THE EFFICACY OF A HOMOEOPATHIC COMPLEX (CHAMOMILLA, BELLADONNA AND SCUTELLARIA LATERIFLORA) IN THE TREATMENT OF PROBLEMATIC PRIMARY DENTAL ERUPTION

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Dissertation submitted in partial compliance
with the requirements for the Master's degree in Technology
in the Department of Homoeopathy at Technikon Natal.

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

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Date of Submission 19/5/1998

DEDICATION

This dissertation is dedicated to my family, in appreciative acknowledgment of the opportunity presented to me, to become a Homoeopath.

ACKNOWLEDGEMENTS

The Author would like to thank the following people :-

The tiny patients- most importantly, for taking part in the study.

Dr. E. Poolman- for her assistance as supervisor.

Dr. F. Burger- for his endless patience, advice and guidance.

Dr. H. Cunningham-Graham- for her dental examinations and advice.

Dr. E. Funk- for her advice as a pediatrician.

Dr. T.S. Pillay- for his advice as a pediatrician.

Dr. M. Seward- for sending her literature from England

Dr. M. Lee- for randomizing the medication.

Ms. M. Maharaj- for assisting with many of the medical examinations.

Mr. Z. Worku -for his statistical advice.

Ms. T. Goldbach- for her support and patience.

The staff of the William Clark Gardens Children's Home for their cooperation, enthusiasm and interest.

ABSTRACT

The objective of this study was to evaluate the efficacy of a Homoeopathic complex (Chamomilla 30 CH, Belladonna 30 CH and Scutellaria Lateriflora D6) in the treatment of problematic primary dental eruption.

The study was a double blind randomized placebo-controlled clinical investigation. The thirty patients involved were between seven and thirty four months of age, and were all in the process of erupting a tooth, or teeth, during the study.

The criteria for the study required that the patient be experiencing signs and symptoms relating to problematic dental eruption. These included the general symptoms of irritability and sleep disturbances, and the local signs and symptoms of painfully inflamed gums.

The efficacy of the treatment was measured by using a questionnaire before and after the treatment. The follow-up consultation was conducted two to three days after the initial consultation due to the acute nature of the condition.

The statistical tests used were non-parametric due to the small sample size. The Mann-Whitney test was used to compare the experiment and the control group, and

Wilcoxon's sign ranked test was used to analyze any differences between the initial and follow-up consultations. Both tests showed significant improvement by the patients who received the complex.

The results of this study confirms that Homoeopathic treatment is efficient in alleviating the signs and symptoms of difficult teething.

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CHAPTER ONE- INTRODUCTION

The eruption of the primary dentition is an incident of great importance to parents as it heralds an important event in their child's development (Ramirez et al 1994). Throughout history, parents have been unable to rejoice until their child had safely survived the period of dentition (Radbill 1965).

Dentition is recorded in the literature as far back as ancient Sumer, about 500 years ago. It is discussed in the old Hindu writings, the Homeric Hymns, the Hippocratic literature, the work of Pliny, Aristotle, Soranus, Galen, Celsus, Oribasius, Aetius, and all subsequent medical texts dealing with children to the present day. At one time it was considered the most common cause of death in infancy.(Radbill 1965.) Teething as a disease entity has subsequently lost its status as a major cause of infant mortality and is no longer viewed as a serious or dangerous pathology (King 1994).

Seward (1972) identified three main schools of thought on the possible relationship between the clinical symptoms and the eruption of the primary teeth. The first school of thought is that teething produces a great many disturbances, systemic and local in nature.

The term 'dentitio-difficilis,' was coined by these physicians, who suggest a cause and effect relationship between the eruption of the primary teeth and clinical symptoms. The second school of thought is comprised of those physicians who consider that mild disturbances are a common and expected consequence of what is primarily a normal physiological process. Finally, there are those who claim that as the eruption of the dentition is a normal process; disease or disturbances cannot occur; teething will produce teeth and nothing more. Holloway and Swallow (1982:141) suggest that the truth about whether 'teething only produces teeth,' which is a popular modern day belief; or whether other pathological symptoms can be attributed to the process, lie somewhere between these two extremes.

The view that teething is an ailment is still common today; especially among mothers of teething children. Commercial interests especially attempt to foster anxiety in mothers and doctors. (Dally 1996.) Steinlechner (1984) claims that Homoeopathic treatment is of benefit in dental treatment and Castro(1992:157) has found, by clinical experience, that homoeopathic treatment is effective in relieving the pain of teething . Research on the Homoeopathic treatment of teething, by a clinical trial, would substantiate and confer credibility to these claims.

CHAPTER 2 - REVIEW OF THE RELATED LITERATURE

2.1 HISTORICAL REVIEW

Hippocrates, in the fourth century B.C, knew that the teeth were formed in utero, and that they began to erupt about seven months after birth. He ended the age of infancy with the shedding of the first teeth at the age of seven years. Hippocrates, in his 25th aphorism listed the symptoms of teething as follows : "At the approach of dentition, itching of the gums, fevers, convulsions and diarrhoea occur." These symptoms have been copied, enlarged upon and expatiated by the world's greatest medical experts ever since. General unrest, sleeplessness, night terrors, drooling, epilepsy, paralysis, vomiting, strangury, skin eruptions (the "red gum" or teething rash which is now usually called eczema), pain, running ears, deafness, colds, coughs (the so called teething cough) , croup, blindness, rickets, hydrocephalus, swelling of the bones, wasting, sudden death and even measles, smallpox and "teething gonorrhea," continued to be associated with difficult dentition through the eighteenth and nineteenth centuries. (Radbill 1965.)

