The Effects of Repeated Depression on Air-Filled Bulbs Used in Tongue Exercises for Swallowing Problems

Mid-Semester Report

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Team Members

Sarah Reichert: Team Leader
John Byce: Communicator
Katherine Lake: BWIG
Chris Besaw: BSAC

Clients

Dr. JoAnne Robbins
Ms. Jacqueline Hind

Advisor

Professor John Webster

Abstract

Our clients, Dr. JoAnne Robbins and Jacqueline Hind, are specialists in swallowing and geriatrics. They have created an exercise protocol to strengthen lingual muscles in patients with swallowing difficulties and disorders. The regimen incorporates the utilization of an Iowa Oral Performance Instrument and attached air-filled bulbs. Some of their patients have expressed difficulty using the bulbs throughout the eight weeks of exercise. In response, our clients have proposed that we investigate if the bulbs are changing with use, identify the factors causing the change if one is present, and redesign the bulbs to eliminate this change. We have begun testing bulbs used for exercise with consistent compression and force values to determine if the output pressure varies over time. After three weeks of testing we can conclude that a change is occurring because compressing the bulbs to the same extent is yielding lower pressure values. Throughout the remainder of the semester we hope to complete this testing, identify the cause of the change, and redesign the bulbs to correct it.

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Background

Client Description

Dr. JoAnne Robbins is the Associate Director of Research for the Geriatric Research, Education, and Clinical Center (GRECC) at the William S. Middleton Memorial Veterans Hospital in Madison, Wisconsin[1]. Her research focuses on how age-related diseases and normal aging affect swallowing ability. She is also investigating how therapeutic treatments can be incorporated in order to delay or prevent swallowing disorders and the potentially life-threatening effects they can have[2]. Dr. Robbins is a Professor in the Department of Medicine at University of Wisconsin – Madison School of Medicine and Public Health. She is also an Affiliate Professor in the departments of Biomedical Engineering, Radiology, and Nutritional Sciences[1].

Jacqueline Hind is a Board Recognized Specialist in Swallowing and Swallowing Disorders. She serves as an Outreach Program Manager and Coordinator for the Swallowing Speech and Dining Enhancement Program at GRECC. She has been working to treat patients with swallowing disorders for over 15 years[1].

Throughout our clients' careers, they have published work in numerous peer-reviewed journals and patented inventions through the Wisconsin Alumni Research Foundation[1]. Some of their current work pertains to an exercise regimen they developed to help increase lingual muscle strength and improve swallowing ability. Patients undergoing the protocol have been reporting difficulty achieving the appropriate exercise values over the course of the therapy. Consequently, our clients have proposed that we investigate aspects of the device used for the regimen to determine whether or not it is changing as a result of exercise.

Dysphagia

Dysphagia, or difficulty swallowing, is a prevalent and hazardous medical symptom that is detrimental to suffering patients worldwide. An estimated 40% of adults 60 years and older experience symptoms of dysphagia[3]. This harmful condition results from weakened muscles in the tongue and cheek or the inability to begin muscle contraction to initiate swallowing altogether[4]. Underlying causes of muscle weakness are generally age-related sarcopenia or repercussions of prior health conditions, including stroke, Parkinson's disease, cerebral palsy, and head, neck, and esophageal cancer. Various underlying diseases are not only precursors to dysphagia, but they also increase the mortality rate of dysphagia-related conditions. Strokes and Parkinson's disease, for example, have both been perceived to heighten the rate of mortality due to aspiration pneumonia. Pneumonia, resulting from the bacterial growth produced by food or liquid aspirated into the lungs, is the most fatal consequence of dysphagia. This complication is the fifth leading cause of death in adults over 65 years old, and third in adults 85 and older[3]. Other detrimental complications that result from dysphagia include dehydration and malnutrition, which are both induced by the inability to swallow necessary foods and liquids. Extreme discomfort and highly limited diet are also associated with dysphagia.

Current treatments of dysphagia are centered upon prescribed behavioral strategies that minimize risk while increasing swallowing comfort. Among these strategies are dietary modification, thickening of liquids, moistening of dry foods, and reduction of bolus size[3]. Although these prescribed methods can be largely effective in preventing aspiration and increasing comfort, they are unable to improve the swallowing mechanism itself. The human swallow is governed by signaling of the sensorimotor neuronal network and the musculature it ultimately controls[5]. Recent studies conducted by Dr. Robbins have proven that swallowing

function can be improved by strengthening the lingual musculature. Furthermore, these studies prove that lingual strength can directly be improved through repetitive exercise, similar to muscle strengthening exercises commonly executed on extremities. Significant improvements in both isometric lingual pressure and maximum lingual strength can occur in as little as eight weeks of exercise. Increased strength and pressure can, in turn, dramatically improve swallowing ability and reduce risks associated with dysphagia[5]. Lingual exercise regimens are currently executed using lingual pressure sensing systems, such as the Iowa Oral Performance Instrument (IOPI), which provide visual feedback as patients firmly push their tongue to the roof of their mouth.

With an exponentially increasing population of elderly in our nation, the negative effects of already fatal dysphagia-related complications will likely increase dramatically. Further development and implementation of treatments that increase the functionality of the swallow, such as lingual exercise, are pivotal in the prevention of dysphasia symptoms.

The Iowa Oral Performance Instrument (IOPI)

The device used by our clients' patients is called the Iowa Oral Performance Instrument (IOPI), and is shown in Figure 1. This device provides a way to measure lingual strength objectively and gives immediate feedback to the patient and doctor. Tongue strength during tongue elevation, protrusion, and laterally directed movements can be measured as well as lip compression strength and fatigability of the tongue and lip. Tongue strength is measured by pressing the bulb against the palate as hard as possible, resulting in a digital pressure readout on the IOPI. Lip compression strength can be found by placing the bulb between the lips and applying a maximum amount of pressure. Fatigability is calculated by applying 50% of a patient's maximum pressure for as long as possible. The IOPI consists of an electronic system

that contains the controls and also digitally displays the pressure readout in kilopascals. This system contains a set of lights that display the increasing percentages of the maximum pressure.

