

The Clinical Effect of a Dentifrice Containing Triclosan and a Copolymer in a Sodium Fluoride/Silica Base on Plaque Formation and Gingivitis: A Six-Month Clinical Study

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A six-month, double-blind clinical study was entered into by three hundred twenty-five (325) male and female adult subjects to assess the efficacy of a dentifrice containing 0.3% triclosan (Irgacare MP, Ciba-Geigy Corp.) and 2.0% of a copolymer of methoxyethylene and maleic acid (Gantrez, ISP Corp.) on supragingival plaque formation and gingivitis compared to a placebo dentifrice over a six-month period. Each dentifrice, the triclosan and the placebo contained 0.243% sodium fluoride in a silica base. Only those subjects who were free of periodontal disease (no pockets > 4 mm), demonstrated a level of at least mild gingivitis (modified Loe-Silness > 1.0) and had a modified Quigley-Hein Plaque Index score of > 1.5 were admitted into the study. Baseline plaque and gingivitis scores were used to stratify the subjects into two balanced groups. A thorough oral prophylaxis was administered to all subjects. They were then assigned either the triclosan/copolymer dentifrice or the placebo dentifrice to use for the next six months. Evaluation for gingivitis and supragingival plaque formation was made after three and six months. Evaluations made after six (6) months demonstrated a 17.0% statistically significant (at the 99% level of confidence) reduction in supragingival plaque formation, provided by the triclosan/copolymer dentifrice compared to the placebo dentifrice. An 18.6% statistically significant (at the 99% level of confidence) reduction in plaque formation on the tooth surfaces with the highest plaque formation was provided by the triclosan/copolymer dentifrice compared to the placebo dentifrice. As compared to the placebo dentifrice, the dentifrice containing triclosan/copolymer provided a 29.0% statistically significant (99% level of confidence) reduction in gingivitis and 47.6% fewer sites with severe gingivitis (i.e., gingival bleeding). This reduction was statistically significant at the 99% level of confidence. No adverse effects to the soft or hard tissues of the oral cavity attributed to dentifrice use were reported or observed. It was concluded from this clinical study that the twice daily use of a dentifrice containing 0.3% triclosan and 2.0% of a copolymer over a six-month period. significantly reduced supragingival plaque formation and gingivitis.