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Chlorhexidine with an Anti Discoloration System. A comparative study

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Abstract Correct oral hygiene is believed to be the basis of primary and secondary prevention. Sometimes, using a toothbrush or other mechanical instruments for oral hygiene may be difficult and it may become necessary to use an antiseptic. Chlorhexidine is an essential component in many available preparations on sale, because of its marked antiseptic qualities. One of the most frequent side-effects is the appearance of stains on the teeth and mucous membranes, which particularly disturbs the patient. A new mouthwash containing chlorhexidine has recently become available, besides maintaining its antiseptic qualities, also avoids the side-effect of staining. Objectives: The aim of this study was to check the capacity of the new mouthwash, which contains chlorhexidine and Anti Discoloration System (ADS), not only to prevent plaque formation like the other mouthwashes containing chlorhexidine but also to avoid staining that is one of the most frequent side-effects. Study design: The comparative study was carried out on a sample of 15 patients treated with two mouthwashes both containing 0.2% chlorhexidine, but different in that the first does not contain ADS, which is instead present in the second, a new product. The results obtained show that in the 15 patients treated, there is no statistically significant difference in the ability of the mouthwash to prevent bacterial plaque, however evidence of the stain was much less with the new mouthwash.

Key words: chlorhexidine; staining; mouthwash; bacterial plaque; oral hygiene

Introduction

The aetiopathogenetic role of bacterial plaque in periodontal disease is now widely demonstrated (1, 2). The importance of

oral hygiene in primary and secondary prevention is no longer disputed (3–8). The use of a toothbrush and instruments for inter-dental hygiene is recommended in order to remove plaques (6, 9). On various occasions it may be necessary to integrate or replace mechanical hygiene with the use of antimicrobial agents (10, 11).

Among antimicrobials, antiseptics are represented by a varied group of chemical substances that carry out an antibacterial action different from normal antibiotic chemical therapies (12).

Of all the biguanides, chlorhexidine is the most widespread and well-known molecule and is perhaps the most studied substance with anti-plaque action, and has been found to be effective in most studies (13–16). Chlorhexidine is used in dentistry as a solution (water + chlorhexidine) in various concentrations (0.2 and 0.12%) or as a gel (1 and 0.5%) or more recently in tablet or spray form (14, 17).

The side-effects of chlorhexidine, are always local and reversible (Table 1). One of the most common side-effect is the appearance of yellow-brown coloured stains that turn blackish on the back of the tongue and on the teeth. The mechanisms that determine the dental colouring caused by the chlorhexidine are still being disputed. The tests available indicate the causes of staining to be: non-enzyme browning, also known as the Maillard reactions, or processes of condensation and polymerization of carbohydrates, peptides and proteins, that causes the formation of brown-staining substances, which are known as melanoidins; the deterioration of the chlorhexidine molecule in order to release parachloranilin; the protein denaturing with the formation of metal sulphides (18, 19). According to Addy, the cause is to be found in the tie that can be created between the adsorbed chlorhexidine and the chromogens present in food and drink (tea, coffee and soft drinks) including polyphenols.

The potential staining-substance depends on the concentration of chlorhexidine. This staining is reversible and can be removed by both suspending use of the mouthwash and by conventional cleaning procedures using bicarbonate or abrasive pastes for prophylaxes (20–22).

Table 1. Reversible side-effects of chlorhexidine

Side-effects of chlorhexidine

Yellow-brown staining of the teeth surface, the back of the tongue, prosthesis and composite restorations Erythemous-desquamative lesions of the mucous membrane Alterations in taste Reversible swelling of the parotid gland Resistance to drugs Therefore, this study will quantify if the chlorhexidine with ADS stained or stained less than the 'classic' chlorhexidine mouthwash.

Materials and methods

A mouthwash A^1 containing 0.2% chlorhexidine and a mouthwash B^2 containing 0.2% chlorhexidine and Anti Discoloration System (ADS) that has the aim of inhibiting the formation of staining, were compared. The ADS system means a formulation that, according to the manufacturer, has been found to be optimal in preventing the main staining reactions that can occur after using mouthwashes containing chlorhexidine. This formulation was obtained by adding two active principles, sodium metabisulphite and ascorbic acid. According to the manufacturer, adding the ADS system does not interfere with the antiseptic and anti-plaque power of the chlorhexidine. This was confirmed by the 'Challenge Test' performed by the manufacturer. The other mouthwash differed only in the absence of the ADS system.

Using the 'single blind' criteria the study was carried out on a randomly chosen sample of 15 patients, who underwent a professional oral hygiene check-up at the Department of Dental Sciences at the University of Bologna.

