Effectiveness of Elevation Training Mask on Mimicking Altitude

A Case Study

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Abstract

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The purpose of this study was to determine how effective the elevation training mask is at replicating the effects that altitude has on physiological responses. In this study, two physically active male track and field athletes were selected, one representing the control group and the other representing the experimental group, also known as the group wearing the elevation training mask for 8 hours a day. Each participant was subject to a series of test conducted before, during, and after the 6-week long study was complete. Resting heart rate, blood pressure, percent saturation, forced vital capacity(FVC), aerobic capacity, hemoglobin and hematocrit all being tested before and after the study. While resting heart rate, blood pressure, hemoglobin and hematocrit were tested biweekly during the duration of the study.

Data suggest that an acute physiological response to wearing the elevation training is not present for heart rate, blood pressure, or percent saturation. Additionally, hemoglobin and hematocrit variables had no significant improvement when comparing pre and post test measurements in the experimental group. This suggest that the elevation training mask is ineffective in mimicking the effects of altitude on physiological responses. However, a positive trend was observed in FVC and VO2max for the experimental group, suggesting that the elevation training mask can improve lung capacity. The improvement might have also been a result of the participants training regimen during the time of the study.

Chapter I

Introduction:

It is well known that individual athletic performance has significantly increased over the years. For athletes to stay competitive and perform at a high level for a longer period, they are constantly looking for ways to maintain and increase athletic performance. One training method that has been explored for many years and has been accepted as one of the best methods to increasing performance is altitude training[6,8].

Altitude training was first considered an option for increasing athletic performance in the conclusion of the 1968 summer Olympic Games in New Mexico City. During the Olympic games, participants not familiar with the conditions of altitude struggled to compete in the hypoxic conditions while runners familiar with the conditions strived. Namely, Kipchoge Keino, a Kenyan athlete who won gold medal honors in the 1500m race over American athlete and favorite in the race Jim Ryun[7]. Physiologist began to wonder if Keino had an advantage because of his living and training conditions, leading to investigations in the potential effects of altitude training on athletic performance[7]. Through the many studies that have been conducted, the most accepted method of obtaining the benefits of altitude training is the “live high-train low” method[1,3,5,6,7]. In this method, athletes live at altitudes approximately 2500m in height and train at altitudes as high as 1250m[4,6]. This allows the athlete to “obtain the benefits of altitude acclimatization and continue to train at high intensities, resulting in improvements of aerobic capacity (VO2max), ventilatory threshold (VT) and performance at sea level”[5].

When it comes to altitude acclimatization, it takes between 3 to 6 weeks of hypoxic exposure before acclimatization begins to take an effect[5]. It is recommended that hypoxic exposure last at least 12 hours a day at around 2500m to receive both hematological and non-hematological benefits[5]. Research suggest that hypoxic exposure less than 12 hours a day will not yield the hematological benefits because erythropoietin (EPO) is not sufficiently produced[5]. EPO is a naturally occurring hormone that is produced in the kidneys when the oxygen levels in the blood are too low[7]. When EPO is produced, it responsible for the production of new red blood cells. This is possible because, when EPO is released from the kidneys and into the bloodstream, it stimulates the bone marrow to increase the production of red blood cells[7]. When the additional red blood cells have been created, more red blood cells are circulating through the body. This in turn will increase the carrying capacity of oxygen in the blood. Increased oxygen circulation is correlated to improvements to VO2max, the measurement of the maximum amount of oxygen than an individual can utilize during intense, or maximal exercise[4,6,7]. Because VO2max increases, more oxygen can be utilized, which would result in an increase in athletic performance, especially at sea level.

With the notion that being exposed to hypoxic conditions such as altitude can increase athletic performance, products have been created to mimic a hypoxic environment without being exposed to altitude. Products include altitude chambers and sleeping tents that use high tech equipment to decrease barometric pressure within an enclosed area to simulate the effects of high altitude[1]. However, equipment that advanced is very expensive and difficult for the general population to obtain. The elevation training mask, specifically series 3.0, is affordable and easy for everyone to obtain. The elevation training mask 3.0 is the newest design of the elevation mask series, being released in June of 2017. Each elevation training mask has the same design, they cover the nose and the mouth and have size adjustable openings for the airflow. Unlike the earlier series models, the elevation training mask 3.0 has a single opening for airflow, in comparison to the three openings of the 2.0. This allows wearers to increase the intensity level and difficulty of work out. In this study, the elevation training mask 3.0 is being used. The elevation training mask is advertised to “stimulate altitudes ranging from 914 m to 5486 m (series 2.0)”[6]. However, for the mask to stimulate altitude, it must be able to decrease the partial pressure of oxygen inside the alveoli, inducing a hypoxic state[7]. Therefore, the purpose of this study is to first, see if the elevation training mask can be effectively used to simulate altitude, and second, determine the effects of wearing the mask on exercise performance variables.

Statement of Purpose:

To investigate the efficacy of the elevation training mask with regard to increasing red blood cell production and mimicking the impact of altitude on physiological responses.

Significant of the study:

This study is significant study for individuals who are interested in improving athletic performance. Because it is a well-known phenomenon that altitude exposure and training can increase red blood cell production and thus, increasing oxygen carrying capacity and athletic performance. It is interesting to think that these benefits can be received even though altitude exposure is not present. If the study works as designed, it will suggest that the elevation training mask is effective in mimicking altitude and increasing athletic performance. This would be significant for athletes because it would allow anyone, no matter their geological location, to receive the physiological benefits of altitude exposure simply by wearing the elevation training mask. Though there are already other mechanisms for simulating altitude, such as the altitude simulation tent, the elevation training mask is significantly more affordable. If the study works as designed, athletes would certainly be willing to spend a little bit of money to further their athletic performance. In addition to the price, the elevation training mask is much more convenient and practical when compared to the sleeping tent and altitude chamber. The elevation training mask can be taken and used anywhere, it is very portable. The tent and the chamber on the other hand would require a lot more effort and is not the devise that would be taken on a trip somewhere.

The study holds additional significance because not much research and experimentation has been done with the elevation training mask, especially the new 3.0 series. And of the experimentation that has been conducted, results are sometimes conflicting, and the information is not consistent. In addition, the elevation training mask has many critics that do not believe the mask has the capabilities to mimic altitude. This adds to the significance of the study because it will seek to determine if the critics have a valid reason to doubt the equipment.

Delimitation:

The conducted study was a longitudinal study that involved two participants. Each participant was placed into a group, one being placed in the experimental group and the other being placed in the control group. The study calls for each participant to adhere to a 6-week program involving testing, exercise, and if in the experimental group, wearing of the elevation training mask. Specifically, the participant in the experimental group is asked to wear the elevation training mask for 8 hours a day for a 6-week period. Originally, the study design asked the participant to sleep with the elevation training mask. However, it was too difficult, and adjustments were made.

During the six-week period of wearing the elevation training mask, the participant is asked to follow an exercise protocol designed by the Hanover College Track and Field coach. The exercise protocol required both the experimental and control members to exercise at moderate to high intensity at least an hour for five days a week. The two individuals conducted the workouts together for accountability purposes.

Before, after, and even during the study, the participants will be tested on several variables. The variables that will be tested before the study is conducted include; resting heart rate, blood pressure, and percent saturation with and without the elevation training mask on. In addition, the participants; hemoglobin/hematocrit, forced vital capacity, and VO2max will be tested before the study. During the study, resting heart rate, blood pressure, and hemoglobin/hematocrit will be tested bi-weekly. And in the conclusion of the study, the participant will be tested for all variables, including; resting heart rate, blood pressure, hemoglobin/hematocrit, forced vital capacity, and VO2max. Devices that will be used include the Garmin chest strap and watch to take heart rate, pulse oximeter to record percent saturation, Parvo Medics Cart to record VO2max, the Puritan Bennett Renaissance II PB700 Spirometry System to record forced vital capacity, stethoscope and blood pressure cuff to record blood pressure, and the Aimstrip hemoglobin meter to measure hemoglobin levels and hematocrit levels.

In this study, control variables include the amount of weekly exercise and the amount of time wearing the elevation training mask. Independent variables in this study include the intensities on the elevation training mask, the amount time wearing the elevation training mask, and the amount of exercise done each day. The dependent variables include heart rate, blood pressure, percent saturation, hemoglobin/hematocrit, forced vital capacity, and VO2max.

Limitations:

- Small sample size.
- Unable to sleep with the elevation training mask, supplementing total hours of sleep throughout the day is the easier solution.
- Little research articles specifically related to the elevation training mask.
- The intensity levels on the elevation training mask do not correspond with exact altitude levels

Assumptions:

- The elevation training mask works appropriately and is not damaged in any way.
- During the 6-week period of wearing the mask, the participants met the required amount of daily exercise.
- The participant wearing the elevation training mask adhered to the protocol and wore the elevation training mask daily for the required amount of time.
- VO2max test are conducted appropriately and the equipment is not faulty in any way.
- Hemoglobin/Hematocrit measurements are conducted correctly and the equipment that is used is not flawed in any way.
- Blood Pressure reading is conducted by a professional to ensure accurate and reliable readings

Hypotheses:

It was hypothesized that an acute response when wearing the elevation training mask will:

- Increase heart rate
- Increase blood pressure
- Decrease percent saturation of hemoglobin

It was hypothesized that following 6 weeks of daily exposure to the elevation training mask will:

- Increase resting heart rate
- Increase forced vital capacity

- Increase blood pressure
- Increase red blood cell production
- Increase hemoglobin
- Increase VO2max

Definition of Terms:

Hypoxia – a condition where the tissues are not oxygenated adequately, usually due to an insufficient concentration of oxygen in the blood. The oxygen deprivation can have severe adverse effects on various body cells that need to perform important biological processes.

Forced Vital Capacity – The amount of air which can be forcibly exhaled from the lungs after taking in the deepest breath possible.

VO2max – a measure of the maximum volume of oxygen an individual can utilize during intense, or maximal exercise. It is measured in milliliters per kilogram of body weight per minute(ml/kg/min).

Heart Rate – The number of heart beats per unit of time. Usually expressed in beats per minute

Blood Pressure – The pressure of the blood in the circulatory system, often measured for diagnosis since it is closely related to the force and rate of the heartbeat and the diameter and elasticity of the arterial walls.

Hemoglobin – protein molecule within the red blood cells that serves as the main transport of oxygen from the lings to the cells.

Erythropoietin – a naturally occurring hormone that is produced in the kidneys when the oxygen levels in the blood are too low. It signals the bone marrow to produce more red blood cells.

Live high-train Low – a method for obtaining the benefits of altitude training.

Percent Saturation – the fraction of oxygen-saturated hemoglobin relative to total hemoglobin (unsaturated + saturate) in the blood.

Partial pressure of oxygen – the amount of oxygen gas dissolved in the blood. It primarily measures the effectiveness of the lungs in pulling oxygen into the bloodstream from the atmosphere.

Oxygen Carrying Capacity – the maximum amount of oxygen that can be carried per deciliter of hemoglobin. The more hemoglobin an individual has, the greater amount of oxygen that can be carried.

Anaerobic threshold – The level of effort at which anaerobic energy pathways start to be a significant part of energy production. When an athlete switches from aerobic to anaerobic metabolism

Acclimatization - process in which an individual organism adjusts to a gradual change in its environment

Brownian Movement - the erratic random movement of microscopic particles in an area.

Hematocrit - the ratio of the volume of red blood cells to the total volume of blood

Chapter II

Part 1

Background:

Altitude training and hypoxic exposure is one of the most well-known and accepted methods for receiving additional athletic performance gains, especially when following the "live high-train low" method[1,3]. Although this method is very popular and widely accepted, it does not mean it is easily achieved. Merely being exposed to altitude and the hypoxic conditions can be taxing on the body and some people are incapable of doing so, especially for multiple hours of the day. However, just because some people are unable to withstand the tough conditions at altitude does not mean they are going to give up on the extra performance gains. That is where nontraditional ways of receiving the physiological effects of altitude come into play. Nontraditional methods include exposure to altitude chambers or sleeping in a hypoxic tent for a period before a race. Though both these methods show promise, they are not as easily obtainable, and they are not as effective as altitude itself. Additional nontraditional method that have been explored to increase athletic performance include blood doping and the use of synthetic drugs. Both methods work very well for enhancing performance but, they are highly illegal and can be very dangerous to the user if done incorrectly.

