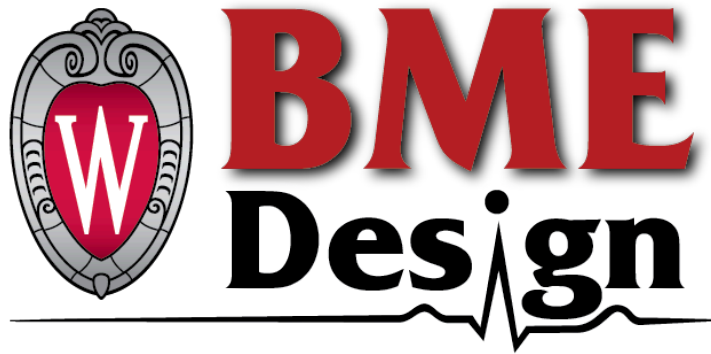




Embouchure Assist Device

Preliminary Report

BME 200/300 Design

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Abstract

Facial paralysis affects 30.5/100,000 annually and can prevent musicians from forming the necessary embouchure required to play a woodwind instrument [1]. The oboe embouchure is particularly difficult to form and has no existing devices to assist oboists with facial paralysis [2]. The project's client experiences this gap in the market firsthand and desires a comfortable and stable assistive device to form paralyzed muscles into an oboe embouchure. The proposed solution is a headset design utilizing an adjustable force arm to apply pressure to the paralyzed facial muscles. The device will be fabricated using existing headset designs and PLA 3D printed force arms padded with silicone. The muscles are pushed forward into a proper embouchure. Testing will include measuring the force necessary to maintain embouchure during play and testing the fabricated design to these force measurements. Additionally, air pressure produced with and without the device will be measured and quantitatively compared. The device's overall performance will be tested both quantitatively and qualitatively by measuring the duration of note sustained and air leaks during play as well as comfort and adjustability with and without the device. The use and analysis of this data will inform the success of this device for assisting facial paralysis patients with embouchure formation. A successful device will improve musician's experience and ability to play the oboe due to a supported embouchure.

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Introduction

Motivation

Each year over 100,000 Americans are diagnosed with a Facial Nerve Disorder (FND) [1]. FNDs are accompanied by weakness and little to no control of facial muscles. Those with facial paralysis often struggle to play instruments, particularly woodwind instruments which require a tight air seal around the mouthpiece. A woodwind musician's embouchure is vital to their play and requires them to engage their buccinators, zygomaticus, and orbicularis oris muscles [3]. These facial muscles are all innervated by the facial nerve (CN VII), so facial paralysis especially limits their function and prevents musicians from forming a strong embouchure [4]. The oboe requires a uniquely strong embouchure due to its double reed and lack of stabilizing mouthpiece [2]. Thus, previously designed solutions struggle to meet oboists' needs. The impact of FND and paralysis on musicians is often overlooked despite its potential to significantly reduce patient quality of life.

Existing Devices

Oboists with facial paralysis have to take frequent breaks from play and cannot sustain play without experiencing air leaks and embouchure failure. In addition to breaks, a current solution is to have a second person manually apply pressure to the oboist's facial muscles to maintain their embouchure. This is not a sustainable force application and prevents independent play.

While there are no oboe embouchure assistive devices, there are existing devices for saxophonists and clarinetists. The Saxophone Embouchure Assist made at the University of California, San Diego is a silicone interface mounted on the saxophone's mouthpiece [5]. The player applies pressure to the silicone interface to seal the gap in their embouchure. The assistive device is reliant on the instrument's mouthpiece, which the oboe lacks. Thus, this device's design would not be suitable for an oboe embouchure assist. A BME Design team designed two embouchure assistive devices in 2012 for a clarinetist [6]. These devices included a Ring Design and a Coil Design. The Ring Design includes a headset design with a force arm protruding from a metal ring encompassing the player's ear [6]. The force arm is adjusted on the metal ring, though this makes the design uncomfortable and difficult to adjust [6]. The force arm applies a force to push the clarinetist's facial muscles into a proper embouchure. The Coil Design is made of two layers of 1095 spring steel wrapped around the player's head [6]. The end of the coil is curved and applies force to the player's facial muscles, pushing them into a proper embouchure. However, the curved nature of the coil design creates unwanted torsional effects on the player's face which causes discomfort [6]. The Coil and Ring designs both supplied 6N and 9N forces respectively, insufficient for the team's goal force of 22N [6].

Problem Statement

Facial nerve disorders (FND) and facial paralysis affect 30.5/100,000 people and alter many aspects of a patient's daily life [1]. One aspect that is often overlooked is patients' reduced ability to play musical instruments. With FND, musicians struggle to maintain an adequate air seal around a mouthpiece due to reduced facial musculature and control. Facial paralysis creates significant challenges for musicians playing woodwind instruments, such as the oboe. Unlike other woodwind instruments, the oboe uses a unique double reed that is unsupported by a traditional mouthpiece, requiring precise and stable embouchure control [7]. The

objective of this project is to develop a tailored device to stabilize the embouchure for oboists with facial nerve weakness.

