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ORIGINAL ARTICLE

Reliability Measurement of TongueFit for Tongue Strength Measurement in Children

Rizky Kusuma Wardhani[1,2], Widjajalaksmi Kusumaningsih[1,2], M. Yanuar Amal[2,3], Stella Kristi Triastari[4], N. G. A. Ayu Putu Tika Andayani[4], Prasandhya Astagiri Yusuf[5]

[1]Department of Physical Medicine and Rehabilitation, Faculty of Medicine, Universitas Indonesia, Jakarta, Indonesia
[2]Dr. Cipto Mangunkusumo Hospital, Jakarta, Indonesia
[3]Department of Radiology, Faculty of Medicine, Universitas Indonesia, Jakarta, Indonesia
[4]Faculty of Medicine, Universitas Indonesia, Jakarta, Indonesia
[5]Department of Medical Physiology and Biophysics / Medical Technology IMERI, Faculty of Medicine, Universitas Indonesia

ABSTRACT

Introduction: TongueFit is a newly available and lower cost orofacial manometer. This device is specifically developed for children to measure and improve tongue strength and endurance which includes a complementary application. This study evaluates the reliability of TongueFit as a measurement device.

Methods: This is a cross-sectional study which recruited 74 subjects. Each subject was screened for clinical symptoms of dysphagia, only healthy subjects included in this study. Children who use visual or hearing aids were excluded. Tongue measurement will be repeated twice, with a 5-minute rest period. This study was analyzed using SPSS version 27. The reliability of TongueFit is assessed using intraclass correlation (ICC) with single measurements, absolute agreement, and a two-way mixed-effects model.

Result: 54 subjects were analyzed in the reliability analysis of TongueFit. There was excellent reliability with ICC 0.993 (0.988-0.996). **Conclusion:** This study showed an excellent reliability for TongueFit with high ICC. These results confirmed that the device is suitable for objective and precise tongue measurements.

Keywords: children, swallowing, tongue measurement, reliability, orofacial manometer

Correspondence Detail:
Rizky Kusuma Wardhani
Department of Physical Medicine and Rehabilitation, Faculty of Medicine Universitas Indonesia,
Dr. Cipto Mangunkusumo Hospital, Jakarta, Indonesia
Email: rizkykusumawardhani@yahoo.co.id

INTRODUCTION

Swallowing is a dynamic process that evolves with a child's growth and development, with the tongue playing a crucial role, particularly during the oral phase. The tongue is composed of highly flexible muscles rich in blood vessels and nerves. These muscles contribute to the biomechanical system of the tongue, enabling it to change position, movement, and shape to perform various activities during eating and swallowing.[1-3] The tongue performs five primary movements: elevation, depression, protrusion, right lateralization, and left lateralization, as well as various combinations of these movements. These motions are critical for intraoral manipulation of food and swallowing, with elevation movements occurring throughout the sequence.[4,5]

Tongue strength and endurance are pivotal in mastication, food control, and bolus clearance. These functions are influenced by the flexibility of the tongue muscles, the accuracy of movement patterns, and the coordination of tongue movements with the jaw. Dysfunction in the tongue muscles may reduce intraoral pressure during swallowing, increasing pharyngeal residue and the risk of aspiration during the pharyngeal phase. Therefore, any muscle dysfunction related to the tongue can lead to dysphagia. Dysphagia caused by impaired tongue function can be observed in various conditions, including sensory, musculoskeletal, neuromuscular, nutritional, and metabolic disorders.[6-8]

Tongue strength is often used as an objective measure of tongue function, typically assessed through maximum isometric pressure (MIP) exerted by the anteromedial tongue against the palate. Objective measurements of tongue strength are essential not only for diagnosis but also for setting therapeutic targets and evaluating treatment outcomes. Various orofacial manometers have been developed to measure tongue strength objectively, and these devices continue to evolve. However, a suitable orofacial manometer specifically designed for children is not yet available.[9,10]

Given the need for effective oral dysphagia management in children and the lack of accessible devices, it is crucial to develop a prototype orofacial manometer (PMO) that incorporates biofeedback, is easy for children to use, affordable, and accessible in Indonesia. This device should also include mechanisms for regulating exercise dosage and provide reference values for normal tongue strength.
In response to these needs, we have developed a medical device prototype called TongueFit, which includes a complementary application that allows users to perform tongue muscle tests and engage in game-based exercises. The device set consists of a manometer, a connecting tube, and an air-filled bulb sensor. The application is specifically designed for children, featuring attractive visuals, easy-to-understand instructions, and interactive video games, all aimed at increasing patient interest and engagement, particularly among pediatric patients.

