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Development of tongue strength and endurance measurement device: A pilot study in healthy adults

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ABSTRACT

Background: Safe and efficient swallowing relies on adequate tongue strength and endurance. Thus, tongue strength and endurance assessments are essential for swallowing rehabilitation for individuals with swallowing difficulties due to tongue structure and function abnormalities. These tongue functions can be objectively measured using a standard device. However, in Thailand, assessing tongue strength and endurance using standard devices is not widespread in clinical practice due to the high cost of importing these devices.

Objective: This study aimed to develop a precise, accurate, and reliable tongue function measurement device for the clinical assessment of tongue strength and endurance.

Materials and methods: This study was divided into three phases: 1) Development of a tongue strength and endurance measurement device in a laboratory setting and administration of a satisfaction questionnaire, 2) Trial of the prototype device with six participants, and 3) Assessment of the test-retest reliability of the developed device and investigation of tongue strength and endurance values with twenty participants.

Results: As a result of this development, a novel device for measuring tongue strength and endurance was obtained, which provides measurements in units of newtons (N) and kilopascals (kPa) for strength and seconds (s) for endurance. The device's development cost was significantly lower compared to imported commercially available devices while maintaining the performance standards for medical measurement devices. This was demonstrated by its accuracy ranging from 96.40% to 100%, high precision with a Coefficient of Variation (% CV) of 0.90% to 4.21%, and moderate to excellent reliability with an Intraclass Correlation Coefficient (ICC) of 0.56 to 0.93. Furthermore, statistically significant differences ($p<0.01$) were observed between genders, especially in anterior tongue strength.

Conclusion: The tongue strength and endurance measurement device developed through this study can be utilized for clinical tongue function assessment, giving patients more access to objective evaluations of tongue strength and endurance at a lower examination cost.

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Introduction

The tongue is an organ located in the oral cavity that is crucial to the oral and pharyngeal phases of swallowing. After food has been placed in the mouth, the tongue carries the food to the post-canine region for chewing to reduce its size, then softens the chewed food with saliva to achieve an optimal consistency and form a bolus.

The tongue propels the bolus from the oral cavity to the pharyngeal cavity. Then, it retracts against the pharyngeal walls to aid in bolus passage through the pharynx and into the upper esophageal sphincter.[1-3] Safe and efficient swallowing relies on adequate tongue strength and endurance.[4] Subsequently, reduced tongue strength and endurance can lead to dysphagia symptoms, including poor bolus formation, oral residue, and premature spillage of the bolus into the pharynx.[1,2,5] Dysphagia resulting from any of these problems causes longer meal times, reduces food consumption, and affects the quality of life.[6,7]

Tongue strength and endurance assessments are essential for swallowing rehabilitation for individuals with swallowing difficulties due to tongue structure and function abnormalities. This includes elderly adults with sarcopenia,[8] individuals suffering from neurological disorders such as stroke, Traumatic Brain Injury (TBI), or Parkinson's disease,[9,10] and individuals with head and neck cancer who have undergone surgery, radiation therapy, or chemotherapy.[11,12] The tongue function assessment is divided into two types: subjective measurement, which involves the observation of tongue movement capabilities, and objective measurement, which uses standard devices to quantify tongue strength and endurance numerically, allowing for repeatable measurement. Assessing tongue function using standard devices is common in clinical practice and research globally, with different regions preferring various instruments. For example, in North America, studies on tongue function predominantly use devices such as the Iowa Oral Performance Instrument (IOPI), the KayPENTAX Digital Swallowing Workstation, and the Madison Oral Strengthening Therapeutic (MOST), which was the early model before changing to SwallowSTRONG later.[13,14] In Europe and Asia, the IOPI is the preferred device, but in Japan, the JMS tongue measurement device and the SwallowSCAN device have been developed and are widely utilized.[15] In Thailand, objective tongue measurement is not widespread in clinical practice due to the high cost of importing these devices. Moreover, the literature review and the researcher's clinical service experiences have identified certain limitations in various aspects of device usage. Examples include the lack of stability of the tongue bulb position and imprecise indications of the force exerted during tongue measurements. Recognizing this issue, the researcher saw an opportunity to develop a new tongue strength and endurance measurement device for clinical tongue function assessment, allowing patients to have increased access to objective evaluation of tongue strength and endurance at a lower examination cost.

