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NovaMin®: Likely Clinical Success

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This is a review of a presentation on new agents used to prevent dental caries. Some of the products formulated with the active ingredient NovaMin® have been used for prevention of sensitivity, reduction in bleeding and gingivitis, whitening, and erosion, as well as in de/remineralization studies. The presentation addresses several important aspects of the prevention or inhibition of demineralization, as well as the enhancement of remineralization. For example, delivery to the active site is important for addressing issues of frequency of application or substantivity after one application. Too much calcium, phosphate, or fluoride may contribute to limited remineralization, and implies that a careful control of supersaturation is necessary if one intends to heal the lesion at its depth as well as its surface. The final answer to the question of Likely Clinical Success is that the data look promising, but more research is needed.

INTRODUCTION

This paper includes material from a PubMed literature search (which revealed a scarcity of peer-reviewed articles) as well as a Google search for NovaMin. This paper then reviewed the clinical data available and speculated on clinical success where no or limited data are available. A class of compounds called bioactive glass has been available since the late 1960s as materials designed to help repair damaged bone. Similar glass compounds (PerioGlas) have been shown to be effective in bone-grafting procedures used in ridge augmentation and repair of periodontal defects (www.novabone.com). There have also been reports of an anti-gingivitis effect which, in one Chinese study, showed a 16% reduction in plaque and a 59% reduction in gingival bleeding (Tai et al., 2006). The key components—SiO₂, Na₂O, CaO, and P₂O₅—are mixed to be highly reactive to aqueous media. The bioglass products have been said to bind to existing bone and act as scaffolds for new bone growth (Kontonasaki et al., 2002). NovaMin is one of these bioactive glass-ceramic materials, which falls into a class of newer agents that provide calcium and phosphate ions that form a hydroxy-carbonate apatite (HCA) with time (www.novamin.com).

SENSITIVITY

In addition to use for bone repair, materials that precipitate calcium and phosphate have been used to decrease hypersensitivity by occluding exposed dentinal tubules. It is this application of NovaMin products that has received approval from the FDA. Numerous studies have focused on the decrease of sensitivity by following the occlusion of open dental tubules. Most of these studies have used SEM to show the patent tubules before treatment and the occluded tubules after treatment (Gillam et al., 2002). Web sites for different products have shown amorphous calcium phosphate (ACP), Recaldent, and NovaMin all occluding tubules with precipitate. NovaMin’s most noted effect is against dentinal sensitivity (Du et al., personal communication). The products containing NovaMin include a homecare toothpaste from Natural Health Organics (Oravive® Revitalizing Paste-5 wt%, which does not contain fluoride), prescription pastes for hypersensitivity marketed by 3M/Omni (SootheRx™) and European distributors (Denshield® - both with 7.5 wt%), and a prophyl paste promoted by Sunstar/Butler (NuCare® - 100 wt% and water). All of the above products have some clinical studies to support their claims as desensitizers. Newer products include a tooth root desensitizer (Vitalmin - 100 wt% NovaMin and water), a fluoride varnish (Durasheild - 10 wt% NovaMin and 5% NaF), and a dentifrice (Renew—5000 ppm fluoride and 5 wt% NovaMin). These Sultan Health Care products claim to decrease sensitivity as well as provide a remineralizing capability (www.SultanHealthcare.com). Likewise, Dr. Collins’ new Restore Remineralizing Toothpaste claims to remineralize as well as decrease sensitivity. Their Web site states that the paste ‘Rebuilds, Revitalizes, and Restores’ and is also fluoride-free (www.drcollinsdental.com). Having received approval as hypersensitivity agents by most often showing the occlusion of dentinal tubules, these products have also claimed the ability to whiten (www.novamin.com) and remineralize, although the evidence may be lacking.

EROSION

Another dental application which relies on precipitation may well be to reduce the amount of erosion occurring from acidic

Key Words

NovaMin, remineralization, salivary enhancer.

