UNIVERSITY OF WISCONSIN – MADISON
DEPARTMENT OF BIOMEDICAL ENGINEERING
BME 400 – DESIGN

Embouchure Assistive Device

Final Report

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Abstract

Bell's palsy is a nervous disorder that may develop into synkinesis. Patients suffering from synkinesis experience involuntary muscular movements accompanying voluntary movements [1]. The 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 minutes. 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 non-pregnant women [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 seen in figure 1. Patients experience abnormal muscle movements during normal movements, such as involuntary squinting while smiling [5].

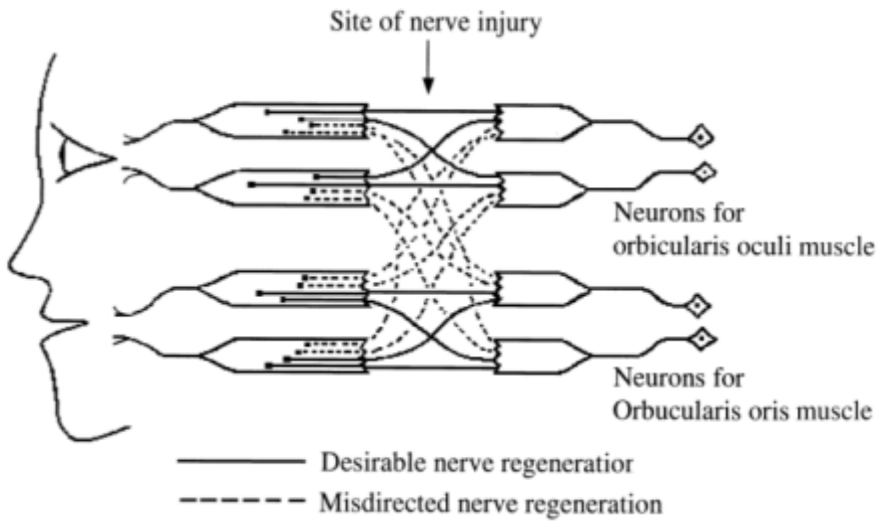


Figure 1. Misdirection of neurons to wrong motor endplates [6].

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 shaping of the lips, or embouchure, 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, Brooke, experiments with different pressures applied to the synkinesis-affected half of her face.

To this end, the device must be able to apply a constant, firm force for an extended period of time. It must not encumber the client while playing for extended periods, 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.

Design Alternatives at Mid-semester

Design Alternative 1: Headgear

As per the client's preference, the team investigated the possibilities of doing a headgear type embouchure device. The team first came up with the piece showcased in figure 3(b). This headset device can rotate up and down, allowing good positioning over the affected cheek. The bar can slide in and out to adjust the distance from the earpiece to the red pressure pad. This allows the amount of forward force on the cheek to be quickly adjusted. Finally, the rod can rotate in and out of the plane for increasing inward pressure on the cheek so that the affected muscles are getting the appropriate amount of pressure. The mechanism for this was envisioned to be similar to that of a geometric compass, where a simple screw can be turned to adjust the angle.

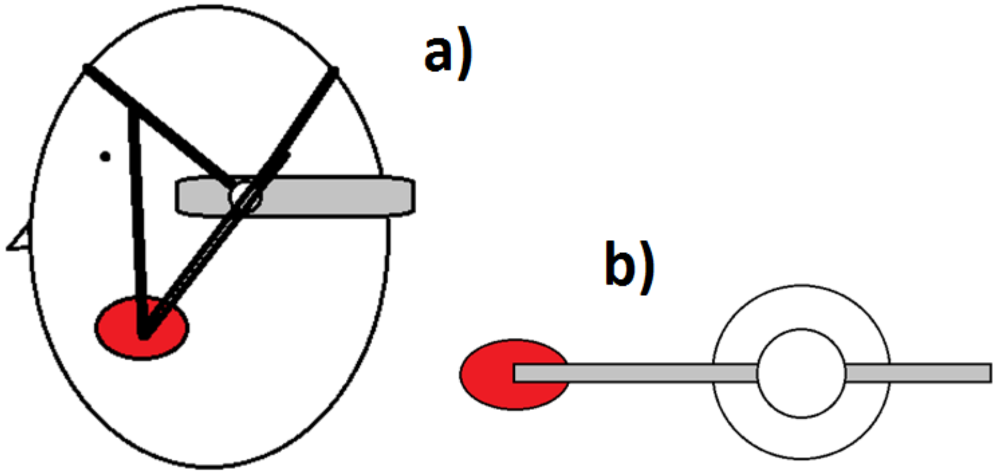


Figure 3. The final headgear designs. a) shows the side view of the apparatus, incorporating the straps, metal bar, and headset pieces. b) is a close-up representation of the headset piece that can apply pressure along every axis. Gray shading indicates a metal piece, red ovals are the pressure applicators, and the thick black lines are straps.

