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XyliMelts time-release adhering discs for night-time oral dryness

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Abstract: Dry mouth can be caused by medication, CPAP use, radiation treatment and a variety of connective tissue diseases, with the prevalence increasing with age. In most individuals, daytime dryness is easily managed. However, except for a new product tested in this study, there is no product lasting longer than an hour that can be used at night to reduce the perception of oral dryness while sleeping. The purpose of this study was to assess whether a self-adhering, slowly dissolving disc that time-releases 500 mg of xylitol, cellulose gum (lubricant and humectant) and mild mint flavour (XyliMelts for Dry Mouth, OraHealth Corp.) used during sleep would reduce perceived morning oral dryness and discomfort. Fifteen subjects self-identified as having morning oral dryness were evaluated first without treatment and again with the use of XyliMelts for Dry Mouth. Measures of initial morning discomfort and perceived wetness demonstrated significant improvement. Perceived oral wetness scores increased more than threefold with the use of XyliMelts for Dry Mouth while sleeping. These findings suggest that XyliMelts for Dry Mouth may be an effective strategy for managing oral dryness that occurs at night.

Key words: clinical trial; collaborative approach; collective; prevention individual; professional practice; research; saliva

Introduction

According to the U.S. NIDCR/CDC 2002 report on the prevalence of xerostomia, people of all ages perceive dryness in the mouth (dry mouth) – more frequently, women – with the prevalence of dry mouth increasing with age (1). Dry mouth is associated with health problems such as diabetes, cancer management, depression, anxiety and autoimmune disease, particularly Sjogren's syndrome. It also results from prescription drugs and non-prescription drugs used to treat these and other conditions (2). Dehydration, mouth breathing, use of positive airway pressure machines, and use of alcohol or chewing tobacco can also cause or aggravate oral dryness.

Symptoms of oral dryness include mouth burning or tingling; throat dryness; tongue, gum and denture ridge soreness; taste dysfunction; speech problems; sore throat; a sticky dry feeling in the mouth; and difficulty swallowing (3). Oral dryness is associated with an increased incidence of oral ulceration, infection (yeast infection – candidiasis), tooth decay, periodontal disease and lip cracking (4). In addition, afflicted individuals can experience halitosis, insomnia, irritability, depression and speech and eating disorders (5).

Most people with dry mouth do not have significant underlying systemic disease causing glandular destruction and are not in need of prescribed medicines to treat the problem (6). During the day, individuals

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with dry mouth can reduce the perception of dryness by frequently sipping cool water (or sugarless drinks) or sucking on ice. However, water is a poor moistener of the oral mucosa, as it does not moisten or lubricate the mucosa as well as saliva and is rapidly dissipated. Patients may also benefit by sucking on sugar-free fruit pastilles or chewing sugar-free gum. In addition, a number of artificial saliva substitutes (in solution) and oral moisturizers (as gels) are available over the counter (7).

For oral dryness occurring during sleep, management can be more problematic. XyliMelts for Dry Mouth (OraHealth Corporation, Bellevue, WA, USA) is recommended for use while sleeping, as well as during the day. XyliMelts discs adhere to gingiva and/or molars in the buccal and time-release 500 mg of xylitol (a natural non-fermentable carbohydrate that tastes like table sugar), cellulose gum (cellulose with added carboxy, hydroxy, methyl and/or propyl groups plus sodium) and a mild mint flavour. How this product improves subjective wetness and oral comfort has not yet been determined. It is hypothesized that the perception of dry mouth is altered by several mechanisms: (i) the discs stimulate saliva flow by time-releasing xylitol flavour and mild mint flavour; (ii) xylitol and cellulose gum coat the mouth much like sugar from a cough drop; (iii) cellulose gum acts as an oral lubricant and humectant; (iv) xylitol decreases oral bacterial burden and biofilm production (8–11).

To date, there has been no research to support the use of time-release oral adhering discs for the management of the symptoms of night-time dry mouth. Hence, the purpose of this study was to assess whether XyliMelts for Dry Mouth reduce the perception of night-time oral dryness and increase the perception of oral comfort following sleep.

