Evaluation of reliability
of perioral muscle pressure measurements
using a newly developed device with a lip piece

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Purpose: We examined the reliability of measurements using a newly developed perioral muscle pressure measuring device with a lip piece in healthy adults. *Methods*: Subjects were 40 healthy men (25.8 years) with normal stomatognathic function. Perioral muscle pressure measuring device with a lip piece was used to measure upper lip, lower lip and tongue pressure, and a balloon-based measurement device was used to measure tongue and cheek pressure. Each measurement was taken twice with a 1-min interval between the two measurements. We determined intra-rater reliability by using the intra-class correlation coefficient as a test of relative reliability. As a test of absolute reliability, Bland–Altman analysis was used to assess systematic bias and the 95% confidence interval of the minimal detectable change was calculated. Additionally, the coefficient of variation was calculated. The Spearman–Brown formula was calculated the number of measurements needed to achieve a confidence coefficient ≥0.9. Each set of measurements was followed by a second set that were taken 1 week later. *Results*: All measurements showed high values of intra-class correlation coefficient. Upper lip, tongue, and cheek pressure can be determined based on a single measurement, while lower lip pressure requires averaging twice. No systematic bias was observed. The coefficients of variation of measurements were almost the same between the two devices. *Conclusion*: Measurements were highly reliable regardless of the type of perioral muscles. Our findings suggest that the method described in this study is useful as a quantitative chair side method for examining perioral muscle pressure.

Key words: tongue pressure, upper lip pressure, lower lip pressure, absolute reliability, relative reliabilit

1. Introduction

Chewing is a series of processes for mastication and swallowing of food. There are numerous methods for examining the functions related to ingestion, crunching, comminution, mixing, bolus formation, and swallowing [11], [14]. In the preparation and oral phases of swallowing, a bolus is formed and is placed by the tongue on the occlusal surface of posterior teeth and buccal mucosa for transport to the pharynx [8], [18], [23]. Thus, strength of the stomatognathic muscles is likely to be an important element in masticatory function.

Various methods have been developed for the objective assessment of oral functions [5]–[7], [17], [21], [22]. In particular, tongue pressure has often been studied to assess the function of the perioral muscles. The literature on devices for measuring perioral muscle pressure includes studies using an IOPI® system [2], [17], the Kay device [17], a sensor sheet for measuring tongue pressure [7], and a balloon-based tongue measuring device [5], [22]. IOPI® devices are easy to use, but the valve on the measuring portion becomes slippery on the tongue surface, making it difficult to take a measurement at a fixed position. The Kay device and the sensor sheet for measuring tongue pressure both have a sensor sheet that is at-

tached to the palate for taking measurements of the front, center, and back of the tongue and can record swallowing pressure measurements without discomfort. However, preparing for and performing such measurements are cumbersome. In contrast, the balloon-based tongue measuring device can be easily used at the chair side, the shape of the probe is similar to a food bolus, and it is disposable, making it hygienic. It also has benefits of being able to measure cheek and lip pressure as well as tongue pressure. Perioral pressure from individual muscles should preferably be well balanced, and thus measurements should be taken of tongue, lip, and cheek pressure when assessing the outcome of functional training of the perioral muscles. A single device that measures pressure at all these perioral sites can simplify the measuring procedure and reduce time and labor. However, it is important to consider the reproducibility of the pressure measurement as reproducibility is likely influenced by the type and sensitivity of the device and by the discomfort experienced by subjects during the measurement. Therefore, such influences should be examined and the pressure measurement procedure standardized.

A recently developed perioral muscle pressure measuring device can be used to assess upper and lower lip pressures and tongue pressure separately. Similar to the balloon-based tongue pressure measurement device [5], [22], this device is portable and can be used at the chair side. It is hygienic and has low running costs, as a sensor cover is placed on the lip piece during measurement. To determine the efficacy of measurements taken by this new device with a lippiece, we compared its results with values measured by the balloon-based tongue pressure measurement device, whose accuracy has already been verified, and examined the relative and absolute reliability of the measurements obtained. In addition, we analyzed correlations between the different perioral muscle pressures to elucidate the relationship between those pressures as a measure of oral function.

