Clinical Evidence:
Colgate® Sensitive Pro-Relief™
Desensitizing Products
with Pro-Argin™ Technology
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Clinical efficacy of Colgate® Sensitive Pro-Relief™ in-office desensitizing paste

T Schiff¹, E Delgado², YP Zhang², D Cummins², W DeVizio², LR Mateo³

Clinical evaluation of the efficacy of an in-office desensitizing paste containing 8% arginine and calcium carbonate in providing instant and lasting relief of dentin hypersensitivity.

In: American Journal of Dentistry 2009;22 (Spec Iss): 8A-15A

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Study objectives:
The objectives of the study were 1. to compare the efficacy of two in-office pastes in reducing dentin hypersensitivity immediately after a single application following dental scaling and 2. to assess the duration of relief over a period of 4 and 12-weeks.

Trial conditions and methods

Products under investigation
Test: Colgate® Sensitive Pro-Relief™ desensitizing paste (Colgate Palmolive, New York, NY) containing 8% arginine in a calcium carbonate/silica base.
Control: Pumice-based fluoride free prophylaxis paste.

Study subjects
A total of 68 male and female subjects (aged between 24 and 56 years) with established dentin hypersensitivity (two hypersensitive teeth with a tactile sensitivity score [Yeaple probe] of 10-50 grams of force and an air blast score of 2 or 3 on the Schiff Cold Air Sensitivity Scale).

Methods
In this double-blind, parallel group study, 68 subjects with established dentin hypersensitivity were randomly assigned to either the test (n=32) or control (n=36) group. Following baseline evaluation of dentin hypersensitivity, subjects received a professional dental scaling, after which tactile and air blast sensitivity scores were determined. The assigned in-office paste was then applied as the final polishing step of the professional cleaning procedure. Tactile and air blast sensitivity scores were determined immediately after product application. Subjects then brushed twice daily with a commercial fluoride anti-cavity
toothpaste and a soft bristled toothbrush for 12 weeks. Dentin hypersensitivity scores were determined after 4 and 12 weeks. Statistical analyses were performed separately for tactile and air blast scores. Within treatment comparisons were performed using a T-test. Comparisons between treatments using baseline adjusted scores were performed using analysis of covariance (ANCOVA).

Results
No statistically significant differences from baseline scores were indicated at the post-scaling examination between the two groups. Immediately post product application and after 4 weeks, subjects assigned to the test product demonstrated statistically significant improvements from baseline in tactile (156.2% and 170.3%, respectively) and air blast (44.1% and 45.9%, respectively) sensitivity scores. At the same time points, subjects assigned to the control product demonstrated statistically significant improvements from baseline in tactile (43.1% and 8.3%, respectively) and air blast (15.1% and 8.9%, respectively) sensitivity scores.

Immediately post product application and after 4 weeks, the test product group demonstrated statistically significant improvements compared to the control group in tactile (79.0% and 149.6%, respectively) and air blast (34.1% and 40.6%, respectively) sensitivity scores. No statistically significant differences between test and control groups were indicated at the post-scaling and 12 week examinations.

Conclusion
Colgate® Sensitive Pro-Relief™ desensitizing paste provides a statistically significant reduction in dentin hypersensitivity as compared to a control prophylaxis paste immediately after a single application following dental scaling. This relief lasts for 4 weeks.
Clinical efficacy of Colgate® Sensitive Pro-Relief™ in-office desensitizing paste

D Hamlin¹, K Phelan Williams¹, E Delgado², YP Zhang², W DeVizio², LR Mateo³

Clinical evaluation of the efficacy of a desensitizing paste containing 8% arginine and calcium carbonate for the in-office relief of dentin hypersensitivity associated with dental prophylaxis.

In: American Journal of Dentistry 2009;22 (Spec Iss): 16A-20A

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Study objectives:
The objective of the study was to compare the efficacy in reducing dentin hypersensitivity of two in-office pastes when applied as a pre-procedure to a professional dental cleaning.

Trial conditions and methods

Products under investigation
Test: Colgate® Sensitive Pro-Relief™ desensitizing paste (Colgate Palmolive, New York, NY) containing 8% arginine in a calcium carbonate/silica base.
Control: Pumice-based fluoride free prophylaxis paste.

