

THE EFFECT OF A HOMEOPATHIC COMPLEX
(SIL-SEL-HEP-K-LAP-PULS) ON ACNE VULGARIS

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I, Monique Lee, do hereby declare that this dissertation represents my own work in both conception and execution.

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ABSTRACT

The purpose of this study is to evaluate the efficacy of a homoeopathic acne complex Sil-Sel-Hep-K-Lap-Puls, which is an abbreviation of its components - Silicea 30CH, Selenium 9CH, Hepar sulphuris 30CH, Kali bromatum 9CH, Arctium lappa 3CH, and Pulsatilla 30CH, in the treatment of acne vulgaris.

This study is a double blind randomised placebo-controlled clinical evaluation.

Convenience sampling was employed to draw 34 patients, of both sex, median age 21 years from the greater Durban area. Those patients suffering from Acne fulminans, Acne rosacea and Conglobate acne or receiving hormonal, vitamin, Schussler tissue salts, antibiotics and other acne treatments that would affect the acne vulgaris would not be accepted into the treatment.

There were 34 patients of which 16 constituted the control group and received only placebo. The remaining 18 were the experimental group and were treated with the homoeopathic acne complex. The homoeopathic acne complex was prepared by the homoeopathic laboratory, Pharma natura.

The effect of the homoeopathic acne complex was measured in terms of the reduction in the total number of lesions ie. The Leeds Technique for assessing acne vulgaris - the counting technique.

The standardized statistical techniques for non-parametric data used, was the Wilcoxon Test and the Mann Whitney U Test. The results showed no significant improvement over the period of 5 consultations within both groups. There was also no significant difference between groups over the 5 consultations.

The result of this research confirms one of the fundamental laws of homoeopathy ie the law of similars. The law of similars directs the physician to select a remedy according to the totality of that patients symptoms, and not merely a universal remedy.

TABLE OF CONTENTS

ACKNOWLEDGEMENTS	I
ABSTRACT	II
LIST OF TABLES	V
DEFINITION OF TERMS	VI
CHAPTER 1 - INTRODUCTION	1
CHAPTER 2 - REVIEW OF RELATED LITERATURE	3
2.1. Historical overview	3
2.2. Aetiology	3
2.3 Pathophysiology	8
2.4. Treatment	11
2.5. Summary	15
CHAPTER 3 - MATERIALS AND METHODS	17
3.1. Study Design and Protocol	17
3.2 Selection	20
3.3 Subjects	21
3.4. Treatment	22
3.5 Statistical Analysis	23
CHAPTER 4 -RESULTS	26
CHAPTER 5 - DISCUSSION	29
5.1 Interpretation	29
5.2 Argument	29
5.3 Speculation	30
CHAPTER 6 - CONCLUSION AND RECOMMENDATIONS	32
REFERENCES	33
APPENDIX - DETAILED RESULTS	

LIST OF TABLES

	Page
Table 1 : Comparison between placebo and experimental group (Mann Whitney Test)	26
Table 2 : Comparison of samples within the experimental group (Wilcoxon signed Rank test)	27
Table 3 : Comparison with the placebo group (Wilcoxon signed Rank Test)	28

DEFINITION OF TERMS

Repertorising The repertory is a book containing detailed listing of symptoms, followed by the various remedies which have demonstrated such a symptom, whether in provings or in cured clinical cases. The homoeopath then selects the remedy indicated most strongly. (Vithoulkas, 1980: 196.)

Law of similars It matches the symptoms manifested by the patient with the analogous symptom of a therapeutic substance manifested in a healthy individual. This matching therapeutic substance is the similimum. (Jouanny, 1993: 11-13)

Placebo An inactive substance or preparation given to satisfy the patients symbolic need for drug therapy and used in controlled studies to determine the efficacy of medicinal substances. Also, a procedure with no intrinsic therapeutic value, performed for such purposes. (W.B. Saunders, 1989: 471)

Acne Vulgaris An inflammatory disease of the skin with the formation of an eruption of papules or pustules. (W.B. Saunders 1989: 7)

CHAPTER 1 - INTRODUCTION

It is clear from the amount of research being done as well as assessments of the psychological well being of patients suffering from acne vulgaris eg Cardiff Acne Disability Index, that it is a condition that needs to be treated (Oakley, 1996).

For the majority of patients with acne the actual appearance of their skin and the consequent lack of self esteem are the most important considerations, as the following quotation suggests: "very embarrassing, not nice to look at, very self conscious" (Cunliffe, 1989 : 9).

In a study of unemployment and acne, it showed that the incidence of those suffering from acne had an unemployment rate of 16.5% compared to 9.2% with those of non acne patients (Walshe, 1972).