Impact of Altitude on the Body

One of the most notable differences between sea level and altitude is the difference in atmospheric pressure. Atmospheric pressure is the "downward forced exerted on the earth's surface due to the weight of the air above that point"[7]. At sea level, the atmospheric pressure is the greatest. However, as altitude increases, and height climbs higher and higher, the atmospheric pressure decreases. Decreases atmospheric pressure results in the air becoming less dense and causes the oxygen molecules to have more Brownian movement[7]. Brownian movement refers to the amount of movement the gas molecules have. More movement results in each inspiration containing less oxygen molecules. Therefore, at altitude, because the atmospheric pressure is so low, each breath contains less oxygen molecules. With less oxygen molecules the body enters a hypoxic state, hindering its ability to do normal physical activities[7].

In this hypoxic state, the body begins to face some issues. One of the first issues the body faces is the increases in respiratory rate. Respiratory rate increases because the body is trying to cope with the hypoxic conditions of altitude[9]. When respiratory rate increases, the body is trying to get as many oxygen molecules into the lungs as possible. Once oxygen molecules get inside the lungs, the primary focus is for the molecules to get inside the alveoli. The alveoli are the "microscopic air sacs located in the lungs where gas exchange occurs between respiratory gases and the blood"[7]. Once enough molecules are inside the alveoli, the oxygen molecules will begin to diffuse into the bloodstream[7]. However, before the oxygen molecules can diffuse into the bloodstream, they need to be accumulated within the alveoli[7]. This in turn will increase the partial pressure within the alveoli and once the partial pressure is high enough, the oxygen molecules can passively transfer into the capillaries[7]. Finally, once the molecules are inside the capillaries, they can pair with hemoglobin within the red blood cells and then be transferred to muscles and organs in the body for additional use[7].

Once the body realizes that respiratory rate increasing is not effective enough to cope with the hypoxic state, cardiac output increases[9]. Cardiac output is the amount of blood pumped by the heart per minute[7]. Because the heart is working harder to get the blood pumping through the system faster, heart rate increases. And with the increase of heart rate comes the increase in blood pressure. Additionally, the lack of oxygenated blood flow influences the brain and the functioning of the central nervous system[10].

This most likely explains most of the accidents that occur at high altitude, because less oxygen gets to the brain the central nervous system begins to fail, leading individuals to have poor judgment and decision making and ultimately being the cause of an accident[10].

In summary, when entering the hypoxic conditions of altitude, the body must adjust to cope with the changes that occurs. First, the respiratory rate increases to get the most use of the oxygen molecules that are available at altitude. And secondly, the cardiac output increases in attempt to circulate the oxygen molecules more rapidly throughout the body. If the body does not adjust to the hypoxic conditions, then the blood will not be oxygenated enough which could lead to a slew of other issues, such as having poor judgement and decision-making abilities. This information is relevant to this study because the elevation training mask was observed to determine if it can also induce a hypoxic state.

Acclimatization

The hypoxic state seems to be very dangerous, however, if exposed to the hypoxic environment gradually and not to an extreme level, it can have benefits. These benefits occur through a process known as acclimatization[9,10]. For acclimatization to occur, the exposure to the hypoxic conditions must occur for approximately 3 to 6 weeks[5]. One way the body can acclimatize to the hypoxic conditions is by breathing faster and more deeply. For the same reasons previously mentioned, faster and deeper breathes allow for the maximization of oxygen circulation throughout the body because more oxygen molecules are getting into the alveoli[7]. In addition, faster and deeper breathing can increase lung capacity, allowing for more oxygen uptake.

Another way the body can acclimatize to this environment is by the heart pumping more blood. This will allow for a greater supply of oxygen being transported to the brain and the working muscles[7,10]. However, it is difficult for the heart to pump more blood if no additional blood has been created. That is where the last and probably most important process of acclimatization comes into effect, the production of red blood cells. New red blood cell production is dependent on the presence of erythropoietin, a naturally occurring hormone that is produced in the kidneys when the oxygen levels in the blood are too low[7]. When erythropoietin is present in the blood stream, it will be detected by the bone marrow where red blood cells are produced. The erythropoietin binds with receptors on the bone marrow and then the production of new red blood cells can occur[6,7,10]. With the additional of new red blood cells comes the addition of more hemoglobin[9,11], a protein within red blood cells that is responsible for transporting oxygen in the blood[7]. When more hemoglobin is present the body can deliver oxygen better.

Hemoglobin transportation occurs due to the heme sites that are present that consist of iron. Once oxygen enters the system it combines with the heme sites on the hemoglobin so that the blood can become oxygenated. Once the blood becomes oxygenated, it is referred to as the oxyhemoglobin saturation represented as a percentage. If 1 gram of hemoglobin is 100% saturated, it has the capabilities to carry approximately 1.34ml of oxygen[11]. And assuming the hemoglobin level is normal, around 14g/dL, hemoglobin carries 20.1mL of oxygen per 100ml of whole blood[11]. However, hemoglobin is rarely 100% saturated, rather 97% and 98% are average saturation levels.

In addition to the oxygen transportation from the lungs to the cells and working muscles, hemoglobin is also responsible for the transportation of carbon dioxide back to the lungs for expiration purposes. Approximately 20% of blood carbon dioxide is transported by the hemoglobin[7]. Additionally, 10% is dissolved carbon dioxide and 70% of carbon dioxide found in the blood is transported as bicarbonate[7].

Some problems that can arise during the acclimatization process that can set people back a bit include too much red blood cell production and stress on the lungs. Starting with too much red blood cell production. If the erythropoietin is produced in excess and the bone marrow continues to make red blood cells past when the body can handle, then it can hurt the body. If a person has too much red blood cells, the blood can become very thick and sluggish, increasing blood pressure and making blood flow significantly more difficult[14]. This in turn will put added stress on the heart because it must work harder to pump the thick blood through the body. The second issue that can arise is too much stress on the lungs. If the body does not acclimatize appropriately, it might only depend on the lungs working harder to get the oxygen it needs to function. If the lungs are working too hard, it can lead to fluid through the oxygenation process of blood to become backed up inside the lungs. Excess fluid in the lungs is known as pulmonary edema and can be very deadly if not taken care of quickly[10].

To summarize, once the body is exposed to the hypoxic conditions of altitude for a longer period, acclimatization occurs. One way the body acclimatizes is by taking deeper breathes. This is done to get more oxygen in per breath. Additionally, the heart will pump more blood to compensate for the reduction in oxygenated blood. And lastly, the body will produce more red blood cells to make sure that all the oxygen available is being taken up by the blood and being delivered by the hemoglobin. This information is relevant to the study because the elevation training mask was observed to determine if it can also cause the body to acclimatize and adjust as needed.

Cheating

The next topic of interest is blood boosting. Blood transfusions have been around for many years for people who have suffered a traumatic event or for patients who suffer from anemia. The purpose of these transfusions is to make sure the individual has enough blood to supply the body with the necessary amount of oxygen it needs to survive. Blood transfusions are often from a donor who has the same blood type, however they can also be done with a persons' own blood, which is what people who blood boost do. This process involves withdrawing the blood from the system and freezing it for preservation purposes. Once the race or event is nearing, the blood is transfused back into the system to help provide a performance increase[12,13]. Blood boosting was never really considered a normal activity for athletes to partake in until the 1984 Olympic games. During these games, blood boosting via transfusion became such an issue that in the following year, 1985, blood posting was banned from all competitive sports due to the competitive edge it gave the competitors. Although the act of blood boosting was banned, some athletes took the risk and did it anyways, if they were caught, then bans were handed out and additionally, honors and awards were stripped[12].

Today, because blood boosting is no longer legally available, athletes have different ways of receiving the benefits of altitude exposure. The primary way athletes receive these benefits are by using drugs, specifically synthetically made EPO drugs. Like naturally producing EPO in the body, these drugs act by stimulating the bone marrow to create additional red blood cells[7,15]. EPO drugs have shown to be very effective mean for increasing performance, with one study showing that EPO use improves performance by as much as 54%[15]. However, similarly to blood doping, the use of EPO drugs is also considered cheating and if caught, the athlete can face serious trouble with the game officials. Unlike blood doping however, EPO drug use can be easily detected simple by have the athlete take urine test or by taking a blood sample from the athlete to check for abnormalities.

To summarize, cheating has been around in sports for a very long time and it appears that it is not going away any time soon. Previously, athletes have used blood boosting to circulate oxygen better in their body and increase performance. Today, athletes have different means of receiving the benefits of altitude expose, such as synthetically made EPO drugs. And though both work, both a very illegal. This information is relevant to this study because the elevation training mask was observed to determine if it can provide similar effects from cheating but by using legal methods.

Part II

Pertinent Information

The following information accepts or rejects the hypothesis within the topics of resting heart rate, resting blood pressure, percent saturation, forced vital capacity, red blood cell production, hemoglobin, and VO2max.

Heart Rate

- **An acute response when wearing the elevation training mask will increase heart rate.**
- **Following 6 weeks of daily exposure to the elevation training mask will increase resting heart rate.**

It is well known that the body will adjust to the hypoxic conditions of altitude by making cardiovascular adjustment, one adjustment being an increase in heart rate. One article by Grover et.al, looked at the cardiovascular adaptations that occur when exercising at high altitude. This article suggested that initially, when entering the hypoxic conditions, that heart rate will increase but with time, heart rate will decrease[16]. Additionally, an article by Peacock supports the notion by reporting that initially, cardiac output will increase when being exposed to altitude, but later will settle back down to sea level values[10]. Both the articles agree that initially, heart rate will increase at altitude but with time, most likely due to acclimatization, the heart rate will fall back to sea level values.

These two articles are pertinent to this study because they both support the hypothesis that an acute response to altitude exposure, or for this study, wearing the elevation training mask, will increase heart rate. Suggesting support for the hypothesis regarding an acute response to wearing the elevation training mask on heart rate. However, both these articles are also in agreement that once exposed to altitude for an increased amount of time, resting heart rate will subside back to values similar to sea level. Rejecting the hypothesis regarding the exposure to the elevation training mask after a six-week period.

Blood Pressure

- **An acute response when wearing the elevation training mask will increase blood pressure.**

An article written by Bärtsch et. Al looked at the effects of altitude on the heart and the lungs. In the article, acute hypoxia exposure is discussed in terms relative to heart functioning. This article suggests that blood pressure will increase in a hypoxic environment but, as an acute response, it will stay the same or even decrease because vasodilation will override the vasoconstriction during the first few hours[17]. Additionally, a study by Raine and Roger looked at the effects of erythropoietin on blood pressure[14]. This study looked at anemia patients taking erythropoietin medication to aid in the production of red blood cells[14]. The study found that patients blood pressure would increase partially during the four months of therapy but stabilize after the therapy[14]. Suggesting that EPO use, or production of EPO, influences individuals blood pressure.

These two articles are pertinent to this study because they have similar ideas, and both can be used to refute the hypotheses regarding an acute response to wearing the elevation training mask on blood pressure. The first article simply states that there is no change in blood pressure when acutely exposed to hypoxia but, there is a change over a three to four-week period. The second article however never mentions an acute response but, it does mention that when doing the EPO therapy that blood pressure increased but not when they were off the therapy. This suggest that EPO use or the production of EPO is why blood pressure increases and not because of acute hypoxic exposure. Both articles suggest that blood pressure will increase when acclimatization occurs and EPO levels raise, rejecting the hypothesis regarding an acute response to wearing the elevation training mask on blood pressure.

