Orthodontics & Craniofacial Research

SPECIAL ISSUE 10th Biennial COAST Conference

RESEARCH ARTICLE OPEN ACCESS

Real-Time Continuous Tongue Pressure Measurement With Mouthguard-Type Pressure-Sensing Device

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Received: 22 November 2024 | **Revised:** 10 July 2025 | **Accepted:** 13 August 2025

Funding: This research was funded by the Japan Society for the Promotion of Science (JSPS) KAKENHI (grant numbers: 19KK0259 and 24K20074) and the Cooperative Research Project of the Research Center for Biomedical Engineering.

Keywords: mouthguard | oral soft tissue pressure | wearable sensor | wireless

ABSTRACT

Objective: It is well-established that occlusion and dental arch form are related to the morphology and function of the oral soft tissues. Oral soft tissue dynamic assessment is important for elucidating the causes of malocclusion and developing effective treatment methods. We previously developed a small mouthguard-type sensing device for measuring oral soft tissue pressure; however, its continuous measurement performance had not been thoroughly evaluated. This study assessed the device's ability to continuously measure tongue pressure applied to the palatal surfaces of the maxillary anterior teeth during multiple swallowing cycles.

Materials and Methods: The device consisting of a pressure sensor, wireless communicator and battery was created. Tongue pressure on the palatal surface of the left maxillary central incisor during swallowing was measured during the swallowing of 10 mL of water, repeated 10 times in a row in one subject.

Results: The number of pressure spikes corresponded to the number of swallows, enabling clear discrimination of each swallowing event. The mean tongue pressure per swallow was $181.97 \pm 31.84\,\mathrm{g/cm^2}$, with a maximum of $224.97\,\mathrm{g/cm^2}$ and a minimum of $137.72\,\mathrm{g/cm^2}$. The mean tongue pressure per swallow measured was comparable to previously reported values for tongue pressure during swallowing.

Conclusions: The MG-type pressure-sensing device developed in this study successfully measured tongue pressure continuously in one subject. Future studies with an expanded sample cohort will facilitate a comprehensive assessment of the device for its ability to continuously monitor oral soft tissue pressure, which fluctuates throughout the day over extended periods.

1 | Introduction

The relationships between the morphology and function of the oral soft tissues and the dental arch form and occlusion have been evaluated by many researchers [1–3]. Tongue thrusting is a representative oral habit that has been reported to be associated with open bite and an increased overjet [4, 5]. A precise understanding of oral soft tissue dynamics is important for elucidating the causes of malocclusion and developing effective treatment methods.

Various methods have been used to assess oral soft tissue dynamics, each of which has its advantages and disadvantages (Figure 1) [6–11]. The first method is the measurement of 'volume', typically used for the tongue, which involves impressions or radiographs. The advantage of this method is that it allows

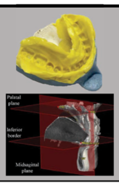
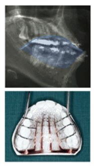
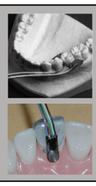
	Target	Pros	Cons
Volume ◆ Impressions ◆ X-rays 	Tongue	✓ Both Tongue volume and oral cavity capacity can be measured simultaneously.	✓ Accurate measurement is difficult. ✓ Measurement is taken at a specific time-point. ✓ Exposure to radiation occurs. (x-rays)
Position ◆ Ultrasounds ◆ Palatograms 	Tongue	✓ Temporal measurement is possible. ✓ The movement can be visualized. (ultrasounds)	✓ Poor visualization of complex structures. (ultrasounds) ✓ Only the contact of the tongue with the palate can be known. (palatograms)
Pressure ◆ Sensor 	Tongue Lips Buccal mucosa	✓ Quantitative measurements are performed temporally.	✓ Measurement is limited and accurate measurement is difficult with existing devices.

FIGURE 1 | Various measurements to assess oral soft tissue dynamics.

simultaneous evaluation of tongue volume relative to oral cavity capacity. However, accurate measurement is challenging because the tongue changes shape depending on its function, and the measurements are taken at a single point in time. Additionally, the tongue and surrounding tissues are exposed to radiation when x-rays are used.