Background

Physiology and biology

Maintaining an oboe embouchure requires the precise and coordinated use of the facial muscles surrounding the oral cavity to create an airtight seal around the double reed of the oboe. The primary facial muscle responsible for creating this airtight seal is the orbicularis oris. The orbicularis oris is a circular muscle that works to close, compress, and protrude the lips as it cushions the oboe reed against the teeth without collapsing the embouchure [8]. The orbicularis oris works with the buccinator muscle in the cheeks. The buccinator muscle compresses the cheeks against the teeth to prevent air pocketing during high-pressure wind instrument playing [9]. These muscles manage the intraoral pressure required to vibrate the oboe's double reed evenly. Both the orbicularis oris and buccinator muscles are connected by the facial nerve, cranial nerve VII (CN VII) [9]. Cranial nerve VII travels directly through the parotid gland, so when a tumor develops in the gland, surgery might be required to remove the tumor. This surgery can cause nerve damage to the facial nerve, which can lead to facial weakness or paralysis [10]. This facial weakness can cause difficulties with closing, compressing, or protruding the lips. These difficulties can then cause severe air leakages when attempting to play with the oboe, since an airtight seal can not be maintained around the oboe reed.

Design Research

Applying a force directed inward on the cheek can help produce the airtight seal necessary for maintaining the oboe embouchure for those with nerve damage in CN VII [11]. The design for this project will incorporate a clamp that rests on the face and will apply a specific amount of force to the user's face to help to mimic the functions of the orbicularis oris and the buccinator muscle. This will allow the user to maintain the embouchure needed to play the oboe for long periods of sustained and continuous play.

Client Information

The client, Ms. Linda Chickering, is an oboist with weak musculature in her lower right facial quadrant due to parotid gland cancer. This prevents her from maintaining the embouchure necessary to play the oboe for more than 15 seconds. Her goal for this project is for the team to develop a device that is capable of pushing facial muscles into a proper oboe embouchure for those with facial palsy that cannot maintain the oboe embouchure.

Design Specifications

The client has tasked the team with developing an assistive device to maintain the needed embouchure for playing the oboe for those that can't maintain it [Appendix A]. The device will function by applying a force to the user's facial cheek to be able to apply and maintain the needed air pressure of 3333 Pa to 12000 Pa to the oboe reed [12]. The air pressure must be maintained for longer than 30 seconds of sustained play and for one to two hours of continuous use [13]. The average career of a professional musician is 25 years, so the device should last up to 25 years [14]. The device must be lightweight, with a maximum weight of 400 g to minimize

any musculoskeletal strain [15], and an ideal weight of 300 g for maximum comfort for the user [16]. The device must also apply a force of less than 620 N so that there will be no tissue damage caused by using the device [17]. Since the device needs to be adjustable to fit different users, the adjustability range for the diameter around the users head should be from 48 cm to 60 cm. This is because the median diameter for an adult male and female head are 54 cm and 53 cm, respectively [18]. The device must follow ISO 8549 because it will be worn externally on the user's face and is intended to compensate for facial musculoskeletal impairment [19]. Since the device is a facial orthosis defined by ISO 8549, it must follow the guidelines set for prescribing orthoses in ISO 8551:2020 [20]. The team has a flexible budget, but the cost of the device should be around \$50.

Preliminary Designs

Design Choices

Design 1: Headset with Clamped Pressure Piece

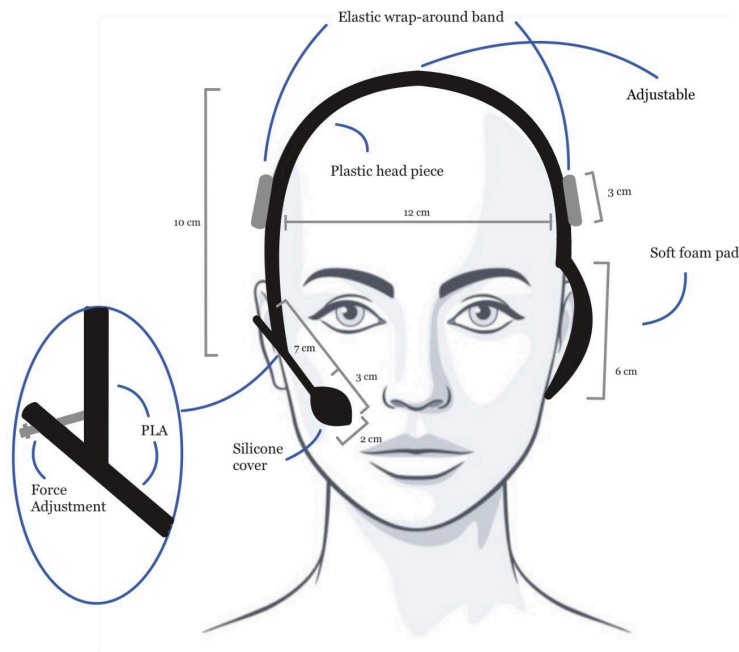


Figure 1: Headset with Clamped Pressure Piece Design

The Headset with Clamped Pressure Piece design features a plastic structure with foam padding, and an adjustable, elastic wrap-around band for stability. A soft foam pad covers the left ear to assist in anchoring the design. The top of the headset features an adjustable portion that can expand or contract depending on the client's needs. The force-application piece will be 3D printed using filament and attached in front of the right ear. This customized piece will have a screw that can be manually operated to move the piece closer or further from the client's face, therefore adjusting the amount of force. It will also have a circular pressure plate that will apply the actual force. This circular pressure plate will be covered in silicone for comfort and added friction for stability. Dimensions will reflect those of the average adult face and specific client needs.

