Effect of a Mouthwash with Tea Tree Oil on Plaque and Inflammation

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Practice – Continued Education

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Keywords: Mouthwash, chemoprevention, tea tree oil

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The oil of the tea tree (*Melaleuca alternifolia*) has antiseptic, fungicidal and bactericidal effects, which have also been confirmed against oral bacteria. Xylitol is known as a sugar substitute and has been shown to be effective against *Streptococcus mutans* and plaque formation. In the present study, the efficacy of a test mouthwash containing 1.5 % of tea tree oil and 10 % of xylitol (Tebodont®) was evaluated in terms of plaque formation and inflammation compared to a placebo mouthwash.

The test mouthwash reduced inflammation from the beginning to 3 months of use significantly (26–32 %). The reduction occurred more clearly at all the points less easily accessible to the toothbrush. Plaque decreased with the test mouthwash, whereas with the placebo mouthwash plaque increased on all surfaces. The difference was between 10–21 %, but was not statistically significant. Accordingly, a positive effect can be identified for the test mouthwash, in terms of both inflammation and plaque accumulation. The trend is clear. However, such small numbers of cases (13 subjects / group) hardly permit achieving statistical significance between the two groups, or at most with exceptionally highly effective mouthwashes. Neither mouthwash produced undesirable changes in the oral cavity. The taste of the study mouthwash was judged to be in need of improvement after 3 weeks, although after 3 months a clear adjustment had already taken place, with far fewer comments being reported.

1. Introduction

It is now generally accepted that toothpaste, together with the toothbrush, is the most important means of personal oral hygiene. In terms of efficiency of tooth cleaning, the toothpaste used was of secondary importance. However, the different compositions of toothpastes have shown in recent years that certain active ingredients integrated into toothpastes can also have a significant effect on plaque deposits and gingival inflammation (SAXER, 1997, 1998, ARWEILER et al 2002). Clearly more effective on plaque and gingivitis, however, are active ingredients that can be effective in the form of mouthwashes.

Many studies were conducted in order to evaluate the cleaning technique. It was found that the cleaning efficiency is determined more by the individual than by the technique used. An essential role is played by the time during which the teeth are cleaned (HUBER et al 1984), as well as the individually received instruction and subsequent controls (GLAVIND, 1990). For this reason, in the present study no influence was taken on the subjects with respect to the tooth-cleaning technique, and no instruction was given either. The mere fact of participating in a study usually improves oral hygiene and thus the situation in each patient in a first period of 3 to 12 weeks.

The chemical action of the individual substances in the oral cavity is known, but in pastes, possible interactions between individual components are difficult to predict (ADDY et al 1990).

In a study running for six weeks only, it was shown that a plant-based toothpaste was significantly more effective in controlling plaque and gingivitis than a conventional fluoride-based toothpaste was (YANKELL et al 1993, SAXER et al 1997). Other toothpastes or mouthwashes have been confirmed to be anti-inflammatory in 6-month- (SVATUN et al 1989 & 1993, OVERHOLSER et al 1990) and 3-year-studies (LINDHE et al 1998, ELWOOD et al 1998). Almost independently of the duration of observation, toothpastes with known chemo-preventive ingredients were found to produce reductions of plaque by approximately 30 % and gingivitis by approximately 25 % (ARWEILER et al 2002).

Tea tree oil has been touted for years and sometimes in old pharmacology textbooks as a "panacea". This tree grows in southeastern Australia, and there, too, tea tree oil is known as a medicine. The Zurich naturopath Saller reported, together with Reichling, on the history and use of the ingredients (SALLER & REICHLING, 1995). These are about 100 constituents, of which terpinolene, limonene and cineole (eucalyptol) are the best known. These essential oils have antiseptic, fungicidal and bactericidal effects (REICHLING et al 2001), which have recently been demonstrated by KULIK et al (2000) to cover oral microbes as well. The minimum inhibitory concentration (MIC) and bactericidal concentration (MBC) for various oral bacteria were demonstrated in comparison with chlorhexidine. *Actinobacillus actinomycetemcomitans* (AAC), *P. gingivalis* and *Prevotella intermedia* were the most sensitive germs. The product may therefore be an anti-gingivitis drug. The effective bacterial concentrations in vitro are in the range of 0.05–3.3 %, where at this concentration the plant extract is accepted in the oral cavity without causing side effects. FRITZ (2000), however, reports increased rates of contact allergies since use of this oil has started surging. However, this effect is mainly attributed to some aged extracts such as terpinolene and ascardiol. Cineole does not appear to trigger this sensitisation, as used to be thought. ARWEILER et al (2000) have recently tested a tea tree oil (by Maxim, Cologne) together with milk as an emulsifier for plaque growth and bacterial vitality and actually not found any effect.

