

**The effectiveness of topical Homoeopathic preparation of
Selenium sulphide 8X shampoo in the management of dandruff
(Pityriasis Capitis).**

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Master's Degree in Technology: Homoeopathy, in the Faculty of Health Sciences
at the Durban Institute of Technology.

I Silvana Teleman, declare that this mini dissertation represents my own work,
both in conception and execution.

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DEDICATIONS

This research is dedicated to:

My Parents

Dorin and Gabriela Teleman for all the love and support they have shown me throughout my life.

My Husband

Jonathan Nienaber who's love has changed my life and made me who I am. His love and endless support has made this possible.

Appendix E

1. Comparison of treatment criteria for the Placebo Group

The Friedman's Test was conducted to determine whether there was any significant difference for each individual variable within the Placebo Group at each consultation.

There were no significant differences found for any individual criteria at each consultation.

1.1. Intra-Group Tests for Placebo Group: Irritation

Table 16- Friedman's Test: Irritation (Placebo Group)

Consultation	Mean Score	Mean Rank	P-Value
Day 1	5.0619	2.75	.000
Day 14	3.2694	1.81	
Day 28	2.5000	1.44	

The above table demonstrates a significant improvement in the variable Irritation for the Placebo Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed.

1.1.1. Dunn procedure for Day 1 and Day 14

$$R_j - R_i \geq z \sqrt{\frac{bk(k+1)}{6}}$$

b= 16

K= 3

α = 0.15

z = 1.914

Therefore:

/5.0619-3.2694/< 10.8272

/1.7925/< 10.8272

The above results showed that there was no significant difference between Day 1 and Day 14 within the Placebo Group for variable Irritation.

1.1.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

/3.2694-2.5000/< 10.8272

/0.7694/<10.8272

The above results showed that there was no significant difference between Day 14 and Day 28 within the Placebo Group for variable Irritation.

1.2. Intra-Group Tests for Placebo Group: Flaking

Table 17- Friedman's Test: Flaking (Placebo Group)

Consultation	Mean Score	Mean Rank	P-Value
Day 1	6.0825	2.94	.000
Day 14	3.8763	1.91	
Day 28	2.6250	1.16	

The above table demonstrates a significant improvement in the variable Flaking for the Placebo Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed

1.2.1. Dunn procedure for Day 1 and Day 14

AS PER 1.1.1.

Therefore:

$$/6.0825-3.8763/< 10.8272$$

$$/2.2062/< 10.8272$$

The above results showed that there was no significant difference between Day 1 and Day 14 within the Placebo Group for variable Flaking.

1.2.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$$/3.8763-2.6250/< 10.8272$$

$$/1.2513/<10.8272$$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Placebo Group for variable Flaking.

1.3. Intra Group Tests for Placebo Group: Greasiness

Table 18- Friedman's Test: Greasiness (Placebo Group)

Consultation	Mean Score	Mean Rank	P-Value
Day 1	4.2088	2.94	.000
Day 14	2.7494	1.75	
Day 28	1.7500	1.31	

The above table demonstrates a significant improvement in the variable Greasiness for the Placebo Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed

1.3.1. Dunn procedure for Day 1 and Day 14.

AS PER 1.1.1.

Therefore:

$$/4.2088-2.7494/< 10.8272$$

$$/1.4594/< 10.8272$$

The above results show that there was no significant difference between Day 1 and Day 14 within the Placebo Group for variable Greasiness.

1.3.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$$/2.7494-1.7500/< 10.8272$$

$$/0.9994/<10.8272$$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Placebo Group for variable Greasiness.

1.4. Intra-Group Tests for Placebo Group: Itching

Table 19- Friedman's Test: Itching (Placebo Group)

Consultation	Mean Score	Mean Rank	P-Value
Day 1	6.9375	2.84	.000
Day 14	3.5625	1.81	
Day 28	2.9375	1.34	

The above table demonstrates a significant improvement in the variable Itching for the Placebo Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed

1.4.1. Dunn procedure for Day 1 and Day 14

AS PER 1.1.1.

Therefore:

$$/6.9375-3.5625/< 10.8272$$

$$/3.3375/< 10.8272$$

The above results show that there was no significant difference between Day 1 and Day 14 within the Placebo Group for variable Itching.

1.4.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$$/3.5625-2.9375/< 10.8272$$

$$/0.625/<10.8272$$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Placebo Group for variable Itching

1.5. Intra-Group Tests for Placebo Group: Percentage of Scalp Involved

Table 20- Friedman's Test: Percentage of Scalp Involved (Placebo Group)

Consultation	Mean Score	Mean Rank	P-Value
Day 1	6.0000	2.81	.000
Day 14	4.0625	1.84	
Day 28	2.6769	1.34	

The above table demonstrates a significant improvement in the variable Percentage of Scalp Involved for the Placebo Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed.

1.5.1. Dunn procedure for Day 1 and Day 14

AS PER 1.1.1.

Therefore:

$$/6.0000-4.0625/< 10.8272$$

$$/1.9375/< 10.8272$$

The above results show that there was no significant difference between Day 1 and Day 14 within the Placebo Group for variable Percentage of Scalp Involved.

1.5.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$$/4.0625-2.6769/< 10.8272$$

$$/1.3856/<10.8272$$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Placebo Group for variable Percentage of Scalp Involved.

1.6. Intra-Group Tests for Placebo Group: Overall Impression

Table 21- Friedman's Test: Overall Impression (Placebo Group)

Consultation	Mean Score	Mean Rank	P-Value
Day 1	6.2706	2.94	.000
Day 14	4.0006	1.91	
Day 28	2.6044	1.16	

The above table demonstrates a significant improvement in the variable Overall Impression for the Placebo Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed.

1.6.1. Dunn procedure for Day 1 and Day 14

AS PER 1.1.1.

Therefore:

$$/6.2706-4.0006/< 10.8272$$

$$/2.2700/< 10.8272$$

The above results show that there was no significant difference between Day 1 and Day 14 within the Placebo Group for variable Overall Impression

1.6.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

/4.0006-2.6044/< 10.8272

/1.3962/<10.8272

The above results showed that there was no significant difference between Day 14 and Day 28 within the Placebo Group for variable Overall Impression

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ABSTRACT

The purpose of this study was to evaluate the effectiveness of topical Homoeopathic preparation, with Selenium sulphide 8X shampoo, in the management of dandruff (Pityriasis Capitis).

This double-blind, placebo-controlled study consisted of 33 subjects, between the ages of eighteen and fifty. These subjects were obtained through advertising on the Durban Institute of Technology campus and news letter, health shops and pharmacies.

Subjects were included into the study if they exhibited signs and symptoms of dandruff, namely: flaking, irritation, greasiness and itchiness of the scalp. The subjects included were randomly divided into two groups. These groups were the Treatment Group (Selenium sulphide 8x shampoo) and the Placebo Group, which contained 15 subjects and 16 subjects respectively. 33 subjects signed on for the study, but during the period of the study 2 subjects withdrew from the research. Two follow-up consultations were scheduled, at intervals of 14 days after the initial consultation, making the total treatment period one month.

The data was obtained by means of a Visual Analogue Scale (V.A.S.), which was completed by the researcher, the patient and an independent third party (a clinician or concomitant-researcher, Kent) at every consultation. Due to the size

of the samples, namely 15 and 16 in each group, the non-parametric Statistical Tests were used, namely The Friedman Test and The Dunn Procedure and The Mann Whitney U Test.

The results showed that there was no significant difference in the total average score of dandruff criteria symptoms between the Treatment Group and the Placebo Group at each consultation (day 1 $p=0.922$, day 14 $p=0.922$, day 28 $p=0.572$), although within both groups there was a significant improvement. Therefore, it is concluded that Selenium sulphide 8X *per se* is not effective in the management of dandruff (Pityriasis Capitis).

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THE DEFINITION OF TERMS

Afferent Nerves

Any nerves that transmit impulses from periphery towards the Central Nervous System (Rook, Wilkinson and Ebling, 1992: 180).

Antimicotic

Product that has antifungal properties (Rook, Wilkinson and Ebling, 1992: 180).

Apocrine Glands

These are sweat glands in the axilla, perianal and pubic areas, scrotum, labia majora and around the nipples, which open into hair follicles, and are stimulated by emotional stress (Bickley, 2003: 96).

Corneocytes

These are dead cells forming the outermost layer of the skin (Rook, Wilkinson and Ebling, 1992: 60).

Cuboidal Cells

Cuboidal cells are epithelial cells that have the shape of a cube (Rook, Wilkinson and Ebling, 1992: 50).

Dendritic Cells

An antigen-presenting immune cell that function to initiate the immune response by activating lymphocytes and stimulating the secretion of cytokines (Rook, Wilkinson and Ebling, 1992: 52).

Desmosomes

Type of adherent junction that links intermediate filaments and cell membranes within and between cells (Montagna and Parakkal, 1974: 25).

Eccrine Glands

These are sweat glands which are widely distributed, they open directly onto the skin surface, and by their sweat production help control body temperature (Bickley, 2003: 96).

Efferent Nerves

These nerves convey impulses from the Central Nervous System to effector organs (Rook, Wilkinson and Ebling, 1992: 180).

Folliculitis

Inflammation of the hair follicles (Rook, Wilkinson and Ebling, 1992: 354).

Heterogeneous

Consisting of or composed of dissimilar elements (Conn, Stumpf, Bruening and Doi, 1987: 601).

Keratilysis

The detachment of keratin cells (Montagna and Parakkal, 1974: 58).

Keratin

A family of scleroproteins that form the primary constituents of epidermis, hair nails and horny tissue (Montagna and Parakkal, 1974: 52).

Keratinisation

The development of or conversion into keratin (Rook, Wilkinson and Ebling, 1992: 74).

Keratinohyalin granules

These are blue-staining granules found in the cells of Stratum granulosum (Montagna and Parakkal, 1974: 58).

Keratostasis

The reduction of keratin production (Montagna and Parakkal, 1974: 58).

Lamellar granules

These are granules that discharge a lipid substance into the intercellular space facilitating intercellular cohesion (Montagna and Parakkal, 1974: 346).

Non-keratinocytic Cells

These are cells that do not produce keratin (Rook, Wilkinson and Ebling, 1992: 60)

Placebo

An inactive agent used for comparison with the substance or method to be tested in a controlled trial and indistinguishable from it (Swayne, 2000: 162).

.

Potency

The stage of altered remedial activity to which a drug has been taken by means of a mathematico-mechanical process of deconcentration with succussion, or by trituration of the medical substance, which is thus brought to a state of diminutive and infinitesimal subdivision (Gaier, 1991: 601).