The patients, of both sexes (aged between 20 and 46 years), had a healthy dental situation with no gingivitis and did not use mouthwashes, had no systemic illnesses and were not taking drugs.

To evaluate the presence of bacterial plaque, a plaque index (IP, Silness and Loe) and a modified gingival index (IG, Loe and Silness) was used to evaluate inflammation. Each patient was observed on the surfaces of 11-12-13-21-22-23-31-32-33-41-42-43. To assess staining, a spectro-shade was used, looking at the cervical and vestibular-mesial interproximal areas of four teeth 11.31.41.42, chosen according to criteria of convenience and observation. To classify colour on the spectro-shade the CIELAB system was used.

This is a three-dimensional system with Cartesian axes on which luminosity is represented on the first axis (L) with a value from 0 (black) to 100 (white); chroma is represented on the second axis (a), from red (positive value) to green (negative value). The colour (b) from yellow (positive value) to blue (negative value) is shown on the third axis. In this system, the difference between the two colours (ΔL) is calculated by the square root of the sum of the squares of the differences

¹Chlorhexidene mouthwash 0.2%, commercially available in Italy. ²'CURASEPT' made by Curaden Healthcare srl Saronno, Italy.

between the three coordinates (*L*, *a*, *b*) of the two colours $\Delta E = [(\Delta)L^2 + (\Delta)a^2 + (\Delta)b^2] \frac{1}{2}.$

Where as the CIELCH System is similar to the CIELAB System, the CIELCH System demonstrates luminosity (L^*) , but the chroma (C^*) increases retreating from the centre, and the colour (H^*) is represented by an angle. Of the two systems the CIELAB System is more accurate to measure colour.

These systems were developed by the International Commission For Brightness (23). In our study, all the patients used both mouthwashes for a period of 2 weeks each, separated by an interval of 15 days, eight patients were given the mouthwash A initially and then B; seven patients were given mouthwash B initially and then A (the sequence of the mouthwashes was carried out randomly). The experiment lasted 6 weeks. At 0, the IP and IG were found, a professional oral hygiene appointment was carried out, and then photos were taken and colorimetric takings were carried out using the spectro-shade of the teeth being studied.

During the same session, all the patients were given the first mouthwash with a registration sheet attached, where the volunteers noted the correct application of the protocol each day. After 15 days of treatment, the IP and IG, colorimetric measurements and photographs were taken and an oral hygiene session was again completed.

After a free interval of another 15 days, professional hygiene was repeated, the IP and IG indexes were read and the colorimetric measurements were taken and each patient was given the second mouthwash.

After 15 days of treatment with the second mouthwash, the index readings and the colorimetric measurements with the spectrophotometer were carried out.

Each volunteer was given single-dose, non-diluted mouthwash sachets, each containing 12 ml of the product at 0.2%, to rinse for 1 min twice a day (morning and evening) for 15 days. For the entire period of the experiment, the volunteers maintained their usual oral hygiene habits, and in order to standardize the protocol, they were given a toothpaste that did not contain chlorhexidine and a medium-bristle toothbrush. The volunteers were asked not to drink coffee, tea or red wine before and after 1 h following the rinse. All measurements were registered by the same operator on a specific sheet before using the mouthwash after 15 days of use. To judge the efficacy of the product, the purpose was not to monitor tooth whiteness, but to measure and confront the colormetric values registered before and after the use of mouthwash. A statistical analysis of the data, to check the significance of the results, was carried out at the end of the study.

Results

To carry out a statistical analysis of the data referring to the findings of the IP and IG, the Wilcoxon test for paired data was used. Given that the not-normal distribution of the indexes, a significant difference was found for each mouth-wash, regarding the base values and the value after 15 days, both for IP and IG (Table 2).

No significant difference was found between the two mouthwashes for IP and IG both at the base condition and after 15 days (Fig. 1).

For the statistical analysis of the results referring to the spectro-shade measurements, the cervical area and the interproximal areas were compared for each element, at day 0 and day 15, for both mouthwashes.

The Kolmogorov–Smirnov test of goodness-of-fitness was applied to the variables being examined (difference in relation to the cervical site and the difference in relation to the interproximal site) to see if their distribution tends towards a Gaussian curve.

The significance of the differences in efficacy between the two mouthwashes was assessed, by teeth and by site, using a parametric test, the Student's *t*-test.

In relation to the cervical site, the difference between the mouthwashes A and B for each element has always been significant with this denoting the superiority of the mouthwash B.

Similar results emerged from the assessment of the differences between mouthwash A and B in relation to the interproximal site (Table 3).

