THE EFFECTIVENESS OF A STABILIZED CHLORINE DIOXIDE MOUTHWASH AMONG SELECTED GROUP OF PATIENTS

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ABSTRACT

This clinical trial aimed to test the efficacy/effectiveness of Durafresh™ mouthrinse and gel on periodontal pockets, halitosis and oral sores among elderly Filipinos and Filipino adults. Thirty two subjects (age ranging from 31 to 81) from two sample populations (La Verna and UP College of Dentistry) were able to complete the study. The following parameters were included in the evaluation: Pocket Probing Depth (PPD) using the Ramjford's Index Teeth, oral sore healing and halitosis scores. The clinical trial was run for four weeks and 5 measurements of each evaluation parameter were taken: baseline, and every week after the start of the rinsing regimen thereafter up to 4 weeks. Means for each clinical parameter were computed and analyzed using Student's t-test to test whether there is significant change in the evaluation parameters over time. Results showed that:

1. Pocket probing depth improves with the use of Durafresh™ mouthrinse.
2. Durafresh™ oral gel hastened the healing of oral sores and provided a degree of palliative effect.
3. Halitosis was significantly decreased with the use of Durafresh™ mouthrinse.

Introduction

Oral hygiene adjuncts and plaque control agents have been in the market for some time. These product which are useful in maintaining good oral hygiene, have been proven to help in reducing plaque and dental caries, and in preventing halitosis or bad breath. Earlier products are mainly alcohol chlorhexidine-based. Although both types of mouth rinses have been documented to be successful adjuncts in treating gingival and periodontal disease, in maintaining oral hygiene, and in some cases, as post surgical rinse, there have been some reported side effects which include drying of the oral mucosa, bad taste, sensitivity and tooth staining.[1] Mouth rinses with very high alcohol concentration have been reported also to contribute to the development of oral cancer.[2]

Recently, a new plaque control/oral hygiene agent with chlorine dioxide (Durafresh) as the active ingredient was developed. First used in 1941 as a water disinfecting agent, stabilized chlorine dioxide's use have expanded to food processing, brewery and is currently being developed into a variety of pharmaceutical healthcare products such as contact lens solution cold sterilizants, and treatment for burns. Most recently, it has found its way in oral health care as a viable alternative to other mouth rinses.[3]

The mechanism of action of chlorine dioxide is through a unique oxidation process, which destroys micro-organisms. The oxidation process degrades volatile sulfur compounds (VOC's), which are the etiological agents of halitosis.[4] Since this new mouthwash contains stabilized chlorine dioxide, its regular use can prevent microbial diseases in the mouth such as gingivitis, periodontitis and can prevent and cure halitosis.

Elderly individuals are susceptible to these oral conditions because of changes in their metabolism, endocrine changes and decrease in salivary flow. The lack of muscular coordination and mood swings can also compromise their oral hygiene habits, which could lead to plaque build-up. This stabilized chlorine dioxide mouthwash does not contain alcohol; it is non-irritating to the mucosa, has relatively more pleasant taste and thus, may prove to be more acceptable to elderly individuals whose sense of taste could be very discriminating.

This product has been tested in the United States and among Caucasians. However, no study has been done yet among the Filipinos.

Objectives of the Study:

1. To test the efficacy/effectiveness of a stabilized chlorine dioxide mouthrinse and ointment on periodontal pockets, halitosis and oral sores among elderly Filipinos and Filipino adults.

Materials and Method:

1. Research Design

A clinical trial that ran from October 2005 to March 2006 to test the effectivity of Durafresh™, a chlorine dioxide based mouthwash, was employed or used by this study. Ramfjord's six index teeth namely namely 16, 11, 26, 36, 31, 44 were noted for periodontal status. The following were the parameters used in the clinical trial.

1.1. Oral examination to determine the over-all impression of each subjects' oral condition which involves the documentation of carious lesions, restorations mucosal condition and other peculiarities present

1.2. Pocket probing depth to determine sites that is normal or periodontally compromised.

1.3. Halitosis rating using the organoleptic scoring scale to measure the intensity of malodor.

1.4. Documentation of the presence and characteristics of existing oral sores.

2. Study Population

Participants to the study were selected from two locations based on the research criteria. Two locations were adult population ages 60+ years while the other was a middle age population. The subjects were then divided into:

Control group – subjects rinsed with distilled water

Experimental group – subjects rinsed with Durafresh^{TM} mouthrinse

The subjects were blinded or were not informed of the contents of the oral rinse they used.

