



HELMET FOR CONTINUOUS LARYNGOSCOPY DURING EXERCISE

PRELIMINARY REPORT

BME Design 200/300

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Abstract

Continuous Laryngoscopy during Exercise (CLE) is a diagnostic tool that is the gold standard for diagnosing exercise induced laryngeal obstructions (EILO) [1]. EILO is a rather unfamiliar but not uncommon condition, as 5-8% of adolescents and young adults experience EILO symptoms, with prevalence increasing to 20-35% for athletes [2][3]. In order for CLE to be performed, a flexible laryngoscope must be securely attached to a head-mounted device that can support the forces generated from intense exercise [4]. Currently, there is no standardized helmet available for purchase for healthcare facilities. A proposed design will address this limitation by providing the UW Health Voice and Swallow Clinic with a solution that will allow the clinic to administer CLE testing.

The final proposed design will consist of two mount plates, a top and bottom mount plate. The bottom mount plate is inserted under the helmet where the top of the head will make contact. The top mount plate will be placed above the helmet slightly in the anterior direction in order for the laryngoscope to reach inside the nasal cavity, just superior to the larynx. The top mount plate houses the laryngoscope mount, which features an angled cone that is contoured to the control body of the laryngoscope. The laryngoscope slots into the cone and is further stabilized by a ring clamp on the base of the cone and a velcro strap on top of the cone to further prevent movement. This design will be rigidly attached to the helmet by a set of screws and stability will be tested by recruiting volunteers to sprint with the helmet on. Additionally, a rigid phone mount will be made for the helmet during testing in order to use Phyphox to measure the acceleration the head is subjected to during sprinting [5]. Lastly, forces will be calculated using the acceleration data and the equipment will be inspected for mechanical failures. The final device should be able to meet the Product Design Specifications (PDS, Appendix 7.1) and successfully administer CLE testing.

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Introduction

1.1 Motivation

Despite the clinical need for Continuous Laryngoscopy during Exercise (CLE) testing, UW-Health currently lacks a functional setup due to no standardized headgear existing on the market. Consequently, clinicians at UW-Health must resort to an unstandardized workaround: having patients walk or run up a flight of stairs before sitting for a static post-exercise laryngoscopy. Because dynamic laryngeal obstructions often clear rapidly once exertion stops, this static approach frequently fails to capture the obstruction, leaving patients undiagnosed. To resolve this diagnostic gap locally, this project aims to design and construct a functional, ergonomically stable helmet and scope mount tailored specifically for UW-Health, enabling reliable real-time evaluation during intense physical exertion.

1.2 Existing Devices

While there is no standardized CLE helmet and mount on the market, several custom headgear have been developed, including the HelpILO and HALOS headgear designs below [6][7]:

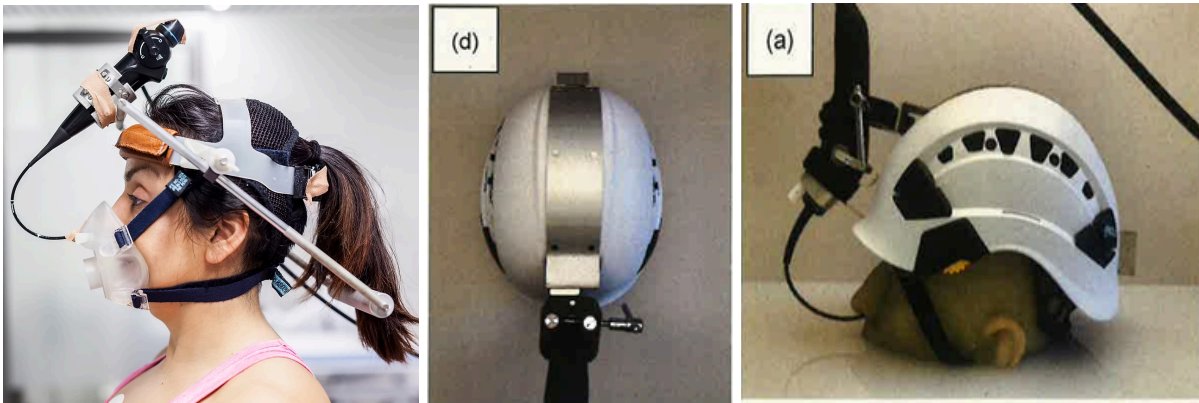


Figure (1): HelpILO headgear on patient [6] Figure (2): HALOS headgear design, top view and side view [7]

The HelpILO system utilizes a mesh and plastic headpiece attached to a rigid metal frame that secures the laryngoscope using ring clamps. The entire assembly is further stabilized by a respiratory face mask, which additionally enables metabolic oxygen consumption tracking during cardiac stress testing. While useful, an additional function for oxygen consumption tracking is not a goal of the team's design and is therefore not seen in the final design.

