

UNIVERSITY OF WISCONSIN – MADISON
DEPARTMENT OF BIOMEDICAL ENGINEERING
BME 402 – DESIGN

Embouchure Assistive Device

Mid-Semester Report

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March 14, 2012

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Abstract

Bell's palsy is a nervous system disorder that may develop into synkinesis. Patients suffering from synkinesis experience involuntary muscular movements accompanying voluntary movements [1]. The team's client suffers from facial synkinesis, which affects her ability to maintain the proper embouchure while playing the clarinet. However, she wishes to be able to play semi-professionally again, which requires practice time to be extended to at least 30 min. Therefore, the aim of this project is to develop an assistive device that would help the client to maintain a proper clarinet embouchure.

Background

Bell's Palsy

There are several conditions that can cause facial paralysis, such as brain tumor and stroke. In cases where the specific cause cannot be identified, the condition is known as Bell's palsy. Bell's palsy is the paralysis of facial muscles due to dysfunction of cranial nerve VII, which is also known as the facial nerve. The nerve travels through a narrow bone canal beneath the ear in the skull. Inflammation of the nerve that causes swelling and compression in the canal may result in nerve inhibition, damage or death, which is thought to be the direct cause for the onset of Bell's palsy. Specific cause for the inflammation is not known, but some viruses of the herpes family are thought to establish infections that can result in the swelling of the facial nerve [1].

Prior to onset of Bell's palsy, patients may experience a cold. Symptoms usually appear on one side only, with rare occasions where the whole face is paralyzed [2,3]. It was found that Bell's palsy is three times more likely to strike pregnant women than those not with child [4], and four times more likely in diabetic patients than in the general population [3]. Currently, there are several treatments available, such as steroids and physiotherapy. However, even without treatments, Bell's palsy tends to carry a good prognosis. Most patients show signs of recovery within half a year, and completely recover within a year. For patients who do not recover, complications may occur, resulting in disorders such as tinnitus and synkinesis [1].

Synkinesis

Synkinesis is the result of misdirected nerves after trauma which may result in the degeneration of neurons. When these neurons regenerate, there is no telling which motor endplates they would regenerate against, as shown in figure 1. Patients experience abnormal muscle movements during normal movements, such as involuntary squinting while smiling [5].

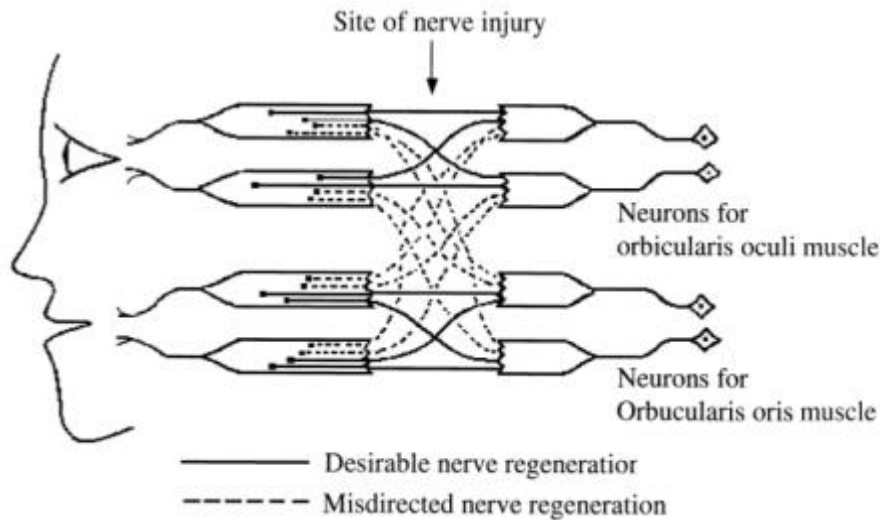


Figure 1. Misdirection of neurons to wrong motor endplates [6].

There are several treatments available for synkinesis: surgery, facial retraining, biofeedback, mime therapy, and Botox. Surgical procedures are very rarely used due to the temporary effectiveness and post-operational complications. Patients usually receive facial retraining treatment coupled with one of the other three methods [5]. The team's client has been receiving Botox treatment while attending facial retraining sessions.

Botox is one of the most potent neurotoxins ever discovered [7]. Minute quantities are injected in overactive muscles to prevent the release of acetylcholine from neurons onto the motor endplates of the muscles, thus reducing muscle activity [7]. This helps to reduce unwanted muscular movements in synkinesis patients. However, due to the short span of Botox effects (usually 4 to 6 months), patients need to receive re-injection approximately every 3 months [5].

Facial retraining is based on the fact that there is constant growth and regression of neuronal projections. By providing neurons with the right stimuli, neuronal projections will be able to regenerate against the correct motor endplates, eventually decreasing synkinesis effects in patients [5].

