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## Effect of an Essential-Oil and a Delmopinol Mouthrinse on Dental Plaque and Gingival Bleeding

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### Research Article

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#### ABSTRACT

**Objective:** This study aims to compare the effects of an Essential-Oil mouthrinse (EO) and a Delmopinol mouthrinse (DM) on gingival bleeding and dental-plaque in healthy adults.

**Methods:** Ninety subjects entered were selected to participate in the clinical trial (49% males and 51% females; mean age of 32.3 years), with a minimum of 6 teeth per quadrant and periodontal pockets depth less than 5 mm. Every patient received a dental hygiene appointment. After the appointment, subjects were allocated to one of three study groups: Group 1 - Cool Mint Listerine (EG); Group 2 - Decapinol (DG); Group 3 - Control (no mouth rinse). Mouth rinse groups were asked to use the solution for two weeks, following manufacturer's instructions. Gingival bleeding was accessed using the Gingival Index (GI), and Dental Plaque was accessed by the Quigley-Hein-Turesky Index.

**Results:** There were no baseline differences between groups regarding dental plaque and bleeding indexes. For GI, only the DG group had statistically significant lower scores than the Control group ( $p < 0.05$ ), with 33.8% difference. DG and EG results were not statistically different. For Plaque Index, only the EG group had a statistically significant lower index score than the Control group ( $p < 0.05$ ). EG and DG did not statistically differ.

**Conclusion:** There was a statistically significant reduction in GI scores for DG group vs. Control group and a statistically significant reduction of Dental Plaque index score in the EG vs. Control. EG and DG groups did not differ between them for both indexes scores. Although statistical significance was attained, clinical significance may not be of consequence.

### INTRODUCTION

To prevent oral diseases, it is necessary to act upon dental plaque. This kind of intervention can be done in two different ways: the physical removal of dental plaque and the chemical approach to affect micro flora's metabolism and colony forming ability <sup>[1]</sup>.

The pathogenic nature of dental plaque can be reduced by the maintenance of a good dental hygiene, which includes daily toothbrush, interproximal cleaning and the use of an antiseptic mouthwash <sup>[2]</sup>. Dental hygiene instructions must be clear and concise, pointing to the need of a meticulous tooth brushing for two minutes <sup>[3]</sup>.

For most of our patients, daily dental hygiene routines are not sufficient to, effectively, control dental plaque. Dental health professionals have the challenge to motivate patients and to find techniques focused on their individual needs <sup>[4]</sup>, presenting them with a product able to provide answers to their needs <sup>[5]</sup>.

In the past few years, products for chemical control of dental plaque have become widely available to consumers. Most of

these products present innovative formulae, therapeutic agents and flavors appealing to people, presenting, at the same time, affordable prices. These characteristics make them a serious option as instruments to be used as coadjutants of individual oral health <sup>[6]</sup>.

The use of an essential-oils or a delmopinol mouth rinse is positive to health promotion and oral diseases prevention <sup>[7,8]</sup>. When compared to other therapeutic agents, such as chlorhexidine or triclosan, delmopinol and essential-oils have the advantage of presenting few to none secondary effects, and, for that same reason, are able to be used for a long time period, inhibiting dental plaque, with no bacterial adaptation or resistance <sup>[5,6,9]</sup>.

Essential-oils, namely menthol, thymol and eucalyptol, are effective in gingivitis and dental plaque reduction <sup>[6,10]</sup>. The alcohol content of the essential oils mouth rinse is a major concern for public and for health providers, for its possible relation to oral cancer. This issue is considered to be of low relevance since there is no scientific evidence of an association between mouth rinse alcohol content and cancer <sup>[6,11-16]</sup>. However patients complain of burning sensation caused by alcohol <sup>[17]</sup> which makes it difficult to use the essential oils mouth rinse on a regular basis <sup>[6,18]</sup>. A slight coloration of teeth surface is also noticed, but it is easily removed with tooth brushing <sup>[19]</sup>.