The second method is the measurement of 'position', primarily achieved through ultrasonography or palatograms. A major limitation of ultrasonography is its difficulty in accurately capturing anatomically complex regions, such as the tongue tip [12]. Additionally, ensuring that the transducer is positioned in precisely the same location across multiple recording sessions is extremely challenging. Consequently, different cross-sections of the tongue may be imaged each time, making reliable comparisons between sessions difficult [13]. Furthermore, a significant drawback of palatography is that it provides information solely about tongue-palate contact, offering no insight into other aspects of tongue configuration.

The third method involves measuring 'pressure', using sensors placed on the tongue, lips or the buccal mucosa. This approach allows for quantitative measurements of oral soft tissue pressure, including tissues other than the tongue, and can perform quantitative measurements over time. However, the installation of sensors inside the oral cavity can limit movement, making accurate measurements challenging with existing devices. Moreover, the area of measurement is limited to the region where the sensors are placed [14].

Several devices have been developed for measuring oral soft tissue pressure, varying in size, communication methods and sensor configurations. Most previous devices relied on wired communication, where the intraoral sensor was connected to an extraoral power source and recording device. This configuration limits measurements to a few minutes under fixed conditions, such as specific body positions. However, oral soft tissue pressure fluctuates with changes in breathing, sleep/wake cycles, body posture and head position, as well as movements like speech, mastication and swallowing [15–18].

Thus, a wireless communication device capable of measuring oral soft tissue pressure over extended periods under varying conditions is preferable. However, the few wireless communication devices available tend to have bulky components that may interfere with oral soft tissue movement, potentially affecting the accuracy of measurements [19].

To address these issues, we previously conceived and reported the development of a small wireless device capable of continuously measuring tongue pressure on the palatal surface of the maxillary central incisors during swallowing [20]. In that previous report, it was demonstrated that the maximum tongue pressure during swallowing could be measured in five participants. However, our earlier report lacked sufficient validation of the device's performance in continuous measurement. Therefore, the aim of the present study is to evaluate the continuous measurement capability of this device by continuously measuring tongue pressure on the palatal surface of the upper left central incisor during swallowing.

2 | Materials and Methods

2.1 | Composition of the Sensor Device

The device consists of a pressure sensor, a wireless communicator and a battery to power the components. To prevent any potential leeching of the device's components into the oral cavity when the battery is installed, we encapsulated the pressure sensor, communicator and battery in mouthguard (MG) materials. However, when the pressure sensor is encapsulated in MG, the applied pressure is absorbed by the MG, resulting in inaccurate transmission of pressure to the sensor. To address this issue, a circular polymethyl methacrylate (PMMA) plate was placed over the pressure sensor to ensure proper pressure transmission. An overview of the proposed device is shown in Figure 2.

