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Clinical Effectiveness of Listerine[R] and Viadent[R] Mouthrinses on Bacterial Plaque and Gingivitis

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by

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ABSTRACT

CLINICAL EFFECTIVENESS OF LISTERINE^{R} AND VIADENT^{R} MOUTHRINSES ON BACTERIAL PLAQUE AND GINGIVITIS

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The purpose of this investigation was to determine the effects of two commercial mouthrinses, Listerine^{R} and Viadent^{R}, on bacterial plaque and gingivitis. Over a six-week period, 24 adults, ages 18-41, were examined for the amount of bacterial plaque and level of gingivitis using Silness and Löe's Plaque Index (PLI) and Gingival Index (GI). At the beginning of each two week period, subjects were examined for the amount of plaque and level of gingivitis and given a different mouthrinse: appointment one--Viadent^{R} (mouthrinse A), appointment two--placebo mouthrinse (mouthrinse B), and appointment three--Listerine^{R} (mouthrinse C). Additionally, subjects were given oral and written mouthrinsing instructions at each appointment. A double-blind, cross-over design was used in this experimental pre-test/post-test research study. Results were tabulated on the basis of change in the mean Plaque and Gingival Index scores. Data were examined using a one-way analysis of variance and Tukey's Studentized Range Test to determine if any statistically significant differences

existed in the mean GI scores and PLI scores throughout all four appointments. Additionally, a Paired-Difference t-test was applied to data to determine if the independent variables, Viadent^{R} mouthrinse and Listerine^{R} mouthrinse, had a statistically significant effect on the dependent variables, gingival inflammation and bacterial plaque. Results showed that rinsing with either Viadent^{R} or Listerine^{R} mouthrinse as an adjunct to routine oral hygiene had no statistically significant effect on the level of gingivitis or the amount of bacterial plaque.

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CHAPTER 1

Introduction

Periodontal disease is a serious dental health problem among most populations. The prevalence of periodontal disease is world-wide and is the leading cause of adult tooth loss. Seventy-five percent of the adult population, age 18-79, have experienced some form of periodontal disease while 50 percent of the missing teeth in adults can be attributed to this oral disease.[1] Although the outcome of this disease may not be fatal, the consequence of missing teeth or an edentulous mouth can affect the nutritional and emotional status of an individual. Furthermore, periodontal disease can result in tremendous economic and social burden upon the individual and upon society.[1,21,23,25]

Gingivitis, an inflammation of the gingiva, is the first sign of periodontal disease. The presence of bacterial plaque has been established as an important etiologic factor in the initiation of gingivitis and its progression to the more severe stage of periodontitis.[1,16,21,26] Prevention and control of dental plaque are of primary importance in preventing periodontal disease. Mechanical removal of dental plaque by the individual with a toothbrush and dental aids such as floss, interproximal brushes, and wood points have been demonstrated to be safe, effective

methods of plaque control.[17,24,26] Thorough removal of plaque on a lifetime basis is essential to prevent periodontal disease; however, lack of motivation, poor manual dexterity, or insufficient knowledge may prohibit a patient from mechanically removing dental plaque effectively from his/her teeth. Therefore, the use of a chemical agent or a mouthrinse that may be an effective anti-plaque agent is appealing to both the public and dental professionals.[18,24]

The purpose of this study was to determine the effectiveness of Listerine^{R} and Viadent^{R} mouthrinses in the reduction of plaque and subsequent gingivitis. Subjects and methods utilized in this study were chosen in order to simulate the population who are most likely to use these rinses and the way in which they would be used.

Many anti-plaque agents have been investigated and many are still under study. Two chemotherapeutic agents, alexidine and chlorhexidine have received considerable attention and research since the early 1970's. Although these antiseptic agents appear to be effective in plaque control and partially effective in reducing gingivitis, due to adverse effects they are not available in the United States.[3,5,7,10,14,15,16,24]

Commercial mouthrinses are available to the public and have been researched for their ability to control plaque and subsequent gingivitis.[4,8,9,11,17,18,20,23,27] In several studies reviewed, subjects were dental students or dental professionals. These subjects may be more aware of their

oral health than the general population, therefore affecting the validity of these studies. Also, in numerous studies the investigator improved the subjects' gingival health and removed all plaque prior to initiation of the study period. Subjects with no plaque on their teeth or gingiva may not be representative of the general population; therefore, results may not be applicable to a population where oral hygiene may be less than ideal. Realistically, individuals using a mouthrinse will have some plaque accumulation and existing levels of gingivitis.

Statement of the Problem

The general research question addressed was: Is there a significant reduction in the amount of plaque and the incidence of gingivitis when a mouthrinse is used as an adjunct to normal oral hygiene practices?

Specific questions addressed were:

1. Over a two week period, will rinsing with Viadent^{R} as an adjunct to routine oral hygiene practices have a statistically significant effect on the amount of plaque formed when compared to rinsing with a placebo rinse?

2. Over a two week period, will rinsing with Viadent^{R} as an adjunct to routine oral hygiene practices have a statistically significant effect on the incidence of gingivitis when compared to rinsing with a placebo rinse?

3. Over a two week period, will rinsing with Listerine^{R} as an adjunct to routine oral hygiene practices

have a statistically significant effect on the amount of plaque formed when compared to rinsing with a placebo rinse?

4. Over a two week period, will rinsing with Listerine[R] as an adjunct to routine oral hygiene practices have a statistically significant effect on the incidence of gingivitis when compared to rinsing with a placebo rinse?

Significance of the Problem

The recognition of dental plaque, and its constituent microorganisms, as the primary etiologic factor in gingivitis has been reported in the dental literature.[1] A major objective of preventive dentistry is the control or elimination of dental plaque.[1] Dental literature has indicated that an effective method for controlling or removing dental plaque is by mechanical means. An effort must be made by the individual to mechanically remove plaque with a toothbrush and dental aids such as dental floss, interproximal brushes, and wood points. However, lack of motivation, poor manual dexterity, or insufficient knowledge may be a problem prohibiting a patient from effectively removing dental plaque solely by mechanical means.

An effective, safe, inexpensive anti-plaque mouthrinse could have a significant impact in preventing or controlling gingivitis in the general population. In addition to the use of an anti-plaque mouthrinse in routine, daily oral hygiene practice, an effective anti-plaque agent may be appealing in numerous clinical situations where daily conventional oral hygiene practices are temporarily

impossible or difficult. These situations might include the treatment of fractured jaws or in orthognathic surgery. An anti-plaque, antiseptic mouthrinse possibly could be used as a disinfectant prior to surgery and as part of the oral hygiene maintenance therapy during the postoperative period when teeth are in fixation. In orthodontics, an anti-plaque mouthrinse could be utilized where treatment with fixed bands is indicated and routine oral hygiene may be difficult.

Handicapped patients could benefit from a mouthrinse to help prevent the formation of dental plaque and subsequent gingivitis, as the capability of these patients to practice mechanical means of plaque removal may be limited. An anti-plaque mouthrinse requiring no manual dexterity could contribute to the overall health of the oral structures.[9] Additionally, an anti-plaque mouthrinse could be utilized in the treatment of acute periodontal infections and in post-surgical treatment.[9]

Listerine^{R} is a commercial mouthrinse that has been under investigation in several clinical studies.[4,8,17,18] Listerine^{R} has been marketed for many years; recently the manufacturer has claimed that the product reduces plaque up to 50 percent in conjunction with regular toothbrushing compared to brushing alone. The majority of the studies performed suggest that Listerine^{R} is effective in reducing plaque; however, its effectiveness in reducing gingivitis at a significant level remains questionable.[4,8,17,18] Viadent^{R}

is a commercial mouthrinse that has recently become available to the public. Because this product is specifically designed to reduce plaque, Viadent^{R} has been used in several clinical trials.[9,11,20,27] Although, the results of these studies indicate that Viadent^{R} may be an effective anti-plaque agent, no clinical evidence exists on its effect on gingivitis.

Convenience, availability, and easy usage of commercial mouthrinses are factors which appeal to the public. This short-term clinical trial investigated the anti-plaque activity of Listerine^{R} and Viadent^{R}. Results of this study may be significant in determining the value of commercial mouthrinses in the control or prevention of periodontal disease.

Definition of Terms

For the purpose of this study, the following terms were defined.

1. Dental Plaque--A dense, noncalcified, complex mass of bacterial colonies in a gel-like intermicrobial matrix which adheres firmly to the acquired pellicle, and hence to the teeth, calculus, and fixed and removable restorations.[25]

2. Gingivitis--Inflammation of the gingiva characterized clinically by gingival hyperplasia, edema, retractability, gingival pocket formation, and no bone loss.[21]

3. Gingival Index (GI)--An index (developed by Löe and Silness 1963) which evaluates the gingival status at the clinical level and assesses the severity of gingivitis

based on color, consistency, and bleeding on probing. Four gingival areas (distal, facial, mesial, and lingual) are examined systematically for the chosen teeth in each arch. Each of the four gingival areas is given a score of zero to three. Scores for each area are totalled and divided by four. The Gingival Index is determined by totalling the scores and dividing by the number of teeth examined. Index scores range from zero to three.[13]

4. Plaque Index (PLI)--This index created by Löe and Silness (1964) corresponds to the Gingival Index systematically. Each of the four gingival areas of the tooth are given a score from zero to three; this score is the Plaque Index for the area. Scores from the four areas of the tooth may be added and divided by four to give the Plaque Index for the tooth. Scores for individual teeth may be grouped to designate the Plaque Index for the groups of teeth. Finally, by adding the scores for the teeth and dividing by the number of teeth examined, the Plaque Index score for the individual is obtained.[13]

5. Commercial Mouthrinses--Mouthrinses that are available to the public without a prescription. The manufacturers of these rinses have made claims concerning the anti-plaque ability of these products.

6. Dental Hygiene Examiner--A dental hygienist who examined the teeth and gingiva of the subjects using the PLI and GI as standard measurements.

7. Subjects--Adults age 18-40 selected from a group

of volunteers.

8. Placebo Mouthrinse--Distilled water with mint extract flavoring.

9. Routine Oral Hygiene--The procedures practiced on a daily basis for the removal of debris and dental plaque from the gingiva and teeth.

Assumptions

For the purpose of this study, the following assumptions were made:

1. The presence or absence of gingivitis at the initial examination is an indicator of the individuals' periodontal health.

2. The amount of plaque present on the subjects' teeth at the initial examination is a true representation of their routine oral hygiene status.

3. The Plaque Index is a valid and reliable method for measuring the amount of dental plaque.

4. The Gingival Index is a valid and reliable method for measuring gingival inflammation.

5. All subjects understood and followed standardized mouthrinsing instructions precisely as given by the principal investigator.

6. All subjects continued to practice their routine oral hygiene procedures with the exception of the experimental rinse throughout the test period.

7. The measuring instruments were scored properly and results were tabulated correctly.

8. The subjects were representative of the population that uses the commercial mouthrinses tested in this study.

9. The subjects did not receive any oral hygiene instruction other than the mouthrinsing instructions given by the principal investigator.

Limitations

The validity and reliability of this study may have been limited by the following:

1. The subjects' awareness of participating in a dental health study may have altered their routine oral hygiene practices. However, subjects were instructed not to alter their routine oral hygiene care with the exception of rinsing with the given mouthrinses.

2. Because it is not possible to supervise home rinsing, subjects may have missed scheduled rinses or not rinsed for the specified time as instructed. However, the subjects were informed of the importance of following precise instructions concerning the frequency of rinsing, amount of mouthrinse, and length of time for rinsing.

3. Over the six week study period subject mortality did occur. Of the initial 30 subjects who started, 24 subjects completed the six week study. Subjects did receive a complimentary prophylaxis at the completion of the study which might have motivated subjects to remain in the study.

4. Because a convenience sample population was used, results may not be representative of the general population.

The sample was selected randomly from a large group of volunteers representative of the population most likely to use commercial mouthrinses.

5. Results might have been limited by the inconsistent scoring of plaque and gingivitis by the Dental Hygiene examiner. However, intrarater reliability was established prior to the study; therefore, inconsistent scoring should have been minimized or eliminated.

Hypotheses

The following null hypotheses were tested at the 0.05 level of significance:

1. There is no statistically significant difference in the incidence of gingivitis of subjects who use a placebo mouthrinse and subjects who do not use a mouthrinse as measured by the Gingival Index.

2. There is no statistically significant difference in the incidence of gingivitis of subjects who use Viadent^{R} mouthrinse and subjects who use a placebo mouthrinse as measured by the Gingival Index.

3. There is no statistically significant difference in the incidence of gingivitis of subjects who use Listerine^{R} mouthrinse and subjects who use a placebo mouthrinse as measured by the Gingival Index.

4. There is no statistically significant difference in the amount of bacterial plaque of subjects who rinse with a placebo mouthrinse and subjects who do not use a mouthrinse as measured by the Plaque Index.

5. There is no statistically significant difference in the amount of bacterial plaque of subjects who use Viadent^{R} mouthrinse and subjects who use a placebo mouthrinse as measured by the Plaque Index.

6. There is no statistically significant difference in the amount of bacterial plaque of subjects who use Listerine^{R} mouthrinse and subjects who use a placebo mouthrinse as measured by the Plaque Index.

Methodology

An experimental, randomized subjects, pre-test/post-test design was used to test the effectiveness of Listerine^{R} and Viadent^{R} mouthrinses on the accumulation of bacterial plaque and the level of gingivitis. Twenty-four adult subjects, ages 18-41, participated in this study for a test period of six weeks.