Materials and methods

This study employed a developmental research design divided into three phases as follows:

Phase 1: Development of a tongue strength and endurance measurement device in a laboratory setting and a satisfaction questionnaire

First, the operational principles of the current standard devices used to assess tongue strength and endurance were studied before developing the conceptual framework of the prototype device. This included devices in both the air-filled bulb type, such as the Iowa Oral Performance Instrument (IOPI® PRO model 3.1, IOPI Medical LLC, USA),[16] the JMS tongue measurement device (Orarize® TPM-02, JMS Co., Ltd. Japan),[17] and the KayPENTAX Digital Swallowing Workstation (KSW model 7200, PENTAX Medical, USA),[18] and the electric sensor type such as the SwallowSTRONG (SwallowSTRONG®, Swallow Solutions LLC, USA),[19] the SwallowSCAN (Swallow SCAN, Nitta Co., Japan),[20] and the OroPress, developed by McCormack *et al*.[14] Additionally, the design process involved a comprehensive review of the relevant literature concerning tongue measurement using standard devices and the researcher's clinical service experiences. Subsequently, these conceptualizations were discussed and refined in collaboration with the Biomedical Engineering Institute (BMEI), Chiang Mai University, to develop the prototype device.

Second, the researcher evaluated the prototype device's accuracy and precision in the laboratory by testing it with standard masses weighing 100 and 200 grams. Each weight was placed on the tongue force sensor 10 times.[21,22] The measured values were then used to calculate the percentage of accuracy (% accuracy) and percentage Coefficient of Variation (%CV).

Then, a satisfaction questionnaire for assessing tongue strength and endurance was developed using the prototype device with six participants in phase 2. The researcher adapted questions from relevant studies[23,24] and examined the content validity with five experts with at least 10 years of knowledge and expertise in dysphagia assessment and rehabilitation or experience in tongue function assessment using standard devices. Questions with an Item-Objective Congruence (IOC) value between 0.50 and 1 were deemed acceptable, whereas those with an IOC value below 0.50 were considered for revision or removal.[25] The researcher refined the questionnaire based on the feedback and submitted it to the experts for further review before implementation.

Phase 2: Trial of the prototype device with six participants

Participants

In phase 2, the participants consisted of 6 healthy adults, comprising 3 females and 3 males, who were divided into three age groups based on 20-year intervals: younger adults aged 20-39 years, middle-aged adults aged 40-59 years, and older adults aged 60-79 years, respectively. Each group included 1 female and 1 male participant and were selected using quota sampling. All participants were recruited voluntarily from the Faculty of Associated Medical Sciences, Chiang Mai University, and informed consent was obtained from each participant before the study.

All participants reported being in good general health with no current or previous swallowing difficulties, as confirmed through interviews conducted by the researcher. Furthermore, each participant underwent an oral motor examination and the 3-oz water swallowing test to ensure their oral mechanism and swallowing-related reflexes were within normal limits.[26]

Participants meeting any of the following criteria were excluded from the study: current or historical medical conditions affecting oral structure and function, potentially impacting swallowing and speech, including neurological diseases, head and neck cancer, obstructive sleep apnea diagnosed by a physician, or a history of surgical procedures within the oral cavity, excluding wisdom tooth extraction; individuals who wore full dentures or experienced issues with ill-fitting dentures; and participants with impairments in posture maintenance, including the inability to sit upright continuously and maintain head positioning for at least 15 minutes.

Procedure

Data collection in this study adhered to the COVID-19 prevention guidelines.[27,28] Before tongue measurement, participants were instructed to rinse their mouths with 0.12% chlorhexidine (C-20 mouthwash) for 30 seconds. The researcher ensured the proper setup, conducted a calibration check, and initiated the measurement process. In phase 2, tongue strength and endurance were measured in a single round, including three measurements each for anterior tongue strength, posterior tongue strength, anterior tongue endurance, and posterior tongue endurance.

1) Tongue strength measurement

The researcher positioned the tongue force sensor on the palate, ensuring correct alignment, and held the handle throughout. Anterior tongue strength was measured first, with participants pressing their tongue tip against the sensor at the midline upper alveolar ridge for 3 seconds, followed by a 30-second rest, and repeating this process three times. After a 5-minute break, posterior tongue strength was measured at the junction of the hard and soft palates. Once both measurements were done, there was a 10-minute break before measuring tongue endurance. Results were recorded as the highest of the three measurements and presented in N (the unit commonly used to measure muscle strength) and kPa (the unit widely used by standard devices)

2) Tongue endurance measurement

Participants sustained tongue pressure at 50% of their maximum tongue force, starting at the anterior region. Circular visual feedback indicating their current pressure level appeared on the application screen. After each round, there was a 2-minute break, and this process was repeated three times, followed by a 10-minute rest before measuring posterior tongue endurance. Endurance was measured until pressure dropped below 50% of the maximum. Results were averaged and presented in seconds. Afterward, the participants completed a satisfaction questionnaire for prototype device improvement.

