Transnasal Endoscopic Model

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Abstract

Patients with throat problems often undergo transnasal endoscopies to assist with their diagnosis. Usually, the clinician performing the procedure is experienced; however, experience is gained through practice. Currently clinicians train on each other, volunteers, or the patients, which may be very uncomfortable for both the clinician and the patient if it is the first time. The goal of the project is to create an anatomical model for training. Four different aspects of the model were conceptualized and evaluated: exterior structure, "no-touch" zones, turbinate pressure sensing, and data processing. The current model incorporates a mannequin head, a fluid pressure system, and microswitches to simulate a human head. Future work includes improving aesthetics, improving sensitivity of the "no-touch" regions, and obtaining a portable pressure transducer for turbinate feedback.

Background

Current Method

Clinicians use transnasal endoscopy to observe and evaluate the health of the vocal cords, larynx, and other throat structures. In the procedure, a flexible endoscope (see Figure 1) is inserted into the nose and maneuvered through the nasal passage to look at those structures. If the clinician lacks fine motor control with the scope, he or she may cause pain.

Figure 1. Flexible transnasal endoscope [1]

Figure 2 shows path of the endoscope through the nasal passages and upper throat region. The clinician enters the scope through one of the patient's nostrils. With the endoscope's controls, the clinician maneuvers the tip through the nasal passage between bone shelves covered in tissue called turbinates. After the nasal cavity, the scope is pointed downwards illuminating the upper regions of the throat, including the tongue base and vocal cords (see Figure 3).

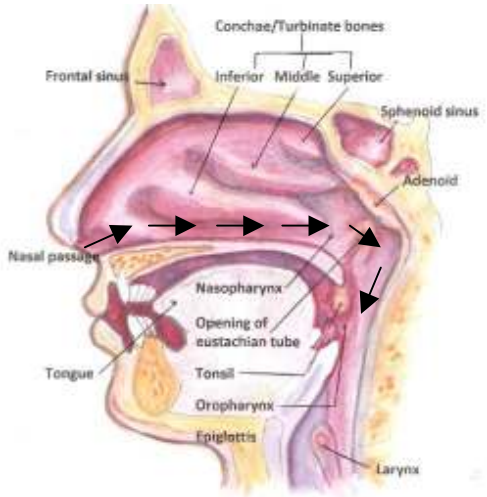

Figure 2. Anatomy of the head showing the nasal and throat passages. The arrows depict the path that the scope takes during the procedure. [2]

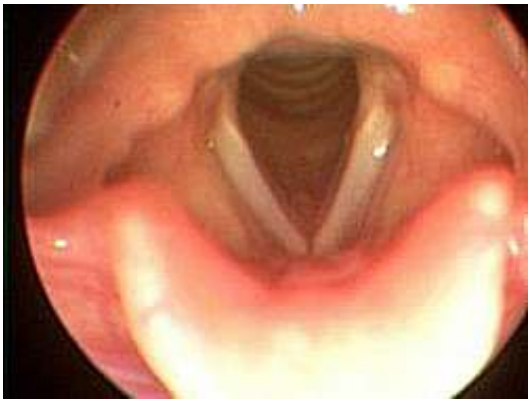

Figure 3. Endoscopic view of vocal cords and throat structures [3]

Motivation

The client is a clinician that works with singers and voice actors, and therefore has experience using the scope. Although he is competent with the procedure, it is difficult for other speech pathologists to receive tailored endoscopy training. Few medical conferences offer training, so speech pathologists are trained by physicians or colleagues. This training uses human volunteers, imposing unnecessary risk and pain. An inexperienced endoscopist may accidentally hit sensitive regions such as the larynx or tongue base. Touching the tongue base with the scope may cause the patient to gag while larynx contact may cause the patient to choke. Similarly, excessive force or a rapid pressure change on the turbinates causes sharp pain in the nasal passage.

A survey of 15 skilled speech pathologists claimed they performed between 20 and 50 procedures before being competent and comfortable. The human subjects for these trials were composed of mostly other clinicians, volunteers or patients. A physical training model allows professionals to be trained without the risks associated with using human subjects. Flexibility and convenience of training are also improved by using a model since supervision and human subjects are not required.

