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The Effect of Mild Jugular Compression during Maximal Exercise on Oxygen Consumption, Blood, and Urine Analysis

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Abstract:	Background: Reduction of concussion or mild traumatic brain injury (mTBI) incidence has been on the forefront of minds across the sports industry. Novel strategies that focus to reduce the movement of the brain within the skull, referred to as SLOSH, are being investigated. Purpose: The purpose of this study is to determine if wearing a device that applies mild jugular vein compression to the neck affects subject performance on a VO2 max test. Methods: Twenty normal, healthy participants completed testing on two separate days: one visit wearing the neck device; the other wearing a sham arm device. Testing consisted of a VO2 max test during each testing session. In addition, a complete blood count with differential and full urinalysis was analyzed in pre- and post-exercise conditions. Results: All blood and urine measures remained in normal ranges and were not statistically altered beyond the expected physiologic response to exercise. Evaluation of monitored urinalysis showed no effect of wearing a mild jugular vein compression device compared to normal and expected values following exercise. Evaluation of monitored Oxygen Consumption Analyses showed no significant effect of wearing a mild jugular vein compression device compared to a Sham arm band. Conclusion: The wearing of a device that places mild jugular vein compression does not affect one's physical performance by way of a maximal effort cardiovascular task (VO2 max) and even at this maximal performance, does not provoke any abnormal response to exercise as demonstrated through blood and urine analysis.
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The Effect of Mild Jugular Compression during Maximal Exercise on Oxygen Consumption, Blood, and Urine Analysis

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ABSTRACT

Background: Reduction of concussion or mild traumatic brain injury (mTBI) incidence has been on the forefront of minds across the sports industry, however no notable progress has been made on actually reducing the injury. Novel strategies that focus on altering the fluid dynamics around the brain to reduce the movement of the brain within the skull, otherwise referred to as SLOSH dynamics, are being investigated. A jugular vein compression device has been developed to emulate a natural occurring protective mechanism, like is seen in woodpeckers and head-ramming sheep and implement this protection in humans.

Purpose: The purpose of this study is to determine if wearing a device that applies mild jugular vein compression to the neck affects subject performance on a VO2 max test, and also, if the effect on common blood and urine measures differs from that expected with normal exercise.

Methods: Twenty normal, healthy participants completed testing on two separate days, one visit while wearing the neck device and the other visit while wearing a sham arm device. Testing consisted of a VO2 max test during each testing session to determine the effect, if any, the neck device has on performance. In addition, a complete blood count with differential and full urinalysis was analyzed in pre- and post-exercise conditions during the neck device-wearing visit.

Results: All blood and urine measures remained in normal ranges and were not statistically altered beyond the expected physiologic response to exercise. Albumin and Bicarbonate (CO2) were significantly different following exercise, which is an expected occurrence post-exercise. Evaluation of monitored urinalysis showed no effect of wearing a mild jugular vein compression device compared to normal and expected values following exercise. Evaluation of monitored Oxygen Consumption Analyses showed no significant effect of wearing a mild jugular vein compression device compared to a Sham arm band.

Conclusion: The wearing of a device that places mild jugular vein compression does not affect one’s physical performance by way of a maximal effort cardiovascular task (VO2 max) and even at this maximal performance, does not provoke any abnormal response to exercise as demonstrated through blood and urine analysis.

INTRODUCTION

Recent attempts to reduce the incidence of concussions have focused on strategies to minimize the impact level and frequency sustained by athletes on the field (through helmet design, rule changes, altering tackling technique, etc.) however, the results in actually reducing concussions or mild traumatic brain injury (mTBI) have not been proven. Novel strategies that focus on altering the fluid dynamics around the brain to reduce the movement of the brain within the skull, otherwise referred to as *SLOSH* dynamics, now exist. This protective alteration of fluid dynamics around the brain may be achieved by applying mild compression to the internal jugular veins, therefore slowing jugular outflow and filling the compensatory reserve volume within the cranium and increasing the stiffness of the brain [1]. Better containment of the fluid movements of the brain allows for less shear and rotary forces experienced inside the cranium during head impacts. The mechanism of collar induced jugular compression with back filling into the cranium mimics a natural occurring system that is found in highly g-force tolerant creatures in the animal kingdom known as the omo-hyoid and digastric muscles (also known to compress the jugulars)[2,3]. Replicating this mechanism in humans could provide valuable protection to the human brain in multiple applications such as sport, military, and others where there is a high risk of brain injury or concussion.