Phase 3: Assessment of the test-retest reliability of the developed device and investigation of tongue strength and endurance values with twenty participants.

The researcher assessed the test-retest reliability of the modified prototype device on 20 participants aged 20-39 years, equally divided into 10 males and 10 females, selected using quota sampling and adhering to the same criteria used in phase 2. Due to safety concerns about the significant pressure required for measuring tongue strength, the Human Research Ethics Committee recommended starting with young adults. If no risks related to sudden changes in blood pressure are observed, middle-aged and elderly volunteers will be included in future studies.

The methods and sequence for measuring tongue strength and endurance in these participants followed the same protocol in Phase 2. Tongue measurements in phase 3 were repeated twice, with a 15-minute interval. The researcher analyzed the test-retest reliability and studied the tongue strength and endurance values using data from both measurement rounds.

Data analysis

All data underwent statistical analysis using SPSS (IBM Corp. Released 2022. IBM SPSS Statistics for Mac, Version 29.0. Armonk, NY: IBM Corp.).[29] This analysis included:

1. Descriptive statistics presented the mean and standard deviation of the participant's demographic data and tongue measurements by gender and age.
2. Accuracy assessment by calculating the percent error (%error) and deriving the percent accuracy (%accuracy).
3. Precision assessment by calculating the Coefficient of Variation (%CV) using the mean and standard deviation.
4. Test-retest reliability assessment using the Intraclass Correlation Coefficient (ICC) with a two-way mixed effects model for multiple raters/measurements.

Results

Phase 1: Development of a tongue strength and endurance measurement device in a laboratory setting and creation of a satisfaction questionnaire

1.1 Prototype device development

The device is divided into three main components: the tongue force sensor, processing unit, and display/recording unit, as shown in Figure 1. The details of each element are as follows:

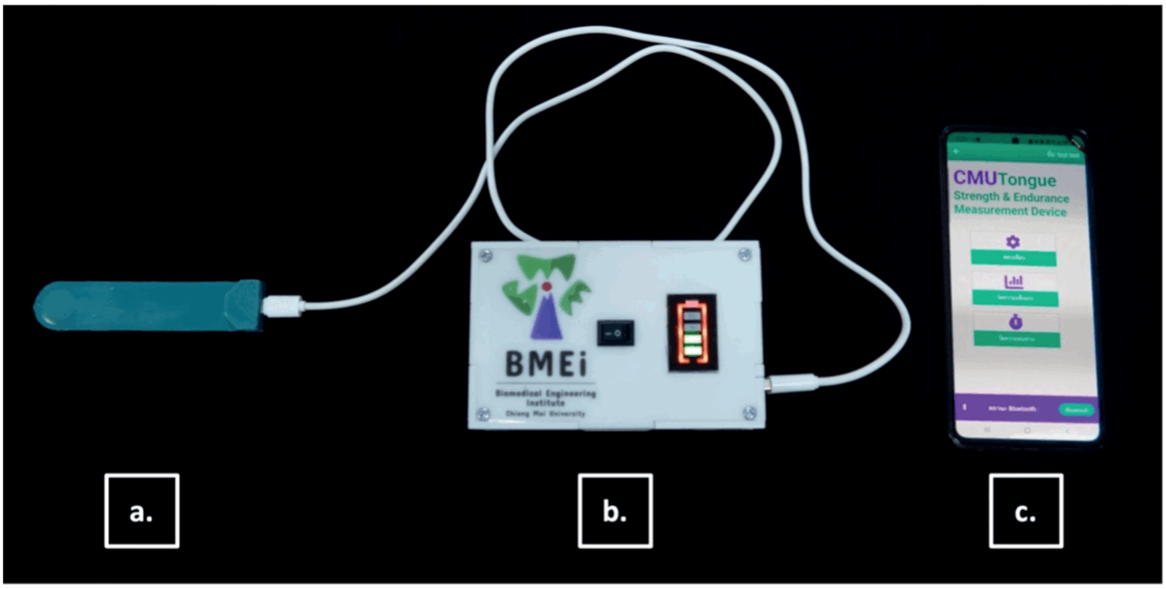

Figure 1. *Tongue strength and endurance measurement device.*
a: tongue force sensor, b: processing unit, c: display/recording unit.