Until the present century teething was believed to have been one of the major causes of deaths in infants and small children. Some of the more ancient treatments of teething included blistering, bleeding, placing leeches on the gums and applying cautery to the back of the head. During the sixteenth century lancing of the gums emerged as the professional treatment of teething. By the 18th century lancets had become a symbol of the profession and were carried by physicians and surgeons. (Dally 1996.) According to Ring (1994) it appeared as though the sole purpose of 18th century dentists was to assist the teeth to erupt, a process they were led to believe was beset by grave dangers. "During the 18th century almost half of all deaths in infancy in France were ascribed to "*teething troubles*"(Koch et al, 1991:273). According to the Registrar General's report in London in 1842, cited by Jaber et al. (1992), teething was the registered cause of death in 4.8% of all infants who died in London under the age of 1 year and 7.3% of those between the ages of 1 to 3 years. During the latter part of the 19th century some doctors began to dispute the accepted treatment of teething, and the diversity of opinion on the subject caused contention within the medical profession. Earlier this century some practitioners, especially dentists and pathologists, still regarded teething as potentially pathological and medical and dental text books still advocated gum lancing to treat a variety of pathological conditions. (Dally 1996.)

2.2 PATHOPHYSIOLOGY

The primary teeth develop from the midgestational period until the end of the twelfth month of the infant's life (Viscardi et al. 1994).Primary teeth growing in the jaws are enclosed within a protective sack. As the tooth forces its way through the gingiva, this sack ruptures. Infants who bite on hard objects may injure their gingiva causing premature rupture which may result in infection. (Foster 1992:65.) Vaughan (1993) discusses other instances of self-inflicted oral injuries which are described under the term 'gingivitis artefacta' or 'factitial gingivitis.' These injuries include local dental factors such as a painful dental papilla which encourages the child to use digital pressure for pain relief. Finger nails and other sharp objects are other causes of damage which frequently involve the gingival margin. Injuries can also occur as the result of habits such as thumb sucking or the use of pacifiers. An unhappy emotional background is another factor in self inflicted oral injuries.

Shortly before the erupting tooth pierces the gingival mucosa, a whitish area is seen corresponding precisely to the imminent point of breakthrough. This area corresponds to the keratinization of the fused dental and oral epithelia. The exposure of the tooth occurs a few days later. The exposure of hard tissue into the oral cavity alters the bacteriological conditions between the soft tissue and the microbial flora of the oral cavity.

Due to the fact that the confluence between oral and dental epithelium is permeable, an accumulation of inflammatory cells occur in the adjacent tissue. The initial phase is dominated by polymorphonuclear leukocytes and is a possible cause of the local reactions noted during the actual eruption of the tooth into the oral cavity. Another cause of difficult or problematic dental eruption is the development of a thick callus on the gingival surface. This thick callus makes it difficult for the tooth to break through and again infection may result. (Foster 1992:65.)

LOCAL COMPLICATIONS

OPERCULUM GINGIVAE

After eruption, soft tissue often remains for a relatively long time in the distal part of the occlusal surface. This is known as an 'operculum gingivae.' The tendency toward a persistent operculum is greater when eruption takes place early in relation to the growth of the jaw. In these cases the tooth erupts partly into the retromolar mucosa, a tissue which is more resistant to resorption than the future gingiva. Inflammation characterized by considerable oedema may be caused by mechanical trauma or plaque accumulation at the site of the operculum. (Koch et al 1991: 272-273.)

ERUPTION CYST

Eruption cysts are an occasional complication of dental eruption which are usually seen over erupting molars. The space over the crown becomes filled with blood and tissue fluid and appears as a dark-bluish tense area which may be surrounded by inflammation. Eruption cysts usually resolve themselves, but occasionally surgical intervention is initiated to remove the roof of the cyst and expose the crown of the underlying tooth. (Parkin 1991:171.) Nunn (1993) states that numerous textbooks on pediatric dentistry urge caution when contemplating surgical intervention of eruption cysts.

GRANULOMA PYOGENICUM

Nunn (1993) describes a clinical case referred to a dental hospital due to complications of dental eruption. Surgical excision was performed in view of a provisional diagnosis of a traumatized eruption cyst. The histopathology report on the excised tissue suggested that the lesion had been a pyogenic granuloma rather than an eruption cyst.

SYSTEMIC COMPLICATIONS

Shapira et al. (1996) describes a case of a 5- month old girl whose condition was severely aggravated by the eruption of the primary teeth. This patient was being treated with bone marrow transplantation for severe combined immunodeficiency. She developed two episodes of severe graft vs. host disease (GVHD) while teething. A dramatic improvement in GVHD was noted after the completion of tooth eruption. It is suggested that the release of interleukin-1, associated with the traumatised gingival tissue, was the triggering mediator for the GVHD. The authors suggest that in view of their findings, teething should be added as a known triggering factor for GVHD.

2.3 SYMPTOMS AND SIGNS

Parkin (1991: 171) divides the signs and symptoms of teething into systemic and local conditions. The author describes the systemic symptoms as the child being irritable, crying excessively and suffering disturbed sleep. Appetite is reduced and thirst is increased. Local symptoms and signs include local inflammation over the erupting tooth, excessive salivation and dribbling, cheek flushing on the affected side and spots around the mouth.

GENERAL DISTURBANCES

Seward (1972) conducted a longitudinal survey of 224 infants which included 4480 episodes of tooth eruption. Data was obtained from questionnaires completed by the mothers over a twelve month period. Nineteen general disturbances were referred to in the questionnaire. These included the psychic manifestations of *irritability, disturbed sleep* and *convulsions*. Changes in appetite and thirst included *reduction of amount eaten, increase of fluid intake* and *reduction of fluid intake*. The digestive disorders of *diarrhoea, hard stools* and *vomiting* were also recorded. *Common colds* were noted with *left* and *right sided rhinorhoea* listed separately.

Rubbing of the ear on the side of the erupting tooth and *coughing* were also recorded. C*ircumoral rash and drooling* were the generalized oral indications considered, while signs of the genitourinary system included *strong urine* and *nappy rash*. The generalized disturbance of p*yrexia* was also registered.

The data collected was divided into anterior and posterior tooth eruption; with the central and lateral incisors constituting the anterior teeth. Analysis of the data revealed that 194 out of the 224 infants had a positive response to at least one of the 19 questions during the 8 separate episodes of anterior tooth eruption. Thus, 87% of the infants included in the survey experienced at least one general complication. Only 30 infants (13.4%) had no disturbances. The largest total number of general disturbances recorded for any one infant during the eruption of the anterior teeth, was 25. The mean value for the frequency of occurrence of the general disturbances experienced by each individual infant for all the anterior teeth was 7.8 disturbances.

