the symptoms provided by the patient to the most similar remedy picture (Vithoulkas, 1980).

Sinusoids

A tiny vessel with a tortuous path and many connections to similar vessels (Freeman, 2000).

Slough

Wound debris which may adhere to the wound bed, interfering with normal wound healing (Naudé, 2005).

Squamous cell carcinoma

Cancer of the skin, commonly occurring on sun-exposed areas (Beers and Berkow, 1999).

Staphylococcus aureus

Micro-organism responsible for producing a superficial cellulitis, in association with an open wound (Beers and Berkow, 1999).

Succussion

Vigorous shaking with impact. Part of the process of making homoeopathic medicines, succussion brings out the medicinal powers of the remedy (Cook, 2002).

Sympathetic nervous system

Part of the autonomic nervous system. Its main effect is to mobilize energy during stress situations (Solomon and Davis 1983).

Thyroid hormone

Hormone released by the thyroid gland, which helps to regulate the rate of metabolism (Solomon and Davis, 1983).

Trace minerals

Minerals required in tiny amounts, and incorporated into enzymes or hormones required in metabolism (Beers and Berkow, 1999).

Transforming growth factor

Factors within cells or on their surface which are responsible for the cessation of growth during wound healing (Rippey, 1994).

Trophic changes

Changes in the nutritive state of the tissues due to prolonged ischaemia (Munro and Campbell, 2000).

Ultra-high dilutions

Dilutions beyond the Avogadro limit (Schulte and Endler, 1998).

Venous leg ulcers

Ulcers occurring due to chronic venous insufficiency, usually in the ankle area of the leg (Thomas, 1998).

Venous hypertension

A rise in blood pressure in the venous system caused primarily by problems in the deep venous circulation or in the superficial and perforator veins (Zimmet, 1998).

Vital force

The biophysical energy of an individual which animates the integrated entity (Vithoukas, 1980).

Wilcoxon signed rank test

Intra-group test for the comparison of a pair of samples (Crichton, 1998).

Xenografts

Skin for grafting onto a wound, taken from an animal (Jones and Nelson, 2006).

CHAPTER 1

1.1 INTRODUCTION

Venous leg ulcers are a relatively common medical problem, particularly in the aged, or those with chronic venous insufficiency. Current optimal treatment involves assessment of the wound and circulation in the affected limb, and a routine of weekly dressing changes and graduated compression bandaging. Successful management of venous leg ulcers represents a significant clinical problem and a major drain on limited financial resources. Seven out of ten venous leg ulcers take twelve weeks to heal with the use of compression bandaging. The rate of healing is less without compression bandaging (Thomas, 1998).

According to Hahnemann, (1755-1843), homoeopathy works on the basis of the Law of Similars. This is a scientific principle, based on the precept that like cures like. A substance that can bring about similar symptoms to the disease, when given to a healthy person, is curative in a patient suffering from those symptoms. Remedies are diluted infinitesimally, and potentised by succussion at each dilution stage. This renders them capable of acting at cellular-energy level, and thereby stimulating healing processes (Kunzli, Naudé and Pendleton, 1982).

The human being is an integrated entity, and its defence mechanism functions holistically. This holistic phenomenon is a form of biophysical energy, sometimes called the 'vital force' (Vithoukias, 1980). This vital force animates the individual, and is disturbed by disease. Symptoms then produced occur on physical, mental or emotional levels. The homoeopathic similimum restores the equilibrium of the vital force, and effects cure (Cook, 2000).

The aim of the homoeopathic consultation is to determine the patient's similimum. This is arrived at by taking into consideration all the symptoms that distinguish a person as an individual, i.e. his family history, past medical history, appetite, thirst, bowel habits, sleep, and temperament, among others (Sankaran, 1991).

Many plants are known to have wound-healing properties and, like homoeopathy, support the body in the natural healing process (Curtis and Fraser, 2003). The use of the homoeopathic mother tinctures of *Hypericum perforatum* and *Calendula officinalis* as a lotion, is in keeping with this traditional knowledge.

1.2 PROBLEM STATEMENT

The purpose of this double-blind placebo-controlled study was to evaluate the relative and combined efficacy of the homoeopathic similimum (taken orally) and the topical application of a lotion (made from the homoeopathic mother tinctures of *Hypericum perforatum* and *Calendula officinalis*) in the treatment of venous leg ulcers.

1.3 ASSUMPTIONS

Participants took the remedy as prescribed.

Participants did not remove or interfere with their dressings or bandages for the duration of the week between dressing changes.

1.4 HYPOTHESES

For the hypotheses below, the null hypothesis states that there is no difference between the variables. The alternative hypothesis states that there will be a significant difference between the three variables.

It is hypothesised that the homoeopathic similimum will have no significant impact on the rate of healing of venous leg ulcers, compared to placebo.

It is hypothesised that the topical lotion will have no significant impact on the rate of healing of venous leg ulcers, compared to placebo.

It is hypothesised that the similimum in combination with the topical lotion will have no significant impact on the rate of healing, compared to placebo, and compared to the use of either the similimum or lotion alone.

CHAPTER 2: REVIEW OF RELATED LITERATURE

2.1 INTRODUCTION

The purpose of this double-blind placebo-controlled study was to evaluate the relative and combined effectiveness of the homoeopathic similimum and topical application of a lotion prepared from the homoeopathic mother tinctures of *Hypericum perforatum* and *Calendula officinalis* in the treatment of venous leg ulcers.

2.2 INCIDENCE

The incidence of venous leg ulcers in South Africa is about 3 – 5%. In Europe and North America it is about 1 – 2%. The estimated costs to the National Health Service in the United Kingdom for treatment of leg ulcers is £300 to £600 million per year, 70% of these are venous leg ulcers (Thomas,1998). There are no statistics available on the treatment costs to the South African government annually.

According to the Royal College of Nursing (RCN) Institute (1998), in their recommendations for assessment of venous leg ulcers, patients often present for help only when the ulcer has become chronic. The RCN Institute also cites difficulties due to inadequate training of medical and nursing personnel with correct diagnosis and evaluation of leg ulcers, so appropriate treatment may be delayed, and more costly as a result.

In the same report, Phillips, Stanton, Provan and Lew (1994) found that the main emotional problems experienced by patients with leg ulcers relate to fear, social

isolation, anger, depression and negative self-image (68%). The fear was not specified, but the researcher has found fear of loss of the limb, and fear of loss of occupation/income reported by patients. Severe pain was present in 65% of surveyed patients, and 76% reported that their financial situation was negatively affected, whilst 81% found their reduced mobility to be a negative factor.

2.3 ANATOMY OF THE VENOUS SYSTEM

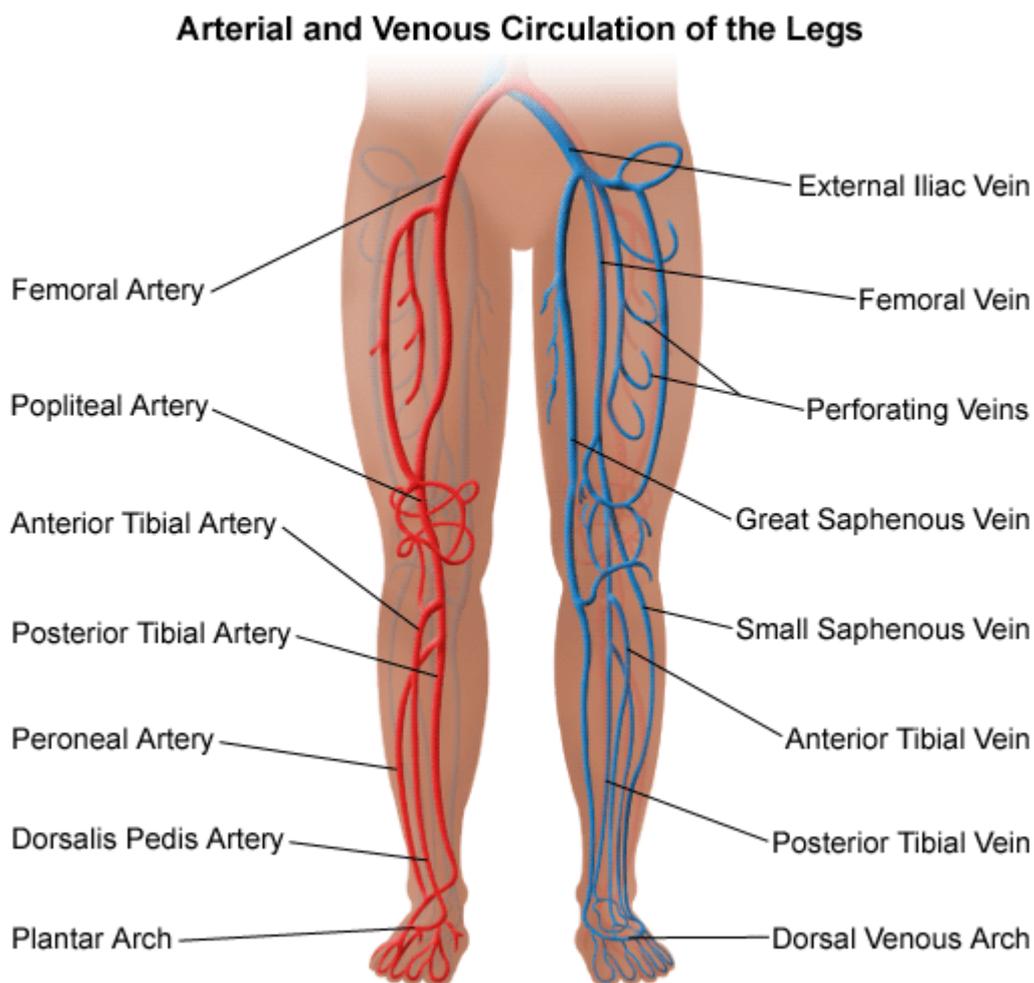


Figure 2.1 Diagram of the arterial and venous circulation of the legs (University of Kentucky HealthCare © 2003)

2.3.1 Deep and superficial veins and their valves

The venous drainage from the lower leg is normally accomplished by a system of deep and superficial veins. The superficial veins are just under the skin in the subcutaneous tissue, whereas the deep veins accompany the arteries and are situated deep within the tissues of the leg. Blood from the superficial venous system flows into the deep veins via perforator (communicating) veins which connect the two systems. These veins all have valves. The valves of the perforator veins normally permit flow only from the superficial system to the deep system (Beers and Berkow, 1999).

2.3.2 The superficial veins

The superficial veins include the long and short saphenous veins.

- **The long saphenous vein**

This begins in the foot, where it receives blood from the toes and foot, and ascends along the medial side of the leg and thigh, to join the femoral vein in the groin.

- **The short saphenous vein**

This also begins in the foot, ascending along the back of the leg to just above the knee joint, where it empties into the popliteal vein (Solomon and Davis, 1983).

2.3.3 The deep veins

The deep veins include the anterior and posterior tibial veins, the popliteal vein and the femoral vein.

- The posterior tibial vein

This begins behind the medial malleolus, and ascends deep within the muscles at the back of the leg. It receives blood from the calf muscles, the perforator veins, and the peroneal veins, which drain the foot. It also receives blood from the valveless sinusoids deep within the calf muscles (Thomas, 1998). It unites with the anterior tibial vein just behind the knee to form the popliteal vein.

- The anterior tibial vein

This drains blood from the foot, and ascends to join the posterior tibial vein to form the popliteal vein.

- The popliteal vein

Formed from the union of the anterior and posterior tibial veins, it receives blood from the superficial short saphenous vein. It then continues above the knee as the femoral vein.

- The femoral vein

This begins as the continuation of the popliteal vein above the knee, and at the groin receives blood from the superficial long saphenous vein.

At the level of the inguinal ligament it becomes the external iliac vein.

Thereafter, it is joined by the internal iliac vein to become the common iliac vein, It unites with the common iliac vein of the opposite leg, and ascending to the heart as the inferior vena cava (Solomon and Davis, 1983).

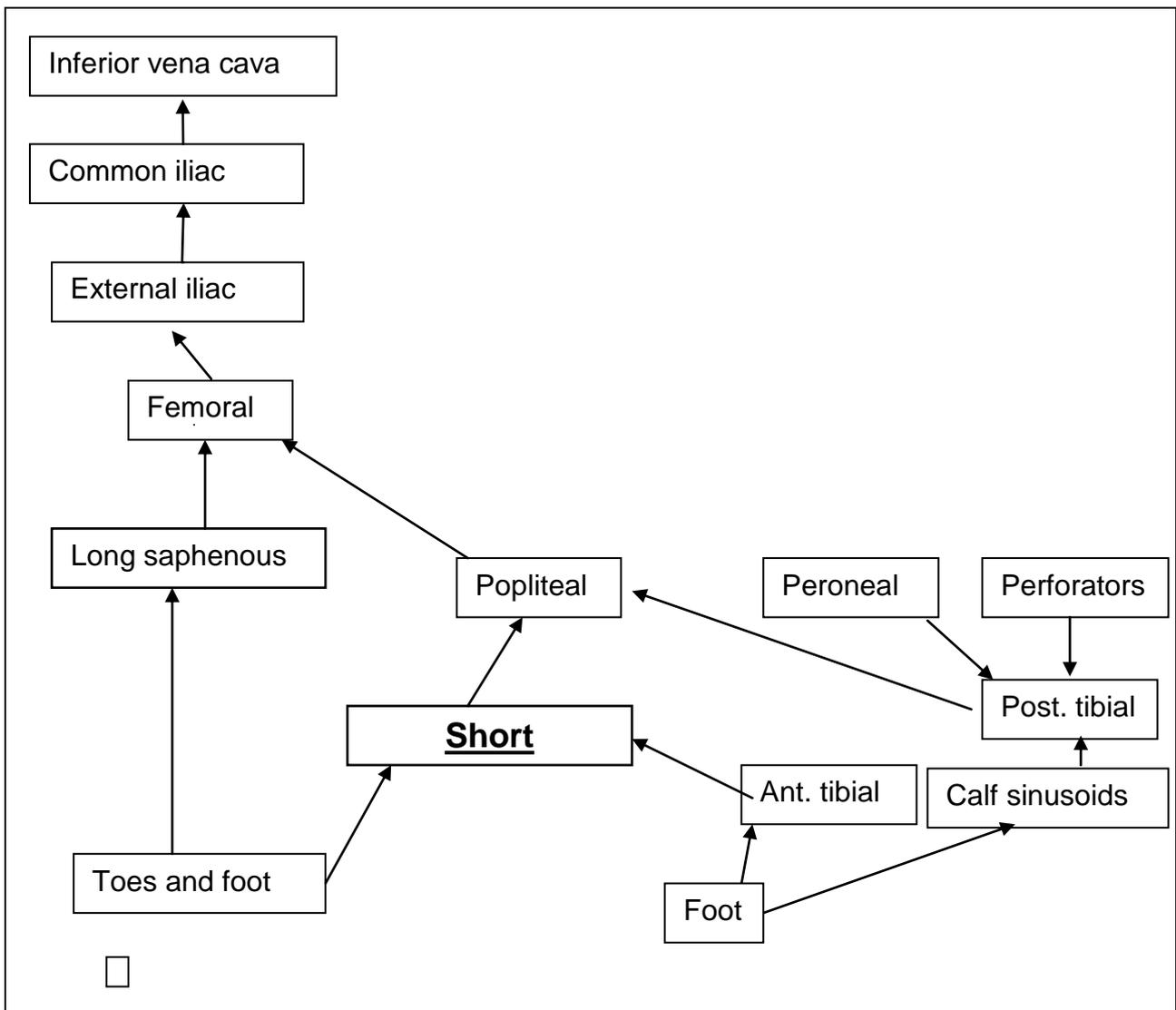


Figure 2.2. Flow diagram of the venous circulation in the right lower extremity (adapted from Solomon and Davis, 1983)

2.4 NORMAL PHYSIOLOGY OF THE VENOUS SYSTEM

2.4.1 The calf muscle pump

According to Guyton and Hall (1997), the venous pressure in the feet would always be about 90mm/Hg, if it were not for the valves in the veins. However, every time the muscles are tightened they compress the veins running through or adjacent to them,

squeezing the blood upwards towards the heart. This lowers the pressure in the veins. This is known as the “muscle pump” and is normally able to keep the venous pressure in the feet of a walking adult near to, or less than, 25 mm/Hg.

The muscle pump does not work when standing still for long periods, or in patients with limited ankle movement (Zimmet, 1998). The venous pressure rises very quickly, causing the pressure in the capillaries to increase sufficiently for fluid to leak from the circulation into the tissues, resulting in oedema. The blood volume may be diminished by ten to twenty percent within the first 15 minutes of standing absolutely still (Guyton and Hall, 1997).