While TongueFit can also be used as a device to improve tongue strength and endurance, this study will focus solely on evaluating its reliability as a measurement device. By concentrating on TongueFit's measurement accuracy, we aim to provide empirical evidence of its effectiveness as a reliable device for assessing tongue strength and endurance. The primary goal is to ensure that the measurement results produced by TongueFit are consistent across multiple sessions. Additionally, confirming its reliability will establish TongueFit as a valuable clinical asset, enabling more precise diagnoses and personalized treatment plans for individuals with tongue-related conditions.

METHODS

The new orofacial manometer device, TongueFit, introduced in a previous article[11] was specifically designed and developed for children to measure tongue strength and endurance objectively and improve them by a game-based exercises simultaneously. The device consists of a physical part and an associated application. The physical part consists of a manometer device along with two variations of bulb sizes that measures the pressure and duration exerted on the air-filled bulb and transmits the information via bluetooth to an android phone, where the application is installed. In addition, the app facilitates the recording of the patients' measurement results.

In this study, reliability measurement was conducted to assess the consistency of measurements taken by a single rater across multiple trials, typically within a short timeframe. Test-retest reliability helps determine whether this measurement device yields consistent results, making it valuable for clinical use.

Subject Selection

Research subjects for this cross-sectional study were selected using simple random sampling. Seventy-four childrens were recruited from middle school and high school in Central Jakarta and were evaluated by the inclusion and exclusion criteria.

Participants were included if they were children aged 12-16 years who are willing to participate in the TongueFit reliability study, indicated by signing an informed consent form, children without eating or swallowing disorders, and children who are able to understand and follow instructions. Meanwhile the exclusion criteria were children who use visual aids (glasses) or hearing aids. The dropout criteria for the study include any child unable to complete the full series of experimental stages during the tongue strength measurement process. The University of Indonesia Ethics Committee approved the study (KET611/UN2.F1/ETIK/PPM.00.02/2024) and written informed consent was obtained from all participants prior to participation.

In this cross-sectional study, the parents of selected research subjects received a comprehensive explanation of the study's purpose, procedures, and potential benefits. Both subjects and parents were informed that participation was voluntary and that subjects may withdraw at any time without negative consequences. Confidentiality of collected data was assured. Once a clear and complete understanding was established, the parents were asked to sign an informed consent form.

Dysphagia Screening

Each subject was screened for clinical symptoms of dysphagia by using a series of standardized questions.[12] A score of zero was taken to indicate that the participant had no swallowing problems, whereas a positive score on any of the elements was taken to indicate that there may be a problem with swallowing. If a subject fails this screening, they were replaced through simple random sampling. This study also recorded contributing factors to tongue strength, including the age, weight, and BMI of the subjects, to better understand their potential influence on the measurement results.

Tongue Strength Measurement

The purpose of this experiment was to ensure the consistency of measurement results using TongueFit. To conduct this experiment, TongueFit device was connected to the application to measure the tongue strength of the subject. The air-filled bulb was put at the anteromedial part of the tongue. Each subject was instructed to press the bulb as hard as possible using their tongue, upward, to measure maximum tongue strength (Figure 1).