The posterior teeth refer to the cuspid and primary molars. During the period of eruption of the posterior teeth, all of 224 infants experienced at least one complication. The largest total number of general disturbances for the posterior teeth was 37 and the smallest total number was 5. The mean value for the posterior teeth was 17 disturbances.

In order to determine which of the general disturbances are the most likely to occur, the 19 disturbances were ranked according to the incidence of each disturbance. This was done by calculating the total number of occurrences of the particular general disturbance, divided by the total number of subjects in the sample. It was thereby calculated that the 6 most common general symptoms to occur were *irritability, disturbed sleep, reduction of amount eaten, increased fluid intake, drooling and circumoral rash.* A significant difference was demonstrated in the incidence of these 6 disturbances as compared with the incidence of the remaining 13. This suggests that these 6 disturbances are more likely to accompany primary dental eruption than the other general disturbances. It is interesting to note that the 3 most infrequent disturbances encountered were *reduced fluid intake, vomiting* and *convulsions.*

FEVER

Jaber et al. (1992) conducted a study to address the question of systemic symptoms and signs associated with teething in a scientific manner by a controlled investigation. The reports of the mothers of 46 healthy infants were examined by the researchers. A daily examination of rectal temperature and examination of the gums for evidence of dental eruption was performed by the parent. The parents were also instructed to note any diarrhoea, convulsions, bronchial symptoms, or any other diseases. Medications and medical examinations were noted.

Professional confirmation on the day of tooth eruption was included in the study. To simplify the analysis of the study, only data collected in association with the first tooth to erupt, were analyzed. The day of dental eruption is referred to as day 0, and all data refers to the previous 20 days. The results showed that the mean daily temperature of the infants from day 19 to day 4 was between 36.9°C and 37.1C. This increased to 37.14°C on day 3, 37.2 °C on day 2, 37.4°C on day 1, and reached its highest value of 37.6°C on the day the tooth erupted. The authors have commented that from the data presented, it would seem that there is an association between fever and dental eruption, however they also stress the danger in attributing fever to teething without ruling out other pathology.

DIARRHOEA

Coreil et al (1995) did a mail survey in the USA to gain a better understanding of current medical opinion on teething diarrhoea (TD). All physicians who were registered members of the Florida Pediatric Society in 1990 were included. A total of 234 of the 575 questionnaires were returned. Their results showed that 35% of the pediatricians associate the occurrence of diarrhoea with tooth eruption in infants and children. The most common explanations cited by these pediatricians were changes in eating habits, increased salivation, stress and coincidence.

Additional attributed causes included viremia, bacteremia and change in parental behavior. Most respondents that they viewed TD as less serious than other types of diarrhoea and managed it accordingly.

LOCAL DISTURBANCES

Seward (1972) conducted a longitudinal study among 224 infants which represented a study of 4480 separate episodes of primary tooth eruption. Aims of this study included establishing the percentage of infants who experience local disturbances during primary tooth eruption and the frequency of the local disturbances. The most common local disturbances and their rank according to incidence was also determined, as was the relationship between the total number of local disturbances.

Five local disturbances were studied. These included inflammation of the gum, eruption cysts, oral ulcers, cheek flush and cheek rash. Analysis of the data from these questions revealed that 165 out of the 224 infants was recorded as having a positive answer to at least one of the 5 questions during the 8 separate episodes of anterior tooth eruption. Thus 74% of the infants experienced at least 1 local disturbance during the eruption of the anterior teeth. Only 59 infants (26%) had no disturbances. The largest number of total disturbances recorded for any one infant during the eruption of the anterior teeth was 8.

For 59 infants no disturbances were recorded. The mean value for the frequency of occurrence of the local disturbances experienced by each individual infant for all the anterior teeth was 2.1.

With regard to the posterior teeth, a positive response was recorded to at least 1 of the 5 questions in the questionnaire for all the 224 infants. The largest total number of local disturbances recorded for the posterior teeth was 16 and the smallest total number was 1 local disturbance. The mean value for the posterior teeth was 7.0 disturbances.

In order to determine which local disturbance is the most likely to occur during primary tooth eruption, the rank or order of the five local disturbances studied was determined. The incidence of each local disturbance was first calculated. Incidence is defined as the total number of occurrences of the particular local disturbance divided by the total number of subjects in the sample. The local disturbance is then allocated a rank according to the incidence of the disturbance. It was thereby determined that the most common local disturbance accompanying anterior tooth eruption is inflammation of the gum. This is closely followed by the phenomenon of cheek flush. Where the posterior teeth were concerned, the most common disturbance was cheek flush with gum inflammation ranked second. The disturbance ranked third in both instances were oral ulcers.

Cheek rash and eruption cyst were ranked fourth and fifth in both anterior and posterior tooth eruption. The author notes that in this survey cheek flush usually accompanied the eruption of the canines and molars. Duration of local inflammation of the gum varied from 2 or 3 days to 10 days and was dependent on many factors including the standard of oral hygiene and general health of the infant. The author also noted that cheek rash may occur on one or both cheeks simultaneously. The eruption may be erythematous, papular or pustular in character and lasts for several days although not remaining at the same intensity for the whole period.

From the analysis of the longitudinal survey, the hypothesis that primary tooth eruption can be accompanied by certain local symptoms was confirmed.

2.4 AGE AND ORDER OF TOOTH ERUPTION

Ramirez et al. (1994) performed a longitudinal study on primary tooth eruption in 114 Spanish children in two Primary Care Centers in Madrid over a three year period. Data from periodic observations and data collected from previously instructed parents were studied. The object of the study was to evaluate the age and order of eruption of the primary dentition in their population of Spanish children. When the findings of this study were compared to studies performed in other populations, it was established that the ages and order of tooth eruption in Spanish children are similar to those found in other populations.