Xylitol is a sugar substitute and moisturiser. Xylitol is globally used in the cosmetic and pharmaceutical industries. Various in vitro studies have shown that xylitol has a growth-inhibiting effect on oral bacteria, especially *Streptococcus mutans*. In a three-month study on 76 subjects with toothpastes containing xylitol and glycerol (9.9 + 20 %) or sorbitol (28 %), a significant reduction of *S. mutans* in saliva was found in the xylitol / glycerol group (SVANBERG & BIRKHED 1991). Recently, in a 6-month double-blind study, addition of 10 % xylitol to a toothpaste containing the active ingredient triclosan significantly reduced *S. mutans* and plaque in over 150 volunteers (JANNESSON et al 2002).

A gel with a tea tree oil extract has been on the market for quite some time (Tebodont®), and this has also been tested in vitro (KULIK et al 2000). The extracts of this gel should now be integrated into a mouthwash with 10 % xylitol and comparatively examined in patients.

The aim of the study was to examine the mouthwash with regard to the following questions:

1. What is the inhibitory effect on plaque during normal use by the end user of the mouthwash?

2. How does the gingival inflammation of the subjects relate to the plaque accumulation and the mouthwash used?

2. Materials and method

2.1. Test solution

1. Test mouthwash (Tebodont®) containing: Tea Tree Oil (1.5 %), Xylitol (10 %), Sorbitol, Glycerol, Propylene Glycol, Aqua, PEG-40 Hydrogenated Castor Oil, Sodium Saccharinum, Aroma

2. Placebo mouthwash containing: Sorbitol, Glycerine, Aqua, PEG-40 Hydrogenated Castor Oil, Sodium Saccharinum, Aroma[1]

2.2. Subjects

In a practice, 30 subjects were selected from a group of approximately 112 interested persons.

The subjects were recruited by advertisements in the daily press, for the purpose of testing a mouthwash against gingivitis. The subjects between the ages of 18 and 65 years had at least 20 teeth each, where in each case no more than 4 teeth

[1] Both preparations were provided by the company Dr. Wild & Co. AG, Basel.

The subjects were insured against any incidents by the company Dr. Wild & Co. AG. The study plan was submitted to the ethics committee of the University of Zurich for evaluation, and the investigation was approved on 13 December 2001.

(about one per quadrant) were permitted to be capped. The subjects were informed orally and in writing about the purpose of the study, and they gave their informed consent to the investigation. All subjects were in good general health. Patients with medical risks and smokers were excluded.

Probing depths greater than 5 mm were not allowed. Apart from the marked gingivitis (SBI on average > 1.5 in the first and third quadrants, each at four points per tooth), the dental condition was good.

Patients had to clean their teeth at least 2 times a day. In terms of the dental cleaning technique, no influence was exerted. Patients were not allowed to use interdental cleansers during the trial period. No attempt was made to improve the oral hygiene of the patients. On the other hand, the patients were instructed to rinse 3 times a day with 10 ml of mouthwash after the daily cleaning, at a 30-minute interval, for at least 60 to about 90 seconds each. Patients were also instructed to use only the assigned Emoform Sensitive toothbrush and the assigned Colgate Gel toothpaste, and not to use any other mouthwashes.

After the preliminary examination, plaque and calculus deposits were removed from the subjects included. After the findings of inflammation in the preliminary investigation, the subjects were randomised to one of the groups. All subjects received a toothbrush (Emoform Sensitive) and the same toothpaste (Colgate Gel), also for the phase until the start of the study. Three to six weeks after the selection and information of the subjects, they presented for the first detailed assessment (baseline examination), and were then assigned to either the test or the control mouthwash. The test subjects were again given a new toothbrush, Emoform Sensitive, and the toothpaste Colgate Gel. All subjects received a professional tooth cleaning. Staining was used to control whether all dental plaque had been removed.

2.3. Study design

Subjects were randomised into two groups by age, sex and inflammation (SBI). The allocation of the mouthwashes took place at the beginning of the individual examination periods. The allocation of the mouthwashes was unknown to the investigator. Subjects then had to use their assigned mouthwashes for 12 weeks each.

2.4. Diagnostics

At the beginning, after 3 weeks, and at the end of the study after 12 weeks, the following parameters were recorded in the given order:

1. Safety assessment

Tongue, hard and soft palate, vestibular folds, buccal cheeks, lips and tongue bottom were examined for change at all examination appointments, classifying each into one of 3 grades.

