

The Homoeopathic treatment of Acne

BY

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Dissertation submitted in partial compliance with the Master's
Diploma in Technology in the Department of Homoeopathy at
Technikon Natal

Date of Submission: February 1994

I, Gillies Malcolme McDavid, do hereby declare that in respect of the following dissertation/ thesis, " The Homoeopathic Treatment of acne"; as far as I know and can ascertain no other dissertation/ thesis exists, and all references as detailed in the dissertation are complete in terms of all personal communications engaged in and published works consulted.

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ACKNOWLEDGMENTS

The author would like to thank the following people for their invaluable help and assistance:

Dr. P. A. Frazer

Dr. R. P. Boyer MD (Montpellier France) D Hom (Fr)

MOMHI MTACMS

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ABSTRACT

The aim of this study was to determine the degree of proficiency of Homoeopathy in the treatment of Acne Vulgaris in terms of its clinical manifestations and the patients perception to the treatment in order to determine the role Homoeopathy plays, if any, in the treatment of this condition.

In this study the specific single variable design chosen was the "before-and-after with control". A sample of thirty patients was randomly taken from the greater Durban area , and from this sample fifteen patients were treated with Homoeopathic treatment and the remaining fifteen received placebo treatment. Patients were screened using a series of delimitations set out in a consent form which was signed by the patients.

An extensive case history was performed on each patient at the first consultation in order to assess their Mental, Emotional and their Physical well being and were seen at regular four week intervals thereafter. The patients were also photographed at the first and all the subsequent visits.

Based on the case history and a physical examination, Homoeopathic medication or placebo was prescribed according to the law of similars. At each of the following consultations the patients completed a questionnaire regarding their perception to the treatment and were rephotographed noting any changes.

The study was conducted using the double blind protocol having a neutral pharmacist dispense the medication/ placebo to the patients.

Three subproblems were derived from the problem statement. The hypotheses of the first two subproblems were tested using a parametric 2 sample analysis technique known as the paired -t test. The third subproblem's hypothesis is tested using the correlation technique.

When testing the hypothesis of the first subproblem, the first and last sets of observations of both the treatment and the placebo groups were compared to give the following results: of the treatment group 60% improved, 33.3% remained unchanged and 6.6% worsened. The paired - t test performed on the data revealed the differences to be statistically significant ($P=0.006$). In the placebo group 33.3% improved, 46.6% remained unchanged and 20% worsened. These differences were found to be statistically insignificant ($P=0.384$).

On testing the hypothesis of the second subproblem, the first and last sets of observations of both the treatment and the placebo groups were compared with each other to give the following results : of the treatment group 60% improved , 6.66% remained unchanged and 33.3% worsened. A paired - t test performed on the data revealed the differences to be statistically significant ($P=0.015$). In the placebo group 73% improved, 0% remained unchanged and 26.6% worsened which was also found to be statistically significant ($P=0.001$). The similarity of these P values indicates that the perception by

the patient to the treatment of both groups were similarly influenced by both the homeopathic medication and the placebo effect.

In the third subproblem, the data was integrated from the first two subproblems and its hypothesis was tested. There was found to be a positive correlation (0.8482) between the clinical manifestations of the patients acne and the patients perception to the treatment in those patients that were given homeopathic treatment. There was found to be a poor correlation (between -0.2567 and 0.6390) between the clinical manifestation of those patients on placebo and their perception to the treatment, .i.e. the patients who were given placebo showed a modification as far as their perception to the treatment was concerned but the clinical manifestations of their acne did not alter proportionately.

As far as the clinical manifestations of Acne Vulgaris were concerned, Homoeopathy played 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.

Although there was an observable effect, it could not however be said that Homoeopathic medication alone played a notable role in the patients perception to the treatment due to the fact that both the placebo effect and the homeopathic medication had similar influences on the patient.

UITTREKSEL

Die doel van hierdie studie was om die doeltreffendheid van Homeopatie vas te stel in die behandeling van Acne Vulgaris in terme van die kliniese manifestasie en die pasiente se persepsie van die behandeling om die rol van Homeopatie, in dien enige, te bepaal in die behandeling van hierdie toestand. Die studie het die enkele spesifieke veranderlike vorm van die "voor-en-na" met kontrole aangeneem. 'n Steekproef is op pasiente uit die groter Durban area gedoen en 30 pasiente is gekies, van wie vyftien Homeopaties behandel is en die ander vyftien toetsmedisyne ontvang het. Die gekose pasiente moes voldoen aan sekere vereistes en het 'n toestemmingsvorm onderteken.

'n Uitgebreide mediese geskiedenis is van elke pasient geneem gedurende die eerste ondersoek om vas te stel wat hulle geestelike, emosionele en fisiese toestand was en hulle is daarna op gereelde vier-weeklikse basis gesien. Foto's is met die eerste en die daaropvolgende besoeke van die pasiente geneem.

Homeopatiese medisyne of toetsmedisyne is volgens die wet van gelyke voorgeskryf gegrond op die mediese geskiedenis en kliniese ondersoek. Met elk van die daaropvolgende ondersoek moes die pasiente 'n vraelys voltooi in verband met hulle waarneming van die behandeling; foto's is geneem en enige veranderinge is aangeteken.

Die studie is uitgevoer deur gebruik te maak van die dubbele blinde protokol met 'n onpartydige apteker wat die medikasie/plasebo aan die pasiente verskaf het.

Drie sub-probleme het voortgespruit uit die probleem. Die hipotese van die eerste twee sub-probleme was getoets deur gebruik te maak van 'n parametriesse twee-monster-ontledings tegniek wat bekend staan as die gepaarde-t toets. Die derde sub-probleem se hipotesis is getoets deur gebruik te maak van die korrelasie tegniek.

Toe die hipotesis van die eerste sub-probleem getoets is, is die eerste en laaste stel bevindings van beide die eksperimentele en die kontrole groepe vergelyk. In die eksperimentele groep het 60% 'n verbetering getoon, 33.3% het onveranderlik gebly en 6.6% het versleg. 'n Gepaarde-t toets wat op die data uitgevoer was het laat blyk dat die verskille statisties beduidend was ($P=0.006$). In die kontrole groep het 33.3% verbeter, 46.6% het onveranderd gebly en 20% het vererger wat statisties onbenullig was ($P=0.384$).

Tweedens, toe die hipotesis van die tweede sub-probleem getoets was, is die eerste en die laaste stel waarnemings van beide die eksperimentele en kontrole groepe met mekaar vergelyk om die volgende resultate te gee: Van die behandelde groep het 60% verbeter, 6.6% het onveranderd gebly en 33.3% het versleg. 'n Gepaarde-t toets wat op die data uitgevoer is het getoon dat die verskille statisties beduidend was ($P=0.015$). In die kontrole groep het 73% verbeter, 0% het onveranderd gebly, en 26.6% het versleg, waardeur ook vasgestel kon word dat dit statisties betekenisvol was ($P=0.001$).

In die derde sub-probleem was die data van die eerste twee sub-probleme geïntegreer en sy hipotese was getoets. Daar is vasgestel dat daar 'n positiewe korrelasie was tussen die kliniese manifestasies van die pasiënte se aknee en die pasiënte se persepsie van die behandeling in die eksperimentele groep. In die kontrole groep is daar 'n swak korrelasie (tussen -0,2567 en 0.6390) tussen die kliniese manifestasies en hulle persepsie van die behandeling. Die pasiënte in die kontrole groep, het 'n verbeterende persepsie van die betrokke behandeling gehad maar die kliniese manifestasies van hulle aknee het nie proporsioneel verbeter nie.

Sover dit die kliniese manifestasies van Acne Vulgaris betref het Homeopatie 'n statisties belangrike en 'n buidende rol gespeel in die behandeling en bestuur van die toestand. Die toetsmedisyne se effek het 'n minderwaardige rol gespeel.

Hoewel daar 'n waarneembare verandering was kan dit nie sonder meer gese word dat Homeopatiese medisyne alleen 'n buidende rol gespeel het in die pasiënt se persepsie tot die behandeling nie, weens die feit dat beide die plasebo en die Homeopatiese medisyne die selfde uitwerking op die pasiënte gehad het.

LIST OF TABLES

TABLE NUMBER

PAGE NUMBER

TABLE 4.1:

50

Figures showing severity of clinical manifestations of acne for photographs taken over 5 consultations for the treatment group.

TABLE 4.2:

51

Figures showing changes in the clinical manifestations of acne for the treatment group.

TABLE 4.3:

53

Figures showing severity of clinical manifestations of acne for photographs taken over 5 consultations for the placebo group.

TABLE 4.4:

53

Figures showing changes in the clinical manifestations of acne for the placebo group.

<u>TABLE 4.5:</u>	55
-------------------	----

Figures showing totals for the patient's perception to the treatment over a period of four questionnaires for the treatment group.

<u>TABLE 4.6:</u>	56
-------------------	----

Figures showing changes in the patients perception to the treatment for the treatment group.

<u>TABLE 4.7:</u>	57
-------------------	----

Figures representing means for the patient's perception to the treatment over a period of four questionnaires for the placebo group.

<u>TABLE 4.8:</u>	58
-------------------	----

Figures showing changes in the patients perception to the treatment for the placebo group.

<u>TABLE 4.9:</u>	59
-------------------	----

A table showing corresponding totals from the photographs of the clinical manifestations and questionnaires for the patients perception to the treatment of the treatment group over a period of four months.

TABLE 4.10:

60

A table showing the correlation between the photographs and the questionnaires of the treatment group taken from table 4.9.

TABLE 4.11:

60

A table showing corresponding observations from the photographs of the clinical manifestations and questionnaires for the patients perception to the treatment of the placebo group over a period of four months.

TABLE 4.12:

60

A table showing the correlation between the photographs and the questionnaires of the placebo group taken from table 4.11.

TABLE 5.1:

63

A table showing the changes in both the treatment and the placebo groups.

TABLE 5.2:

66

A table showing the changes in the patients perception to the treatment in both the treatment and the placebo group.

TABLE 5.3:

68

A table showing the corresponding totals from the photographs and the questionnaires of the treatment group over a period of four months.

TABLE 5.4:

68

A table showing the correlation results from the figures taken from table 5.3.

TABLE 5.5:

70

A table showing the corresponding totals from the photographs and the questionnaires of the placebo group over a period of four months.

TABLE 5.6

70

A table showing the correlation results from the figures taken from table 5.5.

LIST OF FIGURES

<u>FIGURE NUMBER</u>	<u>PAGE NUMBER</u>
<u>Figure 1:</u>	39
Photographic equipment used in the study.	
<u>Figure 2:</u>	52
A graph showing the evolution of the clinical manifestations utilising the averages of the photo's of the treatment group.	
<u>Figure 3:</u>	54
A graph showing the evolution of the clinical manifestations utilising the averages of the photo's of the placebo group.	
<u>Figure 4:</u>	56
A graph showing the evolution of the patients perception to the treatment for the treatment group.	
<u>Figure 5:</u>	58
A graph showing the evolution of the patients perception to the treatment for the placebo group.	

Figure 6: 61

A graph showing the evolution in the correlation between the photo's and the patients perception to the treatment of the treatment group.

Figure 7: 62

A graph showing the evolution of the correlation between the photo's and the patients perception to the treatment of the placebo group.

Figure 8: 64

A graph showing the evolution in the clinical manifestations for both the treatment and placebo groups.

Figure 9: 67

A graph showing the evolution of the patients perception to the treatment for both the treatment and placebo groups.

Figure 10: 69

A graph showing the correlation between the photo's and the patients perception to the treatment of the treatment group.

A graph showing the correlation between the photo's and the patients perception to the treatment of the placebo group.

TABLE OF ABBREVIATIONS

ABBREVIATION

FULL WORD

Tx	- Treatment
Plc	- Placebo
P. acnes	- Propionibacterium acnes
Q'aire(s)	- Quetionnaire(s)
<	- Worse for (Appendix D)
>	- Better for (Appendix D)

INTRODUCTION

As many youth pass through puberty, many changes take place in the process of developing into adults. One of those changes that take place is the altering of hormones in the body. These changing levels of hormones, primarily an increase in androgens, cause many things to develop, one of them being acne (Acne Vulgaris specifically to a large extent).

For many adolescents, acne can be a very unsightly and consequently a very embarrassing condition. It causes the adolescent to become withdrawn and very self-conscious leading to possibly many developmental problems at a later stage, not only for the adolescents themselves but also for the parents of that child. Acne has the capability of becoming very unsightly and may often leave the adolescent with unsightly scarring for, possibly, the rest of his/her life.

In the allopathic treatment of acne, many forms of medication are used, for example hormone therapy in young females. The therapy may cause the acne to diminish or even disappear but there are often other effects on the body. Other forms of treatment are often ineffective and detrimental to the patients, not only physically, but also financially.

Homoeopathy can offer quite a number forms of inexpensive forms of treatment which, as is the point of this study, may be found to be very effective.

There are a number of people that are unaware of firstly Homoeopathy, and secondly that there may be a very effective and inexpensive form of treatment of acne in Homoeopathy.

CHAPTER ONE.....	1
1) THE PROBLEM AND IT'S SETTING	1
1.1) PROBLEM STATEMENT	1
1.2) SUBPROBLEMS	1
1.3) HYPOTHESES	2
1.4) DELIMITATIONS.....	2
1.5) ASSUMPTIONS.....	3
1.6) DEFINITION OF TERMS	4
CHAPTER TWO.....	6
2) REVIEW OF RELATED LITERATURE.....	6
2.1) INTRODUCTION.....	6
2.2) DEFINITION.....	6
2.3) AETIOLOGY.....	7
2.4) PATHOGENESIS.....	9
2.5) CLINICAL MANIFESTATIONS, DIAGNOSIS AND DIFFERENTIATION OF LESIONS.....	11
2.6) ASSESSMENT, CLASSIFICATION AND GRADING.....	16
2.7) PATHOLOGY, COMPLICATIONS AND PROGNOSIS.....	24
2.8) CONVENTIONAL MEDICATION AND MANAGEMENT OF ACNE.....	26
2.9) HOMOEOPATHIC TREATMENT OF ACNE	31
2.10) THE PLACEBO AND IT'S ROLE IN MEDICINAL THERAPEUTICS	33
CHAPTER THREE.....	35
3) MATERIALS AND METHODS	35
3.1) THE DATA.....	35
3.1.1) THE PRIMARY DATA.....	35
3.1.2) THE SECONDARY DATA.....	36
3.2) THE SAMPLE	36
3.3) THE CRITERIA GOVERNING THE ADMISSIBILITY OF THE DATA	37
3.4) THE INSTRUMENTS	37
3.5) THE RESEARCH METHODOLOGY.....	39
3.6) ADMINISTRATION.....	40
3.7) THE SPECIFIC TREATMENT OF EACH SUBPROBLEM.....	42
3.7.1) SUBPROBLEM ONE	42
3.7.2) SUBPROBLEM TWO.....	45
3.7.3) SUBPROBLEM THREE	48
CHAPTER FOUR.....	50
4) RESULTS.....	50
4.1) SUBPROBLEM ONE	50
4.2) SUBPROBLEM TWO.....	54
4.3) SUBPROBLEM THREE	59

CHAPTER FIVE.....	63
5) DISCUSSION.....	63
5.1) SUBPROBLEM ONE.....	63
5.2) SUBPROBLEM TWO	66
5.3) SUBPROBLEM THREE.....	68
CHAPTER SIX.....	73
6) CONCLUSIONS AND RECOMMENDATIONS.....	73
6.1) CONCLUSIONS.....	73
6.2) RECOMMENDATIONS	73
REFERENCES.....	75

CHAPTER ONE

THE PROBLEM AND ITS SETTING

1.1) PROBLEM STATEMENT:

This study proposes to determine the degree of proficiency of Homoeopathy in the treatment of Acne Vulgaris in terms of its clinical manifestations and the patients perception to the treatment in order to determine the role Homoeopathy plays in the treatment of this condition.

1.2) SUBPROBLEMS:

1.2.1) The first subproblem proposes to determine the degree of proficiency of Homoeopathy in the treatment of Acne Vulgaris in terms of it's clinical manifestations in order to evaluate the relationship between Homoeopathic treatment and the clinical manifestations.

1.2.2) The second subproblem proposes to determine the proficiency of Homoeopathy in the treatment of Acne vulgaris in terms of the patients perception to the treatment in order to establish what aspects of acne treatment patients consider significant.

1.2.3) The third subproblem proposes to integrate the data collected on the patients perception to the treatment and the changes in

clinical manifestation (if any) in order to determine the role of Homoeopathy in the treatment of Acne Vulgaris.

1.3) HYPOTHESES

1.3.1) It is hypothesized that there is a relationship between Homoeopathic treatment for Acne Vulgaris and its clinical manifestations which can be measured.

1.3.2) It is hypothesized that the aspects of the treatment that the patients consider significant can be measured.

