AMERICAN JOURNAL OF DENTISTRY

Introducing Pro-Argin™
A Breakthrough Technology Based upon Arginine and Calcium
for In-Office Treatment of Dentin Hypersensitivity

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Dentin hypersensitivity: Beneficial effects of an arginine-calcium carbonate desensitizing paste

Dentin hypersensitivity is a common occurrence and is often a chief concern among patients. The pain associated with dentin hypersensitivity is caused by some type of external stimulus and the sensitivity can range in its intensity from patient to patient. The successful management of dentin hypersensitivity is often very challenging for the dental professional. The cause of the pain and the description of the discomfort reported by the patient can vary.

This Special Issue of the *American Journal of Dentistry* presents the results of studies performed testing an 8% arginine-calcium carbonate desensitizing paste, which is based on Pro-Argin™ technology, a combination of arginine and insoluble calcium compound. The Introduction paper is an overview of dentin hypersensitivity. One paper is a double-blind, stratified, randomized clinical study showing the beneficial effects of the 8% arginine-calcium carbonate desensitizing paste used immediately after dental scaling procedures and its sustained relief over 4 weeks. Another paper presents the results of a double-blind, stratified, randomized clinical study showing the successful desensitizing effect of the 8% arginine-calcium carbonate paste tested, when applied as a pre-procedure to professional dental cleaning.

This Special Issue also includes a study conducted *in vitro,* testing the effect of the desensitizing paste on the surface roughness of common dental materials and human enamel. The outcome revealed no significant alterations on the surfaces of the enamel and the materials tested.

We hope you will find these papers interesting and educational. The *Journal* thanks Colgate-Palmolive Company, the manufacturer of the arginine-calcium carbonate desensitizing paste, for sponsoring this Special Issue.

Franklin García-Godoy, DDS, MS
Editor

Dentin hypersensitivity: Effective treatment with an in-office desensitizing paste containing 8% arginine and calcium carbonate

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Dentin hypersensitivity is a common occurrence and concern among patients. It is characterized by short, sharp pain arising from exposed dentin in response to stimuli, typically thermal, evaporative, tactile, osmotic or chemical, and which cannot be ascribed to any other dental defect or disease.[1,2] The diagnosis of dentin hypersensitivity can be very challenging for the dental professional. The cause of the pain can vary and the patient's description of the discomfort may be insufficient to make a definitive diagnosis. The dental professional must perform differential diagnosis to exclude all other dental defects and diseases that might give rise to similar presentations[1,3] A thorough examination is essential to help the dental professional make a definitive diagnosis and rule out other possible causes of the pain, such as a split or broken tooth, dental caries or periodontal disease. By correctly diagnosing dentin hypersensitivity, the professional is able to develop and implement an appropriate treatment plan to address the problem effectively.[3,4]

Structurally, dentin is composed of hydroxyapatite mineral and organic components.[5] Formed by the odontoblasts during tooth development, dentin is uniquely differentiated from other mineralized tissues in the body because it contains thousands of tubules which run perpendicular to the pulp chamber. The tubules are formed as the odontoblasts migrate away from the dentin-enamel junction during dentin formation. The tubule contains not only the odontoblastic process, but also fluid surrounding the process.[6]

The dentin is normally covered by enamel or cementum. As teeth erupt into the oral cavity, the gingival margin seals the teeth leaving the coronal portion exposed in the oral cavity, and the root portion of the tooth protected from the external environment. To be hypersensitive, dentin must be exposed and the exposed tubules must be open and patent to the pulp.[1,7] The processes of exposure and opening are complex and multifactorial. Nonetheless, current evidence[1,7-9] suggests that gingival recession, resulting from abrasion or periodontal disease, is the primary route through which the underlying dentin becomes exposed, and acid erosion is an important factor in opening exposed dentin tubules (Fig. 1). Once a patient has dentin hypersensitivity, any external stimulus, such as physical pressure or air movement, can cause discomfort for the patient. The external stimulus is usually transitory, and the discomfort is typically present when the stimulus is present and subsides shortly thereafter.

The hydrodynamic theory is now accepted by the dental community as the mechanism by which dentin hypersensitivity occurs.[1,7] The theory suggests that an external stimulus triggers a pressure change in the dentin fluid. As a consequence, fluid movement transmits a signal to the odontoblast process, thereby carrying the stimulus from the tooth surface toward the afferent nerve ending in the dentin tubule, resulting in pain.[10] It is, therefore, understandable that the pain caused by this change is transient – once the stimulus is removed or dissipates, the pressure within the tubule returns to normal and the pain subsides.

Sensitivity triggers and behavioral considerations

Some patients suffer from chronic sensitivity every time their teeth are exposed to specific stimuli. Others experience intermittent, unpredictable discomfort that can be difficult to pinpoint. One or more stimuli, such as tactile, osmotic (sweet), thermal (particularly cold) or evaporative (air movement), can initiate a painful response. Certain clinical activities initiate or heighten dentin hypersensitivity. These include routine examination with a metal explorer, drying the tooth with compressed air, hand scaling a root surface and water temperature changes from the air/water syringe or a power scaler.

Patients who have long-standing, unresolved sensitivity often exhibit a variety of behavioral or postural clues. Behaviors include avoiding needed treatment, insisting on anesthesia for simple procedures, reluctance to schedule a procedure or a vague concern about discomfort. Postural clues include tense facial muscles, rigid torso, clenched hands, crossed arms or awkward head position.

Undiagnosed or untreated dentin hypersensitivity can create barriers to effective dental visits. Patients want to be free from pain and discomfort, but may find it difficult to describe specific clinical symptoms. Clinicians who appear indifferent to vague symptoms, or who do not take the time to establish a dialogue, may miss valuable diagnostic clues. It is important to be empathetic and establish trust. When a dental professional is truly concerned about comfort, patients will be willing to participate in a dialogue that results in effective diagnosis and treatment.

Identifying dentin hypersensitivity and understanding risk factors

Some patients can describe the exact location or the specific trigger that initiates an episode of dentin hypersensitivity. Others, who have lived with untreated sensitivity for years, may think that sensitivity or pain is normal, especially during a dental appointment. Rather than dismiss or devalue a patient's sensitivity, a series of simple questions about the trigger stimulus, frequency, duration, location and type of discomfort can help guide the diagnosis.

As discussed previously, dentin hypersensitivity can have multiple etiologies. A thorough review of the medical and so-
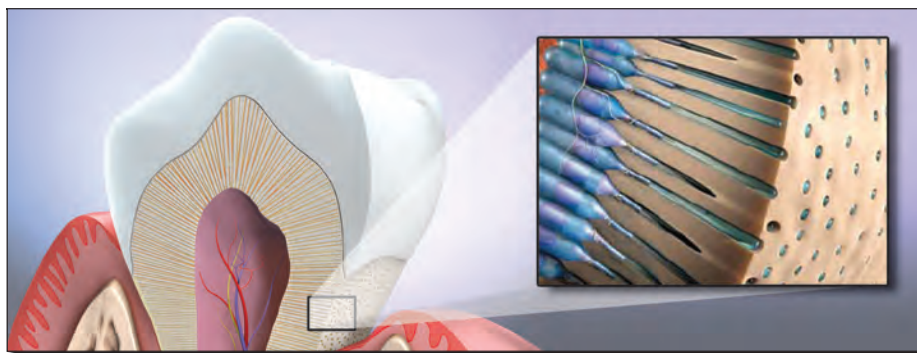
Fig. 1. Hypersensitivity occurs when dentin becomes exposed and tubules are open at the dentin surface. Pain triggers—like cold, heat, air or pressure, reach the intradental nerves through these open dentin tubules.

cial history, lifestyle, medications and supplements, dietary habits and oral hygiene self care is necessary. In addition, it is important to rule out caries, occlusal trauma, defective restorations, fractured teeth, pulpal pathology or gingival discomfort.[1,3]

Saliva can play a critical role in naturally reducing dentin hypersensitivity. Saliva supplies calcium and phosphate, which can enter open dentin tubules and, over time, block the tubules from external stimuli.[11] Insufficient saliva, known as hypo-salivation, is a risk factor for dental caries and tooth demineralization and so, by this means, it may exacerbate dentin hypersensitivity. Dry mouth or xerostomia, a patient's perception of hyposalivation, is a side effect of over 500 prescription and OTC medications. Medical conditions like diabetes, certain autoimmune disorders or a history of radiation treatment in the oral cavity all contribute to xerostomia. Mouth breathing from nasal allergies or obstructive sleep apnea, recreational and illicit drugs, smoking, hormone imbalances and stress all can contribute to dry mouth.

Consumption of both carbonated and non-carbonated soft drinks, sports and energy drinks, bottled teas and juices can promote demineralization and, thereby, may contribute to dentin hypersensitivity.[12] Beverages, sweetened with either sugar or high fructose corn syrup, offer substrate to acidogenic bacteria to initiate the caries process leading to demineralization, while acids used for flavoring and carbonation in these beverages have high erosive potential that can lead to enamel and dentin surface softening and loss of tooth and/or root mineral.[12] Super-sized drinks, prolonged exposure from sipping, ingesting acidic foods or confections and medical conditions that result in nausea and vomiting all may contribute to erosion of tooth and or/root surfaces.

Treatment and prevention methods

Treatment and prevention of dentin hypersensitivity has focused on eliminating the ability of external stimuli to trigger discomfort. This has resulted in the development of two major classes of products – those which occlude dentin tubules and those which interfere with transmission of nerve impulses.

Occluding agents act by physically blocking open, exposed dentin tubules, thereby preventing external stimuli from triggering the movement of dentin fluid and the perception of pain.[7,13] These agents are available in products that can be applied professionally in the dental office, and in "everyday" products that can be used by the patient at home. High concentration fluoride products have been shown to have a positive effect in occluding dentin tubules and providing sensitivity relief. These include fluoride varnish (22,500 ppm fluoride) and prescription level fluoride toothpastes and gels (5000 ppm fluoride).[12,14,15] Fluoride varnish is professionally applied in-office to the areas where dentin is exposed, providing relief of dentin hypersensitivity. The high concentration fluoride pastes and gels may be used in a custom fitted tray worn for a period of time each day by the patient at home, or during regular tooth brushing. These high fluoride home use products usually require continued use before dentin hypersensitivity relief is achieved.

The second approach recommended by dental professionals to help treat dentin hypersensitivity is to interrupt the neural response to pain stimuli.[7,16] Potassium salts are well known nerve "numbing" agents; potassium nitrate delivered in a dentifrice that is applied daily by the patient during regular tooth brushing being the most common. Potassium ions enter the tubule and build up in the dentin fluid, where they have a depolarizing effect on electrical nerve conduction, causing nerve fibers to be less excitable to the stimuli, thereby reducing the patient's sensation of pain.[17] Most products require continued use over a 4- to 8-week period before significant relief may be realized by the patient.[7,16]

For those patients who do not positively respond to the use of occluding agents or nerve desensitizing agents, the dental professional may turn to more permanent measures, such as direct or indirect restorations. These restorations effectively cover the exposed dentin and block the effects of any external stimuli that could cause dentin hypersensitivity. Finally, periodontal surgery, involving the grafting of gingival tissue to cover the exposed dentin may be performed.

Research to evaluate the clinical effects of therapy on dentin hypersensitivity has relied primarily on two methods of stimulating a pain response; these are the tactile and the evaporative or "air blast" methods.[18-20] The method most commonly used to create a standardized tactile stimulus is the Yeaple probe. This device employs a solenoid system to control the force of the probe, typically between 10-50 grams of force, when it is applied to the exposed dentin. The probe is first set at 10 grams and is dragged across the exposed dentin to elicit a pain response. The force is then increased in 10 gram increments each time following the same probing procedure until the patient reports a sensation of discomfort, or 50 grams of force is reached. The force at which discomfort occurs, or 50

grams, is recorded by the examiner. This is a very sensitive and highly reproducible measurement technique in the hands of those who have been calibrated and have experience with the device.