Throughout the years, medical education has relied on use of physical models to train new clinicians. Starting in the 1970s, a simulator known today as SIM man has enhanced to medical education allowing students to learn procedures and their complications on a simulator rather than a living human (Cooper). Borrowing the same idea of the SIM man, a model of the nasal passageway and the larynx can assist in transnasal endoscopy training. Although a physical model does not simulate the anatomy of every patient, basic procedural skills and enhanced hand/eye coordination can be attained prior to performing procedures on human subjects.

Problem Statement

The goal of this project is to create an effective anatomical model for transnasal endoscopy that provides feedback to the trainee. This feedback coincides with action that would cause unnecessary pain or discomfort to the patient, interrupting the exam. *In vivo* contact with these structures may cause a gagging or choking response. The model must be able to determine contact with "no-touch" regions: the tongue base and posterior pharyngeal wall. Additionally, the model must be capable of sensing rapid pressure changes possibly experienced by the turbinates as the scope passes through the nasal passageway. To train effectively, the model must not damage the endoscope.

Design Requirements

The endoscopic model must adhere to the following criteria, as well as the guidelines presented in the Product Design Specification (see appendix):

1. Accurately model the nasal passages and larynx
2. Detect rapid pressure changes on the turbinates
3. Detect contact on the "no-touch" zones
4. Have materials with similar compliance to those of the natural tissue structures
5. No potential damage to the endoscope
6. Cost of prototype is less than $3000

Design Alternatives

The model was broken down into the following components to analyze alternative approaches: physical structures, "no-touch" mechanism, turbinate pressure sensing and data processing. Physical structures involve constructing model exterior and anatomical structures inside to provide a realistic simulation. "No-touch" mechanism refers to the ability to detect contact with the tongue base and posterior pharyngeal wall. Pressure sensing is used to detect rapid changes in applied pressure on the turbinates. Finally, data processing is needed to interpret these pressure measurements to give valuable feedback.

Exterior Structure

The model requires anatomical landmarks to acclimate trainees to the procedure. There were three options considered for the exterior structure: adapting existing physical models, designing the whole model, or using a mannequin head. Anatomically correct models of the nasal passages and larynx are available and could be modified to house feedback mechanisms. However, since the real structures are so small, most models are made at a magnified scale. The other options for the model's exterior are to fabricate a custom frame or to suspend the structures inside a mannequin head.

"No-Touch" Zones

If the endoscope comes into contact with tongue base or posterior pharyngeal wall, panic, choking or vomiting can be induced. Since it is extremely important the endoscopist avoid these structures, a system to detect contact with our "no-touch" structures is required. Two alternatives were considered to address this issue: a system modeled after the popular board game "Operation" or use of shingles with switches.

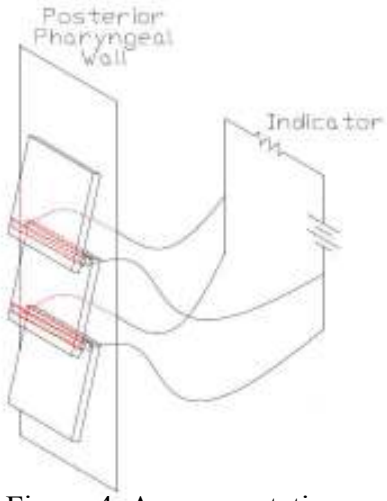

Figure 4. A representation of the shingle-switch

The first design is to affix a metal wire to the end of the scope and make the sensitive structures out of metal. An open circuit is created with these components in series with a buzzer and battery. When the metal wire on the scope tip touches the sensitive structures, the circuit is complete and the buzzer sounds.

The shingle-switch design uses small plates on top of switches (see Figure 4). When the scope touches any of the plates, the switch activates and the buzzer sounds.

Turbinate Pressure Sensing

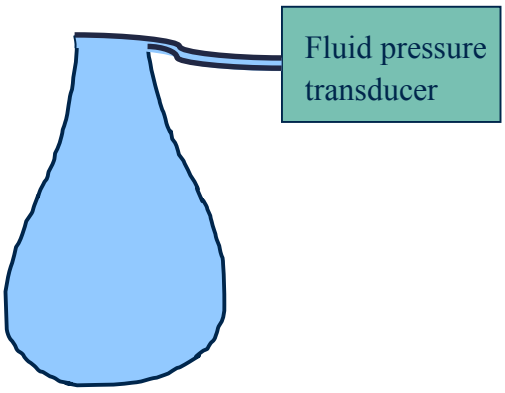

Figure 5. A depiction of the fluid pressure system.