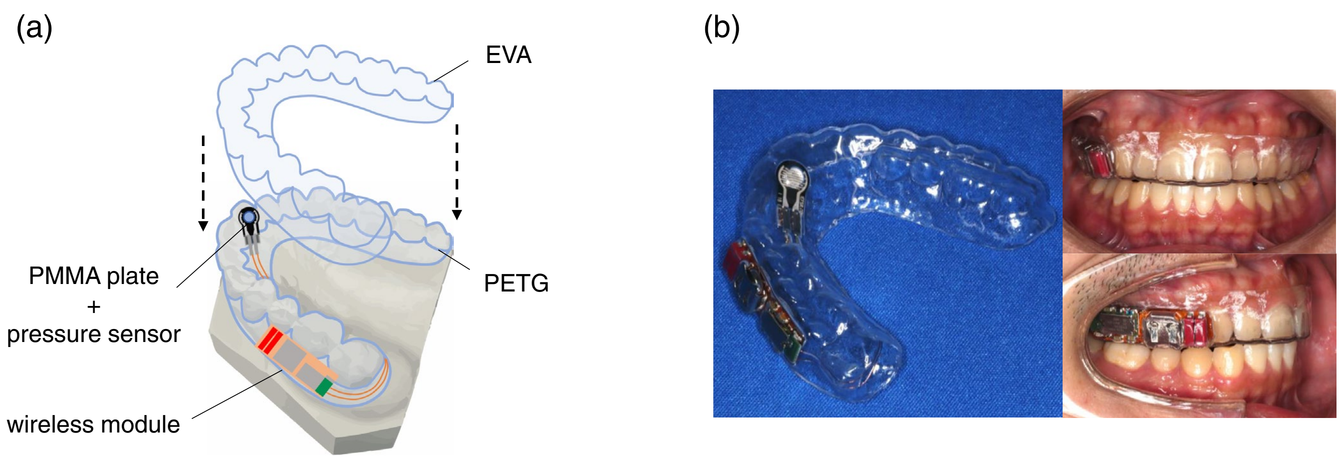


FIGURE 2 | (a) Device configuration and fabrication; (b) Overview of the device.

The procedure for creating the device is as follows. First, impressions of the maxillary dentition were taken using an alginate impression material (HI-TECHNICOL, GC, Tokyo, Japan) and hard plaster (ORTHO MAX, JM ORTHO, Tokyo, Japan) was used to create a plaster dental model. The MG material forming the base of the pressure sensor was pressed against the model using a vacuum forming machine (Vacuum Adapter I, Yamahachi Dental, Aichi, Japan).

A Bluetooth low-energy (BLE) communication measurement device (size: 8.5 × 28 × 3.7 mm; sampling interval: 200 ms–30 s; weight: 0.92 g; radio frequency: 2.4 GHz; applied potential: 0–2.048 V; current consumption: 3.5 mA with BLE communication and 2.2 mA without BLE communication; analogue to digital converter resolution: 22 bits; Discretek, Shizuoka, Japan), a pressure sensor (FSR400 short; upper right of Figure 2a; measurable range: 102–10,710 g/cm^2; width: 6.35 mm; height: 15.8 ± 0.15 mm; thickness: 0.3 ± 0.03 mm; size of sensing area: diameter of 5.08 mm; Interlink Electronics, Camarillo, CA, USA) and a circular PMMA plate (thickness: 1.0 mm; diameter: 4.0 mm) were used herein. Since the purpose is to measure the pressure applied to the teeth during swallowing, a pressure sensor with a sensing area equivalent in size to the palatal side of the upper central incisors was selected. The accompanying PC software included functions to search for nearby wireless measuring devices for MG-type sensors, set data acquisition intervals, record events, and receive, graph and save data. A silver oxide button battery (size: Φ7.9 × 1.65 mm, voltage: 1.55 V and nominal capacity: 21 mAh [SR716SW; Panasonic, Tokyo, Japan]) was used as the power source for the BLE device.

The pressure sensor and circular PMMA plate were fixed to the palatal surface of the left maxillary central incisor. To minimise discomfort, the BLE device was placed on the buccal side of the molar. The MG material on the upper surface of the pressure sensor was softened and pressure-welded. Subsequently, the MG material was trimmed and thermally welded over the tyre circumference using a hot-air gun to seal and waterproof it.

We concluded that the most suitable materials for the MG-type sensor are ethylene vinyl acetate (EVA) for the upper layer (thickness: 1.0 mm, modulus: 7.1×10^5 g/cm^2) and polyethylene terephthalate glycol (PETG) for the lower layer (thickness: 0.5 mm, modulus: 2.1×10^7 g/cm^2) [20]. The device operated for approximately 2 h with a sampling interval of 200 ms. The effective communication range was 2 m.

2.2 | Characterisation and Calibration of the Fabricated Device

The fabricated MG device was attached to a dental model to investigate its response to applied pressure. Continuous measurements were performed at 1 s intervals under varying pressure conditions, and the procedure was repeated three times for evaluation.

2.3 | Continuous Measurement of Tongue Pressure During Swallowing

We conducted an in vivo experiment to evaluate the ability of the developed pressure sensor to continuously measure tongue pressure during swallowing in an adult Japanese male affiliated with our laboratory. The participant provided informed consent after being fully briefed on the purpose and significance of the study. The participant was selected based on the following criteria: permanent dentition, a class I molar relationship, good facial balance determined by visual inspection, no oral habits and no history of orthodontic or surgical treatments.

