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博 士 論 文

Measurement of laryngeal elevation time using a flexible surface stretch sensor

（柔軟膜ひずみセンサを用いた喉頭挙上運動時間計測について）

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Measurement of laryngeal elevation time using a flexible surface stretch sensor

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Keywords: Stretch sensor, videofluorography swallowing dynamics, thyroid cartilage, laryngeal elevation, laryngeal elevation time

ABSTRACT

Background: Dysphagia is a growing health problem in aging societies. An observational cohort study targeting community-dwelling populations revealed that 16% of elderly subjects present with dysphagia. There is a need in elderly communities for systematic dysphagia assessment. Objective: This study aimed to verify whether laryngeal elevation in the pharyngeal phase could be measured from the body surface using thin and flexible stretch sensors. Methods: Thirty-two elderly subjects (17 males, 15 females; mean age ± SD: 89.2 ± 6.2 years) with suspected dysphagia underwent a swallowing contrast examination in which seven stretch sensors were attached to the front of the neck. The elongation of the sensors was measured and compared to the laryngeal elevation time values obtained using videofluorography. The sensor signal detected the laryngeal elevation start time, conclusion of the descent of the larynx, and the laryngeal elevation time. The respective laryngeal elevation times obtained using videofluorography and using the sensor were compared using the Bland-Altman method. Results: The laryngeal elevation time was 1.34 ± 0.46 s with the stretch sensor and 1.49 ± 0.56 s with videofluorography. There was a significant positive correlation between the duration obtained by both methods ($r = 0.69$, $p < 0.0001$). A negative additional significant bias of -0.15 s (95% confidence interval -0.30 to -0.03, $p = 0.046$) was noted in the laryngeal elevation time from the videofluorography measurement. Conclusion: Laryngeal elevation time can be measured noninvasively from the neck surface using stretch sensors.

BACKGROUND

Dysphagia is a growing health problem in aging societies. The assessment and diagnosis of this condition in its early stages has been a focus of recent research studies.(1-3) An observational cohort study targeting community-dwelling populations revealed that 16% of elderly subjects present with dysphagia. This suggests there is a need for a systematic screening system for dysphagia in elderly communities.(3) Dysphagia leads to weight loss, malnutrition, dehydration, aspiration, and pneumonia; the latter condition may be life-threatening in elderly patients. Most representative screening tests of swallowing function include laryngeal elevation, observed in the pharyngeal phase. Laryngeal elevation is caused by sensory stimulation, induced when a bolus passes through the oral cavity and pharynx. This expands the pharyngeal cavity, allowing the bolus to pass.(4,5) A decrease in the movement of hyoid bones and thyroid cartilage and an abnormal correlation between these movements may be related to the risk of aspiration or increased residuals.[6,7]

The gold standard for evaluating the kinematics of the swallowing reflex is to observe the motor function and the transfer of a bolus from the oral stage to the esophagus stage using videofluorography (VF).[8,9] However, VF inspection carries a risk of side effects, including exposure to radiation and a risk of aspirating the contrast agent. In addition, there are a limited number of facilities with the equipment and human resources required to carry out this technique. Thus, attempts to measure laryngeal elevation by non-invasive techniques have been actively pursued over the past ten years. For example, ultrasonography can measure the movement of thyroid cartilage at the bedside, even if the device is used by co-medical staff, and the obtained indexes align well with the evaluation conducted by VF.[10-12] However, this device is still expensive and requires substantial experience and skill to interpret the images. Although ultrasonography has been proposed as a technique to evaluate swallowing conveniently in homecare services, it requires time to analyze the assessment using the device. In recent years, attempts have been made to estimate the laryngeal movement from vibrations and strains on the surface of the neck, and these techniques have gained attention as a non-invasive and convenient alternative to traditional clinical methods.[13,14]

Recent developments in elastomer technology may address these concerns. This new technology consists of a flexible strain sensor, where area change of the sensing portion is linear and related to its capacitance.[15] As the sensor is capable of stretching without interfering with movement, it is a promising application that can act as a human motion sensor. Previous studies have examined the validity of the stretchable strain sensor for measuring various human movements ranging from lower back movements to chest wall movements while breathing.[16,17] Thus, we hypothesized that the sensor could be applied on the human neck to capture laryngeal elevation during swallowing. Our primary objectives were 1) to investigate the validity of the stretchable strain sensor in measuring laryngeal elevation, specifically compared to the VF technique, and 2) to examine the consistency of measuring the duration of the laryngeal elevation between the sensor and the VF technique.