Study subjects
A total of 45 male and female subjects (aged between 23 and 66 years) with established dentin hypersensitivity (two hypersensitive teeth with a tactile sensitivity score [Yeaple probe] of 10-50 grams of force and an air blast score of 2 or 3 on the Schiff Cold Air Sensitivity Scale).

Methods
In this double-blind, parallel group study, 45 subjects with established dentin hypersensitivity were randomly assigned to either the test (n=22) or control (n=23) group. Following baseline evaluation of dentin hypersensitivity, the assigned in office paste was applied as a pre-procedural step prior to professional cleaning. Immediately after completion of the cleaning procedure, subjects were re-evaluated for tactile and air blast sensitivity scores. Statistical analyses were performed separately for tactile and air blast scores. Within treatment comparisons were performed using a T-test. Comparisons between
treatments using baseline adjusted scores were performed using analysis of covariance (ANCOVA).

**Results**
Immediately after the cleaning procedure, subjects assigned to the test product demonstrated statistically significant improvements from baseline in tactile (132.1%) and air blast (48.6%) sensitivity scores. At the same time point, subjects assigned to the control product demonstrated statistically significant improvements from baseline in air blast (13.9%) sensitivity score. The improvement from baseline in tactile sensitivity score (21.7%) in the control subjects was not statistically significant.

Immediately after the cleaning procedure, the test product group demonstrated statistically significant improvements compared to the control group in tactile (110.0%) and air blast (41.9%) sensitivity scores.

**Conclusion**
When applied prior to a professional dental cleaning, Colgate® Sensitive Pro-Relief™ desensitizing paste with 8% arginine and calcium carbonate provides a statistically significant reduction in dentin hypersensitivity measured immediately following the dental cleaning as compared to a control prophylaxis paste.
Comparing the Efficacy in Reducing Dentin Hypersensitivity of a New Toothpaste Containing 8.0% Arginine, Calcium Carbonate, and 1450 ppm Fluoride to a Commercial Sensitive Toothpaste Containing 2% Potassium Ion: An Eight-Week Clinical Study on Canadian Adults.

In: J Clin Dent 2009; 20 (Spec Iss): 10–16

1 Canadian Clinical Research Center, Mississauga, Ontario, Canada
2 Colgate-Palmolive Technology Center, Piscataway, NJ, USA
3 LRM Statistical Consulting, Hoboken, NJ

Study objective:
The objective of the double-blind, randomized study conducted in Mississauga, Canada, was to compare a new toothpaste containing 8% arginine, calcium carbonate and 1450 ppm fluoride as sodium monofluorophosphate (MFP) and a commercial toothpaste containing 2% potassium ion and 1450 ppm fluoride as sodium fluoride (NaF) with respect to the reduction of dentin hypersensitivity over an eight-week period.

Trial conditions and methods

Products under investigation
Test: A new toothpaste (Colgate-Palmolive Inc., NY) containing 8% arginine, calcium carbonate and 1450 ppm fluoride as MFP.
Control: Commercially available desensitising toothpaste containing 2% potassium ion as 3.75% potassium chloride and 1450 ppm fluoride as NaF in a silica base (Sensodyne Total Care Fluoride, GlaxoSmithKline, Middlesex UK).

Study Subjects
A total of 77 adult male (n = 25) and female (n = 52) subjects (age between 18 and 66 years) with established dentin hypersensitivity on at least two hypersensitive teeth with a tactile sensitivity score of 10 to 50 grams of force (Yeaple probe) and an air blast stimulus score of 2 or 3 (Schiff Cold Air Sensitivity Scale).
Methods
In this double-blind, parallel-group study, the 77 subjects with established dentin hypersensitivity were stratified according to their tactile and air blast stimulus scores at baseline and then randomly assigned within strata to either the test (n = 38) or control (n = 39) group. Subjects were instructed to brush their teeth twice a day (morning and evening) for 1 min each time. Tactile and air blast sensitivity assessments were repeated at 3 days and at 2, 4, and 8 weeks. Statistical analyses were done separately for tactile and air blast scores. Within-group comparisons were done using paired t-tests. Comparisons between treatments using baseline-adjusted scores were performed using analysis of covariance (ANCOVA).

