THE EFFICACY OF KALIUM BROMATUM 30CH IN THE TREATMENT OF ACNE VULGARIS

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Mini-dissertation submitted in compliance with the requirements for the Master's Degree in Technology Homoeopathy, faculty of Health Sciences at the Durban Institute of Technology.

I, Candidate: Grant Nijland, do hereby declare that this mini-dissertation represents my own work in both conception and execution.

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ACKNOWLEGEMENTS

I wish to thank my parents Herbert and Maureen, for their unfailing encouragement and conviction.

Thanks also to Clive, Romay and all my good friends for their continued support.

ABSTRACT

The purpose of this study was to evaluate the efficacy of the Homoeopathic remedy Kalium bromatum 30CH compared to placebo in the treatment of Acne vulgaris.

The study was a double blind placebo controlled study. Participants were recruited via advertisements in local newspapers and notices posted at schools, health shops and pharmacies.

Thirty volunteers who complied with the inclusion and exclusion criteria were randomly assigned to an experimental or control group of 15 participants each. The treatment period was four weeks which included three consultations.

The effect of treatment was measured by determining the reduction in the number of lesions found on the faces of the participants. The lesions were divided into three groups, namely non-inflamed lesions, inflamed lesions and comedones. The Leeds Technique for assessing Acne vulgaris was used.

Since the sample size per group was small, non-parametric tests were used to analyse data. An inter-group comparison using the Mann-Whitney unpaired test was used to determine whether there were significant differences between the 2 groups with respect to the variables of interest.

Intra-group comparison, using the Friedman's T-test coupled with the Dunn procedure was used to identify the significant changes between consultations.

The results showed there was no statistically significant difference between the reduction in the number of lesions in the two treatment groups.

It was concluded that Kalium bromatum 30CH, prescribed only on the basis of the presence of acne, is not an effective treatment for Acne vulgaris.

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DEFINITION OF TERMS

Acne vulgaris - A common inflammatory disease of the pilosebaceous glands characterised by comedones, papules, pustules, inflamed nodules, superficial pus-filled cysts, and (in extreme cases) canalizing and deep, inflamed, sometimes purulent sacs (Beers and Berkow, 1999: 811).

Allopathy - The orthodox system of medicine, in which the use of drugs is directed to producing effects in the body that will directly oppose and so alleviate the symptoms of a disease (Oxford Concise Colour Medical Dictionary 6th Edition 1996: 20).

Comedone - A plug of keratin and sebum in a dilated sebaceous gland (Murtagh 2003: 1132).

Papule - A solid, elevated lesion usually < 10mm (Beers and Berkow, 1999: 781).

Placebo - A substance that has no therapeutic effect, used as a control in testing new drugs (The New Oxford Dictionary of English 1998: 1415).

Pustules - Are superficial and elevated lesions containing pus. They may result from infection or seropurulent evolution of vesicles or bullae (Beers and Berkow, 1999: 781).

Homoeopathy - Homoeopathy is a therapeutic method which clinically applies the law of similars and which uses medicinal substances in weak or infintisimal doses (Jouanny 1993: 11).

CHAPTER 1 - INTRODUCTION

Acne vulgaris is the most common skin disorder, affecting nearly 80% of young adults aged 11 years to 30 years (Leyden, 1995). Its prevalence is similar in both sexes but the peak age of severity in females is 16 - 17 years and in males 17 - 19 years. Acne vulgaris clears by the age of 23 - 25 years in 90% of patients but some 5% of women and 1% of men still need treatment in their thirties or even forties (Edwards and Bouchier, 1991: 915). The effects of Acne vulgaris on patients is diverse and vary from psychological effects like withdrawal, developmental problems, depression and anxiety to physical effects like scarring and disfigurement (Callan, 1997).

Allopathic treatment of acne depends on the severity of the lesions (Beers and Berkow, 1999: 811). Treatment is aimed at decreasing sebum production, decreasing bacteria, normalising duct keratinization or decreasing inflammation (Kumar and Clark, 1998: 1170). A variety of allopathic therapies are currently used to treat Acne vulgaris. Topical agents include isotretinoin, benzyl peroxide, antibiotics, oral isotretinoin, corticosteroids, antiandrogens and sex hormones (Bergfield, 1995).

The major side-effects of the allopathic drugs commonly used to treat Acne vulgaris include, drying of the skin and mucous membranes, soreness and irritation, skin pigmentation, gastrointestinal upsets, thrush, dizziness, nausea, weight gain, muscular aches and pains, hyperlipidaemia, liver damage and teratogenicity (Graham-Brown, 1996). In particular, Roaccutane® has many serious side-effects, particularly on the psychiatric level. These include depression, psychosis, suicidal ideation, suicide attempts and suicide (Roche, 2000). Many people seek alternative therapies and according to Master (1993: 354) Acne vulgaris is one of the problems for which patients often consult a homoeopath.

Acne vulgaris is a chronic problem or disease and, according to Dox, Melloni and Eisner (1993: 99), chronic denotes a disease of slow progress and persisting over a long period of time. In outlining the incidence of Acne vulgaris, Edwards and Bouchier (1991: 915) state that it affects the individual for between five to ten years.

In today's health care environment, increasing emphasis is being placed on economic considerations in the treatment of certain diseases. Based on information obtained from Bergfield (1995) the average cost involved in a

20 week course of isotretinoin therapy for Acne vulgaris is U.S.$2318.55. From this it can be seen that there are many shortcomings in the allopathic treatment of Acne vulgaris.

Jouanny (1993: 277 - 284) recommends symptomatic homoeopathic remedies for Acne vulgaris as well as remedies for treating the patient's terrain. Symptomatic remedies referred to by him include: Selenium, Eugenia jambosia, Ledum palustre, Calcarea picrata, Kalium bromatum, Antimonium tartaricum and Graphites. Remedies to treat the patient's terrain include Sulphur, Thuja occidentalis, Natrum muriaticum, Sulphur iodatum and Silicea terra.

Previous studies of homoeopathic remedies and the treatment of Acne vulgaris have found that simillimum treatment and miasmatic treatment was effective (McDavid, 1994; van Niekerk, 1999), and that homoeopathic complex was not effective (Lee, 1997).

In this study, Kalium bromatum 30CH was utilised, compared to a placebo. This homoeopathic remedy has an affinity for the skin symptoms of acne, as well as some of the psychological symptoms which sometimes accompany

these symptoms, such as embarrassment and anxiety (Phatak 1998: 281, 282; Vermeulen 1994: 538).

This study was a double-blind, placebo-controlled, randomized clinical trial. This is regarded as the "gold standard" for assessing new therapy. Furthermore, within the allopathic paradigm, it is a powerful tool that has become almost a prerequisite for demonstrating the efficacy of a new therapy, both for clinicians and for drug regulation authorities (Stein and Pincus, 1999: 353). In many cases, homoeopathic trials seek to emulate that standard in order to gain acceptance by the allopathic community. However, on the whole, the "clinical trial" approach within homoeopathy has had limited success for two reasons. The first is the lack of methodological rigour with which such trials are set up and conducted which means that their results are not consistently reliable (Linde, Clausius, Ramirez, Melchart, Eitel, Hedges and Jonas, 1997; Shang, Huwiler-Müntener, Nartey, Jüni, Dörig, Sterne, Pewsner and Egger, 2005). The second is that the randomised clinical trial (RCT) approach may not be an appropriate methodology for measuring treatment outcome in homoeopathic medical practice. The RCT is based on the premise of single cause, single effect, single treatment. However, homoeopathic medicine focuses on the

stimulation of broad healing processes that have influences on a variety of conditions and symptom patterns (Jonas, Anderson, Crawford and Lyons, 2001). Bearing this in mind, other research methodologies such as case reports and provings (Vickers, McCarney, Fisher and van Haselen, 2001) and the formal case study (FCS) (Thompson, 2004) are being explored by contemporary homoeopathic researchers. Despite the criticisms associated with RCT, this method was selected for this study because the clinical symptom being evaluated was superficial and amenable to objective assessment, and only a single remedy was prescribed, thus conforming to the "single symptom, single treatment" format typical of such trials.

1.1 AIM OF THE STUDY

The aim of this research was to critically evaluate the efficacy of Kalium bromatum 30CH compared to placebo in the treatment of Acne vulgaris in terms of decreased numbers of papules, pustules and comedones, in an attempt to increase the non-allopathic options available to acne sufferers.