2. Methods

2.1. Measurement of perioral muscle pressure

Subjects were 40 healthy men (mean age: 25.8 ± 2.1 years) with normal occlusion. Subjects were ex-

amined with the head in the Frankfurt plane while seated in a chair without a backrest.

We first measured upper lip pressure (ULp), lower lip pressure (LLp), and tongue pressure (Tp-A) using aperioral muscle pressure measuring device with a lippiece (Lip & Tongue Pressure Gauge®, Mamarissimo, Tokyo, Japan) according to the method proposed by Nakao et al. [15] (Fig. 1). To measure ULp and LLp, the measurement device with lip piece was inserted into the oral vestibule and positioned near the labial gingiva of the maxillary or mandibular front teeth, and the lips were pursed to compress the lip piece with maximum force. To measure Tp-A, the lip piece was positioned on the lingual gingiva of the mandibular front teeth, and the tongue was thrust forward to compress the lip piece with maximum force with the lips closed. Measurement time was about 5 s for each measurement.

Fig. 1. A perioral muscle pressure measuring device with a lip piece (Lip & Tongue Pressure Gauge®).
*: lip piece (width: 35 mm, height: 8 mm, thickness: 1.5 mm, radius of curvature; $R = 25$ mm)

Next, we measured maximum tongue pressure (Tp-B) and cheek pressure (Cp) on the habitual chewing side with a balloon-based tongue pressure measurement device (JMS tongue pressure measurement device®, JMS, Hiroshima, Japan)according to the method proposed by Hayashi et al. [5] (Fig. 2).The probe was inflated at a baseline pressure of 19.6 kPa. To measure Tp-B, the balloon was positioned on the anterior palate with the lips closed. Subjects then raised their tongue and compressed the balloon onto the palate with maximal voluntary muscular effort for approximately 7 s. To measure Cp, the balloon was positioned in the space between the upper and lower first molars and the buccal mucosa. Subjects then closed their lips and compressed the balloon against

the buccal surface of the molars with maximal voluntary muscular effort for approximately 5 s.

Each muscle pressure measurement was taken twice with a 1-min interval between the two measurements. Each set of measurements was followed by a second set that were taken 1 week later.
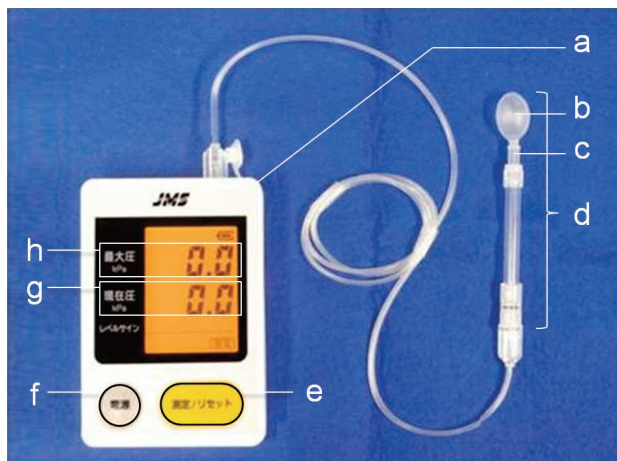

Fig. 2. A balloon-based tongue pressure measurement device (JMS tongue pressure measurement device®):
(a) digital tongue pressure measurement device; (b) balloon (width: 18 mm, height: 25 mm); (c) plastic pipe (width: 6 mm, height: 10 mm); (d) disposable probe; (e) measurement/reset; (f) power; (g) present pressure; (h) maximum pressure

2.2. Analysis method

We determined intra-rater reliability by using the intra-class correlation coefficient (ICC) as a test of relative reliability. Using the Spearman–Brown formula [$k = p1(1 − p2)/p2(1 − p1)$, p1; achieved ICC value, p2; obtained ICC (1,1) value], we calculated the number of measurements (k) needed to achieve a confidence coefficient ≥ 0.9. We then calculated the 95% confidence interval (CI) of the minimal detectable change(MDC) [$MDC_{95} = 1.96 \times \sqrt{2}$] as a test of absolute reliability to determine measurement errors. Bland–Altman analysis was used to assess systematic bias. The 95% CI was calculated from the mean difference of two measurements and the presence or absence of a fixed bias was judged based on the inclusion of zero in that value. Proportional biases were examined by determining the regression formula of the Bland–Altman plot and the uncorrelated test [1], [3], [12], [13]. Additionally, the coefficient of variation (CV) was evaluated to compare the degree of variability. Each set of measurements was followed by a second set of measurements that were taken one week after the first measurement day.

