Embouchure Assist Device

Product Design Specifications

BME 200/300 Design

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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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