2.5 PATHOPHYSIOLOGY OF THE VENOUS SYSTEM

Venous hypertension may be caused primarily by problems in the deep venous circulation, or in the superficial and perforator veins.

2.6 DEEP VEIN PATHOLOGY

In deep vein thrombosis, venous stasis leads to a clot completely obstructing the vein. This occurs commonly as a result of prolonged bed-rest or immobilisation, as well as other factors which reduce the blood flow, such as cardiac failure, post-operative states, obesity, pregnancy, or malignancy (Schoen and Cotran, 2003).

The clot may eventually become a fibrinous mass permanently interfering with normal blood flow. The blood returning towards the heart distal to the thrombus is shunted into the superficial venous system through the connecting perforator veins, thus overloading

the superficial system and adding to the venous hypertension (Schoen and Cotran, 2003).

2.7 SUPERFICIAL VEIN PATHOLOGY

Varicose veins are abnormally dilated, tortuous veins produced by prolonged, increased intraluminal pressure and loss of vessel wall support. The valves become damaged, and cease to function in preventing backwards flow of blood within the vein.

Varicose veins are much more common in the over fifties, obese persons, and women, often initially caused by increased venous pressure during pregnancy. There may also be familial tendency to varicosities, with defective venous wall development (Schoen and Cotran, 2003).

2.7.1 Perforator vein pathology

A chronic elevation in pressure in the perforator veins occurs either after deep vein thrombosis, due to a reversal in the normal direction of flow, or from varicosities of the superficial veins, which may cause their valves to become incompetent. If this occurs, there will be a large rise in the pressure in the superficial system (Thomas, 1998).

Hereditary weakness of the valves and veins of the venous system can be a contributing factor (Schoen and Cotran 2003).

2.7.2 Effects of chronic venous hypertension

Zimmet (1998) describes possible effects of the microcirculatory abnormalities which result from chronic venous hypertension:

- With the rise in capillary hydrostatic pressure, fibrinogen is forced out through the capillary walls and fibrin is deposited as a pericapillary cuff. This acts as an oxygen diffusion barrier, preventing oxygenation of the tissues, and consequently preventing healing. (Fibrinogen is a plasma protein and precursor to the insoluble, fibrous protein – fibrin).
- The fibrinogen and other large molecules which leak out of the capillaries trap growth factor and other proteins, rendering them unavailable for the maintenance of tissue integrity and repair.
- With reduction of blood flow, trains of white blood cells temporarily plug the capillaries. These white cells are then activated to create a chronic inflammatory state, leading to tissue damage and ulceration.
- There may be a reduction in nutritive skin capillaries due to the underlying poor circulation, further compounding the problem.
- According to Thomas (1998) red cells may also be squeezed out of the capillaries and into the surrounding tissue, where they break down, releasing a red pigment, hemosiderin, which causes staining of the skin - an early indicator of possible ulcer formation.

- The patient may complain of a feeling of fullness, or tiredness in the leg, which may ache mildly. This is improved with elevation of the limb (Beers and Berkow, 1999).

2.7.3 Skin changes due to chronic venous hypertension

- A bluish appearance occurs (cyanosis), when the leg is dependent (Schofield and Rees, 2002).
- There may be small pin-point areas of bleeding into the skin (petechiae) (Beers and Berkow, 1999).
- Pigmentation caused by deposits of reddish-brown hemosiderin in the tissues.
- The skin becomes thickened (induration), and scarring may occur, (lipodermatosclerosis), especially in the presence of chronic ulceration. This leads to narrowing of the leg, and a typical “inverted champagne-bottle” configuration of the lower leg (Mitchell and Cotran, 2002).
- Loss of hair (Schofield and Rees, 2002).
- There may be marked pitting oedema (Schofield and Rees, 2002).

2.8 CLASSIFICATION OF LEG ULCERS

Several different types of leg ulcers will be described in order to differentiate them from venous leg ulcers.

Cullum (1994) identifies the following categories of ulcers:

- **Venous Ulcers** are usually shallow, they occur around the medial malleolus, or in the gaiter area of the ankle, and are the result of chronic venous hypertension. There is often oedema, eczema, ankle flare, evidence of lipodermatosclerosis, hyperpigmentation and varicose veins, (as described above).



Figure 2.3. Venous leg ulcer (Khachemoune and Kauffman, 2002)

- **Arterial Leg Ulcers** have a punched-out appearance. The base of the wound is pale, indicating poor blood supply. There may be gangrene, and trophic changes, including loss of hair on the lower leg and foot, the skin may become taut and shiny, and the leg may be cold, pale, or blue, with thickened and ridged nails. Arterial leg ulcers occur on the toes, or points of trauma or pressure on the feet. Gangrene may be present. These ulcers may be severely painful unless there is an accompanying neuropathy which masks it. The pain is typically felt on elevation of the limb, at rest, or when walking (intermittent claudication) (Munro, and Campbell, 2000).



Figure 2.4. Arterial leg ulcer (Khachemoune and Kauffman, 2002)

- **Mixed Arterial and Venous** pathology gives a venous ulcer with signs of arterial impairment.
- **Rheumatoid Ulcers** are deep, and punched-out. They usually occur on the dorsum of the foot or on the calf. The aetiology is an auto-immune vasculitis. This is an inflammation of the small blood vessels which initiates increased

vascular permeability, and results in immune complexes being deposited in various tissues, causing an inflammatory reaction with resultant tissue damage (Mitchell and Kumar, 2003).

- **Diabetic Ulcers** usually occur on the foot over bony prominences such as the hallux or under areas which may be exposed to excess pressure. They often have a sloughy or necrotic appearance, with calloused edges. There may be loss of nerve supply, arterial and venous components, leading to decreased sensation, decreased pulses, and trophic changes (Munro and Capmbell). There is a greater risk of infection if the blood sugar is not well controlled (Schoen and Cotran, 2003).



Figure 2.5. Diabetic ulcer (Khachemoune and Kauffman, 2002)

Other types of ulcers occurring are:

- **Malignant ulcers.** Schofield and Rees (2002), list squamous cell carcinoma, basal cell carcinoma, malignant melanoma and Kaposi's sarcoma as possible malignancies underlying the ulcer. These can be suspected in chronic, non-healing ulcers of the lower limb, which bleed easily and may have heaped-up

edges, and a raised ulcer-bed (Royal College of Nursing Institute, 1998). The malignant cells distort blood vessels and interrupt the blood flow creating hypoxic conditions. This results in loss of tissue viability, with the potential for infection. Biopsy is essential in diagnosis and management (Walsh 2002).



Figure 2.6. Malignant ulcer (Sarkar and Ballentyne, 2000)

- **Pressure ulcers.** These are formed when tissues overlying a bony prominence have been subjected to prolonged pressure against an external object (e.g. bed, wheelchair, cast, or splint). On the lower limbs, they are usually found over the heels, malleoli, or hallux (Beers and Berkow, 1999).

2.9 WOUND HEALING

In order to describe the events that occur during healing of an ulcer, it is necessary to give an overview of the anatomy of the skin and the principles of wound healing.

2.9.1 Anatomy of the skin

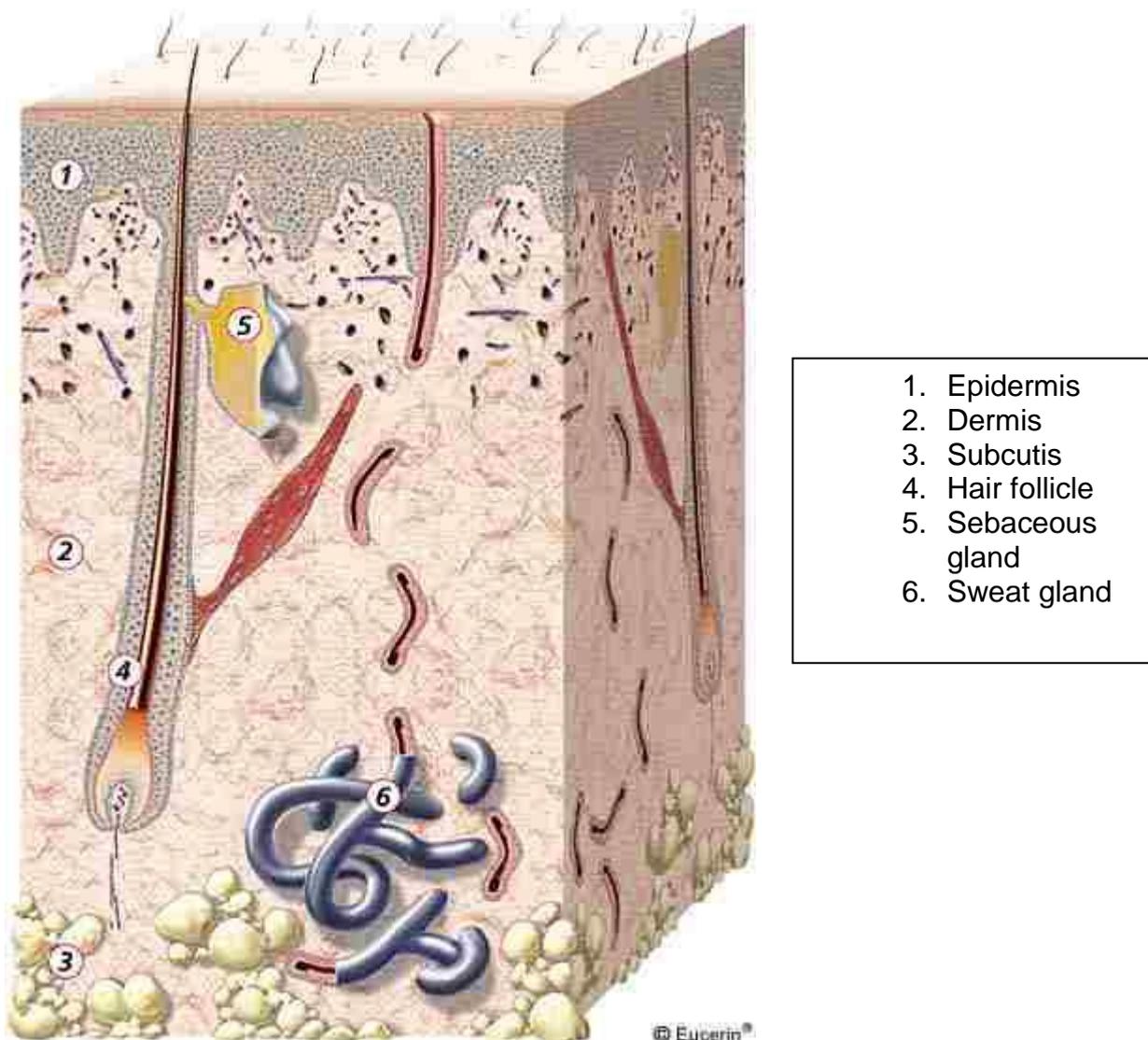


Figure 2.7. Diagram of the layers of the skin (Khachemoune and Kauffman, 2002)

The skin consists of two main layers: an outer epidermis and an inner dermis. Beneath the skin is an underlying subcutaneous layer.

2.9.1.1 The Epidermis

The epidermis is composed of stratified squamous epithelium. Cells continuously proliferate from its deepest region, maturing as they are pushed upward by new cells underneath. Eventually they die and slough off (Naude, 2005).

The epidermis consists of several layers (Beyersdorf, 2005):

- The stratum basale, which is the reproductive layer. Cells constantly divide providing new cells for the upper layers. It also contains melanocytes, cells producing the pigment melanin, which is transferred to other epidermal cells, imparting colour to the skin and hair.
- The stratum spinosum, or prickle cell layer. It consists of about ten rows of cells that fit closely together and are connected to each other. These are also responsible for continuous production of new cells.
- Stratum granulosum. As the prickle cells flatten out they become part of this layer, the cells of which contain many lipid granules. These act as a permeability barrier between the cells.
- The stratum lucidum, which is only present in the thick skin of the palm and soles.
- The stratum corneum. The cells beneath are gradually flattened into this horny layer, which contains much keratin, a tough waterproof protein. The stratum corneum consists of about 20 layers of dead cells in various stages of disintegration.

It takes about two weeks for a basal cell to be pushed up into the stratum corneum, and another two weeks for the dead cells to be sloughed off (Naude, 2005).

2.9.1.2 The Dermis

As described by Naude (2005):

- The dermis is the thick layer of skin beneath the epidermis. It is made up of dense connective tissue, mainly collagen fibres, which give the skin strength and elasticity.
- The upper part of the dermis has small finger-like projections called papillae, which project into the epidermis. The papillae contain networks of capillaries and lymphatic vessels. This layer is important in temperature regulation.
- Blood vessels and nerves are found throughout the dermis, as are hair follicles with their *erector pili* muscles, which raise the hair when they contract.
- Sebaceous glands, under hormonal control, which lubricate the skin, and sweat glands, and help in temperature regulation. (These are involuntarily controlled by the sympathetic nervous system) (Schofield and Rees, 2002).
- The cells of the deeper layers of the epidermis and dermis are bathed in tissue fluid.
- The lower part of the dermis is the reticular layer, which is thicker than the papillary layer. It is characterised by dense fibres, which give rise to Langer's

lines. These give a directional grain to the skin, important in the creation and repair of surgical incisions, reducing tension on wounds, and thereby assisting in healing.

2.9.1.3 The subcutaneous layer

This consists of loose connective tissue, including adipose tissue, and helps to protect the underlying organs from mechanical shock and insulates the body.

With aging, the skin atrophies and thins and the blood supply to the dermis declines. Resident macrophages, which perform an important function in immunity of the epidermis decrease in numbers, and infection is more likely. Also the melanocytes decrease resulting in less protection from ultra-violet light (Schofield and Rees, 2002).

2.9.2 The phases of wound repair

This occurs in three overlapping phases: the inflammatory phase, the proliferation phase and the maturation, or remodelling phase (Fishman, 2005). According to Sholar and Stadelman (2003), acute wounds follow the three phases in an orderly and predictable fashion.

2.9.2.1 The inflammatory phase

During this time bleeding is stopped and white blood cells are attracted to the wound. This functions to prevent deeper penetration by harmful micro-organisms.

The permeability of the capillaries in the surrounding area increases, bringing fluid rich in oxygen and nutrients to the wound, and helping to remove the waste products. This exudate flushes bacteria and debris away from the wound-bed. The same kind of response occurs in infection, but in infection there is a prolonged inflammatory response. Exudate creates the optimum environment for migration and proliferation of the different cells and enzymes (Mitchell and Cotran, 2003).

Various kinds of leucocytes (white blood cells) arrive at different times.

- First are the polymorphonuclear neutrophils, (cells with a distinctive lobed nucleus) which help in engulfing debris, brought along by a chemical attraction process, known as chemotaxis (Rippey, 1994).
- Next are monocytes, developing into macrophages which continue to engulf debris. These are the most important leucocytes in the healing process, producing factors that influence wound healing, such as growth factors (proteins) and prostaglandins. Growth factors induce the migration of new cells to the wound, and promote their proliferation. Prostaglandins are short-range hormones that act locally to cause vasodilation and inhibit clotting (Mitchell and Cotran, 2003).

Lymphocytes arrive after about six days, to assist in antigen-antibody responses in the wound – a further protective mechanism (Rippey, 1994).

2.9.2.2 The proliferation phase

Growth factors produced by the macrophages in the wound attract and stimulate fibroblast and collagen proliferation, which form the framework of new connective tissue, gradually filling the wound from below upwards.

The macrophages support this process by stimulating angiogenesis, (formation of new capillary networks from the surrounding tissue) as the new tissue depends on a good supply of oxygen and nutrients, such as Vitamin C, iron, zinc and copper (Mazzotta, 1994).

This process imparts a healthy, bright red, moist, granular appearance to the wound-bed.

Re-epithelialisation (growth of new epithelial cells) starts from the wound edges, and travels inwards, sometimes with scarring and keloid formation where there has been significant tissue loss. It takes approximately 14 days for the epidermal layer to develop through all the cell layers to the full epidermis (Naude, 2005).

2.9.2.3 The maturation phase

During this time, re-modelling of the wound occurs, leading to improved tensile strength. However, chronic wounds only regain about 70% of their original tensile strength, after a period of about 4 months to a year or more (Sholar and Stadelman, 2003).