Project Motivation

To achieve a good tone, the proper embouchure, shaping of the lips around the clarinet mouthpiece, is required. The main muscles used in forming the proper embouchure are the buccinators, zygomaticus, and orbicularis oris. Synkinesis prevents the engagement of the correct facial muscles while playing the clarinet, resulting in accelerated fatigue and discomfort in the muscles. The embouchure, and thus the tone, is forfeited, and for the client, an air leakage at the corner of the mouth is also present constantly. There are no devices on the market that would benefit the client in this area. Therefore, to compensate for the negative effects of synkinesis, a functional assistive device is needed to help maintain the correct pressure on the clarinet mouthpiece, as well as to reduce the air leakage in order to improve the client's current embouchure and to delay the onset of muscle fatigue.

Project Requirements

With the client's problems in mind, there are several requirements for the device. The client would like to extend her practice time from approximately 10 min to at least 30 min, preferably longer. During this time, she would like as little air leakage as possible, and would like her tone uncompromised. As figure 2 shows, this requires a significant amount of pressure.



Figure 2. The team's client playing clarinet while her Rolfer experiments with different pressures applied to the synkinesis-affected side of her face.

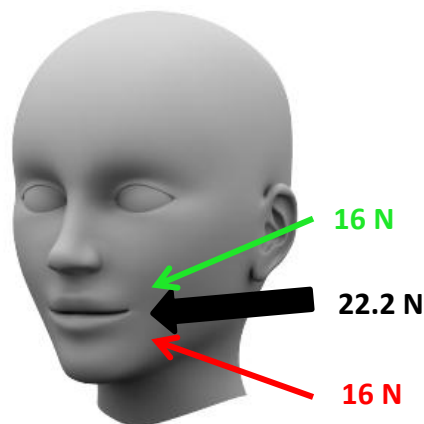
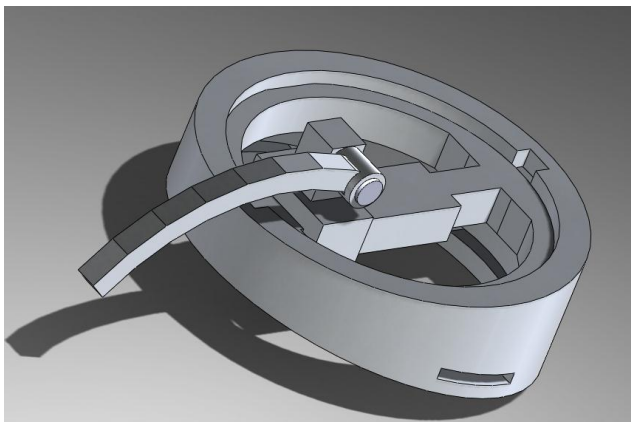


Figure 3. Free body diagram of forces on left cheek supplied by the device. The black arrow is the net force to be applied to the left cheek. The green arrow is the required forward force (tangent to cheek) and the red arrow is the required inward force (normal to the cheek).

To this end, the device must be able to apply a constant, firm force for an extended period of time. The forces it must apply are shown in figure 3. Both the forward component of force, tangent to the cheek, and the inward force, normal to the cheek, will be approximately 16 N each for a net total force of 22.2 N on the left cheek. The device must not encumber the client while playing for extended periods of time, and thus should be lightweight. The device should be easy to use, require no training, and be easy to clean. Additionally, the device and its components must cost less than \$200. The client has also indicated a preference for a 'headgear' style device, which will be incorporated into the final designs.

Prototype Developed First Semester

The headgear prototype developed last semester is shown in figure 4. The outer base was a 0.102 m diameter ring, which was placed over the left ear of the client's face. Three slits around the bottom edge of the base provided attachment positions for the head straps. The base was designed with a beveled surface to provide accurate force application. Around the bottom surface of the base was cushioning that added extra comfort for the team's client as it is pressed against the face. The inner ring fit into a groove made in the base, which was located near the top surface to avoid contact of the inner ring with the client's ear. The groove enabled the inner ring to rotate freely within the base to allow placement of the inner ring in the desired position. A track ran down the middle of the inner ring with a sliding piece affixed to the track by use of a set screw. Loosening the set screw allowed the sliding piece to move forward and backward along the track. Finally, there was a force arm connected to the sliding piece which rotated inwards towards and outwards from the cheek. It was designed to have a curvature to provide accurate inward pressure. Another set screw was used between the sliding piece and the force arm. By loosening the set screw, the force arm could rotate freely until tightened at a desired position. The final piece to the headgear prototype was padding attached at the end of the force arm, which applied enough force to an appropriate cheek area. It was firm, yet comfortable when pressed against the cheek.



(a)



(b)

Figure 4. Last semester's headgear prototype. (a) A SolidWorks™ image of the force apparatus and (b) a picture of the actual constructed headgear device.

