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Dysphagia

Standardized Instrument for Lingual Pressure Measurement

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Abstract. Disease-related atrophy of the tongue muscles can lead to diminished lingual strength and swallowing difficulties. The devastating physical and social consequences resulting from this condition of oropharyngeal dysphagia have prompted investigators to study the effects of tongue exercise in improving lingual strength. We developed the Madison Oral Strengthening Therapeutic (MOST) device, which provides replicable mouth placement, portability, affordability, and a simple user interface. Our study (1) compared the MOST to the Iowa Oral Performance Instrument (IOPI), a commercial pressure-measuring device, and (2) identified the optimal tongue pressure sampling rate for isometric exercises. While initial use of the MOST is focused on evaluating and treating swallowing problems, it is anticipated that its greatest impact will be the prevention of lingual muscle mass and related strength diminishment, which occurs even in the exponentially increasing population of healthy aging adults.

Key words: Dysphagia — Exercise — Sampling rate — Tongue strength — Tongue pressure — Biofeedback — Deglutition — Deglutition disorders.

The prevalence of swallowing disorders in elderly persons is increasing rapidly. It is estimated that 15%–40% of individuals over 60 years have dysphagia [1], translating into more than 6.2 million Americans over 60 who suffer from dysphagia. Other surveys [2] estimate that as many as 50% of nursing home residents have swallowing problems. Although these cases frequently are associated with neurologic ailments such as Parkinson's disease or stroke, it appears that dysphagia becomes increasingly more prevalent with normal aging, even in the absence of these conditions. In addition to work indicating age-related changes in temporal–spatial parameters of oropharyngeal swallowing, a study published by Robbins et al. [3] concluded that a person's overall swallowing lingual pressure reserve declines with age, so that elderly individuals may have to work harder to produce adequate swallowing pressures. One hypothesis for the loss of reserve is that the tongue muscles—the primary propulsive agents of swallowing—atrophy with age. This condition of diminishing age-related muscle mass is generally described as sarcopenia [4]. Unless strength is recovered or maintained through exercise, the age-related reduction in tongue muscle mass results in a less effective swallow. If the tongue cannot efficiently push food into the pharynx and play its important role of initiating and contributing to the swallowing response, food or liquid may enter the airway causing severe health problems such as choking, pneumonia, dehydration, and malnutrition.

Although the physical problems are dangerous, a patient's most challenging tribulations may arise from the social implications of poor swallowing capabilities. Meals play a central role in many societies

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and often highlight holiday celebrations or social gatherings with friends and family. Even mild or moderate dysphagia can lead to choking or discomfort, which can make eating in public embarrassing or deprive a person of pleasure from eating. Individuals with severe swallowing disorders have few alternatives and may even choose to have a feeding tube placed directly into their stomach to receive adequate nutrition and hydration. The impact of these events on quality of life are enormous, not only for the individual, but for care providers, family, and friends as well.

Dysphagia resulting from tongue muscle atrophy may be treated with simple, repetitive, isometric exercises to help build tongue strength [5] and restore its function [6, 7]. Several devices, including the Iowa Oral Performance Instrument (IOPI Northwest Company, LLC, Carnation, WA), Tongue Force Measurement System (TOMS) [8], Kay Elemetrics Swallowing Workstation (Kay Elemetrics, Lincoln Park, NJ), and Lingual Force Transducer [9] have been developed for evaluating the maximum force or pressure output at different locations on the tongue and can be used to help diagnose and strengthen weakened tongue muscles. Although these devices have been used to collect conclusive data 5–7; 10–12], they are not an optimal solution for diagnosing, testing, or treating swallowing problems for the following reasons:

1. High purchase costs ($950–$40,000) prohibit the average patient from buying any of these instruments for home use.
2. With the exception of the Kay Elemetrics Swallowing Workstation, the tongue bulb or pressure sensor can measure pressure only at a single site on the tongue at a given time.
3. The tongue pressure sensors or bulbs are not custom-fit to the individual, precluding reproducible placement at an exact location in a user's mouth, even with careful training.
4. Many of the instruments have limited durability because of numerous connective pieces.
5. The plastic air-filled bulbs of pneumatic instruments are prone to leaks and the material properties can change with use.
6. Target pressure values used during the exercise protocol must be manually calculated, which can be confusing for older individuals.

To address the limitations of currently marketed tongue pressure measurement devices, the Madison Oral Strengthening Therapeutic (MOST) device was developed. The MOST utilizes a custom-fit mouthpiece with multiple sensors to provide (1) reproducible placement in the mouth, (2) simultaneous data recording from multiple locations, (3) a simplistic user interface, and (4) a small, portable package. In addition, the MOST is made from commonplace materials, which will allow for a more competitive retail price.

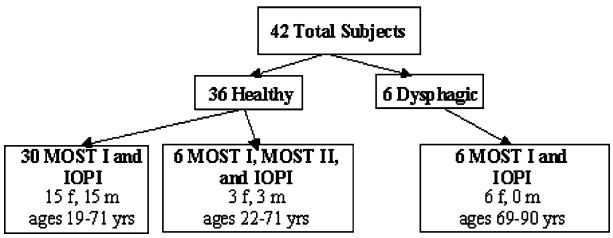

Fig. 1. A total of 42 subjects were enrolled in the study.

