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A Validation Study of a Noninvasive Lactate Threshold Device

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ABSTRACT

International Journal of Exercise Science 12(2): 221-232, 2019. The lactate threshold is considered a key marker of endurance exercise performance and identification of this threshold is important in writing an exercise training program. Unfortunately, assessment of the lactate threshold has traditionally required venous or capillary blood samples and a specialized meter to assess blood lactate concentrations. Recently, a consumer grade, non-invasive device was developed to determine muscle oxygenation and estimate the lactate threshold. Purpose: The aim of this study was to assess the validity of a noninvasive lactate threshold device (NID) to determine lactate threshold heart rate (LTHR). Methods: Twenty-one recreational athletes (14 females, 39 ± 7 years, $29.1 \pm 5.2\%$ fat, 37.8 ± 6.0 ml \cdot kg⁻¹ \cdot min⁻¹; 7 males, 42 ± 9 years, $16.8 \pm 2.2\%$ fat, 45.9 ± 6.4 ml \cdot kg⁻¹ \cdot min⁻¹) completed a personalized graded exercise test on a treadmill. All participants wore the NID and blood lactate samples were taken at the end of 3-minute stages. LTHR was then calculated using two traditional methods (4 mmol/L and >1 mmol/L increase) and compared against the same heart rate values calculated by the NID. Results: No significant differences ($p = .87$) were found in LTHR between the NID and the traditional lactate methods (NID: 167 ± 9 bpm, 4 mmol/L: 167 ± 12 bpm, >1 mmol/L: 167 ± 12 bpm). Conclusions: This study provides preliminary support for the validity of the NID for estimation of LTHR.

KEY WORDS: BSX insight, endurance exercise performance

INTRODUCTION

Over the past 50 years the concept and importance of an individual athlete's lactate threshold (LT) has become more common, especially in endurance sports. Lactate is a marker of the metabolic strain being experienced by the body (7), and the LT can be used to help establish training zones and intensities. For example, when prescribing training for an iron distance triathlete (8+ hour event), the LT helps establish the aerobic zone which is below LT and where the majority of training will take place. Knowing the LT also allows the coach to include workouts designed to increase the LT, and therefore increase the paces that can be maintained in the aerobic zone, below the LT. In addition, multiple testing sessions can also be utilized to track an athlete's progress over time (4).

Lactate threshold testing is most often performed in a laboratory with bench model analyzers, but these models have the downside of cost and inconvenience for most athletes, trainers, and coaches. However, portable lactate analyzers provide a more cost-efficient and convenient option. Several portable models have been tested and found to be valid in their lactate measurements (2, 9, 13). However, these devices require a sample of blood, generally from a finger stick, which can increase measurement error when multiple blood samples are required (9). Additionally, this type of testing requires the assistance of a trained technician. This poses an issue for coaches with large teams or athletes that do not live in the same location as their coach or near a lab facility. Also, while more economical than a bench analyzer, portable blood lactate devices are relatively expensive, and require recurring purchase of additional testing and calibrating strips. These issues have spurred the development of new lactate testing technologies that do not require a blood sample, and can be performed by an individual athlete with limited or no assistance.

Recently a new, non-invasive device (NID) on the market, the BSX Insight (Multisport version, BSX Athletics, Austin, TX) claims to estimate the lactate threshold heart rate (LTHR) via measurements of oxygen saturation of the muscle. This NID is marketed to individual athletes to measure and monitor LT without the need for blood testing or a laboratory facility. The wearable device utilizes near-infrared spectroscopy (NIRS) to measure the oxygen saturation levels in the calf muscle during a graded exercise test (GXT), and applies a proprietary algorithm to determine the point of LT (3, 8). NIRS directs light into the tissue, and the light is scattered or absorbed dependent on the oxygenation of hemoglobin and myoglobin in the tissue (8). Using laboratory measures, Belardinelli and colleagues (3) described a slow decrease in muscle oxygenation over a lower work rate range, followed by a more rapid decrease in the range of the LT and a plateau around VO₂max. From these data, Belardinelli et al. (3) postulated that NIRS could be used as a noninvasive method of monitoring skeletal muscle changes in oxygenation during incremental exercise. Further, Grassi and colleagues (8) evaluated whether measurements of muscle oxygenated blood by NIRS were associated with the onset of blood lactate accumulation. They concluded that there was a high correlation ($r = 0.95$) between the onset of muscle deoxygenation and the lactate threshold.