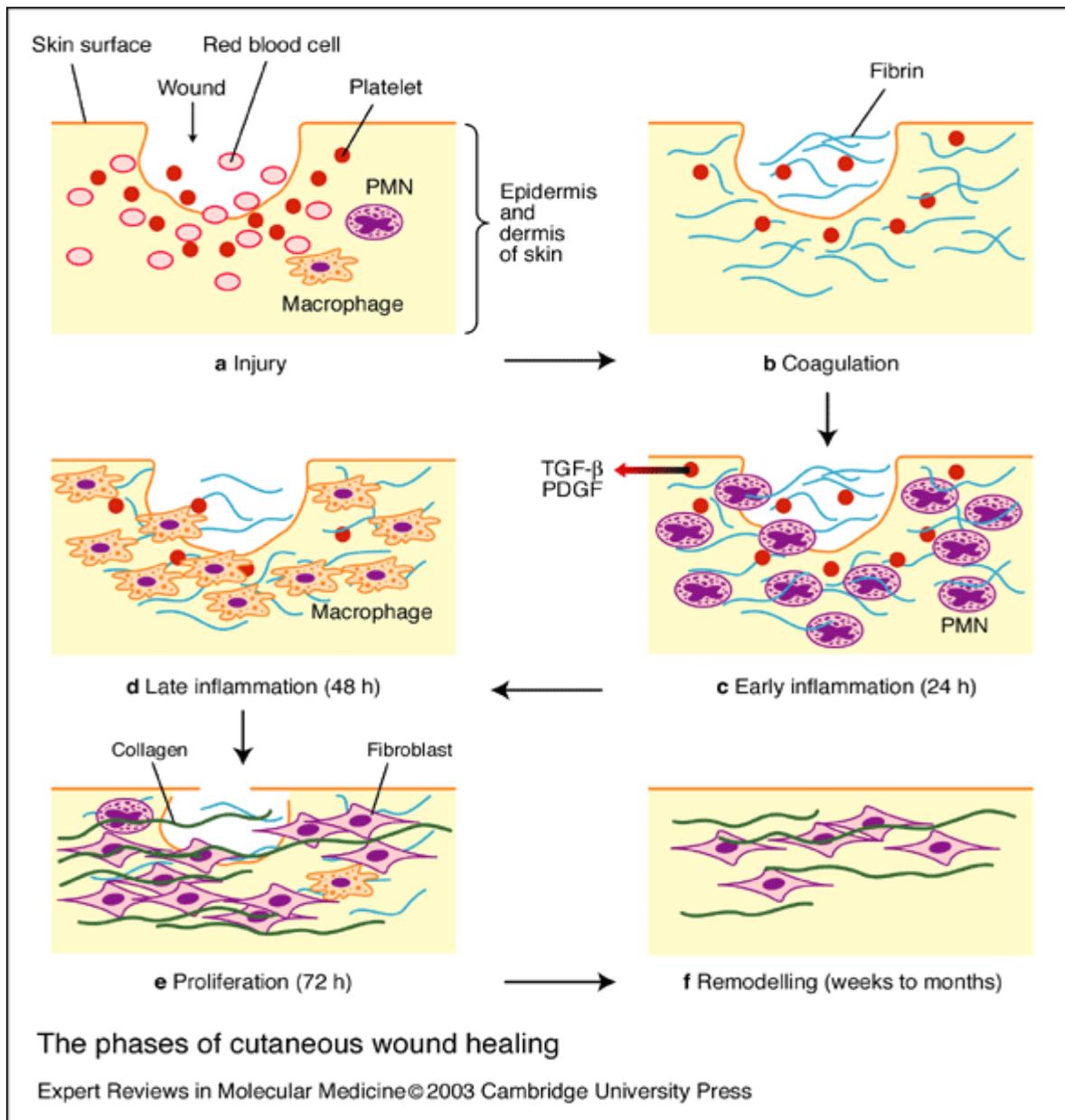


Figure 2.8 Diagram showing the phases of wound healing (Beanes, Dang, Chia, Kang, 2003)

Key to abbreviations:

PMN – polymorphonuclear neutrophils.

PDGF – platelet-derived growth factor.

TGF- β – transforming growth factor- β .

2.9.3 Factors impeding the healing of chronic wounds

A chronic wound is one that has failed to heal normally, due to disruption of one or more of the phases from different causes (Sholar and Stadelman, 2003). These include both local and systemic problems:

2.9.3.1 Local problems

- repeated trauma
- infection
- necrotic tissue in the wound
- excess wound debris (slough) (Sholar and Stadelman, 2003).

Mazzotta (1994) highlights the presence of the following as obstacles to wound healing:

- local infection
- drying
- cooling of the wound-bed
- poor circulation.

A community of micro-organisms which thrive on the surface of a wound may produce a biofilm. Biofilms may be beneficial, preventing infecting organisms from entering the body, or harmful - due to a variety of factors the microbes may proliferate to produce a pathogenic biofilm (Percival and Bowler, 2004).

Zimmet (1998) refers to the wound fluid in chronic ulcers as inhibiting the proliferation of cells involved in wound healing.

2.9.3.2 Systemic problems

According to Beers and Berkow (1999), systemic factors preventing wound healing include:

- diabetes mellitus, with its concomitant poor perfusion of the tissues and higher risk of infection.
- Immunodeficiency.

Sholar and Stadelman (2003) describe the effects of malnutrition on wound healing:

- The malnourished person has impaired ability to meet the high energy demands of wound healing.
- Proteins, which are the building blocks of new granulation tissue, may be deficient in the diet.
- Protein deficiency increases the possibility of chronic inflammation through the presence of prostaglandins.
- Deficiency of Vitamin C or K interferes with coagulation.
- Minerals, including calcium, iron, copper, zinc and manganese are important in making the proteins for the healing process.

Some medications are detrimental to the inflammatory phase of wound healing (Sholar and Stadelman, 2003). These include:

- anti-inflammatory drugs and corticosteroids, which suppress inflammation.

It is therefore important that each patient is evaluated independently to assess the factors impeding healing, and to create a strategy for correcting them.

2.10 TREATMENT BY MEANS OF BANDAGING

The mainstay of treatment of venous leg ulcers at present is compression bandaging, and elevation of the limb to help drainage and reduce the venous hypertension, if this can be achieved, seven out of ten venous leg ulcers will heal in three months (Thomas, 1998).

Following healing of the ulcer, the patient is advised to wear support stockings, exercise regularly, elevate the limb, and where necessary the patient is referred for stripping of varicose veins (Royal College of Nursing Institute, 1998).

To decide on the advisability of using compression bandaging, the arterial blood supply to the affected limb must be assessed. This is done using a Doppler to measure the ankle and brachial systolic blood pressure (Royal College of Nursing Institute, 1998). Normal is 1.0. In venous insufficiency the reading is 0.8-0.9, indicating that high compression is desirable. In arterial disease, the reading may be 0.5-0.6, reflecting considerable reduction in arterial flow and contra-indicating the use of high compression therapy (Thomas, 1998).

2.10.1 Bandage pressure

According to Thomas (2002), the pressure produced by the bandage may be calculated by using the Laplace Law, where:

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

$C \times W$

P = sub bandage pressure in mm/Hg

T = tension in the bandage

N = number of layers of bandage

C = limb circumference

W = bandage width.

From this it follows that sub-bandage pressure is directly proportional to bandage tension and the number of layers applied, but inversely proportional to the radius or curvature of the limb. In a normal shaped limb, when the bandage is applied at the same tension from the base of the toes to below the knee, graduated compression will be achieved.

Correct pressures are: 40mm/Hg at the ankle and 17mm/Hg three centimetres below the knee (Thomas, 2002).

The person applying the bandage system must be thoroughly trained in its correct application, to avoid exerting too much pressure and thereby running the risk of compromising arterial supply, or too little pressure, which renders the method useless in reversing the venous hypertension in the limb.

2.10.2 Types of compression bandages

2.10.2.1 Profore Multi-layer Compression Bandage System

Smith & Nephew's Profore multi-layer compression bandaging system provides graduated pressure when applied in three or four layers depending on the pressure required. Different packs are available for different ankle sizes. The standard pack is designed to give results on ankle circumferences of 18–25 cm. It is applied over a suitable wound dressing. Profore is worn for a period of seven days to be most effective.

Profore was selected as the preferred bandaging system for the patients' legs, as it relieved the patient from having to expose the wound, thereby maintaining the optimum environment for the wound to heal, whilst maintaining the necessary graduated compression.

2.10.2.2 Tensopress High Compression Bandage

Tensopress (BSN Medical) bandages are designed for use in the treatment of venous leg ulcers and associated conditions. They are suitable for patients with an ABPI of more than 0.8, and with an ankle circumference of more than 18 cm.

At 50% extension approximately 36 mm/Hg pressure will be produced at the ankle, reducing to 25 mm/Hg just below the knee. This bandage conforms well to the limb as oedema is reduced, and can be left in place for up to a week if applied at 50% extension, and with a 50% overlap.

Tensopress was used as an alternative bandage when the dressing required changing more than once a week. Tensopress allows the patient to be able to remove the bandage to inspect the dressing and wound, but this can be problematical in providing consistent graduated compression, as reapplying the bandage correctly requires some training, and exposing the wound interferes with the optimum environment for healing.

2.10.3 Dressings

Dressings are available to fulfil the needs of the wound in terms of absorbency, non-sticking, anti-bacterial barriers, and donating moisture where necessary.

In this study, Allevyn (a Smith & Nephew registered product), non-adhesive hydrocellular polyurethane dressings were used, as they can be left in place for up to seven days, and are indicated for shallow, granulating wounds. They are soft, conforming, with a non-adherent wound contact layer and a waterproof outer film. They permit hydration of the wound bed, to enable cell migration and healing, but prevent excessive wetness which inhibits normal healing processes and macerates the wound leading to overgrowth of bacteria (Thomas, 1998).

Alternatively, Biatain, non-adhesive dressings were used. These are a Coloplast registered product, especially suitable for use on fragile skin. Biatain has a central absorbent foam pad, with a waterproof semipermeable film backing. It can absorb large amounts of exudate if necessary, and is very suitable for use under compression bandaging (Andersen, Franken and Gad, 2002). Unmedicated dressings were used, so that the herbal lotion was the only active agent applied to the wound surface.

2.11 MEASUREMENT OF THE ULCER AND MEASUREMENT TOOLS

The dimensions of the ulcer may be obtained in several ways:

- **Measurement of the two maximum perpendicular axes - length and breadth**

The type of measurement used depends on the availability of resources, and the clinical setting (Royal College of Nursing Institute, 1998).

According to Fette (2006), the simplest method of obtaining the wound surface area is by measurement of the linear dimensions with a ruler. This has the drawback of being inaccurate for the uneven shape of most wounds, as it assumes the wound to be a geometric shape. One would have to calculate for a rectangle (length x width), or a circle (diameter x diameter), for example.

Langemo et al (1998) found that ruler measurement of wound length and breadth was less accurate than computerised measurement of length and breadth. Reliability improves if the same person makes the measurement over a period of time (Royal College of Nursing Institute, 1998).

- **Tracing technique (wound mapping)**

Wound tracing requires minimum equipment and no special skills, and is tolerated well by the patient. Each tracing in a sequence can be compared with the others to monitor the progress of healing. Fette (2006) cautions that inaccuracies may occur with the

decision of the measurer as to the exact boundaries of the wound, and the thickness of the pen used.

If the wound is mapped onto a grid (planimetry) the area of the wound can be measured quite easily, by counting the numbers of squares of the grid inside the wound borders, as suggested by (Fette, 2006).

The Visitrak electronic wound measurement device is a refinement of the planimetric wound-mapping method, in that it includes the parts of squares on the grid that cannot be estimated easily otherwise, and a percentage measurement can be obtained for comparison over time (Smith & Nephew, 2005).

Percentage wound area reduction is a better indicator of wound healing than absolute area reduction, according to Flanagan (2003), hence the benefit of using the Visitrak device.

According to Langemo et al (1998), wound tracing with planimetric area calculation is relatively inexpensive, and forms a valuable part of a patient's medical record.

- **Photography**

Where photographs are taken, a camera with a scaled ruler incorporated at the edge of the picture can be useful. The problem with photographic wound measurement is the potential for magnification errors, according to Plassmann (Fette, 2006).

These methods are useful where the wounds are shallow, and without undermined margins. Fette (2006), also states that area measurements do not reflect early changes in deeper wounds, as these begin to heal by granulating from the base of the wound.

This researcher chose the Visitrak wound measurement system, as it gives the combination of a two-dimensional planimetric wound tracing and electronic calculation of the wound measurements. The wounds were measured by the researcher only, so that consistency could be maintained.

Photographs were also taken by the researcher, with a digital camera, but without the scaled ruler. The photographs were not used in the statistical measurement of the wounds, only as a rough comparison of wound size over time.

2.12 USE OF MEDICATIONS AND OTHER NON-HOMOEOPATHIC MODALITIES IN THE TREATMENT OF VENOUS LEG ULCERS

No mention is found in current literature regarding the use of systemic medicines in the cure of venous leg ulcers, although antibiotics are used where necessary for infection.

According to Beers and Berkow (1999), six macrominerals are required by humans, daily, and nine trace minerals.

The macrominerals are:

- Sodium
- Potassium
- Calcium
- Magnesium
- Phosphate
- Chloride

The trace minerals are:

- Iron
- Iodine
- Fluorine
- Zinc
- Chromium
- Selenium
- Manganese
- Molybdenum
- Copper

2.12.1 Mineral deficiencies

Except for deficiencies of iron, zinc and iodine, mineral deficiencies are rare in adults on normal diets. Beers and Berkow (1999) also caution against excess intake of trace minerals, which may be touted as a source of protection against chronic disease.

Accordingly, zinc, iron and iodine were examined in terms of wound healing:

- **Zinc**

According to Mazzotta (1994), zinc is one of the oldest agents that can help in wound healing. It was used topically in Calamine lotion, by the Egyptians, as far back as 1500 B.C.

Wilkinson and Hawke (2004), found that research findings are inconclusive as to the benefits of zinc in wound healing, possibly indicating that zinc supplementation in the presence of normal zinc levels does not affect wound healing, whereas in deficiency, it may be enhanced.

A plasma zinc concentration of between 60–130g/dl is considered normal, according to Beers and Berkow (1999), who also give the approximate dietary intake of zinc by healthy adults as about 6-15 mg/day. Of this about 20% is absorbed.

Many of the body's enzymes require zinc for optimal functioning, including cell proliferation during healing. In zinc deficiency, there is delayed wound closure, and the collagen has reduced tensile strength (Beers and Berkow, 1999).

Marginal zinc deficiency is common, especially in situations of relative malnutrition.

Vegetarians are considered to be at risk for zinc deficiency, as cereal grains are low in zinc, and it is lost in the milling process (Mazzotta, 1994). Meat, liver, eggs and seafood are considered to be especially good sources of zinc (Beers and Berkow, 1999).

Zinc can be supplemented intravenously, or with meals to avoid gastric upset, for adequate healing, bone and joint development, in situations of zinc deficiency (Skidmore-Roth, 2000).

According to Mazzotta (1994), topical zinc chloride as a spray or ointment reduces the size of wounds, and shortens healing time, and zinc oxide inhibits bacterial growth. Zinc oxide is effective in enhancing wound healing, while zinc sulphate is not.

- **Iron**

Both iron and Vitamin B12 are needed for the production of haemoglobin, which transports oxygen in the blood, and thereby provides energy for all metabolic processes (Gray and Cooper, 2001).

Iron is also a component of many enzymes in the body . Dietary iron, found mainly in animal products, is well absorbed, especially in the presence of Vitamin C (Beers and Berkow, 1999).

Both vegetarian and vegan diets are lacking in iron and Vitamin B12, and care has to be taken to ensure dietary requirements are met (Gray and Cooper, 2001).

According to Thompson (2003), iron deficiency anaemia does not necessarily result in impaired wound healing. Paradoxically, excess iron may promote the growth of certain bacteria.

According to Fitzsimmons and Brock (2001), the anaemia of chronic disease may be difficult to distinguish from iron deficiency anaemia, and may be the body's attempt to withhold iron from micro-organisms (Thompson, 2003).

On overview of the research, therefore, iron supplementation is not recommended as a specific aid to wound healing, unless the patient is anaemic.

- **Iodine**

Chronic dietary deficiency of iodine decreases the production of thyroid hormone, leading to a hypothyroid state. This is characterised by slowing down of all the metabolic processes in the body. The skin becomes thick, coarse, dry and scaly, and hair is sparse. There may be fluid retention, leading to oedema, and anaemia (Beers and Berkow, 1999).

Natori, Shimizu, Nagahama and Tanaka (1999) experimentally induced hypothyroidism in mice and found that wound healing was significantly delayed.