Simillimum

The drug picture most like the clinical picture in the patient. It is arrived at through careful analysis of information found in the homeopathic case record (Swayne, 2000: 194).

Squamae

A scale or plate like structure (Rook, Wilkinson and Ebling, 1992: 62)

Thermoinsulation

Thermoinsulation is a process that prevents the body from losing heat (Conn, et al. 1987: 267).

CHAPTER ONE

INTRODUCTION

1.1. OVERVIEW

This study used a quasi Homoeopathic Treatment i.e. prepared according to Homoeopathic principles of dilution and succussion but not prescribed according to the Law of Similars. Smith, Baker and Williams (2002: 59) investigated, a Homoeopathic preparation prepared from therapeutically known allopathic treatment for skin conditions, to assess the effect it will have on dandruff and seborrheic dermatitis in a low homoeopathic potency. In light of the above mentioned study, this study used a Homoeopathic preparation of Selenium sulphide 8X which is a known allopathic treatment for dandruff in its crude form (Wolverton, 2001:164), to assess the effect it had on dandruff symptoms when used in Homoeopathic potency.

Dandruff, also known as Pityriasis capitis, Pityriasis simplex or furfuracea, is a milder form of Seborrheic dermatitis, and the yeast *Pityrosporum ovale* (P.ovale) is involved in its pathogenesis (Baran and Maibach, 1994: 133). The condition is more prevalent between the ages of 18 and 50. At the age of 20, some 50% of the population is affected in some degree (Baran and Maibach, 1994: 133).

Dandruff is not a life threatening disease, but it does however cause low self esteem¹, and therefore this is the reason why this research was conducted.

The conventional treatment for dandruff is based on two concepts; keratostasis (reducing the mitosis rate) and keratolysis (detachment of loose cell complexes in the horny layer of the epidermis). The keratostatic agents are: Tar distillate 1.5%; Sodium ichthammol 2%; Cadmium sulphide 1%; Selenium sulphide 2.5%; Magnesium pyridinethione 1%; Zinc pyridinethione 1-2%. The following agents have keratolytic effects: Surfactants; Magnesium pyridinethione 1% Colloidal sulphur 10%. The treatment consists of anti-dandruff shampoos that contain one or more of the various substances that act in the above-mentioned manner.

Selenium sulphide is one of the most common main ingredients in anti-dandruff shampoos. Selenium sulphide reduces the cell turnover and it has a direct antimicrobial effect (Wolverton, 2001:164).

In a study done to assess the effectiveness of Selenium sulphide in the treatment of dandruff, Selenium sulphide was found to be effective but adverse experiences were reported (Danby, Maddin, Margesson and Rosenthal. 1993: 1011). This study therefore aimed to reduce the side effects of Selenium sulphide in shampoo form through Homoeopathic potentiation.

1.2. AIM OF THE STUDY

The aim of this double-blind placebo-controlled study was to determine the effectiveness of Selenium sulphide 8x shampoo in the treatment of dandruff, as measured by a Visual Analogue Scale (V.A.S).

1.3. RESEARCH OBJECTIVE

To determine the effectiveness of Selenium sulphide 8X shampoo, compared to placebo, in the treatment of dandruff, as measured by a Visual Analogue Scale.

1.4. STATEMENT OF HYPOTHESIS

The null hypothesis (H_0) states that there is no significant difference within the Treatment or Placebo Groups as assessed on the Visual Analogue Scale and compared at the $\alpha = 0.05$ level of significance. The alternate hypothesis (H_1) states that there will be a significant difference in the readings of the Visual Analogue Scale for the Treatment and Placebo Groups.

1.5. THE SIGNIFICANCE OF THE STUDY

The significance of this study is to find a less toxic alternative to the chemical dose of Selenium Sulphide, in the management of dandruff.

CHAPTER TWO

REVIEW OF RELEVANT LITERATURE

2.1. INTRODUCTION

Dandruff does not have many physical implications but it does affect the sufferers on a psychological level.¹ The following discussion focuses on literature related to dandruff. It seeks to explore the current understanding of the subject in terms of aetiology, prevalence, physiology and management. In order to understand this disease the normal skin structure will be discussed.

2.2. STRUCTURE OF THE SKIN

The skin is composed of two distinctive layers, the epidermis and the dermis (Marieb, 1998: 143). As can be seen in Figure 2.1, the epidermis is divided into Stratum corneum, Stratum lucidum, Stratum granulosum, Stratum spinosum and Stratum basale, while the dermis is divided into the Papillary region and the Reticular region.

2.2.1. THE EPIDERMIS

The epidermis is a multilayered stratified squamous epithelium (Figure 2.2) from which the apocrine gland and the eccrine sweat gland arise, and it consists of four cell types and four defined layers (Shier, Butler and Lewis, 1986: 101). It lacks blood vessels and nerve endings (Antony and Jones, 1989: 101).

i) Basal cell/ germinative layer

This is a continuous layer of small cuboidal cells with large, dark stained nuclei and dense cytoplasm. It consists of three to five cell layers in which a drastic change in the appearance of keratinocytes occurs (Marieb, 1998: 144). The basal cell layer is the germinative layer of the epidermis, 50% of the daughter cell population contributing to the developing epidermis (Van De Graaff, 1998:103).

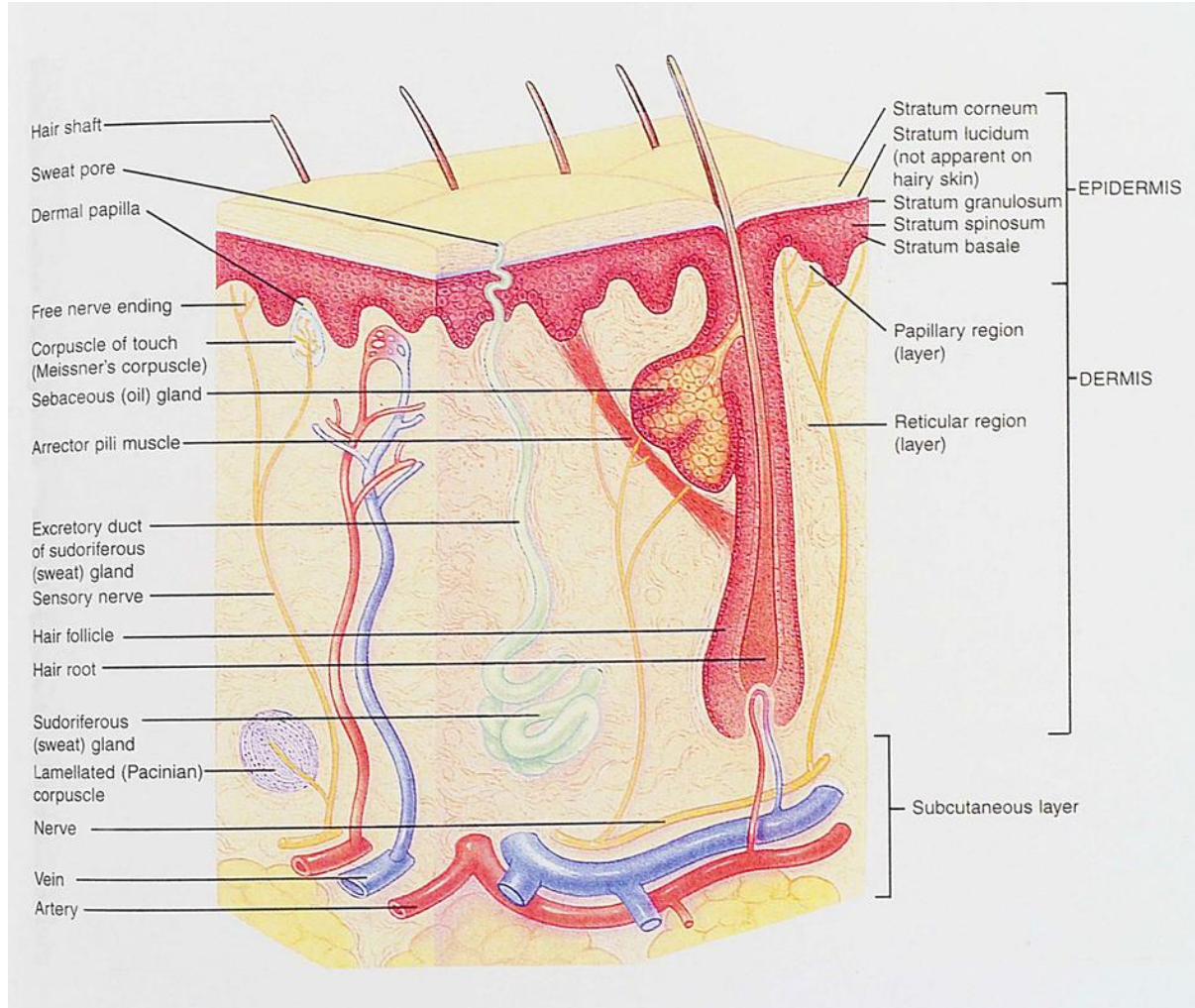


Figure 2.1

Structure of the skin and the underlying subcutaneous tissue

(Tortora and Grabowski, 1996: 986)

