Larynx Model

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Team Members:

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Abstract

The purpose of this project is to develop an electrically controlled larynx model for patient education. We developed a movable plastic and gypsum-based Plaster of Paris framework controlled by motors and cables, with silicone muscles to mimic laryngeal anatomy. Our tests indicate that this model improves comprehension of the larynx anatomy and function by 36%. In the future, we hope to further develop this model by both improving its realism and increasing its movement capabilities.

Table of Contents

Problem Statement

The goal of this project is to develop a physical 3D laryngeal model, with moving laryngeal cartilage, bones, membranes, and muscle to demonstrate nerve and muscle action and interaction in the larynx for voice, airway, and swallowing demonstrations. The model is to be used as a clinical tool for patient education for improved understanding of the laryngeal mechanism, and to plan treatment based on diagnosis of voice, airway, and swallowing disorders.

Background

Problem Motivation

Our client, Sherri Zelazny, is a speech pathologist at the UW-Hospital Voice and Swallowing clinic. Her office currently sees about 500 patients per month. They come to her office for diagnosis and treatment of laryngeal diseases. She helps them understand what is wrong with their larynx and presents a variety of treatment options to them. Working with the patient she then explains rehabilitation exercises via verbal communication and using a static 2x life-size model of the larynx. She would like functional model of the larynx to help her educate and train her patients.

The larynx is part of the body that patients cannot be easily seen in motion, like a bodily extremity can. It is a complicated and intricate instrument which the client says is difficult for her patients to visualize and understand. This lack of concrete patient understanding makes it difficult for our client to guide her patients through the treatment selection process, and treatment education and demonstration process.

The model will also be useful for therapy demonstrations. Our client's patients find comprehending the larynx, along with the treatment exercises, difficult. Thus, the model will be used as clinical tool by our client to both improve her patients' understanding of the larynx, and to help her explain treatment options to patients. The client hopes that with a better understanding, her patients are more likely to complete their treatment exercises and have an overall greater satisfaction with the health care provided (Zelazny interview).

The potential for this model is also something to consider. Functioning models of the larynx and other body parts could be used in a variety of fields and disciplines. Medical school students would benefit from a functioning model. Schools of medicine could purchase these to supplement their student's education; in the 2007-2008 academic year there were 109,294 physicians training in 8,491 different ACGME-accredited programs (ACGME.org). There are countless more students studying for their undergraduate or master's degree in these fields that could benefit from this too. This model could be used for not only speech pathology but also for fields like anesthesiology. Anesthesiologists work around the human larynx multiple times per day in the OR (Tompkins). A model like this could help educate and train the 5,300 anesthesiology medical students currently enrolled (Michalski). The potential for a larynx model is great, and if the same technology could be used to construct functioning models of other body parts, such as a knee for orthopedic medicine, the potential applications would be vast.

Larynx Mechanics

The human larynx, also known as the voice box, is a highly structured instrument in the body. It works through a variety of motions to generate the different pitches and volumes in voice production, known as phonation. This organ is made of cartilage, muscle, and soft tissues, which all work together in phonation, breathing, and swallowing. Hanging just below the hyoid bone in the upper neck, the larynx is located after the pharynx in the respiratory tract and sits atop the trachea (Thibeault interview). Here the vocal folds inside the larynx vibrate as air is exhaled from the body and this generates sound. The vocal folds vibrate at an incredible speed of 100-1000 Hz (Titze). Using six

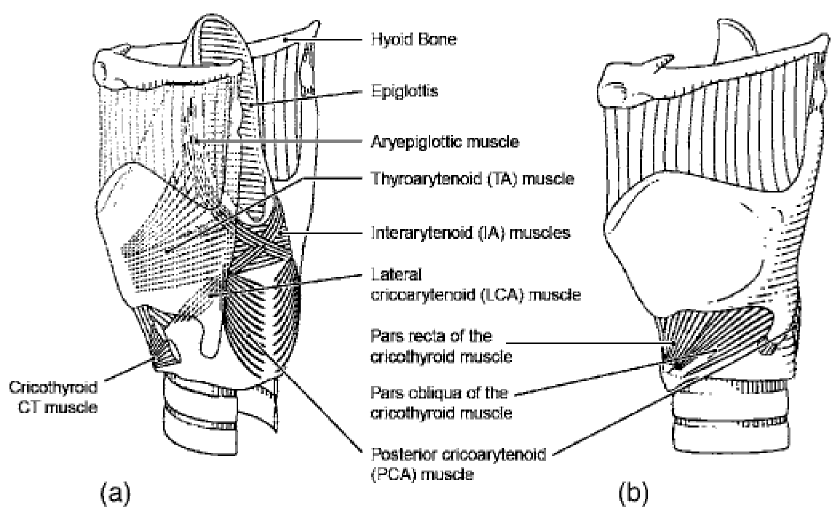

Figure 1: Anatomy of the larynx (Titze)

major muscle groups, the laryngeal cartilages are moved and this causes a manipulation of vocal folds which creates the broad range of vibration speeds. The vocal folds, composed of many layers of soft tissue, are connected to the arytenoid, cricoid, and thyroid cartilages. Cartilage in the larynx is rigid and acts much like bone does. Muscle groups are connected to these and other cartilages, which allow the cartilage to adduct or abduct, closing or opening the vocal folds. Abductor muscles separate the arytenoid cartilages and vocal folds for breathing, while the adductor muscles oppose the abductor muscles to position the arytenoids together for phonation. Vocal folds elongate and tighten with glottal tensors, and shorten and relax by opposing relaxers. This is important in the vocal folds' vibrational behaviors. Two other muscle groups rock the thyroid cartilage back and forth on the cricoid cartilage to elongate and shorten the vocal folds. These muscles are the cricoarytenoid and thyroid muscles; they work as opposing abductors and adductors, respectively, to move the cartilages (Thibeault).