In view of the skin changes due to hypothyroidism, it would seem likely that this condition should be sought during the initial assessment of a leg ulcer patient. Although most causes of hypothyroidism are not due to iodine deficiency, this must be borne in mind (Beers and Berkow, 1999).

Topical applications of povidone-iodine have been used for some years, to treat infection in wounds, and to prevent the complication of infection in a chronic wound (Goldenheim, 1993). Some reports have suggested that povidone-iodine may interfere with wound healing, but in the study by Goldenheim (1993), no adverse effects were found.

Burks (1998), however, found no evidence to demonstrate that povidone-iodine solutions might aid the process of wound healing. Burks (1998) found that concentrations of the solution above 0.05% were toxic to cells involved in the all wound healing phases. The commonly used concentration of 10% was 100% toxic to these cells.

The conclusion from the above references is that chronic wounds should not be routinely treated with povidone-iodine solutions above 0.05%, and that povidone-iodine should be reserved for short term use on heavily infected wounds only.

2.12.2 Local applications

- **Silver**

It was necessary to review the literature on the subject of silver preparations in wound healing, as silver sulphadiazine is commonly used as a local application, and there is much controversy over the ingestion of colloidal silver.

Silver sulphadiazine is used as an antimicrobial in the treatment of infected wounds.

When silver comes into contact with the wound exudate, it becomes highly reactive, entering the cells of micro-organisms, to which it is lethal (Lansdown, 2002).

Recent research suggests that silver sulphadiazine may impair healing by interfering with the normal healing pathways (Cho Lee, Leem, Lee and Park, 2005).

Silver is also taken up by the macrophages in the wound and then passes into the peripheral circulation where it accumulates in the liver and kidneys, causing damage to these organs over time. Some is voided in the urine. Other complications include possible suppression of white blood cell production and bone marrow toxicity, while allergic reactions to the silver are not uncommon (Lansdown, 2002).

Lansdown (2002) also warns against the risk of argyria, a condition of silver toxicity.

From the above references, it would appear that applied topically, where there are pathogens acting as an obstacle to healing, silver preparations have a role to play in wound healing, but the ingestion of large quantities of colloidal silver for its purported health benefits is not without serious risks.

2.12.3 Other medical treatments available

2.12.3.1 Hyperbaric oxygen therapy

Another treatment modality aimed at correcting poor oxygenation of the tissues in chronic wounds is hyperbaric oxygen therapy. According to Wright (1987), hyperbaric oxygen can assist in wound healing. It combats certain harmful micro-organisms in the wound, and enhances the effects of systemic antibiotics, as well as leukocyte and macrophage activity locally. Hyperbaric oxygen therapy is very expensive.

2.12.3.2 Jet therapy

This is the application of purified air under pressure to the skin, with the aim of stimulating the circulation. The jets provide a circulatory massage, without damaging skin tissue, according to the inventors. The results claimed are enhanced wound healing as well as promoting a more stable circulation to the treated part. Clinical trials were run by Mars, Tufts, Naidu, Kleinfeldt and Robbs (2000), and showed an improvement in pain levels and shortened in-hospital stay for patients with diabetic foot ulcers. This therapy is not fully tested and is expensive.

2.12.3.3 Skin grafting

According to Jones and Nelson (2006), non-healing wounds, such as venous ulcers, can be treated with skin grafts to prevent infection and assist the wound to heal. Skin may be taken from a suitable site on the patient and transferred to the ulcer site, or may be taken from cadavers (allografts), or animals, usually a pig (xenograft). The allografts and xenografts are considered to be only temporary, as tissue rejection occurs within seven days of grafting. The problem with application of skin grafts to the ulcer site is that with poor blood flow to the area, compounded by oedema, infection is likely, and ultimately, rejection hence it is of limited use in the treatment of leg ulcers. Skin grafting is also a relatively expensive treatment.

2.12.3.4 Bio-engineered tissue

Bio-engineered skin substitutes closely resemble human skin. Cultivation of the patient's own cells in the laboratory is possible (Badylak, 2004). Bio-engineered

products are very expensive and also come with warnings about allergic reactions, and they have to be stored under special conditions (Hebra, 1998). This would make them impractical for generalised use in a unit with a limited budget.

2.12.3.5 Wound modulating products

Other substances have been created specifically to modulate the events of wound healing, for example:

- Promogran

This is a Johnson and Johnson registered product. The dressing incorporates a matrix of freeze-dried collagen and oxidised regenerated cellulose, which modulates the wound environment, by binding and inactivating excess proteases in the wound. These proteases prevent healing by breaking down protein. The Promogran matrix also protects growth factors, and attracts fibroblasts to the wound. This product must be used on a clean wound, free of necrotic tissue, and is applied directly to the wound where it forms a gel (Cullen, Smith and Silcock, 2002).

There are many products that can be used on wounds where there are obstacles to healing, such as slough, infection and excess exudate. Patients in this study had to have clean wounds, with minimal slough, so that the unmedicated wound dressing appropriate to the level of exudate could be used.

2.13 HOMOEOPATHIC TREATMENT

2.13.1 Principles of Homoeopathy

Homoeopathy follows principles well known to ancient civilizations and because homoeopathy is founded upon natural laws, its tenets remain constant and true (Roberts, 2002).

The first principle is known as the 'law of similars' and can be explained as:

- **that which creates imbalance is also that which can create balance.**

This principle was recognised by Aristotle around 350BC, and Galen in about AD150.

Later, Paracelsus, in about 1500, and Dr. George Stahl, a German physician, in 1623, described the first accurate definition of the law of similars. Only Samuel Hahnemann (1755-1843) a German doctor and pharmacist, who, disillusioned with the accepted medical practices of his day, actually put the principle to the test, developing the theory and philosophy of homoeopathy thoroughly (Cook, 2000).

Following naturally on from the law of similars, and inseparable from it, is the law of least action (formulated by the French mathematician, Malpertius), which states that:

- the quantity of action necessary to effect any change in nature is the least possible; the decisive amount is always a minimum, an infinitesimal (Roberts, 2002).

Hahnemann used it to describe the second important principle:

- **the principle of the minimum dose.**

A herb given in small amounts will cure the symptoms that it will create in larger doses. For example, Belladonna, an important homoeopathic remedy, will cure violent, sudden complaints such as headaches, sweating, fever, and convulsions, whereas in its plant form, it will cause these symptoms (Curtis and Fraser, 2003).

Homoeopathic remedies are prepared by a controlled process of successive dilutions alternating with succussions (shaking in a prescribed manner). These may be continued to the point where there are no more molecules of the original substance in the solution. Each stage of dilution and succussion produces a homoeopathic potency. Low potencies are lesser dilutions, and higher potencies are greater dilutions. The higher the dilution, the greater the potency of the medicine (Cook, 2002).

The Arndt-Schultz law states that small doses of drugs encourage life, large doses of drugs impede life activity, and very large doses of drugs destroy life. Kotschau repeated this work and produced the biphasic response curve, which effectively validates the law of the infinitesimal dose (Wilcher, 1996).

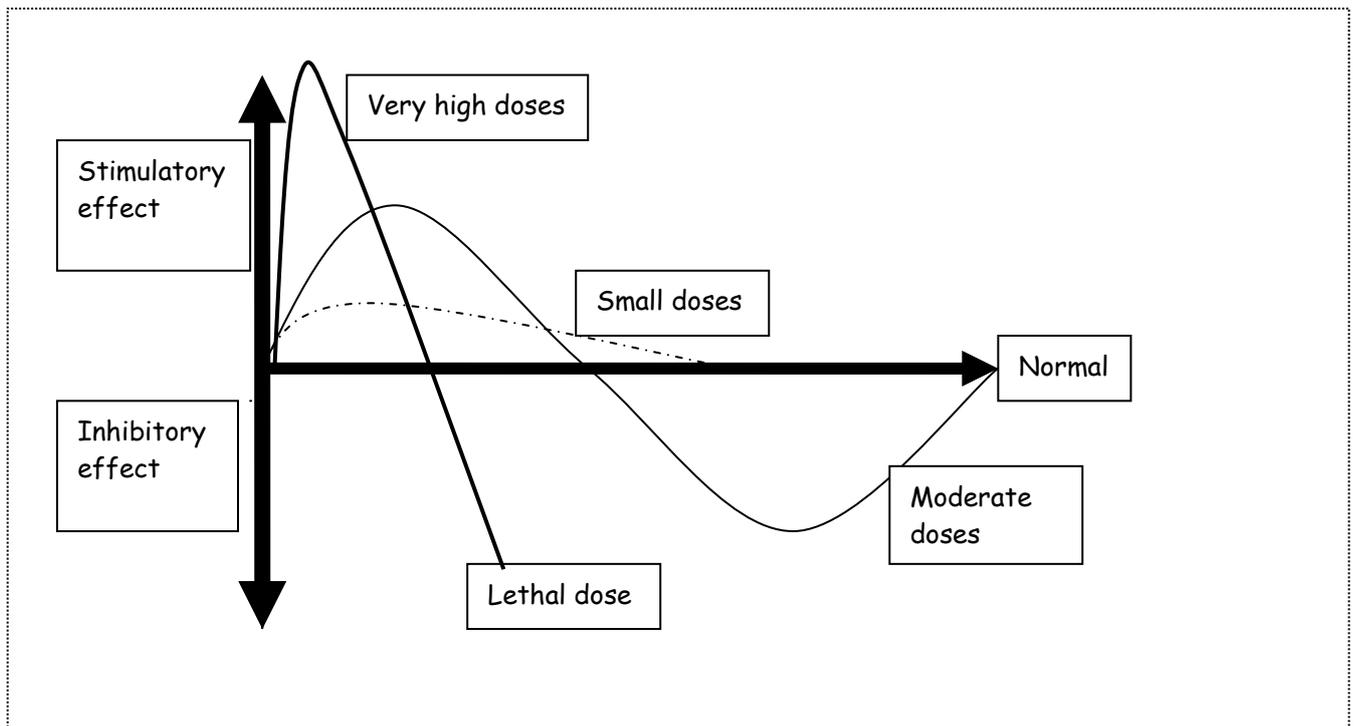


Figure 2.9 Diagram to illustrate the law of the infinitesimal dose: Kotschau's Biphasic Response Curve

The third principle is:

- **homoeopathy treats the person and not the disease** (Digby, 1996).

Homoeopathic remedies are “proved”. During the proving process, the potential remedy is given to a number of healthy people, and they record all effects they may experience - physical, mental or emotional. These are analysed at the end of the proving period. In this way, all the effects of the substance upon the healthy individual can be established and used to build a “picture” of that substance (Digby, 1996).

The aim of the homoeopathic consultation is to determine the patient's simillimum, - the matching of all the symptoms provided by the patient to the most similar remedy picture, thus finding the closest fit (Vithoulkas, 1980). This is arrived at by taking into

consideration all the symptoms that distinguish the person as an individual. This includes his family history, past medical history, appetite, thirst, bowel habits, sleep, and temperament, among others, taking special note of any changes on the mental, emotional and physical levels (Sankaran, 1991).

The principle of treating the person and not the disease recognises the unique individuality of each person, who manifests his disease symptoms in his own way (Digby, 1996).

The fourth principle is:

- **healing takes place from above to below, from the interior to the exterior, and symptoms disappear in reverse order of their appearance.**

This law was described by Hering in 1845, and is a set of observations on how true healing occurs. Traditional Chinese medicine has recognised the direction of cure for over 5000 years (de Schepper, 2001).

Some examples to illustrate this:

- Patients often start to feel better before all the signs and symptoms of their illness have gone (a sense of well-being is registered in the mind before the physical symptoms have completely disappeared).
- A bout of gastro-enteritis is manifested by vomiting and diarrhoea – the body's attempt to exteriorise the disease.

- With homoeopathic treatment for chronic disease, the patient may be surprised to find a manifestation of symptoms that occurred some time previously, but milder, before totally and permanently disappearing as they return to complete health. (de Schepper, 2001).

2.13.2 The Vital Force

Vithoulkas (1980) describes the biophysical energy of an individual, sometimes known as the “vital force”, as that which animates the integrated entity, and includes the normal protective functioning of the defence mechanisms of the body. When disease occurs, it disturbs the normal equilibrium, producing symptoms on the physical, mental or emotional levels.

When the patient is given the homoeopathic similimum it restores the normal balance of the biophysical energy, and effects cure (Cook, 2000).

This biophysical energy has been the subject of much research in recent years.

Anagnostatos (1994) has shown how homoeopathic solutions become stronger with succussion. He describes the small water clusters (clathrates) that occur and multiply during the preparation of homoeopathic dilutions, as being the way in which the characteristic properties of the initial substance, which is no longer present, are maintained.

In addition, the biophysical energy in the ultra-high dilutions has been shown to transfer information by means of long-range electro-magnetic fields. The effects in the body seem to be based on the mutual interaction of the body’s long-range electro magnetic fields with those of the ultra-high dilution (Schulte and Endler, 1998).

This is prefigured by Vithoulkas (1980) in his description of how the homoeopathic similimum works – the symptom manifestation of the patient, when matched to the symptom manifestation of the remedy, enable the principles of resonance to excite and strengthen the defence mechanism of the patient and bring about cure.

2.13.3 Homoeopathic potencies

These are made by a process of sequential dilution and succussion of materials in solution. They are diluted according to the following series:

- the decimal series (1:10) represented by the suffix D or X
- the centesimal series (1:100) represented by the suffix C
- the millesimal series (1:1000) represented by the suffix M
- fifty millesimal scale (1:50 000 dilution), represented by the prefix LM.

The first dilutions are known as 1X, 1C, 1M or LM1 in each scale (Cook, 2000).

As explained by Cook (2000), the Italian physicist, Avogadro, postulated that equal volumes of substances contain equal numbers of molecules. A unit volume (1ml) contains a specific number of molecules – calculated as 6.4×10^{23} .

In this way it becomes possible to dilute out every molecule of the original substance.

Once the dilutions reach 24X or 12C they exceed the Avogadro limit and are considered to have no molecules of the actual solute remaining, only its electro-magnetic energy.

Avogadro's hypothesis has been validated and can be used to understand the lack of toxic effects, but powerful action of high homoeopathic dilutions that have been succeeded at each stage.

2.13.3.1 Plussed potency

The thirtieth centesimal potency was used in this study, as a “plussed” potency. This is given in liquid form. A liquid potency enhances the effectiveness of the remedy (de Schepper, 2001). It is issued to the patient with instructions to succuss the bottle ten times before each once-daily dose of 5 drops.

The rationale behind this is that each dose becomes a little stronger with the daily succussion, the patient is, therefore, not receiving the same potency every day, and the dynamic action of the remedy continues to stimulate the vital force. Hahnemann argued that if the dose is repeated many times in the same potency, it may lead to a worsening of symptoms (known as an aggravation), and a gradual decrease in the body’s responsiveness to the remedy (O’Reilly, 1996). Also, because patients are accustomed to taking allopathic medicines daily, it was decided to give the homoeopathic remedy daily. Many of the patients were also taking allopathic drugs, for example for hypertension, or pain, and frequent repetition of the remedy would ensure it was not being antidoted by the other drugs (de Schepper, 2001).

2.13.4 Tinctures

The tinctures used in this study were produced according to the German Homoeopathic Pharmacopoeia, Method 3(a) (Appendix G), and are homoeopathic mother tinctures. These are the first potencies prepared from the crude drug substance, and form the basis from which homoeopathic remedies are made.

The homoeopathic mother tinctures of a combination of *Calendula officinalis* and *Hypericum perforatum* were chosen for this study because they are commercially available in some European countries as over-the-counter lotions or creams, specifically

indicated for home use in the care of wounds. *Hypercal*, formulated by A Nelson & Co. of London, is made from the homoeopathic mother tinctures of equal parts of *Hypericum perforatum* and *Calendula officinalis*, and is available as a lotion, or in a cream.

Nelson's *Hypercal* is recommended for the wound healing properties of *Calendula officinalis* and the pain relieving properties of *Hypericum perforatum*, but as far as can be determined, this product has not been scientifically studied.

Calendula officinalis and *Hypericum perforatum* were also selected, in combination, and as a lotion, as they cover all the common problems associated with chronic venous leg ulcers, providing pain relief and improved wound healing.

As far as can be ascertained by this researcher, no study has been done using the homoeopathic mother tincture of these two plants in combination for the treatment of venous leg ulcers.

2.13.5 Drug pictures

According to Vermeulen (2002) the natural sciences like homoeopathy make use of a wealth of traditional information about the actions of substances on the body, and advocate that the drug picture should relate to the substance from which it is derived. Knowledge of the traditional uses of plants for healing is recognised in homoeopathy, and used in prescribing remedies in the form of the mother tincture and in low potencies, where there is still a material dose of the original plant, but through the process of potentisation of homoeopathic remedies the invisible medicinal force of the crude plant is brought out to act dynamically on the whole organism (Kunzli et al, 1982).