A double-blind, cross-over design was used which allowed the subjects to serve as their own controls. Subjects attended four appointments at the Old Dominion University Dental Hygiene Clinic. One Dental Hygiene examiner measured the amount of plaque and the level of gingivitis using the Plaque Index and the Gingival Index, respectively. Each subject was supplied with an adequate amount of mouthrinse for a two-week test period. Also, at each appointment, subjects were given standardized written and oral mouthrinsing instructions by the principal investigator. At the initial appointment, baseline Plaque Index and Gingival Index scores were established. After each two

week period subjects were required to attend a dental appointment to be examined for the amount of plaque and the level of gingivitis. The subjects were given a different mouthrinse at each of the three appointments: appointment one--Viadent^{R} (mouthrinse A), appointment two--Placebo (mouthrinse B), appointment three--Listerine^{R} (mouthrinse C). At the end of the study subjects were given a final examination for the amount of plaque and the level of gingivitis using the Plaque Index and the Gingival Index. Results were evaluated using a one-way analysis of variance (ANOVA) and the Tukey's Studentized Range Test to determine if statistically significant differences existed in GI score means and PLI score means throughout the four appointments. A paired-difference t-test was applied to data to determine the effect of the two independent variables, the mouthrinses, on the dependent variables, gingivitis and bacterial plaque.

CHAPTER 2

Review of the Literature

Literature on oral mouthrinses pertinent to this study was reviewed and organized into the two following subtopics: (1) Chemotherapeutic Mouthrinses and (2) Commercial Mouthrinses.

Chemotherapeutic Mouthrinses

Literature has indicated that an effective method for controlling or removing dental plaque is by mechanical methods.[3-5,12,24,25,27] However, low motivation or lack of manual dexterity may be a problem prohibiting a patient from effectively removing dental plaque by mechanical methods.[16,17,24,25] Therefore, the literature suggests that an effective, safe, and inexpensive chemotherapeutic agent is needed if a major impact is to be made on the large number of patients with periodontal disease.[3,4,5,8,12,17,18,19]

Consequently, numerous studies have researched a variety of potential chemotherapeutic agents for their ability to control or eliminate dental plaque.[2-5,8-11,14,15,17-20,23-28] Many chemotherapeutic agents have been proposed, investigated, or are under investigation. Antiseptics, enzymes, herbal extracts, essential oils, and

antibiotics are a few agents that have been tested clinically.[3,16,26] Systemic antibiotics have been used to treat periodontal disease but potential long term use of these antibiotics may cause health problems.[19] Because of these potential health problems, several studies have researched topical antimicrobial agents. Results of these studies suggest that it is possible to eliminate or control the formation of dental plaque and subsequent gingivitis with the aid of a daily rinse or topical application of a non-antibiotic, anti-bacterial agent.[2,3,8,10,12,14,15,17,19,24,27] Two of the anti-bacterial agents that have been investigated since the early 1970's are chlorhexidine and alexidine.

Chlorhexidine

Chlorhexidine used as a therapeutic agent in the prevention or control of periodontal disease is a new application for this drug. Chlorhexidine has been used for many years as an antiseptic, but only recently has it been considered as a possible anti-plaque agent.[5,10] Chlorhexidine was introduced to the medical profession in the early 1950's as a general disinfectant. Since then, its major use has been as a topical antiseptic for presurgical skin preparations.[10]

Chlorhexidine gluconate is commercially available in the United States as a 4.0 percent solution with a mild sudsing base (Hibiclens^{R}) and as a tincture solution containing 0.5 percent chlorhexidine gluconate in 70 percent

isoprophyl alcohol. In the form of a prophylactic ointment, chlorhexidine with a concentration of 1.0 percent has been used to prevent skin infections. Chlorhexidine is an effective topical agent for the treatment of burns and superficial skin lesions. Chlorhexidine was initially introduced to the dental procedure as an agent to wash operation sites and disinfect root canals during endodontic treatment. The first report of chlorhexidine's potential anti-plaque ability was made by Schroeder in the early 1960's. In the late 1960's, studies were conducted to test chlorhexidine's ability to control plaque. Conclusions from these initial studies describe chlorhexidine's action in inhibiting and controlling dental deposits on human teeth.[10,22] Results from these studies did not present sufficient data to make valid conclusions about the anti-plaque activity of chlorhexidine.

Bactericidal properties are crucial to most antiseptic uses and chlorhexidine's antiseptic ability suggests that it may be effective in controlling dental plaque.[10] The bacteriostatic spectrum of chlorhexidine is of a wide activity with gram-positive cocci being especially sensitive. The lethal action of chlorhexidine has been tested on a variety of living organisms. Exposure of suspensions of various bacteria to 0.2 percent chlorhexidine for ten minutes at room temperature reduced the living organisms by about 99 percent. Oral Streptococcus mutans were tested and the extent of destruction of these organisms depended on

whether or not the suspension medium included sucrose. Organisms grown in the presence of sucrose produce extracellular polysaccharide, and chlorhexidine adheres to this material considerably reducing the amount available to act on the bacteria.[10]

Hennessey[10] conducted a pilot study on four adults to determine the sensitivity of the total salivary aerobic flora to chlorhexidine. Total salivary aerobic flora was monitored during a course of daily treatment with chlorhexidine; one subject practiced usual oral hygiene procedures and the other three rinsed with chlorhexidine gluconate solution for one minute immediately after each (twice daily) toothbrushing session. Treatment continued for seven weeks. At intervals, saliva samples were collected and total viable counts were made of culture plates containing different concentrations of chlorhexidine. The proportion of organisms in the control subject was constant on three occasions. The three subjects rinsing with chlorhexidine showed a reduction in sensitivity which appeared to improve as treatment progressed. Results of this clinical trial indicated that the bacteria in saliva from different individuals varied in susceptibility to the bacteriostatic action of chlorhexidine. Additionally, there was a transitory reduction in this sensitivity when treatment was in progress. Changes in susceptibility of organisms described in this pilot study refer to a sensitivity of organisms to the bacteriostatic action of chlorhexidine. No evidence of

alterations in sensitivity to the bacteriocidal action of chlorhexidine existed.

Although Hennessey[10] states that this study was a pilot, the sample size limits the validity of the results. No scientific evidence of alterations in the bactericidal action of chlorhexidine is reported. The bactericidal action is the property required of an antiseptic for its successful use in oral hygiene.

Löe and Schiott[14] conducted a study to compare the effectiveness of chlorhexidine gluconate delivered in three different methods on the formation of dental plaque. The three methods investigated were: two daily mouthrinses with a 0.2 percent solution; one daily rinse with a 0.2 percent solution; and one daily topical application of a 2 percent solution of chlorhexidine gluconate. Twenty-four dental students, age 20-25, had their teeth scaled and polished prior to each experimental period. They were instructed to practice proper oral hygiene using toothbrushing and wood sticks. Subjects were examined periodically to establish a baseline which approached zero using the Plaque Index and the Gingival Index as standardized measurement. After a baseline of zero was established, all oral hygiene procedures ceased and the subjects were assigned randomly to one of four experimental groups. Two groups used chlorhexidine as a mouthrinse. Group A, four subjects, rinsed with 10 ml of 0.2 percent aqueous solution of chlorhexidine gluconate for one minute twice a day. After 22 days, sub-

jects ceased rinsing and continued on a no oral hygiene regimen for the following 11 days. Group B, eight subjects, rinsed with 10 ml of a 0.2 percent aqueous solution of chlorhexidine gluconate for one minute once daily for 40 days. Group D used the topical application as its method of delivery. This group consisted of six students who during the first experimental period had a 2 percent aqueous solution of chlorhexidine gluconate applied daily to their teeth for fifteen consecutive days. Four weeks after completion of this treatment a second treatment was initiated using a placebo solution once daily for fifteen days. Group C served as the control group in this investigation. Six students performed no oral hygiene and did not receive chlorhexidine for 22 days.

Löe and Schiott [14] report the results of this study in two categories; mouthrinsing and topical application. Mouthrinsing Group A demonstrated that substitution of mechanical oral hygiene procedures continued with two daily rinses of 0.2 percent chlorhexidine gluconate resulted in prevention of plaque formation and no gingival changes. Mean Plaque and Gingival Index scores on day 22 were 0.05. When these same subjects discontinued rinsing and practiced no other oral hygiene, the Plaque and Gingival Index scores increased at a rate corresponding to the scores of the non-rinsing control group.

Group B, which rinsed with a 10 ml solution of chlorhexidine gluconate once daily, demonstrated less significant

results. The mean PLI score at the end of the 40 day experimental period was 0.22. All subjects displayed a corresponding development of gingivitis to the formation of plaque as measured by Gingival Index scores as high as 0.46. Results for group D suggest that when a 2 percent topical application of chlorhexidine gluconate is used daily, the formation of dental plaque is inhibited. Plaque and Gingival Index scores ranged from zero to 0.06. Group C using the placebo solution developed plaque according to the normal pattern. On day 15 the mean Plaque Index score ranged from 1.56 to 1.82 and the mean Gingival Index scores ranged from 0.54 to 0.71.

The authors conclude from the results of this investigation that two daily mouthrinses with a 0.2 percent solution of chlorhexidine gluconate effectively prevent plaque formation and subsequent development of gingivitis. In addition, results reveal that one daily rinse with the same concentration of chlorhexidine is not effective in controlling plaque formation and subsequent gingivitis. However, if chlorhexidine is applied topically in a two percent solution once a day and reaches all tooth surfaces, plaque formation is completely inhibited.

No rationale explaining the use of varied number of days in each experimental group was presented in this article. The only assumption is that the investigators were comparing length of treatment, in addition to concentration and method of application of chlorhexidine gluconate. The

number of subjects in each group was limited and not uniform in all four groups, therefore affecting the validity of the study.

In a study by Cumming and Löe[5], the effect of increasing the volume and the concentration of the chlorhexidine rinse needed to control plaque formation was evaluated. Additionally, the authors compared the application of chlorhexidine with an oral irrigator to normal rinsing with the chlorhexidine solution. The amount of staining caused by the various dosages was examined. Each subject received a professional dental prophylaxis and was encouraged to practice thorough oral hygiene prior to the experimental period. Both the Gingival Index scores and the Plaque Index scores were approximately zero at the initiation of the study.

In this double-blind test, subjects were assigned randomly to seven groups. Each group used different volumes of chlorhexidine, 200 ml, 400 ml, 700 ml, applied with an oral irrigator and 20 ml, 50 ml, 100 ml, and 200 ml solutions used in normal rinsing procedures. On a rotational basis, subjects received all concentrations, 0, .01, .025, .05, .075, 0.1, 0.15, and 0.2 percent, once during each nine-day test period. Plaque accumulation was assessed at the end of each trial period using the Plaque Index. Each nine-day test period was separated by five days in which subjects practiced traditional oral hygiene procedures with no applications of chlorhexidine.

Mean Plaque Index scores for each of the seven groups with each of the various concentrations were obtained. After analyzing scores, results revealed that by increasing the concentration of chlorhexidine, the plaque score was lowered. Plaque scores decreased rapidly at first, but then reached a point beyond which further increases in the concentration of chlorhexidine (0.075-0.2 percent concentration) had little effect on lowering Plaque Index scores. The concentration at which there was little effect on the Plaque Index score was identified as the optimal concentration for that particular group.

Optimal concentration, method of application, and volume of chlorhexidine solution for each of the seven groups is as follows:

GROUP NUMBER	METHOD OF APPLICATION	VOLUME	OPTIMAL CONCENTRATION	PLAQUE SCORE
1	ORAL IRRIGATOR	700 ml	0.05%	0.2
2	ORAL IRRIGATOR	400 ml	0.05%	0.3
3	ORAL IRRIGATOR	200 ml	0.1%	0.2
4	NORMAL RINSING	200 ml	0.075%	0.35

GROUP NUMBER	METHOD OF APPLICATION	VOLUME	OPTIMAL CONCENTRATION	PLAQUE SCORE
5	NORMAL RINSING	100 ml	0.075%	0.40
6	NORMAL RINSING	50 ml	0.1%	0.35
7	NORMAL RINSING	20 ml	0.2%	0.40

The authors conclude that concentrations of chlorhexidine gluconate used at a lower percent than the traditional 0.2 can retard plaque accumulation. They continue that it is apparent that good oral hygiene, PLI scores 0.2

to 0.3, are obtained with concentrations as low as .025 to .05 percent and the formation of plaque on several tooth surfaces can be prevented with concentrations of only .01 to .025 percent. Cumming and Löe[5] conclude that if larger volumes are used, concentrations lower than 0.2 percent are necessary. Furthermore, the inhibition of plaque in the posterior regions of the oral cavity is more effective with the use of an oral irrigator than normal rinsing. Also, brown staining of the teeth is decreased with larger volumes of dilute concentrations than with small volumes of stronger concentrations.

A test period of nine days is not sufficient to determine conclusively the relationship between volume, concentration, and degree of staining. The authors recognize this limitation, but state that the results of this study reveal that using larger volumes of chlorhexidine rinse is useful in minimizing degree of tooth staining. Another limitation of this study which may affect the validity of the results is that the subjects tested were periodontaly healthy dental students, and exhibited better oral hygiene than the normal population. Results may not be as positive if the sample population was varied. No statistical analysis of data were presented in this article.

Löe et al.[16] conducted a two-year study of the long term effects of daily chlorhexide gluconate application on the development of dental plaque, calculus, and periodontal disease. The study also monitored changes in oral micro-

biology and any systemic or local side effects following prolonged use of chlorhexidine.

Following an initial screening examination, 120 volunteers, age 20-26, from the dental and medical schools in Aarhus, Denmark, were subjects in this study. An experimental group of 61 medical and dental students used 10 ml of a 0.2 percent aqueous solution of chlorhexidine gluconate daily in addition to toothbrushing and interdental cleansing. A control group of 59 students used a placebo rinse in addition to toothbrushing and interdental cleansing.

A three-month baseline pilot study was conducted to assure that significant levels of plaque and gingivitis were present prior to the introduction of chlorhexidine into the oral hygiene regimen. Data were collected using Plaque, Gingival, and Calculus Indices.

