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

# Embouchure Assistive Device

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Final Report

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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

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 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].

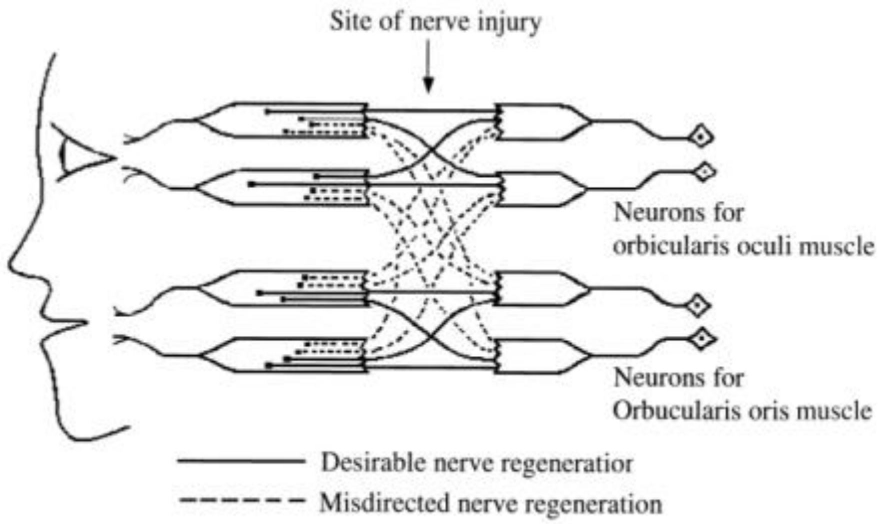



**Figure 1**. Misdirection of neurons to wrong motor endplates [6].

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.

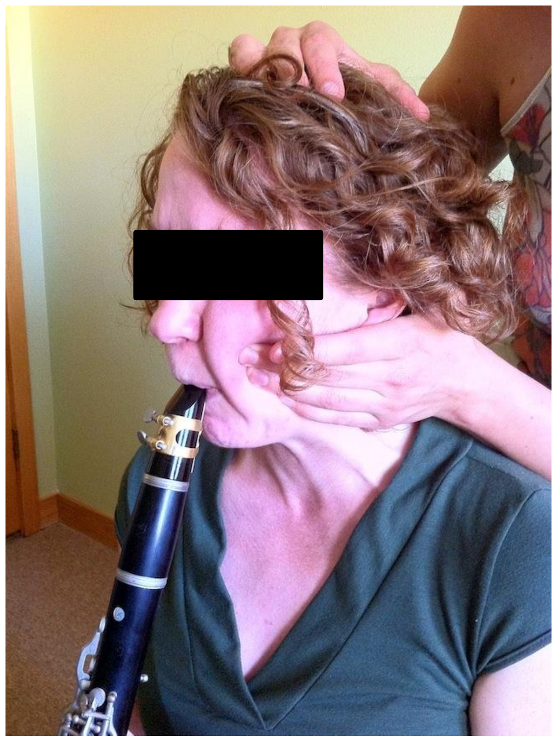


**Figure 2**. The team's client playing clarinet while her Rolfer experiments with different pressures applied to the synkinesis-affected side of her face.

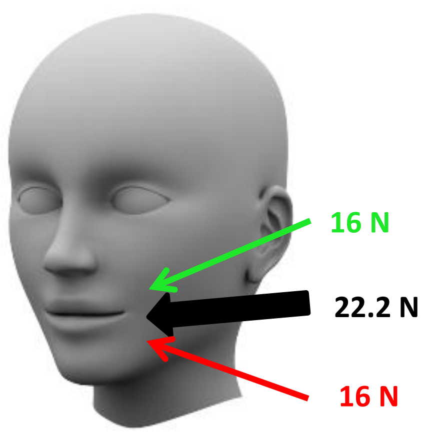


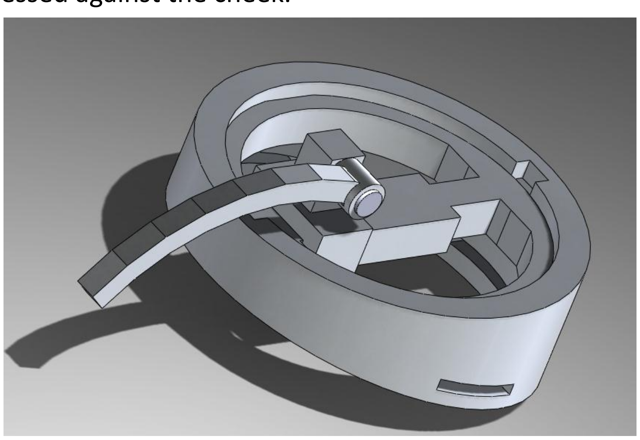

**Figure 3.** Free body diagram of forces on left cheek supplied by the device. The black arrow is the net force to be applied to the left cheek. The green arrow is the required forward force

(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$^{TM}$ 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 at 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.