Essential oils are able to destroy the cell membrane and inhibit the enzymatic activity <sup>[20]</sup>, killing 78.7% of bacteria after its use for 60 seconds <sup>[21]</sup>. It also reduces the acidic properties of bacteria <sup>[22]</sup> helping in the remineralization of early carious lesion when fluoride is present in the mouthrinse <sup>[23]</sup>. An essential oils mouthrinse is effective against dental plaque and gingivitis <sup>[4,19,24-31]</sup> and reduces the amount of periodontal pathogens <sup>[32,33]</sup>.

Delmopinol is effective to prevent gingivitis and present anti-inflammatory properties <sup>[11,34,35]</sup>. It was approved in 2005 by FDA and introduces a novelty concerning the form of action, since it interferes with the formation of the bacterial matrix <sup>[36]</sup> and inhibits bacterial aggregation <sup>[11,37]</sup>. It adheres to the saliva coated enamel <sup>[38]</sup> and reduces bacterial vitality <sup>[39,40]</sup> creating a loose biofilm easily removed with tooth brushing <sup>[11,41,42]</sup>. Some side effects of delmopinol such as numbness of tongue, palatal changes and xerostomia <sup>[11,37]</sup> are transient and do not prevent the use of the product by the patients. Numbness of the tongue happens quite frequently and is reported as the most unpleasant of the side effects. Changes on food taste (palatal changes) are also of concern if the patient performs the mouth rinse before a meal.

## **METHODOLOGY**

This clinical trial allows the comparison and evaluation of the efficacy of an essential oils and a delmopinol mouth rinse on clinical parameters of dental plaque accumulation and gingivitis. Every clinical observation was performed by the same person in order to reduce data collection bias. The study protocol was approved by the Ethics Committee at the Faculdade de Medicina Dentária, Universidade de Lisboa. All subjects signed an informed consent before the start of the clinical trial.

## **PATIENT SELECTION**

Study population, in a total of 90 individuals, was selected among the Dental Hygiene Clinic patients at the Faculdade de Medicina Dentária, Universidade de Lisboa. Inclusion criteria were as follows: presence of two quadrants with, at least, six teeth each; presence of mild gingivitis at the most (Gingival Index < 3) and presence of dental plaque. Every patient had to sign the consent for in order to enter the study. Exclusion criteria consisted on the use of a mouth rinse for dental care at home, dental scaling and polishing in the previous six months and been under age.

## **SUBJECT ALLOCATION**

The subjects were randomly allocated to a treatment group by a computer-generated system. The study design demanded the existence of 3 groups of 30 individuals each and two periods for data collection. With this sample size, the probability is 90 percent that the study will detect a treatment difference at a two-sided 0.05 significance level, if the true difference between treatments is 0.32 times the standard deviation.

Subjects were randomly allocated in a first treatment group (Control Group – CG) in which a dental hygiene appointment took place to collect information on study variables. During that dental hygiene appointment, subjects received dental hygiene instruction and motivation, also dental scaling and polishing was performed. Instruction on regular use of toothbrush and tooth paste use, and appropriate interproximal cleaning were given for regular in-home dental care. This group received no mouth rinse to use at home.

The second treatment group (Essential Oils Group–EG), had the same type of dental hygiene appointment with the same information for home self-care and, also, instructions on the use of Listerine Cool Mint®, twice a day (20 ml for 30 seconds, each time, according to manufacturer's instructions). The amount of mouth rinse needed for the two-week period was given at that appointment.

The third group (Delmopinol Group – DG), received a dental hygiene appointment like the two previous groups and instructions to use the Decapinol® mouth rinse twice a day (10 ml for a minute, each time, according to manufacturer's instructions). The amount of mouth rinse needed for the two-week period was given at that appointment.