Table 1. Relative and absolute reliability of each muscle pressure and their coefficients of variation for measurements taken on the same day; (a) upper lip pressure (ULp), lower lip pressure (LLp), and tongue pressure (Tp-A) were measured by the Lip & Tongue Pressure Gauge®; (b) tongue pressure (Tp-B) and cheek pressure (Cp) were measured by the JMS tongue pressure measurement device®

(a)

	ICC (1,1)	95% CI (N)		P-value	MDC_{95}	Bland-Altman analysis				CV
						fixed bias		proportional bias		
						95% CI		uncorrelated test		
		lower limit	upper limit		(N)	lower limit	upper limit	r	P-value	
ULp	0.904	0.85	0.94	<0.001	2.70	-0.41	0.07	0.075	0.644	0.39
LLp	0.890	0.83	0.93	<0.001	2.32	-0.23	0.23	0.109	0.503	0.31
Tp-A	0.912	0.86	0.95	<0.001	5.31	-0.49	0.29	0.222	0.169	0.35

ICC (1,1): intra-rater reliability
95% CI: 95% confidence interval
MDC_{95}: 95% minimal detectable change
r: Correlation coefficient
CV: Coefficient of variation

(b)

	ICC (1,1)	95% CI (kPa)		P-value	MDC_{95}	Bland-Altman analysis				CV
						fixed bias		proportional bias		
						95% CI		uncorrelated test		
		lower limit	upper limit		(kPa)	lower limit	upper limit	r	P-value	
Tp-B	0.974	0.96	0.99	<0.001	5.12	-0.24	0.84	0.204	0.207	0.25
Cp	0.971	0.95	0.98	<0.001	2.09	-0.35	0.21	0.03	0.853	0.22

ICC (1,1): intra-rater reliability
95% CI: 95% confidence interval
MDC_{95}: 95% minimal detectable change
r: Correlation coefficient
CV: Coefficient of variation

Normality of distribution was analyzed by the Sha-piro–Wilk test. Pearson's product-moment correlation coefficients were used to analyze the correlation between muscle pressures. In addition, regression analysis was performed to determine the regression formulas for muscle pressures that showed correlations.

Statistical analysis was performed using SPSS 17.0 software (SPSS Japan Inc., Tokyo, Japan). Significance was set at $p < 0.05$.

3. Results

Same-day and different-day measurements (means ± standard deviation) for ULp, LLp, Tp-A, Tp-B and Cp are shown in Fig. 3. The measurements for each type of muscle pressure were similar between the first and second day. The ICC, MDC$_{95}$, Bland–Altman analysis results, and CV for each muscle pressure are shown in Tables 1 and 2, the results of the Bland–Altman plots on the same day and on a different day are shown in Figs. 4 and 5. All measurements showed high ICC values. ULp, Tp-A, Tp-B, and Cp required one measurement to achieve a confidence coefficient ≥0.9, and LLp required two measurements. No fixed or proportional biases were

observed on Bland–Altman analysis. The CVs of measurements were almost the same between the two devices. Tp-B showed a lower CV than Tp-A.
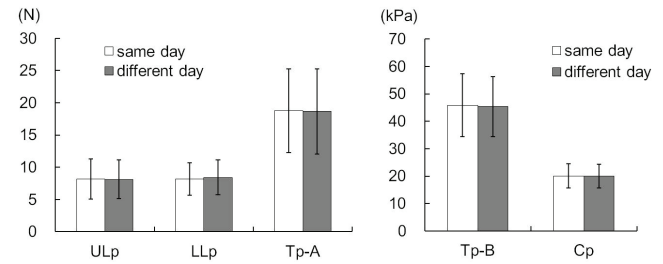