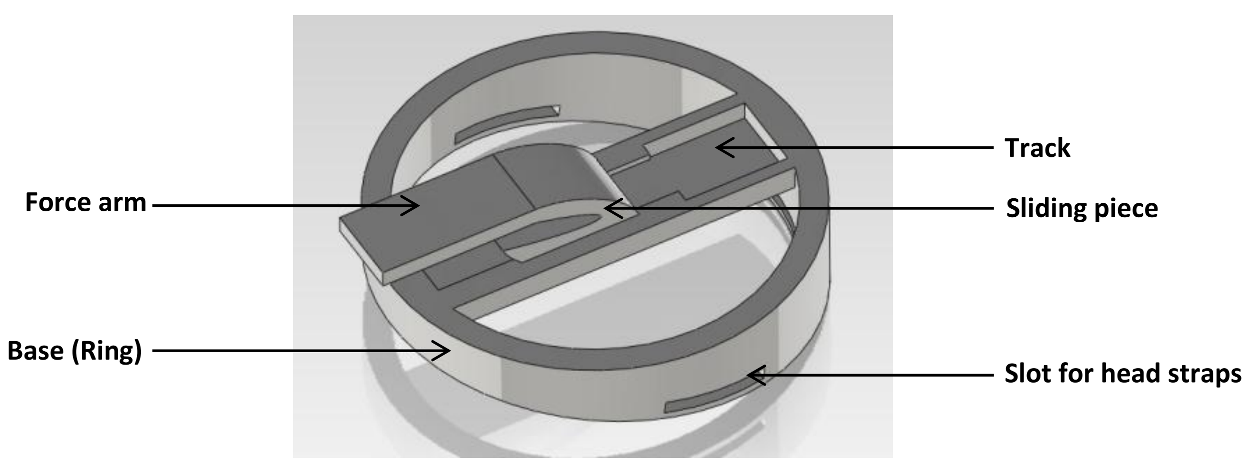



**Figure 6**. The complete SolidWorks™ design for the spring metal headgear design alternative.

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.

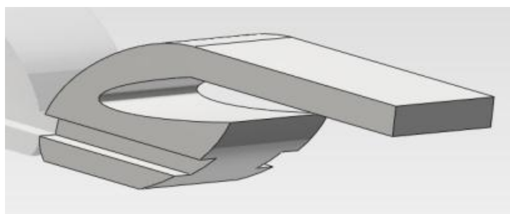


**Figure 7.** SolidWorks$^{TM}$ image of the sliding piece.

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.

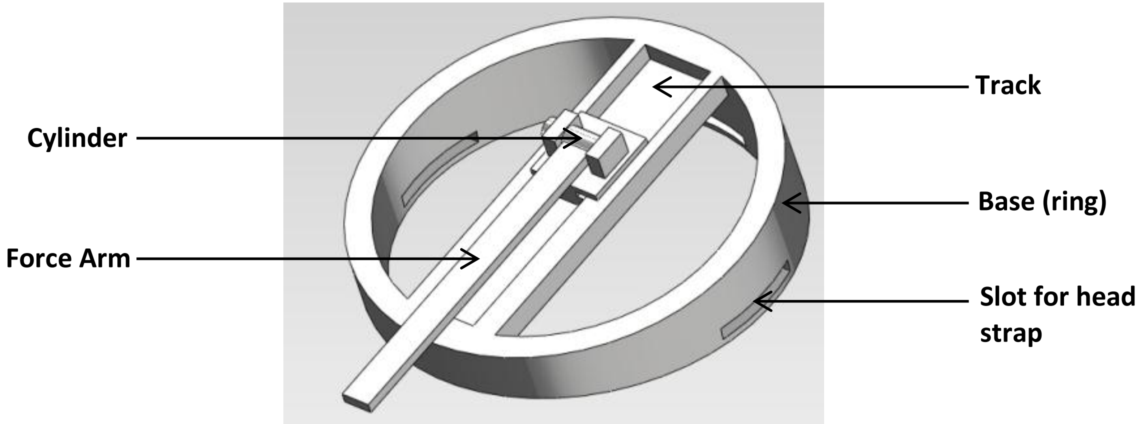
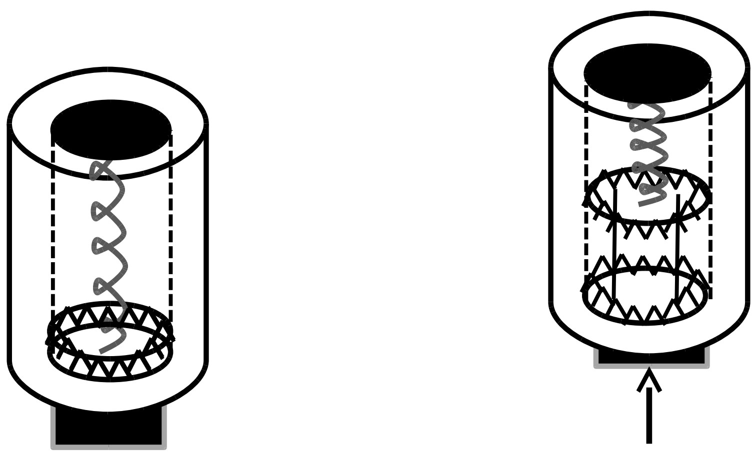



**Figure 8.** The complete SolidWorks™ design for the button adjustment design alternative.

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.