As stated previously, abrupt changes in pressure on the turbinates are major sources of pain for patients during transnasal endoscopies. Therefore, the model must detect abrupt pressure changes in the turbinates and inform the user that they have occurred. Two options were considered for pressure sensing: fluid and mechanical sensors.

Using fluid pressure sensors, the turbinates would consist of a compliant shell filled with fluid. The turbinates would be connected to a fluid pressure transducer with a voltage output (see Figure 5). Therefore, when the endoscope

presses against the surface of the turbinate, the internal pressure will rise, causing a change in output voltage from the transducer.

The other option for detecting abrupt changes in pressure on the turbinates is to use a mechanical sensor in the form of a series of strain gauges. The turbinates would be constructed of a semi-rigid material (such as foam or plastic) containing a flexible metal backbone in the center with a series of strain gauges on it (see Figure 6). When the endoscope presses against the turbinate, the backbone bends causing deformation of the strain gauges. When strain gauges deform, their resistance changes; therefore, the voltage across them would change, just as the voltage output from the fluid pressure transducer would change. The strain gauges do not measure the pressure directly. Instead, they measure the displacement of the turbinate. Fortunately, turbinate displacement and the pressure on the surface are correlated. Furthermore, since it is the change in pressure that is critical, not the pressure value itself, measuring deflection is valid.

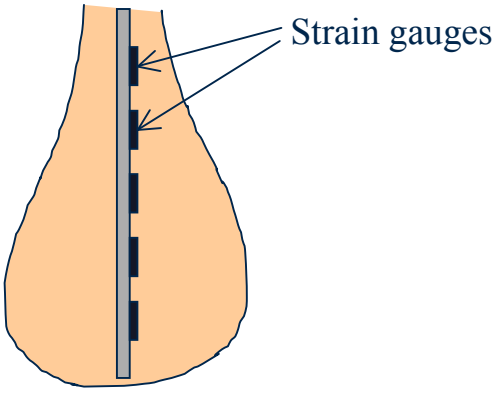

Figure 6. A depiction of the mechanical sensor system.

Data Processing

As discussed, the output of the turbinate pressure sensing will be in volts. To provide feedback, the output voltage must be processed and compared with threshold values to determine if the trainee has successfully passed the turbinates. Two options for processing the signal were considered: analog circuitry and computer programming.

The first option, an analog circuit, uses the voltage output from the pressure transducer and plugs directly into a decision circuit. This circuit utilizes a comparator to compare the change in voltage to some threshold, which could be set using a potentiometer. If the voltage change exceeds the threshold, the comparator activates the indicator (some form of light or buzzer).

The other option is to process the pressure signal on the computer using LabVIEW software. For this to occur, the voltage output from the pressure transducer needs connect to a computer through an analog-to-digital converter. Software can be used to take the derivative with respect to time of the pressure signal. The derivative value reflects the change in pressure and is compared to a set threshold value for to determine if a mistake has been made. Once again, if the value exceeds the threshold the indicator would be triggered.

Decision Evaluation

The following decision matrix (Table 1) was created to evaluate the options for each design component based on the following criteria: accuracy, feasibility, durability, user friendliness, cost, and safety. Components were given a score ranging from 0 to 10 for each criterion. Criteria are weighted with values as shown in the matrix that total to 1. Therefore, a "perfect" option would receive a total score of 10. However, every criterion was not applicable for each design component. In cases where criteria were not applicable, a scale factor was used to inflate the weightings of the other criteria so the total weighting for each component remained equal to 1.

Table 1. Design matrix for the different components of the model.