Currently marketed pressure measurement devices, including the four mentioned above, measure pressures at sampling frequencies that widely vary between 10 and 500 Hz [8, 13]. The optimal frequency (number of times data are measured each second) would minimize the electronic storage demands of the device, making it more compact and less expensive, while still providing an accurate data stream that reveals small, important pressure fluctuations. In this study, normal healthy and dysphagic volunteers performed isometric exercise tasks with two versions of the MOST, referred to as the MOST I and MOST II (developed as a result of internal fundings of this project), and the commercially available Iowa Oral Performance Instrument (IOPI). Resulting data were used to identify a favorable tongue pressure sampling frequency and evaluate the MOST's capacity to effectively measure tongue pressures.

Materials and Methods

Subjects

After receiving approval from the University of Wisconsin Health Sciences Committee Institutional Review Board and the William S. Middleton Memorial Veterans Hospital Research Committee, a total of 42 individuals ranging in age from 19 to 90 years were enrolled in the study (Fig. 1).

Healthy Participants

Thirty-six healthy subjects (18 females, 18 males) responded to community flyers advertising the study and completed tasks on the MOST and IOPI tongue exercise devices. The healthy population was defined as having no history of medical conditions such as dysphagia or medications that could interfere with lingual pressure-generating abilities. The cohort of 36 healthy subjects ranged in age from 19 to 71 years, stratified so that three females and three males

Fig. 2. (**A**) MOST I and (**B**) MOST II mouthpieces are shown, along with the (**C**) MOST I mouthpiece and electrical circuit.

each were included in the following age groups: 18–24, 25–34, 35–44, 45–54, 55–64, and over 65 years. Self-reported weight and height extremes varied from 95 to 250 lbs and 4′ 11″ to 6′ 2 ″ (X = 153.85 lbs, X = 5′ 7.5″). Three of these healthy subjects wore dentures or a partial denture while performing the study tasks.

After participants strongly recommended reducing the MOST mouthpiece size to improve comfort, six healthy subjects (one from each of the six age groups) were called back to evaluate a second version of the device, the MOST II.

Dysphagic Participants

The remaining six subjects (all female) were recommended for study involvement after participating speech language pathologists identified them as (1) displaying symptoms of dysphagia and (2) producing below average lingual pressures (a general guideline of less than 35 kPa was used based on data from the 36 healthy participants and previous studies [12]). The six dysphagic patients completed the same tasks on the MOST I and IOPI tongue exercise devices as the healthy group. Patients participated in the study following their clinical appointments, so that the reported IOPI and MOST pressure values were recorded on the same days.

The dysphagic population was significantly older than the healthy population and ranged in age from 69 to 90 years (X = 79.2 years). All had their own teeth except for one dysphagic subject who wore a partial upper denture. Self-reported weight and height extremes ranged from 108 to 151 lbs and 4′ 11.5″ to 5′ 7″ (X = 129.33 lbs, X = 5′ 4 ″). Significant health conditions present in the dysphagic group included oculopharyngeal muscular dystrophy (OPMD), stroke, inclusion body myositis, parkinsonism, frailty, cricopharyngeal hypertonicity, and esophageal stasis. In addition, one dysphagic subject suffered from macular degeneration and was considered legally blind, in which case survey questions were completed orally and investigators announced the IOPI and MOST pressure values to supplement the visual feedback.

Instruments

The MOST mouthpiece consisted of an adult-sized polymer athletic mouthguard embedded with an Interlink Electronics FSR® 0.5-in. conductive elastomer force sensor. A reproducible custom fit was quickly achieved in less than 1 min by lining the mouthguard with dental putty and forming the mouthpiece to the mouth and palate. The bulkiness of the MOST I (Fig. 2a) mouthpiece was corrected by eliminating the mouthguard side channels, where the molars would fit. The resulting smaller MOST II (Fig. 2b) mouthpiece still provided reproducible, reliable sensor placement because the incisors and anterior hard palate served as primary landmarks for the custom fit.

Pressure readings were obtained by connecting the MOST mouthpiece to a simple electronic circuit (Fig. 2c). The FSR sensor

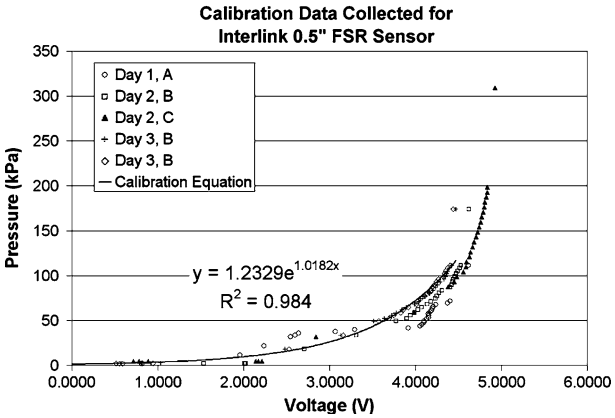

Fig. 3. The exponential calibration curve $y = 1.2329\, e^{1.0182x}$ was calculated based on data collected using calibrated weights and liquid-filled balloons (**A, B, C**) to simulate the tongue pressing on the sensor.