A jugular vein compression device, such as the one used in this investigation, has been developed emulate this natural occurring protective mechanism and implement this protection in humans. Research findings indicate promise behind this jugular vein compression device, which have shown a reduction in resultant Amyloid Precursor Proteins (APP- a signature axonal injury indicator) in rats when a 900 x g force impact was imparted while wearing the device compared to when no device was present [4]. Jugular vein compression has also been shown to reduce hemorrhage in a porcine controlled cortical impact model [5]. In addition, initial investigations in humans also show evidence of effectiveness in high school hockey and football players, where MRI findings pre- and post-season revealed decreases in microstructural changes in the athletes who wore the collar device during a competitive sports season [6,7]. It is imperative that this jugular vein compression device is studied under maximal effort performance, similar to what would be experienced in an athletic or physically challenging situation. Varying degrees of changes in blood physiology can be expected with exercise, depending on the duration and intensity of exercise and the demands placed on the body [8]. For example, 4 hours after marathon running, hematological changes were observed when glucose, albumin, calcium, phosphorous, BUN, creatinine, and white blood cell counts were increased whereas chloride, carbon dioxide, and globulin all decreased and sodium and potassium were unchanged [9]. A single, maximal effort, exercise test revealed increases in leucocytes, granulocytes, monocytes, and lymphoctyes immediately post-exercise [10], which is consistent with an acute immune response to exercise [11]. Even lymphocyte concentrations have been shown to increase during exercise, however the post-exercise response may be dependent on the time elapsed since the start of activity [12]. In that regard, Natale et al investigated the effect of varying exercise demands on blood leukocytes including long, lower intensity cardiovascular exercise, short high intensity cardiovascular exercise, and resistance exercise [13]. Results revealed that all types of exercise can lead to an increase in WBC and most specifically neutrophils and monocytes, also known as leukocytosis, which remains present 3 hours after exercise was complete. In this example, the biggest response was seen in the long duration exercise, followed by the short high intensity exercise, and finally the resistance exercise.

The purpose of this study is to determine if wearing a device that applies mild jugular vein compression to the neck affects subject performance on a VO2 max test, and also, if the effect on common blood and urine measures differs from that expected with normal exercise.

MATERIALS AND METHODS

Twenty normal, healthy volunteers were recruited and divided equally between sexes. All recruited subjects met the inclusion criteria indicated below and were allowed to undergo testing. Participants completed a Physical Activity Readiness Questionnaire (PAR-Q) prior to testing to ensure no contraindications to exercise were present [14].

Inclusion criteria

Normal, healthy volunteer
Able to provide written consent
Able to tolerate hypercapnia for 1-2 minutes
18 years or older

Randomization

All subjects who volunteered to participate and met the study criteria were included in the study, which consisted of two separate testing sessions. During one session, the participants were tested while wearing the mild jugular vein compression device (Neck Collar) and during the other session, they underwent the same testing procedures while wearing a sham device (Arm Band). The order of the testing sessions was randomized by the study coordinator at the time of study enrollment.

This study utilized a randomized cross over study design. Subjects visited the Cincinnati Children's Hospital Human Performance Laboratory on two separate occasions to perform the testing procedures listed in the table below. During one testing session, the subject performed the procedures while wearing the jugular vein compression device and during the other testing session, the subject was wearing a sham arm device, which was placed on the upper arm and did not cause venous engorgement. Study visits were separated by 48 hours and lasted approximately 2 hours each.

The order of the testing sessions was randomized prior to the subject's arrival for the first session. The jugular vein compression device was a standard hockey neck guard, adapted for the purposes of this study and incorporated two foam rubber bulges localized bilaterally over the site of the internal jugular veins. The pressure exerted on the region of the neck superficial to the internal jugular veins akin to the pressure felt when a person yawns or wears a snugly fitting necktie. The subjects were outfitted with each device at each testing session by a staff member appropriately trained in fitting the device in the proper location. To ensure proper fit and placement, an ultrasound was performed to examine the immediate effect of device placement on venous return in the neck or arm. Ultrasound frequency was set at 6.0 MHz to 12 Mhz and the predicted exposure time was 5 minutes per person. Rechecks following the oxygen uptake testing were performed in the collared test condition to confirm that jugular vein outflow was reduced, while flow within the carotid arteries and all portions of the cerebrum are preserved (JA Fisher, unpublished data).