Materials and methods

XyliMelts for Dry Mouth discs (supplied by OraHealth Corporation) are made with a bilayer tablet press that applies a vegetable gum adhesive to one side of the tablet, allowing the disc to be adhered to gingiva or teeth for use at night during sleep. According to the manufacturer, all the ingredients dissolve in saliva, and if a disc were inhaled, it would dissolve and all materials would be transported out of the lungs (12). The product has been reviewed by the USFDA, which allows it to be sold and labelled as food because xerostomia is not considered a disease (12).

This study was conducted as a non-blinded case series with self-reported measures before treatment and self-reports of measures during and after 1 week of treatment. The study was performed with fifteen healthy subjects, recruited through Internet advertisement, who, by phone interview, identified themselves as having morning oral dryness. Each subject signed a standard consent form that explained the nature of the study and described the risks and discomforts, benefits and alternatives to the use of the product. The study design and consent forms were reviewed for ethical issues by Oral Care Research Associates of Seattle Washington and were approved.

Subjects completed a health history questionnaire that detailed medical problems. Initial and follow-up questions

included endorsement of two 100-mm visual analogue scales (anchored by dryness/wetness and comfortable/uncomfortable) defining the perceived level of mouth moisture and the level of oral discomfort upon waking in the morning. In addition, subjects were asked via questionnaire about sleep problems and night awakenings related to dry mouth. Stimulated salivary flow was measured before treatment began and after 1 week of treatment.

Each subject was asked to adhere one XyliMelts disc to the outside (buccal) of a maxillary first molar or the adjacent gingiva (or both) 30 min after taking breakfast, lunch and dinner, and to keep two discs (one on each side of the mouth) before retiring to bed. These were to be left in place until they dissolved. Subjects were asked to note how long the discs lasted during the day and while sleeping. Instructions were delivered to avoid during the study antibiotics and mouth rinses, such as chlorhexidine, Listerine and Cepacol, which are considered to have some antibiotic properties. Subjects were told to take their normal diet and practise their routine oral hygiene habits. They were also asked not to eat, drink or use a XyliMelts disc within 30 min of their scheduled evaluation. A dentist, board-qualified in Oral Medicine, performed the initial and post-treatment oral examinations and administered the questionnaires. Paired *t*-tests were used to compare pre- and post-treatment means.

Results

All but one subject were women. Age ranged from 19 to 66 with a mean of 46. All had 20 or more natural and restored teeth in relatively good condition. Reported medical problems included allergy, asthma, high blood pressure, sinus problems, nervous problems, arthritis, diabetes, lymphoma and Sjogren's syndrome. Several subjects were taking one or more mouth-drying medications. The range of measured unstimulated salivary secretion rates before treatment was 0.004–0.074 ml min⁻¹ with a mean of 0.03. There was no significant ($P < 0.05$) change in the measures of unstimulated or stimulated salivary secretion rates after treatment.

Initial self-assessed oral wetness upon waking ranged from three to 50 (mean = 22.2, SD 15.28). Self-assessed oral wetness upon waking after 1 week of using two discs at bedtime and three more during the day ranged from 32 to 92 (mean = 67.80; SD 14.96). Initial self-assessed discomfort upon waking ranged from 22 to 92 (mean = 65.23; SD 21.81) with post-treatment discomfort ranging from 6 to 55 (mean = 27.63; SD 17.59), as shown in Figure 1. The use of XyliMelts for Dry Mouth oral adhering discs caused perceived morning oral wetness scores to increase more than threefold. Comparison of pretreatment and post-treatment means for oral wetness and discomfort was statistically significant for both factors (wetness, $t = -8.79$, $P < 0.001$; discomfort, $t = 6.43$, $P < 0.017$).