AGES OF ERUPTION

The ages of eruption in months (mean values with the standard deviations) were as follows:

Maxilla

Central incisor	9.42 ± 2.11
Lateral incisor	10.66 ± 2.20
Canine	18.70 ± 3.03
First molar	15.28 ± 1.93
Second molar	26.77 ± 3.93

Mandible

Central incisor	7.20 ± 1.78
Lateral incisor	12.26 ± 3.00
Canine	19.03 ± 3.28
First molar	15.70 ± 2.20
Second molar	25.47 ± 3.53

ORDER OF ERUPTION

The order of primary tooth eruption was determined in a group of 60 infants; 35 boys and 25 girls, in which the total data of dentition was obtained. The most common order of eruption found in this study was central incisors, lateral incisors, first molars, canines and second molars. In the maxilla this order was found in 87.5% of boys and 84% of girls. In the mandible this order was found in 84.3% of boys and 76% of girls. Considering both jaws together, the most frequent order found (almost 25% of the total group) was mandibular central incisors, maxillary central incisors, maxillary lateral incisors, mandibular lateral incisors, maxillary first molars, mandibular first molars, maxillary canines, mandibular canines, mandibular second molars and maxillary second molars. If one takes into consideration the fact that there was no statistically significant difference found in the order of eruption of the first molars and the canines, and this information is thus ignored, the order of eruption increases to 59.3% in boys and 48% in girls, which is more than half of the total group. Other orders were the eruption of any first molar before the eruption of at least one mandibular lateral incisor, which was found in 12.5% of boys and 20% of girls, and the eruption of a maxillary lateral incisor before at least one maxillary central incisor which was found in 9.3% of boys and 12% of girls.

2.5 TREATMENT

MEDICAL TREATMENT

Medical treatment of teething includes application of topical analgesics, systemic analgesics, sedatives and hypnotics.

Topical ointments and jellies have local counter-irritant, anti-inflammatory, systemic and local analgesic, antipyretic and antiseptic properties. These preparations provide rapid albeit short-lived pain relief. Salicylates are a common ingredient in these preparations. The author cites the British National Formulary 1990, which warns that preparations containing salicylate should not be used too frequently as they may give rise to salicylate poisoning. An alternative local analgesic utilised is lignocaine hydrochloride. Antiseptics used include cetalkonium chloride, cetylpyridinium chloride, polyethoxdodecane, anthraquinone glycosides, cetalkonium chloride and ethyl nicotinate. Other anti- inflammatory agents include menthol and myrrh tincture. (Andlaw and Rock 1993:128.)

Parkin(1991:171) states that some authors recommend sedatives such as chloral and dichloralphenazone elixirs to restore the baby's sleeping cycle and give the parents some rest. The reason for this is that the baby's sleep is disturbed by the pain of tooth eruption. He states, however, that it is dangerous to sedate tiny children at any time and that it is just as effective to treat this condition using an analgesic.

HOMOEOPATHIC TREATMENT

Jacobs(1994) suggests that treating children homoeopathically is an attractive alternative to using allopathic drugs. The author suggests that many minor ailments can be treated effectively using homoeopathic remedies. The author also claims that by utilising homoeopathy in these instances, the overall defence mechanisms of the body would be strengthened and the child's general state of health would be enhanced.

Castro(1992:157) has found, by clinical experience, that homoeopathic treatment can ease the pain of teething. The author states that Homoeopathy is also effective in facilitating the eruption of teeth that are having difficulty in breaking through the gums.

Chamomilla is specific for painful dentition and teething difficulties (Foubister, 1989: 12,52). Bodman (1990) mentions that chamomilla is not suitable for patients who bear pain patiently and calmly. The teething infant in need of chamomilla is in a rage; it resents the pain, and will not be soothed unless it is carried. Vermeulen (1994:284-289) describes the chamomilla patient as being peevish, restless, thirsty and hot. Chamomilla so effectively soothes these children that it has been termed 'the opium of homoeopathy.'

Belladonna is a complimentary remedy to chamomilla in conditions of children. It is frequently used to treat fevers in children. Belladonna is indicated in inflammation characterised by redness, pain, throbbing, heat and oedema.(Vermeulen1994:161-168.)

Scutellaria Lateriflora is listed in the *Homoeopathic Medical Repertory* (Murphy 1993:1438) as a remedy for difficult dentition with insomnia. This is a sedative for nervous irritation of children during dentition. It is used to treat sleeplessness, restless sleep and sudden wakefulness (Vermeulen 1994:860).

2.6 SUMMARY

In view of the potential risks involved in treating teething allopathically, parents may be loathe to treat a condition, which is not considered a serious medical pathology, using drugs. The sleepless nights, however, may drive the patients and their families to despair. A homoeopathic alternative to the dilemma; which alleviates pain, reduces inflammation, decreases irritability and restores sleep; is an attractive option.

CHAPTER 3-MATERIALS AND METHODS

The objective of the study was to assess the response of patients to a Homoeopathic complex. The efficacy of the complex in the treatment of problematic primary dental eruption could thus be assessed. The experimental design was 'double blind placebo-control.

3.1 STUDY DESIGN AND PROTOCOL

Thirty patients were selected for this research.

Patients were randomly divided into two groups (experimental and placebo) in such a way that each patient had an equal chance of being selected for either group.

The 30 vials to be used in the trial were given to an independent person. A list of numbers ranging from 1-30 were made. Thirty pieces of paper were placed in a box, 15 were marked "placebo" and 15 "experimental." The 30 pieces of paper were drawn one at a time and thus either "placebo" or "experimental" was allocated to the list of numbers, in order, from 1-30. The vials were numbered 1-30 and returned to the researcher in a box. The independent person retained the list until after the trial was completed.

During the initial consultation, the guardian of the patient, or the researcher, chose a numbered vial from the box. The number chosen was recorded by the researcher.

Prospective patients were examined by the researcher in order to determine whether the patient fulfilled the selection criteria. The *case taking form (Appendix A)* was used for this purpose.

The guardian of patients that fulfilled the criteria were required to fill in the *consent form (Appendix B).* The patient was then examined by Cunningham-Graham and the *Dental Report (Appendix C)* was filled in.

The *teething questionnaire(AppendixD)* was filled in by the researcher. The treatment was then dispensed. The guardian was asked to pay attention to the response of the patient to the medicine with regard to the patient's irritability, sleep patterns, appetite, thirst, salivation, hand and finger sucking, biting of objects, cheek flushing, circumoral rash and stool consistency. The follow-up consultation was performed two to three days later and the *teething questionnaire (Appendix D)* was completed as before.