The air blast measurement is a very simple technique to measure dentin hypersensitivity.[20] The tooth which is sensitive is isolated and a blast of air (approximately 40 psi) is applied to the exposed dentin surface. The response of the subject to the air blast stimulus is assigned using an analog scale, such as the commonly used "Schiff" scale. A value of 0 on the Schiff scale records that the subject did not respond to the stimulus; 1 records that the subject responded; 2 records that the subject responded and requested discontinuation; and 3 records that the subject responded, requested discontinuation and considered the stimulus to be painful.[20]

Use of a novel occlusion technology based upon 8% arginine and calcium carbonate to treat dentin hypersensitivity

Although some of the traditional methods of treating dentin hypersensitivity have been clinically evaluated and found to provide some relief to patients, dental professionals continue to look for more effective, faster acting and longer lasting treatments, because in-office treatments and home use products do not always provide the end results desired. In 2002, Kleinberg *et al*[11] at the State University of New York – Stony Brook, reported the development of a new anti-sensitivity technology based on their understanding of the role that saliva plays in naturally reducing dentin hypersensitivity. The essential components of this new technology are arginine, an amino acid which is positively charged at physiological pH, *i.e.,* pH 6.5-7.5, bicarbonate, a pH buffer, and calcium carbonate, a source of calcium. This technology, called Pro-Argin,[a] has been shown to physically plug and seal exposed dentin tubules and to effectively relieve dentin hypersensitivity.[11] An in-office product based on this technology (ProClude[a]) was marketed in the United States for the management of tooth sensitivity during professionally administered prophylaxis treatment. The technology has also been incorporated into toothpaste (DenClude[a]) for use at home following professional treatment. In 2007, the Colgate-Palmolive Company acquired the rights to the technology and in early 2009, re-launched ProClude as Colgate Sensitive Pro-Relief[b] in-office desensitizing paste (Fig. 2). The dental professional uses the product by applying the product to the teeth exhibiting sensitivity using a prophylaxis cup on a prophy angle. The product should be applied using low speed and a moderate amount of pressure, in essence burnishing the material into the exposed tubules.

In early studies, Kleinberg, *et al*[11] demonstrated that application of the arginine-calcium carbonate in office desensitizing paste to teeth exhibiting sensitivity following a dental prophylaxis resulted in instant relief from discomfort and that relief lasted for 28 days after a single application. Wolff *et al*[21] reported a 71.7% reduction in sensitivity measured by air blast and 84.2% reduction by the "scratch" test immediately following product application.

Recently, two new clinical studies[22,23] have been conducted on the arginine–calcium carbonate in office desensitizing paste by the Colgate-Palmolive Company. In both studies, the

Fig. 2. Colgate Sensitive Pro-Relief Desensitizing Paste.

arginine-calcium carbonate desensitizing paste was compared to a pumice-based prophylaxis paste as a control. An additional study[24] regarding. the effect of the arginine-calcium carbonate paste on surface roughness of human dental enamel and several dental materials, including amalgam, composite, gold and ceramic, revealed that there was no significant effect on the surface texture. The results of these new studies are reported in detail in the accompanying papers of this special issue and are briefly summarized below.

In one study, Schiff *et al*[22] applied the test products, following scaling, as the final polishing step of the dental prophylaxis. Immediately following product application and 4 weeks later, subjects assigned to the arginine-calcium carbonate paste group exhibited statistically significant improvements from baseline with respect to baseline-adjusted mean air blast (44.1% and 45.9% respectively) and mean tactile hypersensitivity scores (156.2% and 170.3% respectively). At the same time points, subjects assigned to the control paste group exhibited statistically significant improvements from baseline with respect to baseline-adjusted mean air blast (15.1% and 8.9% respectively) and mean tactile hypersensitivity scores (43.1% and 8.3% respectively). Importantly, immediately following application and 4 weeks later, the arginine-calcium carbonate paste group demonstrated statistically significant reductions in dentin hypersensitivity with respect to baseline-adjusted mean air blast (34.1% and 40.6% respectively) and mean tactile hypersensitivity scores (79.0% and 149.6% respectively), compared to the control paste group. No statistically significant differences were exhibited between paste groups at the post-scaling and 12-week examinations with respect to baseline-adjusted mean tactile and air blast hypersensitivity scores.

In another study, Hamlin *et al*[23] applied the products prior to a professional dental cleaning procedure and sensitivity measurements were made immediately thereafter. Subjects assigned to the arginine-calcium carbonate paste group exhibited statistically significant improvements from baseline with respect to baseline-adjusted mean tactile (132.1%) and air blast hypersensitivity scores (48.6%). Additionally, subjects assigned to the control group exhibited a statistically significant hypersensitivity improvement from baseline with respect to baseline-adjusted mean air blast hypersensitivity scores (13.9%). The hypersensitivity improvement from baseline indicated for the control group for mean tactile hypersensitivity scores (21.7%) was not statistically significant. Importantly, statistically significant differences were indicated between the arginine-calcium carbonate paste group and the control group

with respect to baseline-adjusted mean tactile (110.0%) and air blast hypersensitivity scores (41.9%).

Several state-of-the art imaging methods have been used to elucidate aspects of mechanism of action of the arginine-calcium carbonate technology *in vitro*. Confocal laser scanning microscopy (CLSM) studies[7,25] have demonstrated that the arginine-calcium carbonate desensitizing paste is highly effective in occluding open dentin tubules. No dentin occlusion was observed with control pastes; one containing calcium carbonate alone, the other containing arginine and an alternative calcium abrasive, dicalcium phosphate dihydrate (Dical). Additionally, CLSM studies have shown that the occlusion achieved is resistant to acid challenge.

High resolution scanning electron microscopy (SEM) images have confirmed that the arginine-calcium carbonate desensitizing paste provides complete occlusion of open dentin tubules and freeze fracture images have shown that the plug reaches a depth of 2 μm into the tubule. Chemical mapping of the occluded surfaces using energy dispersive x-ray (EDX) has shown that the material on the dentin surface and occluded within the dentin tubules primarily consists of calcium and phosphate. Studies using electron spectroscopy for chemical analysis (ESCA) have provided quantitative data which have confirmed these observations and, in addition, have identified the presence of carbonate.[7,25]

Atomic force microscopy (AFM) has been used to further substantiate the blocking mechanism. Images of untreated specimens showed the helical fine structure of the inter-tubular dentin, as well as tubules that were completely open. Images of specimens treated with the desensitizing prophylaxis paste showed that the helical structure on the dentin surface was no longer visible, as a result of surface coating, and the tubules were sealed shut.[7,25]

Together, these results have clearly demonstrated that the arginine-calcium carbonate desensitizing paste reduces dentin hypersensitivity by sealing and plugging dentin tubules.[7,25]

CLINICAL USE OF THE ARGININE-CALCIUM CARBONATE DESENSITIZING PASTE

Dentin hypersensitivity – Clinical implications

Clinicians encounter patients with dentin hypersensitivity on a regular basis. While every patient is different, dentin hypersensitivity is a symptom of altered tooth structure. Chemical erosion, traumatic abrasion, attrition from wear, loss of attached gingival tissue from periodontal disease or surgical intervention and damage related to occlusal trauma can all lead to an exposed root surface and episodes of dentin hypersensitivity.

Prior to initiating treatment, it is important to determine which patients are at risk for dentin hypersensitivity and may benefit from the arginine-calcium carbonate desensitizing therapy. Treatment with the arginine-calcium carbonate desensitizing paste in the clinical setting is simple and highly effective.

Identifying patients who might benefit from desensitizing therapy

Professional application of the arginine-calcium carbonate desensitizing paste has proven to be an effective method for treating dentin hypersensitivity in the clinical setting. Several different clinical scenarios can be anticipated where patients may benefit from treatment with arginine-calcium carbonate desensitizing paste. The most common scenario arises with patients who experience dentin hypersensitivity during a routine dental hygiene visit. This type of patient typically experiences tactile sensitivity from hand or ultrasonic scaling and may also experience thermal sensitivity associated with the temperature of the ultrasonic fluid irrigant or rinsing. Air-drying during the initial or final examination process can also initiate sensitivity. Another scenario arises with patients undergoing specialized treatment procedures, such as periodontal scaling and root planing, which could result in dentin hypersensitivity following the procedure, after the anesthesia wears off.

Clinical application of the arginine-calcium carbonate desensitizing paste

Treatment with the arginine-calcium carbonate desensitizing paste is simple. The paste is gentle to gingival tissues, does not elicit pain when applied and has a pleasant mint flavor. The dental professional applies a small amount of paste to sensitive tooth surfaces by burnishing it in with a slowly rotating soft prophy cup. Paste can also be applied to accessible spots by massaging thoroughly with a cotton-tipped applicator and to furcations and other hard-to-reach areas with a microbrush. The dental professional should carefully burnish the arginine-calcium carbonate desensitizing paste into all sensitive areas, focusing on the CEJ and exposed cementum and dentin. Avoid rinsing immediately after application to enhance clinical efficacy.

It is important to note that this arginine-calcium carbonate desensitizing paste is formulated to treat dentin hypersensitivity. It will not provide symptomatic relief for other conditions, such as fractured teeth, caries or occlusal trauma, which will need to be diagnosed and treated by the dental professional by other means.

Long-term management of dentin hypersensitivity

Treatment of dentin hypersensitivity with a product, such as the arginine-calcium carbonate desensitizing paste, is only one aspect of the management of dentin hypersensitivity. Effective plaque control, dietary modifications and strategies to enhance salivary flow, improve buffering capacity and increase salivary pH may each be important in achieving lasting comfort. Controlling dentin hypersensitivity is an ongoing challenge that requires patient cooperation and participation.

Dentin hypersensitivity is a quality of life issue. Left untreated, patients may suffer needlessly and risk further deterioration of valuable tooth structure. Dental professionals who focus on customizing the dental experience, and provide effective treatment for dentin hypersensitivity to sufferers, develop strong patient relationships that lead to higher patient satisfaction, more referrals, increased case acceptance and fewer cancellations or missed appointments. Taking better care of patients with dentin hypersensitivity using clinically proven, effective, state-of-the art treatment products is both appropriate and responsible.

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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

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ABSTRACT: Purpose: To determine the efficacy of an in-office desensitizing paste containing 8% arginine and calcium carbonate relative to that of a commercially-available pumice prophylaxis paste in reducing dentin hypersensitivity instantly after a single application following a dental scaling procedure and to establish the duration of sensitivity relief over a period of 4 weeks and 12 weeks. **Methods:** This was a single-center, parallel group, double-blind, stratified clinical study conducted in San Francisco, California, USA. Qualifying adult male and female subjects who presented two hypersensitive teeth with a tactile hypersensitivity score (Yeaple Probe) between 10-50 grams of force and an air blast hypersensitivity score of 2 or 3 (Schiff Cold Air Sensitivity Scale) were stratified according to their baseline hypersensitivity scores and randomly assigned within strata to one of two treatment groups: (1) A Test Paste, a desensitizing paste containing 8% arginine and calcium carbonate (Colgate-Palmolive Co); and (2) A Control Paste, Nupro pumice prophylaxis paste (Dentsply Professional). Subjects received a professionally-administered scaling procedure, after which they were re-examined for tactile and air blast dentin hypersensitivity (Post-Scaling Examinations). The assigned pastes were then applied as the final step to the professional dental cleaning procedure. Tactile and air blast dentin hypersensitivity examinations were again performed immediately after paste application. Subjects were provided with a commercially-available non-desensitizing dentifrice containing 0.243% sodium fluoride (Crest Cavity Protection, Procter & Gamble Co.) and an adult soft-bristled toothbrush and were instructed to brush their teeth for 1 minute, twice daily at home using only the toothbrush and dentifrice provided, for the next 12 weeks. Subjects returned to the testing facility 4 and 12 weeks after the single application of Test or Control paste, having refrained from all oral hygiene procedures and chewing gum for 8 hours and from eating and drinking for 4 hours, prior to each follow-up visit. Assessments of tactile and air blast hypersensitivity, and examinations of oral soft and hard tissue were repeated at these 4- and 12-week examinations. **Results:** 68 subjects completed the 12-week study. No statistically significant differences from baseline scores were indicated at the Post-Scaling Examinations for either the Test Paste or Control Paste groups. Immediately following product application and 4 weeks after product application, subjects assigned to the Test Paste group exhibited statistically significant improvements from baseline with respect to baseline-adjusted mean air blast (44.1% and 45.9% respectively) and mean tactile hypersensitivity scores (156.2% and 170.3% respectively). At the same time points, subjects assigned to the Control Paste group exhibited statistically significant improvements from baseline with respect to baseline-adjusted mean air blast (15.1% and 8.9% respectively) and mean tactile hypersensitivity scores (43.1% and 8.3% respectively). Immediately following application of the assigned paste and 4 weeks later, the Test Paste group demonstrated statistically significant reductions in dentin hypersensitivity with respect to baseline-adjusted mean air blast (34.1% and 40.6% respectively) and mean tactile hypersensitivity scores (79.0% and 149.6% respectively), compared to the Control Paste group. No statistically significant differences were exhibited between paste groups at the Post-Scaling and 12-week examinations with respect to mean tactile and baseline-adjusted mean air blast hypersensitivity scores. (*Am J Dent* 2009;22 Sp Is A:8A-15A).

