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## A Pilot Study of Perceived Mouth Dryness, Perceived Swallowing Effort, and Saliva Substitute Effects in Healthy Adults across the Age Range

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### Abstract

**Background/Objectives:** Xerostomia, or perceived mouth dryness, increases with advancing age, but its influence on swallowing effort is unknown. This study: 1) quantified relationships among age, perceived sense of swallowing effort, and ratings of perceived mouth dryness, and 2) examined changes in swallowing effort following application of a gel-based saliva substitute in healthy participants.

**Design:** Cross-sectional observational study.

**Setting:** Data were collected from attendees of a community healthy aging fair.

**Participants:** Forty-two healthy participants (mean age= 65 years; 20 female) were enrolled.

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**Measurements:** Each participant rated perceived effort with swallowing and perceived mouth dryness on a 10-centimeter horizontal, undifferentiated line. After participants applied a gel-based saliva substitute (Biotene® Oral Balance) to their tongue and oral mucosa, they rated perceived effort with swallowing again.

**Result(s):** Age was associated with greater perceived mouth dryness ( $r=0.37$ ,  $p<0.03$ ) but not with perceived swallowing effort ( $r=0.16$ ,  $p=0.32$ ). Perceived mouth dryness was associated with greater perceived swallowing effort ( $r=0.62$ ,  $p<0.001$ ). Perceived swallowing effort declined following application of the salivary substitute (mean difference= $9.39$  millimeters,  $p<0.002$ ). Age was found to be a significant predictor of perceived mouth dryness ( $p<.02$ ); and perceived mouth dryness was found to significantly predict perceived swallow effort ( $p<.001$ ).

**Conclusion:** Perceived mouth dryness increased with advancing age, but perceived swallowing effort did not. Regardless of age, subjects with higher levels of perceived mouth dryness also reported more perceived effort with swallowing suggesting a role for adequate oral lubrication in this perception. Even in healthy participants, use of a gel-based saliva substitute lowered perceived swallowing effort.

### Keywords

xerostomia; swallow; saliva substitute; age; effort; deglutition; deglutition disorders

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### Introduction:

Xerostomia, or the perception of dry mouth, is one of the most common complaints of older adults, with prevalence for those above the age of 50 years ranging from 10% to 40%.<sup>1,2</sup> Hyposalivation, or a measured decrease in salivary flow, frequently leads to xerostomia;<sup>3</sup> however, xerostomia also occurs without hyposalivation.<sup>3</sup> Whole saliva refers to the combination of fluids from the major and minor salivary glands found in the oral cavity.<sup>4,5</sup> Results from a recent systematic review and meta-analysis show that the salivary flow rate of whole saliva decreases with advancing age.<sup>6</sup> This decrease occurs independent of medication or disease-specific effects.<sup>6</sup> However, a variety of medical conditions known to commonly affect older adults may exacerbate these aging-induced xerostomic symptoms, including diabetes mellitus,<sup>7</sup> Alzheimer's disease,<sup>8</sup> Sjogren's syndrome,<sup>9</sup> and radiation treatment for head and neck cancer.<sup>10</sup> Xerostomia also is a common side effect of many prescription and nonprescription drugs.<sup>11</sup>

Given that saliva is a complex bioactive substance that performs a variety of critical functions in the oral cavity,<sup>4,12,13</sup> impaired saliva production can result in poor oral health,<sup>14</sup> increased risk of oral infection<sup>9</sup> and pneumonia development<sup>15</sup>, food avoidance<sup>16</sup>, and inadequate nutritional intake.<sup>17</sup> Hyposalivation may contribute to the development of dysphagia, or swallowing difficulty, that has been shown to lead to insufficient dietary intake.<sup>17</sup> Saliva forms a thin film that coats and interacts with the oropharyngeal mucosa to provide lubrication necessary for smooth bolus formation and transport of food and liquid during swallowing.<sup>9,18</sup> The low viscosity of saliva makes it an ideal "slip" layer for objects to slide along oral surfaces.<sup>19</sup> Patients with xerostomia and hyposalivation, specifically those treated with chemoradiation for head and neck cancer or those with Sjogren's

syndrome, frequently report symptoms of dysphagia.<sup>20–22</sup> It is unknown whether patients with xerostomia alone (without hyposalivation) also experience difficulty swallowing since prior studies have been conducted with patient groups where the two are essentially indistinguishable. One explanation for a putative link between hyposalivation and dysphagia may be that thinning of the salivary film due to a lower salivary production rate could result in poor lubrication during the swallow and thus provides an increased resistance to bolus flow. Accordingly, hyposalivation may contribute to dysphagia if food sticks to the mucosa, a common complaint of patients with hyposalivation,<sup>23</sup> and greater amounts of oropharyngeal residue, or material left in the oropharynx after the swallow.