3.2 SUBJECTS

Thirty babies between the ages of seven months and thirty four months were selected for the study.

The Selection criteria for the study was as follows:

- Patients had to be between 4 months and 2 years and 12 months of age.

- Patients had to be in the process of erupting a tooth.

- Patients had to present with at least two of the following general signs or symptoms, and at least one of the following local signs or symptoms:

<u>General signs and symptoms</u>

irritability

disturbed sleep

decreased appetite

increased thirst

hyperpyrexia of less than 39°

loose stools with no signs of dehydration

Local signs and symptoms

increased salivation with resultant drooling

increased sucking of hands or fingers

biting on toys and other objects

cheek flushing

circumoral rash

inflammatory changes with swelling of the gums

hyperaemia of the gums

Cunningham- Graham (personal communication1997)

The patient had to be within the first week of the approximate three week eruption period. This was intended to decrease the possibility of changes recorded by the researcher being the result of the natural end of dental eruption.

Cunningham- Graham (personal communication 1997)

A patient was excluded from the study if the patient was found, by the researcher, during the preliminary history and physical examination, to be exhibiting signs that could not be attributed to teething. These signs included:

a temperature of higher than 39°

pulse and respiratory rates that are higher than normal for the age of the infant or toddler, as defined by (Heese 1995:681,685).

dehydration

neck stiffness, Kernig's sign, bulging fontanels

lymphadenopathy

moderate to severe diarrhoea

Patients undergoing medical or homoeopathic treatment related or unrelated to primary dental eruption were excluded from the study.

3.3 TREATMENT

The treatment for the experimental group consisted of a "teething" complex. The carrier substance was lactose granules. The carrier substance was impregnated with the following remedies:

Chamomilla 30 CH, Belladonna 30 CH, and Scutellaria Lateriflora D6.

The placebo group was given the carrier substance without the active ingredient.

The treatment was dispensed in a No. 2 vial, ¼ filled with granules. 15 of these units were impregnated and 15 were placebo. The guardian of the patient was instructed to give the patient ¼ capful of granules dry in the mouth, four hourly, whenever the patient was awake, until the follow-up consultation.

3.4 MEASUREMENTS

The efficacy of the complex was measured using a questionnaire. The *teething questionnaire (Appendix D),* was completed by the researcher during the initial consultation by questioning the patient's guardian and by examining the patient. This procedure was then repeated at the follow-up consultation.

The questionnaire was designed by the researcher, in order to determine the efficacy of the complex, in terms of the treatment of the general and local manifestations of problematic dentition.

3.5 STATISTICAL ANALYSIS

Due to the small sample size within the groups being analyzed, parametric tests such as the two-sample unpaired t-test cannot be used. Non-parametric tests are therefore used instead. Data entry and analysis is performed using the statistical computer package *'Statgraphics version 6+'*

GROUPS ANALYSED

Group 1 constitutes the placebo group.

Group 2 constitutes the experiment group.

3.5.1 THE MANN-WHITNEY UNPAIRED TEST

The Mann-Whitney unpaired two sample test is used to compare these two groups to one another. The two groups are regarded as being independent of one another (unpaired). The purpose of this test is to determine whether there is any significant difference between the two groups at the $\alpha = 0.05$ level of significance.

Hypothesis testing :

The null hypothesis Ho states that there is no significant difference between the two groups with regard to questions 1 to 13 of the questionnaire. The alternative hypothesis H_1 states that there is a significant difference between the two groups.

Ho: $\mu_1 = \mu_2$

H_1: μ_1 and μ_2 are significantly different from each other.

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

Decision rule:

For a two- tailed test:

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

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

P is the observed significance level of the test.

(Gulezian 1979:335.)

3.5.2 WILCOXON'S SIGNED RANK TEST FOR GROUP ONE

The Wilcoxon's sign ranked test is used to determine whether there is any significant improvement between the initial and the follow up consultation, within the placebo group. All tests are done at the

$\alpha = 0.05$ level of significance.

Hypothesis testing :

The null hypothesis Ho states that there is no significant improvement, with regard to questions 1 to 13 of the questionnaire, between the initial and the follow-up consultation. The alternative hypothesis H_1 states that there is a significant improvement between the initial and the follow-up consultation.

Ho: there is no significant improvement

H_1: there is a significant improvement

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

Decision rule:

For a two- tailed test:

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

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

P is the observed significance level of the test.

3.5.3 WILCOXON'S SIGNED RANK TEST FOR GROUP TWO

The Wilcoxon's sign ranked test is used to determine whether there is any significant improvement between the initial and the follow up consultation, within the experiment group. All tests are done at the

$\alpha = 0.05$ level of significance.

Hypothesis testing :

The null hypothesis Ho states that there is no significant improvement, with regard to questions 1 to 13 of the questionnaire, between the initial and the follow-up consultation. The alternative hypothesis H_1 states that there is a significant improvement between the initial and the follow-up consultation.

Ho: there is no significant improvement

H_1: there is a significant improvement

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

Decision rule:

For a two- tailed test:

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

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

P is the observed significance level of the test.

(Gulezian:335.)

3.5.4 TABLES

The results of the Mann-Whitney and the two Wilcoxon's signed rank tests are demonstrated in the form of tables.

3.5.5 SUMMARY STATISTICS

Summary statistics (mean, mode, median, standard error, the coefficient of variation) are provided.

CHAPTER 4- RESULTS

Two Mann- Whitney Unpaired tests were done with respect to 13 variables of interest (before and after treatment), to compare the two groups. The 13 variables were *irritability, sleep disturbance, appetite, thirst, drooling, hand sucking, toy biting, hyperaemic gingiva, oedematous gingiva, cheek flushing, peri-oral rash, loose stools* and *temperature.*

For each of the 13 variables, two tests were done, as a result of which 26 P- values were obtained. For each of the 13 variables, the first P-value corresponds to the first test and the second P- value corresponds to the second test. The results of these tests are demonstrated in table 1.

