

The effects of GC Tooth Mousse on cervical dentinal sensitivity: a controlled clinical trial

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Abstract

Purpose: The clinical problem of cervical dentinal hypersensitivity (CDS) can be managed by strategies that occlude patent dentine tubules exposed to the oral environment, or that reduce the excitability of pulpal nerves. **Materials and methods:** This randomized clinical trial with 89 subjects (53 from private practice and 36 from public sector dental clinics) compared the therapeutic effect of a 10% CPP-ACP crème (GC Tooth Mousse) applied topically each night before retiring in conjunction with a conventional dentifrice twice daily, to the twice daily use of an established potassium nitrate dentifrice (Colgate Sensitive). Treatments were used over 6 weeks, and this was followed by a 4 week washout period. CDS responses to 4 types of stimuli were self-rated using a visual-analogue scale at 4, 6, and 10 weeks, and a composite CDS score calculated. All data were analyzed in a blinded manner. **Results:** The two treatment groups were well matched with no significance difference in baseline scores. In both the CPP-ACP and potassium nitrate groups, when compared with their relevant baseline values, CDS scores were reduced significantly at 4 weeks when assessed using a repeated measures ANOVA ($P < 0.02$). This effect was sustained at 6 weeks, and across the ensuing 4 week washout period. At all time points, there was no significant difference between the two treatment groups. The reduction in CDS scores was more pronounced in public sector dental patients than in those drawn from private practice. **Conclusions:** Despite differences in their apparent mechanisms of action, both CPP-ACP crème and the potassium nitrate dentifrice gave similar clinically useful reductions in CDS.

Key words: CPP-ACP, Tooth Mousse, potassium nitrate, dentine sensitivity, clinical trial

Running title: Desensitization using Tooth Mousse

Introduction

Cervical dentinal sensitivity (CDS) is a common complaint in adult patients, and complicates the provision of both restorative and periodontal care. CDS affects 15-20% of the adult population, typically 20 to 50-year-olds, with a peak incidence between 30 and 39 years. Some studies have reported a prevalence of up to 57% in adults,¹ and from 72-98% in periodontal patients.²

CDS is linked to exposure of dentine tubules,

particularly in younger adults, from acidogenic diets, dental erosion, destructive and aggressive toothbrushing and other oral habits, poor tooth brushing techniques, use of tooth whitening products, gingival recession, periodontal debridement and periodontal surgery.³ The commonest sites affected are the buccal aspects of mandibular first molars and premolars, and the commonest initiating factor is cold drinks.⁴ This distribution of sites aligns with the nature of the salivary film and its relative lack of protection in these zones.⁵

Once the dentine tubules have become exposed, microscopic fluid movements trigger reactions from nociceptor nerves associated with odontoblasts. Symptoms of CDS can be elicited by a range of stimuli, including changes in temperature, mechanical stimuli (such as toothbrushing, using interproximal cleaners or wooden sticks), and acidic foods.

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A broad range of in-office and at-home products are available for treatment of CDS. At-home strategies to reduce symptoms of CDS typically focus on either suppressing the excitability of dental pulp nociceptors, or reducing the patency of exposed dentine tubules.⁶ For the first option, the most common approach is to elevate the extracellular potassium concentration in the dental pulp, using dentifrices and topical gels which deliver potassium ions in a readily soluble form, e.g. as potassium nitrate. When such products are used regularly over a period of time, potassium ions move by diffusion down the patent dentinal tubules. As the extracellular fluid potassium ion concentration gradually increases,⁷ the response threshold for nociceptors rises, and their ability to fire when provoked declines.⁸ This desensitizing action is greatest when such products are used on an ongoing basis. There is an extensive literature which supports use of potassium nitrate dentifrices such as Sensodyne™ and Colgate Sensitive™.⁹⁻¹¹

The second strategy used in at-home products is to gradually occlude the opening of patent dentine tubules, and thereby reduce the flow of fluid through them. Partial blockage can be achieved through abrasive particles contained within toothpaste, such as zirconium silicate. Remineralizing agents can promote the deposition of mineral aggregates in the openings of exposed dentinal tubules. For example, high concentration neutral sodium fluoride, stannous fluoride and strontium fluoride gels can form mineral precipitates.¹² Likewise, dentifrices which contain arginine, calcium carbonate, and fluoride can physically seal dentine tubules with a plug that resists normal pulpal pressures and acid challenge, and reduces dentinal fluid flow.¹³

A more recent approach to the management of CDS which targets the surface is the application of topical casein phosphopeptide-amorphous calcium phosphate (CPP-ACP, also known as Recaldent™), in form of topical crèmes such as GC Tooth Mousse (GC Corp, Japan). The peptides of Recaldent bind to the dentine surface, then promote the deposition of mineral deposits within dentine tubules. This process has been shown to significantly decrease dentine permeability by creating precipitates on the dentine surface that reduce the diameter of dentinal tubules.¹⁴⁻¹⁶

