Validation of a Portable Blood Glucose Testing Device in Measuring Masticatory Performance

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Clinical significance
This study confirms that a portable blood glucose testing device can measure the glucose extraction from chewing gummy-jelly as accurately as a spectrophotometer when measuring masticatory performance.

Abstract
Purpose: The purpose of this experiment was to investigate the possibility of objectively evaluating masticatory performance using a portable blood glucose testing device.
Methods: First, the glucose concentrations of four types of glucose solutions with known concentrations were measured using a spectrophotometer and portable blood glucose testing device. Next, 20 healthy subjects were asked to chew gummy-jelly for 20 seconds and the amount of glucose extraction was measured. The results for the two devices were compared.
Results: The glucose concentration according to the spectrophotometer was very close to the true concentration. On the other hand, the glucose concentration according to the blood glucose testing device was not close to the true value, although a statistically significant linearity was found. In regard to measurement of the amount of glucose extraction, there was a significant difference between the results obtained with the two devices. However, by using a regression line and applying the corrections to the values obtained, the values of the blood glucose testing device could be brought close to the values of the spectrophotometer (y=1.036x−2.491, r=0.994, P<0.01).
Conclusion: From these results, it was concluded that, after applying correction, a portable blood glucose testing device could measure the amount of glucose extraction from chewing gummy-jelly as accurately as a spectrophotometer.

Key words: masticatory performance, gummy-jelly, blood glucose testing device, spectrophotometer

Introduction
For evaluating masticatory function, especially masticatory performance, the gummy-jelly (a kind of popularly available jelly candy) has received much attention because the shape and ingredients are well-standardized, hygiene control is relatively easy, and it has been used as a test food to analyze daily masticatory performance.1–3 Tanaka et al,1 who investigated the relation between the masseter muscle activity, duration of chewing, and the amount of glucose extraction from chewing gummy-jelly as measured with a spectrophotometer, concluded that masticatory performance could be quantitatively measured by analyzing the amount of glucose extraction from chewing gummy-jelly. However, one of the drawbacks of this measurement method is that the spectrophotometer used for measuring the amount of glucose extraction is cumbersome to use and expensive.

On the other hand, with the increase in the number of diabetic patients4,5 and the necessity to control the blood glucose levels in these patients, relatively inexpensive and small, portable blood glucose testing devices6–9 have become available in the market, using which patients can easily measure their own blood glucose levels. There is a possibility that this portable blood glucose testing device could be used to measure the amount of glucose extraction from chewing gummy-jelly.

Therefore in this experiment, in order to investigate the possibility of objectively evaluating masticatory performance using a portable blood...
Materials and methods

Experiment 1 was performed for calibration of the portable blood glucose testing device and experiment 2 was performed to investigate the validation of the portable blood glucose testing device in measuring masticatory performance.

Experiment 1

Four graded of glucose solutions with concentrations of 100 mg/dl, 200 mg/dl, 300 mg/dl, and 400 mg/dl were prepared. Each solution was measured five times using a spectrophotometer (Model 200–20, Hitachi, Tokyo, Japan) and a portable blood glucose testing device (Accu-check® comfort, Roche Diagnostic, Basel, Switzerland) with the immobilized enzyme electrode method. The relationship between the known concentrations and the concentrations as measured with the spectrophotometer, and similarly, the relationship between the known concentrations and the concentrations as measured with the blood glucose testing device were compared. The glucose concentration as measured with the spectrophotometer was obtained with the glucose oxidase method. First, 0.02 ml of the glucose solution was transferred to a test tube by a micro-pipette followed by the addition of 3.0 ml of the coloring agent and stirring. As a control, 0.02 ml of distilled ionized water and 3.0 ml of the coloring solution were added to another test tube and stirred. The two tubes were then incubated at room temperature for 15 minutes and the difference in the degree of color absorption between the glucose solution and the distilled water was measured with the spectrophotometer (Fig. 1). The glucose concentration of the solution was calculated using the glucose concentration vs. the degree of color absorption graph.

In the blood glucose testing device method, the glucose concentration was measured simply by placing a few drops of the glucose solution using a micro-pipette on the blood glucose testing strip and reading the valued automatically displayed after 30 to 45 seconds (Fig. 1).

Experiment 2

1. Subjects and test material

Twenty subjects, all in their twenties, consisting of 10 males and 10 females, with an average age of 24.6 years, who were aware of their habitual chewing side and had neither systemic nor masticatory abnormalities were selected for the study. Informed consent was obtained from each of the subjects after explaining to them the general nature of the study to be conducted. The test food was one cylindrically-shaped gummy-jelly with a diameter of 10 mm, height of 10 mm, and weight of 2 g (Table 1).

