



# More Protection with Less Fluoride

JAMES DIMARINO, DMD, MSEd

AS DENTAL HEALTH PROFESSIONALS, we have the opportunity each day to utilize our dental knowledge to improve our patient's oral health by offering the most advanced dental treatment and products. The gift of time and experience offers us the ability to know what works in our hands and what does not. The challenge comes when new products are introduced to the market. What specific research can help us decide if these new products are better for our patients than what we are currently using? This article will introduce the reader to a new dentifrice, Enamelon® Preventive Treatment Gel with 970 ppm fluoride and show how it compares to a 5000 ppm fluoride toothpaste and a remineralization paste.

Throughout my dental career, I have struggled with finding the best treatment for common dental concerns like hypersensitivity, gingivitis, root caries, Early Childhood Caries, erosion, acid reflux, xerostomia, and orthodontic white spot lesions for example. I have recommended

a combination of products to help control two or more of these problems knowing that compliance goes down as the number of products or time required to complete the home care regiment goes up. Desensitizers, prescription-strength 5000 ppm fluoride toothpastes, and remineralization products seem to work for some patients and not others, forcing me to continue my search for a better solution.

Recently, Premier Dental Products introduced Enamelon Preventive Treatment Gel, a novel stannous fluoride gel with Amorphous Calcium Phosphate (ACP) technology, substantivity enhancers, and 970 ppm fluoride, which is designed to help prevent caries, gingivitis, and treat sensitivity. As a dentist, my first request would be to show me the research. How does it compare to the other products on the market? How can it help my patients?

## Understanding the research

The U.S. Food and Drug Administration (FDA) toothpaste monograph requires the toothpaste manufacturer to submit proof that the fluoride in their product is chemically available by submitting either an enamel fluoride uptake study or an enamel solubility reduction study.<sup>1</sup>

Figure 1 shows the results of an enamel fluoride uptake study in which Enamelon provided 2.48 times greater fluoride uptake than a 5000 ppm fluoride paste with TCP and 32 times greater fluoride uptake than a CPP-ACP paste with 900 ppm fluoride.<sup>2</sup>

Figure 2 shows the results of an enamel solubility reduction study in which Enamelon provided 3.03 times greater reduction in enamel solu-

bility than a 5000 ppm fluoride paste with TCP and 8.32 times greater reduction in enamel solubility than CPP-ACP paste with 900 ppm fluoride.<sup>3</sup>

A review of these two test results shows that Enamelon achieved more than 2 times greater fluoride uptake and 3 times greater reduction in enamel solubility than a 5000 ppm fluoride paste with TCP. Remarkably, Enamelon achieved these superior results with 80% less fluoride than the prescription strength fluoride products. These in-vitro studies suggest that Enamelon could be a safer alternative for caries reduction than 5000 ppm toothpastes while also providing the additional benefits of helping to treat gingivitis and providing relief of sensitivity.

## Dentinal hypersensitivity

Dentine sensitivity (DS) or dentinal hypersensitivity (DH) is one of the most commonly encountered clinical problems. It is clinically described as an exaggerated response to application of a stimulus to exposed dentine, regardless of its location.<sup>4,5</sup> Dentinal hypersensitivity has been researched extensively, found to be

### 3x Greater reduction of enamel solubility

Enamel Solubility Reduction FDA Method #33<sup>3</sup>  
Negative Control (Water) recorded a -5.45% Enamel Solubility Reduction

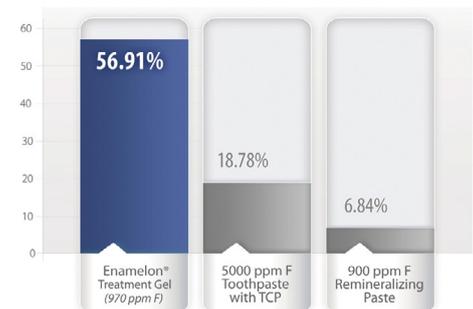


FIGURE 2

under-reported by the patient and is a frequently misunderstood clinical problem.<sup>6</sup> Popular hypersensitivity treatment options include blocking of the pulpal nerve response,<sup>7</sup> through chemical modulators like potassium nitrate which depolarizes the nerve,<sup>8</sup> or tubular occlusion which creates a physical barrier over the tubules.

Enamelon Preventive Treatment Gel contains stannous fluoride along with calcium and phosphate ions which have been proven to be effective for tubule occlusion. By blocking the exposed tubules with a combination of stannous (tin) ions along with fluoride, calcium and phosphate salts, a physical barrier is created that covers open dentinal tubules to prevent external stimuli from causing pain or discomfort.

Figure 3 shows how Enamelon creates a physical barrier over the dentin after five days of use (ten brushings in vitro). By blocking the exposed tubules, a physical barrier is created to prevent stimuli from causing pain or discomfort.