1.2 HYPOTHESIS

Kalium bromatum 30CH is not effective in the treatment of Acne vulgaris.

CHAPTER 2 - REVIEW OF THE RELATED LITERATURE

2.1 ACNE VULGARIS

The term acne refers to an eruption caused by inflammation of the pilosebaceous glands, while Acne vulgaris refers to chronic acne, occurring commonly on the face, chest and back of adolescents and young adults (Dox, Melloni and Eisner, 1993: 6). Acne vulgaris can be 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 (Beers and Berkow, 1999: 811).

In describing the pathogenesis of Acne vulgaris, Graham-Brown (1996) describes two basic defects. The first is a surge of increased sebum production driven by circulating androgens. This gives rise to the clinical appearance of greasiness. Secondly, the mouths of hair follicles become occluded as a result of hyperkeratosis. The reason for this is unclear, but it may also be androgen-dependent. These two phenomena result in dilated chambers full of sebum, in which grow the obligant anaerobe

Propionobacterium acnes. These units are known as comedones and are clinically demonstrable as small, non-inflamed swellings, whiteheads and blackheads. Inflammation is thought to develop around comedones as a result of the diffusion of inflammatory mediators through the follicle wall and into the surrounding dermis. This leads to an acute inflammatory reaction. Graham-Brown (1996) also points out several factors that are irrelevant to the pathogenesis of acne. These include the consumption of sweets, chocolate or fatty foods, lack of personal hygiene and excessive or absent sexual activity.

2.2 ALLOPATHIC TREATMENT

A variety of allopathic therapies are currently used to treat Acne vulgaris. Treatment includes both topical and systemic treatment. Topical agents include isotretinoin, benzoyl peroxide, antibiotics, and other anti-inflammatory agents. Systemic therapy makes use of antibiotics, oral isotretinoin, corticosteroids, antiandrogens and sex hormones. (Bergfield, 1995).

However, according to Rees and Willey (1993) side effects of these

medicines include redness, peeling, contact sensitization, itching, photo-irritation, xerosis, cheilitis, vestibular toxicity, foetal malformation and miscarriage.

Isotretinoin particularly, Roaccutane®, a Vitamin A derivative, has many serious side effects, particularly on the psychiatric level. These include depression, psychosis, suicidal ideation, suicide attempts and suicide. (Roche, 2000). Roaccutane® dramatically reduces sebum excretion and is used for severe Acne vulgaris. Side-effects include drying of the skin and mucous membranes, abnormalities of liver function, musculoskeletal aches and pains and hyperlipidaemia. This drug is highly teratogenic. (Graham-Brown, 1996).

The antibiotics of choice are the tetracyclines. *Propionibacterium acnes* is the most important organism involved in the inflammatory aetiology of Acne vulgaris and it is the aim of many acne therapies to reduce the amount and function of this organism. There are many clinical failures, however, as not all patients respond to such therapies. (Sommer, Bojar, Cunliffe, Holland, Holland and Naays, 1997). According to Gardner, Eady, Cove, Taylor and Cunliffe, (1997) one in five acne patients are carriers of a type of

propioni bacteria which is resistant to the tetracycline class of antibiotics.

Anti-androgens and oestrogen are commonly used in women. This inhibits the androgen drive that causes the excessive sebum production in Acne vulgaris. Treatment needs to be continued long-term. It is, however, contra-indicated in anyone who has a history of thrombosis or any other disorder that contra-indicates the use of the contraceptive pill. Side-effects are weight gain, nausea and the other side-effects associated with taking the contraceptive pill. (Graham-Brown, 1996).

Steroids are used in large cystic acne lesions. Intra lesional injections are used to reduce pain and inflammation. Occasionally surgical excision is used for resistant, unsightly, nodulocystic lesions. (Graham-Brown, 1996).

2.3 HOMOEOPATHIC TREATMENT

Master (1993: 354) states that patients often consult the homoeopath for treatment for Acne vulgaris.

Jouanny (1993: 277-284) recommends symptomatic homoeopathic remedies for Acne vulgaris as well as remedies for treating the patient's terrain.

Symptomatic remedies referred to by him include: Selenium, Eugenia jambosia, Ledum palustre, Calcarea picrata, Kalium bromatum, Antimonium tartaricum and Graphites. Remedies for treating the terrain include Sulphur, Thuja occidentalis, Natrum muriaticum, Sulphur iodatum and Silicea terra.

McDavid (1994) investigated the use of the simillimum in the treatment of Acne vulgaris. The author used an experimental group of 15 which received the simillimum and a placebo group of 15. The treatment period was 4 months with 5 consultations. The prescription could change from consultation to consultation. It was found that homoeopathy improved the clinical manifestations of Acne vulgaris statistically significantly (P = 0.006). The remedies most prescribed were Sulphur iodatum 15CH (22 times) and Kalium bromatum 9CH (18 times).

In another clinical trial, Lee (1997) investigated the role of homoeopathic complex in the treatment of Acne vulgaris. In this study, a control group of 16 patients received placebo and an experimental group of 18 participants received a homoeopathic acne complex of Silicea 30CH, Selenium 9CH, Hepar sulphuris 30CH, Kalium bromatum 9CH, Arctium lappa 3CH and Pulsatilla 30CH. The treatment period was 2 months with 5 consultations.

The result showed no significant improvement within both or between both groups.

Van Niekerk (1999) investigated the relative effectiveness of miasmatic treatment as compared to simillimum treatment in terms of the objective clinical findings in participants with Acne vulgaris. It was found that there was no statistically difference between the two treatments. The miasmatic treatment for participants with Acne vulgaris was found to be as significant as the simillimum treatment. It was found that both treatments reduced the clinical manifestations of the Acne vulgaris significantly. Both simillimum treatment and miasmatic treatment therefore play an important role in the treatment of patients with Acne vulgaris. However, there was no placebo control group against which to measure the effectiveness of the treatment groups.

In this study, Kalium bromatum 30CH was utilised, compared to a placebo. Kalium bromatum 30CH has physical and mental characteristics which are frequently encountered in acne participants. According to the materia medica, Kalium bromatum has the following relevant characteristics:

- Acne of face (Boericke 1994: 366).
- Pustules (Boericke 1994: 366).

- Acne of the face [cheeks and forehead] and the prescence of pustules (Vermeulen 1994: 538).
- Profound indifference and disgust for life (Phatak 1998: 281, 282).

Kalium bromatum is a remedy that is relevant for the ill-effects of embarrassment, and includes the mental symptoms such as nervousness, anxiety, suspicion and fear of people. Patients needing Kalium bromatum as a remedy also experience profound indifference and disgust for life. These symptoms correlate well with the psychological effects of Acne vulgaris.

The 30^{th} potency of Kalium bromatum was selected because it is low enough to effect physical symptoms, but also high enough to effect mental symptoms. Pollock and Steele (personal communication, 2001) recommended the use of 30CH in conditions of a physical nature which also have a psychological component, such as Acne vulgaris.

This study used the Leeds Technique (Burke and Cunliffe 1984).

2.4 SUMMARY

There is a need to research and test natural alternatives to pharmaceutical treatment of Acne vulgaris. Previous research on the role of homoeopathy in the treatment of Acne vulgaris has shown mixed results, but have established the fact that homoeopathic treatment can play a positive role in the management of Acne vulgaris. The present study was conducted in an effort to extend the field of research-based knowledge regarding the Homoeopathic treatment of Acne vulgaris.

CHAPTER 3 - MATERIALS AND METHODS

3.1 SAMPLE

Posters announcing the study and inviting participation were placed on notice boards at secondary schools and in health shops and pharmacies in the Upper Highway area in the Durban region and in the Johannesburg region. Advertisements were also placed in the local newspapers.

3.2 INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria:

- Participants for the research must have papules, pustules and comedones on the face to be included in the research.

Exclusion criteria:

- Volunteers suffering from Acne fulminans, Acne rosacea and Conglobate acne.

- Volunteers receiving any other treatment such as hormonal, vitamin, Schussler tissue salts, homoeopathic remedies, herbs, antibiotics and any other acne treatments.
- Volunteers who are pregnant.

3.3 RANDOMISATION

The first thirty applicants who met the inclusion and exclusion criteria were selected.

A set of 15 units of Kalium bromatum 30CH and the next consecutive set of 15 units placebo were made up. Units were randomly assigned a number between 1 and 30, by means of drawing a number out of a hat. A neutral party held the code. Each participant that was accepted into the study was allocated the next consecutive number from the list and received the unit associated with that number. The code was only revealed after the data collection phase of the study was completed.

