A three month study on the effect of chlorhexidine mouthrinse in the plaque control program of elderly patients in California

Thành Thị Nguyễn

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A THREE MONTH STUDY ON THE EFFECT OF CHLORHEXIDINE MOUTHRINSE IN THE PLAQUE CONTROL PROGRAM OF ELDERLY PATIENTS IN CALIFORNIA

A Thesis
Presented to the
Faculty of
California State University,
San Bernardino

In Partial Fulfillment
of the Requirements for the Degree
Master of Arts
in
Special Major

by
Thanh Thi Nguyen
December 1987
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Approved by:

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Dr. Ruth Wilson, Department of Biology.

Dr. Renate Nummela Caine, Department of Education.

Dr. Durwin Chamberlain, Department of Periodontics, School of Dentistry, Loma Linda University.
ABSTRACT

The effect of Chlorhexidine 0.12% mouthrinse on gingivitis and plaque accumulation in elderly patients was studied. Subjects from three nursing homes were assigned randomly to an experimental or placebo control group. Following a thorough examination and screening, subjects in the experimental group were given 0.12% CH while subjects in the placebo group were given a 0.00% CH placebo mouthrinse. Each group rinsed twice daily with 15 ml CH mouthrinse. Oral hygiene status, measured by plaque score and a bleeding score was evaluated after one, two and three months.

After the three months, results indicated that the 0.12% CH treatment had no significant effect on dental plaque over a placebo treatment. These results suggest that good oral hygiene alone is beneficial and the 0.12% CH mouthrinse provides no additional benefit over the effects of good oral hygiene alone.
ACKNOWLEDGEMENTS

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To Mr. Terence Bates, Unit Manager, Procter and Gamble Distributing Company, for support of this study.
To Mr. Kevin Kelly, Representative Oral B Company, for supplying the toothbrushes.

To the patients and staff in the three convalescent hospitals who participated in this study, for making it all possible.

This thesis is dedicated to my very special mother and sister, Kim Hoa and Huong Nguyen.
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CHAPTER I
INTRODUCTION

The positive correlation between the level of oral cleanliness of patients and the health of their gingival tissues has previously been the primary focus for the control of caries and periodontal disease (Adams, 1970; De La Rosa, 1975). To promote oral cleanliness, various oral physiotherapy agents such as toothbrushes, floss, interdental brushes and toothpick holders are employed by patients. Success is highly dependant upon the motivation and dexterity of the patient. A toothpaste with good anti-plaque properties which could supplement insufficient manual tooth cleaning would therefore be welcomed. Several studies have demonstrated that rinsing with a chlorhexidine solution will significantly reduce the formation of dental plaque (Loe and Schiott, 1970; Cunning and Loe, 1970). Such mouthrinses have become especially useful to handicapped patients and to patients receiving periodontal surgery (Bonesvoll, 1978; Westfelt, et al., 1983).

Although brushing with a gel or toothpaste containing chlorhexidine has been less extensively studied than rinsing, reports demonstrate significant improvement following either brushing with a chlorhexidine containing
gel or rinsing with a mouthrinse, both with regard to plaque scores (Bassiouny and Davies, 1975; Cutress, Brown and Baker, 1977) and gingival inflammation scores (Bassiouny and Davies, 1975). In addition, CH effects decrease the plaque flora of the tongue, oral mucosa and saliva, as well as the microbiota of dental plaque (Bain and Strahan, 1980).

The present study is intended to evaluate whether a mouthrinse containing chlorhexidine could improve the efficacy of mechanical plaque control procedures for periodontal conditions in elderly patients.

This study will:

1.- Compare dental plaque scores and gingival inflammation prevalence among patients in three nursing homes.

2.- Assess any differences between the chlorhexidine treated groups and the control (placebo) group, comparing both groups before mechanical removal of plaque.

3.- Establish routine brushing and flossing techniques for each patient.

4.- Determine the adequacy and effect of the chlorhexidine mouthrinse.

**Statement of Hypotheses**

Based on past studies and reports, significant differences in plaque and bleeding scores are predicted for treatment groups. A test of the null hypothesis will include the following:
1.- There will be no significant differences in plaque scores of patients receiving CH 0.12% and a placebo mouthrinse during the study period.

2.- There will be no significant differences in bleeding scores of patients receiving CH 0.12% and a placebo mouthrinse during the study period.

3.- No significant differences in plaque scores will be found between patients from different locations receiving the CH 0.12% and a placebo mouthrinse during the study period.