### More protection with less fluoride

Enamel Fluoride Uptake (ppm F) FDA Method #40<sup>7</sup>

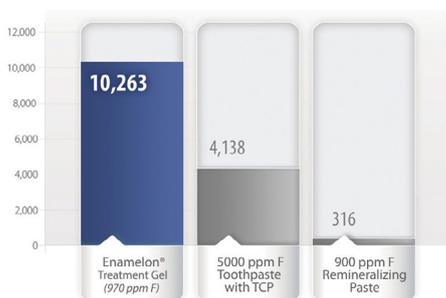
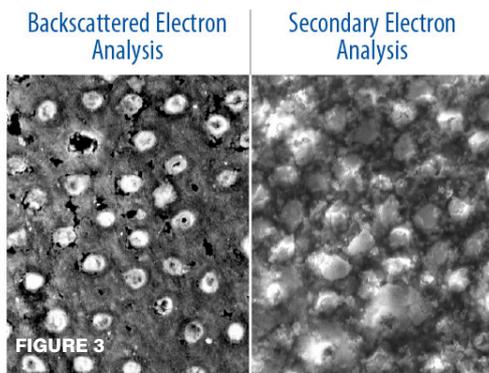


FIGURE 1

Additionally, research of ACP delivering products supports the aforementioned results and has shown that a fluoride varnish designed to deliver ACP (Enamel Pro Varnish by Premier Dental) provides similar semi-permanent occlusion with fluorapatite, as well as a reduction in hydraulic conductance by 73%.<sup>10</sup>

Historically, my treatment for generalized DS included an evaluation to rule out other conditions like caries, fractured or chipped enamel/dentin, pain due to pulpitis, post dental bleaching sensitivity, etc followed by a conservative approach of an OTC dentifrice/rinse. If my conservative efforts fail to provide relief I progress to a desensitizer, then MI Paste Plus, then to prescription products like a fluoride rinse or a 5000 ppm fluoride product. My results have been mixed, some products



**FIGURE 3**  
SEM of the occluded dentinal tubules after day 5 (10 applications) with Enamelon. (10mm, Mag = 1.00k, XEHT = 20.00kv)

work for some patients, while others do not.

It is encouraging to review the results of the research for products designed to deliver ACP like Enamel Pro Varnish and Enamelon presented thus far. Based on this evidence, it seems worth considering an in office treatment with Enamel Pro Varnish followed by daily, home applications of Enamelon Preventive Treatment Gel as a first choice for treatment of DS or DH.

### How can this new product help patients?

Enamelon can be an effective home-care regiment to not only prevent caries and gingivitis, but also to build increasing protection against hypersensitivity caused by temperature, acids, sweets, or contact. Additionally, it is the first formula to combine the protective properties of the stannous ion with the remineralizing potential of ACP technology.

Interestingly, I recollect my patients reporting a significant decrease in generalized hypersensitivity when using a sodium fluoride (NaF) toothpaste designed to deliver ACP in the 1990's. There is a significant body of research showing how dental products (prophy paste, dental fluoride varnish, etc) enhanced with ACP technology produced significant patient benefits,<sup>11,12</sup> and greater fluoride

uptake.<sup>13,14,15,16</sup> There is also a significant body of research showing how the NaF toothpaste enhanced with ACP technology produced significant reduction in enamel solubility, increase in fluoride uptake, and strengthening of tooth enamel.<sup>17,18</sup> Additionally, a clinical study showed that a remineralizing toothpaste (NaF toothpaste delivering ACP) was significantly superior to the conventional fluoride dentifrice in preventing root caries in high risk head and neck radiation patients.<sup>19</sup>

This research shows a history of success for products designed to deliver ACP which, combined with the recent studies showing Enamelon's greater fluoride uptake and resistance to enamel solubility, make it a product worth implementing into clinical practice as a first line of defense against caries, gingivitis, and sensitivity.

### Additional Benefits

Premier has carefully selected Enamelon's ingredients and the packaging so as to overcome common problems associated with dentifrices currently on the market. The product offers a pleasant patient experience for enhanced compliance. Premier incorporated a patented, saliva-soluble ingredient which creates a long-lasting coating that moisturizes and soothes soft tissue, improves therapeutic performance by increasing substantivity, and provides a great mouth-feel after use. Enamelon also has a nice tasting mint flavor, no Sodium Lauryl Sulfate (SLS), and is abrasive-free, gluten-free and dye-free. Another interesting addition is the use of a small dispensing orifice to help reduce waste and provide controlled dispensing as shown in Figure 4.

I also find it encouraging that other highly regarded dental professionals find Enamelon promising as evidenced by Dr. Theodore Croll and Dr. Joel Berg's recent article in Compendium which states: "In view of the lower amount of fluoride content in the treatment gel, the increased fluoride uptake, and the increased resistance to acid challenge of treated enamel, the authors (Dr. Croll and Dr. Berg) expect Enamelon Gel to be a valuable preventive dentistry adjunct in the overall care of high-caries-risk children and teenagers, especially those wearing fixed orthodontic appliances."<sup>20</sup>

Enamelon helps to prevent caries and gingivitis while also reducing hypersensitivity making it suitable for a wide range of patients with conditions of various causes. Enamelon may eliminate the need for remineralizing pastes, prescription-strength toothpastes and take-home rinses which could improve patient compliance and results. The evidence so far points to a promising product that is worth evaluating to determine if it could be a valuable tool for you and your patients.