Thus potentised homoeopathic remedies differ from herbal remedies in their actions upon the organism, but the indications appear to be similar for topical use of diluted forms of either the herbal tincture or homoeopathic mother tincture of the same plant.

2.13.5.1 *Calendula officinalis*

2.13.5.1.1 Classification

Calendula officinalis (Marigold) is a member of the daisy family (*Asteraceae/Compositae*).

2.13.5.1.2 Description

Marigold is an annual or biennial aromatic herb. It has soft glandular leaves and yellow or orange flower heads. The flower heads or petals only are used (van Wyk and Wink, 2004).



Figure 2.10 *Calendula officinalis*

In homoeopathic preparation, this plant promotes healthy granulation and rapid healing of wounds. It can be used as a lotion and applied topically, and according to Savage (1999), is the greatest healing agent for all wounds. In traditional herbal use it is also considered as one of the best herbs for treating slow healing wounds and skin ulcers when applied topically (Hoffmann, 1988).

2.13.5.2 *Hypericum perforatum*

2.13.5.2.1 Classification

Hypericum perforatum: is a member of the *Hypericaceae* family.



Figure 2.11 *Hypericum perforatum* L.

2.13.5.2.2 Description

This is a perennial herb or small shrub, with small leaves containing oil glands. These glands are visible as translucent dots, hence the name 'perforatum'. The flowers are bright yellow with many stamens, which are dotted with small darkly coloured glands. According to Hobbs (1996), there are 400 species of *Hypericum* worldwide, divided into two main families of which the morphological and chemical differences are minimal.

As early as the 17th century a noted English herbalist, Gerard, described the virtues of *Hypericum* in the treatment of wounds. Also Culpeper, in 1650, described its benefits in wound closure (Hobbs, 1996). Furthermore, *Hypericum*, as a lotion, was used by surgeons to clean infected wounds.

Hypericum in homoeopathic preparation is known as a great remedy for injuries to nerves, as well as ulcers and lacerated wounds, and is also indicated for sadness and melancholy (Savage, 1999). In herbal tradition it is used for mild depression, neuralgic pain, and topically, to speed the healing of wounds (Hoffmann, 1988).

2.13.6 Combined herbs

According to van Wyk and Wink (2004) traditional medicine often aims to restore health by using chemically complex plants in their naturally balanced state, or by using a combination of herbs to create a synergistic effect, which improves their interaction with the body's tissues at molecular level.

Calendula officinalis and *Hypericum perforatum* are commonly used in combination in the herbal treatment of wounds, to encourage healing locally (Rogers, 1995). As the traditional use of these two herbs appears to correlate well with their homoeopathic use in tincture form, the homoeopathic mother tinctures used in the study would be expected to have similar results.

2.13.7 Studies using topical homoeopathic applications for wound healing

Research done by Naudé (2001) investigated the use of a combination of homoeopathic tinctures to treat sunburn. The combination included *Calendula officinalis*, *Apis mellifica*, *Aloe vera* and *Urtica urens*. *Apis mellifica* was included for its homoeopathic effectiveness in treating superficial inflammation, with redness, burning and swelling

(Vermeulen, 1997). *Aloe vera* has proven ability to heal wounds ulcers and burns, according to Chevallier (1996). *Urtica urens* speeds healing of minor burn wounds, and diminishes pain (Ullman, 1992). *Calendula officinalis* was included as the remedy of choice for first degree burns, in diluted tincture form (Ullman, 1992).

The double-blind study, randomly divided into three groups compared the experimental group to an untreated control group and a placebo group who received an aqueous cream and ethanol mixture. The parameter of redness (erythema) was used to determine the outcome. Both the experimental and placebo groups improved compared to the control group, but no statistically significant differences between the experimental and placebo groups was found.

The frequency of application was considered to be a possible cause for this, as there were only three applications of the creams in 48 hours. To have increased the application to three times daily for a week might have shown better results. Also the only parameter observed was redness, whereas other effects of the herbs either individually or in combination were not used.

2.13.8 Conclusion

Apart from the research by Naude (2001) who used homoeopathic mother tinctures as the basis for the creams used in his study, it is not clear in reviewing the literature available on previous studies which included the use of *Calendula officinalis* or *Hypericum perforatum*, whether the tinctures used by other researchers were homoeopathic or herbal, and therefore no other studies can be quoted on the use of *Calendula officinalis* or *Hypericum perforatum* (homoeopathic mother tincture), either alone or in combination.

The use of homoeopathic remedies and applications of a homoeopathically prepared lotion in the treatment of venous leg ulcers could provide a very economical adjunct to the necessary compression bandaging and dressings, providing the optimum environment for wound healing both systemically and locally. If the ulcers can be healed more rapidly by the use of these modalities, considerable costs can be saved, and the negative impact of leg ulcers on the patients' lives can be reduced.

CHAPTER 3: METHODOLOGY

3.1 GROUP DESIGN

Thirty-six patients attending the Addington Hospital leg ulcer clinic were recruited according to the following criteria:

- The leg ulcer had to be a result of venous hypertension
- The Ankle Brachial Pressure Index had to be more than 0.8
- Pregnant patients were excluded
- Patients had to be fluent in English.

The study was randomised and double-blind. The patients were divided into three groups. (All patients received the non-medicated dressings and graduated compression bandaging).

- Group A received both the simlimum and the prepared lotion.
- Group B received the simlimum and a placebo wound lotion.
- Group C received placebo simlimum and the lotion.

3.2 RECRUITMENT PROCEDURE

This included the following:

- The purpose of the research project was explained and each patient was given an information letter (Appendix A).

- Informed consent to participate in the project was signed (Appendix B).
- Patients were interviewed to determine their homoeopathic similimum (Appendix C).
- A physical examination was performed (Appendix D).
- Wound assessment, Visitrak wound mapping, and measurement of the ankle-brachial pressure index (Appendix E) were performed.

The cases were discussed with a qualified homoeopathic doctor, for confirmation of the required remedy.

3.3 DISPENSING OF MEDICATION

The remedies and lotion or placebos, which were identical in appearance, were dispensed by a qualified homoeopathic doctor, according to a randomisation sheet, drawn up by the supervisor. This randomisation sheet divided the patients into three groups.

- Group 1: combination group (receiving both similimum and lotion)
- Group 2: similimum group (receiving placebo lotion)
- Group 3: lotion group (receiving placebo similimum)

The contents of the bottles were only known to the dispenser, and they were individually labelled for each patient. Verbal instructions were given to the patients on how to take the remedy/placebo, and these were also written on the label of each bottle.

3.4 HOMOEOPATHIC REMEDIES

The process of preparation of the homoeopathic remedies involves first making the liquid potency from the mother tincture, then medicating lactose granules with the desired potency and allowing them to dry.

The mother tincture is made using the following formula, according to Method 3a of the German Homoeopathic Pharmacopoeia (British Homoeopathic Association, 1991).

(Appendix G):

- $E3 = 2MD \div 100$ (kg).
- M = weight of plant material in kg.
- D = loss on drying in sample, in per cent.
- E = Ethanol 62% - used to adjust to any concentration required as per the Monograph.

Method 10 of the German Homoeopathic Pharmacopoeia (British Homoeopathic Association, 1991) was used to prepare the liquid potency from which the granules used in the making of the plussed potency were made (Appendix F).

The first centesimal dilution (1C) is made in the following manner:

- 3 parts of the mother tincture and
- 97 parts of ethanol 62%.

The second centesimal dilution (2C) is made with:

- 1 part of the first centesimal dilution and
- 99 parts of ethanol 43%.

Subsequent dilutions are made in the same way, with succussion at each stage of dilution.

3.4.1 Preparation of the similimum remedy

The similimum remedies were made up in the dispensary of the Department of Homoeopathy at Durban University of Technology, by a qualified homoeopathic doctor. Ten granules of the remedy in 30CH potency were placed in 18ml distilled water and dissolved, then 2.5ml 96% alcohol was added as a preservative. The bottle was succussed (shaken with impact) ten times, and was labelled. The patients were shown how to take their remedy, and how to succuss the bottle before each dose. Each bottle was measured to last a month. Patients were asked to contact the researcher if they had any queries.

3.4.2 Preparation of the placebo remedy

The placebo was made up in the same manner, but using unmedicated granules.

The granules were placed in 18ml distilled water, and once they had dissolved 2.5ml of 96% alcohol was added. The bottles of placebo were labelled in exactly the same way as the remedy bottles, so that neither the researcher, nor the patient could differentiate between them.

It was assumed that the patients all took the medication as prescribed.

The patients received their remedies on the week following the initial case-taking interview.

3.5 LOTIONS

The lotions were dispensed by a qualified homoeopath in the dispensary of the Department of Homoeopathy at Durban University of Technology, and applied to the wounds by the researcher.

3.5.1 Active lotion

Method 3a of the German Homoeopathic Pharmacopoeia was also used to make the homoeopathic mother tincture of the *Hypericum perforatum* and *Calendula officinalis* lotion (Appendix G). This was manufactured by Parceval ® SA

Six millilitres of lotion were dispensed (1 ml tincture and 5 ml distilled water, giving an alcohol strength of the approximately 1.1%) in individually labelled amber glass bottles.

3.5.2 Placebo lotion

The placebo lotion dispensed contained 6 millilitres of sterile water only. This was subsequently discovered to be a flaw in the study, as the effects of the 1.1% alcohol in the wound could, therefore, not be discounted.

3.6 WEEKLY DRESSING PROCEDURE

The patients were monitored for a period of eight weeks.

The patients were allowed to remove their bandages early in the morning before the weekly visit to the clinic, so that they could clean their legs and feet and apply moisturising unmedicated aqueous cream to the skin of the lower limb.

After removing the old dressing and inspecting and irrigating each wound, it was mapped and the 6 ml of lotion applied and allowed to remain on the wound for a short while before the new dressing was applied. These activities were performed by the researcher.

The Allevyn or Biatain dressings were kept in place by a light bandage, and the Profore applied over this.

The sequence of bandaging using Profore is as follows:

- Natural padding bandage. This is applied from the base of the toes to the knee, in a spiral with a 50% overlap. Any left over bandage is applied to pad bony prominences and to create a tube-like shape to the lower leg, especially when there is emaciation of the gaiter area and great bulging of the calf.
- Light conformable bandage. This is applied over the padding bandage, also in a spiral with 50% overlap, and medium stretch. It is secured with tape.
- Light compression bandage. This is applied in a figure of eight technique at 50% extension and 50% overlap from the base of the toes to the knee. It is secured by tape.
- Flexible cohesive bandage. Applied from the toes to the knee in a spiral, with 50% extension and 50% overlap. On completion, it is lightly pressed over its surface to ensure that it adheres to itself.

Method of application of the Tensopress bandage:

- Bony prominences or areas of calf fibrosis must be protected using a natural padding bandage underneath the Tensopress.
- It is applied at 50% extension, and with a 50% overlap, and fastened with tape or safety pins.

The bandages were not removed during the week between appointments.

3.7 MEASUREMENT TOOLS

3.7.1 Visitrak

A sterile Visitrak grid was placed over the wound, to minimise the risk of cross-contamination, and the wound margins were traced with a fine-point indelible marker-pen by the researcher.

The layer of the grid that had been in contact with the wound was discarded into a designated bin.

The clean outer layer of the grid was attached to the Wound Treatment Record.

Each grid was then placed on the Visitrak electronic device and the traced wound was drawn over with the digital pen.

The device then calculated the wound area and maximum length and breadth of the wound.

This information constituted the basis of the statistical information required to assess the rate and amount of healing of each patient's leg ulcer.

3.7.2 Ankle-Brachial Pressure Index: ABPI

The Doppler ABPI was used by the researcher to assess the quality of arterial circulation in the lower leg, and was not used for statistical purposes in the measurement of healing. The systolic blood pressure reading was taken on the dominant arm, with the patient supine. The Doppler was used to locate the brachial artery at the elbow. The blood pressure cuff was then applied to the lower limb just above the ankle. (The wound was covered with the selected dressing and a light bandage for this procedure). The Doppler was used to locate the anterior or posterior tibial arteries or the dorsalis pedis artery and the systolic blood pressure was recorded.

The ankle systolic pressure was divided by the brachial systolic pressure, giving the pressure index.

The procedure was performed by the researcher, and the results discussed with the surgeon in charge of the clinic. Patients with a reading of > 0.8 were considered suitable for high compression bandaging.

The ABPI was recorded on the Wound Treatment Record (Appendix E).

3.8 DATA COLLECTION

Each patient's wound measurements were entered into the Visitrak Data Capture © programme. These were then produced in chart (Appendix H) and graph form (Appendix J), to show the percentage reduction in wound size over the research period.

All the data were then entered into the SPSS (version 12.1) software programme. This software is manufactured by SPSS Inc, Chicago, USA.

In all the tests applied to the data, the level of significance was set at $\alpha = 0.05$. If the p value was less than 0.05 the result could be declared significant, and the null hypothesis rejected.

3.8.1 Friedman Intra-Group Test

This is a test which compares data within each group – if any difference is found the Wilcoxon test is applied (Dallal, 2000).

3.8.2 Wilcoxon Signed Rank Test

This is an intra-group test for the comparison of a pair of samples. Exact probability can be calculated with sample sizes less than 50 (Crichton, 1998).

3.8.3 Kruskal-Wallis non-parametric analysis of variance (ANOVA).

This is an inter-group test for the comparison of treatment groups to placebo groups (Gaten, 2000).

CHAPTER 4: RESULTS

4.1 CRITERIA FOR ADMISSIBILITY OF THE DATA

Only data collected from the thirty-one patients who completed the study was used for statistical purposes. The patients were allocated groups as follows:

- Group 1: combination group (receiving both similimum and lotion)
- Group 2: similimum group (receiving placebo lotion)
- Group 3: lotion group (receiving placebo similimum)

4.2 DEMOGRAPHIC DATA

4.2.1 Gender

Thirty-one patients completed the study, of whom 9 were male (29 %) and 22 were female (71%).

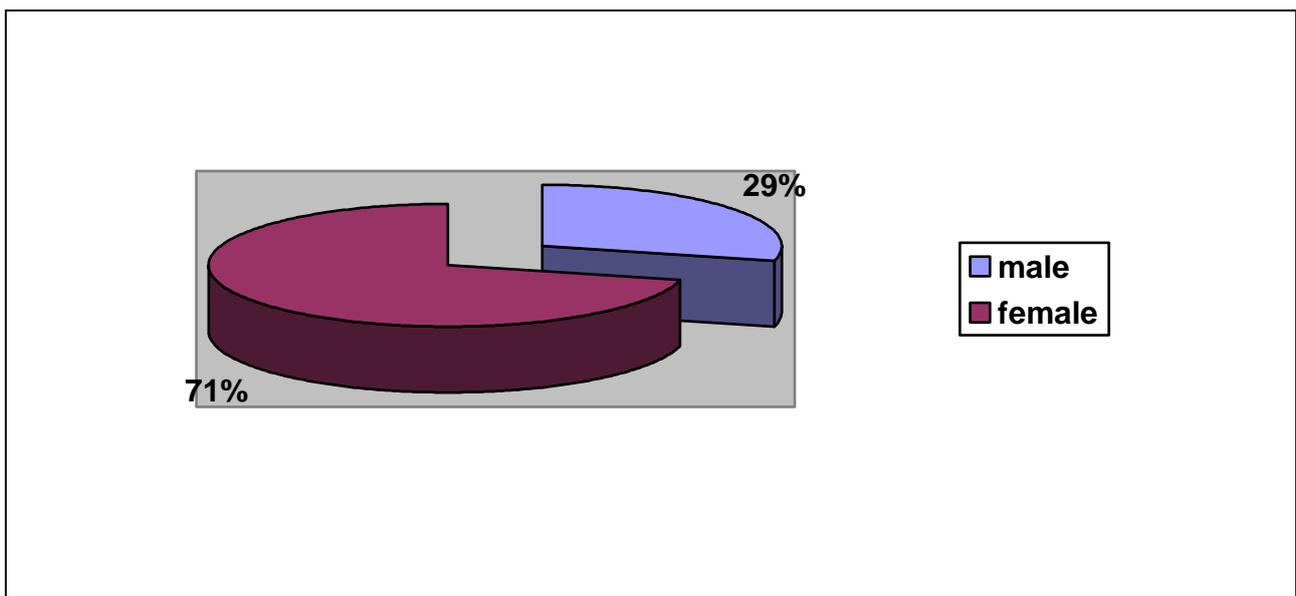


Figure 4.1 Percentage of Male and Female Participants

4.2 2 Age

Age group	30-40	41-50	51-60	61-70	71-80	81-90	90 plus
Number of patients	3	5	11	5	3	3	1
% of total	9.6%	16%	35.4%	16.1%	9.6%	9.6%	3.2%

Table 4.1 Ages of patients in the study

The patients ranged in age from 36 years, to 93 years. The majority of patients were in the 51-60 age group, with the 41-50 and 61-70 age groups being next most prevalent. There were approximately equal numbers of patients in the youngest age group and in the older age groups (above 71 years), declining with more advanced old-age.