Design 2: Shoulder Harness

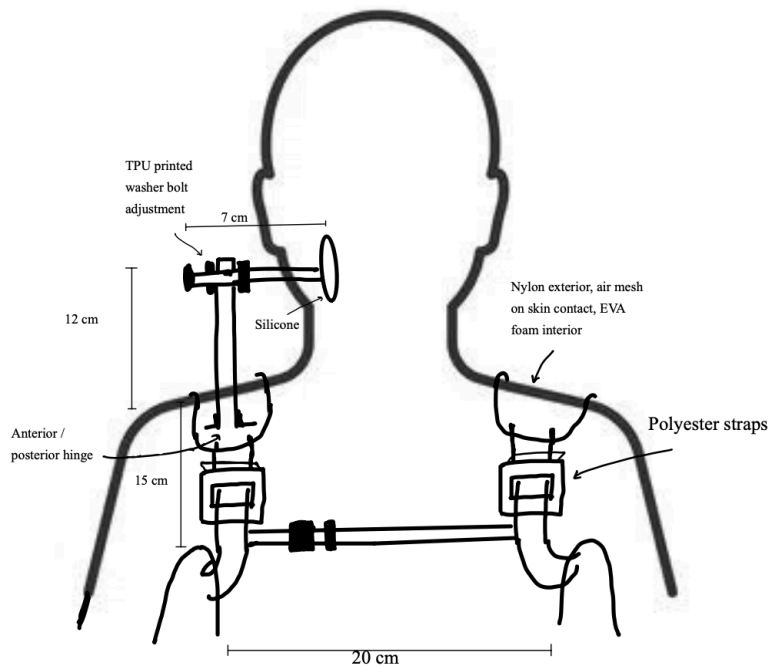


Figure 2: Shoulder Harness Design

The Shoulder Harness design features two plastic shoulder pads lined with foam for comfort. These pads are kept in place by adjustable nylon straps that attach with buckle clips. An adjustable chest strap between the two shoulder pads provides further stability. The right shoulder pad has a 3D printed upright extension. This portion of the design features a hinge at its base that moves the extension closer and further from the client's face. A pressure piece is attached to the top of the extension. The pressure piece is also 3D printed, and can be adjusted from left to right as needed. A circular pressure plate at the end of this customized piece is what will apply force to the client's cheek. This piece will be covered in silicone for both comfort and added friction for stability. Dimensions of this design are taken from average adult measurements.

Design 3: Wrap-Around Headset

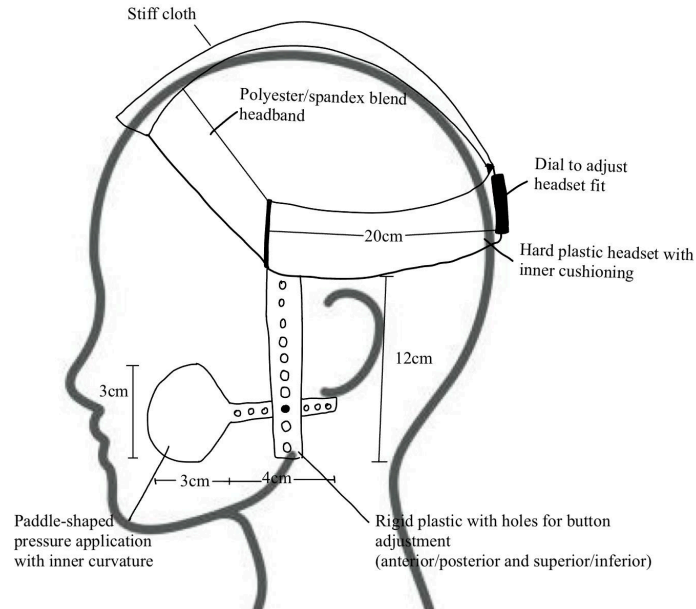


Figure 3: Wrap-Around Headset Design

The Wrap-Around Headset design features a plastic headset with foam padding that stretches from temple to temple. The design is further secured by a stiff cloth that stretches from the forehead across the head to the center of the headset. This cloth is anchored in place by polyester bands attached to the front pieces of the plastic headset. Each portion of the headpiece is adjustable to fit a client's needs. A 3D printed, rigid plastic extension drops down from the right side of the headset. A customized pressure piece is attached to this extension, and its position can be adjusted through a system of buttons and holes. The 3D printed pressure piece features a paddle-shaped pressure plate that will apply the necessary amount of force to the client's cheek. This piece is covered in silicone for both comfort and stability. Dimensions for the design reflect the measurements of an average adult head.

