

# 2-Month Randomized Trial of Combination In-Office and At-Home Oxalate Treatments



C.J. ANDERSON\*<sup>1,3</sup>, G. KUGEL<sup>2</sup>, M. FERRARI<sup>3</sup>, P.A. SAGEL<sup>4</sup>, R.W. GERLACH<sup>4</sup>

<sup>1</sup>Anderson Dental, Fresno, CA, <sup>2</sup>Tufts University, Boston, MA, <sup>3</sup>University of Siena, Siena, Italy <sup>4</sup>The Procter & Gamble Co., Mason, OH

## ABSTRACT

**Objective:** A randomized clinical trial was conducted to evaluate combination oxalate treatments (in-office and at-home) on dentinal hypersensitivity, and to compare possible oral hygiene impact on durable response.

**Method:** After IRB review and consent, adult volunteers with dentinal hypersensitivity were recruited within a dental practice for a two-visit 60-day study. At baseline, sensitivity was stimulated with a 1-sec application of cool air from a dental air syringe, and measured clinically using a standard 4-point scale (Schiff) and subjectively using a tablet-based 100 point pain-ranking scale (VAS). Test sites were treated with professional application of an oxalate acid potassium salt solution (Super Seal® Dental Desensitizing Liner, Phoenix Dental), after which, immediate sensitivity response was retested. Subjects were dispensed blinded at-home test kits containing six 1.5% oxalate gel strips (Crest® Sensi-Stop™ Strips, The Procter & Gamble Co.), a regular manual brush, and one of two randomly assigned pastes (either 0.454% SnF<sub>2</sub> or 0.243% NaF) for unsupervised at-home use through the two-month recall visit.

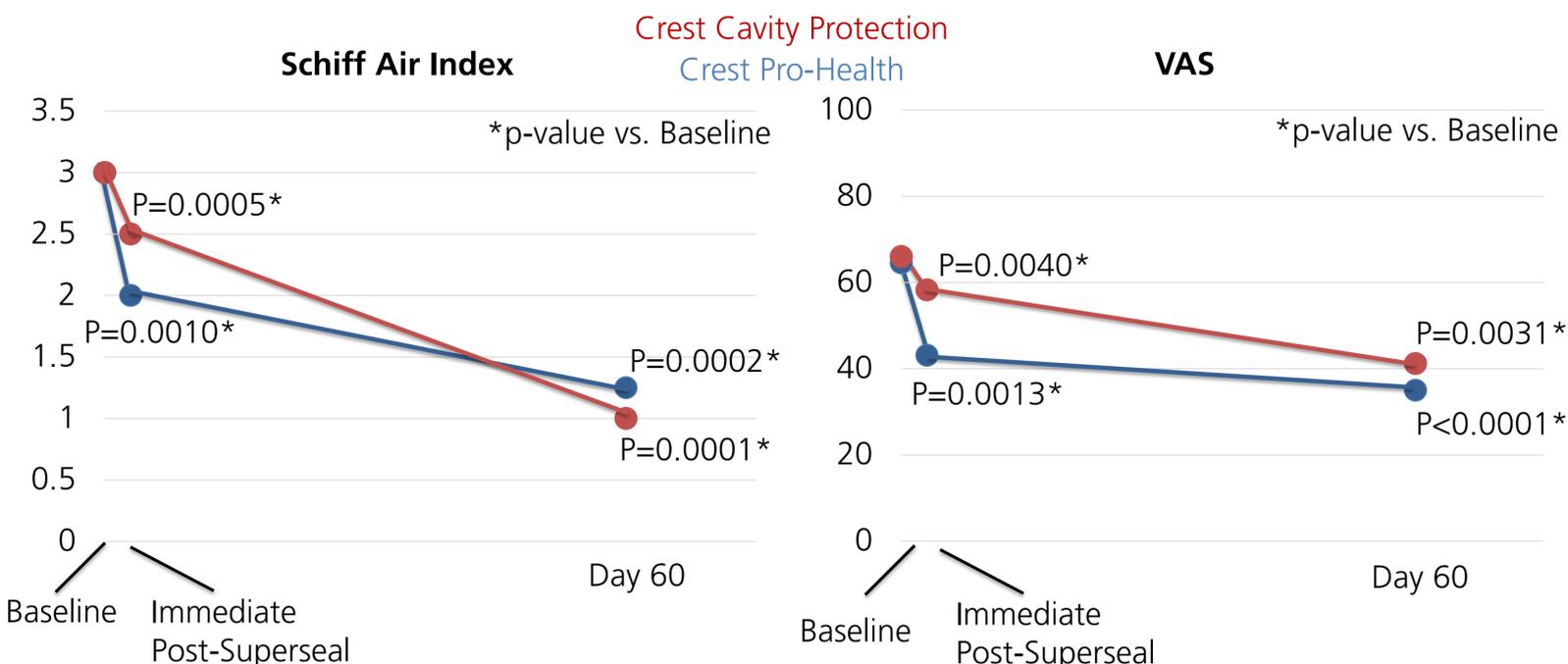
**Results:** The population consisted of 30 subjects (93% female) ranging from 19-66 years of age, 97% of whom completed the 2-month study. The population exhibited appreciable baseline sensitivity with overall means (SD) of 2.7 (0.47) for Schiff air, and 65.3 (13.8) for VAS air. In-office oxalate treatment yielded significant ( $p < 0.004$ ) reductions in clinical and subjective endpoints. After 2 months, clinical sensitivity decreased by 57-58% relative to baseline ( $p \leq 0.0001$ ), while VAS decreased by 37-46% ( $p < 0.004$ ). Hygiene did not significantly ( $p > 0.43$ ) impact durable sensitivity response. One subject reported mild pain and irritation after baseline treatment, and there were no additional adverse events during the unsupervised oxalate strip-oral hygiene phase.