A recent small scale study evaluated the effect of GC Tooth Mousse on CDS in 13 patients with gingival recession, using tactile (probing) and a stream of air from a triple syringe as the test stimuli.¹⁷ Only a single application was delivered, and symptoms were re-evaluated immediately, after 15 minutes, and again at 1



Figure 1: Products used in the clinical trial.

week and 4 weeks. There was an immediate reduction in the number of teeth reacting with strong pain, and many sensitive teeth were now unresponsive. This benefit persisted for the second examination at 15 minutes, however partial relapse in symptoms of CDS was evident at 1 and 4 weeks.¹⁷

This study has been criticized in the literature because of its small sample size and its uncontrolled design.^{18,19} A further problem with it is that a single topical treatment allows binding of the CPP-ACP complex, providing an immediate protein-based partial occlusion of open tubules. The desensitizing activity of CPP can, however, be destroyed by dephosphorylation of the phosphoserines in the peptide by phosphatase enzymes from dental plaque bacteria.¹⁴ This explains why a single application was effective immediately and at 15 minutes, but not after 1 week. A more long lasting effect would be expected if there was sufficient exposure to Recaldent to cause mineralization to occur at the openings of the dentine tubules.^{14,15}

To address these issues, a randomized controlled clinical trial was undertaken, comparing the effectiveness of GC Tooth Mousse as an at-home treatment for CDS to that of the well established potassium nitrate dentifrice, Colgate Sensitive. The trial assessed symptoms of CDS elicited by dietary and lifestyle factors, rather than by the artificial stimuli of dental probing and compressed air. This was important because many studies of both in-office and at-home treatments for CDS have failed to address the patient experience of discomfort from CDS in a realistic manner.

Materials and methods

The study followed a randomized clinical trial design. Patient assignment to one group or the other was

Table 1
Results for Phase 1 of the study (Public sector cohort)

	Tooth Mousse (TM)	Colgate Sensitive (CS)	Statistical Analysis
Week 0	8.4 + 4.2 (N = 18)	10.9 + 5.3 (N = 18)	TM wk 0 vs CS wk 0: Not significant (A)
Week 4	4.4 + 4.1 (N = 18)	5.8 + 4.2 (N = 18)	TM wk 4 less than TM wk 0; P < 0.01. CS wk 4 less than CS wk 0; P < 0.01. TM wk 6 vs CS wk 4: Not significant (A)
Week 6	3.6 + 3.5 (N = 18)	3.9 + 2.9 (N = 18)	TM wk 6 less than wk 0; P = 0.001. CS wk 6 less than wk 0; P < 0.001. TM wk 6 vs CS wk 6: Not significant (A) TM wk 4 vs TM wk 6: Not significant CS wk 4 vs CS wk 6: Not significant
Percent reduction at week 6	57.1%	64.2%	

Data show mean CDS aggregate scores (on a 0-25 scale), with standard deviations and sample sizes. (A) indicates aggregate data used; all other statistical analyses are repeated measures ANOVA using individual patient data.

made on a randomized basis, and the patients in both groups were stratified equally in terms of age. Because of the different delivery systems used, blinding of the patients was not possible, however there was full blinding for both the data collection and its subsequent analysis. While patients were duly informed of the nature of the study, individual counseling regarding causal factors and treatments for CDS was not undertaken, in order to avoid altering the natural course of events. This is consistent with recent recommendations for design of clinical trials for novel agents used to treat CDS.² The study was approved by the institutional medical research ethics committee.

A total of 89 adult patients with a minimum age of 18 years were recruited from general dental practice private and public sector dental clinics across Queensland by final year dental students who undertook a comprehensive clinical assessment and strictly applied the following selection criteria: subjects must have had at least two sensitive teeth, have buccal or cervical erosion/abrasion lesions or gingival recession, and suffer from long standing and regular sensitivity to cold, heat, sweet/sour, or touch. The exclusion criteria were as follows: allergy to any of the ingredients of the dental produces used; suspected pulpitis, cracked teeth or dental caries; extensive or defective restorations; previous endodontic treatment of the sensitive teeth; periodontal surgery in the three

months prior to the study; the presence of teeth or supporting structures with any other painful pathology or defects; physical or intellectual disability; high dependency on medical care; immune compromise; pregnancy; breast feeding; strict adherence to a Muslim/Halal diet; and previous use of the treatment products.