CLINICAL SIGNIFICANCE: The results of this double-blind clinical study support the conclusions that (1) the test paste, an in-office desensitizing paste containing 8% arginine and calcium carbonate, provides a statistically significant reduction in dentin hypersensitivity immediately after a single professional application of the product, which is sustained over a period of 28 days; (2) A single professional application of the test paste provided an instant and lasting level of control of dentin hypersensitivity that is statistically significantly better than that of the control paste, Nupro pumice prophylaxis paste.

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Introduction

Dentin hypersensitivity is an uncomfortable and unpleasant condition that affects up to 57% of patients within a dental practice setting.[1,2] It has been defined as pain arising from exposed dentin, typically in response to external stimuli such as thermal, tactile, osmotic or chemical, that cannot be explained by any other form of dental defect or pathology.[1] For some patients the discomfort of dentin hypersensitivity may represent a minor inconvenience, but to others it can be a very disturbing condition that provokes chronic discomfort and emotional distress.[3] Fearing stimulation of hypersensitive areas, dentin hypersensitivity sufferers tend to modify their behaviors by eliminating certain foods and drinks from their regular diets, by being non-compliant with specific home-care recommendations from their oral care providers, and/or by cancelling appointments for dental care. Discomfort experienced during normal home hygiene regimens is commonly associated with dentin hypersensitivity and may result in the inability to maintain adequate levels of plaque control. As toothbrushing becomes

more difficult, accumulation of dental plaque may increase the risk for caries formation, gingival inflammation and further periodontal problems.[4] Dental professionals recognize dentin hypersensitivity as a problem of growing magnitude in their practices and feel confident about diagnosing the condition. Nonetheless, effective management of hypersensitivity poses challenges to dental professionals.[2] A desired goal for professional treatment of dentin hypersensitivity would be the immediate and lasting relief of discomfort after a single in-office product application, whether used as a stand-alone treatment or as an adjunct to another dental procedure. If this could be readily accomplished, patients would become increasingly compliant to in-office visits for preventive, periodontal or restorative oral health care and for cosmetic procedures, such as tooth whitening, as well as to at-home maintenance programs.

The two most common pathways that lead to dentin exposure and dentin hypersensitivity are gingival recession and enamel erosion. Gingival recession is considered the major predisposing factor for the condition.[1,5,6] When gingival tissue recedes, the cementum layer is easily removed by physical and/or chemical forces, leading to the exposure of the underlying dentin. Patients may induce gingival recession and subsequent dentin exposure through the practice of incorrect oral hygiene techniques or by parafunctional habits.[5,7] The consumption of erosive dietary foods and drinks, common in today's diet, is believed to contribute to loss of enamel and exposure of underlying dentin, which can also lead to dentin hypersensitivity.[8,9] In addition, dental professionals may contribute to dentin exposure by instrumentation of the root surfaces during scaling procedures.[5] A systematic review reported that root sensitivity occurs in approximately half of patients following scaling and root planing.[10]

Regardless of the etiology of dentin exposure, a common feature of hypersensitive dentin is the presence of open dentin tubules which provide a direct link between the external environment and the pulp of the tooth. The most widely accepted theory for dentin hypersensitivity is the hydrodynamic theory proposed by Brännström,[11] who suggested that pain may result from the movement of the dentin fluid in the tubules provoked by external stimuli, such as temperature, physical or osmotic changes which, in turn, trigger nerve fibers within the pulp. Products for the management of dentin hypersensitivity typically aim to control the hydrodynamic mechanisms of pain. Approaches to control the condition fall into two broad categories: agents or products that reduce fluid flow within the dentin tubules by occluding the tubules themselves, thereby blocking the stimuli, and those that interrupt the neural response to stimuli.

While a variety of products and methods for home use and professional treatment of dentin hypersensitivity are available, not many have undergone extensive clinical evaluation and others have shown equivocal efficacy.[12,13] Many clinicians recommend daily at-home use of desensitizing toothpastes, as the first-line of treatment for their patients, before using professional in-office products and procedures, such as the application of varnishes or precipitants, or prescribing toothpastes and mouth rinses with high fluoride levels. More aggressive measures like the placement of restorative materials

for the control of dentin hypersensitivity are usually considered as treatment options of last resort.[14] The majority of desensitizing toothpastes contain a potassium salt which is believed to work by penetrating the length of the dentin tubule and depolarizing the nerve, interrupting the neural response to pain stimuli. Potassium-based toothpastes usually take at least 2 weeks of twice daily use to show measurable reductions in hypersensitivity[15] and longer periods, generally 8 weeks or more, to demonstrate its maximum effectiveness and achieve levels of pain relief that are sustainable for as long as daily use of the desensitizing toothpaste is continued.[16]

It is important to note that saliva plays a role in naturally reducing dentin hypersensitivity by supplying and carrying calcium and phosphate ions into open dentin tubules to gradually bring about tubule blocking and by forming a surface protective layer consisting of precipitable aggregates of the combination of salivary glycoproteins with calcium phosphate.[17] A recent review of biological approaches to therapy proposed that the ideal dentin hypersensitivity treatment should mimic natural desensitizing processes leading to spontaneous occlusion of open dentin tubules.[12] A novel dentin hypersensitivity treatment technology, consisting of 8% arginine, an amino acid found in saliva, in combination with calcium carbonate, is now available as a desensitizing paste for in-office application. This desensitizing technology mimics saliva's natural process of plugging and sealing open dentin tubules. When this product is applied to exposed dentin, the open dentin tubules are sealed with a plug that contains arginine, calcium, phosphate and carbonate. This plug, which is resistant to normal pulpal pressures and to acid challenge, effectively reduces dentin flow and, thereby, reduces hypersensitivity.[18,19]

The objective of this controlled and randomized clinical study, conducted in a group of patients with known dentin hypersensitivity, was to determine the efficacy in reducing dentin hypersensitivity of a desensitizing paste containing 8% arginine and calcium carbonate, instantly after application as a single in-office treatment following a dental scaling procedure, as compared to a commercial prophylaxis paste. A second objective was to establish the duration of sensitivity relief over a period of 4 and 12 weeks.

Material and Methods

This double-blind, stratified, two-treatment, parallel-group design clinical study conducted in San Francisco, California, evaluated the clinical efficacy of two fluoride free pastes on dentin hypersensitivity relief instantly after a single professional application of the product and 4 and 12 weeks later. The products were: (1) a test paste, a desensitizing paste containing 8% arginine and calcium carbonate,[a] and (2) a control paste, Nupro[b] pumice prophylaxis paste.

Inclusion criteria - Eligible study subjects had to be between the ages of 18-70 (inclusive), and in good general health. They were required to possess a minimum of two hypersensitive teeth which demonstrated cervical erosion/abrasion or gingival recession and had a tactile hypersensitivity stimuli score of 10-50 grams of force (Yeaple Probe[c]) and an air blast hypersensitivity stimuli score of 2 or 3 (Schiff Cold Air Sensitivity Scale). Subjects were required to be available for the 12-week duration of the study and to sign an informed consent form.

Exclusion criteria - Individuals were excluded from the study if they had gross oral pathology, chronic disease, advanced periodontal disease, treatment for periodontal disease (within the last 12 months), or hypersensitive teeth with a mobility greater than one. Subjects with teeth that had extensive/defective restorations (including prosthetic crowns), suspected pulpitis, caries, or cracked enamel, or that were used as abutments for removable partial dentures, were also excluded from the study. Current users of anticonvulsants, antihistamines, antidepressants, sedatives, tranquilizers, anti-inflammatory drugs or daily analgesics were excluded. Pregnant or lactating women, individuals who were participating in any other clinical study or who had participated in a desensitizing dentifrice study or who had used a desensitizing dentifrice within the last 3 months were excluded. Subjects with a history of allergy to the test products, or allergies to oral care/personal care consumer products or their ingredients, or subjects with existing medical conditions, which precluded them from not eating and drinking for periods up to 4 hours, were also excluded from the study.

Clinical procedure - Prospective study subjects reported to the clinical facility having refrained from all oral hygiene procedures and chewing gum for 8 hours and having refrained from eating and drinking for 4 hours prior to their examination. All prospective subjects who met the inclusion/exclusion criteria and signed an informed consent form received a baseline tactile hypersensitivity evaluation and an air blast hypersensitivity evaluation, along with an oral soft and hard tissue assessment.

For each subject who qualified for participation in the study, two hypersensitive teeth that satisfied the tactile and air blast hypersensitivity enrollment criteria were identified for evaluation throughout the study. Qualifying subjects were stratified based on baseline tactile and air blast hypersensitivity scores and randomly assigned within strata to one of the two study treatments:
• Test: desensitizing paste containing 8% arginine and calcium carbonate
• Control: Nupro pumice prophylaxis paste

Study subjects received a professional scaling, after which they were re-examined for tactile and air blast dentin hypersensitivity. The assigned paste was then applied as the final polishing step to the professional cleaning procedure. Professional product application consisted of two consecutive 3-second applications of the paste using a rotating rubber cup. Throughout the study, both study examiner and study subjects remained blinded to product assignment. Tactile and air blast hypersensitivity examinations were repeated immediately after paste application. All subjects were then provided with a commercially-available non-desensitizing dentifrice containing 0.243% sodium fluoride (Crest Cavity Protection[d]) toothpaste, and an adult soft-bristled toothbrush for at-home use and were instructed to brush their teeth for 1 minute, twice daily, for the next 12 weeks. There were no restrictions regarding diet or smoking habits during the course of the study.

Subjects returned to the clinical facility 4 and 12 weeks after in-office test or control paste application, having refrained from all oral hygiene procedures and chewing gum for 8 hours and from eating and drinking for 4 hours, prior to each follow-up visit. Tactile and air blast hypersensitivity measurements were repeated and the oral soft and hard tissues were examined. Subjects were also interviewed with respect to the presence of adverse events and the use of concomitant medications.

Clinical scoring procedures

Tactile hypersensitivity - Tactile hypersensitivity was assessed by use of a calibrated Yeaple Model 200A Electronic Force Sensing Probe.[c] The application of pre-set forces (measured in grams) through the attached #19 explorer tip was employed.

Teeth were evaluated for tactile hypersensitivity[20,21] in the following manner:
• The subject was instructed to respond at the point where he/she first experienced discomfort.
• The explorer tip of the probe was applied to the buccal surface of each hypersensitive tooth at the cemento-enamel junction.
• The explorer tip was stroked perpendicular to the tooth beginning at a pre-set force of 10 grams and increased by 10 gram increments until the subject experienced discomfort, or until 50 grams of force was applied.

Scores for each subject were calculated by averaging the values measured on the two baseline-designated study teeth.

Air blast hypersensitivity - Teeth were evaluated for air blast hypersensitivity[22] in the following manner:
• Each hypersensitive tooth was isolated from the adjacent teeth (mesial and distal) by the placement of the examiner's fingers over the adjacent teeth.
• Air was delivered from a standard dental unit air syringe at 60 psi (± 5 psi) and 70°F (± 3°F). The air was directed at the exposed buccal surface of the hypersensitive tooth for 1 second from a distance of approximately 1 cm.
• The Schiff Cold Air Sensitivity Scale was used to assess subject response to this stimulus. This scale is scored as follows:

0 = Subject does not respond to air stimulus.
1 = Subject responds to air stimulus but does not request discontinuation of stimulus.
2 = Subject responds to air stimulus and requests discontinuation or moves from stimulus.
3 = Subject responds to air stimulus, considers stimulus to be painful, and requests discontinuation of the stimulus.

Scores for each subject were calculated by averaging the values obtained from the two baseline-designated study teeth.

Oral soft and hard tissue assessment - The dental examiner visually examined the oral cavity and peri-oral area using a dental light and dental mirror. This examination included an evaluation of the soft and hard palate, gingival mucosa, buccal mucosa, mucogingival fold areas, tongue, sublingual and submandibular areas, salivary glands, and the tonsilar and pharyngeal areas.

Adverse events - Adverse events were obtained from an interview with the subjects and from a dental examination by the investigator.

Statistical analysis - Statistical analyses were performed separately for the tactile and air blast hypersensitivity assessments. Comparisons of the treatment groups with respect to baseline tactile scores and air blast scores were performed

Table 1. Age and gender of subjects who completed the 12-week clinical study.

