

## **ADHA HYPOSALIVATION with XEROSTOMIA SCREENING TOOL PROJECT**

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**Problem Statement:** The number of xerostomia cases has increased greatly over time because people are taking an increased number of medications; there are more than 400 prescription and non-prescription medications associated with xerostomia. Other factors are also involved. In the absence of the protective factors of saliva, a patient becomes more susceptible to oral disease such as caries, candidiasis, and periodontal disease, all of which can result in significant oral care concerns. Thus the major concern for dental healthcare providers is to assess hyposalivation with xerostomia. A hyposalivation with xerostomia screening tool was created for the dental hygienist in dental practice by funding from an Unrestricted Educational Grant provided by GlaxoSmithKline, and utilizes American Dental Hygienists' Association (ADHA) *Standards for Clinical Dental Hygiene Practice* regarding the assessment, etiology, and management of conditions. The screening tool generates an overall susceptibility to hyposalivation with xerostomia, using a simple grading scale ranging from low to moderate to high risk. Using the assessment and diagnosis clinical parameters, the tool comes to a conclusion or dental hygiene evaluation of risk for hyposalivation with xerostomia that allows for planning and implementation of interventions per risk level of the patient by the dental hygienist and rest of the dental team. The tool was presented to the ADHA members via an article in their *Access* magazine. **Purpose:** The validation of the screening tool in a clinical setting. **Proposed Method:** One effective way to obtain objective measurements of quantitative changes in saliva is by collecting saliva. One hundred participants in a selected clinical setting with the primary symptom of xerostomia would be used in the study. Each participant would first be evaluated using the developed tool by a dental hygienist to determine the participant's risk level for hyposalivation. After the evaluation, first unstimulated saliva would be collected and then stimulated saliva, with both being weighed. Later the participant's salivary flow rate for both the unstimulated and stimulated flow is calculated by dividing the amount (weight) of collected saliva by the duration of the collection period (five minutes). Both the responses to the tool and salivary flow rates for each participant would undergo data analysis in comparison to known values to determine the validity of the tool to adequately evaluate the risk level for hyposalivation.

### **Background and Significance of Project**

The goal of the **ADHA Hyposalivation with Xerostomia Screening Tool Project** is to develop a validated screening tool for use in dental practices as an aid to provide greater awareness and accuracy in the screening, assessment, and management of hyposalivation with xerostomia. <sup>1</sup>

Funded initially for its creation by an Unrestricted Educational Grant provided by GSK, the tool utilizes ADHA *Standards for Clinical Dental Hygiene Practice* regarding the assessment, etiology, and management of conditions related to hyposalivation with xerostomia. The tool was presented to the ADHA members via an article in their *Access* magazine (see Attachment), which contains further background and specific aims of the screening tool as well as how to use the tool in an office setting.<sup>2</sup> The tool is also presented on the ADHA website since publication. Seminars related to the use of the tool were also offered and given to ADHA members. An Internet video (YouTube) was also created to inform ADHA membership and was placed on a linked page from the newly revised Association webpage.

### **Preliminary Review of Screening Tool**

At this time, the tool has been reviewed by a dental hygienist that works in high-risk practice for hyposalivation (head and neck cancer patients), **Linda Choquette, RDH, MSHS, CCRP**, who is a Clinical Research Associate at the Multidisciplinary Head and Neck Cancer/Oral Oncology Program, University of Connecticut Health Center, Farmington, CT. She felt after trying it on high-risk patients that it met her needs to importantly discern between moderate and high-risk patients and could be accomplished in under 3 minutes with familiarity without use of the computer for tallying; however, she feels it could be much faster using a computerized tool.

The tool has also been reviewed by one noted expert in the field, **Philip C. Fox, DDS, FDS, RCSEd**, who is the author of the ADHA continuing education course on xerostomia.<sup>3</sup> He is a visiting scientist at the Department of Oral Medicine, Carolinas Medical Center, Charlotte, NC, and an independent biomedical consultant focusing primarily in the area of clinical trial design and analysis. He is also a diplomate of the American Board of Oral Medicine, as well as establishing the first Sjögren's Syndrome Clinic, with the Molecular Physiology and Therapeutics Branch, NIDCR, Bethesda, MD. Dr. Fox felt overall that it met the needs of the dental community but its validation would serve to confirm this.

### **Proposed Methods and Measurements for Validation**

The next step is to clinically validate this screening tool for hyposalivation so the intended audience of dental professionals can know that it is evidence-based in its approach when working with dental patients in dental practice. This could be accomplished by the following suggested methods and measurements using any necessary administrative, clinical, and laboratory resources.