**FIGURE 4**



**JAMES DIMARINO, DMD, MSED** holds a dental and MSED degree from the University of Pennsylvania. He completed a GPR and went into private practice while researching and implementing advanced dental technologies. He has trained and given CE courses to dental professionals in the US, England, Finland, Germany, Japan, and Poland. He has held positions in new product development and as the director of clinical affairs. Dr. DiMarino can be contacted at [jdimarino@premusa.com](mailto:jdimarino@premusa.com).



### References

- Food and Drug Administration Final monograph on antiperspirant drug products for over-the-counter human use. Federal Register. 1995;60:52474-52510.
- Schemehorn BR, DiMarino JC, Movahed N. Comparison of the incipient lesion enamel fluoride uptake from various prescription and OTC fluoride toothpastes and gels. J Clin Dent 2014;25:57-60.3. JCD Method #3
- Schemehorn BR, DiMarino JC, Movahed N. Comparison of the enamel solubility reduction from various prescription and OTC fluoride toothpastes and gels. J Clin Dent 2014;25:61-4.
- Addy M. Tooth wear and sensitivity: Clinical advances in restorative dentistry. In: Addy M, Embery G, Edgar WM, Orchardson R, editors. Dentine hypersensitivity: Definition, prevalence distribution and aetiology. London: Martin Dunitz; 2000. pp. 239-48.
- Addy M. Etiology and clinical implications of dentine hypersensitivity. Dent Clin North Amer. 1990;34:503-14.
- Kamath Deepa G & Nayak Sangeeta U. Dentine hypersensitivity and its management - An informed view. J Pharm Biomed Sci. February; 27(27): 474-479
- Lussi A (ed): Dental Erosion. Monogr Oral Sci. Basel, Karger, 2006, vol 20, pp173-189
- Carpio, Lillian. "No Strong Evidence Supports the Efficacy of Potassium Nitrate Toothpaste for Dentine Hypersensitivity." Evidence-Based Dentistry 3 (2002): 11.
- Tung, M.S., Eichmiller, F.C., Paffenbarger Research Center. ADAHF NIST, Gaithersburg, MD. "Dental Applications of Amorphous Calcium Phosphates" Journal of Clinical Dentistry, Vol.10, Issue 1, 1999.
- "Effect of Calcium Phosphate Containing Fluoride Varnish on Dentin Permeability", Tung, M.S., Torres, J., (ADAHF Paffenbarger Research Center, NIST, Gaithersburg, MD and U.S. Navy Dental Corps, Bethesda, MD), J Dent Res 86(Spec Iss A): 0985, 2008 (www.dentalresearch.org)
- Tung, M.S., Malerman, R., Huang, S. and McHale, WA. "Reactivity of Prophylaxis Paste Containing Calcium, Phosphate and Fluoride Salts", Journal of Dental Research, Vol. 84, Special Issue A, IADR Abstracts, 2005.
- Tung MS, Eichmiller FC. Amorphous calcium phosphates for tooth mineralization. Compend Contin Educ Dent 2004; 25(9 Suppl 1):9-13.
- Schemehorn BR, Wood GD, McHale W, Winston AE. Comparison of fluoride uptake into tooth enamel from two fluoride varnishes containing different calcium phosphate sources. J Clin Dent. 2011; 22:51-54.
- Source: "Final Report: Sound Enamel Fluoride Uptake Study#08-151, Method #40SV", Dental Products Testing Thermometric Technologies Inc., Indiana University Emerging Technologies Center, March 2008
- "Final Report: Sound Enamel Fluoride Uptake Study #08-230, Method #40ST", Dental Products Testing, Indiana University Emerging Technologies Center, September 2008.
- "Final Report: Enamel Fluoride Uptake Study #05-106, Modified FDA Method #40," Dental Products Testing, Indiana University Emerging Technologies Center, December 2005
- Schemehorn BR, Wood GD, Winston AE. Laboratory enamel solubility reduction and fluoride uptake from Enamelon dentifrice. J Clin Dent 1999;10: 9-12.
- Muñoz CA, Feller R, Haglund A, et al. Strengthening of tooth enamel by a remineralizing toothpaste after exposure to an acidic soft drink. J Clin Dent. 1999;10(1 Spec. No.):17-21.
- Papas A, Russell D, Singh M, Kent R, Triol C, Winston A. Caries clinical trial of a remineralizing toothpaste in radiation patients. Gerodontol. 2008;25(2):76-88.
- Croll T, Berg J. Use of Fluoride Products for Young Patients at High Risk of Dental Caries. Compendium. September 2014, Volume 35, Issue 8.