METHODS

1) Participants

The study population included 49 elderly individuals who were referred by clinicians to receive VF assessment for dysphagia. Inclusion criteria were 1) age > 65 years and 2) clear laryngeal elevation recognized by speech therapists. Exclusion criteria were 1) progressive neuromuscular diseases, 2) a history of head and neck cancer, or 3) a history of head and neck surgery. Participants provided written informed consent prior to being enrolled in the study. Data from August 2016 to August 2017 were collected from the medical records of a hospital that had both long-term beds and normal sickbeds. This study was approved by the Ethics Committee of the Kobe University Graduate School of Health Science (No. 471) and all other hospitals that participated, in accordance with the Helsinki Declaration.

2) Apparatus

Stretchable strain sensors were used for measuring laryngeal elevation time at the neck's surface (Figure 1A). The characteristics of the sensor are described elsewhere.[15,18,19] Briefly, the sensor consists of three elastomer layers and two electrodes between the layers working as a condenser. The capacitance of the sensor is related to the area change of the sensing parts. Seven stretchable strain sensors in series, at 8-mm intervals, are enveloped in a thin stretchable cloth and placed around the neck of a participant (Figure 1A–D). The sixth sensor from the top is set on the laryngeal prominence. Each sensor has a height of 5 mm, width of 50 mm, and a thickness of less than 1 mm. This size and interval were designed to be large enough to measure the maximum laryngeal elevation in a Japanese population.[20] The strain sensors were connected to a 16-bit A/D converter (ADInstruments, PowerLab 16/35, Dunedin, New Zealand) for sampling at 100 Hz. Data were stored on a computer for offline analysis. Before the experiment began, photos of the lateral and frontal view of each patient's neck were taken to confirm that the sensor was correctly attached.

Oral and laryngeal movements, while swallowing, and bolus transport were also assessed using a VF from a lateral projection. All VF images were captured digitally using a screen capture software (CV910, AVerMedia, Tokyo, Japan) at 30 frames per second and stored on an SD memory card.

3) Experimental procedure and data acquisition

Participants sat on a wheelchair or a chair and were asked to swallow 3 mL of thick liquid barium water (viscosity 300–500 mPa-s) from a spoon or syringe, as appropriate (command swallowing). VF was performed from a lateral projection to evaluate the swallowing movement. An examiner, an experienced speech therapist, instructed the participant to swallow the whole bolus. VF videos and stretchable sensor data were recorded during the complete procedure. The posture and reclining angle observed during the test were recorded.

Demographic data (height, weight, age, and sex) as well as food type and functional independence measure (FIM) for activities of daily living level were extracted from the clinical records. Screening test outcomes for swallowing function using the Mann Assessment of Swallowing Ability (MASA) were also extracted from clinical records. The MASA consists of 24 items with a maximum total score of 200 points. The MASA total score was used to define two categories as follows: no abnormality (> 169 points) and abnormal swallowing (< 170 points).[(21)]

4) Data analysis

Two speech therapists visually identified the beginning and end time points of each laryngeal elevation. Data from the VF and stretchable strain sensor were extracted from three seconds prior to the starting point to two seconds after the ending point. Because swallowing was repeated two to three times, depending on the patient's condition, the best laryngeal elevation for timing and elevation distance in each participant was selected for analysis. This process resulted in a total of 36 single-swallow video clips for further analysis. Each video frame was submitted to a digitizing software (DIPP-Motion V/2D, DITECT corporation, Tokyo, Japan) to obtain a time series of the two dimensional coordinates of the following four points: anterior-inferior corner of C2, anterior-inferior corner of C4, anterior-inferior point of the hyoid bone, and anterior-superior point of the thyroid cartilage. Figure 1E depicts the coordinate system in the analysis. The Y-axis was defined as the line passing from the point of C4 to C2. The X-axis was defined as the line perpendicular to the anterior direction. The scale of the VF picture was calibrated using the distance of connections between adjacent sensors and was set at 8 mm.