Exclusion Criteria

Excluded from the study are:

1. Thirty years old below
2. Had any sign or record of communicable and infectious disease, psychiatric
3. Non-ambulant
4. Incapable of carrying out instruction
5. Significant cardiac history (i.e., risk of endocarditis)

6. under antibiotic medication
7. undergoing cancer therapy
8. compromised renal function
9. with infectious disease (i.e., HIV, TB, URTI)
10. diabetes
11. oral candidiasis
12. autoimmune or mucocutaneous disease
13. history of dilantin, cyclosporine, calcium channel blockers in the past 12 months
14. use of NSAIDs within last 3 months
15. use of chlorhexidine or sanguinaria based products in the last 3 months
16. bedridden patients who cannot open their mouths or gargle
17. uncooperative patients
18. refusal to be included in the study
19. psychological problems

Trained and calibrated assistants conducted the screening of participants after which they were assigned at random by lottery to either the experimental or actual group.

Participants in the two locations were oriented to the procedure, without informing them whether they belonged to the control or experimental group. Informed consent was obtained before the study started from the heads of the institutions, the caregivers and the participants.

3. Data Collection

The following data were collected at different intervals.

	Baseline	Week 1	Week 2	Week 3	Week 4
Halitosis					
Pocket depth					
Oral sores					

Indices and ratings

1. Organoleptic scoring scale

Score	criteria	description
0	absence of odor	odor cannot be detected
1	questionable odor	odor is detectable, although the examiner could not recognize it as a malodor
2	slight malodor	odor is deemed to exceed the threshold of malodor recognition
3	moderate malodor	malodor is definitely detected
4	strong malodor	strong malodor is detected, but can be tolerated by examiner
5	severe malodor	overwhelming malodor is detected and cannot be tolerated by examiner (examiner instinctively averts the nose)

(Adopted from http://www.cda-adc.ca/jcda/vol-66/issue-5)

2. Oral sores
    a. dichotomous (presence or absence; symptomatic or asymptomatic)
    b. descriptive (size, shape, location, visual appraisal)
3. Periodontal Pocket Depth (PPD)

Ramfjord's six index teeth namely 16, 11, 26, 36, 31, 44 were noted for the Periodontal Pocket Depth measurements. A calibrated periodontal probe was used to measure the pocket depths on four surfaces of each teeth (mesial, distal, facial and lingual) and the scores were averaged.

4. Procedure

The house parents and nursing aid were oriented on the project, their duties and responsibilities followed with the distribution of the written instructions, logbooks, and the rinsing kit which contained the 1 week supply of the Durafresh™ mouthwash, oral gel with gel applicator and measuring cup. The tasks of the house parent and nursing aide included the following: 1. distribution of mouth rinsing kits, 2. supervising daily mouth rinse activities, 3. assisting the bedridden participants in their rinsing activities, 4. application of Durafresh™ gel on oral sores of incapable participants, 5. monitor the study by recording daily participation of the patients in the logbook, 6. report any untoward reaction to the mouthwash and oral gel

Each participant was instructed to do the following during the study period:

1. rinse 10 ml (using the calibrated measuring cup) of mouthwash (experimental) or distilled water (control) two times daily for 60 seconds; once in the morning and once in the evening preferably before sleeping.
2. The subjects with oral sores were asked place to the gel on the sores once a day.
3. Restricted to wear perfume and other scented products, 24 hours before the assessment.

4. Abstain from eating garlic, onion and spicy foods, 48 hours prior to assessment unless these food items were included in the institution's daily menu.
5. Avoid smoking 24 hours before the assessment

An oral examination after 1 week of rinsing was done. The research assistant went cottage to cottage conduct the examination and personally got feedbacks from the participants regarding the mouthwash. All logbooks were collected. Comments from both the participants and house parent/nursing aide were noted. Halitosis rating was performed by scraping the posterior portion of the tongue using wooden popsicle sticks.