It was necessary that the headgear prototype applied both a forward force and an inward force on the cheek. The steps in using the device are as follows. First, the head straps with the connected force apparatus were placed on the head. Second, the inner track was positioned within the base. It was meant for the client to rotate it so that the force arm was positioned on the cheek in the correct location. Third, the set screw was loosened for the force arm and the force arm was rotated inward towards the cheek to apply efficient inward pressure. The set screw was tightened to secure the force arm in place. Fourth, the sliding piece's set screw was loosened and the sliding piece was pushed forward, applying forward pressure to the cheek in combination with the inward pressure applied by the force arm. Once the sliding piece was in position, the set screw was tightened to secure it in place. The anticipated result was an inward and forward pressure combination maintained near the mouth of the client that would have helped the mouth hold pressure around the clarinet's mouthpiece.

There were several faults with last semester's prototype, however. The prototype was bulkier than planned. Both the outer diameter and height of the ring component were larger than needed for the device to work. It was also found that the sliding piece came in contact with the client's ear as it slid down the track, which resulted in the device being uncomfortable to wear and adjust. After watching the client use the headgear prototype, it was determined that there were too many adjustments to consider with only one hand. The rotation adjustment of the inner ring, the forward adjustment of the sliding piece down the track, and the inward adjustment of the force arm were a hassle for the team's client in obtaining the correct pressure required on the cheek. The most important negative result to address was the inadequate application of force the prototype delivered. Lack of friction between the force arm and the sliding piece at the pivot point caused the force arm to move too easily with little perturbation done to it. It is necessary for the inward force to be maintained for the embouchure device to work properly.

Figure 5 was the complete developed prototype of the headgear device on the team's client's head. The headgear prototype was rapid prototyped, so the inner ring, base, and sliding piece were made out of ABS material. The force arm was created out of copper tubing that was bent to the appropriate curvature. Both set screws were 0.025 m wing screws. The padding at the end of the force arm was made out of sponge material and was then covered with a cotton fabric. The total cost for the semester was \$61.00 from materials purchased throughout the semester.



Figure 5. Rapid prototype of complete headgear device tested on the team's client.

Design Alternatives for Mid-semester

Due to improvements needing to be done to last semester's headgear prototype, the team developed three new design alternatives for the current semester.

Design Alternative 1: Spring Metal

The spring metal headgear design is similar to last semester's headgear prototype with modifications done to avoid the issues stated previously. Figure 6 is a SolidWorks™ image of the design. The base of the spring metal headgear design is still a ring component. Unlike the previous prototype, there is only one ring for the base which contains the track and three slots for the elastic head straps to be connected to. The outer diameter of the ring is smaller at 0.075 m rather than 0.10 m and the maximum height of the base is shorter at 0.025 m rather than 0.038 m. Another characteristic of the ring is the beveled bottom to slant the track towards the cheek, promoting more accurate net force. The track was designed with a hollowed out groove for the sliding piece to move within the track rather than the outside, which eliminates the chance for the sliding piece to come in contact with the ear.

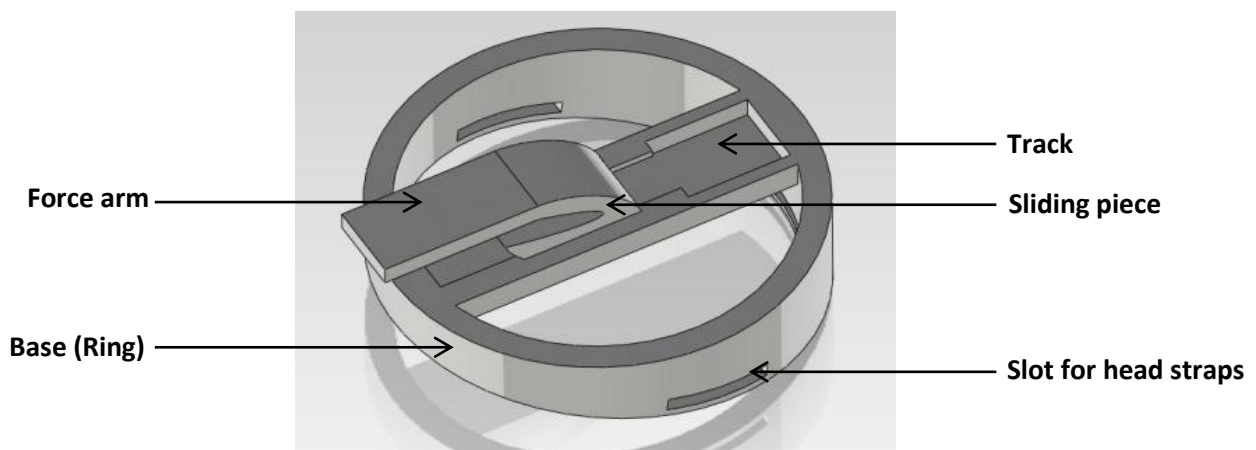


Figure 6. The complete SolidWorks™ design for the spring metal headgear design alternative.

