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Original Article

Evaluation of oral wetness using an improved moisture-checking device for the diagnosis of dry mouth

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ABSTRACT

Purpose: In 2013, we reported the results of a third-generation oral moisture-checking device in a multicentre clinical study involving patients with dry mouth and healthy volunteers. Subsequently, several improvements have been made to the third-generation device, and a fourth-generation device is now commercially available. This study aimed to confirm the usefulness of this improved fourth-generation device in the diagnosis of dry mouth and to assess the physiological wetness of lingual mucosa by using this device.
Materials and Method: This multicentre study comprised subjects with dry mouth (dry mouth group) and those without dry mouth (healthy group).
Results: In this study, the degree of moisture was considerably different between the two groups. Receiver operating characteristic analysis revealed an area under the curve value of 0.831. Sensitivity and specificity values were close to 80% in cases where the degree of moisture ≥29.6 was defined as normal, ≤27.9 was defined as dry mouth, and 28.0–29.5 was defined as borderline dry mouth.
Conclusions: These results suggest that the improved fourth-generation moisture-checking device can be used for the diagnosis of oral dryness.

1. Introduction

In general, measurements of salivary flow rates have been conducted using various tests such as the chewing gum test, Saxon test or the spitting method, and functional assessments of salivary gland secretion by salivary gland scintigraphy have been used to evaluate dry mouth. However, these tests measure not evaluate oral dryness directly, but the ability of salivation. In addition, reproducibility of results in the chewing gum test or the spitting method is affected by intelligibility or to the method of spitting saliva. Therefore, these methods are unavailable to persons with reduced comprehension caused by dementia or oral dysfunction caused by stroke.

In light of the problems associated with these measurement techniques, an oral moisture-checking device was developed in 2002. This device measured electrostatic capacity on the basis of impedance generated by connecting high-frequency waves supplied by a 5-volt battery to plus and minus comb-shaped electrodes attached on the surface of a 7.2-mm [2] sensor. The electrostatic capacity reflects not only the water content of the oral mucosal surface but also intramucosal water content to a depth of about 50 μm. To obtain accurate measurements, it is essential that the sensor surface is in close contact with the mucosal surface. Therefore, the lingual and buccal mucosae have been used as measurement sites [4,6,8]. On June 2, 2010, Mucus® received manufacturing and marketing approval as a body composition analyser, a class II controlled medical device (approval number: 22200BZX00640000) by the Pharmaceutical and Medical Devices Agency of Japan.

In 2013, the third-generation equipment of this device was used in a multicentre clinical study to measure the degree of oral wet-

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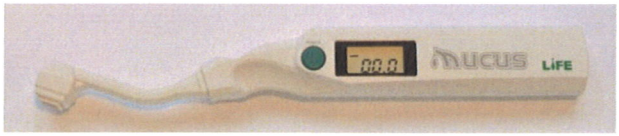

Fig. 1. Oral moisture-checking device (Mucus®, Life Co., Ltd.).

ness in a healthy group and in those with dry mouth [3]. The degree of moisture in the lingual mucosa showed considerable differences between the two groups, whereas that in the buccal mucosa did not. Thus, the lingual mucosa was better suited for moisture checking than buccal mucosa. On the basis of receiver operating characteristic (ROC) analysis, an area under the curve (AUC) value is 0.653 for the lingual mucosa. The findings of the study suggested that the device was a usable screening device for dry mouth, but revealed that the variations measurement values depended on the degree of proficiency of the measurers. Subsequently, several improvements were made, including uniformity of the sensor surface and the film thickness of the sensor covers, and the fourth-generation of this device is now commercially available (Fig. 1).

This study aimed to confirm the usefulness of the improved fourth-generation oral moisture-checking device in the diagnosis of dry mouth and to assess the physiological wetness of lingual mucosa by using this device.

2. Materials and Methods

The study group comprised subjects with dry mouth (dry mouth group) and those without dry mouth (healthy group), who were enrolled from December 2012 to August 2013, at the following four participating medical centres: the Department of Oral and Maxillofacial Surgery, Faculty of Medicine, Saitama Medical University; the Division of Functional Oral Neuroscience, Osaka University Graduate School of Dentistry; the Oral and Maxillofacial Surgery, Dry Mouth Clinic, The Nippon Dental University Niigata Hospital; and the Division of Geriatric Dentistry, Niigata University Medical & Dental Hospital.