The next problem to solve was how to actually mount this headpiece on the client's head. This is a difficult task in that it must be mounted so all of the forces applied by the headset piece are counteracted by the headgear in such a way as to keep the playing unaffected. Due to these concerns, the team did not want to use any kind of strap securing the device on or under the chin. The device would have to be supported by the superior-posterior half of the head.

This was solved using the conformation seen in figure 3(a). Here, the headset piece is attached to a contoured metal bar that wraps around the back of the head like a pair of headphones. This bar is stiff, allowing the piece in figure 3(b) to provide sufficient inward pressure on the cheek. There is padding on the other side of the head (not pictured) to distribute pressure and maintain comfort while playing. This piece is further secured by using the straps in figure 3(a), arranged as a headpiece. These straps provide stability for the superior/inferior forces exerted by the headset piece, as well as the anterior/posterior forces. An additional strap from the red pressure pad to the strap headgear may be necessary for stability, depending on the amount of pressure applied.

This design allows for good directionality of the forces applied to the affected cheek. However, the magnitude of the forces it could apply would be restricted by the modulus of the metal bar chosen and by the client's own strength when adjusting the headpiece. Unfortunately, the metal bar's strength is not adjustable, hindering the modularity of this design. The stability of this design is also somewhat questionable, and it is unclear whether sufficient counteracting forces for the piece in figure 3(b). Finally, the fabrication of this piece is complex and requires expertise to manufacture.

Design Alternative 2: Shoulder

The second design idea the team came up with is a shoulder-mounted embouchure device. This device is mounted on a shoulder pad strapped across the body or mounted on unaltered shoulder pads from sports such as hockey or football. Using these shoulder pads for a purpose other than sports has been popularized in many other places, namely the popular Mad Max movies, earning this design the nickname 'Mad Max.'

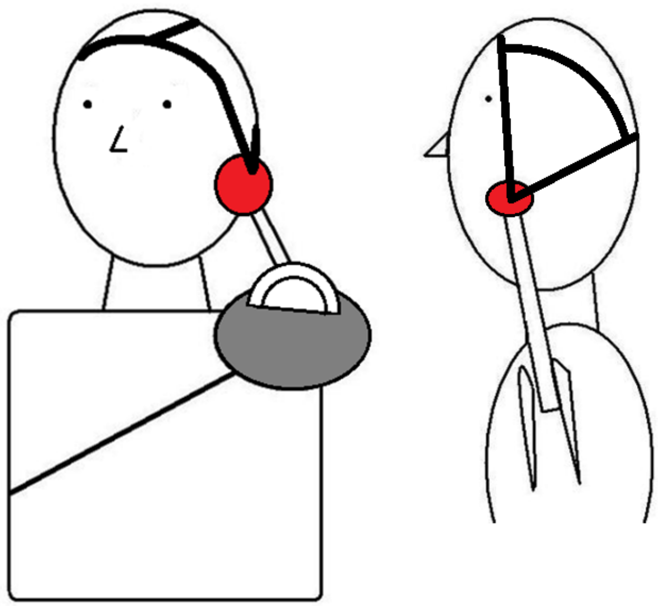


Figure 4. Front and side views of the shoulder-mounted 'Mad Max' embouchure device.

As figure 4 shows, this piece would reach up from the shoulder to apply pressure on the affected cheek. Illustrated in figure 5 is the range of motion of the shoulder piece in greater detail. A curved track is mounted on the shoulder pad that the device would be locked into. This would operate in and out of the sagittal plane. The pressure pad itself is attached to a telescoping metal rod that would operate similarly to the mechanism of height-adjustable crutches. This piece would also come with a strap headpiece similar to that used in design alternative 1 to secure the pressure pad to the face while playing.