At the beginning of the experimental period all subjects were provided a dental prophylaxis. Color photographs were taken of the buccal aspect of the teeth and gingiva to establish the baseline for the presence of stain. Staining subsequently was assessed on a scale designed by the author using one examiner. At the initial and following examinations, the Plaque and Calculus Indices were scored by one examiner, and the Gingival Index and loss of periodontal attachment were scored by another examiner. Thirty-five students were selected at random from both the experimental and the control groups to study the effect of chlorhexidine

on Streptococcus mutans in dental plaque. After initial assessments were completed, subjects were instructed to brush with a toothpaste for 30 seconds every morning using the roll method and for 60 seconds every evening using 10 ml of the prescribed solution. The experimental group was given a 0.2 percent aqueous solution of chlorhexidine gluconate while the control group was given a similar solution not containing chlorhexidine gluconate.

Assessments were made in January, February, June, and September of 1971. Results of the dental examinations performed in September, 1971 revealed that subjects in the control group were maintaining a more effective level of oral hygiene than had been anticipated from the tests made to establish baseline criteria in October and December, 1970.

In October, 1971 all subjects received a thorough prophylaxis. Oral hygiene regimens were adjusted in an effort to produce a more effective use of chlorhexidine. The experimental group was instructed to rinse instead of brush for one minute daily with 10 ml of a 0.2 percent gluconate solution. The control group was instructed to follow the same regimen using a placebo solution. Both groups were allowed to brush in any manner. After a three-month period, dental examinations were conducted.

Statistical evaluation of the data revealed that during the initial eight months of chlorhexidine application, plaque indices decreased in both groups from their reference

baseline. Nevertheless, the chlorhexidine group consistently showed significantly lower plaque scores, at the 0.05 level of significance, than the control group. The mean Gingival Index score of the chlorhexidine group was significantly lower, at the 0.05 level of significance, than that of the control group during the first 18 months. Although the chlorhexidine group demonstrated a substantial decrease in the mean Gingival Index score as compared with that of the control group at the final scoring, this was not a statistically significant reduction. When chlorhexidine was applied with a toothbrush, the results demonstrated a significantly higher degree of toothstaining, than the control group. When chlorhexidine was used as a mouthrinse, the group demonstrated less staining of the teeth and the placebo group exhibited no stain. The chlorhexidine group obtained a higher Calculus Index score than the control group; however, the increase in supramarginal calculus was not statistically significant.

Löe et al.[16] claim that the results from this two-year study demonstrates that chlorhexidine treatment reduces plaque and gingivitis. No general health problems associated with the two-year use of daily antimicrobial treatment were found. The main problem resulting from daily rinses with chlorhexidine is the increased incidence of stain formation on tooth surfaces. Results of this long term study by Löe et al.[16] demonstrated that over a two-year period, one daily application of chlorhexidine, in addition

to conventional oral home care, significantly reduces the growth of plaque on the teeth and gingiva. These results confirm the earlier short term clinical studies conducted by Löe and Schiott[14] on chlorhexidine. However, no statistically significant reduction in gingival inflammation occured as a result of this study. Furthermore, the chlorhexidine group demonstrated a higher Calculus Index than the control group throughout the active part of the study. No statistically significant differences were found between the mean loss of periodontal attachment in the control and experimental groups.[16]

The study by Löe et al.[16] is the only long term study reported in this review and appears to adhere to scientific standards for a clinical investigation. Limitations noted in this long term study are similar to those reported in the short term studies.[5,14] Subjects used in this study were young dental students who may be more aware of their oral hygiene than the general population. All subjects were given a professional prophylaxis prior to and periodically throughout the experimental period. These subjects may not be representative of the general population who have existing levels of gingivitis and plaque accumulation.

Alexidine

Another chemotherapeutic agent that has been under investigation is alexidine. Studies have reported the effectiveness of alexidine in the reduction of dental plaque and gingivitis.[2,3] Alexidine is a synthetic antibacterial

substance and is of interest to the dental profession because of its anti-plaque properties.[3]

Carlson et al.[3] conducted a six month experimental study using alexidine. Purposes of this study were to: (1) determine the safety in adults in a six month twice-a-day use of 0.35 percent alexidine rinse, (2) evaluate the effectiveness of alexidine in controlling gingivitis when used in conjunction with usual oral hygiene, (3) determine the effectiveness of alexidine in reducing dental plaque formation when used in conjunction with usual oral hygiene, and (4) evaluate the extent to which alexidine stains the teeth.

Two-hundred fifty subjects, from a group of 1,000 volunteers, age 18 to 70, were screened using Gingival Index scores as the basis for inclusion in the study. Only subjects with a minimum score of 0.8 were included in the study. Plaque and stain were evaluated prior to the experimental period. Subjects were assigned randomly to a placebo or experimental group.

A week's supply of mouthrinse was given to each subject and participants were instructed that 15 ml of the rinse be used twice daily for one minute, first in the morning after breakfast and second in the evening before retiring. At day 15, each subject was examined for adverse reactions to the alexidine mouthrinse. At days 30, 60, and 180, complete examinations of the teeth and gingiva were conducted.

The six month study was completed by 199 individuals.

Results of data analysis indicated a statistically significant ($P<0.005$) reduction between groups using the alexidine rinse and groups using the placebo rinse according to plaque scores. A reduction in gingivitis after six months use was noted, but scores were not statistically significant. Seventy-five percent of the participants in the experimental group exhibited brown stain on the teeth compared to 40 percent of the placebo group participants. Additionally, stain occurred on the dorsum of the tongue in 14 of 96 subjects using the experimental rinse. Brown stain increased significantly from day zero to day 180 ($P<0.005$) in the experimental group.

Spolsky and Forsythe[24] investigated the long term effect of alexidine mouthwash in retarding or reversing gingivitis in conjunction with routine oral hygiene. Other objectives of this six month study were to determine if there were any side effects associated with using alexidine, to evaluate its potential to stain teeth and to measure its effect on plaque.

Two-hundred fifty subjects randomly selected from a University of California, Los Angeles staff directory participated in this double-blind study. One hundred and three subjects assigned randomly to the experimental group and 111 subjects assigned to the placebo group completed the six-month study. The experimental mouthwash contained 0.035 percent alexidine in a 17.6 percent aqueous alcoholic solution and the placebo was similar with the exclusion of

alexidine.

A baseline examination was performed and subjects were instructed to rinse twice daily with 15 ml of their assigned mouthwash immediately after brushing. Subjects were instructed not to alter their usual oral hygiene practices with the exception of rinsing with their given mouthwash.

On days 0, 30, 90, and 180, subjects were examined for gingivitis, plaque and extrinsic tooth stain. The examiner used the Quigley and Hein Index, the PMA Index of Schour and Massler, and a scale of 0-3. Statistical analysis of the results revealed that plaque scores on day zero were comparable for the alexidine and placebo groups. On days 30, 90, and 180 statistically significant differences were found in plaque scores between the two groups. Using a one-tailed t-test, the differences between the placebo and alexidine groups were significant on day 30 ($P<0.01$), day 90 ($P<0.001$) and 180 days ($P<0.05$).

Analysis of gingivitis scores support that the alexidine mouthwash had a highly significant effect on reducing gingivitis. Over a six-month period, the use of alexidine twice daily, showed a decrease in gingivitis scores of 31.6 percent in the experimental group compared to a decrease of 2.8 percent in the placebo group. By day 30, the differences between the alexidine and placebo groups were statistically significant at the 0.01 level, became more significant ($P<0.001$) by 90 days and remained at that level for the remainder of the study.

Over a six-month period, the use of alexidine mouthwash twice daily resulted in an increase of extrinsic tooth stain. By day 30, a statistically significant difference ($P<0.001$) was found between the alexidine and placebo groups. Differences in tooth staining between the two groups remained significant throughout the six-month study.

The authors conclude that the data presented illustrate the highly significant statistical and clinical decreases in gingivitis due to the twice daily use of alexidine. The increase in plaque scores in both groups at day 30 might be due to several factors. Interexaminer variability might be source of error and/or the Quigley and Hein criteria for measuring plaque might be too insensitive for detecting small changes in plaque that occurred in the first 30 days.

Commercial Mouthrinses

Several commercial mouthrinses are available to the public and could be considered as potential anti-plaque agents. Their value in plaque reduction or the prevention of plaque formation has been under investigation in several clinical studies.[4,8,17,18,27]

Listerine^{R}

Lusk et al.[17] conducted a study to investigate the effects of Listerine^{R} mouthrinse on experimental gingivitis, formed plaque, and plaque formation. Thirteen periodontists, age 30-45, were selected as subjects for this

study. The Navy Periodontal Index and Navy Plaque Index (modified) were used to evaluate the condition of the gingiva and the accumulation of plaque in each subject's mouth. On day one, each subject was examined for gingivitis and was scored using the Navy Periodontal Disease Index. Additionally, each subject was evaluated for plaque accumulation and scored according to the Navy Plaque Index (modified). Subjects received a dental prophylaxis to establish a baseline plaque score of zero. Each participant was instructed to refrain from all oral hygiene procedures for twelve days and to rinse vigorously with water for one minute, three times daily.

On day twelve, participants were examined for plaque and gingivitis using the same scoring criteria as the initial evaluation. A prophylaxis was performed to establish a plaque score of zero with the exception of the mandibular right quadrant. The mandibular right quadrant remained untouched in order to establish the effect of the test mouthwash on twelve-day formed plaque. Following the second evaluation, subjects were instructed to rinse vigorously for twelve days with the test mouthwash for one minute, three times daily without performing any other plaque control procedures. Twelve days later the subjects were examined and scored for plaque and gingivitis. Again a plaque score of zero was established with the exception of the mandibular right quadrant. Subjects were divided randomly into two groups in order to study the effect of a

change in duration and frequency of rinsing on plaque formation and on existing plaque. One group was instructed to rinse with Listerine[R] for five seconds after breakfast, after lunch, and before bedtime. Neither group was allowed to practice any other plaque control procedures.[3] Twelve days later all subjects were examined and scored for gingivitis, plaque formation, and formed plaque.

Statistical analysis of the collected data revealed that the increase in gingivitis was significant ($P<0.01$) after twelve days of rinsing with water exclusively when compared to initial gingival scores. When Listerine[R] was used for one minute, three times a day, significantly less gingivitis ($P<0.01$) was evident when compared to the scores after the first twelve days of comparable rinsing with water. Additionally, less gingivitis was present after using Listerine[R] for five seconds, three times daily, when compared to the water rinse but the difference was not significant. No difference between the mean gingival scores were found after twelve days of rinsing with the test rinse for one minute before retiring than when the subjects rinsed for one minute, three times daily with water.[17]

A significant reduction in plaque formation scores ($P<0.01$) was evident when subjects rinsed with Listerine[R] for one minute, three times daily, for twelve days when compared to twelve days of rinsing with water. Mean plaque scores were significantly greater ($P<0.01$) for the Listerine[R] when compared to mean plaque scores after the subject's own plaque control regimen.

Results of this study suggest the following: (1) Listerine[R] was effective in reducing experimental gingivitis, plaque formation, and existing plaque when compared to a water rinse; (2) Listerine[R] was most effective when used for one minute three times daily; (3) Listerine[R] was less effective when used for one minute, once a day, or for five seconds, three times daily; and (4) plaque reduction was significant on some surfaces even when the test rinse was used for only five seconds three times daily. In conclusion the authors recommend further research of Listerine[R] mouthrinse to determine the effect long term use of this rinse has on the oral flora or changes in soft tissue. Additionally, research is necessary to determine the effect on plaque formation when Listerine[R] is used as an adjunct to mechanical plaque control methods.

Menaker et al.[18] conducted a study to test the effects of Listerine[R] antiseptic mouthrinse on dental plaque. The purpose of the clinical trial was to determine the antimicrobial effect of rinsing with Listerine[R] on plaque accumulation, as a supplement to unsupervised toothbrushing in inhibiting the accumulation of dental plaque.

Thirty-two males and forty-eight females, ages 18-60, were subjects for this study. Prior to the experimental period each volunteer was given a dental prophylaxis. All tooth surfaces were examined for the presence of dental plaque using a disclosing solution of FD and C Green #3. After confirmation of the absence of plaque, subjects

followed routine personal oral hygiene procedures for four weeks to provide a period for plaque growth. Following this period each subject received a periodontal examination and a baseline plaque evaluation. The Turesky Modification of the Quigly-Hein Index was used to score plaque on the buccal and lingual surfaces of all teeth. Subjects then were stratified and assigned randomly to two groups. Each group of 40 subjects contained a comparable number of high and low plaque formers.

The only difference in composition of the control and experimental mouthrinses was that the control rinse did not contain essential oils. All other ingredients in both mouthrinses were identical. Listerine^{R} mouthrinse contains essential oils, thymol, and eucalyptol as its active ingredient.[3,18]

Within 24 hours following the dental prophylaxis, subjects began rinsing with the assigned mouthrinse. On Mondays through Fridays, subjects rinsed twice daily under supervision for 30 seconds with 20 ml of the assigned mouthrinse. On weekends the subjects were instructed to rinse in an identical manner without supervision, using coded mouthrinses provided by the investigators. This regimen was followed for 21 consecutive days. On the 22nd day, subjects were examined for soft tissue changes and plaque accumulation on the buccal and lingual surfaces of all teeth.

Results demonstrated that Listerine^{R} inhibited plaque

accumulation by approximately 43 percent more than the placebo control rinse as measured by surface area during the three-week study period. Plaque reduction compared to the baseline was 38 percent ($P<0.001$) for the experimental group; the effect of the control (4.6 percent increase) was not statistically significant.[18]

Another study investigating Listerine[R] mouthrinse was conducted by Fornell et al.[8] The purposes of the study were to evaluate the effect of Listerine[R] on the rate of dental plaque formation and development of gingivitis during a two week abstinence from active mechanical cleaning of the teeth. Subjects included ten adults, age 19-30. At the initial dental examination, the oral hygiene status of subjects was assessed according to the criteria of the Plaque Index. The gingival condition of the subjects was assessed according to the Gingival Index, and measurements of gingival fluid and crevicular leukocytes were recorded.