4.- No significant differences in bleeding scores will be found between patients from different locations receiving the CH 0.12% and a placebo mouthrinse during the study period.
CHAPTER II

REVIEW OF THE LITERATURE

Recent studies conducted in Europe which evaluate the effects of chlorhexidine mouthrinse programs over a period of time under controlled conditions present positive results. In addition, unique involvement of chlorhexidine mouthrinse in the inhibition of plaque formation has been recognized for many years in Canada, Denmark, Sweden and Switzerland.

Lindhe et al. (1970) reported a significant reduction of plaque and gingival inflammation in a dog treated by topical application of chlorhexidine. Confirming data were reported by Harvey et al. (1983). In an investigation by O'Neil (1976), it was concluded that chlorhexidine mouthrinse was the probable cause for the reduction of plaque and gingivitis in human subjects.

Cancro et al. (1972) noted that most studies evaluating the effectiveness of chlorhexidine gluconate mouthrinse have been done with adult populations who were using chlorhexidine gel or toothpaste and were brushing and flossing. Intraoral rinsing with chlorhexidine has been shown to be an effective means of plaque control. The long-term record of chlorhexidine rinsing seems particularly
good (Foulkes, 1973). There have been occasional reports of side effects associated with chlorhexidine rinsing. In 1972, Flotra, et al. published results of a study designed to clinically assess the effects of chlorhexidine rinsing on the oral health of 50 soldiers. Three of the soldiers developed multiple soft tissue lesions that healed when the rinsing stopped and did not reappear in two of the three when rinsing was resumed.

Langebaek et al. (1976) conducted a study in Canada using the crossover double-blind design to measure the effect of 0.12% CH digluconate mouthrinse on healing after gingivectomy. The healing process of gingivectomy improved when the surgical area covered with Coe Pak. Healing was promoted when chlorhexidine was used and subjects maintained good oral hygiene.

Since the early investigations, much has been done. Articles by Emilson et al. (1976), Bain et al. (1978), and Tryggve et al. (1985) summarized the tremendous amount of work which has been carried out in the United States and the other countries directed toward determining the mechanism underlying the chemical effectiveness of chlorhexidine gel in plaque and gingivitis reduction. Subsequent studies have shown that chlorhexidine mouthrinse is even more beneficial than gel and dentifrices in controlling the extent of dental plaque and gingivitis in an adult population.
Subsequent researchers reached similar conclusions and agreed in general with prior studies (Sturzenberger et al., 1986; Grossman et al., 1986). These researchers stressed the fact that "a more standardized approach will need to be adopted in order to ensure that data from a series of coordinated studies are compatible."

It is interesting to note the statistical information in evaluating the effects of chlorhexidine mouthrinse. Brushing with chlorhexidine gel over a twelve-week period showed significant changes for both oral hygiene level and the gingival inflammation in a group of maintenance care patients with poor oral hygiene (Tryggve et al., 1985).

Brown staining of the teeth has so far been the only adverse effect that has prevented a more extensive long-term use of CH. This stain can be removed with routine polishing procedures. High concentrations of 2% CH digluconate taken over long periods of time may cause burning sensations, dryness and desquamation of the oral tissues (Eriksen et al., 1973). At the end of six months, statistically significant differences were found between the two groups: less gingivitis, gingival bleeding and plaque accumulation were observed in the test group as compared to the placebo group. No significant differences in adverse oral soft tissue effects were observed between the two groups.
However, researchers conducted a study to test the reduction in plaque and gingivitis effect of chlorhexidine mouthrinse in "a population of adult subjects receiving systematic oral health care and prevention and control of gingivitis at home" (Catherine et al., 1980). The results of this study indicated statistically significant differences between the adult subjects participating in the chlorhexidine mouthrinse program and those in the control group.

**Product**

Chlorhexidine is a chlorophenyl biguanide with broad antimicrobial activity. CH gluconate, the most suitable salt, has been used in preparation of the patient as surgical scrub and as a hand wash for health care personnel (AMA, 1983). It has also been used as a preservative for opthalmic products and has been used internally at a 0.2% concentration in the peritoneal cavity and bladder (Case, 1977).

In dentistry, CH has been investigated as a plaque control agent for control of smooth surface caries (Low, Von Der Fehr, and Rindom, 1972) and as a denture disinfectant particularly in regard to Candida Albicans (Budtz and Loe, 1972). CH is the most extensively tested agent with consistently positive results. CH appears both to inhibit the formation of plaque and to control plaque already present. Although CH has even shown some degree of
effectiveness in the absence of home care measures, its use should only be considered to be adjunctive in nature. CH should never be considered as a substitute for thorough initial therapy and the establishment of the best conventional home care possible.