Treatment	Number of subjects			Age	
	Male	Female	Total	Mean	Range
Test paste[1]	13	19	32	36.7	25-51
Control paste[2]	21	15	36	35.2	24-56

[1] Desensitizing paste containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.

Table 2. Summary of the baseline tactile and air blast hypersensitivity mean scores for subjects who completed the 12-week clinical study.

Parameter	Treatment		Baseline summary (Mean ± S.D.)[3]
Tactile hypersensitivity	Test paste[1]	32	10.00 ± 0.00
	Control paste[2]	36	10.00 ± 0.00
Air blast hypersensitivity	Test paste	32	2.53 ± 0.46
	Control paste	36	2.39 ± 0.43

[1] Desensitizing paste containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.
[3] No statistically significant difference was indicated between the two treatment groups at baseline with respect to either tactile or air blast hypersensitivity.

Table 3. Summary of the post-scaling tactile hypersensitivity mean scores for subjects who completed the 12-week clinical study.

Treatment	n	Tactile scores (Mean ± S.D.)	Within-treatment analysis		Between-treatment comparison	
			Percent change[3]	Sig.[4]	Percent difference[5]	Sig.[6]
Test paste[1]	32	10.00 ± 0.00	0.00	NS	0.00	NS
Control paste[2]	36	10.00 ± 0.00	0.00	NS		

[1] Desensitizing paste containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.
[3] Percent change exhibited by the post-scaling mean relative to the baseline mean. A positive value indicates an improvement in tactile hypersensitivity at the post-scaling examination.
[4] Significance of paired *t*-test comparing the baseline and post-scaling examinations.
[5] Difference between post-scaling means expressed as a percentage of the post-cleaning mean for the Control paste. A positive value indicates an improvement in tactile hypersensitivity for the Test paste relative to the Control paste.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

Table 4. Summary of the baseline-adjusted post-scaling air blast hypersensitivity mean scores for subjects who completed the 12-week clinical study.

Treatment	n	Baseline-adjusted air-blast scores (Mean ± S.D.)	Within-treatment analysis		Between-treatment comparison	
			Percent change[3]	Sig.[4]	Percent difference[5]	Sig.[6]
Test paste[1]	32	2.46 ± 0.00	0.00	NS	0.0	NS
Control paste[2]	36	2.46 ± 0.00	0.00	NS		

[1] Desensitizing paste containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.
[3] Percent change exhibited by the baseline-adjusted post-cleaning mean relative to the baseline mean. A positive value indicates a reduction in air blast hypersensitivity at the post-scaling examination.
[4] Significance of paired *t*-test comparing the baseline and post-scaling examinations.
[5] Difference between baseline-adjusted post-scaling means expressed as a percentage of the baseline-adjusted post-scaling mean for the Control paste. A positive value indicates a reduction in air blast hypersensitivity for the Test paste relative to the Control paste.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

using an independent *t*-test. Within-treatment comparisons of the baseline *versus* follow-up tactile hypersensitivity and air blast hypersensitivity scores were performed using paired *t*-tests. Comparisons of the treatment groups with respect to baseline-adjusted tactile hypersensitivity and air blast hypersensitivity scores at the follow-up examinations were performed using analyses of covariance (ANCOVAs). All statistical tests of hypotheses were two-sided, and employed a level of significance of $\alpha = 0.05$.

Results

Sixty-eight subjects complied with the protocol and completed the 12-week study. The gender and age of the study population did not differ significantly with respect to either of these characteristics (Table 1). Throughout the study, no adverse effects on the oral soft or hard tissues of the oral cavity were observed by the examiner or reported by the subjects when questioned.

Baseline data

The mean tactile and air blast hypersensitivity scores measured at the baseline examination for those subjects who completed the clinical study are shown in Table 2.

The mean baseline score for tactile hypersensitivity was 10.00 for both test and control groups. For air blast hypersensitivity, the mean baseline scores were 2.53 for the test group and 2.39 for the control group. No statistically significant difference was indicated between the treatment groups with respect to either hypersensitivity score at baseline.

IMMEDIATE POST-SCALING DATA

Tactile hypersensitivity

The mean tactile hypersensitivity scores immediately after the professional scaling procedure (Post-Scaling Examinations)

Table 5. Summary of the post-application tactile hypersensitivity mean scores for subjects who completed the 12-week clinical study.

Treatment	n	Tactile scores (Mean ± S.D.)	Within-treatment analysis		Between-treatment comparison	
			Percent change[3]	Sig.[4]	Percent difference[5]	Sig.[6]
Test paste[1]	32	25.62 ± 5.22	156.2	P< 0.05	79.0	P< 0.05
Control paste[2]	36	14.31 ± 5.22	43.1	P< 0.05		

[1] Desensitizing paste containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.
[3] Percent change exhibited by the post-application mean relative to the baseline mean. A positive value indicates an improvement in tactile hypersensitivity at the post-application examination.
[4] Significance of paired *t*-test comparing the baseline and post-application examinations.
[5] Difference between post-application means expressed as a percentage of the post-application mean for the Control paste. A positive value indicates an improvement in tactile hypersensitivity for the Test paste relative to the Control paste.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

Table 6. Summary of the baseline-adjusted post-application air blast hypersensitivity mean scores for subjects who completed the 12-week clinical study.

Treatment	n	Baseline-adjusted air-blast scores (Mean ± S.D.)	Within-treatment analysis		Between-treatment comparison	
			Percent change[3]	Sig.[4]	Percent difference[5]	Sig.[6]
Test paste[1]	32	1.37 ± 0.55	44.1	P< 0.05	34.1	P< 0.05
Control paste[2]	36	2.08 ± 0.55	15.1	P< 0.05		

[1] Desensitizing paste containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.
[3] Percent change exhibited by the post-application mean relative to the baseline mean. A positive value indicates an improvement in air blast hypersensitivity at the post-application examination.
[4] Significance of paired *t*-test comparing the baseline and post-application examinations.
[5] Difference between post-application means expressed as a percentage of the post-application mean for the Control paste. A positive value indicates an improvement in air blast hypersensitivity for the Test paste relative to the Control paste.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

are shown in Table 3.

Comparisons versus baseline - The mean post-scaling examination tactile hypersensitivity scores were 10.00 for both test and control groups; there were no differences from baseline values and between treatment groups.

Air blast hypersensitivity

The mean baseline-adjusted air blast hypersensitivity scores immediately after the professional scaling procedure are shown in Table 4.

Comparisons versus baseline - The mean baseline-adjusted post-scaling examination air blast hypersensitivity scores were 2.46 for both test and control groups, no differences were observed from baseline values and between treatment groups.

INSTANT POST-APPLICATION DATA

Tactile hypersensitivity

The mean tactile hypersensitivity scores instantly after product application are shown in Table 5.

Comparisons versus baseline - The mean post-application tactile hypersensitivity scores were 25.62 for the test group and 14.31 for the control group. The percent changes from baseline were 156.2% for the test group and 43.1% for the control group; both were statistically significant.

Comparison between treatment groups - The test group ex-

hibited a statistically significant 79.0% improvement in tactile hypersensitivity scores when compared with the control group.

Air blast hypersensitivity

The mean baseline-adjusted air blast hypersensitivity scores immediately after product application are shown in Table 6.

Comparisons versus baseline - The mean baseline-adjusted post-application air blast hypersensitivity scores were 1.37 for the test group and 2.08 for the control group. The percent changes from baseline were 44.1% for the test group, and 15.1% for the control group, both of which were statistically significant.

Comparison between treatment groups - The test group exhibited a statistically significant 34.1% reduction in mean baseline-adjusted air blast hypersensitivity score when compared with the control group.

4-WEEK DATA

Tactile hypersensitivity

The mean tactile hypersensitivity scores measured 4 weeks after product application are presented in Table 7.

Comparisons versus baseline - The mean 4-week tactile hypersensitivity scores were 27.03 for the test group, and 10.83 for the control group. The percent changes from baseline were 170.3% for the test group and 8.3% for the control group, both of which were statistically significant.

Table 7. Summary of the 4-week tactile hypersensitivity mean scores for subjects who completed the 12-week clinical study.

Treatment	n	Tactile scores (Mean ± S.D.)	Within-treatment analysis		Between-treatment comparison	
			Percent change[3]	Sig.[4]	Percent difference[5]	Sig.[6]
Test paste[1]	32	27.03 ± 3.73	170.3	P< 0.05	149.6	P< 0.05
Control paste[2]	36	10.83 ± 3.73	8.3	P< 0.05		

[1] Colgate Sensitive ProRelief containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.
[3] Percent change exhibited by the 28-day mean relative to the baseline mean. A positive value indicates an improvement in tactile hypersensitivity at the 28-day examination.
[4] Significance of paired *t*-test comparing the baseline and 4-week examinations.
[5] Difference between 4-week means expressed as a percentage of the 28-day mean for the Control paste. A positive value indicates an improvement in tactile hypersensitivity for the Test paste relative to the Control paste.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

Table 8. Summary of the baseline-adjusted 4-week air blast hypersensitivity mean scores for subjects who completed the 12-week clinical study.

Treatment	n	Baseline-adjusted air-blast scores (Mean ± S.D.)	Within-treatment analysis		Between-treatment comparison	
			Percent change[3]	Sig.[4]	Percent difference[5]	Sig.[6]
Test paste[1]	32	1.33 ± 0.52	45.9	P< 0.05	40.6	P< 0.05
Control paste[2]	36	2.24 ± 0.52	8.9	P< 0.05		

[1] Desensitizing paste containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.
[3] Percent change exhibited by the 28-day baseline-adjusted mean relative to the baseline mean. A positive value indicates a reduction in air blast hypersensitivity at the 28-day examination.
[4] Significance of paired *t*-test comparing the baseline and 4-week examinations.
[5] Difference between 28-day baseline-adjusted means expressed as a percentage of the 4-week baseline-adjusted mean for the Control paste. A positive value indicates a reduction in air blast hypersensitivity for the Test paste relative to the Control paste.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

Comparison between treatment groups - The test group exhibited a statistically significant 149.6% reduction in tactile hypersensitivity scores relative to the control group.

Air blast hypersensitivity

The mean baseline-adjusted air blast hypersensitivity scores 4 weeks after product application are shown in Table 8.

Comparisons versus baseline - The mean baseline-adjusted 4-week air blast hypersensitivity scores were 1.33 for the test group, and 2.24 for the control group. The percent changes from baseline were 45.9% for the test group, and 8.9% for the control group, both of which were statistically significant.

Comparison between treatment groups - The test group exhibited a statistically significant 40.6% reduction in mean baseline-adjusted air blast hypersensitivity scores relative to the control group.

12-WEEK DATA

Tactile hypersensitivity

The mean tactile hypersensitivity scores measured 12 weeks after product application are shown in Table 9.

Comparisons versus baseline - The mean 12-week tactile hypersensitivity scores were 10.63 and 10.83 for the test and control groups respectively. The percent changes from baseline were 6.3% and 8.3% for the test and control groups respec-

tively. The control group was statistically significantly different from baseline.

Comparison between treatment groups - There were no statistically significant differences between the two groups with respect to tactile hypersensitivity scores after 12-weeks.

Air blast hypersensitivity

The mean baseline-adjusted air blast hypersensitivity scores are shown in Table 10.

Comparisons versus baseline - The mean baseline-adjusted 12-week air blast hypersensitivity scores were 2.73 for the test group, and 2.70 for the control group. The percent changes from baseline were (-11.0%) for the test group, and (-9.8%) for the control group; only the control group was statistically significantly different from baseline.

Comparison between treatment groups - There were no statistically significant differences indicated between the treatment groups with respect to mean baseline-adjusted air blast hypersensitivity scores.

Discussion

The prevalence of dentin hypersensitivity is likely to increase as the adult population lives longer and retains their teeth later in life,[23] and as populations of all age groups engage in lifestyles and behaviors that promote dentin exposure through

Table 9. Summary of the 12-week tactile hypersensitivity mean scores for subjects who completed the 12-week clinical study.

Treatment	n	Tactile scores (Mean ± S.D.)	Within-treatment analysis		Between-treatment comparison	
			Percent change[3]	Sig.[4]	Percent difference[5]	Sig.[6]
Test paste[1]	32	10.63 ± 2.11	6.3	NS	-1.85	NS
Control paste[2]	36	10.83 ± 1.89	8.3	P< 0.05		

[1] Desensitizing paste containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.
[3] Percent change exhibited by the 3-month mean relative to the baseline mean. A positive value indicates an improvement in tactile hypersensitivity at the 3-month examination.
[4] Significance of paired *t*-test comparing the baseline and 12-week examinations.
[5] Difference between 12-week means expressed as a percentage of the 3-month mean for the Control paste. A positive value indicates an improvement in tactile hypersensitivity for the Test paste relative to the Control paste.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

Table 10. Summary of the baseline-adjusted 12-week air blast hypersensitivity mean scores for subjects who completed the 12-week clinical study.