**(a)** **(b)**

**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 forhead arms to provide flexibility in fit around the forhead.

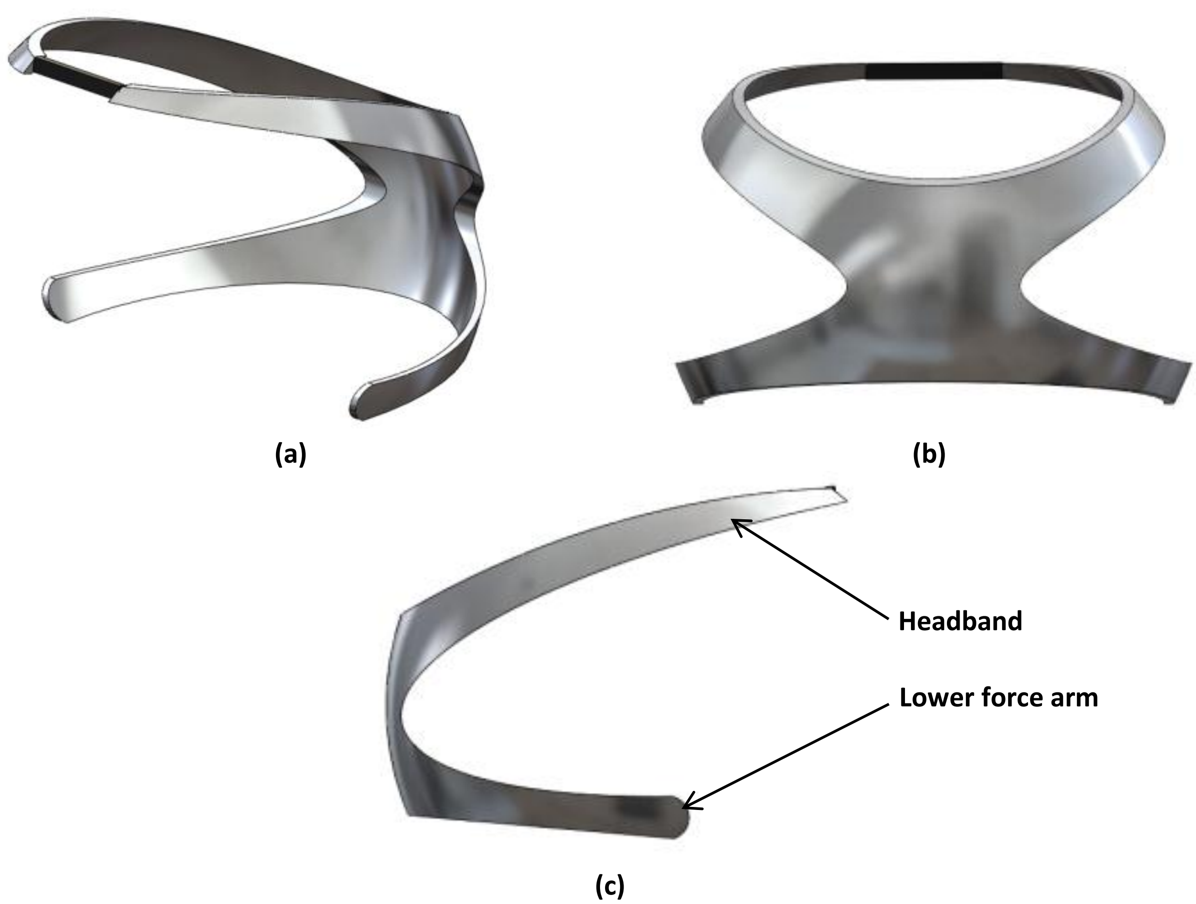


**Figure 10**. The butterfly tiara design. (a) A view of the entire design, (b) the back view, and (c) the side view.

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.

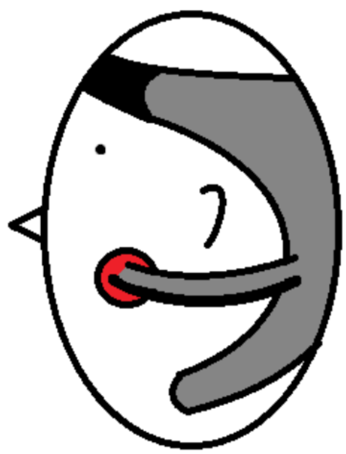


**Figure 11.** Butterfly tiara design alternative on head with additional force arm extending off left side of tiara.

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.

## Proposed Final Designs at Mid-Semester

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.