Despite the support for NIRS for determination of LT, limited testing has been performed on novel portable technology that utilizes NIRS. The previously cited studies on NIRS were conducted with laboratory experiments, and utilized a different testing site (vastus lateralis versus the gastrocnemius). The need for a portable consumer grade lactate-testing device is in high-demand in the endurance community. If valid, this device could provide athletes and coaches with LT data outside of a laboratory setting, while using a noninvasive method of measurement. However, before such technology is endorsed for LT assessment and training prescription, the validity of the non-invasive device must first be determined. Thus, the aim of this study was to assess the validity of the NID in determining the LTHR compared to traditional LT measurement.

METHODS

Participants

Participants were recruited from a local triathlon club. The study was approved by the university institutional review board and all subjects signed an informed consent prior to participation in the study. Demographic information on all participants is listed in Table 1. For inclusion criteria, participants from the triathlon club were required to be currently training for an endurance event, and were required to have had at least 4 weeks of consistent training. Exclusion criteria included less than 4 weeks of training, medical issues that would prevent the participant from completing the graded exercise test, injuries that would prevent them from running on a treadmill, daily carbohydrate intake of less than 40%, and a fatigue index greater than or equal to 8 on a 10 point scale (1 – not at all fatigued; 10 – extremely fatigued) measured with a 1-item scale developed by van Hooff et al (14). Prior to LT testing, body composition was assessed via dual energy x-ray absorptiometry (DEXA, Lunar Prodigy Advance, GE Healthcare, UK).

Table 1. Subject demographics for women and men completing graded exercise test.

	Women (n = 14)	Men (n = 7)
Age (years)	39 ± 7	42 ± 9
Height (cm)	165.1 ± 5.9	178.9 ± 7.7
Weight (kg)	70.2 ± 11.6	83.5 ± 8.0
Body Fat (%)	29.1 ± 5.2	16.8 ± 2.2
Body Mass Index (kg·m ⁻²)	25.7 ± 4.1	26.0 ± 1.4
VO ₂ max (ml·kg ⁻¹ ·min ⁻¹)	37.8 ± 6.0	45.9 ± 6.4

All values represent mean ± SD

Protocol

Before participants arrived at lab, they were briefed on the testing environment and protocols via an email confirming their scheduled test time. Participants were asked to abstain from exercise for at least 24 hours before their scheduled test. Although past research indicates that diet modifications don't affect LT (11, 15), participants were asked to maintain a normal, well-balanced diet prior to testing and record the three prior days of food intake using the MyFitnessPal app. While subjects were allowed to eat prior to testing, they were asked to abstain from caffeine on the day of testing. Upon arrival, informed consents were presented to participants and basic descriptive data were collected (Table 1). Three prior days' macronutrients were evaluated and the participant was asked to rate their fatigue on a scale of 1 to 10 as previously described (14) to screen for exclusion criteria.

Next, the following information about the participant was entered into the BSX Insight app on the iPhone 6 (Apple Inc., Cupertino, CA): conversational pace (min/mile), 10K pace (min/mile), consecutive months of training, training days per week, and running miles per week. These values were determined prior to testing by the participant based on recent race and training data. The app then provided an individualized, incremental graded exercise test protocol for the subject based on the aforementioned information. The protocol consisted of 3 minute stages with speed increasing ~20-30 seconds per mile (~12-18 seconds per kilometer) each stage. A sample

protocol is provided in Figure 1. This individualized graded exercise protocol was continued to exhaustion, and was therefore used for the assessment of the LT and VO₂max. This allowed for one test to assess VO₂max and the LT via the NID and traditional blood lactate measures.