Research was conducted during four consecutive two-week periods using a cross-over research design. During the pre-experimental periods, the first and third, subjects received several professional prophylaxes in order to establish a plaque-free and gingivitis-free baseline. During the second and fourth periods, test and control periods, subjects were instructed to refrain from all mechanical oral hygiene procedures for a two-week period. Five subjects were instructed to rinse three times daily for one minute with 20 ml of Listerine[R] mouthrinse and five subjects were given the

same instructions on rinsing with a placebo solution.

On the first day of the Listerine^{R} and placebo test periods, no significant differences were evident in Plaque Index scores, Gingival Index scores, gingival fluid or crevicular leukocytes between the two groups. Large amounts of plaque developed when no oral hygiene was performed during the control period. Plaque Index scores increased during the first two days from 0.18 to 0.82 and then to 1.36 on day four, 1.66 on day seven and 1.87 on day 14. Development of plaque during day seven, using Listerine^{R} was substantially slower. At the end of the period when the subjects practiced no oral hygiene, the Plaque Index score of the Listerine^{R} group was 0.93, compared to 1.87 for the placebo group. At each examination, Plaque Index scores using the placebo were significantly higher ($P<0.001$) than the corresponding plaque scores using Listerine^{R}.

At the beginning of each of the two no oral hygiene periods, the GI scores were (0.08 ± 0.01) for the Listerine^{R} and (0.11 ± 0.2) for the placebo. During the control (placebo) periods the Gingival Index score increased from 0.11 to 1.29. At the end of this period the gingiva showed signs of mild gingival inflammation. During the experimental (Listerine^{R}) period the gingival score increased from 0.08 to 0.71. This change in the GI score was significantly smaller than that during the control period. The GI scores indicated that on the average every second tooth surface showed signs of mild inflammation.

Fornell et al.[8] claim that three daily one minute rinses with Listerine[R] solution retards the formation of bacterial plaque on the teeth as well as the development of gingival inflammation.

Carter and Barnes[4] conducted a study to determine the clinical effects of three commercial mouthwashes on existing plaque accumulation on the teeth. Contrary to previous studies evaluating commercial mouthrinses, subjects did not receive a prophylaxis prior to the experiment. Consequently, a baseline of a zero plaque score was not present prior to the investigation.

The investigation was a double-blind, two part clinical study. Fifty seven male subjects, age 18 to 43, completing part I of the study were randomly divided into five groups. For two weeks Group A served as controls and received no mouthwash. Group B also served as controls and rinsed with color flavored water. Group C rinsed with a commercial mouthwash containing benzethonium chloride (Colgate 100[R]). Group D rinsed with a commercial mouthwash containing essential oils, thymol, and eucalyptol (Listerine[R]) and Group E rinsed with a commercial mouthwash containing celypyridinium chloride (Cepacol[R]).[4]

Seventy-two female subjects, age 18 to 40, who completed part II of the study were randomly divided into three groups. For three weeks, Group A rinsed with Cepacol[R] mouthwash; Group B with Colgate 100[R] mouthwash; and Group C served as controls and rinsed with colored flavored water.

Subjects of both studies were instructed to rinse with 30 ml of their assigned mouthwash for 60 seconds twice daily. Furthermore, subjects were instructed to continue their routine oral hygiene practices in conjunction with the mouthrinses. During the study, dental prophylaxis and use of mouthwashes other than the ones assigned were prohibited. Subjects in both study parts received the same pre-test and post-test examinations to determine their plaque scores according to the Quigly and Hein Index. Statistical analysis of the results indicated that in both parts of the study only the subjects rinsing with the cetylpridinium chloride (Cepacol^{R}) mouthwash experienced a significant reduction in existing plaque accumulations. Use of Cepacol^{R} resulted in a 23.6 percent plaque reduction ($P<0.02$) in part I and a 24.8 percent reduction ($P<0.001$) in part II.

No plaque reduction in the subjects rinsing with Listerine^{R} in part I of the study was found. Results of this study are in conflict with other data by Lusk et al.[17] who reported a significant reduction in formed plaque resulting from the use of Listerine^{R}.

Differences in research design existed between these two studies and may be the basis for contrasting results. In the study by Lusk et al.,[17] subjects served as their own controls, while in Carter and Barnes'[4] investigation the experimental group was compared with a control group not using the test mouthwash. Additionally, subjects in the study demonstrating positive results were periodontists,

whereas the study revealing negative results used non-dental, non-medical people as subjects.

Carter and Barnes[4] concluded that the use of a commercial mouthwash containing cetylpyridinium chloride (Cepacol^{R}) appears to be partially effective in reducing bacterial plaque accumulation. Although this mouthwash in addition to normal mechanical plaque control practices may be beneficial to patients, further long-term clinical studies are needed to determine its effectiveness in reducing dental disease.

Viadent

Sanguinaria, an herbal extract, has been used to benefit the oral health of native cultures throughout the world for many centuries. In the United States and other countries, sanguinaria extract has been used in a variety of medications; sanguinaria has been used in cough syrups and cold remedies as an expectorant.[23] The chemical structure of sanguinaria is similar to benzophenathridine alkaloids which have been used in oral hygiene since ancient times.[23] Sanguinarine may be a possible antiplaque agent. Anti-plaque effects of sanguinarine are due to a combination of retention in the oral cavity and a chemical effect upon plaque formation.[23]

Viadent^{R} dentifrice and Viadent^{R} oral rinse contain sanguinaria. Due to claims of this active ingredient as a potential anti-plaque agent, Viadent^{R} has been under clinical investigation.

Twenty-four subjects participated in a recent study conducted by Southard et al.[23] at the University of Pennsylvania Dental School. Two blind-coded experimental mouthrinses, one containing sanguinaria extract of 0.045 percent and the other containing sanguinaria extract of 0.03 percent and zinc chloride of 0.2 percent, and a placebo control without sanguinaria or zinc chloride were used in five rinse periods for seven days. Four rinse periods daily were supervised for five days. The fifth rinse period of the day and rinses on the weekends were unsupervised. Each subject rinsed for 15 seconds using 15 ml of solution each rinse period.

The only oral hygiene procedure allowed was supervised brushing once daily before the first rinse in the morning. The Turesky method with disclosure by means of sodium fluorescein and ultraviolet wave source were the criteria used to score plaque accumulation during the experimental period of the study.

Results indicated that the anti-plaque activity of sanguinarine oral rinses containing sanguinarine at 0.045 percent alone reduced plaque scores by 19.4 percent. Sanguinarine, 0.030 percent, combined with 0.2 percent zinc chloride resulted in reduced plaque scores of 20.4 percent during the eight-day test period. The placebo group showed a 21.3 percent plaque growth during the eight day test period. For both of the test groups, the post-treatment plaque scores were significantly lower than baseline scores

($P<0.05$) and the placebo ($P<0.05$). No significant difference was found in plaque reduction between the two experimental groups rinsing with products containing sanguinarine. Both test groups scored significantly lower ($P<0.05$) on post-treatment plaque scores than the control group.

Southard et al.[23] concluded that sanguinarine rinses have both a preventive and therapeutic effect on dental plaque. No difference was present in the anti-plaque efficiency between the rinse containing sanguinarine exclusively and the rinse containing both sanguinarine and zinc chloride.

Nygaard-Oestby and Persson[20] conducted a study to evaluate the combined effect of Viadent^{R} mouthrinse and dentifrice containing sanguinarine compared to a placebo in the control of dental plaque. Twenty-four volunteers participated in a 10-week, double-blind, cross-over study, consisting of two experimental periods of four weeks each separated by a two-week rest period. On the first day of the experimental period each subject was examined and given a score for baseline plaque. Subjects were instructed to brush twice daily and rinse twice daily with two consecutive 15 ml rinses for 15 seconds each. Nineteen of the subjects completed the study and were scored for plaque on days 14, 28, 42, 56 and 70. The 19 subjects were crossed over following the rest period which lasted from day 28 to 42.

Statistical analysis of the data revealed that during the experimental period 79 percent of the subjects demon-

strated improvement in Plaque Index scores. The authors report that use of Viadent^{R} dentifrice and Viadent^{R} oral rinse are effective in the control of dental plaque; however, no statistics were presented. Due to the manner in which the results of this study were presented, it could not be determined whether a statistically significant difference was found in the Plaque Index scores between the control group and experimental group. The authors' conclusion was vague and suggests that further research of Viadent^{R} products is needed.

Klewansky and Venier[11] conducted a double-blind, four-week, parallel group study to compare the effect of Viadent^{R} dentifrice to a placebo dentifrice on plaque. Thirty subjects, age 22-66, were given instruction on the importance of good oral hygiene. No instruction on the methods or frequency of brushing and flossing were given. A dental prophylaxis was not performed prior to the experimental period. An evaluation of plaque was made at the beginning of the study and the end of weeks one, two, three, and four. After four weeks of brushing with the experimental dentifrice or the placebo dentifrice, subjects resumed their regular practices of oral hygiene using their normal dentifrice.

After week three, a comparison between baseline and final Plaque Index scores were calculated using the Plaque Index. Week three was used because seven subjects missed the week four evaluation.

Data indicated that the experimental dentifrice containing sanguinaria extract resulted in highly significant decreases in plaque (64 percent). A significant change in plaque scores was not demonstrated in the placebo group. Klewansky and Venier[11] concluded that a sanguinarine containing dentifrice could be of significant benefit in the control of plaque.

Greenfield and Cuchel[9] conducted a study to evaluate Viadent^{R} dentifrice and oral rinse compared with Zendium^{R} dentifrice and water rinse in the control of dental plaque. Sixty adult subjects participated in a single-blind, randomized cross-over study. There were two experimental periods separated by a two-week rest period. Group A, using Viadent^{R}, was instructed to brush three times daily for two weeks following each brushing with a rinse of 30 ml of Viadent^{R} mouthrinse for 15 seconds. Group B used Zendium^{R} toothpaste and was instructed to brush three times daily for two weeks followed by two 15 ml rinses with tap water. After the 14th day the subjects resumed their normal oral hygiene regimen for two weeks and then crossed over for another two week period.

Results of this study indicated the mean change in plaque scores for Group B to be 0.25 percent and the mean change in plaque scores for group A was 0.45 percent. The difference between the mean plaque scores was statistically significant at the 0.001 level. The Viadent^{R} system was effective on 90 percent of the patients in reducing plaque

scores, while 82 percent of the subjects using the Zendium^{R} had reduced plaque scores. Greenfield and Cuchel[9] claim that the results of this study indicate a statistically significant decrease in plaque scores in patients using sanguinarine products as compared to those using an enzyme system.

Summary

Reports of clinical trials investigating the effectiveness of alexidine and chlorhexidine as anti-plaque agents are found in the dental literature.[3,5,10,12,14,15] The literature reviewed suggests that these chemotherapeutic agents are effective in decreasing the accumulation of bacterial plaque at a statistically significant level.[3,14,15] Although the association of bacterial plaque with gingivitis is well established in the dental literature, the demonstration of anti-plaque activity of a mouthrinse alone cannot guarantee its potential benefits to good periodontal health. Possibly, a reasonable prediction is that agents which reduce or prevent the accumulation of dental plaque will demonstrate some beneficial effects on the gingiva.

Some studies report that chlorhexidine and alexidine do exhibit salutary effects on gingivitis which may be due to their anti-microbial, anti-plaque activity.[3,10,15] Although some reduction in gingivitis was demonstrated, supramarginal calculus increased in participants in a long-term investigation of chlorhexidine by Löe.[15] Supramarginal calculus is not the causative agent in periodontal disease;

however,it could act as a retention area for the growth of new plaque and subsequent gingivitis.

Adverse effects of chlorhexidine and alexidine reported in both short-term and long-term clinical studies are a diffuse brown discoloration of the teeth and restorations. The heaviest stain occurs on the interproximal surfaces and gingival third of the tooth. Other adverse effects noted when rinsing with chlorhexidine are discoloration of the tongue; a strong bitter taste; and dryness, soreness, and burning sensation of the oral cavity.[3,7-11,14,15,23,25] Because of side effects there are some objections to the use of alexidine and chlorhexidine in preventive dentistry.[7] These mouthwashes have not been approved in the United States and are not available to the public.[18]

Controversy exists in the dental literature concerning the effectiveness of commercial mouthrinses as anti-plaque agents. Results of several studies indicate that Listerine^{R} rinse when used three times daily for one minute was effective in reducing experimental gingivitis and plaque formation.[8,15,17] In Carter and Barnes'[4] study comparing Colgate^{R}, Cepacol^{R}, and Listerine^{R}, Cepacol^{R} was the only rinse that significantly reduced plaque accumulation.

The contrast in these results may exist because of variation in study design. Diversity of scoring indices, subject populations, and clinical procedures may provide explanation for the controversy.

Clinical investigations of Viadent® mouthrinse containing sanguinaria resulted in reduced plaque scores.[11,20,22,28] No controversy in the literature was found reporting Viadent's® effectiveness on plaque; however, there was no report on Viadent's® effectiveness on gingivitis. All literature reviewed for this new commercial mouthrinse was provided by Vipont Laboratories, manufacturer of Viadent® products. Investigation of the effectiveness of Viadent® and Listerine® mouthrinse on gingivitis and plaque on subjects who have not had alterations in home care or have not received a professional prophylaxis may provide valuable information contributing to the oral health status of the population.

CHAPTER 3

Methods and Materials

This study was designed to test the effectiveness of rinsing with two different commercial mouthrinses on the control of dental plaque and gingivitis on 24 male and female subjects ages 18-41. Over a six week test period the plaque accumulation and degree of gingival inflammation was measured using the Plaque Index and Gingival Index, respectively.

Sample Description

A convenience sample of 24 patients was selected from a group of volunteers from Old Dominion University. Previous patients from Old Dominion University Dental Hygiene Clinic and students of Old Dominion University were given the opportunity to participate in this study. To be included in this study, the following criteria had to be met:

1. Subjects had to be 18-45 years of age.
2. Subjects were not in the dental profession.
3. Subjects were not dental, dental hygiene students, or dental assisting students.
4. Subjects had to be free of orthodontic appliances.
5. Subjects had to be free of physical and/or

mental handicaps.