Percent Saturation

- **An acute response when wearing the elevation training mask will decrease percent saturation of hemoglobin.**

Many studies suggest that when exposed to varying levels of altitude, percent saturation will drop as elevation gets higher. In an article written by Windsor and Rodway, percent saturation was looked at in hikers at 1530 m in elevation and 5700 m in elevation. According to their findings, present saturation declined from 95% saturation at 1530 m to 82% saturation when climbing to 5700m in elevation[9]. This supports the notion that as elevation increases, percent saturation will decrease. An additional study looking at percent saturation was conducted by Porcari et. Al. In this study, participant wore an elevation training mask during training to determine if the mask could influence hematological variables[6]. The authors of this study note that the elevation training mask failed to observe oxygen desaturation, and as a result, was unable to see any hematological variable changes[6].

Both studies are pertinent to this study because one displays the desired effects from wearing the elevation training mask while the other shows the likely effects from wearing the mask. The first study suggests that merely being exposed to a higher altitude decreases percent saturation. If the elevation training mask has a similar effect as increasing elevation does on percent saturation, then each mask intensity will decrease percent saturation. However, the second refutes that assumption because in their study, the elevation training mask showed no desaturation. Because the elevation training mask is unable to decrease saturation like elevation can, the hypothesis regarding an acute response to wearing the elevation training mask on percent saturation is rejected.

Forced Vital Capacity

- **Following 6 weeks of daily exposure to the elevation training mask will increase forced vital capacity.**

Forced vital capacity refers (FVC) to the amount of air that can be forcibly exhaled after taking the deepest breath possible. In each that was looked at involving FVC, it appeared to be very difficult to increase the values because the previous values were already very good. The first study that looked at FVC was the aforementioned study by Porcari. In the study, FVC for the experimental group decreased from 5.2 to 5.1 L while the FVC in the control group decreased from 5.3 to 5.2 L[6]. Both groups likely decreased due to the already high scores in the FVC test[6]. The second study was conducted by Kido et. Al and used breathing resistance in attempt to improve endurance capacity and respiratory muscle strength[18]. The authors observed an increase FVC in the control group from 4.0 L to 4.1 L and a decrease in FVC for the experimental group from 4.2 L to 4.1 L[18]. Because both studies observed non-significant changes in FVC, it suggests breathing resistance is not effective at further increasing an already high FVC value.

The studies are pertinent to this study because they both agree that FVC is difficult to increase from breathing resistance alone and suggest that the elevation training mask will not improve FVC. Additionally, they have relevance because they present a similar design as this study because they both use some type of breathing resistant mask. When relating the studies back to the hypothesis regarding FVC after wearing the elevation training mask for a six-week period, both studies showed no improvement, rejecting the hypothesis that FVC will increase.

Red Blood Cell Production and Hemoglobin

- **Following 6 weeks of daily exposure to the elevation training mask will increase red blood cell production.**
- **Following 6 weeks of daily exposure to the elevation training mask will increase hemoglobin.**

Many studies following the Live High-Train Low method of training have shown over a 5% increase in hematological variables such as hemoglobin mass and hematocrit. A study conducted by Levine et al. found a 9% increase in red blood cell production in a group of people who lived at 2500m and trained at 1250m in Salt Lake City for a total of 28 days[4]. A similar study to the Levine study was conducted by Wehrlin and Marti looking at hematological variables of two world class runners living at 2456m and training at 1800m for a total of 26 days[8]. This study found a 6.3% increase in red blood cells for the athlete specializing in the 5000m races, and a 5.8% increase for the athlete specializing in marathon races[8]. Additionally, this study found a 7.6% increase and a 3.9% increase in hemoglobin mass for the 5000m runner and the marathon runner[8]. Both studies suggest that living high and training low can increase red blood cell production and likely, hemoglobin mass. However, in the study conducted by Porcari where athletes wore the elevation training mask during training found only a 1.6% increase in the mask group and a 0.9% increase in the control groups[6]. Suggesting no significant change when comparing the mask group and the control group. Additionally, both groups showed declined in hemoglobin percentage by 0.7% during the six-week study[6].

These three studies are pertinent to this study because the first two studies by Levine et al and Wehrlin and Marti suggest red blood cell production can increase when living at altitude. This support the hypothesis regarding red blood cell production after wearing the elevation training mask for a six-week period. The third study by Porcari et al. found the opposite because red blood cell production did not significant increase over a six-week period. Rejecting the hypothesis regarding red blood cell production. It is important to note however that the Porcari study had runners train in the mask but not live in the mask.

Additionally, these studies provider results that rejects and accepts the hypothesis regarding hemoglobin increasing. The study by Wehrlin and Marti suggest that hemoglobin mass can increase as much as 7.6%, accepting the hypothesis that hemoglobin will increase over the six-week period of wearing the elevation training mask. The study by Porcari found a decline in hemoglobin, rejecting the hypothesis that hemoglobin will increase while wearing the elevation training mask for a six-week period.

VO2max

- **Following 6 weeks of daily exposure to the elevation training mask will increase VO2max.**

With regards to performance and VO2max, many studies have found results that are conflicting. Some studies find significant improvements in VO2max while others find decline in VO2max. This is mostly due to some people responding differently when exposed to hypoxic conditions and because some studies are not designed as nicely as others. A meta-analysis was designed looking at the different studies using the live high train low method. The analysis included eight studies, four of which used VO2max as its performance related variable[1]. Two of the studies concluded a significant increase in VO2max when compared to pre-test measurements while the other two studies showed no improvements or even a decline in VO2max[1].

Other studies that have shown improvement in VO2max from beginning to end testing include the previously mentioned studies by Levine et al. and Porcari et al. In the study conducted by Levine, results suggested that both altitude groups significantly increased VO2max, with a 5% increase that was directly proportional to the 9% increase in red blood cell production[4]. In the study by Porcari, VO2max increased by 13.5% for the control group and 16.5% for the mask group, both of which were significant improvements[6]. In other studies, such as the study done by Wehrlin and Marti, performance times improved for both the 5000m runner and the marathon runner[8]. Because performance improved, it is suggested that VO2max increased for both athletes.

These studies are pertinent to this study because they help accept the hypothesis regarding VO2max increasing after wearing the elevation training mask for a six-week period. Most of the analyzed studies showed some type of performance gain from altitude exposure for a prolonged period. Whether the gain is in the form of VO2max and related variables or performance times, it still suggests that altitude exposure can provide some type of gain. Accepting the hypotheses that VO2max will increase after six weeks of daily exposure to the elevation training mask.

Chapter III

Methodology/Protocol:

This study consisted of two experiments. The first experiment tested the acute response of heart rate, blood pressure, and percent saturation while one subject wears the elevation training mask. Each measurement was recorded after resting with the elevation training mask for a total of five minutes. Once the measurements were recorded, the intensity on the elevation training mask was increased and after an additional five minutes, the measurements were taken again. This was done for each intensity on the mask.

The second experiment was a 6-week longitudinal study that consisted of two subjects exercising at moderate to high intensity 5 days a week. Each participant in the study was placed in their own group, one being the control group, and the other being the experimental group. The participant in the experiment group wore the elevation training mask for the 6-week period. During the 6-week period the individual wore the elevation training mask for a total of 8 hours each day to mimic the average amount of sleep a person should get at night. This study used 8 hours of exposure rather then the 12 hours that was suggested in the introduction because it was conducted over a 6-week period as opposed to the 4-week period. In addition to wearing the mask, the individual in the experimental group adhered to an exercise protocol designed by the Hanover College track and field coach. The protocol included at least an hour of moderate to high intensity exercise 5 days a week. Rather than adhering to the exercise protocol and wearing the elevation training mask for the required time, the individual in the experimental group has no additional requirements.

Unlike the participant in the experimental group, the participant in the control group was not exposed to the elevation training mask to any degree. The only requirement the participant in the control group had was to follow the exercise protocol designed by the Hanover College track and field coach.

The participant in the control group and the experimental group had additional testing that took place before the study, during the study, and once again after the study. Before the study, each participant was tested on several health-related variables including; resting heart rate, using the polar heart strap monitor, blood pressure, using a stethoscope and blood pressure cuff, hemoglobin and hematocrit, using the Aimstrip hemoglobin meter, forced vital capacity, using a spirometer, percent saturation, using a pulse oximeter, and VO2max and other related variables using the Parvo Medics Cart. During the study, resting heart rate, blood pressure, and hemoglobin and hematocrit were tested on week 2 and on week 4. These tests were done to determine the change in the variables that occurred throughout the duration of the study. And finally, after the study, the variables tested prior to the study were once again taken to determine the change that occurred.

Subjects:

The subjects for this study included two male participants, one 20 years old and the other 22 years old. Each participant in the study are members of the Hanover College track and field team and both individuals run the short distant events. The primary short distant event the two participants run is the 400-meter hurdles but additionally they run the 4x400 meter relay and the 4x100 meter relay races. One reason the participants used in the study were selected is because the publisher of this senior thesis is one of the two participants. And because the second participant is a member of the same event group on the track and field team as the first participant and partake in the same exercise training, he was also selected.

The two individuals being in the same event group allowed for a controllable exercise protocol during the 6-week period the study took place in.

Material:

Experiment I

- Elevation Training Mask
- Polar Heart Rate Monitor and Watch
- Conductive Gel
- Pulse Oximeter
- Stethoscope and Blood Pressure Cuff
- Stop Watch

Experiment II

- Elevation Training Mask
- Polar Heart Rate Monitor and Watch
- Conductive Gel
- Pulse Oximeter
- Stethoscope and Blood Pressure Cuff
- Puritan Bennett Renaissance II PB700 Spirometry System
- Parvo Medics Cart and Equipment (headpiece, mouthpiece, nosepiece)
- Treadmill
- Aimstrip Hemoglobin Meter and Equipment (cartridge, capillary transfer tube, alcohol pad, lancets)

Procedures:

Pre-Test Measurements:

- **Resting Heart Rate**
    - Using a Polar Heart Rate Monitor provided by the Hanover College Kinesiology Lab, detect resting heart rate for each participant.
    - First, strap the monitor on the chest of the client directly below his or her ribs.
    - Adjust the strap to ensure the monitor is firmly pressed against the chest of the client.
    - Using the heart rate detection watch, ensure the device is detecting the clients heart rate.
    - If the heart rate is not detected, try adjusting or using a new strap that is better fit for the client. Additionally, the use of conductive gel can aid in the detection of the clients' heart rate.
    - Once the heart rate is detected, have the client sit still to replicate resting values.
    - After five minutes of resting, record the reading that is provided from the watch as resting heart rate.
- **Blood Pressure**
    - Using a stethoscope and blood pressure cuff provided by the Hanover College Kinesiology Lab, detect blood pressure at rest for each participant.
    - First, have the client sit still for approximately five minutes to ensure the measurements are taken in the resting position.

    - After approximately five minutes, place the blood pressure cuff on the left arm of the client. Be sure to align the line on the cuff with the brachial artery on the arm, marking on the clients arm with a pen can be done to make sure the cuff is in the correct location.
    - Place the stethoscope on the brachial artery and begin pumping the blood pressure cuff up. Pumping the cuff to 200mmHg is enough.
    - Slowly let the air out of the blood pressure cuff and closely listen for the opening and closing of the artery. The first sound represents the systolic blood pressure and the second sound represents the diastolic blood pressure, both in mmHg.
    - After both values are found, record the reading as resting blood pressure.
- **Hemoglobin and Hematocrit**
    - Using the Aimstrip Hemoglobin Meter provided by the Hanover College Kinesiology Lab, detect the hemoglobin and hematocrit for each participant.
    - Note: during these measurements the administrator must wear latex gloves during the collection process to avoid spreading of disease via blood.
    - First, have the client wash his or her hands thoroughly with soap and warm water.
    - Using a disinfecting pad, disinfect the puncture site on the clients' index finger to ensure cleanliness.
    - Prick the finger of the client using the Unistick 2 lancet to withdraw a small blood for later analysis.
    - Once finger has been pricked, wipe the initial drop of blood away using a dry material.
    - Then, gently massage the base of the finger to the puncture site until enough blood is present.
    - Collect 10 µL of blood in capillary transfer tube, a black line is present on the transfer tube representing 10 µL.
    - To use the capillary transfer tube, hold the tube slightly downward and tough the tip to the blood specimen. The tube will automatically draw the specimen to the fill line and stop, never squeeze the tube during the sampling process
    - Align the tip of the capillary transfer tube with the center hole of the specimen application area of the test cartridge connected to the hemoglobin analyzer.
    - Gently squeeze capillary transfer tube to deposit the blood specimen in the test cartridge to initiate the hemoglobin/hematocrit reading from the hemoglobin analyzer.
    - Record the hemoglobin and hematocrit output that is given from the device.
- **Forced Vital Capacity**
    - Using the Puritan Bennett Renaissance II PB700 spirometry system provided by the Hanover College Kinesiology Lab, detect the forced vital capacity for each of the participants
    - First, plug the device in and start the calibration process by entering the barometric pressure and the temperature of the kinesiology lab.
    - Get a new mouthpiece for each participant and enter the code provided on the mouth piece when prompted to on the device.
    - Connect the mouthpiece to the tube feeding from the left side of the device before testing begins.
    - Begin the testing by selecting the Forced Vital Capacity tab on the home screen of the device.
    - Before the test begins, hold the mouthpiece still for approximately 10 seconds to allow the machine to zero out.

