



The Beneficial Effects of a Supersaturated Calcium Phosphate Rinse on the Oral Cavity in Xerostomia Patients

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Abstract

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Abstract

There are many beneficial effects of supersaturated calcium phosphate rinse for the xerostomia patient. Both calcium phosphate and sodium bicarbonate ions found in supersaturated calcium phosphate rinse play significant roles in healing and protecting tissues of the oral cavity. Supersaturated calcium phosphate rinse is not a cure for xerostomia, but it is one of the most powerful adjuncts in the care and treatment of the wide variety of symptoms and severities associated with xerostomia patients.

Supersaturated calcium phosphate rinse (SSCP) is a highly concentrated electrolyte solution resembling human saliva, designed to moisten, lubricate and cleanse the oral cavity and promote the health of the oral tissues. These rinses may contain sodium phosphate, calcium chloride, sodium chloride, and sodium bicarbonate. These commercially available products were developed for the purpose of preventing and treating xerostomia and oral mucositis secondary to head and neck radiation and chemotherapy. One product contains sodium phosphate, calcium chloride and sodium chloride, supplied as two ampules of aqueous solution. Each ampule, one containing calcium and one containing phosphate, is opened and mixed in a container. The patient is then instructed to rinse with the solution and spit out.¹ Another product contains sodium phosphate, calcium chloride, sodium chloride and also sodium bicarbonate. It is supplied as a unit-dosed powder which is then mixed with a specified amount of water in order to create a supersaturated rinse. The patient then rinses with half the mixed solution for 1 minute, spits out and repeats with the second half. This process is repeated from 2-10 times per day as recommended by the prescriber.²

The addition of sodium bicarbonate to supersaturated calcium phosphate rinse adds a significant salivary buffering quality, making this rinse most effective for radiation induced xerostomia and mucositis and also allows for an added versatility of effectiveness for patients outside the realm of radiation induced xerostomia and mucositis. This course discusses data pertinent to the supersaturated calcium phosphate rinse containing sodium bicarbonate.

Saliva

Human saliva is the most important biological factor affecting the health of the soft and hard tissues of the oral cavity. Saliva plays a critical role in the maintenance of optimum oral health and the creation of an appropriate ecologic balance. The components and properties of saliva play a protective role that drives the development of natural preventative measures. The functions of saliva include:

- Lubrication and protection of oral tissues
- Buffering action and clearance of acid
- Maintenance of tooth integrity

- Antibacterial activity
- Digestion and taste

The characteristics of the saliva have a great impact on the oral environment. Cariogenic bacteria live in the mouth (*S.mutans*) and saliva directly impacts their growth and survival.

Saliva is secreted by three major pairs of salivary glands (parotid, submandibular, and sublingual) plus numerous minor salivary glands.³ Saliva is made up of many components, both inorganic and organic. These include electrolytes as well as proteins, immunoglobulins, enzymes, mucins, urea, and ammonia. The components in saliva help to modulate 1) the bacterial attachment in oral plaque biofilm, 2) the pH and buffering capacity of saliva, 3) antibacterial properties, and 4) tooth surface remineralization and demineralization.

The inorganic components include sodium bicarbonate, which aids in the buffering capacity of saliva. Additionally, there are calcium and phosphate ions in a supersaturated state with the highest concentration in the plaque biofilm⁴ which allow for the maintenance of tooth mineral integrity and promotion of soft tissue healing by permeating the epithelium of injured tissues.⁵ The organic components of saliva consist mainly of proteins and glycoproteins. Most of the proteins are rich in proline (proline-rich proteins or PRP's) which comprise 70% of the total protein. Most of the remaining salivary protein content is amylase. Other proteins such as lysozyme, lactoferrin, peroxidase and secretory IgA, are relatively minor components.⁶

Supersaturated calcium phosphate rinse contains the same inorganic components that are present in natural saliva; calcium, phosphate and sodium bicarbonate. It contains no organic components; however, it is largely the inorganic components of natural saliva that benefit the health of the oral tissues. The same healing properties of saliva are characterized in the use of supersaturated calcium phosphate rinse.^{5,25}

The sodium bicarbonate component acts as a buffering agent. This is important because the salivary pH in a xerostomia compromised oral cavity is commonly acidic, having a pH of 6.4 or less. *S. mutans* bacteria thrive in an acidic environment. In xerostomic patients it is not uncommon to see elevated levels of *S. mutans* bacteria, often exceeding 500,000 colony-forming units (CFU). The elevated levels of *S. mutans* increase the risk for dental caries. By buffering the salivary pH, the levels of *S. mutans* are controlled and returned to lower risk levels (<500,000 CFU). Buffering the salivary pH also allows for less erosive tissue lesions.¹⁷

The calcium and phosphate ions keep mineral concentrations at levels that maintain and strengthen tooth structure. They also promote healing of soft tissues by penetrating the intercellular spaces and permeating the xerostomic injured epithelial tissues.

