

Measurement of mandibular activity during mastication using a three-axis accelerometer in patients with dysphagia after a stroke

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We investigated the reliability, validity, and responsiveness of the mandibular activity measurement of mastication initiation training foods using a three-axis accelerometer of patients with dysphagia after a stroke. The reliability and validity were examined in 16 healthy dentate subjects (12 males and 4 females, with a mean age of 47.7 ± 18.7 years, healthy group) and in 16 dentate patients with dysphagia after a stroke (10 males and 6 females, with a mean age of 62.3 ± 16.9 years, patient group). Ten patients (7 males and 3 females, 57.1 ± 15.6 years) who underwent mastication training for approximately 1 month were included in the study for responsiveness. The test food was 6 g of food for mastication initiation training (Process Lead[®], Otsuka Pharmaceutical, Tokushima, Japan). A three-axis acceleration sensor (UB-301 BT, A&D, Tokyo, Japan) was used to measure mandibular activity. The measurement conditions in this study were found to be reliable and valid for a cross-sectional comparison between healthy subjects and patients. However, it was not possible to determine the effect of chewing training (responsiveness). (J Osaka Dent Univ 2022; 56: 87-98)

Key words : Reliability ; Validity ; Responsiveness Three-axis acceleration sensor ; Dysphagia

INTRODUCTION

Stroke can cause sensory and motor disturbance in the oral organ and its associated structures, and many patients experience masticatory disturbance due to not only dysphagia but also to decreased or impaired oral function. Oral rehabilitation and swallowing rehabilitation aim at the recovery of masticatory function together with oral rehabilitation mainly focusing on tongue function, and masticatory training is carried out as coordinated training with each oral organ. The evaluation of masticatory and swallowing function is mainly qualitative, and quantitative evaluation is necessary to judge the effect of

rehabilitation and treatment, and to understand the temporal change of mandibular movement with masticatory movement in detail. However, it has not been applied to patients with cerebrovascular diseases because of the heavy burden on patients such as holding a posture for a certain period of time and wearing a device in the mouth during measurement. In order to detect the movement of the whole jaw during mastication, we define the amount of displacement obtained by the acceleration sensor as the amount of mandibular activity, which is easy to use in clinical practice.¹

In this study, we aimed to investigate the reliability, validity, and responsiveness of the mandibular

activity measurement of mastication initiation training foods using a three-axis accelerometer to evaluate the mastication and swallowing ability of patients with dysphagia after a stroke.

MATERIALS AND METHODS

Study Population

This study consists of two parts. The first part was the evaluation of the reliability and validity of the amount of mandibular activity using an acceleration sensor. The second part was the evaluation of the responsiveness of the mandibular activity toward rehabilitation. The data of patients with dysphagia were collected in the first part. Those who participated in a swallowing rehabilitation program with the same speech therapist belonging to Wakakusa-Tatsuma Rehabilitation Hospital showed a better post-rehabilitation Mann Assessment of Swallowing Ability (MASA) score² compared to their pre-rehabilitation score were included in the second part.

The participants in the first part received a thorough explanation of the study objectives before the study implementation. These participants consisted of 16 healthy dentate jaws of 12 males and 4 females, with a mean age of 47.7 ± 18.7 years (the "healthy group"), and 16 dentate jaws of 10 males and 6 females with dysphagia due to cerebrovascular disease and with a mean age of 62.3 ± 16.9 years (the "dysphagia group"). The latter were recruited among patients admitted to the convalescent rehabilitation ward of the Wakakusa-Tatsuma Rehabilitation Hospital.

After completing the data collection in the first part, the dysphagia group participated in a swallowing rehabilitation program with speech therapists, and those whose MASA scores improved after rehabilitation were included in the second part of the study. The patients in the second part included 7 males and 3 females, totaling 10 patients (mean age 57.1 ± 15.6 years). The swallowing rehabilitation program content was overseen by the same speech therapist and was performed for a total of 60 minutes per day for approximately 1 month, with 30 minutes of indirect training and 30 minutes of di-

rect training.

The inclusion criteria for the study population were Eichner's classification³ A (Four occlusal support areas) in both groups. The following were inclusion criteria for the dysphagia group: patients with a Mini Mental State Review (MMSE) of 24 points or higher, who understood life instructions, with a functional oral intake scale⁴ (FOIS) of 2 or higher, who were able to perform swallowing training with very small amounts of food, and with no movement of the body or head/neck at the time of examination. The exclusion criteria for both groups were as follows: Eichner's classification³ B (One to three occlusal support areas) and C (No occlusal support area). In the dysphagia group, the following patients were excluded: those with MMSE of 23 points or lower, clinically diagnosed dementia, difficulty in understanding instructions, FOIS of 1 or lower, difficulty in training using food, and marked body movement and head/neck movement at the time of examination.

Age, sex, height, weight, and body mass index (BMI) at the beginning of this study were investigated as survey items for the participant characteristics. In addition, Food intake was assessed by FOIS and swallowing ability by MASA.

This study was conducted with the approval of the Ethics Committee of Osaka Dental University (Approval No.11054) and the Ethics Committee of Wakakusa-Tatsuma Rehabilitation Hospital (Approval No. 19040554).

Test Foods

The test foods used were mastication training foods (chew and swallow managing food [CSMs], Process Lead[®], Green Tea Flavor; Otsuka Pharmaceutical, Tokushima, Japan). The amount of test food was one piece (6 g) per participant; the CSM was divided into eight equal portions.

Three-Axis Accelerometry and Signal Processing of Mandibular Movements.