1) Tongue force sensor

The researcher used the circular Force Sensing Resistor® (FSR) sensor 402 model,[30] encased in food-grade silicone. This sensor has an overall diameter of 23 mm. The tongue force sensor comprises two subparts: the force-receiving area and the handle. The force-receiving area, which is in contact with the tongue, has a smooth surface, while the area contacting the palate is slightly raised, approximately 1 mm higher, creating a 6 mm-wide ridge. This surface difference helped identify where force should be exerted by the tongue.

The handle is 5 mm thick and comfortably fits into the mouth for the posterior tongue region, reducing the risk of position changes during measurements. Additionally, the researcher increased the thickness of the handle's end to 9 mm, reducing the risk of cable damage when plugging in or unplugging the device each time, as shown in Figure 2.

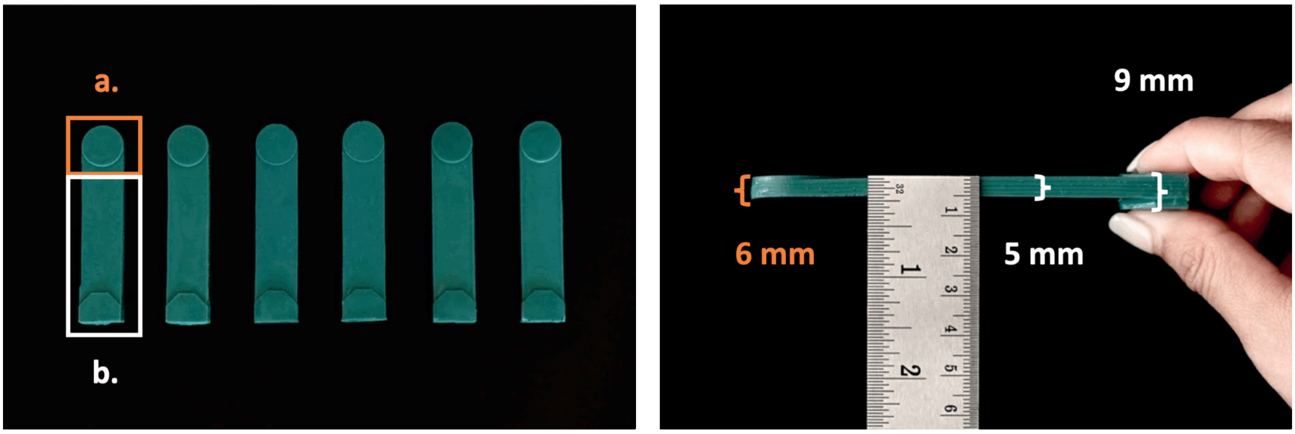

Figure 2. *The tongue force sensor consists of two subparts.*
a: the tongue force-receiving area, b: the handle.

2) Processing unit

The processing unit components are stored inside a waterproof and dust-resistant acrylic plastic box. It consists of two subparts:

2.1) Data processing equipment:

The researcher chose the DOIT ESP32 DevKit v1 Development Board[31] microcontroller for device circuitry. This compact microcontroller with Bluetooth 4.2 effectively transmits signals to display the application results.

2.2) Power supply:

The researcher chose a rechargeable lithium battery as the power source, using an adapter and a USB Type-A to Type-B Micro USB cable for charging. On top of the box, a lithium battery voltage indicator LED display was installed to indicate the battery status. The first version of our application was developed.