As to the methods, initially, one hundred participants in a selected clinical setting with the primary symptom of xerostomia would be used in the study and assigned another study appointment after

signing up to participate.<sup>4,5,6</sup> The participants in the study would not have an intellectual disability or English as a second language or be pregnant or under 18 years of age. Participants would be instructed not to drink, eat, smoke, perform oral hygiene or put anything into their mouths for 90 minutes before this next appointment since saliva samples will be collected in order to measure the participant's salivary flow (sialometry). The appointment confirmation courtesy call would review these instructions.

Each participant would first be evaluated using the developed **Screening Tool** by a dental hygienist to determine the participant's risk level for hyposalivation, not as part of any routine dental visit, but as a separate appointment. The dental hygienist has the necessary background in anatomy, pharmacology, and physiology to complete task, and if in a dental practice setting, would have the necessary practice contact.

One effective way to obtain objective measurements of quantitative changes in saliva is by collecting saliva. Collecting whole saliva is easier and more cost-effective than collecting saliva from an individual gland (parotid, submandibular, or sublingual). Whole saliva would be collected under both unstimulated (resting) and stimulated conditions. After the evaluation, the saliva would be collected in a quiet environment, with the participant sitting in an upright position, head tilted forward and eyes open, with minimal body and orofacial movements.<sup>7,8</sup>

To collect the unstimulated saliva, the participant is asked to swallow any saliva in their oral cavity first, then stay motionless and allow the saliva to drain passively for five minutes over the lower lip into a preweighed 15 ml test tube fitted with a 55 mm diameter funnel, avoiding any further swallowing. After the five-minute collection period, the participant is asked then to void the mouth of saliva by spitting into the funnel.<sup>9,10</sup>

After unstimulated saliva is collected, the stimulated saliva is then collected after asking the participant to chew on a piece of paraffin wax at approximately 45 chews per minute. Wax is used for cost effectiveness and also reduces any individual participant concerns as to taste or texture or content associated with using gum or candy. The participant will void the mouth of saliva by spitting into another similar collection tube every minute for a total of five minutes.

Both collection tubes will be weighed chairside after each collection using a small scale with the numbers entered using the **Saliva Collection Form** (see Attachment). Later the participant's salivary flow rate for both the unstimulated and stimulated flow is calculated by dividing the amount (weight) of collected saliva by the duration of the collection period (five minutes).

The responses to the tool and salivary flow rates for each participant would undergo data analysis in comparison to known values to determine the validity of the **Screening Tool** to adequately evaluate the risk level for hyposalivation. Later this information would be presented to the dental community in various publications.

While there is no general agreement about what constitutes a “normal” salivary flow rate; researchers generally consider an unstimulated flow rate of 0.1 to 0.2 milliliters per minute (or grams per minute) and a chewing stimulated flow rate of 0.7 mL/minute (or g/minute) to be abnormally low flow rates. Currently, clinicians use a 0.1-mL/minute unstimulated whole saliva flow rate as a criterion for the diagnosis of Sjögren’s syndrome. A chart was devised using these values for comparison of normal and abnormal whole saliva flow rates in both unstimulated and stimulated whole saliva (see Table 1).<sup>11</sup>

<b>Known Values for Flow Rates for Whole Saliva *</b>		
<b>Salivary Flow Rates (ml/min)</b>		
	<b>Normal</b>	<b>Low</b>
Unstimulated (resting) Whole Saliva	0.3 - 0.4 ml/min	≤ 0.1 ml/min
Stimulated Whole Saliva	1 - 2 ml/min	≤ 0.7 ml/min
* Whole saliva is the total output from the major salivary glands; no general agreement about what constitutes a ‘normal’ salivary flow rate		

**Table 1: Comparison of normal and low whole saliva flow rates in both unstimulated and stimulated saliva rates.**

**Author of Project**

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Participant ID #

Appointment Date     
Day Month Year

### Saliva Collection Form

1. Has the participant had anything to eat or drink for 90 min. before procedure?  Yes  No

#### Unstimulated whole salivary flow rate (5-minute collection):

2. Time performed (24-hr clock)    
Hour Min

3. Specimen collected today?  Yes  No

4. Pre-collection vial weight: .

5. Post-collection vial weight: .

6. Number of grams collected (*subtract item 4 from item 5*): .

#### Stimulated whole salivary flow rate (5-minute collection):

7. Time performed (24-hr clock):    
Hour Min

8. Specimen collected today?  Yes  No

9. Pre-collection vial weight: .

10. Post-collection vial weight: .

11. Number of grams collected (*subtract item 9 from item 10*): .

12. Did the collection encounter any problems? (*please list*)  Yes  No

**Problem(s) Encountered:**

Examiner ID #:

Signature: \_\_\_\_\_

## Updated References for Project

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