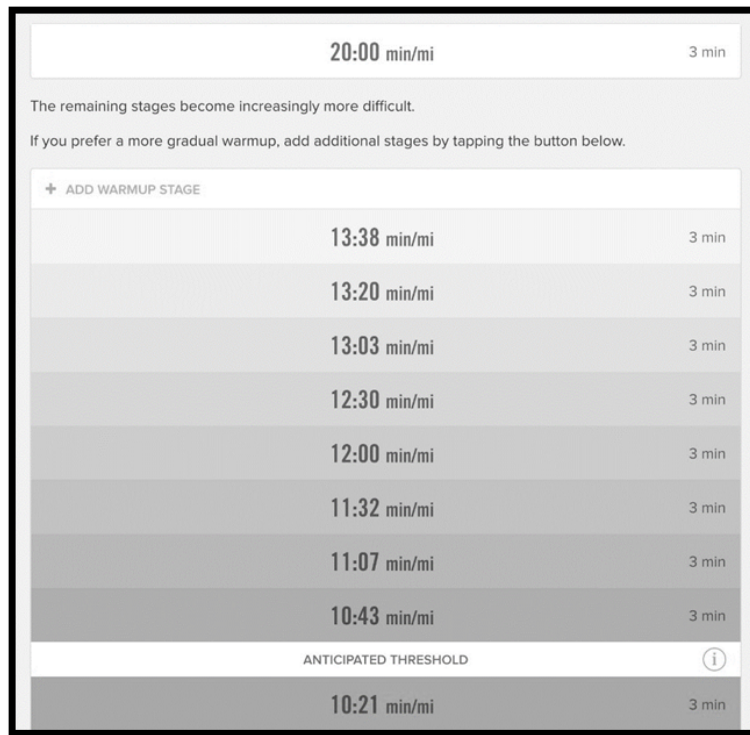


Figure 1. Sample individualized exercise testing protocol

Per NID instructions, the prescribed protocol was checked for length to confirm that each test would last at least 20 minutes to derive sufficient data. The NID was paired with the iPhone via Bluetooth wireless connection, prior to placing it in the compression sleeve, and on the participant's left calf. Appropriate calf sleeve size was determined by measuring the participant's calf at the largest circumference point to the nearest centimeter. The device was then positioned on the back of the left calf at the level of the largest circumference of the calf. The device was also paired with a heart rate monitor capable of transmitting via ANT+ wireless technology (Garmin Heart Rate Monitor 010-10997-00, Garmin Ltd, Olathe, KS).

Participants were familiarized and fitted with a mask for use with the Vista Mini-CPX (VacuMed, Ventura, CA). Measurements of VO₂, VCO₂, and RER were continuously monitored and recorded during the entire duration of the prescribed protocol. VO₂max was determined as the peak VO₂ achieved over a 1 minute average time period during the same graded exercise protocol used to assess the LT. An effort was considered maximal if the subjects achieved any of the following criteria: max heart rate within 10 bpm of age predicted max, RER > 1.1, or a plateau in VO₂ despite an increase in workload.

The test began and followed the paces individually prescribed by the NID protocol. At each stage, the app provided a timer, the current pace/speed, participant's heart rate, and percent muscle oxygenation. Every three minutes a new stage began, and treadmill speed was manually adjusted according to the speed prescribed on the app until volitional fatigue. Results for LTHR and corresponding pace were then immediately available either through the app or the product website. These values were determined by the NID app.

Finger prick blood samples were collected before the start of the test, at the end of each 3-minute stage, and immediately following the end of the test. Blood samples were taken from the tip of the middle or ring finger. The finger site was chosen over the earlobe due to the ease of measurement since these sites can be used interchangeably (12). Aliquots of each sample were analyzed by the Lactate Plus (LP) blood lactate analyzer (Nova Biomedical Corporation, Waltham, MA), which was calibrated and operated in accordance with the manufacturer's instructions.

After graphing the lactate values across stages, the LT at 4 mmol/L and the inflection point where lactate values increased by >1 mmol/L from subsequent stages was also noted. Thus, the LT at 4 mmol was identified as the stage prior to the 4 mmol/L lactate recording, and the LT for the >1 mmol/L increase was identified as the stage prior to the observed 1 mmol/L rise. If a >1 mmol/L rise did not occur between stages, the stage prior to the clear inflection point in lactate levels was considered the LT point for the >1 mmol/L detection method. This exception was to the >1 mmol/L LT criteria was only necessary in two of the subjects. The corresponding heart rates and paces at these stages was then determined as the LTHR and LT pace, respectively.