2. Sulcus bleeding index (MÜHLEMANN & SON, 1971)

Gingival bleeding was measured in two quadrants (maxillary right and lower jaw left) at four sites per tooth (distobuccally, buccally, mesiobuccally, and oral).

3. Plaque index

The plaque index was determined after staining the teeth with the Turesky index in the same quadrant on 6 surfaces per tooth.

4. A semi-standardised photographic image was taken in the posterior region of the right jaw from 3± to 5± with the row of teeth closed.

5. After 3 weeks and at the end of the study, each patient had to complete a questionnaire. The subjects' subjective assessments of the changes noted were to be evaluated.

At the end of the 12-week test period, the subjects received a free tooth cleaning.

The statistical analysis of the data was carried out by the Ward for Oral Epidemiology at the University of Zurich. The clinical data were collected with a specially created acquisition program (HyperCard®-based) and checked for plausibility already upon entry into the computer. The processing of the data (merging and sorting) was done in Microsoft® Excel: mac 2001. The data were evaluated with the statistics program StatView (4.51). Differences between consecutive findings (longitudinally) were tested for statistical significance using a paired t-test. Differences between test and control groups were tested for statistical significance using an unpaired t-test.

3. Results

The results are shown in Tables I–IV and Figures 1–2.

Initially, 30 out of 112 subjects were included into the study. Even before the start, 3 subjects had withdrawn. After the first examination, one subject of the test group would not present for the subsequent investigations. No significant difference in terms of age, sex and SBI was found between the two groups upon screening. SBI was 2.06 in the test group and 1.92 in the placebo group.

Tab. I: Average Sulcus Bleeding Index Total (SBI) (x) and standard deviation (σ) in the subject groups for each study.

Exam / Group / N		Start	Total	After 3 weeks		End after 12 weeks		Difference Beginning / End		Reduction in %
a / test mouthwash	x	2.69		2.41		1.93		**0.76**		**28**
13	σ		0.58		0.75		0.43		0.51	
b / placebo mouthwash	x	2.17		2.04		1.64		**0.53**		**24**
13	σ		0.65		0.92		0.68		0.51	

The changes in the individual groups from the initial to the final findings are highly significant (t-test for paired values: p = 0.002 for test, and 0.003 for placebo).

Tab. II: Average inflammation (SBI) (x) and standard deviation (σ) in the subjects on the mesial surfaces at the three examinations.

Exam / Group / N		Start	Total	After 3 weeks		End after 12 weeks		Difference Beginning / End	Reduction in %
a / test mouthwash	x	3.17		2.82		2.33		0.84	27
13	σ		0.61		0.96		0.57		
b / placebo mouthwash	x	2.52		2.34		1.97		0.55	22
13	σ		0.78		1.14		0.79		

Tab. III: Average plaque index total (Turesky) (x) and standard deviation (σ) among the subjects at the three examinations in the two groups.

Exam / Group / N		Start	Total	After 3 weeks		End after 12 weeks		Difference Beginning / End		Reduction in %
a / test mouthwash	x	2.68		2.56		2.43		-0,25		-9
13	σ		0.67		0.67		0.60		0.32	
b / placebo mouthwash	x	2.52		2.67		2.67		+0.15		+6
13	σ		0.71		0.53		0.63		0.67	
Difference [%]								0.40 §		**15**

§ Difference between groups not significant. A trend is noticeable. (t-test: p = 0.06)

Tab. IV How was the quality rated after the cleaning? (Unless stated otherwise, 3 points were awarded for very good, 2 for good and 1 for disturbed, i.e. the higher the average score of all the patients surveyed, the better the mouthwash worked for the patient).

Quality rating		Test, a		Placebo, b	
		3 weeks	3 months	3 weeks	3 months
Feeling of cleanliness		2.38	**2.54**	2.33	2.31
Absence of plaque formation		2.42	**2.58**	1.92	2.04
Inflammation (bleeding on the gums) was		2.31	1.85	2.25	2.54
Taste change (4 = no impairment)		2.62	2.69	2.67	**2.77**
Taste rating (5 = maximum positive)		1.38	1.38	2.83	**2.08**
No tongue furs	No	100 %	100 %	100 %	100 %
Mucosal alteration	Yes	24 %	8 %	8 %	16 %
	No	76 %	92 %	**24 %**	84 %