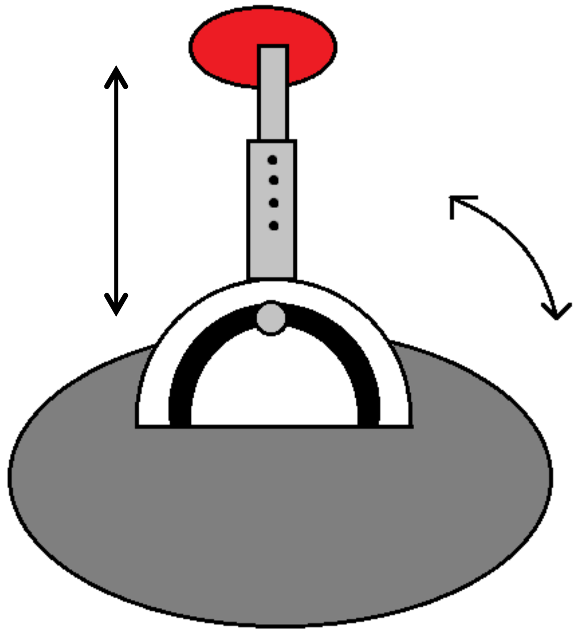
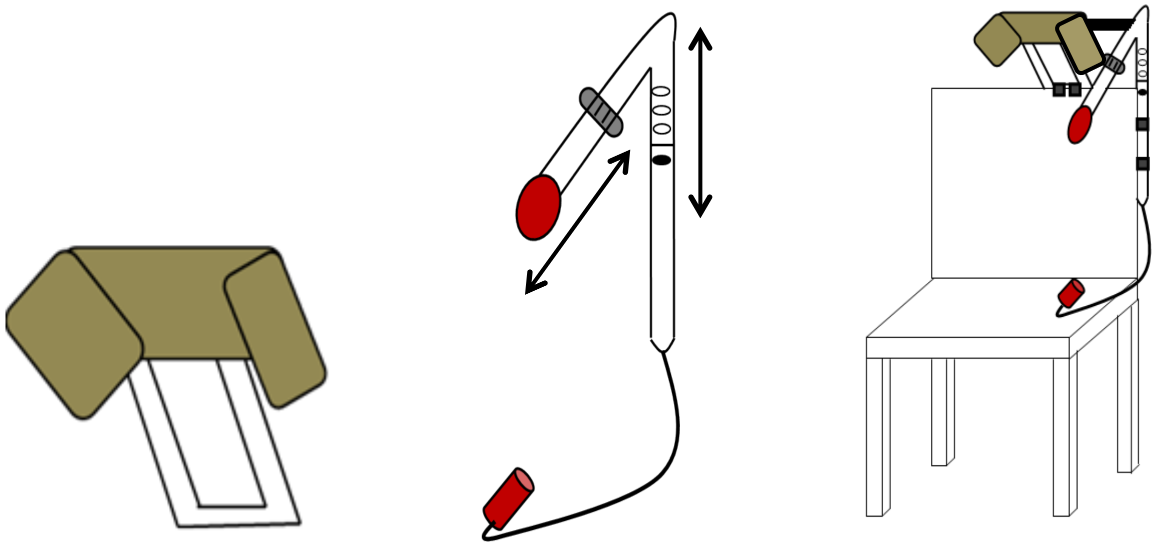


Figure 5. A close up of the 'Mad Max' design. The dark gray oval is the shoulder pad, and the red oval is the pressure applicator.

While this design is easier to fabricate, it does not provide the same directionality as design alternative 1. However, this design can provide larger forces going into the cheek and upwards on the cheek bone. The forward force is largely dependent on the position of the client's shoulders during practice, and partially on the force provided by the front strap on the head piece in figure 4. This piece is easier to adjust than that in design alternative 1, and it is less probable for the client's hair to be caught in the movable parts. This design can also be adjusted while playing because the client is allowed some range of motion to adjust the pressure on the telescoping pad. This extra motion may be a distraction while playing music and would likely tire out the muscles used to apply this extra pressure. Additionally, the shoulder pad(s) is/are bulky and may restrict posture while playing.

Design Alternative 3: Chair Attachment

This design consists of two separate components, a headrest device and an adjustable side attachment, which temporarily connect during use as seen in figure 6. The headrest device is meant to stabilize the head in a secure position, prohibiting head movement in the backward and right directions. Its design contours to the back of the client's head, which will aid in stabilization and comfort. For attachment, a metal extension rising from the back of the headrest connects to a large U-shaped clamp attached firmly to the back of a chair by two tightened bolts. To detach the headrest, the bolts of the U-clamp loosen, allowing removal of the headrest from the back of the chair. For materials, the part of the headrest in contact with the client's head contains an underlying cushion layer for added comfort covered by a cloth material, which can be easily cleaned. The main structure of the headrest is constructed of metal.



a) **b)** **c)**

Figure 6. The chair attachment design. a) The headrest device, b) the side attachment, and c) the combination of both components attached to a chair.

The adjustable side attachment is the component contributing to the forward and inward force applied to the client's left side of the face. Adjustments take place in the horizontal and vertical directions as shown in figure 6(b). A telescoping tube with a spring button locking mechanism allows for movement in the vertical direction to vary the height. The horizontal adjustment is associated with movement of the force applicator forward on the cheek. This is done by sliding the facial force applicator forward and tightening a set screw to secure it in place. For attachment to the chair, two smaller U-clamps are used in a similar manner to the headrest. A material resistant to bending such as aluminum or steel is used for the adjustable side device.