**Adverse Effects**

The adverse effects of CH in a mouthrinse appear to be minimal. Widespread use over many years, especially in Europe, has shown a remarkable safety record. CH is poorly absorbed from the GI tract so that even if some is inadvertently swallowed, the chance of a systemic effect is essentially negligible. CH does not appear to penetrate intact gingiva, but may have toxic effects on exposed subepithelial cells (Tonelli, Hume and Matsunaga, 1982). No significant adverse clinical effects relating to this have been reported. However, poorly defined desquamative lesions have sometimes followed the use of a CH mouthrinse. Surprisingly, an increase in calculus formation may be observed. Dryness and burning sensations have sometimes followed the use of CH rinses.
Potential Benefits

A CH containing mouthrinse, Peridex, has now been approved by the Food and Drug Administration for use in the United States. Although there appears to be little question of the effectiveness and relative safety of mouthrinse containing 0.12% CH, each specific product must be approved on its own merits.

In 1986, Sturzenberger et al. presented a report of a six-month clinical evaluation of 0.12% CH gluconate mouthrinse. They found that the beneficial effects of a prophylaxis against gingivitis were maintained over a six-month test period by the CH rinse, but not by a placebo rinse. Also in 1986, Grossman et al. published a report on a six-month trial of the effects of the same 0.12% CH gluconate mouthrinse on plaque and gingivitis. The 430 adult subjects were instructed to rinse twice daily for 30 seconds with 15 ml of the CH gluconate mouthrinse. Their usual home care procedures were to continue. After three and six months of use, the chlorhexidine group had significantly less gingivitis and gingival bleeding than did the placebo group. No significant differences in adverse oral soft tissue effects were observed between the two groups. It was concluded that a 0.12% CH gluconate mouthrinse can provide an important adjunct to the prevention and control of gingivitis when used with regular personal oral hygiene procedures and professional care.
CHAPTER III

METHODS AND PROCEDURES

This study examined the value of the use of Chlorhexidine mouthrinse in plaque control in elderly patients in California. Information relevant to the study was collected simultaneously from three nursing homes: two in Indio and one in San Bernardino.

Definition of Terms

The following words are defined to ensure a clear understanding of the study:

Plaque Scores: The presence of plaque was disclosed by a 15 second rinse with a standard red dye (Phloxine B Red #28) gel. The quantification of plaque on six surfaces of each natural tooth, (mesio-facial, facial, disto-facial, disto-lingual, lingual and mesio-lingual) was recorded by a dicotomous scoring which indicated either presence or absence of plaque. Plaque was measured as being present at gingival margin when it stained dark with Phloxine disclosing gel and also was easily removed with the side of a probe (Figure 1).

The plaque score for the entire mouth was determined by dividing the total number of tooth surfaces identified as
having plaque by the number of sites examined for each individual patient. Example: \[ \frac{40}{168} \times 100 = 23\% \] Plaque score.

**Bleeding Scores:** The bleeding score was determined after probing of the six defined sites of the tooth and then evaluating for presence or absence of bleeding for each site. By using periodontal probe with Michigan markings (MI, Marquis Dental) the probe was directed at the mesio-buccal, buccal, disto-buccal, disto-lingual, lingual and mesio-lingual margins of the gingiva, resulting in a total of six scores per tooth. The bleeding score for the entire mouth was determined by dividing the total number of sites that exhibited bleeding by the number of sites probed for each individual patient.

Example \[ \frac{10}{168} \times 100 = 5\% \] Bleeding score.

**Chlorhexidine 0.12% mouthrinse:** Chlorhexidine was originally introduced into dentistry to facilitate post-surgical wound healing and for disinfecting root canals. The initial report of CH's antiplaque property was made by Schroeder in 1962. In 1970, Loe and Schiott reported the prevention of gingivitis (inflammation of the gums) with use of 0.20% CH digluconate applied twice daily (Loe et al., 1973).