Fig. 3. Means ± standard deviation of each muscle pressure for measurements on the same day and on a different day; (a) upper lip pressure (ULp), lower lip pressure (LLp), and tongue pressure (Tp-A) taken by the Lip & Tongue Pressure Gauge®; (b) tongue pressure (Tp-B) and cheek pressure (Cp) taken by JMS tongue pressure measurement device®

As Shapiro–Wilk tests revealed normality, Pearson's product-moment correlation coefficients were used to analyze the correlation between muscle pressures. Positive correlations were observed between ULp and LLp, Tp-B and Cp, and Tp-A and Tp-B and a weak positive correlation was observed between ULp and Tp-A (Fig. 6).

Table 2. Relative and absolute reliability of each muscle pressure and their coefficient of variation for measurements taken on a different day; (a) upper lip pressure (ULp), lower lip pressure (LLp), and tongue pressure (Tp-A) were measured by the Lip & Tongue Pressure Gauge®; (b) tongue pressure (Tp-B) and cheek pressure (Cp) were measured by the JMS tongue pressure measurement device®

(a)

| | ICC (1,2) | 95% CI (N) | | P-value | MDC$_{95}$ | Bland-Altman analysis | | | | CV |
| | | | | | | fixed bias 95% CI | | proportional bias uncorrelated test | | |
		lower limit	upper limit		(N)	lower limit	upper limit	r	P-value	
ULp	0.977	0.96	0.99	<0.001	1.81	-0.26	0.34	0.148	0.364	0.37
LLp	0.959	0.92	0.98	<0.001	2.02	-0.56	0.09	0.155	0.339	0.32
Tp-A	0.975	0.95	0.99	<0.001	3.97	-0.58	0.73	0.047	0.774	0.35

ICC (1,2): intra-rater reliability
95% CI: 95% confidence interval
MDC$_{95}$: 95% minimal detectable change
r: Correlation coefficient
CV: Coefficient of variation

(b)

| | ICC (1,2) | 95% CI (kPa) | | P-value | MDC$_{95}$ | Bland-Altman analysis | | | | CV |
| | | | | | | fixed bias 95% CI | | proportional bias uncorrelated test | | |
		lower limit	upper limit		(kPa)	lower limit	upper limit	r	P-value	
Tp-B	0.988	0.98	0.99	<0.001	4.70	-0.29	1.24	0.274	0.087	0.24
Cp	0.989	0.98	0.99	<0.001	1.80	-0.24	0.36	0.150	0.356	0.22

ICC (1,2): intra-rater reliability
95% CI: 95% confidence interval
MDC$_{95}$: 95% minimal detectable change
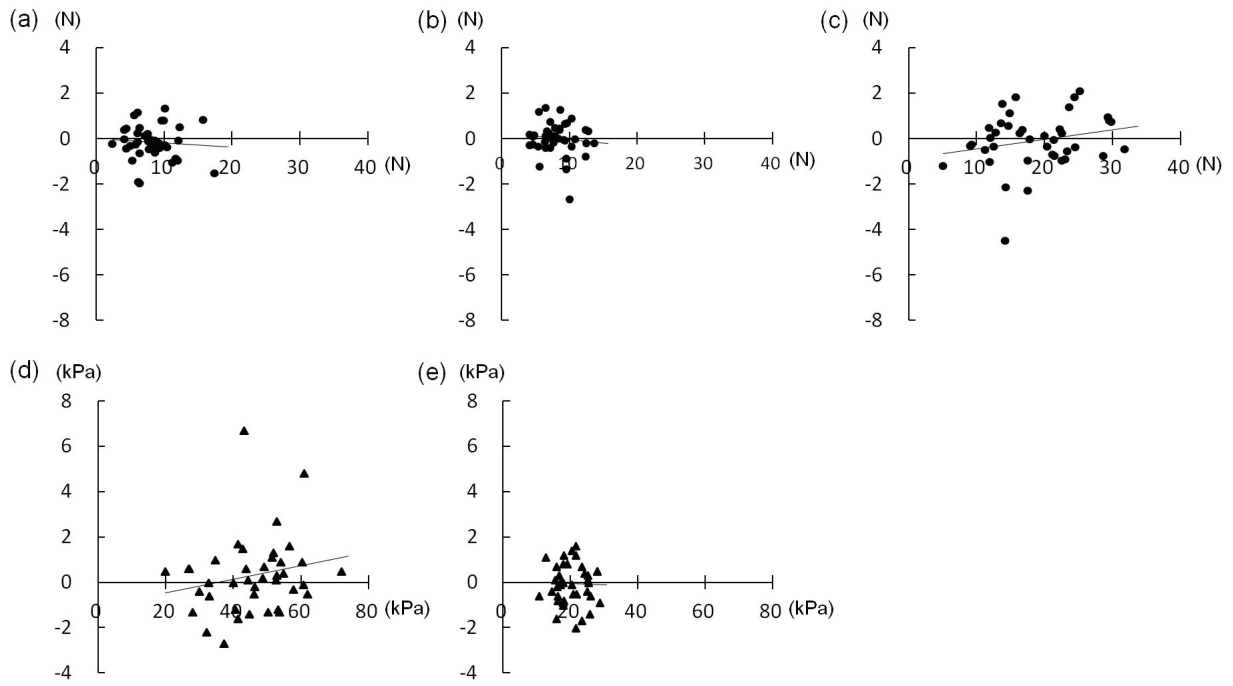r: Correlation coefficient
CV: Coefficient of variation