1.3.3) It is hypothesized that it is possible to integrate collected data on the elements of treatment patients consider significant and the clinical manifestations of Acne; allowing the integrated data to demonstrate the role of Homoeopathy has in the treatment of Acne.

1.4) DELIMITATIONS:

1.4.1) This study delimits itself from any other form of treatment other than Homoeopathy

1.4.2) In this study, no changes will be made to the patients diet and therefore only patients that fulfill specific dietary requirements determined by the answering of specific questions incorporated into the case history will be accepted into this study.

1.4.3) Only patients who are not on any other form of treatment for their acne will be accepted into this study.

1.4.4) Patients who are on any other form of treatment will have to comply with a period of 'flushing out' before being accepted into this study.

1.4.5) Patients with so-called 'sandpaper' acne will be excluded from this study due to the fact they are impossible to classify. (Burke and Cunliffe, 1984)

1.5) ASSUMPTIONS:

1.5.1) It is assumed that homeopathy as a form of alternative medication does in fact work and will not be our aim to demonstrate this.

1.5.2) It is assumed that the Homoeopathic principle of Similimum is valid.

1.5.3) It is assumed that the patients partaking in this study will follow the protocol of Homoeopathic medication taking and not expose the medication to anything that might deactivate/antidote it.

1.5.4) It assumed that the patients taking part in this study will do so unconditionally.

1.6) DEFINITION OF TERMS:

1) SIMILIMUM is defined as that symptom picture of a remedy which, through careful and extensive case history taking by the researcher, matches the symptom picture of the same remedy as recorded in the Materia Medica.

2) ACNE VULGARIS is defined as a common inflammatory pilosebaceous disease characterized by comedones, papules, pustules, inflamed nodules, superficial pus-filled cysts, and, in extreme cases, canalizing and deep, inflamed, sometimes purulent, sacs.

3) FLUSHING OUT is defined as a period in which the selected patients be removed from all forms of treatment for at least four weeks before beginning Homoeopathic treatment in order to eliminate the affects of the other forms of treatment; be they therapeutic or side effects.

4) REPERTORIZING is a Homoeopathic concept that deals with the process of selecting symptoms and signs from the patient, then reading up the relevant remedies for each symptom and sign, and finding the common remedies amongst them.

5) CASE HISTORY is a Homoeopathic and Allopathic technique of acquiring and recording past and present symptoms and signs from patients.

6) CLINICAL MANIFESTATIONS is a medical concept that refers to any observed display or disclosure of characteristic signs or symptoms of an illness.

7) PLACEBO has been defined as ' any therapy or component of therapy that is deliberately used for its non-specific, psychological, or psychophysiological effect, or that is used for its presumed specific effect, but is without specific activity for the condition being treated' (Shapiro and Morris, 1978:369 - 410)

CHAPTER TWO

2) REVIEW OF RELATED LITERATURE:

2.1) INTRODUCTION:

In the literature review an attempt is made to investigate all the aspects of Acne Vulgaris relevant to this study. The main areas investigated are the aetiology; clinical manifestations; diagnosis; differentiation of the different types of lesions; assessment, classification and grading of the lesions; pathology and complications; and conventional medication and management of Acne Vulgaris.

This study was carried out with the aim of learning more about Acne and Homoeopathy and their relationship.

2.2) DEFINITION:

Firstly a definition is required to introduce the manifestations of Acne vulgaris:

Acne vulgaris is a pleomorphic, multifactorial disease involving abnormalities in follicular keratinization, production of sebum, proliferation of propionibacterium acnes (P. acnes) and inflammation affecting approximately 85% of teenagers manifesting at any time during life, even as early as the neonatal period and being perceived by many as a benign condition, emotionally crippling the afflicted individual. It affects mainly the face, chest, back and shoulders and varies from the transient presence of a few comedones and papules to a severe disabling and debilitating condition marked by persistent deep papules, nodules and cysts.

2.3) AETIOLOGY:

It is important to know and understand what causes acne. Once the cause of the condition is reviewed, it will help in monitoring the progress (or lack thereof) of the patients and will also aid in the direction of the treatment.

"Classically, symptoms are classified in order of decreasing importance, as follows:

- 1) Aetiological symptoms
- 2) Psychic symptoms
- 3) Modalities
- 4) General and morphological symptoms
- 5) Local symptoms"(Jouanny,1991)

As can be seen by the above quote, aetiological symptoms rank the highest in importance; thus necessitating the understanding and knowing of its aetiology.

*** SEBUM**

The increased rate of sebum production is the most important factor. The severity of acne is related to the degree of seborrhoea which in turn is directly dependent on the size and rate of growth of the sebaceous glands which are under the control of androgenic hormones. When acne remits spontaneously, sebum production remains higher in acne patients than in age-matched controls (Cunliffe and Shuster, 1969). Although sebum excretion rate is under genetic control the development of clinical acne is modified by other factors.

*** HORMONES**

Most research points to androgens as being the major stimulus to enlargement of sebaceous glands and to increased production of sebum. In girls the sebaceous glands become functional as the levels of circulating androgens rise at adrenarche, which may develop as early as the fifth to eighth year of life and may precede menarche by more than a year (Pochi et al, 1977). In boys the onset of acne is associated with the rise in serum testosterone at puberty (Lee, 1976).

Androgens may be involved in two ways: excessive levels may drive the sebaceous glands, or the glands themselves may be particularly sensitive to normal levels (end-organ hypersensitivity). Acne may indeed result from androgen excess; after exogenous administration of testosterone; in androgen-secreting tumours or in other forms of androgenisation in women such as in polycystic ovary syndrome (Rosenfield,1986).

It is important to know the effect of hormones on the development of acne due to the fact that one of the orthodox forms of treatment is the administering the contraceptive pill to females. This form of treatment can present the patient with many other common side effects such as nausea, weight gain and breast tenderness (Lever and Marks,1990) which the homeopathic practitioner has to take into account when deciding on the remedy for the patient.

*** FOLLICULAR KERATINISATION (Knutson,1974)**

Although the presence of p. acnes in comedones suggests that bacteria might provide the stimulus, bacteria cannot be detected in early comedones (Lavker et al,1981). The end result of follicular hyperkeratinization is the development of a comedo [an open comedo

is known popularly as a black-head and a closed comedo is known as a white-head.]

*** BACTERIA**

Most, if not at all, comedones are colonised by a gram-positive microaerophilic bacterium known as *P. acnes* (Imamura, et al, 1969). Knowing that bacteria is an almost certain cause of acne can throw a new light on the particular course of treatment of the patient.

*** INFLAMMATION**

The inflammation in acne lesions may result from free fatty acids or from the release of other chemoattractants by the *P. acnes* in the follicle (Allaker et al, 1985; Puhvel and Sakamoto, 1987). Furthermore, rupture of the follicle is commonly seen and cornified epithelium itself can provoke an inflammatory reaction (Marks, et al, 1984).

*** OTHER FACTORS**

Acne can also be caused by external physical factors such as friction [acne mechanica] or contact with irritant oils or cosmetics [acne cosmetica] (Fulton, et al, 1984; Kligman and Mills, 1972). Acneiform papules may also arise at the site of treatment with topical steroids.

A severe form of cystic acne occurs in individuals exposed to even minute amounts of halogenated phenolic compounds.

2.4.) PATHOGENESIS

The steps through which an acneiform lesion passes must be understood so that any effects that the treatment might be having may be monitored in order to decide on stimulating the lesion to be

expelled through the skin or resorbing it and reversing its growth process.

The treatment can be directed accordingly if the stage of development of the lesion can be identified. i.e. Treat according to the stage.

The earliest change is a disturbance in follicular epithelial differentiation during which the horny cells lining the impaction, or microcomedo, represents the precursor from which all acne lesions evolve (closed comedones, papules, pustules and nodules). Widening of the follicular infundibulum with horny material produces a closed comedone. As the hyperkeratosis extends to the upper aspect of the infundibulum and dilates its opening, an open comedone is formed.

The sebaceous gland is highly responsive to stimulation by androgens. The gland hypertrophies and secretes sebum into the follicular canal.

Sebum also provides a favorable substrate for the proliferation of *p. acnes*.

P. acnes, an anaerobic diphtheroid, is the pathogenic organism of acne vulgaris. With *P. acnes*, *Staphylococcus epidermidis* and *Oityrosporum ovale* constitute the follicular microflora. Only *p. acnes* possesses a true lipase that can hydrolyze sebum triglycerides into free fatty acids.

P. acnes plays a critical part in the generation of inflammatory lesions. It also produces a low molecular weight chemotactic factor that recruits polymorphonuclear leukocytes. In the process of phagocytizing the bacterium, hydrolases are liberated, which further disrupts the integrity of the follicular wall. The intrafollicular contents - keratinous debris, lipids, hair and *p. acnes* - are extruded into the dermis. If there is a superficial aggregation of neutrophils, a

pustule is formed. With deeper and more extensive inflammatory infiltration, a nodule or cyst is produced. A granulomatous and foreign body reaction supervenes. *P. acnes* further provokes the inflammatory response by activating complement through both the classical and alternative pathways.

2.5) CLINICAL MANIFESTATIONS, DIAGNOSIS AND DIFFERENTIATION OF LESIONS.

It is necessary that one be able to describe and recognise the different lesions diagnostically (clinical manifestations) in order to recognise any changes that may occur, be they bad or good.

Particular attention must be given to the distribution, morphology, and severity of lesions. A review of the non-inflammatory and inflammatory lesions of acne is in order.

*** COMEDONES**

These non inflammatory early lesions appear in two forms: closed and open comedones. The dilated, plugged follicle forms a closed comedo (a whitehead). These lesions are pale, firm, 1mm to 2mm papules that are best visualized with proper lighting and gentle stretching of the skin. With increasing dilation of the follicular orifice the comedonal contents become visible at the skin surface as deeply pigmented large pores. These open comedones or familiar blackheads are often a source of cosmetic concern for the patient (Cunliffe, et al, 1991).

*** PUSTULES AND PAPULES**

Rupture of a comedo can produce various inflammatory lesions. If the process is superficial, a pustule forms. These are raised white

lesions filled with pus. Because of their location, pustules usually resolve within a few days without scarring. Papules, on the other hand, represent a deeper dermal inflammatory reaction. They appear as erythematous, raised solid lesions. They invariably take a longer time to heal and often do so with scarring.

*** *NODULES***

These are the most severe variants of acne. They are suppurative abscesses within the dermis that sometimes extend down to fat. They are warm, tender, firm lesions. Significant scarring can be expected.

*** *SCARS***

Scars can manifest in multiple forms. They can be divided into atrophic and hypertrophic types. In atrophic scars one finds either shallow, broad-based depressions or the deep, steep-sided pits with elevated thick fibrotic plaques often appearing on the chest or back of the hypertrophic type.

Assessment of the severity of acne must be performed at each visit. Newer systems now include lesional counts and lesion types. Serial photographs are taken to follow a patient's progress (Gibson, et al, 1984).

*** *ACNE FULMINANS***

Occurring in male teenagers, acne fulminans is an explosive, devastating condition with acute onset of tender papules and nodulocystic lesions on the trunk and chest. A history of mild preceding acne is noted in most patients. Systemic symptoms of myalgia, arthralgia, fever, chills, leukocytosis, and even osteolytic bone lesions are not uncommon. Therapeutic control is achieved with

systemic corticosteroids and antibiotics. It presents as a distinct entity because of its abrupt nature and location.

The following guidelines have been taken from the Journal of the American Academy of Dermatology on the care of acne vulgaris.

It is suggested that these guidelines be used for the diagnostic procedure of Acne Vulgaris in orthodox medicine.

For the purpose of this study, section I (Appendix A) was incorporated into the initial homeopathic case history (Appendix D) with a view to standardise the diagnostic procedure.

I) Diagnostic criteria

A) Clinical

1) Patient history

2) Physical Examination

Establishment of diagnosis should occur after review of patients history and physical examination of the patient for the clinical criteria of acne.

3) Lesion type

4) Location

5) Gradation

6) Complications

a) Scarring type

b) Scarring grade

7) Other associated findings:

B) Diagnostic tests

C) Inappropriate diagnostic tests

II) Recommendations

A. Treatment

1. Nonsurgical

a) Topical therapy most commonly used but not limited to:

- 1) Benzoyl peroxide
- 2) Benzoyl peroxide-erythromycin
- 3) Benzoyl peroxide sulfur
- 4) Tropical antibiotics
- 5) Tretinoin
- 6) Salicylic acid
- 7) a Hydroxy acid
- 8) Sulphur including Vleminckxs solution.
- 9) Resorcinol
- 10) Miscellaneous: astringents, soaps cleaners.

b) Systemic therapy most commonly used but not limited to:

- 1) Antibiotics, oral
- 2) Isotretinoin, oral

Primary and only approved use is for severe, recalcitrant, cystic acne, refractory.

3) Hormonal treatments may include the following:

- a) Corticosteroids
- b) Sex hormones (for women only)
 - i) Estrogen (oral contraceptive medication)
- c) Anti-androgens

4) Other treatments may include the following:

- a) Dapsone

- b) Diet (in selected cases)
- c) Ultraviolet light
- d) Superficial exfoliation

2) Surgical

a) lesional therapy

- 1) Extraction of comedonal contents
- 2) Drainage of superficial pustules and cysts
- 3) Excision of sinus tracts and cysts

b) Intralesional corticosteroids

c) cryotherapy

d) Dermabrasion (scars)

e) Filing materials (scars)

f) surgical repair (scars)

3) Other recommendations

- a) follow up examinations to gauge degree (or lack) of improvement, tolerance to medications, need to augment or attenuate treatment depending on clinical response, and employment of lesional therapy.

- b) In the early phase of treatment, more frequent follow up visits are required than later when the condition has become less active. (Journal of the American Academy of Dermatology. 1990 Apr; 22 (4) : 670-80)

2.6) ASSESSMENT, CLASSIFICATION AND GRADING:

Determining whether a patient has severe acne or not becomes a subjective assessment. There are two methods which are most useful and statistically reproducible. The first, an overall assessment of the acne severity in a particular area (grade between 0 to 10), is accurate, reproducible, rapid and suitable for use in the routine clinic. The second, for use in detailed work in therapeutic trials, uses a counting system in which one must distinguish between active and less active acne lesions. This technique is relatively simple and reproducible when carried out with attention to detail (Cunliffe, et al, 1991).

**** THE GRADING TECHNIQUE.*** (Cunliffe, et al, 1991)

An overall acne grading system should include assessments of the size and density of lesions, the intensity of lesional inflammation and formation of scars. Classification of acne on morphologic grounds seems to be feasible and reasonably reliable. However, quantification of severity is difficult. Although it is possible to count and describe each lesion according to size, such detail is not feasible in day to day clinical practice.

In this process, three sites are graded: face, back and chest. The face includes the chin and neck anterior to the sternomastoid muscles.

The chest in men is from the waist upwards, but in women only the skin between the breasts and above the bra is included. The back is the area from the waist upwards, in both sexes. Shoulders are included for both the back and chest assessment, but the arms are excluded. Most observations are of the face (Burke, et al, 1984).

Acne grading includes the use of a *pattern-diagnosis* system, which is a global (total) evaluation of lesions and their complications such as drainage, hemorrhage, and pain. Global evaluation takes into account the total impact of the disease, which may be influenced significantly by the disfigurement it causes. Other factors that may be involved in evaluating severity include occupational disability, the psychosocial impact and the failure of response to previous therapies (Cunliffe, 1987). The most destructive forms of the disease (i.e.. acne conglobata, acne fulminans and the follicular occlusion triad [acne inversa]) are undeniably severe, these are easily recognised and should be designated as *very severe*.

The following are some guidelines on how the patient should be graded (Cunliffe, et al, 1991):

- (1) A 0-10 visual-tactile grading system.
- (2) A careful count of the following lesions - less active and active papules less active and active pustules, deep pustules, nodulo-cysts and macules.
- (3) Patient self-assessment with the following categories - worse, no change, fair good and excellent.

*** THE COUNTING TECHNIQUE** (Cunliffe, et al, 1991)

Acne Lesions may be divided into inflammatory/inflamed and noninflammatory/non-inflamed lesions (Hurwitz, 1979).

(a) *Noninflammatory/Non-inflamed lesions* are blackheads and whiteheads. Any intermediate lesions are counted according to their

major component. Prominent follicles, small milia or trichostasis spinulosa must be rigorously excluded as they occur frequently and would badly skew the results. Non-inflammatory lesions consist of open and closed comedones. In general, acne manifested only by noninflammatory lesions can rarely be characterized as severe, unless the number, size and extent of such lesions are so overwhelming as to warrant such a designation (e.g. severe chloracne).

(b) *Inflammatory/Inflamed lesions* are either superficial (papules and pustules) or deep (nodules, cysts and deep pustules). A severity grade based on a lesion count approximation would be assigned as mild, moderate, or severe.