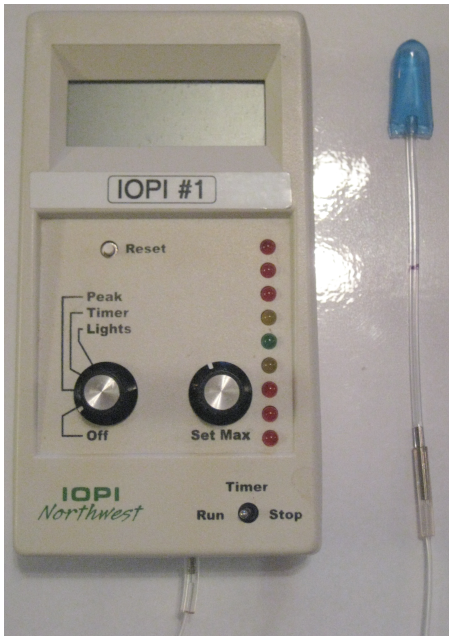

Figure 1: Picture of an IOPI. The air-filled bulb on the right side of the picture is compressed with the tongue, and the measured pressure is displayed by the device on the left side of the picture.

The bulb that is placed in a patient's mouth is made of polyvinyl chloride (PVC) and is attached to the device by clear vinyl tubing[6]. The IOPI is also used in the eight-week exercise regimen that our clients prescribe to their patients. The patients exercise with the device three times per day, three days a week. A single exercise session entails one set of ten repetitions for both the anterior and posterior parts of the tongue. Each repetition consists of pressing the bulb to the palate and holding for three seconds at a particular percentage of the maximum tongue strength. For the first week, the patients exercise at 60% of their maximum, and for the remaining weeks the device is set for 80%.

Bulb Material

The material used in the air-filled bulb attached to the IOPI device is polyvinyl chloride (PVC). PVC has many applications, ranging from medical devices to packaging. PVC is cheap, safe, and durable, which has led to its widespread use. The safety of any product is essential and especially important when it is being used in healthcare, and PVC is one of the safest materials being used today. It is chemically stable, inert, and does not undergo any changes in composition or properties that could end up being dangerous to patients using the plastic[7]. PVC is also durable and resistant to change; it has a maximum temperature usage of around 60 °C, and is resistant to most dilute acids and bases[8]. PVC is, however, permeable to gases, which is a major

concern in the application of pressure readouts on the IOPI device. In order to achieve an accurate reading, there must be a consistent amount of air in the bulb. If there is an air leakage after a certain number of uses, then the pressure readouts could be affected. It has been shown that PVC permeability is strongly dependent of the plasticizer type used in the manufacturing process[9]. The bulbs used in conjunction with the IOPI device are made through a dip casting method, which consists of a mold being coated with a plastic and a particular plastisol and cured[10]. Therefore, using a plastisol with a lower gas permeability could control air leakage.

Current Treatments

Few devices used for an oral exercise regimen currently exist. Our clients currently have their patients use the Iowa Oral Performance Instrument for lingual muscle exercises. The IOPI, as described earlier, utilizes an air-filled bulb attached to a device that measures pressure[6]. When the tongue exerts force on the bulb, a pressure reading is displayed on a handheld device.

The Madison Oral Strengthening Therapeutic Device consists of an oral mouthpiece attached to a handheld device used to measure the force exerted on the mouthpiece[11]. Unlike the IOPI, the Madison Oral Strengthening Therapeutic Device uses a pressure sensor that is able to simultaneously measure pressure exerted in multiple areas within the oral cavity[11]. This device is still under development by our clients and is therefore unavailable for use in lingual strengthening exercises at this time.

Our clients also patented an oral-lever resistance exercise device. The device is comprised of an upper and lower lever attached at a pivot and a resistance element to permit oral exercise[12]. Isotonic and isometric exercises are permitted by the device, and the level of resistance can be altered by changing the resistance element. Suggested resistance elements are elastic bands or springs[12]. See Figure 2 for a detailed drawing of the device. This device is

currently in use by our client, but cannot be used to measure the amount of pressure produced during exercise.

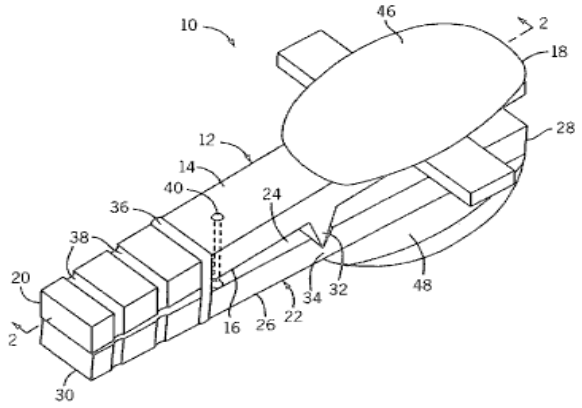

Figure 2: Drawing of an Oral-Lever Resistance Exercise Device[12].
Different elastic bands can be placed around the groves indicated by the numbers 36 and 38 in order to increase or decrease the amount of resistance. The patient then compresses the device by exerting pressure on the surface indicated by number 46.