For pressure application, the inward force would be maintained by use of a spring steel force arm shown in figure 7. The spring steel force arm would be an extension of the sliding piece and it would curve inwards towards the face. The force arm would be longer than the one shown in figure 6. The spring steel would be preset a certain distance inward past the cheek to overcompensate the desired force. When attached to the head, the spring steel force arm would move out, but would try to return to the original preset position, causing the force arm to press against the cheek. As the client moves her head during playing, the inward force should be maintained, which allows the spring steel headgear alternative to be very dynamic during motion. The forward force would be implemented with use of the track. With the sliding piece already applying the inward force, the sliding piece would move forward within the track pushing the cheek forward as it moves.

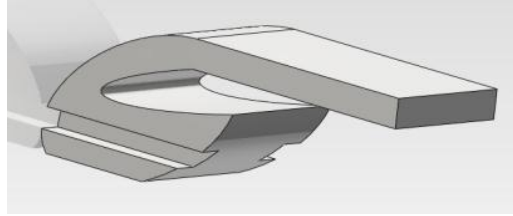


Figure 7. SolidWorks™ image of the sliding piece.

The materials considered for this design alternative include a spring steel such as ASTM grade A684 or A689 for the force arm. These grades were chosen because they have high yield strengths and spring steel returns to its original shape after significant bending. For the base or ring component of the device, either a lightweight metal or plastic is being considered. Aluminum is the lead contender as it is cost effective and it has the ability to be injection molded.

Advantages of the spring metal headgear design alternative are that it is one-hand adjustable, dynamic, and is less bulky than the previous prototype. The only adjustment required is the forward force, which involves moving the sliding piece forward. It is a dynamic design because the net force should be maintained as the client moves her head in any direction with the device on. This headgear design is smaller in size and has a more compact design making it less bulky. A downfall to using this headgear design is the difficulty to manufacture this headgear due to the intricate shape and grooves. The cost may also be a downfall depending on how it is manufactured.

Design Alternative 2: Button Adjustment

The button adjustment headgear design alternative shown in figure 8 also incorporates a ring component as the base and is constructed similar to that of the spring metal headgear design. As described previously, the ring contains three slots for the head straps to attach to, a track for the sliding piece to move forward and supply the forward force, and a beveled base for better net force accuracy. The outer diameter of the ring base is 0.076 m and the maximum height of the ring is 0.025 m.

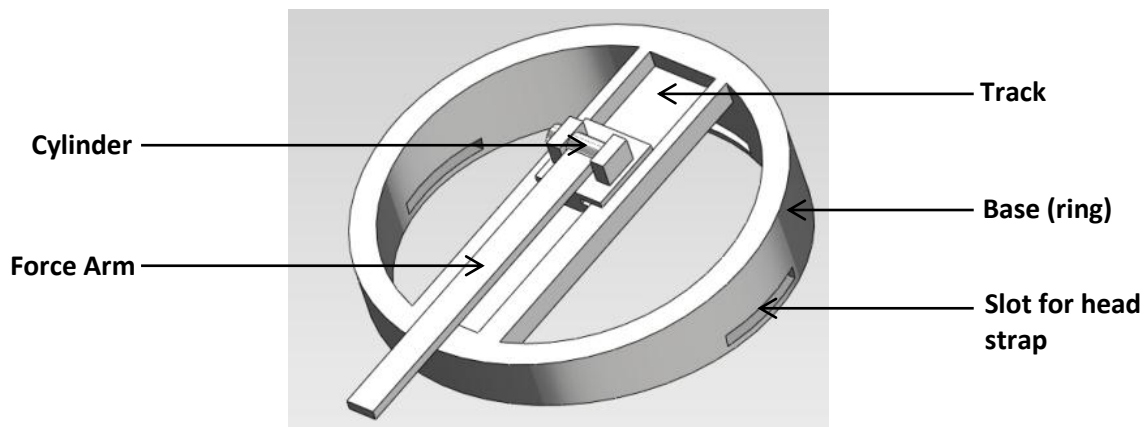


Figure 8. The complete SolidWorks™ design for the button adjustment design alternative.

The separation between the spring metal design and the button adjustment design is the sliding component in combination with the force arm. The force arm would be a preset spring steel arm that permanently extends from a cylinder connected to the sliding component. The preset design of the force arm is meant to add to the inward force. For the main component of the inward force, the cylinder has the ability to rotate around an axle and lock into position, pushing the force arm further into the cheek for maximum inward force. Within the axle is a button-spring mechanism as shown in figure 9, which is how the cylinder locks in place. When the button is pushed, the spring compresses, causing the teeth to pull apart. At this time, the cylinder may be rotated to the desired position. Releasing the button allows the spring to return to its natural length, causing interlocking of the teeth. Hence, no movement may occur and the cylinder and force arm are locked in place.