For acceleration sensor measurement, a three-axis acceleration sensor (wristband-type Life Recorder[®] UB-301 BT; A&D Company, Tokyo, Japan) was used (Fig. 1). The acceleration sensor used in this

study can measure human motion in three axial directions by mounting it on the wrist, as it is a wristband type of activity meter that is 21 mm long, 39 mm wide, 15.5 mm high, and approximately 22 g in weight. In this study, the main body was removed from the wristband before it was utilized. The sam-



Fig. 1 Three-axis accelerometer (Life Recorder[®])

pling rate was 20 Hz, and by transferring the data to the computer through the cradle, it is possible to evaluate living behavior and amount of movement from movement intensity and frequency.

Acceleration sensors were applied with medical tape to the central mandibular mental area of the study population, and acceleration from mouth opening to the end of the first swallowing reflex was measured while the subject was in a 90-degree sitting position. The subjects were instructed to perform free chewing and swallowing movements after being allowed by the operator to eat with a spoon. The participants' movements were also videotaped, and the same speech therapist assessed and confirmed masticatory move-

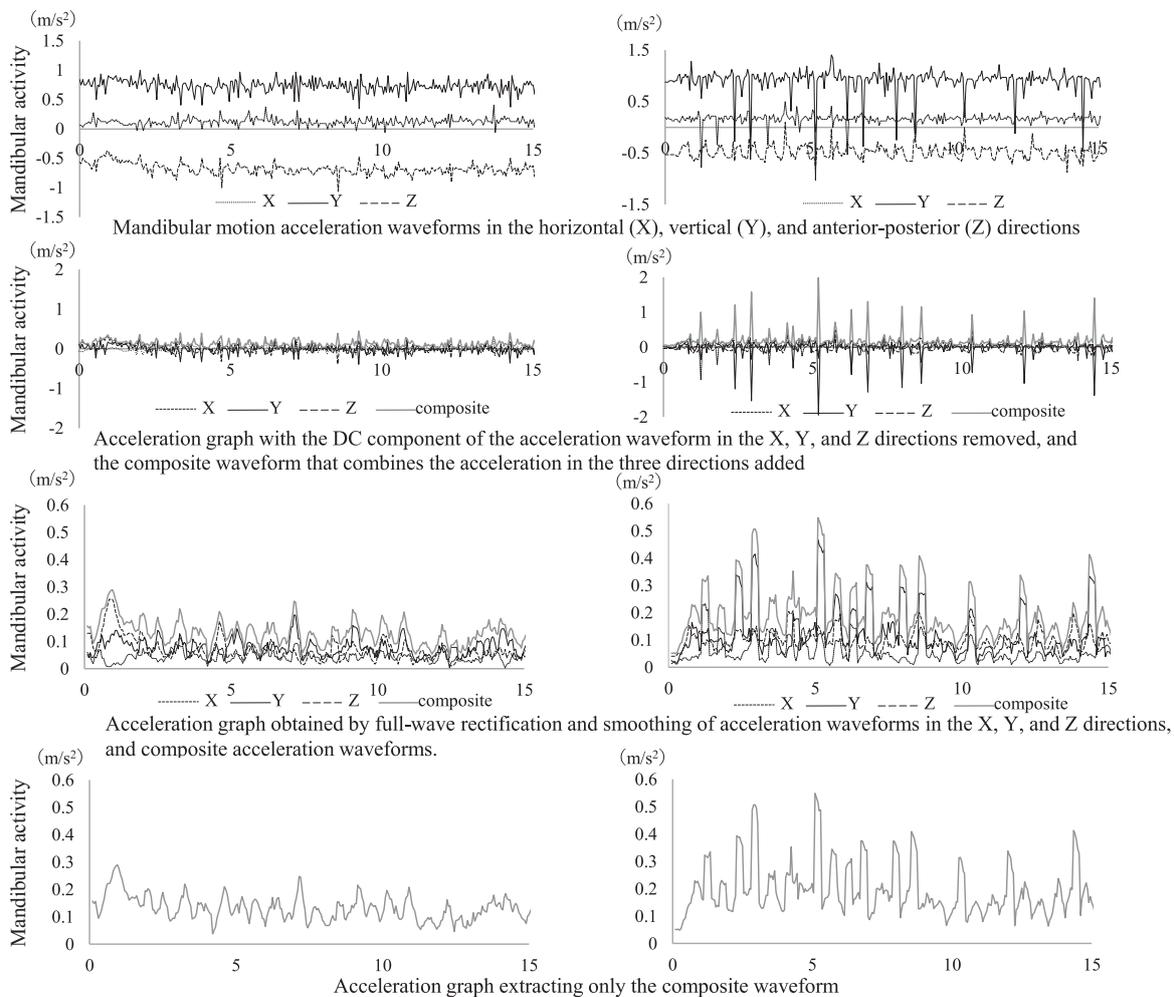


Fig. 2 The process of acceleration waveforms in the 3 directions in one healthy subject and one patient with dysphagia are shown in graph form.

ments and swallowing reflexes by external observation. Each participant attempted the procedure thrice, with sufficient breaks between each trial.

The acceleration signal obtained was to a full-wave rectifying smoothing process by removing the DC component. Integral values were calculated for each of the three lateral, vertical, and anteroposterior waveforms, and the sum of the components in the three directions was considered the total mandibular activity. The processing of the respective acceleration waveforms during the masticatory movements of one healthy subject and one patient with dysphagia is shown in Figure 2.

Statistical analysis

IBM SPSS Statistics Ver. 26 (IBM Corp., Armonk, NY, USA) and MedCalc Ver. 20 (MedCalc Software, Ostend, Belgium) were used for the statistical analysis.