Participant Anthropometrics and Demographics

Height, weight, leg length, and body composition (bioelectrical impedance, Tanita) were recorded and body mass index (BMI) calculated for each study participant.

Blood Collection and Analysis

During the Neck Collar testing session, the subject proceeded to the blood collection station where 4 ml of blood was obtained by a trained phlebotomist via venipuncture (Figure 1). The blood collection took place both before and after exercise testing, for a total of approximately 8 ml per study visit. To reduce the discomfort of the venipuncture, a local anesthetic, Ethyl Chloride Spray USP (Gebauer Co, Cleveland, OH), was used as requested by the participants. No more than 3 cc per kg of body weight was drawn at a visit, per guidelines. After collection, the de-identified blood samples were stored on ice until analysis.

A complete blood count with differential was analyzed in pre- and post-exercise conditions during the neck device-wearing visit. The purpose of this hemoglobin/hematocrit analysis was to demonstrate if the device was associated with injury around the jugular compression site causing any micro or macroscopic bleeding. A renal panel with glucose was analyzed which evaluated for electrolyte disturbances, hypoglycemia, and/or metabolic acidosis caused from reduced blood flow to any tissues resulting in subsequent anaerobic metabolism. Creatine phosphokinase (CPK) was also examined as a marker for increased muscle breakdown.

Urine Analyses

The subjects were asked to provide a urine sample both before and after the device testing session. They had access to a private bathroom in which to provide the sample. A full urinalysis was performed to assess the urine and the presence or absence of changes with exercise and the device, such as increased blood or protein concentrations (markers of muscle breakdown and rhabdomyolysis).

Maximal Oxygen Uptake

Oxygen consumption levels were analyzed by comparing each subject's performance on VO2 max (ml/kg/m) under each testing condition (Figure 2). The purpose of this analysis was to determine the effect of wearing the device(s) on an athlete's ability to perform to a maximum capacity. Maximal Oxygen cost was evaluated using the portable breath-by-breath Cosmed K4b2 system (Rome, Italy). This consists of a sealed facemask which directs exhaled air through an attached turbine. The K4b2 unit was plugged in and warmed up 20-30 minutes prior to testing and then the turbine and analysis system were calibrated according to the manufacturer's instructions. Each subject was then fitted with the appropriate sized facemask and harness. The Cosmed K4b2 is routinely used for clinical assessment of oxygen cost; it is lightweight, portable and telemetric, which allows for an unconstrained gait and use in laboratory conditions or in the community and has been found to be a reliable tool to measure VO2[15]. Participants were also fitted with the Polar heart-rate chest monitor that accompanies the K4b2 unit.

At each study visit, the participants completed a VO2 max test, which was administered while performing the Bruce Treadmill Protocol as seen in Table 1. All participants were healthy and recreationally active college students. The test was ended when the participant signaled that they could not perform at that level any longer. The treadmill was slowed and the participant was given the opportunity to walk for a cool down.

Statistical Analysis

Statistical analyses were performed with SPSS statistical software (SPSS Inc, Chicago IL). Data regarding the oxygen uptake descriptive information (such as mean and standard deviation) were calculated for each variable of interest and compared between the testing conditions (Neck Collar vs. Arm Band) using a paired student T-test. Blood and urine analysis results were compared between pre- and post-exercise samples obtained during the collared condition. Statistical significance was established a priori at $p<0.05$. Bland-Altman plots (95% confidence intervals) were employed to evaluate each variable to determine systematic shift between mean sham arm band condition and compressive neck collared condition and to verify if there were any associations between the differences of the two measures and average.

One female study participant was flagged following testing with pre-test glucose measures exceeding 367 mg/dL. Another female participant indicated that she “felt dizzy” following the maximum oxygen uptake testing and did not feel as though she could complete the vestibular testing. She was stopped from further testing until she felt fully recovered. Both participants were able to complete the testing; however, the study team concluded a priori to statistical analyses that these factors met exclusion criteria (indicated below) and did not include these participants in the final analyses. The descriptive data for demographic and anthropometric measures of the included 8 female and 10 male study participants are presented in Table 2A and 2B, respectively.

