2594: Extrinsic dental stain removal in vivo by gel-to-foam dentifrices

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Introduction

The presence of dental stain is a common finding within the adult population. Information regarding the incidence of stain is not available however stain varies in populations due to habits and practices. The aetiology of stain is multiple and is the result of discolouration of plaque and pellicle on the surface of the tooth and direct chromogen adherence. Stain is attributed to coffee, tea, tobacco, red wine, antimicrobial mouthrinses, some metals and chromogenic bacteria. Sodium tripolyphosphate (STP) incorporated into toothpaste formulations has been shown to be effective against dental stain[1,2].

Objective

To evaluate the oral tolerability and extrinsic stain removal efficacy of two experimental gel-to-foam dentifrices containing 10% and 5% sodium tripolyphosphate (STP) to a STP-free gel-to-foam dentifrice after 6 weeks measured by the MacPherson's Modification of the Lobene stain index (MLSI)[3,4] in a forced stain model.

Materials and Methods

Clinical Procedure

This was a single centre, double blind, three arm, stratified, parallel, randomized study to evaluate the oral tolerability and extrinsic dental stain removal of experimental STP gel-to-foam dentifrices compared to an STP free control in healthy adult volunteers.

After screening and consent, eligible subjects received an oral prophylaxis and began a 2 week stain generation phase using low abrasivity toothpaste, a soft toothbrush, 0.12% chlorhexidine gluconate mouthrinse and a generic instant tea mix. This was followed by a 3-4 day washout period, in which they continued to brush twice daily with the toothpaste and toothbrush provided.

Subjects were instructed to return to the clinic upon completion of the stain generation and washout phase of the study. During this Baseline Visit, a qualified examiner performed an oral soft tissue (OST) exam and a stain assessment using the MacPherson's Modification of the Lobene Stain Index (MLSI)[3,4]. The facial surfaces of the 6 maxillary and mandibular anterior teeth and the lingual surfaces of the mandibular anterior teeth were assessed. OST examinations took place after 1 week. After 6 weeks of product use subjects underwent another OST exam, stain assessments, and intra-oral digital imaging.

322 subjects were screened, 308 were randomised and 304 completed the study. 304 subjects were included in the efficacy analysis, which was based on the per protocol (PP) population.

Modified Lobene Stain Index

Each tooth surface was divided into four areas – gingival crescent and the body which was further divided into 3 separate areas - mesial, body and distal. The intensity and area of stain were scored visually by a trained calibrated examiner using 4-point scales described in Table 1. The MLSI score is the product of the intensity and area (I x A).

Table 1 – MLSI Stain Intensity and Area Scales

Score	Stain Intensity	Stain Area
0	No stain	No stain
1	Light stain	Stain covering up to 1/3 of region
2	Moderate Stain	Stain covering up to 2/3 of region
3	Heavy Stain	Stain covering more than 2/3 of region

Statistical Methods

The number of subjects reporting treatment-emergent clinical observations of oral AEs at 6 weeks was compared to 0% STP using Fisher's exact test. The number and percentage of subjects with treatment-emergent oral AEs, were provided by treatment group.

In order to compare experimental formulations, a mixed model Analysis of Covariance was used to analyze subject's mean change from baseline MacPherson's MLSI Intensity x Area, Intensity and Area scores. Model terms for each efficacy parameter included the subject's mean baseline score for a parameter (a covariate), smoking status (smoker vs. non-smoker) and treatment. Subject was used as a random factor. All pair-wise comparisons were un-adjusted and made at 5% significance level

Results

All treatments produced a statistically significant reduction in extrinsic stain compared to baseline after 6 weeks ($p<0.0001$), summarised in Figure 1. Between treatment differences are summarised in Table 1. Oral adverse events are summarised in Table 3.