		Exterior Options			Turbinate Options		No-Touch Zones		Force Processing	
Criteria	Weight	Mannequin Head	Existing Models	Custom Frame	Mechanical Sensors	Fluid Sensors	Shingles	"Operation Model"	Analog	Computer
Accuracy	0.2	8	10	4	5	8	8	9	6	10
Feasability	0.35	9	7	3	5	8	6	6	7	5
Durability	0.15	8	8	6	8	7	7	7	6	9
User friendliness	0.15	10	9	8	N/A	N/A	N/A	N/A	5	10
Cost	0.05	10	6	10	6	8	7	9	8	5
Safety	0.1	8	8	6	N/A	N/A	7	2	N/A	N/A
Total	1	**8.75**	8.10	5.05	5.67	**7.80**	**6.82**	6.59	6.33	**7.61**

As shown in bold in the decision matrix, the following components rated the highest and were pursued in the prototype: a mannequin head exterior with shingle "no-touch" zones, fluid sensors for detecting pressure on the turbinates, and computerized processing of the pressure signal.

For the exterior surface, we decided to use a hollow plastic mannequin head in order to give the device a clean exterior look. The option of creating the whole model manually is not feasible. A handcrafted sturdy frame would likely not resemble a person's head. The best option was to buy a mannequin head and sculpt passages from foam cross-sections. The shingle "no-touch" mechanism was chosen because the client prefers not to modify the scope and wants to avoid using metal structures that could scratch the endoscope's protruding lens. Use of fluid pressure sensors for the turbinates was preferable because fluid sensors measure pressure directly, require less accompanying circuitry and are cheaper than mechanical sensors. Finally, using a computer for data processing was superior due to the flexibility of setting and altering thresholds as well as analyzing pressure changes as opposed to absolute pressure.

Current Prototype

Structure

The form of the current prototype is composed of a stack of 0.5 in. foam slices inside a plastic mannequin head (see Figure 7). The periphery of each slice is shaped so the slices fit snugly inside the mannequin head. Velcro straps attach the front and rear halves of the mannequin to secure the slices.

A computer model of the human head and neck was used in order to accurately model the sizes, shapes and positions of the throat and nasal passages of interest. Medical imaging software called MIMICS was used to transform CT images of a human head and neck into a 3D computer model of the regions of interest. Figure 8 shows a cutaway of the 3D computer model as well as sagittal, frontal, and horizontal views of the cursor location on the model.

Figure 7. Mannequin head with foam slices.

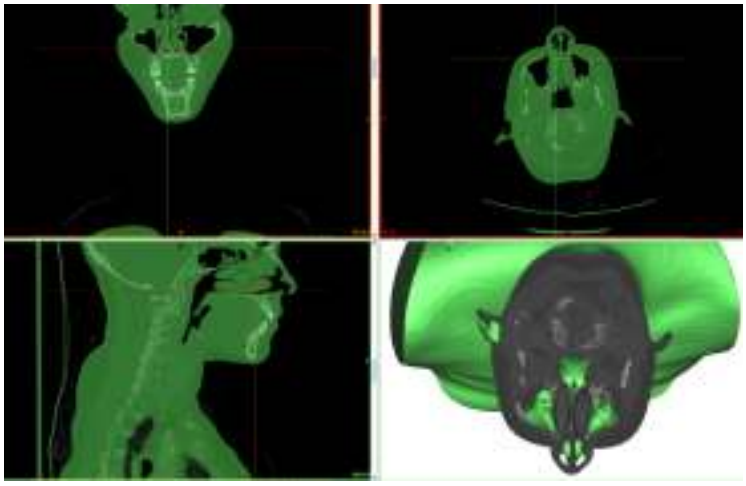

Figure 8. Images from MIMICS of 3D model of head and neck.

Using the 3D computer model, images of horizontal cross-sections were taken every 0.5 in. from the top of the nasal passage down to the vocal cords. Since the foam slices are also 0.5 in. thick, any set of consecutive cross-sections represents the top and bottom of a single foam slice. By maintaining the ratio of feature size to head width, the nasal and throat passages were transferred onto the foam cross-sections at the proper sizes and proportions. Figure 9 shows a foam slice from the nasal passage after the passage space had been removed. By stacking these foam cross-sections, an accurate representation of the nasal and throat passages was produced. To simplify the prototype and conserve space inside the model, the nasal passage was only replicated for one side of the nose, corresponding what would be the patient's left nostril.

Figure 9. Foam cross section with base of nasal passage removed.