RESULTS

Renal and Blood

Complete blood count (CBC) and renal panel tests were performed before and after exercise with the neck collar device. All blood and urine measures remained in normal ranges and were not statistically altered beyond the expected physiologic response to exercise. As noted in the TABLE 2, there were two measures, Albumin and Bicarbonate (CO_2) that were significantly different following exercise.

Urine Analyses

Evaluation of monitored urinalysis showed no effect of wearing a mild jugular vein compression device compared to normal and expected values following exercise. These variables included the screening for protein and blood in the urine. Results from urinalysis testing did not indicate any abnormal or unexpected findings. As seen in Table 3, there was increase in the number of subjects that had an increase in protein in the urine in the post-exercise condition.

Oxygen Consumption

Evaluation of monitored Oxygen Consumption Analyses showed no significant effect of wearing a mild jugular vein compression device compared to a Sham arm band ($p>0.05$) as seen in Table 4. Bland Altman plots (Figures 3-5) provided a visual depiction of each reported measurement's validity and confirmation of equivalence between test conditions (Neck collar vs. Sham arm band) for each of the reported measurements.

DISCUSSION

The present study evaluated athletes' performance and physiological responses to VO2 max test while wearing a collar device designed to provide mild jugular vein compression (for the purpose of reducing concussion incidence). Performance on maximal effort aerobic exercise did not differ between sessions where athletes wore the vascular compression device under investigation verses a sham device. Blood panels and urinalysis revealed that the pre- and post-exercise tested values remained in a normal and safe range and only expected changes between pre- and post-exercise occurred with short, high intensity exercise. Specifically, the variables that demonstrated an expected change in the post-exercise collection, were albumin and bicarbonate. Urinalysis results determined that a greater number of subjects had protein in their urine in the post-exercise condition compared to the pre-exercise condition.

Albumin, a globular protein, is the most abundant plasma protein in humans [16]. Albumin is necessary for maintaining the oncotic pressure for appropriate distribution of body fluids between intravascular compartments and body tissues [16]. It is suggested that the rate of albumin synthesis increases during recovery after intense exercise, which contributes to a rise in plasma osmotic pressure and results in blood volume expansion [17] [18]. A single-exposure protocol that utilized an intense, intermittent exercise demonstrated up to a 10% plasma volume expansion within 24 hours after activity [18]. Prior results provide strong evidence that intense exercise induces an increase in plasma albumin and blood volume. Increased levels of albumin concentrations may be indicative of dehydration [19]. Bicarbonate is present in all body fluids and plays an essential role in regulating the acid-base balance in the human body [20]. Physical exercise, such as that used in testing, will induce the production of lactic acid, which leads to the acidification of blood and muscle [20]. To buffer the build-up of lactic acid and to balance the blood pH, the body predominately uses the bicarbonate buffer system [20]. During periods of intense physical activity, bicarbonate is limited and lactic acid accumulation occurs with the risk of fatigue. Significant effects noted in post exercise measures of both albumin and bicarbonate levels represent a normal and expected physiological response to exercise and further validate the sensitivity of our test measurements to detect changes in the current sample population [20].

Blood concentration of creatine phosphokinase (CPK) is frequently used in the diagnosis of rhabdomyolysis (muscle injury). Exercise-induced rhabdomyolysis occurs chiefly in individuals who undergo excessive physical exertion for which they are not physically prepared. The release of myoglobin into the bloodstream from damaged muscle tissue can lead to acute renal failure. While the exact mechanism has not yet been elucidated, it seems that inadequate ATP stores and the subsequent failure of Na^+-K^+-ATPase pumps result in an increased Na^+

concentration within muscle cells [21]. This leads to an reversal of the Na+-Ca2+ exchange, causing excess Ca2+ influx and resulting in destruction of muscle fibers [22] [23]. The normal physiologic blood concentration of CPK observed in the post-exercise condition is evidence that the jugular vein compression device did not predispose athletes to pathological muscle fiber breakdown during maximal exercise. As such, kidney function was not negatively impacted by the collar use, as demonstrated by the normal blood BUN and creatinine concentrations and normal urinalyses measured in both pre- and post-exercise conditions. In addition, both pre- and post-workout blood glucose levels were similar. The maintenance of blood glucose levels during exercise is of paramount importance, as hypoglycemia reduces the intensity at which an athlete is capable of performing [24]. Similar glucose levels observed before and after a VO2 max test indicate that collar use did not negatively impact the release of catecholamines and glucagon or the subsequent tissue responses necessary to maintain euglycemia during exercise.

