Johnson Health Tech: VO_2 Mask for Biomechanics Research

BME 200/300 Preliminary Design Report | October 20, 2021

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ABSTRACT

VO_2 max testing has become an integral tool used in multiple research areas. By completing a VO_2 max test, the cardiovascular fitness and health of a test subject can be determined. For testing, a subject goes through an intense aerobic activity for a specific amount of time while wearing a VO_2 mask that collects the total inhaled and exhaled air. Once the subject has reached exhaustion or VO_2 max values begin to plateau, the maximum VO_2 level can be observed. Although VO_2 max masks currently on the market are successful at providing accurate results, the comfort of the user is not always considered. Comfort is especially compromised for subjects with glasses since they do not fit over the VO_2 mask, preventing subjects from wearing them during testing. This causes disorientation in these users that could put them at risk for injury or anxiety. Therefore, the goal of this project is to create a VO_2 mask design that allows users to wear glasses during testing while maintaining the reliability of VO_2 max measurements. The design created must be cost effective, meaning under the allocated budget of $400, and maintain its integrity during VO_2 max testing conditions. A VO_2 mask design that adds clips on the sides and front of the mask to hold up the glasses during testing will be developed. The VO_2 max testing results of this design and the current mask used by the client will be compared statistically to show that they produce equivalent results.

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INTRODUCTION

Motivation

For all athletes, avid or elite, maximizing training and performance is key to reaching optimal athletic performance and maintaining healthy fitness. One way to evaluate the aerobic and endurance fitness of an athlete is by conducting VO_2 max tests. During these tests, the total volume of inhaled air, the percentage of oxygen and carbon dioxide in the exhaled air of the subject, and the subject's heart rate are collected through a VO_2 mask to calculate oxygen consumption. The intensity of the aerobic activity will increase periodically by increasing the speed, gradient (incline), power, or resistance of the exercise until the athlete can no longer continue. The greatest VO_2 value collected is the corresponding VO_2 max. Greater VO_2 max values correspond to higher levels of cardiovascular fitness, allowing the athlete to optimize their cardiovascular, lung, and muscle functions. The athlete will be able to work harder for longer and recover faster [1].

It is extremely important for researchers to be able to collect accurate and reliable data during these aerobic fitness tests. Mask leakage must be minimized to ensure the oxygen consumption values of the athlete are accurate in order to provide the athlete with the correct feedback on how to improve their performance. However, the subject should also be comfortable and relaxed during this already high-stress evaluation.

Existing Devices

There are currently many different VO_2 mask products on the market. However, none allow users to comfortably wear glasses during testing.

One of these products is the VO_2 Master Pro. This is a VO_2 mask design made and patented by VO_2 Master Health Sensors Inc. [2]. This battery-powered design holds the VM Pro attachment that contains the sensors, electronics, and tubes needed to power the VO_2 testing process. It attaches to a standard, silicone *Hans-Rudolph Face Mask*, and is held in place by straps running to the rear end of the head [2]. The VO_2 Master Pro is also portable, meaning it can conduct VO_2 max tests virtually anywhere. In addition, it can upload the results of personal testing to a mobile app compatible with most devices.

The K5 Metabolic System is another VO_2 mask design very similar to the VO_2 Master Pro in that it is both battery-powered and portable. Made by COSMED Co., this model also attaches directly to a standard silicone mask [3]. Straps hold the mask, O_2 and CO_2 sensors, and other wires and tubes in place during VO_2 max testing. This design can switch between a variety of testing modes including resting energy expenditure testing, cardiopulmonary testing, and VO_2 max testing [3]. The K5 model also supports the transfer of VO_2 max testing data to a mobile device through bluetooth connection.

Lastly, the CardioCoach System, created by KORR Medical Technologies Inc., uses a machine to power the VO_2 max testing process. This design also uses the standard silicone *Hans-Rudolph Face Mask*, which connects to the machine through a plastic tube [4]. The CardioCoach System controls the flow of air into and out of the mask, then analyzes the results by conducting a VO_2 max test through O_2 and CO_2 sensors [4]. The user must be in close proximity to the machine because the tube only stretches a few feet. This product also supports bluetooth sharing of VO_2 testing results to nearby mobile devices.

