

REDUCTION OF PLAQUE FORMATION AND GINGIVITIS BY A DENTIFRICE CONTAINING 1% CHLORHEXIDINE⁺

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Abstract

The effect of unsupervised brushing with a dentifrice containing antiplaque agent, 1%chlorhexidine, on gingival health, plaque, supragingival calculus, and the oral flora was compared to that of brushing with a non-active control dentifrice. Volunteers were given oral hygiene instruction and their teeth were professionally cleaned. They then were stratified into two groups on the basis of their initial plaque, gingival bleeding, and calculus levels, sex, and age. Over the following 6 months, one group was used as the control while the other used the test dentifrice. Plaque levels, gingival bleeding, and calculus were assessed at baseline and at 3 and 6 months. Supragingival plaque was sampled for microbiological analysis at the initial examination, at 3 and 6 months (conclusion of study period). Representative oral bacteria and the development of bacterial resistance to chlorhexidine were monitored.

Results show that plaque was reduced and gingival health significantly improved. During the experimental period, this improvement was not maintained by the control group as gingival bleeding and calculus increased. In contrast, gingival bleeding and calculus levels of the test group were maintained significantly below those of the placebo group. Plaque levels were lower in the test group after 3 and 6 months, but the groups were not significantly ($P = 0.05$) different. No shifts in oral flora or development of bacterial resistance to chlorhexidine were detected

المستخلص:

تمت مقارنة تأثير الإشراف على تنظيف الأسنان باستعمال الفرشاة ومعجون أسنان يحتوي مضاد بكتيري (١%)كلور هكسدين على صحة اللثة،الصفحة الجرثومية،تكتلات فوق اللثة والأحياء المجهرية المتواجدة في الفم مع تنظيف الأسنان باستعمال معجون أسنان اعتيادي بدون عناصر فعالة.تم إعطاء المتطوعين تعليمات حول صحة الفم ونظاف الأسنان بعد أن تم تنظيفها من قبل مختص وقد قسموا إلى مجموعتين على أساس ابتدائي يشمل الصفحة الجرثومية،نزف اللثة،مستوى التكتلات،الجنس،العمر. تم تقييم مستويات الصفحة الجرثومية،نزف اللثة،ومستوى التكتل قبل البدء وبعد ثلاثة اشهر وست اشهر من استعمال المجموعتين للمعاجين المختلفة (المعجون مع المعقم والمعجون الاعتيادي).تم تشخيص البكتريا المتواجدة في الفم وحدوث مقاومة من قبلها قبل وبعد استعمال المعجون الحاوي على الكلور هكسدين وأظهرت النتائج أن مستوى الصفحة الجرثومية وصحة اللثة تدل على التحسن لثناء فترة التجربة ، ذلك التحسن لم يبق على المستوى نفسه بالنسبة للمجموعة التي تستعمل معجون اسنان اعتيادي إذ أن

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نزف اللثة و التكلسات قد زادت ، على العكس أن نزف اللثة و مستوى التكلسات للمجموعة التي تستعمل معجون الكلور هيكسدين قد بقيت اقل من المجموعة الأخرى ولم يلاحظ ازدياد او تطور مقاومة بكتيرية للكلور هيكسدين.

Introduction

Plaque formation is a progressive, dynamic process which if permitted to continue unhindered results in gingivitis.[1] Whether gingivitis develops when a critical plaque mass is exceeded or specific microorganisms colonize the plaque is not clearly understood.[2] whatever the case

Toothbrushing with a toothpaste is probably perceived by the general public to provide a number of cosmetic and health benefits.[3,4] To the dental profession, however, the regular removal of plaque by mechanical means represents the most logical and simple approach to maintaining gingival health.[5,6]Prevalence figures for gingivitis.[7,8] unfortunately, suggest that compliance with the recommendation for regular toothbrushing, or more likely dexterity in performing toothbrushing, is low. Epidemiological.[9,10] and clinical.(13,14,15,16) data demonstrate that certain teeth and tooth surfaces are poorly cleaned, if at all.