3.4 TREATMENT

The Kalium bromatum 30CH was prepared by the homoeopharmaceutic laboratory assistant in the Department of Homoeopathy, Durban Institute of Technology, using Kalium bromatum 30CH medicating potency (96% ethanol) to triple impregnate sucrose pillules (3.5mm).

The laminar flow cabinet was used. The unit is kept clean and in goodworking condition. Once the fan is switched on, the table is wiped down with 70% alcohol and thereafter only clean, autoclaved glassware is placed on top. The neutral pillules are then measured into beakers and impregnated using new Pasteur pipettes. The ultraviolet light of the unit is never used due to the radiation that it emits (Botha, 2005).

Pillules are triple impregnated to allow for better penetration of the remedy into the pillules. It futhermore speeds up the drying process and prevents clumping of the pillules and reduces the chance of the pillules dissolving in water (Botha, 2005). The placebo was made up from plain sucrose pillules triple impregnated with 96% ethanol alcohol. The remedy and the placebo were dispensed in 10ml plastic vials filled with the impregnated pillules.

Kalium bromatum 30CH was prepared from a medicating potency purchased by the Durban Institute of Technology Department of Homoeopathy from Natura, Johannesburg. A 1DH potency of Kalium bromatum was manufactured in France according to French Pharmacopoeia standards. One part of potassium bromate was diluted in 10 parts distilled water and succussed 100 times. The resultant 1DH potency was then imported and further potentised on a centecimal dilution scale (1/100) in accordance with French Pharmacopoeia standards, dictating 100 succussions at each dilution level.

The prescription protocol was to suck 5 pillules once daily on waking for a 7 day period only following the initial consultation. Jouanny (1984: 200) recommends sucking 5 globules of Kalium bromatum in the treatment of acne. Participants were further instructed not to take any other treatment for acne for the period of the study.

3.5 EVALUATION OF ACNE VULGARIS

Clinical manifestations of the Acne vulgaris were measured using the Leeds Technique, as per Burke and Cunliffe (1984) (See Appendix A for the table

used to record results).

Lesions were divided into inflamed and non-inflamed lesions:

- Lesion1: superficial inflamed (papules and pustules);
- Lesion 2: deep inflamed (nodules);
- Lesion 3: non-inflamed (comedones).

A vernier calipre was used to measure the size of the lesions in order to classify them.

Participants had 3 consultations with the researcher.

At the first consultation a systems review was conducted, to eliminate any latent conditions which may have existed, and vital signs were measured. The Acne vulgaris was carefully observed and the number and type of lesion were counted and tabulated, then photographed from ½ metre distance directly in front of the participant under neon lighting. Only Acne vulgaris lesions on the face were counted. The vial of pillules was dispensed by a third party according to the randomisation list. Participants were instructed to take 5 pillules daily on waking for 7 days and to allow the pillules to dissolve under the tongue. Participants were also instructed to avoid drinking

anything or brushing their teeth for at least 15 minutes before and after taking the dose.

The second consultation was one week later. The lesions were counted and photographed.

The third consultation was three weeks after the second consultation. The lesions were counted and photographed.

3.6 INTERPRETATION OF DATA

The numbers and types of lesions were tabulated to allow for statistical analysis.

In each of the two groups there were 15 participants. Since the sample size per group was small (<30), non-parametric tests were used for data analysis.

STATGRAPHICS version 6+ was used for data entry and analysis. Barcharts were constructed to visually summarize findings of the study.

3.6.1 Procedure 1:

The first procedure was an intragroup comparison using Friedman's

T-test coupled with the Dunn procedure in order to identify any significant changes that had occurred between consultations.

The null hypothesis assumes that the improvement between consultations that are compared are the same.

Accept the null hypothesis if $p > 0.05$.

Reject the null hypothesis if $p < 0.05$.

3.6.2 Procedure 2:

The second procedure was to find out whether or not there was a significant difference between the 2 groups with respect to the variables of interest. To do this the Mann-Whitney U-Test for unpaired data was performed to test the null hypothesis.

The null hypothesis assumes that the reduction in lesions resulting from treatment A (medication) is the same as the reduction in the lesions resulting from treatment B (un-medicated).

Accept the null hypothesis if $p > 0.05$.

Reject the null hypothesis if $p < 0.05$.

CHAPTER 4 - RESULTS

4.1 INTRODUCTION

The results were obtained after statistically analysing the data tabulated according to the Leeds Technique (Burke and Cunliffe 10984). (see Appendix A).

Participants were randomly assigned to either the Treatment Group (A) or Placebo Group (B).

Results were tabulated in three groups according to the type of lesion involved:

* Lesion 1: Superficial inflamed - Number of papules and pustules;
* Lesion 2: Deep inflamed - Number of nodules;
* Lesion 3: Non-inflamed - Number of comedones.

4.2 DESCRIPTIVE STATISTICS

4.2.1 Demographics

4.2.1.1 Gender

Figure 4.1 illustrates the gender distribution of participants in the study.

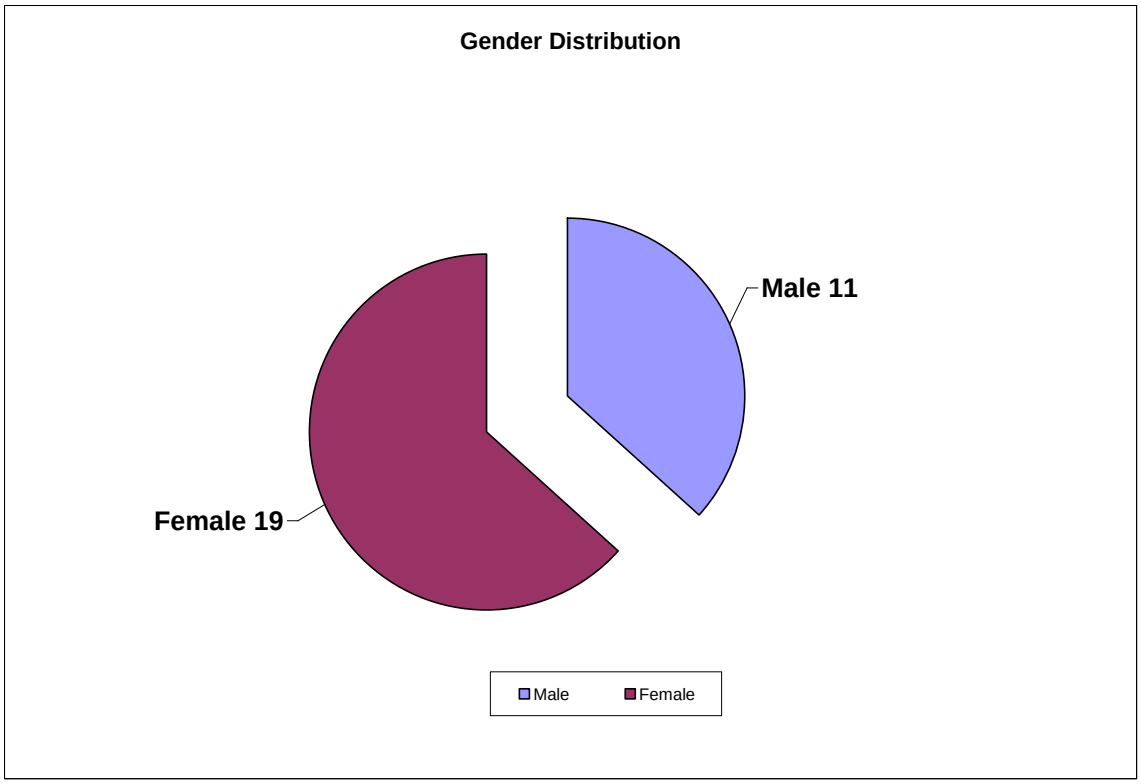

Figure 4.1 Gender distribution of participants in the study.

4.2.1.2 Age

Figure 4.2 illustrates the age distribution of participants in the study.

