Department of Conservative Dentistry & Endodontics
K.L.E. Society's Institute of Dental Sciences
BANGALORE – 560 022 INDIA

ASSESSMENT OF PLAQUE REDUCTION ABILITY OF A NEW TOOTH PASTE (GLODENT)

– A *Clinical Trial* by
DR.JYOTHI NAGESH.

INTRODUCTION

An attempt is done here to test the plaque reduction ability of a new toothpaste 'Naturdent' which contains papain and bromelian, polyethylene glycol, tetrasodium pyrophosphate and miswak extraxts, by comparing it with a placebo toothpaste in a randomized clinical trial.

MATERIALS AND METHODS

A randomized controlled clinical trial was conducted in KLE Dental College, Bangalore. The study subjects comprised of 40 Dental students aged between 18-25 years selected randomly based on the selection criteria. Subjects with a history of smoking, untreated carious lesions or restorations in anterior teeth, discolored anteriors due to trauma, fluorosis and intrinsic staining due to any reasons were excluded from selection. The subjects who gave voluntary informed consent and willingly ready to comply with the instructions were selected. They were randomly allocated into test group and control group using lottery dip method in such a way that each group contained 20 subjects. The subjects were blinded from knowing their group allocation (concealed randomization). Two trained examiners, for plaque assessment using 'Oleary, Drake and Naylor' plaque index at baseline (pre intervention) and at the end of 3 weeks (post intervention). The examiners were also blinded about the group allocation and the purpose of the study. A specially designed format containing a specific questionnaire with 7 questions to assess the perception related to taste, freshness sensation on using the toothpaste, along with tables for recording plaque index was used for every subject.

TEST TOOTHPASTE – INGREDIENTS

(1) Sodium fluoride
(2) Potassium chloride
(3) Papain
(4) Bromelian
(5) Tetra sodium pyrophosphate
(6) Poly ethylene Glycol

(7) Miswak Extracts
(8) Neem
(9) Xylitol
(10) Silica

PLACEBO TOOTH PASTE – INGREDIENTS

(1) Sodium fluoride
(2) Potassium Chloride
(3) Xylitol
(4) Silica

The test tooth paste and the placebo were very similar in their colour, taste and packaging characteristics.

Before starting the study the baseline measurements for plaque score were done independently by the 2 examiners. Plaque assessment for whole mouth was done using Oleary, Drake and Naylor's index after applying the disclosing agent. The subjects were given the respective toothpastes based on the group allocation by the investigator. Subjects were advised to brush twice a day, once in the morning and once at night, using the respective toothpaste and new tooth brushes which were distributed to them using roll on technique.

At the end of 3 weeks the subjects were recalled and assessed for plaque following the same procedure explained above. The data so obtained at base line and at the end of the study including the answers for questionnaire were compiled, tabulated and subjected to statistical analysis using students unpaired 't' test and paired 't' test. The results are presented in the form of tables and bar charts.

RESULTS

In this study 2 subjects in the test group and 2 in the control group opted out and were not accessible at the end of 3 weeks.

The results of the study are presented in 2 components as

1. Report of the questionnaire
2. Plaque assessment

QUESTIONNAIRE REPORT

A majority under the test group have considered the taste of the toothpaste to be fair and good. Only one subject has reported it to be bad.

The duration of taste was reported to be from ½ an hour to 3 hours after using the toothpaste in both the test and control groups.

But more number of subjects in the test group reported the duration of taste to extend for 3 hours.

A majority of the subjects in both test and control group opined a positive feel of freshness on using the tooth paste.

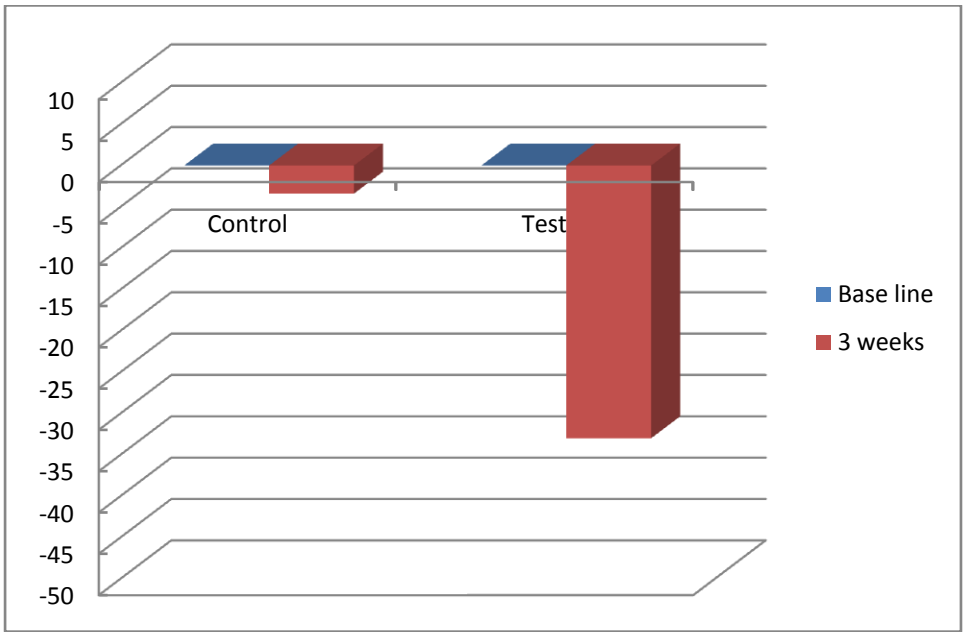
Plaque Assessment :- When plaque scores were compared within the groups, there was a statistically significant reduction in the test group with 'p' value of 0.00 ($P<0.05$).