2. Recording and analyzing method

Subjects were asked to sit in a dental chair with the Frankfort plane parallel to the floor and the head not being fixed but in a relaxed state, and were asked to chew the gummy-jelly using their habitual chewing side for 20 seconds. Thereafter, they were asked to rinse their mouth with 10 ml
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<table>
<thead>
<tr>
<th>Table 1</th>
<th>Size, weight, hardness, and ingredients of the gummy-jelly.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size (mm)</td>
<td>φ 10×10</td>
</tr>
<tr>
<td>Weight (g)</td>
<td>2</td>
</tr>
<tr>
<td>Hardness (kgf)</td>
<td>2.17</td>
</tr>
<tr>
<td>Ingredients</td>
<td>Maltose 40 %</td>
</tr>
</tbody>
</table>

of distilled water and spit the extracted glucose as well as the gummy-jelly into a cup containing a filter. The filtrate served as the test material, and the glucose concentration was measured with both the spectrophotometer and the blood glucose testing device. The measurements for each filtrate was conducted three times, and the average value was taken for the analysis. The relationship between the glucose concentrations measured using the spectrophotometer and those measured using the blood glucose testing device was investigated.

Statistics
For the accuracy of the spectrophotometer and blood glucose testing device, a simple linear regression analysis was performed. For the relationship between two devices, Pearson’s correlation coefficient test was used. All of the data were analyzed with the statistical software SPSS for Windows, version 10.0J (SPSS, Chicago, IL, USA). P values <0.05 were considered to be significant.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>The average and standard deviation of the glucose concentrations of the 4 types of glucose solutions as measured with the spectrophotometer and as measured with the blood glucose testing device.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose solution</td>
<td>100</td>
</tr>
<tr>
<td>Spectrophotometer</td>
<td>100.7 ± 2.38</td>
</tr>
<tr>
<td>Blood glucose testing device</td>
<td>85.8 ± 2.39</td>
</tr>
</tbody>
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<tr>
<th>Table 3</th>
<th>The average and standard deviation of the glucose concentrations of the 4 types of glucose solutions as measured with the blood glucose testing device after correction.</th>
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</thead>
<tbody>
<tr>
<td>Glucose solution</td>
<td>100</td>
</tr>
<tr>
<td>Glucose concentration after correction</td>
<td>101.0 ± 1.99</td>
</tr>
</tbody>
</table>

Results
Experiment 1
The glucose concentrations as measured with the spectrophotometer were very close to the actual concentrations of the prepared glucose solutions (Table 2); a statistically significant linearity was found between the two and the slope of the regression line was infinitesimally close to 1 (y=0.997x+0.887, r=0.999, P<0.01). On the other hand, when the blood glucose testing device was used, the values were lower for the 100 mg/dl solution and higher for the 200 mg/dl, 300 mg/dl and 400 mg/dl (Table 2). However, a statistically significant linearity was found between the measured concentrations and the actual concentrations, although the slope of the regression line was relatively large, being 1.20 (y=1.199x−35.30, r=0.999, P<0.01). Thus, we used this regression line and applied the correction (x=(y+35.30)/1.199) to the values obtained using the blood glucose testing device for obtaining the corrected glucose concentrations (Table 3).

Experiment 2
Although a statistically highly significant linearity was found between the values obtained using the two methods (y=1.243x−38.29, r=0.994, P<0.01), the slope of the regression line was at 1.243 larger than 1. However, by using the regression line obtained from experiment 1 and applying the correction to the values obtained using the blood glucose testing device, the slope of the regression line was brought close to 1, and the amount of glucose extraction measured with the blood glucose testing device became close to the values measured with the spectrophotometer (y=1.036x−2.491, r=0.994, P<0.01) (Fig. 2).
Discussion

Tanaka et al,\textsuperscript{1} investigated chewing ability, consciousness, incompatibility, elasticity, stickiness, hardness and ingestion of 4 types of cylindrical shaped gummy-jelly containing 8% gelatin and varying in size and weight by asking the subjects to chew on their habitual chewing side prior to swallowing; they found that when the length and diameter were 10 mm and the weight was 2 g the subjects were able to chew unconsciously without any stickiness or incompatibility and that the jelly was the most suitable test food. Kuriyama et al,\textsuperscript{4} using 4 types of gummy-jelly that differed in hardness because of varying concentrations of gelatin (5%, 6.5%, 8% and 9.5%), quantitatively analyzed the stability of the rhythm and path of the mandibular incisal point during masticatory movements, and found that the gummy-jelly containing 8% gelatin gave the most stable movements. Based on these reports, the gummy-jelly used by Tanaka et al\textsuperscript{1} was employed as the test food.

