# **Xerostomia**

## Xerostómia

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#### **Abstract**

Xerostomia or oral dryness is developed when the amount of the whole saliva is primarily reduced or even absent. Xerostomia has significant devastating effects not only on the oral environment but also on an individual's general wellbeing. It poses substantial challenges regarding diagnosis and treatment for both patients and clinicians. In recent years, several therapeutic strategies have been proposed to reduce patients' symptoms; however, xerostomia remains an unresolved complaint in human dental practice, especially among elderly subjects. BioXtra is a synthetic product that contains all essential salivary components to relieve the symptoms of xerostomia. In the present study, the effectiveness of BioXtra gel, mouth rinse, and toothpaste were examined on 20 patients who suffered from xerostomia. Based on the findings, BioXtra products can significantly improve the symptoms of patients after 21 days. However, further studies with a large sample size are highly warranted.

**Key words:** xerostomia, mouth dryness, artificial saliva, BioXtra.

#### **Abstrakt**

Xerostómia alebo sucho v ústach sa vyvinie, keď sa výrazne zníži celková hladina slín, alebo sliny úplne chýbajú. Xerostómia má značné nepriaznivé účinky nielen na ústne prostredie, ale aj na celkový zdravotný stav jednotlivca a predstavuje značné problémy týkajúce sa diagnózy a liečby ako pre pacientov, tak aj pre lekárov. V posledných rokoch bolo navrhnutých niekoľko terapeutických postupov na zníženie symptómov u pacientov. Xerostómia však zostáva nevyriešeným problémom v zubnej praxi, najmä u starších osôb. BioXtra je syntetický produkt, ktorý obsahuje všetky nevyhnutné zložky slín na zmiernenie prejavov xerostómie. V tejto štúdii bola skúmaná účinnosť BioXtra gélu, ústnej vody a zubnej pasty u 20 pacientov trpiacich xerostómiou. Na základe zistení môžu produkty BioXtra výrazne zlepšiť príznaky už po 21 dňoch. V budúcnosti budú potrebné ďalšie štúdie s početnejšími vzorkami.

**Kľúčové slová:** xerostómia, sucho v ústach, umelé sliny, BioXtra.

#### Introduction

Normal saliva is defined as a viscous, transparent, and slightly acidic fluid secreted from the major and minor salivary glands. The pH range for saliva is between 6.2 and 7.4; however, various conditions such as nutritional status, infections, drugs, and diseases might have an impact on its production level [16, 21] of course, any change in salivary flow rate or composition of the whole saliva not only results in oral health problems including dental

caries, dry mouth, gingivitis, halitosis, mucositis, candidiasis, and traumatic oral lesions but also has a detrimental impact on the quality of life [6, 24, 9]. Xerostomia, commonly called "dry mouth sensation," is frequently encountered in human dental practice, especially among older patients [13, 15, 10]. It occurs when the amount of the whole saliva that bathes the oral mucous membranes is primarily reduced or even absent; hence, it is a subjective complaint of oral dryness, which may be associated

with oral burning, soreness, or altered taste. It can affect both quantitative and qualitative functions of salivary glands and leads to an increased frequency of dental caries, candida infection, dysarthria, and dysphagia [13, 26, 10, 17, 12]. Xerostomia has a broad range of prevalence ranging from 0.9 % to 64.8 % [5, 4].

There are a wide variety of salivary and non-salivary factors are involved in the development of xerostomia. Xerostomia may occur in transient, prolonged, or permanent types based on the causative agents. For example, psychological problems due to depression, anxiety, and stress, as well as medications, duct calculi, and infections, are temporary causes of xerostomia [13]. However, diseases of the salivary gland (like untreated blockage of the duct of a major salivary gland, surgery or trauma to the ducts, salivary gland aplasia), systemic disorders (like diabetes mellitus, alcoholic cirrhosis, cystic fibrosis, hypertension, cardiovascular disorders, hemolytic anemia, neurological disorders, encephalitis, brain tumors, hormonal imbalance, hypothyroidism, amyloidosis, Parkinson's disease, sarcoidosis, vitamin A deficiency, riboflavin deficiency, nicotinic acid deficiency, iron deficiency, folic acid deficiency), immunological disorders (like Sjogren's syndrome, systemic lupus erythematosus, scleroderma), radiation and/or chemotherapy of the head and neck cancers, and malnutrition, are some biological causes of permanent xerostomia [13, 15, 17, 27, 7]. Management of xerostomia is not simple. To treat xerostomia successfully, identification of the underlying cause is mandatory. In recent years, various therapeutic strategies have been suggested to reduce patients' symptoms with xerostomia or stimulate salivation. Local and systemic stimulation of salivary glands was developed based on the salivary stimulants, mucosal lubricants, topical agents, parasympathetic agonists, saliva substitutes, and systemic sialogogues to maintain proper hydration and increasing night-time humidity. Furthermore, palliative treatments for symptomatic relief and treating other complications of the oral cavity should be considered simultaneously [26, 15]. The treatments can be organized into five major categories, as follows [7]:

- Patient education- Correction of dehydration and increasing water intake is significant for minimizing symptoms of xerostomia and preventing oral complications [10, 7].
- 2. Pharmacological interventions- including the application of oxygen scavengers or radio--protectors can protect salivary glands from free-radical damages [7]. Several preventive therapies have been suggested for preventing salivary gland dysfunction. Amifostine has been

- proven for the prevention of xerostomia after radiotherapy [19, 23]. Furthermore, radioprotective effects of keratinocyte growth factor-1 (KGF-1) against irradiation-induced salivary gland hypofunction were also approved. Although KGF-1 can reduce xerostomia during hyper-fractionated radiotherapy, it has no impact on standard radiation therapy [5, 4].
- 3. Symptomatic Treatment- Symptomatic relief and prevention of oral complications is the primary goal of the management of xerostomia [15, 2]. Saliva substitutes have been proposed to simulate natural human saliva, which can provide a higher viscosity and also protect the oral mucosa [7].
- 4. Systemic and Topical Stimulants- For drug-induced xerostomia, the dosage regimen can be modified, stop or substituted with alternative medication with a mode of action similar to that of the original drug [9, 10]. For example, pilocarpine (5-10 mg three times a day, which can be increased up to 30 mg/day) and cevimeline (30 mg three times a day) is stimulating the secretion of water and electrolytes by muscarinic receptors and prescribed for three months [26, 15, 7, 8].
- **5. Regenerative and Gene Therapies-** Stem cell-based therapy [14, 22] and gene therapy [3, 11, 1] are new promising approaches for the treatment of xerostomia and attempts to repair the damaged salivary glands at the cellular level.

#### Materials and methods

Twenty patients were included in this study, 12 males (60%) and eight females (40%). All of them had confirmed diagnoses of xerostomia, and the diagnosis was based on the patient's discomfort. Before any treatment been used, patients had to fill a questionnaire developed by van der Putten et al. The questionnaire used in this study was developed by van der Putten et al. (33) and composed of some simple and specific questions with two possible answers (yes/no choices) (Table 1, 2).

All of the patients in the study were previously treated with some categories of drugs. 2 patients (10%) were prescribed with one drug category for the treatment of xerostomia; however, the majority of them (10 patients, 50%) had a history of 2-3 drug categories. 40% of patients were in the past prescribed with more than 3- drugs categories of medications (Table 3).

After completion of the questionnaire, all patients were treated with BioXtra gel (three times a day), BioXtra mouth rinse (three times a day), and BioXtra toothpaste (two times a day) for 21 consecutive days.

All patients that finished their treatment period according to the study design were asked again to answers four questions in the questionnaire (Table 4).

After finishing treatment, all of the patients were asked again to answer four questions in the same question are like before treatment.

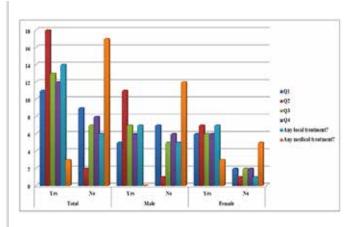
**Table 1.** Questionnaire used for this study (van der Putten et al.)

**Table 1.** Dotazník použitý pre túto štúdiu (van der Putten et al.)

		Quest Pation				
Gender				Age		
Male Female						
1) My mouth feels dry when eating a meal			YES	NO		
2) My mouth fee	2) My mouth feels dry			YES	NO	
3) I have difficult	) I have difficulty in eating dry foods			YES	NO	
4) I have difficu	ties swallowir	ng certain fo	ods	YES	NO	
Any local trea	tment	YES	NO			
If yes was it helped		YES	NO			
Any medical treatment		YES	NO			
Ifyes was it helped		YES	NO			
BioXtra for 2	days					
Gel						
Mouthrinse						
Toothpaste						
		Score 1-	-5, 5 is the best			
<ul> <li>Did th</li> </ul>	Oid the treatment helped?			1 - 2 - 3	4 - 5	
<ul> <li>Was it</li> </ul>	<ul> <li>Was it comfortable to use?</li> </ul>			1 - 2 - 3	1 - 2 - 3 - 4 - 5	
<ul> <li>Will y</li> </ul>	o Will you continiu for local treatment?			1 - 2 - 3	1 - 2 - 3 - 4 - 5	
O Did you feel better during speech?			1 - 2 - 3 -	1 - 2 - 3 - 4 - 5		
1) My mouth fee	My mouth feels dry when eating a meal			YES	NO	
2) My mouth feels dry			YES	NO		
3) I have difficulty in eating dry foods			YES	NO		
4) I have difficulties swallowing certain foods			YES	NO		