comprises two thin polymer films separated by a semiconductive material, causing resistance within the sensor to decrease as the two film layers are brought closer together. A very small, steady current passes through the sensor and circuit, so that changes in resistance (i.e., pressure) bring about a change in voltage. Therefore, the electronic circuit acts to convert the sensor output to a voltage that increases proportionately with pressure. For this study the voltage output from the MOST device was adjusted to range from 0 to 5 V. The voltage was recorded directly at 500 Hz to an electronic text file using data acquisition cards (National Instruments Corporation, Austin, TX; LabJack Corporation, Lakewood, CO) and LabVIEW (Biobench Software, National Instruments Corporation, Austin, TX) based PC programs. A LabVIEW graphical user interface displayed pressure generated as a real-time plot of voltage versus time. The signal was later converted to pressure units using an equation achieved by testing multiple FSR sensors with calibrated weights (Fig. 3).

The commercially available IOPI measures tongue pressure pneumatically using a nickel-sized, air-filled polymer balloon called a tongue bulb. No fitting is required. Unlike the other available devices, it is easy to operate, may be transported without difficulty, provides an isometric endurance test, allows a seminatural swallowing action, and offers a unique LED light display as a form of motivational feedback. Maximum pressure attained was displayed numerically in kilopascals but no other feedback features of the IOPI were used.

Tasks

Each subject completed a brief oral health history to ensure no adverse symptoms were present that would interfere with the ability to generate maximum lingual pressures or, with the dysphagic subjects, to document potential etiologies for reduced pressures.

Mouthpiece Fitting

Mouthpieces were custom fit to each individual by filling the mouthguard tray and superior portion of the sensor mount with a small amount of pliable Reprosil® Dental Putty (DENTSPLY International, York, PA). Subjects then were instructed to carefully place the mouthpiece in their mouth and use their thumbs to push against the mouthpiece until it conformed to the roof of their mouth. After ensuring a comfortable fit, the mouthpiece was removed and allowed to air dry for approximately 5 min until the putty hardened. Most subjects, even those who were frail, were able to fit the mouthpiece to the palate in less than 30 s. Mouthpiece fittings invoked gag reflexes in only two participants; one was able to control the reflex response using panting and conditioning techniques, but the other subject experienced some difficulty performing the exercises with both the MOST I and MOST II mouthpieces.

Exercises

The order in which healthy subjects exercised with either the MOST I or the IOPI was randomized. (Dysphagic subjects could not be randomized because IOPI maximum pressure values obtained during routine clinical care were used as study entrance criteria.) After completing tasks on the first two devices, a subset of six subjects additionally evaluated the MOST II device. For IOPI exercises, the bulb was placed just posterior to the incisors so that pressure was measured at the anterior portion of the tongue. This location most closely matched the positioning of the sensor in both MOST mouthpieces so that resulting pressure values could be compared. Three sets of three isometric exercises, as described by Nicosia et al. [12], were completed with each instrument. Subjects were seated for all tasks and instructed to push the tongue against the pressure sensor as ''hard as possible'' for approximately 3 s. The investigator counted aloud to 3 to maintain time consistency for the duration of each isometric ''push.'' Subjects were allowed to rest between exercise sets at their own discretion. However, three of the six dysphagic subjects completed fewer exercise sets because of reported fatigue.

Survey

Participants also completed written surveys rating the user-friendliness of each instrument. Survey questions addressed the procedure used to fit the mouthpiece, mouthpiece comfort, feedback (numerical, graphical, series of LED lights, and bell/alarm), using the system to perform the exercises on a daily basis, and the estimated difficulty of pushing or swallowing with the mouthpiece. A swallowing task was not included in the protocol, but participants were permitted to experiment with the mouthpiece if they desired.

Data Analyses

Calibration

All MOST data were converted to units of pressure in kilopascals using the exponential calibration equation $y = 1.2329\, e^{1.0182x}$. This equation was determined using calibrated weights and different liquid-filled balloons to simulate the tongue pressing on the sensor (Fig. 3). Barometric pressure and temperature were recorded for each testing session but did not appear to affect the resulting sensor output. To apply the calibration equation, it was assumed that each participant's tongue completely covered the 0.5-in.-diameter circular sensor while performing the exercise tasks.

Table 1. Selected sampling rate frequencies

Frequency	k^a
500	All
250	2
125	4
62.5	8
50	10
25	20
12.5	40

[a] Every k^{th} point is selected.

