2-Month Randomized Controlled Trial of Two Professional Desensitizing Treatments Relief

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ABSTRACT

Objectives: A randomized controlled trial was conducted to compare the durable effects following a single application of one of two marketed professional desensitizing agents in a dental practice.

Methods: Institutional review and informed consent were obtained, and adult volunteers with dentinal hypersensitivity were recruited within a dental practice. At baseline, test sites were selected and eligible subjects were randomly assigned to one of two marketed treatment groups: oxalate acid potassium salt solution (Super Seal® Dental Desensitizing Liner, Phoenix Dental) or 5% sodium fluoride varnish (Acclean®, Henry Schein Dental). Sensitivity was measured after stimulation with a 1-sec application of cool air from a dental air syringe, and measured using two sequential methods. First, sensitivity was measured by a clinical examiner using a standard 4-point scale (Schiff), after which, subjects independently graded sensitivity on a 100 mm pain-ranking scale (VAS). Test products were dispensed in marketed packaging and professionally applied following labeled instructions with subjects blinded to assignment. Response was measured, and subjects were instructed to maintain normal oral hygiene for 2-months.

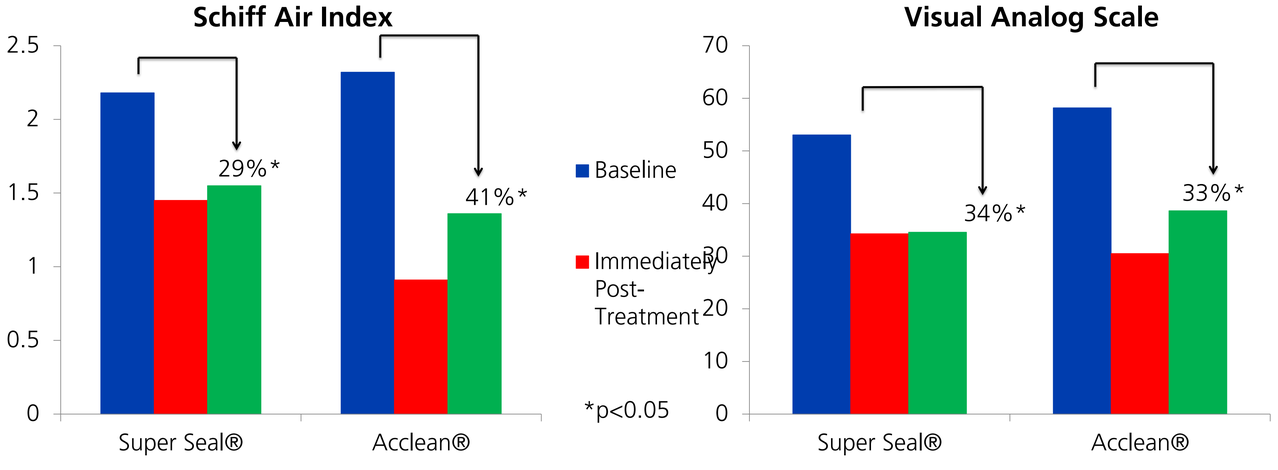
Results: The study population was predominantly female (91%) with ages ranging from 18-73 years of age, 95% of whom completed the 2-month recall. Baseline sensitivity means (SD) were 2.3 (0.74) for Schiff Air (with subject means ranging from 1-3), and 55.6 (14.5) for VAS (with subject means ranging from 32-82). Both groups exhibited significant ($p<0.05$) durable reductions in sensitivity after treatment. At Month 2, this represented 29-41% reductions in clinically-graded sensitivity and 33-34% reductions in self-graded sensitivity, with groups not differing significantly ($p>0.33$) on either endpoint. Both treatments were well-tolerated.

Conclusions: In practice-based research, a single professional application of two different desensitizers – potassium oxalate solution or sodium fluoride varnish – yielded significant 29-41% reductions in both self-assessed and dentist-assessed hypersensitivity two months after treatment.

MATERIALS AND METHODS

This is a randomized, controlled, subject-blind pilot study to assess dentinal hypersensitivity with two different marketed professional treatments for dentinal hypersensitivity. After informed consent, 30 healthy adult volunteers with current dentinal hypersensitivity. Subjects were be randomized to either professionally-applied Acclean® Fluoride Varnish or Super Seal® Desensitizer. Assessments of dentinal sensitivity will be made at Baseline before and immediately following sensitivity treatment, and again approximately 2 months after the sensitivity treatment. Dentinal hypersensitivity was assessed clinically after an air-blast stimulus by subject report and clinical evaluation, while oral tolerability will be assessed by clinical examination. Analysis of covariance was used to compare the treatments, and paired difference t-tests were used to assess changes from baseline.

RESULTS



Month 2 - Analysis of Covariance Summary				
Treatment	N	Adjusted Mean (SE)	Treatment Difference (95% Confidence Interval)	2-sided p-value
Schiff Air Index (Baseline Mean = 2.21)				
Acclean®	11	1.276 (0.255)	-0.371 (-1.152, 0.409)	0.3308
Super Seal®	11	1.647 (0.267)		
Visual Analog Scale (Baseline Mean = 55.31)				
Acclean®	11	36.234 (7.291)	-0.959 (-23.415, 21.497)	0.9295
Super Seal®	10	37.193 (7.655)		

CONCLUSIONS

In practice-based research, a single professional application of two different desensitizers – potassium oxalate solution or sodium fluoride varnish – yielded significant 29-41% reductions in both self-assessed and dentist-assessed hypersensitivity two months after treatment.

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