A decrease in saliva production leads to an increased sense of effort during swallowing because patients need to overcome resistance to bolus flow caused by inadequate lubrication, especially older adults who are at increased risk for xerostomia. In a study by Kays et al.,<sup>24</sup> sense of effort during swallowing increased following a meal in both young and older adults.<sup>24</sup> However, the oldest adults reported the highest levels of effort both mid-meal and post-meal and also demonstrated symptoms of swallowing difficulty during the meal. It was hypothesized that this increased effort was related to tongue muscle fatigue post-meal. While performance on a fatigue-inducing tongue endurance task declined post-meal across all subjects, this was not related to the increase in perceived swallow effort, which may have been influenced by inadequate lubrication.

To alleviate xerostomic symptoms, many patients use commercial salivary replacement products. These products generally fall into three major categories based on their main ingredients: 1) biopolymer-based substitutes including plant mucilage, animal mucin, or xanthan gum; 2) salivary enzyme-based substitutes; and 3) acid-based substitutes. Biotene<sup>®</sup> products, a hybrid between biopolymer plant mucilage and salivary enzyme-based substitutes, have shown effectiveness for reducing perceived mouth dryness for a variety of patient groups with xerostomia.<sup>1,25–27</sup> However, the influence of these products on swallowing has not been considered. These products may improve lubrication of the oropharyngeal mucosa, thereby potentially facilitating ease with swallowing in patients with xerostomia.

The purpose of this pilot study was to: 1) quantify relationships among age, perceived sense of swallowing effort, and xerostomia severity, and 2) examine changes in swallowing effort following application of a Biotene<sup>®</sup> gel-based saliva substitute in healthy participants across the age range. We hypothesized that: 1) those with greater perceived mouth dryness ratings will report greater perceived swallowing effort following a saliva swallow; 2) perceived mouth dryness ratings and perceived swallow effort will increase with advancing age; and, 3) perceived effort of saliva swallows decrease following application of a gel-based saliva substitute.

## Methods

### Participants

This study was declared exempt from review by the Institutional Review Board at this University. These data were collected as part of an educational activity to increase awareness

of dry mouth and swallowing difficulty for attendees of a healthy aging fair. Participants consented for data generated during this activity to be used in a research study.

Prior to consenting participants for use of their data in the study, the study team asked specific questions about medical history. To focus on age-related changes in healthy adults, it was important to ensure a participant group without known swallowing or salivary dysfunction. Therefore, data were excluded for those individuals with a reported a medical condition potentially associated with dysphagia (e.g., neurological or neuromuscular disease); those with a reported medical condition known to cause hyposalivation, specifically Sjogren's syndrome, diabetes, Alzheimer's disease, or thyroid disease; and those who reported previous surgery, chemotherapy, or radiation to head, neck, pharynx, esophagus, or salivary glands.

### Study Procedures

**Questionnaires**—Each participant filled out a short questionnaire with their age and sex and responded yes or no as to whether they are currently experiencing difficulty with swallowing. Each participant also rated perceived mouth dryness at the present time on a 10-centimeter horizontal, undifferentiated line anchored with “no dryness” and “extreme dryness”. Each participant was then instructed to swallow their own saliva once and then to rate perceived swallow effort used during that swallow on a 10-centimeter line anchored with “no effort” and “extreme effort”. The visual analog scales used in this study were based on those developed in previous research of subjective ratings of dry mouth.<sup>28</sup>

**Application of the Gel-Based Saliva Substitute**—Following completion of the initial questionnaire, participants were instructed to apply with their finger approximately 1 centimeter of a gel-based saliva substitute (Biotene Oral Balance Moisturizing Gel) to their tongue and oral mucosa (according to instructions for product use on the package). Immediately following application of the product, each participant rated on a second questionnaire (without access to their previous ratings) xerostomia severity on a visual-analog scale. Next, each participant swallowed his/her own saliva and repeated the rating of perceived swallow effort on the visual-analog scale.

### Statistical Analysis

Based on the Shapiro-Wilk's test, not all variables were normally distributed ( $p < .05$ ). Therefore, the Spearman's rank-order test was used to determine associations among ratings of perceived mouth dryness, perceived swallowing effort, and age<sup>29,30</sup>. Mann-Whitney U tests were performed to examine differences by sex. The Wilcoxon signed-rank test was used to assess change in perceived swallow effort from before to after application of the saliva substitute

Simple linear regression analyses were used to determine whether age or perceived swallow effort were predictive of changes in perceived mouth dryness ratings. All assumptions for parametric testing were met. The critical value for obtaining statistical significance was set at  $\alpha \leq 0.05$ . Analyses were conducted using IBM SPSS (Version 22).