Sampling Rate

For sampling rate analyses, only the final exercise data set (generally set 3) recorded from each individual on an instrument was used. The last data set was chosen for analyses because it was assumed that (1) learning to use the instruments would affect the initial data sets and (2) sufficient rest between exercise sets would minimize later fatigue effects. A MATLAB program (The MathWorks, Inc, Natick, MA) was written to systematically eliminate data points from the original 500-Hz MOST signal, synthesizing data that would have resulted from sampling at lower frequencies. For example, every fourth data point of the 500-Hz signal was included in the synthesized 125-Hz data set. The seven frequencies given in Table 1 were selected because the original 500-Hz signal could be easily divided to produce the lower frequencies.

One exercise set consisted of three maximum isometric exercises. Continuous data were collected from the MOST I and MOST II devices so that one data set consisted of three pressure peaks (Fig. 4) for analyses. The IOPI instrument was set to record only the maximum pressure achieved during a single exercise so that one data set consisted of three numerical peak pressure values (in kPa).

Maximum pressure (Max) and the time to maximum (TTM), two values commonly extracted from tongue pressure data, were calculated for each exercise performed on the MOST instruments. The time to reach maximum pressure was defined as the difference (in seconds) between the time point at the maximum pressure magnitude and the time point of the first upstroke from baseline.

Evaluation of Devices

Participants ranked existing attributes and potential features of the devices on a scale from 1 to 5. For the first five categories (fitting, comfort, and three types of feedback), a value of 5 was considered a favorable marking. For the final three categories (daily use, difficulty of performing exercises, and difficulty swallowing), a value of 5 was considered most unfavorable. In addition, qualitative survey comments were organized into a database and maximum pressure values were directly compared to the IOPI data.

Statistical Methods

The calculated maximum and time to maximum values of the lower-frequency data sets were compared to the original 500-Hz

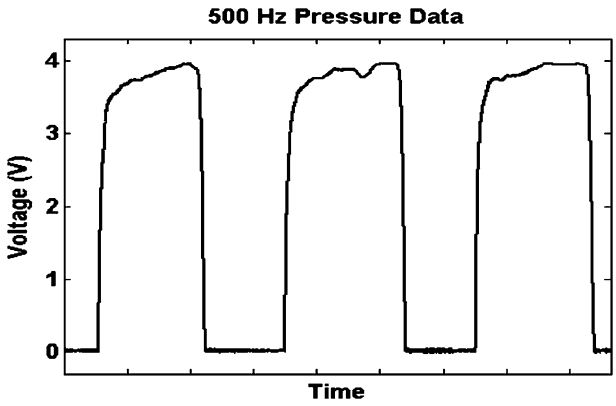

Fig. 4. Each set of MOST pressure data was recorded as a voltage signal showing three maximum pressure generations.

values to determine error incurred by sampling at a lower frequency. Differences were calculated as Difference = Original Data Value – Reduced Frequency Data Value. From this, percent error calculations ([Difference/Original Data Value] × 100%) were averaged, plotted for each sampling frequency, and used to assess the effectiveness of the different sampling rates. Similarly, difference plots for both the maximum and time to maximum values were created by plotting the difference versus the original data value for both the maximum and time to maximum data at each sampling frequency. These plots provided visual estimation of the effectiveness of the different sampling rates.

Note that systematically eliminating data points using the MATLAB program previously described would result in the maximum pressure data point either remaining the same or being eliminated from the synthesized data set (so that only a lower maximum pressure could have been recorded using the reduced sampling rate). Therefore, the difference between the original 500-Hz maximum pressure data value and the synthesized reduced frequency maximum pressure always yielded a positive value. Conversely, the maximum value from the synthesized reduced data might lie before or after the eliminated original maximum data value so that the time to the reduced maximum pressure could increase or decrease when compared to the original data.

Comparisons between the pressure values achieved on the MOST versus the IOPI were evaluated by analyzing the difference between the IOPI and MOST maximum pressure values (MOST maximum – IOPI maximum) and the absolute difference (absolute value [MOST maximum – IOPI maximum]). Microsoft Excel was used to calculate the mean, standard deviation, minimum, maximum, and R^2 values for these difference calculations and the absolute value of the difference calculations within the different subgroups. Survey data were averaged by group to compare the MOST I device to the IOPI instrument and to the MOST II. Excel also was used to compute the mean and standard deviation of the survey responses for each category.

Results

Optimal Sampling Frequency

Evaluation of the maximum (Max) and time to maximum (TTM) data points calculated for each