To achieve a more realistic texture, the walls of the nasal and throat passages as well as structures within them (turbinates, tongue base, vocal cords) were coated with a layer of silicone, giving them life-like compliance. Also, all passages and structures were painted with acrylic paint to achieve a realistic appearance.

Turbinates

As mentioned previously, the endoscope must weave through sensitive shelves of bone and flesh called turbinates. This prototype contains two turbinates, the inferior and middle, which rest inside the nasal passage between the nose and the top of the throat. The turbinates are made of thin sheets of plastic, cut to shape and size and sealed by melting and adding a layer of rubber cement liner. To give them volume, they are inflated with air. Then, just like the passage walls, the turbinates were coated with silicone and painted to feel and appear realistic. Figure 10 shows the inferior turbinate both before and after silicone and paint application.

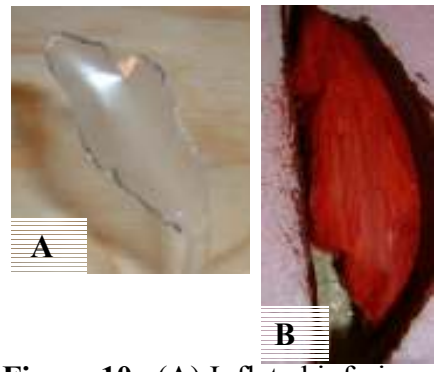

Figure 10. (A) Inflated inferior turbinate. (B) Completed inferior turbinate.

To detect pressure changes on the turbinates, both turbinates are connected to a fluid pressure transducer. To function properly, the turbinates must be inflated fully so the pressure on the turbinate surface causes the air pressure inside to change, rather than simply changing surface geometry and moving air around without changing its pressure. In this prototype, the turbinates are inflated using a hand pump from a blood pressure cuff. By connecting both turbinates to a pressure transducer in a closed system, pressure at any point on the turbinate surface will cause the air pressure inside the system to increase; this change is measured by the pressure transducer. In the current prototype, the pressure transducer has a raw voltage output that must be filtered and amplified by an analog circuit before being connected to a digital multi-meter. The multi-meter will show a voltage corresponding to the pressure inside the system. However, the variable of interest is not the actual pressure inside the system; it is the rapid change in pressure on the turbinates that causes discomfort for the patient.

Therefore, to identify a clinician's mistake (i.e. exerting too rapid a pressure change on the turbinates), the output of the pressure transducer needs to be interfaced to a computer, not just a multi-meter. On the computer, a program can take the derivative of the pressure signal. If the value of the derivative is over a threshold, it indicates the pressure change occurred too quickly and would cause discomfort to the patient. The computer would then inform the clinician a mistake was made. The aforementioned threshold is set by determining the maximum pressure change a skilled clinician exerts on the turbinates during a calibration trial. The threshold value will be set just above that value, so that if a trainee exerts a faster pressure change than the control, it is deemed a mistake. Currently, the client does not possess the proper equipment to interface an analog circuit to a computer at the clinic. Therefore, the pressure transducer needs to be replaced with one that is easier to interface to the computer in order to implement this feedback system.

"No-Touch" Zones

During transnasal endoscopy, it is critical the endoscope does not contact the patient's posterior pharyngeal wall or tongue base. The former can cause the patient to choke while the latter can cause gagging. To detect contact with those surfaces, the prototype is equipped with two lever-arm microswitches, connected in parallel to a battery and buzzer. If either of the switches is closed due to contact from the endoscope depressing the lever arm, the circuit is completed and the buzzer sounds indicating a mistake.

Figure 11. Posterior pharyngeal wall "no-touch" zone before painting.

The surface of the posterior pharyngeal wall is made of a 0.125 in. piece of plastic, coated with silicone, painted and mounted to the lever arm of the microswitch. The microswitch is rigidly fixed to the foam behind the passage. Contact from the endoscope tip on the posterior pharyngeal wall depresses the microswitch lever, closing the circuit and sounding the buzzer. Figure 11 shows the posterior pharyngeal wall with the "no-touch" switch installed, prior to painting.