These products share one common feature: the standard blue silicone mask. However, none of the masks provide a comfortable fit for subjects with glasses. To accommodate these users, the standard mask design will be altered, while still allowing compatibility with the VO_2 max testing systems above.

Problem Statement

Metabolic tests, such as VO_2 max tests are important in determining the cardiovascular and aerobic fitness of athletes. During VO_2 max testing, athletes wear a VO_2 mask with an intake tube while performing an intense and high level form of exercise, like running or biking, until maximal effort and complete exhaustion. The concentration of oxygen inhaled and carbon dioxide exhaled are collected through the mask to determine how much oxygen the athlete uses during exercise as well as the maximum concentration of oxygen consumed. The more oxygen consumed, the more efficient the cardiovascular system is working. This means more oxygen can be delivered to the muscles, generating a greater energy output and enhancing physical performance [5]. There are VO_2 masks used during testing currently on the market, but improvements can still be made to make the testing more comfortable for participants.

Johnson Health Tech, an exercise manufacturing and research company, has faced problems with testing athletes that wear glasses while performing VO_2 max tests since they cannot wear their glasses with the masks. The design must be comfortable, prevent leakage, and allow for the athletes to wear glasses during testing.

BACKGROUND

Importance of VO_2 Max Testing

VO_2 max testing is generally considered to be one of the best indicators of cardiovascular fitness and aerobic endurance in athletes and test subjects. It is a measurement that reflects a person's capability to perform sustained, rigorous exercise by analyzing the maximum rate of oxygen consumption that could be reached during testing. The results of the test can also reflect a subject's health. The results of a VO_2 max test are dependent on three factors: the efficiency of the respiratory system to inhale and absorb oxygen; the ability of the cardiovascular system to efficiently pump, transport, and distribute oxygen around the body; and the muscles ability to consume and use large amounts of oxygen [1]. By analyzing and understanding the outcomes of VO_2 max testing, athletes can work on improving their VO_2 max with training, and other test subjects can focus on improving their fitness lifestyles for an overall healthier life.

VO_2 Max Testing and Normative Values

Although results from VO_2 max data can look different from person to person, the testing procedure is consistent for all subjects. VO_2 max values can be expressed as an absolute VO_2 max, the volume of oxygen consumed in liters per minute (L/min), or as a relative VO_2 max, the volume of oxygen consumed in milliliters per kilogram of bodyweight per minute (ml/kg/min). The typical recording of VO_2 max is in the range 25-45ml/kg/min [1]. However, this value can vary based on many different factors like sex, age, and physical actvity level. In order to measure VO_2 max accurately, the test must take place in a controlled laboratory environment. The tests require special gas analysis equipment including a face mask that is attached to a special gas analyzer. The analyzer measures the volume of inhaled air as well as the percentage of oxygen and carbon dioxide in the exhaled air. From these values, an accurate oxygen consumption measurement can be made.

In order to obtain VO_2 max values, tests require subjects to complete an incremental exercise test. In an incremental exercise test, intensity starts low and continually increases each time a work stage is completed. These increasing increments could be speed and gradient on a treadmill or power and resistance in cycling. The typical interval for increasing intensity is every 30-60 seconds. Incremental exercise tests will continue until the user cannot complete a work period or observed VO_2 levels begin to plateau. Ultimately, VO_2 max is measured from the highest average of VO_2 recorded over a 60 second period. Additional measurements can also be recorded, including heart rate [1].

Face Shape

The team researched variations in face shape prior to modeling the design. It is important to account for this variability in order to construct an appropriate mask that fits all users.

The nasal root breadth measurement outlines the width of the nose bridge. A study which conducted analysis on average facial measurements found that the average measurement for nasal root breadth is 16.6 ± 2.3 mm for males and 16.3 ± 2.0 mm for females [6]. Another important dimension is the subnasale to sellion length, which is the measurement from the base of the nose to the bridge of the nose. The same study found that the average measurement for the subnasale to sellion length is 52.0 ± 4.1 mm for males and 48.2 ± 3.8 mm for female subjects [6]. Lastly, the average nose protrusion length is 21.1 ± 2.7 mm in males and 19.8 ± 2.7 mm in females [6]. The "±" measurements represent the survey's standard deviation range, in which 90% of all subjects' dimensions are located. The other 10% of recorded measurements are outside of this standard deviation range.