It has been seen that the various allopathic approaches to the condition does in numerous cases result in intolerable side effects (Sitbon *et al.* 1994) and relapses (Hughes and Cunliffe 1994).

As antibiotics should not be used for less than three months and may be necessary for two to three years, systemic measures using antibiotics repeatedly over a long period of time may result in the development of resistant strains of bacteria (Edwards and Bouchier, 1991). Hormone therapy for women in the form of oral contraceptives provides therapy that affects the endocrine system and thus produces

the concomitant side effects. (Chompootaweeep *et al.*, 1996).

Topical preparations containing Benzoyl peroxide and retinoic acid is the standard form of local treatment, but act as irritant and drying agents (Edwards and Bouchier, 1991).

The ability to treat the general predisposition to acne cannot be treated allopathically. The correct homoeopathic approach to the patients condition will result in treatment from the point of the general predisposition to develop acne vulgaris. (Vithoulkas, 1980 : 6)

Thus homoeopathy as a form of treatment for acne vulgaris must be investigated. Research into the treatment of acne vulgaris with the use of a homoeopathic similimum has been done with good results (McDavid, 1994). Research however, to evaluate the efficacy of a homoeopathic complex (Sil-Sel-Hep-K-Lap-Puls) on acne vulgaris has not been done.

CHAPTER 2 - REVIEW OF THE RELATED LITERATURE

2.1. HISTORICAL REVIEW

Acne has plagued mankind since antiquity, even King Tutenkamun was found to have scars of this disorder. Daniel Turner (1667 - 1741) wrote the first text book on dermatology and can be credited with suggesting dietary restrictions in the treatment of acne. Ferdinand von Hebra (1816 - 1880) was noted to have said that no one had discovered the cause, except for a few irritants which were only under certain conditions. (Parish and Witowski, 1979 : 7-9.)

2.2 AETIOLOGY

GENETICS

It is often said that acne is an inherited disease, but although the circumstantial evidence is convincing proof is lacking. In an investigation of 95 pairs of identical twins with acne, in 97.9% of pairs, both were affected. (Cunliffe, 1989.)

It has recently been seen that identical twins have identical rates of sebum secretion, but although many have acne, the severity is not identical (Walton *et al.*, 1988).

Eighty two percent of patients with acne in one series gave a history of acne in at least one sibling and in 60% a history of acne was obtained from one or both parents

(Cunliff and Cotterill, 1975: 6).

HORMONES

The unquestionable fact is that acne vulgaris is, in general, hormone dependent. Circumstantial evidence was already clear in 1940 when Sulzberger wrote " It is physiologic for some degree of acne to appear while the skin first begins to feel the influence of the circulating sex hormones". (Ebling, 1988:47)

Androgens from the testes, ovaries and adrenal glands are the main hormones which stimulate sebum secretion. In girls the sebaceous glands become functional as the level of circulating androgens rise at adrenarchy, which may develop as soon as the fifth to eighth year of life and may precede menarchy by more than a year. (Pochi *et al.*, 1977) In boys the onset of acne is often associated with the rise in serum testosterone at puberty (Lee, 1976).

Androgens may be involved in two ways. Excessive levels may stimulate the sebaceous glands, or the glands themselves may be particularly sensitive to normal levels (end organ hypersensitivity). Acne may indeed result from androgen excesses after exogenous administration of testosterone, in androgen- secreting tumors or in other forms of androgenization in women such as polycystic ovary syndrome. (Edwards and Bouchier, 1991: 916)

If acne depends on sebaceous secretion and sebaceous secretion is influenced by androgens, the question is, does acne result from high levels of circulating male hormones? For males, there was general agreement that sufferers from acne did not have abnormally high concentrations of testosterone in their plasma. In females, however, it seemed the situation might be different. Normal females have less than one tenth the levels that males had, but the mean amounts were significantly greater in those with acne. (Ebling, 1988:47)

The menstrual cycle is also thought to affect acne. Of female subjects 60 - 70% notice a deterioration of their acne in the week before menstruation, the lesions being more prominent for the next 7 - 10 days. (Cunliffe, 1989:6)

DIET

Until two decades ago, the general clinical impression among dermatologists was that of a relationship between acne and diet. For many years until around 1970, dermatologists told their patients to avoid certain foods especially pork fat, chocolates, nuts etc. (Cunliffe, 1989:7.)

