

# Clinical evaluation of a new artificial saliva in spray form for patients with dry mouth

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## Abstract

**Objectives:** To determine the efficacy of a new saliva substitute in spray form, for patients with dry mouth.

**Study design:** Thirty-seven patients with dry mouth were selected (16 males and 21 females), with an age of over 60 years and meeting the following inclusion criteria: xerostomia and hyposialia confirmed by sialometry (resting whole saliva / stimulated whole saliva). A new artificial saliva in spray format was applied, with evaluation of the degree of improvement (VAS scale), frequency of application, time to improvement in minutes, duration in minutes, and assessment of organoleptic properties.

**Results:** Twenty of the 37 patients showed almost immediate improvement after application. The mean number of applications/day was 3.89, with a mean duration of effect of 15.3 min. (65% > 15 min.). The flavor was rated as pleasant by 18 patients.

**Conclusions:** Application of the spray is simple and effective, affording immediate relief, and with reasonable acceptance among patients with dry mouth.

**Key words:** Xerostomia, hyposialia, advanced age, artificial saliva.

## Introduction

Subjective dry mouth sensation is known as xerostomia, though when sialometry objectively demonstrates a saliva flow rate of under 0.1-0.2 ml/min (resting whole saliva) and under 0.7 ml/min (stimulated whole saliva), the term hyposialia, sialopenia or salivary hyposalivation is used (1-4). This condition is equivalent to the secretion of less than 500 ml of saliva a day.

The diagnosis of hyposialia must be based on all the case history elements that may be directly implicated in alteration of the salivation reflex (5). The salivary glands should be explored, with the observation of saliva secretion in response to

massage and drainage of the major salivary glands. However, sialometry is the most conclusive technique for both resting and stimulated whole saliva. If duct obstructions or calculi are suspected, gland sialography is indicated. If an autoimmune disease is suspected, a minor salivary gland biopsy of the lip should be made, with the determination of antibodies (6).

In patients with chronic hyposialia, the oral mucosa appears dry as a result of diminished lubrication. This leads to patient discomfort and the first manifestations of dysfunction that markedly affect quality of life, such as speech, chewing or swallowing difficulties (7), and even impaired taste sensation. Likewise, these patients are more susceptible to oral infec-

tions due to the adverse effects of diminished saliva output upon the oral ecosystem (8). There is a direct relationship between diminished salivation and the appearance of dental caries and halitosis. The caries in such situations evolve rapidly and are typically located in the region of the dental neck. The development of chronic erythematous candidiasis is also frequent on the back of the tongue, along with angle cheilitis (5).

The appearance of hyposalivation and/or subjective dry mouth can be due to a number of causes, though in general the condition results from inhibition of the salivation reflex or alterations of the salivary glands. The associated factors include the use of different drugs, psychopathological alterations and other disorders such as autoimmune diseases (Sjögren's syndrome) or radiotherapy for head and neck cancer (9).

The prevalence of xerostomia is high among the general population, and increases with age – affecting approximately 30% of all individuals over age 65 years. Very possibly, such a high incidence in this elderly population is due to the co-existence of several etiological factors such as the presence of chronic diseases, and multiple and chronic drug use (10,11). Thus, xerostomia among the elderly is not fundamentally a physiological condition but rather a consequence of disease or of the side effects of medication. This in turn complicates the wearing of dentures, and can cause the latter to produce mucosal irritation (12).

The treatment of dry mouth first must be planned by adopting an etiological approach. Secondly, salivary stimulation must be attempted by means of sialogogues, and salivary substitutes should be used in all cases to avoid the generation of symptoms and deterioration of the oral tissues (13,14).

Saliva substitutes constitute palliative and coadjuvant treatments that are the option of choice in the case of patients with chronic dry mouth. Such artificial salivas fundamentally act by humidifying and lubricating the dehydrated oral mucosa (15). Likewise, they protect the oral cavity against irritation, and facilitate mechanical functions such as speech and swallowing, among others. Saliva substitutes mainly consist of aqueous solutions containing the same mineral salts as those found in human saliva. As such, they mimic the natural functions of these elements in the oral cavity (16,17). Salts such as phosphates and calcium ions in particular exert a key buffering effect to normalize the oral pH and avoid chemical dissolution of the dental enamel, while restoring the demineralization / remineralization balance of the teeth (18-20). Artificial salivas also usually contain enzymes with antimicrobial action, or mucins as lubricants. Likewise, these formulations sometimes contain elements that afford extra protection, avoiding buccodental over-colonization and thus the development of caries (21).

The present study was designed to demonstrate the subjective improvement afforded by a new artificial saliva in spray form containing an aqueous solution of mineral salts, xylitol and citric acid, in elderly patients with dry mouth.

## Material and Methods

A descriptive study was made of 37 patients between 60-77 years of age (mean 65 years) seen in our Service with a history of dry mouth, and who met the inclusion criteria and gave informed consent to participation in the study. There were 16 males and 21 females. All patients presented hyposaliva as confirmed by resting whole saliva (RWS) <0.1 ml/min and stimulated whole saliva (SWS) <0.7 ml/min.

- Two inclusion criteria were established:

1) Dry mouth sensation (xerostomia), as verified by questioning of the patient during the anamnesis.

2) Objective prior sialometric confirmation of hyposaliva based on the resting whole saliva (RWS) and stimulated whole saliva values (SWS). This criterion was used to ensure homogeneity of the study sample. Two sialometric evaluations were made on different days. The drainage technique was used, collecting saliva in the morning after at least two hours without food or drink, or smoking.

Following the duplicate resting and stimulated sialometric tests, mean resting whole saliva values of RWS1 = 0.11±0.07 ml/min and RWS2 = 0.13±0.12 ml/min were obtained, with mean stimulated whole saliva values of SWS1 = 0.39±0.19 ml/min and SWS2 = 0.40±0.15 ml/min.