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conditions in the mouth. Teeth are daily exposed to many consumables with a low pH that may damage the tooth surface. The increase in consumption of acidic foods and beverages like sodas and sport drinks has made this an issue of concern. Some acidic drinks are able to overcome the saliva’s natural buffering capacity and cause the loss of tooth mineral. This erosion may leave the tooth vulnerable to further decay. At the 54th European Organization for Caries Research Congress, a paper was presented on an in vitro erosion model, comparing the effects of NovaMin with and without fluoride on dental erosion. The study attempted to model the oral environment of individuals with limited saliva function and used a negative water control and 1500 ppm F (monofluorophosphate [MFP]) positive control. Hardness measurements were made on all teeth and showed that fluoride or NovaMin alone could temper the hardness loss, but that fluoride and NovaMin together gave the best results. As stated by the authors, these promising in vitro results will need to be confirmed with clinical trials (Burwell and Greenspan, personal communication).

If NovaMin® is able to fill in small surface defects in tooth enamel and thereby help stop erosion from acidic foods and beverages, it may also enhance tooth esthetics, such as gloss, by this mechanism. Thus, the ability to provide calcium and phosphate to an eroded surface may decrease mineral loss as well as allow remineralization to occur in the surface defects. This topic is summarized by Litkowski et al. (2004), who state that fluoride-containing pastes may increase hardness, but calcium-containing pastes are needed to fill surface defects and thus produce a smoother surface, which may improve “surface gloss” as well. We have mentioned the claims of reduced sensitivity, inhibition or repair of erosion, restoration of surface gloss and whitening, and inhibition of gingivitis. What about the effect on demineralization and remineralization?

**DEMINERALIZATION AND REMINERALIZATION**

In descriptions of the possible in vivo inhibition of demineralization or enhancement of remineralization, several basic parameters must be reviewed. As has been described by Featherstone (2006), the process of caries lesion formation depends on pathological factors outweighing the preventive factors present in the oral environment. Since both de- and remineralization processes occur in the mouth, they are dependent on salivary conditions to determine saturation at any given time. As a fairly constant supplier of calcium and phosphate, salivary changes from super- to undersaturation are mainly due to changes in pH. Since organic acids are produced by plaque micro-organisms, the resulting acidity may exceed the natural buffering capacity of saliva. This then causes the oral fluid to become undersaturated with respect to enamel, and the mineral becomes susceptible to demineralization. These acid conditions may also be generated by the consumption of acidic beverages or food, as mentioned above. The resultant demineralization may take the form of surface loss or erosion, surface-softening, or white-spot lesion formation, which retains a rather intact surface layer. The main clinical sign of demineralization has been said to be the white-spot lesion, which has been identified as having an intact surface zone and subsurface demineralization (Silverstone, 1968). This formation of a white-spot lesion makes it easier to identify areas of demineralization clinically, although the reverse (remineralization) is not as easily measured or observed clinically.

The condition of undersaturation may also be alleviated by an increase in calcium and phosphate, as well as by a change in pH. It would be at this time that additional calcium and phosphate ions from various topical agents could aid in the inhibition of demineralization.

The ions would need to be available in ionic form and participate in increasing solution concentrations to counter the lowered pH. They may also contribute by neutralizing the acidic conditions. In either case, the solubility product will be changed in the direction of saturation, thereby preventing further demineralization.

The inhibition of demineralization requires that the topical agents be delivered at the appropriate time and to the right location within the oral environment. They also have to provide their additional calcium and phosphate at that time. This may occur by application at the right time—perhaps after eating and snacking, or by frequent consumption/usage, or by having oral substantivity so that the agent is available in the mouth when needed. The form in which an agent is retained and the trigger mechanism to release the active ingredients need to be identified and capitalized upon. As the delivery systems are modified and improved, they need to be tested clinically, and then, based on the results, they should be reformulated to enhance their performance. Thus, a circular process occurs which evaluates laboratory and clinical tests in the development of an optimal preventive agent.