The two treatment arms in the study were GC Tooth Mousse (containing 10% CPP-ACP) and Colgate Sensitive dentifrice containing 5% potassium nitrate and 1000 ppm fluoride ion (Figure 1). A 0.5 mL volume of GC Tooth Mousse was applied topically using a clean finger across the buccal and labial surfaces of all teeth each night immediately before retiring. Patients in this group used a conventional 1000 ppm fluoride dentifrice twice daily of their own choosing. Patients in the potassium nitrate positive control group brushed twice daily with 0.5 mL of Colgate Sensitive dentifrice for 2 minutes, in place of their normal fluoride dentifrice. Patient data was collected regarding oral hygiene practices at day 0.

All patients were given verbal and written instructions in using the test products, and were followed up by telephone during the study to reinforce compliance.

The trial was conducted in two separate phases, with two distinct cohorts that were recruited using exactly the same criteria. The first cohort (N=36) were drawn from public sector dental clinics and followed the study protocol with 6 weeks of active treatment. The second

cohort (N=53) were recruited after the first cohort had completed the intervention, and were drawn from private practice rather than from public sector clinics. They completed the same active treatment over 6 weeks, then ceased using the products and reverted to their normal oral care routines, so that a 4-week wash-out period was completed before the final evaluation at 10 weeks.

The intensity of CDS responses to 5 types of stimuli (sour foods, cold water, room temperature water, sweet foods, and frozen food) were self-rated by subjects using a 5 point visual-analogue scale at 0, 4, 6, and 10 weeks. This approach is consistent with the conventional approach used for subjective evaluation of CDS, which is based on a subject's response to certain trigger stimuli.² The ratings ranged from 0 (no pain) through to 5 (extreme, unbearable pain). An active treatment time of 6 weeks was chosen because this interval has been used extensively in past studies of potassium nitrate dentifrices.^{20,21}

From the separate CDS responses, a composite CDS score (out of a maximum of 25) was calculated for each patient at each time point. This was used for repeated measures analysis, and also aggregated for cohort-level analysis. All data were collected and analyzed in a blinded manner, and the code broken at the completion of the study.

Data were analyzed as follows. Changes from baseline (day 0) to the subsequent assessments were examined using repeated measures analysis of variance. The same method was used to compare changes over the various timepoints. Cohort data were assessed for normality using the Kolmogorov Smirnov test, then compared using unpaired two-way analysis of variance, with Dunn post-hoc tests.

Results

All subjects brushed at least once daily; 49% flossed daily; and all patients flossed at least once per week. Only 13% of subjects used products other than toothpaste and dental floss. No subjects had previously used either of the products evaluated in the study.

In both phases of the study, there were similar baseline CDS scores for the Tooth Mousse and Colgate Sensitive arms at the start of the respective phase of the study.

The positive control group, who used Colgate Sensitive, showed a statistically significant reduction in symptoms of CDS from baseline at 4 weeks ($P < 0.02$), and this improvement was sustained until the duration of the study, including the washout period. Differences between scores at weeks 4, 6 and 10 were not statistically significant. These effects were seen in both the smaller (public sector) cohort (Table 1) as well as in

the larger (private practice) cohort (Table 2), however the overall efficacy of Colgate Sensitive was lower in the latter. The highest recorded baseline CDS score of 19/25 reduced to 9/25 after 6 weeks of treatment with Colgate Sensitive.

Exactly the same trends in CDS scores were seen with Tooth Mousse, with a significant reduction in CDS at 4 weeks ($P < 0.02$), which was sustained until the duration of the study, including the washout period. Once again, the overall efficacy of Tooth Mousse was lower in the private practice cohort (Table 2) than in the cohort drawn from the public sector (Table 1). The highest recorded baseline CDS score of 19/25 reduced to 12/25 after 6 weeks of treatment with Tooth Mousse.

At no time point in the study was there any statistically significant difference between the effect of Tooth Mousse crème and that of Colgate Sensitive dentifrice. The null hypothesis that the two treatment regimens gave identical effects on symptoms of CDS was thus confirmed.

In the larger cohort, the completion rate for the wash-out assessment was affected by patients dropping out, with only 55% of Colgate Sensitive and 77% of Tooth Mousse subjects being available for the final data collection point.

Discussion

The results of this study indicate that at-home daily use of GC Tooth Mousse is effective for reducing symptoms of CDS in adult patients, and provides clinical benefits which are identical to those of a "gold standard" potassium nitrate dentifrice, despite the difference in action of these agents. This positive benefit is consistent with previous studies of Colgate Sensitive 9-11 and it supports the inclusion of Tooth Mousse in evidence-based contemporary guidelines for the treatment of CDS. It has been noted in the recent literature that many other novel treatments recommended for CDS lack supporting data from clinical trials in terms of their effect on "real world" pain symptoms.²² This is why the present study used an aggregate of real world exposures to track changes in CDS symptoms in individual subjects.

