Helmet for Continuous Laryngoscopy During Exercise

Preliminary Product Design Specifications

BME Design 200/300

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September 17th, 2026

Function

Continuous laryngoscopy during exercise (CLE) is a diagnostic procedure that allows clinicians to visualize in real time abnormal dynamic changes of the larynx under physical loads, which allows them to diagnose inducible laryngeal obstructions (ILOs) [1]. In order for the test to be performed, a flexible laryngoscope must be securely attached to a head-mounted device that can support the forces generated from intense exercise [2]. Currently, there are no universally standardized helmets for mounting a laryngoscope that have FDA marketing authorization [2]. Without standardized helmets for CLE, a clinician's ability to effectively diagnose and treat unresolved respiratory symptoms is limited due to being unable to purchase the necessary equipment to rule out conditions diagnosed by CLE [3]. The function of this helmet is to provide a standardized helmet that is able to stabilize the dynamic loads on the laryngoscope during exercise, be ergonomic and adjustable for all patients, and made of commercially available materials.

Client requirements

Mr. Tangney has requested the following specifications in regards to the product

- A device that is easily sanitizable.
- The helmet must secure the laryngoscope above the head to prevent the camera from falling out a patient's nose.
- Patients must be able to clearly hear instructions during the testing period.
- The helmet must be adjustable and fit all patients.
- A fully working prototype must be created by Friday, November 7th.
- Minimal movement of both the helmet and scope side-to-side and front-to-back.

Design requirements

1. **Physical and Operational Characteristics**
    a. **Performance requirements:**
        i. The laryngoscope must be held securely under the acceleration of at least 2g (19.6m/s^2) [4].
        ii. Must not add a bending moment of more than 1.5 Nm to the neck at rest [5].
        iii. The Laryngoscope and helmet must not impart a bending moment of greater than 190 Nm at the occipital condyle during exercise in neck flexion and 57 Nm during extension to prevent neck injury [6].
        iv. The laryngoscope must be easily mounted and dismounted for reuse and cleaning as per the client.
        v. The device must withstand frequent cleaning and disinfecting with EPA approved disinfectants, such as a solution with up to 2% bleach, quaternary ammonium compounds, ethanol, and isopropanol without significant degradation to material and performance [7].
    b. **Safety**

i. The helmet must not include additional cords to reduce the number of tripping hazards while sprinting.
ii. The design must minimize patient intimidation, as patients may already experience fear or anxiety associated with ILO symptoms before undergoing CLE examination. [8]

c. **Accuracy and Reliability**
   i. Testing across multiple head sizes, body weights, and heights of patients will prove universality of the helmet. The helmet must receive at least a 3.5/5.0 average in a comfort survey.
   ii. The final product will be within 3 mm of all design dimensions.
   iii. The laryngoscope mount will be designed with a factor of safety of 1.4x the impact forces it is expected to withstand.

d. **Life in Service**
   i. The device will need to maintain functional performance for at least 2 years and withstand at least 300 CLE test/disinfecting cycles.
   ii. The device could be built using a wrestling helmet as a base of attachment, and those helmets last around 2 years before it becomes pungent from patient usage.

e. **Shelf Life**
   i. Our designs consistently utilize velcro and 3D printed pieces made of polyethylene terephthalate glycol-modified (PETG) plastics , which both respectively have a shelf life of up to a decade [9]

f. **Operating Environment**
   i. The device is intended to be used in a clinical setting where patients will perform intense exercise, primarily on treadmill and stationary bicycle. It must tolerate frequent repetitive head movements due to intense exercise [10].
   ii. The device will be exposed to perspiration, increased body temperature of up to 40 degrees Celsius for female and male athletes aged 20-40 years old, and humid conditions during exercise [11]. They must maintain structural and material integrity under moist conditions [11].

g. **Ergonomics**
   i. The helmet must minimize the change to the center of mass when worn to reduce neck loading and improve patient comfort during CLE testing. [12][13]
   ii. The device will distribute its weight equally across the patient's head to avoid excess force on a single area, and must allow the patient to move head naturally without restricting head neck movement.
   iii. The device must minimize slipping and must remain comfortable/stable throughout the CLE test session, including running, walking, and resting phase.

h. **Size**
   i. This helmet must be able to fit a head circumference of 500-610 mm, width of 130-166 mm, length of 171-209 mm, and a forehead width of 98-131 mm to account for all head sizes [14].

i. **Weight**
   i. The total weight of the helmet including the laryngoscope must not exceed 1.20 kg. Increases in headgear mass elevate activity in key stabilizing neck muscles. Under high

physical exertion, elevated muscular demand accelerates localized fatigue, leading to involuntary postural adjustments and head micro-movements. During CLE, neck fatigue can compromise the steady positioning of the laryngoscope, risking scope displacement or nasal airway discomfort [15] [16].