5. Data Processing and Analysis

All clinical parameters were tabulated for each week for every participant. Field codes were used for oral examination results, and pocket probing depth, halitosis rating and age. Pattern codes were used for gender, oral sores (its presence and whether it's symptomatic or not).

A generalization of the population profile which includes the subjects' age, gender, halitosis rating, periodontal and dental status was done using the measures of central tendency. This was based on the quantitative values acquired by the different tools used during the study.

The means for each parameter and for each data collection period were computed and subjected to Student's T-test to determine if there was significant decrease or increase in clinical parameters over time.

RESULTS:

Subjects:

Thirty-two subjects consisting of 11 males and 21 females, with age ranging from 30 years old to 81 years old were able to complete the study. Since there was no significant difference in the scores between the two populations, the data obtained were combined.

Pocket Probing Depth (PPD):

Table 1 shows changes in Pocket Probing Depth over time.

Table1. Pocket Probing Depth scores.

	POCKET PROBING DEPTH (SD)				
	baseline	**wk1**	**wk2**	**wk3**	**wk4**
PPD (N)	3.42 (3.06)	3.92 (4.98)	3.67 (6.67)	3.65 (4.09)	3.75 (5.85)
PPD (X)	4.94 (5.03)	4.69 (3.34)	4.44 (5.49)	4.78 (4.29)	4.75 (3.03)

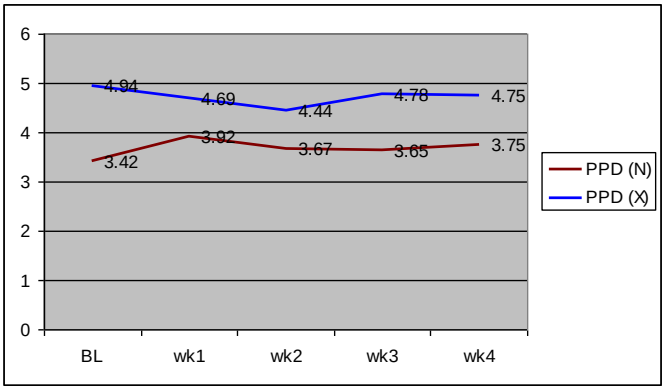

Fig.1. Pocket probing depth

There was a decrease in pocket probing depth from 4.94 to 4.75 after 4 weeks of rinsing with the stabilized chlorine dioxide mouthwash. In the control group, periodontal pocket depth increased after 4 weeks. Scores between control and experimental group were not compared because the baseline data shows that the control group subjects had

lower baseline PPD than the subjects from the experimental group. What is notable is the decrease in PPD in the experimental group from baseline to after 4 weeks of rinsing, while no such decrease in PPD was observed in the control group.

Halitosis:

Table 2 shows the scores for the organoleptic measurement for halitosis.

Table 2. Halitosis scores for control and experimental groups.

	Baseline	**wk1**	**wk2**	**wk3**	**wk4**
Control (N)	1.23 (.93)	1.5 (1.34)	1.52 (1.26)	1.52 (1.17)	1.41 (1.2)
Exptl (X)	1.73 (1.12)*	1.29 (.98)	0.92 (.60)	0.74 (.67)	0.55 (.37)*

* Significant at $p<0.05$

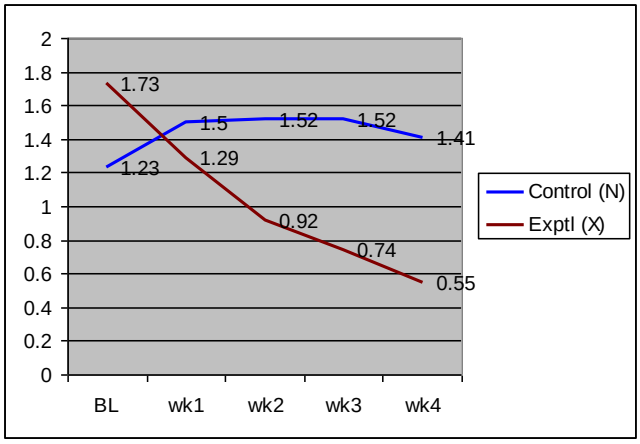

Fig. 2. Halitosis scores from baseline to 4 weeks

Results showed that rinsing with the stabilized chlorine dioxide mouthwash significantly decreased halitosis scores among the subjects.