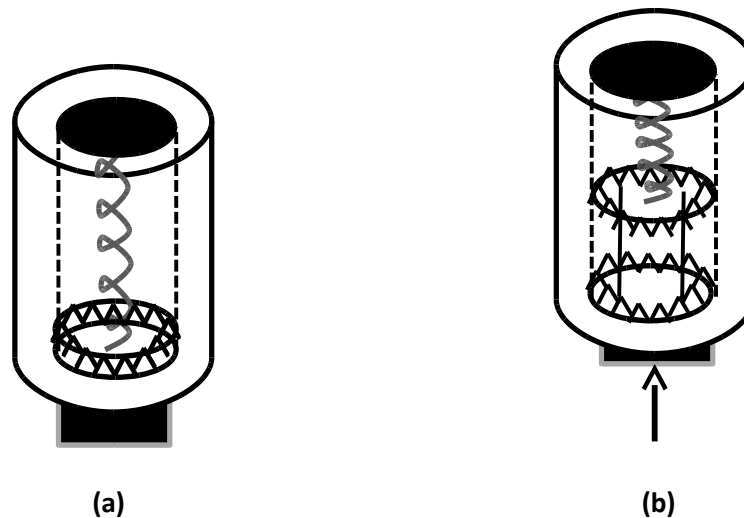


Figure 9. Components inside cylinder which rotates around axle to push force arm inwards towards cheek. (a) Inside the cylinder before the button is pushed and (b) after the button is pushed.

The materials considered for this design are the same as the spring steel design alternative. Spring steel such as ASTM grade A684 or A689 would be used for the force arm. For the base or ring component of the device, either a lightweight metal or plastic is being considered such as aluminum. The cylinder will most likely be made of the same material as the ring.

Advantages of the button adjustment headgear design alternative are that it is one-hand adjustable, has a locked force arm, and is less bulky than the previous prototype. Although there are two adjustments to consider, the forward movement of the sliding piece and the inward movement of the cylinder/force arm combination, this design alternative is still easily adjusted with one hand. It would be a benefit to have the force arm lock securely in place to prevent the force arm from sliding away from the cheek. A downfall to using the button adjustment design is the difficulty to manufacture the internal components of the cylinder and make them function properly. The cost may also be a downfall depending on how it is manufactured.

Design Alternative 3: Butterfly Tiara

The third design alternative, the butterfly tiara, shown in figure 10 goes in a completely different direction compared to the previous prototype or design alternatives described previously. The butterfly tiara is one solid piece of metal that conforms to the client's head. An elastic band as shown in figure 10(a) connects the forehead arms to provide flexibility in fit around the forehead.