The HALOS system adapts a commercial hard hat chassis, using adjustable straps and a temporal ratchet dial to achieve a snug, secure fit. Like the HelpILO, it secures the laryngoscope with a ring clamp assembly. The inherent stability and structural durability of the hard hat construction served as the primary inspiration for the

team's helmet selection for UW Health. In clinical trial testing across 29 participants, the HALOS design received predominantly positive to neutral feedback regarding patient comfort

1.3 Problem Statement

Continuous laryngoscopy during exercise (CLE) is a diagnostic tool that is the gold standard to diagnose exercise induced laryngeal obstruction (EILO). In order to observe the laryngeal obstruction, CLE is performed by attaching a laryngoscope to a head mounted apparatus which is inserted into the patient's nose into the larynx. The patient would sprint or stationary bike at 50% and 100% exertion during the laryngoscopy. Currently, there are no standardized helmets for performing CLE and all CLE helmets are custom made. To design a successful helmet for CLE, the laryngoscope mount must resist 6N of force and a 1.5N*m moment applied in all directions. During full sprint, the laryngoscope must not move more than 5mm from its original position relative to the helmet and must not apply a moment greater than 30N*m on the occipital condyle in both flexion, extension, and bending. Lastly the helmet must not slip and thus rotate relative to the patient's head more than 10 degrees from its initial wear position.

Background

2.1 Physiology and Biology

Exercise induced laryngeal obstruction is a condition where the vocal folds or the muscular structures surrounding them temporarily narrow or fully close during intense exercise. EILO is most common in adolescents and young adults (20-40 years of age) [8]. This condition is most prevalent in women, with 70% of diagnoses being female patients. This is due mainly to the smaller anatomy of women's vocal folds and general throat anatomy, resulting in a higher probability of muscles malfunctioning [9].

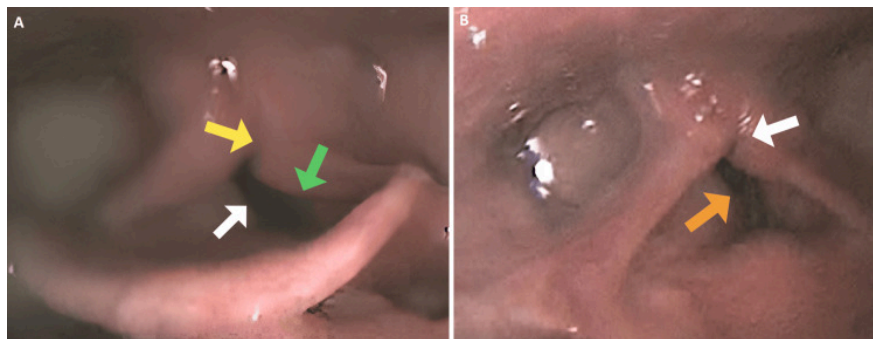


Figure (3): EILO patient's vocal folds at rest (A), versus their vocal folds during peak exercise (B) [8]

EILO is often misdiagnosed as asthma, but there are patients that have both asthma and EILO. While asthma is classified as a lower respiratory issue, issues with how someone exhales, EILO is an upper respiratory issue that prevents correct inhalation. The symptoms for both of these conditions are very similar, as both asthma and

EILO patients have breathing difficulties during exercise, noisy breathing, throat tightness, coughing, and voice changes [8]. The only way to accurately diagnose this condition is to have a laryngoscope inserted into your throat while exercising, known as CLE. Since EILO is an exercise induced condition, patients must be exerting themselves for the malfunctions to become identifiable by specialists. CLE testing includes the patient running on a treadmill or up a flight of stairs with a laryngoscope inserted through their nose and into their throat. This allows the camera to document where the malfunction stems from, and allows specialists to begin planning out therapy plans for the patient [10].

2.2 Client Information

The team's client, Mr. Jacob Tangney works as a speech language pathologist at the university hospital. He specializes in voice disorders, specifically issues surrounding swallowing and breathing. He encounters many patients who experience symptoms of ILO and wants to begin CLE testing on his patients.

2.3 Design Specifications

According to the Product Design Specifications for this project, the goal of this project is to design a stabilizing mount that holds a laryngoscope to the top of a patient's head during CLE testing. The design should be compatible with a chosen helmet that can fit a range of head circumferences from 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 [11]. Since most of the afflicted patients are female, the design must be comfortable around how their hair is held up (ponytails, buns, braids).

The laryngoscope mount will be fabricated from polyethylene terephthalate glycol-modified (PETG) plastic to provide structural support, while Velcro straps will be used to secure the laryngoscope in place. Additionally, quaternary ammonium compound (QAC) treated polyurethane foam will be used for cushioning to improve patient comfort [12][13][14]. The materials must be able to handle up to 40 degrees celcius from the patient's body temperature during testing, and they must be able to undergo continuous bleach cleanings.

The design, including the laryngoscope, must not exceed 1.20 kg. This is because the design must minimize the amount of weight, and therefore the amount of force placed on the patient's neck during exercise, specifically the design cannot add more than 1.5 Nm to the neck at rest and has to withstand a minimum of 2g (19.6m/s^2) [15][16]. Maximizing patient comfort will have patients more willing to participate in CLE testing, and will generate the most accurate testing results.

