Relief® ACP ORAL CARE GEL

CLINICAL SUPPORT

The following studies contain further information regarding the benefits of Amorphous Calcium Phosphate, Fluoride and Potassium Nitrate – all essential components that make up Relief ACP Oral Care Gel.

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Cherng M., Takagi S., and Chow L.C. Reduction in Dentin Permeability Using a Calcium Phosphate Slurry. Journal of Dental Research 83 (Special Issue A); IADR CD-ROM Abstract No. 0119, 2004.

<u>Objective:</u> The goal of this study was to determine the effect of a treatment with slurry of micro size calcium phosphates on the hydraulic conductance (Lp) of etched dentin discs in vitro.
<u>Methods:</u> The treatment slurry (powder to liquid ratio = 1g/1mL) was prepared by mixing a powder mixture DCPA (< 5 µm) and Ca(OH)2 (< 5 µm), with a solution that contained mass fractions of 4% NaF and 2% carboxylmethyl cellulose. The slurry was applied on a dentin surface and then forced in by gently blowing the top of the treated side with N2 gas. After 1 min, the specimen was stored in 100 % humidity at 37 ºC for 15 min, then immersed in a saliva-like solution (SLS) [1.2-mmol/L CaCl2, 0.72-mmol/L KH2PO4, 30-mmol/L KCL and 50-mmol/L HEPES, pH=7.0] for 2 h. A modified Pashley's flow system was used to measure Lp. The specimen was subsequently incubated in a 20 mL SLS changed daily for 8 d, and Lp measurements were taken at the same day points as the baseline Lp.
<u>Results:</u> The mean baseline Lp was (2.07±1.45) mL cm-2 sec–1 H2O cm-1 (mean±S.D.; n=13). After one treatment and (3, 5, and 8) d of incubation in SLS, the mean relative Lps, presented as fractions of baseline Lp, were (65±16, 42±27, 36±26, and 33±27) %, respectively. The Lp values of the baseline and treatment after incubation were significantly different ($p < 0.05$). Scanning electron microscopic examination showed the obturation of dentin tubules in the treated dentin. X-ray diffraction indicated the product formed from the slurry was hydroxyapatite.
<u>Conclusion:</u> Treatments appeared effective in improving the Lp of dentin discs with incubation in a SLS.

Featherstone, John D.B. The science and practice of caries prevention. JADA Vol. 131, July 2000.

<u>Background and Overview:</u> Dental caries is a bacterially based disease. When it progresses, acid produced by bacterial action on dietary fermentable carbohydrates diffuses into the tooth and dissolves the carbonated hydroxyapatite mineral—a process called demineralization. Pathological factors including acidogenic bacteria (mutans streptococci and lactobacilli), salivary dysfunction, and dietary carbohydrates are related to caries progression. Protective factors—which include salivary calcium, phosphate and proteins, salivary flow, fluoride in saliva, and antibacterial components or agents—can balance, prevent or reverse dental caries.
<u>Conclusions:</u> Caries progression or reversal is determined by the balance between protective and pathological factors. Fluoride, the key agent in battling caries, works primarily via topical mechanisms: inhibition of demineralization, enhancement of remineralization and inhibition of bacterial enzymes.

Flaitz C., and Hicks J. Whitening Agents with ACP: Enamel Caries Formation and Progression. Journal of Dental Research 2006;Volume 85 Special Issue A, Abstract 0882

<u>Objective:</u> This in vitro study evaluated the effect of whitening agents containing amorphous calcium phosphate (ACP) on human enamel caries formation and progression.
<u>Methods:</u> 15 teeth with sound enamel surfaces were divided into 4 portions. Each tooth portion was assigned to a treatment group: 1) No Treatment Control; 2) Day White Excel 3 - 9.5% hydrogen peroxide ACP; 3) Nite White Turbo - 6% hydrogen peroxide ACP; 4) Nite White - 16% carbamide peroxide ACP. The teeth were treated according to the manufacturer's recommendations (Discus Dental Inc, Culver City, CA 90232), followed by synthetic saliva, on a daily basis for 14 days. Control tooth portions were exposed only to synthetic saliva. A modified ten Cate solution was used for in vitro enamel caries formation and

progression. The teeth were treated prior to lesion formation, and before lesion progression 1 and lesion progression 2 periods. Longitudinal sections were taken after lesion formation, lesion progression 1 and lesion progression 2 periods for polarized light study and statistical analysis (ANOVA, DMR).
Results: Mean lesion depths were: Lesion Formation Period: Control 108±15um; Day White 93±11um; Nite White Turbo 48±7um (P<.05); Nite White-16% 105±12um. Progression Period 1: Control 171±18um; Day White 126±13um (P<.05); Nite White Turbo 96±9um (P<.05); Nite White-16% 132±12um (P<.05). Progression Period 2: Control 228±20um; Day White 165±17um (P<.05); Nite White Turbo 129±11um (P<.05); Nite White-16% 152±16um (P<.05).
Conclusions: Whitening agents containing calcium phosphate have a reduced susceptibility to in vitro enamel caries lesion initiation and progression.