Treatment	n	Baseline-adjusted air-blast scores (Mean ± S.D.)	Within-treatment analysis		Between-treatment comparison	
			Percent change[3]	Sig.[4]	Percent difference[5]	Sig.[6]
Test paste[1]	32	2.73 ± 0.34	-11.0	N.S.	-1.1	P< 0.05
Control paste[2]	36	2.70 ± 0.34	-9.8	P< 0.05		

[1] Desensitizing paste containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.
[3] Percent change exhibited by the 3-month baseline-adjusted mean relative to the baseline mean. A positive value indicates a reduction in air blast hypersensitivity at the 3-month examination.
[4] Significance of paired *t*-test comparing the baseline and 12-week examinations.
[5] Difference between 12-week baseline-adjusted means expressed as a percentage of the 3-month baseline-adjusted mean for the Control paste. A positive value indicates a reduction in air blast hypersensitivity for the Test paste relative to the Control paste.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

through gingival recession or erosion of protective tooth surfaces.[8,9] Dentin hypersensitivity may be one of the most common painful conditions of the oral cavity, yet it is one of the least satisfactorily treated. A survey among oral care professionals reports that dental care providers feel confident about diagnosing dentin hypersensitivity, but not about treating it.[2] The development of a therapy that can provide both immediate relief following professional application and a lasting desensitizing effect for a significant time period after use would be of great assistance to clinicians in dealing with dentin hypersensitivity. The ability to provide improved oral comfort reinforces a clinician's credibility to their patients, leading to improved patient compliance with professional oral care recommendations and increased acceptance of recommendations to attend to their further oral care needs.

The 8% arginine/calcium carbonate in-office desensitizing paste contains a combination of arginine and calcium carbonate to mimic the natural process of plugging and sealing patent dentin tubules.[17,18] A range of state-of-the-art measurement techniques[18,19] have been used to establish the mechanism of action of this product: confocal laser scanning microscopy (CLSM) studies have demonstrated its effectiveness in occluding open dentin tubules, and that this occlusion is resistant to acid challenge; high resolution scanning electron microscopy (SEM) and atomic force microscopy (AFM) studies have confirmed tubule occlusion; electron spectroscopy for chemical analysis (ESCA) and energy dispersive x-ray (EDX) studies have shown that the occluded mineral contains calcium, phosphate and carbonate; hydraulic conductance experiments have shown that this occlusion blocks fluid movement to inhibit the hydrodynamic mechanism.

An adult population with history of dentin hypersensitivity was enrolled for participation in this study. Before dental scaling and paste application, hypersensitivity symptoms were successfully stimulated in all the teeth included in the trial and tactile and air blast scores were recorded as baseline hypersensitivity values. Dentin hypersensitivity was re-evaluated after the completion of the dental scaling procedure, immediately after paste application, and after 4- and 12-weeks. Relative to baseline, the scaling procedure performed on the hypersensitive surfaces of the study teeth had no significant effect on the level of dentin hypersensitivity. The significant reductions in dentin hypersensitivity demonstrated instantly after product application confirm the work conducted by Kleinberg *et al*,[17] developers of this arginine-based desensitizing technology. The parallel design, controlled study,[17] reported statistically significant reductions of 58.8% in air blast stimulated hypersensitivity and 64.6% in tactile stimulated hypersensitivity for arginine paste group following a single post-scaling application of the 8% arginine/calcium carbonate desensitizing paste, now marketed by Colgate-Palmolive. The same researchers subsequently conducted a monadic design

study to establish the duration of the hypersen-sitivity relief benefit and reported instant hypersensitivity improvements of 71.7% (air blast) and 84.2% (tactile) that were maintained for 28 days after a single application of product.

The results of this double-blind clinical study support the conclusions that:

(1) The test paste, an in-office desensitizing paste containing 8% arginine and calcium carbonate, provides a statistically significant reduction in dentin hypersensitivity instantly after a single professional application of the product and this reduction is maintained for a period of 28 days.

(2) A single professional application of the test product, an in-office desensitizing paste containing 8% arginine and calcium carbonate, provided instant and lasting relief of dentin hypersensitivity that is statistically significantly better than that of the control pumice prophylaxis paste.

a. Colgate-Palmolive Co., New York, NY, USA.
b. Dentsply Professional, York, PA, USA.
c. Yeaple Research of Pittsford, NY, USA.
d. Procter & Gamble Co., Cincinnati, OH, USA.

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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

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ABSTRACT: Purpose: To evaluate the clinical efficacy in reducing dentin hypersensitivity of a professional desensitizing paste containing 8% arginine and calcium carbonate relative to that of a commercially-available pumice prophylaxis paste when applied pre-procedurally to a professional dental cleaning (dental prophylaxis). Methods: This was a single-center, parallel group, double-blind, stratified clinical study, conducted in Langhorne, Pennsylvania. Adult male and female subjects who presented a tactile hypersensitivity score (Yeaple Probe) between 10 and 50 grams of force and an air blast hypersensitivity score of 2 or 3 (Schiff Cold Air Sensitivity Scale) were stratified according to their baseline hypersensitivity scores and randomly assigned within strata to one of two treatment groups. The two treatment groups were: (1) a Test paste, a desensitizing paste containing 8% arginine and calcium carbonate (Colgate-Palmolive Co.); and (2) a Control paste, Nupro pumice prophylaxis paste (Dentsply Professional). Subjects had their assigned paste applied immediately before receiving a professional dental cleaning procedure. After the completion of the dental cleaning procedure, tactile and air blast dentin hypersensitivity examinations were again performed following the same methodology employed for the baseline hypersensitivity examinations. Results: 45 subjects completed the study. At the final hypersensitivity examinations, conducted immediately after the completion of the dental cleaning procedure, subjects assigned to the test group exhibited statistically significant improvements from baseline with respect to baseline-adjusted mean tactile (132.1%) and air blast hypersensitivity scores (48.6%). Additionally, subjects assigned to the control group exhibited a statistically significant hypersensitivity improvement from baseline with respect to baseline-adjusted mean air blast hypersensitivity scores (13.9%). The hypersensitivity improvement from baseline indicated for the control group for mean tactile hypersensitivity scores (21.7%) was not statistically significant. At the final hypersensitivity examinations, statistically significant differences were indicated between the test group and the control group with respect to baseline-adjusted mean tactile (110.0%) and air blast hypersensitivity scores (41.9%). (Am J Dent 2009;22 Sp Is A:16A-20A).

CLINICAL SIGNIFICANCE: The results of this double-blind clinical study support the conclusions that (1) the test paste, a desensitizing paste containing 8% arginine and calcium carbonate, provides a statistically significant reduction in dentin hypersensitivity when applied as a single treatment before a professional dental cleaning procedure; and (2) the test paste, a desensitizing paste containing 8% arginine and calcium carbonate, provides a level of dentin hypersensitivity reduction that is statistically significantly better than that of the control paste, Nupro pumice prophylaxis paste, when applied as a single pre-procedural treatment to a professional dental cleaning procedure.

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Introduction

The impact of patients with sensitive teeth on a professional hygiene schedule is exhausting, rewarding, and frustrating, depending upon the day. The unpredictable nature of dentin hypersensitivity continues to challenge the dental professional team because a validated approach to consistently manage its manifestations has not been identified.

Dentin hypersensitivity associated with mechanical instrumentation, such as dental hygiene prophylaxis, is a well known and accepted, though not desired, reality for over half the patients of the typical practice.[1,2] A systematic review reported that root sensitivity occurs in approximately half of the patients following scaling and root planing.[3]

Dentin hypersensitivity directly affects professionals attempting to provide clinically acceptable care, while minimizing discomfort in their patients. The manifestation of dentin hypersensitivity in the majority of patients is typically a sharp painful response to external stimuli, such as thermal, tactile, osmotic or chemical stimuli, associated with specific areas of teeth where dentin is exposed.[4] Hypersensitivity provoking stimuli can be triggered by regular maintenance and restorative dental procedures.

The dental health impact of pain associated with dentin hypersensitivity on routine dental care is likely related to the degree of discomfort experienced by the patient.[5] Stimuli associated with dentin hypersensitivity are typically avoided by the average person, wherever possible. If professionals can reduce the experience of dentin hypersensitivity pain associated with recommended dental care, such as dental prophylaxis, it is likely that care will become routine, comfortable, stress reduced, and productive. Generally, the overall level of trust of the dental professional, acceptance of treatment, compliance, satisfaction and health outcomes, increasewhen fear

of pain is eliminated from dental procedures.[6]

While several products and methods for professional treatment of dentin hypersensitivity exist, many clinicians opt to recommend the daily at-home use of desensitizing toothpastes as the first-line of treatment for their patients. If and when these products fail to deliver desired level of relief, professional in-office products and procedures, such as the application of varnishes and precipitants, or prescription toothpastes and mouth rinses with high fluoride levels, are typically offered. More aggressive measures, such as the placement of restorative materials for the control of dentin hypersensitivity are usually considered as treatment options of last resort.[7]

Most desensitizing toothpastes contain a potassium salt which is thought to work by penetrating the length of the dentin tubule and depolarizing the nerve, interrupting the neural response to pain stimuli. Potassium-based toothpastes usually take at least 2 weeks of twice daily use to show measurable reductions in hypersensitivity[8] and longer periods, generally 8 weeks or more, to demonstrate its maximum effectiveness and achieve levels of pain relief that are sustainable for as long as daily use of the desensitizing toothpaste is continued.[9]

It is important to note that saliva plays a role in naturally reducing dentin hypersensitivity by supplying and carrying calcium and phosphate ions into open dentin tubules to gradually bring about tubule blocking and by forming a surface protective layer consisting of perceptible aggregates of the combination of salivary glycoproteins with calcium phosphate.[10] A recent review of biological approaches to therapy proposed that the ideal dentin hypersensitivity treatment should mimic natural desensitizing processes leading to spontaneous occlusion of open dentin tubules.[11]

A novel dentin hypersensitivity treatment technology consisting of a combination of arginine, an amino acid found in saliva, and calcium carbonate, mimics the natural process of plugging and sealing patent dentin tubules. When applied to exposed dentin, the open dentin tubules are sealed with a plug that contains arginine, calcium, phosphate and carbonate. This plug, which is resistant to normal pulpal pressures and to acid challenge, effectively reduces dentin flow and thereby reduces hypersensitivity.[12,13]

This controlled and randomized clinical study, evaluated the efficacy in reducing dentin hypersensitivity of an in-office desensitizing paste containing 8% arginine and calcium carbonate as compared to a prophylaxis paste control, when applied prior to a professional dental cleaning in a group of patients with known dentin hypersensitivity.

Materials and Methods

This clinical study employed a stratified, double-blind, two-treatment, parallel-groups design. Adult male and female subjects from the Langhorn, Pennsylvania area were enrolled in the study based upon the following criteria:

Subjects had to be between the ages of 18-70 (inclusive) and in generally good health. They were required to possess a minimum of two hypersensitive teeth which were anterior to the molars and demonstrated cervical erosion/abrasion or gingival recession, and for which a tactile hypersensitivity

stimuli score of 10-50 grams of force (Yeaple Probe, Model 200A Electronic Force Sensing Probe[a]) and an air blast stimuli score of 2 or 3 (Schiff Cold Air Sensitivity Scale) were presented at the baseline examination. Subjects were required to be available for the duration of the study, and to sign an informed consent form. Subjects were excluded from the study if they had gross oral pathology, chronic disease, advanced periodontal disease, treatment for periodontal disease (within the last 12 months), or hypersensitive teeth with a mobility greater than one. Subjects with teeth that had extensive/defective restorations (including prosthetic crowns), suspected pulpitis, caries, cracked enamel or that were used as abutments for removable partial dentures were also excluded from the study. Subjects were excluded from the study if they were current users of anticonvulsants, antihistamines, antidepressants, sedatives, tranquilizers, anti-inflammatory drugs or daily analgesics. Pregnant or lactating women, individuals who were participating in any other clinical study or who had participated in a desensitizing dentifrice study or who used a desensitizing dentifrice within the last 3 months, were not allowed to participate in the study. Subjects with a history of allergy to the test products, or allergies to oral care/personal care consumer products or their ingredients, or subjects with existing medical conditions, which precluded them from not eating and drinking for periods up to 4 hours, were also excluded from the study.