Although CH is widely used in Europe in such countries as Denmark, Great Britain, Sweden, and Switzerland for dental treatment, it was not approved by the FDA for routine

A considerable number of studies show that use of 0.12% CH has decreased plaque accumulation and diminished gingivitis. CH 0.12% mouthrinse is of particular value for patients in convalescent hospitals and people with physical or mental handicaps. Since improper plaque removal is conducive to caries and periodontal disease, an effective chemical may be beneficial for those patients.
Figure 1.- Index for measuring plaque scores

(V) Check indicates presence of stained plaque in boxes corresponding to surfaces with plaque MB, ML, DB, DL, B, L.
**Limitations**

The collection of data was limited to the study of two types of recorded data: plaque and bleeding scores. The data was also limited to the forty-two patients, ranging in age from 50-80 years, whose dental examination records were available. All scoring of those patients was performed by one examiner. It was difficult to examine the oral hygiene practice in those patients with physical or mental disabilities.

**Study Population and Sampling Technique**

The population sampled in this study consisted of fifty elderly patients. Their ages ranged from 50 to 80 years, with a mean age of 65. Eight males and forty-two females were included. Two nursing homes in Indio, CA (Del Rosa) were selected at random from a large sample of convalescent hospitals. The subjects were selected by the nursing staff of each nursing home based on the patients' past history of good oral hygiene and no serious history of health problems. The majority of patients at all three sites had no treatment needs and had neither obvious gum disease nor obvious decay in their teeth. During the course of the study, four subjects died and four others did not complete the program, reducing the number of subjects for analyses to forty-two. In addition, a baseline examination was conducted at the beginning of the study to ensure an adequate number of teeth, at least 8-10 per subject, and to
evaluate present oral hygiene status.

An additional refined data analysis was conducted on a smaller sample size of 25 subjects. Based on baseline scores, subjects were selected for this data analysis if they had a plaque score of between 20 and 40. These are indicated as either (a) for CH placebo or (b) 0.12% CH treatment in Appendix A-3, A-4, A-5, (m = mechanical cleaning). The smaller sample size was a more accurate representation of the population under study.

**Study Design**

Subjects were randomly assigned to either an experimental group (Group A, n = 25) or a placebo control group (Group B, n = 25). For Group A, the mouthrinse contained a 0.12% CH gluconate mouthrinse. For Group B the solution was a placebo made from ethyl alcohol, glycerine, distilled water and food coloring, which matched the CH solution in taste, appearance and texture. The mouthrinse was supplied in pint bottles. Plastic measuring cups and 30-second timers were provided to assist in the dispensation and application of the mouthrinse. In order to assure a double-blind design, neither the nursing staff members nor the investigator knew which group the subjects had been assigned to. Both solutions were coded by a periodontist who placed the coded number with the group assignment of each subject in a sealed envelope to ensure that group assignment was not known to the treatment staff or the
subjects.

After signing a written consent form (Appendix A-1) the subject was provided with oral hygiene instruction. The program consisted of a standard oral hygiene program including disclosure of plaque and instruction in the use of a mouthrinse. The examiner spent four days a week assisting in the dispensing, application, and use of the mouthrinses. Subjects spent one hour daily in improving oral hygiene habits. The mean cost of the program was five dollars per patient per month. Including the baseline examination, the final cost was twenty dollars per patient.

Measures

Three measures (plaque, gingival bleeding, and oral soft tissue effects) were used in this study. The presence of plaque was discovered after staining with a 15 second rinse with a disclosing gel (Phloxine B Red #28). Presence of plaque was recorded if an area of clearly stained plaque was present along the gingival margin and if plaque could be removed with the side of a probe (Figure 1). This assessment for plaque was made at each of the following six tooth surfaces of each natural tooth: mesio-facial, facial, disto-facial, disto-lingual, lingual and mesio-lingual. The percentage of tooth surfaces with plaque out of the total number of examined tooth surfaces was calculated.

The gingival bleeding score was determined by using a periodontal probe with Michigan markings (MI, Marquis
Dental) to probe the mesio-facial, facial, disto-facial, disto-lingual, lingual and mesio-lingual surfaces on each tooth surface of the gingiva resulting in a total of six scores per tooth. During probing of each of the six sites of the teeth, the probe was gently moved twice in the apical direction to secure finding the base of the pocket. After removal of the probe, the gingival margin was examined and the presence of bleeding was recorded. If hemorrhage was noted subsequent to the probing, a positive score was recorded.

Oral soft tissue effects were also evaluated. To monitor oral soft tissue health, a visual tactile examination of the oral mucosa was conducted to detect pathoses which could possibly be attributed to Chlorhexidine uses (V. A. Segreto et al., 1986).

**Procedures**

Both the experimental (group A) and the control or placebo (group B) subjects received identical, standardized oral hygiene instruction about the use of a soft toothbrush and dental floss with the mouthrinse twice daily for thirty seconds.