Xerostomia

Xerostomia is defined as dry mouth resulting from reduced or absent salivary flow. Xerostomia is not a disease, but it may be a symptom of various medical conditions, radiation of the head and neck, or a side effect of a wide variety of medications.

It is also a common complaint of older adults, affecting approximately 20% of the elderly population. However, xerostomia does not appear to be related to age itself. It is likely due to prescription medications that have dry mouth as a side effect.⁷

Xerostomia has many etiologies, varying degrees of severity and may affect other age groups in addition to the elderly.

Dry mouth is often a contributing factor for both minor and serious health problems. It can affect the nutrition, dental and the psychological health of the affected patient. Common problems associated with xerostomia include; constant sore throat, burning sensation in the mouth, difficulty speaking and swallowing, hoarseness, and/or dry nasal passages.⁸ It is thought to be a hidden cause of periodontal disease and tooth loss in approximately 30% of adults.⁹ It is well known that xerostomia, left untreated, decreases the pH of the oral cavity and significantly increases the development of plaque, dental caries and oral candidiasis.¹⁰

The signs and symptoms of xerostomia include patient complaints relating to problems eating, speaking, swallowing and wearing dentures. Dry crumbly foods, such as crackers, etc. may be hard to chew and swallow. Complaints may also include soft tissues sticking together such as the lips sticking together or the tongue sticking to the palate, taste disorders (dysgeusia), a burning or painful tongue or mouth and the increased need to drink water, especially at night. Clinical signs may include an increase in dental caries and root caries, fissuring of the lips (angular cheilitis), cracking of the lips, fissuring of the tongue, a generalized erythema throughout the oral cavity, and halitosis.¹¹ Causes of xerostomia include, but are not limited to, radiation/chemotherapy, medications, autoimmune disorders such as Sjogren's syndrome, sleep habits, and emotional states etc. The symptoms and clinical signs may be singular or multiple and vary in severity depending on the degree of the xerostomia.

Diagnosis of xerostomia may be based on evidence obtained from the patient's history, an examination of the oral cavity and/or sialometry, a simple office procedure that measures the flow rate of saliva. Xerostomia should be considered if the patient complains of dry mouth, particularly at night, or of difficulty eating dry foods such as crackers.¹² The oral mucosa may be dry and sticky or it may appear erythematous due to an overgrowth of candida albicans. The red patches often affect the hard or soft palate and dorsal surface of the tongue. Occasionally, pseudomembranous candi-

diasis will be present, appearing as removable white plaques on any mucosal surface. There may be little or no pooled saliva in the floor of the mouth, and the tongue may appear dry with decreased numbers of papillae. The saliva may appear stringy, ropy or foamy. Dental caries may be found at the cervical margins or exposed roots of the teeth.¹⁰ Several office techniques can be utilized to ascertain the function of salivary glands. In sialometry, or salivary flow measurement, collection devices are used to measure the flow rate of stimulated saliva. Typically the normal flow rate for stimulated saliva is 1-2 mL/min. Values less than 0.1 mL/min are xerostomic, however reduced flow may be measured but not always associated with complaints of dry mouth.¹³

The majority of xerostomia seen in a dental patient is medication induced. Dry mouth is one of the most common side effects of over 400 commonly used prescription medications.¹⁴ The majority of the medications with xerogenic side effects include antihistamines, antidepressants, anticholinergics, anorexiant, antihypertensives, antipsychotics, anti-Parkinson agents, diuretics and sedatives. A very large population of patients are on one or more of these medications. It should be noted that while there are many drugs that affect the quantity and/or quality of saliva, the side effects generally are not a permanent condition.⁹

The most common disease associated with xerostomia is Sjogren's syndrome. Sjogren's syndrome is a chronic inflammatory autoimmune disease that occurs predominantly in postmenopausal women. Approximately 3% of Americans suffer from Sjogren's syndrome, 90% of these patients being women with a mean age of 50 years old.¹⁵ Many other diseases also may cause xerostomia. These include rheumatoid arthritis, systemic lupus erythematosus, scleroderma, diabetes mellitus, hypertension and cystic fibrosis. Other conditions such as bone marrow transplantation, endocrine disorders, nutritional deficiencies, nephritis, thyroid dysfunction and neurological disorders such as Bell's palsy, cerebral palsy and stroke can all have a xerostomic element. Xerostomia can also be exacerbated by activities including mouth breathing, smoking, alcohol consumption, hyperventilation, and CPAP usage for sleep apnea.^{10,11}