The dry mouth group comprised adult patients who were subjectively aware of their condition. Those with unstimulated salivary flow rates (USFR) of ≤1.5 mL/15 min and stimulated salivary flow rates (SSFR) of ≤10 mL/10 min were included in this study, whereas those who routinely used oral moisturizers, took saliva-stimulating agents (such as cevimeline hydrochloride hydrate and pilocarpine hydrochloride) and were considered unsuitable for the study by the investigator were excluded. The healthy group comprised adult volunteers with no subjective awareness of oral dryness, and they presented with USFR and SSFR of >1.5 mL/15 min and >10 mL/10 min, respectively. Those who were diagnosed with dry mouth, Sjögren's syndrome, oral mucosal abnormalities or burning mouth syndrome were considered unsuitable for the study and were excluded by the investigator.

The degree of moisture in the lingual mucosa was measured using the improved Mucus®, fourth-generation oral moisture-checking devices (serial numbers, 401391 to 401398; Life Co., Ltd., Saitama, Japan). According to our previous study [2], to eliminate the effects of stimulants such as food, water, speech and stress on the measurements, the subjects were requested to rest, both physically and mentally, for approximately 5 min before the measurements were taken. The measurement site chosen was the centre of the lingual mucosa, approximately 10 mm from the tip of the tongue (Fig. 2). A disposable cover made of polyethylene was applied to the sensor, which was manually applied to the measurement site at a pressure of approximately 200 g, as practised beforehand with a manometer. Oral mucosal wetness was measured three consecutive times to eliminate outliers, and the median

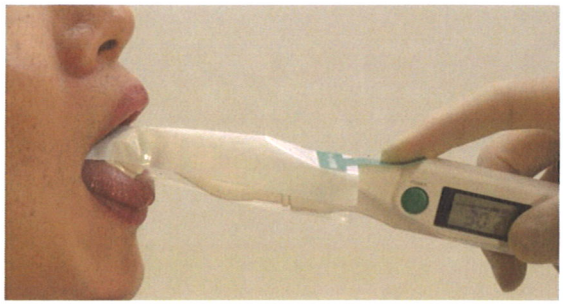

Fig. 2. Measurement of oral moisture degree of the lingual mucosa with sensor cover.

was used as a representative value [1]. The spitting method was used to measure USFR, whereas the chewing gum test was used to measure SSFR. Objective oral dryness (oral dryness, redness of the oral mucosa, atrophy of the oral mucosa and angular cheilitis) was measured as follows: none (0 points), mild (1 point), moderate (2 points) and severe (3 points).

To eliminate bias, the measurements were taken in a predetermined order; oral moisture degree, USFR, SSFR and objective oral dryness evaluation. Salivary flow rates were measured after measuring the degree of oral moisture to avoid experimental bias. The degree of oral moisture was measured using the oral moisture-checking devices in 75 patients (dry mouth group) and 21 volunteers (healthy group), followed by measurements of USFR and SSFR. Normal USFR and SSFR values were observed in 12 patients belonging to the dry mouth group, whereas 3 patients in the healthy group presented with abnormal USFR and SSFR values. In this study, the dry mouth group was defined as subjects who have both subjective awareness of oral dryness and hyposalivation, and the healthy group was defined as subjects who have neither subjective awareness of oral dryness nor hyposalivation. Therefore, these subjects were excluded from the study, and the study group comprised 63 subjects with dry mouth (9 men and 54 women), and 18 healthy subjects with no evidence of dry mouth (6 men and 12 women). The mean age of the subjects was 70.3 years in the dry mouth group and 71.3 years in the healthy group. No considerable differences in male-to-female ratio and average age was found between both groups.