A microswitch was installed beneath the tongue base for the same purpose. However, since the tongue base is not flat like the posterior pharyngeal wall, a piece of rigid plastic was not a feasible option for mounting to the lever arm. Instead, the lever is covered by flexible thin plastic, coated with silicone and painted. The flexible plastic is fixed to the foam frame around its periphery but is free to move up and down in the center over the lever arm. The flexible plastic is taut enough across the lever arm so the pressure does not need to be localized over the lever arm in order to depress it. Thus, contact with the tongue base anywhere will depress the lever and engage the buzzer. Figure 12 shows the tongue base with the "no-touch" switch installed.

Figure 12. Tongue base "no-touch" zone.

Testing and Results

The "no-touch" system, comprised of microswitches connected in parallel to a buzzer was tested to ensure the alarm would sound providing the trainee feedback on his/her performance. Before inserting the microswitches in the appropriate places, the circuit was tested to verify both switches activated the buzzer when depressed. The switches were then glued into the model and their sensitivity was tested. The sensitivity was poor as it took a degree of force beyond surface contact to activate the switches. The sensitivity of this mechanism requires improvement in future prototypes.

The turbinate system was also tested. To verify the turbinates were airtight, they were inflated with air and submerged in water. To test the turbinate feedback mechanism, the turbinates were connected to the pressure transducer, which was connected to an analog amplification and filtration circuit and then a digital multi-meter. The voltage output was monitored as the inflated turbinates were exposed to blunt pressures from a pen tip, modeling the potentially painful interaction between the turbinates and the endoscope. Voltage spikes of 3.3 and 6 mV were detected when pressure changes of 20 and 40 mmHg respectively were applied to the turbinate. These values show this system can detect pressure changes sufficiently.

After completion of the entire assembly, the model was tested by the client, Brian Petty. He passed the flexible endoscope through the nasal passageway and successfully observed the vocal cords (Figures 13-16). His recommendations included improving the anatomy of the larynx through smoothing out the silicone and inverting the vocal cords to be realistic from the endoscopist's viewpoint. Also, he recommended altering the coloring of the turbinates and the passage walls to more realistic pigments. Mr. Petty confirmed the sensitivity of the "no-touch" regions required improvement.

Figure 13. Endoscope entry through nostril

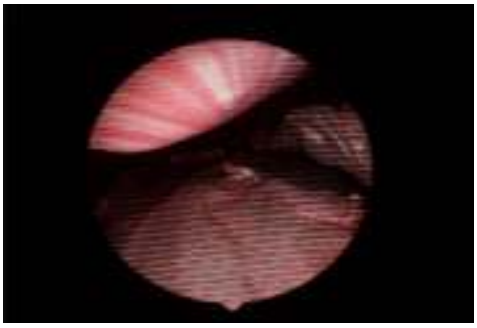

Figure 14. Scope view between turbinates and hard palate

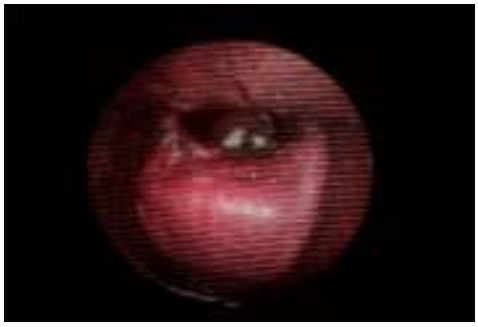

Figure 15. Scope view of larynx

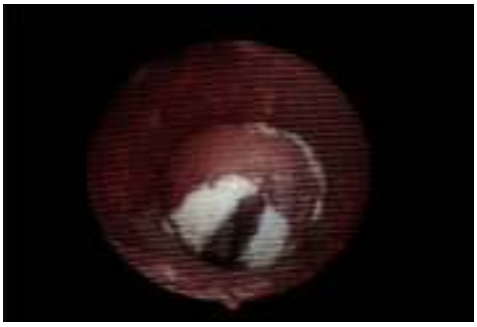

Figure 16. Scope view of vocal cords

Conclusion

Safety and Ethical Considerations

While the device does not directly interact with patients, it does influence their care. Because the model has feedback for the clinicians, it by definition provides some form of certification to their skill with the endoscope. If standards are set too low, patients could be subjected to care by practitioners who are not truly skilled enough in an endoscope's use. Therefore, it is critical detection of contact with "no-touch" regions is as sensitive as possible and turbinate pressure impulse limit is sufficiently rigorous.