To capture the continuous movements of the larynx during swallowing, the sixth sensor from the top was analyzed, which was set on the laryngeal prominence. The signal of the sensor was smoothed by using a 4th order Butterworth filter with a cut off frequency of 10 Hz. The velocity and acceleration of the waveform were calculated using a three-point differentiation. Two seconds before and after the start and end time was set as the analysis window. Within this analysis window, the time points at which acceleration was minimum and maximum were detected as the start point and the end point time points for the stretchable strain sensor, respectively.

5) Statistical analyses

Data were expressed as mean ± standard deviation (SD) or median and interquartile range. The association between the start and end time points as well as duration of laryngeal elevation between the VF and stretchable sensors were evaluated using Pearson's product-moment correlation coefficients. Before examining the agreement of laryngeal elevation duration between VF and stretchable strain sensors, outlier data were defined as data points that were not detected correctly.

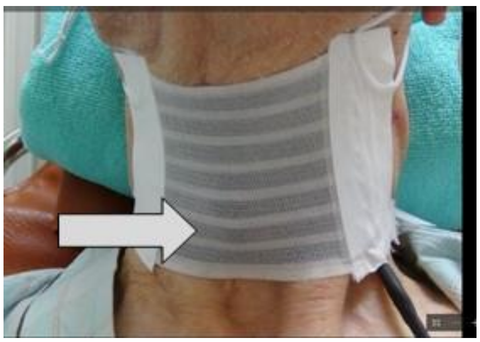
The distribution of each variable was checked for normality using histograms, Q-Q plots, and the Shapiro-Wilk normality test. Duration of elevation time was normally distributed. Thus, to identify differences in the duration of laryngeal elevation measured between VF and stretchable strain sensors, a paired sample t-test was used. In addition, a Bland-Altman plot was used to compare the difference in the laryngeal elevation times obtained using the two methods—VF and strain sensors.[(22)] A Bland-Altman plot is formed by plotting the differences (d) on the vertical axis and the average on the horizontal axis. Mean difference (d) was defined as bias, and the bias ± 1.96 σ was defined as the limit of agreements (LOAs). To assess additional error, 95% confidence intervals (CIs) were computed, and if the intervals included a zero value, no additional error existed. For both bias and LOAs, their 95% CI were computed in all data. According to a CI approach of equivalence, equivalence is assumed if the CI of an observed difference lies entirely within a specified equivalence range.

For sub-analysis, the effect of sex difference and dysphagia grade by MASA (sex × dysphagia) was investigated using two-way analysis of variance (ANOVA). Before the ANOVA, the homogeneity of variances was analyzed by Levene's test. The statistical significance level was set to $p < 0.05$. The data were analyzed using MATLAB® R2017b (MathWorks, USA) and R (ver. 3.31)[(23)] and Excel statistics (Ekuseru-Toukei 2016; Social Survey Research Information Co., Ltd., Tokyo, Japan).

A) Flexible and stretchable strain sensors.

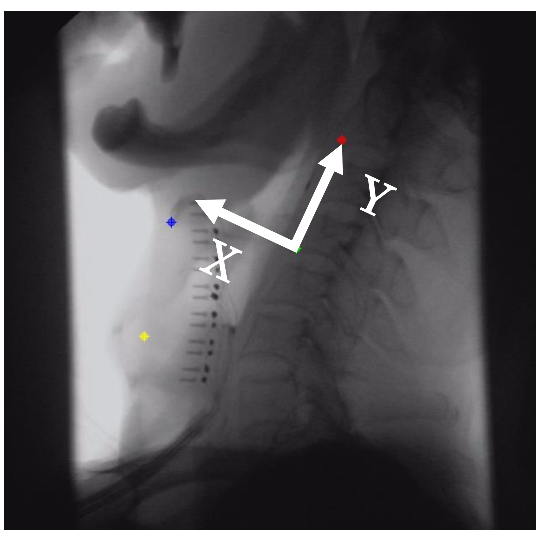
B) A sensor sheet used in the study design.