  - Once the zeroing process is complete, instruct the participant to put the mouthpiece in his or her mouth.
  - Ensure the teeth and the lips fully cover the mouthpiece before giving further instructions.
  - With the mouthpiece correctly in the participants mouth, instruct them to take a deep breath in and follow it up by "blasting out" all the air inside of their lungs. The process might need to be repeated a few times until the participant is fully understands the process.
  - Once the test is completed fully and correctly, collect the results that the device outputs.
- **Percent Saturation**
  - Using a pulse oximeter device provided by Hanover College Kinesiology Lab, detect the percent saturation for each of the participants.
  - To take the participants percent saturation, first plug the pulse oximeter into a power outlet and wait for the device to startup.
  - Once the device is ready to begin, put the finger clamp onto the index finger and allow for the device to take a reading.
  - Once the reading is complete, record the percent saturation given by the device.
  - For the participant in the experimental group, mask group, percent saturation will be taken at each mask intensity to determine if desaturation occurs.
  - This is done the same way as before with the exception that reading will not be taken until five minutes has passed at each intensity.
- **VO2max**
  - Using the Parvo Medics Cart provided by Hanover College Kinesiology Lab, determine each participants VO2max.
  - To begin testing, first the Parvo Medics Cart need to be turned on. It is important that the cart is turned on at least 30 minutes before use to warm up the device.
  - Once the machine is properly warmed up, log in to the computer and click the True One 32 tab to begin the calibration processes, order does not matter here.
  - To conduct the gas calibration, first turn on the gas on the bottom right corner of the cart when prompted to on the screen.
  - After approximately 30 seconds the calibration process will be complete. Once complete confirm the percentages look correct and finish by turning off the calibration gas.
  - To conduct the flow calibration, first assemble the 3-liter syringe instrument. This is done by connecting the tube to the mix box and to the syringe.
  - Also, during the process, the computer requires values for humidity, temperature in Celsius, barometric pressure which can be found on the gauge located on the parvo medics cart.
  - Once this is completed, the calibration can begin. Start the process by conducting five practice strokes with the 3-L syringe.
  - Next, perform stokes in the designated stoke ranges between, 60-80, 100-199, 200-299, 300-399, and 400+. Ensure that the calibration process gives a nice curve when complete.
  - Another component before tested can be done is the client information. This includes weight and height of the participant in the study.
  - Once all the calibrations are complete and personal information is entered, testing preparation can begin.

- This begins by making sure that the mouthpiece is set up correctly. Once the mouthpiece is set up correctly, place the headpiece on the client and adjust it according to head size.
- Next connect the mouthpiece in the headpiece. Once they are connected, connect the tube from the machine to the side of the mouthpiece that allows air to move out.
- Once everything is connected, the final step is to place the nosepiece on the client and begin testing by following the workload designed by the administrator.
- Once testing is complete, remove and clean all the equipment by placing it in bleach water from approximately 10 minutes.
- Print out the results from the test and finish by turning off the Parvo Medics Cart.

Measurements During the Study:

- **Resting Heart Rate**
  - Follow procedures from pre-test measurements
  - Conduct the measurement on week 2 and week 4 during the study
- **Blood Pressure**
  - Follow procedures from pre-test measurements
  - Conduct the measurement on week 2 and week 4 during the study
- **Hemoglobin/Hematocrit**
  - Follow procedures from pre-test measurements
  - Conduct the measurement on week 2 and week 4 during the study

Post-Test Measurements:

- **Resting Heart Rate**
  - Follow procedures from pre-test measurements
- **Blood Pressure**
  - Follow procedures from pre-test measurements
- **Hemoglobin/Hematocrit**
  - Follow procedures from pre-test measurements
- **Forced Vital Capacity**
  - Follow procedures from pre-test measurements
- **Percent Saturation**
  - Follow procedures from pre-test measurements
- **VO2max**
  - Follow procedures from pre-test measurements

Pilot Data:

Prior to the conduction of the study, pilot date was done to establish that what the study intends to measure can be measured. This included familiarization with all the equipment that is used in the study, putting individuals through the testing, and making changes according to the problems that arise during the process.

Elevation Training Mask

The first piece of equipment that was analyzed during pilot data was the elevation training mask. The elevation training mask makes it more difficult to breathe when the intensity of the mask is set high enough. However, this study was designed to determine if the breathing difficulties that are present in the mask are similar to the breathing difficulties present at altitude. To test this, a participant wore the elevation training mask at each intensity and rested at the intensity for five minutes and then percent saturation was taken. If the mask worked similarly to the way altitude works, the percent saturation would decrease with each intensity because it becomes increasingly more difficult to breath. However, what was observed after conducting this test was that the elevation training mask did not affect percent saturation at any intensity. Therefore, the likelihood that the mask can mimic the physiological effects of altitude on the body are slim. However, it is still interesting to see how wearing the mask can affect performance when compared to someone who does not wear the mask during the 6-week period, which is what the results from the study will try to portray.

Also, with the elevation training mask, blood pressure was checked at each intensity to determine if the mask influenced blood pressure. When exposed to altitude, the body has less oxygen to work with. And to compensate for reduced oxygen, the heart works harder in effort to circulate blood faster and get oxygen to the working muscles faster. This in turn would increase the blood pressure because the heart pump is working harder. When testing the masks effect on blood pressure at each mask intensity, no significant increase was observed for either systolic or diastolic values. Once again showing that the elevation training mask does not mimic the physiological effects of altitude on the body.

Originally, the study design was to have the individual in the experiment group wear the elevation training mask each night while sleeping. The participant tried on three separate occasions to sleep with the elevation training mask, but it was too difficult, and the participant did not get any sleep. Because the subject could not follow the original plan, the design was shifted to allow supplemented wearing of the mask throughout the day that mimics the average amount of sleep people get each night, 8 hours total.

Stethoscope and Blood Pressure Cuff

When blood pressure was taken for the first round of pilot data, it was taken on an automatic blood pressure monitor because originally the study included only one participant and the automatic monitor was easiest to test with. The automatic monitor readings were reliable with each other and was determined to be good to use for the actual study. However, shortly after the first round of pilot data an additional participant was added, and the administrator wanted to do manual rather than automatic readings to determine if it was more reliable. Therefore, for the second round of pilot data the administrator took the participants blood pressure three times with the manual and the automatic blood pressure cuff and compared the readings. The average readings for the manual blood pressure and the automatic blood pressure determined to be consistent with each other. However, for the study, it was determined that a manual reading would be best fit because the margin of error is less when a professional takes the reading.

Reliability of the devices is depicted below.

Table 1. Digital and Manual Blood Pressure Values

Subject	Digital Blood Pressure (mmHg)	Manual Blood Pressure (mmHg)
#1	121/65	126/72
	125/70	122/76
	122/67	118/70
#2	124/79	128/72
	126/74	120/78
	131/66	122/70

Table 1 illustrates the digital and manual blood pressure values taken on two subjects.

Pulse Oximeter

The next piece of equipment that was observed was the pulse oximeter. The pulse oximeter is a simple devise, the only requirement is that the participant puts his or her finger in the devise and the it reads the oxyhemoglobin saturation that is present. The reliability of the device was tested by taking the percent saturation five times, each in succession of the other. For each test the saturation did not decrease and stayed at 98 percent saturation each time, which is expected. This determined that the pulse oximeter used for this test was very reliable and accurate. Also, on the pulse oximeter that was used during this test was a heart rate monitor. During the percent saturation readings, the heart rate was also taken to determine if it was accurate, and from the test, each heart rate was within 5 bpm from each other at rest. This determined that the heart rate monitor on the devise was accurate, but it will not be used during the testing because during the VO2max test it would be impossible to test while hooked up to the pulse oximeter. Rather the polar heart rate monitor is used because it allows the administrator to get a hands-free heart rate reading.

Aimstrip Hemoglobin Meter

The next piece of equipment that was tested was the Aimstrip hemoglobin meter. The hemoglobin meter is used to determine how many grams of hemoglobin is present per deciliter of blood. Additionally, the Aimstrip hemoglobin meter will determine the hematocrit, or red blood cell percentage in the blood. To help determine the accuracy and validity of the device and to become more familiar with the device, a subject volunteered to have a blood specimen tested three time, one in succession to the other. From the results of the three tests, each of the hemoglobin readings were within 1% of each other and for the hematocrit they were all within 2% of each other. The results from the tests were not as accurate as expected and due to lack of cartridges, it was impossible to do extended pilot data collection. Reasons to why the results were not as expected would be due to the unfamiliarity to the administration of the test. For the first specimen test, when the first drop of blood was wiped off, it was done with a wet material. This made the transfer of the specimen into the tube very difficult and might have skewed the data some. Also, on the second specimen test an air bubble was present in the capillary transfer tube and the correct amount of blood might not have been taken up. This could skew the data because the instructions specify needing 10 µL of blood. The third test went very smoothly, and no complications arose. Using the hemoglobin meter in the pilot data stage allowed for clearance on how to properly take the specimen and some tips to make it easier, wiping the first drop of blood with dry material rather than a wet material for example.

The results from testing this equipment is depicted below.

Table 2. Hemoglobin (g/dL) and Hematocrit (%) values on three separate occasions

	Hemoglobin (g/dL)	Hematocrit (%)
Test 1	13.5	40
Test 2	15.5	46
Test 3	14.0	41
Average	14.33	42.33
Standard Deviation	0.85	2.62

Table 2 illustrates hemoglobin and hematocrit values for one subject taken on three separate occasions.

Puritan Bennett Renaissance II PB700 spirometry system

Another Piece of equipment that was tested was the Spirometer used to measure forced vital capacity. This device, like the Parvo Medics Cart, had to be calibrated and the clients' personal information had to be entered. When testing this device, the primary focus was to understand how to work everything and how to conduct an accurate forced vital capacity test. The first thing that was discovered was the need to calibrate the device. Calibration was an easy process and the only requirement was to enter the temperature and barometric pressure in the Kinesiology Lab located on the gauge inside the lab. Additionally, the device asks the user to enter a code, which is located directly on the mouthpiece that the subject will use for testing. Once the code was entered, several different tests would pop up for the user to select from and once selected, testing can begin. For the conducted pilot data, focus was on the forced vital capacity test and not the other test that were available. The test was conducted several times to ensure that everything was done correctly, including having the mouthpiece in correctly, expiring all the air inside the lungs after a deep inspiration, and expiring long enough.

Results from the last two trials taken on this device are depicted below.

Table 3. Pilot Data for Forced Vital Capacity Testing

	Trial 1	Trial 2
FVC (L)	5.45	5.59
FVC1 (L)	4.62	4.39
FEV%	85	78
PEF (L/s)	6.83	6.09

Table 3 illustrates forced vital capacity measurements on two separate trials.