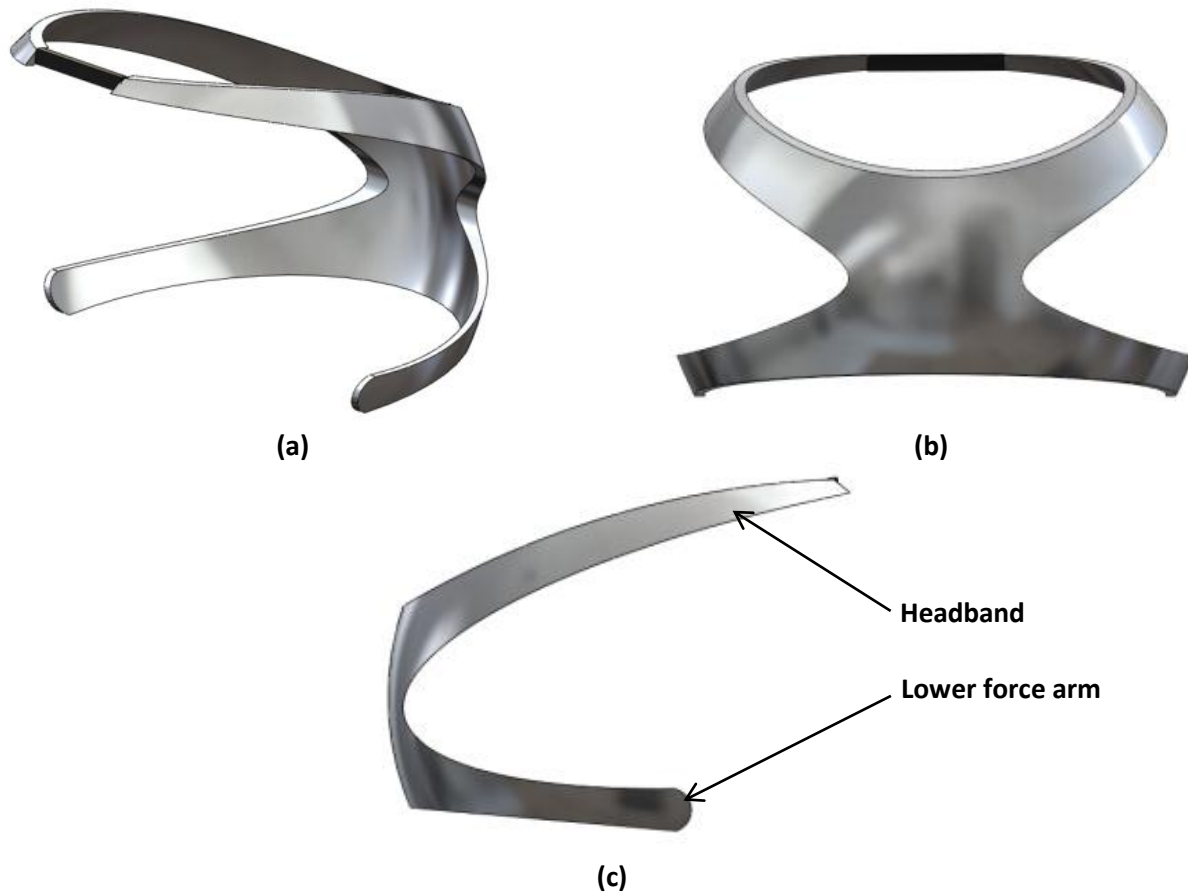


Figure 10. The butterfly tiara design. (a) A view of the entire design, (b) the back view, and (c) the side view.

As for force application, the inward force would be applied manually by the client as she places the device on her head. Lining the side of the lower left arm would be a skin interface made of a textured material that would increase friction between the cheek skin and the lower left arm. As the butterfly tiara is placed on the head, the left arm would push the cheek forward as it proceeds forward. The inward force would be applied by use of a preset spring steel arm on the left side of the butterfly tiara headpiece. There are two ideas to pursue with use of spring steel. One idea is that the lower left arm shown in figure 10 would be the preset force arm that would supply the inward force. Another idea is to add an additional preset spring steel arm on the left side of the headpiece to aid in the inward force.

The additional force arm is shown in figure 11. Further testing is necessary to determine the better solution.

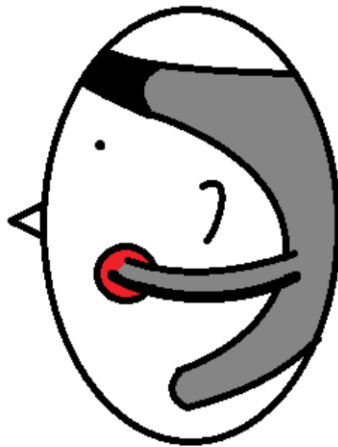


Figure 11. Butterfly tiara design alternative on head with additional force arm extending off left side of tiara.

The entire body will be constructed of spring steel such as ASTM grade A684 or A689. The interface lining the left lower force arm would be a rubber-like material that would provide the friction necessary between the skin and force arm to keep the cheek pushed forward. For added comfort, a thin layer of foam padding would line the inner surface of the butterfly tiara.

Advantages of the butterfly tiara design alternative are that it is one-hand adjustable, it has a professional appearance, it is cost effective, and manufacturing of the device would be easier than the other two design alternatives. There is no adjustment required with this device because it applies force automatically when placed on the head. The smooth lines of the design give it high aesthetic points. The downside to the design is the forward pressure application. Depending on how far the left force arm is preset and how well the butterfly tiara conforms to the client's head, the forward force may not be satisfactory.

Design Matrix at Mid-semester

The spring metal, button adjustment, and butterfly tiara designs were set up in the design matrix illustrated in Table 1 to evaluate the three designs according to five specific criteria. The five criteria were weighted individually based on importance for a combined total of 100 points.

Table 1. Design matrix created to assess the features of each design alternative. The individual sums were out of a total of 100 points.

Weight	Category	Spring	Button	Butterfly Tiara
10	Fabrication	5	2	8
10	Cost	4	4	6
20	Ease of Use	15	15	15
20	Client Preference	15	14	18
40	Directionality/Pressure/Force	32	32	28
100		71	67	75

The criterion chosen to have the most importance was directionality/pressure/force, weighted at 40 points. The reason for this is because the main function of the embouchure assistive device is to supply appropriate force/pressure in both the forward and inward directions. Without this feature, the device would not maintain constant pressure on the left side of the face, making it ineffective. The spring metal and button adjustment design alternatives received the highest score of 32 out of 40 because they both could supply efficient inward and forward forces compared to the butterfly tiara that would be lacking in forward force application.

Both the client preference and ease of use criteria were weighted at 20 points out of 100. Client preference is an important consideration in determining the final design because the client has to approve and be comfortable using the developed product. The butterfly tiara design alternative received the highest score of 18 out of 20 because it has a professional appearance and would be the most inconspicuous, which is important to the team’s client.

Ease of use is equally important as client preference because the client has to set up and use the device with little difficulty. Easy storage and portability also fall under this category. All three design alternatives received 15 out of 20. They all would be fairly easy to use and set up.