**Conclusion:** In practice-based research, the combination of in-office and at-home oxalate use yielded significant 37-57% reductions in dentinal hypersensitivity with two concurrent oral hygiene approaches.

## MATERIALS & METHODS

This was a randomized, controlled, two treatment, parallel group study. Tooth sensitivity was measured via Schiff Index and VAS using cold air as stimuli. All subjects were treated professionally with Superseal and were given Crest Sensi-Stop Strips to use up to 3 times on each of two teeth at home. Additionally, the subjects (15 per group) were assigned to one of two treatment groups: 1) Crest Pro-Health (0.454% Stannous Fluoride), and Oral-B Indicator soft, manual toothbrush or 2) Crest Cavity Protection (0.243% Sodium Fluoride), and Oral-B Indicator soft, manual toothbrush. Sensitivity measurements were taken at Baseline, immediately following treatment with Superseal, and 60 days post-baseline. Treatment groups were compared and mean difference estimated using both parametric and non-parametric analyses of covariance.

## RESULTS



30 subjects were randomized to treatment and all subjects completed the study. Subjects ranged in age from 19 to 66 years with an average of 43.2 years. Seventy-nine percent (93%) of the subjects were female. Treatment groups were well balanced ( $p \geq 0.36$ ) on age, ethnicity, and gender.

### Non-Parametric Analysis of Covariance Schiff Air Index

Treatment	N	Adj. Median	% Change vs. Baseline	Between Treatment 2-sided P-value
<b>Immediate Post-Superseal (Schiff baseline median=3.00)</b>				
Crest Pro-Health	15	2.00	33%	0.0692
Crest Cavity Protection	15	2.50	16.7%	

### Analysis of Covariance VAS

Treatment	N	Adj. Mean (SE)	% Change vs. Baseline	Between Treatment 2-sided P-value
<b>Immediate Post-Superseal (VAS baseline mean=65.30)</b>				
Crest Pro-Health	15	43.12 (5.76)	22%	0.0189
Crest Cavity Protection	15	58.28 (1.91)	10%	
<b>Day 60</b>				
Crest Pro-Health	15	35.02 (4.57)	46%	0.4287
Crest Cavity Protection	15	41.18 (6.14)	37%	

## CONCLUSIONS

In practice-based research, the combination of in-office and at-home oxalate use yielded significant 37-57% reductions in dentinal hypersensitivity with two concurrent oral hygiene approaches.