Problem Motivation

Dysphagia is a condition that affects over six million elderly people in the United States alone, and leads to a drastic decrease in quality of life and, in some cases, death[4]. Difficulty or discomfort while swallowing can lead to a decrease in motivation to eat, loss of weight, or the aspiration of food into the lungs[13]. The average male subject can produce a tongue pressure reading of approximately 65 kPa on the Iowa Oral Performace Device (IOPI), while healthy elderly persons have strengths between 40 and 55 kPa. While there is no clear-cut value that determines whether a person is considered 'weak', any value under 30 kPa has a high probability of needing improvement[6]. There exists a clear correlation between lingual strength and swallowing ability, resulting in various devices and exercise programs to increase the strength of these muscles[14]. Our clients have their patients use the IOPI as part of an eight-week exercise regimen to increase lingual capacities. This regimen consists of connecting the device to a bulb that is placed in the mouth as pressure from the tongue is applied by the patient, giving digitally displayed pressures in kilopascals. Patients have been reporting a decrease in bulb performance after two weeks of use. Our clients have asked us to determine whether this is simply a

psychological belief of the patients or an actual change resulting from an air leakage or change in material properties of the bulb. If a flaw is found to exist, then a design alternative would be proposed for changing either the material used or the manufacturing process with which the bulbs are produced.

Design Requirements

The design requirements governing this project are outlined in the Project Design Specifications in the Appendix, and are explained in detail here. The device must not harm the mouth, tongue, or throat, as it will be placed in the oral cavity between the palate and tongue during exercise. All materials must be non-toxic and comply with the standards of the Food and Drug Administration.

In addition to essential safety requirements, the design must also meet a set of performance standards set forth by our client. The final design of our device should have a life in service of the duration of the exercise regimen, which is eight weeks or approximately 1,500 compressions. The bulb should not change in elasticity or ability to measure force during the exercise regimen. The device must also function at the normal temperature of the oral cavity, 37 °C. In the absence of compression of the plastic or environmental disruptions such as extreme heat (greater than 30 °C), extreme cold (less than 5 °C), or significant humidity (greater than 75%) the product's functionality is not expected to decline.

The device must also provide accurate and precise measurements. Consistent readings are essential so the patient can maintain exercise pressures in accordance with the exercise program. Failure to measure exerted force precisely may result in the patient using an incorrect force to exercise. Failure to use adequate force during exercise could result in a decreased rate of tongue

strength improvement, while excessive force exerted during exercise could cause fatigue or discomfort to the patient.

Ergonomics is a major factor regulating the usability of our device. A large portion of dysphagic patients are geriatric and a significant number have suffered from a stroke or other medical condition. The final device must be easy to control by a patient with below-normal motor functioning. The device should also require minimal set-up and be simple to operate. The device must not require excessive maintenance or re-application once inserted into the oral cavity and displays must be large enough to be clearly read by patients with poor vision. The device must be around 20 mm in diameter to be small enough to fit comfortably within the mouth, but large enough to not pose a significant choking hazard. The device must be lightweight as the user may be weak or easily fatigued.

Design Alternatives

In order to determine the long-term functionality of the air-filled bulb component of the IOPI device, a rigorous testing method was thoroughly planned and enacted. Prior to implementing the chosen test methods, three potential test designs were created and evaluated.

Force Apparatus

The first test was designed to analyze IOPI pressure readings over time while applying a consistent force to the bulb. This test determined if pressure readings on the device differed over time when an air-filled bulb was loaded with a consistent, predetermined force. If the device readings showed a decline in magnitude, a decreased responsiveness of the air-filled bulbs would be present. As show in Figure 3, this test was conducted using an inverted spring scale (intended for weighing mail) that was manually pushed downward onto the air-filled bulbs. Force was

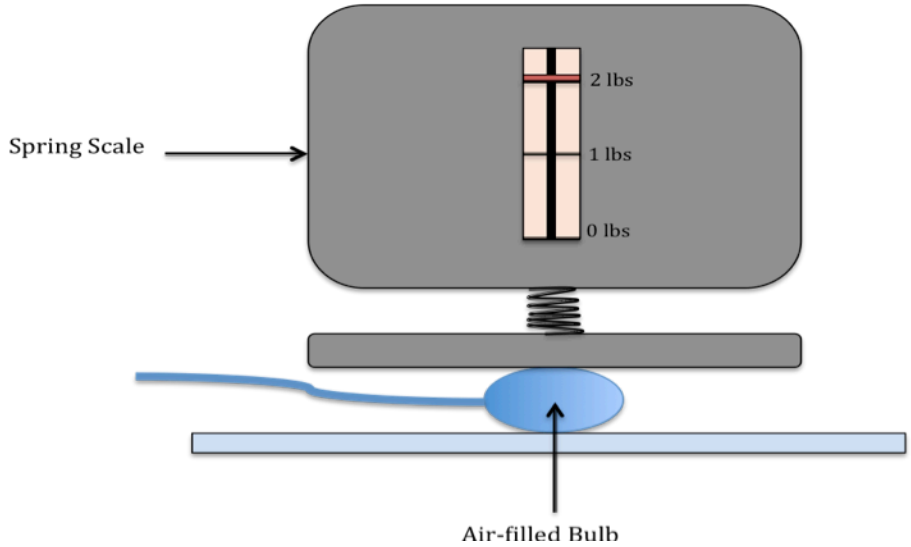

Figure 3: Force Testing Apparatus.
The inverted spring scale is pressed downward on the bulb with 2 lbs of force, and the subsequent pressure reading on the IOPI device is recorded.

applied until the scale reached its desired reading of two pounds. Two pounds was chosen as the compressive force, as it is the highest accurately achievable reading with the spring scale, and also produces a reading that was approximately 50% of the overall lingual maximum. Testing at 50% of the maximum prevents bulb deformation due to many compression repetitions at a near maximum force. Although this method would accurately detect a problem within the electronics or tubing connections, it may not account for small air leakage due to increased permeability or plastic softening over time. In the event of a small air leak or softened plastic, the bulb may be compressed farther by loading a constant two-pound force than it was with a new bulb. Despite this greater compression distance, the two pounds of applied force would likely result in the same pressure reading on the IOPI as a new bulb. This would be misleading, as the reading would suggest no change in the bulb, when in reality the bulb may be compressing different amounts.