Preliminary Designs

3.1 Airsoft Tactical Helmet

The airsoft tactical helmet is an option that provides a stable platform for mounting the laryngoscope. The tactical helmet has a hard outer shell, provides structural support and distributes impact force and adjustable mount able to adjust the helmet both vertically and horizontally, which can help the helmet fit different head sizes while limiting the movement during exercise. The rigid shell also provides a strong surface for attaching the laryngoscope mount and the pre-existing mounting area allows the mount to be positioned securely directly above the patient's head. However, the rigid structure of the helmet can increase the overall weight of the helmet and cause discomfort to the neck during high intensity exercise.



Figure (4): Airsoft Tactical Helmet

3.2 Climbing Helmet

The climbing helmet consists of a lightweight rigid outer shell with durable internal foam layer, with material made out of expanded polystyrene (EPS). EPS foam is lightweight and helps absorb impact energy while also providing cushioning around the user's head [17]. The helmet also contains chin straps that would allow it to be tightened or loosened with a knob in the back of the helmet providing a secure fit. The rigid shell would provide a stable surface for laryngoscope mount installation. The lower weight of the climbing helmet can reduce neck strain and improve patient comfort during CLE testing. However modifying the helmet to install the mount should be taken into account as drilling/cutting through the shell and into the internal foam could weaken the helmet or damage the protective padding.



Figure (5): Climbing Helmet

3.3 Wrestling helmet

The wrestling helmet uses a soft and flexible design that wraps around the patient's head rather than relying on a closed rigid shell. The flexible straps and padding would allow the helmet to accommodate different head shapes and sizes, which helps with reducing slippage during exercise and improve the comfort of the patient. The open design would provide good ventilation reducing sweat build up and would accommodate patients with different types of hair. The openings along the top of the helmet would allow the mount to be strapped around the top of the helmet.



Figure (6): Wrestling Headgear

3.4 Angled Cone Mount

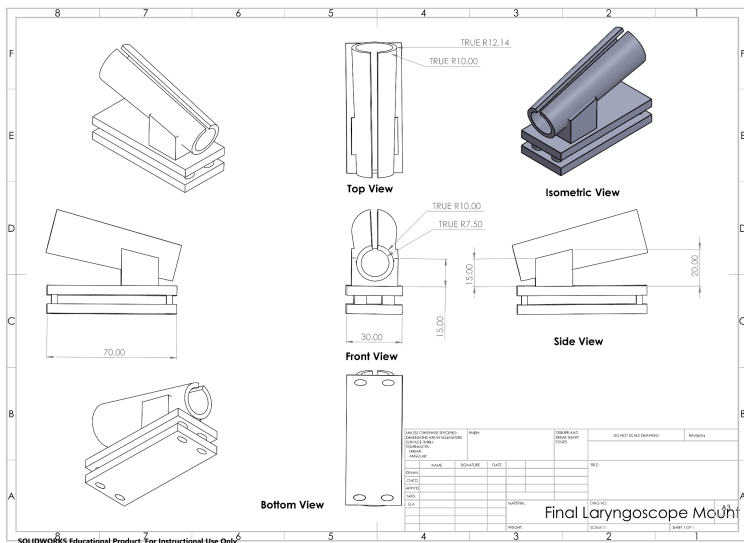


Figure (7): Angled Cone Mount Drawing

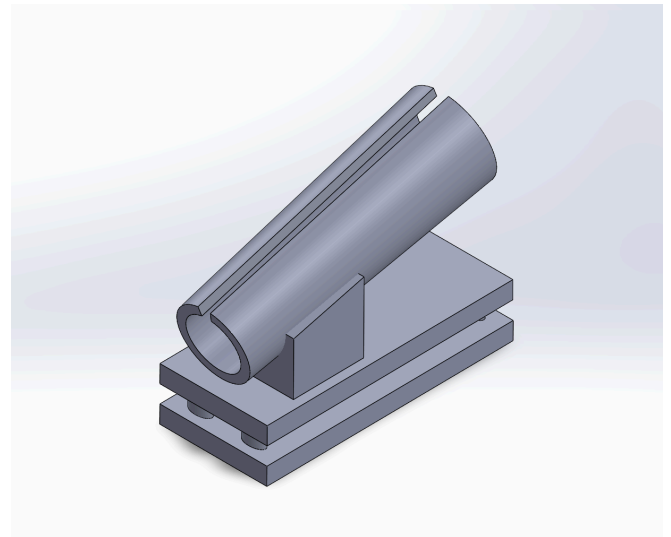


Figure (8): Angled Cone Mount Isometric View

The angled cone mount uses two main components, the top mount plate and bottom mount plate. The use of two mount plates instead of a single mount plate above the helmet increases the moment of inertia along the anterior-posterior axis, which increases torsion resistance. The top mount plate houses the cone. The cone is contoured to the shape of the control body of the laryngoscope and will securely hold the laryngoscope on all

sides. For additional stability, a ring clamp will be mounted onto the cone that will allow for the cone to grip onto the laryngoscope. Lastly, the inside of the cone will be lined with a thin layer of 40-60 Shore A silicone to improve grip as this lining has an average coefficient of static friction of 0.6 with many materials well exceeding this value [18][19].