Included in the side attachment is a pneumatic balloon, which applies the main inward force. A balloon is joined at the end of the force applicator with a hose that runs through the side attachment and connects to a hand pump. The red items in figure 6(b) represent the air balloon and hand pump. Squeezing the hand pump inflates the balloon in a forward/inward direction. Air pressure is released with a valve which, along with the hand pump, is positioned at the client's side at all times for quick control of air pressure.

In order to provide additional stabilization for the force applicator, a resistance cord attaches the headrest to the side attachment, represented as a black strip in figure 6(c). It will be a temporary connection used while playing clarinet.

Design Matrix at Mid-semester

The headgear, shoulder, and chair attachment 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 totals were out of a total of 100 points.

Weight	Categories	Headgear	Shoulder	Chair
10	Fabrication	3	8	4
10	Cost	7	5	2
20	Ease of Use	10	15	14
20	Client Preference	20	10	15
40	Directionality/Pressure/Force	25	20	35
100		65	58	70

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 will not maintain constant pressure on the left side of the face, making it ineffective. Comparing the three design alternatives in this category, the chair attachment received the highest point value of 35. The chair attachment can supply the strongest force and it utilizes the chair as a platform for stability and balances forces on the head. This is unlike the shoulder design which is attached to an unstable platform and the headgear design which has difficulty balancing forces.

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 headgear design was desired the most by the client so it received the highest point value of 20.

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. The shoulder design received the highest point value of 15 because it is the least complicated to use and set up. However, since it is less portable, it did not receive the full point value.

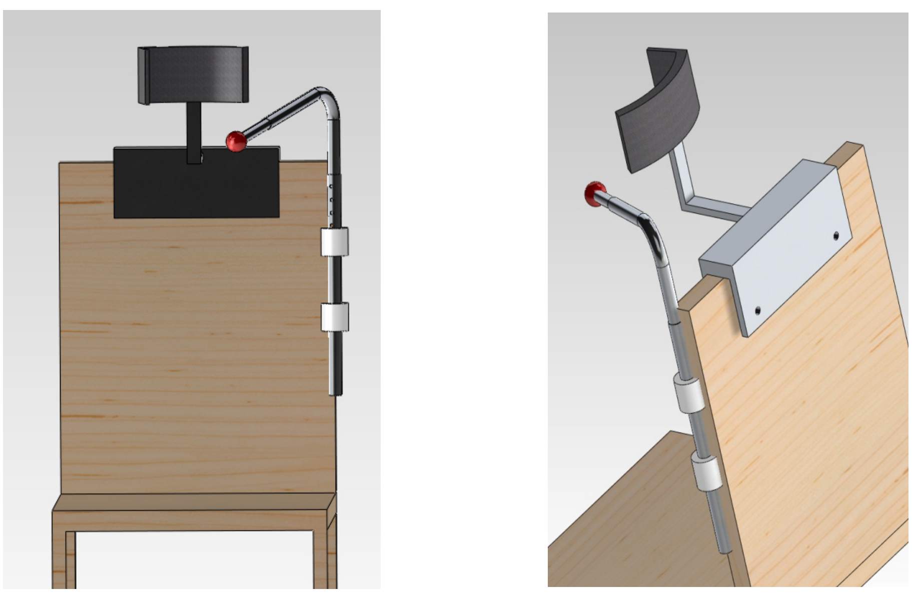
Although fabrication and cost are important, both criteria were weighted at 10 points out of 100. Fabrication includes access to the necessary materials and the ability to manufacture the embouchure device. The device should remain below the team's budget of $200 after fabrication is completed. The headgear design would cost the least to produce due to smaller components and less material, but the shoulder would be the easiest to fabricate.

Proposed Final Design at Mid-semester

Table 2. Summary of final design choice in form of pros and cons list.

Chair Attachment	
Pros	**Cons**
1) Largest pressure application	1) Portability – 2 separate components
2) Stability	2) Cost – Expensive materials and fabrication
3) Utilization of chair to balance forces	3) Large size

Based on the design matrix and the team's knowledge of the three design alternatives, the final design was the chair attachment pictured in figure 8. The chair attachment would have supplied the most pressure and stability while playing clarinet, which overrides possible disadvantages. It also utilized the chair to balance forces applied to the client's face. Disadvantages include portability and cost. The design was less portable because it has two separate components which were not small in size. Since this device was going to be used for practice only, it could have remained on the same chair for a longer period of time. Cost was another disadvantage because it required use of more materials that may have been expensive. Fabrication of a prototype would also have been more expensive than the other two designs. Table 2 is a summary of the pros and cons just described for choosing the chair attachment.



a) b)

Figure 8. A SolidWorks^{TM} representation of the proposed final design for the embouchure assistive device at mid-semester. From left to right, a) is a front view of the device and b) is a back view of the device. Not included in this figure are the hand pump and the resistive cord connecting the side attachment and headrest.