6. Subjects had to be free of complex medical histories. Subjects reporting communicable diseases, diabetic conditions, blood dyscrasias, congenital heart disease, rheumatic heart disease, pregnancy, prosthetic joint replacement, hypertensive heart disease, or any medications that might alter the gingival tissues were excluded from this study.

7. Subjects' teeth had to be free of rampant caries.

8. Subjects had to be free of allergies to commercial mouthwashes.

9. Subjects had to have a minimum of 24 teeth.

10. Subjects' teeth had to be free of heavy supragingival and subgingival calculus deposit. Heavy deposit is characterized by calculus occurring in more than four-millimeter wide deposits on crown or root of tooth.

11. Subjects had to be free of periodontally diseased pockets greater than 4 mm.

12. Subjects had to have no history of periodontal surgery.

Research Design

An experimental pre-test/post-test design was used to determine the effectiveness of two different commercial mouthrinses on the amount of dental plaque and the control of gingivitis in 24 adults. The independent variables were the commercial mouthrinses and the dependent variables were plaque and gingival health as measured by the Plaque Index

and Gingival Index, respectively.

This investigation was double-blind; neither the dental hygiene examiner nor the subject were aware of the mouthrinse being used. The experimental group served as their own control (cross-over technique) in this investigation. The design tested the effect of each independent variable (mouthrinses) on the dependent variables (plaque and gingival health).

This research design controlled for several threats to internal and external validity:

1. Cross-over design controlled for subject relevant variables since each subject served as his/her own control.

2. Standardized instruction on mouthrinsing given by the principal investigator controlled situational variables.

3. One examiner performed measurements of plaque and gingivitis which controlled situation intraexaminer variables.

4. The use of the same operatory, equipment and identical dental materials controlled for environmental conditions.

Methodology

All research was conducted at the Old Dominion University Dental Hygiene Clinic. A cross-over, double-blind design was used which allowed each subject to serve as his/her own control. The scoring procedure was performed by one dental hygiene examiner. Standardized instruction on the mouthrinsing procedure was delivered by the principle

investigator at each appointment. Additionally, each subject was given standardized written instructions and a two week supply of the mouthrinse at each appointment. Twenty-four subjects participated in this clinical trial for six weeks divided into three, two week periods. The first two weeks the subjects were instructed to rinse with Viadent^{R} (mouthrinse A); the following two weeks the subjects rinsed with the placebo rinse (mouthrinse B); and the final two weeks the subjects rinsed with Listerine^{R} (mouthrinse C). At the end of each of the two week periods subjects were examined for plaque accumulation and gingivitis using the Plaque Index and the Gingival Index, respectively. Two week periods were chosen because gingivitis clinically appears in the mouth within this time. Including the initial appointment, each subject was required to participate in four appointments over a six week period. Procedures at each appointment were as follows:

First Appointment

1. Subjects were given a consent form explaining appointment procedures, risks, and benefits (Appendix A). Subjects were asked to read, sign, and return the consent form to the principal investigator.

2. Subjects were given a medical history form (Appendix B) to complete and return to the principal investigator. The principal investigator reviewed the medical history to assure that there were no medical reasons to be excluded from this study.

3. The Plaque Index was utilized to measure the amount and location of plaque for each subject. Four gingival areas (mesial, lingual, distal, buccal) were examined and scored on teeth numbers 3, 9, 13, 19, 25, and 29. If any of the selected teeth were missing, the tooth mesial to the missing tooth was scored. For each subject a mean plaque score for all six teeth was calculated. Data were recorded on a Plaque Index-Gingival Index Chart (Appendix C).

4. The Gingival Index was utilized to assess the severity of each subject's gingival inflammation. Four gingival areas (mesial, lingual, distal, buccal) were examined on teeth numbers 2, 8, 12, 18, 24, and 28. If any of the selected teeth were missing, the tooth mesial to the missing tooth was scored. For each subject a mean gingival score for all six teeth was calulated. Data were recorded on a Plaque Index-Gingival Index Chart (Appendix C.)

5. Standardized written and oral instructions on mouthrinsing (Appendix D) were given to each subject by the principal investigator. Subjects were instructed not to alter their routine oral hygiene regimen in any way with the exception of rinsing with the experimental mouthrinse. Subjects were not allowed to use any other mouthrinse.

6. Subjects were given a two week supply of the experimental mouthrinse in unidentifiable coded bottles. Premeasured dispensers were given to each subject.

Appointments were conducted over a two day period so

that approximately 15 subjects could be evaluated each day. The initial appointment was approximately 45 minutes long: fifteen minutes to complete medical history and consent form; 30 minutes for plaque and gingival evaluation; and 15 minutes for oral hygiene instruction.

Subsequent Appointments

Subjects were required to participate in three subsequent appointments at two week intervals. Appointments two and three were conducted in the same manner as the initial appointment with two exceptions. Subjects were not required to complete a new medical history form or sign a second consent form. However, during each of the three subsequent appointments, the subjects' medical histories were reviewed and updated prior to any procedures. Additionally, subjects were given a different mouthrinse, placebo mouthrinse B and mouthrinse C, during the mouthrinsing instruction period of appointments two and three, respectively. Each subsequent appointment was approximately 30 minutes long.

Final Plaque and Gingival Index scores were calculated at the fourth appointment. No oral hygiene homecare instruction or mouthrinses were given at this final appointment. Subjects received a letter of appreciation (Appendix E) thanking them for their participation and providing information on how to obtain results of this study. Additionally, subjects were offered a complimentary dental prophylaxis including oral examination, radiographs, and fluoride treatment to be performed by an Old Dominion

University dental hygiene student.

Protection of Human Subjects

The rights of the human subjects were protected by using the following guidelines:

1. Subject Population--The proposed investigation required 30 male and female dental patients, 18-45 years of age. Subjects were selected from Old Dominion University's student population, faculty, and Dental Hygiene Clinic patients. This population was selected because of the diversity in age, economic status, and professional goals. These subjects are representative of the population who might purchase the commercial mouthrinses in the study. Subjects must have had a minimum of 24 teeth and been free of periodontal pockets deeper than 5 mm. Subjects must not have had a history of periodontal surgery or been receiving antibiotic therapy. Subjects did not have any mental or physical handicaps. Individuals with orthodontic appliances were excluded from this study. Medically complex patients were not included in this study. This included subjects who reported diabetic conditions, pregnancy, rheumatic heart disease, congenital heart disease, uncontrolled hypertensive disease, epilepsy, blood disease, prosthetic joint replacement, or any medication that might have altered the gingival tissues.

2. Consent Procedures--Prior to participation in this study subjects were required to sign a written consent form explaining the purpose, procedures, and potential risks

of this investigation. Subject participation was voluntary (Appendix A).

3. Potential Risks--An examination of the gingiva using a probe could be a potential risk for individuals having a joint replacement, heart murmur, or a history of heart disease. A bacteremia could occur after probing. This risk was minimized by excluding subjects with a heart murmur, with heart disease, or that have had a joint replacement.

Subjects were required to rinse with two commercial mouthrinses during two separate test periods. The subjects might have experienced slight gingival irritation and/or an allergic reaction to the commercial mouthrinses. If the subject experienced any burning sensation of the mouth or irritation of the gingiva, he/she was given the option to withdraw from the study. Additionally, daily use of these rinses might have caused a light brown stain to occur on the teeth. This stain is extrinsic and completely removable with a professional polishing. This brown stain does not harm the teeth, but may appear aesthetically displeasing to the subject. If the subject would have had a severe allergic reaction to the mouthrinse, the emergency protocol for the Old Dominion University Dental Hygiene Clinic would have been followed.

4. Potential Benefits--The general population and the subjects may benefit if the results of this investigation indicate that rinsing with a commercial mouthrinse as

an adjunct to brushing improves gingival health. Upon completion of the study, the subject received a complimentary dental prophylaxis, fluoride treatment, and dental health education. The subject benefited from this in the form of better oral health.

5. Risk-Benefit Ratio--The likelihood of the serious potential risks occurring was minimal since the risks could be controlled. The risk of a bacteremia or an allergic reaction to the mouthrinse was minimized by means of a thorough screening of the subject's health history for prosthetic joint replacement, heart disease, or allergies. Risks could occur only if the subject had an unknown allergy to the mouthrinse. Possibility of gingival irritation or tissue sloughing from rinsing with an excessive amount of the mouthrinse was controlled by providing written and oral instruction on the usage and amount. Additionally, plastic premeasured cups were given to each subject with a bottle of mouthrinse. Each subject was advised to discontinue use if any untoward effects to oral tissues occurred.

Information provided by this clinical trial may contribute to better oral hygiene care for the public in the future. The potential benefits of the investigation outweighed the potential risks involved.

Instrumentation

Instruments used in this study for data collection included the Gingival Index and the Plaque Index by Silness and Löe.[13] Data were collected at an initial appointment to

establish baseline scores and at three subsequent visits occuring at two week intervals. A Hu-Friedy color coded probe with marks at 3-6-9-12 mm was used during the Gingival Index data collection and a Hu-Friedy #17 explorer was used during the Plaque Index data collection. All data were collected by one dental hygiene examiner.

The Gingival Index was created by Silness and Löe[13] for the assessment of the gingival condition. The Gingival Index clearly distinguishes between the severity of the inflammation and the location as related to the four areas which compose the total circumference of the marginal gingiva. The Gingival Index does not consider periodontal pocket depth, degree of bone loss, or any other quantitative change of the periodontium. Criteria is confined to qualitative changes in the gingival soft tissue. The Gingival Index was used for data collection to obtain a reliable and valid measurement of the subject's gingival condition.

The selected teeth and gingiva were dried and a mouth mirror and probe were used for examination. The probe was used to press on the gingiva to determine the degree of firmness. The probe was placed and moved across the soft tissue wall near the entrance to the gingiva sulcus to evaluate bleeding. In this study teeth numbers 3, 9, 13, 19, 25, and 29 were examined. Each area was evaluated using the following criteria:

0 = Normal gingiva
1 = Mild inflammation--slight change in color, slight

edema. No bleeding on probing.
2 = Moderate inflammation--redness, edema and glazing. Bleeding on probing.
3 = Severe inflammation--marked redness edema. Ulceration. Tendency to spontaneous bleeding.[13]

Scores for each area were totaled and divided by four to calculate the Gingival Index for each tooth. Scores for the chosen teeth in each quadrant were totaled and divided by the number of teeth to determine the Gingival Index for that quadrant. The Gingival Index score for each quadrant was analyzed to determine the effect of the variable on the gingiva. To determine the Gingival Index score for a group, the indices for each member of the group were added and divided by the number of individuals to determine the population average score. A score of 0 indicates healthy gingiva, 0.1-0.9 is good, 1.0-1.9 is fair, and 2.0-3.0 is rated poor gingival health.[25]

The Plaque Index is based on the same principle as the Gingival Index. The purpose of this index is to assess the thickness of plaque at the gingival margin. This instrument was chosen to measure plaque in this study because it matches the Gingival Index systematically.

The procedures followed to determine the Plaque Index score was similar to obtaining the Gingival Index score. The tooth was dried and examined visually for scores according to the scoring criteria. When no plaque was visible, an explorer was used to test the surface. The explorer was passed across the tooth surface in the cervical third and near the entrance to the sulcus. Four gingival

areas (distal, facial, mesial, and lingual) were examined for each tooth chosen. In this study tooth numbers 2, 8, 12, 18, 24, and 28 were examined. The teeth were scored according to the following criteria:

> 0 = No plaque
> 1 = A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque might be recognized only after application of disclosing agent, or by running the explorer across the tooth surface.
> 2 = Moderate accumulation of soft deposits within the gingival pocket, or on the tooth and gingival margin, which can be seen with the naked eye.
> 3 = Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin.[13]

To determine the Plaque Index score for a tooth the scores for each area were totaled and divided by four. Scores for individual teeth may be grouped, totaled, and divided by the number of teeth. For an individual's Plaque Index score, the indices for each of the teeth are added and divided by the number of teeth. To determine the Plaque Index score for a group, the indices for each member of the group were added and divided by the number of individuals to determine the population average score. The nominal scale for patient reference is: 0 for excellent, 0.1-0.9 for good, 1.0-1.9 for fair, and 2.0-3.0 for poor.

Prior to the conduct of this study, calibration of the scorer error was established. The dental hygiene examiner scored eight volunteers, ages 18 to 40, on two subsequent appointments using the Plaque Index and the Gingival Index. The Pearson product moment correlation was used to determine the relationship between the two sets of GI scores and two

sets of PLI scores. The sum of one set of GI and PLI scores was compared to the sum of the second set of scores when calculating the Pearson r. A high positive correlation, r = 0.9759 for Plaque Index scores and r = 0.9500 for Gingival Index scores, demonstrated intrarater reliability (Appendix F).

Statistical Treatment

An experimental pre-test/post-test research design was applied to test the effectiveness of two different commercial mouthrinses on the reduction of dental plaque and the control of gingivitis in 24 adult subjects. The independent variables were the commercial mouthrinses and the dependent variables were plaque and gingival inflammation as measured by the Plaque Index and Gingival Index, respectively. Results were tabulated on the basis of changes in the mean Plaque Index and Gingival Index scores. Results were evaluated using a one-way analysis of variance to determine if the independent variables, the mouthrinses, had any statistically significant effect on changes in the dependent variables, gingival inflammation and bacterial plaque, throughout all four appointments. Also, Tukey's Studentized Range Test (multiple comparison procedure) was applied to the data. A paired-difference t-test was applied to data to determine if any significant difference existed between GI scores and PLI scores from appointment one to three, two to three, and four to three.