Proteinuria (protein in the urine) is a common and expected change across time with exercise and typically presents within 30 minutes of activity and returns to pre-exercise levels within 24-48 hours[25]. It is thought to be a function of the intensity of the exercise and most specifically, moderate or vigorous exercise are contributors to consider with proteinuria. The reason for an increase in protein excretion after exercise has not been fully identified, however researchers suspect the process occurs at the level of the nephron and involves filtration at the glomerular membrane [26]. Specifically, the level of angiotensin II increases during exercise, which plays a role in the filtration of protein through the glomerular membrane. In addition, experts suspect that the permeability of the glomerular capillary membrane is increased with exercise because of the concomitant rise of sympathetic nervous system activity that accompanies high intensity exercise, as performed by the participants in this study [27].

CONCLUSION

The wearing of a device that places mild jugular vein compression (as a mechanism to prevent injuries to the brain sustained through head impacts) does not affect one's physical performance by way of a maximal effort cardiovascular task (VO2 max) and even at this maximal performance, does not provoke any abnormal response to exercise as demonstrated through blood and urine analysis. Mildly raising the intracranial volume and pressure through jugular compression, even during maximal exercise, appears to be well tolerated and provides no alteration in peak exercise performance or physiologic detriment by way of multiple tested parameters.

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Figure Legends:

Figure 1: Depiction of Subject Venous Blood Draw
Figure 2: Subject Performing VO_2 max testing.
Figure 3. Bland Altman Plot of VO2 max results with Neck and Arm Device.
Figure 4. Bland Altman Plot of Respiratory Ratios from VO2 Max test with Arm and Neck Device.
Figure 5. Bland Altman plot of max HR during VO2 max test with Arm and Neck Device.

Table 1. Bruce Treadmill Protocol			
Stage	**Speed (mph)**	**Grade (%)**	**Duration (min)**
1	1.7	10	3
2	2.5	12	3
3	3.4	14	3
4	4.2	16	3
5	5.0	18	3
6	5.5	20	3
7	6.0	22	3

Table 2. Mean and p-value (significance) for Renal Panel and Complete Blood Count data in Neck Device sessions								
Renal Panel Results (Normal Range)	**Mean PRE**			**Mean POST**			**Mean diff**	**p-value**
Albumin Level (3.4 - 5.0 mg/dL)	**4.1**	**±**	**0.3**	**4.4**	**±**	**0.2**	**0.2***	**0.023***
Bun (7.0 - 18.0 mg/dL)	13.9	±	3.8	14.1	±	3.5	0.2	0.881
Calcium (8.3 - 10.10 mg/dL)	8.9	±	0.4	9.1	±	0.3	0.2	0.116
Chloride Level (98.00-107.00 mmol/L)	104.3	±	1.2	103.9	±	1.7	-0.4	0.461
CO2 Level (21.00-31.00 mmol/L)	**26.8**	**±**	**2.2**	**22.2**	**±**	**3.6**	**-4.6***	**0.000***
Creatinine Level (0.51-1.17 mg/dL)	0.9	±	0.1	0.9	±	0.2	0.1	0.293
Glucose Level (65.00-106.00 mg/dL)	90.9	±	17.3	89.9	±	15.1	-1.0	0.867
Phosphorus (Phosphate) 2.5-4.9 mg/dL)	3.1	±	0.7	3.0	±	0.8	-0.1	0.623
Sodium Level (136.00-145.00 mmol/L)	140.3	±	1.6	139.8	±	1.4	-0.5	0.341
Blood CBC	**Mean PRE**			**Mean POST**			**mean diff**	**p-value**
HCT (35.00-52.00%)	43.1	±	4.1	44.4	±	3.7	1.3	0.369
HGB (11.7-17.70 gm/dL)	15.1	±	1.5	15.4	±	1.4	0.3	0.605
Platelet (135.00-466.00 K/mcL)	234.6	±	46.5	251.3	±	53.8	16.7	0.369
Potassium Level (3.5-5.10 mmol/L)	3.8	±	0.2	3.9	±	0.3	0.1	0.218
WBC (4.5-11.00 K/mcL)	6.3	±	1.4	7.3	±	1.4	0.9	0.087