The bottom mount plate is inserted inside the helmet at the bottom surface where the top of the patient’s head will make contact. The top mount plate is directly above the helmet and bottom mount plate. These two plates will be screwed together to be rigidly mounted onto the helmet. The angled cone mount is a highly cost effective design that can stabilize the laryngoscope under heavy loads. What makes this design stable and durable is also what makes it not very adjustable given that it is one whole piece with no moving parts.

3.5 Split Ring Mount

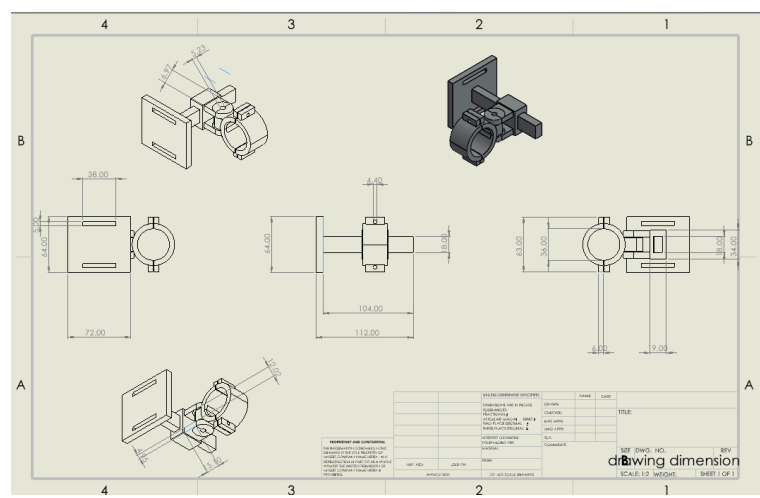


Figure (9): Split Ring Mount Drawing

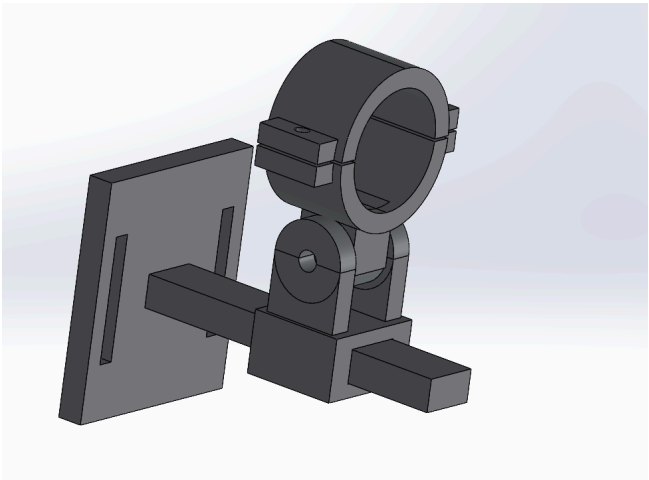


Figure (10): Split Ring Mount 3D Rendering



Figure (11): Basic Split Ring

The split ring mount utilizes one main body featuring two ring clamps as the main stabilizing factor. The ring clamp is adjustable in diameter and clamping force, making it suitable for many different types of

laryngoscopes. Additionally, the split ring mount offers two degrees of freedom for adjusting the position of the laryngoscope. First, the hinge that connects the ring clamp to the mount allows the angle between the laryngoscope and patient to be adjusted. Secondly, the rail at the base of the mount allows the mount to be adjusted anteriorly and posteriorly.

The main body of the split ring mount will be fabricated from PETG due to its balance of cost, shelf life, chemical resistance, and yield strength of 53MPa. [20][12][21] while the ring clamps will be made of 316 stainless steel due to its high yield strength of 205 MPa and corrosion resistance to most commercial disinfectants [22][23]. This design is very versatile and is also very stable, however, long term durability may be a concern due to a greater number of moving parts.