Tongue pressure on the palatal surface of the left maxillary central incisor during swallowing was measured during the swallowing of 10 mL of water. As previous reports using electropalatography have indicated that the contact time between the tongue and palate during swallowing ranges from 1.1 to 2.9 s [21]. To ensure that each swallow's effect on the sensor output was fully eliminated, swallowing was performed at 15-s intervals. Measurements were taken 10 times in succession, with participants seated on a chair, maintaining a natural head position while keeping their gaze fixed forward. To reduce discomfort due to the device and to stabilise the sensor's temperature, participants rested for 5 min after wearing the device and before beginning the subsequent measurements. The water temperature was set to 37°C to minimise temperature fluctuations during swallowing.

Following the removal of the device, the participant was interviewed to obtain feedback on the comfort and overall experience of wearing the device.

The participant was not informed about the measurement details. Additionally, the participant was not involved in the analysis phase to avoid bias.

3 | Results

A key characteristic of the fabricated device is its integration of a battery, a BLE communication module and a pressure sensor within a compact form factor. This configuration facilitates wireless pressure measurement. The device demonstrated sufficient water resistance, with no leakage or flooding observed during water immersion, as confirmed by visual inspection. Tongue pressure was calculated from the output current based on the calibration. The calibration results revealed the following relationship between the pressure applied to the sensor region of the device and the corresponding output current.

$$\text{force}\ \left(\text{g/cm}^2\right) = \frac{\text{output current}\ (\mu\text{A}) + 1.0391}{22.336} \times 510\ (R = 0.98836)$$

The time profiles of tongue pressure against the palatal surface of the maxillary left central incisor during swallowing are shown in Figure 3.

The number of pressure spikes corresponded to the number of swallows ($n=10$), enabling clear discrimination of each swallowing event. The mean tongue pressure per swallow was $181.97 \pm 31.84\,\text{g/cm}^2$ with a maximum of $224.97\,\text{g/cm}^2$ and a minimum of $137.72\,\text{g/cm}^2$.

The participant provided the following feedback: Although he initially experienced some discomfort when wearing the device, he gradually became accustomed to it and was able to swallow in a near-physiological manner after approximately 5 min. The device was comfortable and felt that it could be worn for several hours. The device had no noticeable taste, both during and after wearing it.

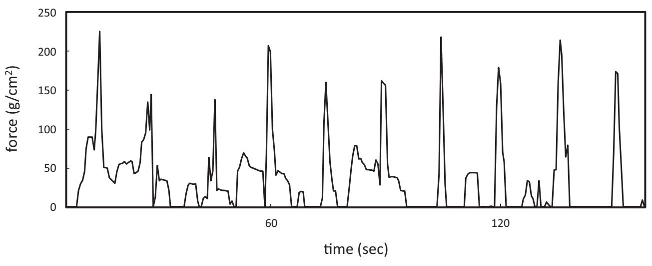


FIGURE 3 | Continuous measurement of tongue pressure during swallowing.

4 | Discussion

In this study, a wireless MG-type pressure sensor device was successfully developed by integrating a pressure sensor with a BLE telemeter. The mean tongue pressure per swallow measured by this device was comparable to previously reported values for tongue pressure applied to the palatal surface of the maxillary anterior region during swallowing. Haroon et al. [11] reported that the pressure applied to the palatal surface of the maxillary central incisors during swallowing in males with an Angle Class I molar relationship was $139.61 \pm 1.58\,\text{g/cm}^2$. Sinem et al. [22] investigated patients with anterior open bite who were treated with a tongue crib, and reported that the swallowing pressure on the crib area decreased from $216.43 \pm 65.79\,\text{g/cm}^2$ at the initial visit to $142.95 \pm 29.2\,\text{g/cm}^2$ after 10 months of appliance use. These results indicate that the device can reliably and continuously measure tongue pressure on the palatal surface of the maxillary left central incisor during swallowing.

Pressure was also detected at times other than swallowing every 15 s. This may be due to distortion of the entire device during swallowing or residual deformation of the MG material around the pressure sensor caused by swallowing. However, since the detected pressure was much smaller than the pressure during swallowing, it is thought to have no effect on the measurement of pressure during swallowing.