Reliability

Reliability was estimated test-retest reliability.⁵ Systematic errors and random errors were estimated. The presence of systematic errors in⁵ the three trials was examined using single-factor, within-subjects analysis of variance (ANOVA). The level of statistical significance α was set at 0.05. Random errors were quantified for relative and absolute reliability.^{5,6} Relative reliability was calculated for intraclass correlation coefficient: ICC (3,1) and ICC (3,3).⁶⁻⁸ For absolute reliability (measurement error), the standard error of measurement (SEM) was calculated.^{6,9}

Validity

Validity was examined for criterion validity.¹⁰ The reference standard was healthy individuals and MASA. An unpaired t-test was used to compare the differences in mandibular activity in the measured means between the healthy and dysphagia groups. A receiver operating characteristic (ROC) curve was drawn to investigate the cutoff value to determine the presence of diseases according to the amount of mandibular activity. Youden's index was used to obtain the cutoff value for the point that

was the most distant from the diagonal with an area under the curve of 0.50. Pearson's correlation coefficients were calculated for the association between mandibular activity and MASA in the dysphagia group.^{11,12} The level of statistical significance α was set at 0.05.

Responsiveness

Responsiveness was examined in terms of internal and external responsiveness.^{10,13} Rehabilitation was performed and data from 10 patients with improved MASA were used. The internal responsiveness of MASA and mandibular activity was calculated as the standardized response mean (SRM).¹³⁻¹⁵ Standard error of prediction (SEP)^{6,16} was calculated for the means of mandibular activity volumes obtained from the three trials prior to rehabilitation. The 95% confidence intervals of the minimal detectable change (MDC95)^{5,6} for each patient were calculated and compared with the post-rehabilitation measurements. External responsiveness was calculated using Pearson's correlation coefficient for the association between changes in mandibular activity before and after rehabilitation and changes in MASA in the dysphagia group. The level of statistical significance α was set at 0.05.

RESULTS

Characteristics of subjects

The dysphagia group had lower levels of maximal tongue pressure, masticatory force, and MASA compared with the healthy group (Table 1).

Table 1 The status of age, BMI, tongue pressure, mastication and swallowing ability in healthy subjects and dysphagia patients

Variables	Healthy (n=16)	Dysphasia (n=16)
Age (yrs)	47.7±18.7	62.3±16.9
Gender: male / female	12 / 4	10 / 6
BMI (kg/m ²)	21.5±4.2	21.0±5.6
Maximum tongue pressure (kPa)	39.7±11.5	19.0±7.3
Mastication (level)	4.8±0.4	2.2±1.0
FOIS (level)	7.0	4.8±1.4
MASA (point)	198.0±0.6	154.1±21.2

Mean (1SD).

Reliability

In the three measurements of mandibular activity, a higher amount of mandibular activity was observed in the dysphagia group compared with the healthy group (Fig. 3). Repeated measures ANOVA revealed no significant differences (systematic error) between the trials of both groups (Tables 2 and 3). The point estimate of the ICC (3,1) for the single measurement of the healthy group was 0.688 and for the average of the three measurements was 0.868. The point estimate for the single measurement of the dysphagia group was 0.620, with an average measure of more than 0.830. The ICC (3,3) of the three mean determinations in both groups were more than 0.75, and SEM was 1.6 times higher in the dysphagia group compared to the healthy group (Table 4).

Table 2 Analysis of variance table for 3 measurements of mandibular activity for healthy subjects

Source	Sum of Squares	df	Mean Squares	F-value	P-value
Between subjects	9.700	15	0.647		
Within subject					
Between trials	0.144	2	0.072	0.840	0.441
Residual	2.568	30	0.086		
Total	2.712	32	0.085		
Total	12.411	47	0.264		

df: degree of freedom

Validity

The mean of mandibular activity was higher in the dysphagia group than in the healthy group. Unpaired t-test results showed a significant difference between the two groups ($p < 0.01$, Fig. 4). ROC curves were plotted with convex curves on the upper left side. The area under the ROC curve and 95% CI were 0.879 (0.715-0.967), respectively ($p < 0.05$). Youden's index yielded 1.618 m/s^2 as the

Table 3 Analysis of variance table for 3 measurements of mandibular activity for dysphagia patients

Source	Sum of Squares	df	Mean Squares	F-value	P-value
Between subjects	20.985	15	1.399		
Within subject					
Between trials	0.102	2	0.051	0.215	0.808
Residual	7.129	30	0.238		
Total	7.232	32	0.226		
Total	28.217	47	0.600		

df: degree of freedom

Table 4 Reliability and measurement error of Mandibular activity in healthy subjects and dysphagia patients

	Single measurement ICC (3,1) (95% CI)	SEM	Average of measurements ICC (3,3) (95% CI)	SEM
Healthy	0.686 (0.431-0.864)	0.293	0.868 (0.695-0.945)	0.168
Dysphasia	0.620 (0.341-0.829)	0.488	0.830 (0.609-0.936)	0.275

ICC: Intraclass correlation coefficient, CI: Confidence interval
SEM: Standard error of the measurement (m/s^2)