Results
When used over a period of 8 weeks, the novel toothpaste containing arginine and MFP in a calcium carbonate base significantly reduced dentin hypersensitivity (p < 0.05) in response to both the tactile and air blast stimuli. Compared to the commercial toothpaste with 2% potassium ion and NaF, the arginine containing toothpaste was significantly (p < 0.05) more effective in reducing hypersensitivity scores after 2, 4, and 8 weeks of use (16.2%, 22.4%, and 21.4% for tactile stimuli; 16.2%, 29.2%, and 63.4% for air blast stimuli).

Conclusion
A new toothpaste with 8% arginine, calcium carbonate and 1450 ppm fluoride (MFP) provided significantly (p< 0.05) greater dentin hypersensitivity relief after 2, 4, and 8 weeks of use than a desensitising toothpaste containing 2% potassium ion and 1450 ppm fluoride (NaF).
Comparing the Efficacy in Reducing Dentin Hypersensitivity of a New Toothpaste Containing 8.0% Arginine, Calcium Carbonate, and 1450 ppm Fluoride to a Commercial Sensitive Toothpaste Containing 2% Potassium Ion: An Eight-Week Clinical Study in Rome, Italy

In: J Clin Dent 2009; 20 (Spec Iss): 17 – 22

1 University of Rome at Tor Vergata, Rome, Italy
2 Colgate-Palmolive Technology Center, Piscataway, NJ, USA
3 Boston University School of Dental Medicine, Clinical Research Center, Boston, MA, USA
4 LRM Statistical Consulting, Hoboken, NJ

Study objective:
The objective of the double-blind, randomized study conducted in Rome, Italy, was to compare a new toothpaste containing 8% arginine, calcium carbonate and 1450 ppm fluoride as sodium monofluorophosphate (MFP) and a commercial toothpaste containing 2% potassium ion and 1450 ppm fluoride as sodium fluoride (NaF) with respect to the reduction of dentin hypersensitivity over an eight-week period.

Trial conditions and methods

Products under investigation
Test: A new toothpaste (Colgate-Palmolive Inc., NY) containing 8% arginine, calcium carbonate and 1450 ppm fluoride as MFP.
Control: Commercially available desensitising toothpaste containing 2% potassium ion as 3.75% potassium chloride and 1450 ppm fluoride as NaF in a silica base (Sensodyne Total Care Fluoride, GlaxoSmithKline, Middlesex UK).

Study Subjects
A total of 80 adult male (n= 24) and female (n= 56) subjects (age between 19 and 69 years) with established dentin hypersensitivity on at least two hypersensitive teeth with a tactile sensitivity score of 10 to 50 grams of force (Yeaple probe) and an air blast stimulus score of 2 or 3 (Schiff Cold Air Sensitivity Scale).
Methods
In this double-blind, parallel-group study, the 80 subjects with established dentin hypersensitivity were stratified according to their tactile and air blast stimulus scores at baseline and then randomly assigned within strata to either the test (n = 40) or control (n = 40) group. Subjects were instructed to brush their teeth twice a day (morning and evening) for 1 min each time. Tactile and air blast sensitivity assessments were repeated at 2, 4, and 8 weeks. Statistical analyses were done separately for tactile and air blast scores. Within-group comparisons were done using paired t-tests. Comparisons between treatments using baseline-adjusted scores were performed using analysis of covariance (ANCOVA).

Results
When used over a period of 8 weeks, the novel toothpaste containing arginine and MFP in a calcium carbonate base significantly reduced dentin hypersensitivity (p < 0.05) in response to both the tactile and air blast stimuli. Compared to the commercial toothpaste with 2% potassium ion and NaF, the arginine containing toothpaste was significantly (p < 0.05) more effective in reducing hypersensitivity scores after 2, 4, and 8 weeks of use (37.0%, 30.0%, and 12.2% for tactile stimuli; 23.9%, 32.0%, and 29.3% for air blast stimuli).