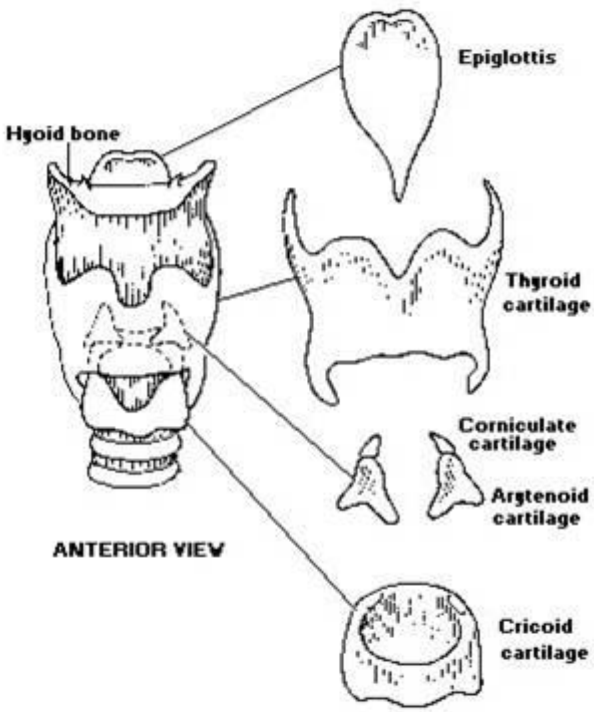

Figure 2: Cartilages of the larynx (Hessney, 2003)

Larynx Diseases and Disorders

Our client sees patients after their larynxes have been damaged, usually by injury or infection. Many things can cause the larynx to improperly function. Symptoms include hoarseness, loss of voice, throat pain, and swallowing difficulties. The client most commonly sees patients with vocal fold paralysis, arytenoid cartilage dislocation, and general vocal fold flexibility loss (Zelazny interview). Vocal fold paralysis can be a result of tissue infections and can affect one (unilateral) or both (bilateral) sides of the larynx. Arytenoid cartilage dislocation is the complete separation of the cartilage from the joint space, resulting from injury or intubation trauma (eMedicine). Loss of vocal fold flexibility creates a symptom of “low pitch” voicing. The patient is unable to elongate the vocal folds, thus cannot produce high frequency vibrations. This disorder is caused by underuse, aging, swelling, and scarring (Thomas). Muscles in the larynx act much like other voluntary muscles in the body and can be repaired through rehabilitation exercises. The client teaches patients how to complete disorder-specific exercises in an effort to help them recover lost laryngeal abilities. If the model could demonstrate these disorders, it would help the patient to understand what is wrong with their larynx and would solidify their comprehension of the rehabilitation exercises the client describes to them. She hopes that this model will aid her in teaching her patients these exercises about these disorders, and wishes for the model to demonstrate these disorders, especially unilateral paralysis.

Competition

Right now, our client uses a static model to educate her patients on the function of the larynx, but a model of that type does not provide an adequate resource. There are a number of flaws in the static models currently available, exemplified by the problems our client has with her model. Although these models offer an accurate representation of the anatomy of the larynx, they don’t offer much insight into the attachment and function of the muscles included. Without the ability to show motion, these models lack a key element for patient education.

Figure 3: A partially movable acrylic cartilage model (Kappa Medical)

Figure 4: A partially movable acrylic cartilage model (APHNT Images)

A slight improvement upon the static model can be seen in the models currently available that offer limited motion. However, these models typically don’t include many of the motions that are essential to understanding the physiology of the larynx. In addition, limited-motion models normally do not include muscles, and therefore do not allow the user to understand what causes the motions achievable with the model. Although these models can mimic the motions that certain cartilages undergo, they cannot offer a realistic representation. Because there is no regulation of the motion when someone pulls on the drawstrings that move the cartilages, there is no guarantee that the speed, range, or timing of the motions is accurate.

Design Specifications

In order to improve upon the flawed models that are currently available, our team, in conjunction with our client, created design specifications to create a more suitable model.

1. **Size:** The model must be at least three times life size
   A magnified model will give a clear view of the anatomy of the larynx, as well as the muscle contractions driving its motions.

2. **Transportability**: The model must be movable by one person without difficulty, preferably under 2.5 kg.

   Our client will need to move the model between rooms in the clinic where she works, and potentially to other buildings for educational purposes.

3. **Anatomy**: The model must include the area spanning from the hyoid bone down to the second tracheal ring. The model must include the motion of the thyroarytenoid, cricothyroid, and interarytenoid muscles.

   These anatomical guidelines ensure that all major parts of the larynx and muscles essential for vocal cord manipulation are included.

