

Effect Upon Plaque Formation and Gingivitis of a Triclosan/Copolymer/Fluoride Dentifrice: A six-month Clinical Study.

Denepitiya J, Fine D, Singh S, DeVizio W, Volpe A, Person P, Am J Dent 5: 307-311, 1992

A total of 159 adult male and female subjects between 18 and 63 years of age, were entered into a 6 month, double-blind clinical study to assess the effects of a dentifrice containing 0.3% triclosan and 2% of a copolymer of methoxyethylene and maleic acid on supragingival plaque formation and gingivitis, as compared to a placebo dentifrice. Both the triclosan and placebo dentifrices contained 0.243% sodium fluoride in a silica base. The subjects had to demonstrate at least mild gingivitis (modified Loe-Silness score > 1.0), be free of advanced periodontal disease, have a modified Quigley-Hein Plaque Index score of at least 1.5 and have a minimum of 20 natural, uncrowned teeth. The subjects were stratified into two balanced groups according to baseline plaque and gingivitis scores. At zero time or baseline, all subjects received a complete and thorough oral prophylaxis and were assigned to the use of either the placebo dentifrice or the triclosan/copolymer dentifrice for the next 6 months. Subjects were evaluated for gingivitis and supragingival plaque formation after 3 and 6 months product use. After 3 months, when compared to the placebo dentifrice, the triclosan/copolymer dentifrice provided the following statistically significant reductions (at 99% confidence levels): (1) a 10.0% reduction in supragingival plaque formation; (2) a 20.8% reduction in plaque formation on tooth surfaces with highest baseline plaque scores; (3) a 21.9% reduction in gingivitis, and (4) 30.5% less sites with severe gingivitis, i.e., gingival bleeding. After a 6 month use, when compared to the placebo dentifrice, the triclosan/copolymer dentifrice provided the following statistically significant reductions (at 99% confidence levels): (1) an 18.4% reduction in supragingival plaque formation; (2) a 29.2% reduction in plaque formation on tooth surfaces with highest baseline plaque scores; (3) a 31.5% reduction in gingivitis, and (4) 57.1% less sites with severe gingivitis, i.e., gingival bleeding. There were no reported or observed adverse effects involving the soft or hard tissues of the oral cavity after 6 months use of either of the dentifrices. It can be concluded that twice daily use of the dentifrice containing 0.3% triclosan and 2.0% copolymer reduces supragingival plaque formation and gingivitis very significantly. Further, these results do confirm and extend results of other long-term clinical studies, all of which compared the effects of the same triclosan/copolymer/fluoride and placebo dentifrices on gingivitis and supragingival plaque formation.