Xerostomia is the most common toxicity associated with standard fractionated radiation therapy to the head and neck.⁹ Acute xerostomia from radiation is due to an inflammatory reaction, while late xerostomia, which can occur up to one year after radiation therapy, results from fibrosis of the salivary gland and is usually a permanent condition. Radiation causes changes in the serous secretory cells, resulting in a reduction in serous salivary output thus increasing the viscosity of the saliva. A common complaint following radiation therapy is thick or sticky saliva. The degree of permanent xerostomia depends on the volume of salivary gland tissue exposed to radiation and the dose of

radiation. When the total dose exceeds 5200cGy, salivary flow is reduced and little or no saliva is expressible from the salivary ducts. These changes are typically permanent.¹⁶

Certain chemotherapeutic drugs may also cause xerostomia but the condition is usually temporary.

The risks of infection from the normal oral flora are high among patients experiencing xerostomia from radiation therapy and/or chemotherapy. Oral ulcerations can become the nidus of invasive gram-positive and gram-negative infections, and opportunistic infections by fungal organisms such as candida albicans.¹⁷

Since 1968, it has been argued and established in the scientific community that *S. mutans* bacteria in the oral cavity is the major etiologic agent of dental caries.¹⁸ We also know that pH plays a significant role in the pathological shifts of the biofilm in the oral cavity: the lower the pH of the saliva, the higher the concentration of *S. mutans* bacteria, and thus, the higher the risk for dental caries.¹⁹

In a case with normal salivary flow, you see a normal pH (6.5 – 7.1). As much as 1.7 liters of saliva is secreted into the oral cavity each day.²² Also, the highest flow is found in mid-afternoon and the lowest flow usually around 4:00AM.²³ The pH value of saliva will continuously change, becoming more acidic with the introduction of foods and beverages, especially those with fermentable carbohydrates; i.e., foods and drinks with high sugar contents. In a healthy, non-xerostomic situation, the pH will return to its normal range in approximately 30 – 60 minutes because of the natural buffering capacity of the saliva.²⁰ With normal salivary flow, as foods are introduced and the pH decreases, the levels of supersaturation of calcium and phosphate ions also decreases. Thus, the risk of demineralization of tooth structure increases. While there is no exact pH at which demineralization begins, we do know that a pH range from 5.0-5.5, is considered critical for tooth minerals to dissolve. But with normal salivary flow, the supersaturation levels of calcium and phosphate ions will renew and reduce the likelihood of demineralization of the tooth structure.

Conversely, in the case of xerostomia, with diminished or no salivary flow, there is already a low pH. With less saliva, the aciduric and acedogenic bacteria flourish in higher concentrations. Therefore, a low flow of saliva generally means a lower pH. Reduced salivary flow also means a lower renewal rate of bicarbonate ions so the buffering effect seen in normal saliva is diminished. Additionally, low pH and diminished salivary flow means a loss of the normal renewal rate of calcium and phosphate ions. In a xerostomic situation, there is a greater risk of dental caries because the tooth structure is at high risk for demineralization. This demineralization occurs in an environment with an elevated population of *S. mutans* bacteria, the primary etiologic agent in dental caries.²¹

There is a wide variety of products on the market, both OTC and prescription, that have been designed to

support the xerostomia patient. Most OTC products are rinses, pastes or lozenges containing glycerin, glycols, and fluoride as active agents. Some of these products are acidic, having a pH of 6.0 or less. A supersaturated calcium phosphate rinse containing sodium bicarbonate may help re-adjust the overall conditions in a xerostomic oral cavity to conditions similar to a healthy oral cavity. Supersaturated calcium phosphate rinse will allow for active correction of pH, buffering capacity, remineralization and soft tissue healing by its mechanism of action.⁵

Severe manifestations of xerostomia are found predominantly in radiation and Sjogren's patients. The question arises regarding which xerostomic dental patients might benefit from using supersaturated calcium phosphate rinse?

Supersaturated calcium phosphate rinses were developed specifically to manage the severe and painful symptoms related to mucositis found with severe xerostomia. The mechanism of action of supersaturated calcium phosphate rinse will allow this rinse to be effective for many patients with xerostomia.