These measurements offer valuable insight into the face structure of a typical human. The variability of these dimensions are important to consider because the target audience of this project includes a wide range of people, who all rely on this mask to fit them comfortably and reliably.

Client Information

Johnson Health Tech is a worldwide fitness and wellness equipment manufacturer and distributor based out of Cottage Grove, WI. The company develops exercise products such as treadmills, stationary bikes, ellipticals, and stair steppers across multiple brands. Outside of development, the company also utilizes a biomechanics lab where research is conducted to validate and support analysis claims as well as to conduct competitor comparison studies to evaluate their products against others on the market [7]. Johnson Health Tech also carries out VO_2 max studies as part of their ongoing data collection. Although the company already has a VO_2 mask for testing, the mask is not compatible or comfortable for users with glasses. The clients for this project under Johnson Health Tech have requested for a mask design to be developed that is compatible with glasses.

Design Specifications

Aiming to allow users to wear masks during VO_2 max testing, Johnson Health Tech has requested a mask that is compatible with glasses that can be worn during the entirety of testing. The mask must be conducive to the intense exercise environment subjects are put in and should not alter the exercise gait of the participants during testing. The mask must withstand rigorous activities like biking or running for at least 20 minutes and should be reusable between tests after cleaning it with soap and water. Air leakage from the mask must also be minimized, so the mask should not move around on the face of the user and should be securely fit to their face. This will allow the VO_2 max values to be collected accurately across all subjects. The mask should be harmless and easy to use for the subject. For the design to be competitive in the market and meet the client's requirements, the budget of the design should not exceed $400. A complete list of specifications can be found in **Appendix A**.

PRELIMINARY DESIGNS

Design 1- Clips and Lower Bridge

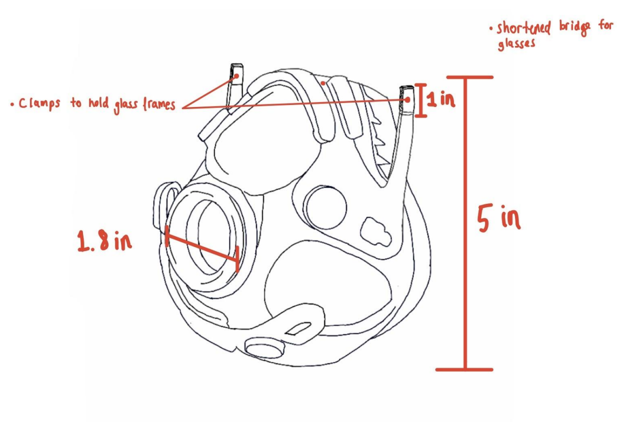

Figure 1: Sketch of the Clips and Lower Bridge design

The first design is the Clips and Lower Bridge design, shown in **Figure 1**. This design lowers the area that covers the bridge of the nose by one inch to allow glasses to comfortably fit on the nose without interference from the mask. Two clips are attached to the sides of the mask, allowing the mask to secure the glasses in place. This prevents the mask from damaging the glasses during high intensity activities. The clips will latch onto the glasses legs, firmly holding them up. All other aspects of the mask will remain the same. The main concern with this design is that leakage of air from the mask could be possible by lowering the nose bridge. Depending on the face shape of the user, the mask might not fit as securely on their face if the nose bridge was lowered.