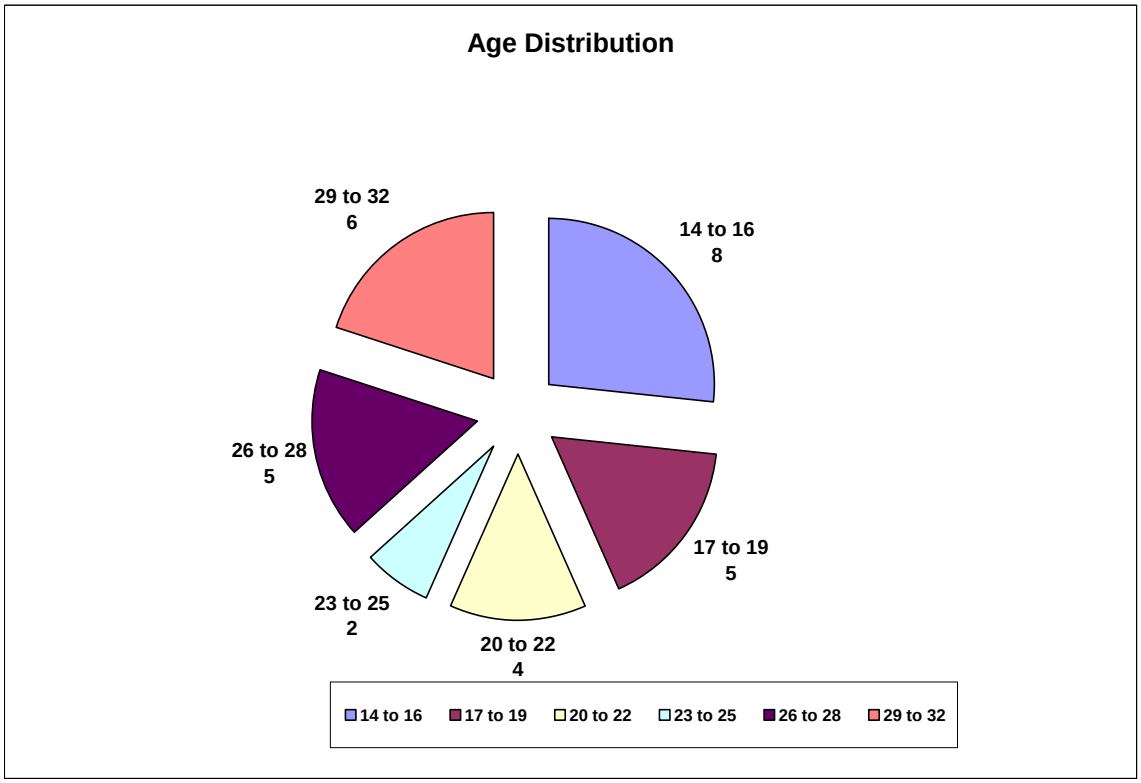

Figure 4.2 Age distribution of participants in this study, grouped in 3 year cycles ranging from 14 to 16 years of age to 29 to 32 years of age.

4.2.2 Number of lesions

4.2.2.1 Lesion 1

Figure 4.3 illustrates the total number of Lesion Number 1.

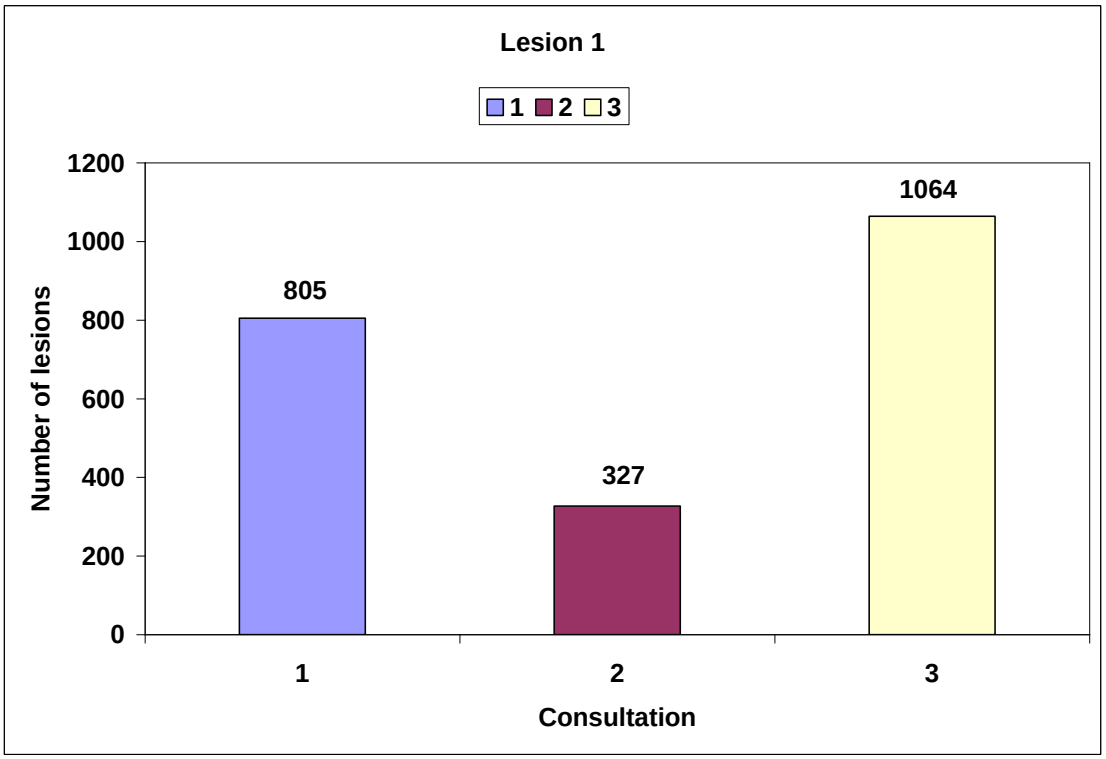

Figure 4.3 Total number of Lesion Number 1 counted at each consultation.

4.2.2.2 Lesion 2

Figure 4.4 illustrates the total number of Lesion Number 2.

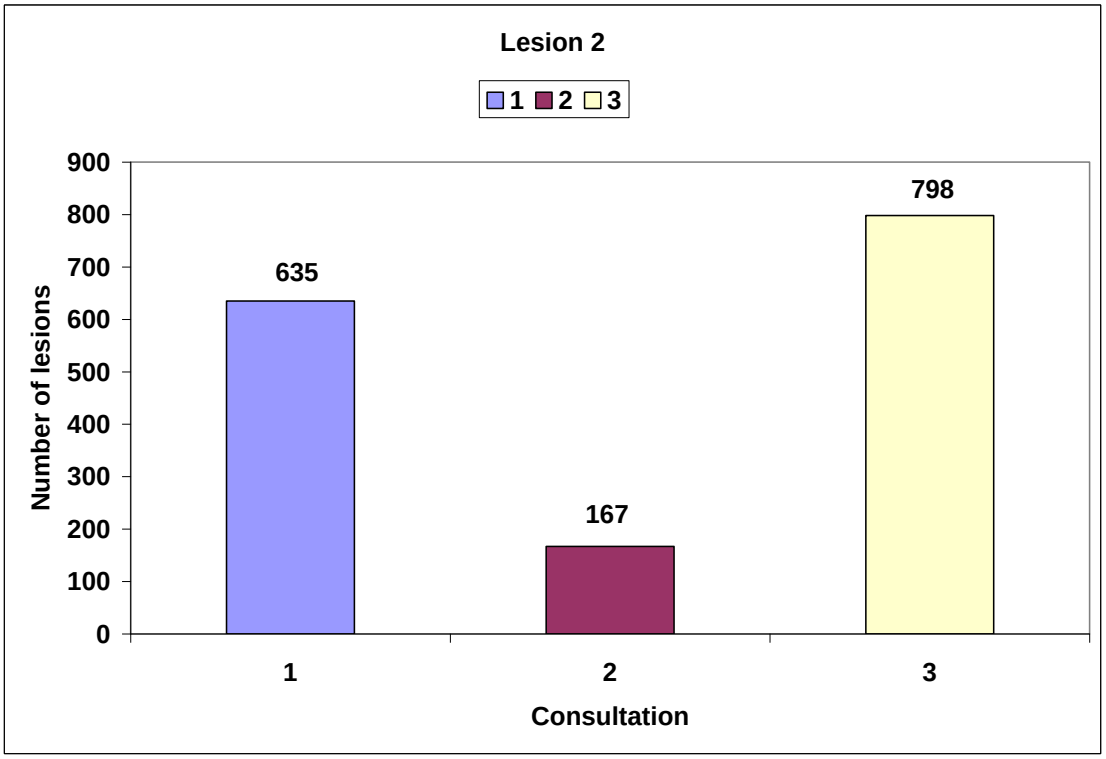

Figure 4.4 Total number of Lesions Number 2 counted at each consultation.