Final Design at End of Semester

The final design at mid-semester was going to be the chair attachment design. It was determined after mid-semester to develop a headgear device instead as it would allow more freedom of movement while playing clarinet and would be easier to adjust with one hand. It would also be small in size which would be efficient for storage and portability. The chair attachment restricted movement and was inconvenient in terms of transport and adjustment. The headgear design was evaluated with the past mid-semester design options. Table 3 is the current design matrix.

Table 3. Revised design matrix incorporating the new headgear design.

Weight	Categories	Headgear	Shoulder	Chair	Headgear 2.0
10	Fabrication	3	8	4	4
10	Cost	7	5	2	7
20	Ease of Use	10	15	14	15
20	Client Preference	20	10	10	20
40	Directionality/Pressure/Force	25	20	35	30
100		65	58	65	76

The developed headgear design was not either of the headgear design option created at mid-semester. The only similarity was the head straps which secure the force apparatus of the headgear device to the client's head. Figure 9 is the force apparatus designed for the final headgear prototype.

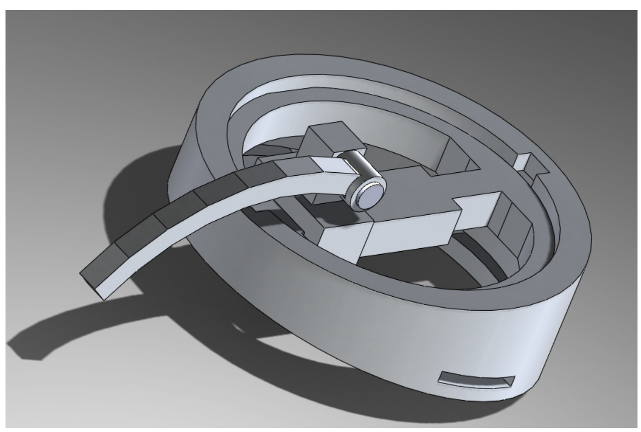


Figure 9. SolidWorks™ image of the force apparatus for the final headgear device. Secured to the head by head straps.

The outer base is a ring, 4 inches in diameter, which is placed over the left ear of the client's face. Three slits around the bottom edge of the base provide attachment positions for the head straps. The base was designed with a beveled surface to provide accurate force application. It does this by slanting inwards towards the cheek, allowing a stronger inward force to be applied during the forward force application. Around the bottom surface of the base is cushioning that adds extra comfort for the team's client as it is pressed against the face. The base component is pictured in figure 10. The inner ring fits into a groove made in the base which is located near the top surface to avoid contact of the inner ring with the client's ear. The groove enables the inner ring to rotate freely within the base. The team's client would be able to correctly place the inner ring in the desired position. A portion of the inner ring is a track that runs down the middle (figure 11). A sliding piece is affixed to this track by use of a set screw (figure 12). Loosening the set screw allows the sliding piece to move forward and backward along the track. The set screw is tightened to secure the sliding piece in place. Finally, there is a force arm connected to the sliding piece which rotates inwards towards and outwards from the cheek (figure 13). It has designed to have a curvature to provide accurate inward pressure. Another set screw is used between the sliding piece and the force arm. By loosening the set screw, the force arm can rotate freely until the set screw is tightened to secure its position. The final piece to the force apparatus was padding attached at the end of the force arm. It was designed to be three fingers width thick to apply enough force to an appropriate cheek area. It was firm, yet comfortable when pressed against the cheek.

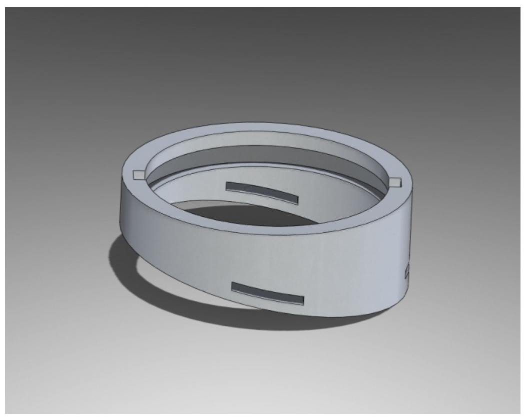


Figure 10. SolidWorks™ image of base component for force apparatus.