Design 2- Divot

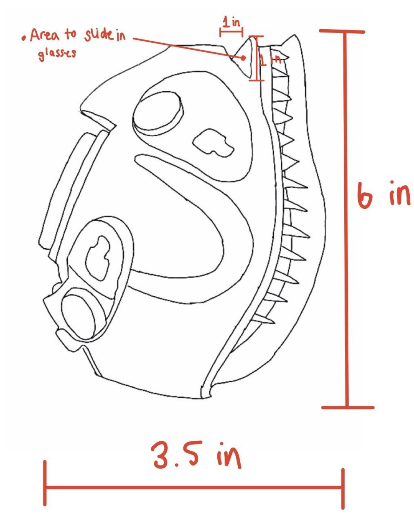

Figure 2: Sketch of the Divot design

The second design is the Divot design, shown in **Figure 2**. This design allows the bridge of the glasses to fit into a 1 inch by 1 inch trench incorporated on the mask. All other aspects of the mask will remain the same as the current mask. This will ensure that the user is able to comfortably wear the mask while also wearing their glasses. The 1 inch by 1 inch trench was determined to be inclusive of all glasses possibilities [8]. However, by creating this divot at the nose bridge area, the mask could easily tear and be susceptible to air leakage. This would cause errors in the VO_2 readings during testing.

Design 3- Nose Clip and Mouthpiece

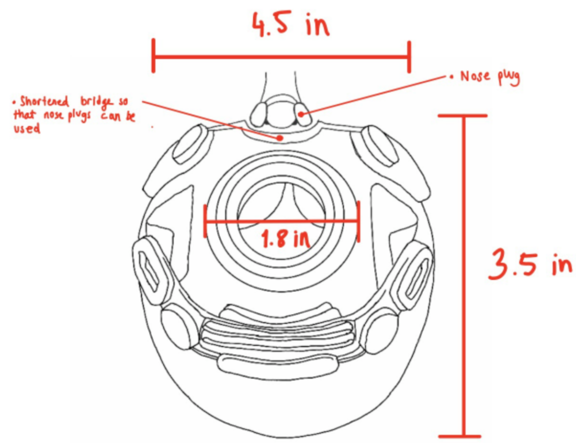

Figure 3: Sketch of the nose clip and mouthpiece design

The nose clip and mouthpiece design, pictured in **Figure 3**, accounts for the most changes to the current design. First, the mask no longer covers any aspect of the nose. Instead, a nose plug clip is applied to the external part of the user's nose and does not allow air to flow in or out of the nose. All air flow will be filtered and collected through the mouth through a mouthpiece. The mask is shortened to 3.5 inches and the top of the mask rests in between the bottom of the nose and the upper lips of the user. All other aspects of the mask remain the same. Although this design would easily allow the user to wear glasses during testing, the comfortability of the design would be jeopardized.

PRELIMINARY DESIGN EVALUATION

Design Matrix

Criteria	Weight	Design 1 - Clips and Lower Bridge		Design 2 - Divot		Design 3 - Nose Clip	
Comfort	25	3/5	15	2/5	10	1/5	5
Accuracy	25	5/5	25	3/5	15	2/5	10
Durability	20	3/5	12	4/5	16	4/5	16
Ease of Use	15	4/5	12	5/5	15	3/5	9
Safety	10	5/5	10	4/5	8	4/5	8
Cost	5	5/5	5	5/5	5	5/5	5
Total	100		79		69		53

Table 1: The team's design matrix

<u>Comfort</u>

Comfort can be defined as the physical ease from pain that the mask user feels during testing. This category was tied for the highest weight because the client has stressed how the mask must not only allow users to wear glasses during testing, but it must also be comfortable for the user. Design 1 was awarded the highest score for this category because the user would likely experience the least discomfort from these modifications. The lower bridge of this mask would allow more facial freedom and the clips would comfortably hold glasses in place. The second design earned a slightly lower score because the indentation could potentially irritate the user's nose. Finally, the third design was named least comfortable because the nose clip needed to cut off air flow from the nose would be tight and likely harsh on the user's face.

Accuracy

The accuracy of the mask was tied with comfort for the highest weight category. Although the mask needs to allow users to wear glasses during testing, accuracy and reliability of the VO_2 max results cannot be compromised. The accuracy scores were determined based on how each design's results are expected to compare with the current Johnson Health Tech mask's results. Less expected variance between results would lead to a higher score on the design matrix. The first design is predicted to exhibit little to no deviation from the original design's results because the mask would be similarly secured to the face. Additionally, it was predicted that the second design could diverge from the previous results because the divot could put the mask at risk for air leakage from potential tears. The third design would be the least accurate because the nose airway is completely cut off from the rest of the mask.