The objective of the present study was to evaluate the subjective improvement afforded by a new artificial saliva formulation fundamentally composed of an aqueous solution of potassium thiocyanate, potassium chloride, sodium chloride, calcium chloride, magnesium chloride, potassium dihydrogen phosphate, xylitol and citric acid.

The solution was supplied in spray format for more convenient administration during the day to improve oral mucosal hydration. The patients were required to use the product for 7 days, as often as required according to the intensity of oral dryness, and with a minimum frequency of two applications a day. A questionnaire was supplied for recording information on the perceived effects of the product. In this way, the degree of improvement (reduction of dry mouth sensation) was rated by a visual analog scale (VAS) from 0-10 (0 = no improvement; 10 = total improvement). The patients were also questioned about the frequency of application of the spray, the time to onset of improvement (in minutes), and the duration of improvement. Finally, their opinion was requested regarding the organoleptic properties of the formulation (particularly flavor), likewise rated on a VAS from 0-10. A descriptive analysis of the data was made, reporting the results as absolute frequencies and percentages for each study variable.

## Results

All the patients (n=37) selected for this study presented some antecedent of disease characteristic of the age involved. A total of 29 patients were receiving medication for the treatment and/or prevention of such disease. The most common pathologies in this sense were hypertension, type 2 diabetes, depression and rheumatic problems. Almost one half

of the subjects (n=15) were using some psychoactive drug for anxiety or depression, and three subjects had received radiotherapy for head and neck cancer.

All the subjects complained of dry mouth, with difficulties for basic oral functions such as speech, eating or swallowing.

Twenty patients (54%) reported some improvement after using the spray. Such improvement was immediate in 19 cases, while one patient reported improvement after one minute. There was no relationship between such improvement and the background disease or drug use.

All the patients applied the product at least twice a day, and a maximum of 7 times a day (mean 3.89 daily applications). A total of 54% of the patients used the spray three or four times a day.

The duration of the humidification effect ranged from 6-28 minutes, with an average of 15.3 minutes. In 90% of the cases the duration of the effect was 10 minutes or more, while in 65% of the cases the effect lasted for 15 minutes or more.

The flavor of the solution was favorably rated by 18 patients, with a mean score of 7.45 among those who noted improvement after using the spray. No adverse effects were associated with the use of the product.

## Discussion

Dry mouth is a common problem among elderly patients seen in dental practice. When this problem becomes chronic, it can lead to important oral pathology, with an increased risk of infections and rampant caries. On the other hand, hyposialia has a marked negative effect upon patient quality of life, as a result of the impairment of oral functions (22). As has been reported by Bergdahl and Bergdahl (2), age and medication play a very important role in patients with hyposialia.

As has been commented by Guijarro et al. (1), when treating dry mouth it is important not to forget the adoption of preventive measures to reduce the complications. It is also important to evaluate the existing functional salivary gland parenchyma, to allow mechanical, chemical or gustative stimulation (23). Such low intensity stimulation of the salivary glands can be achieved with simple measures such as xylitol chewing gum, sugar-free essence-containing sweets, increasing the frequency of meals, or encouraging the consumption of acidic beverages (5). However, when these measures no longer prove effective, other options must be sought. In this context, use can be made of drugs that stimulate secretion, such as pilocarpine in droplets or tablet form, though the associated undesirable effects are highly varied and frequent (24). These characteristics preclude such treatment in patients with hyposialia secondary to chronic illnesses or the administration of multiple drug substances. As a result, in these patients, which constitute the great majority of subjects with dry mouth, and particularly in those over 65 years of age, saliva substitutes represent the best palliative management option – though no ideal artificial saliva has been developed to date (25). These formulations replace the components and functions inherent to natural saliva, which are lost to one degree or other as

a result of dry mouth. Thanks to their lack of undesirable effects, saliva substitutes can be used for prolonged periods of time as palliative or coadjuvant treatment, depending on the severity of hyposialia (26). Likewise, these products can be used as often as considered necessary, and are thus adaptable to the needs of each individual patient, and to the degree of oral dryness.

The product evaluated in the present study is an artificial saliva containing mineral salts and ingredients needed for maintaining a correct buffer effect and for ensuring the remineralization of dental enamel – which according to Moore and Guggenheimer (11) are the specifications required for the palliative management of xerostomia. However, the spray also contains saliva-stimulating elements such as xylitol and citric acid, though its most important effect is lubrication of the oral mucosa (27).

The spray format in turn facilitates administration among patients not used to such treatments, or with problems for using other alternatives (e.g., chewing gum), particularly elderly patients with disabilities or who wear dentures.

The study patients had been selected from a larger cohort of elderly individuals in which dry mouth was identified from the case history and posteriorly confirmed by duplicate sialometric determinations of RWS and SWS. Most of the subjects, with 3-4 daily applications of the product, found the spray format to be convenient and easier to use than other formulations such as oral rinses. Likewise, most of the patients found the product flavor to be pleasant. In turn, the very favorable acceptance of the product probably contributes to improve treatment compliance. In effect, as pointed out by Gerdin et al. (3), the great majority of patients that need saliva substitutes are elderly people, and thus require easy access and use of the treatment (28).

It should be noted that those patients who reported improvement of dry mouth with the use of the product experienced effect almost immediately, with an important mean duration of the latter. The lack of side effects allowed repeated application of the spray as many times as desired, with prolongation of symptoms relief and thus of the beneficial effects for the oral cavity.

In conclusion, it is considered that this saliva substitute in spray format is simple to use and is clinically effective, with the provision of immediate relief from the symptoms of dry mouth. Improved oral health and comfort among these patients is thus afforded.

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