4. **Timing**: Each movement must last no less than two seconds per repetition.

   Delaying the timing in such a manner will give the viewer, who may not be well educated in laryngeal physiology, an easy to understand representation of the motions of the larynx. It also guarantees that a clear view of the individual muscles and cartilages that are involved in each motion are visible.

Proposed Designs

To meet these specifications, we developed the following designs:

1. Piezoelectric Circuit System

Piezoelectric material changes its shape and volume when placed in an electric current. This design option uses a piezoelectric material to form the moving muscles in our model (i.e., the cricothyroid, thyroarytenoid, and interarytenoid muscles). In order to have each muscle respond independently, each muscle is integrated into its own circuit, yielding three separate circuits in the model. Each circuit is composed of a voltage source and the respective muscle connected with wires. When the user wants to contract one of the three muscles, the voltage source would be turned on, sending a current through the piezoelectric material. This would change the volume of the material, replicating muscle contraction. In order to return the muscle to its original position, the voltage source would be turned off and the piezoelectric material would return to its original shape, representing muscle relaxation.

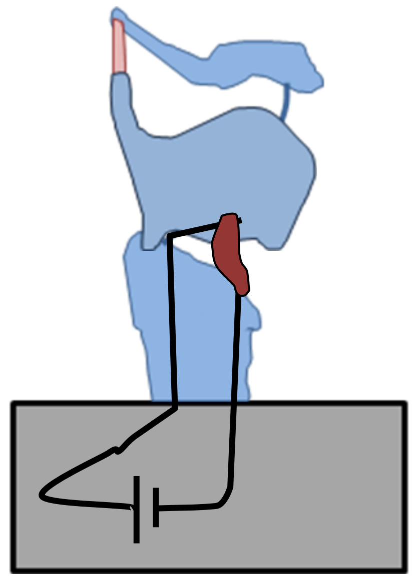

Figure 5: Illustration of the pneumatic actuator system, showing a voltage source connected to the muscle via two wires

2. Pneumatic Actuator System

Pneumatic actuators use an air flow source to change their volume and the volume of materials surrounding them. They can regulate this air flow in order to expand and contract on command. This design option incorporates five separate actuators into the model, with each located inside one of the three muscles being replicated (two of the muscles are bilateral). Each of the muscles would be made of silicone, which

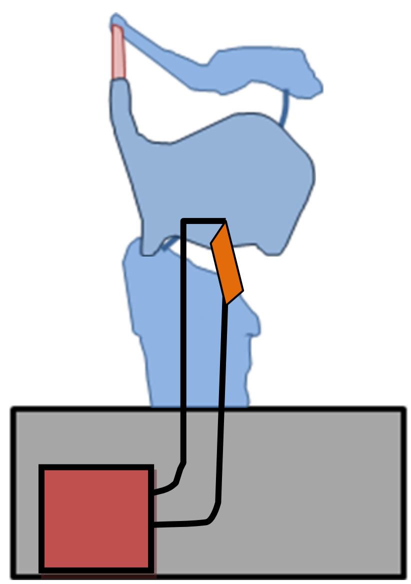

Figure 6: Illustration of the pneumatic actuator system, showing an air controller (air source not shown) connected to the actuator via two air hoses

would stretch or contract when the actuator inside of it expanded or contracted. Activating the actuators with air flowing in one direction would decrease the volume of the actuator and the muscles surrounding it, representing muscle contraction. When the air flow was reversed, the actuator volume would increase, and the volume of the surrounding muscle would return to its original state, representing muscle relaxation. This design would require an airflow source alongside the model at all times in order to function.

Figure 7: A linear pneumatic actuator, with two ports (top and bottom) for air connections (Bimba)

3. Precision Motor System

The precision motor system design uses three reversible electric motors, similar to the motors found in remote control cars, to induce muscle movement in the larynx model. These motors could be activated in both the forward and reverse directions, which is necessary in our model because we need to replicate muscle contractions and relaxations. Attached to each motor axel is flexible wire that is integrated into the inside of a silicone muscle, which is attached between two of the cartilages. When a motor turns in the forward direction, its wire winds around its axel, creating a tensile force within the muscle to which it is attached. This tensile force will pull the respective muscle into its contracted position at which point the motor will be stopped, no longer winding the wire around its axel. In order to return the muscle back to its relaxed position, the motor will be reversed, and natural rubber elastic attached from the solid model base to the muscle's cartilage will provide the tensile force needed to pull the muscle back to the relaxed state.

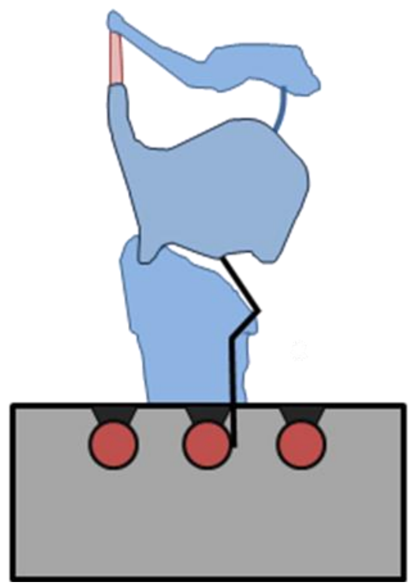

Figure 8: Illustration of the precision motor system, showing a motor connected to the thyroid cartilage via a flexible wire

The motor housing would consist of a box containing three motors (one for each muscle group mimicked). Two of the tracheal rings, the cricoid cartilage, and the hyoid bone would be mounted on top of this. These cartilages would be combined to form a single piece, and would serve as a foundation for the moving thyroid and arytenoid cartilages.