3.6 Magnet and Velcro Mount

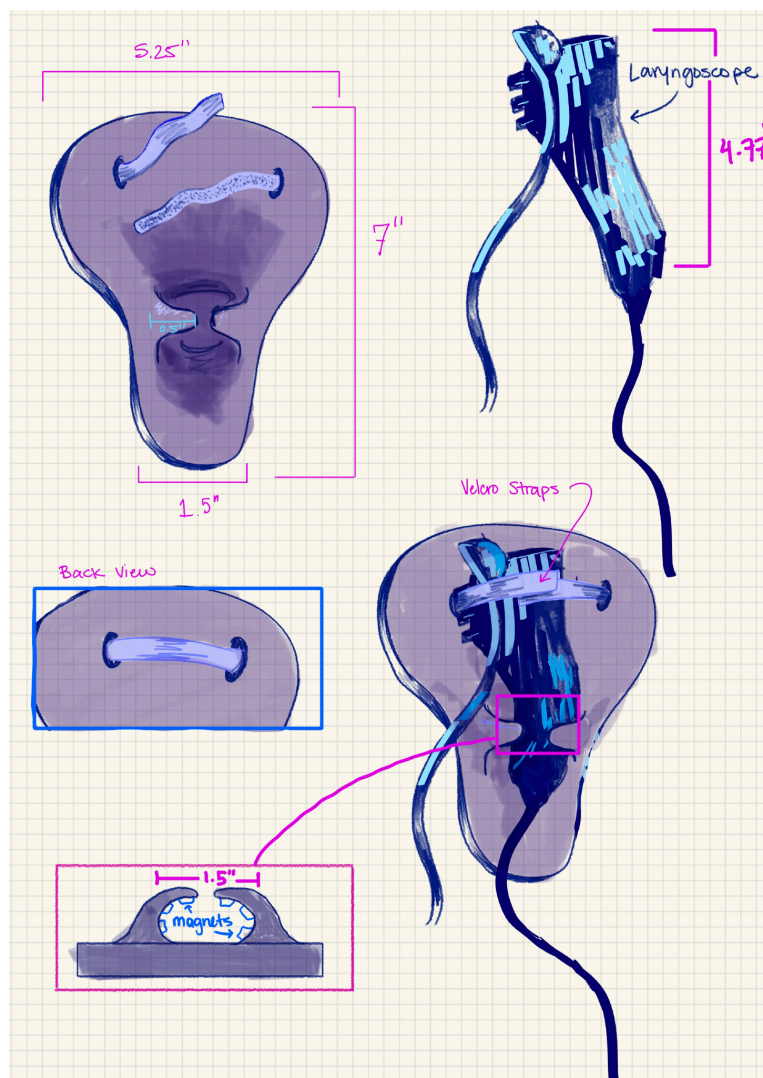


Figure (12): Magnet and Velcro Mount Drawing

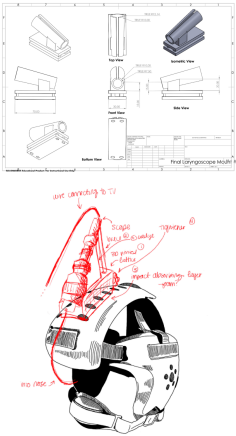
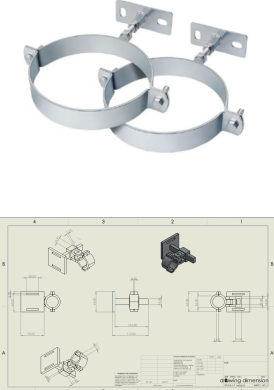
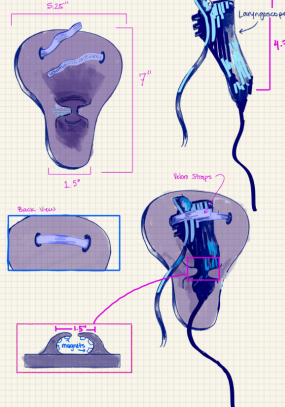
The magnet and velcro mount utilizes a velcro strap and magnets as the main stabilizing factors. The velcro is also intended to bond the mount to the helmet while strapping the laryngoscope tightly. The magnets at the bottom of the mount are intended to further stabilize it while keeping the form factor small. The base of the mount is made of TPU and the top and bottom surfaces are lined with a high friction rubber to prevent the laryngoscope from sliding. The base also has a contour to cradle the laryngoscope, providing additional contact area for friction to stabilize the laryngoscope. This design will fit the most variety of laryngoscopes however it compromises the stability of the laryngoscope.

Preliminary Design Evaluation

4.1 Helmet Design Matrix

Criteria (Weight)	Design #1: Airsoft Tactical Helmet		Design #2: Climbing Helmet		Design #3: Wrestling helmet	
	Raw Score	Weighted Score	Raw Score	Weighted Score	Raw Score	Weighted Score
Stability (40)	4.5/5	36	4/5	32	4/5	32
Durability (15)	5/5	15	4/5	12	3.5/5	10.5
Price (10)	4/5	8	4/5	8	4/5	8
Comfort (10)	3.5/5	7	3.5/5	7	5/5	10
Fit (15)	3/5	9	3/5	9	5/5	15
Ease of Use (10)	4/5	8	5/5	10	2/5	4
Total (100)	83		78		79.5	

4.2 Laryngoscope Mount Design Matrix

Criteria (Weight)	Angled Cone Mount		Split Ring Mount		Magnet+Velcro Mount	
						
	Raw Score	Weighted Score	Raw Score	Weighted Score	Raw Score	Weighted Score
Stability (40)	4/5	32	4/5	32	2.5/5	20
Durability (15)	5/5	15	4/5	12	4.5/5	13.5
Ease of Fabrication (15)	5/5	15	4/5	12	4.5/5	13.5
Weight (10)	4/5	8	3/5	6	5/5	10
Adjustability (10)	2/5	4	5/5	10	4.5/5	9
Price (10)	5/5	10	4/5	8	3/5	6
Total (100)	84		80		72	