(i) *Superficial papules and pustules* vary in size from 0.1cm (with minimal erythema) to 0.5cm (with a marked macular flare). Pustules are similar in size to papules but have a visible central core of purulent material. The smaller less inflammatory lesions are referred to as "less active papules or pustules", The larger erythematous lesions as "active papules or pustules". The lesion is assigned according to its major component. (Plewig and Kligman, 1975b)

(ii) *Deep inflamed lesions* are predominantly nodules which are 0.5cm or larger. Palpation is essential, since some nodules are almost invisible but easily palpable. (Lever and Marks, 1990) These nodules may become suppurative or haemorrhagic. Nodular lesions, particularly when suppurative, have commonly been referred to as cysts because of their resemblance to inflamed epidermal cysts. Persons with moderate nodular acne will, more often than not have varying degrees of papular and/or pustular lesions as well, moderate papulopustular plus moderate nodular acne would amount to severe inflammatory acne.

(iii) *Macules* represent the resolving phase of either superficial or deep lesions and are either large or small. They should be included in

acne assessment as they contribute to the overall degree of inflammation. The counting of individual lesions may then be very difficult.

Inflammatory acne lesions are usually located on one or more of the following sites: face, neck, back and chest. Often the resolution of inflammatory lesions may leave erythematous and/or pigmented macules that can persist for months or longer.

Other factors are also important in assessing severity. These include ongoing scarring, persistent purulent and/or serosanguineous drainage from lesions or the presence of sinus tracks (Winston, et al, 1991).

The clinical diagnosis of severe acne should be based on the presence of *any* of the following characteristics: persistent or recurrent inflammatory nodules, extensive papulopustular disease, ongoing scarring, persistent purulent and/or serosanguineous drainage from lesions or the presence of sinus tracks.

In addition to the severity of a patients clinical disease as determined by the examination of the skin, additional factors, from the patients standpoint, are important in the designation of a particular case of acne as a severe one. These factors include psychosocial circumstances, occupational consequences of their disease and inadequate therapeutic responsiveness. These are important factors to be taken into account as they may influence the choice of remedy chosen.

To confirm the reproducibility of the method, two doctors should examine the patients. Patients are counted on consecutive days in order to compare reproducibility by the same doctor and a

comparison between doctors should be made assessing the same patients on the same day (Cunliffe, et al, 1991).

Lesion counting is not easy and perfection takes time. Attention to the following points will help to avoid errors:

- (1) The patient should be sitting comfortable so that the observer can move around him easily to count each area.
- (2) In addition to good background fluorescent lighting, it is recommended that a Brighton 1001 fluorescent lamp, which can be easily moved to illuminate both sides of the patient during the examination, is used.
- (3) When counting, divide the face into the right and left sides and count both sides. In some patients the lesions are clustered around the midline, making a right-left division difficult; then count on forehead, cheeks and chin separately combine counts.
- (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 the skin will increase the number of whiteheads and blackheads that are visible, but as the degree of stretching might vary, this is not permitted. Similar reasons, it is recommended that no lens is used. If a lesion is impalpable, and not obvious with good lighting, then such a vague lesion is best ignored (Hurwitz, 1979).

Pitfalls for the unwary:

**** Prominent follicles:***

Confusion of non-inflamed lesions with prominent follicles is a problem around the nose and on the chin. It is recommended that non-

inflamed lesions are not counted either on the nose or around the edge of the nose.

**Sandpaper acne:*

Two per cent of youngsters have the so-called "sandpaper" acne. In these patients the forehead is covered with many (usually 100 or more) very superficial lesions, which are impossible to classify correctly. Such patients should be excluded from clinical trials.

**Hair styles:*

Long, uncut hair may mask non-inflamed lesions. Avoid counting them around the hair line. However, there is usually no difficulty in recognising inflamed lesions in this area.

**Shaving:*

Patients may grow a moustache or a 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. 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.

**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.

**Ultraviolet 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 summer.

**Establishing a baseline for clinical trials:*

When performing clinical trials in acne subjects should not have used acne treatment for at least 4 weeks before the start of the study in order to establish an adequate baseline, particularly when comparing drugs whose efficacies may be similar, but in practice this is normally impossible.

Results from previous studies indicate quite clearly that grade and lesions significantly increase up to the eighth week after stopping therapy(Burke, et al,1984).

The techniques of grading and counting are not perfect, but they are reproducible. There has, for some time however, not been any improvement in the technique, nor have there been any further pitfalls highlighted(Burke, et al, 1984).

Due to the fact that one of the diagnostic/measurement techniques to be used in this study was the photograph, it is necessary to discuss it's features as such a tool.

Lesion counting, grading systems and photographic methods all have their positive and negative features. Photographic methods allow a permanent record to be kept but do not allow palpation of the lesions. Photography has three more major drawbacks(Gibson, et al,1984). First there are technical problems. Constant lighting, a constant distance between the patient and camera and constant developing procedures are essential and difficult to maintain accurately.

Secondly, photographs will never adequately detect the small non-inflamed lesions.

Thirdly, photography is two-dimensional; it can never replace palpation, and errors in distinguishing deep lesions from active superficial lesions or macules will never occur. It is also suggested that an overall grading system can replace spot counting. Lesion counting is a relatively tedious and lengthy process and a 50% reduction of certain lesions is not always reflected by a 50% improvement in the patients appearance. The overall grading system is quick and reproducible and eminently suitable for use in the clinic. There is doubt, however, in the wisdom of discarding spot counting in therapeutic trials. Spot counting is a more sensitive technique in that it distinguishes small differences better than an overall grade.

A grade assessment is also complicated by the presence of erythema and scaling - a not infrequent side effect of several effective topical treatments. Spot counting also gives some insight into the morphogenesis of acne lesions before and during treatment.

It is suggested that acne assessed and graded by using photographs should be done on the following basis (Gibson, et al,1984):

(1) Severity of acne according to a 0-4 scale with half points ratings where 0=no acne, 1= minimal acne, 2=mild acne, 3= moderate acne and 4= severe acne.

(2) Change in acne severity using a scoring system where -2= much worse, - 1=worse, 0=no change, 1= minimal improvement, 2 = fair improvement, 3 = good improvement and 4= excellent improvement.

The assessment and grading should take place by the following method:

The patient is seated in front of the photographic equipment in a specific manner which is standardised for this study.

Photographs of the patients whole face, cheeks, nose and forehead are taken.

Problems may arise in allocating a grade to patients with numerous non-inflamed and few inflamed lesions or those with few very isolated deep inflamed lesions. Both inter and intradoctor correlation tends to be poor in these cases and is usually noted down as "difficult to grade".

In light of the grading and counting techniques put forward by Cunliffe, et al, 1991, and Gibson, et al, 1984, and their discussions regarding both the effectiveness and pitfalls of each method, a combination of the two techniques were utilised in order to obtain the most effective method for this study (Appendix B).

2.7) PATHOLOGY, COMPLICATIONS AND PROGNOSIS:

It is once again important for as many factors concerning Acne Vulgaris to be known so that the one can be on the outlook for elements such as scars . Each person, according to the principles of Homoeopathy, is a separate identity as far as disease processes go. Sir George Pickering, in considering the aetiological aspects of disease, summarised the situation as follows: "The state in which the animal (man) finds itself at any time is determined by two prime factors- its

inherited constitution and the effects of its environment past and present; the common causes of disease thus ..." (Golomb , 1968)

As one knows, each persons inherited constitution is different and no two people are subjected to the same environmental factors at the same time. The reaction to disease processes of each person is therefore different.

During routine examination of the skin, it has been found that many patients have an asymptomatic eruption on the upper part of the trunk consisting of numerous 1 to 6 mm, slightly hypopigmented, firm, rounded papules (Plewig and Kligman, 1975b). Many papules are oriented about a follicular orifice. Some larger ones are oval rather than round and follow skin lines.

In a study of post acne lesions, patients were examined for the presence of these cutaneous eruptions. The papules were present in 57 % of patients who had a history of acne vulgaris and in 9% of patients who denied ever having had acne. Of patients demonstrating the papules, 81% had a history of acne on the back or chest. Biopsy specimens from five patients revealed circumscribed perifollicular or para-follicular lesions in which both elastic and collagen fibers were attenuated in comparison with those in normal adjacent dermis. These changes are consistent with scar. It was concluded that the papules are a scarring process secondary to acne vulgaris and propose calling the lesions papular acne scars.

These papules range in number from a few to hundreds. The distribution may be limited to a small area or involve the entire upper part of the trunk and sometimes the upper part of the arms. Although these lesions do not present any symptoms specific of their

own, in some individuals however the papules are large, prominent and of considerable cosmetic concern.

Data supports the hypothesis that acne vulgaris is probably the most frequent precursor lesion. Although patients are evaluated for the presence of papules prior to being questioned about acne the potential for observer bias exists when acneiform lesions can be seen on physical examination. It is doubted that this accounts for the highly significant relation between the papules and the acne documented. Another factor that supports the hypothesis that acne may play a role in the pathogenesis of the papules is the absence of lesions in prepubertal persons, a population rarely afflicted with acne.

2.8) CONVENTIONAL MEDICATION AND MANAGEMENT OF ACNE:

A brief overview of the orthodox forms of medication is given. It is noted that they do not claim to cure the patients acne. It seems that the only effects it does have on the patient is that of palliation apart from the side effects noted.

Mild acne can be controlled with topical preparations, but patients with severe acne require oral therapy with antibiotics, anti-androgens or retinoids. Combinations of topical and systemic treatments are often appropriate. The choice of drug requires knowledge of their efficacy, ease of use and possible adverse effects (Lever and Marks, 1990).

PRINCIPLES

The aim of therapy is to interrupt the pathogenic pathway at one or more points by reducing : increased secretion of sebum; abnormal follicular keratinisation; bacterial colonisation and local inflammation.

This may be accomplished by the appropriate use of one or more of the treatments described below.

**topical treatments :*

Topical therapy may be used alone for mild to moderate acne or in combination with systemic therapy for more severely affected patients. Topical preparations should not be applied to individual lesions but to the whole area affected by acne to prevent new lesions from developing. A single therapeutic agent may suffice for mild cases but a combination of therapies is often more effective.

**benzoyl peroxide:*

One of the most effective and widely used topical treatments for acne is benzoyl peroxide, an organic peroxide which is almost completely metabolised to benzoic acid in the skin (Nacht, et al,1981). Controlled trials of benzoyl peroxide have shown that it is effective therapy for mild acne (Ede,1973) and can also be combined with other treatments for severe acne (Cunliffe,1987). Although benzoyl peroxide has a potent antibacterial action (Nacht, et al,1983), it may be comedolytic and appears to increase the rate of desquamation (Marks R. unpublished observation; Plewig and Kligman, 1975b). There is some controversy whether benzoyl peroxide increases or decreases the rate of sebum production (Cunliffe, et al,1983 ; Melski and Arndt,1980)

Benzoyl peroxide is available in a variety of formulations. Gels are more effective vehicles than creams or oil-based lotions regarding release of active substance, although they may be more irritant (Cunliffe, et al, 1979). The most frequent adverse effect of benzoyl

peroxide is irritant reactions, but these effects may be partly responsible for its therapeutic efficacy (Hurwitz, 1979). Allergic contact dermatitis can occur, but is uncommon (Cunliffe and Burke, 1982). Benzoyl peroxide can bleach clothes and hair.

Studies have shown that benzoyl peroxide can have a skin tumour-promoting effect.

**retinoic acid:*

Topically applied tretinoin is a very effective treatment for mild to moderate acne (Juhlin, 1975). High concentrations may be applied to the skin without causing systematic toxicity. The principal action of this agent is to increase the rate of epidermopoiesis, resulting in decrease in the cohesion between corneocytes. This reduces follicular hyperkeratosis, preventing the formation of comedones.

**combining topical treatments:*

Topical tretinoin 1% has been shown to be more effective than benzoyl peroxide 5% (Cunliffe, 1987; Kligman, et al, 1969) in solving acne lesions but better results with less irritation can be achieved with a combination regimen of benzoyl peroxide plus tretinoin, applied alternately morning and evening (Hurwitz, 1979). Tretinoin can be usefully combined with topical or systemic antibiotics (Kligman, et al, 1975 ; Mills et al, 1975).

**antibiotics:*

Moderate to severe acne requires oral antibiotic therapy but topical antibiotics may be effective in milder cases. Their precise role in the management of acne remains uncertain. The most widely used topical antibiotics are clindamycin, tetracycline and erythromycin. Studies using topical clindamycin and erythromycin have confirmed that

clinical improvement is accompanied by reduction in counts of p. acnes.

**systemic therapy:*

Systemic therapy is indicated if topical treatment fails or if acne is more severe with the presence of cysts and nodules increasing the possibility of scar formation.

**oral antibiotics:*

Tetracyclines, erythromycin and cotrimoxazole are all active in vitro against p. acnes. Tetracycline hydrochloride is the antibiotic most frequently prescribed in patients with acne.

**hormonal treatment:*

Reduced sebum production and improvement of acne in women can be achieved by administration of oral oestrogens or anti androgens.

**retinoids:*

The oral retinoic acid derivative isotretinoin is highly effective in the treatment of severe nodulocystic acne in patients who have been proved unresponsive to conventional therapy (Peck, et al, 1979). It has also been used successfully to treat patients with severe acne which although non cystic is still resistant to treatment and has a potential for scarring (Shalita, et al, 1983). Isotretinoin is, however, highly teratogenous and strictly prohibited in pregnant ladies or even in ladies liable to procreate (Horvilleur, 1994)

**conclusions:*

The choice of drug depends on the extent and type of the patient's acne, on possible adverse effects and partly on the patient's own

preferences. Systemic treatment should be considered when the condition is more severe or if response to treatment is poor. Isotretinoin is particularly potent but its adverse effects and cost limit its use to patients with severe or resistant disease or where there is significant risk of scarring.

Acne can be a major source of disability for some young people and the physician must allow adequate time for counseling

In the use of Tretinoin, there is a variable degree of skin irritation but slight erythema and scaling is to be expected (Peachey and Connor, 1971). Patients with greasy skin may find the drying effect acceptable (Papa, 1975). The degree of irritation is influenced by the concentration of the product, the amount applied and the frequency of application.

The concomitant use of other irritants such as alkaline soaps, detergents and alcoholic astringents worsens the irritation caused by Tretinoin. Increased irritation after exposure to ultraviolet light (photo-irritation) was seen in patients treated with 0,05% tretinoin gel in one series and patients should therefore be cautioned to avoid exposure.

Absorption of oral tetracycline is readily impaired by food and by ingestion of milk, iron preparations and antacids (Leyden, 1985).

Long-term administration of oral antibiotics leads to asymptomatic alteration of bowel flora. It has been noted that it is possible to isolate *Clostridium difficile*, the organism associated with pseudo membranous colitis, from the bowel of 8% of asymptomatic acne patients undergoing long term antibiotic therapy (Adams, et al, 1985; Lever, et al, 1985). Induction of antibiotic resistance in *P. acnes* is also possible during routine treatment of acne patients (Leyden, et al, 1983).

In hormonal treatment adverse effects such as nausea, weight gain and breast tenderness are fairly common.

The use of oral oestrogens or anti androgens are inappropriate treatments for men because of their adverse effects of impotence and gynaecomastia.

In the light of the afore mentioned adverse affects caused by the use of orthodox medication, it can be seen that the choice of treatment offered to the patient as far as conventional medication is concerned is very limited.

One needs to bare in mind the side effects of orthodox medicine since one might have to treat the adverse effects first before embarking on actually treating the acne itself.

It can see that there many forms of orthodox medicine for the treatment of acne vulgaris, along with their numerous side effects, but no cure is offered. There is an obvious need for an alternative form of treatment.

2.9) HOMOEOPATHIC TREATMENT OF ACNE VULGARIS:

Before delving into this particular aspect of the treatment of acne, one quote is noted from probably the worlds most esteemed leaders:

" HOMOEOPATHY IS THE ADVANCED AND REFINED METHOD OF
TREATING PATIENTS ECONOMICALLY AND NONVIOLENTLY."

(MAHATMA GANDHI)

The treatment of acne using Homoeopathy does not differ from the treatment of any other condition as far as the finding of the remedy through careful case taking is concerned.

The general health of the patient above everything is to be consulted in the treatment of this disease as far as therapeutic measures are concerned. One cannot treat acne as a disease as it is only an expression of some internal disturbance we must necessarily correct, and in proportion as we correct it the acne will disappear. The deepest acting long term remedies will have to be studied in these chronic cases, as they are all dependent on a deep-seated constitutional and general hereditary taint.

This means that Homoeopathically speaking, one needs to treat every patient in a totally different way as we all have different inherited taints as apposed to treating them in the orthodox fashion of set rules for set conditions. Above all things, in these cases it is very important to give oneself plenty of time, as the patient is very apt to make light of the case there being no special constitutional symptoms to deal with present. There are certain foods/stimulants to be avoided whilst presenting with the condition of acne vulgaris but, due to the fact that this study is limiting itself to the effects of Homoeopathy and not the effects of diet change in the treatment of acne, the role of diet change will not be taken into consideration as far treatment is concerned. Patients will however undergo screening before taking part in the research program (Re: delimitation 1.4.2).