## TREATMENT PROTOCOL

Data collection occurred during two appointments with an interval of two weeks. The first appointment was called the baseline data, and gave the researchers demographic information and initial clinical data. The second appointment allowed for the collection of the clinical data, necessary to evaluate treatments in comparison to baseline values. The two-week interval was selected according to the literature that mentions this period of time between observations as adequate to evaluate the effect of a mouthrinse on gingival health, dental plaque accumulation and oral microflora [32-34,43-48].

## CLINICAL MEASUREMENTS

The evaluation of the effect of an Essential-Oil and a Delmopinol mouth rinse, on dental plaque and gingival bleeding, was performed clinically. The indexes used for data collection were the Plaque Index (PI) by Quigley and Hein, modified by Turesky et al. and the Gingival Index (GI) by Löe and Silness, widely accepted for use in clinical trials [49,50]. The clinical parameters were measured at day 1 (baseline) and then again at day 15 (end of the study). Data was registered in clinical sheets created for this clinical trial.

## STATISTICAL ANALYSIS

Data was analyzed with descriptive statistical techniques. Treatment groups were compared with one-way analysis of variance (ANOVA) with treatment as a single factor at baseline and at the end of the trial, with a 0.05 significance level.

Comparison among treatments was performed using one-way analysis of covariance (ANCOVA) with treatment as factor and the baseline values of clinical parameters as covariant, with a 0.05 significance level. The ANCOVA is accepted as the adequate statistical test to analyze the efficacy of dental plaque removal in clinical trials [51].

Baseline and end of study data were compared using a paired t-test with a 0.05 significance level. These comparisons were performed for the study of mean values of GI and PI between EG vs. CG; DG vs. CG and EG and DG.

## RESULTS

A total of 90 subjects participated in this clinical trial. The total sample was well balanced for gender with 51.1% of females, the distribution of age groups shows that 34% of subjects were under 24 years of age, 51% of subjects were between 25 and 44 years old, 13% were in the 45 to 64 years' group and 2% of subjects had more than 65 years of age.

The 90 subjects presented a DMFT of 6.9, with 58.9% of individual with no cavities experience and 45.6% with full dentition.

Data for the three treatment groups shows that, at baseline, there were no statistical difference among them for age ( $p = 0.095$ ) and gender ( $p = 0.842$ ). Baseline clinical parameters also presented no statistical difference among treatment groups (**Table 1**).

**Table 1.** Comparison of mean values (sd) for clinical parameters at baseline.

Variable	Treatment group			P value
	Control Group	Essential Oils Group	Delmopinol Group	
Gingival Index	1.19 (0.34)	1.04 (0.62)	1.14 (0.60)	0.550
Plaque Index	2.28 (0.85)	2.48 (0.97)	2.32 (0.80)	0.646

After treatment period, the clinical data for the three groups are presented as mean values adjusted to baseline, and the standard error. For the Plaque Index by Quigley and Hein modified by Turesky it was the DG that had the lowest average (1,617), same for the Gingival Index by Löe and Silness. The CG had the highest average (1,750), as (**Table 2**). In this table it is presented the mean values adjusted to the baseline and the standard sampling error (since the data are adjusted, the standart deviation can't be displayed).

**Table 2.** Mean values and standard error of the dependent variables after using the Essential- Oil and Delmopinol mouth rinse for a trial period of two weeks.

Variable	Mean Values Adjusted <sup>§</sup> (Standard Error)		
	Control Group	Essential Oils Group	Delmopinol Group
Gingival Index by Löe and Silness	0.730 (0.41)	0.487 (0.46)	0.483 (0.50)
Plaque Index by Quigley and Hein, modified by Turesky et al.	1.750 (0.68)	1.680 (0.74)	1.617 (0.68)

<sup>§</sup>The corresponding values obtained in the first appointment were used as a covariant.

The reduction values, in percentage, for the Gingival Index by Löe and Silness compared to the baseline values, within each group (**Table 3**), along with the values of statistical significance for the difference.

The reductions for the Gingival Index by Löe and Silness were statistically significant for all experimental groups. The DG showed the highest percentage of reduction of the Gingival Index by Löe and Silness (57,63%), followed by the EG (53,17%) and the CG (38,65%).