## Final Devices Developed at End of Second Semester

There were two final devices the team constructed this semester for the client to use. These were the modified ring headgear device similar to last semester’s prototype and the coil headgear device, which is different than the butterfly tiara design described at mid-semester.

### *Ring Headgear Device*

The ring headgear design shown in figure 12 is a smaller version of last semester’s prototype with only one ring component that rests over the left ear. For the ring, it was rapid prototyped out of ABS plastic, which is strong enough for the team’s purposes. Padding was added to the bottom of the ring for added comfort when its worn over the ear. The ring was painted with a metallic finish to improve its appearance. The ring is secured to the head with an elastic strap that comes across the forehead and goes around the lower portion of the back of the head. The length of the elastic strap can be adjusted depending on the client’s preference. Built into the ring is a track that crosses through the middle of the ring. It is level with the top of the ring and is as thin as possible to reduce contact between the track and the ear. Unlike last semester, the sliding piece was designed to slide within the track rather than the outside to also eliminate uncomfortable contact with the ear. Dimensions for both the ring and the sliding piece are attached in Appendix B.

**Figure 12.** Ring headgear device developed at end of semester.

For the force arm, it was meant to work like a preset cantilever beam. The force arm was permanently bent inwards towards the cheek to a point where the end of the force arm would pass the position of the cheek. As the force arm is pulled back away from the cheek when the ring is being placed on the head, it would return back to its original position once the ring was secured; this would lead to the force arm pushing into the cheek. The force arm was made out of two layers of 1095 spring steel. The 1095 spring steel was chosen because of its high strength and elastic properties. By layering the force arm, it would increase its strength and would be able to apply more force to the client's face. The force arm was permanently attached to the sliding piece at one end with two small screws. Also connected to the top of the sliding piece was a handle that would make the moving of the sliding piece and, hence the force arm, easier. Padding was added to the end of the force arm to make it more comfortable when the force was applied and to increase the contact area of the cheek to make the force more uniform and efficient.

To use the ring headgear device, the ring is placed over the left ear and the straps are situated over the head to hold the ring in place. The force arm is already pushing on the cheek, so all that is needed to be done by the user is pushing the sliding piece forward. This causes the end of the force arm with the padding to push the cheek forward. The user can stop pushing the sliding piece once the overall force is applied to the appropriate position.

Advantages to the ring device are that it is easy to use, it can be easily adjusted with one hand, and it is lightweight. When the head moves, the force arm should continue applying force due to the preset cantilever beam. This makes the ring headgear device very dynamic. Disadvantages to the ring device are that the force is not easily relieved if the client wants to take it off between songs and the sliding piece does not slide as easily as expected back and forth. Reason for this is because when the force arm is applying force to the cheek, it is also causing the sliding piece to pull up within the track. This causes the sliding piece to push more on the track and increase the tension, making it difficult to move.

### *Coil Headgear Device*

The coil headgear device shown in figure 13 is a very simplistic alternative to the ring headgear device. The coil device is made of two layers of 1095 spring steel that circles around the head and continues into a force arm that ends on the cheek. The spring steel is bent and coiled tighter than the circumference of the client's head so that when placed on the head, it will wrap nicely around the client's head as it recoils back inward. This recoil also helps push the force arm into the cheek. To increase the force applied by the force arm and to aid in directing the force correctly, a reinforcement bar of 0.0048 m iron bar stock was attached to the backside of the coil where it extends over the force arm. The reinforcement bar, shown in figure 14, helps the coil maintain its shape and it pushes in on the force arm. For added comfort, the inside of the coil is padded. To enhance the stability of the coil device on the head, the entire length of coil was wrapped with black grip tape which creates a friction interface between the client's head and the coil. The black tape also adds in the aesthetics of the device. In addition to the grip tape improving the coil device's overall appearance, covers were created to go over the coil. This provides more options for the appearance of the device and the client can choose the type of cover she wants from day to day. The covers are also washable, which will help keep the device sanitary.


**Figure 13.** Coil headgear design developed at end of semester.

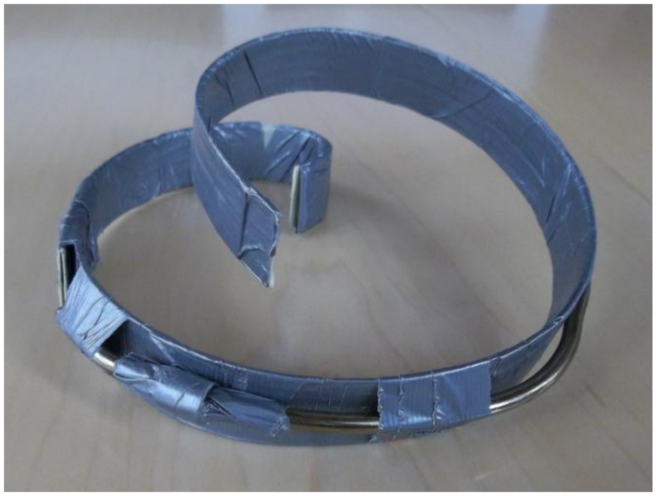


**Figure 14.** The reinforcement bar placed on the backside of the coil design.

Using the device is very simple. The coil is stretched out and placed on the head, adjusting it to the appropriate position on the head so that the correct force is being applied to the cheek. The coil would remain in its fixed position once released.