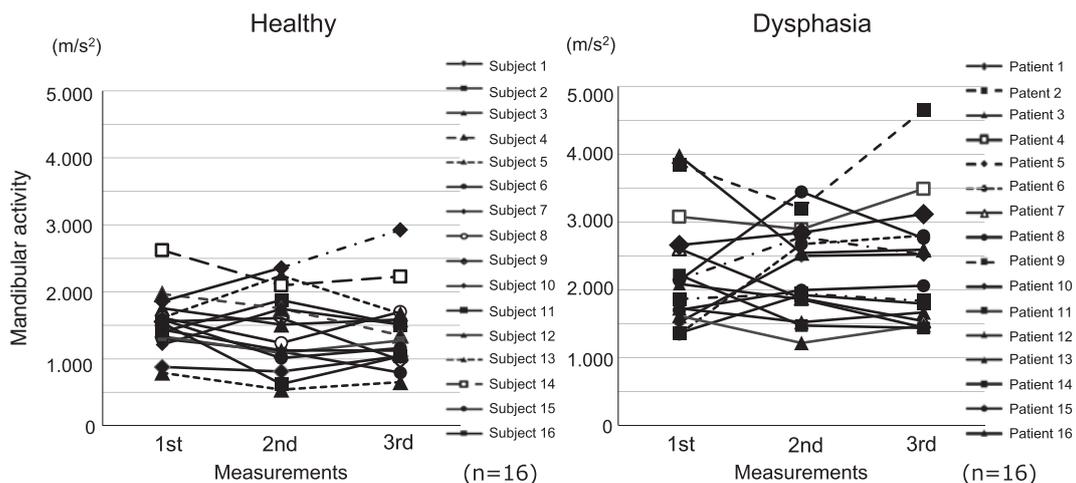


Fig. 3 Three measurements of mandibular activity

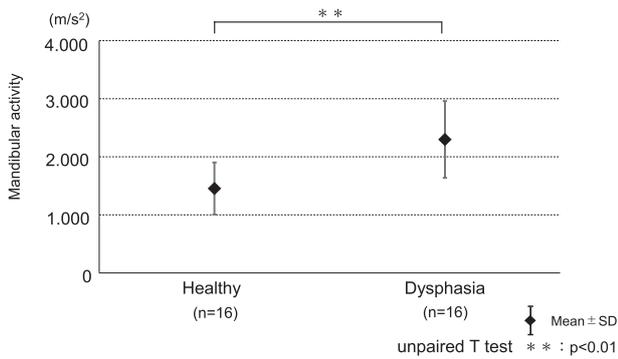


Fig. 4 Comparison of mandibular activity in healthy subjects and dysphagia patients

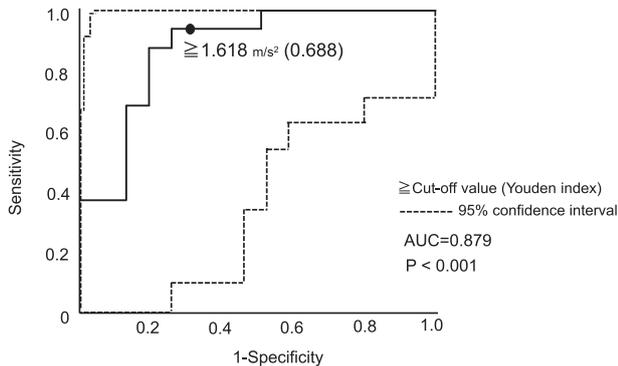


Fig. 5 ROC curve for mandibular activity

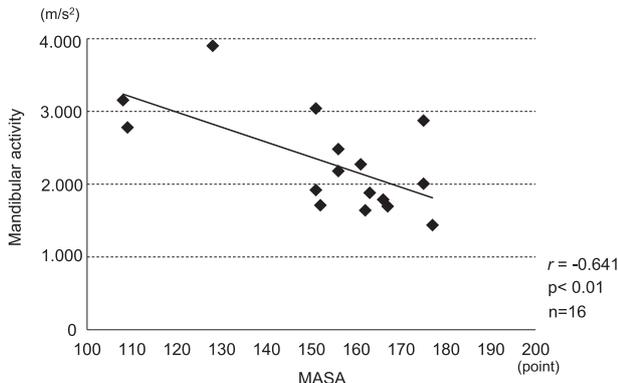


Fig. 6 Scatter Plot of Mandibular Activity and MASA in patients with dysphagia

appropriate cutoff. The sensitivity in this case was 93.75%, and the specificity was 75.00% (Fig. 5). Significant correlations were shown for the association between mandibular activity and MASA in the dysphagia group ($r = -0.641$, $p = 0.007$) (Fig. 6).

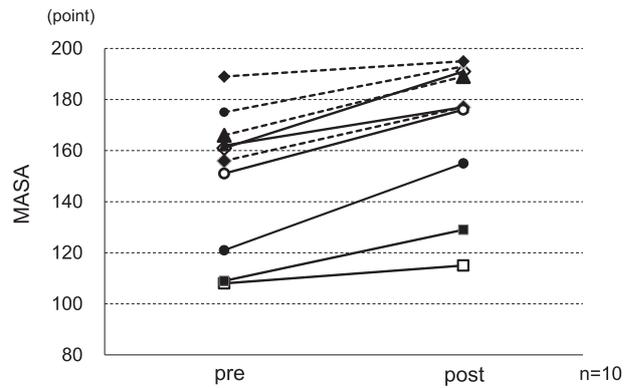


Fig. 7 Comparison of MASA before and after rehabilitation in dysphagia patients

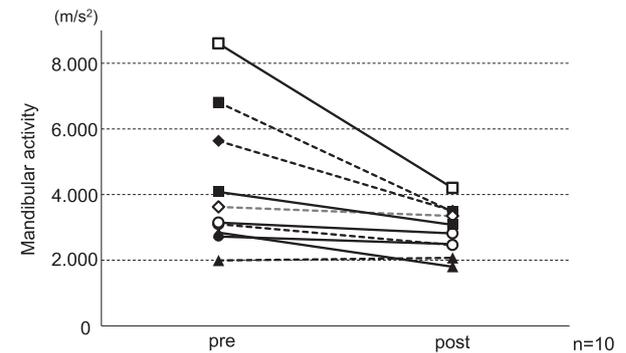


Fig. 8 Comparison of Mandibular activity before and after rehabilitation in dysphagia patients