For application to the consumer, the present study utilized the 3-minute staged protocol individually established by the NID. While some research has shown that longer duration stages are better for the assessment of LT (5), other research has shown that stage durations between 3 and 6 minutes are sufficient to obtain precise lactate measurements to determine the desired metabolic inflection points especially in trained participants (10). Therefore, since there is not a consensus in the research, and 3-minute stages have been shown to be accurate, the present study opted to use the individualized 3-minute staged protocol established by the NID.

Statistical Analysis

Three methods were used to examine the validity of the NID in identifying the LTHR and LT pace. Mean values of LTHR were examined between the NID and the standard LT testing methods (4 mmol/L and >1 mmol/L increase) using repeated measures ANOVA. Pearson correlations were also used to examine linear relationships between the NID and the two standard methods for LTHR and LT pace. Lastly, Bland-Altman plots were constructed to further examine level of agreement between LTHR and LT pace measurements using estimation from the NID and the standard measures (1). All statistical tests were conducted using IBM SPSS Statistics 25.

RESULTS

Mean values \pm SD for LTHR, as determined by the NID and the traditional 4mmol/L and >1mmol/L methods are shown in Figure 2. Mauchly's test showed that the assumption of sphericity was not met, $X^2(2) = 10.35$, $p = .006$, therefore the degrees of freedom were adjusted using the Greenhouse-Geisser estimates ($\epsilon = .70$). Repeated measures ANOVA showed no significant differences in LTHR between the NID and the traditional methods, $F(1.41, 28.17) = .074$, $p = .87$.

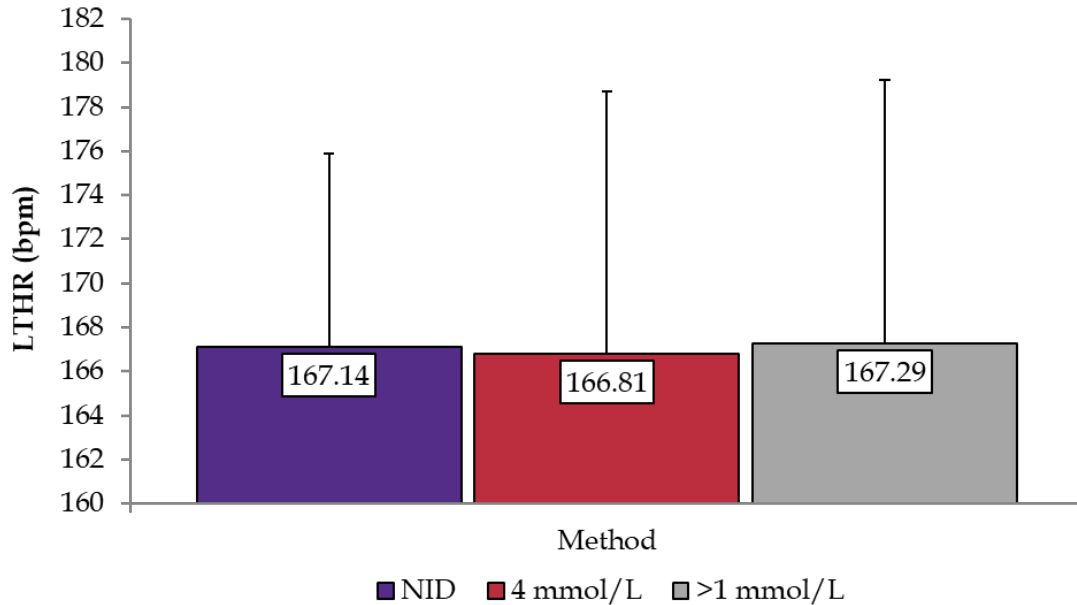


Figure 2. The mean \pm SD of the lactate threshold heart rate (LTHR), as determined by the noninvasive device (NID) and traditional lactate threshold methods (4mmol/L and >1mmol/L increase). $n = 21$.