Fig. 4. Results of the Bland–Altman plots on the same day,
[*X*-axis: the average value of the measured values; *Y*-axis: the difference between the measured value];
(a) upper lip pressure (ULp), (b) lower lip pressure (LLp), (c) tongue pressure (Tp-A),
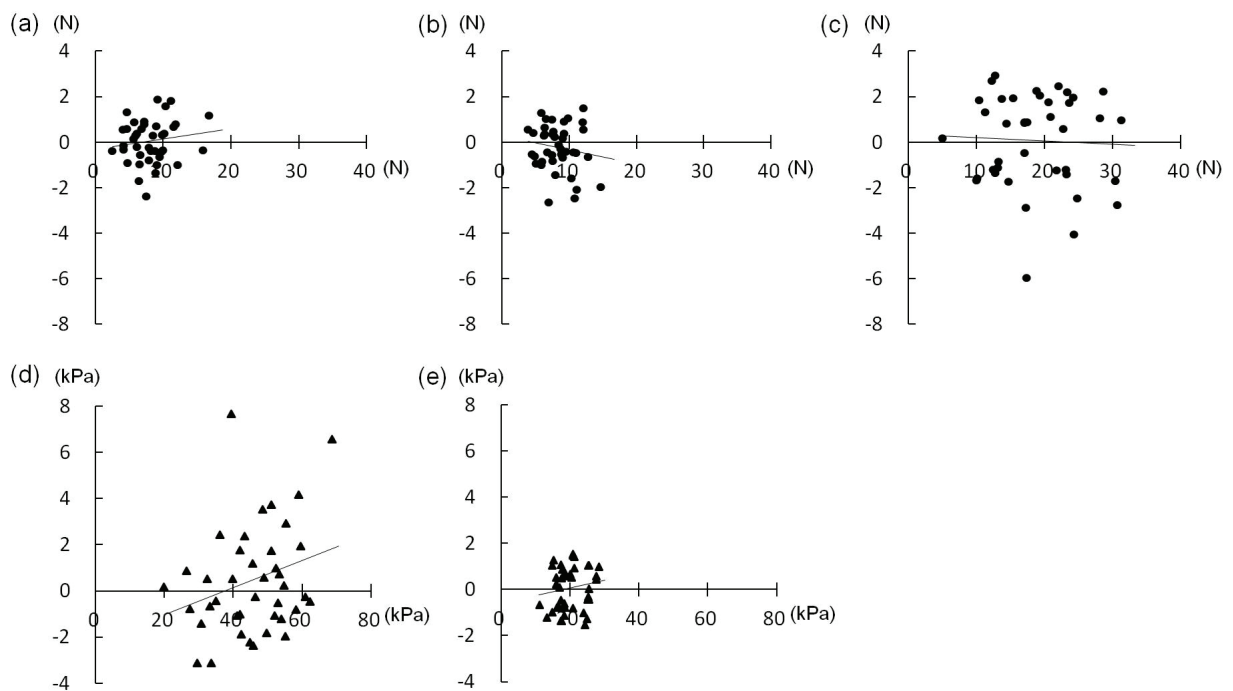(d) tongue pressure (Tp-B), and (e) cheek pressure (Cp)