Although fabrication and cost are important, both criteria were weighted at 10 points out of 100. Fabrication includes access to the necessary materials and the ability to manufacture the embouchure device. The device should remain below the team’s budget of \$200 after fabrication is completed. The butterfly tiara scored the highest with 6 out of 10 for cost and 8 out 10 for fabrication because it would be constructed of cost effective material and it would be easy to construct as it includes mainly one sheet of spring steel that would be bent to the correct curvature.

Final Design Choice

After assessing each design option with the design matrix, it was determined that the team would pursue the ‘Butterfly Tiara’ design, as it achieved the highest score. However, it is also the most

radical of the design options, and while it has the potential to meet the client's preferences for both sufficient force application and pleasing aesthetics for the lowest cost, there is no guarantee it can be developed into a working prototype. For this reason, the team has also decided to continue working on the 'Spring' design option, which was only a few points behind the 'Butterfly Tiara' design in the design matrix.

The 'Spring' design incorporates many of the same favorable traits as last semester's prototype: it is mechanically simple, easy to prototype and test, and can be adjusted between songs using only one hand. While it may be more of an eyesore, there is a greater chance that it will effectively supply the correct force to the client's embouchure and help her return to playing clarinet semi-professionally. Whereas the 'Butterfly Tiara' excels at aesthetics, fabrication, and cost, the 'Spring' excels at force application, and is a suitable 'back-up' plan in case the 'Butterfly Tiara' is unable to be developed to a sufficient degree as to allow client recovery.

Future Work

Testing

The use of surface electromyography (SEMG) was investigated to monitor the activity of the muscles on the unaffected side of the client's face. It is expected that the prototype will relieve stress on the compensating muscles, leading to significantly less muscle activity. A study done by Van Swearingen and Brach measured the contractions of the zygomaticus (a muscle that contributes to optimal embouchure) in a patient with facial synkinesis who was asked to smile [8]. SEMG data was taken before and after facial retraining, revealing a visually different signal as shown in figure 12. This shows that SEMG should be sufficiently sensitive to detect small changes in muscle contractility that accompany changes in embouchure.

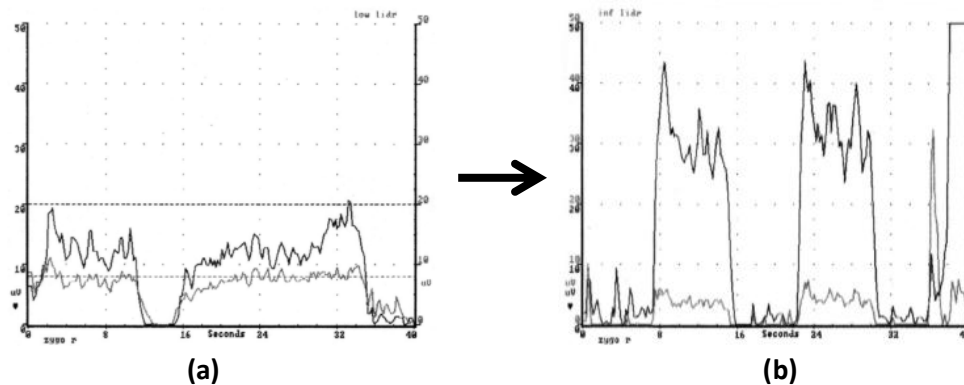


Figure 12. SEMG data taken for a smiling patient with synkinesis (a) before facial retraining and (b) after facial retraining [8].

A mannequin will be used to model the placement of the embouchure device, and then test the forces it could apply on the mannequin's face using a transducer array. This would be able to tell us the

spread and area of the forces applied, as well as their magnitude. It is important to include this type of testing so that it is known quantitatively that the device can apply the necessary force.

Finally, the efficacy of the prototype will be evaluated using more qualitative measures including, but not limited to, categories of comfort, ease of use, ease of forming and maintaining embouchure, and tone improvement. Each category will be scored on a scale from one to ten. Ten would be the improvement the client would expect if a facial therapist were applying the pressure manually.

Functional Improvements

The 'Butterfly Tiara' design will be fabricated out of a thin sheet of metal; preferably steel or aluminum. The exact material that will be used still needs to be evaluated. Additionally, the headband connecting the top two wings could either be an elastic material or a rigid, but adjustable one. These design options also need evaluation, and elastic, sweat-resistant, and grip-able materials still need to be found for this application. The material used to pad the inside of the 'Butterfly Tiara' design needs to be chosen as well. After these initial hurdles, the design will be fabricated and further functional improvements will be determined.

The 'Spring' design utilizes many of the same design characteristics of last semester's prototype and exhibits several functional improvements over it: the diameter of the ring has been shrunk by 25%, and the thickness has been reduced accordingly as well. The bulkiness of the original prototype was one of its major drawbacks, and hopefully this size reduction helps with both the aesthetics and function of the new prototype. Additionally, the slider on the track has been moved from the outside, where it contacted the client's ear, to the inside, where it will not contact the client's ear, thereby allowing better freedom of movement and greater comfort. Additionally, the new slider design allows it to be adjusted with only one hand, whereas the old design required two, and was a major drawback since the client only has one hand free in a performance environment.