A 2013 study by the author was designed to evaluate the effectiveness of supersaturated calcium phosphate rinse on dental patients with varying degrees of xerostomic symptoms.²⁴

Thirty xerostomic patients and thirty non-xerostomic dental patients (control group) were tested for:

- 1) Elevated levels of *S. mutans* bacteria (> 500,000 CFU/ml were considered elevated in this study).
- 2) Salivary pH (salivary pH levels of 6.4 or less were considered acidic for this study).
- 3) Patients were asked to fill out a dry mouth questionnaire regarding the severity of symptoms of xerostomia they were experiencing. They were asked to rate the ability to swallow, drink, eat, talk, and taste on a scale from 0 (no limitation noted) to 4 (unable to perform).

Patients were instructed to rinse with supersaturated calcium phosphate rinse 2-3 times per day for 28 days. Patients were monitored at 7 day intervals by phone.

Patients were retested at 28 days for *S. mutans* levels, and salivary pH. Patients were also asked to repeat the dry mouth questionnaire.

The results of the study were as follows:

S.mutans population	Initial baseline sample	28 day sample
Control Group	<500,000cfu/ml	<500,000cfu/ml
Test Group	>500,000cfu/ml	<500,000cfu/ml

AVERAGE SALIVARY pH	Initial baseline sample	28 day sample
Control group	7.1	7.2
test group	5.9	7.0

Dry mouth questionnaire:

Control group:

No changes

Test group:

90% noted improvement in swallowing

93% noted improvement in drinking

80% noted improvement in eating

90% noted improvement in talking

86% noted improvement in dysgeusia

It should be noted that of the patients recruited for this study only one was post-radiation in the head and neck region and none were Sjogren's syndrome patients. The majority (all but one) were dental patients with a typical complaint of dry mouth. Most of these patients were on one or more prescription medications. These were the type of patient one sees on a regular basis in any dental office.

This data shows that pathogenic levels of *S. mutans* bacteria were present at degrees of severity lower than the extreme degree of severity associated with post-head and neck radiation patients and Sjogren's patients. More importantly, the results indicate that within this patient population, the regular use of supersaturated calcium phosphate rinse reduced the levels of salivary *S. mutans* bacteria, provided movement towards a normal salivary pH and a generalized improvement in the relief of symptoms associated with xerostomia.

Patient management of xerostomia in the dental setting should be a primary concern of the dental practitioner. The secondary effects of xerostomia are all detrimental to the overall health of the oral cavity. By managing complaints of dry mouth and interviewing patients that are on one or more prescription medications, it may be possible for the dental practitioner to not only alleviate the subjective symptoms of xerostomia but also to manage the oral microflora by buffering the salivary pH and thus, limit the population of *S. mutans* bacteria to non-pathogenic levels. It is important for dental professionals; dentist and dental hygienist alike, to realize the importance of supersaturated calcium phosphate rinse as a dentifrice and part of normal preventative care for many patients. The beneficial effects of supersaturated calcium phosphate rinse to the xerostomia patient are well established by research.

The mechanisms of action of supersaturated calcium phosphate rinse are as follows:

- 1- The action of the calcium and phosphate ions to promote healing of painful/inflamed tissues by permeating the intercellular spaces of the the injured epithelial tissues.
- 2- The action of the calcium and phosphate ions in a supersaturated concentration to promote and maintain healthy tooth structure by supplying the minerals needed to prevent demineralization.

- 3- The action of sodium bicarbonate ions to buffer the salivary pH which, in turn, helps maintain non-pathogenic levels of salivary *S. mutans* bacteria in the oral cavity.

A large population of dental patients may benefit from the use of such a rinse. Applications of supersaturated calcium phosphate rinse may be extrapolated to case specific situations. For instance, the non-compliant orthodontic patient; rinsing with supersaturated calcium phosphate rinse on a regular basis might help prevent demineralization of tooth structure and decay. Other patients who may benefit include patients with GI problems such as acid reflux, which can cause changes to the pH of the oral cavity and in turn, change the levels of pathogenic *S. mutans* bacteria. There are many dental case scenarios where the mechanism of action of supersaturated calcium phosphate rinse may be applicable.

Supersaturated calcium phosphate rinse is not a cure for xerostomia but it may be a powerful adjunct in the care and maintenance of xerostomic patients. Supersaturated calcium phosphate rinse can also be an adjunct to the care and maintenance of any patient whose symptoms might benefit from the additional presence of calcium, phosphate and/or sodium bicarbonate ions.

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