Fig. 5. Results of the Bland–Altman plots on a different day.
[*X*-axis: the average value of the measured values; *Y*-axis: the difference between the measured value];
(a) upper lip pressure (ULp), (b) lower lip pressure (LLp), (c) tongue pressure (Tp-A),
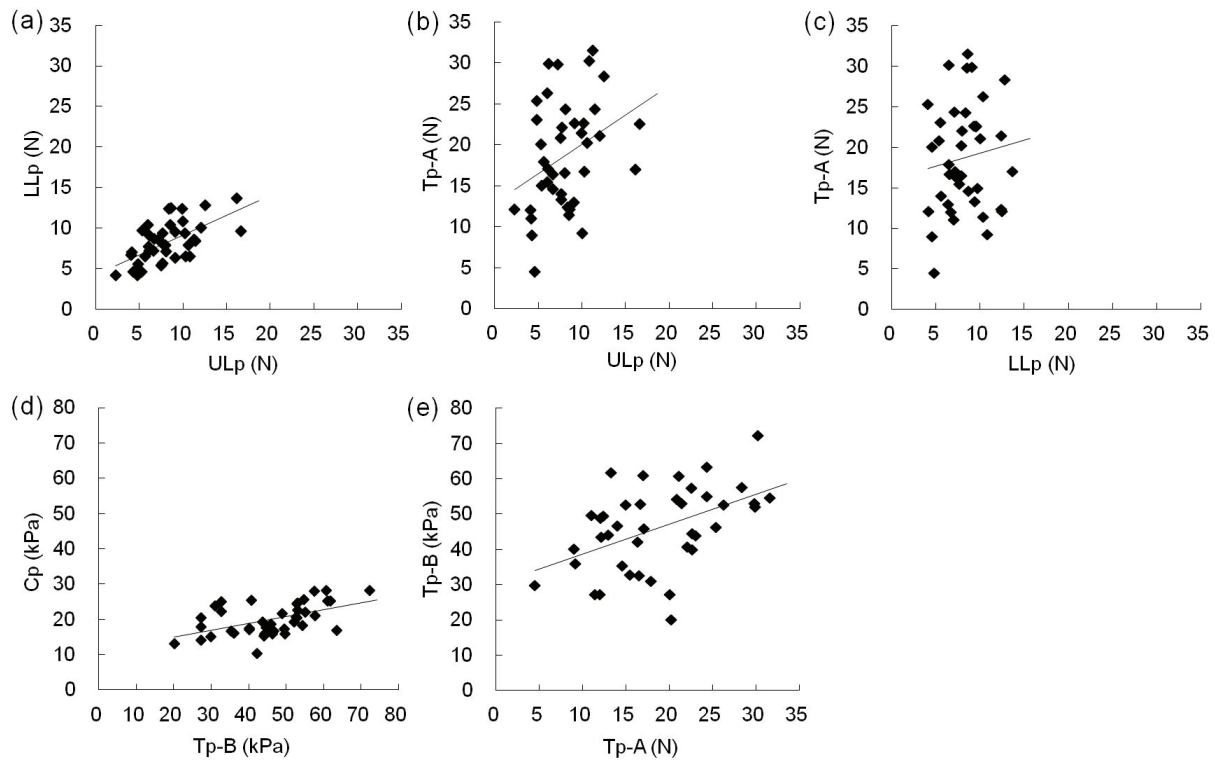(d) tongue pressure (Tp-B), and (e) cheek pressure (Cp)