Responsiveness

The mean difference for those who underwent rehabilitation and had elevated MASA levels was 19.90 points (Fig. 7). Mandibular activity decreased in nine patients (Fig. 8). The SRM of mandibular activity was 0.419, which was approximately 19% compared to MASA (Table 5). The SEP calculated from the measured value before rehabilitation was 0.913 m/s². After training, there were two individuals who showed changes beyond MDC₉₅ (Table 6). Regarding the association between the changes in mandibular activity before and after rehabilitation and the changes in MASA in the dysphagia group, no significant correlation was found ($r = -0.307$, $p = 0.388$) (Fig. 9).

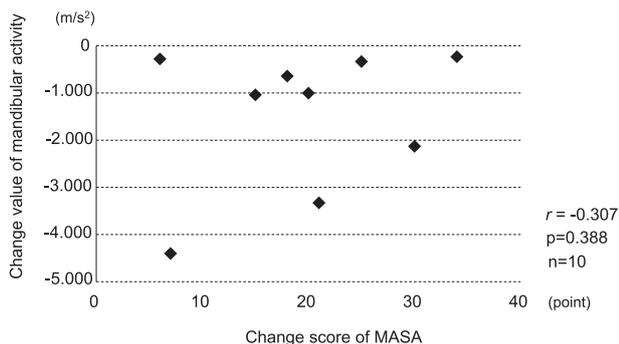
Table 5 Internal responsiveness (sensitivity to change) before and after rehabilitation

	pre	post	SRM (95% CI)
MASA (point)	149.800(27.868)	169.700(27.929)	2.217(1.348–3.551)
Mandibular activity (m/s ²)	4.255(2.102)	2.925(0.737)	0.419(0.361–0.445)

SRM: Standardized response mean CI: Confidence interval

Table 6 Mandibular activity before and after rehabilitation and MDC₉₅

Patients	Mandibular activity		MDC ₉₅		Patients beyond the MDC ₉₅
	pre	post	lower	upper	
1	6.807	3.479	4.790	8.368	*
2	2.841	1.802	1.178	4.756	
3	8.602	4.202	6.425	10.003	*
4	5.634	3.506	3.341	7.299	
5	2.721	2.491	1.069	4.647	
6	3.101	2.461	1.416	4.993	
7	3.147	2.814	1.457	5.035	
8	1.991	2.069	0.405	3.983	
9	3.624	3.346	1.891	5.469	
10	4.080	3.077	2.307	5.884	

Unit: m/s² MDC 95: 95% confidence interval of minimal detectable change**Fig. 9** Scatter plots of changes in mandibular activity and MASA before and after rehabilitation

DISCUSSION

In general, measurements are the cornerstone of medical research and clinical practice. Quality assessment is of great importance and is evaluated with three properties: reliability is defined as the degree to which there is no measurement error in the measurement; validity, the degree to which the measurement instrument actually measures the construct being measured; and responsiveness, the

ability of the measurement instrument to detect changes in the construct of the measurement object over time.^{10, 17} The difference between validity and responsiveness is that validity implies the validity of one score (estimated based on cross-sectional measures) while responsiveness implies the validity of a change in scores (estimated based on two longitudinal measures).^{10, 17} Since the scores obtained from measurement instruments are affected by the population being measured and measurement conditions, the aforementioned characterization is now focused on the scores produced by measurement instruments rather than on the measurement instruments per se.^{10, 17} In this study, we aimed to investigate the three properties of mandibular activity measurement using a three-axis acceleration sensor during mastication of the training initiation food for patients with dysphagia in the 'measured conditions set here.'

Study Population

Swallowing disorder is present in 30-70% of stroke patients. There are many patients with dysphagia due to cerebrovascular diseases,¹⁸ particularly pseudobulbar palsy. Apart from the pharyngeal phase, patients often have disorders in the preparatory and oral phases.¹⁹ This study was conducted to select patients with cerebrovascular disease (cerebral infarction, cerebral hemorrhage, and subarachnoid hemorrhage) with pseudobulbar palsy and dysphagia with oral dysfunction and masticatory dysfunction in each oral structure. In the classification of cerebrovascular disease in the dysphagia group, 50% of the patients had cerebral infarction. In the modified Ranking Scale²⁰ (mRS), which is the seriousness rating scale of cerebrovascular disease and neurological disease, five patients had severe failure of grade 5 (bedridden and requiring constant

assistance) in this study.