Additionally, LT running pace ($\text{km} \cdot \text{hr}^{-1}$) identified by the NID and the 4 mmol/L and >1 mmol/L methods is displayed in Figure 3. Mauchly's test showed that the assumption of sphericity was not met, $X^2(2) = 16.92$, $p < .001$, therefore the degrees of freedom were adjusted using the Greenhouse-Geisser estimates ($\epsilon = .63$). Repeated measures ANOVA showed no significant differences in LT pace between the NID and the traditional methods, $F(1.26, 25.16) = 2.19$, $p = .15$.

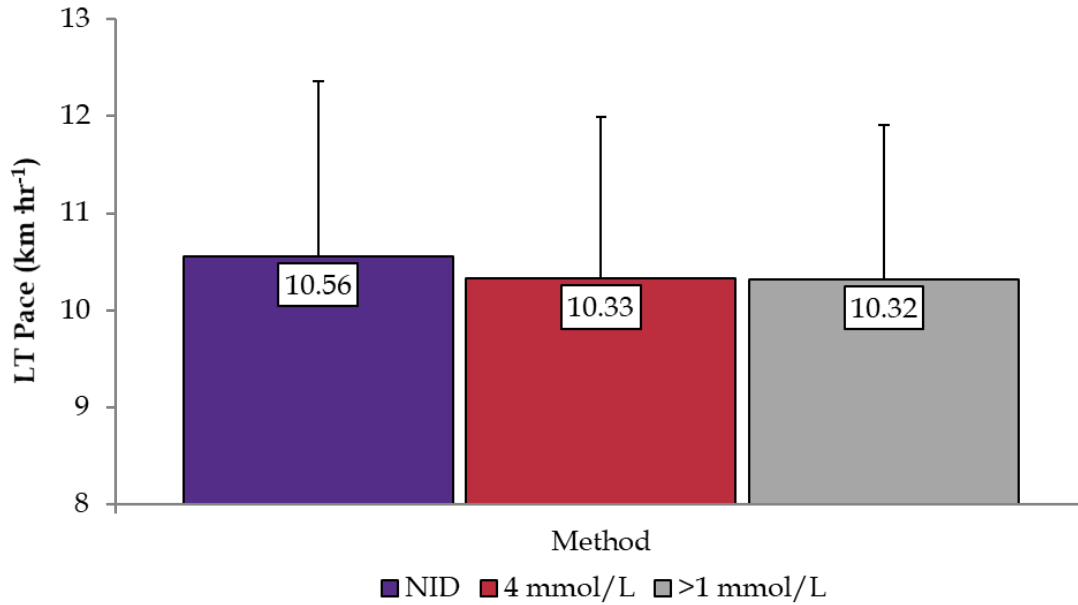


Figure 3. The mean \pm SD of the lactate threshold (LT) running pace ($\text{km}\cdot\text{hr}^{-1}$) as determined by the noninvasive device (NID) and traditional LT methods (4mmol/L and >1mmol/L increase). $n = 21$.

Table 2 shows the Pearson correlation (r) of LTHR from the NID to the traditional estimation methods.

Table 2. The Pearson correlation coefficient and associated p -values for the NID device compared with traditional estimation procedures of the lactate threshold heart rate.

Method	LTHR via NID	
	r	p
4mmol/L	.849	< .001
>1mmol/L increase	.816	< .001

Table 3 shows the Pearson correlation (r) of the LT running pace from the NID to the traditional LT estimation methods in addition to the estimated 10k running pace initially input to setup the study protocol for the NID.

Table 3. The Pearson correlation coefficient and associated p -values for the NID device compared with traditional estimation procedures of the lactate threshold running pace.