In diabetic patients, because of the progression of the disease and the complications associated with hyperglycemia, there is a strong need for the patients to monitor and control their blood glucose level. Therefore, several small portable blood glucose testing devices have been developed, using which diabetic patients can easily measure their own blood glucose levels.\textsuperscript{6-9} Out of all these simple devices, the Accu-check\textsuperscript{®} comfort developed by Roche Diagnostic has come to be among the better known because of its ability to measure the blood glucose concentration with an accuracy close to that of the larger devices used in hospitals.\textsuperscript{10} However, until now, these devices have only been used to measure the glucose concentrations in the blood, and not for those in the saliva. In order to investigate whether they might also be suitable for measurement of the glucose concentration in the saliva, in this experiment, we compared the glucose concentrations of solutions measured with spectrophotometer and those measured using a blood glucose testing device.

By measuring the concentrations of a set of graded solutions with known glucose concentrations, it was found that the results obtained using the spectrophotometer were very accurate whereas those obtained using the blood glucose testing device were not so accurate. However, with the application of a correction to the results obtained using the blood glucose testing device from the linear regression line, the concentrations could be brought close to the accurate results obtained using the spectrophotometer. In regard to the amount of glucose extraction from chewing gummy-jelly, a statistically significant linearity was found between the glucose concentrations as measured with the spectrophotometer and the concentrations as measured with the blood glucose testing device, provided correction with the linear factor was applied to the values obtained using the blood glucose testing device and the slope of the regression line was virtually brought to 1. These results indicate that with the application of corrections, glucose concentrations in the saliva can be measured as accurately with

Fig. 2 The relationship between the amount of glucose extraction as measured with the spectrophotometer and that as measured with the blood glucose testing device.
a blood glucose testing device as with a spectrophotometer.

When the blood glucose testing device was used to measure the glucose concentration of the solutions with known glucose concentrations, it was found that lower values were obtained for the 100 mg/dl solution and higher values were obtained for the 200 mg/dl, 300 mg/dl and 400 mg/dl solutions. Two reasons for this discrepancy were contemplated. One is that the blood glucose testing device lacked accuracy when measuring glucose in solution, which was probably due to the fact that it was designed to measure glucose concentration in arterial blood taken from a finger tip. A much larger testing devices in hospitals was built for use in hospitals to measure the glucose concentrations in blood of the veins of the forearm, so the smaller portable blood glucose testing device had to change the glucose concentration value of the finger tip to that of the forearm. The other reason is that when diabetic patients use these devices to control their blood sugar levels, values lower than the actual can be very dangerous; for that reason, since the normal value range for blood sugar is 65−110 mg/dl on an empty stomach and 65−160 mg/dl right after a meal, the blood sugar measuring device may have been preset to display higher than actual values for concentrations above 160 mg/dl.

As a quantitative method of evaluating the masticatory efficiency, the sieve method had been used for a long time in the field of dentistry, but it has its shortcomings, e.g., the procedure is complex and time-consuming. On the other hand, measuring the amount of glucose extraction from chewing gummy-jelly with a spectrophotometer takes only 20 to 25 minutes for recording and analysis, however, it is costly, special agents are required for quantitative determination of color, and procedure is relatively troublesome. In contrast, the blood glucose testing device tried in this experiment only requires the patient to rinse his/her mouth with 10 ml of distilled water and place the test strip in the filtrate, and the glucose concentration would be automatically displayed after in 30 to 45 seconds. It was found in this experiment that although the glucose concentrations were not measured accurately with the glucose testing device, application of correction factors yielded results that were close to the accurate results obtained using the spectrophotometer, and that therefore, this method may be useful for clinical evaluation of masticatory performance through measurement of the amount of glucose extraction.

**Conclusion**

In order to investigate the possibility of objectively evaluating masticatory performance using a portable blood glucose testing device, the amount of glucose extraction from chewing gummy-jelly measured using a spectrophotometer was compared with that measured with a portable blood glucose testing device. Based on the results, it was concluded that the amount of glucose extraction from chewing gummy-jelly measured using the blood glucose testing device was as accurate as that measured using the spectrophotometer when corrections were applied. In other words, the blood glucose testing device could quantitatively measure masticatory performance as accurately as the spectrophotometer, and may thus offer a simple and comparatively inexpensive alternative to more complex and expensive methods.

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