## Results

Forty-two participants were enrolled and ranged in age from 20 years to 94 years (mean age= 65 years). Given that these data were collected at a healthy aging fair designed for older adults, the majority of participants were above 60 years of age (see Table I for age distribution). There were 20 female (mean age= 69 years) and 22 male (mean age= 62 years) participants. Six of the 42 participants reported current difficulty with swallowing.

### Associations among Age, Mouth Dryness Ratings, and Perceived Swallow Effort Ratings

Descriptive statistics for perceived mouth dryness and perceived swallow effort ratings can be found in Table II. Age was significantly and moderately correlated with ratings of perceived mouth dryness (Spearman's rank-order test:  $r_s(40)=.317$ ;  $p<.05$ ). Participants of older age had higher ratings of perceived mouth dryness. Age was not significantly correlated with perceived swallow effort (Spearman's rank-order test:  $r_s(42)=.431$ ;  $p=.13$ ). Perceived mouth dryness ratings were significantly and moderately correlated with ratings of perceived swallow effort (Spearman's rank-order test:  $r_s(40)=.555$ ;  $p<.001$ ). That is, participants with greater reported mouth dryness, regardless of age, had higher ratings of perceived swallow effort.

### Sex-based differences in Visual-Analog Ratings

Median perceived mouth dryness ratings for males (32) and females (36.5) were not statistically different,  $U=238.5$ ,  $z=.772$ ,  $p=.44$ . Median perceived swallow effort ratings for males (10.5) and females (9) also were not statistically different,  $U=211.5$ ,  $z=-.216$ ,  $p=.829$ .

### Saliva Substitute Effects on Visual Analog Scale Ratings

There was a significant median decrease in perceived swallow effort from before application of the saliva substitute (10) to after application (5),  $z=-3.22$ ,  $p<.002$ .

### Regression Analyses

Age significantly predicted perceived mouth dryness,  $F(1,38)=5.99$ ,  $p<.02$ , accounting for 13.6% of the variation in perceived mouth dryness with adjusted  $R^2=11.4\%$ . For every yearly increase in age, perceived mouth dryness increased by .623 mm (95% CI [.108 to 1.14]). Perceived mouth dryness was found to significantly predict perceived swallow effort, ( $F(1,38)=21.33$ ;  $p<.001$ ), accounting for 36% of the variation in perceived swallow effort with adjusted  $R^2=34\%$ . For every 1 mm increase in perceived mouth dryness, perceived swallow effort increased by .435 mm (95% CI [.464 to 1.19]). However, age was not a significant predictor of perceived swallow effort ( $F(1,40)= 1.03$ ,  $p=.315$ ; Table III).

## Discussion

The purpose of this pilot study was to define relationships among age, perceived mouth dryness and perceived swallowing effort and to examine effects of a gel-based saliva substitute on perceived swallowing effort in healthy adults across the age range. We hypothesized that perceived mouth dryness and perceived swallowing effort would be greater in those of older age and those with higher ratings of perceived mouth dryness. We

also hypothesized that application of a saliva substitute would result in less reported swallowing effort. Our findings supported these hypotheses in part. We discovered age to be a significant predictor of perceived mouth dryness, which also predicted perceived swallowing effort. Additionally, perceived swallow effort was found to decrease significantly following application of a saliva substitute. However, despite the relationship between age and increasing perceived mouth dryness, perceived swallowing effort was not found to be higher in those of older age.

The increase in perceived mouth dryness with advancing age found in this study is consistent with previous research showing a high incidence of xerostomia in older adults.<sup>1,31</sup> Age-related decreases in salivary flow combined with xerostomia-inducing medications commonly prescribed to older adults are likely responsible for these dry mouth symptoms.<sup>6</sup> We did not record medication use in this study and therefore were not able to examine the potential effects of medications on perceived mouth dryness. Compositional changes in saliva have also been observed with advancing age,<sup>32</sup> including decreases in protein levels.<sup>33</sup> These compositional changes, along with hyposalivation, may impact the thickness or adherence of the salivary film to the oral mucosa contributing to the perception of mouth dryness.

Given the known decline in physiologic function of swallowing musculature and subsequent change in swallowing biomechanics that occurs with advancing age, we expected perceived swallow effort to increase with advancing age. While the participants in this study represented a wide range of ages, the majority of participants were above 65 years of age, which may have affected the observed association between advancing age and perceived swallow effort. Additionally, participants were instructed to base their rating of perceived swallow effort on a saliva swallow rather than swallows of liquid or solid boluses. Kays et al<sup>34</sup> reported increased perceived swallow effort ratings following mealtime in young and old participants with the oldest participants in the study demonstrating the highest ratings. With a saliva swallowing task, we may not have elicited the age-related swallowing changes that most contribute to the perception of swallow effort.