The thyroid and arytenoid cartilages would be held in place with imitation muscles, made from silicone formed around a natural rubber or silicone rubber base. The wires connecting the movable muscles with the motors would be threaded through holes in the cartilages, and would thus be hidden from observers. The entire model would then be covered in a series of colored elastomeric membranes to mimic the membranes in the larynx, and dyed or painted as necessary to make them look realistic.

Design Selection

The three designs were evaluated using a design matrix, which is shown in Table 1. The primary factors considered in evaluating the designs were realism (i.e. how realistically the model mimicked the larynx) and feasibility (i.e. how probable it was that the project could be successfully completed in one semester). Other factors considered included how easy the design would be to operate, how much the design would cost, and how easily the design could be expanded in the future to include other movements and functions.

Table 1: Design Matrix

Design Option	Realism 0.3	Feasibility 0.3	User Friendliness 0.15	Cost 0.1	Durability 0.1	Future Expandability 0.1	Total
Precision Motor	**4** 1.2	**5** 1.5	**4** 0.6	**5** 0.5	**4** 0.4	**5** 0.5	**4.45**
Pneumatic Actuator	**3** 0.9	**3** 0.9	**2** 0.3	**3** 0.3	**4** 0.4	**2** 0.2	**2.9**
Piezoelectric	**5** 1.5	**1** 0.3	**4** 0.6	**1** 0.1	**5** 0.5	**4** 0.4	**3.2**

Despite its realistic appearance and high user friendliness, the piezoelectric system was rejected, primarily due to its high cost. Mere membranes of piezoelectric materials that offered a large enough change in volume (about 20% of their size) cost approximately $75. The feasibility of forming a realistic muscle out of the material was also a concern.

The pneumatic actuator design was also rejected, primarily due to its low user friendliness, high cost, and low expandability. A pneumatic actuator system requires a constant supply of compressed air, which is frequently unavailable in a clinical setting, and could require the operator to carry around a tank of compressed air. The system's high cost stems primarily from the fact that it would require an actuator in each of the movable muscles. Linear pneumatic actuators cost several hundred dollars each, so if more muscles were added to the design in the future, the cost would quickly become prohibitive.

The precision motor system was selected as the final design primarily because of its high realism and feasibility, and its low cost. Electric reversible motors (i.e. stepper motors) can be easily and precisely controlled, allowing for an accurate depiction of the muscle movements. They are also relatively inexpensive, allowing the model to be easily expanded in future semesters.

The Final Design

Materials:

When selecting the materials to use for the larynx model, we took both realistic properties and durability into account. Not only did we want materials that mimicked the respective appearances and properties of the laryngeal components they are replicating, we also wanted materials that would withstand the forces exerted upon them. The laryngeal muscles, vocal chords, connection between the arytenoid cartilages, and connection between the hyoid bone and thyroid cartilage are made of silicone rubber, Platsil Gel-10. This material has properties similar to muscle, and it was painted using acetoxy silicon and fleshy pigments to mimic the muscle appearance. In addition, silicone can stretch and return to its original shape without being deformed; this is necessary to replicate the muscle contractions and relaxations of the larynx. Since the silicone must withstand tensile forces while remaining glued to the plaster cartilage we performed a spring loaded test to find out how much force it would take to either rip the silicone or detach the silicone glue from the plaster. Using a spring scale, a 5¾ lb.force was applied to the end of the silicone not attached to the plaster, the silicone adhesive detached from the plaster. This force is greater than any force that would be applied by the model, so this test proved that the silicone will not rip or become detached from the plaster. As mentioned earlier we used plaster to mold the cartilages and hyoid bone, as the plaster provides structural stability and attachments for the muscles being replicated. For the thyroid cartilage and arytenoid cartilages, we used plastic from the larynx model that we purchased to mold the cartilages. These cartilages were too complex for us to mold, but we proved with our other cartilage moldings that we would be able to produce our own molds with the proper technique. The base of our model which houses the circuitry and motors is constructed of wood because we wanted a stable, weighted base to make the model bottom rather than top heavy. Metal rods attach the hyoid bone to the base and anchor the cricoid cartilage to the base. These rods provide additional structural stability and a means to run 20 lb. fishing line from the motors to the cartilages.