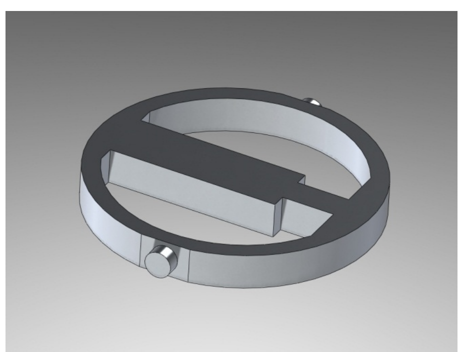


Figure 11. SolidWorks™ image of inner ring with track for force apparatus.

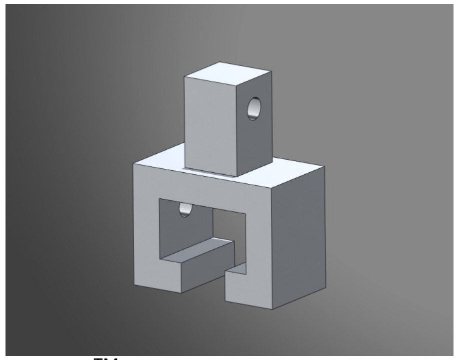


Figure 12. SolidWorks™ image of sliding piece for force apparatus.

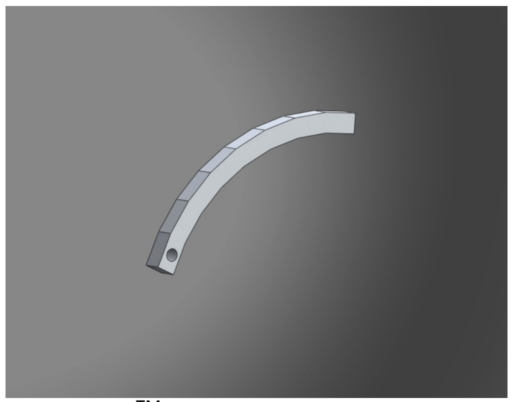


Figure 13. SolidWorks™ image of force arm for force apparatus.

It was necessary that this headgear device 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 are placed on the head. The straps can be tightened if desired. Second, the inner track is positioned within the base. The team's client would rotate it so that the force arm was positioned on the cheek in the correct location. Third, the set screw would be loosened for the force arm and the force arm would be rotated inward towards the cheek to apply efficient inward pressure. The set screw would be tightened to secure the force arm in place. Fourth, the sliding piece's set screw would be loosened and the sliding piece would be pushed forward, applying forward pressure to the cheek in combination with the inward pressure applied by the force arm. Once the sliding piece is in position, the set screw is tightened to secure it in place. The final result is an inward and forward pressure combination maintained near the mouth of the client that helps her hold the pressure around the clarinet's mouthpiece.

Figure 14 is the complete developed prototype of the headgear device on the team's client's head. The final product 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 1 inch 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. Included in Appendix B are dimensions for all the components in the final design the team developed.

Figure 14. Rapid prototype of complete headgear device tested on the team's client.

Prototype Testing

Due to the extended design period of this semester, the team did not conduct any tests using the initial prototype. However, the team did model the applied forces using SolidWorks^{TM} incorporated stress analysis software, which looked at the Von Mises Stress and Factor of Safety (FOS) of the design. Stress analysis was not able to be performed on the assembly of every piece in the final design and was performed on a piece-by-piece basis.

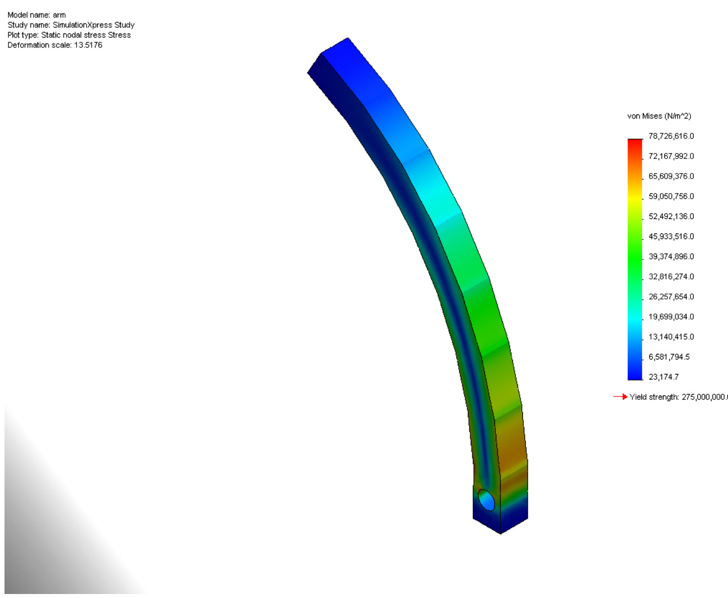


Figure 15. Strength testing of force arm. Maximum stress is 78.7 MPa with 10 lb force. Aluminum yields a factor of safety of 3.5.