Table 1: Comparison between the placebo and experimental groups (Mann Whitney Test)

VARIABLE	GROUP	P-VALUE	H_0 DECISION
irritability	placebo	0.885	accept
irritability	experiment	0.018	reject
disturbed sleep	placebo	0.766	accept
disturbed sleep	experiment	0.000	reject
decrease in appetite	placebo	0.730	accept
decrease in appetite	experiment	0.001	reject
increase in thirst	placebo	0.304	accept
increase in thirst	experiment	0.312	accept
drooling	placebo	0.512	accept
drooling	experiment	0.982	accept
sucking hands	placebo	0.692	accept
sucking hands	experiment	0.482	accept
biting on toys	placebo	0.827	accept
biting on toys	experiment	0.556	accept
hyperaemic gingiva	placebo	0.881	accept
hyperaemic gingiva	experiment	0.000	reject
oedematous gingiva	placebo	0.089	accept
oedematous gingiva	experiment	0.000	reject
cheek flushing	placebo	1.000	accept
cheek flushing	experiment	0.332	accept
peri-oral rash	placebo	0.317	accept
peri-oral rash	experiment	0.317	accept
loose stools	placebo	0.731	accept
loose stools	experiment	0.014	reject
temperature	placebo	0.675	accept
temperature	experiment	0.675	accept

The level of significance is fixed as $\alpha = 0.05$
Decision rule: reject H_0 if $p < 0.025$
accept H_0 if $p \geq 0.025$

CONCLUSION

The table clearly demonstrates a statistically significantly improvement achieved by the Homoeopathic complex in six of the thirteen variables. Remarkable improvements were achieved in terms of the patients' irritability, sleep disturbances and appetite. Hyperaemia and oedema of the gums and consistency of the stools were also indisputably improved by the complex.

Reduction in the patients' thirst, drooling, sucking of hands and biting of toys was not successfully achieved by the complex. Cheek flushing and peri-oral rash were also unaffected by the remedy and no change in temperature was noted.

TABLE 2: COMPARISON BETWEEN INITIAL AND FOLLOW-UP CONSULTATION FOR GROUP 1- 'PLACEBO' (WILCOXON'S SIGN RANKED TEST)

VARIABLE	P-VALUE	H_0 DECISION
irritability	0.479	accept
disturbed sleep	0.133	accept
decrease in appetite	0.617	accept
increase in thirst	1.000	accept
drooling	1.000	accept
sucking hands	0.479	accept
biting on toys	1.000	accept
hyperaemic gingiva	0.073	accept
oedematous gingiva	0.133	accept
cheek flushing	1.000	accept
peri-oral rash	unable to test -	nothing to compare
loose stools	1.000	accept
temperature	0.026	accept

The level of significance is fixed as $\alpha = 0.05$

Decision rule: reject H_0 if $p < 0.025$

accept H_0 if $p \geq 0.025$

CONCLUSION: There was no statistically significant change in any of the variables, between the initial and follow -up consultations.

TABLE 3: COMPARISON BETWEEN INITIAL AND FOLLOW-UP CONSULTATION
GROUP 2 - 'EXPERIMENT'
(WILCOXON'S SIGN RANKED TEST)

VARIABLE	P-VALUE	H_0 DECISION
irritability	0.002	reject
disturbed sleep	0.000	reject
decrease in appetite	0.023	reject
increase in thirst	0.002	reject
drooling	0.248	accept
sucking hands	0.073	accept
biting toys	0.073	accept
hyperaemic gingiva	0.002	reject
oedematous gingiva	0.000	reject
cheek flushing	1.000	accept
peri-oral rash	unable to test-	nothing to compare
loose stools	0.023	reject
temperature	0.023	reject

The level of significance is fixed as $\alpha = 0.05$

Decision rule: reject H_0 if $p < 0.025$
accept H_0 if $p \geq 0.025$

CONCLUSION: In eight of the variables a statistically significant improvement was achieved by the Homoeopathic complex.

CHAPTER 5- DISCUSSION

5.1 INTERPRETATION AND ARGUMENT

It can be deduced from the results of the study that the complex tested was effective in the treatment of problematic primary dentition.

Inflammation is characterized by oedema, hyperaemia and pain. The complex was found to have effectively reduced the hyperaemia and oedema of the gingiva. The decrease of pain achieved by the complex was effective in reducing the patient's irritability and sleep disturbances. It can thus be deduced that a reduction in the inflammation of the gingiva was successfully achieved by the Homoeopathic complex. These conclusions concur with the findings of Steinlechner (1984) who used Homoeopathy extensively in his dental practice, successfully treating conditions such as inflammatory changes of the mucosa, primary dentition and mental and physical trauma.

It was found by the researcher that a significant number of patients experienced loose stools while teething and that the complex was effective in treating this particular condition. This study thus supports the opinion that there is indeed a relationship between teething and diarrhoea as was demonstrated by the mail survey conducted by

Coreil et al (1995). The most common explanation for the relationship between teething and diarrhoea given by the respondents of the survey were changes in eating habits, increased salivation and stress. Due to the fact that the complex was ineffective in reducing the amount of drooling (increased salivation), but was effective in improving the appetite of the patients and the irritability and sleeping patterns; the research tends to support the opinions that the causes of the diarrhoea are changes in eating habits and stress. The drooling, or increased salivation, did not seem to play a significant role.

The role of temperature in a study of this nature is questionable. It was found that there was no correlation between the temperature of the patient, the eruption of the teeth, and the Homoeopathic treatment. A possible explanation for this is that the study referred to in the literature review, in which a correlation was found between fever and dental eruption, was a longitudinal one. The rise in temperature correlated to specific stages of the eruption process. In this study, the selection criteria did not include precise stages of eruption (Jaber et al 1992).

5.2 SPECULATION

This study has demonstrated that a Homoeopathic complex was used successfully in the treatment of the acute manifestations of problematic dental eruption. There were, however, symptoms and signs that were not successfully treated by the complex. It is

the author's speculation that the utilization of a 'Homoeopathic similimum' would have yielded better results. The reason for this suggestion is that it was found, by the researcher, that the symptoms presented by each individual patient did not always correspond to the symptom picture of the remedies that constituted the complex being studied.

CHAPTER SIX-CONCLUSIONS AND RECOMMENDATIONS

Based on the fact that that the objective of the study was to determine the efficacy of the Homoeopathic complex on the treatment of problematic primary dental eruption, in terms of its general and local manifestations, it can be concluded that the treatment was successful. This conclusion is based on the number of statistically significant improvements observed in the experiment group in contrast to the lack of improvement detected in the placebo group.