Framework

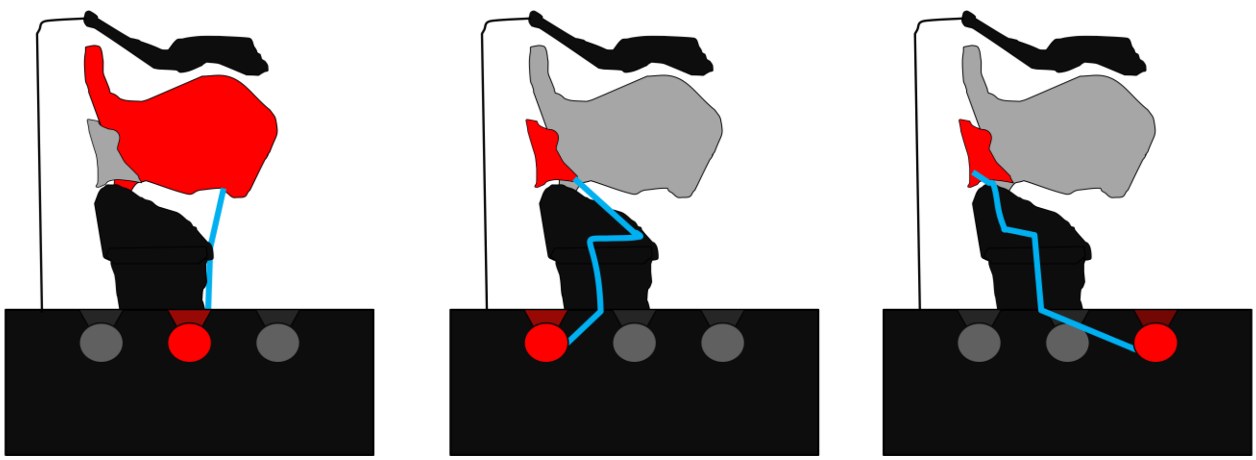

Figure 9: Each motor controls a different muscle group

In the base of the model are three motors, one for each respective muscle movement being replicated. 20 lb. fishing line is attached from the motor axels to the cartilage, and upon activation of the motors a tensile force causes the respective cartilage to move, mimicking muscle contraction. After being contracted, the silicone returns the cartilages back to their original positions, representing muscle relaxation. When the thyroid cartilage rocks forward upon contraction of the cricothyroid muscle, the vocal chords lengthen. When the thyroarytenoid muscle is contracted, the arytenoid cartilages tilt forward, shortening the vocal chords. When the interarytenoid muscle is contracted, the arytenoid cartilages rotate, opening the vocal chords. These muscle contractions and cartilage movements are replicated with our model, with the cricothryoid muscle and thyroid cartilage moving upon motor activation.

The Circuit

The circuit used in this model is shown in Figure 1.

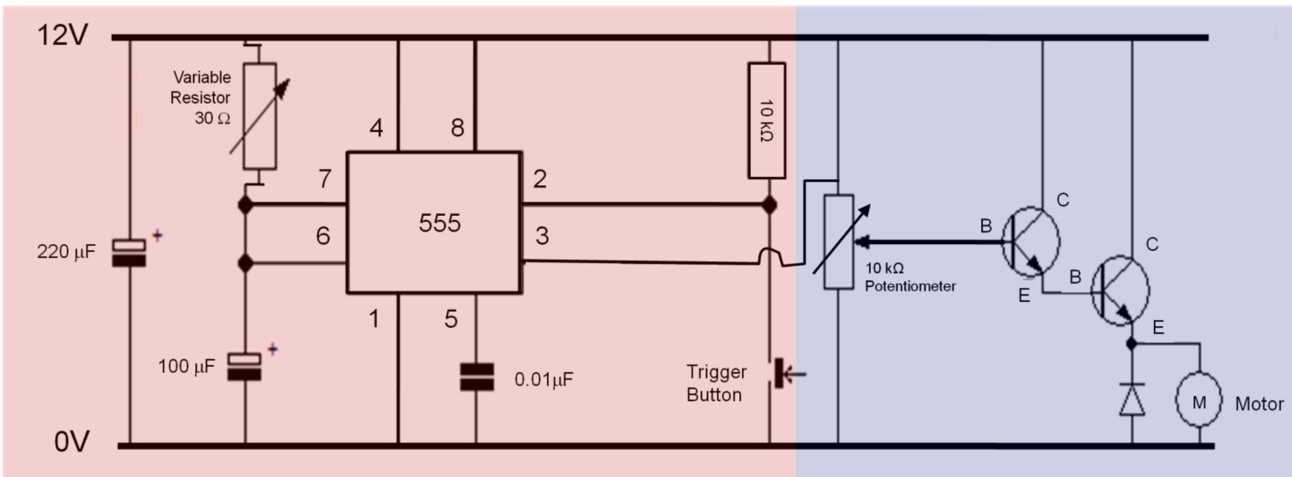

Figure 5: The circuit is divided into two major subsections: the timer circuit (red) and the speed control circuit (blue). The 220 µF capacitor is an optional component to stabilize the source voltage, and was not included in the final circuit.

The purpose of the circuit in this project was to activate a motor for an adjustable period of time (roughly 2 seconds), and then release the motor, allowing it to unwind back to its original position. The motor speed also needed to be adjustable. Thus, the circuit was composed of two major subunits: the timer circuit, and the speed control circuit.

The timer circuit was built with a 555 timer in a monostable conformation, allowing the timer to emit a constant voltage pulse for a selected period of time after being activated by the trigger button. The duration of the output pulse is determined by the resistor and capacitor connected to pins 6 and 7 of the timer, and is governed by the following equation:

$$T = 1.1 \cdot R \cdot C$$

In the above equation, T is the pulse duration in seconds, R is the resistance in Ohms, and C is the capacitance in Farads. Thus, for a pulse duration between 3.3 and 2.2 seconds, a capacitance of 100 μF and a variable resistance between 20 and 30 kΩ were selected. The pulse duration could easily be reduced to values around 1 second by reducing the variable resistance to between 10 and 20 kΩ̃

Although the timer circuit supplies a constant 12 V pulse, it isn't able to supply enough current to drive the motor, which requires up to 1.98 A. Thus, we needed a circuit which would be activated by the voltage pulse, and would immediately turn off when the voltage pulse ended. Transistors seemed ideal for this function because they regulate current flow, and can be controlled by fairly small input currents.