Conclusion
A new toothpaste with 8% arginine, calcium carbonate and 1450 ppm fluoride (MFP) provided significantly (p< 0.05) greater dentin hypersensitivity relief after 2, 4, and 8 weeks of use than a desensitising toothpaste containing 2% potassium ion and 1450 ppm fluoride (NaF).
Mechanism of Action and Acid Resistance of Colgate® Sensitive Pro-Relief™ In-Office and Toothpaste Products

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A Breakthrough Therapy for Dentin Hypersensitivity: How Dental Products Containing 8% Arginine and Calcium Carbonate Work to Deliver Effective Relief of Sensitive Teeth

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² University of California at Los Angeles, Los Angeles, CA, USA

Study objective
To gain insight into the mechanism of action, especially the nature and extent of dentin tubule occlusion and its acid resistance, of a new technology based upon 8% arginine and calcium carbonate that has been clinically proven to provide instant and lasting relief of dentin hypersensitivity.

Study methods

Test products under investigation
Colgate® Sensitive Pro-Relief™ desensitizing paste (Colgate Palmolive, New York, NY) containing 8% arginine in a calcium carbonate/silica base and Colgate Sensitive Pro-Relief toothpaste (Colgate Palmolive, New York, NY) containing 8% arginine in a calcium carbonate base.

Methods
Confocal laser scanning microscopy (CLSM), scanning electron microscopy (SEM), and atomic force microscopy (AFM) were used to assess tubule occlusion. Energy dispersive x-ray (EDX) and electron spectroscopy for chemical analysis (ESCA) were used to characterize the composition of the occluded dentin plug. CLSM was also used to establish the need for both arginine and calcium carbonate in the occlusion process and to demonstrate the resistance of the occlusion to acid challenge. Additionally, hydraulic conductance was used to assess the effectiveness of the occlusion in arresting dentin fluid flow and to confirm the acid resistance of the dentin plug.

Results

The CLSM (Figure 1), SEM (Figure 2) and AFM studies demonstrated that the new arginine-calcium carbonate technology is highly effective in rapidly and completely occluding open dentin tubules.
The EDX and ESCA (Table) studies show that the occluded dentin plug contains high levels of calcium and phosphate, as well as carbonate.

<table>
<thead>
<tr>
<th>Dentin specimen</th>
<th>%CaCO₃</th>
<th>%Ca</th>
<th>%P</th>
<th>Ca/P ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Untreated</td>
<td>----</td>
<td>1.06 +/- 0.49</td>
<td>0.87 +/- 0.39</td>
<td>1.21</td>
</tr>
<tr>
<td>Treated</td>
<td>1.51 +/- 0.39</td>
<td>11.50 +/- 1.08</td>
<td>8.39 +/- 1.10</td>
<td>1.37</td>
</tr>
</tbody>
</table>

Table: ESCA analysis of dentin specimens before and after treatment with arginine-calcium carbonate in office desensitizing paste

CLSM confirmed that the in office desensitizing paste and the toothpaste have the same mechanism of action, and that both the arginine and the calcium carbonate are essential for effective tubule occlusion. The hydraulic conductance studies demonstrate that the occluded dentin plug results in highly significant reductions in dentin fluid flow and that the tubule plug is resistant to normal pulpal pressure (Figure 3). Together, the CLSM (Figure 4) and hydraulic conductance studies (Figure 3) also show that the occluded dentin plug is resistant to acid challenge.

Conclusion

Both Colgate® Sensitive Pro-Relief™ in office desensitizing paste and toothpaste, containing 8% arginine and calcium carbonate, work by enhancing the natural mechanisms of tubule occlusion to deposit a dentin-like material containing calcium and phosphate, that is resistant to acid, within the dentin tubules and in a protective layer on the dentin surface.
Comparing the efficacy in providing instant relief of dentin hypersensitivity of a new toothpaste containing 8.0% arginine, calcium carbonate, and 1450ppm fluoride to a benchmark desensitizing toothpaste containing 2% potassium ion and 1450ppm fluoride, and to a control toothpaste with 1450ppm fluoride: A three-day clinical study in Mississauga, Canada.