It is recommended that, should future studies of this nature be conducted, certain changes be made in the questionnaire. It is suggested that hand and finger sucking, and biting of toys and other objects, be combined into one question. The reasoning behind this suggested alteration is that it was found that the values assigned to these questions were frequently identical. It is also recommended that cheek flushing and circumoral rash be excluded from the questionnaire due to the fact that, in such a small study , these signs did not appear commonly enough to be of statistical value.

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APPENDIX A

CASE TAKING FORM FOR TEETHING RESEARCH

Name _____ Date _____
Date of birth _____ Age _____
Address _____
_____

Parent's details
Name of Mother _____ Father _____
Occupation _____ Occupation _____
Tel _____ Tel _____

History of main complaint _____
_____
_____
_____
_____
_____

Past History and treatment _____
_____
_____
_____

Birth History _____
_____
_____
_____

Vaccinations _____
_____

Allergies _____
_____
_____

Feeding and diet _____
_____
_____
_____

Sleep patterns _____

_____

_____

_____

Systems Review

ENT _____

_____

_____

_____

_____

_____

Respiratory System _____

_____

_____

_____

_____

_____

Digestive System _____

_____

_____

_____

_____

_____

Genito-urinary System _____

_____

_____

_____

_____

CardiovascularSystem _____

_____

Musculoskeletal System _____

_____

Physical examination

VITAL SIGNS

Temperature _____
Pulse rate _____
Respiratory rate _____

GENERAL EXAMINATION

Colour of mucosa _____
Dehydration _____
Lymph nodes _____
_____
Neck stiffness, Kernig's sign _____
Fontanelles _____
Dipstix (if indicated by urinary system history or unexplained pyrexia)_____

ENT
Ears
Right _____
Left_____
Throat_____
_____
Nose _____
_____
_____

ORAL EXAMINATION _____
_____
_____

CHEST EXAMINATION _____
_____
_____
_____
_____

ABDOMINAL EXAMINATION_____
_____
_____
_____
_____

APPENDIX B

INFORMED CONSENT FORM

(To be completed in duplicate by patient/subject*) *Delete whichever is not applicable.

TITLE OF RESEARCH PROJECT

_____

_____

NAME OF SUPERVISOR

_____

NAME OF RESEARCH STUDENT

_____

DATE:

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the research information sheet? YES/NO

2. Have you had an opportunity to ask questions regarding this study? YES/NO
3. Have you received satisfactory answers to your questions? YES/NO

4. Have you had an opportunity to discuss this study? YES/NO
5. Have you received enough information about this study? YES/NO

6. Who have you spoken to? _____

7. Do you understand the implications of your involvement in this study? YES/NO

8. Do you understand that you are free to withdraw from this study? YES/NO
   a) at any time
   b) without having to give a reason for withdrawing, and
   c) without affecting your future health care.

9. Do you agree to voluntarily participate in this study? YES/NO

PATIENT/SUBJECT* Name_____ Signature_____
(in block letters)

PARENT/GUARDIAN* Name_____ Signature_____
(in block letters)

WITNESS Name_____ Signature_____
(in block letters)

RESEARCH STUDENT Name_____ Signature_____
(in block letters)

APPENDIX C

HOMOEOPATHIC TEETHING RESEARCH

DENTAL REPORT
BY DR. H. CUNNINGHAM-GRAHAM

Name _____ Age _____
Date _____

ORAL EXAMINATION
Evidence of:

Angular cheilitis _____
Candidiasis _____
Dental decay _____
Eruption cyst _____
*Fracture of jaw _____
*Fracture of tooth _____
*Gingivitis _____
*Herpes _____
*Streptococcal infection _____
*Staphylococcal infection _____

(Patients with any of the conditions marked with a * will not be accepted into the research)

NAD (no abnormality detected) _____

Evidence of dental eruption _____

If yes, the following tooth (teeth) is erupting:

_____
_____
_____

Signature _____ Date _____

APPENDIX D

TEETHING QUESTIONNAIRE

Yvette Lever (Researcher)

Name _____
Number _____
Date _____
Initial consultation___ Follow up ___

Key : 0- not at all
1 - slight
2 - moderate
3 - severe

Please assess the following by referring to the key above and circling the appropriate number :

1. Is the patient irritable ?		0 1 2 3
2. Is the patient experiencing disturbed sleep ?		0 1 2 3
3. Is there a decrease in appetite ?		0 1 2 3
4. Is there an increase in thirst ?		0 1 2 3
5. Is the patient drooling ?		0 1 2 3
6. Is the patient sucking her/his hands and fingers ?		0 1 2 3
7. Is the patient biting on toys and other objects ?		0 1 2 3
8. Is the gum around the erupting tooth red ?		0 1 2 3
9. Is the gum around the erupting tooth swollen ?		0 1 2 3
10. Is there flushing of the cheeks?	Both cheeks	0 1 2 3
	Only left	0 1 2 3
	Only right	0 1 2 3
11. Is there a rash around the mouth?		0 1 2 3
12. Are the stools loose ?		0 1 2 3
13. Temperature		_____

APPENDIX E - DETAILED RESULTS

SUMMARY STATISTICS FOR ALL VARIABLES

Variable: y11

Average	1.6
Median	2.
Mode	3.
Standard error	0.349149
Range	3.
Coeff. of variation	84.515425

Variable: y12

Average	1.5625
Median	2.
Mode	2.
Standard error	0.288224
Range	3.
Coeff. of variation	73.785274

Variable: y21

Average	1.6
Median	2.
Mode	3.
Standard error	0.375436
Range	3.
Coeff. of variation	84.515425

Variable: y22

Average	0.3125
Median	0.
Mode	0.
Standard error	0.119678
Range	1.
Coeff. of variation	153.188337

Variable: y32

Average	2.125
Median	2.
Mode	2.
Standard error	0.179699
Range	2.
Coeff. of variation	33.825661

Variable: y41

Average	2.2
Median	3.
Mode	3.
Standard error	0.279455
Range	3.
Coeff. of variation	49.196615