3) Display/recording unit

This device displays the results on a mobile application for the Android operating system, named 'CMU Tongue Strength & Endurance Measurement Device,' or simply 'CMU Tongue' (version 1.0). The application's functionality comprises three sections, as shown in Figure 3. The details of each section are as follows:

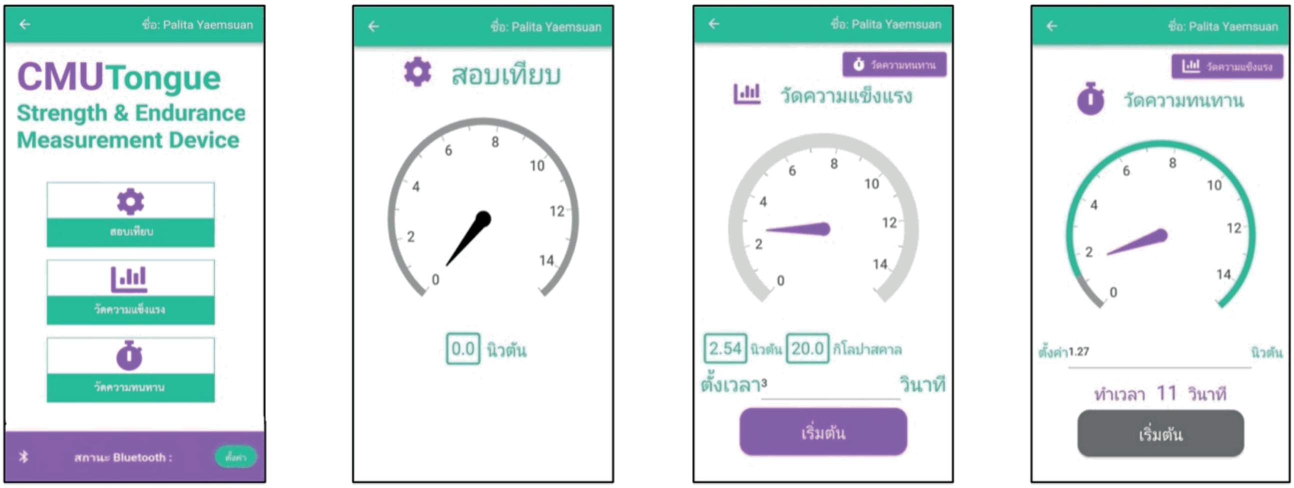

Figure 3. *An example of a 'CMU Tongue' (Version 1.1) application is displayed in each section.*

3.1) Calibration section:
Before each measurement, the researcher navigated to the 'Calibration' menu. A light finger press was applied to the force-receiving area, and the changing values were observed.
3.2) Display section:
The 'Measure Strength' function on the main menu was selected to measure tongue strength. A countdown was initiated, and participants were instructed to exert maximum force on the force-receiving area for 3 seconds. The resulting tongue strength was displayed in both N and kPa units. Subsequently, the endurance measurement was conducted. The researcher returned to the main menu and entered the 'Measure Endurance' tab. The researcher set the initial force level at 50% of the maximum tongue strength achieved in the previous strength measurement. If participants failed to sustain the tongue force within this range, the needle dropped, triggering the end of the test, and the endurance value was displayed in seconds.
3.3) Results recording section:
The researcher initiated the measurement process by registering user accounts, and each measurement was recorded under the respective user account. The data was stored internally on the device and backed up on the Firebase platform, enabling Google to store data online. Data can be downloaded as CSV or XLSX files for offline analysis using Microsoft Excel (version 2007 or higher). This study utilized Microsoft Excel for Mac version 16.81.

1.2 Accuracy testing

The device demonstrated accuracy within the 96.40% to 100% range, indicating its ability to measure tongue force close to the standard weight measures used in testing. The obtained percentages are within an acceptable threshold.[32]

1.3 Precision testing

Precision ranged from 0.90% to 4.21%, which is well within the acceptable limit of 5%, highlighting the high precision of the tongue pressure measurement component and its suitability for application as a reliable instrument in physiological measurements.[33]

1.4 Satisfaction questionnaire creation

All questionnaire items achieved a content validity index of 0.80 or higher.[34] After adjustments to improve clarity and incorporation of expert suggestions, the revised questionnaire was deemed suitable for further use.

Phase 2: Trials of the prototype device with six participants

The satisfaction scores from the participants regarding the intraoral component (tongue force sensor) were rated very satisfactory, ranging from 4.17 to 4.67. Similarly, satisfaction with the extraoral component (application) scores ranged from 3.83 to 4.67.[34] After considering participant feedback, the researcher and the BMEI team adjusted the tongue force sensor and updated the 'CMU Tongue' application from Version 1.0 to Version 1.1. These adjustments and improvements included:

- The silicone rim surrounding the tongue force sensor was modified. This adjustment involved modifying the silicone mixture to create a softer edge while maintaining the shape and preventing excessive tongue force absorption.
- The initial scale ranged from 0 to 30 N. Participants found it challenging to see their tongue force clearly, feeling they were applying less force. Therefore, the scale was adjusted to 0 to 15 N, and the display segments were made larger to improve

the visibility of the exerted force.