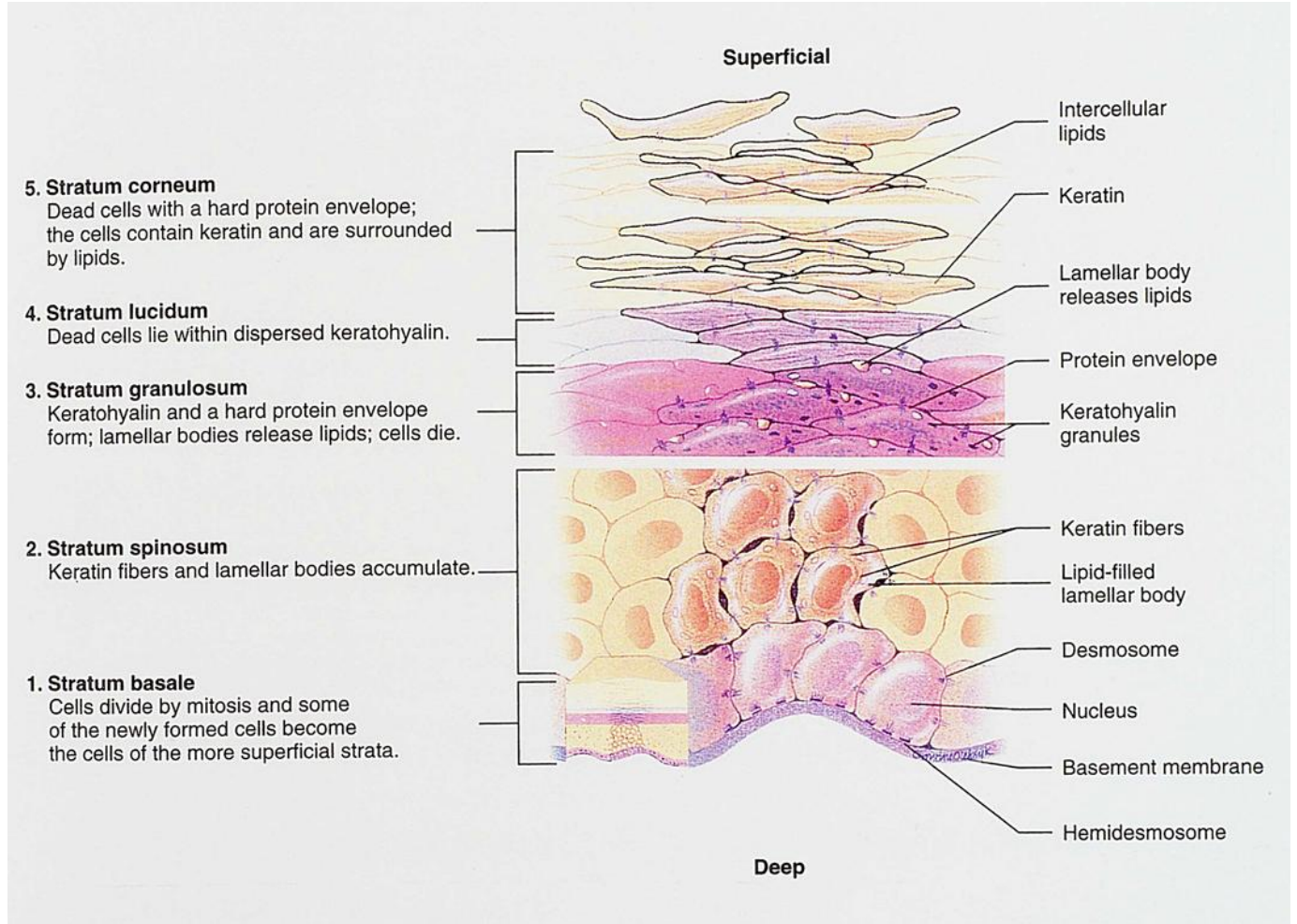


Figure 2.2

The layers of the epidermis

(Steeley, Stephens and Tate, 1998)

The cells found in the basal layer are: Melanocytes, Merckels cells and Langerhans cells.

(a) Melanocytes

These are dendritic cells, which contain melanin granules that are responsible for skin and hair colouration (Marieb, 1998: 144).

(b) Merkels cells

These are non-keratinocytic cells which attach to adjacent keratinocytes by desmosomes. These cells are thought to function as slowly adapting sensory touch receptors (Marieb, 1998: 144).

(c) Langerhans cells

These cells are found in the suprabasal layer and have dendritic processes, which extend between keratinocytes. These cells are thought to play a role in delayed hypersensitivity reaction (Marieb, 1998: 144).

ii) Stratum Spinosum

The Stratum Spinosum is several layers thick. The cells contain intermediate keratin filaments (Marieb, 1998: 145).

iii) Stratum Granulosum

This layer consists of three to five layers of cells and is so called due to the presence of keratinohyalin granules. These granules are found within the cytoplasm of these cells giving the cells a granular appearance. Lamellar granules also contribute to the granular appearance of these cells. These granules discharge a glycoprotein into the intercellular space facilitating intercellular cohesion (Marieb, 1998: 144).

iv) Stratum corneum

Keratin and the thickened plasma membranes of cells in this layer protect the skin against abrasions and penetrations, and the glycolipid between its cells waterproofs this layer. The shingle-like cells remnants of this layer are referred to as cornified, or horny cells, which constitute the flakes associated with dandruff (Marieb, 1998: 145).

2.2.2 THE DERMIS

The dermis is a strong, flexible connective tissue layer. It is richly supplied with nerve fibres, blood vessels, and lymphatic vessels (Marieb, 1998: 145).

2.2.3. CUTANEOUS BLOOD VESSELS

The cutaneous blood supply, in the form of two vascular plexuses, arises from blood vessels within the subcutaneous fat. The deep vascular plexus lies at the interface between the dermis and the subcutaneous fat. The superficial plexus lies in the upper reticular dermis (Van De Graaff, 1998: 108).

2.2.4. CUTANEOUS NERVES

The dermis of the skin has an extensive innervation. The efferent nerve supply is derived from the sympathetic division of the autonomic nervous system and it controls cutaneous vasculature and skin appendages. The afferent nerve supply consists of a number of sensory receptor types (Van De Graaff, 1998: 108).

2.2.5. SUBCUTANEOUS FAT

This layer of fat plays an important role in thermoinsulation and nutritional storage (Marieb, 1998: 143).

2.3. DANDRUFF

Dandruff is a common scalp condition that occurs when dead skin is shed, producing irritating white flakes (Balch and Balch, 2000: 313). Dandruff is a subclinical, chronic, hyperproliferative disorder of the scalp that follows from disruption of cohesion between corneocytes (the cells that make up the stratum corneum which is the outer most layer of the epidermis). The condition may be episodic, recurrent or constant.¹

2.3.1 PATHOPHYSIOLOGY

In a healthy scalp, the basal cells formed in the stratum germinativum migrate through subsequent layers towards the surface, eventually reaching the outer most layer, the stratum corneum. As they move upwards, the cells flatten, gain keratohyaline and lose their nucleus.⁴

The normal shedding process runs through a 30 day cycle. In dandruff, the cell turnover, which causes shedding, is accelerated and cells reach the epithelium in 10-15 days.⁴

Dandruff appears as an abundance of small white or grey scales called squamae that accumulate on the scalp in localized or defused patches. Borders around the affected area are usually indistinct, but individual patches that shed loose cells may be observed. The size of the scales is heterogeneous at a given site on the scalp and their abundance may vary from one location to another and over time.¹

2.3.2. PITYROSPORUM OVALE

Historically, the first mention of an infectious organism as a possible cause was in 1873, when Rivolta demonstrated the presence of a micro-organism isolated from a patch of seborrheic dermatitis in his own beard. The same organism was also identified the following year by Malassez, in 1887 by Unna, and in 1904 by Sabouraud (Wolverton, 2001: 164). Researchers have disagreed openly for more than a century about the possible role of a fungus or a yeast, as the aetiologic origin of dandruff and seborrheic dermatitis.

The identity of the microorganism was eventually confirmed to be the lipophilic yeast *Pityrosporum ovale* (*P. ovale*) of the *Malassezia* genus, a known inhabitant of the human cutaneous flora (Peter and Richarz- Barthauer, 1995: 132).

In 1984, researchers concluded that *P. ovale* fulfilled all the postulates for its positive identification as the cause of dandruff and seborrheic dermatitis. Results from several subsequent investigations confirmed this (Peter and Richarz- Barthauer, 1995: 132).

It is theorized that the causative microorganism changes spontaneously from one morphological form to another. This has led to the conclusion that *P. ovale*, *P. orbiculare*, and *Malassezia furfur* are variants of the same organism (Peter and Richarz- Barthauer, 1995: 132). The majority of the scientific community recognizes that *Malassezia* is the more proper term to describe the causative yeast.

The human scalp is extensively colonized by microorganisms at a density of between 10^3 and 10^5 organisms per mm^2 (Fitzpatrick, Eisen, Wolff and Austen, 1987: 978). They include *staphylococci*, *Propionibacterium* spp., and yeasts of the *Malassezia* genus. Within this population, the relative proportion of *Malassezia* yeasts is multiplied by a factor of 1.5 to 2 on the scalp of persons with dandruff, where they may represent almost 75% of the total flora.¹ *P. ovale* comprises 46% of

the scalp flora in healthy individuals, 74% in patients with dandruff and 82% in patients with seborrheic dermatitis (Peter and Richarz- Barthauer, 1995: 132). Even though the role of *P. ovale* is still disputed, it has been shown that patients with dandruff have an increased population of *P. ovale* on the scalp (Baran and Maibach, 1994: 133) and patients with dandruff also have high antibody titres to pitysporum (Rook, Wilkinsons and Ebling, 1992: 546).

Even with evidence mounting over the years that a yeast was the aetiologic cause of dandruff and seborrheic dermatitis, the postulate that a single microorganism might be responsible for inciting either or both afflictions was not readily accepted by everyone in the scientific community.¹

According to Schuster (1984: 235) a number of factors may have contributed to this disbelief:

- a) The most important was the introduction into therapy and widespread use of powerful corticosteroid drugs. The temporary benefit conveyed by topical corticosteroids was probably responsible for general acceptance of the theory that the symptoms and signs of dandruff were due to primary cellular (epidermal) hyperproliferation (Schuster, 1984: 235).
- b) There were no effective topical antifungal therapies available to eradicate the postulated microorganism and thereby confirm it to be the causative agent (Schuster, 1984: 240).

- c) The pure simplicity of the theory of cellular hyperproliferation encouraged its general acceptance (Schuster, 1984:241).

In the early 1970s, the pathogenesis of dandruff was separated from that of seborrheic dermatitis. It became the vogue to consider that dandruff was due to cellular hyperproliferation, and seborrheic dermatitis to an inflammatory process.⁴

The outcome of a 1982 study determined that patients with pityrosporal folliculitis who were treated with oral Ketoconazole (an antifungal) showed clinical improvement. This improvement was subsequently confirmed by biopsy and mycology studies. The outcome established that the clinical response was related to the presence or absence of *Pityrosporum* yeasts (Peter and Richarz- Barthauer, 1995: 132).

From these study results, it was demonstrated that the intensity of symptoms correlated directly to the quantity of *Pityrosporum* organisms present in the total microfloral content of the scalp. A detailed review of the literature confirmed that the yeast *Pityrosporum* was the direct, probable cause of both dandruff and seborrheic dermatitis. The severity of this condition increases with the number of organisms present on the scalp (Hay and Graham-Brown, 1975: 4.)