C) Front photograph of the typical placement of the sensor sheet on a patient's neck.



D) Side view of the same patient wearing the sensor sheet.

E) Representative photograph of the coordinate system used to analyze the video frames of videofluorography (VF)



F) Flow chart of participant enrollment

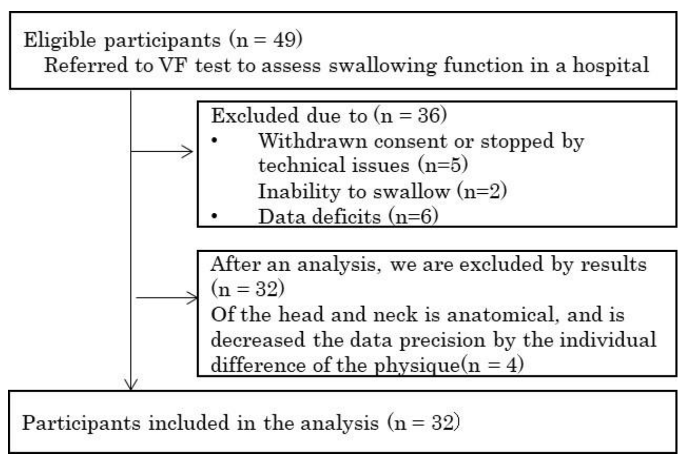


Figure 1. Representative photographs of the stretchable strain sensors

RESULTS

1) Study population

A total of 49 patients who were referred for VF testing during the data collection period participated in the study. Among these patients, 13 (26.5%) were excluded from analysis due to withdrawn consent, data deficits, or other technical issues, and 4 (8.2%) were excluded due to reduced data accuracy based on individual differences in the head and neck. Figure 1F shows that a total of 32 individuals were included for analysis. Among the included patients, 8 (25.0%) moved their mouth to chew the bolus before laryngeal elevation. Moreover, in 4 (12.5%) patients, the laryngeal prominence was difficult to observe in a frontal view (Figure 2A). A space was observed between the neck and the sheet of the stretchable sensors in 15 (46.9%) patients whose sternocleidomastoid muscles bulged (Figure 2B).

Table 1 represents baseline characteristics of the participants analyzed. The mean age of the 32 participants (15 females, 17 males) was 89.2 ± 6.2 years. Eighteen (56.2%) participants were classified as having severe dysphagia (MASA < 140). Only nine (28%) participants ingested food by mouth.

Table 1. Characteristics of study participants

Characteristics	N = 32
Age (years)	89.2 ± 6.2
Women	15 (46.9%)
BMI (kg/m^2)	18.9 [5.2]
< 25	29 (90.6%)
MASA	135 [50]
< 140	18 (56.2%)
FIM	
Motor	18 [5]
Cognitive	11 [10]
Total	29 [14]
Food intake	
By mouth	9 (28%)
Tube feeding	2 (6%)
Intravenous nutrition	21 (66%)
Laryngeal elevation time (s)	1.34 ± 0.46

Data are presented as mean ± SD, median [IQR], or n (%), appropriately. BMI: Body mass index; MASA: The Mann Assessment of Swallowing Ability; FIM: Functional independence measure

2) Outcomes

Figure 2C shows a typical wavelength formation of the stretchable strain sensor and the thyroid vertical position in a subject. The output voltage decreased and increased as the larynx of the patient ascended and descended while swallowing, respectively. The total durations of the laryngeal elevation were compared between the two methods (i.e., the VF and stretchable sensor). The mean duration of laryngeal elevation time was 1.34 ± 0.46 s for VF and 1.49 ± 0.56 s for the stretchable sensor. Although we had not set an upper limit in this study, the highest value observed during the experiment using VF was 2.43 s. There was a significant positive correlation between the duration obtained by the two methods (r = 0.69, p < 0.000014, Figure 3A).