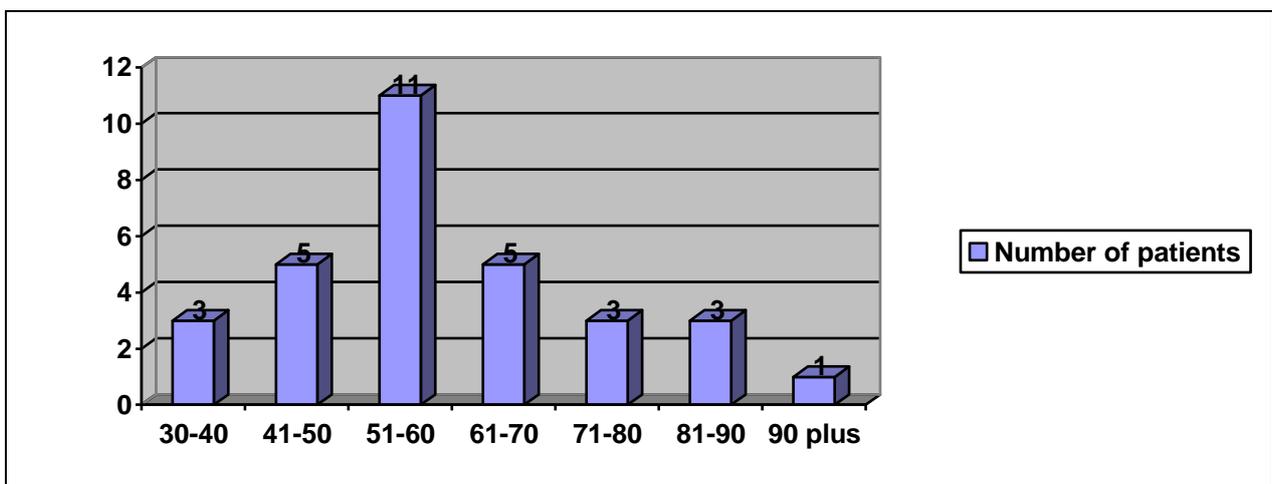


Figure 4.2 Number of patients in each age group

4.2.3 Allocation of patients to each group

There were 11 patients in the lotion group, and 10 each in the combined and similimum groups.

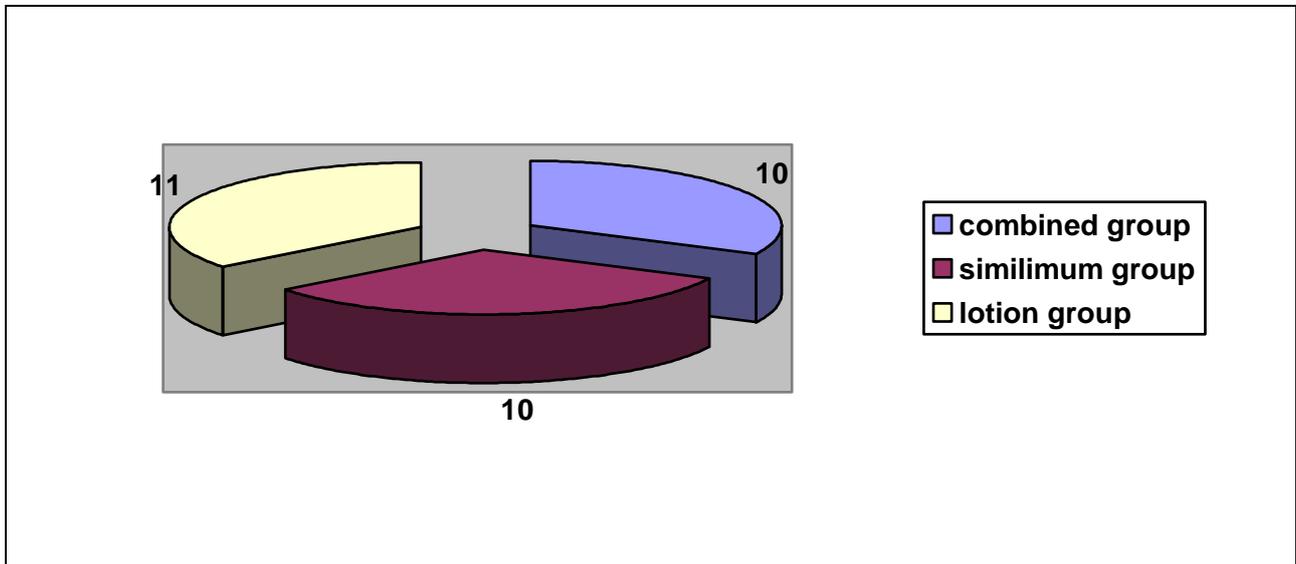


Figure 4.3 Number of patients allocated to each group

4.3 PROCEDURE 1 (INTRA-GROUP): FRIEDMAN TEST

	Group 1 (p value)	Group 2 (p value)	Group 3 (p value)
Length	.061	.061	.003
Width.	.013	.050	.006
Area	.058	.061	.006

Table 4.2 Results of the Friedman Test: summary in p-values for length, width and area within each group. (Numbers in bold are significant values)

Table 4.2 reveals the following:

The level of significance is set at 0.05. If the p value is less than 0.05 it is declared as a significant result. There was a significant reduction in wound width in Group 1. In Group 3 there was a significant reduction in wound length, width, and area between the three readings in each variable, but no statistically significant reduction in wound area in the other two groups, although the actual area of the wounds decreased. In Group 2 no significant changes showed in any of the three variables.

4.4 PROCEDURE 2: (INTRA-GROUP) WILCOXON SIGNED RANK TEST

Group 1	Width FU1 – Baseline	Width FU3 –FU2	Width FU3 - Baseline
P value	.028	.019	.011

Table 4.3 Wilcoxon test: group 1 wound width reduction between baseline and second measurements, and third to second measurements and third to baseline measurements

Table 4.3 reveals that a difference was noted in the Friedman test for the wound width variable in Group 1, between baseline and second, third to second and overall measurements, and on application of the Wilcoxon test a significant difference was confirmed.

Group 3	Length FU2 – Baseline	Length FU3 – FU2	Length FU3 - Baseline
P value	.006	.006	.008

Table 4.4 Wilcoxon test: Group 3 wound length reduction between baseline and second, second to third, and third to baseline measurements

Table 4.4 reveals that a difference which was noted in the Friedman test for Group 3, wound length, was confirmed to be statistically significant after application of the

Wilcoxon test, through all readings (baseline to second, second to third and on comparing the third to baseline readings).

Group 3	Width	Width	Width
	FU2 – Baseline	FU3 – FU2	FU3-Baseline
P value	.028	.013	.011

Table 4.5 Wilcoxon test: Group 3 wound width reduction between baseline and second, second to third, and third to baseline measurements

Table 4.5 shows that in Group 3, wound width, the results of the Friedman test were significant, and on application of the Wilcoxon test, confirmed that the differences were statistically significant in all readings (Baseline to second, second to third and third to baseline).

Group 3	Area	Area	Area
	FU2 – Baseline	FU3 - FU2	FU3 - Baseline
P value	.016	.029	.016

Table 4.6 Wilcoxon test: Group 3 wound area reduction between baseline and second, second to third, and third to baseline measurements

Table 4.6 likewise confirms the findings of the Friedman test, when the Wilcoxon test was applied. Group 3, area measurements were statistically significant when comparing baseline to second, second to third and third to baseline measurements.

The above three tables show that the Wilcoxon test confirmed the significant values found in the Friedman test for length, width, and area in Group 3.

4.5 PROCEDURE 3: (INTER-GROUP) KRUSKAL WALLIS TEST

	Length (Baseline)	Length (FU2)	Length (FU3)
P value	.637	.513	.294

Table 4.7 Kruskal-Wallis test: comparison of length between all three groups

	Width Baseline	Width (FU2)	Width (FU3)
P value	.163	.292	.435

Table 4.8 Kruskal-Wallis test: comparison of width between all three groups

	Area (Baseline)	Area (FU2)	Area (FU3)
P value	.489	.461	.383

Table 4.9 Kruskal-Wallis test: comparison of area between all three groups

Tables 4.7, 4.8, and 4.9 show that there was no statistical difference in the variables length, width, and area when the three groups were compared to each other.

4.6 DESCRIPTIVE STATISTICS

The group variables, length, width, and area were described in terms of minimum, maximum, and mean values between their respective measurements.

	N	Minimum	Maximum	Mean	S/Deviation
Length (Baseline)	10	1.60	7.30	3.7800	1.88432
Length (2nd reading)	10	.60	7.80	3.7400	2.22171
Length (3rd reading)	10	.00	5.90	2.8400	2.29841

Table 4.10 Group 1: descriptive statistics – length of ulcer in cm

	N	Minimum	Maximum	Mean	S/Deviation
Width (Baseline)	10	1.00	6.50	4.1800	1.88550
Width (2nd reading)	10	.70	6.60	3.2500	1.89634
Width (3rd reading)	10	.00	6.20	2.3000	2.04831

Table 4.11 Group 1: descriptive statistics – width of ulcer in cm

	N	Minimum	Maximum	Mean	S/Deviation
Area (Baseline)	10	1.20	35.70	13.3500	11.00073
Area (2nd reading)	10	.20	25.10	11.0200	9.82512
Area (3rd reading)	10	.00	22.20	7.3000	8.05826

Table 4.12 Group 1: descriptive statistics – area of ulcer in cm²

	N	Minimum	Maximum	Mean	S/Deviation
Length (Baseline)	10	.80	.11.90	5.1600	3.42222
Length (2nd reading)	10	.70	9.30	4.1100	2.91107
Length (3rd reading)	10	.00	10.70	3.5500	3.24765

Table 4.13 Group 2: descriptive statistics – length of ulcer in cm

	N	Minimum	Maximum	Mean	S/Deviation
Width (Baseline)	10	.90	6.40	3.1700	1.73144
Width (2nd reading)	10	.60	5.80	2.5400	1.44852
Width 3rd reading	10	.00	6.80	2.0500	2.00901

Table 4.14 Group 2: descriptive statistics – width of ulcer in cm

	N	Minimum	Maximum	Mean	S/Deviation
Area (Baseline)	10	.50	34.00	12.5900	11.03061
Area (2nd reading)	10	.20	38.40	9.960	11.10127
Area (3rd reading)	10	.00	51.50	8.9400	15.34704

Table 4.15 Group 2: descriptive statistics – area of ulcer in cm²

	N	Minimum	Maximum	Mean	S/Deviation
Length (Baseline)	11	1.80	12.40	4.3182	3.11314
Length (2nd reading)	11	.80	11.20	3.1636	3.05917
Length (3rd reading)	11	.00	7.70	1.8636	2.55314

Table 4.16 Group 3: descriptive statistics – length of ulcer in cm

	N	Minimum	Maximum	Mean	S/Deviation
Width (Baseline)	11	.60	13.20	3.7818	4.74801
Width (2nd reading)	11	.40	12.40	3.2273	4.33730
Width (3rd reading)	11	.00	7.90	1.8818	2.91576

Table 4.17 Group 3: descriptive statistics – width of ulcer in cm

	N	Minimum	Maximum	Mean	S/Deviation
Area (Baseline)	11	.80	118.50	18.3182	35.17777
Area (2nd reading)	11	.30	101.10	14.4818	30.33812
Area (3rd reading)	11	.00	32.90	5.7727	10.50325

Table 4.18 Group 3: descriptive statistics – area of ulcer in cm²

Tables 4.10, to 4.18 describe the actual differences in wound size in each group over the period of the study.

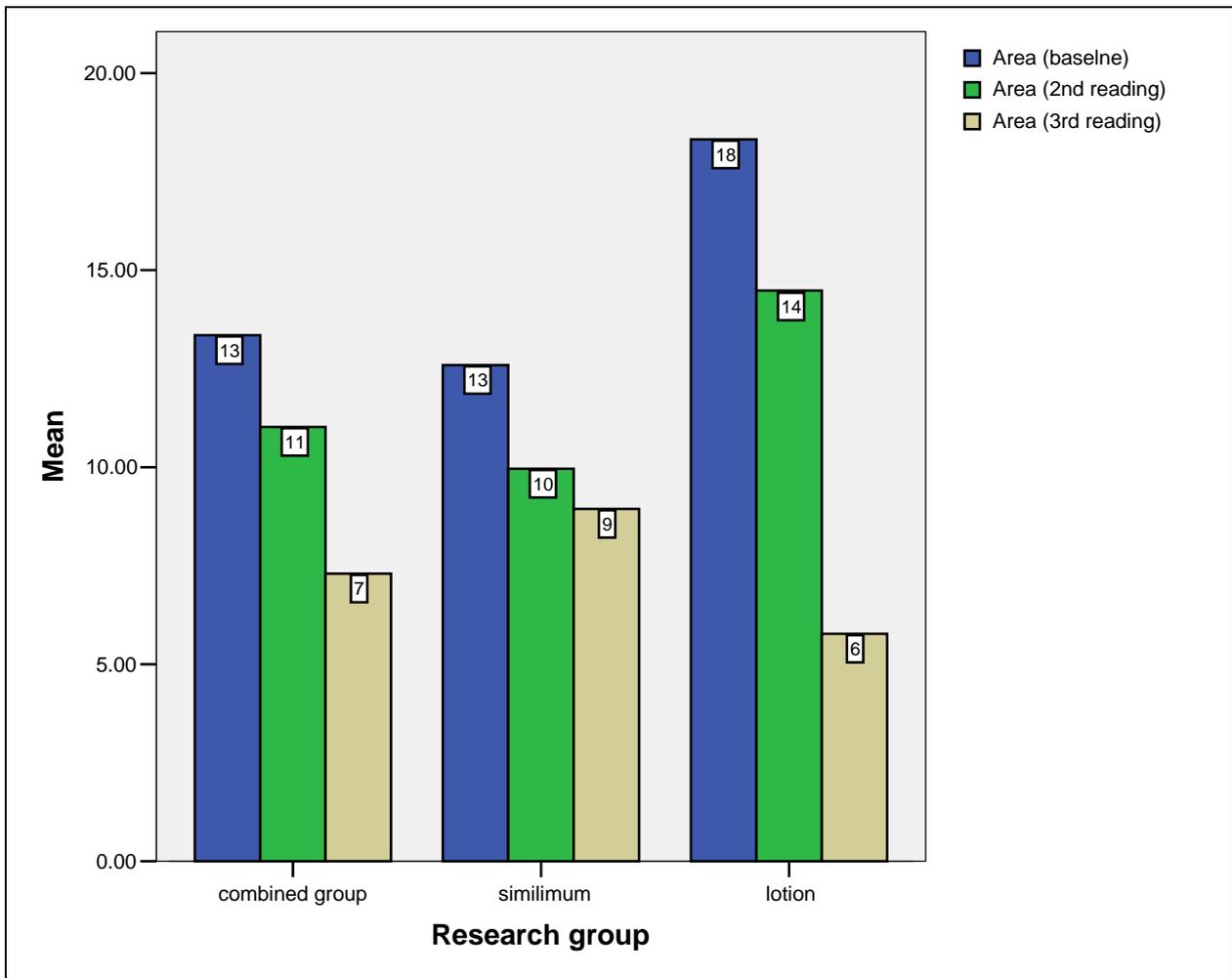


Figure 4.4 Mean wound area reduction in cm² between combined, similimum and lotion groups

Figure 4.4 summarizes the mean wound area reduction in size, from the three measurements. The reduction in wound area gives a better indication of overall healing than either length or width alone.