Subjects in both the experimental (Group A) and placebo (Group B) groups were evaluated at baseline (day 0) and at four weeks, eight weeks and twelve weeks in the study period.

Each treatment period lasted for four weeks during
which the subject rinsed twice daily for thirty (30)
seconds with 15 ml of the mouthrinse. At each examination,
the examiner used portable equipment, perio probes, and
mouth mirrors, examined the patients and recorded plaque and
bleeding scores.
CHAPTER IV

RESULTS

Twenty five experimental (Group A) and twenty five control (Group B) subjects were solicited from the three nursing homes for the study. Of the fifty subjects who enrolled in this study, forty two completed three months of mouthrinse use. The eight dropouts were patients who either died or could not meet examination schedules.

Each subject received an evaluation of plaque and bleeding indices (baseline scores) prior to receiving either the placebo or 0.12% CH mouthrinse (Table 1, Figure 1).

Initial evaluations by the investigator indicated observable differences in oral hygiene prior to start of the study. The results of an analysis of variance shows significant differences (p<.001) in plaque and bleeding (p<.002) scores of patients at baseline that was dependent upon location. Subjects in Desert Palm nursing home had significantly higher (worse) scores for both plaque and bleeding than patients at both Mul Care and Del Rosa.
Table 1. Mean plaque and bleeding scores by location (Mul Care, Del Rosa and Desert Palm nursing homes) at Baseline.

<table>
<thead>
<tr>
<th>Locations</th>
<th>Plaque scores (a)</th>
<th>Bleeding scores (b)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± S D</td>
<td>Mean ± S D</td>
</tr>
<tr>
<td>Desert Palm</td>
<td>37.230 ± 9.86</td>
<td>17.615 ± 7.85</td>
</tr>
<tr>
<td>Del Rosa</td>
<td>27.692 ± 7.57</td>
<td>7.846 ± 5.97</td>
</tr>
<tr>
<td>Mul care</td>
<td>25.500 ± 9.25</td>
<td>9.875 ± 7.02</td>
</tr>
</tbody>
</table>

a. Sig of f, p<.001
b. Sig of f, p<.002
Figure 1a. Mean Plaque scores and Bleeding scores by locations (Desert Palm, Mul Care and Del Rosa nursing homes) at Baseline.
Baseline plaque and bleeding scores are shown in Table II and represented in Figure 2. An analysis of the variance showed no significant differences in plaque and bleeding scores of patients at the start of the study that was dependent upon the group (A, treatment; (B), placebo) to which they had been randomly assigned.
Table II. Mean Plaque and Bleeding scores by groups 0.12% Chlorhexidine vs. Chlorhexidine placebo at baseline.

<table>
<thead>
<tr>
<th></th>
<th>Desert Palm</th>
<th>Del Rosa</th>
<th>Mul Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque</td>
<td>39.666</td>
<td>35.142</td>
<td>28.142</td>
</tr>
</tbody>
</table>
Figure 2. Mean Plaque and Bleeding scores by groups 0.12% CH vs. CH placebo at baseline.
Plaque and bleeding at baseline, one, two, and three months are shown in Table III and represented in Figure 3. An analysis of the variance yielded a significant $F$ (F (1,36) = 12.3, p<.001) for changes in both plaque and bleeding (F (1,36 = 1.57, p<.002) scores for subjects.
Table III. Comparison of ANOVA in Plaque and Bleeding scores over three months time.

<table>
<thead>
<tr>
<th></th>
<th>One month</th>
<th>Two months</th>
<th>Three months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>F    df  sig f</td>
<td>F    df  sig f</td>
<td>F    df  sig f</td>
</tr>
<tr>
<td>Plaque Scores</td>
<td>12.3 (1,36) P&lt;.0013</td>
<td>41.15 (1,36) P&lt;.0001</td>
<td>76.13 (1,36) P&lt;.0001</td>
</tr>
<tr>
<td>Bleeding Scores</td>
<td>1.57 (1,36) P&lt;.2176</td>
<td>6.74 (1,36) P&lt;0.0136</td>
<td>29.11 (1,36) P&lt;.0001</td>
</tr>
</tbody>
</table>

There are significant changes in Plaque (p<.001) and bleeding (p<.002) scores for both experimental and control groups over three months time.
Figure 3. Mean Plaque and Bleeding scores over time.