In: Journal of Clinical Dentistry 2009; 20 (Spec Iss): 115 –122

1 Canadian Clinical Research Center, Mississauga, Canada
2 Colgate-Palmolive Technology Center, Piscataway, NJ
3 LRM Statistical Consulting, Hoboken, NJ

Study objectives:
To compare the efficacy in reducing dentin hypersensitivity of toothpaste containing 8.0% arginine, calcium carbonate, and 1450ppm fluoride to a desensitizing and to a fluoride control toothpaste, immediately after direct application using a fingertip, and after subsequent twice daily brushing for 3 days.

Trial conditions and methods

Products under investigation
Test: Colgate® Sensitive Pro-Relief™ toothpaste containing 8.0% arginine, calcium carbonate, and 1450ppm fluoride as MFP.
KNO₃ control: Toothpaste containing 5% KNO₃ and 1450ppm fluoride as NaF.
Fluoride control: Toothpaste containing 1450ppm fluoride as MFP. (Colgate Palmolive, New York, NY)

Study subjects
120 subjects (aged 18 - 66 years) with established dentin hypersensitivity (two hypersensitive teeth with a tactile sensitivity score [Yeaple probe] of 10-50 grams of force and an air blast score of 2 or 3 on the Schiff Cold Air Sensitivity Scale).

Methods
In this double-blind, parallel group study, 120 subjects were stratified and randomly assigned to the test (n=41), the KNO₃ (n=40) or the fluoride (n=39) group. Subjects first applied a pea-sized amount of toothpaste directly to the sensitive area of each of the baseline designated teeth with a fingertip and massaged each for 1 minute. Subjects then brushed with their assigned product and a soft bristled toothbrush twice daily for 3 days. Tactile and air blast
sensitivity scores were determined immediately after direct topical application, and after 3 days of product use. Statistical analyses were performed separately for tactile and air blast scores. Comparisons of treatment groups with respect to baseline were performed using analysis of variance (ANOVA). Comparisons between treatments using baseline adjusted scores were performed using analysis of covariance (ANCOVA).

**Results**
Immediately after direct application and after 3 days, subjects in the test group experienced statistically significant improvements from baseline in tactile (189.4% and 190.4%, respectively) and air blast (56.6% and 59.7%, respectively) sensitivity scores. Moreover, at the same time points, the test group experienced statistically significant improvements compared to the KNO$_3$ group in tactile (130.7% and 104.9%, respectively) and air blast (43.8% and 44.5%, respectively) sensitivity scores, and statistically significant improvements compared to the fluoride group in tactile (139.5% and 136.1%, respectively) and air blast (49.6% and 53.2%, respectively) sensitivity scores.

In respect of the control groups, subjects in the KNO$_3$ group experienced statistically significant improvements from baseline in tactile (32.2% and 49.4%, respectively) and air blast (23.5% and 28.4%, respectively) sensitivity scores immediately after direct application and after 3 days use. Subjects in the fluoride group experienced statistically significant improvements from baseline in tactile (27.1% and 29.4%, respectively) and air blast (15.3% and 15.5%, respectively) sensitivity scores. No statistically significant differences between the two control groups were indicated immediately after direct application. After 3 days use, the KNO$_3$ group demonstrated a significant reduction in mean air blast scores (15.6%) relative to the fluoride group, but there was no significant difference in tactile sensitivity scores.

**Conclusion**
Colgate® Sensitive Pro-Relief™ toothpaste provides statistically significant relief of dentin hypersensitivity, immediately after direct application with a fingertip, relative to a KNO$_3$ toothpaste and to a fluoride toothpaste.
Clinical efficacy of Colgate® Sensitive Pro-Relief™ toothpaste

S Nathoo¹, E Delgado², YP Zhang², W DeVizio², D Cummins², LR Mateo³

Comparing the efficacy in providing instant relief of dentin hypersensitivity of a new toothpaste containing 8.0% arginine, calcium carbonate, and 1450ppm fluoride to a benchmark desensitizing toothpaste containing 2% potassium ion and 1450ppm fluoride, and to a control toothpaste with 1450ppm fluoride: A three-day clinical study in New Jersey, USA.

In: Journal of Clinical Dentistry 2009; 20 (Spec Iss): 123 –130
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³ LRM Statistical Consulting, Hoboken, NJ

Study objectives:
To compare the efficacy in reducing dentin hypersensitivity of toothpaste containing 8.0% arginine, calcium carbonate, and 1450ppm fluoride to a desensitizing and to a fluoride control toothpaste, immediately after direct application using a fingertip, and after subsequent twice daily brushing for 3 days.