In a 1987 study investigating the relationship between acne severity and diet (Cunliffe, 1989:7) one hundred subjects were interviewed by a dietician to establish their eating habits. The interviews were conducted 2 months into therapy to prevent bias by the subjects facial acne (the interviewer did not see the patients trunk). On

computer analysis no link was found between acne severity and total caloric intake. Nor was there any correlation between acne severity and types of food ingested. Thus it seems unlikely that dietary manipulation will significantly modify the acne problem. (Cunliffe, 1989:8)

VITAMINS

A number of investigations of the effects of vitamin A deficiency in animals and man and its treatment with natural products containing Vitamin A were carried out in the twenties and thirties. In 1942, a clinical study in patients with acne treated with vitamin A yielded encouraging results. Further trials in the forties and fifties, trying to confirm the beneficial effects of oral vitamin A in acne met with equivocal success. In the sixties all trans retinoic acid (tretinoin) became clinically available. (Hartmann and Bollag, 1993)

ENVIRONMENTAL FACTORS

It has been demonstrated that acne is more common and more severe in industrial and mining areas than the countryside (Rook, 1957).

PSYCHOLOGICAL FACTORS

In acne, as in many skin diseases stress has been implicated as a causative factor. The

possibility that stress aggravates acne will be difficult to prove. (Cunliffe, 1989:9)

Kenyon (1966) found in the the predisposed individual that exacerbations of acne can occur as a result of emotional stress. Other studies have demonstrated flare ups of acne in medical students (8 males and 1 female) associated with the stress of a compulsory academic examination. (Krauss, 1970)

SEBUM

Increased sebum secretion need not alone cause acne for example, patients with acromegaly and Parkinsons disease have high sebum secretion rates but no acne. Sebum seretion may also remain high even though the acne has healed. The sebum of patients with acne contains an excess of free fatty acids. (Edwards and Bouchier, 1991) It is however generally accepted that the greater the sebum production is, the greater the tendency will be to develope acne. (Hommel *et al.*,1996)

FOLLICULAR KERATINIZATION

Although the presence of Proprianobacterium acnes (P. Acnes) in comedones suggests that bacteria might provide the stimulus, bacteria cannot be detected in early comedones. The end result of follicular hyperkeratinization is the development of an open comedo. (Knutson, 1974)

INFLAMMATION

P. acnes break down the triglycerides to free fatty acids in the sebum, and sparks off the anti inflammatory response (Edwards and Bouchier, 1991: 916).

OTHER FACTORS

Cosmetics, irritant oils and the topical application of other medicinal chemicals can provoke a flush of acne (Cunliffe, 1989).

2.3. PATHOPHYSIOLOGY

Acne vulgaris is a disease characterized by both non inflammatory (comedones) and inflammatory lesions (papules, pustules and nodular cystic lesions).(Ebling,1988:77)

The current concept of the pathogenesis of acne shows a common pathway for the development of a precursor lesion, the micro-comedo, which may then develop into inflammatory or non inflammatory lesion. The exact mechanism which controls whether a micro-comedo will result in a mature comedo or an inflammatory lesion is not yet understood. (Dolitski and Shalita, 1988)

The earliest pathological change in acne is altered follicular epithelial differentiation showing follicular retention hyperkeratosis, the micro-comedo. The earliest of these lesions appear before the colonization of the follicle by bacteria. (Knutson, 1974)

Inflammatory lesions develop after the follicle has been colonized by *P. Acnes* and involves a variety of pathogenic factors including *P. Acnes*, inflammatory mediators and host immunity (Dolitski and Shalita, 1988).

Historically, the free fatty acid proportion of sebum was felt to be the crucial aetiological factor inducing inflammation known as the "free fatty acid theory" of acne pathogenesis. Later the free fatty acid theory of acne pathogenesis was questioned when it was shown that intradermal injections of free fatty acids, in amounts calculated to represent those of sebaceous follicles did not induce inflammation. (Puhvel and Sakamoto, 1977.)

They did however did not take into account the continuous generation of new free fatty acids in the follicle, and may thus have decreased the actual amount of free fatty acids in the follicle over a period. (Dolitski and Shalita, 1974). However, recent studies suggest that free fatty acids in the follicle may contribute to inflammation by both chemotactic and cytotoxic properties towards polymorphonuclear leukocytes and monocytes (Tucker *et al.*, 1990). It was then demonstrated that intra follicular free fatty acids are derived mainly from the hydrolysis of sebum triglycerides by the follicular microflora mainly *P. Acnes* (Shalita, 1974)

Free fatty acid derivatives such as peroxide of squalene and oleic acid in the follicular infundibulum are more highly comedogenic than the free fatty acids themselves. (Motoyosh, 1983). Further more as a secondary effect, squalene oxidation sets up

the micro-aerophilic condition ideal for the proliferation of propionobacteria. Finally squalene oxide may have intrinsic cytotoxic and inflammatory properties. (Saint Leger *et al.*, 1986)

The follicular flora of patients with all forms of acne contain the anaerobic diptheroid propionobacterium *acnes* in high concentrations, in combination with aerobic cocci, *staphylococcus epidermis* (Puhvel *et al.* 1975) and the yeast *Pitysporium ovale* (Leeming *et al.* 1986). Although all 3 organisms are capable of producing lipases in vitro (Shalita, 1974), *P. Acnes* is the organism which regulates the levels of free fatty acids in vivo. The result obtained from experiments show that the inhibition of *P. Acnes* alone produces a significant decrease in skin surface free fatty acids (Ebling, 1985).