Regardless of age, perceived swallowing effort was higher in those with greater perceived mouth dryness. This suggests that adequate lubrication during the swallow may be important for ease with swallowing and avoidance of fatigue during the swallowing process. When individuals perceive more effort with swallowing, they may avoid eating or limit their dietary intake in ways that do not support adequate nutrition. While strength of the oropharyngeal musculature involved in swallowing likely plays an important role in the perception of increased swallowing effort, it may be just as critical to consider the impact of perceived mouth dryness due to reduced saliva production and altered salivary composition.

The findings of this study also suggest that application of a gel-based saliva substitute has the potential to reduce swallowing effort. In the healthy participants studied here, average ratings of perceived mouth dryness (mean= 32mm) and perceived swallow effort (mean= 18mm) were on the low end of the scale (below 50mm) even before application of the substitute. When comparing mean perceived mouth dryness ratings in those above age 65 years (mean= 41mm) to ratings for those under 65 years (mean=18mm; see Table II), it is

clear that mean ratings across the entire sample in this study were lower due to inclusion of the younger participants. It is expected that these ratings would be higher in older patients with medical diagnoses and medications known to impact saliva production. If a saliva substitute can positively impact ease of swallowing in healthy participants regardless of xerostomia severity, its application has the potential to positively impact swallowing effort in older adults with xerostomia. Two previous studies focused on patients with head and neck cancer treated with chemoradiation have shown conflicting results in regards to the effects of salivary substitute use on swallowing.<sup>25,35</sup> Saliva substitutes are typically recommended to older adults for use throughout the day to ease symptoms of xerostomia, but this is the first study to suggest positive effects of a saliva substitute on perceived swallowing effort in healthy older adults.

There were several limitations to this study. In this preliminary work, we did not validate or establish the test-retest reliability of these visual-analog rating scales for perceived mouth dryness and perceived swallow effort. Given that data were collected as part of an educational activity, we also did not include a sham control group to compare with those given the gel-based saliva substitute. We did not collect objective data on saliva production (e.g., salivary flow rate) or swallowing function (e.g., videofluoroscopic swallow evaluations). It will be important for future studies to incorporate these objective measures and to examine their relationship to the patient-reported measures of mouth dryness and perceived swallowing effort. Additionally, we examined only the immediate effects of application of a saliva substitute on perceived swallowing effort. Future work will need to determine the length these effects last as well as the need for repeated application. These variables were studied in a group of self-reported healthy participants. The findings may differ in a group of older adults with documented hyposalivation or dysphagia. Also, we did not collect data on medication use and therefore were unable to exclude those individuals taking medications known to induce hyposalivation or xerostomia. While we excluded individuals with medical conditions known to cause hyposalivation, there may be other conditions leading to hyposalivation or xerostomia that we did not exclude. These variables (medical condition and medication use) may have been confounders in our analysis and should be considered in future studies. Finally, as shown in Table II, the standard deviations of these variables (perceived mouth dryness and perceived swallow effort) were relatively wide and, in several cases, exceeded the mean. This high level of variability in the measures may have been related to the study sample size and could have affected the detection of statistically significant associations/differences.

In conclusion, these preliminary findings of increased perceived swallow effort with greater perceived mouth dryness regardless of age support the importance of adequate lubrication during the swallowing process. Given that perceived mouth dryness ratings were higher in those of older age, it is necessary to develop treatments for older adults that are effective in alleviating perceived mouth dryness as well as providing the lubrication necessary for efficient swallowing. Further research to examine the use of gel-based saliva substitutes to support ease of swallowing in older adults is needed.

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**Table I:**

## Age Distribution

Age Range (years)	Number of Participants
20-30	2
31-40	3
41-50	1
51-60	5
61-70	11
71-80	12
81-90	6
91-100	2

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**Table II:**

Descriptive Statistics for Perceived Mouth Dryness and Perceived Swallow Effort Ratings

<b>Descriptive Statistics</b>	<b>Perceived Mouth Dryness Ratings</b>	<b>Perceived Swallow Effort Ratings Before Substitute</b>	<b>Perceived Swallow Effort Ratings After Substitute</b>
<b>Median</b>	23	10	5
<b>Standard Deviation</b>	29.5	21.27	11.20
<b>Range</b>	0-94	0-72	0-45
<b>Interquartile Range</b>	46.5	25	14

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**Table III:**

Simple Linear Regression Analyses

Predictor	Dependent Variable	R	R Square	Adjusted R square	F	df	Significance (p value)	$\beta_0$	$\beta_1$
Age	Perceived Mouth Dryness	0.369	0.136	0.114	5.99	1,38	0.019	7.43	0.623
Mouth Dryness	Effort	0.600	0.359	0.343	21.33	1,38	0.00	4.87	0.44
Age	Effort	0.159	0.025	0.001	1.034	1,40	.315	5.48	.197

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