Methods	LT Running Pace via NID	
	r	p
4mmol/L	.924	< .001
>1mmol/L increase	.922	< .001
Estimated 10k Pace	.952	< .001

Bland Altman plots showing the mean difference and 95% limits of agreement for the NID and the standard methods of LTHR are shown in Figures 4 and 5. LTHR estimated by the traditional

4mmol/L method appeared to have the closest agreement with the NID, especially around mean heart rates of 160 to 170 bpm. For the 4 mmol comparison (Figure 4), at higher LTHR levels (>170 bpm) the NID underestimated the LTHR slightly in 6 of the 7 subjects in this range.

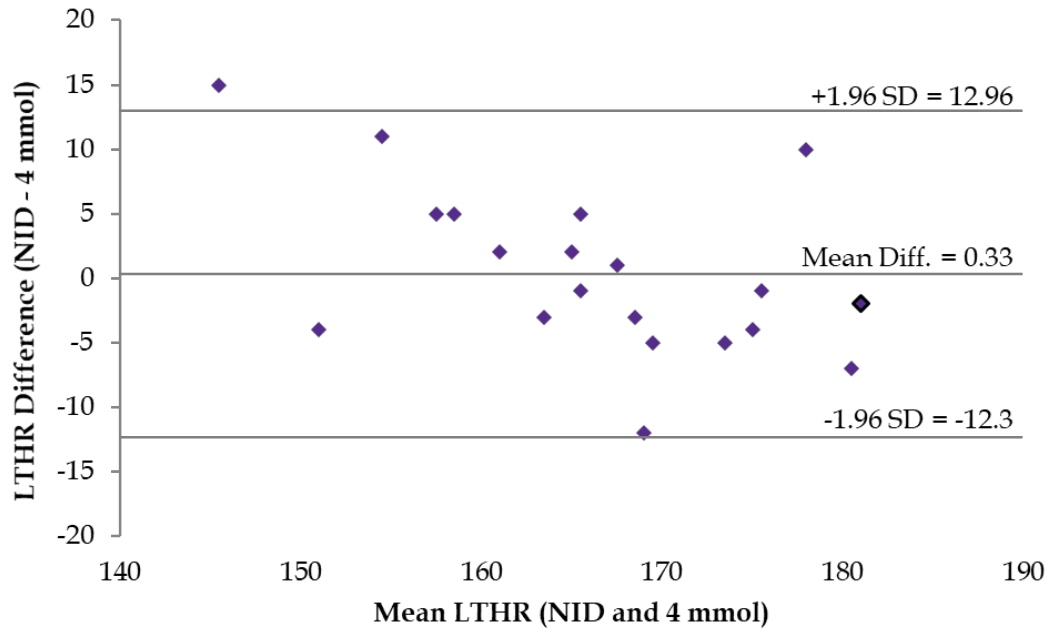


Figure 4. Bland Altman plot comparing lactate threshold heart rate (LTHR) determined by non-invasive device (NID) and traditional 4 mmol/L blood lactate method. Bordered marker indicates duplicate data point for two subjects. n = 21.