The model must also meet basic safety requirements. The insulation foam is purposely non-flammable since it houses current-carrying wires. The structures near the scope are also intentionally inert materials: silicon rubber and acrylic paint. So, in the event the scope is not completely sanitized after use with the model, it should nonetheless avoid any adverse affects on patients.

Future Work

Following the completion of our first prototype, our client and his colleagues are going to test and evaluate it on criteria including anatomical correctness, tactile sensation and usefulness. Hopefully they can provide criticism in order for us to make improvements to our device. In some preliminary testing, our client did indicate some items to improve. There are some sharp edges in the nasal passage that need to be smoothed down for anatomical accuracy, as there are no sharp corners in the body.

Furthermore, the color of the paint inside the passages is too dark; the next version of the prototype needs a lighter hue of red. Also, the turbinates should possess a slight blue tint. Additionally, the silicone surface on the hard palate was rough in places and caused the scope to bind up due to an excess amount of friction. The prototype revision should include a method for smoothing the silicone's surface.

Another feature that requires improvement is the sensitivity of the "no-touch" regions. Either more sensitive microswitches need to be used or a new mechanism for detecting contact needs to be implemented. The feature that will require the most attention is the pressure sensing turbinate system. While the device works while connected to a computer through a multipurpose data acquisition electronics board, we need to adapt our design to allow it to be plugged in anywhere and used. Our plan is to purchase a pressure sensor that can be connected to a computer via USB so the device is universally compatible. We then need to create a computer program that analyzes the pressure data and gives the user feedback. After this is complete, we will submit the prototype to our client for a second round of testing and set the appropriate turbinate pressure impulse limits.

References

Cooper, J.B. and Taqueti, V.R. (2004). A brief history of the development of mannequin simulators for clinical education and training. *Qual. Saf. Health Care* 13;i11-i18.

Fig. [1] http://www.olympus-global.com/en/corc/history/chron/n260.cfm
Fig. [2] http://www.sinus-cure.com.au/nasana3.jpg
Fig. [3] http://www.udel.edu/PR/UDaily/2008/jul/vocal073107.html

Project Design Specification

December 10, 2008

Team Members: Justin Lundell, Karissa Thoma, Alice Tang, Mike Socie

Problem Statement:
To train clinicians to perform transnasal endoscopy of the larynx, a model with realistic and anatomically correct structures of the nasal passages and larynx must be developed. Currently, training is conducted on human subjects in the form of volunteers and/or patients.

Client Requirements:
- Anatomically correct model of nasal passages and larynx
- Materials should have a compliance similar to living tissue
- Costs less than $3000
- Force against a turbinate is painful, touching the larynx causes choking, touching the tongue base causes gagging. Feedback to the user would be helpful if contact with these structures is made.

1. Physical and Operational Characteristics

a. Performance requirements: Needs to accurately simulate environment and obstacles involved in transnasal endoscopy. Simulate a real face as best as possible.

b. *Safety*: The model must contain non-toxic materials. The materials included may not damage the endoscope.

c. *Accuracy and Reliability*: The model must be anatomically correct for training purposes. The model should be durable.

d. *Life in Service*: 5 years

e. *Shelf Life*: No specific requirements by client, but to be determined by materials used.

f. *Operating Environment*: Office / classroom (non-sterile).

g. *Ergonomics*: Should be small enough to place on a table or desktop.

h. *Size*: Accurate in terms of anatomy.

i. *Weight*: 25 pounds so it's light enough for one person to move by hand.

j. *Materials*: Non-toxic materials.

k. *Aesthetics*, *Appearance, and Finish*: The outer surface should look like a face. The inner structures should be the same color, shape and texture as the living structures.

2. Production Characteristics

a. *Quantity*: One.

b. *Target Product Cost*: Less than $3000.

3. Miscellaneous

a. *Standards and Specifications*: Model should comply with anthropometric data.

b. *Customer*: Voice pathologists and other medical professionals working with transnasal endoscopy and its training.

c. *Patient-related concerns*: Any material allergies such as latex need to be taken into concern. The scope needs to be cleaned after use with the model since it is not sterile.

d. *Competition*: Existing commercial larynx models and human subjects (volunteers and/or patients).