Trial conditions and methods

Products under investigation
Test: Colgate® Sensitive Pro-Relief™ toothpaste containing 8.0% arginine, calcium carbonate, and 1450ppm fluoride as MFP.
KNO₃ control: Toothpaste containing 5% KNO₃ and 1450ppm fluoride as NaF.
Fluoride control: Toothpaste containing 1450ppm fluoride as MFP. (Colgate Palmolive, New York, NY).

Study subjects
125 subjects (aged 18 - 74 years) with established dentin hypersensitivity (two hypersensitive teeth with a tactile sensitivity score [Yeaple probe] of 10-50 grams of force and an air blast score of 2 or 3 on the Schiff Cold Air Sensitivity Scale).

Methods
In this double-blind, parallel group study, 125 subjects were stratified and randomly assigned to the test (n=42), the KNO₃ (n=41) or the fluoride (n=42) group. Subjects first applied a pea-sized amount of toothpaste directly to the sensitive area of each of the baseline designated teeth with a fingertip and massaged each for 1 minute. Subjects then brushed with their assigned product and a soft bristled toothbrush twice daily for 3 days. Tactile and air blast
sensitivity scores were determined immediately after direct topical application, and after 3 days of product use. Statistical analyses were performed separately for tactile and air blast scores. Comparisons of treatment groups with respect to baseline were performed using analysis of variance (ANOVA). Comparisons between treatments using baseline adjusted scores were performed using analysis of covariance (ANCOVA).

**Results**
Immediately after direct application and after 3 days, subjects in the test group experienced statistically significant improvements from baseline in tactile (185.6% and 216.4%, respectively) and air blast (60.5% and 74.2%, respectively) sensitivity scores. Moreover, at the same time points, the test group experienced statistically significant improvements compared to the KNO₃ group in tactile (161.2% and 147.1%, respectively) and air blast (59.8% and 70.1%, respectively) sensitivity scores, and statistically significant improvements compared to the fluoride group in tactile (180.2% and 181.2%, respectively) and air blast (58.0% and 70.9%, respectively) sensitivity scores.

In respect of the control groups, subjects in the KNO₃ group experienced statistically significant improvements from baseline in tactile (13.3% and 32.6%, respectively) and air blast (5.8% and 17.3%, respectively) sensitivity scores, and subjects in the fluoride group experienced statistically significant improvements from baseline in tactile (1.9% and 12.5%, respectively) and air blast (1.8% and 7.6%, respectively) sensitivity scores. No statistically significant differences between the KNO₃ and the fluoride control groups were indicated immediately after direct application or after 3 days of twice daily brushing.

**Conclusion**
Colgate® Sensitive Pro-Relief™ toothpaste provides statistically significant relief of dentin hypersensitivity, immediately after direct application with a fingertip, relative to a KNO₃ toothpaste and to a fluoride toothpaste.
Clinical efficacy of
Colgate® Sensitive Pro-Relief™ toothpaste

T Schiff¹, E Delgado², YP Zhang², W DeVizio², D Cummins², LR Mateo³
The clinical effect of a single direct application of a dentifrice containing 8.0%
arginine, calcium carbonate, and 1450 ppm fluoride on dentin hypersensitivity: The
use of a cotton swab applicator versus the use of a fingertip.

In: Journal of Clinical Dentistry 2009; 20 (Spec Iss): 131 – 136
¹ Scottsdale Center for Dentistry, San Francisco, CA
² Colgate-Palmolive Technology Center, Piscataway, NJ
³ LRM Statistical Consulting, Hoboken, NJ

Study objectives:
To compare the effects of a toothpaste containing 8.0% arginine, calcium
carbonate, and 1450ppm fluoride in providing instant relief of dentin
hypersensitivity when delivered as a single direct topical application using a
cotton swab applicator versus using a fingertip, and to evaluate the effects after
subsequent twice daily brushing for seven days.