P. Acnes undoubtedly plays a major role in the evolution of inflammatory lesions. When viable organisms are injected into non inflamed cysts, they cause severe inflammation (Kirstenbaum and Kligman, 1963). It also produces biologically active mediators including proteases, phosphatases, hyaluronidase and neuraminidase, which contribute to an increase in the permeability of the follicular epithelium (Puhvel and Reisner 1972); (Holland *et al.*, 1978).

During its active growth phase, *P. Acnes* usually liberates low molecular weight, dialysable, heat stable chemotactic factors which theoretically could diffuse through the follicular wall and attract neutrophils to migrate towards the follicle. *P. Acnes* is readily phagocytosed by neutrophils in the presence of serum (antibody). This

triggers the release of lysosomal hydrolases which then contribute further to the breakdown of the follicular wall. (Week *et al.*, 1977) This allows for the escape of other higher molecular weight chemotactic factors (Lee *et al.*, 1982).

In addition the follicular contents consisting of sebaceous lipids, cornified cells and P. Acnes organisms are released into the surrounding dermis and this will incite foreign body reaction (Ebling, 1988 : 78).

P. Acnes and its cellular constituents can propagate inflammation by the activation of complement via both classical and alternate pathways, thereby generating C5 chemotactic factors (Webster *et al.*, 1978; Knop *et al.*, 1982; and Pigato *et al.*, 1983). Anti P. Acnes antibodies in the serum of acne patients enhance this complement consumption (Pigato *et al.*, 1983).

Cytotoxic agents may escalate inflammation by damaging host cells, causing them to liberate inflammatory substances. It was first demonstrated that titres of complement fixing antibodies to P. Acnes are significantly higher in patients with acne than in the control group. (Puhvel *et al.*, 1966)

2.4 TREATMENT

Allopathic treatment

Comedones and papular acne is managed by local treatment alone. Pustular cystic

and scarring acne requires local and systemic treatment (Edwards and Bouchier, 1991:917).

Topical treatment - Azelaic acid is an option of topical treatment of acne vulgaris. It offers effectiveness similar to that of other agents without the systemic side effects of oral antibiotics, or allergic sensitization of topical benzoyl peroxide and with less irritation than tretinoin. Whether it is safe and effective when used in combination with other agents is not known. (Mackrides and Shaughnessy, 1996)

Silicol gel is also effectively used to reduce the number of acne lesions and sebum production (Lassus, 1996).

Four percent Nicotamide gel has proved to be of comparable efficacy when compared to 1% Clindamycin gel in the treatment of acne vulgaris. Because topical clindamycin like other antimicrobials, is associated with the emergence of resistant micro-organisms, nicotamide gel is considered a desirable alternative to treatment for acne vulgaris. (Shalita, *et al.*, 1995)

Preparations containing benzoyl peroxide and retinoic acid are irritant and drying (Edwards and Bouchier, 1991: 917).

SYSTEMIC MEASURES

Current therapy is aimed towards modulating the pathogenic factors in the inflammatory response. Broad spectrum antibiotics appear to exert their beneficial therapeutic effect by increasing the population of *P. Acnes*, and possibly by inhibiting *P. Acnes* lipase production and thereby suppressing the formation of free fatty acids. (Shalita, 1974)

The clinical efficacy of Isotretinoin can be partially attributed to its effect on the inflammatory pathways. Isotretinoin directly reduces *P. Acnes* count by altering micro-environments and it inhibits neutrophil chemotaxis (Pigatio, *et al.*, 1983). It also inhibits lysosomal enzyme release (Camis, *et al.*, 1982). The T - helper -cells of treated patients is also stimulated (Holland, *et al.* , 1984).

Antibiotics are generally used initially. They should not be used for less than 3 months and may be necessary for 2 - 3 years. Oxytetracycline (up to 250 mg. Q.I.D) are suitable doses for adults with moderate acne, but larger doses may be required. (Edwards and Bouchier, 1991:917)

The follicular reservoir and sustainable sebum excretion rates can be profoundly reduced by the end of a course of Isotretinoin (Hughes and Cunliffe, 1994).

The contraceptive pill in its commonest combination ie mini pill (0.03 ug

Ethinylestradiol) probably has limited, if any, effect on acne but there is evidence that the maxi pill containing larger amounts of oestrogen (0.05 ug ethinylestradiol) has considerable greater effect on acne lesions (Pochi *et al.*, 1973).