**Table 3.** Percentage and p value of the reduction of the Gingival Index by Loe and Silness, after the trial period of two weeks.

Gingival Index by Loe and Silness	Baseline	After 2 weeks	% of reduction	P value
Control group	1.190	0.730	38.65	0.001*
Essential-oils group	1.040	0.487	53.17	0.001*
Delmopinol Group	1.140	0.483	57.63	0.001*

\* Statistically significant.

The Plaque Index by Quigley and Hein modified by Turesky shows reductions in all experimental groups, when compared with the baseline values. The percentage of reduction can be observed in **Table 4**, along with the p values for the statistical significance. The reduction of the Plaque Index by Quigley and Hein modified by Turesky were statistically significant for all experimental groups. The EG showed the highest percentage of reduction of the Plaque Index by Quigley and Hein modified by Turesky (32.25%), followed by the DG (30.30%) and the CG (23.24%).

**Table 4.** Percentage and p value of the reduction of the Plaque Index after the trial period of two weeks.

Plaque Index by Quigley and Hein, modified by Turesky	Baseline	After 2 weeks	% of reduction	P value
Control group	2.280	1.750	23.24	0.001*
Essential-oils group	2.480	1.680	32.25	0.001*
Delmopinol group	2.320	1.617	30.30	0.001*

\* Statistically significant.

When the three groups were studied, the statistical evaluation of the results showed that there were statistically significant differences between the experimental groups for the Gingival Index by Loe and Silness ( $p = 0.040$ ) but there were no statistically significant differences for the Plaque Index by Quigley and Hein modified by Turesky ( $p = 0.068$ ).

The univariate study of the analysis of covariance indicates that the participants of the EG and the DG reveal statistically significant differences, when compared with the CG, (**Table 5**), along with the percentages of reduction of the indexes values.

**Table 5.** Differences between the experimental groups and the control group, after the trail period of two weeks, in percentage of reduction and p value.

Variable	Percentage of reduction and p value		
	Essential-Oils vs. Control	Delmopinol vs. Control	Essential-Oils vs. Delmopinol
Gingival Index by Loe and Silness	33.28% ( $p = 0.075$ )	33.83% ( $p = 0.013$ ) *	0.83% ( $p = 0.524$ )
Plaque Index by Quigley and Hein (1962), modified by Turesky et al.	4.0% ( $p = 0.042$ ) *	7.6% ( $p = 0.054$ )	3.75% ( $p = 0.624$ )

\* Statistically significant ( $p < 0.05$ ).

At the end of the clinical trial, the DG presented a lowest mean value of the Gingival Index by Loe and Silness, which resulted in a statistically significant percentage reduction when compared with the control group ( $p = 0,013$ ). The EG when compared with the CG did not reach statistical significance ( $p = 0,075$ ). Between the EG and the DG there was no statistically significant difference ( $p = 0,524$ ).

With regard to the Plaque Index by Quigley and Hein modified by Turesky, and after two weeks of study, the participants of the EG had a statistically significant percentage when compared with the CG ( $p = 0,042$ ).

The participants of the DG also presented a lower value of reduction for the Plaque Index by Quigley and Hein modified by Turesky, when compared with the CG, however, this is not statistically significant ( $p = 0,054$ ). There were no statistically significant differences between the EG and DG ( $p = 0,624$ ).

## DISCUSSION

A healthy gingival sulcus, being an anatomic space that facilitates bacterial accumulation <sup>[46]</sup>, presents very specific characteristics, with predominance of non-viable bacteria <sup>[47]</sup>.

In the clinical part of this study there was a statistically significant reduction on the Gingival Index by Loe and Silness values in the DG when compared with the CG, and there was also a statistically significant reduction on the Plaque Index by Quigley and Hein modified by Turesky values for the EG when compared with the CG. The EG did not differ from the DG to any of the indexes.