Trial conditions and methods

Products under investigation
Colgate® Sensitive Pro-Relief™ toothpaste containing 8.0% arginine, calcium carbonate,
and 1450ppm fluoride as MFP (Colgate-Palmolive, New York, NY).

Study subjects
84 subjects with established dentin hypersensitivity (two hypersensitive teeth with a
tactile sensitivity score [Yeaple probe] of 10-50 grams of force and an air blast score
of 2 or 3 on the Schiff Cold Air Sensitivity Scale).

Methods
This seven day clinical study employed an examiner-blind, stratified, two-
treatment, single product design. Subjects applied a pea-sized amount of
toothpaste directly to the sensitive area of one baseline-designated tooth using
a cotton swab and massaged the sensitive area for 1 minute. Subjects replicated
the procedure on the other baseline-designated tooth with a fingertip. A
randomization procedure was used to determine, on a per-subject basis, which
tooth and mode of application was to be treated first. Subjects then brushed
with the product and a soft bristled toothbrush twice daily for 7 days. Tactile
and air blast sensitivity scores were determined immediately after direct topical
application, and after 7 days of product use. Statistical analyses were performed
separately for tactile and air blast scores. Comparisons of treatment groups (cotton swab and fingertip) with respect to baseline were performed using analysis of variance (ANOVA). Comparisons between treatment groups using baseline-adjusted scores were performed using analysis of covariance (ANCOVA).

**Results**
Immediately after direct application and after 7 days, teeth treated with the cotton swab experienced statistically significant improvements from baseline in tactile (182.1% and 190.5%, respectively) and air blast (56.3% and 58.2%, respectively) sensitivity scores. At the same time points, teeth treated with a fingertip experienced statistically significant improvements from baseline in tactile (191.7% and 191.7%, respectively) and air blast (58.1% and 57.4%, respectively) sensitivity scores.

There were no statistically significant differences indicated in either tactile or air blast sensitivity scores between the swab test teeth and the fingertip test teeth immediately after direct application, or after subsequent twice daily brushing for 7 days.

**Conclusion**
Colgate® Sensitive Pro-Relief™ toothpaste provides statistically significant relief of dentin hypersensitivity immediately after direct application, using both cotton swab and fingertip methods, and after a subsequent period of twice daily brushing for 7 days. Neither the cotton swab nor the fingertip method of application provided a level of control of dentin hypersensitivity that differed significantly from the other.
Clinical efficacy of Colgate® Sensitive Pro-Relief™ toothpaste

R Docimo¹, L Montesani¹, P Maturo¹, M Bartolino¹, YP Zhang², W DeVizio², E Delgado², D Cummins², S Dibart³, LR Mateo⁴

Comparing the efficacy in reducing dentin hypersensitivity of a new toothpaste containing 8.0% arginine, calcium carbonate, and 1450ppm fluoride to a benchmark desensitizing toothpaste containing 2% potassium ion: An eight-week clinical study in Rome, Italy.

In: Journal of Clinical Dentistry 2009; 20 (Spec Iss): 137–143
¹ University of Rome at Tor Vergata, Rome, Italy
² Colgate-Palmolive Technology Center, Piscataway, NJ
³ Boston University School of Dental Medicine, Boston, MA
⁴ LRM Statistical Consulting, Hoboken, NJ

Study objectives:
The objective of the double-blind, randomized study conducted in Rome, Italy, was to compare a new toothpaste containing 8.0% arginine, calcium carbonate, and 1450ppm fluoride as sodium monofluorophosphate (MFP) and a commercial toothpaste containing 2% potassium ion, as potassium nitrate, and 1450ppm fluoride as sodium fluoride (NaF) with respect to the reduction in dentin hypersensitivity over an eight week period (Sensodyne Total Care Gentle Whitening, GlaxoSmithKline, Middlesex, UK).

Trial conditions and methods

Products under investigation
Test: Colgate® Sensitive Pro-Relief™ toothpaste containing 8.0% arginine, calcium carbonate, and 1450ppm fluoride as MFP (Colgate Palmolive, New York, NY).
Control: Commercially available desensitizing toothpaste containing 2% potassium ion, as 5% potassium nitrate, and 1450ppm fluoride as NaF in a silica base (Sensodyne Total Care Gentle Whitening, GlaxoSmithKline, Middlesex, UK).