The patients in the present study had moderate rather than severe CDS, and in such patients, adequate counseling regarding avoidance of erosive foods, maintenance of salivary protection and the prescription of Tooth Mousse or a desensitizing dentifrice such as Colgate Sensitive provides a conservative combined approach to what in essence is a multi-factorial problem.^{23,24} If several such reversible options have been unsuccessful, then non-reversible in-office should then be employed.²⁵

Table 2

Results for Phase 2 of the study (Private practice cohort)

	Tooth Mousse (TM)	Colgate Sensitive (CS)	Statistical Analysis
Week 0	13.0 +3.0 (N = 31)	13.0 + 3.5 (N = 22)	TM wk 0 vs CS wk 0: Not significant (A)
Week 4	11.0 +3.2 (N = 30)	10.0 + 3.75 (N = 21)	TM wk 4 less than TM wk 0; P < 0.02. CS wk 4 less than CS wk 0; P < 0.01. TM wk 4 vs CS wk 4: Not significant (A)
Week 6	9.0 + 3.9 (N = 28)	9.0 + 3.3 (N = 20)	TM wk 6 less than TM wk 0; P = 0.001. CS wk 6 less than CS wk 0; P < 0.005. TM wk 6 vs CS wk 6: Not significant (A) TM wk 4 vs TM wk 6: Not significant CS wk 4 vs CS wk 6: Not significant
Week 10 (washout)	10.0 + 3.7 (N = 37)	9.0 + 4.2 (N = 12)	TM wk 10 less than TM week 0; P < 0.005. CS wk 10 less than CS wk 0; P < 0.02. TM wk 10 vs CS wk 10: Not significant (A) TM wk 10 vs TM wk 4 and TM wk 6: Not significant CS wk 10 vs CS wk 4 and CS wk 6: Not significant
Percent reduction at week 6	30.8%	30.8%	

Data show mean CDS aggregate scores (on a 0-25 scale), with standard deviations and sample sizes. (A) indicates aggregate data used; all other statistical analyses are repeated measures ANOVA using individual patient data.

It is particularly noteworthy that the benefits seen in the present study were obtained by simple home use of the products, rather than by more complex in-office interventions. Both products gave effects which were sustained for 4 weeks after their use was discontinued, which is a positive observation, although neither could completely abolish all symptoms of CDS. In general, self-applied treatments for CDS are popular because they are both economical and easy to use.²⁶ This is true for both agents used the current clinical trial. The daily application of a tooth crème to teeth immediately before retiring has been found to be effective in other studies using Tooth Mousse as a remineralizing agent for cervical carious lesions involving dentine or enamel.²⁷

The disadvantages of self-administered agents used for the treatment of CDS include compliance, whether delivery to specific sites is possible, a slow onset of action, and a requirement for repeated or continuous use. In the present study, compliance was enhanced by regular follow-up of patients by dental students, whereas in a

clinical setting such contact could come from a dental professional or from office staff or dental assistants.

Recently, a form of Recaldent technology which incorporates fluoride has been developed, and this is now available in some countries as Tooth Mousse Plus™. The inclusion of fluoride (at a level of 900 ppm) is relevant to CDS because fluoride is an inhibitor of bacterial protease production,¹⁴ as well as a contributor to remineralization for tubule occlusion.²⁸ Thus, an improved benefit in terms of treatment of CDS would be expected from this new formulation.

There is growing recognition that dental erosion and other forms of non-carious tooth structure loss play a major role in the aetiology of CDS.^{5,22,29-32} These conditions are increasing in frequency as individuals age, but retain their natural teeth longer. It is therefore important that treatments for CDS are directed at the underlying causes rather than the symptoms of this condition. Tooth Mousse has been shown to prevent erosion of both enamel and dentine caused by black cola

softdrinks and wine, which are known dietary contributors to dental erosion.³³⁻³⁵

A final observation from the present study arises from the use of cohorts derived from either public sector dental clinics or private practice. The lower impact of desensitizing measures in the latter group can be explained by their much higher baseline scores (indicating that they experienced more severe levels of CDS). This suggests that both treatments are more effective on milder forms of CDS, which is consistent with the literature on self-applied treatments for CDS.²³⁻²⁵ Additional points of difference between the cohorts could include their concurrent use of other oral health care products, or a greater intake of erosive drinks. There was no attempt made to alter the patient's lifestyle or their normal home care routine other than adding in Tooth Mousse, or replacing their existing dentifrice with Colgate Sensitive, and thus any erosive factors present at the start of the study would have continued to operate during it.

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