Durability

Durability was weighted the next highest since the mask must withstand exercise tests without exhibiting damage. The first design received a three because the clips could potentially break off the mask after repeated use and testing. The second and third design scored fours because the designs would most likely not have many durability issues. These designs lack any additional attachments to the mask itself, thus, there is nothing to break off of them. The second design did not receive a perfect score due to the fact that the divot could potentially rip. The third design did not get a perfect score either, as the nose clip may be flimsy and perhaps not last long during testing.

Ease of Use

Ease of use was weighted based on how easy it would be for a user to use the mask. A higher score indicated that the design was easier to use. The first design scored a four because it is fairly easy to use. The user will only need to attach the clips to their glasses prior to testing. The second design got a perfect score because there are no additional steps that the user needs to take to put on or take off the mask. The third design earned the lowest score because the nose clip and mouthpiece could both present difficulty when putting it on since there are two separate components. This multistep process to put on and take off the mask earned it the lowest score.

Safety

Safety was weighted the next highest criteria. Safety relates to how much risk the user is at while wearing the mask. A higher score means that the user is at lower risk of harm. All three masks were relatively low risk. The first design is low risk since the mask does not have components that could jab, pierce, or hit the user. The clips could be seen as a safety risk, but their plastic coating will keep the user safe. The second design got a near perfect score because there is only a small potential that the divot could hurt the user's nose. Lastly, the third design scored as it did because there is a chance that the nose clip could be a safety concern.

<u>Cost</u>

Cost was weighted last in the team's design matrix since each design would be relatively inexpensive to fabricate and would stay within the client's budget of $400. All three designs received a perfect score since creating them will remain under the client's budget. None of the intended materials for developing the mask are very expensive, so production cost should be low for all of them.

Proposed Final Design

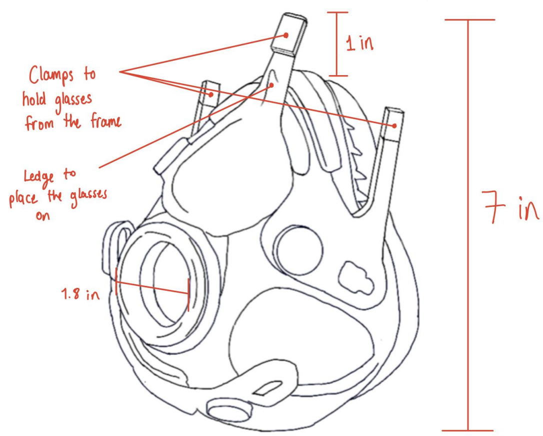

Figure 4: The team's proposed final design

The proposed final design contains aspects of designs 1 and 2 and is illustrated in **Figure 4**. In terms of design 1, the final design will have two clips on the side that attach the glasses legs to the mask. In place of the divot, but in hopes to keep the general idea of design 2, the team is adding a third clip that will secure the bridge of the glasses to the mask as well. There will be a "ledge" on the center clip that will ensure the glasses do not slip out of place and will minimize vertical movement of the glasses. The mask will have the same dimensions as the original mask, but three clips will be added. This will ensure that the glasses are able to fit, that they stay in place, and that the mask is still able to function properly.

FABRICATION AND DEVELOPMENT PROCESS

Figure 5: Korr Medical Technologies VO_2 mask existing model

Fabrication

To generate a physical prototype of the mask, the team began by performing a 3D scan of the existing mask provided by the client [9]. The client instructed the team to prototype the larger mask size, which can then be transferred to the dimensions of the smaller mask size if the design is deemed successful. This 3D scan can be manipulated in a 3D modeling software such as SolidWorks, allowing the team to make the proposed alterations to the design. When the SolidWorks model is completed, the team plans to 3D print a physical prototype of the VO_2 mask at the Makerspace [10]. Research will be done to select an appropriate material to best replicate the flexible, elastic materials used in the existing masks. The existing masks consist of a main silicone piece, a deformable inner layer that comes in contact with the user's face, and plastic pieces which attach to the straps that secure the mask to the user's face. The existing mask is pictured in **Figure 5**. The client has no issue with the materials present on the existing masks, so the team will focus on material options that most closely resemble those material properties. Some potential options at the Makerspace that could be appropriate for the mask are the Formlabs Elastics and Formlabs Flexible materials [10]. 3D printing is an effective option for prototyping this design because it is relatively inexpensive and quick. The goal is to assess user comfort and glasses fit while wearing the mask. Therefore, several physical prototypes may have to be produced because these qualitative variables will be hard to assess using computer models. The team will also need to verify that the mask produced is compatible with the straps and attachments used with the existing masks.