Statistical analysis of the data, revealed the ability of the mouthwash (12 ml of the 0.2% product twice a day for 15 days) in preventing bacterial plaque and gingivitis.

Table 2. Descriptive statistics and Wilcoxon test significance for each mouthwash between the base values and the values after 15 days, for plaque index (IP) and gingival index (IG)

		<i>P</i> -value
Mouthwash A		
IP		0.001
Baseline	1 ± 0.17	
15th day	0.2 ± 0.11	
IG		0.005
Baseline	0.53 ± 0.13	
15th day	0	
Mouthwash B		
IP		0.001
Baseline	1 ± 0.17	
15th day	0.2 ± 0.11	
IG		0.005
Baseline	0.53 ± 0.13	
15th day	0	



Fig 1. Difference between mouthwash A and B regarding plaque index and gingival index in base values and the values after 15 days.

Table 3. The difference between mouthwash A and B according to each element of the cervical and interproximal sites, in relation to the spectro-shade measurements. Descriptive statistics significance values (P) and confidence interval (CI) is 95%

Tooth	Mouthwash A	Mouthwash B	P-value	CI
Cervical site				
11	4.55 ± 0.59	1.50 ± 0.24	0.003	0.95-3.70
31	4.83 ± 1.14	1.94 ± 0.51	0.002	1.66-6.29
41	4.45 ± 0.50	2.32 ± 0.54	0.003	0.97-3.90
42	5.86 ± 0.74	2.20 ± 0.59	0.0001	2.07-3.92
Interproximal site				
11	5.70 ± 0.88	2.38 ± 0.58	0.0001	1.79-4.79
31	7.46 ± 0.98	2.59 ± 0.42	0.010	1.19-7.32
41	7.70 ± 0.76	2.93 ± 0.40	0.0001	2.50-5.51
42	7.13 ± 1.26	3.46 ± 0.81	0.007	1.42–7.24

With regard to the side-effect of staining, a statistically significant difference between the two mouthwashes was found, showing that mouthwash B (Curasept – Curaden Healthcare) significantly prevented the formation of staining.

Further research is needed, to test the mouthwash in the case of patients with periodontitis or periodontitis that cause recessions, exposing the radicular cementum which can easily be stained because of its rough surface.

Discussion

This study was conducted to verify the statement of the manufacturer that CHX with the ADS system could eliminate or reduce pigmentation and maintain anitplaque activity. In the literature there are articles comparing CHX for their antiplaque activities, but as for staining only one other study is sited. Stain, plaque and gingivitis reduction by combining chlorhexidine and peroxyborate, Gründemann *et al.* (24).

The result of this study is that there is less staining of the tooth surface when adding an oxidizing mouthwash. The study that was conducted at the University of Bologna, Italy, revealed the potential of the ADS system for antiplaque activity besides reducing or eliminating pigmentation.

The ADS system has two principal agents, which, with a synergizing action, interfere with the mechanisms that cause pigmentation.

A further study with CHX and ADS is needed to examine and evaluate the effect of CHX and ADS on the periodontalinvolved patient, and in addition it would be very interesting to do a comparative study of CHX to CHX with ADS, and CHX with peroxyborate following the protocol used in the Bologna study.

To assess staining, colorimetric measurements are performed with the spectrophotometer and not the gingival modification of the stain index (GMSI; 25). In this method the tooth is divided in four zones and colour intensity in each zone is scored by the criteria described by Lobene (0, no stain; 1, light stain; 2, moderate stain and 3, heavy stain; 23, 25).

In the above cited study by Gründemann *et al.* the measurement used to quantify stain is subjective to the interaction of the human eye of the operator (24). The colorimetric measurement may give a more precise reading, because the precision of colour is the result of a physiologic reply to a physical stimulus.

It is an individual's experience and the rays of light produced are objective. Therefore, a conditioned multifactor system was developed to automatically register the coordinated chroma without relying on the human eye. This approach consents to measure objectively the precise colour (23).

In the 'Bologna Study', the spectrophotometer was selected because it is able to measure the transmission of light that is reflected off of an object. It is an instrument that compares each wave length that radiates energy, which refract from an object after having passed through those, existing on the surface. They are then automatically transcribed to a computer, which analyses the data. This approach consents to measure objectively the precise colour. For this reason the GMSI Index (25) was not used. Again sustaining that a colorimetric reading gives a more accurate measure (23, 26).

With our observances, it should be possible to propose a prepared mouthwash that inhibits plaque, gingivitis and eliminates or reduces pigmentation on the tooth surface and ideal for the dental professional.

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