Oral problems, such as tooth loss, affected the masticatory performance, bolus formation ability, and subsequent swallowing function during the preparation and oral phases. Mandibular movements in mastication have been shown to be regulated by stimulation from peripheral sensory receptors, such as the periodontal ligament, masticatory muscles, and oral mucosa in the masticatory center of the brainstem, to be executed in a size-and strength-dependent manner,²¹ and to increase mandibular movements in the absence of the periodontal ligament by the inadequate input of pressure-sensing stimuli.²² In this study, the sensation obtained from the physical properties of food was inputted into the center using the periodontal sensation during mastication, and the masticatory force and mandibular movement were adjusted unconsciously to match the physical properties of the food; Therefore, in this study, healthy subjects and patients with no missing teeth were included. FOIS, which was used in the evaluation of this study, assesses the actual feeding situation in seven stages, and its reliability and validity in patients with stroke were verified.³ MASA is a method of differential screening of dysphagia and aspiration of stroke by the clinical evaluation.²³ Items, such as higher brain function, oral cavity, pharynx, laryngeal function, and respiratory function, are comprehensively evaluated, with a perfect score of 200 points for the swallowing function. Each endpoint is assessed by a score of 5 or 10, and if dysphagia is severe, the score on each assessment is also low. From the total score, the degree of dysphagia and aspiration can be classified into four grades. Dysphagia criteria are as follows: normal: 178-200 points; possible: 168-177 points; probable: 139-167 points; and definite: 138 points or less.² For patients with acute stroke, higher results have been reported regarding MASA intra-rater or inter-rater reliability.^{2, 23} In addition, the face validity and the content validity of the evaluation items are also reported when setting the cutoff value of MASA in patients with acute stroke.^{2, 24}

Test Food

This study used a Process Lead[®] (Otsuka Pharmaceutical) commercially available as a food for chewing and swallowing training. This food correspond to code 3 or 4 of the Japanese Dysphagia Diet 2013 by the Japanese Society of Dysphagia Rehabilitation. It has a hardness that requires mastication, can be masticated, can form a bolus, can be fed, and becomes paste-like when swallowed. Its physical property is such that a series of movements until swallowing can be safely performed. This food has been positioned as a food for training in chewing and swallowing prior to initiating feeding training with jelly and pasty foods and transitioning to forms requiring chewing in feeding and swallowing rehabilitation.²⁴

The amount of test meal used in previous studies was 4 g.²⁵ When the amount in the mouth is small, chewing is often performed by crushing the food item between the tongue and palate, and chewing using teeth is observed in many cases or with hardness of the food. Swallowing exercises using 2 to 5 mL of gelatin in older adults with poor eating function often result in the swallowing of 2 to 3 mL of gelatin per person.²⁶ There is a lack of consensus on the appropriate bite size for measuring mandibular movement volume in patients with mastication and food mass formation movement disorders. Therefore, in this study, 6 g was specified based on clinical experience and preliminary experiments.

Three-Axis Accelerometry and Signal Processing of Mandibular Movements

Several reports have measured mandibular movement using acceleration sensors.^{27, 28} Measurements by two axial accelerometers can calculate the amount of displacement of the mandible,²⁹ and the mandibular acceleration data during mastication can be applied to estimate the hardness of food.³⁰ Isaji *et al.*²² measured the mandibular movement during the mastication of dentulous individuals and denture wearers using a two-axis acceleration sensor and performed an acceleration analysis. They reported that the general denture wearer has a larger jaw movement than does the dentulous per-

son and that the complexity was reduced by a regular monotonous rhythm. Shikano *et al.*³¹ noted that mandibular movements of complete denture wearers cause the strong impact of the mandible against the upper jaw regardless of the nature of the food, and that chewing movements were performed with a certain tendency. The loss of the periodontal ligament made it difficult for denture wearers to sense the denture, resulting in poorly controlled mandibular movements. However, no reports to date applied acceleration sensors to patients with dysphagia due to cerebrovascular disease and measured mandibular movements.

Reliability

In the dysphagia group, the values of mandibular activity and the fluctuation were higher compared with the healthy group (Figs. 3 and 4). The amount of mandibular activity obtained in this study was significantly increased, with a waveform larger and more irregular in amplitude compared to that of healthy individuals. Because of the existence of sensory and motor disturbances caused by cerebrovascular disease and the lowering of stimulation input from oral structures, physical properties could not be sensed, and the regulation of mandibular movement by the chewing center of the brainstem seemed to be difficult. Mastication has been shown to be subject not only to the brainstem but also to the control of the cerebrum. The primary facial motor area of the corticofacial area is involved in the motor coordination of the mandible and tongue during food uptake and transfer.³² The cortical masticatory area is responsible for the initiation of mastication, the formation and maintenance of rhythmic masticatory movements, transition from mastication to swallowing, and regulation of swallowing-related muscles.³³ In addition, the basal ganglia and prefrontal cortex have also been suggested to be involved in masticatory motor regulation.³⁴⁻³⁶ The patients with dysphagia included in this study had foci in areas including the frontal lobe, basal ganglia, corticofacial areas, and cortical masticatory areas, which were considered to have caused masticatory movements that differed from those of the healthy

group as a result of problems in regulation from the cerebral cortex and the brainstem.

A prerequisite for obtaining valid measurements is to first establish higher reliability.⁵ Variation in observed measurements is considered to be largely related to within-subject variability. Reliability is defined as the degree of the absence of measurement error; the measurement error is classified into systematic error and random error.^{5, 6, 17} The presence or absence of systematic error was investigated in this study with repeated measures ANOVA. For random errors, model 3 of ICC, which does not take into account the effect of variance of systematic errors as a relative index, and SEM as an absolute index were calculated.⁶

No systematic error of the three measurements was detected in the healthy and dysphagia groups. This means that there was no systematic increase or descending tendency of the measured values, such as due to fatigue of the subjects at the time the measurement was taken. The variability of the measured values was found to be due to random error. ICC was interpreted as reliable as the value approached 1.0, and multiple calculation formulas have been proposed according to the measurement conditions. In the current study, we calculated ICC (3,1) showing the degree of reliability in single measurement taken by the same person and ICC (3,3) estimating the reliability (average measurements) of average values of triplicate measurements in healthy individuals and patients with dysphagia.^{5, 6} This indicator is intuitively understandable because the resulting values are expressed as relative values. In this study, the ICC values of the dysphagia group were lower than those of the healthy group. However, since the ICC values for the average measurements in both groups exceeded 0.83, from the ICC value, 'good' reliability⁶ was shown. In SEM, which shows measurement error in actual measurement units, the value of the dysphagia group was 1.6-fold higher and had a larger random error compared to the healthy group. The variations in the acceleration sensor measurement data in this study seemed to be due to the fact that the influence on the movement of the body

movement, especially the head and neck, could not be excluded from the measurement of the application site of one site in the mental area, variations in the application sites with different measurement dates, the type and quantity of test foods, and the selection of analysis intervals.