Fig. 6. Results of the correlations between muscle pressures by Pearson's product-moment correlation coefficients: (a) between upper lip pressure (ULp) and lower lip pressure (LLp) [$r = 0.609$, $P < 0.001$; a positive correlation was observed, with the correlation expressed as (ULp = LLp × 0.76 + 1.85)]; (b) between upper lip pressure (ULp) and tongue pressure (Tp-A) [$r = 0.338$, $P < 0.05$; a weak positive correlation was observed, with the correlation expressed as (ULp = Tp-A × 0.16 + 5.09)]; (c) between lower lip pressure (LLp) and tongue pressure (Tp-A) [$r = 0.122$, $P = 0.453$; no correlations were observed]; (d) between tongue pressure (Tp-B) and cheek pressure (Cp) [$r = 0.512$, $P < 0.01$; a positive correlation was observed, with the correlation expressed as (Tp-B = Cp × 1.35 + 18.94)]; (e) between tongue pressures (Tp-A and Tp-B) [$r = 0.569$, $P < 0.001$; a positive correlation was observed, with the correlation expressed as (Tp-A = Tp-B × 0.31 + 4.29)]

4. Discussion

It has been demonstrated that perioral muscle pressure measurements can be used to objectively assess oral function and are therefore clinically important [2], [5], [7], [17], [19], [20]–[22]. Well-balanced tongue pressure, cheek pressure, lip pressure, and lip closure force in younger year's leads to proper tooth alignment and masticatory function in adulthood, they are essential factors for maintaining good oral function that governs activities such as chewing and swallowing, and they aid longevity [7], [17], [22]. A device that enables quick and highly reliable assessment of oral function with minimal discomfort would be extremely useful, particularly for routine clinical application. Measurements using aperioral muscle pressure measuring device with a lippiece, such as the Lip & Tongue Pressure Gauge® used in this study, can be taken at the chair side quickly and are hygienic and economical. However, it is unclear whether quantitative data can be obtained easily without discomfort to the subject. Accordingly, we investigated the reliability of measurements taken with such a device withthat of the previously reported measurements for the balloon-based tongue pressure measurement device.

Among studies reporting ICC as a measure of relative reliability, Landis et al. [10] determined ≥0.81 to be almost perfect, while Kuwabara et al. [9] determined ≥0.90 to be excellent. The lower limit for the 95% CI should ideally be ≥0.75 [16]. Tsuga et al. [21] reported tongue and cheek pressures using a balloon-based tongue measuring device, which were reliable. The relative reliability of each muscle pressure in the present study satisfied the above conditions and thus are deemed to be highly reproducible. Also, Tp-B had a lower CV than Tp-A, which is consistent with the reported high accuracy of the balloon-based tongue pressure measurement device. However, the CVs of

measurements of several types of muscle pressure were largely the same between the two devices, indicating that both devices have similar precision.

Absolute reliability was evaluated by examining the type of measurement errors and the magnitude of errors using MDC_{95}. As a fixed bias and proportional bias were absent, the measurement error is a random error. It can be reduced by calculating the means of multiple measurements for use as representative values [4], as well as the measurement value obtained in the present study. The results of the reliability test indicate that variations in measurement values could be attributed to specific examiners and subjects. In this study, it is unlikely that examiner bias existed because all subjects were healthy adults and measurements were digitally displayed on the device. Although results may differ depending on the subject, they should nevertheless be useful in understanding the features of the device, by providing an index that assists both in predicting the effect on the analysis of variance based on the characteristics of the measurements and in establishing an appropriate test plan.

Previous studies on perioral muscle pressures have shown that a relationship exists between tongue and cheek pressures and between cheek and lip pressures in healthy, completely dentate adults [19], [20]. In addition, aging and disease have been shown to affect lip pressure [6]. Yoshikawa et al. [24] compared three different tongue pressure measurement devices (IOPI[®], Kay device, and balloon probe prototype) and found that all three were capable of taking accurate measurements. In the present study, the CV of the measurement value obtained by each device were equivalent, it was suggested that measurements for each muscle pressure could be measured with the same precision. We also found a positive correlation between tongue pressure measurements taken by the perioral muscle pressure measuring device with a lippiece and those taken by the balloon-based tongue pressure measurement device, indicating that both are highly reliable and useful for measuring tongue pressure. Correlations were also seen between the upper and lower lip pressures and between upper lip and tongue pressures measured by the perioral muscle pressure measuring device with a lippiece, but no correlation was seen between lower lip and tongue pressures. This indicates that lower lip and tongue pressures increase with the rise in upper lip pressure but lower lip and tongue pressures are unrelated. In the future, it is necessary to consider the association between lower lip pressure and oral function or lip closing force. However the units of two measurement devices were different, numerical value units displayed on each device would become a reference value when being clinically applied in the future. For this reason, we were using the values that were denoted without the conversion of units in the analysis.