In the scientific literature different methods are described to study the effectiveness of essential- oils and delmopinol on the control of dental plaque accumulation and on the gingivitis prevention. The most common situations describe a comparison of the essential-oils, or the delmopinol mouthwash, with a water mouthwash, as placebo, or with a control, composed by an alcoholic solution in different concentrations <sup>[19,30,40,52-55]</sup>. Also described, in the scientific literature, there are clinical trials in which the control group is composed of individuals who performed only mechanical techniques of oral hygiene (brushing and dental floss), as it occurred in this clinical trial <sup>[56]</sup>.

Due to organoleptic properties of the essential-oils elixir, the use of water or a hydroalcoholic solution does not appear adequate for the comparison of efficacy of the mouth rinse, because it prevents the “blind” utilization of the product by the individual who participates on the study.

The use of the essential-oils elixir, along with unsupervised brushing, is described in the literature as producing beneficial effects in reducing dental plaque and gingivitis [57].

The results obtained in clinic trials with the use of essential-oils elixir and the use of same indexes, or similar, by several other studies to the evaluation of the dental plaque accumulation and/or gingivitis (Table 6) [19,30,40,48,52-56].

**Table 6.** Percentual reduction of the Plaque Index and Gingivitis in studies using essential-oils QHT- Plaque Index by Quigley and Hein, modified by Turesky.

Author	Duration	Experimental Groups	Dental plaque		Gingivitis	
			Index	Reduction vs. placebo or control (%)	Index	Reduction vs. placebo or control (%)
Sekino (n = 21)	2 weeks	Listerine Control (saline)	QHT	27.5	GI	n.a
Riep (n = 24)	5 days	Listerine Control (hydro alcoholic)	QHT	23.0	---	---
Gordon (n = 85)	9 months	Listerine Placebo (water)	QHT	14.9	GI	20.0
Grossman (n = 481)	6 months	Listerine Placebo (water)	QHT	24.2	GI	9.4
Overholser (n = 124)	6 months	Listerine Control (hydro alcoholic)	QHT	36.1	MGI	35.9
Charles (n = 107)	6 months	Listerine Control (hydro alcoholic)	QHT	18.8	GI	14.0
Tufekci (n = 50)	6 months	Listerine Control (mechanical)	QHT	53.2	BI	74.5
Present study (n=90)	2 weeks	Listerine Control (mechanical)	QHT	4%	GI	33.28%

GI – Gingival Index by Löe and Silness; MGI – Modification of the Gingival Index by Lobene.; BI – Bleeding Index by Saxton and van der Oudera; n.d – not disclosed/ impossible to calculate through the article data.

A systematic review of long term studies, carried out in 2007 by Stoeken, is said that the essential-oils has constantly significant results in gingivitis and dental plaque reduction, regardless of the index which the variable is evaluated, compared with a control [29]. In the clinical trial developed in this study, relatively to the reduction of dental plaque when used the essential-oils elixir, a reduction of 4% was found when compared with the CG, a far lower value than reported in general literature.

In the present clinical trial in the EG, the Gingival Index value was 33.28% lower when compared with the GC. This value is similar to the values found in a study by Overholser and is located within the reduction of Gingival Index range described by Santos, relatively to dental plaque control and gingivitis, referring to the use of essential-oils as reducing gingivitis between 23% and 36%. When compared with a study by Tufekci, which used mechanical oral hygiene as a control group, we notice that the value found in present clinical trial is much lower. However, the index used in Tufekci’s study cannot be directly compared with the Gingival Index by Löe and Silness, since only evaluates the bleeding index.

Analyzing studies of delmopinol, described in literature, we can divide them into studies in which the daily use of mouthwash was supervised by the investigator (except on weekends) or in studies in which the mouthwash was unsupervised.

The results of the reduction of Plaque index and gingival index (Table 7) [35,40,54].