In an attempt to enhance mechanical toothcleaning, a large and varied range of chemicals have been employed usually in toothpastes or mouthwashes.[11-13] Such chemical adjuncts to oral hygiene could prevent bacterial adherence, inhibit bacterial growth, or actually remove plaque. The modes of action and effectiveness of chemical plaque control agents have been reviewed and it is apparent that, chlorhexidine, successes to date to be the modest.[11-17] .chlorhexidine is strong base and dicationic at PH levels above 3.5 ,with the 2 positive charges on either side of the hexamethylen bridge .[18] ,it is the dicationic nature of chlorhexidine,making it extremely interactive with anions,which is relevant to its efficacy,safety,local side effects .

Chlorhexidine has a broad antimicrobial action including a wide range of Gram-positive and Gram-negative bacteria.[19].It is also effective against some fungi and yeasts,including candida,and some viruses including HBVandHIV.Bacterial resistance has not been reported,including during long-term oral use,nor evidence of superinfection by fungi,yeast or viruses.Long-term oral use resulted in a small shift in the flora towards the less sensitive organisms but this was rapidly reversible at the end of the 2-year study.[20] .The aim of this study is to determine the effectiveness of chlorhexidine containing tooth paste

Materials and Methods

The test dentifrice contained 1% chlorhexidine as the antiplaque agent. Other ingredients included alumina, sodium monofluorophosphate, and foaming agent. The active ingredient was carefully incorporated into the dentifrice to maximize clinical efficacy. The control and test dentifrices were identical, except for the exclusion of the antiplaque agent from the control.

Subjects

Volunteers of both sexes were recruited for the double-blind study and 60 initially participated. Ages ranged from 17 to 51 years, with a mean age of 28 years. Selection criteria included the presence of at least mild gingivitis, the absence of periodontal pockets of > 3.5 mm, and the absence of any adverse medical history or long-term medication.

Clinical Study

At the start, the teeth were professionally cleaned to remove all deposits, and the patients received oral hygiene instruction which included the use of floss and interdental toothbrushes. Patients were divided into groups defined by combinations of sex, 10-year age intervals, and total calculus (4 levels). Within each group patients were ranked according to gingival bleeding score.. The test dentifrice was assigned at random to one group and the other group received the control. All participants were instructed to brush twice daily as normal..

Clinical examinations were performed by a single investigator at the start of the study, and after 3 and 6 months. Plaque was assessed using the Plaque Index[21] and gingival health by the number of gingival sites that bled after gentle probing using a CPITN probe.[22] The probe was inserted into the gingival sulcus to a depth of approximately 2.0 mm and moved around the tooth, stroking the soft tissue walls of the facial, distal, mesial, and lingual surfaces. The Mean Plaque and Bleeding Index scores for the mouth were calculated by combining scores of the four sites and dividing by the number of sites assessed. Where subjects exhibited calculus, it was assessed across three planes after thorough air drying of the lingual surfaces of the lower anterior teeth.[23].

In addition to the clinical assessment of the gingiva, all oral tissues were examined for signs of adverse conditions, such as irritation, desquamation, ulceration, and discoloration and the subjects were asked about their experience in this respect.

Plaque Sampling

Plaque samples were taken for microbial analysis from 10 participants selected at random from each group. All patients brushed their teeth on the morning prior to sample collection. Interproximal plaque was removed from two sites in each patient chosen for sampling between the permanent upper left and lower right premolars. If these teeth were missing, or did not make interproximal contact, plaque was removed from the upper right and lower left premolars. Plaque samples were collected at the start of the study prior to prophylaxis, at 3 and 6 months in the experimental phase of the study.

Samples were removed by means of unwaxed dental floss and transferred immediately into pre-reduced transport fluid (RTF).[24] Microbiological laboratory procedures commenced as soon as possible, usually within 1 hour of sample collection.

Microbiological Procedures

Plaque samples were diluted 10-fold with pre-reduced, sterile physiological saline. The diluted plaque samples were plated onto a variety of selective and non-selective agars by means of a spiral plater. The plates were incubated under growth conditions optimum for each population.

After incubation, the total numbers of aerobic and anaerobic colonies per plaque sample were counted.. The identity of selected colonies was confirmed by Gram stain and commercially available biochemical tests.