Oral Sores:

A summary of the results for oral sores is shown in Table 3.

Table 3. Results for oral sores after four weeks of rinsing with Durafresh.

CODE	WEEKLY PROGRESS OF SUBJECTS WITH ORAL SORES				
	WEEK	SORE	SIZE (mm)	PAIN	DESCRIPTION
24	base	53-54	linear	NONE	along posterior palatal seal
	1	30	5	+	(along the ridge) whitish lesion
	2	30	5	+	(along the ridge) whitish lesion
	3				NONE
	4				NONE
40	base	14	7 x 5	+	erythematous & defined (lip biting)
	1	14	5x7	+	slight reddish & less whitish lesion
					on the lips
	2	14	5 x14	+	slight erythema, defined borders
					ulceration starting to heal
	3				NONE
	4				NONE
44	base	32A	0.5	+	white lesion that cant' be scraped off
					and painful upon palpation
		32B	3	+	reddish tissue fold which is
					painful upon palpation
	1	32	1.5	+	less painful whitish vesicular lesion
	2	18B	3	-	white flat lesion
		22A	0.5	-	white, elevated round lesion
		22B	1	-	elevated round lesion, same in color
					with the gingiva
		32A	1	+	elevated round lesion, same in color
					with the gingiva but painful esp when
					denture presses on it
	3				NONE
	4				NONE
45	base	51	2-3	-	reddish elevated lesion, asyptomatic
					cobblestone appearance
	base	52	2-3	-	reddish elevated lesion, asyptomatic
					cobblestone appearance
	base	bet 51,52	2-3	-	reddish elevated lesion, asyptomatic
					cobblestone appearance
					diffused erythematous lesion and

					white lacing
	1				NONE
	2				NONE
	3				NONE
	4				NONE

Subjects reported that pain abated within two weeks of rinsing with Durafresh and most lesions disappeared within 2 weeks of rinsing. Worthy to note is the palliative effect of the gel reported by most subjects.

DISCUSSION:

The active ingredient of Durafresh^{TM} is stabilized chlorine dioxide. Unlike majority of mouthrinses, it does not contain alcohol. The oral gel also contains 0.05% aloe powder.

The positive effects of Durafresh in the study in the reduction of periodontal pocket depth, hastening of the healing and its palliative effect on oral sores and decrease in halitosis can be largely attributed to the abovementioned components of Durafresh^{TM}. The antibacterial effect of the stabilized chlorine dioxide and its ability to degrade volatile sulfur compounds produced by bacteria and their by-products may be responsible for the reduction of periodontal pocket depths in the subjects after four weeks of rinsing. The ability of the mouthrinse to reach the pockets may also have aided in the reduction of pocket depths. Although the results on pocket depths are somewhat inconclusive due to some limitations of the present study, the results promises to show that Durafresh may be a useful adjunct in the treatment of periodontal pockets.

The absence of alcohol and presence of aloe powder explains the non-stinging and palliative effect of Durafresh oral gel on oral sores. As to its rapid effect on the healing of

oral sores, this may be attributed to the antimicrobial action of the chlorine dioxide and also to its effect on volatile sulfur compounds.

The positive results of Durafresh mouthrinse in decreasing halitosis is attributed to the strong action of the chlorine dioxide in degrading the volatile sulfur compounds present in the oral cavity and those that are lodged in the tongue, gingival crevices, throat and other hard to reach areas of the oral cavity.

CONCLUSIONS:

Based on the results of the study, it is concluded that:

1. Pocket probing depth improves with the use of the said mouthrinse. Pocket depths decreased. This may be explained by the ability of the mouthrinse to reach the pocket areas, which are not usually reached by toothbrushing. However, a longer duration of study is needed to establish the effect of Durafresh in treating periodontal pockets.
2. The said mouthrinse hastened the healing of oral sores and provided a degree of palliative effect. Most lesions resolved within a week.
3. Halitosis was significantly decreased with the use of the mouthrinse; indicative of the potent action of chlorine dioxide in degrading volatile sulfur compounds.

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