4.3 Design Matrix Criteria Analysis

To evaluate the designs for all three helmets, six different criteria were set in place that best agree with the goals outlined in the product design specifications (Appendix 7.1). The first of these criteria is stability. Stability refers to the ability of the helmet to limit independent movement between the helmet and the head as well as the ability for the helmet to properly secure a mount. This category constitutes the highest importance of all six categories. For a CLE test, stabilization of the laryngoscope is important because movement can lead to poor video quality, reduced patient experience, and possible misdiagnosis [24][25]. The airsoft tactical helmet was given the highest rating in this category due to its straps. Its straps are the largest of the three and are featured in both the vertical and horizontal directions. Additionally its thick shell can support the proper

installation of a mount. Overall, the tactical helmet can be secured tighter than the climbing helmet while providing a rigid shell for the mount that the wrestling helmet cannot do. The second criteria when evaluating the helmets is durability which refers to both physical toughness and chemical resistance. The tactical helmet consists of an acrylonitrile-butadiene-styrene (ABS) shell while the climbing helmet features a polycarbonate (PC) shell [26][28]. Polycarbonate (PC) has a relatively high tensile strength in comparison to acrylonitrile-butadiene-styrene (ABS), leading to the climbing helmet having an overall tougher shell [27]. When exposed to medical grade disinfectants, both ABS and PC showed slight degradation, showing moderate durability against ammonium-based disinfectants and alcohols [29]. Regarding the wrestling helmet, its *popfoam* material is designed for both shock absorption and water resistance, showing minimal chemical durability [30]. Considering both factors and its heavy-duty nature, the tactical helmet received the highest score for durability. The prices regarding each helmet were within a 10 USD range leading to the same score for each helmet [26][27][28]. The comfort of each helmet was evaluated based on both the level of padding and breathability. The wrestling helmet outperformed both the tactical and climbing helmet due to its *popfoam* material which produces lightweight comfort, multiple openings for the expulsion of heat, and the ability for women to put up their hair via gaps in the padding [30]. The wrestling helmet was additionally determined to have the highest degree of fit due to the conformity of the soft *popfoam* material. Lastly, the ease of putting on the helmet supported the climbing helmet due to its similarities to a traditional bike helmet, featuring a singular chin strap and tightening wheel [27].

To evaluate the designs of all three mounts, six similar criteria were set in place that best align with the product design specifications (appendix 7.1). The first design was again stability, referring to the ability of the mount to resist motion of the laryngoscope during exercise. Stability was ranked the most important factor due to both the discomfort of the laryngoscope shifting within the patient's larynx as well as the potential of dropping/damaging the laryngoscope itself, which costs up to 18,292 USD itself [31][25]. The angled cone mount provided a near 360 contact surface while the split ring clamp provided an adjustable clamp that can be tightened as desired. Both proved to be effective in securing the laryngoscope in different ways, leading to the same scores being given. The magnet-velcro mount did not have any form of vertical stability, merely tightening the laryngoscope to the surface of the helmet via velcro and magnets, thus receiving the lowest score. Durability refers to the ability to maintain structural integrity through repeated uses. The angled cone mount was determined to have the highest durability due to its few number of components and dispersion of pressure points. This feature contrasts the other two designs which feature multiple pieces fastened together. Ease of fabrication refers to how easily a specific mount can be implemented. The angled cone mount was determined to have the highest ease of fabrication due to its entirely 3D-printed nature. The fabrication process would be to simply print and install the mount into the helmet while both the split-ring and velcro-magnet mounts require additional interacting components. The weight of each mount was considered due to the potential of causing added strain for patients performing a CLE test. The magnet-velcro mount was determined to have the least amount of weight due to its relatively compact design and absence of metal and large 3D printed components. Adjustability refers to the ability to adjust the position of the laryngoscope while mounted and the housing of different sized laryngoscopes. The split ring mount features a degree of rotation on its frontal axis and a tightening system that can tighten to different sized laryngoscopes. Both features are absent in the angled-cone and magnet-velcro mount; thus, the split-ring mount was given the highest score. Finally, the angled-cone

mount was determined to be the cheapest due to its purely 3D printed nature, avoiding the purchase of additional materials such as metal rings and magnets.

4.4 Proposed Final Design

After evaluating the design matrices, the final proposed design is the airsoft tactical helmet paired with the angled cone mount. The entire prototype will be three separate pieces, namely the airsoft tactical helmet and two separate pieces that comprise the angled cone mount. The airsoft tactical helmet will act as the base of the prototype while the angled cone mount will be secured to the top of the airsoft tactical helmet and hold the laryngoscope during testing. As the user performs testing for EILO, both the airsoft tactical helmet and angled cone mount will be responsible for preventing movement and stabilizing the laryngoscope.