2.1. Statistics

The male-to-female ratio and average age of the subjects in the two groups were statistically compared. Subsequently, we examined the following variables: oral moisture degree, cut-off values and correlations of oral moisture degree with salivary flow rates and objective oral dryness scores. ROC analysis, Student's t-tests, Pearson correlation coefficients and Spearman correlation coefficients (Medcalc version 11.3 for Windows) were used for statistical analysis. AUC was calculated, and the value providing the best balance between sensitivity and specificity was used as a cut-off point. P values of <0.05 were considered to indicate considerable differences.

All subjects in the present study received thorough explanations about the methods, requirements of the examinations and methods used, the associated risks, protection of privacy and personal information, anticipated benefits, and alternative examinations that were available; and they were provided with the freedom to give or withdraw consent. All subjects signed the informed consent forms, and ethical approval for this study was obtained from the Institutional Review Board of Saitama Medical University (approval number: 12-047-1) and the institutional review boards of each participating medical centre.

Table 1
Cut-off values for the lingual mucosa.

Cut-off value	Sensitivity	95% CI	Specificity	95% CI	Positive likelihood ratio	Negative likelihood ratio
29.6	81.0	69.1–89.5	61.1	41.0–86.7	2.33	0.33
29.4	77.8	65.5–87.3	66.7	35.7–82.7	2.08	0.31
29.0	71.4	58.7–82.1	72.2	46.5–90.3	2.57	0.40
28.0	65.1	52.0–76.7	77.8	52.4–93.6	2.93	0.45
27.9	65.1	52.0–76.7	83.3	58.6–96.4	3.90	0.42

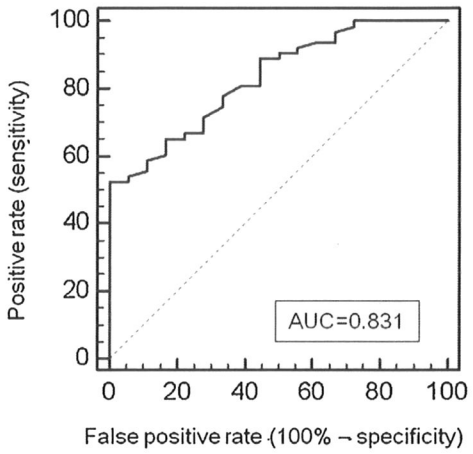

Fig. 3. Receiver-operating characteristic curve for the lingual mucosa.
The solid and dotted lines represent the ROC curve and its 95% confidence interval, respectively.

Table 2
Relationship between oral moisture degree and saliva flow rates.

		USFR	SSFR
Lingual mucosa	Correlation coefficient	0.35*	0.43*
	95% CI	0.14 to 0.53	0.24 to 0.60

* $P < 0.05$.

3. Results

The degree of oral moisture in the lingual mucosa was significantly lower in the dry mouth group (24.7 ± 6.3 [mean ± standard deviation]) than in the healthy group (30.1 ± 4.2, $p < 0.001$). AUC, calculated by ROC analysis, was 0.831 (Fig. 3). The best balance between sensitivity and specificity was achieved at a cut-off point of 29.0, with sensitivity and specificity values of 71.4% and 72.2%, respectively. With a cut-off point of 27.9, the sensitivity and specificity values were 65.1% and 83.3%, whereas with a cut-off point of 29.6, these values were 81.0% and 61.1%, respectively (Table 1).

USFR, SSFR and objective oral dryness scores were measured in all 81 subjects. The correlation coefficients of the oral moisture degree with USFR and SSFR were 0.347 and 0.434, respectively, indicating weak positive correlations ($p < 0.05$) (Table 2). The correlation coefficients of oral moisture degree with the objective oral dryness scores for oral dryness, redness of the oral mucosa and atrophy of the oral mucosa were −0.716, −0.287, and −0.582, respectively, indicating negative correlations ($p < 0.05$) (Table 3).