Geiger S., Matalon S., Blasbalg J., et al. The clinical effect of amorphous calcium phosphate (ACP) on root surface hypersensitivity. Oper Dent. 2003;28:496-500.

Conclusion: Dentin hypersensitivity is a transient condition that often resolves with the natural sclerotic obturation of dentin tubules. A method of rapidly forming calcium phosphate compounds within these tubules can mimic sclerosis and lead to rapid reduction in hypersensitivity. Amorphous calcium phosphates (ACP) can be formed in situ by the sequential application of calcium and phosphate solutions. In this clinical study, 30 patients with reported dentin hypersensitivity were randomly assigned to parallel treatment or placebo groups. In the experimental treatment group, ACP was formed by topical application of a 1.5 mol/L aqueous solution of CaCl2 followed by topical application of 1.0 mol/L aqueous K3PO4. The placebo group was treated with a topical application of 1.0 mol/L aqueous solution of KCl followed by topical application of distilled water. Treatments were repeated at the 7-day and 28-day recall appointments. Response to air and tactile stimuli were measured immediately before treatment using a visual analog scale initially on day 1, then on days 7, 28 and 180. The results showed that both the experimental and placebo treatments resulted in a reduction in hypersensitivity at 180 days. However, the ACP treatment group showed a much more rapid reduction in hypersensitivity over time. The change in sensitivity was much more apparent using the air stimulus than the tactile stimulus. These results show that topical placement of ACP can rapidly reduce dentin hypersensitivity.

Haywood, V. Dentine hypersensitivity: bleaching and restorative considerations for successful management. IDJ (2002) 52, 376-384.

Conclusion: here are many causes of and treatments for tooth sensitivitiy. The dentist must explore all possibilities, form a definitive diagnosis or diagnoses, then implement management strategies that address all causes and predisposing factors to reduce or eliminate the sensitivity. Treatments may range from simple topically applied medications at home but the patient to restorations, pulp removal or muco-gingival surgery. The severity and extent of the sensitivity will dictate variations in treatment options. Chronic problems with teeth not having restoration or obvious pathology are most disconcerting. The use of a desensitizing agent such as 5 per cent potassium nitrate-fluoride gel (toothpaste) applied in the bleaching tray as needed for tooth sensitivity can be effective and gives the patient more control over the condition. This tray delivery technique reduces tooth sensitivity from nightguard bleaching in a majority of patients, which allows most patients (including those undergoing long-term treatment for tetracycline staining) to continue whitening to successful completion.

Markovic M., Fowler B.O., and Tung M.S. Preparation and Comprehensive Characterization of a Calcium Hydroxyapatite Reference Material. Journal of Research of the National Institute of Standards and Technology, Volume 109, Number 6, November-December 2004.

Conclusion: Numerous biological and chemical studies involve the use of calcium hydroxyapatite Ca^d10^(PO^d4^)^d6^(OH)^d2^, HA. In this study detailed physicochemical characterization of HA prepared from an aqueous solution was carried out employing different methods and techniques: chemical and thermal analyses, X-ray diffraction, infrared and Raman spectroscopies, scanning and transmission microscopies and Brunauer, Emmett, and Teller (BET) surface-area method. The Ca, PO^d4^, OH, HPO^d4^, H^d2^O, CO^d3^, and trace constituent contents, the Ca/P molar ratio, crystal size and morphology, surface area, unit-cell parameters, crystallinity, and solubility of this HA were determined. This homogeneous, essentially pure and crystalline HA is certified as a National Institute of Standards and Technology (NIST) standard reference material (SRM 2910).