Advantages to using this device are that it is easy to use, has a sleek design, provides an appropriate force, is comfortable, has a professional appearance, and it is easy to disengage the force between songs. Disadvantages to using this device are that the force cannot be adjusted; it is one magnitude of force as long as the coil stays tight on the head.

## Testing

### *Force testing*

Force testing was done using a mechanical spring-loaded compressive strain gauge that measured 1 N to 175 N. The testing setup can be seen in figure 15. Briefly, the strain gauge was clamped vertically, so that it could not move. Each design was then pressed on the table, using a support to make it flush with the top of the strain gauge. The force arm of each design contacted the top of the strain gauge, in order to mimic the force being applied when the device would actually be worn. This was done three times for both the ring and coil designs, respectively. The results of this testing can be seen in table 2.

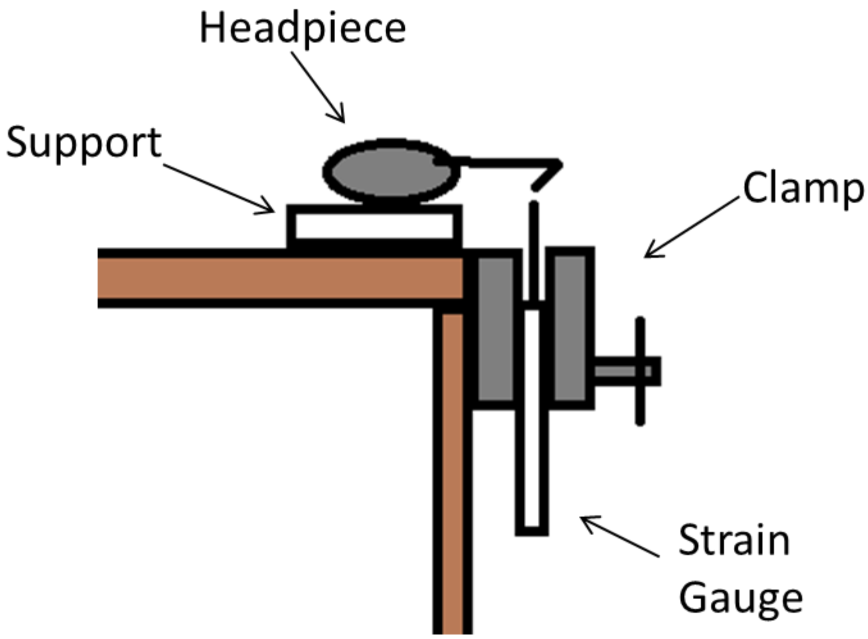



**Figure 15.** Force testing setup.

**Table 2.** Measurements from force testing.

| **Trial** | **1** | **2** | **3** | **Avg.** |
|---|---|---|---|---|
| **Ring** | 8.8 N | 10.12 N | 8.8 N | 9.24 ± 0.62 N |
| **Coil** | 4.4 N | 6.6 N | 6.6 N | 5.87 ± 1.04 N |

In this manner, it was determined that the ring design applied a greater force of 9.24 N compared to the coil design's 5.87 N. The goal this semester was to design devices that were able to apply approximately 22 N of force, however, and thus these designs fell short of the proposed design goals.

### *User testing*

In addition to the more quantitative force testing, user testing was also done with the client, who can be seen wearing each design in figure 16. Each design was evaluated with regards to comfort, ease of use, function, and aesthetics.

The ring design was tried first, since it excelled in the force testing. The ring over the ear, elastic straps, and force applicator pad were comfortable and easy to use, although it provided insufficient force and was aesthetically unappealing. Although the ring design is smaller and has an inner track, the contact with the client's ear was still deemed unsuitable. Additionally, it is possible that by positioning this prototype over the ear, there may be some attenuation of the sound the client hears while playing in a rehearsal or performance setting. It was also found that the elastic straps, while effective in the previous design, were unable to counteract the force applied by the cantilever on the client's cheek. This reduced the amount of force the ring design was able to apply. While the force was still noticeable, it was found to be unsuitable for prolonged practice sessions. Finally, the sliding track mechanism was also found to be difficult to adjust using only one hand, due to frictional forces supplied from the connected cantilever.

