A Comparison of the Breath and Antimicrobial Efficacies of Various Antimicrobial Systems Present in Commercial Dental Products

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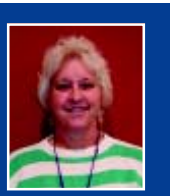


ABSTRACT

Objective: The purpose of this study was to profile and compare the breath, germ kill, and anti-inflammatory properties of several different anti-microbial systems used in commercial dental products in an acute use human trial. **Methods**: 18 volunteers participated in a single blind, randomized, Latin square crossover, negative-controlled, clinical trial. There were 9 treatment legs in total; 5 legs had commercial products while 4 were experimental products (results not reported here). The commercial products tested and their respective antimicrobial systems were: Crest® Cavity Protection (negative control), Colgate® Total (triclosan), Listerine® Essential Care (essential oils), and Crest Gum Care (SnF_2), and mouthrinse – Peridex (chlorhexidine). Subjects treated themselves three times over a single day – morning, afternoon, and bedtime – brushing with their assigned dentifrice for 1 minute or rinsing with their assigned mouth rinse for 30 seconds. Prior to treatments, baseline measures were taken followed the next day by final measures. Subjects were measured primarily for breath status (morning breath and cysteine challenge) and total facultative and gram-negative anaerobes present on tongue, along gum line, and within a gingival pocket, and, secondarily, for sub-gingival IL1-β levels. **Results:** Products containing either chlorhexidine or SnF_2 provided significant (one sided $p < 0.05$) mean reductions versus the negative control across nearly all primary measures. Overall, reductions observed with chlorhexidine were generally greater than those seen with the SnF_2 system. The triclosan-containing product generated a significant mean reduction in one primary measure – sub-gingival, total facultative anaerobes. The essential oils antimicrobial system produced no significant reductions in any measure. Only chlorhexidine and SnF_2 systems produced directional (sig. at $p < 0.15$) reductions in IL1-β levels. **Conclusions:** Based on their overall efficacy profile, this study suggests that the rank order in potency of the various antimicrobial systems present in commercial dental products is: chlorhexidine >SnF_2>triclosan ≥ essential oils.

INTRODUCTION

This study investigated the relative *in-vivo* potency of several OTC and one Rx dental products on plaque bacteria. These products contain various antimicrobial agents which control plaque by varying mechanisms of action ranging from non-specific membrane disruption (CHX, essential oils) to enzyme inhibition (SnF_2, triclosan). They are similar in their *in-vitro* (MIC) potencies but it is not well established how they rank in potency under similar clinical test conditions. It is believed that significant reductions in the oral bacterial load will lead to long-term gum health benefits.

METHODS

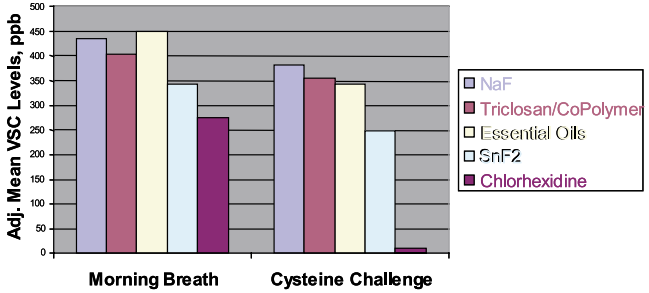
Study Design: 18 volunteers participated in a single blind, randomized, Latin square crossover, negative-controlled, clinical trial. There were 9 treatments in total; 5 treatments were commercial products while 4 were experimental products (results not reported here). Subjects self-treated 3 times over a single day (morning, afternoon, and at bedtime) for each period, with at least 60 hours washout between periods. Efficacy measures were taken before first treatment in morning (baseline) and 24 hours later the next morning (following bedtime treatment). Subjects brushed for 1 minute with their dentifrice, then expectorated and then rinsed once with water. The Peridex treatment involved rinsing for 30 seconds followed by expectoration and no brushing was allowed for the day.