Compression Apparatus

The second testing method, a consistent compression apparatus, was designed to account for the complication described above. In compressing the bulb to a fixed displacement rather than with the same amount of force, a leaky or softened bulb would give a lower reading on the IOPI device than a new air-filled bulb. This compression test was conducted using a device commonly used for clamping and stabilizing wood, as shown in Figure 4. This device has two rigid plates, one of which is fixed while the other is adjusted by a rotating handle. As the handle is twisted, the adjustable plate slides along two support rails and moves closer to the fixed plate. In testing, an air-filled bulb was placed between the rigid plates, which were then adjusted to a predetermined separation of 4.75 mm. This separation was sufficiently small to result in visual compression of the bulb. The value of 4.75 mm was used as a predetermined compression displacement, as it was an easily repeatable value that resulted in a similar pressure reading as the force test previously described. A digital calipers was used to measure the separation gap between each rigid plate to ensure the same compression distance was achieved in each trial. Although this test provided insight into how a consistent

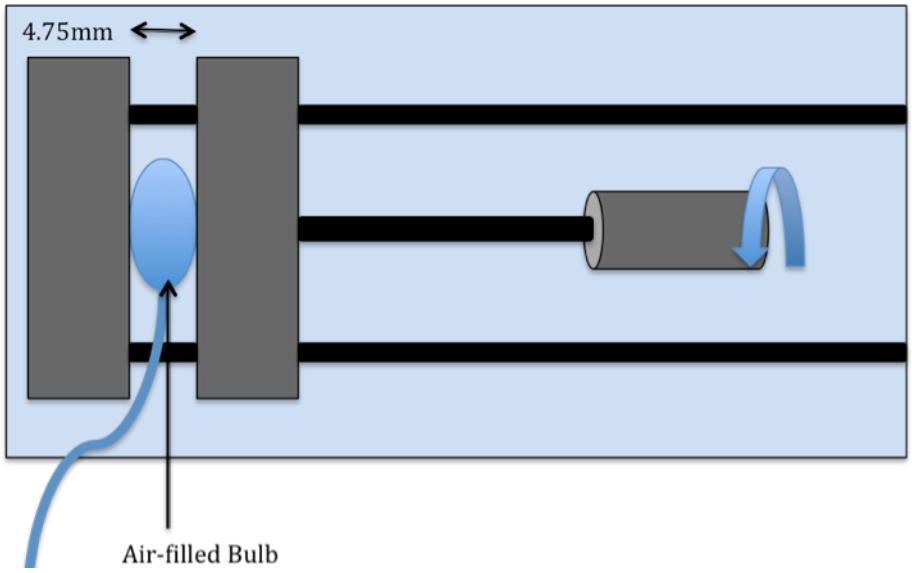

Figure 4: **Compression Testing Apparatus.**
As the knob is twisted the moveable rigid plate slides along the parallel tract towards the fixed plate, compressing the air-filled bulb. The pressure reading that results from compression is then recorded.

compression may change over repeated testing, it did not assess how much force was exerted on the bulb itself.

Instron Electromechanical System

Instron manufacturers a wide assortment of mechanical testing equipment. Its eletromechanical systems can be used to perform tensile or compression force testing on materials in a static state[15]. A control panel or operating computer enables programs to be established and run repeatedly on the machine. See Figure 5 for an image of an Instron electromechanical system. For our testing two flat load cell plates would be interchanged for the hydraulic load cell clamps shown. A bulb would be secured to the lower plate so that it does not shift during the course of data collection. A program would then be set to lower the upper load cell a specified amount in order to perform a compression test. As the load cells compress the bulb a standard distance, they measure the force required to accomplish this compression. The computer then displays the peak force measured during the trial. This process can be repeated numerous times to establish an average peak force value with standard deviation. Because the maximal force exerted on the bulbs by patients' tongues is no more than 45 N (10 lbf), this is the maximum force that we want to achieve during testing. Typical load forces measured by Instron electromechanical machines

Figure 5: Image of an Instron Electromechanical System[15]. This Instron system has two hydraulic load cell clamps that can be used to pinch a material and then pull it to determine how much force is required to break it. For our project, we would replace the hydraulic clamps with two flat load cell plates that could then be used to compress the bulbs to a certain extent and measure the force required to do so.

range from 0.5 kN to 600 kN (112 lbf to 135,000 lbf), meaning that the data obtained from them for our project would be fairly inaccurate[15].

Design Matrix

To determine which tests were most beneficial in assessing the long-term functionality of the air-filled bulbs, a comparative examination of the three proposed methods was conducted with a design matrix, included in Table 1 below. The design matrix provided a quantitative analysis of which test best evaluated the responsiveness of the IOPI bulbs. The five categories used in the design matrix were precision, cost, scope of testing, imitation of clinical use, and variability for experimental conditions. Based on the point breakdown shown below, the constant force with the spring scale method received the largest allotment of points. Due to its limitation in the scope of testing described below, however, we have chosen to pursue testing with both the consistent force and consistent compression methods.

Table 1: Design Matrix
The maximum point values are indicated in parentheses in the row headings. Both the compression and spring scale test methods will be used in proceeding analyses.

	Compression	**Force**	**Instron**
Precision (30)	25	30	10
Cost (10)	8	8	2
Scope of Testing (30)	15	15	25
Imitation of Clinical Use (10)	5	8	4
Variability for Experimental Conditions (20)	12	15	10
Total (100)	**65**	**76**	**51**

Precision

Precision was allotted nearly one third of the 100 points possible, as having a test method that did not produce precise results would be futile. Results and conclusions produced by an imprecise test could potentially be invalid. The first test method, the consistent force test, received a perfect score of 30 points in this category. This high score was based on trial runs using this testing method that produced extremely precise results between successive trials. The second method, consistent compression, had a slightly lower value of 25 points. This test was still sufficiently precise, however it was not as precise as the first testing method in observed trial runs. This largely resulted from human error, as the conduction of the force test was more easily repeatable. The third and final method, the Instron machine, received the lowest value of ten points. This low value is attributed to the limited capabilities of the Instron machines available through the UW-Madison Department of Engineering. The available machines are specialized in heavy, sustained loads and would be largely inaccurate in producing small-order compressions ranging from two to five pounds in numerous repetitions[16].

