

TABLE 9.—MEAN GINGIVAL INDEX SCORES FROM THE MANKODI STUDY

Group	Baseline	3 months	6 months
Mean Gingival Index Score (adjusted for 3 and 6 months)			
Essential Oils	1.19	0.93	0.87
Essential Oils plus Mint	1.22	1.00	0.91
Control	1.23	1.10	1.18

A second study by Mankodi *et al.* (Ref. 116) compared the effects of the combination of essential oils, chlorhexidine gluconate, and a 5-percent water-alcohol control. There were 34 subjects (mean age 32 years) in the essential oils group, 36 subjects (mean age 31.4 years) in the

chlorhexidine gluconate group, and 38 subjects (mean age 32.2 years) in the water-alcohol control group. The protocol was similar to the earlier studies with the exception of the use of the Russell Periodontal Index “to further describe the study population,” and the use of the Loe and Silness

Gingival Index for assessment. The results (see Table 10 below) showed a statistically significant difference between the essential oil and control groups at 6 months, with the mean gingival index score for the essential oils group being 14.0 percent less than the mean score for the control group.

TABLE 10.—MEAN GINGIVAL INDEX SCORES FROM THE MANKODI STUDY

Group	Baseline	3 months	6 months
Mean Gingival Index Scores			
Essential Oils	1.31	1.22	1.04
Essential Oils Plus Mint	1.35	1.04	0.99
Control	1.27	1.18	1.21

A third study by Mankodi (Ref. 117) compared the effects of the combination of essential oils, the same combination plus flavor, and a 5-percent water-alcohol control. There were 48 subjects in the essential oils group (mean age 32 years), 43 subjects in the essential oils plus mint group (mean age 32 years), and 50 subjects in the water-alcohol control group (mean age 34 years). The protocol was similar to previous studies, but supervision on weekdays was

limited to one of the two daily rinses, and this study used the Lobene modification of the Loe-Silness Gingival Index. Subjects received a prophylaxis following their baseline examination. Gingivitis was scored at baseline, 3 months, and 6 months. All intraoral examinations were performed by a single qualified dental examiner. Units of statistical analysis were the respective mean index scores determined for each subject. Gingival

indices were analyzed by the analysis of variance, using baseline scores as the covariant. Results of gingival index scoring (see Table 11 below) are adjusted means for 3 and 6 months. Mean score percent reduction from control at 6 months for the combination of essential oils plus flavor was 10.8 percent and 10.2 percent for the combination without flavor. Both active groups are statistically significantly different at 6 months.

TABLE 11.—MEAN GINGIVAL INDEX SCORES FROM THE MANKODI STUDY

Group	Baseline	3 months	6 months
Essential Oils Plus Mint	2.16	1.68	1.66
Essential Oils	2.20	1.63	1.67
Control	2.19	1.82	1.86

An eighth 6-month controlled trial (Ref. 118) used the fixed combination of essential oils and a “flavor variant” control. The results showed the mean gingival scores significantly lower than the control group at 6 months.

These studies demonstrated that the fixed combination of essential oils has some effectiveness in preventing inflammation of the gingiva. The initial analyses relied solely on statistical

hypothesis testing (the use of p values), which does not convey important quantitative information. However, a number of concerns (strength of the effect and its statistical significance, the generalizability of the studies to the population which can most benefit, and the unit of analysis (subject versus site)) were resolved to make a valid determination as to the strength of

antigingivitis efficacy for these ingredients.

Generalizability of randomized, controlled trials to the population who will use the product is a concern. These studies use young populations, weighted with dental students, where supervision and timing of use is present. Much of the population that will benefit from an antigingivitis agent is middle-aged and older, having fully crowned