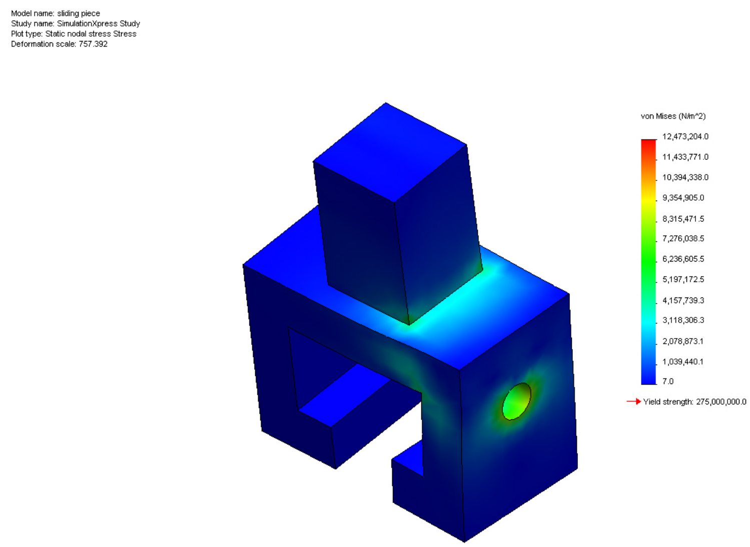


Figure 16. Strength testing of sliding piece. Maximum stress is 12.5 MPa with 10 lb force. ABS yields a factor of safety of 4.

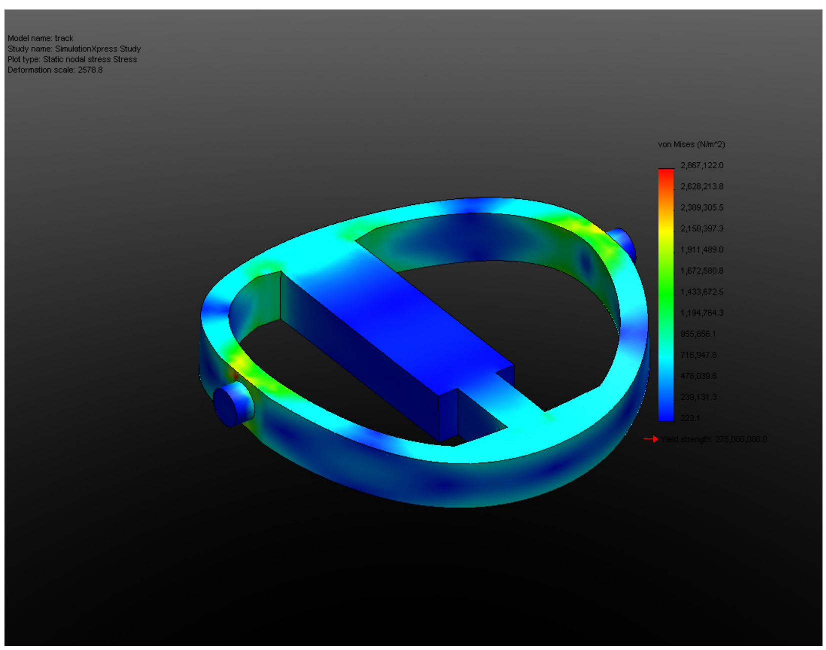


Figure 17. Strength testing of inner ring. Maximum stress is 2.7 MPa with 10 lb force. ABS yields a factor of safety of 18.