4.2.2.3 Lesion 3

Figure 4.5 illustrates the total number of Lesion Number 3.

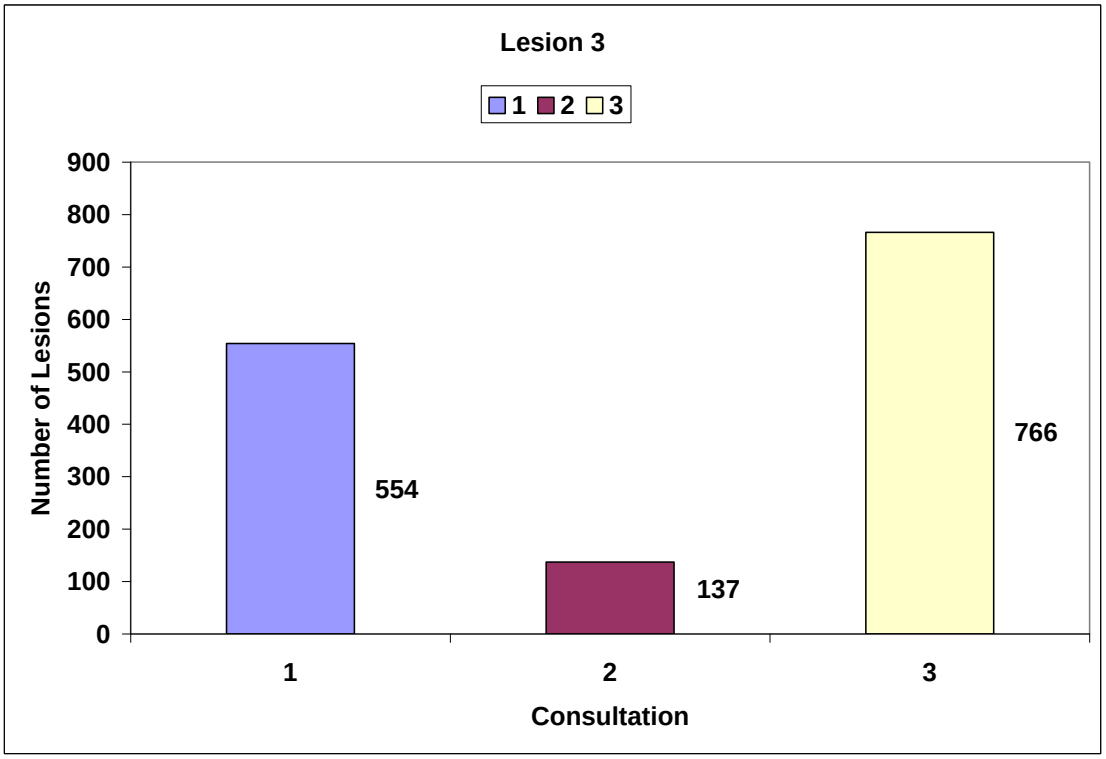

Figure 4.5 Total number of Lesion Number 3 counted at each consultation.

4.3 STATISTICAL ANALYSIS

4.3.1 Procedure 1: Intra-group analysis of the improvement of lesions between consultations

Table 4.1 illustrates the means and standard deviations for the rate of change between consultations.

Group Statistics

	Code - A / B	N	Mean	Std. Deviation	Std. Error Mean
Percentage change Lesion 1 - First to Second Consultation	A	14	7.3741	52.43656	14.01426
	B	16	29.7798	26.19185	6.54796
Percentage change Lesion 2 - First to Second Consultation	A	14	61.0322	35.39907	9.46080
	B	16	49.3148	56.90421	14.22605
Percentage change Lesion 3 - First to Second Consultation	A	14	18.5259	21.39934	5.71922
	B	16	33.1789	24.72853	6.18213
Percentage change Lesion 1 - First to Third Consultation	A	14	-1.7177	60.76538	16.24023
	B	16	34.1729	45.16828	11.29207
Percentage change Lesion 2 - First to Third Consultation	A	14	62.4324	42.61487	11.38930
	B	16	46.3140	70.16815	17.54204
Percentage change Lesion 3 - First to Third Consultation	A	14	14.5780	55.40931	14.80876
	B	16	34.7030	25.42298	6.35575
Percentage change Lesion 1 - Second to Third Consultation	A	14	-27.2024	101.07157	27.01251
	B	15	28.9304	32.91825	8.49946
Percentage change Lesion 2 - Second to Third Consultation	A	9	-.6894	75.76304	25.25435
	B	10	6.0221	54.87572	17.35323
Percentage change Lesion 3 - Second to Third Consultation	A	14	-3.9087	56.39162	15.07129
	B	15	4.2641	30.29117	7.82115

Table 4.1 Intra-group comparison of the improvement of lesions between consultations, Friedman test (Group Statistics). These are graphically illustrated for each Lesion in Figures 4.3 - 5.

Figure 4.6 illustrates the Percentage change Lesion 1.

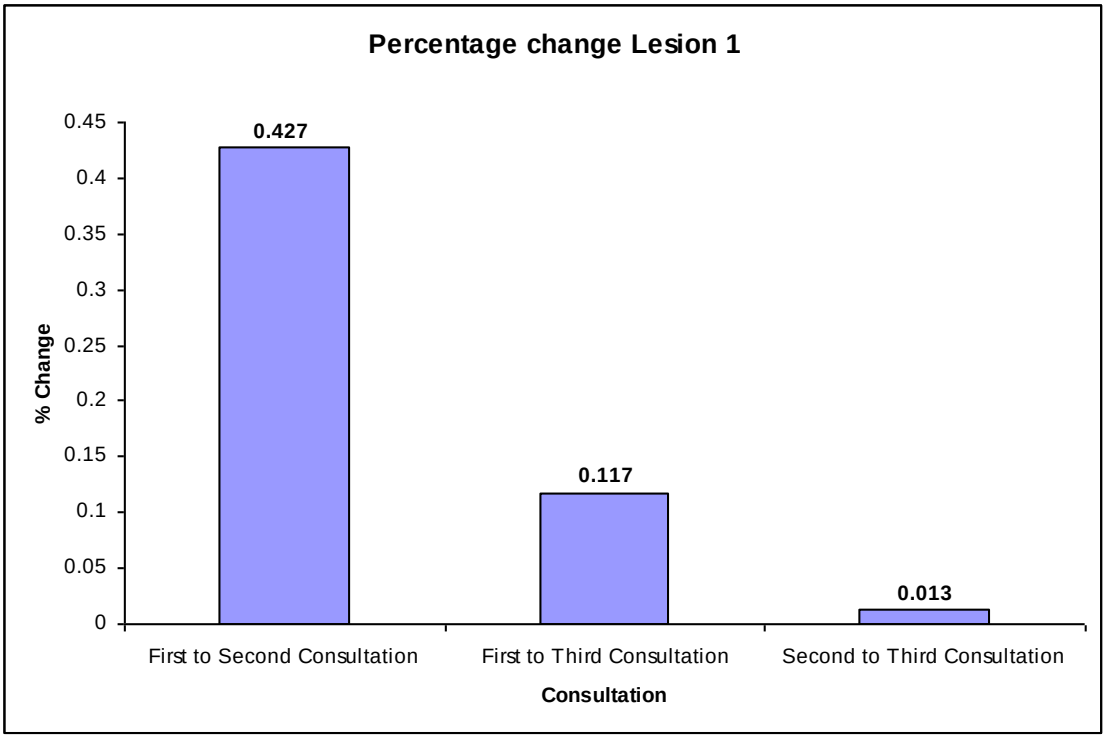

Figure 4.6 Percentage change Lesion 1.

Figure 4.7 illustrates the Percentage change Lesion 2.

