

The Cleaning Effectiveness of Experimental, Multiple-Benefit Triclosan Dentifrice

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ABSTRACT

Four-day non-brushing studies have been used successfully to demonstrate short-term anti-plaque efficacy of triclosan-containing dentifrices. As an alternative, a 4-day lingual brushing model was utilized for this trial in order to deliver dentifrice in a manner which more closely approximates in-home use. This randomized, double-blind, crossover study was conducted to evaluate the anti-plaque efficacy of three triclosan dentifrices: Experimental, Multiple-Benefit Triclosan dentifrice (Product A), Crest® Ultra (Product B) and Colgate® Total (Product C) relative to one another and relative to Crest® Wintergreen Light paste (Product D). Sixty-five adult subjects brushed the lingual surfaces of their teeth with their assigned dentifrice for 30 seconds, and prior to expectorating, swished the saliva/dentifrice slurry to the facial/buccal tooth surfaces for an additional 30 seconds. The procedure was repeated twice. Each treatment phase lasted for 4 days. On Day 5, plaque levels were scored using the Turesky modification of the Quigley-Hein Plaque Index (PI). A washout period intervened between treatment periods where subjects brushed with Product D (gel). The whole mouth average PI data were analyzed by analysis of variance for a crossover design. The treatment effect was tested by determining if the average PI scores for a test product was significantly different from the average PI score for a comparative product. There was a statistically significant treatment effect for Product A, Product B and Product C against Product D, respectively ($p \leq 0.01$). In addition, the treatment effect for Product A versus Product C was statistically significant ($p = 0.003$). **All three triclosan dentifrices reduced plaque formation significantly when compared to Product D. There were statistically significant reductions in plaque formation observed when subjects used the Experimental, Multiple-Benefit Triclosan dentifrice in comparison to Product C using the limited brushing model. (This study was sponsored by The Procter & Gamble Company)**

INTRODUCTION

Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) is a broad-spectrum antibacterial agent which is widely used in soap and deodorant products. Triclosan targets the cytoplasmic membrane of both Gram-negative and

Gram-positive microorganisms. At bacteriostatic concentrations the transport of essential amino acids across the cytoplasmic membrane is inhibited, while at bactericidal concentrations the membrane is disrupted and leaches intracellular contents to the external environment¹. The non-ionic nature of triclosan enhances its incorporation into dentifrices. The substantivity of triclosan in the oral cavity has been demonstrated, with bactericidal concentrations remaining in dental plaque².

A 4-day limited brushing model was used in this study where subjects were allowed to brush only the lingual surfaces of their teeth. The slurry of dentifrice and saliva formed from brushing was used to bathe the facial/buccal surfaces of the teeth before expectorating. When carefully executed, the model separates the effects of toothbrushing on plaque reduction from the antiplaque properties of a dentifrice so each can be assessed *in vivo*. The 96-hour duration of the model is based upon analysis of plaque formation in the absence of brushing, where the quantity of plaque plateaus in most subjects ranging from 48-96 hours.^{3,4} Changes in bacterial composition continue to occur with time.

OBJECTIVE

To evaluate the anti-plaque efficacy of three triclosan-containing dentifrices.

Products Tested:

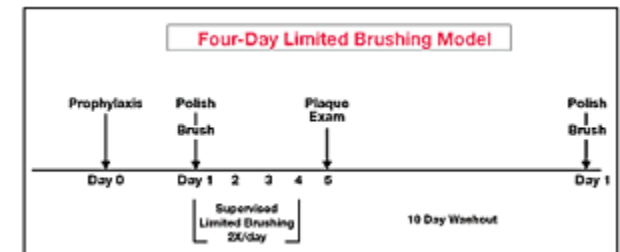
- Product A—Experimental, Multiple-Benefit Triclosan dentifrice
- Product B—Crest® Ultra
- Product C—Colgate® Total
- Product D—Crest® Wintergreen Light (NaF control)

STUDY DESIGN

- Randomized, double-blind
- Four period cross-over, with at least 10 days washout between periods
- 4-day limited-brushing model
- Supervised brushing, two times per day
- 65 subjects

Limited Brushing Procedures

1. Weigh 0.5 g dentifrice on 2 toothbrushes;
2. Brush lingual surfaces only, for 30 sec. with one toothbrush;
3. Swish saliva/dentifrice slurry to facial/buccal tooth surfaces for 30 sec.;
4. Expectorate;
5. Repeat steps 2- 4 with second toothbrush and dentifrice.



Benefits Over Traditional 4-day Non-Brushing (Slurry) Model

Increased compliance due to:

1. Ability to partially brush;
2. More closely mimics true dentifrice/saliva slurry formation.

RESULTS

Plaque Efficacy

-Turesky modification of the Quigley-Hein Plaque Index (PI)

-Whole mouth average PI scores were analyzed with an ANOVA for crossover design

-Efficacy analyses were conducted at a one-sided, 5% level of significance

Subject Demographics at Baseline

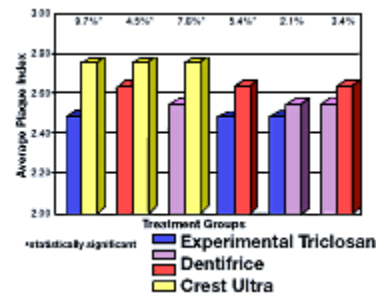
Characteristics		All Subjects (N=65)
Age (Years)	Minimum	24.0
	Maximum	58.0
	Mean	38.12
Sex	Male	24
	Female	41

Mean Baseline PI Scores

Treatment	N	Mean
Product A	57	2.63
Product B	54	2.68
Product C	55	2.66
Product D	54	2.69

PI Efficacy Results

Treatment	LS Means
Product A	2.48
Product B	2.54
Product C	2.63
Product C	2.75



REFERENCES

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2. Gilbert RJ, Williams PE. The oral retention and anti-plaque efficacy of triclosan in human volunteers. *Brit J Pharm* 1987; 23:579_83.
3. Addy M, Willis L, Moran J. Effect of toothpaste rinses compared with chlorhexidine on plaque formation during a 4-day period. *J Clin Periodontol* 1983; 10:89_99
4. Schachtele CF. Dental caries. In: Schuster GS, ed. *Oral microbiology and infectious disease*, Third Edition. Philadelphia, PA: B.C. Decker, Inc, 1990:487_8.

CONCLUSION

-There were statistically significant treatment differences ($p < 0.01$) in favor of all three triclosan dentifrices when compared to the sodium fluoride control, Crest® Wintergreen Light (Product D).

-There was a statistically significant treatment difference in favor of the Multiple-Benefit Triclosan dentifrice (Product A) when compared to Colgate® Total (Product C) ($p = 0.003$).