Cost

Cost of testing, although less important than precision, was still a limiting factor in selecting a testing method for our air-filled bulbs. The consistent force and compression tests received equivalent allotments of eight out of a possible ten points, as both methods were under $20 and were therefore considered to be relatively cheap. The Instron machine, however, would have been more expensive. Despite the use of the machine itself being provided by university faculty, purchasing a specialized load cell capable of the task at hand would have been out of our projects' budget.

Scope of Testing

The third category, scope of testing, was extremely pivotal in the final selection of a test method, and as such was allotted 30 possible points. Scope of testing as a category includes the ability to assess both the force applied to the bulb during each test, as well as the compression distance achieved in each trial. As described in the testing alternatives, both of these categories may be needed to truly assess any defects are present in the air-filled bulbs. The consistent force test solely analyzes force, and the consistent compression test only yields compression results. Because each of these first two methods is only capable of one scope of our desired overall analysis, they each received one half of the possible points. The Instron machine, however, is highly technical and computer-based, allowing both the compression distance and force to be recorded in each trial. This resulted in the Instron machine receiving 25 points in the scope of testing category. Five points were subtracted from the possible 30 for the Instron machine method, as it is incapable of accurately measuring a constant force on a small scale.

Imitation of Clinical Use

Although not as important as some of the previously discussed categories, the ability of each test method to mock the clinical use of the bulbs may have a significant affect on interpreting test results. Out of a possible ten allotted points, the consistent force test received the highest rating of eight points in this category. The consistent force method was allotted the highest score, as it is the only test method that relatively mimics the force loading exerted by the tongue. The exertion of force can be slowly and evenly applied in this method, whereas the other two test options have very rigid mechanical movements that do not represent lingual loading. Secondly, the spring-loaded plate is less rigid that the Instron load cells and the compression apparatus plates. Less rigidity provides a slight yielding that is more representative of the palate

of a human oral cavity. Finally, the Instron machine was assigned a lower value of four points than the compression apparatus, which was given five points, as its movements are most rapid and mechanical, whereas the compression speed can be controlled.

Variability for Experimental Conditions

The fifth and final category used to analyze the proposed testing alternatives was the ability to test different experimental conditions. This category entailed the incorporation of different external conditions into the testing apparatuses with ease and accuracy. Some possible external conditions that will be evaluated include elevated temperature and variable pH. Variable conditions may largely affect bulb function, and testing these conditions may be essential in accurately determining bulb malfunction. Because of its future importance, this category was allotted 20 total points. As the consistent force method only has a one-plate surface it would be most easily incorporated into variable conditions. As a result, this test received a score of 15 points. Conversely, the compression test has two fixed plates necessary for accurate testing. Varying the external environment would thus require modifying one of the apparatus plates to accommodate this change. Because of this slight modification requirement, the compression method was awarded 12 points. The Instron machine would be the least susceptible to modification for variable external environments, as the highly specialized load cells would be more complicated to adjust. This increased complexity may make testing under different conditions less accurate, and led to a score of 10 points.

Exercise Regimen

To test whether the air-filled bulbs are in fact changing as a result of our clients' exercise protocol, two of our members are completing the entire eight-week regimen. We are following

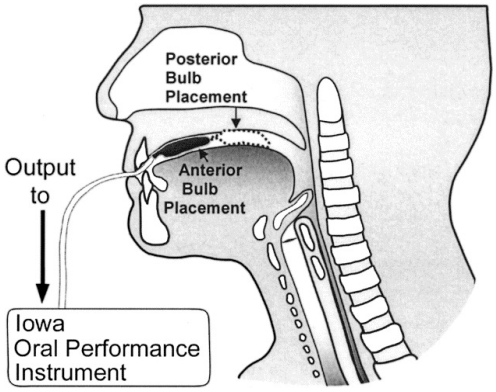

Figure 6: Positions of Air-Filled Bulb[5]. During exercise, one set is completed when ten repetitions are achieved in the anterior position, and ten repetitions are achieved in the posterior position.

the same exercise program that our clients' used in "The Effects of Lingual Exercise in Stroke Patients with Dysphagia". First, each participant had baseline peak pressures measured. This consisted of them performing two sets of three attempts to achieve a peak value in both the anterior and posterior bulb positions as shown in Figure 6[5]. As the protocol calls for the individuals to exercise at 60% of their maximums for the first week, these measurements were then multiplied by a value of 0.60. Similarly, the measurements were multiplied by a value of 0.80 to find the exercise pressures for the second week, when the participants exercised at 80% of their maximums. These values were then doubled so that when the bulb was compressed the proper amount necessary to achieve the exercise value for that week, the central green bulb on the IOPI device would be illuminated. See Figure 1 on page 7 for a picture of an IOPI device and location of the central green bulb in the bulb array.

A week's worth of exercise consisted of three days of three sets of exercises each day. Each set involved executing ten repetitions in both the anterior and posterior positions by compressing the bulb with the tongue until the central green bulb was illuminated. The individual would continue pressing with the same amount of force for three seconds, and then relax the tongue muscle[5]. Exercises were performed after meals to prevent the potential of improper swallowing leading to choking or aspiration due to fatigued lingual muscles.