A few remedies are noted for interest sake only and not as a rule for the treatment of the condition:

Arsenicum Album, Belladonna, Carbo vegetabilis, Pulsatilla, Sepia officinalis, Kali iodatum , Bryonia alba, Solanum Dulcamara....

THE PLACEBO AND IT'S ROLE IN MEDICINAL THERAPEUTICS:

Many of the changes which follow the taking of drugs are now known not to be caused by the chemical action of the drug. In fact, the same changes occur if the individual takes an inert substance which has a superficial resemblance in appearance to the active drug. This is the phenomenon known as the placebo response and its manifestations are both well documented and dramatic. The placebo response can involve widespread changes in physiological state, behavioral response and subjective experience. The placebo response is clearly not a fixed personality characteristic.

Placebo responses can involve both improvement and deterioration in functioning. On the one hand, placebo responders have reported marked improvements in mental feelings and their performance is more efficient. The placebo response has however included drowsiness, nausea, dizziness, slowness, and a wide range of changes including a deterioration in efficiency (Griffiths , 1986).

The use of placebo in the management of certain difficult patients is well known and favourable effects can be noted in some patients following the oral administration of placebos. In contrast, during the course of double blind cross over studies in drug evaluation, it is not uncommon to observe "toxic side effects" among patients receiving placebos (Remenchik and Talso , 1968).

A small number of the patients will report a worsening of their symptoms following placebo administration and this has been referred to as the nocebo effect (Kissel and Barrucand, 1974).

In any trial though, a proportion of the patients will fail to take their medication, i.e. they will not comply with the treatment given. This however can be minimised by ensuring that the patient understands what is required of him, both by explanation and clear labeling of the labels (Lawson and Richards, 1982).

In certain conditions such as mild depression the placebo factor may account for over 40% of the improvement seen. On the other hand, even in conditions such as severe cancer, spontaneous remissions, although rare, are possible (Lawson and Richards, 1982).

However the proportion of placebo responders in particular samples may vary from 0 to 100% although the number commonly falls in the 30% to 50% range; where psychiatric disorders are concerned it is not infrequently as high as 75% (Jospe, 1978; Parkhouse, 1963; Shapiro and Morris, 1978).

CHAPTER THREE

3) MATERIALS AND METHODS :

3.1) THE DATA:

The data of this research is of two sources: primary data and secondary data. The description of these two types of data will be given briefly below.

3.1.1) THE PRIMARY DATA:

The primary data was collected by means of communication (i.e. A questionnaire), observation (i.e. The patients acne was observed and recorded by means of the written case history and photography) and experimentation (i.e. Once the acne was observed, a Homoeopathic stimuli was introduced and the effects of this stimuli on the patients were observed) although this does not take place in a controlled environment.

Three types of primary data were needed:

- 1) The responses of patients according to specific questions asked in the case history.
- 2) The clinical manifestations obtained from observation and photographs taken of the patients.
- 3) The integration of the patients perception to the treatment from a standardized questionnaire and the response of the acne to the medication given.

3.1.2) THE SECONDARY DATA:

The normative and the current data on all aspects of Acne Vulgaris was needed. Journals, documents and books on the aetiology, pathogenesis, clinical manifestations; the assessment, classification and grading; pathology, complications and diagnosis of Acne Vulgaris were needed. The data was obtained from the following sources:

- Medical journal articles on acne vulgaris.
- Homoeopathic journal articles on acne vulgaris.
- Medical textbooks containing information on acne vulgaris..
- Past and current Medical research on acne vulgaris.
- Past and current Homoeopathic research on acne vulgaris.
- Homoeopathic Repertories.
- Materia Medica's.
- Literature on questionnaire design.
- Lecture material

3.2) THE SAMPLE:

The sample used in this study was drawn randomly from the population in Natal.

Possible candidates must qualify in the following areas;

- 1) Patients must be from the greater Durban environment with easy access to Technikon Natal.
- 2) Refer to the delimitations.

Due to financial restrains, this group study limited itself to a random sample of thirty.

3.3) THE CRITERIA GOVERNING THE ADMISSIBILITY OF THE DATA:

- * Only information concerning changes in the clinical manifestations in Acne Vulgaris collected from patients who took Homoeopathic medication made according to those principles set out in the Homoeopathic pharmacopoeia were accepted into this study.
- * Only information which was obtained from patients who were on Homoeopathic medication or placebo were accepted in this study.
- * Data regarding the patients perception to the treatment was extracted using a questionnaire completed under the researchers personal supervision only.
- * Data regarding the stage the evolution of the acne was allowed admissibility if recorded by means of photography only.

3.4) THE INSTRUMENTS:

The data was extracted using a questionnaire[Appendix C] (which assesses the patients response to the treatment) and colour photographs using standardised photographic equipment.

The use of computer based spread sheets (Microsoft Excel) allowed for the capture and manipulation of the above data. The computer program for statistical analysis of the captured data was the Statgraphics Plus Version 6.0, supplied by Manugistics Inc..

PHOTOGRAPHIC MATERIALS, METHODS AND SPECIFICATIONS:

Mr. V. Wait, Head of Department of Photography at Technikon Natal (1993), suggested that for this type of photography a Nikon Medical lens should be used. Unfortunately due to budget constraints this was not possible as the item cost R10 000.00. He also suggested that oblique lighting should be used and possibly be bounced off a polystyrene board to soften the light. A Kodak gray card should be placed next to the item one is photographing (for the first photograph of every spool) and ask the laboratory developing the film to ensure the gray card comes out gray. The flash being used must be of a reasonable quality otherwise the light quality will change during the course of the research. (The following flash was recommended; A Metz 45 cti, but due to budget constraints a cheaper flash had to be purchased). The photographer must try to keep the depth of field high (highest F numbers), so that the surface of the acne and the skin below are in focus.

Tony Smith (1993), a professional photographer recommended by the Head of Department of Photography at Technikon Natal- Mr. V. Wait, suggested that for this type of photography oblique lighting should be used with the aim of creating a shadow. The further away the lighting source is from the object to be photographed the less the fall-off. The flash should be fixed to a metal bracket which in itself is connected to the camera. Only one flash should be used because soft lighting is required. If more lighting is required place a piece of white cardboard behind the object being photographed.

Two standard colours (gray and skin tone) should be placed in the first photograph of each spool, so that the type of development of all

photographs may be standardised. The position of the flash along the metal bracket and the angle of the flash (trajectory) should be standardized (Appendix E). If fluorescent lighting is utilized, use a shutter speed that overpowers the fluorescent light.

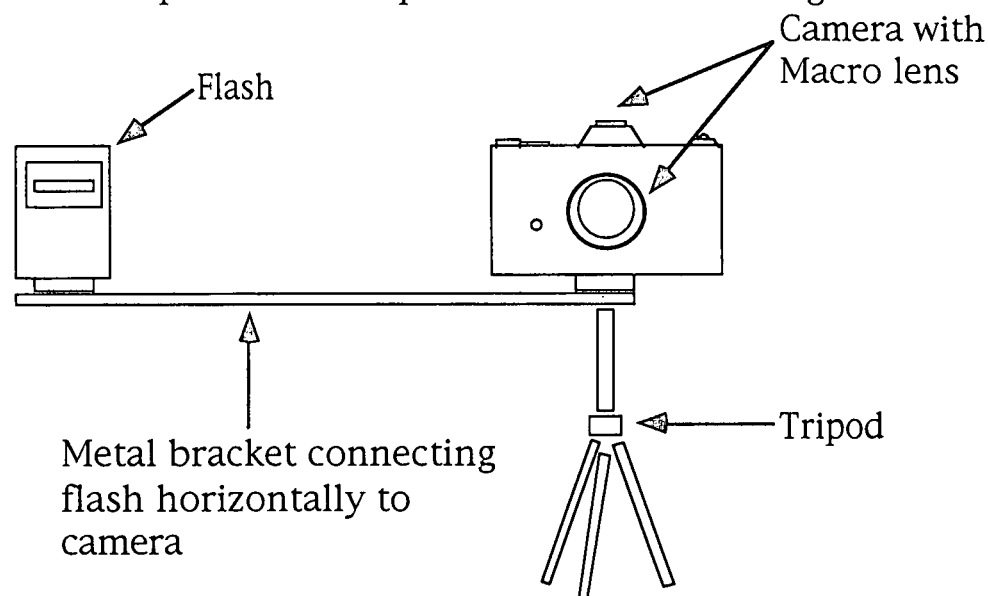


Figure 1: Photographic equipment used in the study.

Mr. Tony Smith also recommended two types of films that are used when working with skin tones; The AGFA Portrait expose at 100 ASA or the FUJI Reala. Specifications concerning the magnifications and F no.'s to be used were recommended by Mr. T. Smith (Appendix G). A record was kept of all the settings of the camera, patient position, lighting e.t.c. for each patient (Appendix F).

3.5) THE RESEARCH METHODOLOGY:

Since the purpose of this study was to determine the degree of proficiency of Homoeopathy in the treatment of Acne Vulgaris in terms of its clinical manifestations by obtaining data about the acne before and after treatment, the research methodology utilized was the experimental method.

In this method the researcher determined the influence of Homoeopathic treatment (independent variable) on the clinical manifestations of Acne Vulgaris as presented by the patient (dependent variable) whereby the independent variable (the treatment) is manipulated to measure the effect on the dependent variable (the acne).

The experimental design which was utilised in this study was the single variable design. The specific single variable design chosen was the "before-and-after with control". In this experimental method, there were two test units (groups of 30 patients), one acting as the control. The problem with this experimental method was that there was no control over the influence extraneous forces which may have caused secondary variations. An attempt to overcome this was done by selecting sufficient number of test units at random. Randomisation means that a random selection process is used to assign the treatments within the experiment. All sources of extraneous variation were largely controlled because treatment variables are equally exposed and equally affected by extraneous factors.

In this particular study, the use of a control raises the question of medical ethics: "Is it right not to treat a patient who has sought the assistance of a practitioner for the specific gains of that practitioner?"

3.6) ADMINISTRATION:

The following steps were taken in the execution of the study;

1. Advertise for patients in the Newspaper and on the notice boards at Technikon Natal and Durban University.
2. Assess whether the patients that responded to the advertisements are suitable for the study i.e. Delimitations.
3. A sample of thirty chosen.

5. The acne graded according to those techniques set out in Appendix B.

6. The acne on all thirty patients is photographed in colour with standardized lighting, film, background colour and distance (equal zoom factor).

7. Each case studied carefully and a prescription submitted to a Homoeopathic pharmacist .

8. The sample of thirty divided in half by a neutral Homoeopathic pharmacist allocating valid Homoeopathic medicine to fifteen and placebo to the other fifteen.

9. Homoeopathic medicine handed to the patients a day after taking the case history, allowing the researcher time to analyze the case and correspond with significant personalities.

10. A period of three to four weeks passes during which the patients take their medication.

11. The case history and physical examination of all thirty patients is reviewed. (Should the medication for a patient change, the prescription will be handed to the Homoeopathic Pharmacist noting whether to continue a placebo or prescribe a new medicine.)

12. Each patients acne is re-photographed.

13. The entire process is repeated five times allowing each patient a treatment time of four months.

14. All the data collected is analyzed, interpreted and the hypotheses tested.

15. The following statistical tools are used;

- correlation and regression
- paired-T test

3.7) THE SPECIFIC TREATMENT OF EACH SUBPROBLEM:

SUBPROBLEM ONE:

The first subproblem proposes to determine the degree of proficiency of Homoeopathy in the treatment of Acne Vulgaris in terms of it's clinical manifestations in order to evaluate the relationship between Homoeopathic treatment and the clinical manifestations.

3.7.1.1) THE DATA NEEDED:

The data needed for testing the hypothesis of subproblem one was that data concerning the clinical manifestations of Acne Vulgaris before and after the introduction of Homoeopathic treatment.

The data was obtained from photographs of the patients acne, case histories and physical examinations (Appendices A, B and D) performed on the respective patients and the respective medication given.

The following data from the patients photographs was needed;

- a. Vertical shots of the acne.
- b. Location of the acne.
- c. Colour of the acne.
- d. Size and number of acne lesions.
- e. Surface texture of the skin.
- f. Concomitant features e.g. Haemorrhaging, ulceration, scars.
- g. Type of acne lesions i.e. Classification.
- h. Condition of surrounding tissue.

- i. Number of acneiform lesions.

3.7.1.2) THE LOCATION OF THE DATA:

The data required was located upon each patient, extrapolated using photography and the visual-tactile technique, then transferred onto a spreadsheet. The data concerning the specific remedies to be given may be found in respective Materia Medica's and repertories.

3.7.1.3) HOW THE DATA WAS SECURED:

The data was secured from the case history and physical examination of the patients, taken by the researcher. Included in the case history is the grading of the acne (Appendix B) and the taking of photographs of the lesional areas on the patients for both diagnostic and for record keeping purposes. The photographs of the acne were taken on the initial visit and every month thereafter for four months. The photographs were taken personally by the researcher using equipment ensuring that each picture complied to the same standard. The data was obtained by grading the acne on the patients from the photographs. At the end of the clinical period of the study the patients were divided into their respective treatment or placebo groups. The figures for each patient from the same consultation number of the treatment group were then added together to give totals for the 5 consultations. The same was then done for the placebo group.

3.7.1.4) THE TREATMENT OF THE DATA:

The data concerning the clinical manifestations was reported by means of a standardised diagnostic questionnaire (Appendix A) which was incorporated into the homeopathic case history (Appendix D). The data was reported by the use of a standardised photographic lesion grading system and two other standardised lesion grading and counting techniques (Appendix B) incorporating the visual-tactile technique of grading. The data was interpreted by means of the paired -t test.

From the case history and physical examination, data about the patients health and habits were used to;

- help the researcher decide on a appropriate Homoeopathic medicine. (Refer to the literature review to understand why this is necessary.)
- diagnose the acne.
- diagnose any concomitant diseases that are relevant to acne treatment.

Colour photographs of the acne provided the following data;

- type of acne.
- size of the acneiform lesions.
- number of acneiform lesions.
- colour of the acne.
- surface texture and condition of the skin on and around the acne.
- any concomitant features e.g. Haemorrhaging.

This data was transferred onto spread sheets. The values on the spread sheets were used to test the hypothesis.

3.7.1.5) INTERPRETATION OF THE DATA:

The data was interpreted by:

A) Studying the values of **each** patient, i.e. the general condition of the acne, enabling the researcher to highlight any trends in the treatment of an **individuals'** acne.

B) Studying the values of **all** the patients, i.e. the general condition of the acne, enabling the researcher to highlight any trends in the treatment when comparing **all** the patients together.

The manipulated data from the spreadsheets was then be used to test the first hypothesis.

All the statistical analysis of data was performed with the necessary guidance from a statistician.

SUBPROBLEM TWO:

The second subproblem proposes to determine the proficiency of Homoeopathy in the treatment of Acne vulgaris in terms of the patients perception to the treatment in order to establish what aspects of acne treatment patients consider significant.

3.7.2.1) DATA NEEDED:

The data needed for testing the hypotheses of subproblem two was that data concerning the patients perception to treatment.

The data needed for testing the hypothesis of subproblem two was obtained from the answers to the questions of the questionnaire to the patients.

The following data from the patients was needed;

- a) How the patient has thus far perceived the treatment to be.
- b) How severe does the patient rate their acne.
- c) Whether the acne has changed in degree of severity.
- d) If the acne changed in severity, how did it change.
- e) Whether the acne changed in colour.
- f) Whether the surface texture of the skin changed.
- g) If any pain or tenderness is experienced at the location of the acne.
- h) If the acne bleeds.
- i) How the patient would rate their acne now as compared with the period before the Homoeopathic treatment started.
- j) Whether their attitude concerning their condition has changed since the Homoeopathic treatment began.
- k) How the patients attitude concerning their condition changed since they began with the Homoeopathic treatment.

3.7.2.2) THE LOCATION OF THE DATA:

The data required was located within and on each patient extrapolated by a questionnaire and then transferred onto a spreadsheet. The data concerning the specific remedies to be given may be found in respective Materia Medica's and repertories.

3.7.2.3) HOW THE DATA WAS SECURED:

All the data was obtained from specific questions asked in the standardised questionnaire (Appendix C).

The questionnaire was given to the patients on their second visit, and every month there after for three months. A letter of introduction explaining the nature of the research was included with the first questionnaire. The questionnaire was completed verbally during an interview conducted by the researcher.

3.7.2.4) TREATMENT OF THE DATA:

Screening of the completed questionnaires (on patients response to treatment) was done to determine whether all were filled out correctly and whether all respondents met all the selection criteria.