Validity

In this study, we examined the criterion validity in which the reference standard were healthy individuals and MASA.¹⁰ Validity focuses on the scores produced by the measurement method, not the measurement method itself.¹⁵ Criterion validity refers to the extent to which the metric score matches the reference standard of the configuration concept to be measured, which is applied when there is a reference criterion.¹⁷ The concurrent validity of this concept is considered to be diagnostic utility.³⁷ In this study, the ROC curve was drawn and Youden's index was calculated to determine the cutoff value.^{11,12} As a result, the sensitivity and specificity of the detected cutoff values were very high, and the results of the unpaired t-test showed that the determination of the amount of mandibular activity in this study was highly discriminatory for the presence or absence of disease. Furthermore, the amount of mandibular activity in this study were correlated with MASA scores for comprehensive assessment of swallowing function in the dysphagia group, suggesting the possibility that swallowing function can be quantitatively assessed based on the amount of mandibular activity.

Responsiveness

There are two major aspects of responsiveness, each defined and evaluated.¹³ Internal responsiveness is the ability of a measuring instrument to detect a change in score when the patient's condition actually changes.¹³ The index of internal responsiveness is expressed as a ratio of signal (true change) and noise (variation of random error). SRM is a type of effect size that is the change score before and after the intervention divided by the standard deviation of the change score.^{16,17} For internal responsiveness, values of 0.20, 0.50, and 0.80 are

interpreted as small, medium, and large, respectively.^{13,15} This study found that the SRMs of mandibular activity were roughly moderate but considerably less responsive when compared to MASA, which was the reference standard. In addition, when interpreting the change in scores, interpretation considering measurement error is required. Not all changes in measurements⁵ are actual or true changes.⁵ MDC_{95} is the 95% CI of the smallest amount of measured change required to eliminate the possibility that measurement error alone is causal. In this study, SEPs recommended by Charter¹⁶ and Dudek¹⁸ were calculated as measured errors. In multiple trials, 95% of the study populations showed random variation below this amount.⁵ In this study, after rehabilitation, the tendency of lower mandibular activity volume compared to that before rehabilitation could be captured, although 2 out of 10 individuals showed lower values than the lower limit of MDC_{95} . It is interpreted that the pre- and post-rehabilitation changes in the remaining eight individuals were within the measurement error range.

External responsiveness refers to the degree to which a change in a measurement over a particular time frame correlates with a change in a reference standard.¹³ In this study, no correlations were found between the amount of change in MASA and the amount of change in mandibular activity. Although the amount of measurement error, that the present measurement condition had, was acceptable for cross-sectional validity, it may have acted as a large noise for the detection of longitudinal changes. When measuring instruments are used for cross-sectional observation (e.g., healthy vs. patient comparison), an ICC value of 0.70 is acceptable, and high ICC values of 0.90 to 0.95 are required to apply these instruments to longitudinal observation of individual patients.³⁸ From the result of this study, it was proven that in order to detect the time-dependent change of mandible activity quantity of the deglutition disorder patient patients with dysphagia after a stroke, it was necessary to examine the measurement condition with higher reliability and responsiveness.