Figure 1 – Summary of reduction in stain intensity, area and MLSI (I x A) from baseline after 6 weeks twice daily use

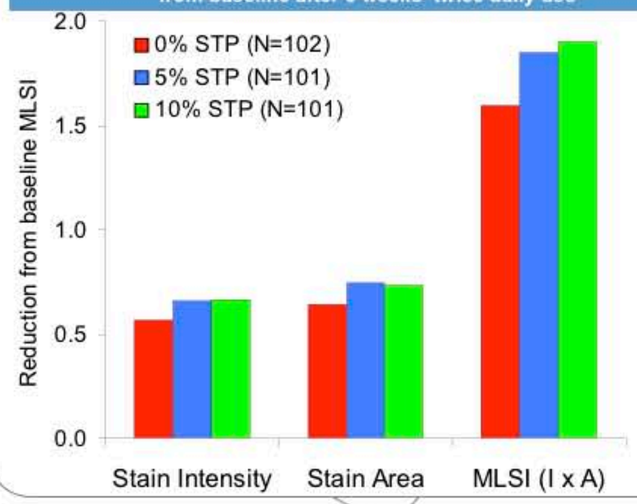

Table 2 – Between Treatment Stain Intensity x Area after 6 weeks

Gel-to-Foam Dentifrice	Tooth Area	Treatment Difference [1]	95% C.I.	p-value
10% STP vs. 0% STP	Whole Tooth	-0.257	-0.472, -0.043	0.0189
	Interproximal	-0.338	-0.673, -0.004	0.0476
5% STP vs. 0%STP	Whole Tooth	-0.309	-0.523, -0.094	0.0050
	Interproximal	-0.459	-0.794, -0.125	0.0073
10% STP vs. 5% STP	Whole Tooth	0.051	-0.164, 0.266	0.6394
	Interproximal	0.121	-0.214, 0.456	0.4787

[1] Treatment difference is first treatment minus second treatment, a negative difference favours the first treatment.

Table 3 – Subjects with treatment emergent oral adverse events

Oral Adverse Events	10% STP (N=103)	5% STP (N=102)	0% STP (N=103)
Subjects with oral adverse events: n (%)	6 (5.8)	4 (3.9)	3 (2.9)
Erythema	4 (3.9)	1 (1.0)	0 (0.0)
Oral ulceration	2 (1.9)	2 (2.0)	1 (1.0)
Gingival bleeding	0 (0.0)	0 (0.0)	1 (1.0)
Gingival soreness	0 (0.0)	0 (0.0)	1 (1.0)
Herpetic lip lesion	0 (0.0)	0 (0.0)	1 (1.0)
Tooth sensitivity	0 (0.0)	1 (1.0)	0 (0.0)
% Difference STP minus 0% STP of subjects with oral AEs	2.91	1.01	-
P-value comparing STP and 0% STP	0.4980	0.7211	-

Conclusions

STP significantly improved the stain removal ability of the gel-to-foam dentifrices. However, there was no significant difference in stain removal between 5% and 10% STP after 6 weeks use.

The 5% and 10% STP gel-to-foam dentifrices were well tolerated and had comparable rates of oral adverse events to 0% STP control with no significant difference observed.

References

1. Shellis RP, Addy M, Rees GP. In vitro studies on the effect of sodium tripolyphosphate on the interactions of stain and salivary protein with hydroxyapatite. J Dent (2005) 33, 313-324
2. Creeth J., Bosma, ML., Butler A., Smith S., Littlejohn S., Sharma N., Kleber CJ., Milleman K., Chaves E., Gallagher A. (2006) Silica abrasivity and STP: effect on tooth stain removal in-vivo, AADR 37th Annual Meeting and Exhibition Dallas, Abstract 0914
3. Lobene, R. R. (1968). Effect of dentifrices on tooth stains with controlled brushing. Journal of the American Dental Association 77, 849–855.
4. MacPherson LMD, Stephen KW, Joiner A, Schafer F, Huntington E: Comparison of a conventional and modified tooth stain index. J Clin Periodontol 2000; 27: 854–859. C Munksgaard, 2000.