Questionnaires (assessing the patients perception to the treatment in the form of a semantic differential scale) provided values for each question which was transferred onto a spread sheet and a total calculated for each questionnaire. The same procedure was performed three to four weeks later. The values obtained and calculated from the questionnaires were then transferred onto spread sheets.

3.7.2.5) INTERPRETATION OF THE DATA:

For each patient, the total values for each questionnaire were compared with themselves over a period of time (four months).

Once all thirty patients completed four questionnaires each, a statistical tool was used to compare all the questionnaires to

determine if there are any trends, and if in fact these trends correlate with the data obtained for the photographs of the acne (subproblem one).

All the statistical analysis of data was performed with the necessary guidance from a statistician.

SUBPROBLEM THREE:

The third subproblem proposes to integrate the data collected on the patients perception to the treatment and the changes in clinical manifestation (if any) in order to determine the role of Homoeopathy in the treatment of Acne Vulgaris.

3.7.3.1) DATA NEEDED:

The data needed to test the hypothesis of subproblem three was the information gathered from subproblem one [the clinical manifestations (photographs, case histories and physical examination) and the treatment given] and subproblem two [the questionnaires (assessing the patients perception to the treatment)].

3.7.3.2) THE LOCATION OF THE DATA:

The data was taken from subproblem one and subproblem two.

3.7.3.3) HOW THE DATA WAS SECURED:

The data concerning the clinical manifestations of the condition was secured from the case history of the patients taken by the researcher.

Included in the case history was the taking of photographs of the lesional areas.

The data concerning the patients perception to the treatment was secured from specific questions asked according to a standardised questionnaire.

3.7.3.4) TREATMENT OF THE DATA:

The data obtained from subproblems one and two were integrated and compared using a statistical tool in such a way as to note if there was any correlation between the two sets of data, allowing them to demonstrate what role (if any) Homoeopathy or placebo has to play in the treatment of acne.

The data was interpreted using Pearsons coefficient of correlation.

3.7.3.4) INTERPRETATION OF THE DATA:

Interpretation of the data was done by comparing the data from subproblem one, two and whether Homoeopathic medicine or placebo given.

CHAPTER FOUR

4) RESULTS:

4.1) SUBPROBLEM ONE:

This subproblem proposes to determine the degree of proficiency of Homoeopathy in the treatment of Acne Vulgaris in terms of it's clinical manifestations in order to evaluate the relationship between Homoeopathic treatment and the clinical manifestations.

These figures represent severity of acne according to a 0-4 scale where 0= no acne, 1= minimal acne, 2= mild acne, 3= moderate acne and 4= severe acne from the treatment group:

PATIENT	PHOTO 1	PHOTO 2	PHOTO 3	PHOTO 4	PHOTO 5
A1	3	3	3	3	3
A2	3	2	2	1	1
A3	3	2	3	3	2
A4	4	4	4	4	3
A9	3	3	3	2	1
A13	2	2	3	2	2
A17	3	2	2	2	2
A18	2	2	2	2	1
A20	2	2	2	3	1
A24	3	3	3	3	3
A25	2	2	2	2	2
A26	1	1	1	2	2
A27	3	3	2	2	2

A32	3	2	2	2	2
A33	2	2	2	2	2
TOTAL	39	35	36	35	29

TABLE 4.1: Figures showing severity of clinical manifestations of acne for photographs taken over 5 consultations for the treatment group.

For the 15 patients in the treatment group, this table indicates in what distribution the changes, if any, took place .

Tx GROUP	
9 (60%)	Improved
5 (33.3%)	No Change
1 (6.6%)	Worsened
15 (100%)	TOTAL

TABLE 4.2: Figures showing changes in the clinical manifestations of acne for the treatment group.

A paired - t test was performed utilising the first and last set of observations taken from table 4.1 and P was found to have a value of 0.006, thus making the differences tabulated in table 4.2 significant. A P value of < 0.05 is considered statistically significant.

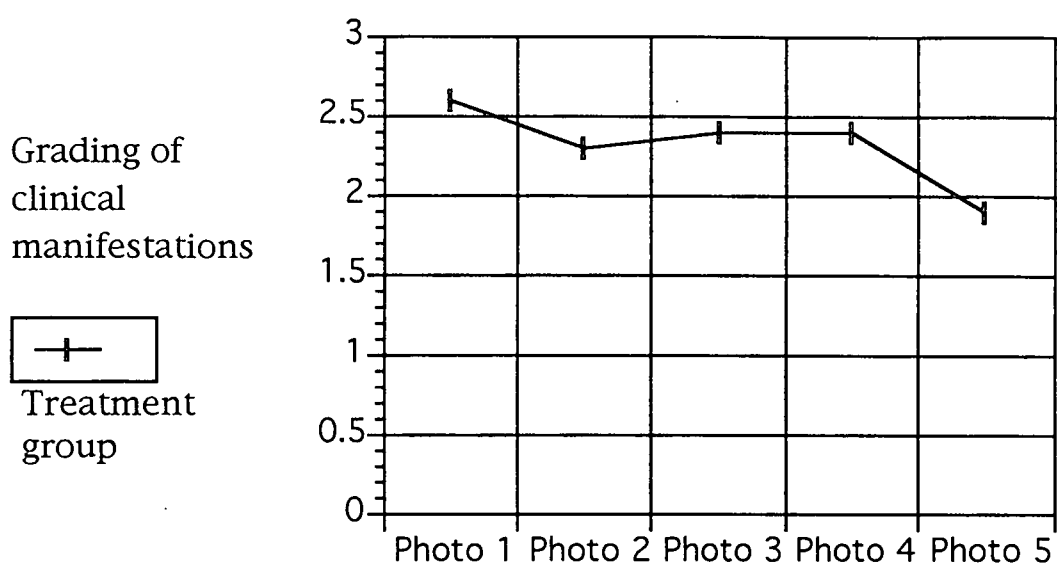


Figure 2: A graph showing the evolution of the clinical manifestations utilising the averages of the photo's of the treatment group.

This graph indicates that the significant difference obtained from the paired-t test utilising the observations in table 4.1 is that of improvement.

The following figures represent severity of acne according to a 0-4 scale where 0=no acne, 1= minimal acne, 2=mild acne, 3= moderate acne and 4= severe acne from the **placebo** group.

PATIENT PHOTO 1 PHOTO 2 PHOTO 3 PHOTO 4
PHOTO 5

A5	1	1	1	2	2
A6	2	2	1	1	0
A8	2	2	3	3	2
A11	2	2	2	2	2
A12	2	2	2	2	2

A15	3	3	3	2	2
A16	3	3	2	2	2
A19	2	2	2	2	2
A21	3	2	1	2	2
A22	2	2	2	2	3
A23	2	2	2	2	3
A30	1	1	1	0	0
A31	3	3	3	3	3
A34	3	3	3	3	3
A35	2	2	2	2	2
TOTAL	33	30	30	30	30

TABLE 4.3: Figures showing severity of clinical manifestations of acne for photographs taken over 5 consultations for the placebo group.

The following table represents the changes in the clinical manifestations, if any, in the patients in the placebo group .

Plc GROUP	
5 (33.3%)	Improved
7 (46.6%)	No Change
3 (20%)	Worsened
15 (100%)	TOTAL

TABLE 4.4: Figures showing changes in the clinical manifestations of acne for the placebo group.

A paired -t test was performed utilising the first and last observations taken from table 4.3 and P was found to have a value of

0.384, thus making the differences tabulated in table 4.4 statistically insignificant.

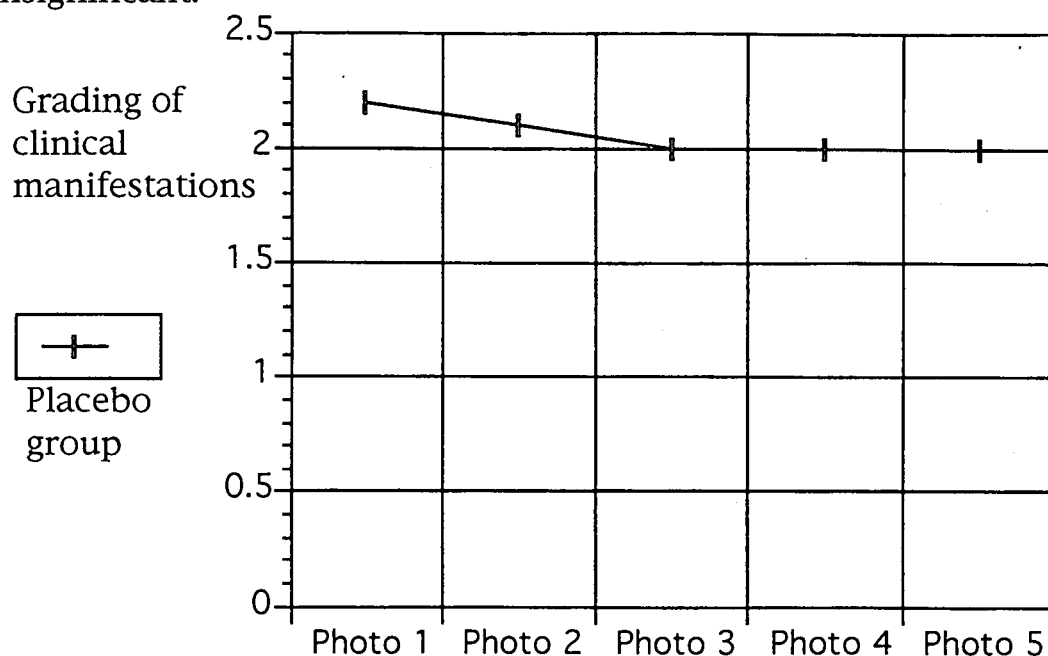


Figure 3: A graph showing the evolution of the clinical manifestations utilising the averages of the photo's of the placebo group.

This graph validates the insignificant difference obtained from the paired-t test utilising the observations in table 4.3.

SUBPROBLEM TWO:

This subproblem proposes to determine the proficiency of Homoeopathy in the treatment of Acne vulgaris in terms of the patients perception to the treatment in order to establish what aspects of acne treatment patients consider significant.

The following table reflects the figures of the patient's in the treatment group of their self-assessment under the following

categories - worse, no change, fair, good and excellent graded on a scale from 1 to 5 .

Each figure represents a **mean** of the totals taken from each questionnaire.

PATIENT	Q'aire 1	Q'aire 2	Q'aire 3	Q'aire 4
A1	2.8	3.0	2.6	2.2
A2	2.3	1.4	1.4	1.9
A3	2.5	2.1	2.7	2.9
A4	3.3	3.9	3.4	2.1
A9	3.4	2.5	2.7	2.5
A13	2.4	1.5	1.3	1.5
A17	1.5	1.7	2.7	2.0
A18	2.9	1.3	2.1	1.8
A20	2.4	2.4	3.0	2.4
A24	1.6	1.9	1.9	1.1
A25	2.4	2.8	1.3	1.9
A26	1.6	2.7	3.0	1.8
A27	1.7	1.7	1.3	1.5
A32	2.5	1.9	1.4	1.2
A33	2.2	2.2	2.2	2.4
TOTAL	35.5	33	33	29.2

TABLE 4.5: Figures showing means for the patient's perception to the treatment over a period of four questionnaires for the treatment group.

The following table represents the changes in the patients perception to the treatment, if any, in the patients in the treatment group .

Tx GROUP	
9 (60%)	Improved
1 (6.66%)	No Change
5 (33.3%)	Worsened
15 (100%)	TOTAL

TABLE 4.6: Figures showing changes in the patients perception to the treatment for the treatment group.

A paired -t test was performed utilising the observations taken from table 4.5 and P was found to have a value of 0.015, thus making the differences tabulated in table 4.6 statistically significant.

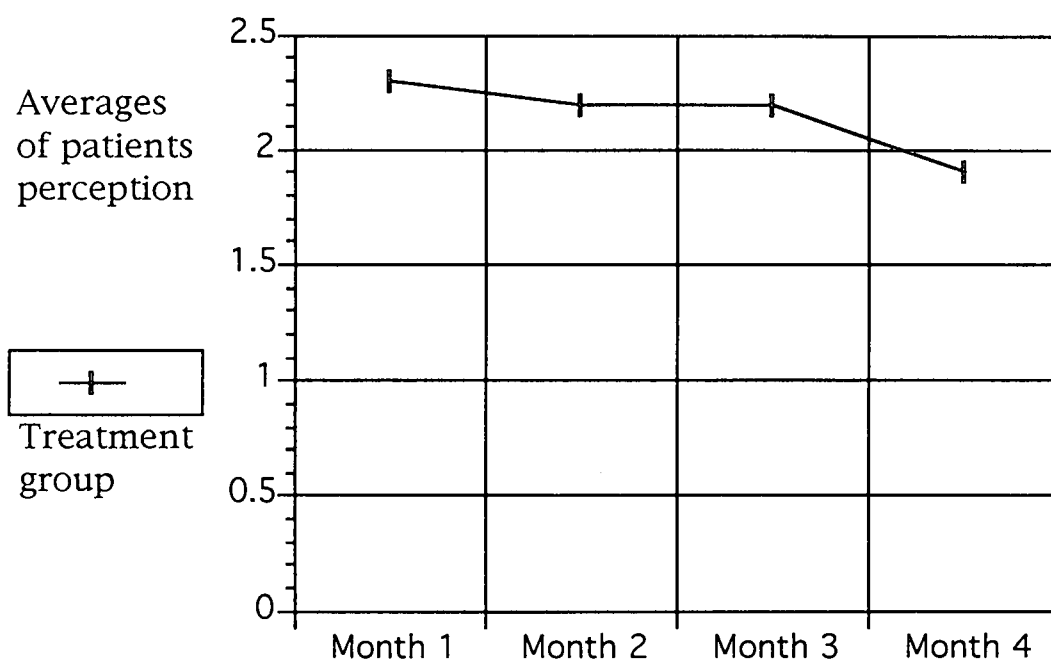


Figure 4: A graph showing the evolution of the patients perception to the treatment for the treatment group.

This graph indicates that the significant difference obtained from the paired-t test utilising the observations in table 4.5 is that of improvement.

The following reflect the figures of the patient's in the placebo group of their self-assessment under the following categories - worse, no change, fair, good and excellent graded on a scale from 1 to 5 .

PATIENT	Q'aire 1	Q'aire 2	Q'aire 3	Q'aire 4
A5	2.5	2.8	4.0	2.9
A6	2.3	2.0	2.0	1.8
A8	2.8	1.6	1.6	1.2
A11	3.5	2.2	2.4	2.4
A12	3.3	2.1	2.2	2.2
A15	3.3	2.9	2.3	2.6
A16	2.0	2.8	2.0	1.6
A19	2.3	1.6	1.1	1.5
A21	2.6	1.8	1.9	1.5
A22	2.8	3.2	2.7	3.1
A23	2.9	2.9	2.1	1.8
A30	2.8	2.3	1.8	1.8
A31	2.2	2.2	2.8	2.3
A34	3.3	3.2	2.2	1.7
A35	2.2	2.1	2.6	2.3
TOTAL	40.8	35.7	33.7	30.7

TABLE 4.7: Figures representing means for the patient's perception to the treatment over a period of four questionnaires for the placebo group.

The following table represents the changes in the patients perception to the treatment , if any, in the patients in the placebo group .

Plc GROUP	
11 (73%)	Improved
0 (0%)	No Change
4 (26.6%)	Worsened
15 (100%)	TOTAL

TABLE 4.8: Figures showing changes in the patients perception to the treatment for the placebo group.

A paired -t test was performed utilising the observations taken from table 4.7 and P was found to have a value of 0.001 , thus making the differences tabulated in table 4.8 statistically significant.

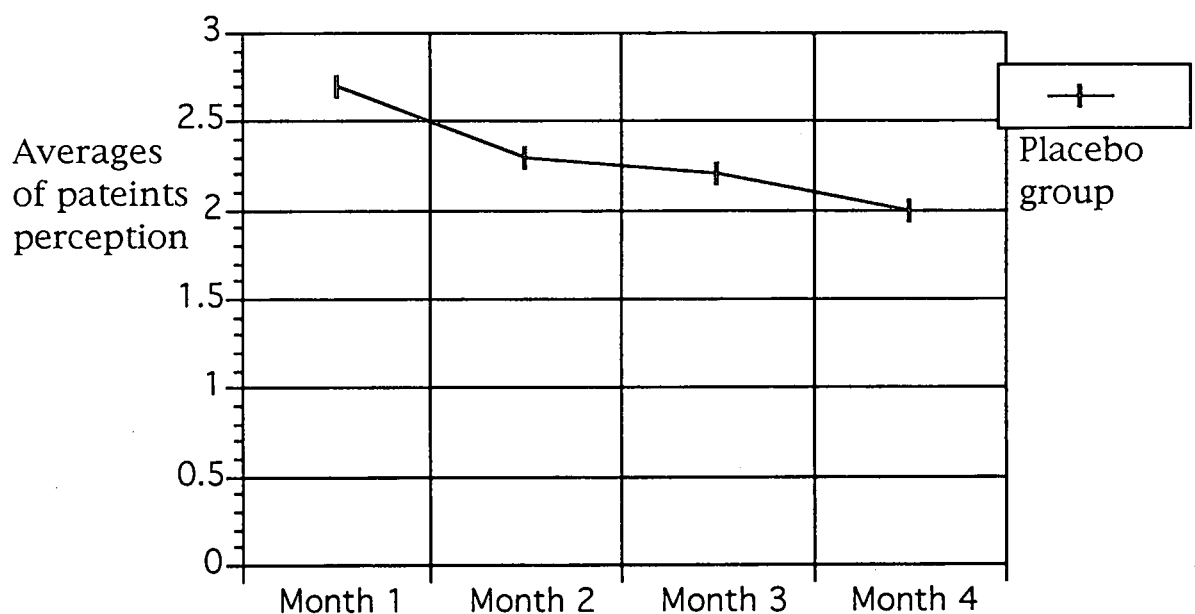


Figure 5: A graph showing the evolution of the patients perception to the treatment for the placebo group.