Material Choices

Thermoplastic Polyurethane (TPU)



Figure 4: TPU [21]

Thermoplastic polyurethane (TPU) is a flexible and durable material that combines properties of hard plastic and rubber. TPU is highly resistant to abrasion and does not degrade when exposed to chemical or bodily fluids. TPU has an elastic modulus of 9.4 MPa, a tensile strength of 29 MPa, and an elongation at break of 330%. TPU is highly resistant to temperature changes and is long-lasting. The density of TPU is between 1.2 to 1.24 g/cm³ [22].

Polylactic Acid (PLA)



Figure 5: PLA [23]

Polylactic acid (PLA) is a rigid and brittle biocompatible polymer. PLA is a highly popular 3D printing filament with a low melting point and strong aesthetic properties. PLA has an elastic modulus of 3600 MPa, a tensile strength of 60 MPa, and an elongation at break lower than 10%. PLA is resistant to warping and eco-friendly. The density of PLA is 1.25 1.24 g/cm³ [24].

Silicone



Figure 6: Silicone [25]

Silicone rubber is a synthetic polymer with high flexibility, durability, and resistance to temperature changes. This is a material commonly used in biomedical devices, due to its high biocompatibility and chemical resistance. Silicone has a tensile strength of 5.5 MPa, an elongation at break of 450%, and a maximum operating temperature of 250°C [26].

Latex



Figure 7: Latex [27]

Latex rubber is a biopolymer with exceptional elasticity, resistance to abrasion, and rebound ability. Latex is a biocompatible material, however, latex allergies are a concern. Latex has a tensile strength of 25 MPa, an elongation at break of 830%, and a maximum operating temperature of 70°C [28].

Preliminary Design Evaluation

Design Matrix

Table 1: Design Matrix

Designs		Design 1: Headset with Clamped Pressure Piece		Design 2: Shoulder Harness		Design 3: Wrap-Around Headset	
Rank	Criteria	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
1	Applied force (25)	4/5	20	4/5	20	4/5	20
2	Comfort (25)	4/5	20	3/5	15	5/5	25
3	Sustained stability (15)	5/5	15	4/5	12	5/5	15
4	Adjustability (15)	5/5	15	4/5	12	3/5	9
5	Ease of use (10)	4/5	8	3/5	7	4/5	8
6	Safety (5)	4/5	4	4/5	4	4/5	4
7	Cost (5)	4/5	4	3/5	3	2/5	2
			86		73		83

The three preliminary designs were compared in a design matrix (Table 1). Criteria were selected to analyze each device. Applied force denotes the amount of pressure applied by the device to the patient's cheek. Comfort refers to the fit of the design and the user's comfortability levels while wearing it. Both applied force and comfort were weighted highly, as they refer to the effectiveness of the design and the patient's ability to don it for extended periods of time. Sustained stability alludes to the design's ability to consistently apply force in the desired position throughout performance. Adjustability refers to the device's capacity to be custom fit to the user. Ease of use highlights the ability of the patient to adjust and utilize the device without assistance. The three aforementioned criteria were given equal, medium weights as they are of importance but not necessarily as significant to the patient. Safety refers to the amount of risk posed to a user of the device. Cost indicates the monetary expenditure necessary to fabricate the design. Safety and cost were given low weights, as none of the devices have significant safety concerns or high projected fabrication costs.

The Headset with Clamped Pressure Piece had the strongest performance in the design matrix. Its high scores in criteria three through five contributed heavily to its overall result. The Shoulder Harness struggled due to its more complex design posing difficulties for the user. The two headset designs scored similarly across many categories, but ultimately the Wrap-Around Headset's low adjustability and high cost put it in second. Design 1 was selected to move forward from the results of the design matrix.

Materials Matrix

Table 2: Materials Matrix

Materials			TPU + Silicone		TPU + Latex		PLA + Silicone	
Rank	Criteria	Weight	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
1	Biocompatibility	25	5/5	25	3/5	15	4/5	20
2	Mechanical Properties	25	2/5	10	2/5	10	4/5	20
3	Ease of Fabrication	20	5/5	20	2/5	8	5/5	20
4	Comfort	15	4/5	12	4/5	12	3/5	9
5	Cost	10	3/5	6	3/5	6	4/5	8
6	Aesthetics	5	4/5	4	2/5	2	4/5	4
	Total	100		77		63		81

Three material combinations were considered for the final design: TPU and silicone, TPU and latex, and PLA and silicone. These pairings were evaluated by six different metrics. Biocompatibility refers to the materials' interactions with skin and bodily fluids. Mechanical properties highlights the strength, toughness, and elasticity of the material. Both biocompatibility and mechanical properties received the highest weight due to their necessity to the function of the design. Ease of fabrication describes the difficulty of the fabrication process and its attainability. This criterion was given an above average weight due to its importance to the success of the project. Comfort refers to the feel and fit of the material. This was given an average weight as all selected materials are generally comfortable. Finally, cost relates to the price while aesthetics relates to the appearance of the material. These criteria were given below average and low weightings as the chosen materials were relatively low cost with similar aesthetics.