- Connectivity issues between the application and the processing unit were identified and resolved. This involved extending the Bluetooth connection time to ensure seamless data transmission between the app and the device. Additionally, a new protocol was implemented to automatically pair the app with the device whenever the researcher switched between measuring tongue strength and endurance.

Phase 3: Assessment test-retest reliability of the developed device and the investigation of tongue strength and endurance values with twenty participants

3.1 Maximum tongue strength and endurance variables in 20 participants

Table 1 shows the results of tongue strength measurements: females have an average anterior strength of 1.98±0.36 N (15.52±2.83 kPa) and a posterior strength of 2.29±0.80 N (17.94±6.27 kPa). Conversely, males exhibit greater tongue strength, with an anterior strength of 2.56±0.56 N (20.05±4.45 kPa) and a posterior strength of 2.51±0.96 N (19.67±7.50 kPa).

Regarding endurance, females have an average anterior endurance of 18.10±8.10 seconds and posterior endurance of 8.80±7.44 seconds. In contrast, males show markedly greater endurance, with anterior endurance of 28.90±17.32 seconds and posterior endurance of 13.30±5.95 seconds.

Table 1. Maximum tongue strength and endurance in healthy young adults, categorized by gender. (N=20)

Gender	Age	Tongue Strength				Tongue Endurance	
		Anterior (N)	Posterior (N)	Anterior (kPa)	Posterior (kPa)	Anterior (second)	Posterior (second)
Female (N=10)	23.90±3.41	1.98±0.36	2.29±0.80	15.52±2.83	17.94±6.27	18.10±8.10	8.80±7.44
Male (N=10)	26.60±4.20	2.56±0.56	2.51±0.96	20.05±4.45	19.67±7.50	28.90±17.32	13.30±5.95
Total (N=20)	25.25±3.97	2.27±0.55	2.40±0.87	17.79±4.31	18.81±6.79	23.50±14.28	11.05±6.95

Note: values are presented as mean±SD.

Table 2 shows statistical analysis using an independent t-test for the variance of tongue strength and endurance, using Levene's test with a 95% confidence interval, revealed that the variance of males and females was equal. The comparison of mean values of tongue strength and endurance between males and females revealed statistically significant differences (p<0.01), specifically in anterior tongue strength.

Table 2. Difference in tongue strength and endurance between genders. (n=20)

Measurement		Female (N=10)	Male (N=10)	t	Sig. (2-tailed)	Mean difference	95% CI	
							Upper	Lower
Tongue strength (N)	Anterior	1.98±0.36	2.56±0.56	2.74	0.01*	0.58	0.13	1.02
	Posterior	2.29±0.80	2.51±0.96	0.57	0.58	0.22	-0.61	1.05
Tongue endurance (second)	Anterior	18.10±8.10	28.90±17.32	1.79	0.09	10.80	-1.91	23.51
	Posterior	8.80±7.44	13.30±5.95	1.50	0.15	4.50	-1.83	10.83

**The mean difference is significant at the 0.01 level.*

3.2 Test-retest reliability

Table 3 shows the test-retest reliability analysis, which revealed that the intraclass correlation coefficients (ICCs) for anterior tongue strength, posterior tongue strength, anterior tongue endurance, and posterior tongue endurance were 0.61, 0.90, 0.93, and 0.56, respectively. These values indicate that the measurements obtained from the developed device were consistent across repeated administrations ranging from moderate to excellent.[35]

Table 3. Intraclass Correlation Coefficients (ICCs) for tongue strength and endurance.

	Intraclass Correlation[b]	95% CI		F Test with True Value 0			
		Lower	Upper	Value	df1	df2	Sig
Anterior tongue strength	0.61[a]	0.25	0.83	4.18	19	19	0.00
Posterior tongue strength	0.90[a]	0.76	0.96	18.42	19	19	0.00
Anterior tongue endurance	0.93[a]	0.83	0.97	26.56	19	19	0.00
Posterior tongue endurance	0.56[a]	0.17	0.80	3.55	19	19	0.00

Note: Two-way mixed effects model where people effects are random, and measures effects are fixed. a: the estimator is the same, whether the interaction effect is present, b: type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Discussion

In designing and developing the device, the researchers considered various factors, including the device production cost, practical utilization, maintenance requirements, and measurement quality.