Future Testing

In order to test the effectiveness of the mask design, the team will undergo research to collect data affected by the mask. One participant, most likely one of the team members, will complete two VO_2 max endurance tests; one test will be done using the VO_2 mask already used by Johnson Health Tech, and the other will be with the design developed by the team with the glasses clips. The participant will also be wearing glasses to assess the comfortability of both. These tests will be carried out in the biomechanics lab at Johnson Health Tech under their protocols and procedures [11,12]. The VO_2 max measurements collected from both masks during the tests will be compared to each other to show that they produce similar results. Equivalence and noninferiority analysis tests and calculations will be carried out to show the similarities in data between both masks. The equivalence test shows that if the VO_2 max values are within an equivalence margin, then the values are considered "close enough" to be equivalent. The inferiority test also utilizes the equivalence margin to state that data from one mask is not inferior or superior to the other [13]. These tests will help to ensure the team's mask design does not compromise comfort for accuracy of VO_2 max measurements.

CONCLUSION

VO_2 max testing is a powerful tool in assessing cardiovascular and aerobic fitness levels. Unfortunately, of the VO_2 masks currently available, none provide a mask compatible with glasses. Subjects with glasses are required to perform the test without glasses, which could cause anxiety for the subject and result in an unsafe testing environment. Johnson Health Tech has asked the team to provide a solution that allows subjects to wear glasses during testing and accommodate users with diverse facial profiles and different glasses sizes. The team will quantitatively prove that the new mask provides consistent VO_2 mask readings with those supplied while using the existing masks. To create this device, the team researched facial anatomy and measurements, commercially-available VO_2 masks, and possible mechanisms for securing the user's glasses during activity. Based on this preliminary research, the team developed three design alternatives which were evaluated using the weighted criteria in the design matrix. The final proposed design combined aspects of the Clips and Lower Bridge design and the Divot design. The mask will have two lateral clips to secure the arms of the glasses as well as a third clip in the center to secure the bridge. Other aspects of the design will remain the same as the existing masks to maintain consistent testing results and proper fit. Going forward, the team will focus on material selection and fabrication of the mask. Using the 3D scan as a base, the design will be formed in SolidWorks, and 3D printing will be used to create the physical prototypes. Materials will be selected for 3D printing which best match the material properties of the existing VO_2 masks. After a physical prototype is produced that allows the user to wear glasses in conjunction with the msak, quantitative testing can proceed. An individual will perform VO_2 max testing following the Johnson Health Tech protocols, and equivalence and noninferiority testing will be used to demonstrate the consistency in VO_2 readings. These calculations, along with overall user comfort and glasses fit, will provide support for this design's use in VO_2 testing to reduce anxiety and improve safety for individuals with glasses.

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APPENDIX

Appendix A: Product Design Specifications

Function:

Aerobic endurance tests, such as VO_2 max tests, are important in determining the aerobic fitness of athletes. During VO_2 max testing, athletes wear a VO_2 mask with an intake tube attached while performing an intense and high level form of exercise like running or biking. The concentration of oxygen inhaled and carbon dioxide exhaled are collected through the mask to determine how much oxygen the athlete uses during exercise as well as the maximum concentration of oxygen consumed. The more oxygen consumed, the more efficient the cardiovascular system is working, meaning more oxygen can be used to enhance physical performance. There are VO_2 masks used during testing currently on the market, but improvements can still be made to make the testing more comfortable for participants. Participants that wear glasses have posed a big concern, resulting in the need for the development of a VO_2 mask that can be worn comfortably with glasses. With current products on the market, users cannot wear glasses during testing. This can cause anxiety and worry in users since they can feel disoriented and uncomfortable, putting them at risk during testing. The design must be comfortable, prevent leakage, and allow for the athletes to wear glasses during testing while being able to function in the operating conditions and cost less than $400 to produce.