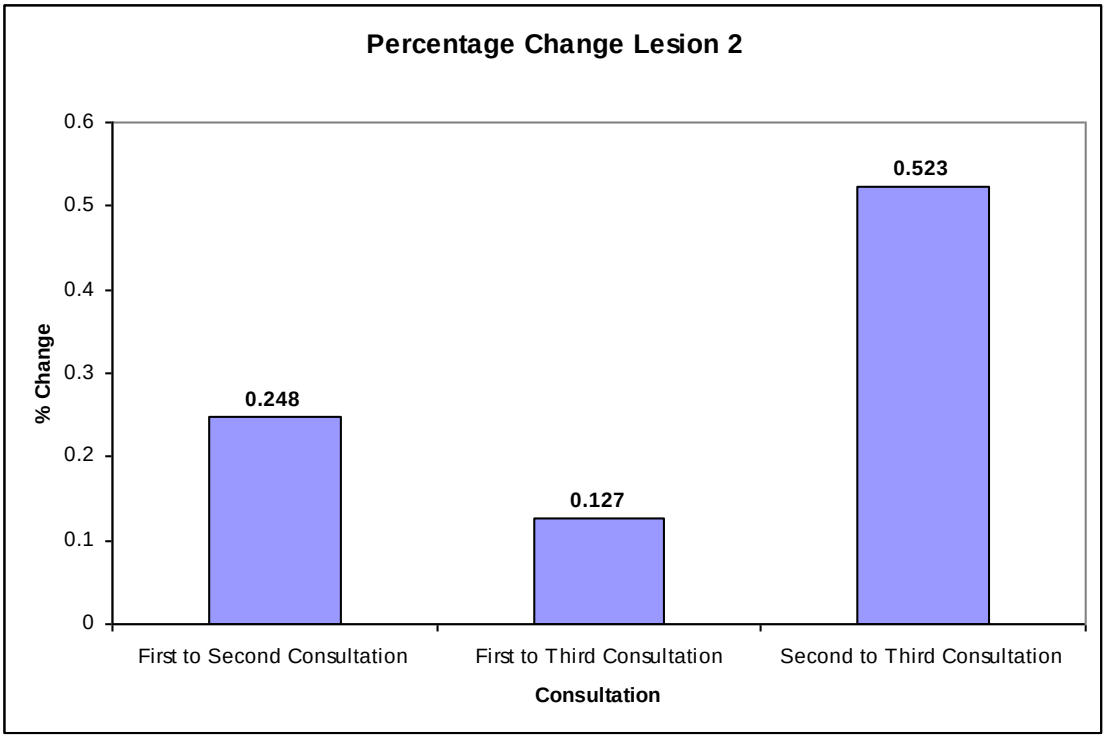

Figure 4.7 Percentage change Lesion 2.

Figure 4.8 illustrates the Percentage change Lesion 3.

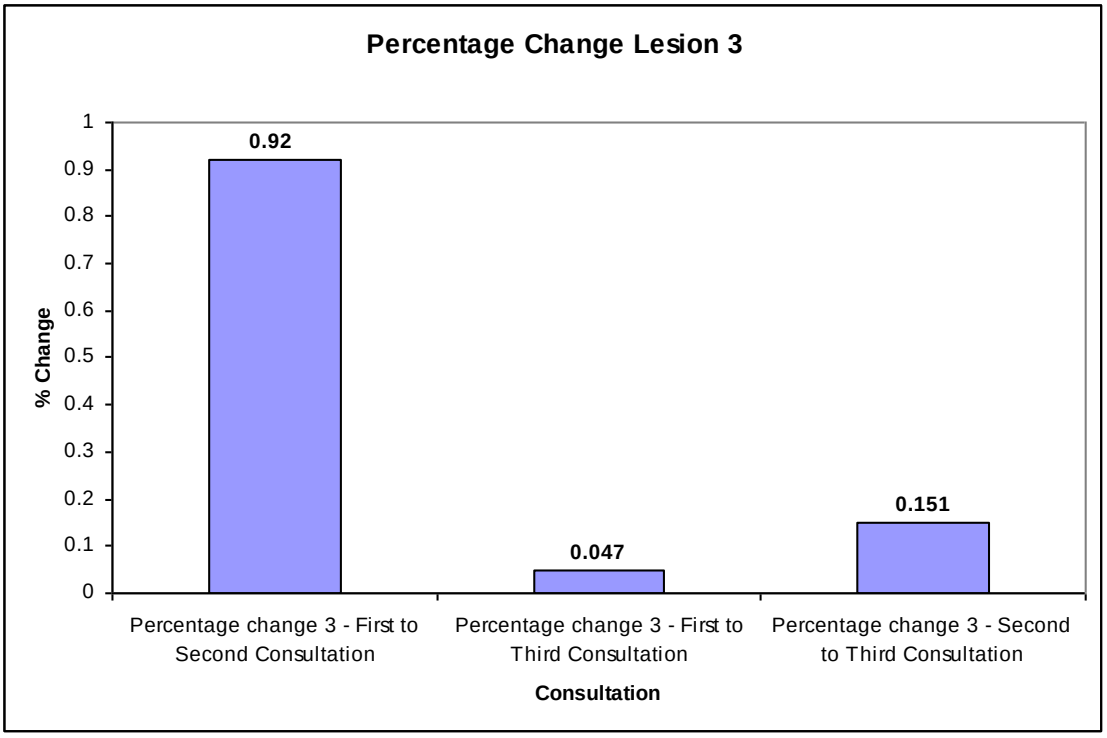

Figure 4.8 Percentage change Lesion 3.

Table 4.2 illustrates Friedman's Test for significance of intra-group change between consultations. The only significant result is that for Lesion 1 in the Control Group, between the second and third consultation ($p = 0.013$).

			T-test for Equality of Means							
		F	**Sig.**	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
% change Lesion 1 –First to Second Consultation	al variances assum	0.65	**0.427**	-1.51	28	0.142	-22.40561	14.83888	-52.80168	7.99047
	Equal variances not assumed			-1.448	18.53	0.164	-22.40561	15.46853	-54.83724	10.02603
% change Lesion 2 - First to Second Consultation	Equal variances assumed	1.394	**0.248**	0.665	28	0.511	11.71742	17.61373	-24.36267	47.7975
	Equal variances not assumed			0.686	25.457	0.499	11.71742	17.08471	-23.43722	46.87206
% change Lesion 3 - First to Second Consultation	Equal variances assumed	0.01	**0.92**	-1.723	28	0.096	-14.65295	8.50578	-32.07626	2.77035
	Equal variances not assumed			-1.74	27.999	0.093	-14.65295	8.42189	-31.90444	2.59853
% change Lesion 1 - First to Third Consultation	Equal variances assumed	2.612	**0.117**	-1.851	28	0.075	-35.89057	19.39012	-75.60943	3.82829
	Equal variances not assumed			-1.814	23.79	0.082	-35.89057	19.78019	-76.734	4.95286
% change Lesion 2 - First to Third Consultation	Equal variances assumed	2.473	**0.127**	0.747	28	0.462	16.11837	21.59111	-28.10902	60.34575
	Equal variances not assumed			0.771	25.154	0.448	16.11837	20.91505	-26.94361	59.18034
% change Lesion 3 - First to Third Consultation	Equal variances assumed	4.298	**0.047**	-1.306	28	0.202	-20.12494	15.40391	-51.67841	11.42854
	Equal variances not assumed			-1.249	17.71	0.228	-20.12494	16.11505	-54.02124	13.77137
% change Lesion 1 -Second to Third Consultation	Equal variances assumed	7.11	**0.013**	-2.04	27	0.051	-56.13275	27.51038	-112.57939	0.31389
	Equal variances not assumed			-1.982	15.56	0.065	-56.13275	28.31813	-116.3028	4.0373
% change Lesion 2 - Second to Third Consultation	Equal variances assumed	0.425	**0.523**	-0.223	17	0.826	-6.71145	30.11336	-70.24507	56.82218
	Equal variances not assumed			-0.219	14.47	0.83	-6.71145	30.64174	-72.23155	58.80866
% change Lesion 3 - Second to Third Consultation	Equal variances assumed	2.186	**0.151**	-0.491	27	0.627	-8.1728	16.64757	-42.33079	25.98519
	Equal variances not assumed			-0.481	19.623	0.636	-8.1728	16.97982	-43.63574	27.29014

Table 4.2 Intra-group comparison of the improvement of lesions between consultations, Friedman's Test (T-test for Equality of Means).

4.3.2 Procedure 2: Inter-group analysis of the improvement of lesions between consultations.

Table 4.3 illustrates the level of significance of the differences between the Control and Treatment Groups.