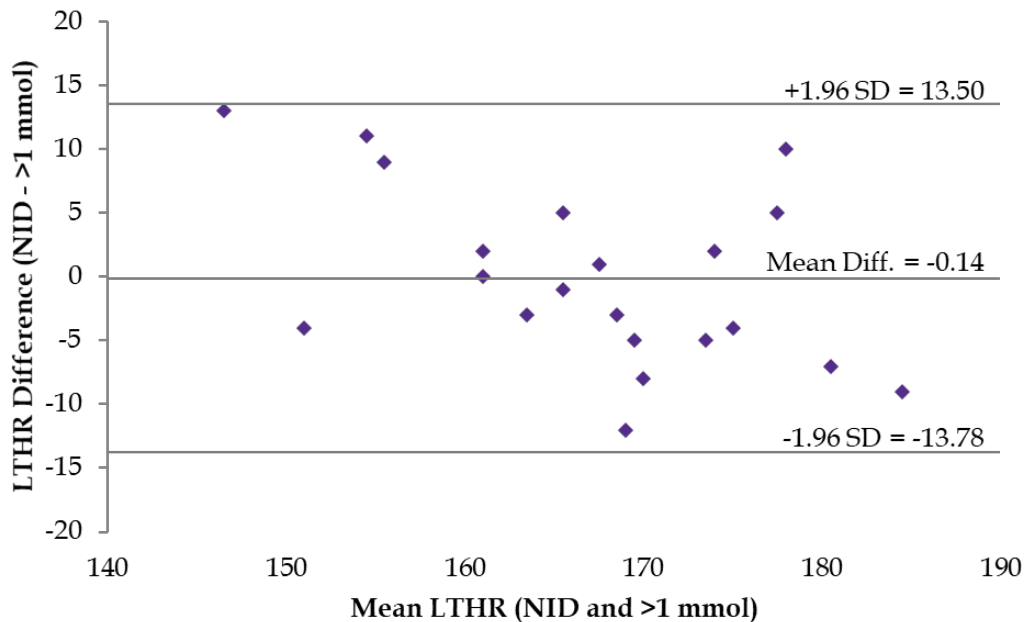


Figure 5. Bland Altman plot comparing lactate threshold heart rate (LTHR) determined by non-invasive device (NID) and traditional >1 mmol/L increase in lactate method. n = 21.

A Bland Altman plot was also constructed to show the relationship between LT running pace determined by the NID and the pace input by the user as their estimated 10k pace prior to the test (Figure 6). The average difference between these two paces was 0.01 km/hr with 95% limits of agreement falling between -1.19 and 1.21 km/hr, indicating the LT pace determined by the NID is very similar to the estimated current 10k pace input by the user prior to the testing protocol.

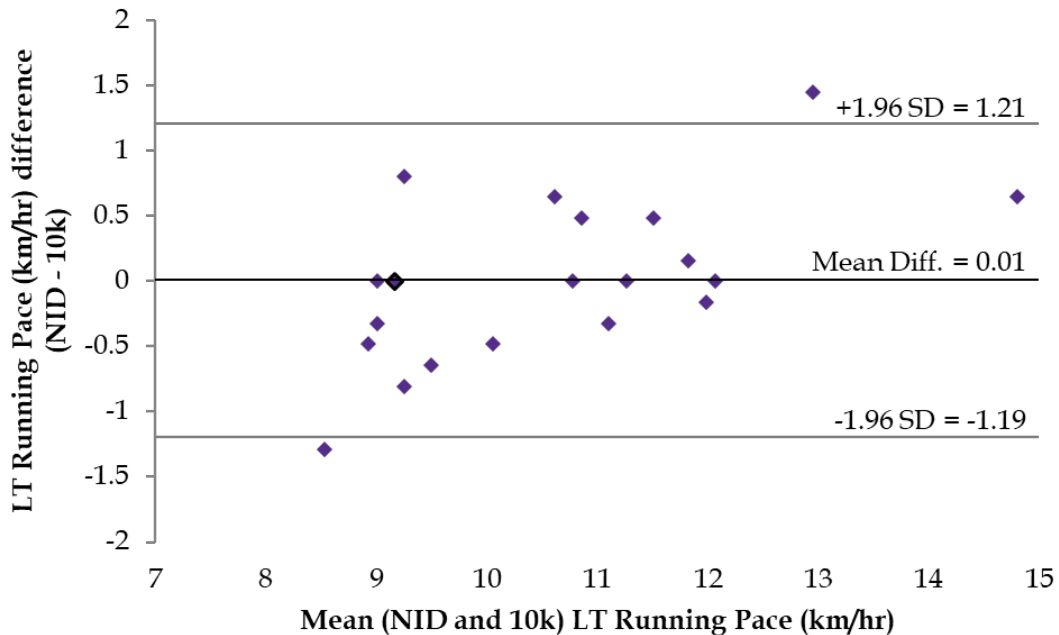


Figure 6. Bland Altman plot comparing lactate threshold pace determined by non-invasive device (NID) and the estimated 10k pace input by the subject. Bordered marker indicates duplicate data point for two subjects. n = 21.

DISCUSSION

The purpose of this study was to determine the validity of a non-invasive device to calculate heart rates at the lactate threshold during exercise. In general, the present findings provide preliminary support for the validity of the NID during a treadmill GXT to volitional fatigue.