In control group though a slight reduction in the plaque score was observed by the end of 3 weeks, it was not found to be statistically significant ($p = 0.784$) as shown in Table no. 1.

Method of Statistical Analysis:-

The results were averaged (mean $\pm$ standard deviation) for each parameter and are presented in table and figure. The means between 2 groups were compared using student 't' test. A paired student 't' test was performed to determine whether there were difference between the baseline and 3 weeks. Proportions were compared using chi-square test.

In all above tests 'p' value less than 0.05 was taken to be statistically significant. The data was analysed using SPSS package (V 10.5).



Annexure

		N	Mean	Std. Deviation	Min	Max	't' value	'p' value
P I at Baseline (%)	**Control**	18	48.7394	25.030	8.50	90.62	-1.474	.150
	Test	18	60.5500	22.988	16.07	100.00		
P I at the end of 3 weeks (%)	**Control**	18	47.0772	20.386	12.50	84.48	1.007	.321
	Test	18	40.5661	18.343	11.60	69.53		

To test the equality of means among test and control group student 't' was used separately for baseline and at 3 weeks. The mean PI at baseline is 48.74±25.03(ranging from 8.5 to 90.62) and 60.55±22.99(16.07 to 100) in control and test group respectively. The difference observed was not statistically significant (p>0.05).
Similarly at 3 weeks mean PI was 47.08±20.39 (ranging from12.50 to 84.48) and 40.57±18.34(ranging from 11.60 to 69.53) in control and test group respectively. The difference observed was not statistically significant ([p>0.05).

Group		**Paired Differences**			**'t' value**	**'p' value**
		Mean	**Std. Deviation**	**Std. Error Mean**		
Control	**P I at Baseline (%) - P I at the end of 3 weeks (%)**	1.6622	25.2949	5.9621	.279	.784
Test	**P I at Baseline (%) - P I at the end of 3 weeks (%)**	19.9839	17.3863	4.0980	4.877	.000

The Change in PI from baseline to end of 3 weeks compared using Student paired 't' test, the difference in the PI change 19.98± 17.39 was statistically significant in test group suggesting that PI levels decreased considerably. The difference in the PI change 1.66± 25.29 was not statistically significant.

To summarize, the result of the study suggests that the PI concentration decreased considerably from baseline to 3rd week in test group compared to control group.

Discussion:

This study although initially contained 40 subjects, at the end of the study there were 4 drop outs 2 in the test and 2 in the control group. The results reveal a significant reduction in the plaque level from baseline to the end of the study period in the test group which was found statistically significant ($p<0.05$). Even in the control group a minor reduction in the plaque score is observed but is not statistically significant. The test tooth paste with many ingredients having antiplaque ability like Miswak, neem, papain, bromelian might have reduced the plaque formation. The reduction observed in the control group may be because of standardized tooth brushing schedule, technique which was prescribed for both the study and control groups. Any tooth whitening dentifrice is expected to reduce plaque formation and inhibit stain formation. Since the test toothpaste showed better reduction of plaque it may facilitate tooth whitening provided it has effective tooth whitening agents also.

The study shows a significant reduction in the plaque level in the test group when compared to control group.

References

1. Gerald McLaughlin / George A. Freedman – 'Colour Atlas of tooth whitening'.
   - Ishiyaku Euro America Inc. 1991

2. Ronald E Goldstein – 'Esthetics In dentistry'.
   - 2nd Ed. Vol.2, 2000. B.C.Decker Inc.

3. Linda Greenwall – 'Bleaching Techniques in restorative dentistry' – An illustrated guide. 2001, Martin Dunit Publication.

4. 'Dental product Spotlight' – JADA, Vol. 132. No.8. 1146-47.

5. C. Morris Cappl et al – 'An in vitro study to test the efficacy of five whitening agents' - JDR 73 : 866, 354 1995.