Client Requirements:

- The VO_2 mask must be designed to allow subjects with glasses to wear their glasses during testing
- Leakage of air must be limited
- Must be practical and user friendly
- Operational during intense exercise activity such as running, biking or using an elliptical
- Production costs must not exceed $400
- Withstand testing for around 20 minutes
- Reusable with cleaning

Design requirements:

1. Physical and Operational Characteristics

a. Performance Requirements: The mask design must allow users with glasses to wear their glasses during the entirety of the VO_2 max data collection. The mask must be conducive to the intense exercise environment subjects are put in and should not alter the exercise gait of the participants during testing. To prevent air leakage, it should not move around on the face of the user and should be securely fit to their face. This will allow the VO_2 max values to be collected accurately across all subjects.

b. Safety: The user must be allowed to wear glasses while the mask is on. Visual impairment causes a high safety risk as the user is performing testing at high speeds on a treadmill or bike. Performing the testing with their glasses on will also help the user feel more comfortable and less anxious. The mask should provide a snug fit, making sure all air is going through the mask in order to provide the most accurate VO_2 measurement. The mask also should not cause skin irritation or be uncomfortably tight on the user's face.

c. Accuracy and Reliability: To validate the design, the team will perform VO_2 max testing following the provided protocol that is used with the existing VO_2 masks at Johnson Health Tech. A study will be done comparing the VO_2 readings using the new and existing masks. The volume of O_2 consumed per minute (VO_2) and the volume of air expired per minute (V_e) are the only variables being measured that the mask could impact [1]. The VO_2 readings using the new masks must be within the equivalency margin of the VO_2 readings using the existing masks.

d. Life in Service: The mask will be used for no longer than 20 minutes at a time for testing. The mask should also be reusable and easy to sanitize. It will be washed with soap and water and will be allowed to dry in between uses [1].

e. Shelf Life: The masks are aimed to be used for a long period of time since they will be reusable and easy to sanitize. They should be kept at room temperature where the material of the mask will not be damaged. The mask should go through sanitary gaps after every use. Soap and water will be sufficient to clean the mask.

f. Operating Environment: The mask will be exposed to human contaminants such as saliva, mucus, sweat and other pollutants in the body, albeit for only short periods of time. Temperature and humidity will also be contributing factors, even in an indoor environment, due to the participants expelling body heat and sweat. In storage, the mask is susceptible to common contaminants like dirt, dust and other particles. These pollutants should have no impact during use, as the user of the VO_2 mask should be able to clean dirty areas before use.

g. Ergonomics: This design is based primarily on user comfort. The straps that run behind the head and around the ears should be able to be adjusted to where the net movement of the mask is zero. The silicon mask should not be able to slide off the front of the face and should be comfortable for the user to wear. In addition, the user of the VO_2 mask should not experience any noticeable forces acting upon their glasses while in use. This design should be able to withstand any significant bending or movement at maximum human velocity, which is around 12 m/s or 28 mph [2]. Given this speed, the final design should be able to withstand 560 N or about 125 lbs of force [3].

h. Size: The client has directed the team to make two versions of the mask: a larger fitting one and a smaller fitting one. Each of the sizes must securely fit while preventing air leakage, and fit existing intake tubes. There are no direct size limitations on the mask, but the design should replicate the sizing of the current masks being used at Johnson Health Tech while incorporating the accommodation for glasses and comfort on the subject's face. The current measurements of the mask are 6" in height, 4.25" in width, and 3" in depth.

i. Weight: The client has made no indication about a weight restriction for the mask, however, there should not be much variance between the masks created and the existing masks. The optimal weight is similar to the existing weight, allowing for user comfort.

j. Materials: The mask will likely be made out of a rubber or silicone material, as the client's previous masks have been made out of rubber and/or silicone. There are no restrictions to material, but the chosen materials should cater to the user's comfort. The design will be 3D printed with a rubber or silicone-like material available at the MakerSpace. The clips will also be made out of plastic. The tubes and valves that fit into the mask and are used in the client's BioMech Lab will also be provided.

k. Aesthetics, Appearance, and Finish: The shape of this mask will be very similar to a standard VO_2 mask and will be formed of a soft material, like silicone or rubber. The color of this mask will be blue and red, which also matches the sample VO_2 mask received. In general, this section is subject to change as the team works through the design process; however, professional and practical choices in terms of aesthetics, appearance, and finish for this product will be maintained.

