

# EFFECTS OF A TRICLOSAN DENTIFRICE ON PLAQUE FORMATION, GINGIVITIS AND GINGIVAL BLEEDING IN PREGNANT WOMEN: FIVE-MONTH CLINICAL RESULTS

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**Abstract.** The objective of this study was to determine the effects of a triclosan/copolymer dentifrice on plaque formation, gingivitis and gingival bleeding in pregnant subjects. This double-blind clinical study was carried out in 180 women at 3 months of pregnancy. The subjects were stratified into two balanced groups according to their baseline plaque, gingivitis and bleeding scores. Subjects received a thorough dental prophylaxis and were assigned to brush with either a placebo or triclosan dentifrice for five months. They were instructed to brush their teeth as they normally would, twice a day for one minute per brushing. Follow-up examinations after five months of dentifrice use evaluated supragingival plaque, gingivitis and gingival bleeding. After five months, the triclosan dentifrice significantly reduced plaque formation, gingivitis and gingival bleeding by 40.5%, 22.5% and 35.3%, respectively, compared to the placebo group ( $p < 0.05$ ).

## INTRODUCTION

Bacterial plaque is a major etiologic factor in gingivitis and periodontal disease. The prevention of plaque formation is the best approach to reduce gingivitis and periodontal disease (Loe *et al*, 1965; Socransky, 1970). Gingivitis during pregnancy is extremely common, occurring between 30-100% of the time, with cases ranging from mild inflammation to severe hyperplasia, pain and bleeding (Jensen *et al*, 1981; Ferris, 1993). The clinical changes in the periodontal tissues during pregnancy are increased gingival probing depths, increased gingival inflammation, increased bleeding upon probing and increased tooth mobility (Miyazaki *et al*, 1991; Raber Durlacher *et al*, 1994; Tilakaratne *et al*, 2000).

Data obtained from epidemiological studies and an understanding of the pathogenesis of periodontal disease stimulate the interest in the possible relationship between periodontal disease and pregnancy complications, respiratory diseases, cardiovascular disease and diabetes. Periodontal disease may be considered to be a reservoir of bacteria, their products and inflammatory mediators, and these can disseminate to other parts of the body and contribute either indirectly or directly to systemic disease. Several studies have reported that periodontal disease during pregnancy is a significant risk factor for low birth weight and pre-term birth and have suggested that periodontal intervention may reduce the incidence of adverse pregnancy outcomes (Offenbacher *et al*, 2001; Madianos *et al*, 2002; Scannapieco *et al*, 2003).

This double-blind clinical study was designed to assess the efficacy of a triclosan/copolymer dentifrice on plaque, gingivitis and gingival bleeding compared with a placebo

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dentifrice over five months in pregnant subjects.

## MATERIALS AND METHODS

One hundred eighty women at 3 months of pregnancy were assessed for baseline plaque, gingivitis and bleeding scores on the facial and lingual surfaces of all natural teeth excluding the third molars. Plaque was assessed using the Turesky modification (Turesky *et al*, 1970) of the Quigley-Hein method; gingivitis was measured using the Talbott modification (Talbott *et al*, 1977) of the Loe-Silness method; bleeding was assessed using the method used by Saxton and van der Ouderaa (1989).

Following baseline examination, subjects received dental prophylaxis. Subjects were stratified into two balanced groups according to baseline plaque, gingivitis and bleeding scores. The subjects were then randomly assigned either to the triclosan or the placebo dentifrice group. Subjects were instructed to brush their teeth as they normally would, twice

daily for 1 minute using only their assigned dentifrice and soft toothbrush. After 5 months of dentifrice use, subjects were reevaluated and plaque, gingivitis and bleeding were recorded by the same dental examiner using the same methodology.