A comparison between the developed device and previously reported devices is presented in Table 1 [19, 23]. Our device is one of the smallest and most comfortable among the limited number of wireless pressure sensor devices. As a result, it is considered capable of long-term measurement, which is difficult to achieve with conventional wired or wireless devices. Although the data acquisition interval is longer compared to previously reported devices, it is still short enough to accurately capture brief oral events such as swallowing.

In terms of measurement range, the minimum detectable pressure of our device is $51\,\text{g/cm}^2$, which is higher than that of previous devices. While this value is sufficient for measuring tongue pressure during swallowing, as noted in previous reports, this range is inadequate for measuring resting tongue pressure or

TABLE 1 | Comparison of the developed device with previously reported devices.

	Communication method	Size	Prolonged wear	Data acquisition interval (msec)	Mesurement range
Takada et al.	Wire	Small	Impossible	5	Not described–510 g/cm²
Kato et al.	Wireless	Large	Impossible	1.4	Not described–90 g/cm²
Our device	Wireless	Small	Expected to be possible	200	51–510 g/cm²

pressure exerted by the lips and buccal mucosa, which are generally lower.

For future improvements, the following two points are considered essential.

4.1 | Long-Term Measurement Under Various Conditions

The utility of the developed device has only been validated for measuring tongue pressure on the maxillary anterior teeth during swallowing in a seated position. Further investigations are required to confirm the device's capacity for long-term measurement. With extended measurement capabilities, it may become possible to observe changes in oral soft tissue pressure under conditions that have been difficult to assess previously, such as different body positions and sleep–wake states.

4.2 | Expansion of the Measurement Range

The current measurement range of the device (51–510 g/cm^2) is sufficient for detecting tongue pressure during swallowing; however, it is inadequate for measuring lower pressure events such as resting tongue pressure or the forces exerted by the lips and buccal mucosa. Future improvements should aim to expand the measurable range to include these lower pressures. This could be achieved by employing higher sensitivity pressure sensors or MG materials with improved pressure transmission efficiency. Achieving this would allow for a more detailed understanding of the dynamics of oral soft tissue pressure.

In the future, long-term measurement of tongue pressure against the anterior teeth in patients with anterior open bite and tongue thrust could yield novel insights into the aetiology of open bite. Moreover, improvements to the device may enable the measurement of pressure from a wider range of oral soft tissues and conditions, contributing to a deeper understanding of the causes of various malocclusions and the development of effective treatment methods.

In orthodontic treatment, myofunctional therapy is sometimes employed, and tongue dynamics during swallowing are typically assessed through visual observation; however, accurate evaluation is often difficult. The use of this device allows for more precise assessment of tongue movement, potentially enabling more effective guidance.

5 | Conclusions

The MG-type pressure-sensing device developed in this study successfully measured tongue pressure continuously on the palatal surface of the maxillary central incisor during swallowing in one subject. Future studies with an expanded sample cohort will facilitate a comprehensive assessment of the device for its ability to continuously monitor oral soft tissue pressure, which fluctuates throughout the day over extended periods.

Author Contributions

H.M. and K.Mi.: conceptualisation. H.M., K.I. and K.Mi.: methodology. K.I.: software. H.M.: validation. H.M., K.I. and K.Mi.: formal analysis. H.M.: investigation. K.I. and K.Mi.: resources. H.M.: data curation. H.M.: writing – original draft preparation. K.I., K.Mi. and K.Mo.: writing – review and editing. K.Mi. and K.Mo.: supervision. K.I. and K.Mi.: project administration. K.Mi.: funding acquisition. All authors have read and agreed to the published version of the manuscript.

Acknowledgements

We would like to express our sincere gratitude to all members of the Department of Maxillofacial Orthognathics and Biomedical Devices and Instrumentation at Institute of Science Tokyo for their continuous support.

Ethics Statement

This study was approved by the Ethics Review Committee of the School of Dentistry at Institute of Science Tokyo (approval no. D2018-054). The study was conducted in accordance with the Declaration of Helsinki.

Consent

Written informed consent was obtained from the participant prior to inclusion in the study.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding authors K.Mi. (Kohji Mitsubayashi) and K.Mo. (Keiji Moriyama) upon reasonable request.

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