j. **Materials**
   i. Straps and fasteners of the helmet will be made of copper infused nylon for its strength, durability, and antimicrobial properties [17].
   ii. Cushioning for the helmet needs to be made of quaternary ammonium compound (QAC) treated polyurethane foam where the QAC is chemically bonded to the foam. QAC polyurethane foams are great for comfort, safety, and antimicrobial properties [18][19].

k. **Aesthetics, Appearance, and Finish**
   i. The visual appearance of wearable gear directly impacts patient psychological comfort and clinician acceptance. Sturdy, aesthetically cohesive equipment lowers perceived risk, mitigating patient apprehension and improving overall testing satisfaction [20][21].
   ii. A clean finish without burrs, scratches, or exposed glue will give a more professional appearance.
   iii. The device will minimize gaps or crevices to ensure a clean finish and easy cleaning.
   iv. Tested and sized to allow for patients to utilize earbuds while also wearing the helmet during physical tests to provide an extra layer of comfort and familiarity for the patient.

2. **Production Characteristics**
   a. **Quantity**
      i. One device will be produced.
   b. **Target Product Cost**
      i. The project budget is 500 USD. The team anticipates a total product cost of 250 USD.
3. **Miscellaneous**
   a. **Standards and Specifications**
      i. According to ISO 19054:2005, including a locking mechanism intended to prevent accidental removal and force and torque for mounts. Although this standard is intended for horizontal rail system mounts, its locking mechanism and mechanical testing principle can be a good reference when designing the mounting system [22].
      ii. According to ASTM F3357-19, reusable medical devices will be able to withstand repeated cleaning processes and use materials that are compatible with the cleaning agent that is used by the clinic. Most common cleaning/disinfecting agents may include bleach wipes or quaternary ammonium compound disinfecting wipes, so the selected materials need to be resistant to degradation, corrosion, and loss of performance after repeated exposure [23].
      iii. The design needs to minimize crevices, gaps, sharp corners, and rough uneven surfaces where it becomes easy for contaminants to accumulate and become difficult to clean.

According to ASTM F3357-19, these features can make reusable medical devices more difficult to clean and become a possible hazard. Components that can't be easily cleaned need to be reduced/removed [23].

iv. The helmet needs to minimize the amount of force and moment that will be applied to the patient's neck during intense exercise. FMVSS 208 states axial tension must not exceed 3300 N, flexion bending moment must not exceed 190 Nm, extension bending moment must not exceed 57 Nm, axial compression must not exceed 4000 N, and shear force must not exceed 3100 N. Although FMVSS 208 is intended for automotive crashes, the stress loading principle would provide useful guidance for minimizing excessive neck stresses from the helmet [24].

b. **Customer**
   i. For patients with exercise-induced laryngeal obstruction (EILO), the larynx appears normal at rest; However, at high minute ventilation, typically induced by high ventilation exercise, the larynx experiences closure, leading to airflow obstruction and breathing problems [25].
   ii. Elite athletic performers. ILO is recognized in elite athletes and military personnel due to high levels of "irritant" exposure. Hyperventilation-associated ILO is characterized by "hyperventilation" and triggered by "airborne and inhaled triggers" [26]. Hyperventilation by athletes that are already engaging in high ventilation rate activities can be dangerous.
   iii. Women. 70% of ILO cases are in women. The larynx and vocal cords of women are generally smaller than men, meaning women are more susceptible to the side effects, including respiratory distress, as compared to men. Additional risks that accompany women are hormonal fluctuations during pregnancy and the menstrual cycle/menopause which can affect mucus production, leading to additional airway obstruction [26].

c. **Patient-related concerns**
   i. The stabilization device must be structured in a way that is comfortable and breathable for the user. Potential discomfort can cause poor customer satisfaction and inaccurate CLE test results by adding a potential limiting factor.
   ii. The weight of the stabilizing device needs to be kept to a minimum with effective weight distribution as an unbalanced system will again lead to discomfort and poor satisfaction.
   iii. To have a functional stabilizing tool for multiple patients, a mechanism must be set in place to adjust and conform to the head size of various patients to ensure minimal slippage and movement as any movement of the stabilization device could also cause movement of the laryngoscope, potentially affecting the results of a CLE test.
   iv. Due to the nature of a CLE test where maximum effort is often required, sweat and bacteria will accumulate on the device between usages. The stabilization device must be able to be cleaned and sanitized between usages. Without the ability to clean/sanitize the device, possible skin irritation, disease, and discomfort can occur

d. **Competition**
   i. Headgear Accessory for Exercise-induced laryngeal obstruction studies (HALOS). The HALOS system utilizes a hard hat with a chin strap, front mounted metal clamps, and a rear counterweight to stabilize the helmet. Components of the helmet allow for quick

disinfecting and cleaning, with some velcro straps intended for single use. However, design is relatively heavy and may create discomfort or instability during exercise due to rigid parts. [27].

ii. Similar design Jackson Safety 370 Headgear model with polypropylene supports, scope holder, and rear counter weight. Reports show that the Jackson Safety 370 Headgear appears to be easy to use and produces no complication. However rigid parts may cause discomfort [2].

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