

The effects of Chlorhexidine containing toothpastes and Tea Tree Oil containing mouthwashes on plaque and gingival inflammation

A thesis submitted in partial fulfilment for the Degree of Masters of Dental Surgery (Periodontics)

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Dental School The University of Adelaide November 1999 This is dedicated to my family, especially my parents, sister, brothers and nephew

Signed Statement

This research report is submitted in partial fulfilment of the requirements of the Degree of Master of Dental Surgery (Periodontics) in the University of Adelaide.

This study contains no material that has been accepted for the award of any other degree or diploma in any university or any other tertiary institution. To the best of my knowledge and belief, it contains no other material previously published or written by another person except when due reference is made in the text of the report.

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Summary

This study tested the plaque inhibitory effects of a newly formulated chlorhexidine toothpaste; and the plaque inhibitory and anti-gingivitis effects of a mouthwash containing tea tree oil.

(1) Chlorhexidine toothpaste

The aim of this study was to evaluate the effect of a newly formulated chlorhexidine containing toothpaste on plaque formation and the amount of discolouration of teeth using the four day plaque growth model as described by Addy et al (1983). The efficacy of chlorhexidine mouthwash in preventing plaque accumulation is well documented. Considering that toothbrushing combined with the use of toothpaste is the most commonly used form of oral hygiene, it seems logical to develop a toothpaste containing a proven antiseptic. Toothpastes containing chlorhexidine have had limited plaque inhibitory activity and the results of this study concur with those of previous studies (Johansen et al. 1975; Dolles et al. 1979). However, these results are in contrast to another study which reported a reduction in gingivitis when compared to a placebo (Sanz et al. 1994).

One chlorhexidine containing toothpaste was tested in a blind crossover randomised 4 day plaque growth model (Addy et al. 1983) with a washout period of at least 16 days between preparations. Plaque was scored using the Quigley and Hein Plaque Index (1962). Thirty healthy non-smoker subjects completed the trial. The ranking from the lowest to highest plaque index score was:

• 0.12% chlorhexidine mouthwash (the positive control),

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- chlorhexidine toothpaste,
- Colgate Total® and
- the chlorhexidine toothpaste base with no active agent.

Stain was scored using the Discolouration Index System (DIS) by Lang and Raber (1981). The ranking from the highest to lowest stain index score was:

- 0.12% chlorhexidine mouthwash (positive control),
- chlorhexidine toothpaste,
- the chlorhexidine toothpaste base with no active agent and
- Colgate Total®.

Statistical analysis by t-tests showed that there was no significant difference between plaque index scores of the chlorhexidine containing toothpaste and Colgate Total[®]. All other comparisons were significantly different.

The chlorhexidine containing toothpaste did not exhibit the pronounced plaque inhibitory effect that would be expected of a chlorhexidine containing agent. It is likely that the chlorhexidine in the toothpaste was either inactivated by, chemically bound to, or in competition with other ingredients in the toothpaste.

(2) Tea tree oil mouthwash (TTO)

The aim of this study was to evaluate the effect of a TTO mouthwash on plaque formation, and on the amount of discolouration of oral structures, again using the four day plaque growth model and the effect of one TTO mouthwash on gingival health in a 6 week home use study. Preparations tested in the 4 day plaque growth study were the TTO containing mouthwash, Listerine[®], 0.12% chlorhexidine mouthwash and a mouthwash base. In the 6 week trial, the TTO mouthwash was tested against a mouthwash base.

TTO is a naturally occurring antibacterial which has been used as a disinfectant for many decades. TTO mouthwash was tested in a blind crossover randomised 4 day plaque growth model with a washout period of at least 16 days. Twenty five healthy non-smoking subjects completed the trial. The same plaque and stain indices were used here as with the trial before. The ranking from the lowest to the highest plaque scores was:

- TTO mouthwash,
- Listerine®,
- 0.12% chlorhexidine mouthwash and
- placebo.

The ranking of the stain scores from highest to lowest was:

- TTO mouthwash,
- 0.12% chlorhexidine mouthwash,
- Listerine® and
- placebo.