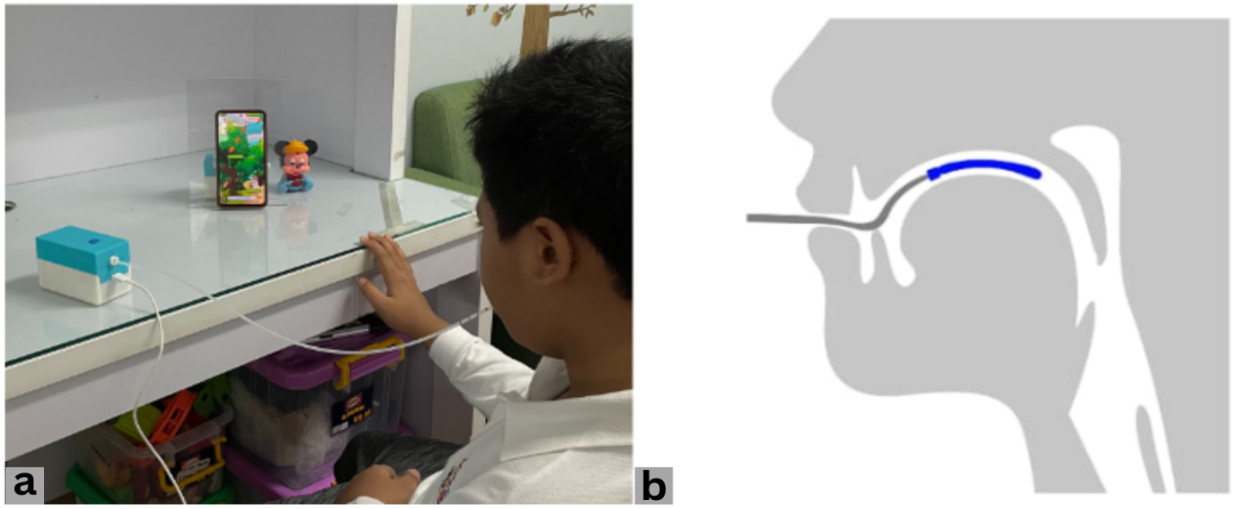

Figure 1. Tongue Strength Measurement. (a) Measurement on subject. (b) Lateral view of air-filled bulb's location at the tongue.

TongueFit's device was connected to the application and allowed users to measure tongue strength. The procedure of tongue strength measurement was executed according to Diaz-Saez study.[13] The measurement was repeated twice, with a 5-minute rest period between trials. The measurement's result showed on the application as seen in Figure 2. Tongue strength data was collected for the reliability measurements of TongueFit.

Statistical Analysis

The measurement data obtained were recorded and processed using Microsoft Excel

(Microsoft Office 2019 version). Data analysis was conducted using SPSS software version 27. The intra-rater reliability was assessed using intraclass correlation (ICC) with single measurements, absolute agreement, and a two-way mixed-effects model. The test-retest reliability was applied exclusively to the new testing devices. A correlation coefficient of less than 0.5 indicates poor reliability, a range of 0.50 to 0.749 indicates moderate reliability, 0.75 to 0.90 reflects good reliability, and values greater than 0.90 indicate excellent reliability.

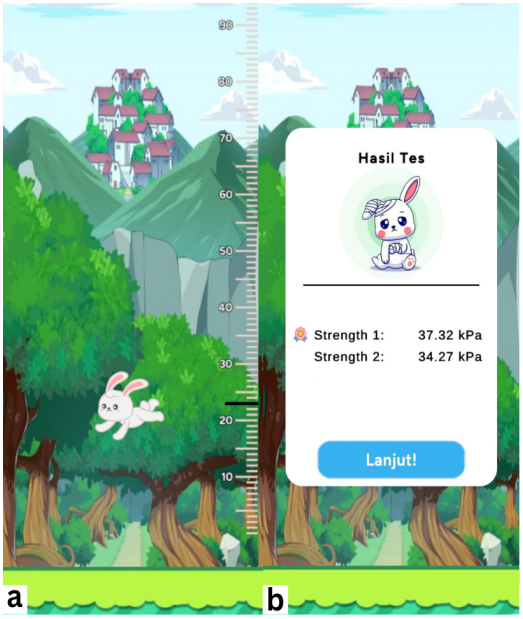

Figure 2. The TongueFit Application. (a) Tongue strength test. (b) Tongue strength measurement's result in kPa, standardized unit of tongue strength.

RESULTS

A total of 74 subjects were recruited for eligibility. Of those, 6 subjects did not meet the inclusion criteria because they did not pass the dysphagia screening, and 14 subjects met the exclusion criteria because they wear visual aid/glasses. Finally, 54 healthy subjects were included in the reliability analysis (42.6% boys and 57.4% girls). Characteristics of the participants are presented in Table 1.

Table 1. Characteristics of participants, data are Mean ± SD

	Age (years)	Weight (kg)	Height (cm)	BMI (kg/m^2)	Mean (kPa)
Healthy children (*n = 54)*					
Boys	13.7 ± 0.9	51.8 ± 12.3	158.9 ± 7.2	20.4 ± 4.1	40.9 ± 10.2
Girls	14.6 ± 1.4	51.9 ± 8.8	154.4 ± 5.2	21.8 ± 5.6	39.5 ± 8.2
All participants	14.2 ± 1.3	51.9 ± 10.4	156.3 ± 6.4	21.2 ± 3.8	40.1 ± 9.6

The measurement of tongue strength on each subject using TongueFit shows varying results from fifty-four samples. The mean of tongue strength in boys' subjects is slightly higher than girls.

However, the mean tongue strength of the subjects in the first test and the retest was quite similar. The mean tongue strength in the first test was 40.2 ± 9.6, while in the second test (retest), it was 40.0 ± 9.7. The

descriptive data for reliability measurement and ICC with the 95%CI is 0.993 (0.988-0.996). Overall, TongueFit demonstrates excellent reliability ($p<0.01$), as indicated by the ICC values exceeding 0.99. This signifies an almost perfect agreement between TongueFit's measurements and those obtained from the standard manometer.