TPU and silicone fared best in biocompatibility, due to TPU's superior resistance to degradation and the prevalence of latex allergies. However, PLA and silicone beat out the other two options in mechanical properties, as TPU's elasticity was determined to be a hindrance to the intended function of the design. Pairings one and three performed strongly in ease of fabrication due to silicone's customizability. Options one and two did well in comfort, as PLA's rigidity will not allow it to conform to the user. PLA and silicone scored slightly higher in cost due to PLA having a lower cost than TPU. For the final category, aesthetics, designs one and three performed best due to silicone's sleek finish. Ultimately, PLA and silicone scored highest within the materials matrix and were selected for the proposed final design.

Proposed Final Design

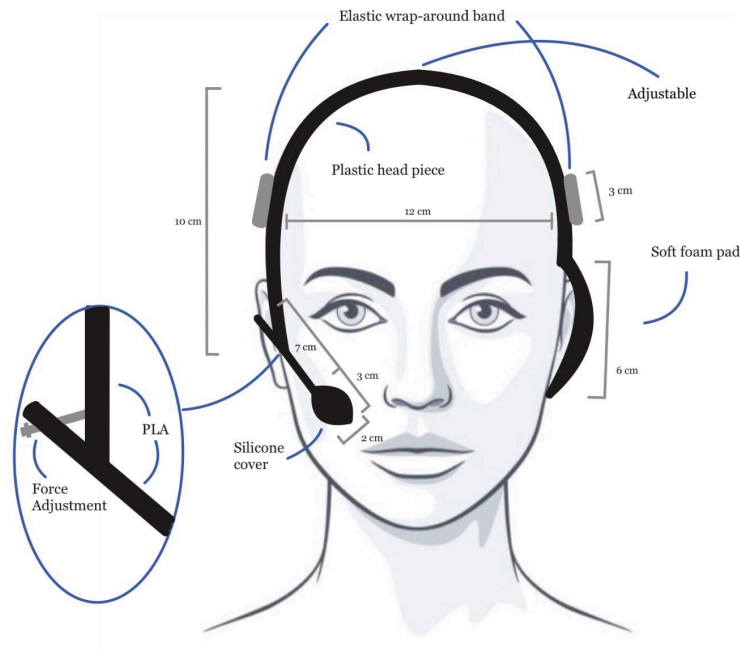


Figure 8: Headset with Clamped Pressure Piece Design

The Headset with Clamped Pressure Piece design has been selected to advance into the fabrication stage. Its high scores across the design matrix were major contributors to this decision. This design is secure, adjustable at multiple points, and comfortable. It does not interfere with the oboe itself, and its simplicity makes it easy for the user to put on and take off. A specific strength of this design is the force adjustment screw. This piece allows the user to customize their preferred amount of force and ensures that they are able to use the device safely.

The device will be created through a combination of bought materials, elastic, foam, PLA, and silicone. The printed, custom pressure piece will be printed from PLA and coated in silicone. These materials specifically were chosen due to their strong performance in the materials matrix (Table 2). PLA's rigidity and tensile strength were key factors in its selection. The filament is also highly biocompatible, easy to fabricate, and cost-effective. Silicone's biocompatibility and lack of allergy concerns were the main reasons for its success. The rubber is also customizable with high aesthetic quality.

Fabrication

Materials

The final product will be made primarily out of PLA for the hard structural components, including the headband and the force-application arm. The headband needs to remain securely positioned on the user's head, while the cheek-pushing bar must be sturdy enough to apply consistent pressure to the cheek without bending or shifting. Using PLA for these components will ensure the device maintains its intended structure and shape and provides reliable performance during playing. Additionally, PLA is well suited for prototyping and iteration because it can be easily 3D printed into complex shapes, allowing the components to be customized to fit the intended design. Additionally, silicone will be used on any of the surfaces that come in contact with skin. This is because the silicone is biocompatible, flexible, and comfortable against the skin. Unlike the PLA, silicone can conform to the skin which will result in a more comfortable use for the user.

Methods

The PLA components of the device, including the headband and force-application arm, will be manufactured using 3-D printing. The components will first be designed using CAD, allowing the dimensions and geometry to be adjusted to fit the intended user and provide the necessary positioning and force. Once the designs are finalized, the parts will be exported into a STL file and 3-D printed using PLA filament. The silicone portions of the device will be created separately and applied to the areas that come into contact with the user's skin. A mold or master model of the desired padded surfaces will be prepared, and silicone will either be molded, plastered, or dipped onto the master project depending on the geometry and thickness required. The silicone will then be left to cure or set according to the material's recommended curing time. After both the 3D printed and silicone components have been completed they will be assembled with a glue like adhesive and finalized with any sanding and shaving for detail.

Testing and Results

Force Testing

The objective of this protocol is to evaluate the force the Embouchure Assist Device exerts on the cheek of the wearer. According to the PDS the device should not exceed a force of 620 Newtons on the cheek. Preliminary testing will define an ideal range of force values for proper embouchure technique using force sensitive resistors in the voltage divider configuration outlined in Appendix B. After running the test method outlined in Appendix B, the average of the peak force for each trial will undergo a 90% confidence interval to determine success. A successful force test will have the entire confidence interval within the ideal range defined via testing with the client.