Every two weeks, the maximum peak pressures will be re-measured. This entails having the participants perform two sets of attempting to achieve a maximum value three times. The measurements obtained will then be multiplied by values of 0.80 and 2, as described earlier, so

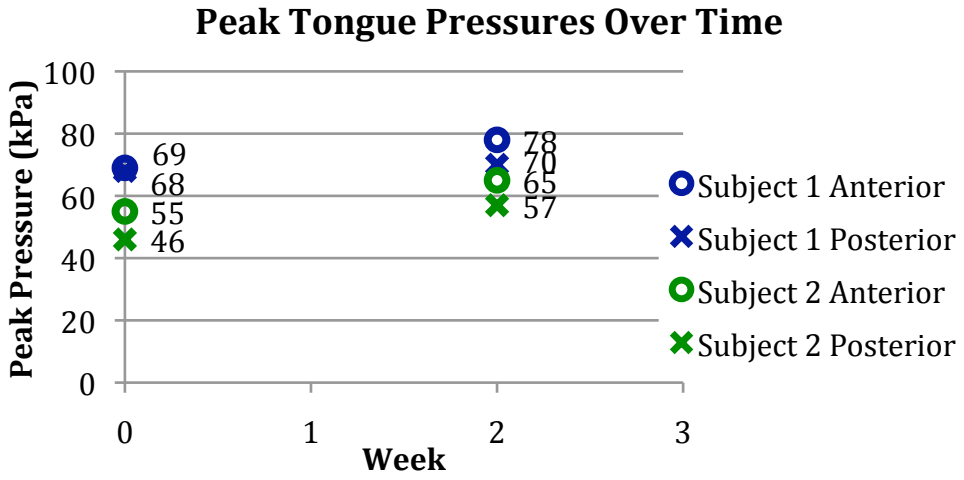

Figure 7: Change in Peak Tongue Pressure Values After 2 Weeks of Exercise.
There is an increasing trend in the measured peak pressure values after 2 weeks of exercise.

that the individuals can continue to exercise at 80% of their new maximums[5]. The results from two weeks of exercise are shown in Figure 7, and the calculated percent increases in peak pressure are listed in Table 2. As indicated by the figure and table, the values increased for both individuals in both positions over the two-week period. This is in accordance with what our clients have found in their past studies[5]. It is expected that these values will continue to increase throughout the remainder of the exercise protocol.

Table 2: Percent Increase in Peak Pressures
After two weeks of exercise, attainable peak pressures in the anterior and posterior positions for both subjects demonstrated an increase in value.

	Anterior	**Posterior**
Subject 1	113.04%	102.94%
Subject 2	118.18%	123.91%

Testing

As previously stated, we decided to pursue both the compression and force testing alternatives in order to obtain the appropriate data necessary to determine if the air-filled bulbs are transforming over the course of the exercise regimen. The resulting pressures obtained by applying a consistent force of 9.8 N (2 lbs) and a consistent compression to 4.75 mm (0.19 in) can be seen in Figure 8 and Figure 9, respectively.

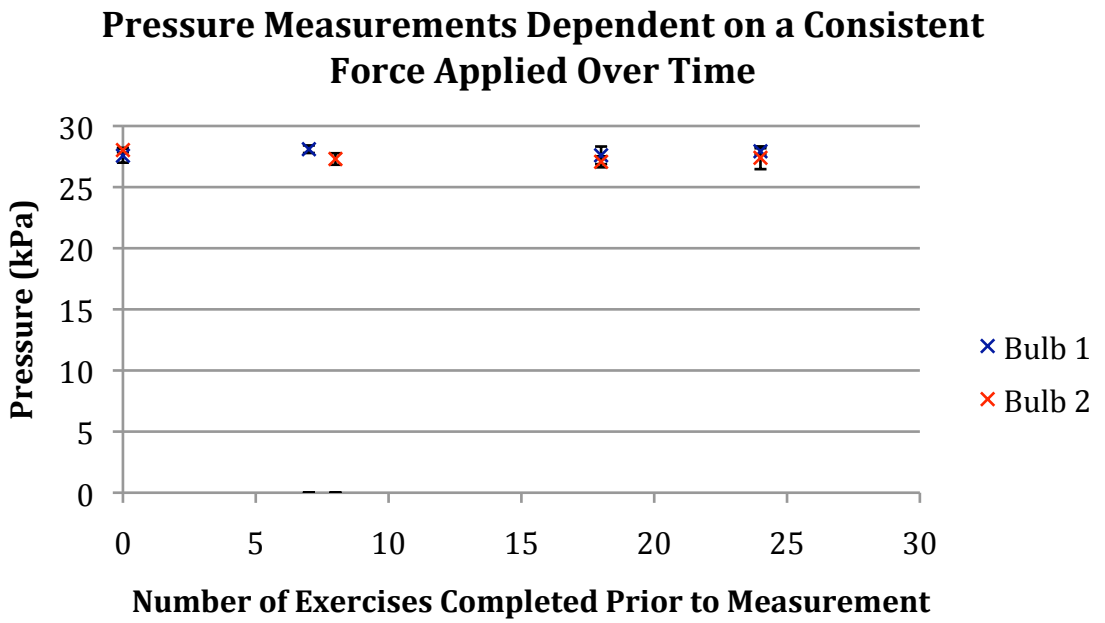

Figure 8: Pressure Due to a Consistent Force Applied Throughout the Exercise Regimen. As shown in the plot, there does not appear to be a significant difference in the pressure produced by the application of a consistent force over the course of the exercise protocol completed thus far.