PHYSICAL MEASURES

Cysts can be incised and drained under local anaesthetic. Intra lesional injections of Triamcinolone acetonide (0.1 - 0.2 ml of a 10 mg/ml solution) hastens the resolution of stubborn cysts. (Edwards and Bouchier, 1991:917)

AYURVEDIC TREATMENT

Research has been done using Ayurvedic formulations. Four different Ayurvedic treatment schedules were given orally for 6 weeks. Significant reduction in lesion count was observed with patients receiving Sunder Vati. (Paranjpe and Kulkarni, 1995)

HOMOEOPATHIC TREATMENT

Homoeopathic treatment was formulated by Samuel Hahneman and is based on the Law of similars. It is thus important to understand the symptom pictures (relating to acne) of the remedies used to compile the homoeopathic acne complex. (Vermeulen, 1994)

* Silicea : Painful pustular eruptions , disposition to boils, stinging on touch (Vermeulen,1994 : 884) .

* Selenium : Comedones and an oily surface on the skin. Acne (Vermeulen, 1994 : 886).

*Hepar Sulphuris Calcareo : Abscesses. Papules prone to suppurate and extend. Acne in youth.(Vermeulen, 1994 : 486)

* Kalium bromatum : Acne of face, pustules, itching acne, chest shoulders and face (Vermeulen,1994 : 538).

*Arctium lappa : Eruption, sticky on face, many small painful boils (Vermeulen, 1994 : 584).

*Pulsatilla pratensis : Acne at puberty (Vermeulen, 1994 : 802).

2 5. SUMMARY

The allopathic drugs have side effects severe enough to make most sufferers consider alternative forms of therapy. The frequency of relapses after symptomatic treatment with allopathic drugs is frustrating to the patients. The use of hormone therapy in the form of oral contraceptive for women is not always acceptable.

Dietary modifications have always been considered an important part of any medical condition to improve overall health. It has however, not shown to improve the condition to any significant degree. Vitamin supplements have shown to have an influence in improving the condition. The effect of psychological stress has proved

to be an aggravating factor. There have been encouraging results in the treatment of acne with Ayurvedic and homoeopathic simillimum. Thus there is a need to test the efficacy of a homoeopathic complex in the treatment of acne vulgaris.

CHAPTER 3 - MATERIALS AND METHODS

The objective of the research was to assess the patients progress in response to the homoeopathic treatment in reducing the overall total number of lesions.

The experimental design was "double blind placebo-control".

3.1. STUDY DESIGN AND PROTOCOL

THE LEEDS TECHNIQUE FOR ASSESSING ACNE VULGARIS

The counting technique (Burke and Cunliffe, 1984)

Lesions were divided into inflamed or non inflamed lesions as follows:-

A. Non-inflamed lesions : Open comedos (black heads) and closed comedos (white heads). Prominent follicles, small milia were rigorously excluded as they occur frequently and would badly distort the results.

B. Inflamed lesions were either superficial (papules and pustules) or deep (nodules, cysts and deep pustules)

- i superficial papules and pustules varied in size from 0,1 cm (with minimal erythema) to 0,5 cm (with a marked macular flare)
- ii Deep inflamed lesions were predominantly nodules which were 0,5cm or larger . Palpation was essential, since some of the the nodules were almost invisible but easily palpable.
- iii Macules represent the resolving phase of either superficial or deep lesions

and were either large or small. They were included in acne assessment as they contribute to the overall degree of inflammation

Lesion counting is not easy and attention to the following points helped to avoid errors:-

1. The patient should be sitting comfortably so that the observer can move around the patient easily to count each area.
2. In addition to good fluorescent lighting, a fluorescent lamp, which can be easily moved to illuminate both sides of the patient during the examination is recommended
3. When counting, the face is divided into the right and left sides and counted both sides. In some patients the lesions are clustered around the midline making a right left division difficult. Forehead, cheeks and chin were then counted separately and the counts combined.
4. Palpation is necessary because some macules may look like a nodule, but on palpation show no depth at all. Conversely a nodule may hardly be visible and yet can be felt to lie deep in the skin.
5. Stretching of the skin will increase the number of whiteheads and blackheads that are visible, but as degree of stretching might vary, this is not permitted for similar reasons. It is recommended that no tension is used. If a lesion is impalpable and not obvious with good lighting, then such a vague lesion is best ignored.

PITFALLS FOR THE UNWARY (Burke and Cunliffe, 1984)

A. Prominent Follicles

Confusion of non-inflamed lesions with prominent follicles is a problem around the nose and chin, especially in mid-teenager. In therapeutic trials it is recommended that non inflamed lesions are not counted either on the nose or around the edge of the nose.

B. Hairstyles

Many young people change their hairstyles frequently. Long uncut hair may mask non-inflamed lesions and are thus avoided in the count. However there is usually no difficulty in recognizing inflamed lesions in this area.