CHAPTER 4

Results and Discussion

Twenty-four subjects, ages 18 to 41, participated in a double-blind crossover research study at the Old Dominion University Dental Hygiene Clinic. An experimental pre-test, post-test design was used to test the effectiveness of Viadent^{R} and Listerine^{R} mouthrinses on the amount of bacterial plaque and the level of gingivitis. Over a six-week period, subjects attended four appointments at two-week intervals. Gingival inflammation and bacterial plaque were measured at each appointment using the Gingival Index and the Plaque Index. Subjects were instructed not to change their usual oral hygiene routine during the six-week period with the exception of rinsing with the given mouthrinse. Additionally, subjects were provided with a two-week supply of the mouthrinse and written mouthrinsing instructions at each appointment. Gingival Index scores and Plaque Index scores were collected and calculated for each of the 24 subjects (Appendices G and H). Data were analyzed using a Generalized Linear Model (analysis of variance) to determine if the independent variables, the mouthrinses, had a statistically significant effect on the dependent variables, gingivitis and bacterial plaque, throughout the four appointments. Tukey's Studentized Range Test (HSD, multiple comparison procedure) was applied to data to determine if a

statistical significant difference existed in Plaque and Gingival Index mean scores between the four appointments. A Paired-Difference t-test provided analysis of means for each of the commercial mouthrinses compared to the placebo mouthrinse. A computerized statistical package, Statistical Analysis System, was used for data analysis.

Results

Compliance with the written mouthrinsing instructions was required to determine the effectiveness of Viadent^{R} and Listerine^{R} mouthrinses on bacterial plaque and gingivitis. Because mouthrinsing was not directly supervised, patient cooperation and compliance during the six-week test period could not be assured. However, results of the statistics computed for Gingival Index scores and Plaque Index scores demonstrated that the amount of plaque and level of gingivitis was low among all subjects, throughout the four appointments. The highest mean Gingival Index score was 1.20 at appointments one and two, and the highest mean Plaque Index score was 1.07 at appointment one (Appendix I). The range of mean Gingival and Plaque Index scores was small with the largest mean Gingival Index score range of 0.38 at appointment two, and largest mean Plaque Index score range of 1.40 at appointment four (Appendix J).

Data were first examined using an analysis of variance (ANOVA--Generalized Linear Model) to determine if any statistically significant difference existed among mean Gingival Index scores or among mean Plaque Index scores

between the four appointments. An analysis of variance of the total mean scores for the Gingival Index for the four appointments revealed no statistically significant difference between any of the appointments when tested at the 0.05 level of significance (F value = 0.24, df = 92, p-value = 0.8658). Results of analyzed data using an ANOVA on mean Plaque Index scores revealed that no statistically significant differences existed between any of the appointments when tested at the 0.05 level of significance (F value = 1.00, df = 92, p-value = 0.3991).

In addition, data were analyzed using a multiple comparison procedure, Tukey's Studentized Range Test, to determine if a statistically significant difference existed between appointments. Results revealed that a statistically significant difference did not exist between mean GI scores for the four appointments. Table 1 demonstrates that the highest mean GI score was at appointment two after subjects had spent a two-week period rinsing with Viadent^{R} mouthrinse. The lowest mean GI score was at the fourth appointment after subjects had been rinsing with Listerine^{R} mouthrinse for a two-week period. Additionally, mean reductions of GI scores at appointments two, three, and four did not reveal any statistically significant differences (see Table 1).

Table 2 presents the results of the Tukey's Studentized Range Test on the independent variable, bacterial plaque. Analysis of data revealed that no statistically significant

Table 1

Comparison of Mean Scores for the Gingival Index Between Appointments using Tukey's Studentized Range Test

Comparison Appointment Number	$\bar{x}$	$\bar{x}$-reduction
1	1.2008	0.0034
2	1.2042	
1	1.2008	0.0046
3	1.1962	
1	1.2008	0.0279
4	1.1729	
2	1.2042	0.0080
3	1.1962	
2	1.2042	0.0313
4	1.1729	
3	1.1962	0.0233
4	1.1729	

Note: alpha = 0.05, df = 92
Critical value of studentized range = 3.700
Minimum significant difference = 0.105985

Table 2

Comparison of Mean Scores for the Plaque Index Between Appointments Using Tukey's Studentized Range Test

Comparison: Appointment Number	$\bar{x}$	$\bar{x}$-reduction
1	1.0750	0.1338
2	0.9412	
1	1.0750	0.675
3	1.0075	
1	1.0750	0.0175
4	1.0575	
2	0.9412	0.1167
3	1.0075	
2	0.9412	0.1163
4	1.0575	
3	1.0075	0.0500
4	1.0575	

Note: alfa = 0.05, df = 92
Critical value of studentized range = 3.700
Minimum significant difference = 0.222184

difference existed between PLI score means of the four appointments. The highest PLI score mean was at the baseline appointment and the lowest PLI mean was at the second appointment after subjects had been rinsing with Viadent^{R} mouthrinse for a two-week period. Mean reductions of PLI scores at appointments two, three, and four did not reveal any statistically significant differences (see Table 2).

After general data from the four appointments had been analyzed, data were examined by appointment. This data analysis was required to test the null hypotheses. A Paired-Difference t-test was used to determine the difference in GI and PLI scores for each subject between baseline and placebo; Viadent^{R} and placebo; and Listerine^{R} and placebo. After these scores were calculated the mean and standard deviation were calculated for these variables. All hypotheses were tested at the 0.05 level of significance.

Hypothesis one. Data were examined using a Paired-Difference t-test to determine if a statistically significant difference existed in the incidence of gingivitis in subjects who used a placebo mouthrinse and subjects who did not use a mouthrinse. The purpose of this comparison was to establish whether the placebo created a mouthrinsing effect on gingivitis. Analysis of data revealed no statistically significant difference between baseline GI scores at appointment one and the placebo GI scores at appointment three ($t = 0.13$, $df = 46$, $p = 0.8990$); therefore, the null

hypothesis was not rejected. Table 3 presents results of the Paired-Difference t-test for the four appointments. Descriptive statistics for appointments one and three are presented in Table 4.

Hypothesis two. Data were analyzed to determine if a statistically significant difference existed between the level of gingivitis in subjects who used Viadent^{R} mouthrinse and subjects who rinsed with a placebo mouthrinse. A Paired-Difference t-test was calculated for Gingival Index scores from appointment two (Viadent^{R}) and appointment three (placebo). Analysis of the data from appointment two and appointment three revealed no statistically significant difference between GI scores of subjects when they rinsed with Viadent^{R} mouthrinse and when they rinsed with a placebo mouthrinse; therefore, the null hypothesis was not rejected ($t = 0.34$, $df = 46$, $p = 0.7362$). Results of the Paired-Difference t-test for all four appointments is presented in Table 3. Descriptive statistics for appointments two and three are illustrated in Table 4.

Hypothesis three. Data were examined to determine if a statistically significant difference existed between the level of gingivitis in subjects who rinsed with Listerine ^{R} mouthrinse and level of gingivitis in subjects who rinsed with a placebo mouthrinse. Results of the Paired-Difference t-test revealed that no statistically significant difference existed between GI scores of subjects at appointment one and GI scores of subjects at appointment four; therefore the

Table 3

Paired-Difference t-test Between Appointments for Gingival Index Scores

Appointment	$\bar{x}$	s	t-value	p-value
1 & 3	0.0046	0.1749	0.13	0.8990
2 & 3	0.0080	0.1137	0.34	0.7362
4 & 3	0.0233	0.0247	0.94	0.3552

Note: To reject null hypothesis t>2.021
Tested at 0.05 level of significance
df = 46

Table 4

Descriptive Statistics for Gingival Index Scores

Appointment	$\bar{x}$	s	range
1	1.2009	0.1630	0.540
2	2.2042	0.1553	0.5800
3	1.1962	0.1111	0.4100
4	1.1729	0.1248	0.5000

null hypothesis was not rejected (t = 0.94, df = 46, p = 0.3552). Results for all four appointments are shown in Table 3. Table 4 presents descriptive statistics for appointments three and four.

Hypothesis four. Data from appointment one and appointment three were analyzed using the Paired-Difference t-test to determine if a statistically significant difference existed in the amount of bacterial plaque of subjects at the baseline appointment compared to the same subjects at the placebo appointment. The purpose of this comparison was to determine if the placebo rinse had a mouthrinsing effect on the plaque. Data analysis presented in Table 5 indicates that a difference existed between PLI scores from appointment one and three. Although a difference existed, it was not statistically significant; therefore, the null hypothesis was not rejected (t = 1.76, df = 46, p = 0.0925). Table 2 illustrates that the mean reduction between appointments one and three was the most significant when compared to the mean reductions of the other appointments. General statistics are presented in Table 6.

Hypothesis five. Data were examined to determine if a statistically significant difference existed in the amount of plaque when subjects used Viadent^{R} mouthrinse and when subjects used a placebo mouthrinse. Table 5 presents data that does not reject the null hypothesis (t = 1.38, df = 46, p = 0.1824). Descriptive statistics in Table 6 revealed

Table 5

Paired-Difference t-test Between Appointments for Plaque Index Scores

Appointment	$\bar{x}$	s	t-value	p-value
1 & 3	0.0670	0.1872	1.76	0.0925
2 & 3	0.0662	0.2360	1.38	0.1824
4 & 3	0.0500	0.2187	1.12	0.2743

Note: To reject null hypothesis t>2.021
Tested a 0.05 level of significance
df = 46

Table 6

Descriptive Statistics for Plaque Index Scores

Appointment	$\bar{x}$	s	range
1	1.0749	0.2828	0.9600
2	0.9412	0.2648	0.9100
3	1.0075	0.2914	1.0400
4	1.0575	0.3331	1.400

that a mean reduction existed between PLI scores when subjects used Viadent^{R} mouthrinse and when subjects used a placebo rinse; however, it was not significant.

Hypothesis six. Data were examined to determine if a statistically significant difference existed in the amount of plaque when subjects rinsed with Listerine^{R} mouthrinse and when subjects rinsed with a placebo rinse. Results of the Paired-Difference t-test revealed no statistically significant difference between PLI scores from appointment three and PLI scores from appointment four; therefore, the null hypothesis was not rejected ($t = 1.12$, $df = 46$, $p = 0.2743$). Table 5 illustrates t-test data for PLI scores for the four appointments. Descriptive statistics in Table 6 revealed that there was an increase in the mean plaque score from appointment three to appointment four.

Discussion

Analysis of the mean reduction in GI and PLI scores revealed that no statistically significant differences, reduction or increase, existed between any of the four appointments. Tukey's Studentized Range Test supports that no statistically significant differences existed in GI or PLI scores of subjects from the baseline appointment, to the Viadent^{R} appointment, to the placebo appointment, or to the Listerine^{R} appointment.

Hypothesis one. Data analysis revealed that gingival inflammation decreased in subjects from appointment one (baseline appointment) to appointment three (placebo

appointment). The mean reduction was slight and was not statistically significant. This slight decrease in gingivitis might be the result of a rinsing action on the bacterial plaque. Although subjects rinsed with water as a part of their routine oral hygiene prior to participation in the study, throughout the study subjects were instructed to rinse with a pre-measured amount of water for a specific time. This controlled regimen of rinsing in conjunction with the subjects' awareness of oral hygiene during the study might have affected GI scores.

Hypothesis two. Results of data examined revealed no statistically significant difference in the level of gingivitis when subjects rinsed with Viadent^{R} mouthrinse and when subjects rinsed with the placebo mouthrinse for a two-week period. The mean GI score increased by a small degree when subjects rinsed with the Viadent^{R} mouthrinse compared with the placebo mouthrinse. This slight increase in mean GI scores demonstrates that on the average a higher level of gingival inflammation was present in subjects after using Viadent^{R} mouthrinse for a two-week period. A higher level of inflammation possibly could be the result of an inflammatory effect of Viadent^{R} mouthrinse on the gingiva. Burning sensation of the tongue, buccal mucosa, and gingiva was a common complaint of subjects after using Viadent^{R} mouthrinse. Additionally, 100 percent compliance to the frequency and length of rinsing might not have been practiced by all subjects because of this burning sensation. Because

subjects may not have complied with the Viadent^{R} mouth-rinsing instruction, results might have been affected. Southard et al.[23], Nygaard-Oestby and Persson[20], Klewansky and Venier[11] and Greenfield and Cuchel[9] conducted research on Viadent^{R} mouthrinse evaluating the mouthrinse's effect on the growth of bacterial plaque or on existing plaque accumulation; but, no research was found reporting Viadent's^{R} effect on gingivitis.

Hypothesis three. Statistical analysis of data revealed that no statistically significant difference in gingivitis existed when subjects rinsed with Listerine^{R} mouthrinse compared to when subjects rinsed with a placebo mouthrinse for a two-week period. The Paired-Difference t-test showed that rinsing with Listerine^{R} as an adjunct to routine oral hygiene care did not significantly decrease the level of gingivitis. Although mean Gingival Index scores were slightly lower in subjects after rinsing with Listerine^{R} when compared to rinsing with a placebo rinse, these results were not statistically significant. Conflicting results presented by Lusk et al.[17] and Fornell et al.[8] demonstrated that the use of Listerine^{R} mouthrinse was effective in reducing gingivitis when compared to rinsing with a placebo rinse. Results of the study conducted by Lusk et al.[17] demonstrated a statistically significant reduction in gingivitis. Subjects participating in Lusk et al.'s[17] study were periodontists; consequently, they might have had heightened awareness of the purpose of the research.

Therefore, they might have been biased to the study. Additionally, periodontists might not reflect an accurate representation of the population who might use Listerine[R] mouthrinse; therefore, results might not be applicable to the general population.

Fornell et al.'s[8] study demonstrated that three daily, one-minute rinses with Listerine[R] retard the development of gingival inflammation; however, no statistical information was provided. The recommended length and number of rinses by the manufacturer of Listerine[R] is one minute two times daily as was instructed in this research. Past research which demonstrated positive results had subjects rinse three times daily. Additionally, in both of the studies conducted by Lusk et al.[17] and Fornell et al.[8], subjects received a professional prophylaxis prior to establishing a baseline GI score. This prophylaxis might have lowered the GI score of subjects participating in the studies; therefore, possibly affecting the results. In this research subjects were not given a professional prophylaxis; therefore, gingivitis was present at the baseline appointment. Although, two weeks is normally a sufficient period of time for symptoms of gingivitis to subside; demonstration of a statistically significant difference in the level of gingivitis may require a longer length of time.