This graph indicates that the significant difference obtained from the paired-t test utilising the observations in table 4.7 is that of improvement.

SUBPROBLEM THREE:

This subproblem proposed to integrate the data collected on the patients perception to the treatment and the changes in clinical manifestation (if any) in order to determine the role of Homoeopathy in the treatment of Acne Vulgaris.

The hypothesis of this subproblem was tested by correlating the following figures representing those obtained from the treatment group of patients from Subproblem 1 (Photo-Tx) and Subproblem 2 (Q'aire-Tx).

Total Photo-Tx	Total Q'aire-Tx	
39		Month 0
35	35.5	Month 1
36	33	Month 2
35	33	Month 3
29	29.2	Month 4

TABLE 4.9: A table showing corresponding figures from the photographs of the clinical manifestations and questionnaires for the patients perception to the treatment of the treatment group over a period of four months.

Correlation results:

Tx Group	Q'aire
Photo	0.8482

TABLE 4.10: A table showing the correlation between the photographs and the questionnaires of the treatment group taken from table 4.9.

The following figures represent those obtained from the placebo group of patients from Subproblem 1 (Photo-Plc) and Subproblem 2 (Q'aire-Plc).

Photo-Plc	Q'aire-Plc	
33		Month 0
30	40.8	Month 1
30	35.7	Month 2
30	33.7	Month 3
30	30.7	Month 4

TABLE 4.11: A table showing corresponding observations from the photographs of the clinical manifestations and questionnaires for the patients perception to the treatment of the placebo group over a period of four months.

Correlation results:

Plc Group	Q'aire 1	Q'aire 2	Q'aire 3	Q'aire 4
Photo 2	0.447			
Photo 3		0.4005		
Photo 4			0.639	
Photo 5				-0.2567

TABLE 4.12: A table showing the correlation between the photographs and the questionnaires of the placebo group taken from table 4.11.

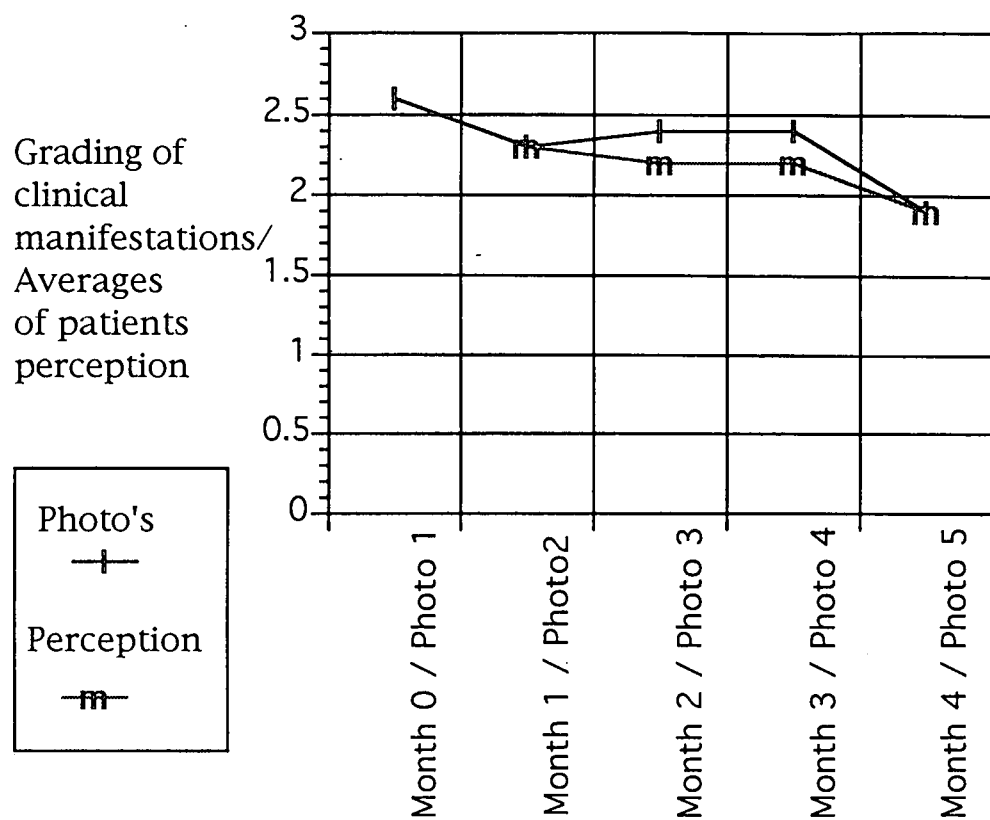


Figure 6: A graph showing the evolution in the correlation between the photo's and the patients perception to the treatment of the treatment group.

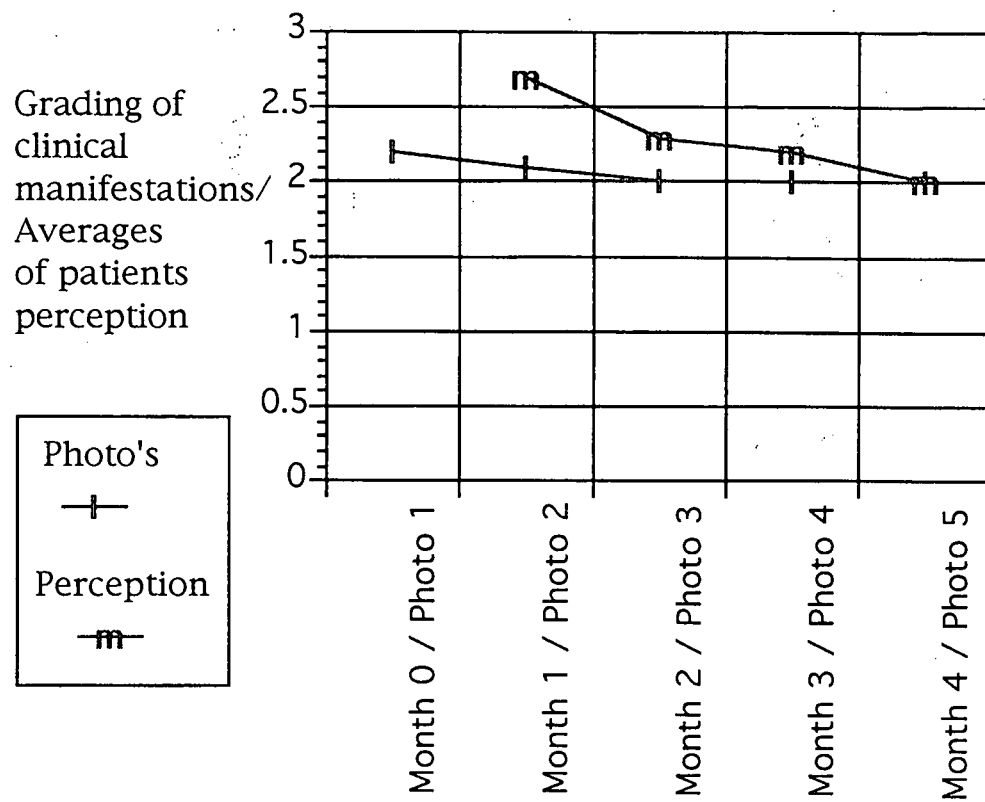


Figure 7: A graph showing the evolution of the correlation between the photo's and the patients perception to the treatment of the placebo group.

CHAPTER FIVE

DISCUSSION:

This study aimed at the observation and monitoring of the management of patients with Acne treating them either with Homoeopathic medication or placebo.

Patients were screened according to delimitations set out in a consent form which was signed by the patients (Appendix H).

In total, 35 patients were accepted into the study and allocated to either a treatment or placebo group according to a predesignated random sequence to prevent unwanted and unintentional bias on the part of the researcher. The designation was performed by a neutral qualified Homoeopathic pharmacist.

Of the 35 patients accepted into the study, 5 dropped out for reasons unknown to the researcher.

SUBPROBLEM ONE:

The following table represents the differences in the clinical manifestations of the acne between the first and last sets of observations of both the treatment and placebo groups.

	Improved	No Change	Worsened	TOTAL
Tx Group	9 (60%)	5 (33.3%)	1 (6.6%)	15 (100%)
Plc Group	5 (33.3%)	7 (46.6%)	3 (20%)	15 (100%)

TABLE 5.1: A table showing the changes in both the treatment and the placebo groups

On performing the paired - t test utilising the observations represented by the changes tabulated in table 5.1, it was seen that

there was a statistically significant difference in the treatment group ($P=0.006$) but no statistically significant difference in the placebo group ($P=0.384$) although there was a minor observable clinical difference in this group.

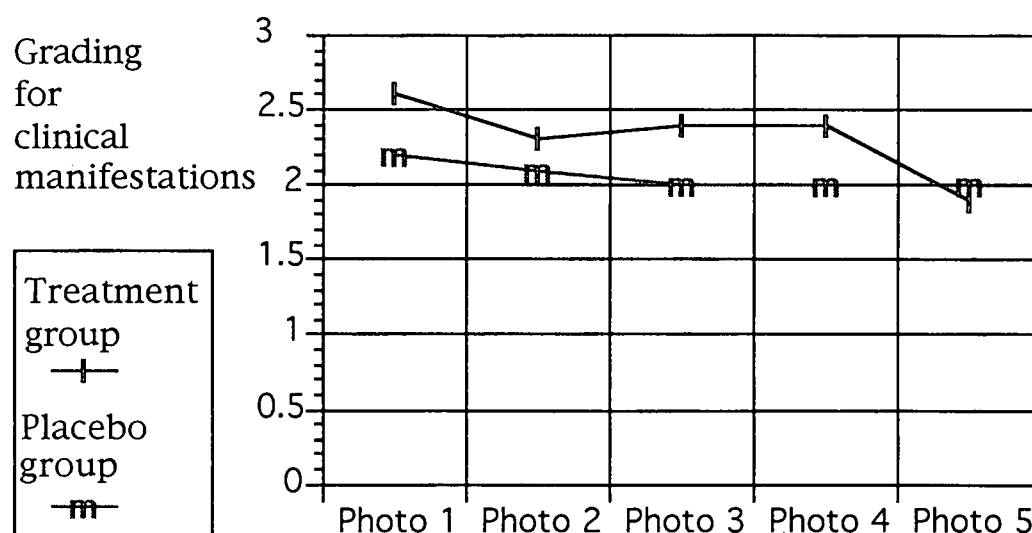


Figure 8: A graph showing the evolution in the clinical manifestations for both the treatment and placebo groups.

When comparing the difference between the first and last totals in the treatment group from the above graph, it can be seen that a figure of 10 indicates a far greater improvement compared to a difference of 3 taken from the first and last totals in the placebo group. This observation corresponds with that obtained from the paired -t test.

It was noted that in the treatment group, 60% of the patients improved. It was however difficult to determine what role the homeopathic medication played in their amelioration due to the fact that studies indicate that 33% to 50% of patients receiving placebo show improvement (Griffiths, 1968; Jospe, 1978; Parkhouse, 1963; Shapiro and Morris, 1978).

It is also observed that the clinical manifestations of a certain percentage of the patients in the treatment group either did not

change or worsened. This can be due a number of extraneous factors, including those factors which affect the efficacy of the medicine, .i.e. eating while taking the medication, deactivation of the medication by aromatic substances (tooth paste) , sunlight e.t.c.. It could also partly be attributed to the fact that in any trial, a proportion of the patients will fail to take their medication, i.e. they will not comply with the treatment instructions given. This however can be minimised by ensuring that the patient understands what was required of him, both by explanation and clear labeling of the labels (Lawson and Richards, 1982).

The possibility that the wrong medication was given to the patients for their particular type of acne was curtailed by the fact that all the prescriptions were approved by a qualified homeopath before dispensing the medication to the patient.

It was also noted that the clinical manifestations of a certain percentage of the patients in the placebo group worsened. This could be ascribed to the fact that, either the patients were not receiving any homeopathic medication nor were they influenced by the placebo effect. It may also be due to the fact that some patients react unfavourably to almost any drug or even to a placebo because they are psychologically opposed to the use of drugs or medication of any kind (Remenchik and Talso, 1968). Although this study indicated that patients participated totally voluntarily (Appendix H), there could have been extraneous factors unknown to the researcher that may have forced the patients to take part against their will.

The clinical manifestations of 33.3% of the placebo group did in fact improve. This figure parallels with the findings done in studies by Griffiths, 1968; Jospe, 1978; Parkhouse, 1963 and Shapiro and Morris, 1978.

SUBPROBLEM TWO:

The following table represents the differences in the patients perception to the treatment between the first and last sets of observations of both the treatment and placebo groups.

	Improved	No Change	Worsened	TOTAL
Tx GROUP	9 (60%)	1 (6.66%)	5 (33.3%)	15 (100%)
Plc GROUP	11 (73%)	0 (0%)	4 (26.6%)	15 (100%)

TABLE 5.2: A table showing the changes in the patients perception to the treatment in both the treatment and the placebo group.

On performing the paired - t test utilising observations represented by the changes tabulated in table 5.2, it was seen that there was a statistically significant difference for both the treatment group ($P = 0.015$) and the placebo group ($P=0.001$) .

This would indicate that the perception by the patient to the treatment was influenced similarly by both the medication and the placebo effect. As can be observed by the following graph, both the groups did in fact show a trend towards improvement. The placebo group however showed a slightly greater improvement validated by both the graph and the paired-t test figure of 0.001 as apposed to the treatment group figure of 0.0015.

This graph incorporates the data for both the treatment and the placebo groups allowing a comparison to be made between the two sets of data.

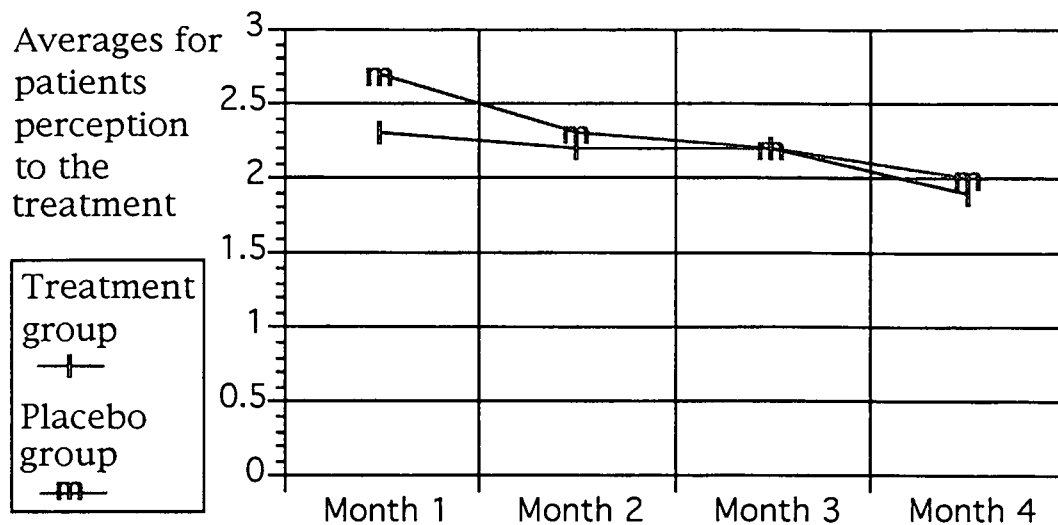


Figure 9: A graph showing the evolution of the patients perception to the treatment for both the treatment and placebo groups.

There are however other extraneous factors that could play a role in influencing the patient's perception towards the treatment, be it placebo or homeopathic medication. Factors such as stress, unintentional diet changes, emotional influences, changes in exercise regimens e.t.c. could influence the patients and their perception towards the treatment.

These factors were not investigated during the study due to the fact that this was a double blind study and one could not ascertain which factors were influencing the evolution of the acne and thus the patients perception towards the treatment.