Additionally, improvements to the force applicator arm will need to be made. The radius of curvature and length of the applicator arm still need to be determined based on the dimensions of the client's face. Improvements also need to be made to the force applicator pad on the end of the arm. The client wants something that feels as natural a three finger-widths pushing on the affected facial muscles. The current design is functional, but not optimal. In future prototypes, three-finger molds will be investigated.

Ethics

The current prototype is being designed with the intent of being used solely by the client. This both simplifies and complicates the ethical implications of the project. With a single client, there is the opportunity for detailed instruction on the use of the prototype, so it may not need to be as intuitively designed. However, because other patients could use the device for some other purpose, it still should be designed so that a novice user can use it safely. Also with an individual client, it is sometimes easy to assume the consent of the client during the testing phase of prototype development. However, it is still necessary to give the client the option to not participate in testing that they are not comfortable with. Finally, just as in other research and design settings, it is important to avoid wishful data interpretation

in data analysis, which may come into play in the SEMG data. Even though it may be unintentional, it would be unethical to let any bias come into play that may cause exaggeration of the efficacy of the device.

References

- 1) Bell's Palsy. http://en.wikipedia.org/wiki/Bell's_palsy
- 2) Bell's Palsy. <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001777/>
- 3) Bell's Palsy Information Site. <http://www.bellspalsy.ws/>
- 4) Facing Bell's Palsy while Pregnant. <http://pregnancyandbaby.sheknows.com/pregnancy/baby/Facing-Bells-Palsy-while-pregnant-5398.htm>
- 5) Synkinesis. <http://en.wikipedia.org/wiki/Synkinesis>
- 6) Nakamura, K., Toda, N., Sakamaki, K., Kashima, K., & Takeda, N. (2003). Biofeedback Rehabilitation for Prevention of Synkinesis after Facial Palsy. *Otolaryngology -- Head and Neck Surgery*, 128(4): 539 - 543
- 7) Botulinum Toxin. http://en.wikipedia.org/wiki/Botulinum_toxin
- 8) VanSwearingen, J. M., & Brach, J. S. (2003). Changes in facial movement and synkinesis with facial neuromuscular reeducation. *Plastic and reconstructive surgery*, 111(7): 2370.

Appendix A: PDS

Product Design Specifications – September 13, 2011

Project 12: Embouchure Device

Team Members

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Problem Statement

Bell's Palsy, a condition affecting the 7th facial nerve, can cause hemifacial paralysis and weakness in facial muscles. During recovery, the facial nerve can regenerate forming new pathways causing voluntary and involuntary muscle contractions simultaneously. For a patient with this disorder, known as synkinesis, maintaining proper embouchure is problematic as the buccinator, platysma, and zygomaticus counter-contract. Therefore, an embouchure assistive device will be designed for a clarinetist afflicted with synkinesis to help maintain pressure on the mouthpiece of the clarinet which will reduce air leakage.

Client Requirements

- Maintain embouchure by counteracting unwanted facial muscle hyper-contractions
- Easy to engage and disengage as needed
- Removable cloth covering
- Preferably a headpiece
- Lightweight
- Device will increase playing time to at least thirty minutes

Design Requirements

1. Physical and Operational Characteristics

- a. Performance requirements
 - Maintain constant corrective force on cheek while playing clarinet
 - Intended for daily use
- b. Safety
 - Materials used should not cause allergic response
 - Should not inhibit breathing or vision
- c. Accuracy and Reliability
 - Able to provide a wide range of supportive forces
 - Adjustable point of contact within cheek area
 - Capable of fine adjustment
- d. Life in Service
 - 1000 engage/disengage cycles (approximately three years if used daily)
- e. Shelf Life
 - Non-perishable
 - Should tolerate wide temperature range during storage
 - -30°C to 50°C
- f. Operating Environment

- Used in warm environment
 - 37°C based on body temperature
 - In contact with perspiration, skin oils and saliva
- g. Ergonomics
- Only intended for cranial use
 - Device should not cause undue stress on neck and shoulder
 - Training not required
 - No force greater than 3 kg applied to face
 - Engage/Disengage time less than 30 sec
- h. Size
- Small enough for transportation in one hand
 - Should not encroach on surrounding musicians' vision
- i. Weight
- Less than 1.5 kg
 - Weight should not induce fatigue
- j. Materials
- Avoid latex
 - Lightweight
 - Durable
 - Cloth covering
 - Easy to wash
 - Capable of sterilization
- k. Aesthetics, Appearance, and Finish
- Inconspicuous
 - Neutral colors
 - Professional appearance

2. Production Characteristics

- a. Quantity
- One device
- b. Cost
- Less than \$200 for development and materials

3. Miscellaneous

- a. Patient-related concerns
- Device will be sterilized between uses