Prospective study subjects reported to the clinical facility having refrained from all oral hygiene procedures and chewing gum for 8 hours, and having refrained from eating and drinking for 4 hours prior to their baseline examination. All prospective subjects who met the inclusion/exclusion criteria and signed an informed consent form received a baseline tactile and air blast hypersensitivity evaluation along with an oral soft and hard tissue assessment.

For each subject who qualified for participation in the study, two hypersensitive teeth that satisfied the tactile and air blast hypersensitivity enrollment criteria were identified for evaluation throughout the study. Qualifying subjects were stratified based on baseline tactile and air blast hypersensitivity scores and randomly assigned within strata to one of the two study treatments:
• Test paste: Desensitizing paste containing 8% arginine and calcium carbonate[b].
• Control paste: Nupro[c] pumice prophylaxis paste.

Subjects had their assigned paste applied immediately before receiving professional dental cleaning. This pre-procedural application consisted of two 3-second applications of the product at the gingivo-facial third of the teeth using a disposable prophylaxis angle. The professional dental cleaning consisted of a scaling and tooth polishing using the control (prophylaxis) paste. Immediately after completion of the dental cleaning procedure, tactile and air blast dentin hypersensitivity examinations, as well as oral soft and hard tissue assessments, were performed by the same examiner and following the same methodology employed at the baseline examinations. Subjects were also interviewed with respect to the presence of adverse events.

Clinical scoring procedures

Tactile hypersensitivity - Tactile hypersensitivity was assessed by use of a calibrated Yeaple Probe[a] (Model 200A

Table 1. Age and gender of subjects who completed the clinical study.

Treatment	Number of subjects			Age	
	Male	Female	Total	Mean	Range
Test paste[1]	6	16	22	45.9	27-66
Control paste[2]	6	17	23	44.1	23-60

[1] Desensitizing paste containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.

Electronic Force Sensing Probe). The application of pre-set forces (measured in grams) through the attached #19 explorer tip was employed.

Teeth were evaluated for tactile hypersensitivity[14,15] in the following manner:

- The subject was instructed to respond at the point where he/she first experienced discomfort.
- The explorer tip of the probe was applied to the buccal surface of each hypersensitive tooth at the cemento-enamel junction.
- The explorer tip was stroked perpendicular to the tooth beginning at a pre-set force of 10 grams and increased by 10 gram increments until the subject experienced discomfort, or until 50 grams of force was applied.

Scores for each subject were calculated by averaging the values measured on the two baseline-designated study teeth.

Air blast hypersensitivity - Teeth were evaluated for air blast hypersensitivity[16] in the following manner:

- Each hypersensitive tooth was isolated from the adjacent teeth (mesial and distal) by the placement of the examiner's fingers over the adjacent teeth.
- Air was delivered from a standard dental unit air syringe at 60 psi (± 5 psi) and 70°F (± 3°F). The air was directed at the exposed buccal surface of the hypersensitive tooth for 1 second from a distance of approximately 1 cm.
- The Schiff Cold Air Sensitivity Scale was used to assess subject response to this stimulus. This scale is scored as follows:

0= Subject does not respond to air stimulus.
1= Subject responds to air stimulus but does not request discontinuation of stimulus.
2= Subject responds to air stimulus and requests discontinuation or moves from stimulus.
3= Subject responds to air stimulus, considers stimulus to be painful, and requests discontinuation of the stimulus.

Scores for each subject were calculated by averaging the values obtained from the two baseline-designated study teeth.

Oral soft and hard tissue assessment - The dental examiner visually examined the oral cavity and peri-oral area using a dental light and dental mirror. This examination included an evaluation of the soft and hard palate, gingival mucosa, buccal mucosa, mucogingival fold areas, tongue, sublingual and submandibular areas, salivary glands, and the tonsilar and pharyngeal areas.

Adverse events - Adverse events were obtained from an interview with the subjects and from a dental examination by the investigator.

Table 2. Summary of the baseline tactile and air blast hypersensitivity scores for subjects who completed the clinical study.

Parameter	Treatment		Baseline summary (Mean ± S.D.)[3]
Tactile hypersensitivity	Test paste[1]	22	18.18 ± 8.94
	Control paste[2]	23	16.52 ± 6.29
Air blast hypersensitivity	Test paste	22	2.45 ± 0.38
	Control paste	23	2.52 ± 0.35

[1] Desensitizing paste containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.
[3] No statistically significant difference was indicated between the two treatment groups at baseline with respect to either tactile or air blast hypersensitivity.

Statistical methods - Statistical analyses were performed separately for the tactile hypersensitivity assessments and air blast hypersensitivity assessments. Comparisons of the treatment groups with respect to baseline tactile scores and air blast scores were performed using an independent *t*-test. Within-treatment comparisons of the baseline *versus* final tactile sensitivity and air blast sensitivity scores were performed using paired *t*-tests. Comparisons of the treatment groups with respect to baseline-adjusted tactile hypersensitivity and air blast hypersensitivity scores at the follow-up examinations were performed using analyses of covariance (ANCOVAs). All statistical tests of hypotheses were two sided, and employed a level of significance of α= 0.05.

Results

Forty-five subjects complied with the protocol and completed the clinical study. The gender and age of the study population is presented in Table 1. The treatment groups did not differ significantly with respect to either of these characteristics. Throughout the study, there were no adverse effects on the oral soft or hard tissues of the oral cavity as observed by the examiner or reported by the subjects when questioned.

Baseline data - The mean baseline tactile and air blast hypersensitivity scores recorded before product application and the professional dental cleaning procedure are shown in Table 2.

The mean baseline tactile hypersensitivity scores were 18.18 for the test group and 16.52 for the control group. For air blast hypersensitivity, the mean baseline scores were 2.45 for the test group and 2.52 for the control group. No statistically significant differences were indicated between the treatment baseline tactile and air blast hypersensitivity scores.

POST-CLEANING (FINAL) EXAMINATION DATA

Tactile hypersensitivity

The baseline-adjusted mean tactile hypersensitivity scores recorded immediately after the completion of the professional dental cleaning procedure are shown in Table 3.

Comparisons versus baseline - The post-cleaning baseline-adjusted mean tactile hypersensitivity scores were 42.2 for the test group and 20.1 for the control group. The percent changes from baseline were 132.1% for the test group and 21.7% for the control group. The test group exhibited a statistically significant reduction from baseline; whereas the control group did not.

Table 3. Summary of the baseline-adjusted post-cleaning tactile hypersensitivity mean scores for subjects who completed the clinical study.

Baseline-adjusted tactile scores Treatment	n	(Mean ± S.D.)	Within-treatment analysis		Between-treatment comparison	
			Percent change[3]	Sig.[4]	Percent difference[5]	Sig.[6]
Test paste[1]	22	42.2 ± 9.25	132.1	$P < 0.05$	110.0%	$P < 0.05$
Control paste[2]	23	20.1 ± 9.25	21.7	NS		

[1] Desensitizing paste containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.
[3] Percent change exhibited by the baseline-adjusted post-cleaning mean relative to the baseline mean. A positive value indicates an improvement in tactile hypersensitivity at the final examination.
[4] Significance of paired *t*-test comparing the baseline and final examinations.
[5] Difference between baseline-adjusted post-cleaning means expressed as a percentage of the baseline-adjusted post-cleaning mean for the Control paste. A positive value indicates an improvement in tactile hypersensitivity for the Test paste relative to the Control paste.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

Table 4. Summary of the baseline-adjusted post-cleaning air blast hypersensitivity mean scores for subjects who completed the clinical study.

Baseline-adjusted air-blast scores Treatment	n	(Mean ± S.D.)	Within-treatment analysis		Between-treatment comparison	
			Percent change[3]	Sig.[4]	Percent difference[5]	Sig.[6]
Test paste[1]	22	1.26 ± 0.58	48.6	$P < 0.05$	41.9	$P < 0.05$
Control paste[2]	23	2.17 ± 0.58	13.9	$P < 0.05$		

[1] Desensitizing paste containing 8% arginine and calcium carbonate.
[2] Nupro pumice prophylaxis paste.
[3] Percent change exhibited by the baseline-adjusted post-cleaning mean relative to the baseline mean. A positive value indicates a reduction in air blast hypersensitivity at the final examination.
[4] Significance of paired *t*-test comparing the baseline and final examinations.
[5] Difference between baseline-adjusted post-cleaning means expressed as a percentage of the baseline-adjusted post-cleaning mean for the Control paste. A positive value indicates a reduction in air blast hypersensitivity for the Test paste relative to the Control paste.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

Comparison between treatment groups - The test group exhibited a statistically significant reduction of 110.0% in baseline-adjusted mean tactile hypersensitivity relative to the control group.

Air blast hypersensitivity

The baseline-adjusted mean air blast hypersensitivity scores recorded immediately after the completion of the professional dental cleaning procedure (final examinations) are shown in Table 4.

Comparisons versus baseline - The post-cleaning baseline-adjusted mean air blast hypersensitivity scores were 1.26 for the test group and 2.17 for the control group. The percent changes from baseline were 48.6% for the test group and 13.9% for the control group, both of which were statistically significant.

Comparison between treatment groups - The test group exhibited a statistically significant reduction of 41.9% in baseline-adjusted mean air blast hypersensitivity relative to the control group.

Discussion

The purpose of this study was to evaluate the efficacy of a novel in-office desensitizing product on acute dentin hypersensitivity in a real world population in a real world situation. The study results should allow the dental practitioner to reduce the negative impact of dental cleaning procedures on sensitivity patients by clinical adoption of the product tested and the technique of use.

The practice of modern dentistry continues to seek measures for pain reduction. Techniques or products that have been demonstrated by clinical research to reduce pain, and its associated anxiety, in our dental patient population certainly have a place chair side and deserve professional consideration of their potential impact on the overall outcome of care.

Experiences remembered by patients may influence their anticipation of discomfort during the next visit. Negative perceptions may make a patient hesitant about seeking further diagnostics and/or care.[17] Since we cannot accurately predict what stimuli or what patient pain response is likely to manifest in dentin hypersensitivity sufferers on any given day, from any given procedure, it would help if a non-anesthetic, non-analgesic approach could be routinely offered to all such patients in advance of treatment, such as to patients with dentin exposure prior to a dental prophylaxis procedure. As demonstrated in this study, the effective use of the test product requires less than 1 minute of time to apply, is very easy to use, and has the advantage of pre-treating suspected hypersensitive areas. The product, used as directed in dentin hypersensitivity patients, should allow far less coaching by the hygienist, reduced verbal and non-verbal pain responses by the patient, and better overall opinions about the office and its recommendations for further care.

The tested in-office arginine and calcium carbonate desensitizing paste mimics the natural process of plugging and sealing patent dentin tubules.[12] A range of state-of-the-art measurement techniques[12,13] have been used to establish the mechanism of action of this product: confocal laser scanning

microscopy (CLSM) studies have demonstrated its effectiveness in occluding open dentin tubules, and that this occlusion is resistant to acid challenge; high resolution scanning electron microscopy (SEM) and atomic force microscopy (AFM) studies have confirmed tubule occlusion; electron spectroscopy for chemical analysis (ESCA) and energy dispersive X-ray (EDX) studies have shown that the occluded mineral contains calcium, phosphate and carbonate; hydraulic conductance experiments have shown that this occlusion blocks fluid movement to inhibit the hydrodynamic mechanism.

In this study, an adult population with a pre-existing history of dentin hypersensitivity was enrolled for participation. During the baseline hypersensitivity examinations, hypersensitivity symptoms were successfully stimulated from all the teeth to be included in the trial. Before performing a professional dental cleaning procedure, one of two pastes was applied by a dental hygienist using a rubber prophy cup at low speed. The pre-procedure application was conducted without the examiner or subject being aware of which treatment was assigned. Dentin hypersensitivity was again evaluated after the full mouth dental cleaning was complete. Dentin hypersensitivity was statistically significantly reduced in the test group as compared to the control group on both outcome measures: tactile and air blast stimulated hypersensitivity.

Independent clinical trials have reported statistically significant dentin hypersensitivity relief instantly following a single post-scaling application of an in-office 8% arginine/ calcium carbonate desensitizing paste, as well as hypersensitivity relief lasting for 28 days.[10,18] The results from this study demonstrate that this in-office desensitizing paste can also provide relief when applied in advance of dental procedures, such as dental cleaning during maintenance visits, especially when sensitivity is expected. This product has the potential to be of great assistance to clinicians in dealing with acute dentin hypersensitivity, especially when used in advance of known sensitivity stimuli that may affect the course of dental treatment for the individual.