All the commercial dentifrices to be tested were supplied un-blinded in original tubes. On the second day, subjects reported to the clinic without brushing and all breath and clinical samples were collected to evaluate product efficacy. **Sample collection and processing:** Morning breath status was assessed for Volatile Sulfur Compound emissions (VSC) utilizing a halimeter (Interscan Corporation, CA). Tongue samples were taken from the anterior third dorsal surface of the tongue using a toothbrush. The brush head was clipped off into a vial containing transport fluid. Samples were diluted with saline and spiral plated onto ETSA-NV and ETSA plates to enumerate total GNAs and total facultative anaerobes, respectively. Results were reported as log colony-forming units (Log CFU) per mL. A supragingival plaque sample was taken by moving a sterile synthetic cotton swab along the gingival gum line of the upper buccal surfaces. The swab head was clipped off into a vial containing transport fluid. Sample was diluted with saline and spiral plated onto Streptococci selective agar plates and ETSA plates to enumerate total streptococci and total facultative anaerobes. GCF samples were collected by inserting a strip of Periopaper (Ora Flow Inc., Plainview, NY) into the pocket of the sampling site for 30 seconds. GCF samples were placed into transport fluid until processed. The GCF sample was diluted and cultured for Facultative anaerobes and GNAs. The ETSA and ETSA-NV plates were incubated anaerobically while the Streptococci selective agar was incubated in a 5% CO_2 incubator. The GCF sample was also analyzed for IL-1β using a quantitative sandwich enzyme immunoassay technique (Quantikine DLB50 human IL-1β kit, R&D Systems Inc., MN). After all microbial samplings, bacterial metabolic activity was monitored using the Cysteine Challenge (CC) test where each subject rinsed with a 1 mM solution of cysteine for 30 seconds. Five minutes after expectoration of cysteine the subjects were assessed for their breath status using a second halimeter. All breath measures were assessed at baseline before treatment and then at a final time, the next day after 3 self treatments. All microbial and cytokine samples were obtained for analysis at baseline before treatment and again the next day after 3 treatments for the final timepoint.

RESULTS

Products containing chlorhexidine or SnF_2 provided significant (one sided $p < 0.05$) mean reductions versus the negative control across nearly all primary measures. Overall, reductions observed with chlorhexidine were generally greater than those seen with the SnF_2 system.

Figure 1 Breath Status of Antimicrobial Systems



RESULTS (Cont.)

Figure 2 Gram Negative Anaerobes

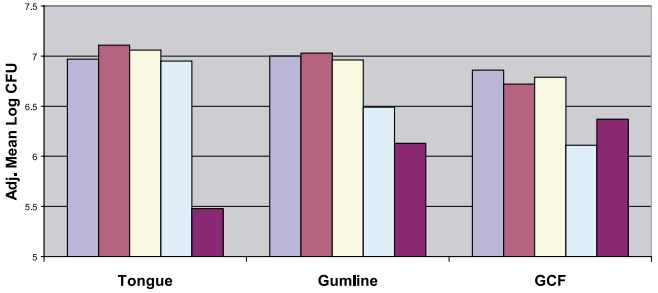
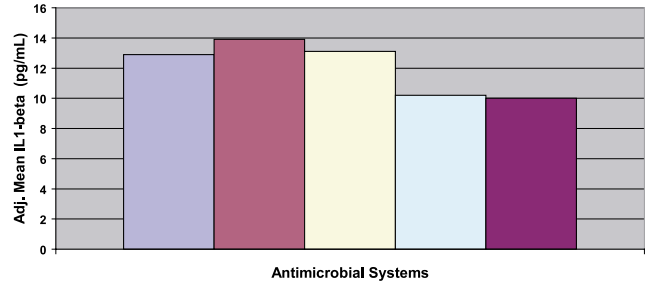


Figure 3 GCF IL1-beta Levels



Summary Profile of Efficacy Measures (1-tail *p*-values vs. Placebo)

Active Systems	Breath Status: Morning	Breath Status: Cysteine Challenge	Germ Kill: Tongue GNA	Germ Kill: Tongue Total Anaerobe	Germ Kill: GCF GNA	Germ Kill: GCF Total Anaerobe	Germ Kill: Gum Swab Strep.	Germ Kill: Gum Swab Tot. Ana.	IL-1β
Triclosan CoPolymer	P = .19	P =.39	P =.75	P =.70	P = .28	P = .07	P = .36	P = .61	P = .64
Essential Oils	P =.64	P =.34	P =.67	P =.60	P = .39	P = .62	P = .44	P = .34	P = .53
SnF2	**P =.005**	**P =.05**	P =.46	P =.20	**P = .0013**	**P = .0001**	**P = .0002**	**P = .0001**	P = .13
Chlor-hexidine	**P =.0001**	**P =.0001**	**P =.0001**	**P =.0001**	**P = .008**	**P = .05**	**P = .0001**	**P = .0001**	P = .11

PINK = SIGNIFICANCE P = .05 GREEN = TREND TO SIGNIFICANCE .05≤ P ≤ .15

CONCLUSION

Based on their overall efficacy profile, this study suggests that the rank order in activity of the various antimicrobial systems present in commercial dental products is:

chlorhexidine>SnF_2>triclosan≥essential oils.