Table 3. Urinalysis Results (Number of subjects with each result)				
	Blood - PRE	**Blood - POST**	**Protein - PRE**	**Protein - POST**
Neg	15	14	14	5
Small	2	2	0	0
Trace	0	2	3	6
Moderate	10	0	0	0
30 mg/dL (Protein Only)	N/A	N/A	1	7

Table 4. Comparison of mean VO2 measurment data between arm and neck band								
	Mean ARM (± SD)			Mean NECK (± SD)			Mean diff	p-value
VO2 Respiratory Rate (R)	1.3	±	0.1	1.3	±	0.1	0.0	0.878
VO2 Maximum Heart Rate (bpm)	187.1	±	10.1	171.2	±	45.5	0.0	0.170
VO2 Maximum (ml/kg/min)	40.8	±	7.6	41.8	±	8.6	0.0	0.729

Figure 1

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Figure 2

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Figure 3

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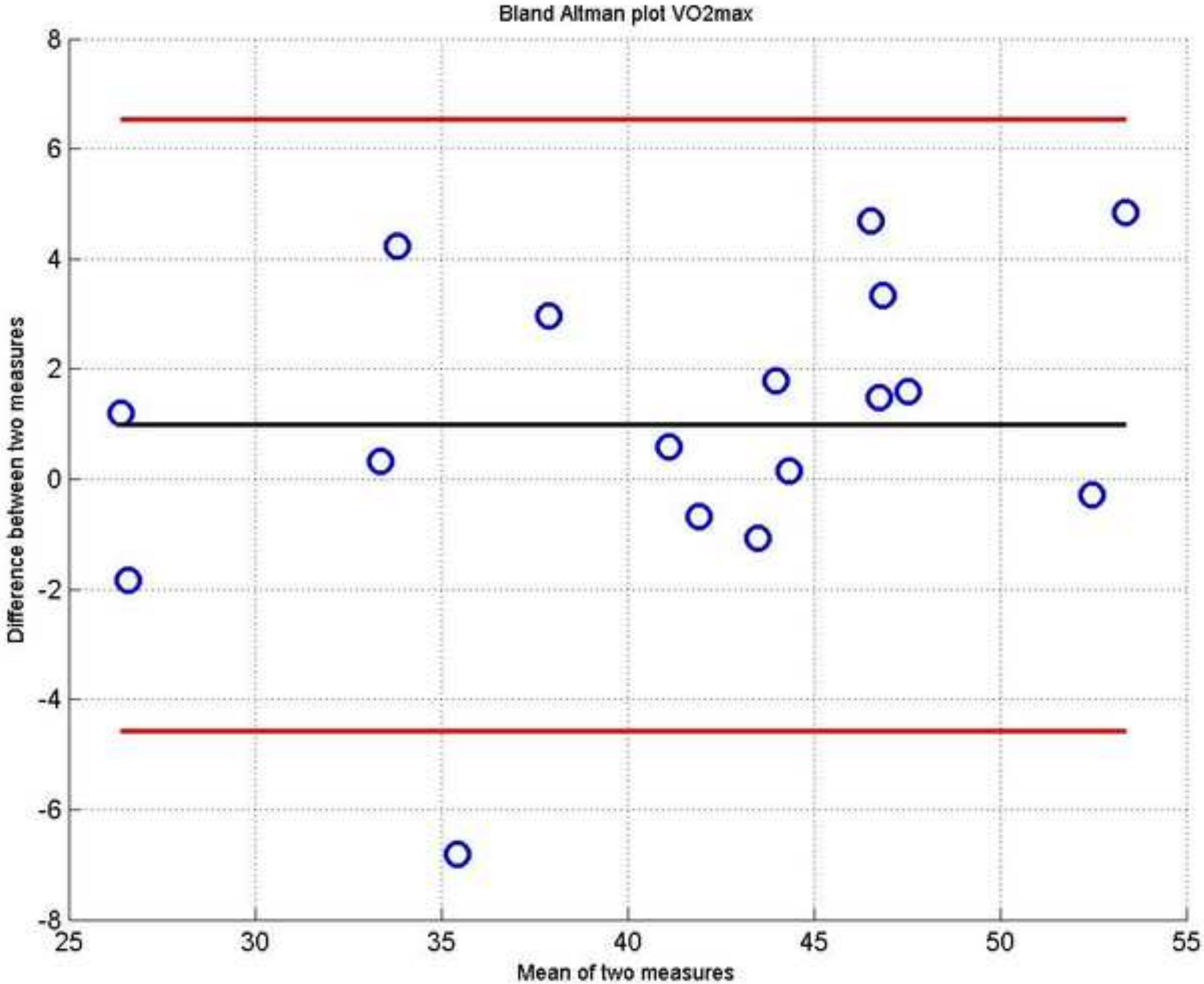