No significant differences in LTHR means were found between the NID and traditional LTHR estimation methods. The Bland Altman plots of LTHR comparing traditional LT methods to the NID show no differences on average with 95% limits of agreement within ± 12 beats per minute. For higher LTHR (>170 bpm), the NID tends to underestimate the HR by a small degree (approximately 5-10 bpm), particularly for the 4 mmol/L method (Figure 4). In regards to under or over estimation of LT, recent research (6) found that the NID had a tendency to overestimate LT when compared with traditional methods, but previous research with NIRS (8) showed an underestimation of the heart rate at which LT occurred compared with fixed values.

It could be speculated that underestimation of the LT may be more favorable than overestimation, as this would prevent the athlete from crossing their LT in training and

potentially fatiguing too quickly. However, an argument could also be made that this could result in undertraining and less than optimal adaptations.

This study was completed on a sample of participants with a wide range of athletic ability (VO₂max range = 27.4 to 56.5 ml/kg/min). Compared to the findings of Borges and Diller (6), our participants were older, heavier and had a higher mean BMI. With the lower values, the present sample represented a more recreational group of triathletes than elite. While the present sample might be limited in generalizability to elite triathletes, our preliminary results support accuracy of the NID for those most likely to purchase and use it without the presence of a coach for every test and workout.

Also, these results support that the device has the capability to estimate LTHR with slower athletes which would benefit beginners. Advanced and elite athletes could also benefit from the device but need to be aware that it might underestimate threshold heart rates if threshold is at a high level due to our finding that the NID had a small degree of difference in regards to higher LTHR.

Not only does the NID collect data from athletes, it analyzes and presents the data in a format that athletes can use immediately. With standard devices, lactate values are obtained but then a person with specialized training is required to analyze those points and determine LT, training zones, and training paces for an athlete to work within.

Our findings also indicate a strong relationship ($r = .95$) between the LT pace determined by the NID and the estimated current 10k pace input by the user. Furthermore, the Bland Altman plot for this comparisons indicates virtually no difference on average between these paces with a 95% limit of agreement of ± 1.2 km/hr. This relationship is significant because if the goal is to identify the LT pace with limited testing and equipment, simply knowing an athlete's 10k pace may be adequate for prescribing training at the LT at least in this population of recreational triathletes. Future research would need to determine if the relationship between the LT pace determined by the NID correlated as strongly with the 10k paces of faster or slower runners.

There are some limitations of the present investigation that should be noted. First, as a preliminary investigation, a relatively small sample was utilized. Our sample of 21 participants is similar to other validation studies with this specific device (6). However, larger samples and further research could continue to provide further, more concrete support for the validity of this specific device across varying fitness levels. In addition, the smaller sample did not allow for the testing of gender differences for validity of the device in estimating LTHR. Also, reliability of the device wasn't examined in the present study, as participants were only tested with the same device, one time. Both inter- and intra-reliability is an important factor in establishing validity as athletes would use this device to track performance over time.

Several additional investigations need to be done with regards to the NID. This study used the prescribed 3-minute protocol established by the NID but LTHR values need to be compared

with those from a more traditional LT test with longer stages at lower intensities. In addition to the present study to validate the device, reliability testing is also warranted.

In addition, the NID requires an input of 10K race pace when it creates the GXT protocol. The LT pace determined by the NID was highly correlated ($r = .95$) with this input 10k pace (Table 3). If the proprietary algorithm of the device considers this input 10K race pace estimate into the LT prediction, tests need to be run where the athlete under- or over-estimates their 10K pace to see if the device is still determining the same LT.

Finally, this study validated a specific noninvasive, near infrared spectroscopy device while running. This particular NID is meant to be worn over the calf. To ensure the relationship between the LT and muscle oxygenation in the calf does not differ based on the mode of exercise, validation of the device during other modes of exercise (biking, swimming) could be necessary.

In conclusion, this study provides preliminary support for the validity of the NID for estimation of LTHR. Acceptable levels of agreement were found between the two devices when measuring HR at lactate threshold. This preliminary support is encouraging for the recreational athlete who could utilize such a device to assess LTHR for training purposes in their own environment, without relying on a specialized lab in their area.

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