This known difference in concentrations opens the door to an interesting postulate; that is, it may help explain the exacerbation of dandruff symptoms during the winter. Fungal organisms thrive when the skin area is warm and moist and circulation of air is restricted. This condition would be maximized during winter with sweating while wearing tightly-fitting caps or hats.¹

2.3.3. SIGNS AND SYMPTOMS

The symptoms of dandruff are described as adherent or loose scales; with or without the presence of irritation and itching (Danby, et al. 1993: 1008). Uncommon in children before puberty, the appearance of dandruff begins to increase precipitously with onset of puberty when the sebaceous glands are most active. It is most prevalent between ages 18 and 40 years.² The dandruff-shedding process levels off in middle age and declines in advancing years (Wolverton, 2001: 164). Dandruff is more common in males, although many reports state that it does not favour either gender. Dandruff does not occur on bald spots.¹

Dandruff is a mild form of seborrheic dermatitis. Left untreated, affected individuals will not experience further symptoms other than minor pruritus from time to time.

Dandruff does not cause inflammation, and it is not allergic in origin.⁴ Its appearance does not suggest underlying pathology. It is unsightly and embarrassing. Its effects are entirely cosmetic; because of this, however, dandruff may cause an intense social stigma.¹

It is made worse by conditions that increase perspiration. Emotional stress has been found to influence its course unfavourably (Domonkos, 1992: 221). Dandruff has a more cosmetic effect rather than a pathological one. Due to its visible cosmetic effects, dandruff has a negative psychological impact. Persons with dandruff are highly self conscious and worried about the visibility of their dandruff (Balch and Balch, 2000: 313).

2.3.4 TREATMENT

Two approaches are possible in the pharmacotherapy of dandruff (Orfanos and Happle, 1990: 996):

1. Keratostasis. The cause of dandruff formation is an increase in the rate of mitosis in areas of the epidermis. A long-term treatment should therefore reduce the mitosis rate (keratostasis).
2. Keratolysis. This consists of the detachment of loose cell complexes in the horny layer of the epidermis

2.3.4.1. Keratostatic agents

a) Tar distillate

Crude coal tar (1.5%) is a product of the destructive distillation of bituminous coal. It is an extremely complex mixture of thousands of polycyclic hydrocarbon compounds. Classed as an antiproliferative agent, it reduces the size and number of epidermal cells (Orfanos and Happle, 1990: 996).

It is not the best choice for the majority of affected persons. In addition to its aesthetically unappealing (i.e., obnoxious) odour and disagreeable visual appearance, coal tar can stain the skin and hair an orange color, especially if the hair is naturally light (gray or blond) or has been artificially bleached. It can also cause folliculitis, irritant dermatitis, and allergic dermatitis. Coal tar may cause photosensitivity reactions in susceptible individuals.¹

b) Zinc Pyridinethione (1%-2%)

This is not indicated for the use of patients with seborrheic dermatitis because of its stimulating effect on sebaceous gland secretion. Pyrithione zinc was originally formulated because of its antimicrobial property.¹ The pyrithione half is the active portion of the molecule. Pyrithione zinc is effective in treating mild dandruff (Orfanos and Happle, 1990: 996), but not as effective in treating the symptoms of severe or

chronic dandruff,⁴ and this is why Selenium sulphide was used in this study. It is approved for use in concentrations of 0.3% to 2% in over the counter products that are intended to be applied and washed off after a brief exposure⁴.

Adverse effects resulting from long-term use of pyrithione zinc have rarely been reported. The antifungal drug is relatively insoluble in water and not readily absorbed through skin or mucous membranes¹.

c) Ketoconazole

It helps to control the itching and flaking associated with dandruff. It does however cause irritation and sometimes discolouration of the hair.⁴

d) Selenium sulphide

It is an effective method of treatment, but it has many side effects such as systemic absorption, irritation of the skin and discolouration and staining of skin.⁴

2.3.4.2. Keratolytic agents

Keratolytic products are indicated particularly at the beginning of dandruff treatment and consist of:

a. Several surfactants

An effect has been established for the surfactant mixture of Softigen 767 and ElfanTS (Orfanos and Happle, 1990: 996)

b. Colloidal sulphur

Sulphur exerts antifungal action, possibly being fungicidal. It is effective for self-therapy of mild symptoms of dandruff.¹

2.4. SELENIUM SULPHIDE

Selenium sulphide is one of the most common main ingredients in anti-dandruff shampoos. Selenium sulphide reduces the cell turnover and it has a direct antimicrobial effect (Wolverton, 2001: 164).

A bioassay of Selenium sulphide was done on rats and mice to assess its possible carcinogenicity. In giving them 20-100 mg/kg/day it was found to be carcinogenic.²

In the treatment for dandruff however, it is administered topically in a shampoo form at a concentration of 2.5% and the patients are advised to use it three times per

week and leave it on for 2-3 minutes only before washing it off in the shower to reduce the possible systemic absorption while sitting in a bath (Wolverton; 2001).

An isolated report documented that a patient with damaged scalp skin using the shampoo two to three times per week developed selenium intoxication where systemic absorption was evidenced by tremors, perspiration, garlicky breath, weakness, vomiting and abdominal pain (Wolverton, 2001: 164).

In a study done to assess the efficacy of selenium sulphide in the treatment of dandruff, selenium was found to be effective. However, adverse experiences were reported. These side effects included burning sensation of the scalp, eruption near the hair line, psoriasis, lightening/ bleaching of hair colour, orange staining of the scalp and a chemical taste while being shampooed (Danby, et al. 1993: 1011).

Selenium sulphide is a highly effective method, for the treatment of stubborn and chronic dandruff (Wolverton, 2001: 164). It is for this reason that this study aimed to investigate alternative forms of treatment for dandruff that will decrease the side effects and at the same time maintain, if not improve, its efficacy in the treatment of dandruff.

2.5. HOMOEOPATHY

Homoeopathy is a gentle form of medicine in which infinitesimal doses of medication are administered. This is achieved by the process of dilution and potentisation during which the therapeutic effect increases while simultaneously nullifying the toxic effect of the original substance (Vithoulkas, 1998: 102).

2.5.1. POTENCY AND POTENTISATION

Potency is described as imparting by serial dilution, the pharmacological message of the original substance by means of trituration or succussion (Gaier, 1991: 441). This process, if performed according to the prescribed mathematico-mechanical attenuation procedures for potentisation (dynamization), increases both the physical solubility and the physiological assimilability of the drug, while also changing its therapeutic activity in its use as a homoeopathic remedy (Gaier, 1991: 432). This has its origin in Samuel Hahnemann's attempts at reducing the toxicity of Homoeopathic substances by dilution. The result was decreased toxicity but also a proportionally reduced therapeutic efficacy. Hahnemann then refined this technique by the introduction of kinetic energy through succussion and / or trituration according to solubility. The resulting combination of serial dilution and succussion/ trituration brought Hahnemann to the conclusion that the more a substance is diluted and succussed/ triturated the more effect it has therapeutically, while at the same time

nullifying any toxic effect (Kunzli, Naude and Pendleton, 1986).

After the process of dilution and potentisation, Homoeopathic substances are prescribed according to the law of quantity and dose, also known as the Arndt-Schulz law (Gaier, 1991: 265). According to this law, the low potencies will have an inhibitory effect, medium potencies a stabilizing effect and high potencies a stimulatory effect (Gaier, 1991: 265). This study has used Selenium sulphide in a 8X potency and according to this law will have an inhibitory effect on *P.ovale*, as 8X is considered to be a low potency.

Low potencies are indicated in acute, superficial diseases or gross pathological states which lack characteristic symptoms, present only with pathological symptoms or changes (Rawat, 1996: XXXIV).

Selenium sulphide has not been proven Homoeopathically, but it has however, been proven and used medically, as a successful form of treatment for dandruff (Danby, et al. 1993: 1018).

In this study the Law of Similars is not applied to the formulation of the prescription for each patient. However, the Law of Infinitesimal Dose has been used in the preparation of the medication. In this way, this study aimed to maintain the beneficial effect of Selenium sulphide but decrease the mentioned side effects.

2.5.2. HOMOEOPATHIC TREATMENT OF SKIN CONDITIONS

The treatment of skin conditions varies not only in different conditions, but in the same disease as it occurs in persons of different diathetic tendencies (Douglass, 1995: 38). Treatment is usually individualized to suit the patient, the disease or both. If both the patient and the skin are affected, constitutional treatment is of preference (Master, Pooran, Petigara, Weisz and Arnold, 1995: 62). When only the skin is affected local applications to alleviate the symptoms are acceptable (Roberts, 1993: 174).

2.5.3. TOPICAL HOMOEOPATHIC TREATMENT

Topical treatment, although classically not a very common form of Homoeopathic treatment, is indicated in external distress and conditions which do not amount to what may be called a full disease condition. It is in these instances that local applications are indicated (Gaier, 1991: 190). These types of diseases are non-dynamic and the treatment of these, with externally applied Homoeopathic medicine is both allowable and commendable (Rawat, 1996: XXXIV). Dandruff is not a systemic disease but because it causes emotional distress¹ it does need treatment.

The external use of Homoeopathic medicine ensures the action of the remedy upon the part affected, and so hastening a return to health (Rawat, 1996: XXXIV). The

selection of low potencies is based on a general rule whereby low potencies are indicated for diseases which are localized and do not affect the patient's health (Pratt, 1985: 82).

2.5.4. SELENIUM METALLICUM AND SULPHUR

There is no Materia Medica for Selenium sulphide, but both Selenium and Sulphur have dandruff symptoms in the Materia Medica.

The Materia Medica scalp symptoms for Selenium metallicum include eczematous eruptions which ooze thin fluid after scratching and hair falls off the scalp and all parts of the body (Murphy, 2000: 1583).

The scalp symptoms of Sulphur include constant itching, scaly moist and dry eruptions, much dandruff in the hair and loss of hair.⁵

2.5.5. HOMOEOPATHIC TREATMENT OF DANDRUFF

A study conducted by Smith, Baker and Williams (2002), researched the effect that Homoeopathic oral dose complex made of Potassium bromide 1X, Sodium bromide 2X, Nickel sulfate 3X and Sodium chloride 6X had on chronic dandruff. The above substances had been previously known to be beneficial in treatment of seborrheic dermatitis and chronic dandruff. This study was performed to assess the efficacy of

the same substances but in homoeopathic dilution. 41 subjects were taken into the study, and were assigned to either the Treatment or the Placebo Group. The study was conducted over a period of 10 weeks. At the end of the study the results showed a significant improvement ($p= 0.04$) and there was a 38,5% improvement of the symptoms in the Treatment Group.

As Selenium sulphide is known to be effective in the treatment of dandruff (Danby, et al. 1993: 1011), this study aimed to assess its effectiveness in homoeopathic dilution.