Length of study (3 months)

Plaque: O-O
Bleeding: □-□
Plaque scores at baseline, one, two, and three months for the experimental and placebo groups are shown in Table IV and represented in Figure 4. An analysis of the variance yielded no significant differences in plaque scores over the three month study period that was dependent on receiving a 0.12% CH mouthrinse or a placebo solution.

Table IV. Comparison of treatment groups over three months time for mean Plaque scores.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean Plaque Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
</tr>
<tr>
<td>CH Placebo</td>
<td>26.81</td>
</tr>
<tr>
<td>0.12% CH</td>
<td>32.81</td>
</tr>
</tbody>
</table>

Baseline vs. 1 month $F(1,36) = .06$, $p < .80$
Baseline vs. 2 months $F(1,36) = 1.51$, $p < .20$
Baseline vs. 3 months $F(1,36) = 1.38$, $p < .20$
Figure 4. Plaque scores schedule of 0.12% CH vs. CH Placebo over time (3 months). There are no significant differences between plaque scores of experimental and control groups over time (3 months).
Bleeding scores at baseline, one, two, and three months for the experimental and placebo groups are shown in Table V and represented in Figure 5. An analysis of the variance yielded no significant difference in bleeding scores over the three month study period that was dependent on receiving a 0.12% CH mouthrinse or a CH placebo solution.

Table V. Comparison of treatment groups over three months time for mean Bleeding scores.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean Bleeding Scores</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>One month</td>
<td>Two months</td>
<td>Three months</td>
<td></td>
</tr>
<tr>
<td>CH Placebo</td>
<td>11.00</td>
<td>11.52</td>
<td>9.62</td>
<td>6.95</td>
<td></td>
</tr>
<tr>
<td>0.12% CH</td>
<td>12.29</td>
<td>14.57</td>
<td>9.43</td>
<td>6.71</td>
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Baseline vs. one month $F(1,36) = 0.68$, p<.400
Baseline vs. two months $F(1,36) = 0.90$, p<.35
Baseline vs. three months $F(1.36) = 0.69$, p<.40
Figure 5. Bleeding scores schedule of 0.12% CH vs. CH placebo over time (3 months).

There are no significant differences between bleeding scores of experimental and control groups over time (3 months).
Refined Data Analysis

Because of the wide variance in baseline plaque scores, ranging from 6 to 63, a refined data analysis was used. Only patients with plaque scores between 20 and 40 were included. This eliminated subjects with extreme scores. Refined analysis followed the basic application of ANOVA and student's t tests to the data.

Statistical analysis of plaque at baseline for three convalescent hospitals was established with a sample size of 25 (combined placebo and CH groups).

Mean plaque at baseline in Desert Palm was 31.375
Mean plaque at baseline in Del Rosa was 30.181
Mean plaque at baseline in Mul Care was 27.000

Comparison plaque P (Placebo or control) 1 month vs. 3 months was noted. Significance was found between the placebo group in the amount of plaque at one month vs. three months, F (1,26 = 71.217, p<.001. There were also significant differences between the CH group in the amount of plaque at one month vs. three months, F (1,20) = 18.949, p<.001.

Therefore, the improvement was due to treatment and mechanical brushing, but no significant difference was found between CH and Placebo groups:

Baseline: At baseline, there was no significant difference in plaque scores between the experimental group and the control group, F (1,23) = .056, p<.97.
One month vs. three months: At one month vs. three months, no main effects were found between CH and Placebo groups, $F(1,26) = 6.411, p<.941$.

Although improved scores were noted for both CH and Placebo, the CH and Placebo groups did not diverge significantly from each other.
CHAPTER V

DISCUSSION

This study was conducted to evaluate the gingival bleeding and plaque scores of elderly patients at three nursing homes and to assess the effectiveness of 0.12% CH mouthrinse during three months of twice daily use. Side effects such as oral pathoses, calculus formation and tooth stain were also monitored.

There were no significant differences in bleeding between the baseline and time 1 (one month) measurements ($F_{(1,36)} = 1.57, p<.217$). There was a significant difference from the baseline to time 2 (two months after baseline) ($F_{(1,36)} = 6.74, p<.013$), as well as a significant difference from the baseline to time 3 (three months after) ($F_{(1,36)} = 29.11, p<.0001$).

Measurement showed a significant decrease in plaque at the one month ($F_{(1,36)} = 12.13, p<.001$) as well as significant differences from the baseline and the two months ($F_{(1,36)} = 41.15, p<.0001$), and baseline to the three months ($F_{(1,36)} = 76.13, p<.0001$).