Air Pressure Testing



Figure 9: Water Manometer Example [29]

The objective of the air pressure test protocol is to establish proper air pressure within the embouchure technique. An ideal air pressure test will fall within 3333Pa to 11999Pa established in Appendix A. An air manometer will be inserted into the mouth along with the oboe reed. The manometer tube will rest in the oral cavity without interrupting lip seal or being blocked by the tongue. For both the control and test groups, the subject will play for 15 seconds; the control without the embouchure assist and the test with the assist. Using a two sample t-test, statistical significance will be calculated. A successful air pressure test will prove statistical significance between the control and test groups, proving the embouchure assist aids in maintaining internal air pressure within the mouth.

Performance Testing

The purpose of this test is to determine both effectiveness and comfort of our final design. The team will measure the duration of note sustained and number of air leaks during play with and without the device. The client will provide qualitative feedback on adjustability and comfort of the device through surveying.

Discussion

No results are currently available, as quantitative and qualitative testing have not yet been conducted. Following the completion of testing, the collected force, torque, and usability data will be analyzed to determine whether the final design satisfies the performance criteria established in the Product Design Specification (PDS). Quantitative results will undergo statistical analysis to evaluate consistency across trials and determine how closely the measured values align with the design requirements. Qualitative feedback from the user will be evaluated to assess comfort, ease of use, and overall effectiveness of the device.

Potential sources of error include limitations in the precision and accuracy of measurement tools, such as the force sensitive resistor and water manometer, as well as inconsistencies in device placement between trials, and variations in participant embouchure technique or facial anatomy that may influence force and air pressure

measurements. Additionally, air leaks unrelated to the device, fluctuations in breath support, and user adaptation during repeated trials may affect test results. For qualitative and performance testing, subjective differences in the client's perceptions of comfort, adjustability, and effectiveness may introduce variability in the evaluation of the device.

There are several ethical considerations to keep in mind when developing an embouchure stabilization device for musicians with facial nerve weakness. The most important concern is user safety. The device must not put too much pressure on facial tissues or make it difficult for the user to breathe, speak, or play their instrument. It should also support the musician's natural embouchure rather than completely replacing it, allowing the user to maintain as much control and independence as possible.

Accessibility and affordability are also important because people with facial nerve weakness may have different physical needs and financial resources. When testing the device, participants should provide informed consent and have the opportunity to share feedback about comfort, effectiveness, and ease of use. This feedback should be used to improve the design. Finally, because the device is intended to assist people with a disability, it should promote inclusion and help musicians participate fully in musical activities without making them feel stigmatized or overly dependent on the device.

Conclusions

Oboists with facial paralysis struggle to maintain a proper, sealed embouchure during play. This product aims to develop a device that pushes facial muscles into a proper oboe embouchure. The device will consist of a headset with an adjustable, clamped pressure piece that will allow the user to customize the positioning and posture of the embouchure-assisting pressure piece. The design aims to provide a stabilized embouchure for upwards of 30 minutes of play.

The team will begin fabrication in the near future. The first step will involve ordering all necessary materials, including the headset base, as well as various hardware and raw materials. Concurrently, an initial testing procedure will be performed with the client to determine the necessary pressure that must be applied by the device. Once the materials arrive, the team will utilize the Design Innovation Lab to perform the fabrication procedures on each component. Simultaneously, the 3D-printed components will be designed in SolidWorks and 3D-printed. After each individual component has been completed and independently tested, the final assembly of the device will take place. Final testing will then be performed to verify proper functionality and safety.

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Appendix

Appendix A: Product Design Specification

Function

Facial nerve disorders (FND) and facial paralysis affect 30.5/100,000 people and alter many aspects of a patient's daily life [1]. One aspect that is often overlooked is patients' reduced ability to play musical instruments. With FND, musicians struggle to maintain an adequate air seal around a mouthpiece due to reduced facial musculature and control. Facial paralysis creates significant challenges for musicians playing woodwind instruments, such as the oboe. Unlike other woodwind instruments, the oboe uses a unique double reed that is unsupported by a traditional mouthpiece, requiring precise and stable embouchure control [2]. The objective of this project is to develop a tailored device to stabilize the embouchure for oboists with facial nerve weakness.

Client requirements

The client requires that the Embouchure Assist Device must:

- Help maintain a tight and controlled oboe embouchure
- Not interfere with the oboe's keys, reed, or sound
- Allow for sustained play longer than 30 seconds
- Maintain a comfortable facial position during use

Design requirements

1. *Physical and Operational Characteristics*

a. Performance requirements

The Embouchure Assist Device must be designed for daily use, as musicians are recommended to practice for between one to two hours every day [3]. The device must be able to withstand this continuous use and maintain its shape and performance throughout. This daily use is likely to continue for significant periods of time, and thus durability is a priority. Weight distribution and comfortability is also of importance. A lightweight, well-fitted design is integral to ensuring that the user can maintain focused and unhindered performance. The design must also not irritate or injure the skin throughout continuous use. The device should be simple to put on and take off, and have a design that is straightforward and understandable. The client must also be able to don the device without assistance. As users are expected to have a range of facial features and measurements, the design needs to be adjustable. Finally, the device should be sleek and not a visual distraction. This is especially a concern for musicians who participate in performances.