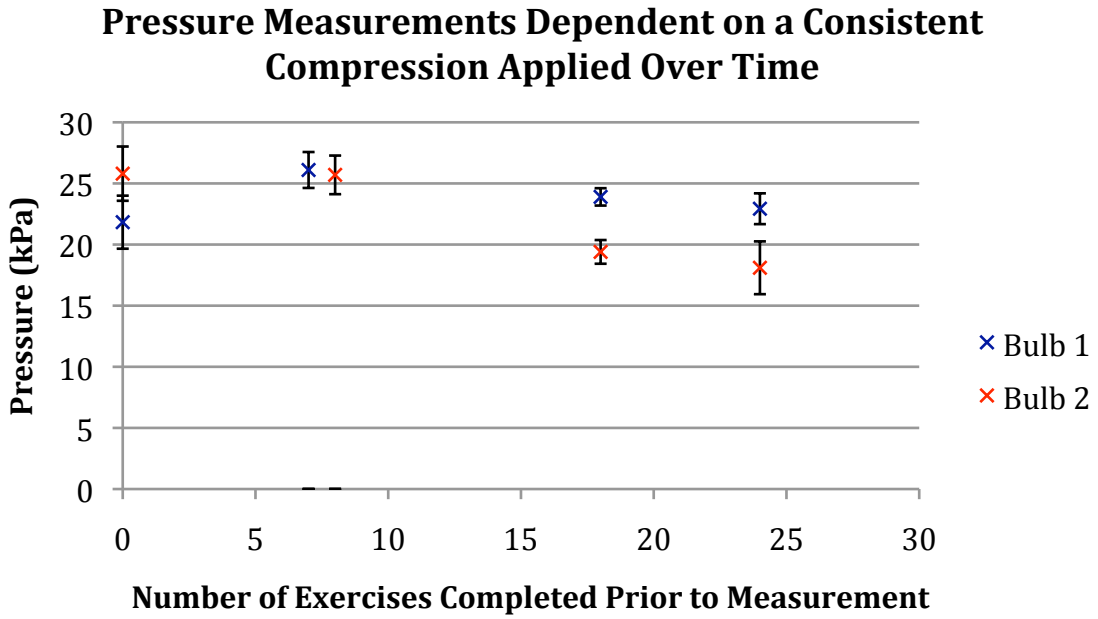

Figure 9: Pressure Due to a Consistent Compression Applied Throughout the Exercise Regimen. As shown in the plot, there appears to be a decrease in the pressure produced by the application of a consistent compression, beginning at the data collected after 18 exercises had been completed prior to measurement.

To determine whether or not the pressure values changed over time, a statistical t test was performed. A t test evaluates if two separate sample averages are equal to one another, a condition known as the null hypothesis. If the null hypothesis is proven true, then any variation between the two samples can be considered as due to random error. However, if the null hypothesis is not proven true, then the two averages are considered to be different, a condition known as the alternative hypothesis[17]. Values of t for the average pressures of bulbs were calculated using the following equation:

$$t = \frac{(\bar{y}_1 - \bar{y}_2) - (\mu_1 - \mu_2)}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}} \quad (1)$$

where y_1 is the average of the first sample (from baseline data), y_2 is the average of the second sample (from data obtained after 24 exercises had been completed), $\mu_1 - \mu_2 = 0$ because the null hypothesis is that the two sample averages are equal, s is the standard deviation of the sample, and n is the number of samples. The number of degrees of freedom in the samples was then calculated using the following equation:

$$\mathrm{df} = \frac{(\mathrm{SE}_1^2 + \mathrm{SE}_2^2)^2}{\mathrm{SE}_1^4/(n_1 - 1) + \mathrm{SE}_2^4/(n_2 - 1)} \text{ with } \mathrm{SE}_{\bar{y}} = \frac{s}{\sqrt{n}}. \quad (2)$$

The calculated degrees of freedom were then rounded down to the nearest tens digit to be compared to values obtained from a Student's t distribution table[17]. The results of applying Equations 1 and 2 to the data collected are shown in Table 3.

Table 3: t Test Values for Bulb Pressure Data.
Equations 1 and 2 were applied to the pressure values obtained from the consistent force and compression tests. t_{table} values were obtained from a Student's t distribution table. The t_{table} values listed are for a confidence level of 95%[17].

	Bulb 1 Force	Bulb 2 Force	Bulb 1 Compression	Bulb 2 Compression
t	1.584	1.822	1.201	6.808
df	30	30	40	50
t_{table}	2.024	2.024	2.021	2.009

If $t < t_{table}$, then the null hypothesis is true. If $t > t_{table}$ then the alternative hypothesis is true[17]. Accordingly, we can be 95% confident that the Bulb 1 and Bulb 2 Force values are the same, and therefore the pressure output by having a consistent force applied to the bulbs does not change over time. At the 95% confidence level the Bulb 2 Compression values are not the same, which implies that applying a consistent compression to the bulbs will cause a change in the amount of pressure produced over time. The fact that this test concludes that we can be 95% confident that the Bulb 1 Compression values are the same is an error due to the fact that baseline values for Bulb 1 Compression were unusually low. This was likely due to an error in the testing (not compressing the bulb completely to 4.75 mm). If compared to values obtained after 7 exercises had been completed instead of the baseline, a difference in the values is found. As we continue the exercise regimen and testing, we expect that the continual decrease in pressure produced by the same amount of compression will compensate for this error and a t test will be able to conclude that the values are not the same.

Future Work

We plan on completing our clients' exercise regimen and our weekly pressure measurements for the air-filled bulbs. Although it has already been proven that some aspect of the bulbs is changing, continuing both of these for the remainder of the eight weeks specified in the protocol will give increasing evidence of this change and provide data to which altered bulbs can be compared to determine if the modifications were beneficial.

Additionally, we would like to test alternative conditions on the air-filled bulbs in an attempt to identify the factor that is necessitating that an increasing compression be applied to achieve the same pressure output over time. Potential factors to be investigated include temperature, moisture, pH, and enzymatic activity of saliva. One bulb will be tested at a control

for each condition, and the other will be tested as the condition is in the oral cavity. Table 4 lists these control and oral cavity conditions.