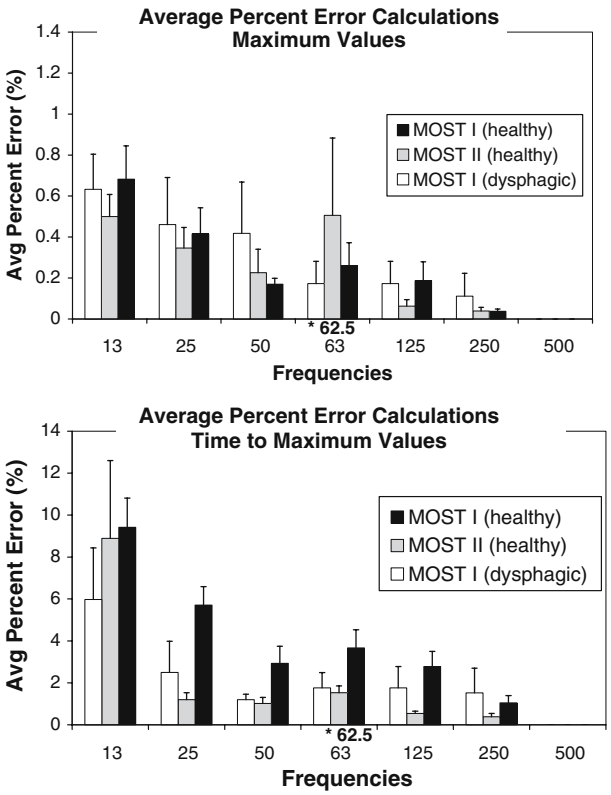

Fig. 5. Percent error was calculated as [(Original 500-Hz Data Value – Reduced Frequency Data Value)/Original 500-Hz Data Value] × 100% for both the maximum and time to maximum data values. Results from each participant group were averaged to create the above plots.

pressure peak indicated that a sampling rate of 62.5 Hz sufficiently captured details from isometric exercise data. The greatest error was incurred in calculating the TTM values, where the percent error (Fig. 5) quickly rose above 4% at frequencies less than 50 Hz. Difference scatterplots (Figs. 6 and 7) visually confirmed that a sampling rate of at least 50 Hz is desirable. The scatterplots also depicted that the dysphagic group produced the lowest maximum pressures on the MOST device and required more time to reach their maximum pressures when compared with nondysphagic subjects.

Survey Responses

Complete results are presented in Table 2. The graphical or numerical feedback implemented in the MOST and IOPI devices was preferred by both the healthy and the dysphagic populations when compared to an array of lights or an auditory alarm that would indicate the target pressure value had been reached. The healthy population slightly preferred the graphical feedback provided by MOST I and

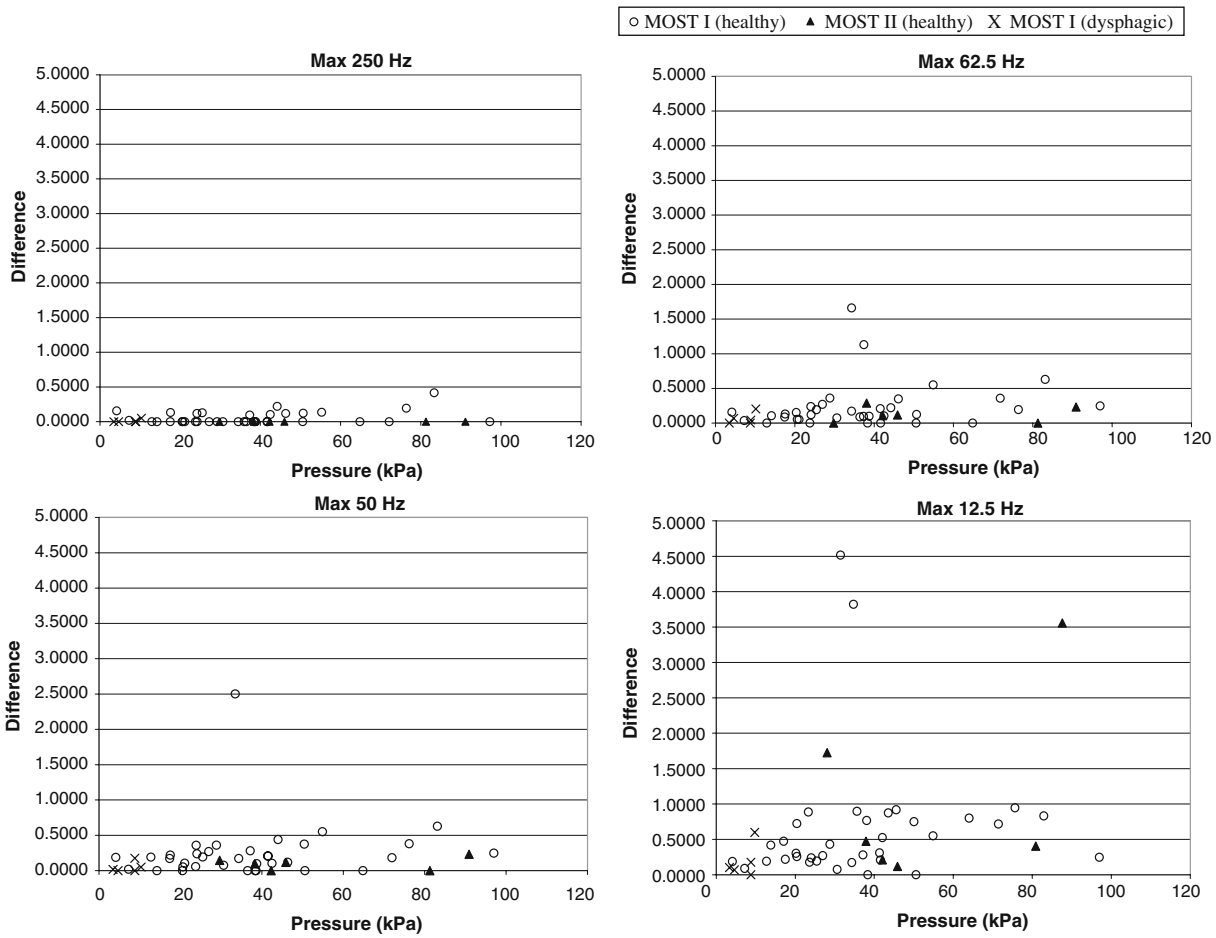

Fig. 6. Difference (Original 500-Hz Data Value – Reduced Sampling Rate Data Value) plots visually confirmed that sampling rates of 62.5 Hz or 50 Hz satisfactorily represented the maximum pressure data.