Beginning **After 3 weeks** **After 3 months**

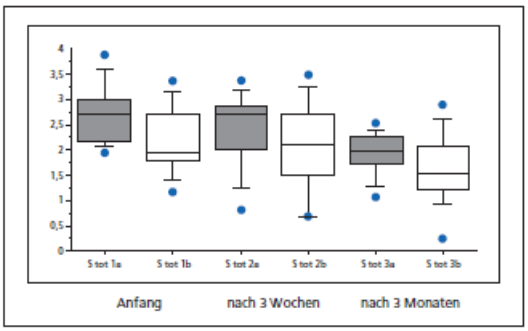

Fig. 1: Total Sulcus Bleeding Index (SBI) and scattering presented as box plots in the groups of subjects and the individual examinations (grey: test mouthwash)

Beginning **After 3 weeks** **After 3 months**

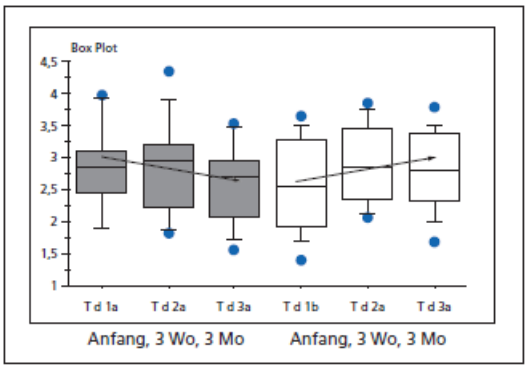

Fig. 2: Plaque index distal (Turesky) and scattering presented as box plots in the groups of subjects and the individual examinations (grey: test mouthwash)

Safety

Most of the subjects had no mucosal changes. In 29 subjects in the test and 31 in the placebo group, slight changes were noted, but these could not be associated with the product. The mouthwash had not led to changes in the mucous membranes in any of the subjects.

Inflammation

Table I shows the inflammatory values. The SBI was initially 2.69 in the test group and 2.17 in the control group. This difference was statistically not significant, as shown in Figure 1 of the box plot. In both groups, the index was reduced slightly at 3 weeks and significantly at 3 months ($p < 0.01$), but the values did not differ significantly.

The reduction in SBI was 0.76 in the test mouthwash group and 0.53 in the placebo group. Table II shows the changes in the SBI at the mesial surfaces. Here the reduction was 0.84 and 0.55, respectively. Figure 1 clearly shows firstly that the inflammation was reduced in the test mouthwash group, and secondly that the mouthwash worked well for all, since the scattering of the individual values (box plot) was small in the end.

Plaque accumulation / plaque index

In Table III and Figure 2, the data for the plaque index are shown. Initially, the plaque index was 2.68 in the test group and 2.52 in the placebo group. After three weeks, the index was slightly reduced in the test group (2.56) and slightly increased (to 2.67) in the placebo group. At the end of the observation period, the index in the test group was again slightly reduced (2.43) and unchanged in the placebo group 2.67. Similar observations were made with respect to plaque accumulation on the other surfaces, with plaque accumulating on both buccal surfaces in both groups.

Table IV shows the subjects' answers to the questions. Here it is striking that both solutions were accepted, but that the taste of the test solution was unpleasant to the test subjects, especially in the first 3 weeks.

4. Discussion

The mouthwash data showed well-interpretable results in terms of both sulcus bleeding index and plaque index, which did, however, not significantly differ between the two mouthwashes. In the screening examination, the bleeding indices of the two groups were comparable; 3–6 weeks later there was some difference that was, however, not significant. However, the bleeding index was lower in the placebo group. The difference must be ascribable to the initial calculus removal. Some patients had a very marked inflammation, as evidenced by the scatters as well as the box plots. Statistically, the differences were compared, so the initial situation did not affect the result. The SBI was clearly and significantly reduced with both mouthwashes from the beginning to the first 3 months, slightly more pronounced in the group with the test solution, where the reduction amounted to 28 %, than in the control group (24 %). In the first 3-week period, the professional calculus removal contributed to a reduction by 10 % or 6 %, respectively, but the reduction of 28 % resp. 24 % after three months is mainly due to the additional rinsing.

In other comparable studies, for example, reductions in inflammation from 1.5 to 1.3 during 6 months were found in the test group, while the placebo group remained unchanged. In studies with more than 100 subjects, such differences are significant (LINDHE et al 1993), although the reduction in gingivitis was only 20 %.

A somewhat clearer reduction in inflammation can be seen on the buccal surfaces, with the plaque index having rather increased particularly at these areas. It should be noted, however, that the index was generally low at these toothbrush-exposed tooth surfaces, at 1.7–1.8. Changes in the plaque index (Table III) show a slight reduction from 2.7 to 2.4 (-9 %) in the test group, and an increase from 2.5 to 2.7 in the placebo group (+ 6 %), The difference is barely non-significant in this small number of subjects ($p = 0.06$). At the distal tooth surfaces, the difference between the test and placebo solutions is 20 %, which is also clearly shown in Fig. 2, which is why the median values of the box plots in the test group are getting lower from examination to examination, while those in the placebo group are increasing.