Study subjects
A total of 80 adult male (n=24) and female (n=56) subjects (aged 19 – 70 years) with established dentin hypersensitivity (two hypersensitive teeth with a tactile sensitivity score [Yeaple probe] of 10-50 grams of force and an air blast score of 2 or 3 on the Schiff Cold Air Sensitivity Scale).

Methods
In this double-blind, parallel group study, 80 subjects with established dentin hypersensitivity were stratified according to their tactile and air blast scores
at baseline and randomly assigned to the test (n=40) or control (n=40) group. Subjects were instructed to brush their teeth twice a day (morning and evening) for 1 minute each time. Tactile and air blast sensitivity assessments were repeated at 1, 2, 4, and 8 weeks. Statistical analyses were performed separately for tactile and air blast scores. Comparisons of treatment groups with respect to baseline scores were performed using an independent t test. Comparisons between treatments using baseline-adjusted scores were performed using analysis of covariance (ANCOVA).

Results
When used over a period of 8 weeks, the novel toothpaste containing arginine in a calcium carbonate base significantly reduced dentin hypersensitivity (p<0.05) in response to both tactile and air blast stimuli. Compared to the commercial toothpaste, the arginine-containing toothpaste with 2% potassium ion and NaF was significantly (p<0.05) more effective in reducing hypersensitivity scores after 2, 4, and 8 weeks (38.9%, 28.8%, and 11.6% for tactile stimuli; 16.8%, 26.4%, and 33.8% for air blast stimuli).

Conclusion
Colgate® Sensitive Pro-Relief™ toothpaste, a new toothpaste with 8.0% arginine, calcium carbonate and 1450ppm fluoride (MFP) provided statistically significantly (p<0.05) greater dentin hypersensitivity relief after 2, 4, and 8 weeks of use than a desensitizing toothpaste containing 2% potassium ion and 1450ppm fluoride (NaF).
Study objective:
The objective of this in vitro study was to compare the effectiveness of three commercial sensitivity toothpastes in occluding open dentin tubules and, thereby, in reducing fluid flow across dentin samples using hydraulic conductance measurements.

Materials and Methods

Products under investigation
Test 1: Colgate® Sensitive Pro-Relief™ toothpaste (Colgate Palmolive, New York, NY) containing 8% arginine and 1450 fluoride as sodium monofluorophosphate (MFP) in a calcium carbonate base.
Test 2: Sensodyne Original toothpaste (GlaxoSmithKline, Middlesex, UK) containing 10% strontium chloride in a silica base.
Test 3: Macleans Sensitive Multi Defence (GlaxoSmithKline, New South Wales, Australia) containing 8% strontium acetate and 1000 ppm fluoride as sodium fluoride in a silica base.

Methods
Human dentin segments were cut from extracted molars, cleared of pulpal tissue and mounted on acrylic blocks, etched (30sec, 34% phosphoric acid) and connected to a Flodec apparatus to measure fluid flow rate (hydraulic conductance) through dentin. Segments were divided into three groups; each group of three samples was treated by lightly brushing each sample (<20grams pressure) for 30 seconds with one of the test toothpastes and rinsed with DI water. Conductance was measured (70cm water pressure) and reported as a % reduction relative to the etched baseline for each segment. Comparison of the effects of Colgate® Sensitive Pro-Relief™ to the strontium-containing toothpastes was conducted using a one way ANOVA with a Tukey multiple comparison test to assess the significance of pair wise differences.

Results
Results expressed as % reductions (+/- st dev) in fluid flow are shown in the Figure below. Each of the three toothpastes provided a numerical reduction
Conclusion

In a hydraulic conductance test, dentin treated with Colgate® Sensitive Pro-Relief™ toothpaste demonstrated statistically significantly higher reductions in dentin permeability than dentin treated with either one of the two commercial sensitivity toothpastes containing strontium. These results indicate that Colgate® Sensitive Pro-Relief™ toothpaste is significantly more effective (in vitro) in occluding dentin tubules than both the toothpaste containing strontium chloride (Sensodyne Original) and the toothpaste containing strontium acetate (Macleans Sensitive Multi Defence).