In the previous two subproblems, it was noted that in the placebo groups a certain percentage of the patients did in fact improve or stayed unchanged (i.e. did not worsen). According to Jospe (1978); Parkhouse (1963) and Shapiro and Morris (1978), this could be due to the fact that studies indicate the number placebo patients in

particular samples showing an improvement may vary from 0 to 100% although the number commonly falls in the 30% to 50% range.

SUBPROBLEM THREE:

Subproblem 3 integrates all the data obtained from subproblem 1 and subproblem 2.

The following figures represent those obtained from the **treatment** group of patients from Subproblem 1 (Photo-Tx) and Subproblem 2 (Q'aire-Tx).

Total Photo-Tx	Total Q'aire-Tx	
39		Month 0
35	35.5	Month 1
36	33	Month 2
35	33	Month 3
29	29.2	Month 4

TABLE 5.3: A table showing the corresponding totals from the photographs and the questionnaires of the treatment group over a period of four months.

Correlation results:

Tx Group	Q'aire
Photo	0.8482

TABLE 5.4: A table showing the correlation results from the figures taken from table 5.3.

This correlation figure for the **treatment group** indicates that when the clinical manifestations of the individuals acne improved, so their

perception to the treatment showed a similar improvement. This fact can be noted by observing the following graph.

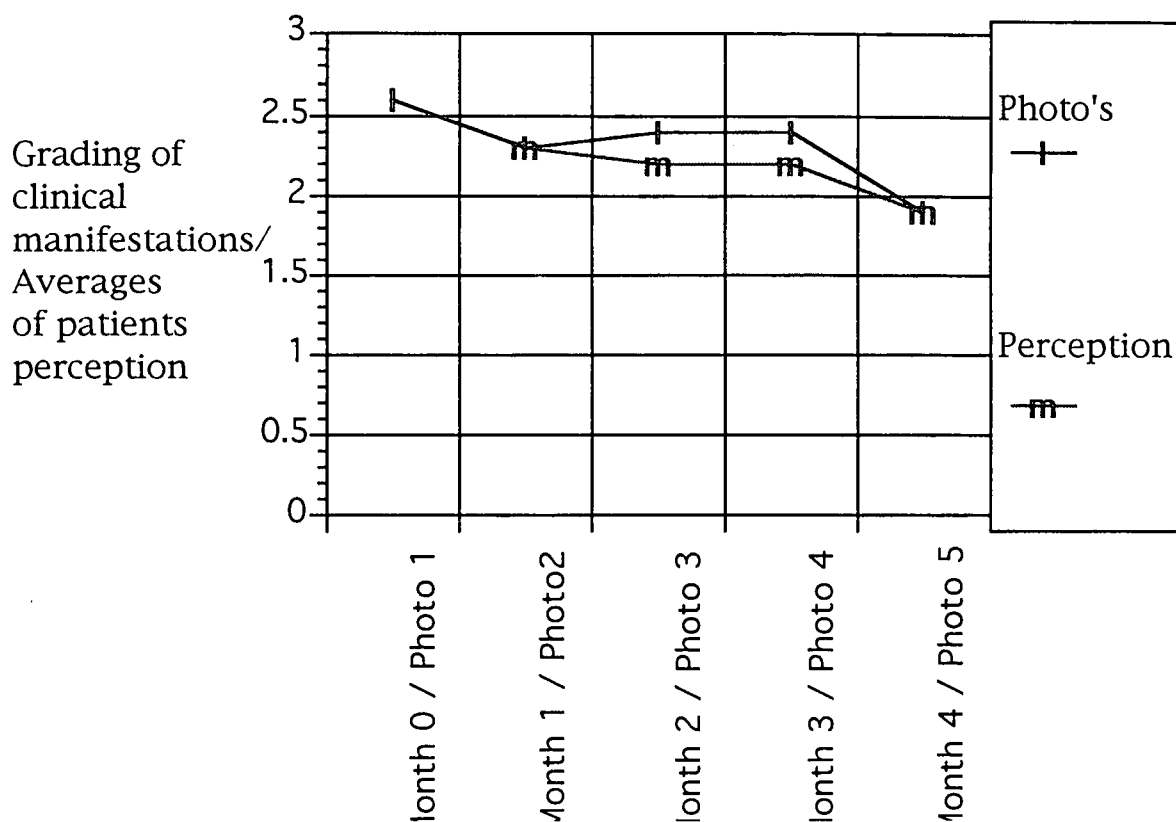


Figure 10: A graph showing the correlation between the photo's and the patients perception to the treatment of the treatment group.

The following figures represent those obtained from the placebo group of patients from Subproblem 1 (Photo-Plc) and Subproblem 2 (Q'aire-Plc).

Total Photo-Plc	Total Q'aire-Plc	
33		Month 0
30	40.8	Month 1
30	35.7	Month 2
30	33.7	Month 3
30	30.7	Month 4

TABLE 5.5: A table showing the corresponding totals from the photographs and the questionnaires of the placebo group over a period of four months.

Correlation results:

Plc Group	Q'aire 1	Q'aire 2	Q'aire 3	Q'aire 4
Photo 2	0.447			
Photo 3		0.4005		
Photo 4			0.639	
Photo 5				-0.2567

TABLE 5.6: A table showing the correlation results from the figures taken from table 5.5.

These figures show a poor correlation for the placebo group indicating that when the clinical manifestations of the acne stayed unchanged, improved or worsened for the individual patients, their perception to the treatment did not change correspondingly , if at all. The following graph shows the trends taken by the means of the sets of data indicating the minor correlation between the sets of data. As can be seen, the patients perception to the treatment improved quite notably where the patients clinical manifestations show a minor modification.

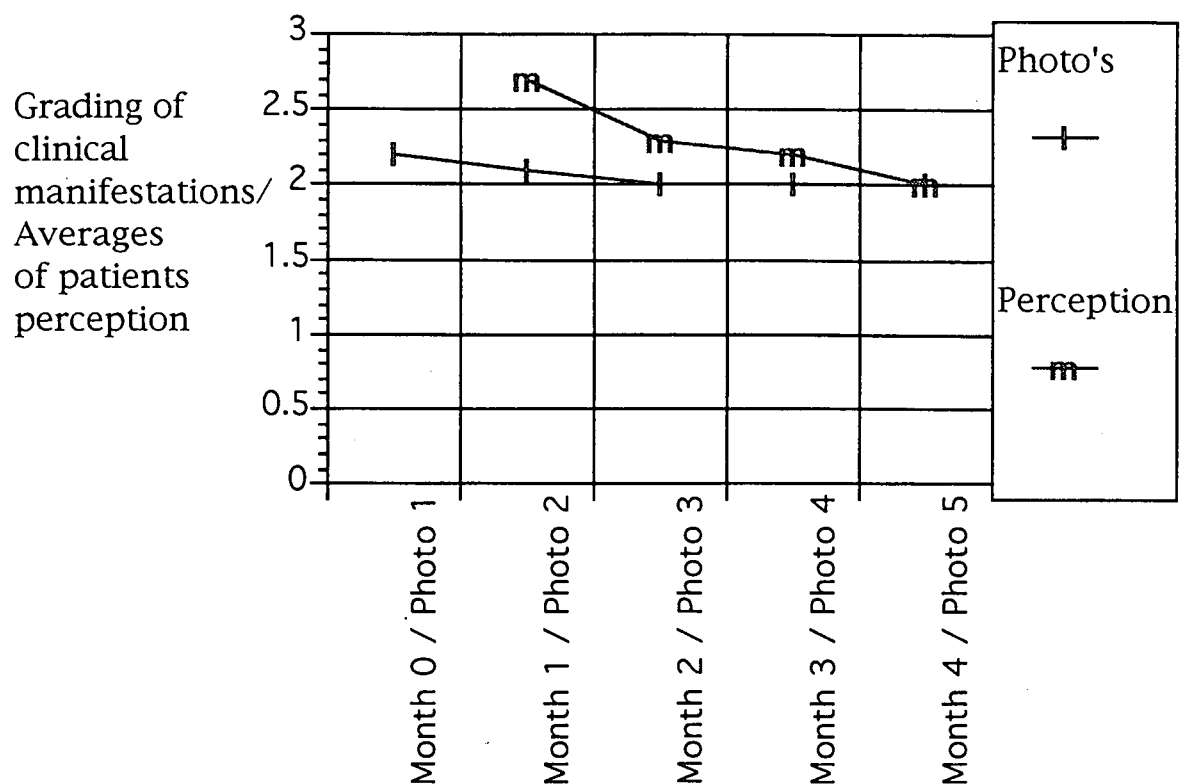


Figure 11: A graph showing the correlation between the photo's and the patients perception to the treatment of the placebo group.

The fact that there is a poor correlation between the data can be noted by the fact that the clinical manifestations of only 34% of the patients receiving placebo improved compared to a reported 76% improvement by the patients in their perception to the treatment. According to Jospe (1978); Parkhouse (1963); Shapiro and Morris (1978), the proportion of placebo responders in particular samples may vary from 0 to 100% although the number commonly falls in the 30 to 50% range; where psychiatric disorders are concerned it is not infrequently as high as 75%. However according to Griffiths (1968) the proportion of placebo responses is said to be constant across investigations (approximately one in three individuals - 33%) , although this proportion was made up of different individuals on separate occasions.

It can be noted that the correlation figure for the final photo and questionnaire was actually a negative figure which means that when individual patients reported an improvement in their perception to the treatment there was an actual increase/worsening in their clinical manifestations.

During this study a number of specific remedies were chosen due to their pathogenesis and symptomatically prescribed in the management of this condition. A table representing those remedies prescribed with their potencies and the frequency with which they were prescribed for the treatment group indicating those producing changes, if any, for both the clinical manifestations and the patients perception to the treatment can be viewed in appendix I and J

CHAPTER SIX

6) CONCLUSIONS AND RECOMENDATIONS:

6.1) CONCLUSIONS:

In this study, the researcher attempted to determine the degree of proficiency of Homoeopathy in the treatment of Acne Vulgaris in terms of its clinical manifestations and the patients perception to the treatment in order to determine the role Homoeopathy plays in the treatment of this condition.

It is safe to state that as far as the clinical manifestations of Acne Vulgaris are 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.

Although there was an observable effect, it cannot however be said that Homoeopathic medication alone plays a notable role in the patients perception to the treatment due to the fact that both the placebo effect and the homeopathic medication had similar influences on the patient.

RECOMMENDATIONS:

If future studies are carried out concerning this particular topic, it is recommended that a placebo group not be included in the test units. The main motivation for this is one of ethics. It raises the question: "Is

it right not to treat a patient who has sought the assistance of a practitioner for the specific gains of that practitioner?"

Future studies could monitor a sample of patients who, by individual choice, are not on any form of medication in order to follow the natural history of their condition in order to compare them to test units receiving medication. This however could however prove difficult due to the management of extraneous variables.

One could also monitor test units on medication who act as their own control.

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APPENDICES

A) Diagnostic questionnaire:

I) Diagnostic criteria

A) Clinical

1) patient history

a) Duration, to include progression to point of maximal severity

b) Location

c) Seasonal variation

d) aggravation by stress

e) For women

1) Premenstrual flare-up

2) Menstrual history and pregnancy status

3) Increase of androgen-dependent hair

4) Thinning of scalp hair

5) Oral contraceptives and effect on acne

6) Hormone tests

7) Cosmetics and moisturizers; type and frequency

f) Current treatments: topical and systemic

1) of acne

2) Of other diseases

g) Past treatment(s): topical and systemic

1) Of acne

2) of other disease

h) Family history of acne

i) Other skin disorders, especially but not limited to:

1) atopy, personal or familiar(Because of occasional irritation to topical acne preparations.)

2) Hidradenitis suppurativa

- j) Drug allergies
- k) General health, especially but not limited to:
 - 1) Hepatic disease
 - 2) Renal disease
 - 3) Endocrine

2.) Physical Examination

Establishment of diagnosis should occur after review of patients history and physical examination of the patient for the clinical criteria of acne.

3.) Lesion type

- a) noninflammatory
 - 1) open comedones
 - 2) closed comedones
- b) Inflammatory
 - 1) papules
 - 2) pustules
 - 3) nodules and/or cysts

4) Location

- a) face/neck
- b) back
- c) anterior chest
- d) extremities

5.) Gradation

- a) mild, moderate, severe
- b) for each predominant lesion type
- c) location

6.) Complications

a) scarring type

1) Atrophic

a) localization

b) severity

c) Discoloration

2) Hypertrophic

a) localisation

b) Severity

c) discolouration

3) Keloids

a) localisation

b) severity

c) discoloration

b) Scarring grade

1) Definition

2) location

3) Degree

7.) Other associated findings include but are not limited to:

a) Postinflammatory macular lesions

b) Postinflammatory hyperpigmentation and
hypopigmentation

- c) Hirsutism for women
- d) Alopecia for women
- e) Asymmetry of distribution of acne
- f) Excoriations

B) Grading techniques:

- (1) A 0-10 visual-tactile grading system.
- (2) Patient self-assessment with the following categories - worse, no change, fair good and excellent graded on a scale from 1 to 5 where 1= worse, 2= no change, 3= fair, 4= good, 5= excellent. (Appendix C)
- (3) Severity of acne according to a 0-4 scale with half points ratings where 0=no acne, 1= minimal acne, 2=mild acne, 3= moderate acne and 4= severe acne.

C) Perception questionnaire:

Questionnaire assessing the patients perception to the treatment

Please note: this questionnaire is to be conducted personally by the researcher.

Identifying data;

Name:

Age:

Sex:

Date:

Introduction

This research project investigates the Homoeopathic treatment of acne. We are trying to determine how proficient Homoeopathy is in treating acne, and whether in fact Homoeopathy has a place in the medical areana for such treatment. Your honest participation in this research project will contribute to the Homoeopathic pool of knowledge and more important it will educate the public that there are other, safe and effective forms of treatment for acne. To sum up, this questionnaire is attempting to assess if you the patient are aware of any changes after taking the prescribed medication i.e. we are attempting to understand and record the patients perception to the treatment so that the researcher may

identify what aspects of the treatment the patients consider to be significant.

If it is necessary, the researcher will give the patient a brief definition and explanation of Homoeopathy.

Instructions

Please answer this questionnaire with complete honesty. Each question is graded using a *semantic differential scale*. Place a cross over the number that best describes how you feel.

E.g. If a question asked how you felt about rainy days, and you love them, then a cross placed over the number that resembles your closest feeling.

I hate them _ _ _ _ _X_ I love them
1 2 3 4 5

Please note that the larger the number you choose the more positive the response is. Complete all the questions, Thank you.

1. Thus far, how have you perceived the treatment to be ?

Not good at all _ _ _ _ _ Very good treatment

1 2 3 4 5

2. How severe would you rate your acne ?

very severe _ _ _ _ _ mild

1 2 3 4 5

3. Has your acne changed at all ?

Not at all _ _ _ _ _ Very much

1 2 3 4 5

3.1. If your acne has changed , how has it changed ?

Getting worse _ _ _ _ _ Getting better

1 2 3 4 5

4. Has the surface texture of your skin changed ?

Becoming rougher _ _ _ _ _ Getting smoother

1 2 3 4 5

5. Are you experiencing any pain or tenderness with your your
acne ?

Very much pain _ _ _ _ _ No pain at all

1 2 3 4 5

6. Has your acne been bleeding ?

Very much bleeding _ _ _ _ _ No bleeding at all

1 2 3 4 5

7. How would you rate your acne now as compared with the period before the Homoeopathic treatment started ?

No change at all ___ ___ ___ ___ ___ Very much better
1 2 3 4 5

8. How has your attitude concerning your condition changed since taking Homoeopathic medicine ?

deteriorated(-ve) ___ ___ ___ ___ ___ Very much better(+ve)
1 2 3 4 5

9. How do you feel people percieve your condition to be?

severe___ ___ ___ ___ ___ mild
1 2 3 4 5

(D) Standard homoeopathic case history:

Date of Hx:

Identifying Data

Name: *allergies* *alcohol/smoker* *TB*

Age:

Sex:

Address:

Place of birth:

Marital Status:

Occupation:

Source of referral:

Source of history:

Reliability:

PSH: Any operations since you were born ?

PMH:

(Rheumatic fever, Pneumonia, TB, Jaundice, High BP)

1) Have you ever had any serious medical problems ?

(Mumps, Measles, Chicken Pox, German Measles, TB)

2) Can you remember your childhood illnesses ?

3) Have you ever had any illnesses requiring hospitalisation ?

4) Do you have any allergies ?

(Tetanus, Pertusis, Diptheria, Polio, Measles, Rubella, Mumps, Influenza,
Hep B, Haemophilus influenza type B)

5) What vaccinations / immunizations have you had recently or previously?

(Know: onset, duration, dosage)(Pill, vit's ,Homoeopathic medicine,
Minerals,Herbs)

6) Are you taking any medication ?