The Bland-Altman plot for total duration of laryngeal elevation showed limits of agreement of -0.97 to 0.67 s for the stretchable strain sensor and VF (Figure 3B). The bias and 95% CI were -0.15 and -0.3 to -0.003, (t (31) = -174, p

= 0.046), respectively, for the stretchable strain sensors compared with VF data. As the confidence interval did not include a zero, there was a slight but negative additional error between the two methods. No significant correlation between the difference and average values of the duration of the laryngeal elevation was found (r = -0.25, p = 0.91), indicating proportional error between the two methods. Descriptive statistics for the difference in times between VF and the stretchable sensor are summarized in Table 2. In the total 32 measurements, 19 measurements (59.4%) were within 20% of the relative difference. The two-way ANOVA revealed that neither the interaction nor the main effect of both sex and the degree of dysphagia was significant (p > 0.05, Table 3). These results indicate that the measurement error of laryngeal elevation durations was not affected by these factors.

Table 2. Summary of the difference in time data between videofluorography and the stretchable strain sensor

	Bias	LOA
Elevation start time	-0.15	[-1.13, 0.83]
Elevation end time	0.10	[-0.62, 0.82]
Laryngeal elevation time	-0.05	[-0.91, 0.81]

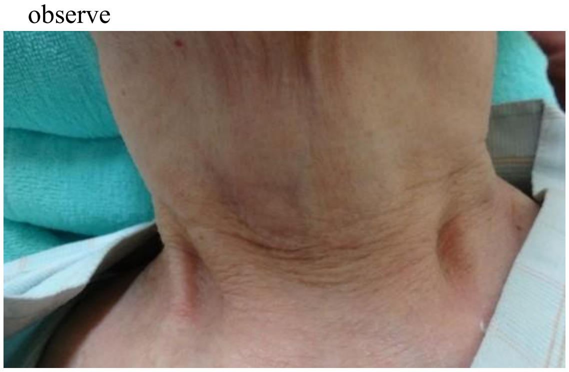
LOA: Limit of agreement

Table 3. Results of the two-way analysis of variance for sex and the degree of dysphagia

	d.f.	SS	MS	F	P
MASA	1	0.064	0.064	0.354	0.557
Sex	1	0.041	0.041	0.229	0.636
MASA * Sex	1	0.011	0.011	0.059	0.809
Residuals	28	5.055	0.181		

MASA: The Mann Assessment of Swallowing Ability

A) Frontal neck photograph of a typical patient whose laryngeal prominence is difficult to observe



B) a typical patient whose ternocleidomastoid muscles bulge

C) Typical waveforms of the stretchable strain sensor (black line) and thyroid vertical position in a subject (gray line).

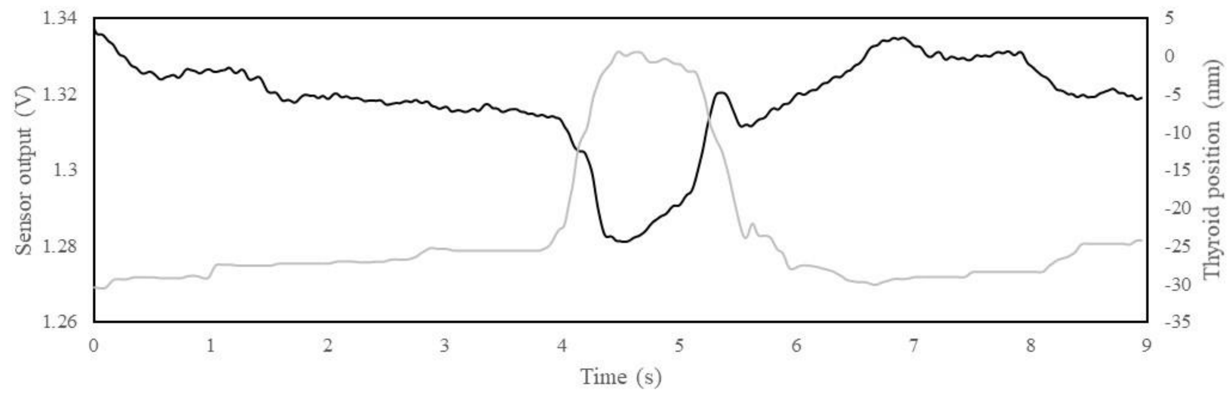
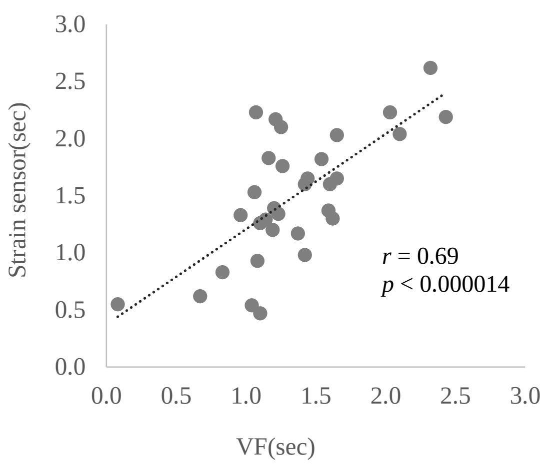