When a single transistor was used, the timer couldn't supply enough current to sufficiently activate the transistor. Thus, the single transistor was replaced with two transistors set up in a Darlington pair configuration. In this setup, the timer activated a transistor which in turn activated another transistor. This double activation sufficiently activated the second transistor to supply enough current to drive the motor.

One problem created by the transistor setup was that the transistors drew all of the current that the timer could supply, which both altered the pulse duration and overloaded the timer, causing several timers to explode. Thus, a circuit component was needed which would limit the timer's current output. This component would also need to be adjustable to allow the motor speed to be adjusted—the motors couldn't be adequately controlled by placing resistors in series with them because their high current demands would cause the resistors to generate an unacceptable high amount of heat.

The first current regulation option attempted was a 10 to 30 kΩ resistor placed between the timer and the transistors worked, but this setup had a very narrow range of resistances which would work, making the motor speed difficult to control. Thus, a 1 kΩ potentiometer was used instead. This allowed more precise control over the voltage supplied to the transistors, which in turn allowed more precise control over motor speed.

Thus, a circuit was successfully created which allows a user to push a button to activate a motor at an adjustable speed for an adjustable period of time.

Testing

The purpose of the larynx model is to educate patients about the different functions of the muscles in the larynx, so to test the effectiveness of our model vs. the effectiveness of the static model our client was already using, we decided to give random groups of people a presentation about the different muscles and their functions, and then test to see how much of the presentation they comprehended. The test is included with this report in appendix 1. The following four groups of people were tested:

1. Baseline—no presentation
2. Static Model
3. Our Model Without Movement
4. Our Model With Movement

Each group (with the exception of the baseline group) was given a brief 2-3 minute presentation with all the information they would need to answer the test question and this was supplemented with whichever model was being tested. The participants were then allowed to use that model for reference while they took the test. We allowed them to reference the models while taking the tests because we wanted to test their ability to understand, rather than memorize, laryngeal functions.

The test results are shown in graph 1 and table 2. Our results indicate that the static model doesn't provide a statistically significant increase over baseline ($p=.135$). This conclusion is important to reinforce the motivation for this project, that the current means are inadequate. Although there isn't a statistically significant difference between our model with and without movement ($p=.136$), there is a statistically significant difference between the static model and our model with and without movement ($p=1.98E-5$ and $p=4.79E-4$, respectively). This shows that our model does a superior job in helping to educate patients in functions and the anatomy of the larynx.

Graph 1: Test scores for each of the four groups tested, with standard error shown in the error bars.