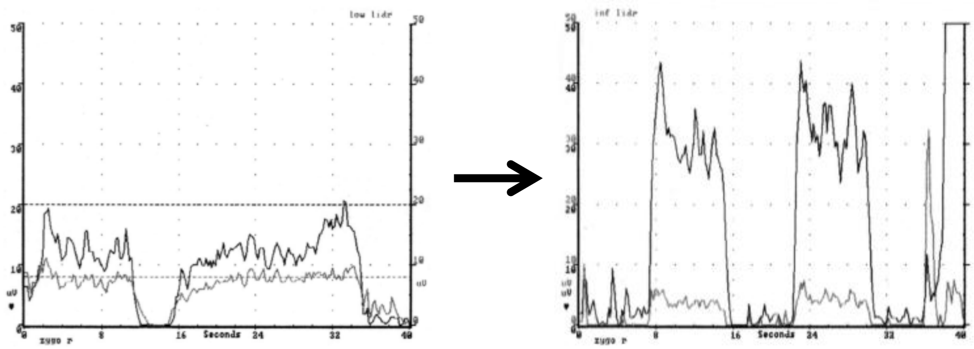
The coil design was also tested and was found to be less comfortable, but had preferable aesthetics, supplied greater force, and was easier to use than the ring design. While the force supplied from the coil design was found to be greater than that of the ring design in user testing, the force supplied was still insufficient for playing times greater than approximately 10 min. Additionally, the lack of a force applicator pad made the contact of the force arm with the face less comfortable than the ring design. During user testing it was also noted that there are unwanted torsional effects while wearing the coil that make it less comfortable and less efficient at force application. However, the design was much more aesthetically pleasing, maintained its position well, and, importantly, did not seem obstruct the client's hearing or uncomfortably contact either ear.

**Figure 16.** Client wearing the ring (left) and coil (right) prototypes.

## Future Work

### *Further 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 17. This shows that SEMG should be sufficiently sensitive to detect small changes in muscle contractility that accompany changes in embouchure.



**(a)** **(b)**

**Figure 17**. 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. This system could be used to help determine the long-term efficacy of the device.

### *Improvements*

Improvements will need to be made to each prototype, assuming the client wishes to pursue each design. For longevity, the ring design would be made out of aluminum, although the force arm would still be 1095 blue spring steel. The elastic straps would be replaced with tougher, inelastic straps to counteract the force from the cantilever. These straps would also be padded for comfort and, if necessary, also have some adhesive properties to maintain the headpiece's position on the head. The sliding piece on the inner track would need to be smoothed to reduce friction, making it easier to move with one hand. Additionally, a greater depth of the ring may be preferable so that the track does not contact the ear. To apply more force, another sheet of 1095 spring steel may need to be incorporated into the cantilever. Alternatively, the cantilever could be preset in towards the face further, thereby applying more force. Finally, an engage/disengage mechanism would need to be designed so that the client could remove the force being applied in-between pieces of music.

The coil design also requires some design improvements before regular use. The efficacy of the coil design is largely dependent on the supporting iron bar. This bar could be extended along the force arm, which would effectively shorten it and allow it to apply a greater force on the cheek. A mechanism could be designed to make this elongation adjustable for varying amounts of force. This same mechanism could also fulfill the requirement of an engage/disengage function. Addition of a force applicator pad to the cantilever is also desirable to make the device more comfortable and to mimic the more natural feel of three fingers applying pressure to the cheek. Additional padding along the inner surface of the coil could also make the design more comfortable to wear for extended periods. Since the coil design is heavier than the ring design, the supporting iron bar could be replaced with a similarly rigid, but lightweight alternative, such as aluminum or titanium. It is also possible that a hollow rod of any of these materials may be able to confer a similar structural stability to the solid bar while making the device lighter overall. Finally, removable coverings for the coil design with improved aesthetics could be designed to better match client preference.

## Ethics

The current prototype was 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.

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## Appendix A: PDS

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

**Team Members**
Megan Jones – Leader
Vivian Chen – BSAC and Communicator
Patrick Cassidy – BWIG

**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°C to 50°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 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