4. Discussion

In our previous work, using the third generation device, we demonstrated considerable differences in the degree of moisture in the lingual mucosa between subjects belonging to the dry mouth and healthy groups. However, the AUC of lingual mucosa in the ROC curve was only 0.651 in that study. Consequently, the fourth-generation device contains improvements, such as enhancement of the coating process of the sensor and uniformity of the thickness of the sensor cover. This resulted in the increase in AUC to 0.831 in the present study, thereby achieving accuracy comparable to the diagnostic accuracy of fasting blood glucose levels for the diagnosis of diabetes, indicating the efficiency of the oral moisture-checking device for the diagnosis of dry mouth. However, at a cut-off point of 29.0, the sensitivity and specificity in the lingual mucosa were 71.4% and 72.2%, respectively. Using this cut-off point, it may be difficult to clearly demarcate dry mouth patients from healthy subjects, making it necessary to set a border range between dry mouth and non-oral dryness. In the present study, the cut-off value providing a sensitivity of at least 80% was 29.6 (sensitivity, 81.0%), indicating that dry mouth will not be diagnosed in about 2 of 10 patients with this condition. The cut-off value with a specificity value of at least 80%, was 27.9 (specificity, 83.3%), indicating that dry mouth is misdiagnosed in less than 2 of 10 healthy subjects. Considering these results and taking into account the popularity and convenience of the measurements, as well as the facts that a moisture degree of 28.0–29.5 is regarded as the borderline zone for diagnosing dry mouth, a value ≥29.6 is normal and a value ≤27.9 is dry mouth, the sensitivity and specificity values in the present study are close to 80%, thereby making this fourth-generation oral moisture-checking device a usable screening instrument for dry mouth. Thus, compared to the prior generation device, in improved the fourth-generation device AUC of ROC is increased and the width of the border zone for diagnosing dry mouth is reduced.

In the present study, weak correlations were found between the degree of moisture in the lingual mucosa and the saliva flow rates (USFR and SSFR). A recent study by Osailan et al. showed correlations between mucosal wetness of the anterior tongue and USFR in dry mouth patients [5]. However, Won et al. had reported that moisture in the oral cavity depends on unstimulated whole saliva collection and is not always decreased at least in some patients [7]. Salivary flow rates do not necessarily reflect the secretory function of the salivary glands, and although decrease in saliva secretion is known to cause dry mouth, xerostomia can occur due to excessive oral vaporization without any reduction in salivary flow rate. In the present study, oral dryness and the degree of lingual moisture showed a relatively strong inverse correlation. Osalian et al. showed that USFR is accompanied by a decrease in moisture wetness and suggested the presence of inverse correlations between

Table 3
Relationship between oral moisture degree and objective dryness scores.

		oral dryness	redness of the oral mucosa	atrophy of the oral mucosa	angular cheilitis
Lingual mucosa	Correlation coefficient	−0.72*	−0.29*	−0.58*	−0.05
	95% CI	−0.81 to −0.58	−0.48 to −0.07	−0.71 to −0.41	−0.27 to 0.18

* $P < 0.05$.

clinical oral dry scores and moisture wetness [5]. Thus, to a certain extent, reduced moisture wetness appears to be related to increased objective oral dryness scores and clinical signs of oral dryness. Conversely, angular cheilitis did not seem to be correlated to oral wetness in the present study, probably owing to the fact that the angle of the mouth is outside the oral cavity. There was an inverse relationship between objective oral dryness scores and mucosal wetness, suggesting that oral wettability reflected our clinical oral findings.

In general, the salivary flow rate measurements such as chewing gum test are used for the evaluation of dry mouth state. However, it is difficult to apply these measurement methods to incommunicable individuals and patients with oral functional disorders caused by conditions such as a stroke. In view of the increased rates of population ageing, it is vital to understand the importance of oral care. It is essential to evaluate the state of dry mouth, both objectively and conveniently, to achieve adequate oral care. We believe that the fourth-generation device described in the present study will aid in the evaluation and thereby proper treatment of oral dryness in the population.

5. Conclusions

The degree of oral moisture in patients with dry mouth and in the subjects belonging to the healthy group was measured using a fourth-generation oral moisture-checking device. Considerable differences in the degree of moisture were observed between the groups. ROC analysis revealed an AUC value of 0.831. The sensitivity and specificity values were close to 80%, in conditions where a moisture degree of ≥29.6 was defined as normal, ≤27.9 was defined as dry mouth and 28.0–29.5 was defined as the borderline zone of dry mouth. These results suggest that this moisture-checking device has sufficient diagnostic capability for oral dryness.

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