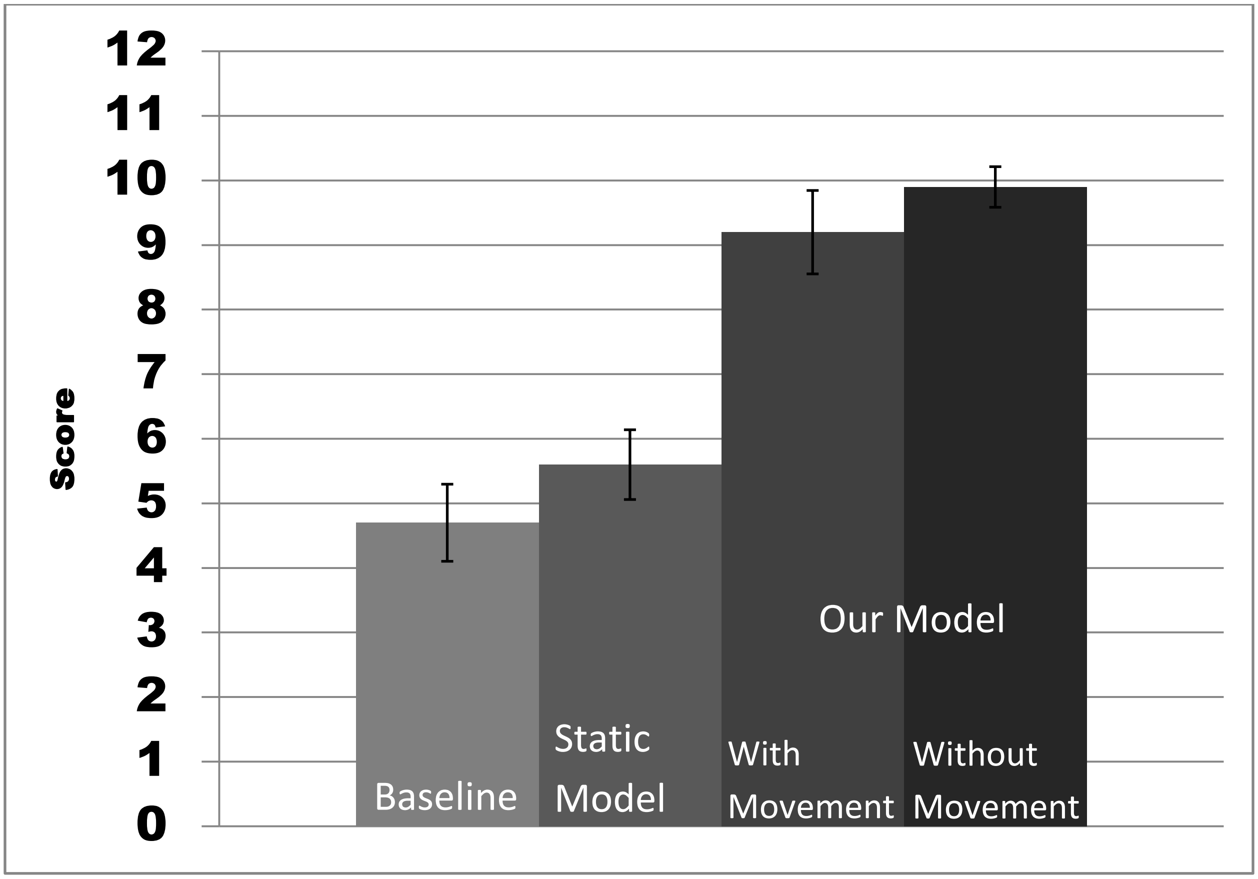

Table 2: Test scores

Group	Average Score	Standard Deviation
Baseline	4.7	1.89
Static Model	5.6	1.71
Our Model Without Movement	9.2	2.04
Our Model With Movement	9.9	0.994

To prevent the test results from being skewed by people listening for the answers to the test questions, no one was tested twice, or was allowed to review the test before hearing the presentation. The presentations were all given by the same person, to prevent the results from being skewed by differences in presenter teaching abilities. Unfortunately, this tactic also introduces the possibility of bias error. Presenters tend to teach better when they want their students to succeed, our presenter, a member of our team, wanted the students taught with our model to succeed in answering the quiz question. Thus, it is possible that with an impartial presenter test results can be viewed as completely conclusive. Despite this problem, our results so strongly support our model as the most effective that it is unlikely that presenter bias had a major impact.

Several other factors need to be tested before our results can be confirmed as conclusive. The first factor is a labeling factor; our model had labeled components, but the static model didn't. This may have skewed our results in favor of our model, as people given our model for reference could more easily answer anatomy-related questions. Thus, another two tests should be done, one in which a static model with labeled components is used, and another in which our model without labeled components is used. This would give a better indication of how labeling affects comprehension.

Another problem encountered during testing was the model's movement capabilities; several circuit components were unavailable to us during the testing period, so the arytenoids were moved by pulling on the strings, which run through the base, by hand. While this is a good approximation of the movement that would be given by the motors, the test should be repeated when the circuit components are added to ensure that the approximation was a good one.

One potential problem shown in the test results is the relatively insignificant difference between our model with and without movement. It almost seems from the test results that the movement capabilities aren't a necessary component of the model. Though this may be true for the three muscles we mimicked this semester, we predict that when more complicated muscles are added to the model, and more coordinated movements are displayed, the ability to see the movements will be much more important than it currently is.

Thus, although more testing should be done to confirm our results, our tests indicate that our model is a more effective teaching tool than the static model our client currently uses, increasing comprehension of laryngeal function by an average of 36%.

Future Work

In order to improve upon our current design, we have decided to focus upon creating a more accurate representation of laryngeal motion. To do this, we plan to fine-tune our circuits and motors in order to create a more realistic motion when each muscle contracts. This will give the viewer a less misleading depiction of the interactions between the cartilages and vocal folds as each muscle manipulates them. Variables included in this category include the timing and length of each contraction. Next, we plan to add more muscles and tissues to the model in order to account for pieces that up to this point may not contribute significantly, but may play a larger role as the scope of the model expands. Finally, we would like to include more complex movements such as swallowing and demonstrations of the effects of laryngeal disorders such as paralysis. These motions would involve the coordination of multiple muscles at once, and would greatly increase the complexity of the mechanics of the model, but would be immensely useful for the education of patients who are suffering from conditions affecting the motion of certain parts of the larynx.

Conclusion

In conclusion, we successfully developed a larynx model that can demonstrate the movements of the thyroarytenoid, interarytenoid, and thyrcricoid muscles. Our tests indicate that this model improves comprehension of these muscles' location and function by 36%. In the future, we hope to expend our project to include more complex muscles and movements, demonstrating movements like swallowing, and include disorders such as partial paralysis.