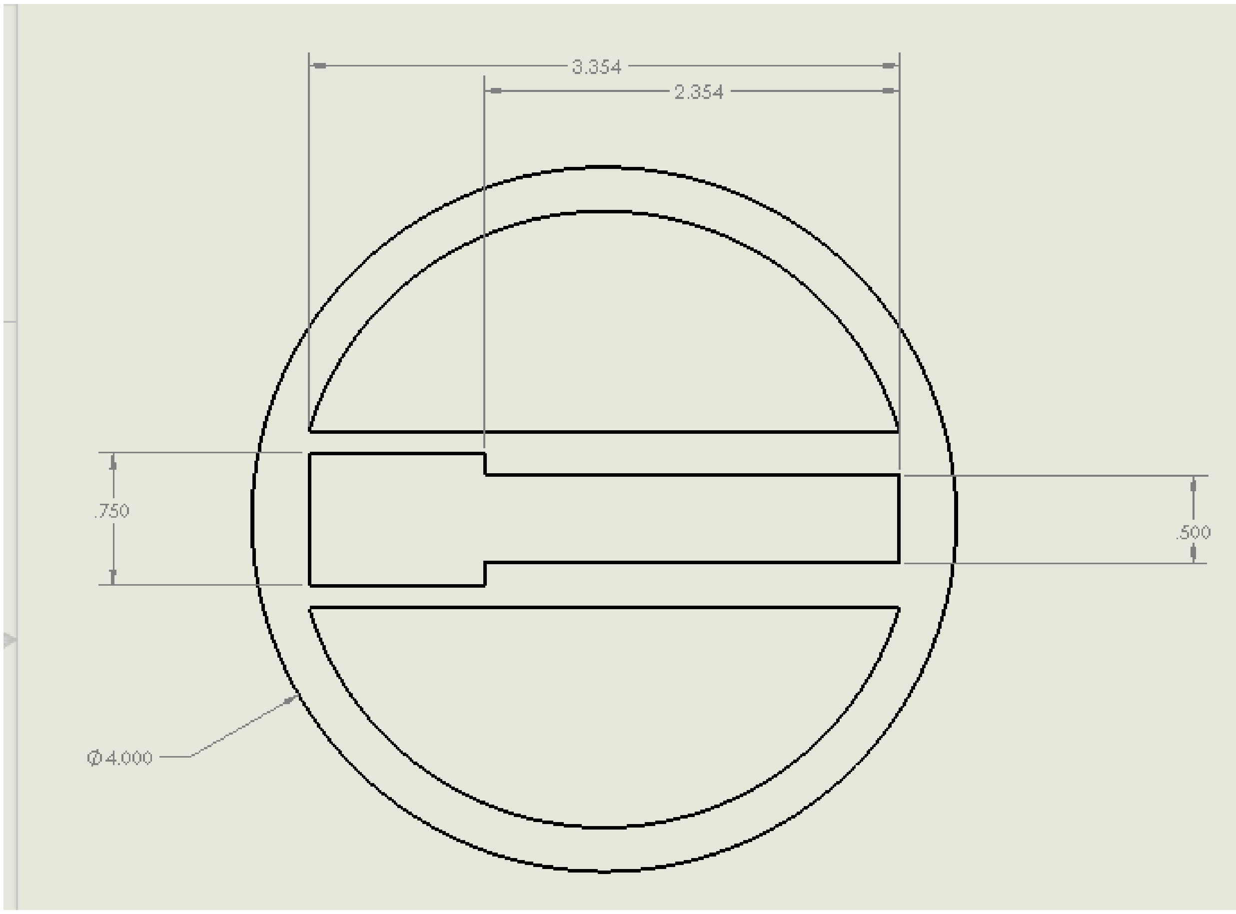
b. Cost
- Less than $200 for development and materials