Several subjects reported less sleep disturbance associated with night-time oral dryness. No subject reported an increase in sleep disturbance. Mean duration before a disc dissolved when used during the day was reported to be 1.18 h, with a

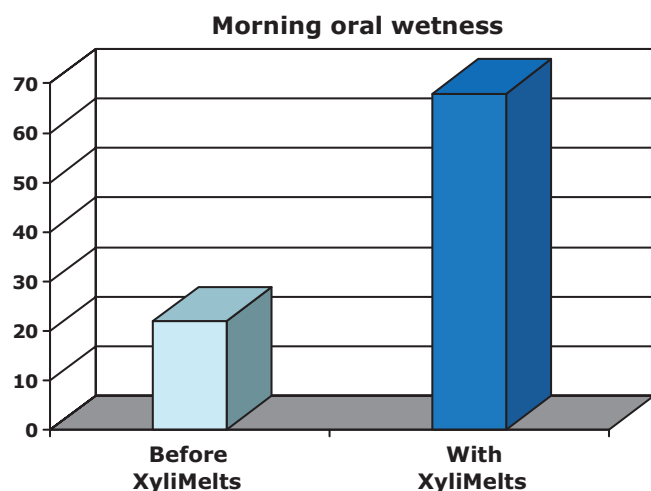


Fig. 1. Perceived oral wetness upon awakening when using XyliMelts for Dry Mouth while sleeping, Visual Analogue Scale (VAS), 15 subjects.

range of 45 min to 2 h. Some subjects reported that the discs lasted longer while sleeping. All subjects reported that they perceived the taste of XyliMelts in the morning upon waking, suggesting that the released ingredients persisted in the mouth throughout sleep. No subject reported adverse effects while using XyliMelts.

Discussion

The study participants experienced a significant improvement in subjective wetness ($P < 0.001$) and a significant decrease in perceived morning discomfort ($P < 0.02$) with 1 week of use of the discs. This study shows that the use of XyliMelts time-release adhering discs can improve perceived oral wetness upon waking and decrease the perception of discomfort from night-time dry mouth.

Several subjects reported less sleep disturbance associated with night-time oral dryness, and no subject reported an increase in sleep disturbance. All subjects noted that the discs were easily placed and that there were no complications or adverse reactions associated with their use. There is no evidence of residual effect on saliva flow (13) after 1 week of use.

Saliva serves many purposes. It lubricates the intraoral tissues, acts to 'wash' the mouth of oral bacteria causing dental plaque, protects enamel through pH buffering, reduces tooth wear from friction, aids in digestion through enzymatic degradation of food and its effect on swallowing, acts as a defence barrier for the mucosa, and helps to modulate sensation and speech (14). Oral dryness can be problematic in individuals susceptible to dental caries, oral and periodontal disease or gastrointestinal problems (15). Although the issue of night-time oral dryness, as it specifically relates to caries susceptibility and periodontal disease, has not been studied to date, it is reasonable to conclude that night dryness may be particularly troublesome for such individuals, as well as for those using drying medication, for the elderly and for people with compromised salivary function, regardless of daytime stimulated flow

levels. To date, products that are directed towards the management of daytime oral dryness are not recommended for use during sleep and therefore do not address the night-time issue of oral dryness. The XyliMelts product tested in this study appears to present a novel and useful strategy for controlling night-time oral dryness as manifested by the sensation of morning dryness and discomfort.

In addition to other ingredients, each XyliMelts disc contains 500 mg of xylitol. It is known that xylitol, delivered into saliva at this dose (16), selectively inhibits *streptococcus mutans* when it is delivered via chewing gum (10). The literature suggests that xylitol delivered in gum reduces dental cavities in children (10, 11). Although studies of its use in older adults have not been reported, it is likely that xylitol would have a similar effect on the development of caries in this population group as well. Chewing gum, however, cannot be used at night when saliva flow is normally reduced, and protection from decay-causing bacteria is most needed. In contrast to other xylitol-containing products offered for daytime use, XyliMelts offers the benefit of time-released delivery during sleep without apparent adverse effects. In this study, all subjects indicated that they perceived the taste of XyliMelts, and benefits of wetness and reduced discomfort upon waking, suggesting that a residue of the product persisted in the mouth throughout sleep. It is to be expected that the product would last longer while sleeping because the two factors that most affect dissolution rate, saliva flow and mouth movement, are both reduced while sleeping.

While this study suggests that XyliMelts can be effective in reducing sleep disturbance associated with night-time dry mouth, this result should be interpreted with caution as the number of participants was limited, the subjects were not homogeneous in terms of age, history or in their use of medications causing dryness and, with this kind of product, a placebo group could not be included for comparison. Nonetheless, these data suggest that the product tested is effective in altering the perception of dryness and discomfort.

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