Figure 4

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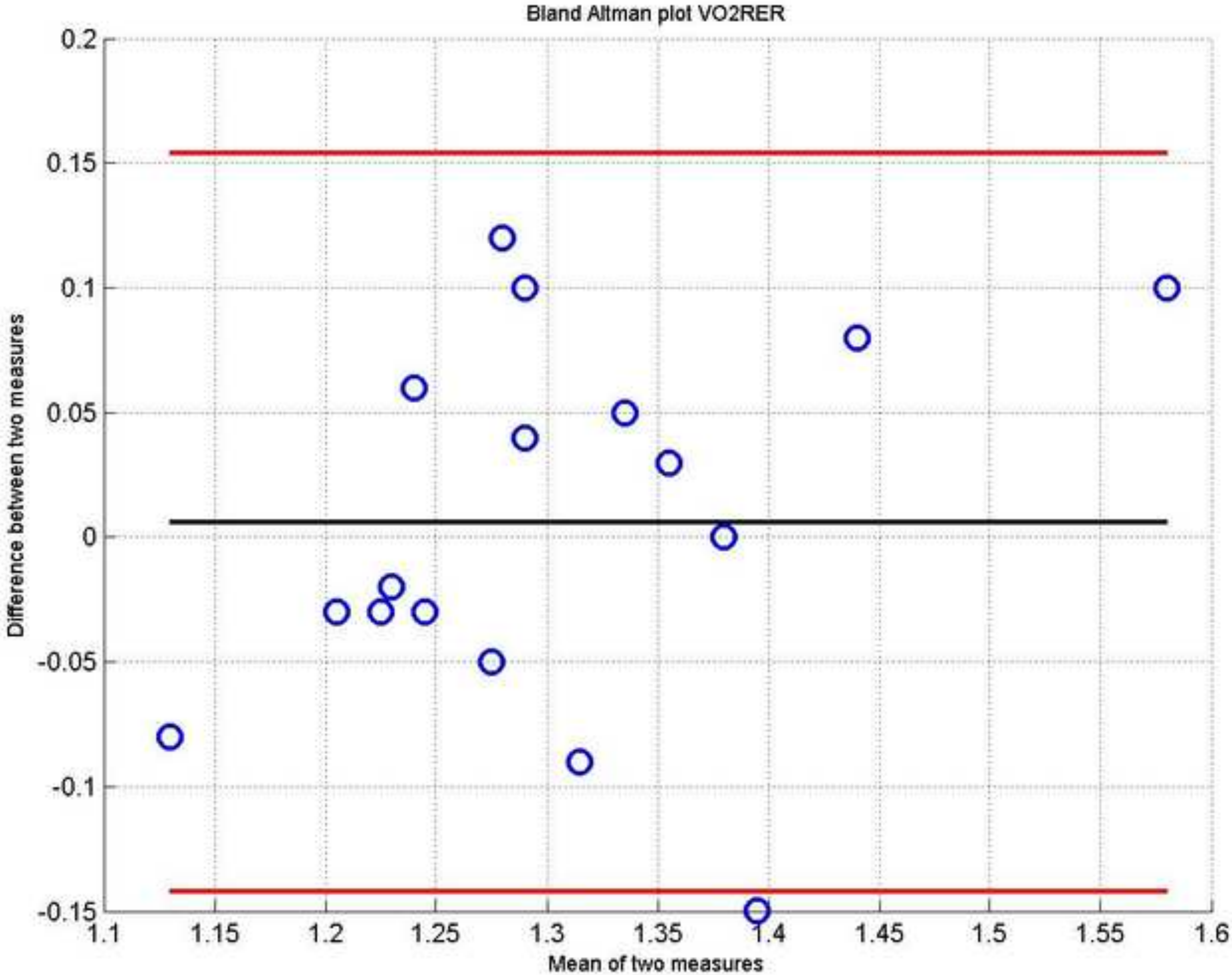

Figure 5

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