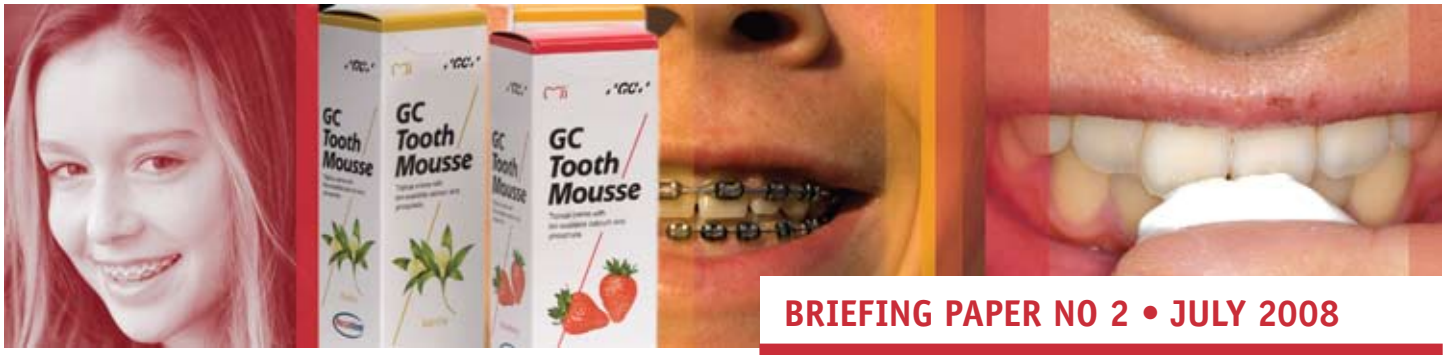

BRIEFING PAPER NO 2 • JULY 2008

PUBLISHED BY THE COOPERATIVE RESEARCH CENTRE FOR ORAL HEALTH SCIENCE

Clinical Trial of Tooth Mousse on White Spot Lesions

White spot lesions are the first visible sign of tooth decay and are more prevalent in people with orthodontic brackets – or braces. In this clinical trial, the effect of the treatment Tooth Mousse was tested on orthodontic patients who had multiple white spot lesions immediately following the removal of fixed brackets.

The results of the 12-week study show that subjects using Tooth Mousse experienced significantly greater regression of their white spot lesions than subjects not using Tooth Mousse.

Clinical Trial of Tooth Mousse on White Spot Lesions conducted by the Cooperative Research Centre for Oral Health Science at The University of Melbourne.

Researchers: MV Morgan, DL Bailey, GG Adams, C Tsao, A Hyslop, K Escobar, D Manton and E C Reynolds.

The results of this trial have been presented at ORCA Congress 2008 (Groningen, The Netherlands) and the International Association of Dental Research Symposium 2008 (Toronto, Canada).

oralhealthscience
cooperativeresearchcentre

Cooperative Research Centre for Oral Health Science
Level 6 720 Swanston Street Carlton VIC 3053 Australia www.crcoralhealthscience.org.au

Background

Fixed orthodontic brackets, or braces, make conventional oral hygiene methods more difficult and predispose the wearer to an increased accumulation of plaque. This can often lead to the formation of white spot lesions in the tooth enamel, which is the first stage of caries, or dental decay.

The aim of this clinical trial was to study the effect of a 12-week home application of Tooth Mousse on white spot lesions.

Tooth Mousse is a topical creme containing Recaldent™, which is a calcium and phosphate nanocomplex developed in the School of Dental Science at The University of Melbourne by Professor Eric Reynolds and his research team. The complex is derived from peptides isolated from the milk protein casein, complexed with calcium and phosphate, and has been shown to be effective at replacing lost minerals in decay-damaged teeth.

This trial sought to investigate the effectiveness of Tooth Mousse at regressing white spot lesions in a sample group of people with a higher than average number of white spot lesions.

Study sample

The sample group was 45 adolescents (12-18 years) who had recently completed fixed orthodontic treatment and had their brackets removed within seven days of commencing participation in the study.

Subjects were required to have a minimum of two white spot lesions on the buccal surfaces of anterior teeth. The lesions were required to be a minimum $2mm^2$ in size.

The 45 subjects were randomly divided into two groups: 23 into the intervention (Tooth Mousse) group and 22 into the control (placebo creme) group. The Tooth Mousse and the placebo creme were dispensed in identical tubes and neither subjects nor dental examiners were aware of which treatment the subjects were receiving.

At 12 weeks, in lesions coded as 2 and 3 for severity, 31% more had regressed with Tooth Mousse than with the placebo creme.

Patients with milk protein allergies, and regular users of medications causing dry mouth were excluded from the study.

The subjects were recruited from private orthodontic practices in and around Melbourne.