C. Shaving

Patients may grow a moustache or beard during the trial and this will complicate the results. Patients may also develop low grade folliculitis on the chin and neck as a result of shaving trauma. However, the papules and pustules associated with a folliculitis are much less easily felt than acne lesions. Patients should shave daily, preferably at a constant time as stubble can affect the interpretation of all lesions.

D. Cosmetics

Despite advice to the contrary, some females will use make up. This must be removed and the patient observed 30 minutes later, when the erythema resulting from washing has settled.

E. Ultra violet radiation - this will camouflage the non inflamed lesions and make the inflamed lesions look less inflamed. For this reason, trials should not be

performed in the summer season.

F. Other dermatosis - Sycosis barbae may occur in association with acne and low grade seborrhoeic eczema may simulate a primary irritant dermatitis seen commonly with such treatments as benzoyl peroxide.

3.2 SELECTION

A minimum of 34 patients were selected between the ages of 14 and 30 years. The selection was done by convenience sampling. The patients were of both sexes and from the greater Durban area. They were randomly divided into two groups (experimental and placebo) in such a way that each patient had an equal chance of being selected for either group. Finally there were 18 experimental patients and 16 placebo patients.

3.1.1. Area to be assessed

Only the face area was assessed, which included chin and neck. Patients with spots on their backs and chest as well as their face had only their faces assessed. Since the back and chest area are difficult to define, counts for clinical trials are usually confined to face and neck (Cunliffe, 1989).

3.1.2. Establishing the baseline

All 34 patients had to be off acne treatment of any form for at least 4 weeks, before the start of the research.

In an ideal world subjects should be off treatment for at least 3 months before starting the research but in practice this is normally impossible. This ensures that subjects are off treatment for a selected minimum period before a clinical trial in order to establish an adequate base line (Burke and Cunliffe 1984).

3.2. SUBJECTS

3.2.1 Selection Criteria

The selection criteria determined that any patient under the following treatment would be excluded from the research:-

- * any dermatological therapy - ie medicinal or surgical
- * antibiotic treatment
- * hormonal therapy including - cortisone therapy
Oral contraception
Anti androgens
- *vitamin and mineral therapy
- * Schussler tissue salts

The selection criteria also determined that anyone with the following conditions would be excluded from the research-

- * Acne fulminans
- * Conglobate acne
- * Acne rosacea

Patients were advised not to change their life style and dietary habits during the trial.

All 34 patients were assessed using the Leeds technique for assessing acne vulgaris (Burke and Cunliffe, 1984) The patient at each consultation was evaluated by the same researcher and a medical colleague.

3.3. TREATMENT

This was a double blind study in which an independent researcher allocated the homoeopathic acne complex or placebo to the patient.

The homoeopathic acne complex for the experimental group consisted of a carrier substance ie saccharum lactus pillules impregnated with the following:

Kalium Bromatum 9CH

Selenium 9CH

Pulsatilla Pratensis 30CH

Hepar sulphuris calcarea 30CH

Silicea 30CH

Arctium Lappa 3CH

prepared by the homoeopathic laboratories - Pharma Natura.

The control group was given the placebo i.e. Saccharum lactus pillules unmedicated.

The homoeopathic acne complex and placebo pillules were dispensed in a No. 2 Vial (10 ml). Both groups were instructed to take 3 pillules every alternate morning.

A full case history was taken and a physical examination performed at each initial consultation. The treatment program lasted for ten weeks and the patients condition was reviewed and recorded every 2 weeks. Each patient was informed that neither the researcher nor the patient would know who was issued with the placebo or

homoeopathic acne complex. The patients would only be accepted into the trials once they were informed and accepted the possibility of being put in the control group.

3.4 STATISTICAL ANALYSIS

3.4.1 Procedure one.

Comparison between Experimental and Placebo Groups using the Mann-Whitney Test. The two groups were treated as being independent of one another (unpaired).

The purpose is to find out whether there is significant difference between the placebo group and the experimental group, at the $\alpha = 0.05$ level of significance.

Hypothesis testing :

The null hypothesis states that there is no significant difference between consultations within the placebo group and the experimental group. The alternative hypothesis states that there is a significant difference within the experimental group and within the placebo group.

$$H_0 : \mu_1 = \mu_2$$

$H_1 : \mu_1$ and μ_2 are significantly different from each other.

$\alpha = 0.05$ = level of significance of test.

Decision rule:

Reject H_0 if $p \leq \alpha/2 = 0.025$

Accept H_0 if $p > \alpha/2 = 0.025$

P is the observed probability value which is equal to half of the two-tailed Z -value.

That is : $P = (\text{two-tailed } z\text{-value}) / 2$. (Gulezian, 1979 : 335.)