Based on the design matrix, the airsoft tactical helmet scored the highest of the three proposed helmets, best meeting the requirements of the Product Design Specification (Appendix 7.1). This helmet performs the best with regards to stability, durability, and price. The airsoft tactical helmet also performed runner-up in comfort, fit, and ease of use, granting it the highest score of 83/100. Similarly, the angled cone mount scored the highest of the three proposed mounts, also best meeting requirements of the Product Design Specification (Appendix 7.1). The angled cone mount scored the highest in stability, durability, ease of fabrication, and price. Additionally, it performed secondary in weight. Those two factors combined granted the angled cone mount the highest score on the matrix with 84/100. Both of these factors combined make both the airsoft tactical helmet and angled cone mount the best options for Mr. Tangney.

Lastly, multiple different mounts and helmets will be tested going forwards as approved by Mr. Tangney.

Fabrication

5.1 Materials

The outer shell of the airsoft tactical helmet is constructed from acrylonitrile butadiene styrene (ABS), which is a durable thermoplastic commonly used in medical device housings and available in grades suitable for contact with intact skin [32]. ABS also exhibits good resistance to moisture and perspiration, making it suitable for prolonged wear [32]. The inner lining is made of ethylene-vinyl acetate (EVA) foam which is notable for its resistance to tearing and cracking along with having a relatively low density from $\sim 30\text{-}60\text{ kg/m}^3$, minimizing weight applied directly to the head during testing [33]. In addition, the angled cone mount will be 3D printed out of polyethylene terephthalate glycol (PETG). PETG is effective in resisting damage from cleaners such as bleach, hydrogen peroxide, and isopropyl alcohol [34,35]. Prolonged exposure to these chemicals will be experienced in a lab setting, so the tested and proven resistance is critical for the repeated use in an experimental setting. Lastly, the angled cone mount will be lined with a thin layer of 40-60 Shore A silicone in

order to improve grip. This silicone does not exhibit physical changes due to sanitation [36]. Combined, the highly biocompatible nature and proven resistance of tearing of the airsoft tactical helmet paired with the resistance of PETG to cleaning chemicals provides a stable helmet that will be able to withstand multiple uses.

5.2 Methods & Final Prototype

The CLE system consists of a base helmet and is fitted with a rigid mount. The helmet base will be a purchased airsoft tactical helmet that provides stability, comfort, and durability. This helmet features an outer shell made from ABS and an inner lining made of QAC foam, both of which resist degradation due to bodily fluids, namely sweat, and repeated sanitation in a clinical setting. This ensures a single prototype can endure numerous test-cycles with little-to-no wear. Attached to the base helmet is an angled cone mount. This mount is 3D printed out of PETG that includes a thin coating of 40-60 Shore A silicone on the inner portion of the cone in order to increase grip of the laryngoscope. The upper portion of the mount secures the laryngoscope, while an accompanying backplate is placed on the underside of the helmet and the entire mount is secured using threaded fasteners going from the backplate to the upper portion of the mount.