2. Production Characteristics

a. Quantity: There will be a total of two masks created: one large mask and one small mask. The masks will likely be quite similar in design, the only significant difference being the size.

b. Target Product Cost: The total budget for the mask is $400. The target is to keep the cost under the budget. The goal is to build a mask that meets the client's needs and is cost efficient.

3. Miscellaneous

a. Standards and Specifications: For the mask to be in use, there are certain requirements. First of all, it should be in agreement with FDA standards and specifications. It should be compatible with all sizes of glasses and should not interfere with any movement or exercise that could cause any danger. During testing, ventilation should be measured throughout the duration, while heart rate and VO_2 data should be monitored every 15 seconds. The mask should be durable enough to go through three different three minute tests with 20, 25, and 30 bpm trials [4]. There should be two mask sizes; the larger mask should be approximately 4.5 inches long, measuring from the centerline of the face while the smaller mask should be approximately 4 inches long, measuring from the centerline of the face. It should be a snug fit with minimal air leakage. Finally, it should not be stored in temperatures higher than 45 ℃ or lower than 0 ℃ [4].

b. Customer: The main concern of the customer is that the current mask model does not allow the wearer to wear glasses while simultaneously wearing the mask. The client prefers the mask to be made out of rubber or silicone, but the team is able to prototype with whatever materials they see fit. The goal is that the mask is a snug fit and that there is minimal leakage to best measure VO_2 levels. The customer would like the team to account for the biggest glasses size possible to ensure that the mask is designed for all glasses wearers. There should be no prejudice against people of any size, weight, age, gender, or background. The mask should be accessible to all people.

c. Patient-Related Concerns: The current mask covers the bridge of the nose, which does not allow the wearer to place glasses in the correct position. Not being able to wear glasses during these activities causes high levels of anxiousness in the wearer. This can also result in patient injury, as the wearer is unable to see correctly. The stresses and anxiety surrounding these activities can be greatly reduced if the wearer is able to successfully wear glasses and see correctly while performing these tasks. The device requires full sanitation between uses. This typically involves a soap and water mixture, as well as disinfectants. This allows the same mask to be used by many patients, after a sanitation gap, which increases the shelf life of the product. All data collected by the VO_2 testing should remain confidential.

d. Competition: Many of the competing designs follow most of the same testing protocols and goals for use. One of the more recent designs has been used throughout the COVID-19 pandemic. This device includes a face piece, headgear, breathing valve adapter, breathing valve, and filter. A benefit of this device is that it is reusable and autoclavable. This allows for a longer shelf life, less product waste, and less cost associated long term. This mask is made of silicone and has a ripped support where it comes into contact with the face in order to prevent leakage out of the mask. A negative of this design is that it also does not allow glasses wearers to wear the mask and glasses at the same time [5]. Another similar device is the Master Analyzer. This is able to measure performance testing and resting metabolic testing simultaneously. Benefits associated with this design is that there are no backpacks, cables, or hoses, no calibration syringes or gas tanks, validated against the gold standard, filters ensure sanitation between users, and free mobile application for guided testing. Annual calibration and yearly maintenance allows for a long shelf life. This mask is also unable to provide for glasses wearers [6]. A final, more refined design was by simply using a mouthpiece and nose clip, rather than an entire headgear apparatus. Significantly less discomfort was experienced by users using the mouthpiece. The leakage from the mouthpiece compared to the headgear was found to be unproblematic. The methods associated with collecting data from mask users have proven to be difficult "due to the high incidence of losing the nose clip during exercise, the awkwardness and discomfort of the apparatus, and the loss of oral communication" [7]. Of the competing designs, the mouthpiece design is the only design on the market that allows the participants to wear glasses at the same time.

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