A concurrent study (Kent, 2005) conducted at Durban Institute of Technology, is assessing the effectiveness of oral Homoeopathic treatment with Selenium sulphide 12X, in the management of dandruff. The two studies were run simultaneously, but separately. The results of Kent's study have not yet been published, but while the results have showed a significant improvement within the Treatment Group ($p= 0.000$), there was no significant improvement when compared to the Placebo Group.

2.6 MEASUREMENT TOOLS

The Visual Analogue Scale (V.A.S.) is a self-report device that measures the magnitude of the state of interest. Conventionally, the V.A.S. is a 100-mm line that is horizontally orientated with anchors placed at both poles. Subjects place a mark somewhere on the line that best indicate the magnitude of the state of interest.⁴ The V.A.S. has previously been used to assess the severity of skin conditions, including seborrheic dermatitis and dandruff (1992, Journal of the American Academy of Dermatology).

V.A.S. is used in studies where subjective measures of symptoms or quality of life is assessed, such as mood, pain, quality of life and some dermatologic conditions (Jaeschke, Singer and Guyatt. 1990: 43). Dandruff is seen as one of those conditions which is subjectively assessed (1992, Journal of the American Academy of Dermatology).

The V.A.S. was used and measured irritation, scaling, greasiness, overall impression and percentage of scalp involved. The subjects assessed their own irritation, flaking, greasiness itching and overall impression on the V.A.S. The V.A.S. carries the numbers from 0 to 10 at intervals of 1 centimetres apart (0= none; 1-2= almost none/very slight; 3-4= mild; 5-6= moderate; 7-8= marked; 9-10= severe/heavy), (Danby, et al.1993; 29: 1009).

CHAPTER THREE:

MATERIALS AND METHODS

3.1. SAMPLE SIZE

The trial sample was made up of two groups; a placebo group and a treatment group. 33 subjects were taken into this study from which 2 subjects withdrew during the course of the trial. The treatment group consisted of 15 subjects and the placebo group of 16 subjects. Subjects who agreed to participate were given an information letter (see Appendix A). Those who were entered into the study were required to sign an informed consent form (see Appendix B).

3.2. SELECTION OF TEST SUBJECTS

To recruit subjects, advertisements were placed on Durban Institute of Technology (D.I.T) campus, in newspapers and hairdresser salons.

3.2.1. INCLUSION CRITERIA (Danby, et al. 1993).

- Noticeable flaking of the scalp
- Irritation of the scalp
- Itchiness of the scalp
- Greasiness of the scalp

3.2.2. EXCLUSION CRITERIA (Danby, et al. 1993).

- Psoriasis
- Atopic or irritant contact dermatitis
- Tinea capitis (ringworm of the scalp)
- Parkinson's Disease
- Pregnant or lactating females
- Immunodeficiency (chronic diseases)
- Current usage of antibiotics or antimycotics
- Allergy or sensitivity to shampoo/soap
- Open cuts/abrasions on the scalp and/or hands

3.3. RANDOMIZATION

The subjects were selected and divided into each group by means of a randomization sheet drawn up by the supervisor. The dispenser gave the subjects the appropriate treatment according to this randomization sheet.

3.4. PREPARATION OF MEDICATION

The Selenium sulphide was procured from Sigma-Aldrich (Pty) Ltd (Johannesburg), batch number 10519 HA.

The shampoo was dispensed in a 250 millilitre plastic bottle, comprising of a 10% volume/volume concentration of Selenium sulphide 8X, in a detergent vehicle.

Selenium sulphide is insoluble; therefore trituration was used in its preparation.

The Selenium sulphide was triturated to a 6X, and then, taken to an 8X liquid dilution.

The medicine was prepared by Natura Homoeopathic Laboratories of the quality and according to the standard set out in the German Homoeopathic Pharmacopoeia according to Method 6 and Method 8a as described below:

Method 6: (British Homoeopathic Association, 1991).

Preparations made according to this method are triturations of solid basic drug materials with lactose as a vehicle. Triturations up to and including the 4th dilution are triturated by hand or machine in a ratio of 1 to 10 (decimal dilution) or 1 to 100 (centesimal dilution).

Trituration by machine: (British Homoeopathic Association, 1991).

Triturations are made in a machine fitted with a scraping device that ensures even trituration. To produce a triturate by machine, triturate 1/3 of the lactose, add the basic drug material and triturate; finally add the remaining lactose in two

equal portions and triturate. Dilutions above the 4X or 4C are made by diluting with 9 parts of lactose or 99 parts of lactose and combining 1/3 of the required amount of lactose in a suitable mixer with the whole of the previous dilution and mix until homogenous. Add the 2nd 1/3 of the lactose, mix until homogenous, and proceed in the same way with the last 1/3 of the lactose.

Method 8a: (British Homoeopathic Association, 1991).

To produce a 6X dilution 1 part of the 4X triturate is dissolved in 9 parts of water and succussed. 1 part of this dilution is combined with 9 parts of ethanol to produce the 6X liquid dilution by succussion. In the same way, the 7X liquid dilution is made from the 5X triturate, and 8X liquid dilution from the 6X triturate.

The impregnation of the detergent vehicle was done by the researcher. Each medicated shampoos had a 25 ml Selenium sulphide 8X in 20% alcohol. The placebo shampoos contained 25 ml alcohol (20%), as to prevent visual dissimilarity between the two shampoos. Each bottle had a dosage and direction for use label and an auxiliary label, where the subjects was warned to keep the contents out of reach of children and that it was only for external use.

The subjects were instructed to shake the bottle before use and apply 5-10 ml of shampoo onto wet hair and leave it on the scalp for 2-3 minutes, after which the

scalp was to be rinsed thoroughly. This procedure was to be repeated 3 times per week as per instructions of the commercial product Selsun® (1998).

3.5. CONSULTATION

The subjects that met the inclusion criteria were entered into the study and were required to sign an informed consent form (see Appendix B). At each of the 3 consultations the subject, the researcher and a clinician on duty or concurrent researcher (Kent, 2005) completed a Visual Analogue Scale (V.A.S.) that assessed the dandruff on 5 criteria (see Appendix C).

3.6. TREATMENT AND SUBJECTS ADVICE

Subjects that fitted the criteria were telephonically instructed to cease the use of any anti-dandruff products 1 week prior to the initial consultation, as to obtain a true reading assessment of the severity of dandruff symptoms (Baran and Maibach, 1994: 102).

At the initial consultation, 1 week after the stoppage, a Visual Analogue Scale was done which was used as a baseline. There were two subsequent follow-up appointments, each at two weeks apart (1992, Journal of the American Academy of Dermatology). The subjects were advised to abstain from any anti-dandruff products for the rest of the study.

It was assumed that the subjects followed the instructions on how to apply the shampoo and were questioned about it at their follow-up consultations.

3.7. MEASUREMENT

The Visual Analogue Scale (V.A.S.) (1992, Journal of the American Academy of Dermatology) (see Appendix C) was used and measured irritation, scaling, greasiness, overall impression and percentage of scalp involved. The V.A.S. was performed by the subjects, the researcher and an independent 3rd party. The independent 3rd party was either the clinician or concurrent researcher (Kent).

The subjects assessed their own irritation, flaking, greasiness itching and overall impression on the V.A.S. The V.A.S. carries the numbers from 0 to 10 at intervals of 1 centimetres apart (0= none; 1-2= almost none/ very slight; 3-4= mild; 5-6= moderate; 7-8= marked; 9-10= severe/heavy), (Danby, et al.1993). The readings were done on Days 1, 14, 28 of treatment period (1992, Journal of the American Academy of Dermatology).

3.8. DATA ANALYSIS

3.8.1. STATISTICAL METHOD

The data used for the statistical analysis were the results of the V.A.S. (comprising six variables) which indicated the severity of the dandruff according to the subjects, the researcher and co-researcher/ clinician. The average of the three measurements i.e. subjects, researcher and clinician, were used to calculate a score which in turn, was used for statistical analysis. All the variables were averaged with the exception of itching (only the subjects's perception) and percentage of scalp involved (only the perception of the researcher and the independent 3rd party).

The six continuous variables of interest were analysed using non-parametric methods of data analysis.

3.8.2. STATISTICAL ANALYSIS

Upon completion of the study, the data was collected and interpreted by the following means:

3.8.2.1. Procedure 1- Friedman's Test for intra-group differences

The Friedman's Test was used to compared and assess for any significant changes during the treatment period within the Treatment Group and within the Placebo Group

(i) Hypothesis testing

The null hypothesis (H_0) states that there is no significant difference within the Treatment or Placebo Groups as assessed on the Visual Analogue Scale and compared at the $\alpha = 0.05$ level of significance. The alternate hypothesis (H_1) states that there will be a significant difference in the readings of the Visual Analogue Scale for the Treatment and Placebo Groups.

(ii) Decision rule

Reject the null hypothesis (H_0) if $P < \alpha$ or accept the alternative hypothesis at the same or higher level of significance. If the null hypothesis is rejected then the Dunn Procedure for Friedman's Test must be used to determine at which consultation there is a significant improvement. A 95% confidence interval was required to reject the null hypothesis.

3.8.2.2. Procedure 2 - Dunn's procedure for intra-group differences (Daniel, 1978: 231)

Let,

- R_i and R_j , be the means of the ranks of the i th and j th samples respectively.
- α : be the experimental
0.20 and 0.25 depending upon the value of k (as k increases, α
.....)

$$\dots\dots\dots z \sqrt{\frac{bk(k+1)}{6}}$$

In the above formula:

k = number of readings

b = number of subjects

Z = the value of inverse normal distribution corresponding to $(1 - \alpha/k(k-1))$

If $k=3$, $\alpha= 0.15$, $z= 1.914$

The difference $|R_i - R_j|$ is declared significant at α level.

3.8.2.3. Procedure 3- Mann Whitney U Test for inter-group differences

The Mann Whitney U Test was used to determine if there was any significant difference between the Treatment and Placebo Groups with regards to the six variables of the study.

(i) Hypothesis testing

The null hypothesis (H_0) states that there is no significant difference between the Treatment Group and the Placebo Group as assessed on the Visual Analogue Scale and compared at the $\alpha = 0.05$ level of significance. The alternate hypothesis (H_1) states that there will be a significant difference in the readings of the Visual Analogue Scale between the Treatment Group and the Placebo Group.

(ii) Decision rule

Reject the null hypothesis (H_0) if $P < \alpha$ or accept the alternative hypothesis at the same level of significance. A 95% confidence interval was required to reject the null hypothesis.

CHAPTER FOUR

STATISTICAL ANALYSIS OF DATA

4.1. INTRODUCTION

This chapter presents the results of the trial. The results were taken from Visual Analogue Scales completed by the subject, the researcher and the independent 3rd party.