b. Safety

The device should not pinch, pull, or injure the skin. Adjustable components should be covered. Materials utilized must be non-abrasive, durable, and easy to clean and disinfect.

c. Accuracy and Reliability

The design must operate reliably for one to two hour long periods of continuous use [3]. The device should perform comparably across a range of facial shapes and sizes. The design must also be reversible, with the ability to operate with placements on both the right and left sides of the face.

d. Life in Service

The device is expected to operate daily, for one to two hours, for the entirety of a musician's career. Expectations for this time period vary, with some putting down their instrument after only a few months and others continuing for decades. However, the average career length of a professional musician is 25 years [4].

e. Shelf Life

The components of the device will not use any materials that will require crucial consideration in regards to shelf life. The device will be put into use once fabricated. However, the materials used must have the ability to be stored in a controlled indoor environment.

f. Operating Environment

The device will be primarily used in controlled indoor environments. The device must be able to withstand a standard indoor temperature range of 20°C to 26°C and humidity of 30% to 60% [5].

g. Ergonomics

The device must be lightweight and not have any features or edges that could potentially disturb the user's face. The device must also apply a force on the user's face that makes it comfortable for them to apply the needed air pressure of 3333Pa to 11999Pa to the oboe double reed for long periods of time [6].

h. Size

The average diameter of a human head is 17 centimeters [7]. Thus, the device's adjustable elements should have a range of 11 to 23 centimeters to accommodate all users.

i. Weight

The device will be lightweight, so that the user can comfortably use it for an entire practice session. The average human head can support an attached weight of 400 grams without discomfort for prolonged periods of time [8]. Thus, the device's weight will have a maximum weight of 400 grams and ideally less than 300 grams [9].

j. Materials

The product will be made out of a TPU 3D printing filament. This is a medical grade material with strong biocompatibility with the oils on a client's skin [10]. TPU 3D printing filament is a flexible and strong filament which will maintain comfort and sturdiness of the device.

k. Aesthetics, Appearance, and Finish

The final design will have a smooth finish that is comfortable when in contact with a client's skin. The device should be fit closely to the user's existing facial musculature, and have minimal protruding elements. It is important for the design to be sleek and plain, so as to not draw attention during professional performances.

2. Production Characteristics

a. Quantity:

One prototype will be fabricated for the client. The fabrication process must be easily replicated and standardized for scalable production.

b. Target Product Cost:

The project has an estimated cost of \$50 due to 3D printing and material costs. The client has indicated flexibility in the budget for an additional \$150, with justification.

3. Miscellaneous

a. Standards and Specifications:

- i. The embouchure assist device is a low risk device, so according to CFR Title 21, Section 890.3025, it will be classified as a Class I medical device.

1. CFR Title 21, Section 890.3025 defines the embouchure assist device as a Class I medical device since only general controls are used, so there is reasonable assurance of safety and effectiveness [11]. If electrical components are added, defined as special controls in the standard, the classification would shift to Class II [11].
- ii. The device will be worn externally on the face and is intended to compensate for facial musculoskeletal impairment, so it must follow ISO 8549 [12].
 1. This terminology standard defines a facial orthosis device as worn externally on the face and intended to support, position, or compensate for facial musculoskeletal impairment [12]. According to ISO 8549, the embouchure assist device is a facial orthosis and must also follow other standards set for orthoses. [12]
- iii. The device is a facial orthosis defined by ISO 8549, so it must follow guidelines set in ISO 8551:2020 for prescribing orthoses.
 1. ISO 8551:2020 provides guidelines for evaluating functional deficiencies in patients and setting clinical objectives when prescribing orthoses [13]. This includes defining impairments that require the orthosis, including muscle strength and neuromuscular control in terms of the embouchure assist orthosis [13].
- iv. The embouchure assist device comes in contact with the human body, so ISO 10993-1 must be considered.
 1. ISO 10993-1 requires a medical device that comes in contact with the human body to be evaluated with risk management processes. All materials that come in contact with the user's face must be evaluated for biocompatibility according to ISO 10993-1, considering the type and duration of contact. The risk-based assessment considers skin irritation, sensitization/allergic reactions, cytotoxicity, chemicals that could leach from device material, duration of contact with skin, and whether the device contacts intact or damaged skin [14].

b. Customer:

The client has requested a headpiece that allows for embouchure support during oboe playing. This product will substitute for and support weakened musculature and allow precise, stable embouchure control. The client prefers a lightweight, comfortable, and repeated-use product that will protect against musculoskeletal strain for the user. The client prefers that the product be adjustable and aesthetically non-descript.

c. Patient-related concerns:

The product must not contribute to any muscular discrepancies that the patient currently experiences as a result of partial paralysis and muscular atrophy [15]. The product must also not contribute to any muscular discrepancies that the patient may experience as a result of medical problems related to general oboe use [16]. The product must be able to be sterilized between uses [17].

d. Competition:

Existing solutions have been developed to assist musicians who experience facial weakness or paralysis while maintaining a proper embouchure, but none address oboists' needs. A recent example is a 3D-printed embouchure-assistive device designed specifically for a saxophonist with facial palsy [18]. The device provides external support to the affected side of the face, helping maintain an airtight seal around the mouthpiece and enabling continued performance despite reduced facial muscle control. The custom-fabricated design can be tailored to an individual musician's anatomy and degree of impairment. Additionally, extraoral support devices have been developed for woodwind players with Bell's palsy, including a digitally designed prosthetic for a clarinetist that restores cheek support and improves embouchure stability during performance [19]. Similarly, a University of Wisconsin–Madison design team developed a custom headgear-style clarinet embouchure assistive device that applied adjustable inward and forward pressure to the affected cheek, helping maintain mouthpiece pressure, reduce air leakage, and extend playing time for a clarinetist with facial synkinesis [20]. These devices utilize the respective instruments' mouthpieces, so cannot be used on the oboe as it lacks a mouthpiece component. However, the designs demonstrate the potential for personalized assistive technologies to compensate for facial muscle weakness and reduce air leakage while playing. Furthermore, products such as OboFit® focus on embouchure training and stabilization by strengthening oral musculature, minimizing excessive reed pressure, and promoting optimal playing posture. While intended primarily as a training aid rather than a medical device, OboFit highlights the growing interest in ergonomic solutions that improve embouchure efficiency and reduce strain for oboists [21].

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Appendix B: Force testing protocol

1. Build voltage divider circuit
 - a. Connect to force sensitive resistor and fixed resistor to be able to read voltage change
 - b. Arduino will read change in voltage and determine force from that
 - i. $V_o = V_{cc} + (R/(R + FSR))$
 1. V_{cc} = Analog voltage
 2. R = 10kOhm resistor
 3. V_o = Voltage across resistor
 4. FSR = Force sensitive resistance

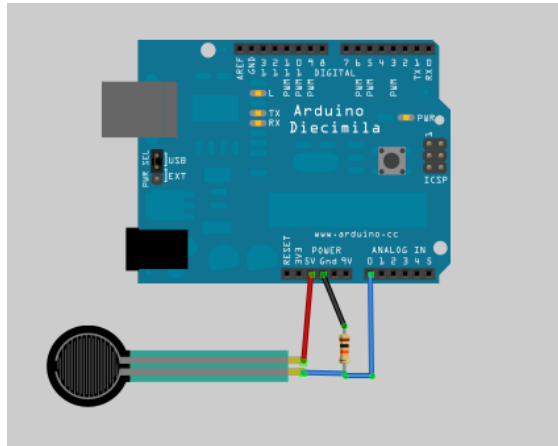


Figure 1: Arduino FSR voltage divider physical setup [1]

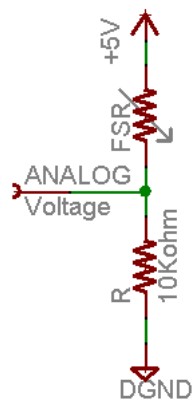


Figure 2: Arduino FSR voltage divider diagram [1]

2. Find ideal value for force applied for proper embouchure and define acceptable boundary conditions for success.
3. Measure average value and standard deviation of force applied with device over ten seconds
 - a. Code for measuring voltage

```
int fsrPin = A0;

const unsigned long testTime = 10000; // 10 seconds

void setup() {
  Serial.begin(9600);
}

void loop() {
```

```

unsigned long startTime = millis();

float voltageSum = 0;

int count = 0;

Serial.println("Starting 10-second test...");

Serial.println("Apply the desired force now.");

while (millis() - startTime < testTime) {

    // Read the FSR

    int adcReading = analogRead(fsrPin);

    // Convert ADC reading to voltage

    float voltage = adcReading * (5.0 / 1023.0);

    // Add voltage to running total

    voltageSum += voltage;

    count++;

    delay(10); // Take a reading every 10 ms

}

// Calculate average voltage

float averageVoltage = voltageSum / count;

Serial.println();

Serial.println("==== RESULTS =====");

Serial.print("Number of readings: ");

Serial.println(count);

Serial.print("Average voltage: ");

Serial.print(averageVoltage, 4);

Serial.println(" V");

Serial.println("=====");

```

```

delay(3000);

}

```

- b. Create a calibration curve manually to convert voltage to force using known force readings.
 - c. Apply average voltage found to calibration curve to determine average force and calculate standard deviation
4. Perform a 90% confidence interval to determine whether the mean applied force from the device falls within the acceptable range of success.

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Appendix C: Current Materials

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	#	Cost Each	Total	Link
Category : 3D Printing + DI Lab										
3-D Print	Force arm prop (TPU)	DI Lab				9/29/2026	1	\$0.32	\$0.32	
3-D Print	Force arm prop (PLA)	DI Lab				9/30/2026	1	\$0.17	\$0.17	
Category 2: Online purchases										
Pressure Sensors	Sensor pads	MECCANIXITY	FSR 406B	Amazon		10/03/2026	1	\$12.34	\$12.34	Thin Film Pressure Sensor, FSR406B 20g-10Kg Force Sensing Resistor
								TOTAL:	\$12.83	