Table 4: Testing Conditions for Investigating Potential Factors.
Each factor will be tested at the two conditions listed to determine how its condition in the oral cavity affects the air-filled bulbs used in the exercise regimen.

	Temperature	Moisture	pH	Enzymes
Control	20 °C	None	Neutral (7.0)	None
Oral Cavity	37 °C	Moist	5.6-6.9	Saliva

An assessment to determine if the bulbs are leaking air will also be performed. The first way to do this is to simply hold a bulb filled with air under water. If air bubbles are created, it indicates that air is leaking from between one of the connections are directly through the bulb or attaching tub. However, if the leak rate is extremely slow, this test may not be able to detect the leak. Another way to evaluate leakage, regardless of the rate is to perform a helium leak test. The bulbs and their attachments would be enclosed in a vacuum chamber. Air from around the outside is then evacuated and helium gas is pumped into the bulbs. A mass spectrometer with a highly sensitivity can then detect the presence of helium on the outside, indicating a leak is present[18].

Once all of our testing and determination of a causing factor is completed, we will investigate ways to alter the air-filled bulbs. This could consist of changing the material of the bulb or the processes by which they are manufactured. After these modifications are made, we can evaluate their effectiveness by putting them through the same exercise regimen and testing as the current bulbs and compare the results.

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Appendix

Project Design Specifications
October 20, 2010

Group Members: Sarah Reichert, John Byce, Katherine Lake, Chris Besaw

Advisor: Professor John Webster

Function:

Dysphagia, or difficulty swallowing, is a symptom that is experienced by up to 76% of stroke patients and 22% of people 55 years and older. Without treatment, pneumonia, malnutrition, dehydration and airway obstruction can result in patients having higher rates of morbidity and mortality. The Iowa Oral Performance Instrument (IOPI) is a device that has been used in exercises that progressively strengthen the tongue, but it has been reported to have a decreased responsiveness over time. We aspire to determine whether the IOPI bulb undergoes alterations after repeated use and if so, what the cause of these changes are. We will then seek to modify the design of the bulb in order to alleviate these problems.

Client Requirements:

- Alterations should prevent IPOI bulb from changing in elasticity during 8 weeks of use.
- Must be harmless to the tongue, palate, and other interior surfaces of the mouth.
- Must hold up to the standards and regulations of the Food and Drug Administration.

1. Physical and Operational Characteristics

A. **Performance requirements**: This product will need to deliver accurate and consistent results for the entire 8-week duration of the exercise regimen.
B. **Safety**: The product cannot be harmful to the mouth, tongue, or throat, as it will be placed between the palate and tongue during exercise.
C. **Accuracy and Reliability**: Consistent readings from the device are essential, so that the patient can continue exercising in accordance with the program. The bulb must be designed so that there is no pressure loss or material degradation over time.
D. **Life in Service**: The bulb must be usable 60 times a day, 3 days a week, for the 8-week length of the exercise regimen. This amounts to 1,440 uses at 37 °C.
E. **Shelf Life**: The product should be capable of being stored at standard room temperature and pressure for an extended time period. Without compression of the plastic or disruptions from the environment (i.e. extreme heat: >30 °C, extreme cold: <5 °C , or significant humidity >75%) the product's functionality is not expected to decline.
F. **Operating Environment**: The product design must be made to function in the oral cavity of a human patient. A typical oral cavity contains extensive amounts of human saliva, which must not interfere with proper function of the device. The normal temperature of the oral cavity is 37 °C.

G. **Ergonomics**: As a great majority of patients suffering from dysphagia are geriatric and a significant portion have suffered from a stroke or other medical condition, ergonomics is extremely important. The final product must be easy to control by a patient with below-normal motor functioning. The product must also have minimal set-up and be easy to operate. The device must not require excessive maintenance or re-application once it is inserted into the mouth, and it must have displays that are large enough to be clearly read by patients with considerably poor vision.
H. **Size**: The product must be small enough to fit inside the oral cavity of users. Current products on the market are approximately 20 mm, as this size reduces choking hazards while still being small enough to easily operate.
I. **Weight**: The product should be as lightweight as possible without impeding functionality or usability, as the user may be weak or easily fatigued. A heavy product may cause physical strain or discomfort to the user.
J. **Materials**: All of the materials used in this project must be compliant with the standards of the Food and Drug Administration, as this device is designed for use on human subjects. The materials must also be resilient enough to withstand eight weeks of use without changing properties in any way.
K. **Aesthetics, Appearance, and Finish**: The product should be simple to use. Print on the product should be readable to users with vision problems.

2. Production Characteristics

A. **Quantity**: One air-filled bulb will be used for a maximum of eight weeks of exercising.
B. **Target Product Cost**: Current air-filled bulbs are available from $3.50 to $4.00 each, so modified bulbs should be similar in price.

3. Miscellaneous

A. **Standards and Specifications**: The final product will require the approval of the Food and Drug Administration. If the current plastic (polyvinyl chloride, PVC) is used it is already approved for this application.
B. **Customer**: The intended customer is likely to be a stroke or geriatric patient, and will therefore desire a product that is relatively simple to use, comfortable, can effectively improve their ability to swallow, and is reasonably priced. All of these factors must be considered when altering the design of the current device.
C. **Patient-related Concerns**: In order to become available to patients for therapeutic use, our changes to the device must be in compliance with all restrictions enforced by the Food and Drug Administration. It must not be harmful to its user in any way. The final product must also be ergonomic to allow use by unqualified patients.
D. **Competition**: Once it is fully developed, our design could potentially become a competitor to the current bulbs used with the IOPI device. These bulbs are used to measure tongue strength and fatigability via tongue squeezing. They are sold in sealed packages and can be sterilized with cold gas as they are clean but not sterile upon delivery. They cost between $3.50 and $4.00 a piece and are recommended for single use only.