Variable: y42

Average	0.5
Median	0.
Mode	0.
Standard error	0.182574
Range	2.
Coeff. of variation	146.059349

Variable: y51

Average	0.866667
Median	1.
Mode	0.
Standard error	0.273716
Range	3.
Coeff. of variation	122.319095

Variable: y52

Average	0.75
Median	0.
Mode	0.
Standard error	0.25
Range	3.
Coeff. of variation	133.333333

Variable: y61

Average	1.066667
Median	1.
Mode	0.
Standard error	0.315725
Range	3.
Coeff. of variation	114.637433

Variable: y62

Average	0
Median	0
Mode	0
Standard error	0
Range	0
Coeff. of variation	-32768

Variable: y71

Average	1.333333
Median	1.
Mode	0.
Standard error	0.30342
Range	3.
Coeff. of variation	88.135448

Variable: y72

Average	1.75
Median	2.
Mode	2.
Standard error	0.214087
Range	3.
Coeff. of variation	48.934219

Variable: y81

Average	1.266667
Median	1.
Mode	0.
Standard error	0.330464
Range	3.
Coeff. of variation	101.043233

Variable: y82

Average	0.6875
Median	1.
Mode	1.
Standard error	0.15052
Range	2.
Coeff. of variation	87.575233

Variable: y91

Average	0.933333
Median	0.
Mode	0.
Standard error	0.358126
Range	3.
Coeff. of variation	148.608708

Variable: y92

Average	1.125
Median	1.
Mode	0.
Standard error	0.30104
Range	3.
Coeff. of variation	107.036396

Variable: y101

Average	1.066667
Median	0.
Mode	0.
Standard error	0.358126
Range	3.
Coeff. of variation	130.03262

Variable: y102

Average	0.9375
Median	0.5
Mode	0.
Standard error	0.280903
Range	3.
Coeff. of variation	119.85176

Variable: y111

Average	1.
Median	0.
Mode	0.
Standard error	0.351866
Range	3.
Coeff. of variation	136.277029

Variable: y112

Average	1.125
Median	0.5
Mode	0.
Standard error	0.340037
Range	3.
Coeff. of variation	120.90196

Variable: y121

Average	1.133333
Median	0.
Mode	0.
Standard error	0.376281
Range	3.
Coeff. of variation	128.587905

Variable: y122

Average	0.6875
Median	0.
Mode	0.
Standard error	0.25362
Range	3.
Coeff. of variation	147.560512

Variable: y131

Average	0.933333
Median	0.
Mode	0.
Standard error	0.330464
Range	3.
Coeff. of variation	137.130101

Variable: y132

Average	0.9375
Median	0.5
Mode	0.
Standard error	0.295363
Range	3.
Coeff. of variation	126.02175

Variable: y141

Average	1.
Median	0.
Mode	0.
Standard error	0.338062
Range	3.
Coeff. of variation	130.930734

Variable: y142

Average	0.625
Median	0.
Mode	0.
Standard error	0.239357
Range	3.
Coeff. of variation	153.188337

Variable: y151

Average	1.333333
Median	1.
Mode	1.
Standard error	0.210819
Range	3.
Coeff. of variation	61.237244

Variable: y152

Average	1.3125
Median	2.
Mode	2.
Standard error	0.218303
Range	2.
Coeff. of variation	66.530473

Variable: y161

Average	1.666667
Median	2.
Mode	2.
Standard error	0.210819
Range	3.
Coeff. of variation	48.989795

Variable: y162

Average	0.375
Median	0.
Mode	0.
Standard error	0.125
Range	1.
Coeff. of variation	133.333333

Variable: y171

Average	1.4
Median	1.
Mode	1.
Standard error	0.190238
Range	3.
Coeff. of variation	52.627743

Variable: y172

Average	1.875
Median	2.
Mode	2.
Standard error	0.239357
Range	3.
Coeff. of variation	51.062779

Variable: y181

Average	1.666667
Median	2.
Mode	2.
Standard error	0.210819
Range	3.
Coeff. of variation	48.989795

Variable: y182

Average	0.3125
Median	0.
Mode	0.
Standard error	0.15052
Range	2.
Coeff. of variation	192.665513

Variable: y191

Average	0.066667
Median	0.
Mode	0.
Standard error	0.066667
Range	1.
Coeff. of variation	387.298335

Variable: y192

Average	0.125
Median	0.
Mode	0.
Standard error	0.125
Range	2.
Coeff. of variation	400.

Variable: y201

Average	0.133333
Median	0.
Mode	0.
Standard error	0.133333
Range	2.
Coeff. of variation	387.298335

Variable: y202

Average	0
Median	0
Mode	0
Standard error	0
Range	0
Coeff. of variation	-32768

Variable: y211

Average	0
Median	0
Mode	0
Standard error	0
Range	0
Coeff. of variation	-32768

Variable: y212

Average	0
Median	0
Mode	0
Standard error	0
Range	0
Coeff. of variation	-32768

Variable: y221

Average	0
Median	0
Mode	0
Standard error	0
Range	0
Coeff. of variation	-32768

Variable: y222

Average	0
Median	0
Mode	0
Standard error	0
Range	0
Coeff. of variation	-32768

Variable: y231

Average	0.466667
Median	0.
Mode	0.
Standard error	0.191899
Coeff. of variation	159.262147

Variable: y232

Average	0.5
Median	0.
Mode	0.
Standard error	0.158114
Range	2.
Kurtosis	0.027473
Coeff. of variation	126.491106

Variable: y241

Average	0.533333
Median	0.
Mode	0.
Standard error	0.215289
Range	2
Coeff. of variation	156.33926

Variable: y242

Average	0
Median	0
Mode	0
Standard error	0
Range	0
Coeff. of variation	-32768

Variable: y251

Average	36.566667
Median	36.4
Mode	36.4
Standard error	0.117379
Range	1.8
Coeff. of variation	1.243225

Variable: y252

Average	36.50625
Median	36.4
Mode	36.4
Standard error	0.151236
Range	2.7
Coeff. of variation	1.6571

Variable: y261

Average	36.44375
Median	36.25
Mode	36.2
Standard error	0.136005
Range	2.1
Coeff. of variation	1.492768