Schemehorn B.R., Orban J.C., Wood G.D., and Fischer G.M. Remineralization by Fluoride Enhanced with Calcium and Phospate Ingredients.The Journal of Clinical Dentistry, Vol.X, No.1. 1999; 10 (1 Spec):13-6

Conclusion: The effectiveness of fluoride ions provided by toothpastes and mouthrinses in promoting remineralization can be limited by the low concentrations of calcium and phosphate ions in saliva. The purpose of this study was to determine whether improved remineralization can be obtained from toothpastes or mouthrinses that simultaneously deliver fluoride, calcium, and phosphate ions from dual-dispensing systems. Enamel specimens with artificial lesions between 60 and 90 microns deep were cycled 15 times through demineralization for 30 minutes, treated for 5 minutes with an experimental or control fluoride toothpaste or mouthrinse, and remineralized for 60 minutes. In the toothpaste study, surface hardness increased by 11.5 +/- 9.2 and 2.7 +/- 3.6 Vickers hardness units, and enamel fluoride content was 5984 +/- 521 ppm and 3971 +/- 531 ppm for the experimental and control fluoride toothpastes, respectively. Remineralization was confirmed by x-ray microradiography. In the mouthrinse study, surface hardness increased by 8.8 +/- 7.7 and 2.2 +/- 3.7 Vickers hardness units, and enamel fluoride content was 6111 +/- 1078 ppm and 3160 +/- 364 ppm for the experimental and control fluoride mouthrinses, respectively. Use of a non-fluoride control mouthrinse led to a decrease in surface hardness of 3.7 +/- 5.2 Vickers hardness units despite a fluoride content of 402 ppm. The results demonstrate that calcium and phosphate supplementation in a toothpaste or mouthrinse can improve remineralization and increase fluoride uptake.

Tung M.S., and Eichmiller F.C. Amorphous Calcium Phosphate for tooth mineralization. Compend Contin Educ Dent, Vol 25, No 9 Suppl 1, Sep 2004, pp 9-13. Journal Code 9600713, Journal Subset MEDJSD, ISSN 1548-8578. Corporate Author: American Dental Association Foundation.

Conclusion: The destruction of tooth structure through caries and erosive processes is due to two types of acidic challenges that affect the tooth in different ways. Acidic attacked by cariogenic bacteria initially produces subsurface lesions that weaken the enamel and, if left, unchecked, can progress through the enamel and dentin and eventually into the pulpal cavity. Erosive attack by acidic foods and beverages removes mineral from the surface of enamel and initially causes dulling and loss of tooth luster; if left unchecked, it can progress to a more severe loss of enamel thickness and contour. This article focuses on the potential means of improving the cosmetic appearance of teeth by depositing mineral into surface defects. Several approaches use the unique properties of amorphous calcium phosphate (ACP) compounds, which have the highest rates of formation and dissolution among all the calcium phosphates. ACP can include toothpastes, mouth rinses, artificial saliva, chewing gums, topically applied coatings, and other vehicles for topical use. When applied, they readily precipitate ACPs on and into tooth-surface defects. These products hopefully will provide users with new tools to restore and enhance the smoothness and luster of their teeth.

Zhang L., Li Z., Dong Y., and Chin J. Experimental study of phosphopeptide in promoting tooth remineralization. Dent Res. 2000 May;3(1):27-30.

Objective: To explore a new method for effective and safe prevention and treatment of caries.
Methods: Following the theory of tooth remineralization, we searched for the mechanism and clinical application of tooth remineralization with phosphopeptide.
Results: Phosphopeptide, with calcium and phosphorus, had a high affinity for hydroxyapatite and could enhance tooth remineralization.
Conclusions: Phosphopeptide was effective in the prevention and treatment of tooth decay. Clinically, it could be safely applied.

The following studies contain further information regarding the benefits of Calcium and Phosphate:

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Chow L.C., Vogel GL. Enhancing remineralization. Oper Dent. 2001; 26(suppl 6):27-38.

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Grant L.P., Thompson A., Tanzer J.M. Caries inhibition in rats by a remineralizing toothpaste. J Clin Dent. 1999;10 (1 spec no):30-33.

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Munoz, Stephens, Proskin, Ghassemi. Clinical Efficacy of a Fluoride Dentrifice Containing Calcium, Phosphate, and Sodium Bicarbonate on Surface-Enamel Smoothness and Gloss. Compendium Vol. 25, No. 9 (Suppl 1) Sep 2004.

Skrtic D., Antonucci J.M., Eanes E.D. Amorphous calcium phosphate-based bioactive polymeric composites for mineralized tissue regeneration. J Res Natl Inst Stand Technol. 2003;108:167-182.

Zero, Dominick. Applications of Clinical Models in Remineralization Research. Journal of Clinical Dentistry Vol. X, No 2, pp 74-84