Title of The Study

CLINICAL EFFICACY OF BIOMIN F, COLGATE SENSITIVE PRO-RELIEF AND SENSODYNE RAPID ACTION DENTIFRICES IN DENTIN HYPERSENSITIVITY

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Background:

Dentin hypersensitivity (DH) was a clinical condition with acute pain of short duration that adversely influenced the patient's daily life. Clinical management of DH had been a challenging issue for practitioners with different treatment modalities. Numerous over the counter (OTC) and in-office desensitization formulations including Potassium, Fluorides, Arginine, Strontium, Bi-Fluorides, And Casein Phosphopeptide–Amorphous Calcium Phosphate (CPP-ACP) and Bioactive Glasses (BAGs) had been advocated clinically and claimed commercially for immediate and sustained treatment of DH without definitive outcome. Prime focus of treatment options was now trending towards utilization of the remineralization potential of dentinal tubules for occluding exposed tubular endings. Currently no gold standard treatment modality and product for DH is available worldwide. Clinical testing was essentially required to substantiate the claims of different OTC products, to seek out permanent management of DH without industrial influences. The potential impact of DH on the patient's daily life by altering dietary habits, speaking, and its impact on social status needed to be ascertained.

Objective**:**

The aim of the study was to compare three different formulations of OTC dentifrices; these are 8% Arginine, 8% Strontium acetate, and fluoro-calcium-phospho-silicate (FCPS) BAGs to measure their clinical efficacy for immediate and sustained reduction in the pain of DH.

Methods**:**

This study was a randomized, controlled clinical trial with four equal treatment arms. 140 healthy individuals of more than 18 years of age were included in the study. They had at least two sensitive teeth anterior to molars and were selected from clinically diagnosed patients of DH after written informed consent. Parallel treatments were assigned for sensitive teeth with four OTC dentifrices.

Dentifrices having flouro-calcium-phospho-silicate formulation were provided in experimental group, having 8% Arginine formulations were provided in active comparator 1, having 8% Strontium Acetate formulation were provided in active comparator 2 and having Sodium Fluoride (NaF) formulation were provided in placebo comparator. DH was tested with Air blast/Evaporative stimulus, Mechanical stimulus, and Water jet stimulus. Change in the pain response was measured over time by Visual Analogue Scale (VAS) and Schiff Cold Air sensitivity (SCHIFF) Scale with five minutes gap between applications of each stimulus for internal reliability. Interim efficacies were assessed in one minute after topical application on sensitive teeth, in five minutes after application, on third day, and four weeks respectively. Dentin Hypersensitivity Experience Questionnaire (DHEQ) was administered before and after treatments.

Statistical Analysis:

The software used for data analysis was SPSS version 16. Baseline characteristics and DH scores were assessed in terms of mean, standard deviation and mean difference within the treatment group and between the treatment groups at different time points to compare the baseline scores with the measures taken immediately after treatment, on day – 3, in week – 4. Statistical analysis was done independently for air blast stimulus associated DH, mechanical stimulus associated DH, and water jet stimulus associated DH. Baseline characteristics were observed by comparing means statistics for the age, gender and baseline DH score on SCHIFF scale and VAS by groups. Paired sample t-test was performed to compute mean scores of each follow up respective to baseline. Percent change from baseline was assessed Within the treatment group by using ANOVA for each group. Statistical significance of percent change for baseline versus follow ups was assessed by paired sample t-test with level of significance 0.05. Between treatment groups comparison was done by performing ANOVA to compare different treatments at different follow ups and reported as percent difference between

groups at Level of significance 0.05. Adjustment for multiple comparisons was done by Tukey HSD with level of significance 0.05. For Mechanical and Water jet stimulus responses pre-application and post-application responses were assed in subjects enrolled for the 6- week clinical trial. Those who did not respond at baseline were considered in missing values.