Figure 2

A) Scatter plot of laryngeal elevation times. Values in the figure are the correlation coefficient and probability value obtained using a Pearson product moment correlation analysis.



B) Bland-Altman plot for comparing laryngeal elevation time. The horizontal dotted line is the bias of the difference in laryngeal elevation times. The horizontal longdash_dotted line is the 95% confidence intervals. The horizontal dashed line is the limit of agreements.

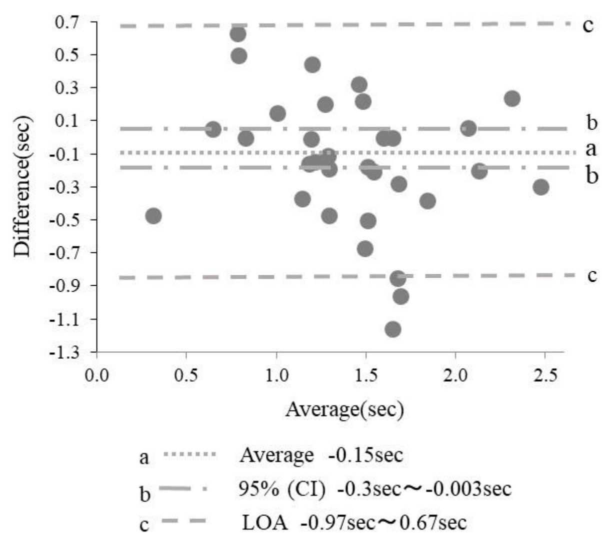


Figure 3. Comparisons of laryngeal elevation time obtained by videofluorography (VF) and the stretchable strain sensor

DISCUSSION

The laryngeal elevation time was measured using a stretch sensor in elderly patients who also received VF due to suspected dysphagia. In most cases, the output of the sensor showed a pattern of decreasing voltage as the laryngeal elevation started, followed by an increase with the descent of the larynx. The laryngeal elevation time detected from the stretch sensor was positively correlated with the data from the VF. The LOA of laryngeal elevation duration was less than ± 1.64 s. Participants' sex and the severity of dysphagia had no significant effect on the error of laryngeal elevation time measurements.

The mechanism of swallowing can be understood as the sequence of events culminating in laryngeal elevation. A bolus is delivered to the esophagus by relaxing the cricopharyngeal muscles and elevating the larynx to render the esophageal opening patent. The cricopharyngeal muscles then contract, and the larynx quickly returns to its original position. Laryngeal elevation, observed as a patterned and repetitive movement during swallowing, is reflexive,

The flexible stretch sensor is effective as a wearable sensor that can easily measure laryngeal elevation time on the surface of a complicated or curved neck. We chose time measurement using this sensor as a minimally invasive and valid parameter as it allows for the application of rehabilitation feedback devices such as the Mendelson's method.