Parvo Medics Cart

The final piece of equipment that was used during the pilot data stage was the Parvo Medics Cart. The metabolic cart consists of a computer, calibration gas tank, 3-liter syringe, flow meter, mixing chamber, oxygen and carbon dioxide analyzers, Hans Rudolf mask, tubing to measure the expired oxygen during testing, nose clip, headpiece, and mouthpiece.

The first issue that arose when working with the equipment was the assembly of the Hans Rudolf mask. The mask is designed to allow airflow to come in from one direction and exit from another direction. This is regulated by the valves that are located on both sides of the assembled mask. When assembling the mask, it is important to make sure that the valves are placed in the mask correctly and it allows air to come in from one direction and leave in the other direction. Once the valves are in the correct position, the mouthpiece is added to the front of the mask to complete the assembly process. Additionally, make sure that the spit trap is attached to the bottom of the mask before beginning the testing.

The next part of the Parvo Medics Cart is the calibration process. Before testing can occur, flow calibration and gas calibration must occur. To calibrate the flow meter, using the 3 L syringe filled with air and connected to the machined via the tubing, push all the air out into the flow meter to achieve a baseline of air flow. The air was pushed out of the syringe at varying rates to allow the system to read the ventilation rate per minute ranging from 60L to 400L. When conducting this process, it is important to stay within the range of stroke given on the parvo medics cart to have the most accurate calibration. Additionally, it is important to make sure the computer is picking up that the syringe is expelling very close to 3 L each time. If the syringe is giving values that are too far from 3 L, then something is not working correctly. The flow calibration was conducted several times correctly to ensure the researcher knew how to use it.

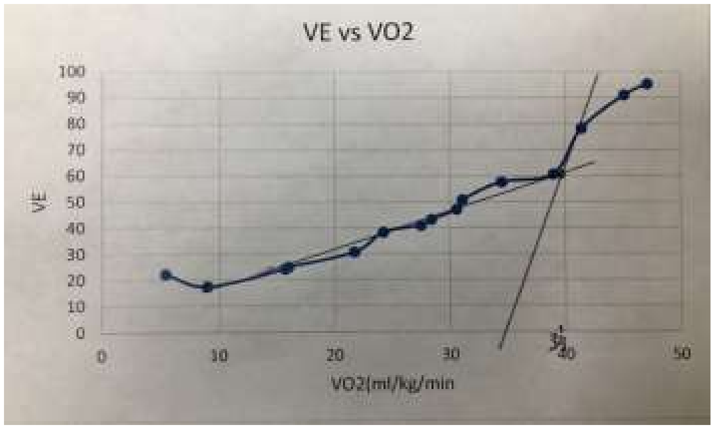
The second calibration process is the gas calibration. This is used to calibrate oxygen and carbon dioxide analyzer by using 16% oxygen and 4% carbon dioxide as a reference point[2]. Room air is sucked into the oxygen and carbon dioxide analyzer, classified as 20.93% oxygen and 0.03% carbon dioxide, as well as the calibration gas to calibrate for FEO2%, oxygen concentration in the inhaled and mix gasses, and FECO2%, carbon dioxide concentration in the inhaled and mix gasses[2]. This calibration allows the computer to have a reference point of the ranges of oxygen and carbon dioxide percentage that the analyzer may have been presented with during the VO2max testing[2]. The process of doing this only involves the user to turn the gas handle when prompted to on the computer screen. And once the calibration is complete, ensuring the gas is turned off so the calibration gases are not wasted.

Once all the calibrations are complete and the mask is constructed correctly, and everything is equipped on the individual, testing can begin. For pilot data purposes, VO2max was tested on one individual on three separate occasions. The first test was done as a trial run and the administrator was instructed step by step by a professional. The second test was a more independent test that allowed the administrator to show the instructor that they understood how everything in the process worked. And the third test was a VO2max test that involved adding a restrictive barrier to the intake valve on the mask to determine how much performance is sacrificed when simulating more difficult breathing similar to altitude.

During each VO2max test, every 30 seconds the system is designed to take a reading. The reading includes many variables, but the variables of focus include; heart rate, respiratory rate (RR), respiratory exchange ratio (RER), ventilatory equivalent (VE), VE/VO2, FEO2, FECO2, and tidal volume (VT). In the conclusion of the test, each variable was plotted against VO2max that was observed though the duration of the test. This was done to establish if the anaerobic threshold, the point in which the body switches from aerobic to anaerobic metabolism, given when VE is plotted against VO2max is accurate. Anaerobic threshold is visibly noticeable on a graph because it will show a breaking point in an otherwise linear line. Where the breaking point intersects the linear line is the anaerobic threshold. The average anaerobic threshold when looking at the 6 variables (VE, VE/VO2, FEO2, FECO2, RR, VT) plotted against VO2max was 39.33 ml/kg/min, approximately 83% of VO2max. The anaerobic threshold when looking at VE plotted against VO2max was 38.1 ml/kg/min, approximately 80.3% of VO2max. Because the average percentages agree, it shows that VE plotted vs VO2max is effective at determining the anaerobic threshold during the testing. The same process was completed for each VO2max test.

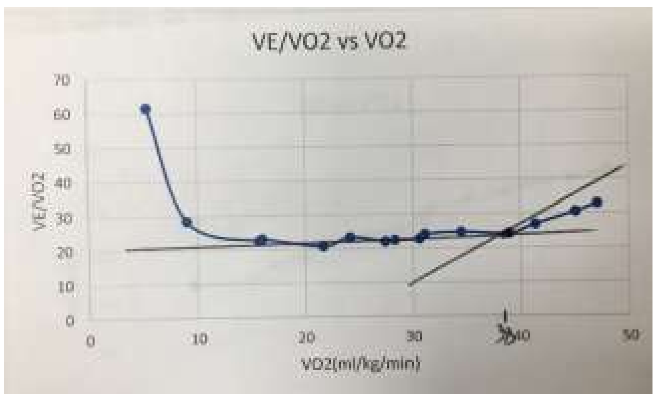
The different tests are depicted below.

Graph 1. VE plotted against VO2(ml/kg/min)



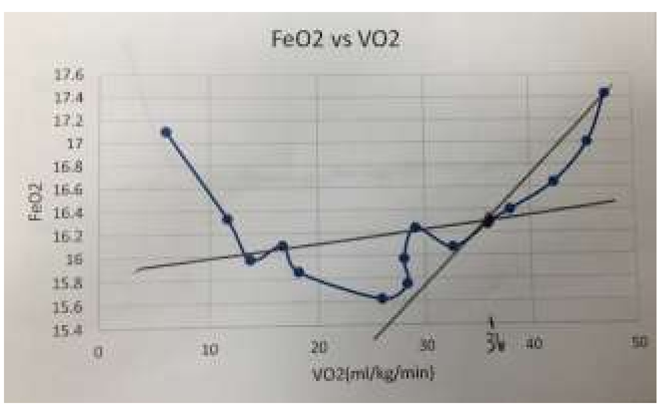
Graph 1 depicts VE plotted again VO2max and depicts two lines intersecting, representing anaerobic threshold.

Graph 2. VE/VO2 plotted against VO2(ml/kg/min)



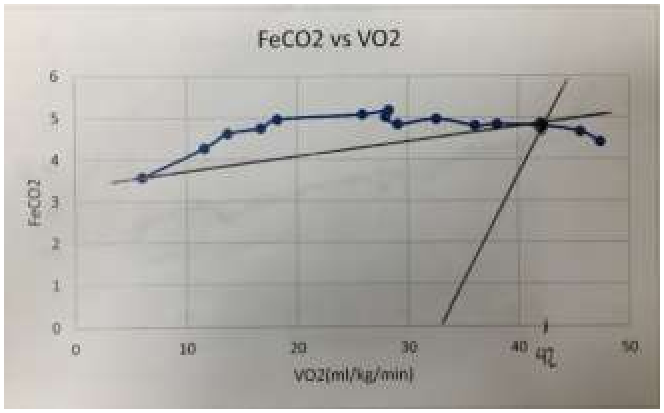
Graph 2 depicts VE/VO2 plotted again VO2max and depicts two lines intersecting, representing anaerobic threshold

Graph 3. FEO2 plotted against VO2(ml/kg/min)



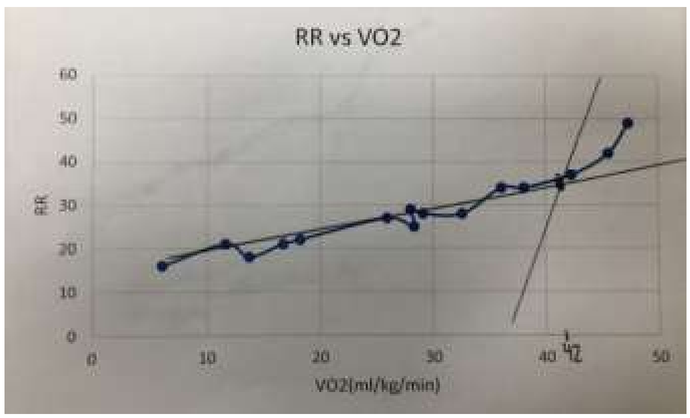
Graph 3 depicts FEO2 plotted again VO2max and depicts two lines intersecting, representing anaerobic threshold

Graph 4. FECO2 plotted against VO2(ml/kg/min)



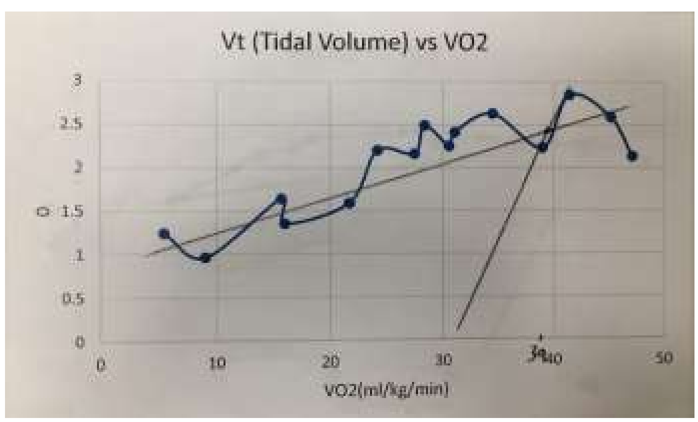
Graph 4 depicts FECO2 plotted again VO2max and depicts two lines intersecting, representing anaerobic threshold

Graph 5. RR plotted against VO2(ml/kg/min)



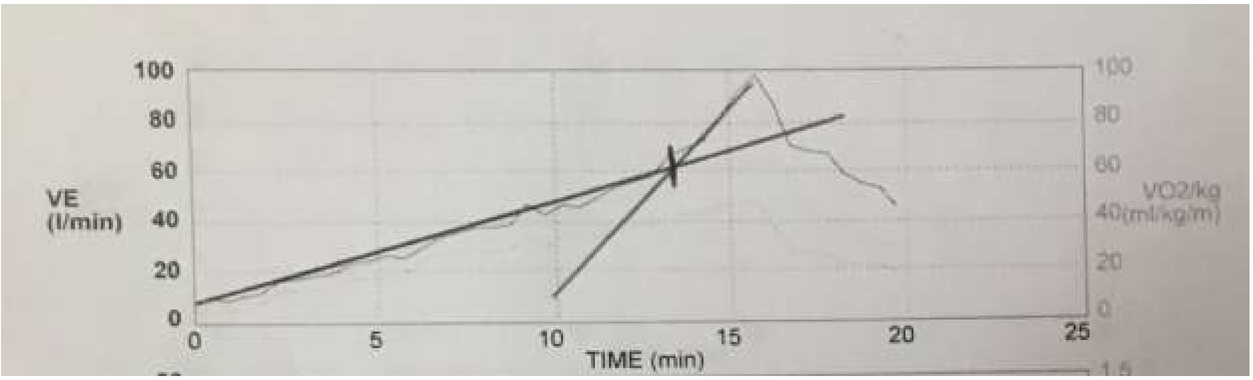
Graph 5 depicts RR plotted again VO2max and depicts two lines intersecting, representing anaerobic threshold.