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REFERENCES

- Otsuka K, Iwashita A, Konishi Y, Tanaka M. Quantification of mandibular movement during mastication using a 3-axis acceleration sensor. *J Yamato Univ* 2020; **6**: 3-7. (Japanese)
- Mann G. MASA: The mann assessment of swallowing ability. New York: Thomson Learning, Clifton Park, 2002.
- Eicher K. Über eine Gruppeneinteilung des Lückengebisses für die Prothetik. *Dtsche Zahnärztl Z* 1955; **10**: 1831-1834.
- Crary MA, Mann GDC, Groher ME. Initial Psychometric Assessment of a Functional Oral Intake Scale for Dysphagia in Stroke Patients. *Arch Phys Med Rehabil* 2005; **86**: 1516-1520.
- Portney LG. Foundations of Clinical Research: Applications to Evidence-Based Practice, 4th ed. Philadelphia: F. A. Davis, 2020: 115-126, 486-508.
- Weir JP. Quantifying test-retest reliability using the intraclass correlation coefficient and the SEM. *J Strength Cond Res* 2005; **19**: 231-240.
- Shrout PE, Fleiss JL. Intraclass correlations: Uses in assessing rater reliability. *Psychological Bulletin* 1979; **86**: 420-428.
- McGraw K, Wong S. Forming inferences about some intraclass correlation coefficients. *Psychol Methods* 1996; **1**: 30-46.
- Harvill LM. Standard error of measurement. *Educ Meas* 1991; **10**: 33-41.
- Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, Bouter LM, de Vet HC. International consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes: results of the COSMIN study. *J Clinical Epidemiology* 2010; **63**: 737-45.
- Youden WJ. Index for rating diagnostic tests. *Cancer* 1950; **3**: 32-35.
- Perkins NJ, Schisterman EF. The inconsistency of "optimal" cutpoints obtained using two criteria based on the receiver operating characteristics curve. *Am J Epidemiol* 2006; **163**: 670-675.
- Husted JA, Cook RJ, Farewell VT, Gladman DD. Methods for assessing responsiveness: a critical review and recommendations. *J Clin Epidemiol* 2000; **53**: 459-68.
- Cohen J. Statistical power analysis for the behavioral sciences. rev. ed. New York: Academic Press; 1977.
- Liang MH, Fossel AH, Larson MG. Comparisons of five health status instruments for orthopedic evaluation. *Medical Care* 1990; **28**: 632-42.
- Charter RA. Revisiting the standard error of measurement, estimate, and prediction and their application to test scores. *Percept Mot Skills* 1996; **82**: 1139-1144.
- Dudek FJ. The continuing misinterpretation of the standard error of measurement. *Psychol Bull* 1979; **86**: 335-337.
- Martino R, Foley N, Bhogal S, Diamant N, Speechley M, Teasell R. Dysphagia after stroke: incidence, diagnosis, and pulmonary complications. *Stroke* 2005; **36**: 2756-2763.
- Itoda M, Kusumoto T, Kawazoe T. Effect of occlusal support on swallowing in patients with a low degree of independence in daily life. *J Osaka Odontol Soc* 2004; **67**: 121-135. (Japanese)
- van Swieten JC, Koudstaal PJ, Visser MC, Schouten HJ., van Gijn. Interobserver agreement for the assessment of handicap in stroke patients. *Stroke* 1988; **19**: 604-607.
- Lund JP, Kolta A. Brainstem circuits that control mastication: do they have anything to say during speech? *J Commun Disord* 2006; **39**: 381-390.
- Isaji K. Validity of acceleration analysis in masticatory movement natural dentition and denture wearers. *Jpn J Gerodont* 2001; **16**: 156-164. (Japanese)
- Mann G, Hankey GJ, Cameron D. Swallowing disorders following acute stroke: prevalence and diagnostic accuracy. *Cerebrovascular Disease* 2000; **10**: 380-386.
- Tohara T, Kikutani T, Yajima Y, Igarashi K, Tanaka Y, Tamura F. An attempt to evaluate masticatory performance using commercially sold masticatory training food. *Jpn J dysphagia rehabil* 2017; **21**: 3-10. (Japanese)
- Nakagawa K, Matsuo K, Shibata S, Inamoto Y, Ito Y, Abe K, Ishibashi N, Fujii W, Saitoh E. Efficacy of a novel training food based on the process model of feeding for mastication and swallowing – A preliminary study in elderly individuals living at a residential facility –. *Jpn J Comprehensive Rehabil Science* 2014; **5**: 72-78. (Japanese)
- Takahashi T, Sonoda A, Kouda E, Nakamura S, Ogoshi H. Physical properties of gel-type food, and how the intake quantity per mouthful affects the masticating method and frequency of swallowing. *Jpn J Nutrition and Dietetics* 2008; **66**: 231-240. (Japanese)
- Grant AA. Some aspects of mandibular movement: acceleration and horizontal distortion. *Ann Acad Med Singap* 1986; **15**: 305-310.
- Yamabe Y, Fujii H. An experimental study on body motion during mandibular movement with accelerometers. *J Jpn Soc Stomatognath Funct* 1997; **3**: 121-129. (Japanese)
- Sekita T, Hasegawa S, Hayakawa I. Fundamental study on the development of a measuring device using an accelerometer. *J Stomatol Soc Jpn* 2002; **69**: 251-257.
- Ogai K, Kitamura K, Nemoto T. A basic study for prediction of food hardness based on an acceleration monitoring of lower jaw during mastication. *Jpn J Nurs Sci* 2015; **2**: 9-14. (Japanese)
- Shikano Y. Clinical study of evaluation on masticatory function in complete denture wearers a comparison of masticatory movements between normal natural dentition and complete denture wearer. *Jpn Prosthodont Soc* 1990; **34**: 318-332. (Japanese)
- Yamamura K, Narita N, Yao D, Martin RE, Masuda Y, Sessle BJ. Effects of reversible bilateral inactivation of face primary motor cortex on mastication and swallowing. *Brain Res* 2002; **944**: 40-55.
- Narita N, Yamamura K. Recent insights in the mechanisms of cerebral cortex controlling mastication and swallowing. *Jpn J Soc Mastication Sci Health Promotion* 2003; **13**: 3-12. (Japanese)
- Isogai F, Kato T, Fujimoto M, Toi S, Oka A, Adachi T, Maeda Y, Morimoto T, Yoshida A, Masuda Y. Cortical area inducing chewing-like rhythmical jaw movements and its connections with thalamic nuclei in guinea pigs. *Neurosci*

Res 2012; **74**: 239-247.

35. Masuda Y, Kato T, Hidaka O, Matsuo R, Inoue T, Iwata K, Morimoto T. Neuronal activity in the putamen and the globus pallidus of rabbit during mastication. *Neurosci Res* 2001; **39**: 11-19.
36. Narita N, Kamiya K, Kawasaki S, Matsumoto T. Prefrontal Cortex activity related to chewing gum. *J Jpn Soc Stomatognath Funct* 2009; **15**: 154-155.
37. Messick S. Test validity and the ethics of assessment. *American Psychologist* 1980; **35**: 1012-1027.
38. Nunnally J, Bernstein I. (1994). *Psychometric Theory*. 3rd edition. New York: McGraw-Hill.