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Larynx Model Survey

Answer with one of the following: IA TA CT

Muscle function

1. What muscle causes rotation of the arytenoid cartilages? ______________________
2. What muscle causes rocking of the arytenoid cartilages? _______________________
3. What muscle tilts the thyroid cartilage forward? _____________________________
4. What muscle connects the thyroid to the cricoids cartilage? ____________________
5. What muscle is responsible for lengthening the vocal chords?___________________
6. What muscle is responsible for shortening the vocal chords?____________________
7. What muscle is responsible for opening the vocal chords? ______________________

Muscle Location

8. What muscle connects the thyroid to the arytenoids? _________________________
9. What muscle connects the arytenoid cartilages together? ______________________

Cartilage: Answer with one of the following: Thyroid, Cricoid, Arytenoid

10. What cartilage tilts forward, lengthening the vocal chords?______________________
11. What cartilage is stationary, providing structure and stability?___________________
12. What cartilage rotates and rocks forward, opening and shortening the vocal chords, respectively?______________________

The Product Design Specifications (5/12/08)

Larynx Model

Team Members: Jonathan Meyer, Kevin Hanson, Nick Ladwig, Kenny Roggow

Function:

The goal of this project is to develop a physical 3D laryngeal model, with moving laryngeal cartilage, bones, membranes and muscle, to demonstrate nerve/muscle action and interaction in the larynx for voice, airway, and swallowing. The model is to be used as a clinical tool for patient education for improved understanding of the laryngeal mechanism; and to plan treatment based on diagnosis of voice, airway, and/or swallowing disorder. The goal for the current semester is to develop a model that will demonstrate the function of the cricothyroid, thyroarytenoid, and interarytenoid muscles in vocal fold adduction, abduction, and elongation.

Client Requirements:

- The model must be 3x scale or greater

- The model needs to be light enough and small enough for one person to easily move it.
- The model must contain the section of the larynx spanning from the hyoid bone to the first 2 tracheal rings and show soft tissues, major muscles, bone, and cartilage.
- The model must show movement of the larynx opening and closing, and the elongation of the vocal folds
- Each of the movements should take no less than 2 seconds

Design Requirements:

1. **Physical and Operational Characteristics**
    a. *Performance requirements:*
    The model must demonstrate the function of the muscles and cartilage in the larynx during both normal function and partial paralysis. The motion should be automated, and should not require human force to drive it. It should allow the user to see the mechanism of the movement of the larynx, not just the motion, to allow for explanations of the cause of paralysis and the problems it causes.

    b. *Safety:*
    The model must not have any small, detachable parts that could become hazardous if a small child is left in vicinity of the product. Moving parts should be shielded so that fingers, hair, etc cannot be caught in them.

    c. *Accuracy and Reliability:*

The model should be proportionate to the human larynx.

d. *Life in Service:*
The model will be used potentially daily for education of patients, for as long as is necessary each time. It must be able to travel throughout hospital or to another area for educational use.

e. Shelf Life:
The model should be kept clean, through periodic cleaning to minimize dust build up. Also will need to have some sort of power source, to be determined as of right now.

f. *Operating Environment:*
Temperature range: must function at room temperature (20-30°C), and be able to withstand winter temperatures without damage (as low as -10°C). Humidity: must withstand normal indoor humidity (40% to 60%). Dirt or dust: must be undamaged by dirt or dust accumulation from periods of nonuse or handling with dirty hands, and must be easily cleanable. Corrosion from fluids/handling: must be able to withstand frequent handling and gentle rubbing without damage to its structure or finish. Noise: must be quiet, so that it doesn't interfere with a conversation. Operators: The device is to be designed for operation by medical and educational personnel. Durability: must be able to be dropped from 3 ft. onto carpet without breaking. Life span: must last ten years with only minor repair (i.e. motor repair and repainting).

g. Ergonomics:
The movement of the cartilages and vocal cords must not damage (i.e. cut or pinch) the operator's fingers.

h. *Size:*
The size of the larynx portion of the model should be 33 x 14 x 16cm, mounted on a box no larger than 25 x 25 x 16 cm (specific sizes of the individual cartilages will be added when the plastic model arrives).

The model must be transported without difficulty from room to room by one adult. It must be easily stored either as a countertop display or in a box for long term storage or shipping.

i. *Weight*:
The product must weigh less than 2.5 kg.

j. *Materials*:
Bone and cartilage: Polycarbonate, or a comparable thermoplastic. Muscle: made from silicone formed around a wire or natural rubber core. Membrane: a durable, colorable elastomer

k. *Aesthetics*, *Appearance, and Finish*:

The final model should look like a genuine human larynx, with the soft tissues tinted red, the focal folds tinted white, and the trachea tinted blue-gray.

2. Production Characteristics

a. *Quantity*

One prototype for use by our client. Further production of additional models will be determined by the client.

b. *Target Product Cost:*

The model should have a production cost of less than $1000.00

3. Miscellaneous

a. *Standards and Specifications:*
The larynx model is to be produced solely for one client, not mass produced, and thus does not require FDA approval. The model will be handled by both the client and patient, and will need to be safe for direct contact with skin.

b. *Customer*:
The model should be large enough to demonstrate the function of the larynx, but small and light enough to be easily moved and held with one hand. The model should be relatively odorless and non-distracting for both client and patients. The preliminary model should be able to demonstrate larynx function with human application, in the future a remote control is preferred in order to operate the model.

c. Patient –related concerns:
The model will mainly be handled by the client, and potentially by patients as well. Thus, it should be cleaned regularly (once a day) to prevent the spreading of germs. The model should not contain any sharp or harmful elements since it will be handled directly by the client and patient.

d. Competition:
The client currently owns a hard larynx model with separate parts that does not effectively demonstrate the function of the larynx. There are hard models on the market that demonstrate epiglottis and cartilage movement but not to the extent desired by the client. Models demonstrating laryngeal vocal fold movement could not be found. Prices generally range from $100 to $500 for a single larynx model unit.