There was no significant difference between the plaque inhibitory effects of TTO mouthwash and Listerine®.

The longer term effects on oral health of TTO mouthwash over 6 weeks were compared to a placebo, and assessed using the plaque, papillary bleeding and gingival indices.

Forty nine healthy non-smokers completed this trial. The TTO plaque score decreased and stain score increased significantly over 6 weeks when compared with the placebo. The TTO was not significantly different from the placebo with regard to the gingival and papillary bleeding index scores. As with the TTO mouthwash in the 4 day plaque growth study, other plaque inhibitory agents had been added to the TTO test mouthwash. The suppliers were responsible for the composition of the TTO mouthwash and it was revealed at the completion of the trial that other antiseptic agents had been included with the TTO. The supplier had added triclosan and cetylpyridinium chloride to TTO mouthwash which was tested in both the randomised 4 day plaque growth and 6 week long term studies. In addition, the chlorhexidine mouthwash positive control had been supplied in an inactive form. This rendered the trial involving TTO mouthwash of little value in regard to scientific evidence about the plaque inhibitory effects of TTO. Further research is required to test the TTO agent on plaque and oral health independently from other plaque inhibitory agents.

Collecting information about plaque levels, oral staining and gingival health is a time consuming process in large scale clinical trials. Reducing the number of teeth scored, or the tooth surface scored (or both) would make trials easier to carry out, provided that teeth/surfaces data sets were reflective of the whole mouth score. Therefore, it was decided to compare the analyses of data using different data sets such as that of 28 and 20 teeth, and for buccal and lingual surfaces. Different data sets were compared in order to establish the minimum number of teeth / tooth surfaces that can be used in future studies that still are representative of whole mouth scores.

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Different sets of data were analysed using the mean total score (a maximum of 56 readings - buccal and lingual surfaces of 28 teeth divided by 56); 28 teeth analysis (which was the average of 12 scores - buccal and lingual surfaces of anterior and posterior teeth in the maxilla and mandible), and 20 teeth analysis (which was the average of 12 scores - buccal and lingual surfaces of incisors and canine/premolars in the maxilla and mandible)

The ranking of preparations in the 4 day plaque trial were listed in the previous pages. This ranking in relation to the individual indices for the total mean scores were reflected in the following data sets:

- plaque index 28 and 20 teeth mean score, mandibular teeth score in 28 teeth analysis, lingual surfaces in 28 and 20 teeth analysis, 20 teeth maxillary score;
- stain index 28 and 20 teeth mean score, 28 and 20 teeth mean score, mandibular teeth score in 28 teeth analysis;
- gingival index 28 and 20 teeth mean score, and mandibular teeth score in 28 teeth analysis.
- bleeding index no other data sets showed the same results in terms of ranking of preparations with the total mean score.

These data sets may provide the same results (in terms of ranking) for each index in future studies.

A new plaque index to better score plaque coverage and sparseness was developed, but it has not been tested. In conclusion,

- chlorhexidine toothpaste was significantly different to chlorhexidine mouthwash in its plaque inhibitory activity in the 4 day plaque growth study (ie. the chlorhexidine toothpaste was less effective than the chlorhexidine mouthwash);
- TTO mouthwash was significantly different from the placebo in the 6 week long term use study.

TTO mouthwash could not be analysed against chlorhexidine mouthwash in the 4 day plaque growth study because the chlorhexidine mouthwash had been supplied in an inactivated form.

Future recommendations are:

- to test the effectiveness of the plaque index developed from this study;
- to further develop chlorhexidine toothpaste formulations to liberate the true plaque inhibitory potential of chlorhexidine;
- to conduct a study to test the true plaque inhibitory activity of TTO; and
- to test the contents of industry-supplied mouthwashes and other preparations prior to issue.

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Quote

" I never take a walk with three persons, without finding that one of them has something to teach me"

" To know what you know and know what you don't know is the characteristic of one who knows ..."

CONFUCIUS

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List of Abbreviations

TTO	tea tree oil	
ch	chlorhexidine	
tp	toothpaste	
m w	mouthwash	
sig	significant	