Test products

The intervention product – Tooth Mousse – is a water-based topical creme containing the calcium phosphate complex Recaldent™. The complex has been shown to prevent enamel demineralization and promote remineralization of enamel subsurface lesions in animal and human *in situ* studies.

The placebo creme was an identical formulation in taste and smell to Tooth Mousse, but containing no Recaldent™.

Method

All subjects were instructed to apply 1ml of tooth creme twice daily at home for 12 weeks after normal oral hygiene practices.

Subjects were supplied with toothpaste containing 1000ppm of fluoride and a soft texture tooth-brush for use during the study. Subjects were also provided with a fluoride mouth rinse at each assessment visit. Any difference measured in caries progression or regression would be over and above the effect of these standard oral hygiene measures.

Measurement

Clinical assessments were performed by three experienced, calibrated dental examiners at baseline (within seven days of bracket removal), 4 weeks, 8 weeks and 12 weeks.

These assessments scored each white spot lesion according to severity and activity using the ICDAS II (International Caries Detection and Assessment System 2005) criteria. Surfaces were examined each time whilst wet and after air drying.

Table 1: ICDAS II Severity Scoring

Appearance	Score
Sound enamel	0
Localized white opaque area, visible only after air drying	1
Localized white opaque area, visible whilst wet	2
*Localized enamel breakdown – no visible dentine	3
*Underlying dark shadow from dentine +/- localized enamel breakdown	4
*Distinct cavity with visible dentine	5
Extensive cavity with visible dentine on walls and base, involves at least half of a tooth surface	6

* If in doubt, or to confirm visual assessment, a CPI probe (ball-ended) can be used with NO digital pressure to confirm the loss of surface integrity.

Table 2: ICDAS II Activity Scoring

Appearance	Score
*Enamel is whitish/yellowish, opaque with loss of luster, rough to probe across surface, usually in plaque stagnation area	Active
*Enamel is whitish/brownish/black, shiny and feels hard and smooth to probe, usually away from plaque stagnation areas	Inactive
*Dentine feels soft or leathery	Active
*Dentine is shiny, feels hard on gentle probing	Inactive

*A CPI probe (ball-ended) can be used with NO digital pressure to determine surface hardness.

A transition matrix was used to assess transitions in lesions between baseline and follow-up examination scores. Transitions were coded as progressing, regressing or stable.

Transition scores were analyzed using a proportional odds ordinal logistic regression model. Robust variance estimates were calculated to account for the clustering of lesions within subjects.

Results

In the 45 subjects, a total of 408 white spot lesions were recorded – an average of nine lesions per subject.

At baseline, 86.3% of these lesions were found to be active. In terms of severity, 7.8% were scored as code 1, 89.7% were scored as code 2, and 2.5% were scored as code 3.

At 12 weeks, in lesions coded as 2 and 3 for severity, 31% more had regressed with Tooth Mousse than with the placebo creme.

Differences in the regression rates between the two treatments were not statistically significant at the 4- and 8-week marks.

In both treatment groups, active lesions were more likely to regress than inactive lesions.

Conclusion

The study concluded that significantly more post-orthodontic white spot lesions regressed with the use of Tooth Mousse compared to a placebo control over a 12-week period demonstrated using ICDAS II criteria and transition scoring.

Glossary

Buccal surfaces	Outward-facing tooth surfaces
Caries	Tooth decay
ICDAS II	International Caries Detection and Assessment System 2005
Demineralization	The weakening of tooth structure through the loss of minerals
Dentine	The part of the tooth beneath the enamel and surrounding the pulp chamber and root canals
In-situ studies	Studies conducted on samples of human tissue that have been placed in another human
Recaldent™	An anti-decay technology containing CPP-ACP (casein phosphopeptide-amorphous calcium phosphate)
Remineralization	The strengthening of tooth structure by incorporation of calcium, phosphate, and/or fluoride
White spot lesion	First visible sign of caries in a tooth's surface. Slightly rougher than surrounding enamel; white and chalky appearance when dried with air. The surface layer of a white spot lesion is porous but still mineral rich, the subsurface region of the lesion has low mineral content

Acknowledgements

The Cooperative Research Centre for Oral Health Science gratefully acknowledges the assistance of the patients, parents and orthodontic practices who participated in this study. The Centre also acknowledges the support of study sponsor GC Corporation.

oralhealthscience
cooperativeresearchcentre

THE UNIVERSITY OF MELBOURNE

ESTABLISHED AND SUPPORTED UNDER THE AUSTRALIAN GOVERNMENT'S COOPERATIVE RESEARCH CENTRES PROGRAMME.

Cooperative Research Centre for Oral Health Science
Level 6 720 Swanston Street Carlton VIC 3053 Australia www.crcoralhealthscience.org.au

The Cooperative Research Centre for Oral Health Science brings together scientists, dentists, population health experts and manufacturers to find new and efficient ways of reducing the burden of oral disease in Australia and internationally.