Graph 6. Tidal Volume plotted against VO2(ml/kg/min)



Graph 6 depicts VT plotted again VO2max and depicts two lines intersecting, representing anaerobic threshold.

Graph 7. VE plotted against Time(min)



Graph 7 depicts VE(L/min) plotted against time and depicts two lines intersecting, representing what time interval anaerobic threshold occurs.

The restrictive VO2max was conducted to determine how much performance, measured in VO2max, would be sacrificed when simulating breathing difficulties people face at altitude. The restrictive breathing test involved taping the intake valve on the Hans Rudolf mask with tape so that the opening for the air to pass through is smaller. This in turn made it more difficult for the subject to breathe and get air into their lungs. The circular opening on the mask was reduced to a small rectangular opening measuring ¼ by ½ inches. This opening size was approximately the same size as intensity 1 on the elevation training mask. Interesting results from this study found that the VO2max, when compared to the non-restrictive test, decreased very slightly, 47.4ml/kg/min to 47.1ml/kg/min. The most interesting results from this test was the average RR and tidal volume. RR is the amount of breaths taken per minute. In the restrictive conditions, the participants RR was 23, but in the normal conditions it was 28. Additionally, the tidal volume, the volume of air taken in per breath, was 2.07 L in the restrictive conditions and 1.81 L in the normal conditions. This suggest that in restrictive conditions, the subject adjusted for the difficult breathing by breathing less often and taking in more per breath.

Restrictive conditions are depicted below.

Image 1. Restrictive Conditions for VO2max Test

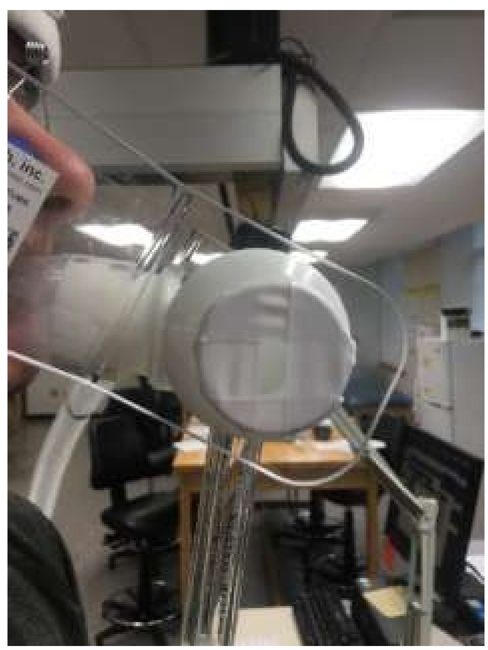


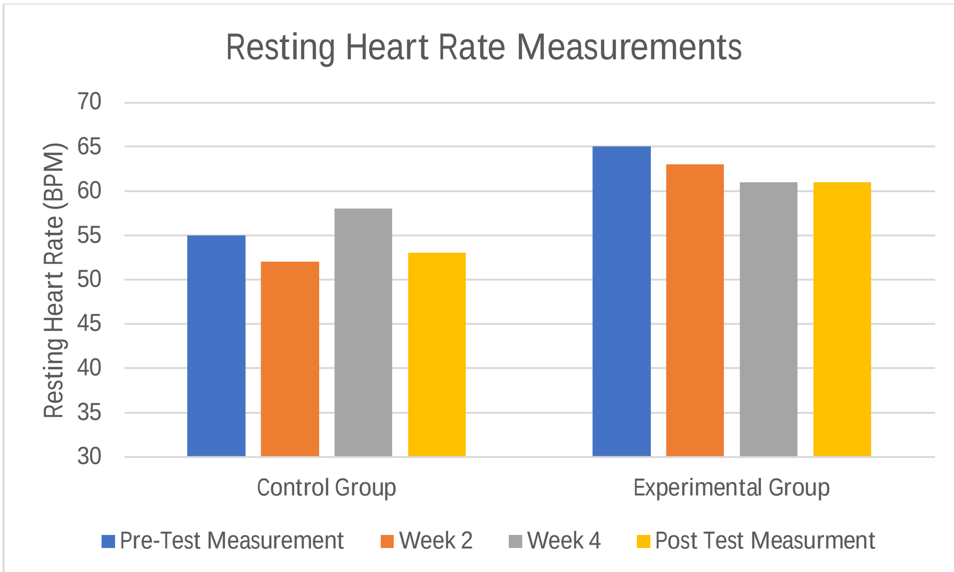
Image 1 illustrates the restrictive conditions for VO2max test. As the picture shows, breathing was impeded by adding tape to the intake valve with a new opening ¼ by ½ inches wide.

Chapter IV

Results:

Resting Heart Rate

Graph 8. Resting heart rate (BPM) before the 6-week study, during the study, and after the study was complete for both the control and experimental group.



According to graph 8, the hypothesis stating that resting heart rate will increase following 6-weeks of daily exposure to the elevation training mask, was rejected. When the body is exposed to the hypoxic conditions of attitude, one physiological response is for the heart to work harder, effectively increasing heart rate at rest and during exercise[17]. However, if the hypoxic exposure is of a larger amount, the body will acclimatize, and as a result, work less to produce the same amount as before, resulting in a decrease in heart rate at rest and during exercise. Therefore, the decline in resting heart rate could have been a result of the body getting used to the mask, or because the body became more fit from the exercise protocol.

Forced Vital Capacity

Graph 9. Forced vital capacity (L) before the 6-week study and after the study was complete for both the control and the experimental group.

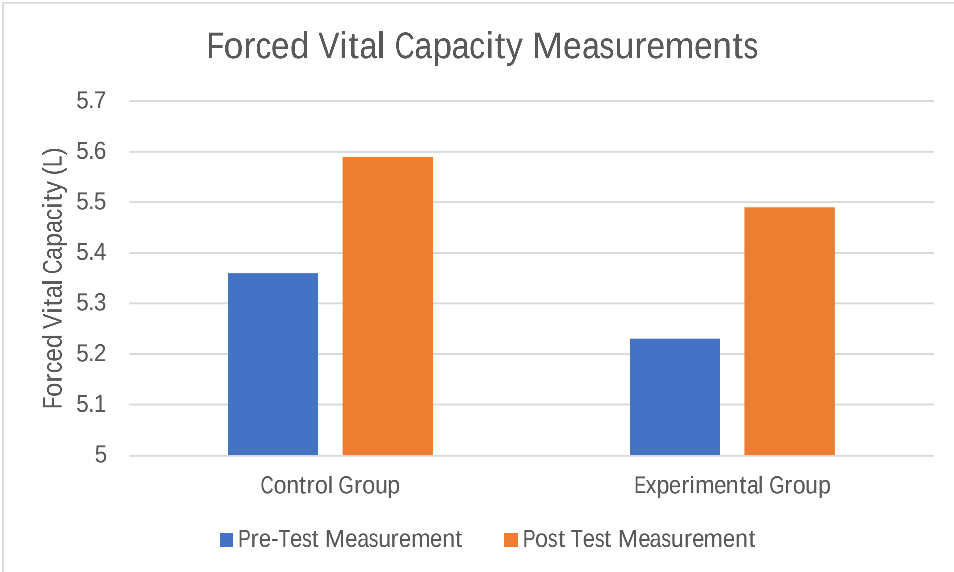


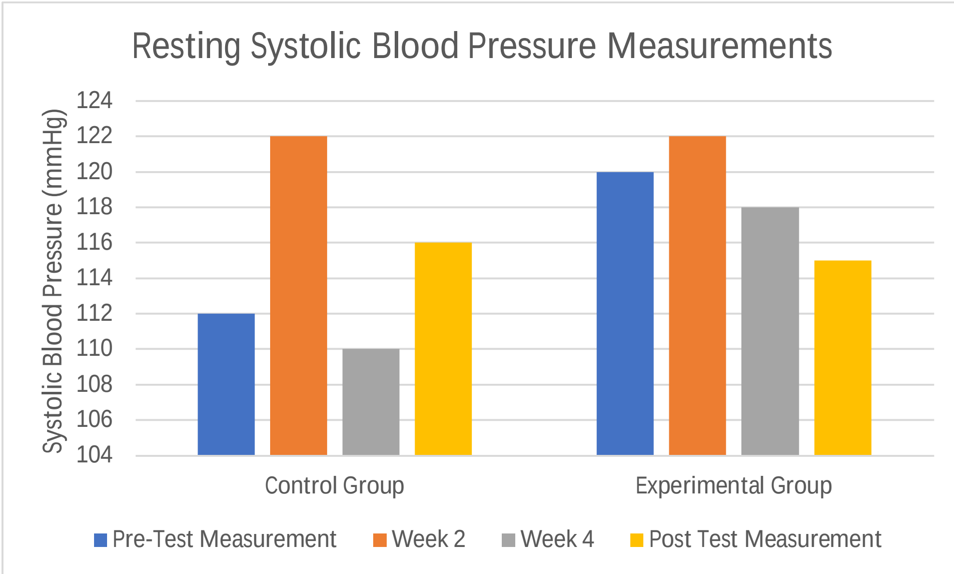
Table 4. Peak FVC levels for the control and experimental group, in addition to the percent change in FVC levels from pre to post test measurements.

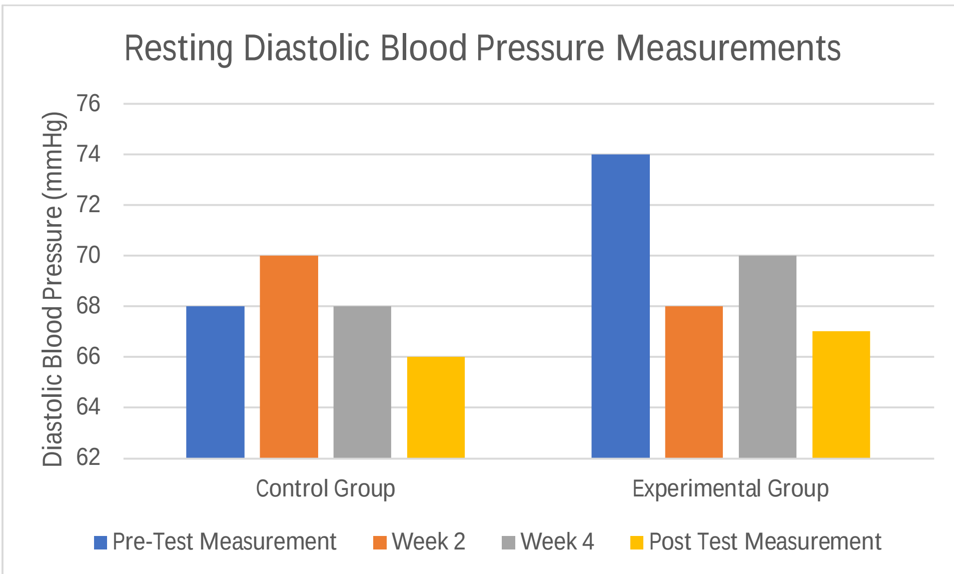
	Peak Forced Vital Capacity (L)	Percent Change in Pre and Post Test Forced Vital Capacity (%)
Control Group	5.59	4.3%
Experimental Group	5.49	4.9%

According to figure 9 and table 4, the hypothesis stating that forced vital capacity will increase following 6-weeks of daily exposure to the elevation training mask, was accepted. When wearing the elevation training mask, it is expected that the strength of the respiratory muscles will increase because the muscles are overcoming the difficulty of wearing the mask. Resulting in an increase in forced vital capacity. Although forced vital capacity increased in the experimental group, a similar increase was observed in the control group, suggesting that wearing the elevation training mask does not provide additional benefits to forced vital capacity.

Blood Pressure

Graph 10 & 11. Resting blood pressure (systolic and diastolic (mmHg)) before the 6-week study, during the study, and after the study was complete for both the control and experimental group.