MOST II, while the dysphagic participants favored the IOPI numerical display. Despite the crudeness of the MOST prototypes, survey results showed that 92% of the healthy subjects found the MOST I satisfactory (≤ 3) for daily use, and 64% gave it the highest positive ranking of 1 when asked about using the instrument daily. In the dysphagic participants, 67% reported they would find the MOST I satisfactory (≤ 3) for daily use. Responses tended toward a neutral value of 3 when asked if the mouthpieces made the exercises difficult, but replies indicated that the act of swallowing was complicated by the presence of the mouthpiece. Responses regarding the smaller mouthpiece of the MOST II were more positive when asked about the ease of swallowing. The MOST II also received more positive responses than the MOST I in the comfort category.

Qualitative comments confirmed that the IOPI instrument could be difficult for users. One healthy participant wrote, the ''exercises were more difficult because [the bulb] slides around too much.'' Another healthy participant replied that ''the number that corresponds to the pressure found seems to correlate to where you push on the bulb, not how hard,'' and a dysphagic patient said, ''... sometimes you have to find the right spot to push on the bulb.'' Healthy and dysphagic subjects found the MOST I mouthpiece too large, bulky, and uncomfortable. Comments such as ''opening my mouth that big is very uncomfortable'' and ''difficult to swallow saliva with mouthpiece in place'' were fairly common, although one healthy subject did say that the ''mouthguard seemed more natural.'' Healthy subjects who used the MOST II device replied that the smaller mouthpiece was more promising. ''This reduced device makes it easier to swallow'' and ''the smaller mouthpiece [is] more comfortable, less intimidating, [and] held in place fine.''

Maximum Pressure Values

Maximum pressure values using the MOST devices were plotted against the maximum pressure values