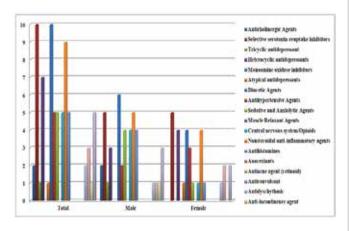
**Table 2.** Pre-treatment answers to each specific question in the questionnaire. Q1) My mouth feels dry when eating a meal; Q2) My mouth feels dry; Q3) I have difficulty in eating dry foods; Q4) I have difficulties swallowing certain foods.

**Table 2.** Odpovede na jednotlivé otázky v dotazníku položené pred liečbou. Otázka č.1: Mám pocit sucha v ústach, keď jem jedlo; Otázka č. 2: Mám pocit sucha v ústach; Otázka č. 3: Mám ťažkosti s jedením suchých jedál; Otázka č. 4: Mám ťažkosti s prehĺtaním určitých potravín.



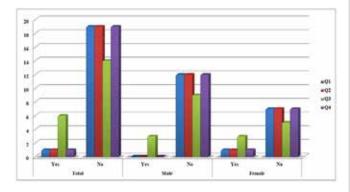
**Table 3.** Categories of drugs that previously prescribed to patients with xerostomia

**Table 3.** Kategórie liekov, ktoré boli predpísané pacientom s xerostómiou.



**Table 4.** Post-treatment answers to each specific question in the questionnaire. Q1) My mouth feels dry when eating a meal; Q2) My mouth feels dry; Q3) I have difficulty in eating dry foods; Q4) I have difficulties swallowing certain foods.

**Table 4.** Odpovede na jednotlivé otázky v dotazníku položené po liečbe. Otázka č. 1: Mám pocit sucha v ústach, keď jem jedlo; Otázka č. 2: Mám pocit sucha v ústach; Otázka č. 3: Mám ťažkosti s jedením suchých jedál; Otázka č. 4: Mám ťažkosti s prehĺtaním určitých potravín.



#### Results

The main goal of this study was to relief discomfort in patients suffering from xerostomia.

Based on the findings of this study, treatment of patients who suffered from xerostomia with a combination of BioXtra gel, BioXtra mouth rinse, and BioXtra toothpaste can significantly improve their symptoms after 21 days, along with better acceptance among patients. Our results are in agreement with the previous studies. As outlined above, BioXtra products have a good potency to prescribe for patients with xerostomia; however, further studies on large cohorts of patients with different cause of xerostomia are highly recommended.

#### Discussion

Xerostomia is frequently encountered in human dental practice and represents a serious oral health problem in nearly half of the elderly population and about one-fifth of younger adults and it is associated with health-related quality of life.

The diagnosis of xerostomia is based on a careful medical history with attention to the symptoms and medication use.

To manage xerostomia effectively, the identification of the underlying cause is mandatory. In recent years, various therapeutic strategies have been suggested to reduce the symptoms of patients; however, xerostomia remains an unresolved common complaint in human dental practice.

BioXtra is a synthetic product that contains all essential salivary components which work as an enzymatic basis to eliminate symptoms of xerostomia.

The present study is designed to assess the effectiveness of BioXtra products for improving the symptoms of xerostomia.

There are some validated questionnaires (singleitem approaches or multi-item scales) with acceptable sensitivity and specificity that have been developed to assess patients with xerostomia. However, the questionnaire used for this study was developed by van der Putten et al.

The pre-treatment status of patients was assessed based on the answers to each specific question in the questionnaire. Among patients who had a history of any local treatment (n = 14), only one patient reported that it was helpful. Besides, none of the patients who had a history of any medical treatment (n = 3) reported that it was helpful.

During this study and after completion of the questionnaire, all patients were treated with BioXtra gel (three times a day), BioXtra mouth rinse (three times a day), and BioXtra toothpaste (two times a day) for 21 consecutive days.

All patients that finished their treatment period according to the study design were asked again to answers four questions in the questionnaire. The post-treatment status of patients was assessed based on the answers to each specific question, and based on the findings of this study, treatment of patients with BioXtra improved their symptoms after 21 days.

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