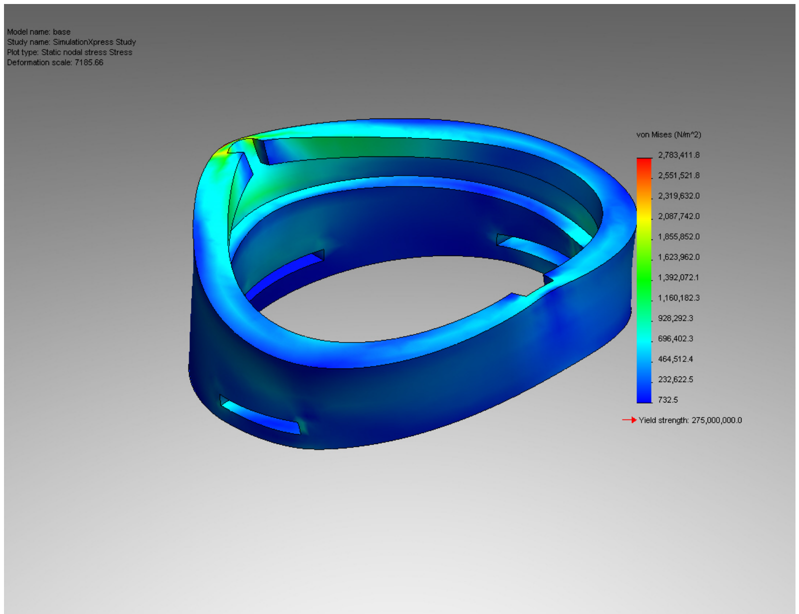


Figure 18. Strength testing of base ring. Maximum stress is 2.8 MPa with 10 lb force. ABS yields a factor of safety of 17.

The Von Mises Stress is calculated from all of the interacting forces on a given piece and tells you whether the stress combination at a given point will cause failure. In the computational study, the material selected for each part is 6061 aluminum, which is what the final design will be constructed from. It is important to note that the absolute values of the Von Mises Stress will not be changed for ABS plastic, but that ABS plastic has a lower yield strength and would be more likely to fail. From the results, it is apparent that the only part of the design that would fail using ABS plastic is the force applicator arm, figure 15. For the current prototype, the ABS plastic arm was discarded and replaced with a chrome-plated copper tube. This change was not using computational analysis.

Another helpful result of the preliminary stress analysis is the Factor of Safety (FOS). It is calculated using:

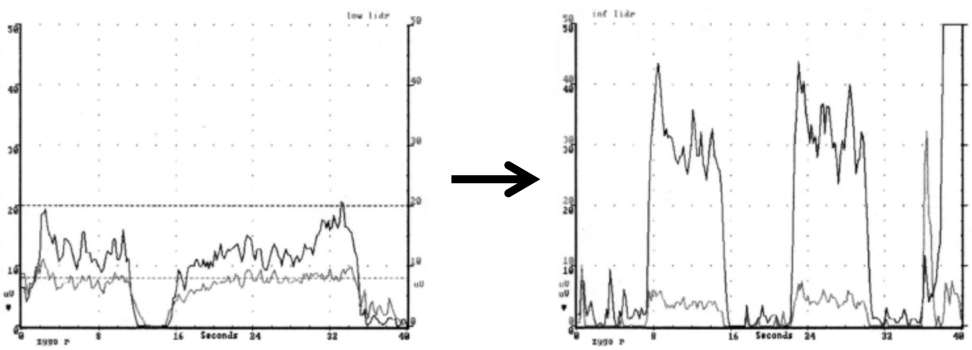
FOS = Material Strength/Design Load

Most applications require an FOS of >1, typically between 2 and 3. All of the designs had an FOS >3 for ABS plastic, with the exception of the force applicator arm, which had an ABS FOS of 0.6, but was 3.5 after making the switch to 6061 aluminum. These results confirm that 6061 aluminum in the final design will be able to withstand the forces placed on it.

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 19. This shows that SEMG should be sufficiently sensitive to detect small changes in muscle contractility that accompany changes in embouchure.



a) b)

Figure 19. SEMG data taken for a 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

There are still a number of things that need improvement on the prototype. Perhaps the most important improvement is the redesign of the adjustment mechanisms. The current design has two set screws that loosen to adjust placement of the force applicator and tighten to fix them in place. While mechanically simple, the set screw system requires two hands to operate, and in a performance environment, the client would only have one hand with which to make the adjustment. Other possible design alternatives for this will be investigated.

After initial construction, the headpiece has also been found to be too bulky, and it is estimated the size could be reduced up to 33% with no loss in efficiency. A further prototype to validate this will need to be constructed.

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.

Finally, the team will need to fabricate the final design out of aluminum instead of the current ABS plastic and chrome-plated copper tubing. This will make the design consistent with the team's computational specifications and give the design a higher durability.

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

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Appendix A: PDS

Product Design Specifications – September 13, 2011
Project 12: Embouchure Device

Team Members
Megan Jones – Leader
Andrew LaCroix – Communicator
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Patrick Cassidy – BSAC

Problem Statement

Bell's Palsy, a condition affecting the 7^{th} 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
     - $-30^{o}C$ to $50^{o}C$

f. Operating Environment
    - Used in warm environment
        - 37^{o}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 3kg applied to face
    - Engage/Disengage time less than 30s

h. Size
    - Small enough for transportation in one hand
    - Should not encroach on surrounding musicians' vision

i. Weight
    - Less than 1.5kg
    - 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