The output pattern of the observed sensor may be interpreted from the dynamics of the larynx in the swallowing reflex. Prior to swallowing, the sensor on the laryngeal prominence was pushed forward and stretched. During laryngeal elevation, the laryngeal prominence moved out of the sensor field, resulting in the shortening of the sensing section of the device. After the activity of the elevator muscle group declined, the larynx descended to its original position due to gravity and the viscoelasticity of the surrounding tissue, resulting in the stretching of the sensor again. Synchronization of the movement of the thyroid cartilage and the output change obtained from the VF image supports this hypothesis. Therefore, these data suggested that the two important change points of the signal (rapid decrease and cessation of the increase) accurately reflect laryngeal elevation while swallowing. The positive correlation between the laryngeal elevation duration obtained by the two methods demonstrates clearly the association between the signal variation and swallowing movements. These results confirm previous findings using neck bending sensors.14

Despite these promising results, several problems remain unsolved in determining the validity and reliability of measuring laryngeal elevation time with the stretch sensor. Our results show that the error of the laryngeal elevation time acquired by the stretch sensor in some subjects was quite large. More specifically, while analyzing the accuracy of the test, we found that the error of the measurement exceeded 50% in 20% of subjects. When errors were 50% or more, there was involuntary movement before starting laryngeal elevation motion. The sensor falsely detected motion in this scenario. Three factors could be considered to improve the accuracy of the elevation time measured by the sensor: the individual anatomical differences of the head and neck, body motion artifact at the time of measurement, and the different approach of the time detection algorithm.

The point to discuss is the neck anatomical features, namely the height of the larynx at rest and the forward protrusion of the cricoid cartilage. If the larynx is at a high position of the neck at rest (e.g., at a position close to the lower jaw margin), the sensor may sense a slight change in the posture of the head or movement of the mouth and the face. Since the seven sensors were wrapped in a single stretchable fabric and were loosely connected, the elongation of the sensor near the lower jaw may have also been transmitted to, and analyzed by, the fifth sensor. As previously stated, another potential influence on accuracy was the forward protrusion of the cricoid cartilage. If the cricoid cartilage or the thyroid gland protrudes substantially, they could stretch the sensor, and thus, the output may have increased as soon as the output decreases due to the lifting of the laryngeal protuberance. This behavior of the sensor could cause earlier offset error. Since there was no sex effect in the error observed in the sub-analysis, this factor may not be as significant when compared to other factors.

In some patients, the sternocleidomastoid muscles bulged due to weight loss occurring with age and increased respiratory assistance muscle tone, and as such, the larynx can be recessed in between these muscles. In such a patient, the projecting left and right sternocleidomastoid muscles are not in sufficiently close contact with the larynx to lift the sensor like a bridge girder. In these cases, the output fluctuation due to laryngeal elevation of the sensor tends to be very small, at 0.1 volts or less. Therefore, further research on a method to address this limitation in patients with prominent sternocleidomastoid muscles is needed.

In this study, onset is defined as the change point where a sudden output reduction of the sensor signal starts in the pharyngeal phase, and offset is defined as the point where the increase of the sensor signal changes abruptly. This method assumes laryngeal elevation causes the most abrupt change in the pharyngeal phase. Therefore, if the sensor output greatly fluctuates due to other factors (e.g., body movement), an erroneous time is recognized as the change point. One example of this limitation was highlighted in the current study when some patients chewed the bolus just before swallowing. Additional approaches, including pattern matching or identification of the specific movement patterns using machine learning, may be effective in attenuating this error. However, more data on laryngeal elevation by the sensor will need to be accumulated first.

There were several limitations in this study that must be addressed in future work. First, the sample size was relatively small. The effects of swallowing function and sex difference to sensing accuracy might have been underestimated due to this small sample size. Second, the impact on the sensor caused by laryngoptosis induced by aging, sagging skin, creasing of skin, and physical size was not measured. Further studies need to include these biomechanical factors to improve detecting sensitivity of laryngeal elevation.

Our findings demonstrate that in elderly patients with dysphagia, the stretchable strain sensor on the neck measures the duration of laryngeal elevation during swallowing with an error of less than 20% compared to the standard VF technique. However, to apply the sensor in clinical settings, reducing variability in the accuracy is necessary. Further studies need to investigate whether measurement accuracy can be improved when anatomical characteristics of the head and neck and the size and position of the sensor are taken into account.

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