## RESULTS

The baseline characteristics for 180 women examined for plaque, gingivitis and gingival bleeding are presented in Table 1. The mean plaque, gingivitis and bleeding index scores for the placebo dentifrice group were 2.926, 1.682 and 0.981, respectively. For the triclosan group, the scores were 3.067, 1.693 and 1.023, respectively. There were no significant differences between the two groups with regard to baseline plaque, gingivitis and bleeding index scores (Student's *t*-test,  $p > 0.05$ ).

Comparisons of the mean plaque, gingivitis and bleeding index scores for the two dentifrice groups after 5 months of use are presented in Table 2. The placebo group had

Table 1  
Baseline characteristics and baseline scores for plaque, gingivitis and bleeding indexes in women completing the 5 month study.

Dentifrice group	Number of women	Age		Plaque index (mean $\pm$ SD)	Gingivitis index (mean $\pm$ SD)	Bleeding index (mean $\pm$ SD)
		Mean	Range			
Placebo	88	26.43	(20-38)	2.926 $\pm$ 0.710	1.682 $\pm$ 0.440	0.981 $\pm$ 0.513
Triclosan	92	26.84	(20-37)	3.067 $\pm$ 0.762	1.693 $\pm$ 0.416	1.023 $\pm$ 0.497
Total	180					

Table 2  
Comparisons of mean plaque, gingivitis and bleeding indexes for the two dentifrice groups after 5 months.

Dentifrice group	Plaque index		Gingivitis index		Bleeding index	
	Mean $\pm$ SD	Percent reduction	Mean $\pm$ SD	Percent reduction	Mean $\pm$ SD	Percent reduction
Placebo	2.219 $\pm$ 0.663		0.968 $\pm$ 0.641		0.385 $\pm$ 0.418	
Triclosan	1.321 $\pm$ 0.929	40.5	0.750 $\pm$ 0.569	22.5	0.249 $\pm$ 0.418	35.3

mean plaque, gingivitis and bleeding index scores of 2.219, 0.968 and 0.385, respectively, while the triclosan group had mean plaque, gingivitis and bleeding index scores of 1.321, 0.750 and 0.249, respectively. The triclosan dentifrice provided 40.5, 22.5, and 35.3% reductions in plaque, gingivitis and bleeding, respectively, compared to placebo ( $p < 0.05$ ).

## DISCUSSION

Maintenance of gingival health is critical in preventing gingivitis and its progression to periodontal disease. Because of the direct causative association between microbial dental plaque and gingivitis, the use and application of antimicrobial agents has been the primary chemotherapeutic approach toward improving periodontal health. A number of mouthwashes and dentifrices incorporating antimicrobial agents have successfully demonstrated clinical efficacy for the reduction of plaque and gingivitis; such as triclosan dentifrice (van der Ouderaa, 1991; Ciancio, 1992; Cummins and Creeth, 1992). The purpose of this clinical study was to evaluate the effect of a triclosan/copolymer dentifrice on plaque, gingivitis and gingival bleeding in pregnant women. The results demonstrated a significant reduction in plaque (40.5%), gingivitis (22.5%), and bleeding (35.3%), over a 5-month period of twice daily use. There were no adverse events reported with the use of the dentifrice. The results of this study confirm the findings of previous clinical studies in healthy adult subjects which demonstrated significant reductions in plaque and gingivitis from 20% to 60% (Triratana *et al*, 1993, 1994; Nogueira-Filho *et al*, 2000; Volpe *et al*, 2002).

Triclosan is a broad spectrum antimicrobial agent and has low toxicity. The dentifrice formulation used in this study combined triclosan with a polyvinyl methylether/maleic acid copolymer to stabilize the triclosan in a

bioavailable form within the product matrix, facilitate its release during tooth brushing and ensure its adherence in the oral cavity for a prolonged period. In addition, the triclosan copolymer formulation was shown to inhibit several potent mediators responsible for gingival inflammation (Gaffar *et al*, 1990, 1995; Mustafa *et al*, 1998).

In summary, the triclosan/copolymer dentifrice in this study delivered statistically significant and clinically relevant benefits in the control of dental plaque and treatment of gingivitis and gingival bleeding in pregnant women.

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