Although improvements in the indices are generally found in all such studies, which can be explained by the participation effect, yet the tendency is confirmed on all tooth surfaces that are generally not so easily accessible to the toothbrush, so an effect of the test mouthwash is clinically confirmed. The presentation of the data in Figure 2 with the box plots shows that there is this clear tendency, which can be expected to become significant with increasing duration of study or larger numbers of subjects. Obviously, the subjects had the impression that they had were receiving a potent agent that affected plaque and inflammation. In the control group, this effect was clearly evident, as the plaque on all surfaces increased significantly. However, the differences between the two groups were not significant in the plaque index either in any comparison. It was interesting to note that the plaque accumulation rather tended to increase, which should actually have resulted in an increase in gingivitis. By contrast, however, in both groups the inflammation decreased, which cannot be attributed simply to the motivation effect, because the plaque increased in the placebo group.

From the questionnaire, it is clear which of the two solutions was unpleasant to the subjects in terms of taste. It is striking, however, that all subjects accepted the test solution, and significantly more so after 3 months than at the 3-week appointment. The clear perception of the active substance could have led to the subjects with the drug solution using rather less mouthwash per rinse at the beginning than the agreed 10 ml.

5. Conclusions

The tee tree oil (melaleuca alternifolia) has antiseptic, fungicide and bactericide effects. The efficiency against oral bacteria was also evident. Xylitol is known for counterattacking the cariogenic effect caused by the streptococcus mutans. Less plaque was developed during the time of the study.

In this in vivo study, a mouth rinse containing 1.5% tea tree oil and 10% Xylitol (Tebodont®) was evaluated regarding plaque and the influence on inflammation in comparison with a placebo rinse. The test solution significantly reduced the inflammation (26–32%) from the start of the application and during the following 3 months. The reduction of the inflammation was even more pronounced on the areas where the toothbrush does not reach the surface of the teeth.

While applying the test rinse the plaque amount was reduced significantly on all tooth surfaces but when using the placebo rinse the plaque increased. The difference was between 10–21%, but this difference was not significant. Thus, the test product was able to reduce the inflammation as well as the plaque growth. The tendency is obvious but in studies with such small case numbers (13 volunteers per group only) a statistic with significant evidence is very difficult to achieve.

Reactions in the oral cavity

Both solutions did not influence the oral cavity regarding reactions on the oral tissue and the oral mucosa. At the beginning of the study the taste of the test rinse was considered rather unpleasant but after some time the volunteers seemed to get used to the taste and less negative statements were registered.

Resumé

L'efficacité d'un bain de bouche à base de l'huile de l'arbre à thé contre la plaque et l'inflammation.

L'huile de l'arbre à thé (Melaleuca alternifolia) dispose de propriétés antiseptiques, fongicides et bactéricides qui ont également été démontrées envers des germes oraux. Le xylitol est connu comme succédané de sucre et s'avère efficace contre les streptococci mutans et la formation de la plaque. Dans la présente étude, l'efficacité d'un bain de bouche test (Tebodont®), contenant 1,5% d'huile de l'arbre à thé et 10% de xylitol, a été testée quant à la formation de la plaque et de l'inflammation, en comparaison à un bain de bouche placebo.

Le bain de bouche test réduisait significativement l'inflammation dès le début et jusqu'à 3 mois de son utilisation (26–32%). La diminution était plus distincte à tous les endroits difficilement accessibles avec la brosse à dents. La plaque dentaire a diminué avec le bain de bouche test, alors qu'elle a augmenté au niveau de toutes les surfaces avec le placebo. La différence se situait entre 10–21% mais le resultat n était pas significant. Pour le bain de bouche test, on peut confirmer un effet positif aussi bien contre l'inflammation que la formation de la plaque. La tendance est évidente.

Etant donné le nombre restreint de cas (13 sujets/groupe), il est difficile d'atteindre un résultat significatif entre les deux groupes à moins d'utiliser des bains de bouche à efficacité exceptionnellement forte. Les deux bains de bouche n'ont pas suscité d'effets indésirables au niveau de la cavité buccale. Après 3 semaines, on a jugé que le goût du bain de bouche test devrait être amélioré, cependant après 3 mois, une nette adaptation a été observée, vu que nettement moins de remarques ont été faites à ce sujet.

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