Results

Clinical Observations

Participation in the three examinations shows no adverse reactions on soft tissues, the teeth, or restorations were recorded. The mean plaque index for the control and the test group at the pre-study assessment was 0.72 and 0.70, respectively, and percentage of sites bleeding on probing was 31.8 and 31.9, respectively at the 3- and 6-month examinations, plaque levels of both groups remain relatively low. While there was a lower plaque score for the test group. Over the same period, significantly lower levels of gingival bleeding were observed in the test group ($P < 0.001$) at both assessments. Both groups exhibited similar responses within groups and across treatments. The mean calculus score per site at the pre-study examination was approximately 0.6 mm. At both the 3- and 6-month assessments the calculus level in the test group was significantly lower than for the control group.

Microbiological Observations

Streptococci, aerobic, and anerobic bacteria were isolated from all the samples analyzed, but detectable level of bacteria was not present in test samples from several subjects. Since less than half the subjects had non-detectable levels, there were significant differences between placebo and test groups for Streptococcus, Lactobacillus, and Actinomyces.

Very few Gram-negative rods, Candida albicans, or other yeasts were found in plaque samples from either the test or placebo group at any time during the study, in spite of the detectable levels of Gram-negative rods were found in samples from only two participants in the test group during the whole study. Likewise, none of the subjects in the test group had detectable levels of chlorhexidine resistant bacteria after 6 months use of test dentifrice.

Discussion

Maintenance of a low level of plaque, consistent with gingival health, is an important element of any dental health program. A high level of oral hygiene can be maintained over extended periods by individuals who are provided with regular toothcleaning instruction and scaling.[25]. Normally, however, individuals who have participated in experimental dental health programs fail to comply with the instructions they have been given.[26] As a result, there is some return to pre-study plaque levels,[27] although some benefits from the programs remain. . It can be concluded from the gradual deterioration of the baseline level of gingival health over the following months, that without frequent professional intervention, individuals gradually fail to comply with oral hygiene instructions.[28].

The present unsupervised trial has demonstrated that the users of the test dentifrice significantly maintained their oral health when compared to the control group. This is in full agreement with previous studies on chlorhexidine containing products, albeit that formulation contained a lower concentration.[29].

In addition to the observed significant difference in the average scores in gingival bleeding for both groups, At 6 months, subjects on the test formulation had less than 5% of sites bleeding compared to 15% of subjects in the control group. While subjects with this level of bleeding sites are not healthy in an absolute sense, this cut-off point of 5% bleeding sites has been used before as a realistic parameter for

health in clinical studies.[30,31]. Finally, the benefit obtained for the test product was independent of age of subjects.

The results with respect to plaque levels at 3 and 6 months show a difference between test and control. Although the difference is not statistically significant at $P = 0.05$, the trend is in agreement with other studies in which the antiplaque effect of formulation containing chlorhexidine has been established.[11-13] and it could be speculated that this is due to the thoroughness of brushing by both groups.

The anti microbial chlorhexidine, when incorporated into a dentifrice, can clearly help to control the development of gingivitis. However, such antimicrobial agent, if present in a dental product that is used daily, may cause population shifts in the oral flora by selective activity, or by allowing overgrowth of opportunistic pathogens following the suppression of the predominant organisms.

After 6 months regular use of the dentifrice, no significant population shifts in the oral flora were detected. In contrast, regular use of other antimicrobial agents has been shown to cause population shifts in the oral microflora.

Bacterial tolerance, or resistance to an antimicrobial agent, may also induce population changes in the oral flora. This is a particularly important consideration when a dentifrice is intended for daily use.

Several studies have shown that prolonged use of antimicrobials results in the oral flora, particularly *Actinomyces* and *S. sanguis*, becoming less sensitive with time after prolonged use.(12-14). However, there was no evidence for the development of resistance to chlorhexidine by any oral bacteria after 6-months use of the dentifrice. The inclusion of chlorhexidine in the primary isolation media, in a manner analogous to that used previously for fluoride,would have allowed detection of low numbers of chlorhexidine-resistant bacteria if they had been present.

In conclusion, this study has demonstrated that a dentifrice containing chlorhexidine, used regularly over 6 months, promoted gingival health, without affecting the balance of the oral flora.

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