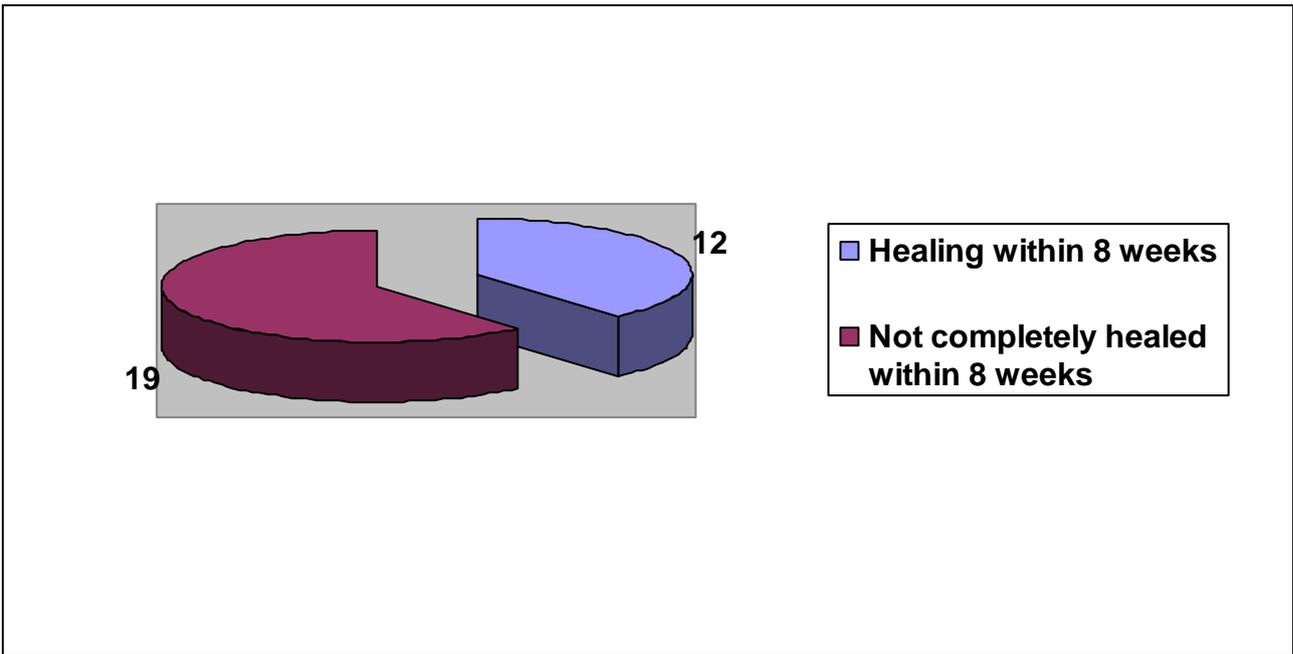


Figure 4.5 Patients whose wounds healed completely within 8 weeks

Figure 4.5 shows that 38.7% of patients (12 out of 31) healed completely within eight weeks.

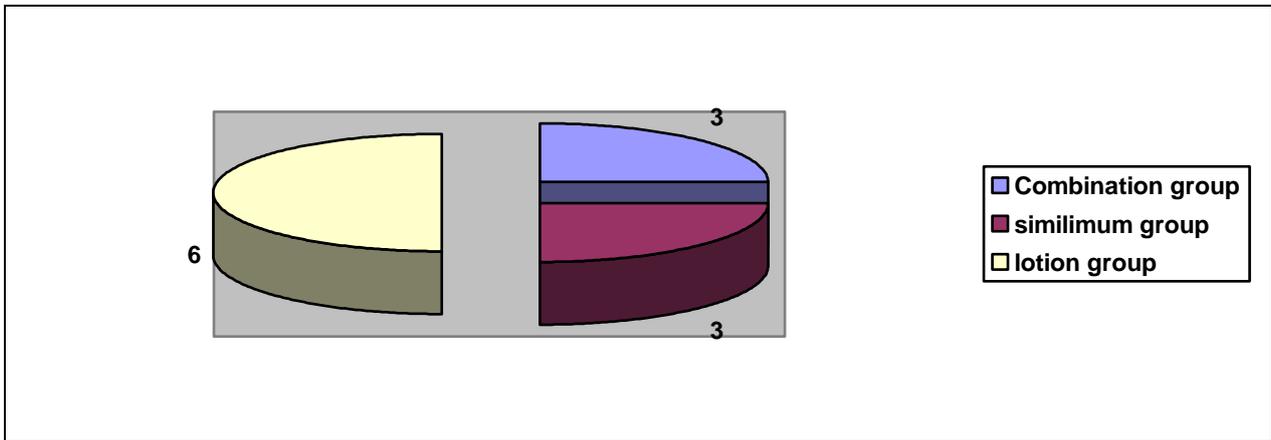


Figure 4.6 Patients in each group whose ulcers healed in eight weeks

Figure 4.6 shows that half of the patients who healed within the eight week period of the study were in the lotion only group, and the other half were divided equally between the combination and similimum only groups.

4.7 HOMOEOPATHIC REMEDIES PRESCRIBED

4.7.1 Total remedies prescribed in the study

Remedies were prescribed after the first consultation, and changed if the patient revealed further symptoms indicating another remedy.

Arsenicum album	1
Calcarea carbonica	6
Calcarea phosphoricum	1
Carcinosinum	1
Causticum	1
Graphites	1
Lycopodium clavatum	4
Naja tripudians	1
Natrum carbonicum	2
Natrum muriaticum	3
Nitricum acidum	1
Nux vomica	1
Pulsatilla praetensis	4
Sepia	2
Silicea	1
Staphysagria	1
Sulphur	4

Table 4.19 Total remedies prescribed during the study

4.7.1.1 The most frequently prescribed remedies

- Calcarea carbonica (6)
- Pulsatilla praetensis (4)
- Sulphur (4)
- Lycopodium clavatum (4)
- Natrum muriaticum (3)

4.7.2 Treatment groups – remedies received

Calcarea carbonica	4
Calcarea phosphoricum	1
Causticum	1
Lycopodium clavatum	3
Naja tripudians	1
Natrum carbonicum	1
Natrum muriaticum	2
Nux vomica	1
Pulsatilla praetensis	2
Sepia	1
Staphysagria	1
Sulphur	3

Table 4.20 Remedies prescribed and received in the treatment groups

The most frequently prescribed remedies in the treatment groups were

- Calcarea carbonica (4)
- Lycopodium clavatum(3)
- Sulphur (3)
- Natrum muriaticum (2)
- Pulsatilla praetensis (2)

4.7.3 Placebo group – remedies prescribed but not received

<u>Arsenicum album</u>	1
<u>Calcarea carbonica</u>	1
<u>Carcinosinum</u>	1
Graphites	1
Lycopodium clavatum	1
Natrum carbonicum	1
Natrum muriaticm	1
Pulsatilla praetensis	2
Sepia	1
Silicea	1
Sulphur	1

Table 4.21 Remedies prescribed in the placebo group

The most frequently prescribed remedy in the placebo group was Pulsatilla (2).

DISCUSSION - CHAPTER 5

The purpose of this double blind placebo controlled study was to evaluate the relative and combined effectiveness of the homoeopathic similimum and topical application of a lotion (*Hypericum perforatum* and *Calendula officinalis*) in the treatment of venous leg ulcers.

The baseline treatment for all patients was compression bandaging with suitable non-medicated dressings. The measurement tool used was Smith & Nephew's Visitrak system for electronic wound measurement.

In this study thirty-six patients were recruited, of whom thirty-one completed the eight week period of treatment and evaluation, or healed completely within this period.

There were 9 male and 22 female patients, which is in keeping with the demographics of venous leg ulcers. The main aetiology of venous leg ulcers being chronic venous hypertension, often caused by varicose veins, which most commonly occur in women due to childbearing and the influence of the reproductive hormones. Those occurring in men appear to be occupationally related, as in prolonged standing, or hereditary in origin.

The age distribution of the patients showed a wide range, with most being in the 51-60 year age-group. A possible reason for this is that many of the patients had had their ulcers for many years duration, and were only seen as a last resort at the Leg Ulcer Clinic. Patients in the younger age groups and who were economically active sought treatment for their ulcers sooner to reduce their frequent absence from work necessitated by the discomfort caused by leaking of the exudate through dressings and bandages, and pain. Patients in the more senior age groups were generally cared for by other family members for many years before finally seeking referral to professional care.

People of advanced age, with chronic venous hypertension, may also be more likely to develop ulceration from a small injury, which takes longer to heal, and may not be felt as acutely painful. The aged may also be more accepting of the ulcer, as they may have some expectations of discomfort due to the aging process.

The intra-group analysis for Group 1 showed a significant result for wound width after the Friedman test, but when the Wilcoxon test was applied to confirm this, it proved to be of no statistical significance. Likewise, the results of the Friedman test in Group 3 showed significance in length, width, and area reduction. This was in comparison to other measurements over time in the same group, and was confirmed by the Wilcoxon test.

When the Kruskal-Wallis inter-group test was applied, the significance was no longer observed. This test compared the measurements over time between the three groups, and the result showed that there was no statistically significant difference between the healing rates in any group. Therefore the null hypothesis was accepted.

These results indicate that there is no greater benefit from giving the combined homoeopathic similimum and topical lotion, compared to either on its own.

It is interesting to note that in the raw data the lotion appeared to have a significant effect on the healing of the ulcers. This study might be repeated using a more frequent application of the lotion, which would be more likely to produce significant results.

It is possible that the homoeopathic remedy given was not in fact the patient's similimum, in which case no improvement in healing could be expected. This may be due to the case-taking procedure being curtailed by the circumstances of the Leg Ulcer Clinic, and in a further study provision could be made for this.

From the descriptive analysis (Tables 4.10 to 4.18) and illustrated by the bar chart (Figure 4.4), it can be seen, however, that there was healing over the period of the study for all groups. Twelve (38.7%) of the 31 patients healed completely within the eight week period of the test. Of these 50% were in the lotion (with placebo similimum) group, and three patients each in the other two groups. Considering that 80% of patients with venous leg ulcers may recover in 12 weeks with compression bandaging alone, this study could be repeated with a longer trial period, as the descriptive results are encouraging.

The most common remedies prescribed in this study were *Calcarea carbonica*, *Pulsatilla praetensis*, *Lycopodium clavatum*, and Sulphur. A brief description of the remedy profile follows in order to highlight the similarities between the actions of the remedy and the symptoms of the patients.

Calcarea carbonica (calcium carbonate) is a major homoeopathic remedy, whose main action is seen in states of impaired nutrition, especially of the glands, skin and bones (Savage, 1999). It is prepared from the middle layer of the oyster shell, which is secreted by the mollusc as a protective covering for its soft, toneless and vulnerable body. The oyster is able to firmly and rapidly close its shell when under threat, demonstrating that it has the potential for strong muscle spasm, and a desire to shield itself from outside threats. The person requiring this remedy exhibits similar features of 'clamming up' when under pressure to conceal the turmoil and anxieties within.

Physically *Calcarea carbonica* patients have a lack of tone and muscular weakness, are often flabby, inactive, pale, and perspire about the head in particular. Their circulation is poor, with cold, clammy hands and feet, or these may occasionally be soft, warm, and moist. They are prone to varicose veins and the skin is described as being unhealthy

and prone to ulceration, with even small wounds taking a long time to heal (Harling and Kaplan, 1987).

Pulsatilla praetensis (pasque flower, or wind flower) is a member of the *Ranunculacea* family and grows primarily on chalk lands in Europe, where it flowers in spring and autumn. It has very attractive deep purple flowers with a rich golden centre. The juice may cause a severe contact dermatitis when exposed to the skin (Van Wyk and Wink, 2004), and may cause ulcers if it enters an open wound (Harling and Kaplan, 1987).

The name of the plant (wind flower) suggests variability which is a prominent feature of a patient requiring this plant in homoeopathic form. The patient may be described as tender-hearted, easily hurt or discouraged, but responding rapidly to kindness and consolation. This person is generally good-tempered, mild and yielding, but may exhibit surprising irritability if upset and can have moods that vary like the wind. Physically, they may be somewhat overweight, with a tendency to swelling of the feet and ankles, which feel tired and heavy. The veins may be distended and become varicose. The skin may ulcerate and produce a green or yellowish exudate, and may have a tendency to bleed, with burning or itching pains that are relieved by cold applications (Harling and Kaplan, 1987). The patient needing *Pulsatilla* needs lots of fresh air and is intolerant of heat.

Lycopodium clavatum (Club moss) falls between the mosses and ferns in its botanical classification. It is found on heath-land where it puts out long hairy stems and roots at intervals. Its above-ground parts are scaly spikes which grow on the ends of stalks.

The prickly character of the plant is mirrored in the features of a person requiring *Lycopodium*, who may exhibit an explosive temper or brilliant talk, and also shows great tenacity to a task, somewhat like the tenacity required of the plant to survive.

Consequently, this patient is uncomfortable in a group, being very self-conscious,

although he dislikes complete solitude. He is apprehensive before an ordeal, but usually rises to the occasion very well. He suffers from poor circulation and physique, as well as the fear of failure under stress (Savage, 1999), and may reveal a somewhat domineering personality to counteract this feeling of inadequacy (Harling and Kaplan, 1987). The legs are described as having tearing pains, cramps, or numbness. Varicose veins and ankle oedema with ulceration and much itching and chronic induration of the skin are features of the patient requiring this remedy.

Sulphur is one of the fundamental constituents of body tissues, and has a centrifugal effect (from within outward). Its main effects are seen on the skin where it produces heat and a burning sensation with itching, made worse by warmth (Savage, 1999). The patient requiring Sulphur often has a dry scaly skin and a tendency to produce eruptions of different kinds, which may become infected easily. These patients often have warm, sweaty hands and feet, and a lack of muscle tone giving a characteristic tendency to slump whilst sitting. The Sulphur patient is averse to water, dislikes getting wet, and is often thirstless. The leg ulcers of Sulphur patients are burning and intensely itchy, with a tendency to become chronic due to constant scratching which helps relieve the itch initially, but eventually gives rise to more burning. The ulcers also develop hypergranulation, giving them a raised, red appearance. There may be varicose veins and oedema in the lower limb, giving rise to ulcers with a yellow, burning exudate (Harling and Kaplan, 1987).

A common theme of these remedies is a lack of muscle tone which can lead to varicosities from weakness of the smooth muscle coat of the veins, and ulceration of the lower limbs, which then becomes chronic. It would be expected that patients who were given the appropriate homoeopathic remedy, which most closely fits the totality of their

symptoms, would benefit by improved healing, as well as a sense of improvement in their general health.

This study has shown that there was no significant difference between the use of a combination of the lotion and similimum, compared to the individual use of each, in their benefit to patients with venous leg ulcers, and confirms the demographics of what is already known about this common and debilitating condition.

CHAPTER 6 CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

The study revealed that although there was no statistically significant difference in the use of the combination of the homoeopathic similimum and topical application of a lotion made from the homoeopathic mother tinctures of *Calendula officinalis* and *Hypericum perforatum*, as opposed to either one or the other treatment alone, the trend was towards a general improvement or complete healing in the eight week period of the study.

The use of the topical lotion was not statistically proven to enhance the rate of healing, although most of the patients who healed within eight weeks were in the lotion (with placebo similimum) group. Possibly the lotion needs to be applied more frequently than was the case in this study.

The placebo lotion was sterile water only, which did not therefore have the same alcohol content as the active lotion (1.1%). This made the effects of the alcohol in the lotion difficult to estimate.

Many homoeopathic remedies are well suited to the treatment of patients with venous leg ulcers. Although the 30CH plussed potency was used for standardisation, it might be better to match the potency more accurately to the patient's particular needs and energy. Some patients might have responded better to a higher potency in less frequent dosage, for example.

This study compared the variables against a baseline treatment of compression bandaging which is known to be effective in healing venous leg ulcers.

6.2 RECOMMENDATIONS

The following recommendations are made for further research:

- Increase the sample size of the study
- Conduct a study in which one group receives similimum only, and another group receives the active lotion only, with the standard compression bandaging.
- Apply the topical lotion at least three times weekly, as once a week was found to be insufficient. Use the same strength alcohol for the placebo lotion as the active lotion for better comparison of effects in a wound.
- Another study might investigate the differences in effectiveness between a lotion prepared from a homoeopathic mother tincture and a lotion prepared from a herbal tincture.
- Consider using different potencies, suited more to the individual, rather than standardizing the potency and dose.
- Conduct the trial over a 12 week period.
- Consider the need to set up a suitable case-taking environment.

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APPENDICES

APPENDIX A

RESEARCH INFORMATION LETTER

TITLE OF RESEARCH PROJECT:

The relative and combined efficacy of the homoeopathic similimum (taken orally) and topical application of a lotion (prepared from the homoeopathic mother tinctures of *Hypericum perforatum* and *Calendula officinalis*) in the treatment of venous leg ulcers.

NAME OF SUPERVISOR: Dr. Ingrid Couchman (M.Tech. Hom.)

NAME OF CO-SUPERVISOR: Dr. David Naude (M.Tech. Hom.)