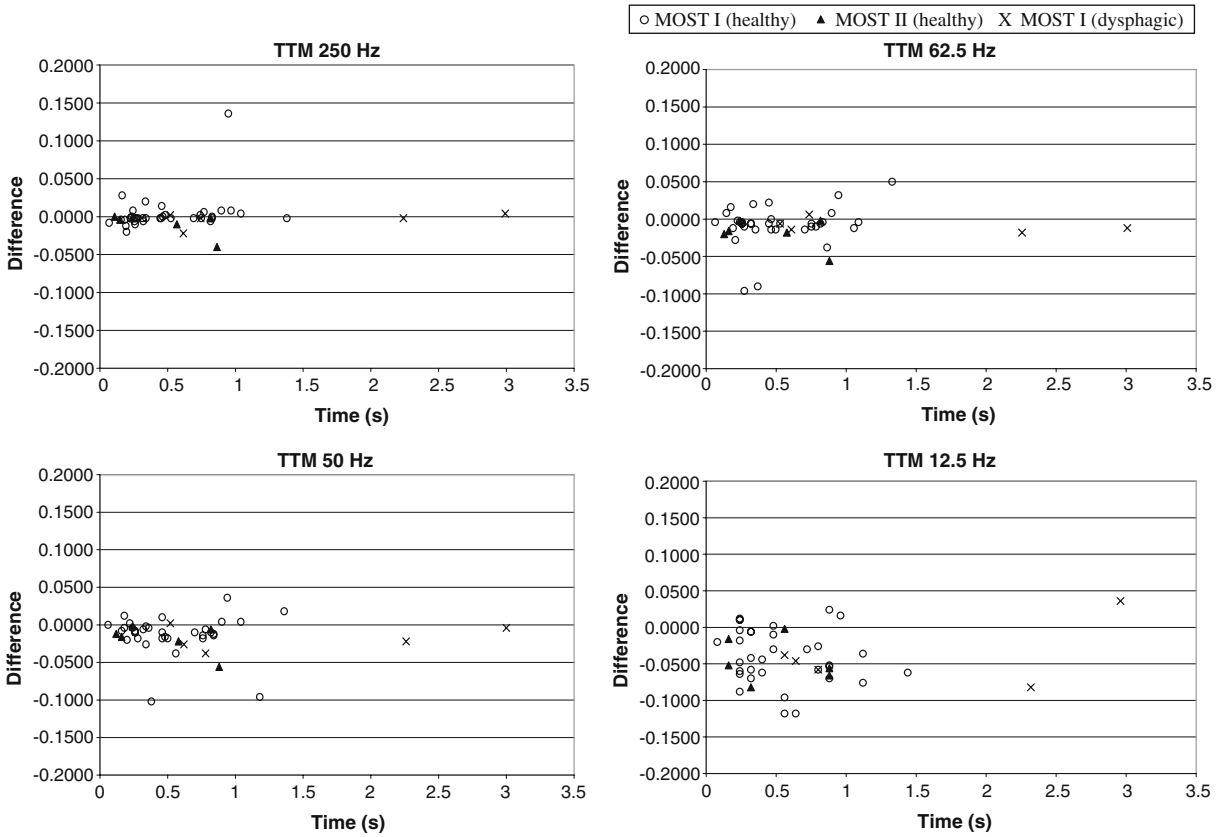

Fig. 7. Difference (Original 500-Hz Data Value – Reduced Sampling Rate Data Value) plots were used to visually assess the time to maximum pressure data, showing that large deviations from the 500-Hz data values began to occur at sampling frequencies less than 50 Hz.

Table 2. Complete average numerical responses from survey questionnaires

		Fitting (1 = dislike)		Comfort (1 = dislike)		Feedback: graphical/ numerical (1 = dislike)		Feedback: adding lights (1 = dislike)		Feedback: adding auditory (1 = dislike)		Daily use (5 = dislike)		Exercise difficult (5 = yes)		Swallow difficult (5 = yes)	
		M1	I	M1	I	M1	I	M1	I	M1	I	M1	I	M1	I	M1	I
MOST I (M1) vs. IOPI (I)																	
Healthy	Avg	3.5	4.2	3.4	4.4	4.8	4.3	3.0	3.1	2.4	2.4	1.8	2.1	2.3	2.5	3.1	2.4
(n = 36)	stdev	0.9	0.8	1.0	0.8	0.4	0.8	1.2	1.2	1.2	1.2	1.1	1.3	1.4	1.5	1.4	1.2
Dysphagic	Avg	2.7	4.3	2.3	4.2	3.8	4.2	4.2	3.8	3.7	3.7	2.5	2.8	2.7	2.7	4.0	3.5
(n = 6)	stdev	1.0	0.8	1.0	1.2	0.8	1.1	1.3	1.8	1.5	1.6	1.4	1.5	2.0	1.0	1.7	1.5
		M1	M2	M1	M2	M1	M2	M1	M2	M1	M2	M1	M2	M1	M2	M1	M2
MOST I (M1) vs. MOST II (M2)																	
Healthy	Avg	3.4	3.4	3.2	3.8	N/A		N/A		N/A		1.3	1.3	2.2	1.7	3.8	3.0
(n = 6)	stdev	1.1	1.1	1.2	0.8							0.8	0.8	1.3	0.8	1.6	1.4

attained using the IOPI instrument (Fig. 8). Pressure values achieved with the smaller MOST II mouthpiece tended to correlate reasonably well with resultant IOPI pressures. However, MOST I maximum pressures tended to be less than the IOPI maximum pressures, regardless of which instrument was used first. This was especially evident in the dysphagic population, which used the IOPI device before using the MOST I. As Table 3 shows, the average difference between the maximum pressure

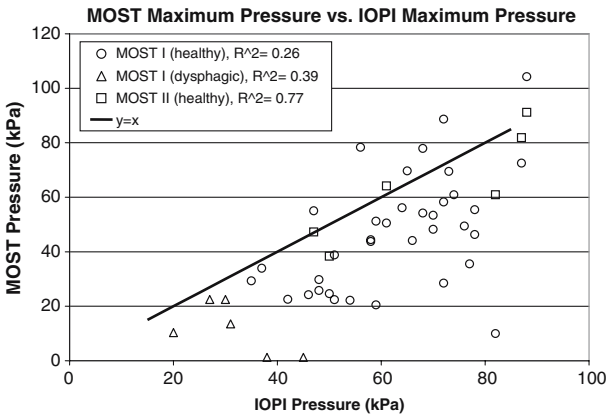

Fig. 8. Subjects' maximum pressure values using the MOST device were plotted against their maximum pressure values attained using the IOPI instruments.

values attained using the MOST device compared to the IOPI for the dysphagic participants was −19.95, or about 20 kPa less than their corresponding IOPI values.

Unexpectedly, two of the six dysphagic patients (dx: (1) frailty, cricopharyngeal hypertonicity, macular degeneration and (2) frailty, esophageal stasis) were unable to complete any exercises on the MOST device, despite having the highest maximum IOPI pressures of the dysphagic group. No fault could be found with the mouthpieces, sensors, or circuitry that would explain the inability to reach a pressure above baseline. It seems that the bulkiness of the MOST I mouthpiece may limit maximal pressure generation. Most participants produced lower maximum pressures on the MOST I than on the IOPI (Fig. 8, Table 3) regardless of which instrument was used first, but maximal pressures from the MOST II correlated better with IOPI pressures ($R^2 = 0.77$). Fatigue may be an issue for the dysphagic participants, who first executed exercises on the IOPI instrument and then often completed a videofluoroscopic swallowing examination or clinical therapy immediately preceding study participation. Another factor may be a loss of oral sensation and inability to locate the sensor on the MOST mouthpiece. If this is the case, the problem might be resolved by adding a textured surface to the areas covering the mouthpiece sensors.