4.2. CRITERIA FOR THE ADMISSIBILITY OF THE DATA

Only the data from this trial was accepted for use in the results chapter. The data used in the analysis was collected in the manner described in Chapter 3.

4.3. RESULTS

The subjects were assessed by the researcher, the independent 3rd party and the subject themselves, using a Visual Analogue Scale for the following six criteria:

- Irritation
- Scaling/Flaking
- Greasiness
- Percentage of the scalp involved
- Itching
- Overall impression

4.3.1. Intra-Group Tests for the Treatment Group

The Friedman's Test was conducted to determine whether there was any significant difference in the total average score of dandruff symptoms between the three consultations of the Treatment Group.

Table 4.1- Intra-Group Tests for the Treatment Group

Consultation	Mean Score	Mean Rank	P-Value
Day 1	34.8533	3.00	.000
Day 14	21.1680	1.87	
Day 28	12.8667	1.13	

The above table demonstrates a significant improvement in the totality of the dandruff symptoms within the Treatment Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed.

4.3.1.1. Dunn procedure for Day 1 and Day 14.

$$|R_j - R_i| \geq z \sqrt{\frac{bk(k+1)}{6}}$$

b= 15

K= 3

α= 0.15

z= 1.914

Therefore:

/34.8533-21.1680/ > 10.4834

/13.6853/ > 10.4834

The above results showed that there was a significant difference between Day 1 and Day 14 within the treatment group.

4.2.1.2. Dunn procedure for Day 14 and Day 28

$$|R_j - R_i| \geq z \sqrt{\frac{bk(k+1)}{6}}$$

b= 15

K= 3

α = 0.15

z= 1.914

Therefore:

$|21.1680 - 12.8667| < 10.4834$

$|8.3013| < 10.4834$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Treatment Group.

4.3.1.3. Comparison of treatment criteria for the Treatment Group

The Friedman's Test was conducted to determine whether there was any significant difference for each individual variable within the Treatment Group at each consultation (for graphs see Appendix D).

There were no significant differences found for any individual criteria at each consultation.

4.3.2. Intra-Group Test for the Placebo Group

The Friedman's Test was conducted to determine whether there was any significant difference in the total average score of dandruff symptoms between the three consultations of the Placebo Group.

Table 4.2- Intra-Group Test for Placebo Group

Consultation	Mean Score	Mean Rank	P-Value
Day 1	34.5612	2.94	.000
Day 14	21.5206	1.81	
Day 28	15.0937	1.25	

Table 4.2 demonstrates a significant improvement in the totality of the dandruff symptoms within the Placebo Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed.

4.3.2.1. Dunn procedure for Day 1 and Day 14

$$R_j - R_i \geq z \sqrt{\frac{bk(k+1)}{6}}$$

b= 16

K= 3

α = 0.15

z= 1.914

Therefore:

/34.5612-21.5206/ >10.8272

/13.0406/ >10.8272

The above results showed that there was a significant difference between Day 1 and Day 14 within the Placebo Group.

4.3.2.2. Dunn procedure for Day 14 and Day 28

$$R_j - R_i \geq z \sqrt{\frac{bk(k+1)}{6}}$$

b= 16

K= 3

α = 0.15

z= 1.914

Therefore:

/21.5206-15.0937/ <10.8272

/6.4269/ <10.8272

The above results showed that there was no significant difference between Day 14 and Day 28 within the Placebo Group.

4.3.2.3. Comparison of treatment criteria for the Placebo Group

The Friedman's Test was conducted to determine whether there was any significant difference for each individual variable within the Placebo Group at each consultation (for graphs see Appendix E).

There were no significant differences found for any individual criteria at each consultation.

4.3.3. Inter-Group Test between the Treatment and the Placebo Groups

The Mann Whitney U Test was conducted to determine whether there was any significant difference in the total average score of dandruff criteria symptoms between the Treatment and Placebo Groups at each consultation.

Table 4.3- Inter-Group Test between the Treatment and Placebo Groups

Consultation	Group	Mean Score	Mean Rank	P-Value
Day 1	Treatment	34.8533	16.20	.922
	Placebo	34.5612	15.81	
Day 14	Treatment	21.1680	16.20	.922
	Placebo	21.5206	15.81	
Day 28	Treatment	12.8667	15.03	.572
	Placebo	15.0937	16.91	

The Null Hypothesis was accepted ($P > 0.05$) at each of the three consultations.

This shows that there was no significant difference between the two groups at each consultation.

Figure 4.3 is a visual illustration of the mean scores of the two groups on Day 1, Day 14 and Day 28.

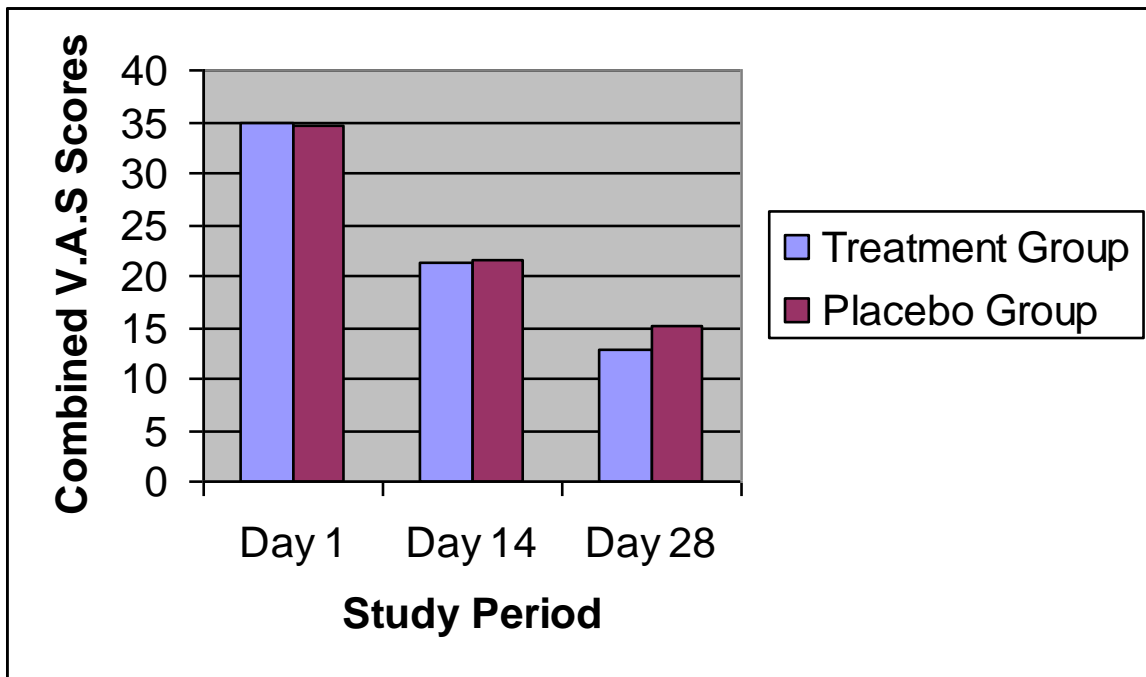


Figure 4.3– Comparison of the Combined V.A.S. Mean Scores in the Treatment Group and the Placebo Group over the study period.

4.3.3.1. Comparison of treatment criteria between the Treatment and Placebo Groups

The Mann Whitney U Test was conducted to determine whether there was any significant difference in the individual criteria scores of dandruff symptoms between the Treatment and Placebo Groups at each consultation.

There were no significant differences found for any individual criteria at each consultation, as can be seen from Tables 4.4 to 4.9.

(a) Inter-Group Test for Irritation

Table 4.4- Mann Whitney U Test: Irritation

Consultation	Group	Mean Score	Mean Rank	P-Value
Day 1	Treatment	4.8887	16.03	.984
	Placebo	5.0619	15.97	
Day 14	Treatment	3.2673	16.13	.937
	Placebo	3.2694	15.88	
Day 28	Treatment	2.0213	14.63	.415
	Placebo	2.5000	17.28	

The Null Hypothesis was accepted for all the consultations as no significant differences were found.

(b) Inter-Group Test for Flaking

Table 4.5- Mann Whitney U Test: Flaking

Consultation	Group	Mean Score	Mean Rank	P-Value
Day 1	Treatment	6.0873	16.33	.843
	Placebo	5.0619	15.69	
Day 14	Treatment	3.6013	15.30	.677
	Placebo	3.8763	16.66	
Day 28	Treatment	2.1567	14.63	.415
	Placebo	2.6250	17.28	

The Null Hypothesis was accepted for all the consultations as no significant differences were found.

(c) Inter-Group Test for Greasiness

Table 4.6- Mann Whitney U Test: Greasiness

Consultation	Group	Mean Score	Mean Rank	P-Value
Day 1	Treatment	4.8233	17.23	.462
	Placebo	4.2088	14.84	
Day 14	Treatment	3.1993	17.47	.383
	Placebo	2.7494	14.63	
Day 28	Treatment	1.8887	16.37	.827
	Placebo	1.7500	15.66	

The Null Hypothesis was accepted for all the consultations as no significant differences were found.

(d) Inter-Group Test for Itching

Table 4.7- Mann Whitney U Test: Itching

Consultation	Group	Mean Score	Mean Rank	P-Value
Day 1	Treatment	6.8000	15.73	.873
	Placebo	6.9375	16.25	
Day 14	Treatment	4.0000	16.17	.919
	Placebo	3.5625	15.84	
Day 28	Treatment	2.4000	14.77	.454
	Placebo	2.9375	17.16	

The Null Hypothesis was accepted for all the consultations as no significant differences were found.

(e) Inter-Group Test for Percentage of Scalp Involved

Table 4.8- Mann Whitney U Test: Percentage of Scalp Involved

Consultation	Group	Mean Score	Mean Rank	P-Value
Day 1	Treatment	6.1667	16.70	.676
	Placebo	6.0000	15.34	
Day 14	Treatment	3.4333	14.40	.340
	Placebo	4.0625	17.50	
Day 28	Treatment	2.2667	14.80	.340
	Placebo	2.6769	17.13	

The Null Hypothesis was accepted for all the consultations as no significant differences were found.

(f) Inter-Group Test for Overall Impression

Table 4.9- Mann Whitney U Test: Overall Impression

Consultation	Group	Mean Score	Mean Rank	P-Value
Day 1	Treatment	6.0873	15.63	.827
	Placebo	6.2706	16.34	
Day 14	Treatment	3.6667	15.43	.735
	Placebo	4.0006	16.53	
Day 28	Treatment	2.1333	14.60	.405
	Placebo	2.6044	17.31	

The Null Hypothesis was accepted for all the consultations as no significant differences were found.