Hypothesis four. Data analysis indicated that a reduction in the amount of plaque existed in subjects who used a placebo rinse for a two week period when compared to the

baseline scores. Although results indicated a decrease in plaque, the amount was slight and had no statistical significance. Findings conflict with results reported by Löe and Schiott[14] who reported an increase in plaque scores of subjects using a placebo solution from day one to day fifteen of the study. Löe and Schiott's[14] results are supported by Lusk et al.[17] and Fornell et al.[8] Results of these studies revealed a significant reduction in plaque scores when subjects rinsed with Listerine[R] mouthrinse compared to subjects who rinsed with a placebo rinse.

Hypothesis five. Statistical analysis of data revealed that no statistically significant difference existed in the amount of bacterial plaque when subjects rinsed with Viadent[R] mouthrinse compared to when subjects rinsed with a placebo rinse. This finding conflicts with results of studies conducted by Southard et al.[23] and Greenfield and Cuchel.[9] Southard et al.[23] found a statistically significant difference between pre-treatment plaque scores (no Viadent[R] rinse) and post-treatment (Viadent[R] rinse) plaque scores. In Southard et al.'s[23] study, four rinse periods daily were supervised for five days and the fifth rinse period of the day and on the weekends were unsupervised. The only oral hygiene procedure allowed in Southard et al.'s[23] study was supervised brushing once daily before the first rinse in the morning. Supervised toothbrushing and mouthrinsing possibly could have caused a decrease in plaque when compared to baseline plaque scores where

subjects had no supervised oral hygiene. These results are also supported by a study completed by Nygarrd-Oestby and Persson[20] in which the combined effects of Viadent[R] mouthrinse and dentifrice were investigated. Subjects were not supervised during mouthrinsing, but were given specific toothbrushing instructions. Results of their research demonstrated improvement in plaque index scores in 79 percent of the subjects. Although a decrease in plaque was demonstrated, no statistically significant reduction existed in plaque scores of subjects rinsing with Viadent[R]. Improvement in PLI scores in Greenfield and Cuchel[9] and Nygarrd-Oestby and Persson's[20] studies may be attributed to the mechanical removal of bacterial plaque from toothbrushing.

Although not statistically significant, a mean reduction in the amount of plaque in subjects who had been rinsing with Viadent[R] for a two-week period was found when compared to rinsing with the placebo mouthrinse. Subjects reported that they were aware of their teeth feeling cleaner and that a "fuzzy feeling" from plaque was no longer present on their teeth. Mean reductions of plaque scores might have been statistically significant if mouthrinsing methods had been directly supervised guaranteeing 100 percent subject compliance.

Hypothesis six. Data analysis revealed that no statistically significant difference existed in the amount of plaque when subjects rinsed with Listerine[R] mouthrinse and

when subjects rinsed with a placebo mouthrinse. These results were supported by Carter and Barnes.[4] In the study conducted by Carter and Barnes[4] subjects were not given a professional prophylaxis; consequently, a baseline of zero was not established prior to the test period. Methods and design of Carter and Barnes'[4] study were similar to methods and design of this research.

In this study a slight increase in bacterial plaque was present in subjects who had rinsed with Listerine[R] when compared to the same subjects who had rinsed with the placebo mouthrinse. The small increase in plaque might be attributed to a decrease in compliance of subjects. Listerine[R] mouthrinse was the last rinse used in this study. Possibly, subjects were less motivated and less interested than at the beginning of the study; therefore, compliance with mouthrinse instructions may have been reduced. Additionally, several subjects complained of the strong medicinal taste of Listerine[R] mouthrinse and admitted to not rinsing with it the recommended length of time on the instruction sheet. Therefore, 100 percent compliance with the mouthrinsing instructions was not practiced possibly affecting results of this study.

Results of this study were not supported by Lusk et al.[17], Menaker et al.[18] and Fornell et al.[8] These studies demonstrated that Listerine[R] mouthrinse decreased the amount of either formed bacterial plaque or the formation of bacterial plaque. Positive results reported in these studies

might have been attributed to: supervised rinsing, interest and motivation of subjects, or increased number of daily rinses.

CHAPTER 5

Summary and Conclusions

The effects of commercial mouthrinses, used as an adjunct to routine oral hygiene, on the incidence of gingivitis and on the reduction of bacterial dental plaque is uncertain. Several research studies have been conducted to determine the effects of commercial mouthrinses on plaque and gingivitis. Results of studies are not in agreement suggesting that further research is needed. The purpose of this investigation was to determine if Viadent^{R} or Listerine^{R} mouthrinses used as an adjunct to routine oral hygiene had any effect on the oral health status of subjects over a two-week period. Results of this research study demonstrated that two commercial mouthrinses, Viadent^{R} and Listerine^{R}, did not show a statistically significant reduction in plaque accumulation or the incidence of gingivitis. Mechanical removal, such as brushing and flossing, remains as the most effective means of reducing bacterial plaque and subsequent gingivitis.

Twenty-four subjects between the ages of 18 and 41 participated in a clinical research study at the Old Dominion University Dental Hygiene Clinic. An experimental pre-test/post-test design was used to test the effectiveness of Viadent^{R} and Listerine^{R} mouthrinses on the accumulation

of bacterial plaque and the incidence of gingivitis. A double-blind, crossover design was used in which 24 subjects served as their own controls. Subjects attended four appointments over a six-week period. One dental hygiene examiner measured the amount of bacterial plaque and the level of gingivitis using the Plaque Index and the Gingival Index, respectively. At each appointment subjects were given an adequate amount of mouthrinse for a two-week period and standardized mouthrinsing instructions. At the initial appointment a baseline Plaque Index score and Gingival Index score were established. After each two-week period subjects were required to attend a dental appointment to be examined for the amount of bacterial plaque and the level of gingivitis. At each of the three appointments, subjects were given a different mouthrinse: appointment one--Viadent^{R} (mouthrinse A), appointment two--placebo (mouthrinse B), and appointment three--Listerine^{R} (mouthrinse C). A Generalized Linear Model (Analysis of Variance and the Tukey's Studentized Range Test (HSD)) was used to determine if a statistically significant difference existed in GI score means and PLI score means throughout the four appointments. Additionally, a Paired-Difference t-test provided analysis of score reductions for each mouthrinse from baseline appointment (appointment one) to placebo appointment (appointment three), from Viadent^{R} appointment (appointment two) to placebo appointment (appointment three), and from Listerine^{R} appointment (appointment four) to placebo

appointment (appointment three).

Statistical analysis of data from each appointment revealed that no statistically significant difference existed at the 0.05 alpha level for the experimental variable, the mouthrinses; therefore, (1) the null hypothesis that there is no statistically significant difference in the incidence of gingivitis of subjects who use a placebo mouthrinse and subjects who do not use a mouthrinse as measured by the Gingival Index was not rejected; (2) the null hypothesis that there is no statistically significant difference in the incidence of gingivitis of subjects who use Viadent^{R} mouthrinse and subjects who use a placebo mouthrinse as measured by the Gingival Index was not rejected; (3) the null hypothesis that there is no statistically significant difference in the incidence of gingivitis of subjects who use Listerine^{R} mouthrinse and subjects who use a placebo mouthrinse as measured by the Gingival Index was not rejected; (4) the null hypothesis that there is no statistically significant difference in the amount of bacterial plaque of subjects who rinse with a placebo mouthrinse and subjects who do not use a mouthrinse as measured by the Plaque Index was not rejected; (5) the null hypothesis that there is no statistically significant difference in the amount of bacterial plaque of subjects who use Viadent^{R} mouthrinse and subjects who use a placebo mouthrinse as measured by the Plaque Index was not rejected; and (6) the null hypothesis that there is no statistically

significant difference in the amount of bacterial plaque of subjects who use Listerine^{R} mouthrinse and subjects who use a placebo mouthrinse as measured by the Plaque Index was not rejected.

Considering the discussion and limitations of this study, the following conclusions are offered:

(1) Rinsing the mouth with Viadent^{R} mouthrinse, twice daily as recommended, after mechanical removal of bacterial plaque does not reduce the level of gingivitis when compared to a water rinse.

(2) Rinsing the mouth with Viadent^{R} mouthrinse, twice daily as recommended, as an adjunct to routine oral hygiene does not decrease the amount of plaque significantly when compared to a water rinse.

(3) Rinsing the mouth with Listerine^{R} mouthrinse, twice daily as recommended, as an adjunct to routine oral hygiene does not significantly reduce the level of gingivitis when compared to a water rinse.

(4) Rinsing the mouth with Listerine^{R} mouthrinse, twice daily as recommended, as an adjunct to routine oral hygiene does not significantly decrease the amount of plaque when compared to a water rinse.

Considering the results and design of this research, the following recommendations for future study are offered:

(1) Replication of this investigation is indicated to verify findings and to determine the long term effects of rinsing with Viadent^{R} mouthrinse.

(2) Replication of this study is indicated to verify findings and to determine the long term effects of rinsing with Listerine ^{R} mouthrinse.

(3) Replication of this study is indicated using a larger sample size to assure population validity.

(4) This investigation should be repeated with direct supervision of mouthrinsing to assure compliance with recommended mouthrinsing instruction.

(5) This investigation should be repeated using a longer test period for each mouthrinse to allow adequate time for gingiva to manifest clinical changes.

(6) Further research is needed to determine the effectiveness of mouthrinses on subjects with periodontitis.

This study revealed that rinsing with either Viadent^{R} or Listerine^{R} mouthrinse as an adjunct to routine oral hygiene does not reduce bacterial plaque or the level of gingivitis at a statistically significant level. Results suggest that the use of these mouthrinses as adjuncts to routine oral hygiene are not more effective than rinsing with water.

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APPENDIX A

CONSENT TO PARTICIPATE FORM

Consent To Participate Form

Project Name: The Effectiveness of Mouthrinses Used as Part of the Oral Hygiene Regimen

Principal Investigator: Debra P. Powell, R.D.H., B.S.

Date _____

You are invited to participate in a study to investigate the effectiveness of mouthrinses in adjunct to routine oral hygiene homecare procedures. You were selected as a possible participant because you do not have advanced gum disease and any medical complications that would effect participation.

Your participation will require that you follow the given homecare instructions accurately. You will be asked not to alter your routine oral hygiene homecare regimen in any form with the exception of rinsing with the prescribed mouthrinse daily. Each appointment will involve a partial examination of the teeth and gums, and some sensitivity of the gums may occur during this examination.

I understand that the study will involve four dental appointments at the Old Dominion University Dental Hygiene Clinic. Each appointment will be approximately one hour.

I have completed the medical history provided and verify that all questions have been answered truthfully and to the best of my knowledge.

The investigation and the nature of my participation has been described to me in this form and I understand the explanation. I understand that I am one of the 30

individuals participating in this research project.

I understand that I may withdraw from this study at any time during the study. My decision will not prejudice future relations with Old Dominion University Dental Hygiene Clinic.

I understand that the results of this study may be published or presented orally, but I will not be identified individually.

I understand that participation in the study is strictly voluntary and no monetary compensation will be given.

I understand that upon completion of this study I am entitled to one complimentary dental prophylazis to be performed by a dental hygiene student at the Old Dominion University Dental Hygiene Clinic.

I understand potential risks of participating in this study are the same as if I were having my teeth cleaned professionally.

I understand that if an allergic reaction occurs from the given mouthrinse, I can contact the Principal Investigator or the Old Dominion University Dental Hygiene Clinic. Signs of an allergic reaction may be raised patches on the gums or in the mouth, severe sloughing of tissue, or any extreme changes that occur in my mouth or general health.

I understand that a light brown stain may occur on my teeth after rinsing with the given mouthrinse for a period of two weeks and that this stain is removable by a pro-

fessional cleaning.

I acknowledge that I was informed of any potential risks to my health and well-being that may be associated with my participation in this research.

I understand that no medical or psychological assistance will be made available to me by either Old Dominion University or any member of the research team as a result of any physical or emotional harm that I may experience as a result of this research project.

I acknowledge that I have been advised of how I may obtain a copy of the results of this research project, and that upon my making such a request, a copy will be provided without charge.

I understand that the information obtained from this study may mean better dental care for the public in the future.

I have been informed that I have the right to contact the Old Dominion University Institutional Review Board for the Protection of Human Subjects should I wish to express my opinions regarding the conduct of this study.

You are making a decision whether or not to participate. Your signature indicates that you have decided to participate, having read the information provided above.

I acknowledge any potential risks involved with my participation in this study.

Signature of Volunteer	Date
Signature of Investigator	Date
Signature of Witness	Date

HEALTH HISTORY

Medical Alert

DENTAL HYGIENE CLINIC
OLD DOMINION UNIVERSITY

For safe, personalized dental hygiene care, a complete and accurate health history is necessary. Dental procedures may complicate or be complicated by existing conditions elsewhere in the body; general health factors influence response to treatment. Please give each question below careful consideration and answer to the best of your knowledge.

Name:_____ Birthdate:_____Sex: M or F
(last) (first) (middle initial)

Address:_____ Home Phone:_____
(street) (city) (zip)

Occupation:_____ Work Phone:_____

Physician's Name:_____ Dentist's Name_____

Location:_____ Location:_____
(city) (state) (city) (state)

In case of emergency, notify:_____
(relationship)

DENTAL HEALTH

Reason for visit:_____

Date of last dental appointment:_____

Treatment rec'd:_____

Date and Type of last x-ray examination:_____

How often do you visit the dentist?_____

How would you rate the dentistry performed in your mouth in the past? Good Fair Poor

How and when do you clean your mouth?_____

COMMENTS:

_____

_____

MEDICAL HEALTH

How would you rate your present health? Good Fair Poor

Has there been a change in your health in the past year?