However, these decreases in both bleeding and plaque scores were seen in both groups, control and experimental. No significant differences were found between the CH
treatment group and the placebo group in the amount of plaque and bleeding, (CH mean = 24.35, p<.129) at either one month, two months or three months. Significant differences were found between the nursing home locations and of plaque and bleeding scores (F (2,36 = 8.16, p<.001). It seemed that these differences were due to the lower level of oral hygiene in patients at Desert Palm whose plaque score (mean = 30.42) was higher than the other two locations (Del Rosa, mean = 18.10, Mul Care, mean = 19.35).

There were no significant differences between the CH and placebo over time. Differences did exist at the study start however, in plaque that were dependant on location. At the start plaque was different at the nursing homes, Desert Palm, Mul Care and Del Rosa.

The mean bleeding scores of both groups were increased in the first month. Ten subjects were sick and unable to take care of their oral hygiene (Figures 1 & 2). Otherwise, the 0.12% CH group showed significant improvements (83%) in both bleeding and plaque scores at the end of the third month. The placebo group showed (67%) improvement in bleeding and plaque.

This study did not demonstrate significant effect of 0.12% CH treatment. This could possibly be due to the types of patients used in this study. The 0.12% CH mouthrinse did not work in older patients who were less mentally and physically active and who may not have been able to fully
Subjects, there were differences in taste between CH mouthrinse in comparison to the placebo. In fact, the 0.12% CH mouthrinse produced a slight burning sensation in the mouth, so the subjects did not like the mouthrinse compared to the placebo subjects. They suggested one could expect better compliance with mouthrinse containing less than 0.12% CH. Therefore, they may not have followed the instructions for using the mouthrinse sufficient for 0.12% CH to have had a successful impact on plaque and gingival bleeding.

Several past studies have demonstrated that rinsing with a 0.12% CH solution will significantly reduce the formation of dental plaque (Loe and Schiott, 1970; Cunning and Loe, 1973). Greenstein (1984) discussed the evaluation of gingival bleeding as not only more diagnostic, but also reflective of histological, clinical and bacteriological tissue alterations. Researchers also state "the absence of bleeding in previously inflammed tissue can be interpreted that there has been an improvement on the periodontal status" (Greenstein, 1984).

In addition, 0.12% CH has been shown to reduce aerobes, anaerobes, anaerobes and actinomyces by 54-97%. Consequently, the reduced gingivitis may be partly due to the reduced pathogenity of the plaque (Briner et al., 1968a).

Articles by Loe et al., (1976) and Lange et al., (1982) showed reduction in gingivitis even though there was an
showed reduction in gingivitis even though there was an increase in supragingival calculus. In this study, the examiner observed the subjects' supragingival calculus in the 0.12% CH treated group. There were no significant increase in supragingival calculus, but there was a significant decrease in gingivitis. There was also no sign of extrinsic tooth staining in the 0.12% CH treated group. This may be due to low levels of compliance. No significant differences in adverse oral soft tissue effects were noted between the two groups.

The results of this study suggest that oral hygiene is beneficial. The improvements in bleeding and plaque scores were possibly due to patients being influenced by the attention of the dental professionals who cared for them. Motivational education is necessary to produce lasting behavioral changes. A good plaque control program, effectively maintained in nursing homes, is important for good oral care.

The design of this study does not allow separate interpretations of the effect of the improved oral hygiene and the effectiveness of the mouthrinse. Only one month of observation was scheduled between the start of the oral hygiene and the first treatment. During this month, ten patients were sick, so the plaque and bleeding scores were affected in the treatment.
Recommendations

Based on the experiences of this research process, the following recommendations are suggested for future studies of Chlorhexidine mouthrinse:

1. It would be useful to have dental health records available for each subject in order to make a more accurate evaluation of their dental health;

2. Patients should be individually scored on their pre-test oral hygiene conditions and divided into groups with equal plaque scores (high plaque, low plaque) from which random division into test and control groups would be made;

3. Since reliability of scoring is compromised with one scorer, a team of scorers should be trained, and their techniques standardized prior to study start;

4. Since this study clearly demonstrated the need for oral hygiene in nursing home patients, future studies might address different application procedures to increase compliance by elderly patients;
5. Studies might be conducted in dental clinics or dental schools instead of the convalescent hospitals to increase reliability of Chlorhexidine application.
CHAPTER VI

SUMMARY AND CONCLUSIONS

Forty two patients from Del Rosa, Desert Palm and Mul Care convalescent hospitals were involved in a study of the effect of 0.12% CH mouthrinse in producing changes in their oral hygiene habits as well as the reduction in plaque and gingivitis. Subjects were divided into a control and an experimental group. The oral hygiene effectiveness of the subjects was measured with a plaque score and bleeding score at baseline, one, two and three months after using 0.12% CH mouthrinse.