CHAPTER FIVE

DISCUSSION OF THE RESULTS

The results of the Friedman's Test (Table 4.1) demonstrated a significant improvement in the totality of the dandruff symptoms within the Treatment Group over the period of the trial ($P= 0.000$), to a 99% confidence interval. When comparing the results from each of the consultations, it was found that there was significant improvement between Day 1 and Day 14, but not between Day 14 and Day 28. Overall, from the Dunn Test results, one can see that the most improvement occurred between Day 1 and Day 14, after which improvement levelled off.

The results of the Friedman's Test (Table 4.2) demonstrated a significant improvement in the totality of the dandruff symptoms within the Placebo Group over the period of the trial ($P= 0.000$), to a 99% confidence interval. When comparing the results from each of the consultations, it was found that there was significant improvement between Day 1 and Day 14, but not between Day 14 and Day 28. Overall, from the Dunn Test results, one can see that the most improvement occurred between Day 1 and Day 14, after which improvement levelled off.

The results of the Mann Whitney U Test (Table 4.3) which compared the Treatment Group to the Placebo Group showed that there was no significant difference between the two groups at each consultation. On Day 1 there was no significant difference between the two groups ($P= 0.922$) which showed that there was no bias in the group allocation and assessment of patients.

Although there was no significant difference between the two groups ($P=0.922$) at Day 14, both groups had improved significantly from Day 1 (see Table 4.3) but neither group has improved more than the other.

On Day 28 the results show that both groups have improved. The Treatment Group, however, had improved more than the Placebo Group but not significantly ($P=0.572$).

Comparing the different variables between the two groups (Treatment and Placebo) showed no significant difference between the groups at any of the three consultations. The results showed that, even though both groups have improved significantly, the Treatment Group improved more than the Placebo Group even though the difference in improvement was not significant. If the trial was conducted over a longer period of time, a significant difference between the Treatment Group and the Placebo Group may have emerged.

Even though there was no significant difference in results from the Treatment Group when compared to the Placebo Group, the Treatment Group has improved more than the Placebo (see Figure 4.3).

Form the results obtained it can be stated that Homoeopathic Treatment with Selenium sulphide 8X shampoo did not have a significant effect in the management of dandruff symptoms when compared to the Placebo Group.

When comparing the results of this study to those of Kent's study (2005), the results showed that both the Treatment Groups i.e. the Selenium sulphide 8X shampoo and Selenium sulphide 12X oral treatment, did not have a significant effect in the management of dandruff symptoms when compared to the separate Placebo Groups.

The results of this study were different to that of Smith, Baker and Williams (2002: 59) who found that using Homoeopathic preparation combining Potassium bromide 1X, Sodium bromide 2X, Nickel sulphate 3X and Sodium chloride 6X, provided a significant improvement in dandruff. Possible reasons for their results are:

- a) The substances used i.e. Potassium bromide, Sodium bromide, Nickel sulphate and Sodium chloride, which are known allopathic treatments for dandruff (Smith, Baker and Williams, 2002: 59).

- b) The medication was in lower potencies; therefore, particles of crude substance were still present.
- c) The study was assessed over a longer period of time.

In this study there was a significant difference within the Treatment and the Placebo Groups respectively, however, there was no significant difference between the two groups, i.e., the Placebo preparation statistically, was as effective as the Treatment Group. The following factors could have led to this result:

- a. The shampoo detergent vehicle could have acted as an anti-dandruff agent;
- b. The alcohol concentration of the shampoo could have had an effect on the mitotic rate of scalp epidermis and therefore the rate of dandruff production.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1. CONCLUSION

The results of this study indicate that the Homoeopathic topical preparation of Selenium sulphide 8X is not effective in the management of dandruff.

However, because there was a significant improvement within both the Treatment and Placebo Groups, it is possible that the alcohol content in both the shampoos could have been the active ingredient.

6.2. RECOMMENDATIONS

1. A clinical study using topical treatment with Selenium sulphide 8X as a method of treating dandruff should be conducted on a larger sample group to improve the statistical power of the data analysis.
2. A clinical study using Selenium sulphide 8X should be conducted over a longer period of time as to assess the results as the patients are taken off the treatment slowly.

3. A clinical study using Selenium sulphide 8X prepared with water and not alcohol to assess if the alcohol could be causing the decrease in the dandruff symptoms and to compare the effects of water to alcohol in the management of dandruff.
4. Clinical studies should be conducted using Homoeopathic potency of other substances used in the conventional treatment of dandruff.
5. A clinical study using the substances used by Smith, Baker and Williams (2002: 59), prepared in higher potencies.
6. A clinical study using Selenium sulphide in a lower potency (2X).

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Appendix A

Subject Information Letter

Title of Research Project: The effectiveness of topical Homoeopathic preparation, of Selenium sulphide 8X shampoo in the management of dandruff (Pityriasis Capitis).

Name of Supervisor: Dr. Ingrid Couchman.

Name of Researcher: Silvana Teleman.

Date:

Dear Participant

I am a fifth year Homoeopathy student at the Durban Institute of Technology. In order to obtain my Masters Degree, I am required to complete a mini dissertation. In this research I will be investigating the effect of selenium sulphide shampoo in a Homoeopathic dose on the symptoms of dandruff.

The clinical trials will be conducted at the Homoeopathy day clinic during the afternoons.

You will be required to attend four consultations, all of which will be supervised by a qualified Homoeopath. The consultations will be conducted firstly on inclusion into the study and then on day one, fourteen and twenty-eight of the trial. Each participant must comply with certain criteria in order to enter the study.

If you fulfil the criteria and are willing to participate, you will be accepted into the trial and I appeal for your full cooperation and assistance. This a double blind, randomized, placebo controlled trial. This means that you have a 50% chance of being in the placebo group. Both groups will get a shampoo to use. You will be required to wash your hair every second day. "Double blind" refers to the fact that neither the patient nor the researcher will be aware of what treatment the patient is receiving. Only at the end of the data collection phase will the patient's group be revealed. One week prior to the beginning of the trial and for the duration of the trail, no other treatment for dandruff will be permitted.

Benefits: You may experience relief from your symptoms of dandruff.

Risks:

No major risks are involved in this study. In the case when the treatment is found to be inefficient, you may experience worsening of your dandruff symptoms. The same may happen if you are placed into the placebo group, but in this case at the end of the trial you will be offered the effective treatment free of charge.

Confidentiality:

All information provided by the participants will remain confidential and will be destroyed on completion of the research, in which the anonymity of the patients will be assured.

Questionnaires:

On day 1; 14 and 28 of the trial you will be asked to complete a form consisting of scales graded from 0 to 10 (0= none; 1-2= almost none/ very slight; 3-4= mild; 5-6= moderate; 7-8= marked; 9-10= severe/heavy). On these scales you will be grading the following symptoms of dandruff: Irritation; flaking; greasiness; itching and your overall impression.

Your participation in this study is completely voluntary and if, at any point during this study, you decide to withdraw, no reason need be given.

All consultation and treatment cost will be covered by the Durban Institute of Technology.

If you have any questions or experience any problems during this study, please do not hesitate to contact my supervisor or myself on the following numbers:

Dr. I Couchman: 031 – 2042041

Silvana Teleman: 072 – 474 2324

Thank you for your assistance

Silvana Teleman
Department of Homoeopathy
Durban Institute of Technology

APPENDIX B

INFORMED CONSENT FORM

(To be completed in duplicate by patient/subject)

*Delete whichever is not applicable

TITLE OF RESEARCH PROJECT: The effectiveness of topical homoeopathic preparation of Selenium Sulphide 8X shampoo in the management of dandruff (Pityriasis Capitis)

NAME OF SUPERVISOR: Dr Ingrid Couchman

NAME OF CO-SUPERVISOR: Dr Madhu Maharaj

NAME OF RESEARCH STUDENT: Silvana Teleman

PLEASE CIRCLE THE APPROPRIATE ANSWER:

- | | |
|--------------------------------------------------------------------------|--------|
| 1) Have you read the subject information letter? | YES/NO |
| 2) Have you had an opportunity to ask questions regarding this study? | YES/NO |
| 3) Have you received satisfactory answers to your questions? | YES/NO |
| 4) Have you had an opportunity to discuss this study? | YES/NO |
| 5) Have you received enough information regarding this study? | YES/NO |
| 6) Who have you spoken to? _____ | |
| 7) Do you understand the implications of your involvement in this study? | YES/NO |
| 8) Do you understand that you are free to withdraw from this study? | YES/NO |
| a) at any time | |
| b) without having to give reason for withdrawing, and | |
| c) without affecting your future healthcare | |
| 9) Do you agree to voluntarily participate in this study? | YES/NO |

If you have answered NO to any of the above, please obtain the information before signing.

PATIENT/SUBJECT* NAME: _____
(in block letters)

SIGNATURE: _____

WITNESS NAME: _____
(in block letters)

SIGNATURE: _____

RESEARCH STUDENT NAME: _____
(in block letters)

SIGNATURE: _____

Appendix C

Visual Analogue Scale

(1992, Journal of the American Academy of Dermatology)

Individual completing the V.A.S: Clinician ف Researcher ف

Date: / /

Name:.....

Consultation: Day 1 ف Day 14 ف Day 28 ف

Irritation

Flaking

Greasiness

Percentage of scalp involved

Overall impression

- 0 :none
- 1-2: almost none / very slight
- 3-4: mild
- 5-6: moderate
- 7-8: marked
- 9-10: severe/ heavy

Patient's questionnaire
(1992, Journal of the American Academy of Dermatology)

Date: / /

Name:.....

Consultation: Day 1 ث Day 14 ث Day 28ث

Irritation

Flaking

Greasiness

Itching

Overall impression

- 0:none
- 1-2: almost none / very slight
- 3-4: mild
- 5-6: moderate
- 7-8: marked
- 9-10: severe/ heavy

Appendix D

1. Comparison of treatment criteria for the Treatment Group

The Friedman's Test was conducted to determine whether there was any significant difference for each individual variable within the Treatment Group at each consultation.

There were no significant differences found for any individual criteria at each consultation.

1.1. Intra-Group Tests for Treatment Group: Irritation

Table 10- Friedman's Test: Irritation

Consultation	Mean Score	Mean Rank	P-Value
Day 1	4.8887	2.90	.000
Day 14	3.2673	1.83	
Day 28	2.0213	1.27	

The above table demonstrates a significant improvement in the variable Irritation for the Treatment Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed.