When calcium and phosphate ions are applied with fluoride, their low solubility often causes unwanted precipitation and has made it difficult for investigators to determine the optimal conditions for clinical remineralization. Larger quantities of insoluble or complexed calcium and phosphate ions may be used, but may not have easy delivery systems, may not find their way to the appropriate tooth surface, and must ‘de-complex’ or be released to be capable of diffusing into the subsurface enamel lesion. When low concentrations of calcium and phosphate ions are applied, they are soluble, but these concentrations may not be enough to diffuse substantially through the biofilm and localize on the tooth surface. The natural response to this problem is merely to increase the amounts of calcium and phosphate and/or fluoride ions. In vitro as well as in vivo experiments have shown that we can have too much of a good thing. When the supersaturation of the solution becomes too large, one will get immediate de novo precipitation, which eliminates the ions needed for remineralization. The other effect is to clog the surface with precipitate and not allow diffusion into the lesion. This was noted by Koulourides and Housch (1983), using laboratory models, as well as by Silverstone and Wefel (1981) when trying to remineralize caries-like lesions. Remineralization of white-spot lesions found clinically is not an easy task. The solution concentrations cannot become too great, or unwanted precipitation occurs on the surface before diffusion into the lesion. A more modest supersaturation maintained over long time periods would seem to be the more ideal condition. This is normally maintained by a reasonable
salivary flow. Thus, a special need for these “salivary enhancers” is during times of reduced salivary flow or impairment due to disease, drugs, or loss of function. Persons with xerostomia would have a unique need for salivary enhancers and may well benefit more than the normal population from their use.

Laboratory studies using NovaMin and reported as research reports from the company have shown that a generally linear relationship exists between exposure time and mineral deposition, indicating that increased exposure time yields increased mineralization for at least up to 40 min. This report suggested that the current bioglass particles could be manipulated for use in the oral cavity and were not limited to bone repair processes. A more recent NovaMin Research Report (Alaudin and Fontana, 2007) evaluated a test dentifrice containing NovaMin and fluoride (MFP). A pH-cycling regimen was used over a 20-day period, and the amount of mineral change was measured via confocal scanning microscopy (CFSM) with rhodamine B dye. The results showed that the test dentifrice showed more mineralization than a commercial MFP dentifrice. The commercial dentifrice tended to result in mineralization limited to the surface, whereas the NovaMin product led to mineralization throughout the lesion depth. Two studies were reported at the IADR General Session in New Orleans (2007) that dealt with dentin surfaces as opposed to enamel surfaces. Featherstone et al. (personal communication) reported that NovaMin-containing dentifrices with or without fluoride could inhibit root caries progression. They also concluded that the results will need to be confirmed by clinical studies. At the same meeting, Burwell and Greenspan (personal communication) compared two existing products known for their ability to reduce hypersensitivity by occluding open dental tubules. After pH cycling and daily two-minute treatments, all dentin surfaces were measured for microhardness. The results showed that a greater amount of protection was afforded by the SoothRx™ group than the Prospe MI paste (GC America) group. It was concluded that these results help explain the reductions in hypersensitivity following treatment. Another NovaMin Research Report (Burwell, 2006) compared the use of DenShield with GC Tooth Mousse (the European product names) on bovine root surfaces by guest on November 15, 2010adr.sagepub.comDownloaded from

One other point must be made in terms of remineralization with NovaMin products, which are reported to form hydroxy-carbonate-apatite. It is well-known that the first mineral to dissolve from enamel is the Mg and carbonate-containing mineral component (Robinson et al., 1983). Therefore, enamel is improved in quality by the de/remineralization process, which removes unwanted impurities in the enamel and replaces this mineral with fluoro-hydroxyapatite. The rapid precipitation of carbonate apatite may be responsible for the occlusion of dentinal tubules and the quick relief from sensitive surfaces; however, this is not the preferred mineral for the long term, since it will be more soluble. It may well be transformed in the oral environment, but I have found no papers or abstracts addressing this issue. This is another area in which more research is needed.

CONCLUSIONS

The statement “NovaMin—likely Clinical Success” can also be taken as a question which can be answered in one word—PROMISING. Most current information supports the claim of sensitivity relief in the short and long term by blocking the dentinal tubules. This is in concurrence with Brännström’s theory of hydrodynamic fluid movement in the tubules causing sensitivity (Brännström, 1963). For claims of caries prevention and remineralization, we certainly need more research to look at ideal formulations and delivery systems. Once these agents are formulated, they need to be tested in clinical trials so that the results can be used to modify the products or delivery systems to optimize the formulations. This circular process should continue until the optimal agents are found, clinically tested, and accepted for use. Their use in special populations, like those with reduced or no salivary flow, should be specified, along with instructions for appropriate use in these populations.

REFERENCES


‘Not all remineralization products are the same!’ www.sultanhealthcare.com (accessed 2-26-09).