A statistical analysis was done to determine the effect of 0.12% CH. There was no significant difference between the treatment group and placebo group. There were significant improvements in the oral hygiene of the elderly in both groups. The results indicated that there was a significant difference in the gingival bleeding measured from the baseline measurement at time 2 (two months after baseline) and time 3 (three months after). There were also significant differences in plaque from the baseline and "two months after" and "three months after."

The following conclusions were drawn:

1) oral hygiene is beneficial,
2) patient motivation had an influence in the reduction of plaque and bleeding scores when used in conjunction with personal and professional oral hygiene procedures,

3) the 0.12% CH mouthrinse did not seem to have any clinical benefits to those elderly patients.
APPENDIX
CONSENT TO PARTICIPATE IN STUDY

I, ________________________, do hereby agree to be a participant in a three (3) month study period measuring the effects of tooth brushing and flossing versus the same tooth brushing and flossing technique in conjunction with the use of a predetermined amount of chlorhexidine (CH) mouth-rinse.

I have been informed that I will receive an initial prophylaxis treatment, including scaling, to establish equal dental hygiene conditions for both study groups. I will be given the tooth brushing and flossing instructions necessary to participate in this study, and I will be given periodic oral examinations to determine the results of this care. I am aware that I may or may not be in the group receiving the mouthrinse supplement.

CH was originally introduced into dentistry to inhibit the formation of plaque and to control plaque already present and lower the incidence of gingivitis, (both inflammation and bleeding gums).

Side effects of CH .12% are relatively minimal, although it has a bitter taste, and with chronic use a brown discoloration may occur. This stain can be removed with routine polishing procedures. High concentrations of CH .2% taken over long periods of time cause burning sensations, and/or dryness of the oral tissues.

If I am in the group using the placebo solution mouthrinse, I will have access to treatment after the study. I will be assigned a code number. This number, not my name, will be used for recording at all four examination test periods.

I may withdraw from participation in this study for any reason and at any time. My participation is voluntary and my willingness or lack thereof will not affect the care I am receiving.

SIGNATURE DATE
WITNESS DATE
FORM II. LETTER CONCERNING DENTAL CARE

December 18, 1987

To: Tri County Dental Hygiene Association

I have currently been observing the dental health care of elderly patients as part of my Master's thesis on 0.12% CH mouthrinse. As health care providers, Dental Hygienists or Dental Professionals have an obligation to help these patients improve oral health care.

For this reason, and based on my awareness of the Dental Public Health needs of elderly patients in convalescent hospitals in California, I would propose a program to use RDHs or Dental Hygienist students to:

1. Assist patients in Dental Health Education and to make dental knowledge and services available to them.

2. Help reduce periodontal disease and dental caries by improving the oral health care of these patients.

Measurable improvements will result from in-service programs conducted by Dental Professionals practicing dental health education in convalescent hospitals. My observation, based on my study of the effectiveness of 0.12% CH mouthrinse in three California nursing homes, is that current programs for oral hygiene and plaque control are very poor. More and better attention to oral health care is needed. Instruction and continued follow-up supervision would be effective in reducing plaque and bleeding scores in these patients.

I ask your consideration and cooperation in providing highly skilled Hygienists and Dental Professionals to contribute to the Preventive Dentistry Program and the control and prevention of periodontal disease in nursing home patients.

Sincerely,

Thanh T. Nguyen, R.D.H.

TtN:cw

cc: Tri County DHA
Dr. Judson Klooster, Dean, School of Dentistry, Loma Linda University
Ms. Joni Self, Chairperson, Dental Hygiene Department School of Dentistry, Loma Linda University.
Dr. Clifton Dummett, U.S.C.
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a = CH placebo used for refined analysis
b = 0.12% CH used for refined analysis
m = mechanical treatment between check up
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### DEL ROSA

**Subjects**

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\(^a\) = CH placebo used for refined analysis  
\(^b\) = 0.12% CH used for refined analysis  
\(^m\) = mechanical treatment between check up
BIBLIOGRAPHY


AMA Division of Drugs. AMA Drug Evaluation, Ed. 6, Phil.: Saunders, 1983.