Taken together, the reliability of measurements taken by the perioral muscle pressure measuring device with a lippiece was comparable to those taken by the balloon-based tongue pressure measurement device, suggesting that the former is useful for quantifying perioral muscle pressure and that the measurement method we used has high reproducibility and possible clinical applications. The gripper of the balloon-based tongue pressure measurement device probe is about 10 mm, and differences in the position of the probe when it is gripped by the front teeth during measurement might affect the measurement values. Therefore, we instructed subjects to grip the probe in the same position (e.g., position closest to the balloon) for every measurement. In contrast, as the lip piece of the perioral muscle pressure measuring device matches the curvature of the dentition, the vertical positioning of the crowns may affect measurements. Subjects were therefore instructed to position the lip piece on the cervical portion of the part being measured. Prior to measurement with either device, the subjects used a mirror to position the probe or lip piece to ensure they were placed in the same position for every measurement. The measurement procedure and methods for both tools are easy for technicians and enable measurement without burdening elderly patients or those with systemic illnesses. Moreover, as the measurements are highly reliable, only one or two measurements are needed for use as representative values on a particular day. Measurement devices might be sufficiently reliable for use in screening or for observing temporal changes in perioral muscle pressure. None of the subjects in this study experienced pain or difficulties when placing the device in the oral cavity and during measurement. In addition, all subjects were able to maintain its correct position during measurement, which is attributable to the design of the device. More precisely, the shape of the lip piece of the measuring part of the device is designed to fit the dental arch. This enables the measurement of muscle pressure under conditions that are similar to the movements be done in everyday life, which reduces subjects' burden during the measurement. Also, the grip of the probe helps stable positioning. All subjects were healthy adults in the present study, but other subjects may need assistance with placement of the device depending on their physical condition. In the future, further studies are needed to examine the

effect on measurements when the device is held by the operator.

Perioral muscle pressure measuring device with a lippiece used in this study was considered to be suitable for assessing oral function of some point in time. As main ones, objective assessment of oral functions by evaluating one point in time, or the determination of the effect of oral function training before and after by comparing more time points. In particular, oral function of denture wearers or the elderly has been reduced compared to healthy edentulous or young people [8], [21]. Therefore, first it is considered as very significant and is important to clarify the specific numerical values, and it is necessary to show as a target value for subsequent functional training.

As our studies plan, first, we would like to clarify the difference in the muscle pressure value due to the background of the subject. In this study, we selected healthy dentulous as its base. According to the background of the subjects, it would be presumed that the consideration appeared; note at the time of measurement, or the difference of the necessary number of measurements. As a next step, we hope to reveal muscle pressure value according to the state of the denture wearer. Measurement for denture wearer to keep constant positioning of the measuring instrument is to be done while wearing the dentures. The shape of devices used in this study is such that can be measured in the same place by holding it by tooth when positioned in the mouth. It would be more practical if the measurement values could use the decision of the design of dentures such as the evaluation of the neutral zone of muscle pressure or the arrangement position of artificial teeth. In order to realize, further studies of the shape measurement part is expected in the future.

5. Conclusions

We examined the reliability of measurements of perioral muscle pressure (upper lip, lower lip, and tongue pressure) using a newly developed perioral muscle pressure measuring device with a lippiece in healthy adults. Measurements were highly reliable regardless of the type of perioral muscles. Upper lip pressure and tongue pressure can be determined based on a single measurement, while lower lip pressure requires averaging two measurements. Our findings suggest that the method described in this study is useful as a quantitative chair side method for examining perioral muscle pressure.

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