3.4.2 Procedure 2

10 Wilcoxon's Signed Rank Tests were used within the experimental group to find out whether there is any significant improvement between successive consultations.

Hypothesis testing :

The null hypothesis states that there is no significant improvement between consultations.

Ho : There is no significant improvement

Hi : There is significant improvement.

Alpha = 0.05 = Level of significance.

Decision Rule :

Reject Ho if $P \leq \alpha/2 = 0.025$

Accept Ho if $P > \alpha/2 = 0.025$

P is the observed probability value which is equal to half of the two- tailed Z- value
(Gulezian, 1979 : 335.)

3.4.3 Procedure 3

10 Wilcoxons Signed Rank Tests were used within the placebo group to find out whether there was any significant improvement between successive consultations.

Hypothesis Testing:

The Ho states that there is no significant improvement between consultations.

H_0 : There is no significant improvement

H_1 : There is significant improvement

Alpha = 0.05 = level of significance

Decision rule:

Reject H_0 if $P \leq \alpha/2 = 0.025$

Accept H_0 if $P > \alpha/2 = 0.025$

P is the observed probability value which is equal to half of the two-tailed Z-value.

$P = (\text{two-tailed Z-value}) / 2$

$P = (\text{two-tailed Z-value}) / 2$. (Gulezian, 1979 : 335)

CHAPTER 4 - RESULTS

Table 1 : Comparison between placebo and experimental group.
(Mann Whitney Test)

Group	Consult	SL	P-value	Ho
placebo	5	0.05	0.39	accept
experiment	5	0.05	0.39	accept
placebo	4	0.05	0.38	accept
experiment	4	0.05	0.38	accept
placebo	3	0.05	0.46	accept
experiment	3	0.05	0.46	accept
placebo	2	0.05	0.08	accept
experiment	2	0.05	0.08	accept
placebo	1	0.05	0.09	accept
experiment	1	0.05	0.09	accept

SL : Significance level

Ho : There is no significant difference between experimental and placebo groups

Consult : Consultation

Conclusion : There appears to be no significant difference between both experimental and placebo groups over the five consultations at the $\alpha = 0.05$ level of significance.

Table 2 : Comparison of samples within the experimental group.
(Wilcoxon Signed Rank Test)

Samples	SL	P-value	Ho
sample 1 M11	0.05	0.04	reject
sample 2 M21	0.05	0.04	reject
sample 1 M11	0.05	0.4	accept
sample 2 M31	0.05	0.4	accept
sample 1 M11	0.05	0.16	accept
sample 2 M41	0.05	0.16	accept
sample 1 M11	0.05	0.001	reject
sample 2 M51	0.05	0.001	reject
sample 1 M21	0.05	0.4	accept
sample 2 M31	0.05	0.4	accept
sample 1 M21	0.05	0.4	accept
sample 2 M41	0.05	0.4	accept
sample 1 M21	0.05	0.3	accept
sample 2 M51	0.05	0.3	accept
sample 1 M31	0.05	0.23	accept
sample 2 M41	0.05	0.23	accept
sample 1 M31	0.05	0.1	accept
sample 2 M51	0.05	0.1	accept
sample 1 M41	0.05	0.13	accept
sample 2 M51	0.05	0.13	accept

SL : Significance level

M11 : consultation 1 experimental group

M21 : consultation 2 experimental group

M31 : consultation 3 experimental group

M41 : consultation 4 experimental group

M51 : consultation 5 experimental group

Ho : There is no significant improvement between samples at the $\alpha = 0.05$ level of significance

Conclusion : There is a significant improvement between the following consultations ;

M11 and M21; M11 and M51 at the $\alpha = 0.05$ level of significance

: There is no significant improvement between the following consultations ;

M11 and M31; M11 and M41; M21 and M31; M21 and M41;

M21 and M51; M31 and M41; M31 and M51; M41 and M51 at the $\alpha=0.05$ level of significance.

Table 3 : Comparison of samples within the placebo group.
(Wilcoxons Signed Rank Test)

Samples	SL	P-value	Ho
sample 1 M12	0.05	0.4	accept
sample 2 M22	0.05	0.4	accept
sample 1 M12	0.05	0.03	reject
sample 2 M32	0.05	0.03	reject
sample 1 M12	0.05	0.0005	reject
sample 2 M42	0.05	0.0005	reject
sample 1 M12	0.05	0.012	reject
sample 2 M52	0.05	0.012	reject
sample 1 M22	0.05	0.04	reject
sample 2 M32	0.05	0.04	reject
sample 1 M22	0.05	0.6	accept
sample 2 M42	0.05	0.6	accept
sample 1 M22	0.05	0.019	reject
sample 2 M52	0.05	0.019	reject
sample 1 M32	0.05	0.273	accept
sample 2 M42	0.05	0.273	accept
sample 1 M32	0.05	0.06	accept
sample 2 M52	0.05	0.06	accept
sample 1 M42	0.05	0.5	accept
sample 2 M52	0.05	0.5	accept