The results of this double-blind clinical study support the conclusions that the test paste, an 8% arginine and calcium carbonate desensitizing paste for in-office use provided:

- A statistically significant reduction in dentin hypersensitivity when applied as a single treatment before a professional dental cleaning procedure.
- A statistically significant reduction in dentin hypersensitivity compared to a control pumice prophylaxis paste when applied as a single pre-procedural treatment to a professional dental cleaning procedure.

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b. Colgate-Palmolive Co., New York, NY, USA.
c. Dentsply Professional, York, PA, USA.

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Effect of a desensitizing paste containing 8% arginine and calcium carbonate on the surface roughness of dental materials and human dental enamel

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ABSTRACT: Purpose: To evaluate the effect of an 8% arginine-calcium carbonate fluoride-free desensitizing paste on the surface roughness of resin composite, porcelain, amalgam, gold, and human dental enamel both prior to and following simulated toothbrushing. **Methods:** A resin composite (Filtek Supreme), a commercial porcelain (IPS Empress), an amalgam (Dispersalloy), gold (JIF-PF) and human dental enamel were used, as well as commercial finishing and polishing instruments. Eight two-sided samples were fabricated for each group. The composite and amalgam samples were stored at 100% relative humidity and 37°C for 48 hours prior to measuring the surface roughness and completing the subsequent finishing and polishing procedures. Enamel blocks were cut from human lesion-free teeth and embedded in acrylic. The blocks were then polished flat with high polishing pastes. For gold and porcelain, the same size was used and the materials processed by a professional dental laboratory. Following storage, each surface was polished using the Super-Snap (Shofu) system. The amalgam was polished with conventional polishing techniques. Roughness (Ra and R_Y) was evaluated with both a 3D non-contact profilometer and a stylus profilometer. With the two-sided samples only one side was polished with the desensitizing paste and the other side was left unpolished without paste. The 8% arginine-calcium carbonate desensitizing paste was applied to a surface for 15 seconds using a single disposable prophy cup. Each polished surface was measured by the profilometers and three roughness values per surface were recorded as the "initial prophy" surface. Following initial surface analysis, each side of every sample was treated with a simulated toothbrushing technique using a toothbrushing device (V-8). A 50:50 (w/w) slurry of toothpaste (Colgate Cavity Protection) and deionized water was used. Each surface was brushed 10,000 times. Then, the samples were rinsed with tap water and stored in 100% humidity until roughness values were obtained using the profilometers as previously described ("toothbrush surface"). After analyzing the brushed surfaces, the samples were returned to their original treatment group ("desensitizing paste"). Each surface was re-polished with the desensitizing paste as previously stated. Those surfaces (referred to as "recall paste") were measured as previously described for final surface roughness. Data was analyzed using repeated measures two-factor ANOVA with Tukey HSD pairwise comparison as appropriate ($\alpha=0.05$). Two additional samples were made of each material in order to measure step-heights. Tape was placed on the surface of each sample to separate the treatment side and the non-treated side. The tape was removed before each profilometry reading. **Results:** The desensitizing paste containing 8% arginine and calcium carbonate did not have a significant effect on the surface roughness of the substrates tested. Although the 3D non-contact profilometry images showed slight roughness after toothbrushing followed by the use of the desensitizing paste, these changes were not statistically significant ($P> 0.05$). (*Am J Dent* 2009;22 Sp Is A:21A-24A).

CLINICAL SIGNIFICANCE: The 8% arginine-calcium carbonate fluoride-free desensitizing paste tested did not significantly affect the surface roughness of the substrates tested.

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Introduction

Prophylaxis pastes are commonly used in dentistry to remove dental biofilm and stains. During the prophylaxis process, as well as during toothbrushing with dentifrices, enamel and restorative materials may be affected.[1-5]

The smooth surface of a restoration is important for the longevity of a restoration[6,7] as well as a highly polished restoration.[8] However, conventional prophylaxis pastes can remove surface layers and ultimately increase the roughness of enamel and restorations.[5]

This study evaluated the effect of a novel fluoride-free desensitizing paste containing 8% arginine and calcium carbonate[a] on the surface roughness of resin composite, porcelain, amalgam, gold, and human dental enamel both prior to and following simulated toothbrushing.

Materials and Methods

A resin composite (Filtek Supreme[b]), a commercial glass/ceramic porcelain (IPS Empress[c]), an amalgam (Dispersalloy[d]), gold (JIV-PF[e] Au 72.5%; Cu 13.6%; Ag 10.2%; Pt 2.8%), and human dental enamel were used as well as com-mercial finishing and polishing instruments. An 8% arginine-calcium carbonate desensitizing paste was used in this study.

Eight, two-sided samples were fabricated for each restorative material. For the resin and amalgam, 12.5 x 1.5 mm disks were made from Teflon tubing. The molds were slightly overfilled with material, covered on each side with a Mylar matrix strip and pressed between two glass slides. The top side of the sample was polymerized with a halogen light curing unit (Optilux 501[g]), for 20 seconds. A Demetron[h] radiometer was used to verify light intensity (750 mW/cm^2).

For gold and porcelain, 12.5 x 1.5 samples were used and the materials processed by a professional dental laboratory.

Enamel blocks (3 x 3 mm) were cut from lesion-free human enamel using an Isomet[i] saw and then embedded in acrylic for stability. The blocks were then polished flat with high polishing pastes.

Table. 3D non-contact and stylus profilometry data (Ra).

Profilometry	Baseline Mean (SD)	1st prophy Mean (SD)	Brushing Mean (SD)	2nd prophy Mean (SD)
3D non-contact				
Enamel control	0.082 (0.05)		0.112 (0.08)	
Enamel prophy	0.089 (0.08)	0.095 (0.06)	0.095 (0.02)	0.097 (0.02)
Filtek control	0.052 (0.02)		0.239 (0.08)	
Filtek prophy	0.050 (0.01)	0.083 (0.02)	0.251 (0.05)	0.245 (0.05)
Porcelain control	0.368 (0.06)		0.337 (0.06)	
Porcelain prophy	0.327 (0.08)	0.409 (0.14)	0.356 (0.07)	0.307 (0.05)
Amalgam control	0.760 (0.26)		0.435 (0.05)	
Amalgam prophy	1.142 (0.43)	0.986 (0.25)	0.532 (0.13)	0.394 (0.05)
Gold control	0.092 (0.09)		0.191 (0.03)	
Gold prophy	0.467 (0.02)	0.059 (0.01)	0.133 (0.04)	0.134 (0.03)
Stylus				
Enamel control	0.035 (0.02)		0.044 (0.02)	
Enamel prophy	0.087 (0.06)	0.061 (0.03)	0.094 (0.02)	0.062 (0.02)
Filtek control	0.038 (0.001)		0.154 (0.07)	
Filtek prophy	0.032 (0.001)	0.042 (0.01)	0.148 (0.05)	0.162 (0.05)
Porcelain control	0.792 (0.14)		0.670 (0.09)	
Porcelain prophy	0.694 (0.11)	0.689 (0.11)	0.548 (0.12)	0.598 (0.17)
Amalgam control	1.243 (0.49)		0.560 (0.14)	
Amalgam prophy	1.268 (0.37)	1.010 (0.28)	0.606 (0.15)	0.419 (0.07)
Gold control	0.028 (0.001)		0.0858 (0.02)	
Gold prophy	0.277 (0.01)	0.073 (0.04)	0.1132 (0.06)	0.088 (0.02)

Fig. 1. 3D non-contact and stylus profilometry data.

All samples were stored at 100% relative humidity and 37°C for 48 hours prior to measuring the surface roughness and completing the subsequent finishing and polishing procedures.

Following storage, each surface was polished using Super-Snap[j] finishing and polishing system. A single operator performed all finishing and polishing following the manufacturer's directions using a slow speed handpiece[k] at 3,000 rpm and a light pressure in a circular pattern for 20 seconds per disk. Each surface was polished with a new disk. The amalgam was polished with conventional polishing tech-niques, including tin oxide in a prophy cup for 20 seconds. The samples were then tested for roughness using a 3D non-contact profilometer and a stylus profilometer[l] for a tracing length of 2.00 mm and a cut-off value of 0.25 mm. Each sample was rotated 120° among three readings that were averaged on each surface. The instrument provided a readout of average surface roughness (R) per tracing in microns. R_Y is the arithmetic average height of roughness component irregularities from the mean line measured within the sampling length.

Each treatment group consisted of eight two-sided samples where only one side was polished with the desensitizing paste and the other side was left unpolished. The desensitizing paste was applied to a surface for 15 seconds using a single disposable prophy cup[m] with a slow speed handpiece at 3,000 rpm using moderate to light pressure. After polishing, the samples were rinsed in tap water and stored at 100% relative humidity. Each polished surface was measured by the profilometer as previously described and three roughness values per surface were recorded as the "initial paste" surface.

Following initial surface analysis, each side of every sample was treated with a simulated toothbrushing technique using a toothbrushing device (V-8 Crossbrushing Machine[n]). The brushing heads were fitted with nylon bristles (ADA standard brus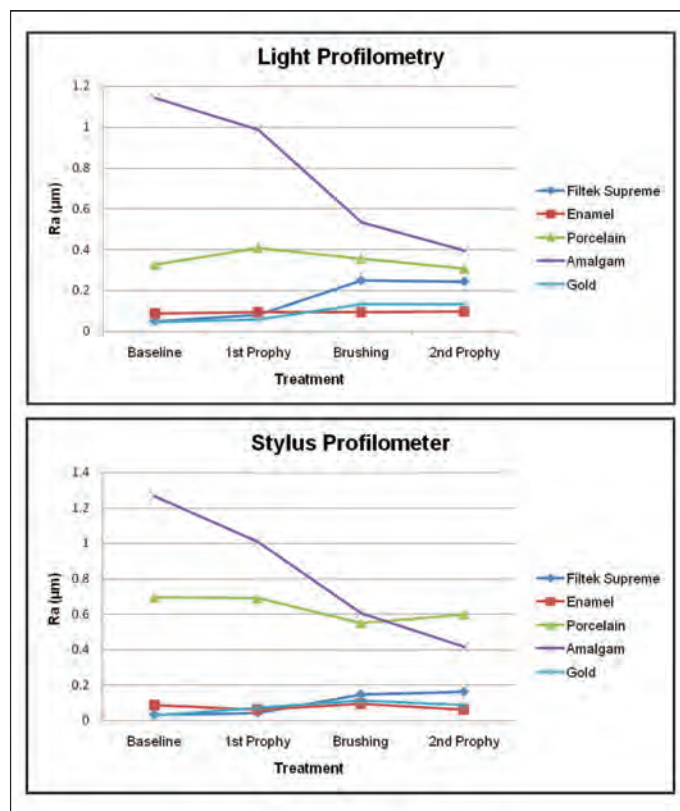hheads, straight head[o]). Care was taken to ensure that the bristles were perpendicular to the surface of each sample and touched the surface evenly. A 50:50 (w/w) slurry of toothpaste (Colgate Cavity Protection[a]) and deionized water was used as the abrasive medium. The volume of slurry needed to maintain a constant supply of abrasive between the brushes and the sample surfaces were provided by 37.5 grams of dentifrice and water (75 grams total). Each surface was brushed 10,000 times at 1.5 Hz using a brush-head force of 350 grams. After the simulated brushing technique, the samples were rinsed with tap water and stored in 100% humidity until roughness values were obtained using the profilometer as previously described ("toothbrush surface").

After analyzing the brushed surfaces, the samples were returned to their original treatment group ("desensitizing paste"). Each surface was re-polished with prophy paste as previously stated. Those surfaces (referred to as "recall paste") were measured as previously described for final surface roughness. Data was analyzed using repeated measures two-factor ANOVA with Tukey HSD pairwise comparison as appropriate (α=0.05).

Two additional samples were made of each material in order to measure step-heights. Tape was placed on the surface of each sample to separate the treatment side and the non-treated side. The tape was removed before each profilometry reading.

Results

The desensitizing paste with 8% arginine and calcium carbonate did not have a statistically significant effect on the surface roughness of any of the substrates tested (Table, Fig. 1).