5.3 Final Prototype

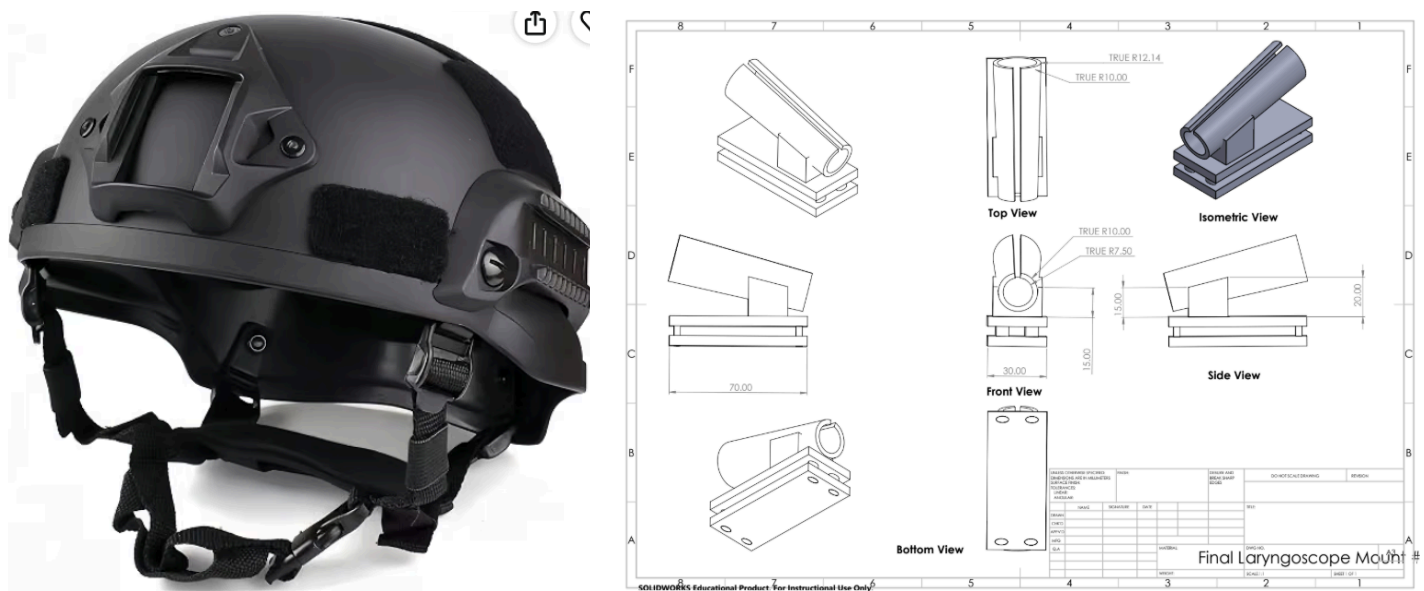


Figure (13): Final helmet and mount prototype selection

Testing and Results

6.1 Testing and Results Process

Based on the PDS, the laryngoscope mount must be able to withstand 6N of force and 1.5Nm of torque in all directions without sustaining any deformations and without rotating the position of the helmet 10 degrees relative to the patient's head [15]. In addition, the proposed design must fit head sizes from 50-61cm in circumference. Lastly, the design must be able to last a minimum of 300 test cycles.

In order to test for maximum force imparted on the laryngoscope mount by the laryngoscope during sprinting, a rigid phone mount will be made to be attached onto the helmet. Since smartphones have built in accelerometers, acceleration data in three dimensions can be collected through the Phyphox app [5]. Once the phone is mounted onto the helmet, a human volunteer will wear the helmet with a laryngoscope substitute with similar shape and mass mounted on to it. Once the helmet is on securely, the volunteer will sprint 10 intervals of one minute bursts at 100% effort with 1-2 minute breaks in between each interval. This will be repeated for a minimum of 5 subjects in order to obtain 50 sets of acceleration data, which will be processed and plotted on MATLAB. Once the maximum acceleration in each direction is obtained from each interval, the magnitude of the force can be calculated with $F = ma$ in all directions [37]. The mean and standard deviation of the peak acceleration and calculated force will be determined for each participant to evaluate the consistency of the mount's performance. Simultaneously, while the acceleration data collection is occurring, the angle of rotation of the helmet relative to the head can also be measured. By marking the relative position of a point on the helmet to the ear before and after sprinting, an angle can be obtained after each sprint.

Once data collection is complete, the design team will thoroughly inspect the helmet for any mechanical failures, such as cracks, plastic deformations, and corrosion to disinfectants. Any and all defects will be considered a failed test. Any failed test will result in an investigation of the failure mode, designs to correct it, and retesting until a design passes the testing.

Discussion

The angled cone mount design mounted on the airsoft tactical helmet provides a solution for the UW Health Speech Clinic that can be used to administer CLE testing, which will greatly aid clinicians in the diagnosis and treatment of patients with EILO. The most significant challenge is designing a CLE helmet that can accommodate all patients. If the helmet is the right size, it is possible that the laryngoscope mount is now too close or too far to the patient's nose given the fixed length of the laryngoscope probe. If multiple sizes of helmets are needed, it is possible that the laryngoscope cannot be mounted in the same relative position due to the fixed length of the probe. Thus a form of adjustability will need to be added to the angled cone mount that can slide anteriorly and posteriorly to account for that. Proceeding with a truly accurate test raises ethical concerns and will require several months to gain permission to start. Thus testing will need to be a simulation of the CLE procedure, where a laryngoscope model is made to replace the laryngoscope and insertion of the camera probe will need to be omitted in order to perform the testing on schedule. This raises concerns about accuracy which will need to be addressed in more extensive, long term testing.

Conclusions

Given that there are no standardized helmets that can effectively carry out CLE testing, there is demand for a device that is effective in stabilizing a laryngoscope for CLE purposes. To address this problem, a helmet base has been chosen and a laryngoscope mount has been designed to fit the helmet, which will be the airsoft tactical helmet and angled cone mount. The device will be tested by simulating the conditions as closely as possible of a CLE test to assess for maximum force applied to the mount and a qualitative assessment of the device for any mechanical wear or failures. The device will be deemed successful if it can withstand more than 6N of force and 1.5N*m of torque in all directions without sustaining any mechanical failures and if the helmet does not rotate 10 degrees relative to the head during the test.

In the future, if the design does not meet the specified performance requirements, more design iterations will be made and tested until it is successful in meeting the Product Design Specifications. Once the design is successful, the focus of the project will be shifted towards improving stability, patient comfort, sustainable manufacturing, and reducing costs. This will improve sustainability as well as making incremental improvements to the existing design.

References

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Appendix

7.1 Product Design Specifications

HELMET FOR CONTINUOUS LARYNGOSCOPY DURING EXERCISE

PRELIMINARY PRODUCT DESIGN SPECIFICATIONS

BME Design 200/300

Lab Section: 303

Team Members:

Leader: Evan Zheng

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Client: Jacob Tangney M.S

Advisor: Dr. Randolph Ashton PhD

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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