First, to minimize production costs, the researchers used commercially available components, including force sensing resistors, a microcontroller, and USB cables, which were adjusted to meet the operational requirements. Some elements, namely the sensor silicone casing and processing box, were newly developed to meet specific requirements. The production cost of the prototype device was approximately 15,000 baht, significantly lower than the imported device set priced at 137,075 baht (as confirmed by the quotation from the distributor in Thailand to the Department of Occupational Therapy, Faculty of Associated Medicine Sciences, Chiang Mai University, on November 29, 2021).

Second, in terms of usability, limitations were identified in the current standard device's tongue bulb and handle, which might lead to imprecision in measurements or difficulties in measuring the strength and endurance of the posterior tongue region. To address this, the researchers designed a flat circular tongue force-receiving area with a diameter not exceeding the average width between the maxillary intercanine teeth.[36] This design allows for tongue strength and endurance measurement across all palate sizes without the need for individualized sensor molding. Additionally, the handle was designed to be approximately 5 mm thick, consistent with the findings of Arakawa *et al.*,[37] who compared the IOPI and JMS instruments and highlighted the advantages of the JMS handle, providing a more secure grip compared to the plastic tubing handle of the IOPI device. Upon comparison with this developed device, it was found that the tongue force sensor handle, approximately 5 mm thick, was comparable to the JMS handle, contributing to a secure grip and minimizing position changes during measurement. Furthermore, the researchers designed the thickness difference in the silicone covering of the tongue force-receiving area and handle to help identify the appropriate position during measurement, allowing the participants to exert tongue force more accurately. Finally, the overall design of the entire device comprises a few components, with a simple method of connecting the device to a smartphone, enabling other therapists and patients to readily use the device immediately after receiving instructions and demonstrations.

Next, the maintenance factor was considered by designing each component to be detachable for easy cleaning. The tongue force sensor is classified as a medium-risk device for infection. After detachment, it can be easily cleaned by rinsing with clean water and then disinfected by immersion in Opal® solution containing ortho-phthalaldehyde (OPA) at a concentration of 0.57%, for 6 minutes at 20 °C.[38] This disinfectant solution is commonly used in hospitals and clinics. As for the processing box and smartphone used for displaying and recording the results through the application, these components can be wiped clean with 70% ethanol solution after detachment.

Finally, regarding the device measurement quality testing, it was found that all six tongue force sensors exhibited acceptable accuracy,[32] with the Coefficient of Variation (%CV) suggesting a high level of consistency[33] and the test-retest reliability indicating consistent measurements over repeated tests.[35] These findings confirm that the developed device is reliable and suitable for clinical assessment and rehabilitation planning for tongue function.

When considering the tongue function values obtained from 20 healthy young adults, the preliminary findings revealed that males exhibited higher tongue strength and endurance in both the anterior and posterior regions than females. However, the statistical significance was only observed in anterior tongue strength. Previous studies on gender-related factors influencing tongue strength have presented varying results. Moreover, this study was consistent with Arakawa's findings,[15] suggesting significant differences in tongue strength between genders in individuals under 60, possibly due to males having greater overall muscle mass, including tongue muscles. Additionally, there were no statistically significant gender differences in tongue endurance values, which was consistent with prior studies.[39,40] Thus, these tongue strength and endurance values provide preliminary support for this developed device and serve as a basis for further research using larger sample groups in the future.

Limitation

The present study did not investigate the correlation between tongue strength and endurance measurements obtained from the developed device and those obtained from imported standard devices. This limitation was due to the constraints of the study timeline, and the study collected data during the severe outbreak situation of the COVID-19 pandemic.

Conclusion

The developed tongue strength and endurance measurement device through this study has a lower cost of development compared to imported commercial devices while maintaining performance standards and demonstrating acceptable accuracy, precision, and reliability. This device has high potential for use in clinical settings, allowing patients more access to objective assessments of tongue strength and endurance at a lower examination cost. This device's objective evaluation may help develop efficient rehabilitation programs to improve tongue function in the elderly and individuals with tongue-related disorders.

Conflict of interest

The authors have declared that no competing interests existed at the time of publication.

Ethical approval

The study was approved by the Research Ethics Committee of the Faculty of Associated Medical Sciences, Chiang Mai University (Approval ID: AMSEC-64FB-004). All participants received all necessary information related to the research, and informed written consent was obtained before enrolling.

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