After 10,000 cycles of toothbrushing with the dentifrice and further   prophylaxis with the desensitizing paste, the 3D non-
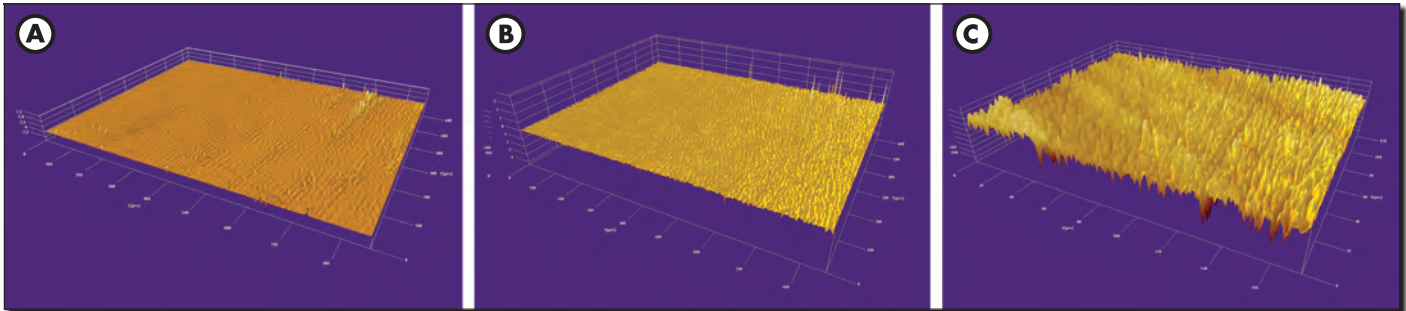
Fig. 2. **A**. 3D non-contact profilometry. Enamel - before 8% arginine-calcium carbonate desensitizing paste – Baseline. **B.** Enamel - after 8% arginine-calcium carbonate desensitizing paste. **C.** Enamel - after toothbrushing and 8% arginine-calcium carbonate desensitizing paste.
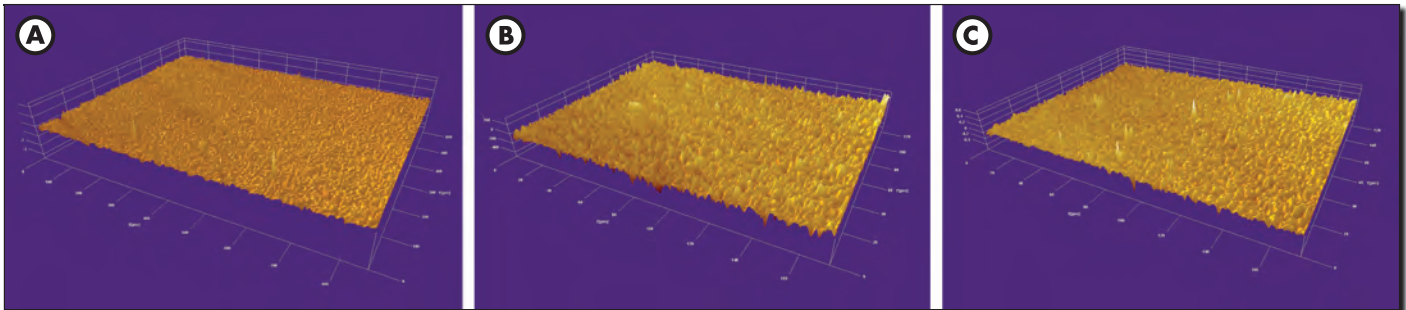

Fig. 3. **A.** 3D non-contact profilometry. Filtek Supreme - before 8% arginine-calcium carbonate desensitizing paste – Baseline. **B.** Filtek Supreme – after 8% arginine-calcium carbonate desensitizing paste. **C.** After toothbrushing and 8% arginine-calcium carbonate desensitizing paste.
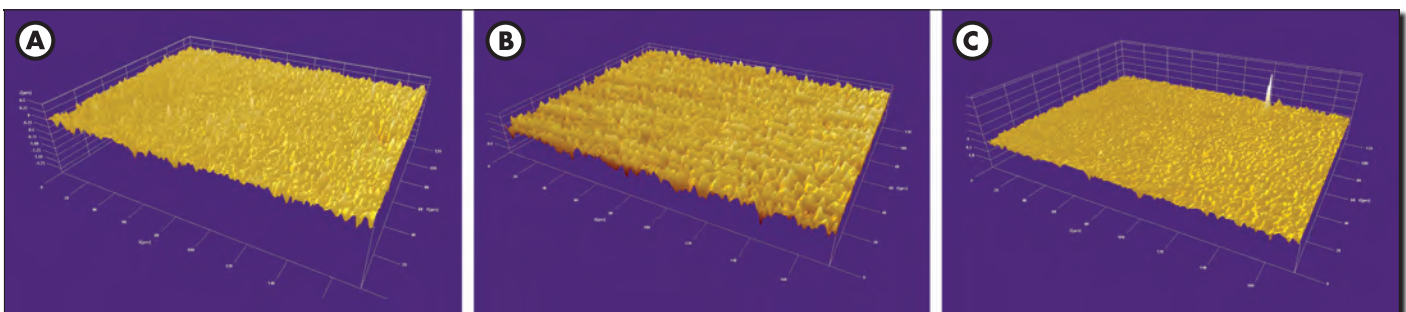

Fig. 4. **A.** 3D non-contact profilometry. Porcelain - before 8% arginine-calcium carbonate desensitizing paste – Baseline. **B.** Porcelain - after 8% arginine-calcium carbonate desensitizing paste. **C.** Porcelain - after toothbrushing and 8% arginine-calcium carbonate desensitizing paste.

contact profilometry images showed slight roughness (Ra) mainly due to the intense toothbrushing cycles, but the additional use of the desensitizing paste did not increase the roughness significantly (P> 0.05) (Figs. 2-6). Using the 3D non-contact profilometry, the second prophylaxis after mechanical toothbrushing produced a significantly smoother surface (P< 0.05) on the amalgam and gold samples. Using the stylus profilometer, this was only detected on the amalgam samples, probably due to the higher sensitivity of the 3D non-contact profilometer.

Discussion

Different substrates are available in the oral cavity (*i.e.* teeth, restorative materials, dental implants, prostheses), all with different surface characteristics. In a healthy situation, a dynamic equilibrium exists on these surfaces between the forces of retention and those of removal. However, an increased bacterial accumulation often results in a shift toward disease.

Both *in vitro* and *in vivo* studies underline the importance of supragingival plaque formation.[9] Rough surfaces will promote plaque formation and maturation, and high-energy surfaces are known to collect more plaque, to bind the plaque more strong-

ly. Although both variables interact with each other, the influence of surface roughness overrules that of the surface-free energy.[9] For the subgingival environment, with more facilities for microorganisms to survive, the importance of surface characteristics dramatically decreases. However, the influence of surface roughness and surface-free energy on supragingival plaque justifies the demand for smooth surfaces with a low surface-free energy in order to minimize plaque formation, thereby reducing the occurrence of caries and periodontitis.[9]

A correlation between bacterial adhesion and surface roughness of restorative materials or hydrophobicity was not confirmed.[10] However, Brambilla *et al*[11] showed that certain dental materials may favor biofilm formation and one other study[12] showed that polishing the resin composite tested led to increased biofilm formation. One other study[13] concluded that bacterial accumulation was the highest with the glass-ionomers tested, demonstrating the specificity of biofilm formation on the different brands of restorative materials tested.

Moreover, the amount of plaque accumulation showed an association to the earlier reported surface roughness values of the studied materials. It was concluded that in the oral environ-
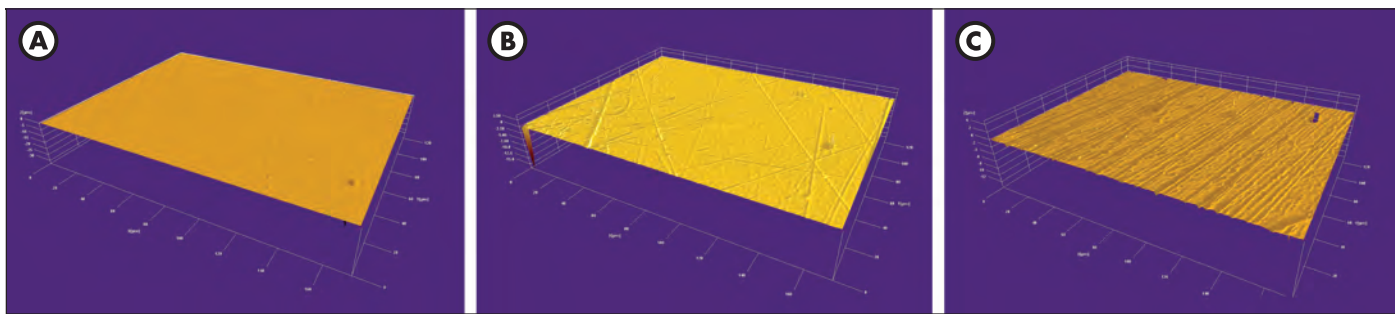
Fig. 5. **A.** 3D non-contact profilometry. Gold - before 8% arginine-calcium carbonate desensitizing paste – Baseline. **B.** Gold - after 8% arginine-calcium carbonate desensitizing paste. **C.** Gold - after toothbrushing and 8% arginine-calcium carbonate desensitizing paste.
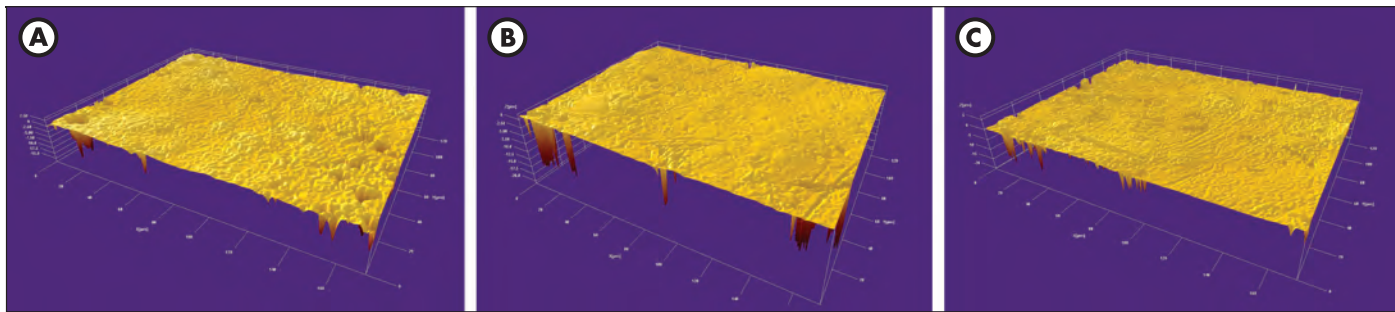

Fig. 6. **A.** 3D non-contact profilometry. Amalgam - before 8% arginine-calcium carbonate desensitizing paste – Baseline. **B.** Amalgam - after toothbrushing and 8% arginine-calcium carbonate desensitizing paste. **C.** Amalgam - after 8% arginine-calcium carbonate desensitizing paste.

ment, polyethylene fiber-reinforced composites promoted plaque accumulation and adhesion of mutans streptococci more than glass fiber-reinforced restorative composite and dental ceramic.[14] One other interesting result was that S. mutans growth on resin composite increased the surface roughness without affecting micro-hardness. This change in surface integrity may promote biofilm accumulation.[14]

It is not clear in the literature the number of toothbrushing cycles needed to simulate 1 year's brushing.[4] Ranges from 4,320[1] to 16,000[3] have been suggested. In a pilot clinical study, we found that the average person brushes between 25-30 cycles per day on a given tooth surface. This equates to 9,125 to 10,950 cycles per year. Therefore, in this study, 10,000 strokes were used to simulate 1 year of brushing.

In conclusion, the 8% arginine-calcium carbonate desensitizing paste directly applied on materials or used after toothbrushing for 10,000 cycles did not significantly affect the surfaces roughness of the substrates tested.

a.   Colgate-Palmolive, New York, NY, USA.
b.   3M Espe, St. Paul, MN, USA.
c.   Vivadent, Schaan, Liechtenstein.
d.   Dentsply, York, PA, USA.
e.   Jensen Industries, North Haven, CT, USA.
f.   SS White Co, Philadelphia, PA, USA.
g.   Kerr Corporation, Orange, CA, USA.
h.   Demetron/Kerr, Danbury, CT, USA.
i.   Buehler, Lake Bluff, IL, USA.
j.   Shofu, Tokyo, Japan.
k.   KaVo, Biberach, Germany.
l.   Phase Shift, Tucson, AZ, USA.
m.   Young Dental, East Earth City, MO, USA.
n.   Sabri Enterprises, Lombard, IL, USA.
o.   ADA, Chicago, IL, USA.

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