According to graph 10 and 11, the hypothesis stating that forced blood pressure will increase following 6-weeks of daily exposure to the elevation training mask, was rejected. When exposed to hypoxic conditions, the body produced erythropoietin to create more red blood cells. Erythropoietin has been shown to provide increases to blood pressure[14]. If the elevation training mask works like altitude and stimulates hypoxic conditions, then EPO levels will increase, resulting in an increased blood pressure. However, an increased blood pressure was not observed in the experimental group in the current study. Suggesting that the elevation training mask cannot increase EPO levels and increase blood pressure.

Hemoglobin

Graph 12. Hemoglobin measurements (g/dL) before the 6-week study, during the study, and after the study was complete for both the control and experimental group.

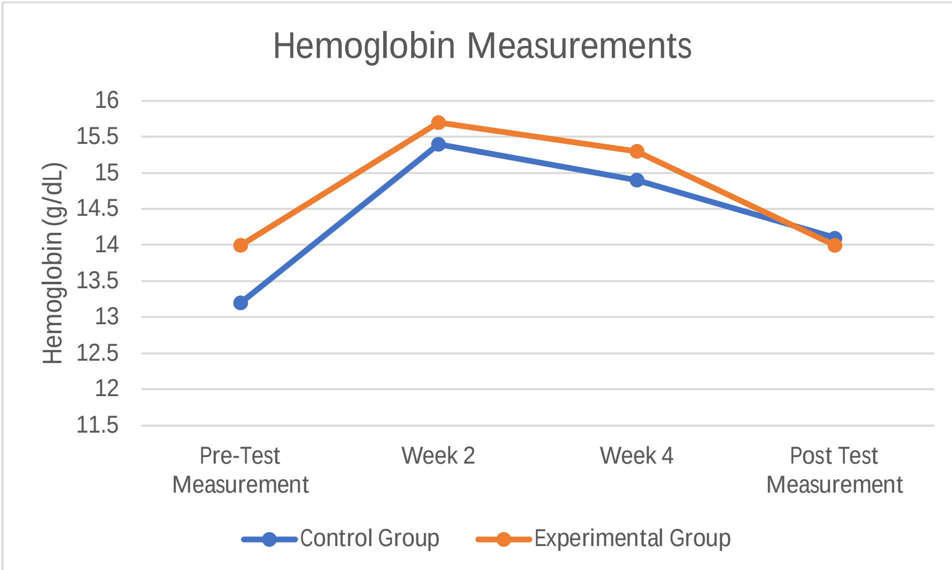


Table 5. Peak hemoglobin levels for the control and experimental group (both occurring week 2), in addition to the percent change in hemoglobin levels from pre to post test measurements.

	Peak Hemoglobin Levels (g/dL)	Percent Change in Pre and Post Test Hemoglobin Levels (%)
Control Group	15.4	6.8%
Experimental Group	15.7	0%

According to graph 12 and table 5, the hypothesis stating that hemoglobin will increase following 6-weeks of daily exposure to the elevation training mask, was rejected. When exposed to hypoxic conditions, studies have showed that hemoglobin levels will increase in the red blood cells to carry more oxygen[8]. However, in the current study, hemoglobin levels did not increase in the experimental group after the 6-week long study.

Additionally, the hypothesis stating that red blood cell production will increase following 6-weeks of daily exposure to the elevation training mask was also rejected. Because the hemoglobin levels were the same in the pre and post test measurements, it is unlikely that red blood cells were elevated at the end of the study. However, increased red blood cells might have occurred earlier in the study, likely week 2 or 4 due to the higher hemoglobin levels.

VO2max

Graph 13. VO2max (ml/kg/min) before the 6-week study and after the study was complete for both the control and the experimental group.

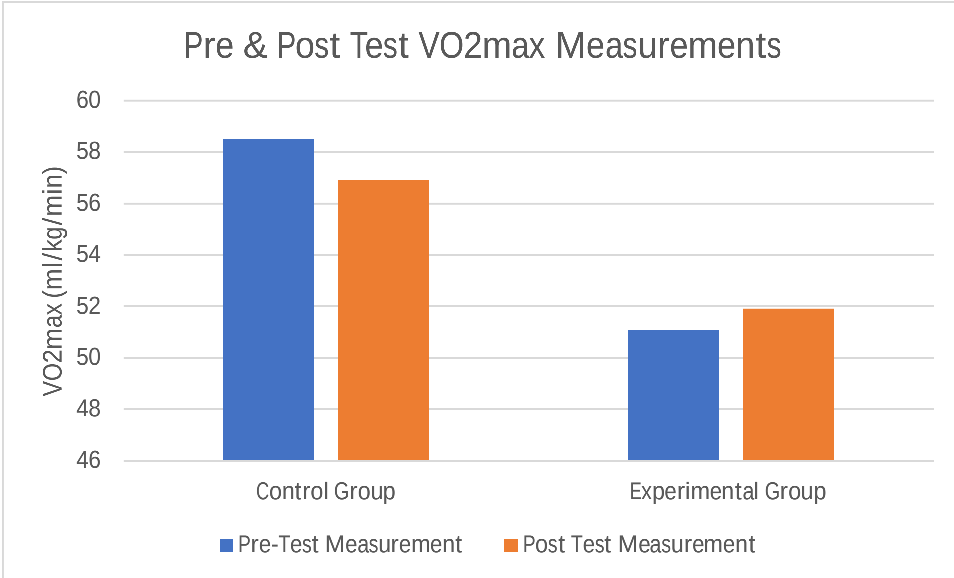


Table 6. Peak VO2max levels for the control and experimental group, in addition to the percent change in VO2max levels from pre to post test measurements.

	Peak VO2max Levels (ml/kg/min)	Percent Change in Pre and Post Test VO2max Levels (ml/kg/min)
Control Group	58.5	-2.7%
Experimental Group	51.9	1.5%

According to graph 13 and table 6, the hypothesis stating that VO2max levels will increase following 6-weeks of daily exposure to the elevation training mask, was accepted. When exposed to altitude, studies have been shown to observe increases in VO2max or performance times, permitted that the study is designed well[1]. This is because the benefits that altitude exposure provides to performance. The current study confirmed what other studies have found by observing a 1.5% increase in VO2max for the experimental group.

Chapter V

Discussion

Experiment I:

The first experiment of this study was conducted to determine the acute responses of wearing the elevation training mask. The three variables that were looked at during this experiment included; resting heart rate, blood pressure, and percent saturation. The first variable, resting heart rate, is known to increase as an acute response to altitude exposure. When entering a hypoxic environment, the body immediately notices a difference between sea level and altitude, notably, the change in atmospheric pressure. At sea level, the atmospheric pressure is very high, resulting in very dense air and allowing for an abundance of oxygen uptake per breath. However, as elevation grows higher and higher, the atmospheric pressure decreases. As a result, the air becomes less dense and causes the oxygen molecules to move around much more freely, resulting in less oxygen uptake per breath[7]. The body automatically responds to the lack of oxygen in several ways, one way the body responds is by increasing the work of the heart[17]. This is done in attempt to utilize all the oxygen available and circulate more in the blood and to the working muscles. As the work of the heart increases, heart rate will increase at the same rate.

In the current study, if the elevation training mask was effective at mimicking altitude, an acute response would be to increase heart rate. However, when wearing the elevation training mask and simulating rest, sitting for 5 minutes at each mask intensity, no resting heart rate change was observed. This is likely because the elevation training mask is unable to decreases the atmospheric pressure and simulate hypoxic conditions when wearing at sea level. This would result in no need for the body to adjust because oxygen uptake can continue at a high rate, no matter the intensity the mask is set on. Because an increase in resting heart rate was not observed, the hypothesis stating, heart rate will increase as an acute response when wearing the elevation training mask, was rejected.

An additional way the body will acutely respond to a situation where oxygen is lacking is by increasing myocardial contractility[17]. Myocardial contractility refers to the innate ability of the heart muscle to contract. In normal conditions, the amount of force needed during the contraction of the heart is smaller than abnormal conditions, such as high altitude. This is because the heart does not need to move blood as rapidly and does not want to waste energy. However, at altitude, the body receives a lack of oxygen and needs to transport oxygenated blood more rapidly to compensate for the lack of oxygen the muscles are receiving[17,19]. This is done by increasing the force of myocardial contractions, allowing for faster and more powerful blood flow. The ability to produce changes in force during myocardial contraction is by increasing the binding between different types of tissues, namely between the filaments of actin and myosin tissue. As the force of myocardial contractions increase, blood pressure with the addition to heart rate would increase.

If the elevation training mask used in the current study was effective at mimicking altitude, then, as an acute response, the force of myocardial contraction would increase, effectively increasing blood pressure and heart rate. However, an acute response to wearing the elevation training mask, at each intensity, did not provide a change to blood pressure or resting heart rate. This suggest that the heart muscle did not need to increase the force of contractions because the lack of oxygen was not present. Further supporting the previous statement that the elevation training mask is unable to simulate hypoxic conditions when worn at sea level. Because an increase in blood pressure was not observed, the hypothesis stating, blood pressure will increase as an acute response to wearing the elevation training mask, was rejected.

The third variable that was analyzed during the first experiment in this study was percent saturation, formally known as oxyhemoglobin saturation. As mentioned earlier, oxyhemoglobin saturation refers to the amount of blood, represented as a percentage, that is paired with oxygen during the loading process. If blood is 100% saturated with oxygen, then 1 gram will be able to carry 1.34 ml of oxygen[11]. Although 100% saturation is rare, the body is still very efficient at loading oxygen with blood when at sea level, with average levels being between 97% and 98% saturation. However, when exposed to the hypoxic conditions of altitude, oxygen uptake and blood pairing becomes significantly more difficult, and as a result, percent saturation drops. Research by Windsor and Rodway suggest that percent saturation is around 95% at 1530m and 82% at 5700m at elevation, with higher altitudes providing even larger drops in percent saturation[9]. With the decline in percent saturation at altitude, the body has less oxygen molecules that can be used as energy, resulting in earlier onset of fatigue when compared to sea level.

Once again, if the elevation training mask was effective at mimicking the effects of altitude, then an observable decline in percent saturation would be present. Percent saturation, similarly as resting heart rate and blood pressure, did not change as expected, and no change was observed. This is likely because the elevation training mask is not making the concentration of oxygen molecules change, but rather, the mask is just making it harder to breathe in the molecules. Although the breathing is more difficult, the body continued to be very efficient in saturating the blood and desaturation was not observed at any mask intensity. This further supports the notion that the elevation training mask is unable to provide the same acute responses that altitude has on the body. Additionally, because desaturation did not occur, the hypothesis stating that percent saturation would decrease as an acute response to wearing the elevation training mask, was rejected.

To summarize experiment #1, prior to the start of the experiment, it was hypothesized that an acute response when wearing the elevation training mask will increase resting heart rate, increase blood pressure, and decrease percent saturation. Each of these claims proved to be incorrect because the elevation training mask was unable to make the heart work harder and increase heart rate, contract with more force and increase blood pressure, and cause issues to the saturation process of the blood. Because each of these variables were unchanged in the experiment, it is suggested that the elevation training mask is unable to provide the same acute responses that altitude has on the body.

Experiment #2

The second experiment of this study was conducted to determine if wearing the elevation training mask for a longer period, specifically a 6-week period and 8 hours a day, would affect variables related to performance. The variables analyzed in experiment #2 included resting heart rate, forced vital capacity, blood pressure, red blood cell production, hemoglobin, and VO2max. Additionally, it was hypothesized that each of the variables would increase after the 6-week period of exposure to the elevation training mask.

Each of the variables listed above were hypothesized to increase due to the acclimatization process that occurs when exposed to altitude. Acclimatization is known as the process in which an individual organism adjusts to a gradual change in its environment. When considering altitude, for acclimatization to occur, the exposure to the hypoxic conditions needs to be at least 3-6 weeks long. Studies have recommended at least 12 hours of daily exposure to altitude at heights around 2500m to receive both hematological and non-hematological benefits[5]. Additionally, it is suggested that exposure less that 12 hours a day will not provide hematological benefits because of the lack of EPO production[5]. However, the study discussed above lasted only 4 weeks and found both hematological and non-hematological benefits. This was taken into consideration when designing the current study, which required less daily exposure, 8 hours daily, but for a longer period of time, 6-weeks long.