DISCUSSION

Tongue pressure represents the force generated by contact between the tongue and the hard palate. Initially, the tongue contacts the anteromedial part of the hard palate, followed by the lateral part, and finally the posteromedial part. Tongue pressure rapidly peaks and then gradually declines until it dissipates completely, with the highest pressure occurring in the anteromedial region.[14,15] Tongue pressure measurements are widely used to assess oral functions related to swallowing and speech and have been linked to grip strength, clear articulation, and swallowing ability. Additionally, tongue pressure has proven valuable in quantitatively assessing swallowing function, as it can predict decreased oral function and food residue in the pharynx.[16,17] To address the need for a child-friendly assessment device, we developed a new orofacial manometer, TongueFit, designed to measure and enhance tongue pressure, including tongue strength and endurance. In this study, we evaluated the reliability of TongueFit by comparing repeated measurements of anteromedial tongue strength to ensure consistent and reliable results.

This study showed varying results on tongue strength in children aged 12–16, with age being a primary influencing factor. Tongue strength generally increases with age, peaking in early adulthood and gradually declining afterward. According to Potter et al., tongue strength rises sharply between ages 3 and 8, then continues to increase at a slower rate until around 16. By age 16, tongue strength reaches approximately three times that of a 3-year-old but begins to decline in older adulthood. [18,19] Tongue strength is also influenced by gender and body weight. Studies indicate that males have slightly higher tongue strength than females, though the difference is not statistically significant. Trends show that girls often have greater tongue strength than boys at age 10, but by ages 14 and 16, boys tend to surpass girls in this metric. [18,20] Asami et al.'s research found a moderate correlation between tongue pressure and body weight in children, though Potter et al.'s study indicated that age is a stronger predictor of tongue strength than body weight. This aligns with the data in the current study, which shows slightly higher tongue strength in males compared to females with quite similar body weight.[15,20]

The purpose of the current study was to evaluate the reliability of TongueFit by examining its reliability under controlled conditions. The results suggested that this device provides consistent measurements across multiple trials and users, which is crucial for establishing its utility in clinical and research settings where precise and repeatable measurements of tongue strength are essential. High reliability is particularly significant in assessing progress or decline in individuals with conditions impacting oral motor function, such as dysphagia, stroke, or neuromuscular disorders.

Reliability, as reflected in a high intraclass correlation coefficient (ICC >0.75), demonstrates that the same evaluator can produce consistent results across repeated assessments, suggesting that the device minimizes variability related to user technique or interpretation. This consistency is essential for clinical contexts to monitor a patient's progress. High device reliability was achieved because measurement results from each session show strong consistency, with minimal variation between trials, indicating dependable performance. Thus, TongueFit can be deemed a reliable device for assessing tongue strength. The high ICC values recorded in this study align with previous findings using other tongue strength assessment devices, indicating that the new device achieves a similar level of measurement precision.[9]

Previous tongue measurement devices that have been developed, such as the tongueometer and the JMS tongue pressure measurement device (TPM-01), have utilized the IOPI as the gold standard to validate or compare their measurement results.[21-23] The present study has demonstrated an excellent interrater reliability for tongue strength measurements (ICC 0.99). This value was greater than those found for the reliability measurements of tongue strength using the IOPI device, which ranged from 0.77 to 0.90. Prior study also showed this value was slightly similar with those found for the reliability measurements of tongue strength using the tongueometer device, which ranged from 0.92 to 0.99.[24-26]

As far as the authors know, this is the first study evaluating the reliability of TongueFit. This was also the first study testing the reliability of a device on the pediatric population. This study demonstrated that the newly developed tongue force device is reliable for measuring tongue force in different directions within and in between professionals. The new device overcomes some limitations from the tongue devices commonly used in the literature. This validated, safe,

portable, and easy-to-use device can allow patients to perform tongue exercises at home, and the ability of the device to display the tongue activity in real time may increase their motivation to progress with their rehabilitation program. All these features add to the fact that it is a low-cost instrument. We recommend that future studies are needed to test the tongue force device including patients with dysphagia.

CONCLUSION

In conclusion, this study showed an excellent reliability for TongueFit, the newly developed device to measure and improve tongue pressure. These results confirmed that the device is suitable for objective and precise tongue measurements independently of the subject that is using this device. The new device seems to be an improved tongue force measurement device that is safe, validated, reliable and more accessible than others in the market.

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