

product except the essential oils), or a water control. Of the 145 subjects who entered the study, approximately 62 percent were male and 20 percent were smokers. Inclusion criteria were 20 natural teeth exclusive of large carious lesions, orthodontically banded, fully crowned, abutment, and third molar teeth, and a minimum score of 2.0 using a modified Loe-Silness Gingival Index plus a minimum score of 1.8 using the Turesky modification of the Quigley-Hein Plaque Index. Of 129 subjects completing the study, 45 were in the essential oils group (mean age 26.1 years), 43 were in the vehicle control group (mean age 27.9 years), and 41

were in the water control group (mean age 24.7 years).

Subjects were supervised as they rinsed twice daily from Monday to Friday with 20 mL for 30 seconds. Coded 3-ounce (oz) bottles and graduated plastic cups were distributed for twice daily unsupervised weekend use. Coded 16-oz bottles were distributed for holidays and recesses. Subjects were required to maintain a diary of unsupervised rinse use. Subjects followed their usual oral hygiene regimen, with no dental treatment, scaling, or polishing prior to the rinse regimen.

All intraoral examinations were performed by the same examiner. Gingivitis was scored using the modified Loe and Silness Gingival Index which adds an additional score between the 1 and 2 of Loe and Silness, thus having two levels of "Mild Inflammation," and eliminates the bleeding component from the original criteria for "Moderate Inflammation." This index was later published by Lobene (Ref. 112) and is used in five of the eight "definitive" studies. Results (see Table 4 below) showed a continuous decline in adjusted mean gingivitis scores for each of three groups from baseline through 6 months.

TABLE 4.—RESULTS OF THE LAMSTER STUDY GROUP

Group	Baseline	1 month	3 months	6 months
Essential Oils	2.62	2.08	1.57	1.20
Vehicle Control	2.67	2.20	1.94	1.66
Water Control	2.66	2.32	1.93	1.67

Mean scores for the fixed combination of essential oils were statistically significantly less than controls at 3 and 6 months and 28 percent less than either control group mean score at 6 months. Control groups of this monitored, supervised, mostly young, dental school population continued to show a decrease in mean gingival index scores over time. No bleeding assessments were made.

A second study (Ref. 104) involved mostly dental students and staff of the same university, with the same inclusion criteria. Subjects were randomized into three groups, with 44 in the essential oils group (mean age 25 years), 38 in the vehicle control (a 26.9-percent hydroalcoholic vehicle containing all the ingredients in the test

product except the essential oils) group (mean age 29 years), and 45 in the water control group (mean age 27 years). Upon entering the study, all subjects had a dental prophylaxis (defined as a scaling and rubber cup polishing), followed in 3 weeks by a baseline 1 examination. Two additional prophylaxes were done for each subject 4 to 7 days apart, followed in 3 to 4 days by a baseline 2 assessment. Prior to the first rinse, another (fourth) polishing was done. Subjects were randomly assigned to either the fixed combination of essential oils, a vehicle control, or a colored water control.

Supervision of rinsing and monitoring was the same as in the first study and gingivitis was scored as before. No bleeding assessment was done. Results

(see Table 5 below) were recorded at 1, 3, and 6 months, with all assessments performed by one examiner. No intra-examiner variability testing is noted. Eighty-five subjects completed an additional 3 months of unsupervised rinsing. Most of the subjects who did not participate for the additional 3 months of the study were recently graduated dental students who were not available for the 9-month examination. The 6-month mean gingival index score for the essential oils was 10.4 percent less than the water control and 6.5 percent less than the vehicle control, but no statistically significant differences existed between groups for any interval.

TABLE 5.—MEAN GINGIVAL INDEX SCORES FROM THE GORDON STUDY

Group	Baseline 1	Baseline 2	1 month	3 months	6 months
Mean Gingival Index Score					
Essential Oils	1.60	1.39	1.54	1.27	1.31
Water	1.60	1.38	1.55	1.38	1.46
Vehicle	1.59	1.33	1.49	1.25	1.37

Mean gingival index scores for the 127 subjects who completed 6 months of the study were as follows: 1.23 for the essential oil group, 1.42 for the vehicle control group, and 1.57 for the water control group. Results for the 85 subjects who completed 9 months

showed a statistically significant difference in mean gingival index scores, as follows: 1.12 for the essential oils, 1.43 for the vehicle control, and 1.52 for the water control.

The investigators stated that the lack of difference for gingivitis observed

between groups for 6 months was probably due to improvement in gingival health resulting from four prophylaxes initially, followed by continuation of usual oral hygiene.

A third study involving 115 subjects in two study groups (essential oils and