(Onset, Amount/Day, Type)

7) Do you smoke ?

(Onset, Amount/Day, Type)

8) Do you drink any form of alcohol ?

Family Hx:

1/ Are both your parents alive ?

1.1/ Did/Do any of them have any medical problems ?

1.2/ If any of them died why ? and when ?

2/ Do you have any siblings and are they all alive ?

2.1/ If not how did they die and when ?

2.2/ Did your siblings have any medical problems ?

3/ Do you have any children, and are they all alive ?

3.1/ Do any of your children have any medical problems?

Possible family medical problems : Diabetes

Tuberculosis

Heart diseases

High blood pressure

Stroke

Kidney diseases

Cancer

Arthritis

Anemia

Headaches

Epilepsy

Mental illness

(Duration)

Main Complaint: What seems to be the problem today ?

(Onset, Location, Aetiology, Duration, Character, Modalities, Concomitants, Radiation, Pt's response to Sx's & incapacities)

Hx of the Main Complaint:

(Onset, Aetiology, Location, Character, Duration, Modalities, Associated manifestations, Radiation, Pt's response to Sx's and incapacities)

Principle symptoms:

Social history: 1/ Hobbies, exercise and leisure activities ?

2/ Any travelling (i.e. out of Durban) ?

3/ Any recent shocks or griefs ?

4/ Sleep patterns ?

5/ Diet ?

Psychosocial history: 1/ Home situation and significant others?

2/ Daily life ?

3/ Important experiences ?

4/ Religious beliefs ?

5/ The Pt's outlook ?

Summary of thoughts and hypothesis:

Systems review;

(Usual Wt, Recent Wt change, Weakness, Fatigue, Fever)

1) General :

(Rashes, Lumps, Sores, Itching, Dryness, Colour change, Changes in hair & nails)

2) Skin:

(H/A's, Head injuries)

3) Head:

(Vision, Glasses, Contact lenses, Pain, Extensive tearing, Redness, Double vision, Cataracts)

4) Eyes:

(Hearing problems, Tinnitus, Vertigo, Earache, Infection, Discharge)

5) Ears:

(Frequency of colds,Nasal stuffiness,Discharge or itching,Hayfever, Nose bleeds, Sinus trouble)

6) Nose & Sinuses:

(Bleeding gums,Sore tongue,Frequency of sore throat,Hoarseness)

7) Mouth & Throat:

(Swollen glands,Pain or stiffness in the neck)

8) Neck:

(Cough,Sputum,Haemoptysis,Wheezing,Asthma,Bronchitis,Emphysema,Pneumonia,TB,Pleurisy)

9) Respiratory:

(Heart trouble, High Bp, Rheumatic fever,Heart murmurs, Chest pain or discomfort, Palpitations, Dyspnoea, Orthopnoea, Paroxysmal nocturnal dyspnoea, Oedema,Any heart tests)

10) Cardiac:

(Any trouble swallowing, Heartburn, Loss of appetite, Nausea,Vomiting, Regurgitation,Vomiting of blood, Indigestions, Haemorrhoids, Constipation, Diarrhoea, Abd pain, Food intolerance, Excessive belching or passing of gas, Jaundice, Liver or gall bladder trouble, Hepatitis)

11) GIT:

(Polyuria, Nocturia, Burning or P on urination, Haematuria, Urgency, Reduced caliber or force of urinary stream, Hesitancy, Incontinence, Urinary infection, Stones)

12) Urinary:

(Hernias, Discharge from or sores on the penis, Testicular P or masses, Hx of venereal Dx, Sexual interest)

13) Genitoreproductive:

(Intermittent claudication, Leg cramps, Varicose veins, Thrombophlebitis)

14) Peripheral Vascular:

(Muscular and joint P's, Stiffness, Arthritis, Gout, Backache)

15) Musculoskeletal:

(Fainting, Blackouts, Seizures, Weakness, Paralysis, Numbness, Tingling, Tremor or other involuntary movements)

16) Neurologic:

(Anemia, Easy bruising or bleeding, Past transfusions & possible reactions)

17) Haematologic:

(Thyroid trouble, Heat or cold intolerance, Excessive sweating, Diabetes, Excessive thirst or hunger, Polyuria)

18) Endocrine:

(Nervousness, Tension, Depression, Memory loss)

19) Psychiatric:

On Examination (O/E):

Vital Sg's;

Pulse:

Resp:

Bp:

T°C:

Weight & Height:

(Observe the state of health, stature, habitus and sexual development, posture, motor activity & gait, dress, grooming & personal hygiene, odors of body or breath. Facial expression, manner, affect, reaction to person and things in the environment. Listen to Pt's speech, note state of awareness and level of consciousness)

General inspection:

General examination:

1) Position the Pt on their backs at 45°

(NOTE: Muscle condition, colour, nails[clubbing, spooned, splinter haemorrhage], sweat, temp, circ, any nodules, any lesions, joint P)

2) Hands:

(Hair distribution, Colour, Temp, Muscle condition, Skin lesions, any Pain)

3) Forearm->Arm->Shoulder:

(Neck stiffness, Thyroid gland, Tracheal deviation, JVP, Glands, any Pain)

4) Neck:

(Twitches of facial muscles, droopings, swellings, lesions, inflam, skin, Hair distrib, Colour, any Pain)

5) Face:

(Ophthalmoscopic examination, visual acuity, pupil reaction to light, extraocular mm movement, any Pain)

6) Eyes:

(Anosmia, any Pain, Epistaxis, Runny nose, Hayfever, Lesions)

7) Nose:

(Pain, H/A's, Post nasal drip)

8) Sinuses:

(Colour, Lesions, Pain)

9) Lips:

(Bad breath, Taste, Lesions, Pain)

10) Mouth:

(Condition, Pain, Colour, Caries, Types of fillings)

11) Teeth:

(Bleeding, Colour)

12) Gums:

(Indentations, Colour, Mapped, Pain, Lesions, Taste)

13) Tongue:

(Inflammation, Pain, Tonsils, Deposits, Voice)

14) Throat:

(Hearing, Lesions, Pain, Tympanic membrane, Wax colour)

15) Ears:

(Skin, Lesions, Hair distrib, Chest wall movement and shape, Resp rate depth rhythm effort, Tender areas, Tactile fremitus, Percussion, Auscultation)

16) Thorax and Lungs:

(Rate, Rhythm, Amplitude, Contour, Bruits, Thrills)

17) Heart:

(Pain, Tender areas, Skin, Spider naevi, Distension, Borborigmy, Liver, Kidneys, Spleen, Rebound tenderness, Muscle guarding)

18) Abdomen:

(Skin, Lesions, Pain, Contour of spine, Moles, Kidney Pain)

19) Back:

(Only if indicated, Glands, Sexual development, Lesions, Skin, Pain)

20) Pelvis & Perineum:

(Pain, Skin, Hair distribution, Oedema, Varicose veins, Temp, Colour/Filling, Sensory)

21) Lower limbs:

(Nails, Temp, Colour, Skin, Pain, Lesions, Warts, Athletes foot, Odour)

22) Feet:

Additional Homoeopathic Questions

Mind;

1) Fears:

(Position, Type, Dreams, On waking)

2) Sleep:

3) Confusion/Cloudiness:

4) Excitement:

5) Anxiety:

(Hurried, Nasal, Lost/Difficult, Slow/Monotonous)

6) Speech:

7) Imagination:

8) Memory:

Emotions;

1) Depression:

2) Melancholia:

3) Mood:

Physical;

(Cravings, Aversions, Add salt, Drink in gulps or sips, Hot or cold drinks,

Love eggs)

1) Diet:

2) Best time of day:

3) Coast or inland:

(Ars)

4) Particular:

(Calc)

5) Brittle hair:

6) Modalities:

- a) Cold:
- b) Warmth:
- c) Movement:
- d) Touch:
- e) Rest:
- f) Riding in car:
- g) Humidity:
- h) > for being seated, bending forward:
- i) < at night & between sundown and sunrise:
- j) > in mountains:
- k) < between 4pm & 8 pm, the height occurring at 5pm:
- l) > for lying on stomach:
- m) Seaside:
- n) Night:
- o) Consoled:
- p) Morning upon awakening:
- q) After meals:
- r) < by anger & intellectual effort:
- s) Winter & Summer:
- t) Strong pressure:
- u) > by being outside & moving around:
- v) > slow motion, by changing position:
- w) < going up & down stairs:
- x) Dark:
- y) Standing still:
- z) < for heat of bed and water:
- z1) < for wine and stimulants:

Differential Diagnosis

(E) Cardboard flash standardizing system

The purpose

The purpose of this system is to ensure that the flash is in the same position previously used for the relevant patient.

The method

1. Position the flash as needed for the particular patient.
2. On the medial aspect (i.e. the side closest to the camera) of the flash hold a piece of cardboard flush against the flash.
3. With the help of an assistant make sure the piece of cardboard is perpendicular to the flash bracket.
4. Trace the shape of the flash onto the cardboard.
5. With a black permanent marker, mark the exact position of the cardboard in relation to the flash bracket on the flash bracket.
6. Make sure all the adjusting screws on the flash are firm.

To reset the flash for follow-up photographs

1. Place the respective piece of cardboard on the black line (previously marked on the flash bracket).
2. With the help of an assistant make sure the piece of cardboard is perpendicular to the flash bracket.
3. Position the flash so that it fits into the previously traced diagram.
4. Fasten all adjusting screws on the flash.

(F) Photo-session record sheet

Name: _____

Tel No: _____

Photo-ID code and its position with respect to the lesion: _____

Date: ____/____/____

Time: _____

Type of film: _____

Type of camera: _____

Type of macro lens: _____

Type of flash: _____

Flash settings: _____

Accurately describe the position of the patient (draw a diagram if necessary):

Accurately describe the position of the camera with respect to the patient (draw a diagram if necessary): _____

Accurately describe the exact area on the patient
p h o t o g r a p h e d (draw a diagram if
necessary):_____

_Was the tripod used?_____

Accurately describe the position and trajectory of
the flash/s (draw a diagram if necessary): Consult the
specific cardboard flash standardizing protocol.

Magnification used:_____

Apperture (F no):_____

Shutter speed:_____

No of vertical photo's and the respective negative
number/s (Negative numbers are read after loading the
camera):_____/_____

Position of black screen:

Setting of the room (Draw a diagram):

Exact position of grey card with respect to the lesion

(Draw diagram):

Was the grey card held with tweezers or by
hand: _____

(G) Magnification and F no readings

Macro Lens:

Magnification:

10

2

8

12

F no:

11

betw 16-22

11 hand

8 whole arm

Normal Lens:

Magnification:

3ft/10m

4ft

F no:

4&5,6 full length(green)

8,,5 half body

(H) : Patients consent form

Patient information

Full Name : _____

Date : ____/____/____

Age : _____

Sex : _____

Introduction

Thank you for considering to be a part of this study. The fifth year students of Homoeopathy are required to complete a *Thesis* as partial fulfillment of their Masters Diploma in Homoeopathy. The *thesis* is undertaken with the purpose of adding to the Homoeopathic pool of knowledge and promoting Homoeopathy.

It is important that this research , which has been approved by the Higher Education Committee of Technikon Natal, is conducted because Acne on publicly visible parts of the body causes a certain amount of psychological stress to individuals that are sensitive to their appearance. There are many different causes for the development of Acne Vulgaris and one of the main contributing factors is the change in hormone levels, especially in the pubescent teenager. Other factors involved are stress, immunosuppressive drugs given during the therapy of other conditions, cosmetics, topical steroids e.t.c.. Not much scientific research has been accomplished in the Homoeopathic treatment of Acne. There are many different methods of treating Acne Homoeopathically and we need to analyze which method works

best and why?, And whether in fact Homoeopathy has a place for treating acne.

The public might not be aware that there is an alternative form of treatment for Acne, and this study will demonstrate Homoeopathy's degree of proficiency. Medical treatment for Acne are not inexpensive and not without side-effects and Homoeopathic treatment will offer a more economical alternative. There are no known "side-effects" with Homoeopathic treatment although a slight Homoeopathic aggravation may be experienced by a few patients.

By carrying out this research project certain benefits will be afforded. The first benefit will be adding to the current knowledge of acne treatment an alternative method. Homoeopathy will receive more respect in the scientific community. If we are allowed to show Homoeopathy's effectiveness in treating acne, through this study we can pave the way to a future where individuals may be educated in other forms of treatment.

In order to ensure that this research project complies with the scientific method only certain people may be accepted as part of the research project. The sample of thirty patients used in this study will be drawn randomly from the population in Natal.

Possible candidates must qualify in the following areas;

- 1) Patients must be from the greater Durban environment with easy access to Technikon Natal.
- 2) Patients must not be undergoing some other form of treatment for their acne. Patients who are on any other form of

treatment will have to comply with a period of 'flushing out' before being accepted into this study.

- 3) Patient will be required, in a disciplined manner, to take a prescribed amount of medicine per day. Therefore it is assumed that the patients will participate unconditionally, taking their medicine as directed and not exposing the medicine to any situation that might antidote it. Conditions that will antidote the action of the medication are: Exposing the medication to direct sunlight and very high temperatures; Exposing the medication to aromatic substances such as camphor, peppermints e.t.c..
- 4) Once the study commences the patient will be required to be consistent about his/her diet.(i.e. not to go on any fad diets.)
- 5) Patients with so-called 'sandpaper' acne will be excluded from this study due to the fact they are impossible to classify.
- 6) Patients taking part in this study do so voluntarily.

The following steps will be taken in the execution of the study;

1. Advertise for patients in the Newspaper and on the notice boards at Technikon Natal and Durban University.
2. Assess whether the patients that responded to the advertisements are suitable for the study i.e. Delimitations.
3. A sample of thirty will be drawn randomly from those applicants.
4. A Case history and Physical examination will be performed on all thirty patients.
5. The acne on all thirty patients will be photographed in colour, with standardized lighting, photographic film, background colour, distance (equal zoom factor) for the acne.

6. Each case will be repertorized and a prescription will be submitted to a Homoeopathic pharmacist.
7. Of the thirty patients randomly drawn from the applicants, fifteen will receive Homoeopathic treatment and fifteen will receive placebo.
8. The Homoeopathic pharmacist is a neutral member in the study and will dispense the medicines.
9. The medicine is handed to the patients a day after taking the case history, giving the researcher time to analyze the case and correspond with significant personalities.
10. A period of approximately three weeks is allowed to pass during which the patients take their medication.
11. The case history and physical examination of all thirty patients is reviewed, and depending on the patients clinical manifestation their medication might change.
12. Each patients acne will then be re-photographed.
13. The entire process is repeated five times allowing each patient a treatment time of four months.
14. All the data collected will then be analyzed, interpreted and the hypothesis will be tested.

Patient-practitioner confidentiality will be strictly adhered to.

I, _____, *DO HEREBY AGREE TO ABIDE BY THE
DELIMITATIONS AND CONDITIONS SET OUT IN THE ABOVE
DOCUMENT.*

(signature)

(I) : The remedies and their potencies:

Patient	Improved	No change	Worsened	REMEDY	POTENCY
A1	¶	✓		Sulph. lod. Ant. Tart.	15 CH 9 CH
A2	✓ ¶			Sulph. lod. Graph.	15 CH 9 CH
A3	✓		¶	Puls. Sulph. lod	15 CH 9 CH
A4	✓ ¶			Sulph. lod. Kali Brom. Eug. Jamb.	15 CH 9 CH 9 CH
A9	✓ ¶			Sulph. lod. Kali Brom. Ant. Tart.	15 CH 9 CH 9 CH
A13	¶	✓		Sulph. lod. Ant. Tart.	15 CH 9 CH
A17	✓		¶	Sulph. lod. Kali Brom.	15 CH 9 CH
A18	✓ ¶			Sulph. lod. Kali Brom.	15 CH 9 CH
A20	✓	¶		Sulph. lod. Kali Brom.	15 CH 9 CH
A24	¶	✓		Sulph. lod. Ant. Tart.	15 CH 9 CH
A25	¶	✓		Sulph. lod. Ant. Tart.	15 CH 9 CH
A26			✓ ¶	Sulph. lod. Kali Brom.	15 CH 9 CH
A27	✓ ¶			Sulph. lod. Kali Brom.	15 CH 9 CH
A32	✓ ¶			Sulph. lod. Kali Brom.	15 CH 9 CH
A33		✓	¶	Sulph. lod. Kali Brom.	15 CH 9 CH

KEY:

	SYMBOL
Photo's	✓
Perception	¶

(J) : Frequency table of remedies prescrbed:

REMEDY	POTENCY	FREQUENCY
Sulphur lod.	15 CH	22
Kali. Brom.	9 CH	18
Ant. Tart.	9 CH	11
Sulphur	15 CH	5
Eug. Jamb.	9 CH	3
Sulphur lod	9 CH	3
Pulsatilla	15 CH	1
Graphites	9 CH	1