1.1.1. Dunn procedure for Day 1 and Day 14.

$$|R_j - R_i| \geq z \sqrt{\frac{bk(k+1)}{6}}$$

b= 15

K= 3

α = 0.15

.....

Therefore:

$|4.8887 - 3.2673| < 10.4834$

$|1.6214| < 10.4834$

The above results showed that there was no significant difference between Day 1 and Day 14 within the Treatment Group for variable Irritation.

1.1.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$/3.2673-2.0213/ < 10.4834$

$/1.246/ < 10.4834$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Topical treatment group for variable Irritation.

1.2. Intra-Group Tests for Treatment Group: Flaking

Table 11- Friedman's Test: Flaking

Consultation	Mean Score	Mean Rank	P-Value
Day 1	6.0873	3.00	.000
Day 14	3.6013	1.83	
Day 28	2.1567	1.17	

The above table demonstrates a significant improvement in the variable Flaking for the Treatment Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed.

1.2.1. Dunn procedure for Day 1 and Day 14.

AS PER 1.1.1.

Therefore:

$$/6.0873-3.6013/< 10.4834$$

$$/2.486/< 10.4834$$

The above results showed that there was no significant difference between Day 1 and Day 14 within the Treatment Group for variable Flaking.

1.2.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$$/3.6013-2.1567/< 10.4834$$

$$/1.4446/<10.4834$$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Treatment Group for variable Flaking.

1.3. Intra-Group Tests for Treatment Group: Greasiness

Table 12- Friedman's Test: Greasiness

Consultation	Mean Score	Mean Rank	P-Value
Day 1	4.8233	2.87	.000
Day 14	3.1993	1.93	
Day 28	1.8887	1.20	

The above table demonstrates a significant improvement in the variable Greasiness for the Treatment Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed.

1.3.1. Dunn procedure for Day 1 and Day 14

AS PER 1.1.1.

Therefore:

$$/4.8233-3.1993/< 10.4834$$

$$/1.624/< 10.4834$$

The above results show that there was no significant difference between Day 1 and Day 14 within the Treatment Group for variable Greasiness.

1.3.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$3.1993 - 1.8887 < 10.4834$

$1.3106 < 10.4834$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Treatment Group for variable Greasiness.

1.4. Intra-Group Tests for Treatment Group: Itching

Table 13- Friedman's Test: Itching

Consultation	Mean Score	Mean Rank	P-Value
Day 1	6.8000	2.80	.000
Day 14	4.0000	2.00	
Day 28	2.4000	1.20	

The above table demonstrates a significant improvement in the variable Itching for the Treatment Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed

1.4.1. Dunn procedure for Day 1 and Day 14.

AS PER 1.1.1.

Therefore:

$$/6.8000-4.0000/< 10.4834$$

$$/2.8000/< 10.4834$$

The above results show that there was no significant difference between Day 1 and Day 14 within the Treatment Group for variable Itching.

1.4.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$$/4.0000-2.4000/< 10.4834$$

$$/1.6000/<10.4834$$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Treatment Group for variable Itching.

1.5. Intra-Group Tests for Treatment Group-Percentage of Scalp Involved

Table 14- Friedman's Test: Percentage of Scalp Involved

Consultation	Mean Score	Mean Rank	P-Value
Day 1	6.1667	2.90	.000
Day 14	3.4333	1.80	
Day 28	2.2667	1.30	

The above table demonstrates a significant improvement in the variable Percentage of Scalp Involved for the Treatment Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed.

1.5.1. Dunn procedure for Day 1 and Day 14.

AS PER 1.1.1.

Therefore:

$$/6.1667-3.4333/< 10.4834$$

$$/2.7334/< 10.4834$$

The above results show that there was no significant difference between Day 1 and Day 14 within the Treatment Group for variable Percentage of Scalp Involved.

1.5.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$$/3.4333-2.2667/< 10.4834$$

$$/1.1666/<10.4834$$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Treatment Group for variable Percentage of Scalp Involved.

1.6. Intra-Group Tests for Treatment Group: Overall Impression

Table 15- Friedman's Test: Overall Impression

Consultation	Mean Score	Mean Rank	P-Value
Day 1	6.0873	2.93	.000
Day 14	3.6667	1.93	
Day 28	2.1333	1.13	

The above table demonstrates a significant improvement in the variable Overall Impression for the Treatment Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed.

1.6.1. Dunn procedure for Day 1 and Day 14

AS PER 1.1.1.

Therefore:

$$/6.0873-3.6667/< 10.4834$$

$$/2.4206/< 10.4834$$

The above results show that there was no significant difference between Day 1 and Day 14 within the Treatment Group for variable Overall Impression

1.6.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$$/3.6667-2.1333/< 10.4834$$

$$/1.5334/<10.4834$$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Treatment Group for variable Overall Impression.

Appendix E

1. Comparison of treatment criteria for the Placebo Group

The Friedman's Test was conducted to determine whether there was any significant difference for each individual variable within the Placebo Group at each consultation.

There were no significant differences found for any individual criteria at each consultation.

1.1. Intra-Group Tests for Placebo Group: Irritation

Table 16- Friedman's Test: Irritation (Placebo Group)

Consultation	Mean Score	Mean Rank	P-Value
Day 1	5.0619	2.75	.000
Day 14	3.2694	1.81	
Day 28	2.5000	1.44	

The above table demonstrates a significant improvement in the variable Irritation for the Placebo Group. The Null Hypothesis was therefore rejected ($P= 0.000$) and the Dunn procedure was performed.

1.1.1. Dunn procedure for Day 1 and Day 14

$$R_j - R_i \geq z \sqrt{\frac{bk(k+1)}{6}}$$

$$b = 16$$

$$K = 3$$

$$\alpha = 0.15$$

$$z = 1.914$$

Therefore:

$$|5.0619 - 3.2694| < 10.8272$$

$$|1.7925| < 10.8272$$

The above results showed that there was no significant difference between Day 1 and Day 14 within the Placebo Group for variable Irritation.

1.1.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$/3.2694-2.5000/ < 10.8272$

$/0.7694/ < 10.8272$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Placebo Group for variable Irritation.

1.2. Intra-Group Tests for Placebo Group: Flaking

Table 17- Friedman's Test: Flaking (Placebo Group)

Consultation	Mean Score	Mean Rank	P-Value
Day 1	6.0825	2.94	.000
Day 14	3.8763	1.91	
Day 28	2.6250	1.16	

The above table demonstrates a significant improvement in the variable Flaking for the Placebo Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed

1.2.1. Dunn procedure for Day 1 and Day 14

AS PER 1.1.1.

Therefore:

$$|6.0825 - 3.8763| < 10.8272$$

$$|2.2062| < 10.8272$$

The above results showed that there was no significant difference between Day 1 and Day 14 within the Placebo Group for variable Flaking.

1.2.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$$|3.8763 - 2.6250| < 10.8272$$

$$|1.2513| < 10.8272$$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Placebo Group for variable Flaking.

1.3. Intra Group Tests for Placebo Group: Greasiness

Table 18- Friedman's Test: Greasiness (Placebo Group)

Consultation	Mean Score	Mean Rank	P-Value
Day 1	4.2088	2.94	.000
Day 14	2.7494	1.75	
Day 28	1.7500	1.31	

The above table demonstrates a significant improvement in the variable Greasiness for the Placebo Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed

1.3.1. Dunn procedure for Day 1 and Day 14.

AS PER 1.1.1.

Therefore:

$|4.2088 - 2.7494| < 10.8272$

$|1.4594| < 10.8272$

The above results show that there was no significant difference between Day 1 and Day 14 within the Placebo Group for variable Greasiness.

1.3.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$|2.7494 - 1.7500| < 10.8272$

$|0.9994| < 10.8272$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Placebo Group for variable Greasiness.

1.4. Intra-Group Tests for Placebo Group: Itching

Table 19- Friedman's Test: Itching (Placebo Group)

Consultation	Mean Score	Mean Rank	P-Value
Day 1	6.9375	2.84	.000
Day 14	3.5625	1.81	
Day 28	2.9375	1.34	

The above table demonstrates a significant improvement in the variable Itching for the Placebo Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed

1.4.1. Dunn procedure for Day 1 and Day 14

AS PER 1.1.1.

Therefore:

$$|6.9375 - 3.5625| < 10.8272$$

$$|3.3375| < 10.8272$$

The above results show that there was no significant difference between Day 1 and Day 14 within the Placebo Group for variable Itching.

1.4.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$$|3.5625 - 2.9375| < 10.8272$$

$$|0.625| < 10.8272$$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Placebo Group for variable Itching

1.5. Intra-Group Tests for Placebo Group: Percentage of Scalp Involved

Table 20- Friedman's Test: Percentage of Scalp Involved (Placebo Group)

Consultation	Mean Score	Mean Rank	P-Value
Day 1	6.0000	2.81	.000
Day 14	4.0625	1.84	
Day 28	2.6769	1.34	

The above table demonstrates a significant improvement in the variable Percentage of Scalp Involved for the Placebo Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed.

1.5.1. Dunn procedure for Day 1 and Day 14

AS PER 1.1.1.

Therefore:

$/6.0000-4.0625/ < 10.8272$

$/1.9375/ < 10.8272$

The above results show that there was no significant difference between Day 1 and Day 14 within the Placebo Group for variable Percentage of Scalp Involved.

1.5.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$/4.0625-2.6769/ < 10.8272$

$/1.3856/ < 10.8272$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Placebo Group for variable Percentage of Scalp Involved.

1.6. Intra-Group Tests for Placebo Group: Overall Impression

Table 21- Friedman's Test: Overall Impression (Placebo Group)

Consultation	Mean Score	Mean Rank	P-Value
Day 1	6.2706	2.94	.000
Day 14	4.0006	1.91	
Day 28	2.6044	1.16	

The above table demonstrates a significant improvement in the variable Overall Impression for the Placebo Group. The Null Hypothesis was therefore rejected (P= 0.000) and the Dunn procedure was performed.

1.6.1. Dunn procedure for Day 1 and Day 14

AS PER 1.1.1.

Therefore:

$$|6.2706 - 4.0006| < 10.8272$$

$$|2.2700| < 10.8272$$

The above results show that there was no significant difference between Day 1 and Day 14 within the Placebo Group for variable Overall Impression

1.6.2. Dunn procedure for Day 14 and Day 28

AS PER 1.1.1.

Therefore:

$|4.0006 - 2.6044| < 10.8272$

$|1.3962| < 10.8272$

The above results showed that there was no significant difference between Day 14 and Day 28 within the Placebo Group for variable Overall Impression