As mentioned above, altitude can provide hematological and non-hematological benefits. What exactly are these benefits and how do they come about? For the ease of understanding, first the non-hematological benefits will be discussed. One of the first ways the body acclimatizes to the hypoxic conditions of altitude is by becoming more efficient at breathing and increasing the strength of the respiratory muscles. When exposed to hypoxic conditions, the body is faced with a lack of oxygen availability. To compensate for the lack of oxygen, the bodies respiratory rate increases in attempt to maximize the amount of oxygen molecules moving into the lungs[9]. At first, the respiratory rate is going to be high because the body is not conditioned for the environment and not as effective at breathing in the conditions. However, once the body has been exposed to the hypoxic conditions for a long enough period, acclimatization will occur. Once acclimatization occurs, the body becomes much more efficient at breathing in the hypoxic conditions and can take in the same amount of oxygen molecules at a much lower respiratory rate. This is likely because the respiratory muscles become much stronger and the breathing patterns changed to be more efficient at altitude.

Relating this adaptation back to the current study, forced vital capacity can be discussed. Forced vital capacity is the amount of air that can be forcibly exhaled after taking the deepest breath possible. Generally, individuals with a higher FVC scores have stronger lungs because they can expire air with much more force than others. With this being said, if the strength of the respiratory muscles is increased when acclimatized to altitude, then FVC should also be increased. In the current study, this was tested by measuring FVC levels before and after the 6-week study was complete. The results found a 4.9% increase in FVC in the experimental group from pre to post test measurements. This is positive news for the elevation training mask because it suggests that the mask can increase the strength of the respiratory muscles. However, interestingly, a similar increase in FVC was observed in the control group, observing a 4.3% increase. This suggest that wearing the elevation training mask is only slightly better at increasing FVC when compared to not wearing the mask at all, and this was after a 6-week period. Therefore, the hypothesis stating that FVC will increase following 6-weeks of daily exposure to the elevation training mask, was accepted. Although accepted, the claim is weak, and the increase can most likely be attributed to the familiarization of the FVC test and a greater understanding of how the test works.

Although respiratory rate is an important change that occurs for people exposed to altitude, it is not enough to cope with the difficult environmental conditions of altitude by itself. Therefore, the body must acclimatize even more to survive in hypoxic conditions. The additional acclimatization occurs through changes in different hematological variables. The primary hematological variables include red blood cell production and hemoglobin. However, as a result to these two variables changing, additional variables such as blood pressure and heart are also affected.

The additional acclimatizing occurs when the body realizes that increasing respiratory rate and strength of the respiratory muscles is not enough to keep the body going. Instead of relying only on respiratory changes, the body begins to rely on the heart pumping more blood. When the heart pumps more blood, it is in attempt to increase the supply of oxygen being transported to the working muscles and organs such as the brain[7,10]. However, the heart cannot just pump more blood, first more blood needs to be created. The creation of new red blood cells is the last, but probably most important way the body acclimatizes during prolonged altitude exposure. New red blood cell production is dependent on a naturally occurring hormone called erythropoietin. Erythropoietin is produced in the kidneys when the oxygen levels in the blood are too low, which is very common in a hypoxic environment[7]. Once erythropoietin is produced and present in the blood stream, the bone marrow detects the hormone and creates new red blood cells. The new red blood cells will finally be created when the erythropoietin binds with receptors on the bone marrow[6,7,10]. Because new red blood cells have been created, more blood is going to be circulating through the body. With the addition to the newly created red blood cells, hemoglobin, a protein within red blood cells that is responsible for transporting oxygen in the blood, will also be increased[7,9,11]. This is because more red blood cells account for larger levels of hemoglobin. Additionally, as a result to the increase in red blood cell production, blood pressure is going to increase. The increase in blood pressure is because of the increase of hematocrit, known as the ratio of red blood cells to total blood volume. Once the hematocrit levels are too high, the blood becomes very viscous, requiring an increase in blood pressure to pump blood throughout the body. The increase in blood pressure required the heart to work harder, resulting in an increase in heart rate at rest and during exercise.

Relating this information back to the current study, variables such as red blood cell production, hemoglobin, resting heart rate, and blood pressure can be further analyzed. According to the information presented above, it is clear that each of the variables should increase when exposed to a hypoxic environment. In the current study, each variable was tested before the study began, biweekly during duration of the study, and once again at the end of the study. This was done to determine if a change had occurred at any point during the data collection process. According to the results, all four variables showed no increase when comparing measurements done before and after the study. However, some variation, whether increasing or decreasing, did occur on some instances during the biweekly measurements.

When looking at the results from the hemoglobin measurements, a 0% increase was observed when comparing pre-test measurements to post-test measurements in the experimental group. This suggests that at the end of the study, the participant in the experimental group did not have a change in hemoglobin levels, thus, did not create new red blood cells after the 6-week study was complete. And because new red blood cells were not created, the blood did not become more viscous, resulting in no increase in blood pressure or resting heart rate. However, in week 2 of testing, the participant in the experimental group did observe a 12.1% increase in hemoglobin levels, increasing from 14.0g/dL to 15.7g/dL. This could have been a result of the body thinking that it was exposed to hypoxic conditions because the participant went from wearing the mask zero hours a day to wearing the mask 8 hours a day. However, this is unlikely because at the same point during the study, the participant in the control group observed a 16.7% increase in hemoglobin levels, increasing from 13.2g/dL to 15.4g/dL. Rather, the large percent change could be attributed to the two participants being early on in a new workout regimen. Therefore, the hypotheses stating that an increase in resting heart rate, blood pressure, red blood cell production, and hemoglobin will occur following 6-weeks of daily exposure to the elevation training mask, were all four rejected.

When acclimatization to altitude is all said and done, ideally, people will have higher levels of red blood cells to circulate throughout the body, more hemoglobin to bind more oxygen to the red blood cells, and stronger, more efficient respiratory muscles. If the body can acclimatize to altitude appropriately, athletic performance gains can be observed. In studies conducted by Porcari et al. and by Wehrlin and Marti, VO2max has been shown to increase by upwards to 16.5%, with the addition to elite runner performing at all time high levels following an altitude training program[6,8]. Because studies and research on altitude have provided such significant results, altitude training has been widely accepted and considered one of the best ways to receive further athletic gains. The findings have shown such significance that people have even began cheating to try and mimic the effects that altitude has on the body. The way people cheat is usually in the form of synthetic drugs or via blood doping to rapidly receive the benefits, usually before a big performance or game. This is very dangerous because, not only is it illegal, it can also be very detrimental to a person health. Instead of cheating, permitted equipment or money is available, people can train in elevation tents or altitude chambers that are designed to decrease the atmospheric pressure in an enclosed area. However, if the equipment is not available and money is an issue, people can purchase equipment such as the elevation training mask for a much cheaper price with the hope that it will provide even the smallest of performance gains.

Whether the elevation training mask is effective at all in mimicking altitude is exactly what this study is trying to answer. As most of the results above suggest, the elevation training mask is not able to effectively impact the body the same way that altitude does. The mask is not able to increase blood pressure, heart rate, hemoglobin, or red blood cell count. Additionally, it is not very effective at increasing respiratory muscles either. However, can the elevation training mask increase performance? According to the current study, a 1.5% increase in VO2max was observed from pre to post test measurements. This suggest that, if worn enough, the elevation training mask can provide small improvements to performance. To further the idea that the elevation training mask can improve performance, the results from the control group can be analyzed. According to the results from the control group, a 2.7% decline in VO2max was observed from pre to post measurements. Because VO2max increased in the experimental group, the hypothesis stating that VO2max will increase following 6-weeks of daily exposure to the elevation training mask, was accepted. Although an increase was observed, it is hard to conclude whether the increase was attributable to wearing the elevation training mask or to the participant gaining fitness from the training program. Nonetheless, a positive trend was still observed in the experimental group and not the control group.

To summarize experiment #2, prior to the start of the experiment, it was hypothesized that resting heart rate, blood pressure, forced vital capacity, hemoglobin, red blood cell production, and VO2max would increase following 6-weeks of exposure to the elevation training mask. Of the hypotheses, VO2max and FVC were the only variables that observed an increase after the 6-week period. Because the variables increased, it is suggested that the elevation training mask, if worn for a 6-week period, can provide minor increases to respiratory muscles strength and performance. Additionally, because the other variable had no increase during the 6-week study, it is suggested that the elevation training mask is unable to provide hematological benefits.

Conclusion

- An acute response to wearing the elevation training mask does not provide increases to:
  - Resting Heart Rate
  - Blood Pressure
  - Percent Saturation
- After 6-weeks of daily exposure to the elevation training mask:
  - FVC increased by 4.9%, .6% more than the control group
  - Resting HR did not increase
  - Blood Pressure did not increase
  - Hemoglobin did not increase
  - Red Blood Cell Production did not increase
  - VO2max increased by 1.5%, 4.2% more than the control group

Appendix

Informal Consent

You are being asked to be a participant in a research study I am doing for my senior thesis. The purpose of the study is to determine if wearing the elevation training mask (series 3.0), can effectively mimic the impact of physiological response at altitude, looking specifically at the red blood cell production.

The study will require you to perform a VO2max test on two separate occasions, one at the beginning and one at the end of the testing period. Additionally, you will be asked to do a simple finger prick blood test at the beginning of the test and every two weeks until the conclusion of the test. This study will also include testing resting heart rate, blood pressure, percent saturation, and forced vital capacity.

One risk that can be associated with this study is the blood sampling. Working with blood samples can be risky for a variety of reasons. Fortunately, the risk can be reduced substantially by taking the proper steps during collection. These steps include wearing protective gloves, always using sterile equipment, cleaning up completely after every test, and disposing of used equipment properly in approved containers. These steps will be taken during the collection of every blood sample to ensure nothing will go wrong.

A second risk associated with this study includes the use of the Parvo Medics Cart. The use of this equipment can be dangerous because it includes using a treadmill at near maximal effort. At maximal effort, a subject might begin to stumble or even fall while using the treadmill. To prevent this from happening, at least two individuals will be in the room during the test, one as the administrator, and the other serving as an aid to the administrator to help with the conduction of the testing and assist if any issues do arise.

Potential benefits of being part of this study include having an idea of your resting blood pressure, heart rate, and forced vital capacity. Also, from the blood test, you will know how much hemoglobin and hematocrit you have and can see how you compare to the average population. And additionally, from doing the VO2max test before and after 6 weeks of exercise, you will be able to get a feel of how much you have improved in 6 weeks and how good of shape you are in.

A copy of this document will be given to you for your own personal records. With your signature, it indicates that you have read and agreed to all the above terms and agree to be a participant in this study.

Print Name ________________________________ Date:_______________________

Signature__________________________________ Date:_______________________

Study 2017106 approved by IRB

IRB-do-not-reply@hanover.edu

Wed 1/24, 4:09 PM

Andrew Strong

Inbox

Study number 2017106, titled Effectiveness of the Elevation Training Mask on the Production of Red Blood Cells has been approved by the Hanover College Institutional Review Board. The study was classified as "Expedited."

Specifically, the IRB found that the study qualified as Expedited4: "Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual." [reference].

This approval authorizes the authors of this application to begin data collection. This approval will expire on Jan 24, 2019.

Any changes to the procedure must be approved by the IRB prior to making those changes. Authors may request a modification to their procedure by logging in to irb.hanover.edu, navigating to the approved application, going to the Submit section, and clicking the *Request Modification* button. This will create a clone of the original application with a new study number, to which modifications can be made. If you have any questions, please contact either the IRB webmaster, Bill Altermatt, at altermattw@hanover.edu, or the chair of the Hanover College Institutional Review Board, Dean Jacks, at jacks@hanover.edu

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