

## Comparison of the Clinical Anticaries Efficacy of an 1100 NaF Silica-based Dentifrice Containing Triclosan and a Copolymer to an 1100 NaF Silica-based Dentifrice Without Those Additional Agents: A Study on Adults in California

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Recent years have seen much work in the development of dentifrice containing the antimicrobial agent triclosan, a broad spectrum antibacterial agent manufactured for use in oral products by the Ciba-Geigy Corporation. Studies have shown that the incorporation of this agent into dental products, in combination with a PVM/MA copolymer (the non-proprietary designation for a polyvinylmethyl ether maleic acid copolymer), can provide several important dental therapeutic benefits, including an antigingivitis effect. Much research on the therapeutic benefits of such dentifrices has been reported in the literature. The present study is a component of a large-scale program of clinical research to investigate the anticaries effectiveness of fluoride dentifrices containing 0.3% triclosan and 2.0% PVM/MA copolymer. The study included two treatment groups, each consisting of adults living within a 50-mile radius of Loma Linda, California, who were assigned to the use of one of the following sodium fluoride (NaF) dentifrices: 1) a dentifrice containing 0.3% triclosan and 2.0% PVM/MA copolymer in a 0.243% NaF/silica (1100 ppm F) base; or 2) a dentifrice containing 0.243% NaF/silica (1100 ppm F). Conducted in accordance with the guidelines for caries clinical studies published by the Council on Dental Therapeutics of the American Dental Association, the study employed clinical diagnostic criteria as described in the August, 1997 National Institute of Dental Research (NIH/NIDR) publication. Dental radiographs were not employed. Principal comparisons of the dentifrices tested were implemented through the construction of 90% confidence intervals for the ratio of mean 3-year caries increments, using Feller's theorem. Of those subjects who met the initial inclusion/exclusion criteria for this study, 1,542 were available for the 36-month examination. DFS (resp., DFT) increments over this period were 2.07 (0.63) for the triclosan/copolymer dentifrice, and 2.16 (0.68) for the dentifrice without those additives. The confidence interval calculations for both incremental DFS and DFT support the conclusion that a dentifrice containing 0.3% triclosan and 2.0% PVM/MA copolymer in a 0.243% NaF/silica (1100 ppm F) base provides a level of anticaries efficacy which is "at least as good as" that provided by a dentifrice containing 1100 NaF/silica without those additive agents. As such, the results of this clinical study clearly indicate that the addition of triclosan and a copolymer to a 1100 NaF/silica dentifrice does not compromise its anticaries efficacy. (*J Clin Dent* 7:85-89, 1996.)