

Comparison of two topical treatments for dentine sensitivity

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Abstract - This study compares two commercially-available products for treating dentine sensitivity, Duraphat®, a fluoride varnish, and SuperSeal®, an oxalate preparation. 48 patients with dentine sensitivity were recruited. Sensitivity was assessed by visual analogue scales (VAS) to record pain following stimulation of exposed dentine surfaces by tactile stimulus (sharp probe at 60g force), thermal stimulus (ethyl chloride) and evaporative stimulus (air drying). Patients were randomised to treatment with either Duraphat® or SuperSeal®. After 4 weeks, sensitivity assessments were repeated. Both treatments resulted in statistically significant reductions in VAS scores for all stimuli ($P < 0.05$). However, analysis of covariance failed to identify statistically significant differences in the magnitude of reductions in sensitivity achieved by each of the products ($P > 0.05$). The treatments had similar efficacy and both can be considered effective therapies for treating dentine sensitivity.

KEY WORDS: Dentine sensitivity; Topical desensitising agent; SuperSeal®, Duraphat®

INTRODUCTION

Dentine sensitivity has been defined as short, sharp pain arising from exposed dentine in response to stimuli which cannot be attributed to any other dental defect or pathology¹. The provoking stimulus can be tactile, osmotic, evaporative, thermal or chemical in nature². Before reaching a diagnosis of dentine sensitivity, the patient must be carefully examined to exclude the possibility of caries, chipped tooth, fractured restorations, marginal leakage, cracked tooth syndrome or palato-gingival grooves³. The reported prevalence of dentine sensitivity varies⁴, but most studies have recorded population prevalence rates of about 15%⁵. Dentine sensitivity is most frequently present at the buccal cervical regions of the permanent teeth, which are also the sites that most often exhibit dentine exposure. Although exposed dentine may be present at the occlusal and lingual tooth surfaces, it is not common to experience dentine sensitivity at those sites⁶.

Not all patients with dentine sensitivity seek help from their dentist, and many that do have only slight or moderate symptoms. For these patients, education about diet and oral hygiene, in conjunction with explaining the possible benefits of using desensitising dentifrices, will be helpful. For dentine sensitivity of moderate severity, the use of fluoride varnishes (e.g. Duraphat®) can be effective. Fluoride varnishes such as Duraphat® have become accepted as a standard treatment for this condition, and in vitro and in vivo studies have demonstrated the incorporation of fluoride into the outer smooth surface of enamel after application. Fluoride varnishes are also reported to pos-

sess the advantage of remaining on the teeth for several hours after application, enhancing fluoride uptake as well as providing a temporary coating on the affected tooth surfaces⁶. The manufacturers of Duraphat® suggest that it releases fluoride for 28 weeks, and two thirds of the fluoride is released by 6 months. These properties suggest that fluoride varnishes may be an effective treatment for dentine sensitivity. Duraphat® is an alcohol suspension of natural resins containing 5% sodium fluoride (2.26% F). A potential problem with the use of topical varnishes such as Duraphat®, however, is that the varnish may be washed off the tooth surface by saliva flow.

Oxalate salts have also been reported to be effective treatments for sensitivity. These act by removing the smear layer and replacing it with a layer of oxalate crystals⁷. Recently, an oxalate-containing preparation (SuperSeal®) has been reported to yield precipitation of oxalate crystals to a depth of 120 µm into the dentinal tubules, thereby potentially reducing the opportunity for fluid flow and subsequent pain. This, however, needs to be confirmed in clinical studies.

The primary objective of this 4-week study was to compare the clinical efficacy of a new topical oxalate preparation (SuperSeal®) to that of an established topical fluoride preparation (Duraphat®) in the treatment of dentine sensitivity.

METHODS

Study cohort

Subjects with a diagnosis of dentine sensitivity were recruited. Inclusion criteria for the study included: age 18 years or older; good general health; at least one sensitive tooth to two stimuli (air flow and tactile stimulation). The diagnosis of sensitivity was confirmed on two separate occasions (initial screening to assess eligibility

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for participation and the baseline appointment). Exclusion criteria were in accordance with those detailed in the 1997 guidelines for the design and conduct of clinical trials on dentine sensitivity⁸.

Study Design

This was a 4-week, randomised, two-arm, single blind study for which approval was obtained from the appropriate ethics committee before commencement. At baseline, informed consent was obtained, the medical history was recorded, and the patient was provided with standard non-desensitizing toothpaste (Aquafresh, GlaxoSmithKline) to use for the duration of the study. The study was designed following consideration of the 1997 guidelines on clinical trials of dentine sensitivity⁸, although was not double-blind because of the different application protocols and physical properties of the two treatments.