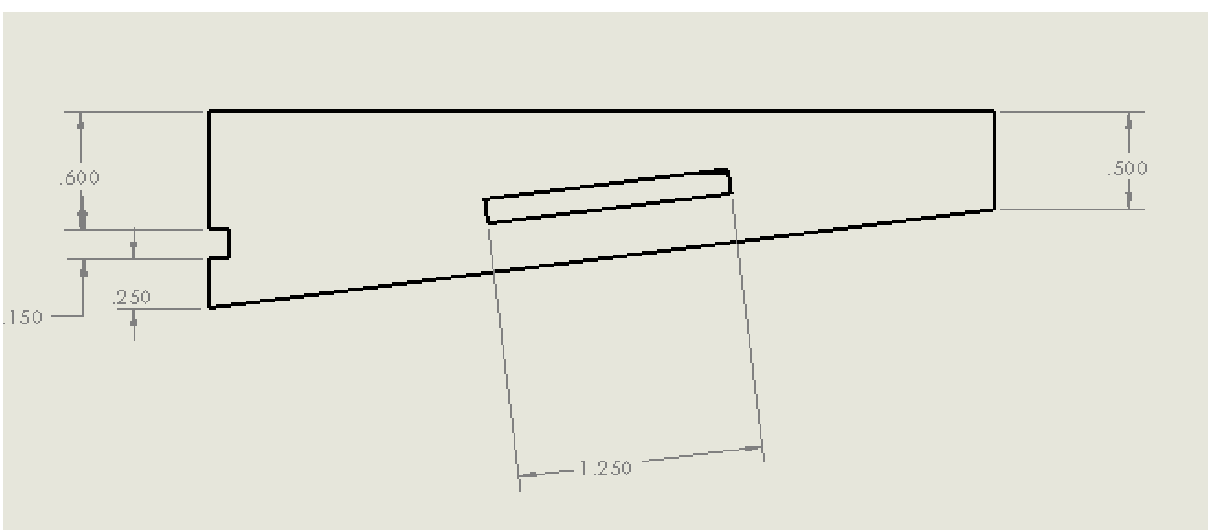
**3. Miscellaneous**

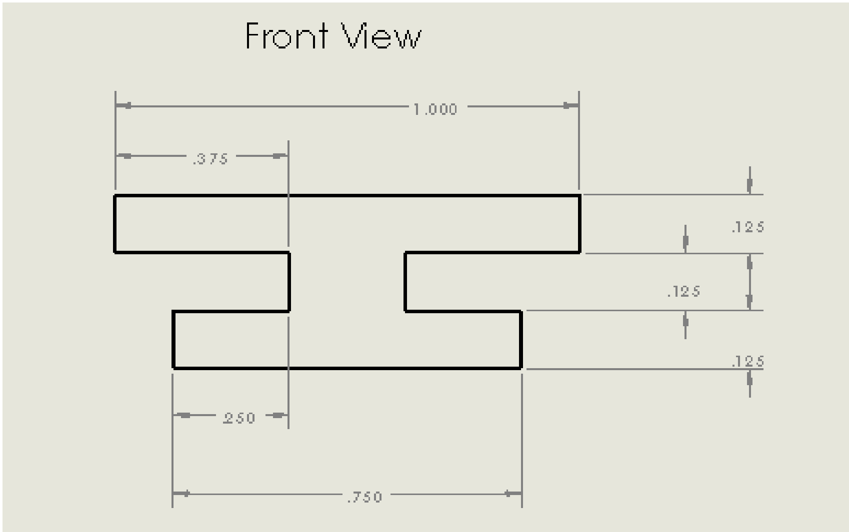
a. Patient-related concerns
- Device will be sterilized between uses

# Appendix B: Dimensions of Ring Headgear Device

-Units: inches




Front View
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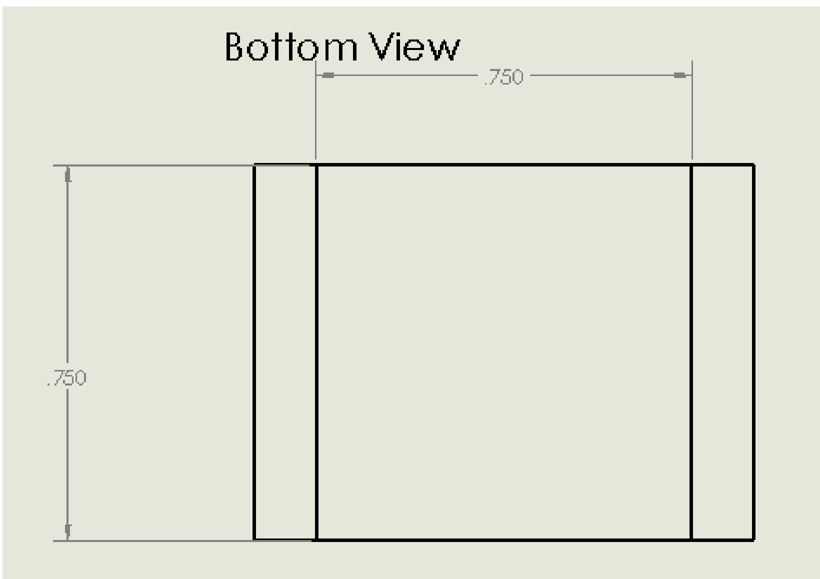
.125
.125
.125
.250
.750


Bottom View
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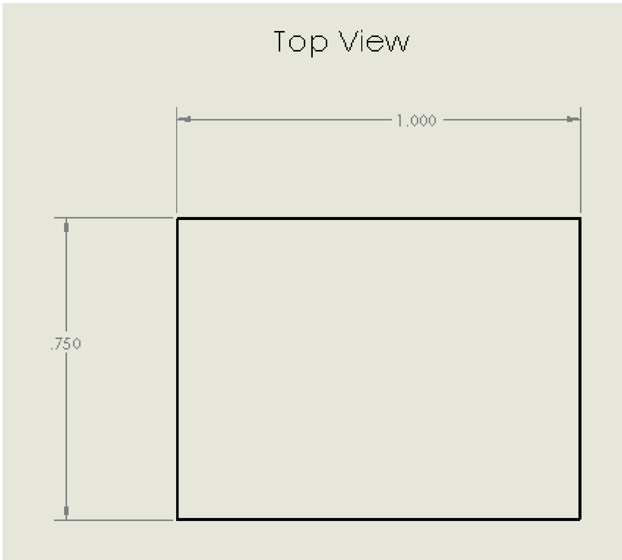
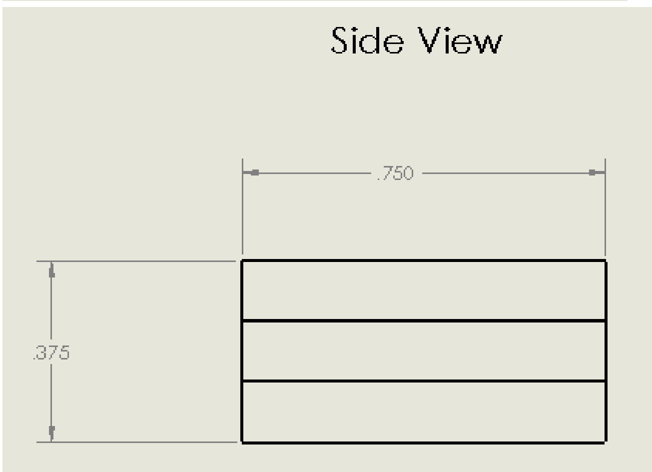

Top View
1.000
.750


Side View
.750
.375