SL : Significance level

M12 : consultation 1 placebo group

M22 : consultation 2 placebo group

M32 : consultation 3 placebo group

M42 : consultation 4 placebo group

M52 : consultation 5 placebo group

Ho : There is no significant improvement between samples at the $\alpha = 0.05$ level of significance

Conclusion : There is no significant improvement in the placebo group between consultations ;
M12 and M22; M22 and M42; M32 and M42; M42 and M52 at the $\alpha = 0.05$ level
of significance.

: There is significant improvement in the placebo between consultations ;
M12 and M32; M12 and M42; M12 and M52; M22 and M32;
M22 and M52 at the $\alpha=0.05$ level of significance.

CHAPTER 5 - DISCUSSION

5.1. INTERPRETATION

It can be seen that the homoeopathic complex chosen for this research did not produce a statistically significant decrease in the number of acne lesions (Table 2). Similarly the placebo group showed no statistically significant improvement in the condition (Table 3).

According to Tables 1 and 4 the comparison between the experimental and placebo group indicated that there was no statistical significance between the two groups in reducing the number of acne lesions .

Thus the investigation proved that the treatment of acne vulgaris in terms of its clinical manifestations with this homoeopathic complex was not effective.

5.2 ARGUMENT

The treatment of acne vulgaris with the homoeopathic similimum has however provided encouraging results. It is safe to state that as far as the clinical manifestations of acne vulgaris is concerned, homoeopathy plays both a statistically significant and observably notable role in the treatment and management of this condition. The placebo effect however, played a somewhat minor role.(McDavid,

1994 :73)

It can be seen that the correct homoeopathic remedy selected, i.e. according to the law of similars, was the most effective. Thus if the correct remedy was not present in the homoeopathic complex, the patient would not be cured.

5.3. SPECULATION

In further studies which would determine the efficacy of homoeopathic complexes on such conditions as acne vulgaris I would suggest successive clinical trials.

Firstly the patients would receive the complex and at the end of the trial whether the patient was cured or not the case would be repertorized.

After a course of time ie to allow the effect of the complex to settle, the similimum determined would be administered and the results recorded.

Thus a comparative study would have been done between the complex and similimum on the same patient. If the complex contained the similimum, then the efficacy of the single remedy can be compared to being administered together with the other remedies.

In homoeopathic research involving chronic conditions and taking into consideration the sophistication of the case taking procedure to determine the similimum, it would be advisable that there should not be a language barrier. If there is a problem with

language it will affect the quality of the therapy and thus the research.

CHAPTER 6 - CONCLUSION AND RECOMMENDATION

6.1 CONCLUSION

In this study the researcher attempted to investigate the effect of a homoeopathic complex in reducing the number of lesions in acne vulgaris.

It can be seen that it did not play a statistically significant role in improving the condition although there was a general tendency to improvement.

6.2. RECOMMENDATIONS

In the future studies associated with this topic may include the presence of scarring as part of the lesional count or this can be done as a separate topic for research.

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APPENDIX - DETAILED RESULTS

Variable	m11
Average	19.833333
median	19.
Mode	19
Standard error	2.719153
Range	41.
Coeff. Of variation	58.166659

Variable	m12
Average	20.3125
Median	18.5
Mode	18.0
Standard error	2.38523
Range	32.
Coeff. Of variation	46.970686

Variable	m21
Average	16.277778
Median	16.5
Mode	11
Standard error	2.330258
Range	37.
Coeff of variation	60.735851

Variable	m22
Average	17.0625
Median	15.5
Mode	10.
Standard error	2.288502
Range	26.
Coeff of variation	53.649854

Variable	m31

Average	16.22222
Median	11.5
Mode	7.
Standard error	2.4058
Range	41.
Coeff. Of variation	62.9199

Variable	m32

Average	15.5625
Median	13.5
Mode	6.
Standard error	2.49016
Range	41.
Coeff. Of variation	57.8060

Variable	m41

Average	17.4444
Median	16.
Mode	12.
Standard error	2.719153
Coeff. Of variation	73.2593

Variable	m42

Average	12.5
Median	11.
Mode	6.
Standard error	2.1813
Coeff. Of variation	69.8035

Variable	m51
Average	15.1111
Median	15.
Mode	6.
Standard error	2.7191
Range	34.
Coeff. Of variation	60.6894

Variable	m52
Average	11.5
Median	8.
Mode	4.
Standard error	2.5996
Range	36.
Coeff. Of variation	90.4236