Ranks

	Code - A / B	N	Mean Rank	Sum of Ranks
Percentage change 1 - First to Second Consultation	**A**	14	13.68	191.50
	B	16	17.09	273.50
	Total	30		
Percentage change 2 - First to Second Consultation	**A**	14	16.21	227.00
	B	16	14.88	238.00
	Total	30		
Percentage change 3 - First to Second Consultation	**A**	14	12.57	176.00
	B	16	18.06	289.00
	Total	30		
Percentage change 1 - First to Third Consultation	**A**	14	12.71	178.00
	B	16	17.94	287.00
	Total	30		
Percentage change 2 - First to Third Consultation	**A**	14	16.11	225.50
	B	16	14.97	239.50
	Total	30		
Percentage change 3 - First to Third Consultation	**A**	14	14.00	196.00
	B	16	16.81	269.00
	Total	30		
Percentage change 1 - Second to Third Consultation	**A**	14	12.46	174.50
	B	15	17.37	260.50
	Total	29		
Percentage change 2 - Second to Third Consultation	**A**	9	10.11	91.00
	B	10	9.90	99.00
	Total	19		
Percentage change 3 - Second to Third Consultation	**A**	14	15.07	211.00
	B	15	14.93	224.00
	Total	29		

	Mann-Whitney U	Asymp. Sig. (2-tailed)
Percentage change 1 - First to Second Consultation	86.500	.287
Percentage change 2 - First to Second Consultation	102.000	.669
Percentage change 3 - First to Second Consultation	71.000	.088
Percentage change 1 - First to Third Consultation	73.000	.105
Percentage change 2 - First to Third Consultation	103.500	.715
Percentage change 3 - First to Third Consultation	91.000	.382
Percentage change 1 - Second to Third Consultation	69.500	.119
Percentage change 2 - Second to Third Consultation	44.000	.934
Percentage change 3 - Second to Third Consultation	104.000	.965

Table 4.3 Level of significance of the differences between the Control and Treatment Groups. Inter-group comparison of the improvement of lesions between consultations, Mann-Whitney test.

As can be seen from Table 4.3, at $p < 0.05$ level of significance, there was no significant difference between the two groups. Therefore, the null hypothesis is accepted i.e. Kalium bromatum 30CH has no significant effect in the treatment of Acne vulgaris.

4.4 PHOTOGRAPHIC RECORD

Every patient was photographed before and after treament. Because none of the results are significant only a sample of the photographic record is reproduced here. Plates 4.1 – 4 illustrates the acne condition of 2 patients before and after treatment.

Plate 2.1 illustrates a patient before treatment.

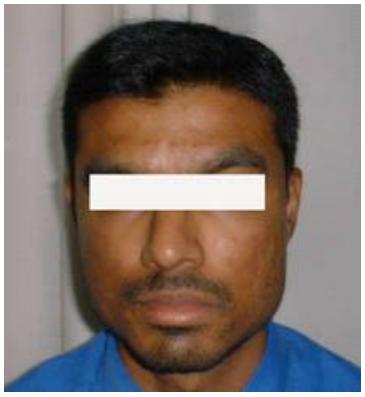

Plate 2.1 Patient 2 before treatment.

Plate 2.2 illustrates a patient after treatment.

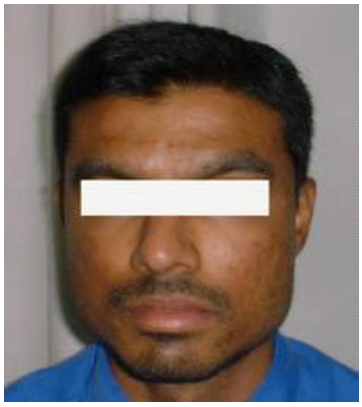

Plate 2.2 Patient 2 after treatment.

Plate 2.3 illustrates a patient before treatment.

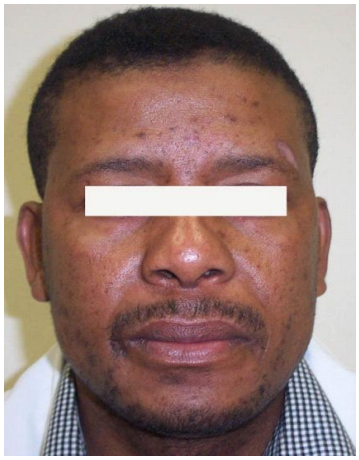

Plate 2.3 Patient 11 before treatment.

Plate 2.4 illustrates a patient after treatment.

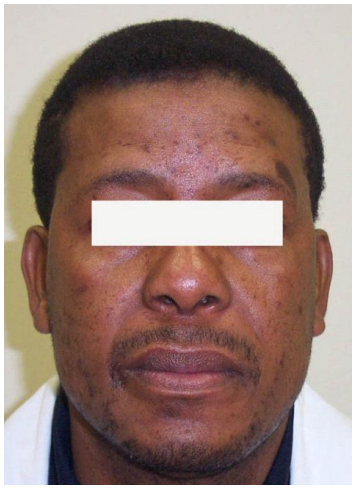

Plate 2.4 Patient 11 after treatment.

CHAPTER 5 - DISCUSSION

As can be seen from the results in Chapter 4, there was no significant difference between the improvement of lesions between treatment with Kalium bromatum 30CH and placebo. The only improvement noted was between the second and the third consultation with regards to Lesion 3 and the improvement was noted in the placebo group. In this particular study, therefore, it was shown that Kalium bromatum 30CH is not effective in the treatment of Acne vulgaris.

However, certain intervening variables may have effected the reliabilty of the outcome. These variables include proximity to menses, proximity to puberty and dietary patterns. These variables need to be taken into consideration in future studies.

A possible weakness in the study was the great variation in the number of lesions from patient to patient. For instance, patients with as little as 2 or as many as 105 lesions of Lesion 1 were included, which may have distorted statistical analysis. Future studies could have a numerical upper and or lower threshold for entry into the study.

A further limitation of this study is that although a general question regarding completion of the prescription was asked, careful checking on compliance with the prescription protocol was not conducted. Therefore, medication may have been skipped, or taken in too close proximity to food etc. Such behaviour could have interfered with the effectivity of the homoeopathic medication.

Although the methodologies adopted by the homoeopathic studies referred to in 2.3 and this study are not precisely the same, one can make the observation that the results of this study are similar to those of Lee (1997) and Van Niekerk (1999) who found that complex and miasmatic treatment were not effective for Acne vulgaris. The one study that did find a significant difference was McDavid (1994), who prescribed in the homoeopathic tradition of simillimum. The results of these 4 studies reveal a trend that prescribing one remedy or a complex on the basis of a superficial physical symptom only does not seem to be as effective as the traditional homoeopathic method of prescribing one remedy based on a complete case analysis.

On further reflection, this study is an example of how the "single symptom, single prescription" methodology of homoeopathic practice is unlikely to yield positive clinical results, because it's premise is unhomoeopathic! It's premise is that one size fits all - a similar premise to allopathic medicine. But homoeopathic remedies are not as powerful as allopathic medicines which can force the body to change it's symptoms. Homoeopathic remedies can only cause the body to change it's symptoms if there is cooperation (resonance) between the symptom and the remedy. In traditional homoeopathic theory, this can only occur when a patient is treated with the simillimum. In this study, it would have been sheer coincidence if the symptom of a patient resonated with the prescribed remedy at the prescribed potency, Kalium bromatum 30CH. Besides recommending that future acne studies should be simillimum based, one can also recommend the methodology where patients are carefully screened to see if their acne symptoms as well as their overall symptoms of health and disease match the Kalium bromatum pattern or "type" and so are more likely to be responsive to treatment with that remedy. Only those participants who match are then included in the study. This is the methodology adopted by Fisher, Greenwood, Huskisson, Turner and Belon (1989) as cited by Jones *et al* (2001). Future researchers should also consider alternative methodologies to

the RCT, such as the formal case study (Thompson, 2004).

CHAPTER 6 - CONCLUSION AND RECOMMENDATIONS

The aim of the research was to investigate the relative effectiveness of Kalium bromatum 30CH as compared to placebo treatment in participants with Acne vulgaris. It was found that there was no significant difference between the two groups. Therefore, the conclusion reached in this study is that Kalium bromatum 30CH prescribed on the basis of the presence of acne *per se* is not effective in the treatment of Acne vulgaris.

Recommendations:

1. Repeat the study with an inclusion criteria that participants must adequately match the “pattern” of Kalium bromatum as represented in a particular materia medica (e.g. Vermeulen, 1994). Details of how to determine "adequate" will have to be determined in conjunction with an experienced homeopath.
2. Conduct a series of simillimum studies with an evaluation of a different variable on each occasion e.g. age, gender, proximity to puberty, proximity to menstruation, type of diet (e.g. vegetarian, non-vegetarian: convenience food dominated; home prepared food dominated).