Discussion

Findings from this study indicate that the first-generation MOST prototype will make a positive contribution to existing devices by providing a unique combination of features, including reliable mouth placement, affordability, simplistic user interface, simultaneous data recording from multiple sensors, and timing information (i.e., time to maximum pressure may be calculated). Results indicate that a sampling rate of 62.5 Hz will sufficiently capture detail from isometric exercise data and that a sampling rate as low as 50 Hz may even be suitable. However, as more is learned about pressure generation during swallowing compared with the isometric pressures studied extensively in these trials, the sampling rate may need to be increased. Swallowing pressures invoke more variability than isometric pressures and, therefore, a higher sampling rate may be required to attain appropriate resolution for analyses of swallowing pressure data.

While the normal subjects mainly clarified a preference for a smaller mouthpiece, dysphagic users presented a number of considerations for further device development. Our goal is to address the neurophysiologic needs of the patient with optimal materials and design, because the tongue-strengthening exercises have proven useful for dysphagic patients [6, 7, 14]. The MOST device's usefulness will be optimized by addressing this important interface through redesigning the pressure measurement components, improving upon the materials used for construction, and identifying an optimal combination of biofeedback.

Pressure Components

The current FSR sensor has limited low-range sensitivity and cannot reliably detect subtle changes within the minimal pressure ranges (< 26 kPa) measured in the dysphagic population. This low-end threshold likely arises in part as a result of the polyolefin covering surrounding the mouthpiece, which must first be slightly deformed before any pressure is applied to the sensor. Identification of a more suitable sensor to integrate into the mouthpiece will be pursued along with minimizing any force-absorbing capacities of the mouthpiece covering. Another important modification to the existing MOST prototype will be the incorporation of a microcontroller, which will record the pressure data (and thus compliance with the exercise program for clinical review) and automatically calculate target pressure values.

Materials

The study showed that developing an even smaller version of the MOST II mouthpiece that preferably

Table 3. MOST vs. IOPI maximum pressure differences

	Healthy subjects		Dysphagic subjects	
	MOST I	MOST II	MOST I	Overall
Sample size	36	6	6	42
MOST – IOPI difference[a]				
mean, std dev	−15.54, 18.50	−4.61, 10.37	−19.95, 16.46	−14.72, 17.67
min, max	−72.00, 22.31	−21.07, 3.19	−43.77, −4.51	−72.00, 22.31
MOST – IOPI absolute difference[a]				
mean, std dev	19.86, 13.60	7.13, 8.49	19.95, 16.46	18.28, 13.87
min, max	3.03, 72.00	0.28, 21.07	4.51, 43.77	0.28, 72.00
R^2	0.27	0.77	0.39	0.47

[a] IOPI pressure values were subtracted from MOST pressure values for each participant.

can be custom fit without using dental putty is desirable. Although the dental putty worked well, many participants were not eager to use it because they associated it with negative dental work experiences.

Feedback

Developing an optimal combination of user feedback also merits further research. The majority of healthy participants preferred graphical feedback to the alternatives: numerical values, a series of lights, or a quiet alarm that sounded when the target pressure was reached. However, the dysphagic population preferred numerical feedback. One subject commented that the numerical feedback provided opportunities to set short-term goals so that a pressure increase as small as 1 kPa could be identified and grant a sense of achievement. Other subjects stated that an alarm or some sort of pleasant audio feedback really would be desirable. A participant with poor eyesight noted that audio feedback would be necessary to allow use of the device without any assistance. Another healthy participant commented that an alarm would permit completion of the exercises while doing other household tasks. It seems that an ideal instrument would provide graphical, numerical, and auditory feedbacks if budget and space constraints allowed it.

Availability

As the MOST instrument is still in development, it is not possible to project the cost of the device; however, a goal is to ensure affordability for patients. Ideally, marketable products resulting from this research would be available as premade mouthpieces in several generic sizes. Appropriate materials would be included to allow clinicians to custom fit the mouthpiece to each patient using the 5-min procedure previously described in the Methods section. The mouthpieces could plug into units containing an electrical circuit for data recording and user feedback, which would allow multiple patients to each have their own mouthpiece but share recording equipment. Hospitals and clinics wishing to purchase these recording units could make this type of therapy readily accessible and inexpensive for their patients.

In conclusion, the current work is an important beginning for active rehabilitation of the swallowing mechanism. Patients' interest and enthusiasm toward the exercise protocol and their demonstrated ability and desire to improve their pressure generation clearly indicate that further efforts in this area are warranted. The patients who have successfully increased lingual strength expressed a sense of empowerment and satisfaction. Future work may reveal the more pervasive impact of this tool on the prevention of swallowing disorders through exercise. Seniors willing to lift weights to maintain bone density and muscle tone or walk for cardiovascular gains may find benefit in incorporating tongue exercises into their weekly routine to maintain their swallowing health.

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