**Table 7.** Percentage reduction of the plaque index and gingivitis in long term studies using delmopinol.

Author	Duration	Experimental Groups	Dental plaque		Gingivitis	
			Index	Reduction vs. placebo or control (%)	Index	Reduction vs. placebo or control (%)
Lang (NS) (n = 132)	6 months	Delmopinol Placebo (water)	PI	35.0	BOP	3.0
Claydon (NS) (n = 422)	6 months	Delmopinol Placebo (water)	QHT	16.4	MGI	1.0
Hase (NS) (n = 130)	6 months	Delmopinol Placebo (water)	QHT	13.0	BOP	18.0
Claffey (NS) (n = 246)	3 months	Delmopinol Placebo (water)	QHT	17.4	MGI	7.3

Addy (NS) (n = 218)	6 months	Delmopinol Placebo (water)	QHT	21.9	MGI	6.8
Van Steenberghe (NS) (n = 234)	3 months	Delmopinol Placebo (water)	QHT	22.5	MGI	5.1
Hugoson (S) (n = 77)	2 months	Delmopinol Placebo (water)	QHT	30.4	MGI	2.9
Bergenholtz (S) (n = 72)	2 months	Delmopinol Placebo (water)	QHT	16.7	MGI	11.8
Attstrom (S) (n = 69)	6 months	Delmopinol Placebo (water)	QHT	22.0	MGI	6.7
Adriaens (S) (n = 83)	5 months	Delmopinol Placebo (water)	QHT	19.0	MGI	3.4
Present study (NS) (n = 90)	2 weeks	Delmopinol Control (mechanical)	QHT	7.6	GI	33.83

\*The participants did not carry out any other measures of oral hygiene, including brushing or flossing, during the study.  
(S)- Supervised; (NS) – non supervised QHT – Plaque index by Quigley and Hein, modified by Turesky ; GI – Gingival Index by Loe and Silness; MGI – Modification of the gingival index by Lobene.; PI – Plaque index by Silness e Loe; BOP – Bleeding on Probing; BI – Bleeding Index by Saxton and van der Oudera GI – Gingival Index by Loe and Silness.(S) –

Apart from this studies, Collaert in 1992, elaborated a trial with 16 volunteers, who did not had methods of mechanical dental plaque removal for a period of 2 weeks and used delmopinol with a concentration of 0.2%. Collaert found reductions of 55% in the Plaque Index (presence of dental plaque assessed by dye application), when compared with the baseline value <sup>[34]</sup>.

In this clinical trial, to the experimental group using delmopinol mouthrinse, the reduction of dental plaque accumulation compared to the control group was 7.6%, which again, is less than the values found in literature. In the systematic review made by Pareskevas, the values of the dental plaque reduction, when compared with the control group or placebo, varied between 9, 3% and 35% <sup>[57]</sup>. The delmopinol mouth rinse has been shown to have also good properties in gingival health promotion. This clinical trial obtained statistically significant results to the Gingival Index when compared with the control group. The value of the Gingival Index by Loe and Silness was reduced by 33.83%, much higher than 1% to 18% set out in articles analyzed by Pareskevas.

## CONCLUSION

The two product samples showed different results, registering however an improvement in the values of the Plaque Index by Quigley and Hein modified by Turesky and the Gingival Index by Loe and Silness, in both cases.

When compared with the control group, statistically significant differences were only observed in reducing the Gingival Index by Loe and Silness by the delmopinol mouth rinse and in reducing the Plaque Index by Quigley and Hein modified by Turesky by the essential oils mouth rinse.

There were no statistically significant differences between the two experimental groups (the use of essential-oils mouth rinse and the use of delmopinol mouth rinse) for any of the studied indices. The reduction value of the Plaque Index by Quigley and Hein modified by Turesky and the Gingival Index by Loe and Silness, relative to the control group, results from brushing and interproximal oral hygiene methods, after an oral hygiene appointment.

The results of this clinical trial are of particular relevance and innovation, since there is no scientific literature that directly compare the essential-oils and delmopinol mouth rinse, used in this study. Thus, the results presented represent the production of new scientific knowledge for dental professionals.

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