3. Conduct future studies with an inclusion criteria which sets an upper and/or lower limit to the number of lesions in each category.
4. Conduct a future study utilising the methodology of formal case study (Thompson, 2004).
5. Future studies must include rigorous questioning of participants regarding adherence to the prescription protocol. Non-adherence should result in exclusion from the study.

REFERENCES:

Beers, M.H., Berkow, R. 1999. *The Merck Manual.* 17th Edition. Whitehouse Station: Merck and Co., Inc.

Bergfield, W.F. 1995. The evaluation and management of acne: economic considerations. *Journal of the American Academy of Dermatology.* 32(3): 52 - 56.

Boericke, W. 1994. *Materia Medica with Repertory.* 9th Edition. New Delhi: B.Jain Publishers Pvt. Ltd.

Botha, I. 2005. Personal communication to G. Nijland, 18 November 2005.

Burke, M. and Cunliffe, W.J. 1984. Assessment of Acne vulgaris. *British Journal of Dermatology*. 111:83-95.

Callan, A.W. 1997. A GP's guide to the management of acne in women. *Modern Medicine of South Africa. The Journal of Clinical Medicine.* 22(4): 22 - 36.

Dox, I.G., Melloni, B.J. and Eisner, G.M. 1993. *The HarperCollins Illustrated Medical Dictionary.* New York: HarperCollins Publishers, Inc.

Edwards, C.R.W. and Bouchier, I.A.D. (ed.) 1991. *Davidson's Principles and Practice of Medicine.* 16th Edition. London: Churchill Livingstone.

Fischer, P., Greenwood, A., Huskisson, E.C., Turner, P. and Belon, P. 1989. Effect of homoeopathic treatment of fibrositis (primary fibromyalgia). *British Medical Journal*. 299:365-366.

Gardner, K.J., Eady, E.A., Cove, J.H., Taylor, J.P.and Cunliffe, W.J. 1997. Comparison of serum antibiotic levels in acne patients receiving the standard or a modified release formulation on minocycline hydrochloride. *Clinical and Experimental Dermatology.* 22(2): 72 - 76.

Graham-Brown, R. 1996. Modern management of acne. UPDATE: *The Journal of Continuing Education for General Practitioners.* X(3): 152 - 171.

Jonas, W.B., Anderson, R.L., Crawford, C.C. and Lyons, J.S. 2001. A systematic review of the quality of homoeopathic clinical trials. *BMC Complementary and Alternative Medicine*. 1:12. The electronic version of this trial is the complete one and can be found online at: http://www.biomedcentral.com/1472-6882/1/12

Jouanny, J. 1993. *The Essentials of Homoeopathic Therapeutics.* Sainte-Foy-les-Lyon: Boiron.

Jouanny, J. 1984. *The Essentials of Homoeopathic Materia Medica.* Sainte-Foy-les-Lyon: Boiron.

Kumar, P.J., and Clark, M.L. 1998. *Clinical Medicine 4th Edition*. Edinburgh: W.B. Saunders.

Lee, M. 1997. The Effect of a Homoeopathic Complex (Sil-Sel-Hep-K-Lap-Puls) on Acne Vulgaris. M.Tech.(Hom) dissertation, Technikon Natal, Durban, South Africa.

Leyden, J.J. 1995. New understandings in the pathogenesis of acne. *Journal of the American Academy of Dermatology*. 32(3): 15 - 25.

Linde, K., Clausius, N., Ramirez, G., Melchart, D., Eitel, F., Hedges, L.V. and Jones, W.B. 1997. Are the clinical effects of homoeopathy all placebo effects? A meta-analysis of randomized, placebo controlled trials. *The Lancet*. 350: 834-843.

Master, F.J. 1993. *Diseases of the Skin (including exanthemata).* Delhi: B. Jain Publishers.

McDavid, G.M. 1994. Homoeopathic Treatment of Acne. M.Tech.(Hom) dissertation, Technikon Natal, Durban, South Africa.

Murtagh, J. 2003. *General Practice.* New York: The McGraw Hill Companies.

Oxford Concise Colour Medical Dictionary. Martin, E.A. ed. 1996. Oxford: Oxford University Press.

Phatak, S.R. 1988. *Phatak's Materia Medica of Homoeopathic Medicines.* London: Foxlee-Vaughan Publishers.

Pollock, J. 2001. Personal communication to G. Nijland, 20 April 2001.

Rees, A.M. and Willey, C. eds. 1993. *Personal Health Reporter: excerpts from current articles on 148 medical conditions and treatments and other health issues.* Detroit: Gale Research.

Roche, Package Insert. March 2003. Isando.

Shang, A., Huwiler-Müntener, K., Nartney, L., Jüni, P., Dörig, S., Sterne, J.A., Pewsner, D. and Egger, M. 2005. Are the clinical effects of homoeopathy placebo effects. Comparative study of placebo-controlled trials of homoeopathy and allopathy. *The Lancet*. 366:726-732.

Steele, R. 2001. Personal communication to G. Nijland, 28 September 2001.

Stein, C.M. and Pincus, T. 1999. Placebo controlled studies in rheumatoid arthritis: ethical issues. *The Lancet.* 353: 400 - 404.

Sommer, S., Bojar, R., Cunliffe, W.J., Holland, D., Holland, K.T. and Naays, H. 1997. Investigation of the mechanism of action of 2% fusidic acid lotion in the treatment of acne vulgaris. *Clinical and Experimental Dermatology*. 22(5): 211 - 215.

The New Oxford Dictionary of English. Pearsall, J. ed. 1998. Oxford: Oxford University Press.

Thompson, T.D.B. 2004. Can the caged bird sing? Reflections on the application of qualitative research methods to case study design in homoeopathic medicine. *BMC Medical Research Methodology*. 4:4. The electronic version of this article is the complete one and can be found online at: http://www.biomedcentral.com/content/pdf/1471-2288-4-4.pdf

Van Niekerk, K. 1999. The relative effectiveness of miasmatic treatment as opposed to simillimum treatment in terms of the objective clinical findings in patients with acne vulgaris. M.Tech. (Hom) dissertation, Technikon Natal, Durban, South Africa.

Vickers, A., McCarney, R., Fisher, P., van Haselen, R. 2001. Can homeopaths detect homeopathic remedies? A pilot study for a randomised, double-blind, placebo controlled investigation of the proving hypothesis. *British Homeopathic Journal*. 90: 126 - 130.

Vermeulen, F. 1994. *Concordant Materia Medica.* Haarlem: Merlijn.

APPENDIX A

Leeds Technique

	1st Consultation	2nd Consultation	3rd Consultation
Date			
Number papules and pustules (Superficial inflammed lesions)			
Number nodules (Deep inflammed lesions)			
Number comedones (Non-inflammed lesions)			

APPENDIX B

Raw data

	Consultation 1			Consultation 2			Consultation 3		
Patient No.	**Lesion 1**	**Lesion 2**	**Lesion 3**	**Lesion 1**	**Lesion 2**	**Lesion 3**	**Lesion 1**	**Lesion 2**	**Lesion 3**
1	4	1	2	2	0	2	2	0	1
2	28	12	40	26	12	40	26	10	40
3	2	4	16	2	0	12	2	1	14
4	2	2	54	0	0	35	4	0	22
5	24	3	12	20	1	12	20	1	8
6	85	15	45	68	8	40	45	6	22
7	40	22	8	32	10	10	28	7	14
8	6	2	3	6	4	0	4	3	1
9	38	4	65	28	5	55	12	8	65
10	5	4	12	3	4	8	12	3	15
11	25	2	20	18	0	12	17	0	12
12	25	64	74	18	34	45	35	20	50
13	42	6	64	36	3	40	14	5	30
14	4	1	35	4	0	30	3	0	28
15	3	6	85	1	6	90	0	6	90
16	95	2	12	85	0	8	80	0	14
17	30	62	85	22	34	60	20	25	58
18	4	1	15	4	1	12	3	2	10
19	2	1	4	2	0	3	3	0	1
20	6	5	15	16	0	6	8	0	6
21	5	2	12	4	1	12	2	0	8
22	85	29	35	60	16	20	40	9	25
23	45	11	65	30	7	45	18	6	35
24	15	28	36	9	11	18	8	11	15
25	12	6	20	8	3	18	22	8	45
26	2	2	20	1	1	12	0	0	10
27	6	1	15	6	0	12	6	0	10
28	15	6	65	9	0	40	8	0	28
29	45	5	25	35	0	11	32	0	11
30	105	18	105	80	6	90	80	6	78