Assessments of sensitivity were performed using three different diagnostic tests including tactile stimulation, thermal stimulation and air drying. One tooth per subject was investigated. The stimuli were applied in the same order on each occasion. The tactile stimulus was applied first using the PDRC sensitivity probe (based on the Florida probe)⁹. A probing force of 60 g was applied to the sensitive root surface by drawing the sharp probe across and perpendicular to the exposed root surface (Figure 1), and the sensitivity elicited was recorded (see below). Thermal stimulus (ethyl chloride) was then applied using a standardised cotton pledget for 2 seconds. Finally, an evaporative stimulus (air drying) was applied. The adjacent teeth were isolated and a gentle stream of air was directed at right angles to the root surface using the dental air syringe at a distance of 1 cm for 2 seconds. With respect to the evaporative stimulus (air drying), the air temperature was constant at 16-20°C and the air pressure was 40 p.s.i. Immediately following each stimulus, the patient was asked to record his/her perception of pain/discomfort arising from that stimulus using a 100 mm visual analogue scale

(VAS), the extremes of which were labelled “no pain at all” (0 mm) and “unbearable pain” (100 mm). The stimuli were applied at intervals of 5 minutes.

Subjects were assigned to receive treatment with either SuperSeal® (Phoenix Dental Inc.) or Duraphat® (Colgate Oral Pharmaceuticals Inc.), according to a predetermined randomisation schedule. The agents were applied to the sensitive tooth surface on one occasion only, in accordance with the manufacturers’ instructions.

Patients returned to the study centre at 4 weeks following baseline. At the 4 week appointment, identical assessments of dentine sensitivity as were undertaken at baseline were performed.

Statistical considerations

Descriptive analyses of demographic data were calculated. Statistical analyses focused on the assessments of dentine sensitivity using VAS scores. Assessment of differences between the groups at baseline (if any) was done using independent samples *t* tests. The significance of between-groups differences (if any) in VAS score changes between baseline and week 4 was tested by analysis of covariance (ANCOVA), using week 4 VAS scores as the dependent variable, treatment group as factor and baseline VAS scores as covariate. Additional analyses included a term for gender as covariate.

An intent-to-treat strategy was used for those patients who were lost from the study. The randomisation was predetermined, and was undertaken using a permuted blocks of 4 design.

Power calculations revealed that approximately 20 subjects per treatment arm were required to complete the study to provide a 95% power for detecting a significant difference as a result of treatment, assuming $\sigma = 23$ mm (interpolated from previously published data), a mean difference between baseline and week 4 of 20 mm, and using $\alpha = 0.05$. Allowing for a drop-out rate of up to 20%, 48 subjects were



Figure 1. The PDRC sensitivity probe in use. The tip of the probe is kept perpendicular to the surface of the exposed dentine as it is dragged across the tooth surface.

recruited, with 24 in each treatment arm.

RESULTS

48 subjects met the inclusion criteria and were enrolled in the study. Their baseline demographic characteristics are presented in Table 1. There were 3 drop-outs in total; 2 subjects in the Duraphat® group and 1 subject in the SuperSeal® group. Thus, 45 subjects completed the study, 22 subjects in the Duraphat® group and 23 subjects in the SuperSeal® group. Statistically, there were no significant differences between the demographic profiles of the two study groups ($P > 0.05$).

No statistically significant differences in VAS scores existed between the two groups at baseline following application of any of the stimuli ($P > 0.05$). Within-groups paired comparisons of VAS scores recorded after application of each of the stimuli at baseline and week 4 are presented in Table 2. As can be seen from Table 2, both treatments were effective, resulting in statistically significant reductions in VAS scores between baseline and week 4 ($P < 0.05$).

SuperSeal® tended to result in greater reductions in VAS scores over the course of the study compared to Duraphat®, particularly when considering the tactile and thermal stimuli. However, the differences between the two products failed to achieve statistical significance ($P > 0.05$). A trend towards a statistically significantly greater reduction in VAS scores following tactile stimulation was observed in the SuperSeal® group, which demonstrated an adjusted week 4 mean (95% CI) VAS score of 17.7 mm (10.9 to 24.6 mm), compared to the Duraphat® group which demonstrated an adjusted week 4 mean (95% CI) VAS score of 26.2 mm (19.2 to 33.2 mm), with a mean (95% CI) dif-

ference between treatments of 8.4 mm (-1.3 to 18.3 mm) ($P = 0.08$). It is also apparent from Table 2 that different stimuli elicited differing levels of pain/discomfort, and the cold stimulus (ethyl chloride) elicited the most sensitivity of the applied stimuli. Including terms for gender did not alter the outcomes of the primary analyses, and males and females did not differ significantly in sensitivity scores at any time point ($P > 0.05$).

DISCUSSION

Dentine sensitivity has been estimated to affect 40 million adults in North America at some time in their life and, in addition, it affects more than 10 million individuals as a chronic condition⁶. In a recent study, it was reported that more than 40% of the global population suffers, or has suffered, from dentine sensitivity⁴. Patent dentine tubules were suggested to be a major etiology. Hence, the treatment of the condition is focused towards the obturation of the orifices of the dentinal tubules. Due to the fact that dentine sensitivity is a very prevalent condition, a variety of symptomatic treatments exist¹⁰. They may be either self-applied by the patient (i.e. toothpastes) or professionally-applied by the dentist (i.e. varnishes).

The aim of this study was to compare the clinical efficacy of two professionally-applied topical desensitizing agents for the treatment of dentine sensitivity (Duraphat® and SuperSeal®). Duraphat® is a product that has been used for several decades for the treatment of dentine sensitivity while SuperSeal® is a new desensitizing agent.