_____ If yes, explain:_____

Have you ever had a serious illness or an operation?_____

If yes, explain:_____

Have you been hospitalized in the past 5 years?_____

If yes, explain:_____

Date of last physical examination?_____ Lab tests:_____

Results of exam and tests:_____

Are you currently under a physician's care?_____

If yes, explain_____

Are you currently taking any medication? (including aspirin, vitamins, birth control pills) Yes No

Medicine	Daily Dosage	Condition for which taken
_____	_____	_____
_____	_____	_____
_____	_____	_____

Have you ever been treated for or been told by a doctor you have or had any of the following:

1. Allergies (ex: hayfever, medications, food, mouthrinses, flavorings).....YES NO
2. Unusual reaction to Novacaine, other medication.....YES NO
3. Respiratory disorders (ex: asthma, bronchitis).....YES NO

4. Congenital heart disease (ex: heart murmur....YES NO

5. Rheumatic Fever.....YES NO

6. Cardiac Surgery.....YES NO

7. Coronary artery disease (ex: angina, heart attack).....YES NO

8. Cerebrovascular accident (stroke).....YES NO

9. Hypotension (low blood pressure), Hypertension (high blood pressure.....YES NO

10. Nervous system disorders (ex: seizures, epilepsy, cerebral palsy).....YES NO

11. Blood disorders (ex: anemias, leukemias, bleeder).....YES NO

12. Diabetes.....YES NO

13. Hepatitis (ex: jaundice, liver disease).....YES NO

14. Blood transfusion.....YES NO

15. Veneral Disease (ex: syphillis, gonorrhea, herpes).....YES NO

16. Tuberculosis (positive TB test).....YES NO

17. Kidney Disease.....YES NO

18. Arthritis, Rheumatism.....YES NO

19. Cancer.....YES NO

20. Women: Are you pregnant? Trimester:_____....YES NO

21. Radiation Therapy.....YES NO

22. Have you had a total joint replacement or any other orthopedic-prosthetic replacement?.....YES NO

Please explain all "Yes" answers:_____

_____

_____

Have you experienced any of the following?

1. Pain, pressure, tightness in chest upon exertion.....YES NO

2. Shortness of breath after mild exercise.....YES NO
3. Shortness of breath lying down.....YES NO
4. Swelling of ankles.....YES NO
5. Persistent cough.....YES NO
6. Bruise easily.....YES NO
7. Prolonged bleeding.....YES NO
8. Frequent headaches.....YES NO
9. Dizziness, fainting.....YES NO
10. Frequent urination (more than 6 times a day)...YES NO
11. Frequent thirst.....YES NO
12. Frequent dry mouth.....YES NO
13. Weight gain or loss of more than 10 pounds.....YES NO
14. Hives, rash.....YES NO
15. Slow healing.....YES NO

Please explain all "Yes" answers:_____

_____

_____

Is there any additional information about your health that has not been covered above?_____

_____

To my knowledge, the preceding information is correct and I consent to having dental hygiene services at Old Dominion University.

DATE	B.P.	STUDENT SIGNATURE	PATIENT SIGNATURE	SSN	INSTRUCTOR
UPDATE:					

APPENDIX C

GINGIVAL INDEX AND PLAQUE INDEX

SCORING CHART

OLD DOMINION UNIVERSITY
DEPARTMENT OF DENTAL HYGIENE

SUBJECT # _____
DAY/DATE _____

GINGIVAL AND PLAQUE INDICES

APPOINTMENT # _____

GINGIVAL INDEX

	MAXILLA			MANDIBLE			TOTAL SUM
TOOTH #							
DISTAL							
BUCCAL							
MESIAL							
LINGUAL							
MEAN GI							

APPOINTMENT # _____

PLAQUE INDEX

	MAXILLA			MANDIBLE			TOTAL SUM
TOOTH #							
DISTAL							
BUCCAL							
MESIAL							
LINGUAL							
MEAN PLI							

APPOINTMENT # _____

GINGIVAL INDEX

	MAXILLA			MANDIBLE			TOTAL SUM
TOOTH #							
DISTAL							
BUCCAL							
MESIAL							
LINGUAL							
MEAN GI							

APPOINTMENT # _____

PLAQUE INDEX

	MAXILLA			MANDIBLE			TOTAL SUM
TOOTH #							
DISTAL							
BUCCAL							
MESIAL							
LINGUAL							
MEAN PLI							

APPOINTMENT # _____

GINGIVAL INDEX

	MAXILLA			MANDIBLE			TOTAL SUM
TOOTH #							
DISTAL							
BUCCAL							
MESIAL							
LINGUAL							
MEAN GI							

APPOINTMENT # _____

PLAQUE INDEX

	MAXILLA			MANDIBLE			TOTAL SUM
TOOTH #							
DISTAL							
BUCCAL							
MESIAL							
LINGUAL							
MEAN PLI							

APPOINTMENT # _____

GINGIVAL INDEX

	MAXILLA			MANDIBLE			TOTAL SUM
TOOTH #							
DISTAL							
BUCCAL							
MESIAL							
LINGUAL							
MEAN GI							

APPOINTMENT # _____

PLAQUE INDEX		MAXILLA			MANDIBLE			TOTAL SUM
	TOOTH #							
	DISTAL							
	BUCCAL							
	MESIAL							
	LINGUAL							
	MEAN PLI							

APPENDIX D

MOUTHRINSING INSTRUCTIONS

MOUTHRINSING INSTRUCTIONS

MOUTHRINSE A

Thank you for volunteering to participate in this dental research study. In order to remain in this study the following mouthrinsing instructions must be carried out exactly as stated for a two week period.

Mouthrinsing Instructions: Appointment One

1. Do not alter your oral hygiene routine in any way with the exception of rinsing with the given test mouthrinse.
2. Do not use any other mouthrinse during the two week test period besides the given test mouthrinse.
3. Use the given test mouthrinse in the morning and in the evening after you complete your usual oral hygiene routine.
4. Rinse twice consecutively for 15 seconds each time with 15 ml (1 capful) of the given mouthrinse. You will use the 30 ml (2 capfuls) in the evening.

If you have any questions concerning these instructions or this study, please contact the principal investigator, Debra P. Powell RDH., at 440-4310.

I understand the above instructions and intend to follow them to the best of my ability.

_____ _____

Signature of Volunteer Date

_____ _____

Signature of Investigator Date

MOUTHRINSING INSTRUCTIONS

MOUTHRINSE B

Thank you for volunteering to participate in this dental research study. In order to remain in this study the following mouthrinsing instructions must be carried out exactly as stated for a two week period.

Mouthrinsing Instructions: Appointment Two

1. Do not alter your oral hygiene routine in any way with the exception of rinsing with the given test mouthrinse.
2. Do not use any other mouthrinse during the two week test period besides the given test mouthrinse.
3. Use the given test mouthrinse in the morning and in the evening after you complete your usual oral hygiene routine.
4. Rinse full strength with 1 ounce (1 dispenser full) of the given test mouthrinse for 30 seconds, once in the morning and for 30 seconds, once in the evening.

If you have any questions concerning these instructions or this study, please contact the principal investigator, Debra P. Powell RDH., at 440-4310.

I understand the above instructions and intend to follow them to the best of my ability

_____ _____

Signature of Volunteer Date

_____ _____

Signature of Investigator Date

MOUTHRINSING INSTRUCTIONS

MOUTHRINSE C

Thank you for volunteering to participate in this dental research study. In order to remain in this study the following mouthrinsing instructions must be carried out exactly as stated for a two week period.

Mouthrinsing Instructions: Appointment Three

1. Do not alter your oral hygiene routine in any way with the exception of rinsing with the given test mouthrinse.
2. Do not use any other mouthrinse during the two week test period besides the given test mouthrinse.
3. Use the given test mouthrinse in the morning and in the evening after you complete your usual oral hygiene routine.
4. Rinse full strength with the given test mouthrinse for 30 seconds with 2/3 ounce (4 teaspoonfuls) once in the morning and once in the evening.

If you have any questions concerning these instructions or this study, please contact the principal investigator, Debra P. Powell RDH., at 440-4310.

I understand the above instructions and intend to follow them to the best of my ability.

_____ _____

Signature of Volunteer Date

_____ _____

Signature of Investigator Date

APPENDIX E

THANK YOU LETTER TO SUBJECTS

April 15, 1985

Dear Volunteer,

Today is the last dental appointment of the Research Study on mouthrinses. Upon completion of this study, I would like to thank you for participating in my research. Your participation in this study is greatly appreciated and without your time and dedication the study would not have been a success.

Because this was a double-blind study, I was not permitted to tell you the names of the mouthrinses during the study period. Thank you for your patience and not asking questions during the study. Since the study has been completed, I can tell you the names of the three mouthrinses. Mouthrinse A was "Viadent" which is a new rinse on the market manufactured by Vipont Laboratory. Mouthrinse B was a placebo rinse composed of distilled water and mint extract flavoring. Mouthrinse C was "Listerine" manufactured by Warner Lambert Company.

Results of this study will not be available until my thesis is completed. The anticipated date of completion is September, 1985. At that time if you are interested in the results, please contact me through the Dental Hygiene Department, 440-4310 and I will share them with you.

Also, you are entitled to a complimentary dental exam and cleaning at the Old Dominion University Dental Hygiene Clinic. Since there are only three weeks of clinic time

left in this semester, your appointment will have to be scheduled during the summer school session. The clinic secretary will have a list with your name and social security number on it. When you make your appointment please tell her you participated in my dental research study.

Again, thank you for your participation in my dental research study. Without your help this valuable research would not have been possible.

Sincerely,

Debra P. Powell, RDH, BS

APPENDIX F

INTRARATER RELIABILITY DATA FOR PLI SCORES AND GI SCORES

INTRARATER RELIABILITY DATA
FOR PLI SCORES

Pearson r Computed from the Sum of Scores for Two Sets of Plaque Index Scores (x,y)

Subject	x	y
1	.58	.29
2	.66	.58
3	.37	.54
4	.62	.62
5	.62	.66
6	.58	.45
7	.50	.87
8	.75	.70
Total	46.8	47.1

r = 0.9500

INTRATATER RELIABILITY DATA
FOR GI SCORES

Pearson r Computed from the Sum of Scores for Two Sets of Gingival Index Scores (x, y)

Subject	x	y
1	0.83	1.04
2	1.00	1.00
3	0.58	0.70
4	1.12	1.00
5	1.29	0.62
6	0.79	0.70
7	0.41	0.70
8	0.66	1.04
Total	66.80	68.00

$r = 0.9759$

APPENDIX G

RAW GINGIVAL INDEX SCORES

BY APPOINTMENT

RAW GINGIVAL INDEX SCORES
BY APPOINTMENT

Subject Number	Baseline	Appointment Two	Appointment Three	Appointment Four
1	1.00	1.04	1.12	1.16
2	1.12	1.41	1.25	1.08
3	1.45	1.45	1.37	1.33
4	1.12	1.08	1.29	1.12
5	1.08	1.12	1.20	1.16
6	1.00	1.00	1.16	1.16
7	1.04	1.08	1.12	1.04
8	1.33	1.33	1.33	1.37
9	1.00	1.08	1.04	1.08
10	1.20	1.08	1.16	1.12
11	1.00	1.04	1.04	1.04
12	1.29	1.58	1.41	1.16
13	1.20	1.29	1.20	1.08
14	1.37	1.16	1.16	1.16
15	1.37	1.33	1.20	1.50
16	1.12	1.33	1.45	1.37
17	1.08	1.16	1.12	1.08
18	1.33	1.33	1.16	1.12
19	1.16	1.16	1.29	1.20
20	1.04	1.04	1.16	1.00
21	1.41	1.08	1.08	1.33
22	1.54	1.16	1.12	1.16

RAW GINGIVAL INDEX SCORES
BY APPOINTMENT

Subject Number	Baseline	Appointment Two	Appointment Three	Appointment Four
23	1.37	1.37	1.12	1.25
24	1.20	1.20	1.08	1.08

APPENDIX H

RAW PLAQUE INDEX SCORES

BY APPOINTMENT

RAW PLAQUE INDEX SCORES
BY APPOINTMENT

Subject Number	Baseline	Appointment Two	Appointment Three	Appointment Four
1	1.00	0.91	0.83	1.16
2	0.79	0.70	0.66	1.00
3	1.09	1.12	1.08	1.20
4	1.33	1.29	1.58	1.50
5	0.83	0.79	0.54	0.75
6	1.37	1.20	1.12	1.12
7	1.04	0.95	0.93	1.08
8	0.79	1.08	0.75	0.91
9	0.83	0.83	0.87	0.83
10	0.70	0.91	0.79	0.54
11	1.16	0.87	0.75	0.10
12	1.37	0.83	1.20	1.33
13	0.95	0.87	0.91	0.87
14	1.58	1.45	1.37	1.45
15	1.29	1.29	1.16	1.41
16	1.37	1.08	1.41	1.33
17	0.91	0.70	0.87	1.08
18	1.54	1.45	1.45	1.50
19	1.29	0.75	0.91	1.08
20	0.62	0.62	0.95	1.00
21	1.12	0.54	1.25	1.37
22	0.87	0.62	0.70	0.83

RAW PLAQUE INDEX SCORES
BY APPOINTMENT

Subject Number	Baseline	Appointment Two	Appointment Three	Appointment Four
23	1.29	1.12	1.45	1.16
24	0.66	0.62	0.75	0.70

APPENDIX I

GENERAL STATISTICS FOR PLI SCORES AND GI SCORES BY APPOINTMENT

GENERAL STATISTICS FOR PLI SCORES

AND GI SCORES BY APPOINTMENT

Appointment	Mean GI	Mean PLI
One	1.20083333	1.07495833
Two	1.20416667	0.94125000
Three	1.19625000	1.00750000
Four	1.17291667	1.05750000

APPENDIX J

RANGE OF PLI SCORES AND GI SCORES

BY APPOINTMENT

RANGE OF PLI SCORES AND GI SCORES

BY APPOINTMENT

Appointment	GI Range	PLI Range
One	0.54000000	0.96000000
Two	0.38000000	0.91000000
Three	0.41000000	1.04000000
Four	0.50000000	1.40000000