NAME OF RESEARCH STUDENT: Delia Hoffmann (6th year Homoeopathy student).

Dear Participant,

This research project is aimed at investigating the healing of venous leg ulcers by the use of homoeopathic treatment in conjunction with the application of a lotion of *Hypericum* and *Calendula*. It forms the basis of a mini-dissertation to complete the Masters Degree in Technology: Homoeopathy.

Patients participating in the research must meet the following selection criteria:

- Leg ulcer due to venous hypertension
- ABPI more than 0.8
- Must not be pregnant
- Must be fluent in English.

If you meet these criteria, and are willing to participate in the research, you will be accepted into the study group.

The study will last for a maximum of eight weeks, and the researcher will see you weekly, when the dressings are changed. There will be no extra costs for the weekly visits.

The first consultation will include the following:

Full homoeopathic case-taking interview, to determine which homoeopathic remedy is your similimum.
Physical examination,
Doppler ankle/brachial blood pressure reading.
Wound measurement.

The homoeopathic interview takes about an hour, and afterwards will be discussed in detail with a qualified homoeopathic clinician, before your similimum is prescribed. You will be seen at the Leg Ulcer Clinic at Addington Hospital, thereafter, on a weekly basis for dressing changes and re-bandaging, and to be able to give you the similimum remedy.

The Doppler ABPI, is a measurement of the arterial blood pressure in the affected limb as a ratio of the blood pressure in your upper arm. It is a non-invasive procedure. Your blood-pressure is taken in the normal way on your arm, and then the blood-pressure cuff is wrapped around your lower

leg and the blood-pressure taken again. Instead of using a stethoscope, a Doppler probe is placed over the artery to listen for the pulse.

2

The wound is measured by applying a sterile two-layer grid over the wound. The wound is traced with a permanent marker. The backing is removed and discarded, and the grid is attached to the Wound Treatment Record. The grid is subsequently re-traced with a digital pen to give the dimensions of the wound. This will be repeated weekly.

The study will be a "double-blinded" placebo-controlled study, which means that there will be a random allocation of participating patients into three groups, and neither the patient, nor the researcher will know who is in each group.

One group will receive the homoeopathic remedy and the lotion; another group will receive the lotion and a placebo remedy; the third group will receive the homoeopathic remedy and a placebo lotion.

The homoeopathic remedy will be in liquid form, with drops to take as prescribed. The placebo medication will appear and taste exactly the same as the active remedy, and will be given in the same form.

The lotion will be used at each dressing change, every week for a maximum of eight weeks. The placebo lotion will have the same appearance as the active lotion.

At the end of the study the code will be broken and the information gathered can be analysed statistically

All participants will have dressings changed weekly, and a suitable wound dressing applied to the ulcer. Compression bandaging will be applied over this, from the toes to just below the knee. This helps to improve the circulation in the area and to assist in healing, and must not be removed or interfered with between visits. It must be kept dry. You are encouraged to continue with your normal daily activities and to elevate your leg whenever possible.

On completion of the study, participants who received the placebo, will be offered free homoeopathic treatment for their leg ulcers. The consultation and treatment costs will be covered by the Durban Institute of Technology.

All the information gathered will be kept strictly confidential, and at the end of five years files will be destroyed by shredding.

Your participation in this research is entirely voluntary, and you are free to withdraw at any stage, and without giving any reason should you so wish. If you have any questions about the research study, please contact me or my supervisor on the following number: (031) 204 2041 (Durban Institute of Technology, Homoeopathy Department).

Thank you in advance for assisting in this study.

_____ Date: _____
DELIA HOFFMANN.

APPENDIX B

PATIENT CONSENT FORM

TITLE OF RESEARCH PROJECT:

The relative and combined efficacy of the homoeopathic similimum (taken orally) and topical application of a lotion (prepared from the homoeopathic mother tinctures of Hypericum perforatum and Calendula officinalis) in the treatment of venous leg ulcers.

NAME OF RESEARCH STUDENT: Delia Hoffmann (5th Year Homoeopathy Student)

NAME OF SUPERVISOR: Dr. Ingrid Couchman (M.Tech. Hom.)

NAME OF CO-SUPERVISOR: Dr. David Naude (M.Tech. Hom.)

IT IS IMPORTANT THAT YOU UNDERSTAND THE NATURE OF THIS RESEARCH AND YOUR PARTICIPATION THEREIN.

PLEASE READ THE FOLLOWING QUESTIONS AND CIRCLE THE APPROPRIATE ANSWER:

- Have you read the research information letter? YES/NO
- Have you had the opportunity to ask questions about the research? YES/NO
- Have you received satisfactory answers to your questions? YES/NO
- Have you received enough information about the research? YES/NO
- Do you understand the implications of your involvement in this research? YES/NO
- Do you understand that you are free to withdraw from this research at any time? YES/NO
- Without having to give any reason for withdrawing? YES/NO
- Without your withdrawal affecting your future health care? YES/NO

IF YOU HAVE ANSWERED “NO” TO ANY OF THE ABOVE, PLEASE ASK FOR MORE INFORMATION BEFORE SIGNING BELOW.

PATIENT NAME (in block letters): _____

SIGNATURE: _____

WITNESS NAME (block letters): _____ SIGNATURE _____

RESEARCH STUDENT NAME (block letters) _____

SIGNATURE: _____

APPENDIX C

CASE HISTORY

Name:	Date:
Age:	File No:
Occupation:	Tel:

Main complaint and ulcer history: (Duration; previously healed; trauma; radiation; intermittent claudication; recent immobilisation).

Family history:

Medical History: (illnesses/injuries/surgery/tests/menstrual/gynae/obs)

Diabetes:	Yes/No	Cardiac problems:	Yes/No
Tuberculosis:	Yes/No	Renal problems:	Yes/No
Varicose veins:	Yes/No	SLE;	Yes/No
Rheumatoid arthritis:	Yes/No	DVT:	Yes/No

Drug History: (specifically – Steroids; cytotoxic agents; aspirin/warfarin) (Include vaccinations).

Allergies:

Smoking:

Alcohol:

Sleep: (hours/position/dreams):

MODALITIES:

Appetite & food preferences/aversions:

Thirst:

Weather & climate preferences;(wind/drafts/sunshine/cloudy/rain/dry/thunderstorms)

Temperature preferences & perspiration: (warm/chilly)

Time modalities:

Laterality:

Mental symptoms: (Fears? Anxiety? Expression of emotions? Sensitivity? Irritability? Moody? Tearful? Joys/depressions? Jealousy? Self-confidence? Open? Closed? Fastidiousness? Methodical? Hurried? Music? Noise?)

Activities of Daily Living: (ADL)

GENERAL SYSTEMS ENQUIRY:

Nervous system: (including headaches)

ENT: (How frequently do you get colds or flu? Sinus trouble?)

CVS:

Resp:

GIT: (Incl. Dyspepsia/bowel habits)(Comment on nutritional status: normal/obese/malnourished)

GU:

Muscular-skeletal:

Skin: (including hair/nails/varicose veins/eczema)

APPENDIX D

PHYSICAL EXAMINATION

Name:	Date:
Age:	File No:

Pulse:	Blood pressure:
--------	-----------------

Jaundice:	Anaemia:	Cyanosis:	Clubbing:
Oedema:	Lymphadenopathy:	Dyspnoea:	

Leg:

Shape: normal/ muscle wasting/inverted champagne bottle. Ankle circumference:

Skin: normal/shiny/pale/eczematous changes

Hair: present/absent

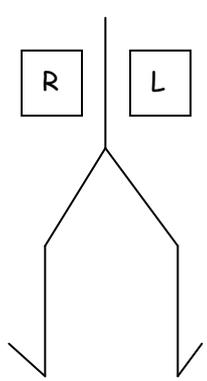
Oedema: Generalised/ankles only/progressive/constant.

Toenails: normal trophic changes/

Feet: Deformities/dorsiflexion

Sensation: Normal/peripheral neuropathy/autonomic neuropathy.

Pulses: Femoral/popliteal/posterior tibial/dorsalis pedis.



GENERAL SYSTEMS EXAMINATION

ENT:

RESP:

CVS:

GIT:

GU:
M/SKELETAL;

CNS/PNS:

SKIN (including leg ulcer)

Wound bed:	Healthy Slough	Granulating Necrosis	Epithelialising
Borders:	Healthy Macerated	Well defined	Punched-out
Exudate:	High	Moderate	Low
Odour:	None	Some	Offensive
Signs of infection?			

(Adapted from Addington Hospital Leg Ulcer Clinic History Sheet)

APPENDIX E

WOUND TREATMENT RECORD

Name:	Date:
File No:	

ABPI (1) Date:	ABPI (2) Date:	ABPI (3) Date:
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VISITRAK WOUND MEASUREMENT:

(1) Date:	(2) Date:	(3) Date:
(4) Date:	(5) Date:	(6) Date:
(7) Date:	(8) Date:	

WEEKLY DRESSING & BANDAGE CHANGE:

DATE	DRESSING USED	COMMENTS
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		

APPENDIX F

METHOD 10 – GERMAN HOMOEOPATHIC PHARMACOPOEIA

Method 10: Granules (Globuli).

Preparations made by Method 10 are granules (globuli). They are produced by transferring dilution to sucrose granules (size 3: 110-130 granules weigh 1g) by moistening 100 parts of sucrose granules evenly with 1 part of dilution. The ethanol content of the dilution should be not less than 60 per cent. If this is not the case, it will be necessary to go against Methods 1 to 4b and produce the final potentization of the decimal or centesimal dilution which is to be used with ethanol 62 per cent.

Following impregnation in a closed vessel, the granules (globuli) are air-dried. They are labelled with the dilution stage of the dilution used to impregnate them.

The following granule sizes may be used in special cases:

- Size 1 470-530 granules weigh 1g
- Size 2 220-280 granules weigh 1g
- Size 3 110-130 granules weigh 1g
- Size 4 70- 90 granules weigh 1g
- Size 5 40– 50 granules weigh 1g
- Size 6 22– 28 granules weigh 1g
- Size 7 10 granules weigh approx. 1g
- Size 8 5 granules weigh approx. 1g
- Size 9 3 granules weigh approx. 1g
- Size 10 2 granules weigh approx. 1g

APPENDIX G

METHOD 3a GERMAN HOMOEOPATHIC PHARMACOPOEIA

Method 3a: Mother tinctures and liquid dilutions

Mother tinctures for Method 3a are produced according to Method 2a (ethanol content approx. 60 per cent), with the following difference: The required amount of ethanol 86 per cent (E3), is calculated according to Formula (3)

$$E3 = \frac{2 M D}{100} \text{ (kg)}$$

- M = weight of plant material in kg
- D = loss on drying in sample, in per cent.
- Use ethanol 62 per cent to adjust to any concentration required as per Monograph.
- Following careful selection and identification, the plants or parts of plants are finely minced. A sample is used to determine loss on drying. Eighty-six per cent ethanol is added to the minced plant material according to the formula. It is stored in well sealed containers at a temperature not exceeding 20 degrees centigrade. (This alcohol content ensures sterility of the herbal tincture). The mixture is allowed to stand for not less than 10 days and shaken repeatedly. It is then expressed and filtered. This is known as the Mother Tincture, and from this the homoeopathic remedies can be made, by the processes of serial dilution and succussion.

The homoeopathic mother tincture was used to make the lotion, (diluted with 5 parts sterile water and 1 part tincture) as recommended by Parceval SA, the manufacturer. The alcohol strength of the final lotion is then approximately 1.1%. Homoeopathic remedies are made up from the mother tincture by a process of serial dilution and potentization.

- **Potentization**

The first decimal dilution (1x) is made with

- 3 parts of the mother tincture and
- 7 parts of ethanol 62 per cent,

the 2nd decimal dilution (2x) with

- 1 part of the 1st decimal dilution and
- 9 parts of ethanol 62 per cent.

Subsequent dilutions are produced in the same way. For dilutions from the 4th decimal onwards use ethanol 43 per cent.

The 1st centesimal dilution (1c) is made with

- 3 parts of the mother tincture and
- 97 parts of ethanol 62 per cent,

the 2nd centesimal dilution (2c) with

- 1 part of the 1st centesimal dilution and
- 99 parts of ethanol 43 per cent.

Subsequent dilutions are produced in the same way.

APPENDIX H: VISITRAK DATA (example)

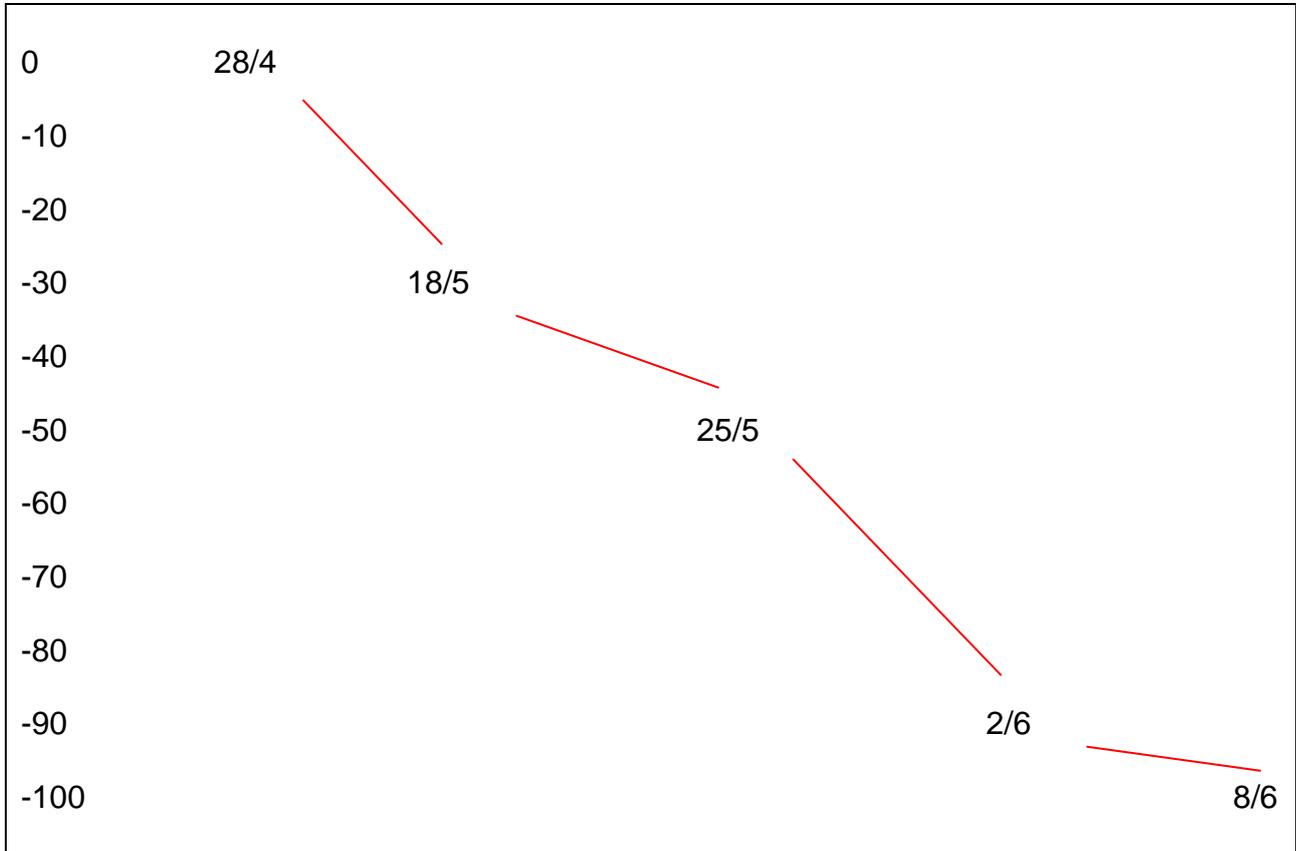
(Copied from Visitrak Data Capture, courtesy of Smith & Nephew).

Patient name						
Date of birth						
Reference no.						
Wound location	Foot-dorsum-lateral-right					
Wound type	Venous leg ulcer					
Date	Assessments to date	Area Cm ²	Length Cm	Width cm	% Area Change from initial	% Area Change From last
8 June	5	0.0	0.0	0.0	-100.0	-100.0
2 June	4	1.1	1.1	1.9	-86.7	-71.1
25 May	3	3.8	3.1	2.1	-54.2	-36.7
18 May	2	6.0	2.8	2.5	-27.7	-27.7
28 April	1	8.3	3.6	3.0	0	0

APPENDIX J: VISITRAK GRAPH (example)

(Copied from Visitrak, courtesy of Smith & Nephew)

Percent area change from initial



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