The two groups of patients were very similar with respect to the pain elicited following stimulation of sensitive root surfaces at baseline, and no statistically significant differ-

Table 1. Demographic characteristics of the two treatment groups

		Duraphat® (n = 24)	SuperSeal® (n = 24)
Age (years)	Mean (range)	26 (19-52)	28 (19-54)
Gender	Male	11	7
	Female	13	17
Race	White Caucasian	21	22
	Asian	1	1
	African	1	0
	Indian	1	1
Tobacco use	Non-smoker	14	17
	Ex-smoker	4	4
	Smoker	6	3

Table 2. VAS scores recorded at baseline and week 4 after application of each stimulus

	Duraphat®				SuperSeal®			
	Baseline VAS Mean ± SD (mm)	Week 4 VAS Mean ± SD (mm)	Δ (mm)	P	Baseline VAS Mean ± SD (mm)	Week 4 VAS Mean ± SD (mm)	Δ (mm)	P
Tactile stimulus	40.0 ± 23.4	26.2 ± 17.6	13.8	0.02	39.4 ± 20.2	17.7 ± 16.3	21.8	<0.01
Thermal stimulus	60.9 ± 22.9	46.8 ± 22.6	14.2	<0.01	64.5 ± 24.6	40.4 ± 27.8	24.1	<0.01
Evaporative stimulus	34.9 ± 22.5	18.8 ± 18.9	16.1	<0.01	42.9 ± 29.0	26.0 ± 27.7	16.7	<0.01

Δ: mean paired difference between VAS scores at baseline and week 4 (within-groups comparisons)

ences existed between VAS scores recorded at baseline in the two treatment groups. It is encouraging that both treatments resulted in statistically significant reductions in sensitivity over the short duration of this study. Thus, both treatments appear to have similar efficacy in the reduction of symptoms of dentine sensitivity. The mean reductions in VAS scores from baseline to week 4 tended to be (non-significantly) greater for SuperSeal[®] than for Duraphat[®]. For example, mean reductions in sensitivity were more than 50% greater for SuperSeal[®] than Duraphat[®] when considering the sensitivity elicited by the 60 g tactile stimulus (mean reductions: SuperSeal[®] 21.8 mm, Duraphat[®] 13.8 mm) and the thermal stimulus (mean reductions: SuperSeal[®] 24.1 mm, Duraphat[®] 14.2 mm) (Table 2). However, analysis of covariance failed to identify statistically significant differences between the reductions in VAS scores achieved by the two products. In contrast to the reductions in VAS scores following the tactile and thermal stimuli, the reductions in VAS scores following the evaporative stimulus were very similar for the two products. The reason for this is not clear, but could result from the relatively greater number of dentinal tubules that are potentially stimulated by an air blast compared to the tactile or thermal stimulus.

The development of desensitising agents containing oxalate (such as SuperSeal[®]) commenced with the observation that dentine surfaces treated with oxalate solutions became less permeable and increasingly acid resistant⁷. SuperSeal[®] is a potassium oxalate which removes the smear layer and physically blocks the tubules. It demineralises the organic and mineral debris of the smear layer and the outmost ring of peritubular dentine, and within minutes restructures the demineralised material as a calcium oxalate precipitate⁷. The ability of SuperSeal[®] to block dentinal tubules has been previously studied by Kolker et al who evaluated the effect of five desensitizing agents on dentine tubule permeability using hydraulic pressure and scanning electron microscopy¹¹. The five agents investigated were Seal & Protect[®], Gluma Desensitizer[®], HurriSeal[®], D/Sense 2[®], and SuperSeal[®]. Dentine disks from extracted human molars were used in the study. The permeability of dentine was measured at baseline and after the treatment using bovine serum and phosphate-buffered saline at 10 psi. Pairwise comparisons revealed that SuperSeal[®] had a better effect in reducing dentine permeability than the other agents used in the study, as measured by differences in the degree of dentinal tubule occlusion¹¹.

The efficacy of Duraphat[®] in reducing dentine sensitivity has also been studied. Clark et al evaluated the efficacy of Duraphat[®] and desensitizing toothpaste containing strontium chloride. After one month, the combination of Duraphat[®] and the strontium chloride toothpaste was more effective than the use of the toothpaste alone⁶. The ability of Duraphat[®] to decrease the pain of dentine sensitivity probably arises from formation of calcium fluoride and fluorapatite in the outer surfaces of dentine and this blocks

the transmission of stimuli to the pulp⁶.

To summarize, this study evaluated the efficacy of two topical desensitizing agents for the treatment of dentine sensitivity. Both Duraphat[®] and SuperSeal[®] diminished the sensitivity experienced following application of stimuli to exposed sensitive dentine, with statistically significant reductions in VAS sensitivity scores at 4 weeks compared to baseline. However, analysis of covariance failed to identify statistically significant differences in the magnitude of reductions in sensitivity achieved by each of the products. Clearly, further studies of these agents involving larger patient populations are indicated.

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