



## Original Research

## Wearable positive end-expiratory pressure valve improves exercise performance



Stephen F. Crouse<sup>a,\*</sup>, Jason R. Lytle<sup>a</sup>, Sean Boutros<sup>b</sup>, William Benton<sup>c</sup>, Michael Moreno<sup>d</sup>, Patrick C. McCulloch<sup>e</sup>, Brad S. Lambert<sup>e</sup>

<sup>a</sup> Department of Health and Kinesiology, Texas A&M University, College Station, TX, USA

<sup>b</sup> My Houston Surgeons, 9230 Katy Freeway, Suite 600, Houston, TX, USA

<sup>c</sup> PEEP Performance, LLC., 96 Stivanoy Blvd, Eastchester, NY, USA

<sup>d</sup> Department of Mechanical Engineering, Texas A&M University, College Station, TX, USA

<sup>e</sup> Houston Methodist Hospital, Houston, TX, USA

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## ABSTRACT

We tested a PEEP (4.2 cmH<sub>2</sub>O) mouthpiece (PMP) on maximal cycling performance in healthy adults. Experiment-1, PMP vs. non-PMP mouthpiece (CON) [*n* = 9 (5♂), Age = 30 ± 2 yr]; Experiment-2, PMP vs. no mouthpiece (NMP) [*n* = 10 (7♂), Age = 27 ± 1 yr]. At timepoint 1 in both experiments (mouthpiece condition randomized) subjects performed graded cycling testing (GXT) (Corival® cycle ergometer) to determine  $\dot{V}O_{2peak}$  (ml\*kg\*min<sup>-1</sup>), O<sub>2</sub>pulse (mlO<sub>2</sub>\*bt<sup>-1</sup>), GXT endurance time (GXT-T<sub>(s)</sub>), and  $\dot{V}O_{2(ml*kg*min^{-1})}$ -at-ventilatory-threshold ( $\dot{V}O_{2@VT}$ ). At timepoint 2 72 h later, subjects completed a ventilatory-threshold-endurance-ride [VTER<sub>(s)</sub>] timed to exhaustion at  $\dot{V}O_{2@VT}$  power (*w*). One week later at timepoints 3 and 4 (time-of-day controlled), subjects repeated testing protocols under the alternate mouthpiece condition. Selected results (paired T-test, *p* < 0.05): Experiment 1 PMP vs. CON, respectively:  $\dot{V}O_{2peak}$  = 45.2 ± 2.4 vs. 42.4 ± 2.3 *p* < 0.05;  $\dot{V}O_{2@VT}$  = 33.7 ± 2.0 vs. 32.3 ± 1.6; GXT-TTE = 521.7 ± 73.4 vs. 495.3 ± 72.8 (*p* < 0.05); VTER = 846.2 ± 166.0 vs. 743.1 ± 124.7; O<sub>2</sub>pulse = 24.5 ± 1.4 vs. 23.1 ± 1.3 (*p* < 0.05). Experiment 2 PMP vs. NMP, respectively:  $\dot{V}O_{2peak}$  = 43.3 ± 1.6 vs. 41.7 ± 1.6 (*p* < 0.05);  $\dot{V}O_{2@VT}$  = 31.1 ± 1.2 vs. 29.1 ± 1.3 (*p* < 0.05); GXT-TTE = 511.7 ± 49.6 vs. 486.4 ± 49.6 (*p* < 0.05); VTER 872.4 ± 134.0 vs. 792.9 ± 122.4; O<sub>2</sub>pulse = 24.1 ± 0.9 vs. 23.4 ± 0.9 (*p* < 0.05). Results demonstrate that the PMP conferred a significant performance benefit to cyclists completing high intensity cycling exercise.

## Introduction

PEEP is defined as the positive pressure above atmospheric that remains in the pulmonary airways after exhalation. PEEP has been widely applied in clinical populations, commonly accompanied by mechanical ventilation.<sup>1–4</sup> Three to five cmH<sub>2</sub>O PEEP increases transpulmonary pressure and alveoli recruitment in patients with a variety of pulmonary complications, including chronic obstructive pulmonary disease (COPD), acute respiratory distress syndrome, and severe respiratory failure.<sup>1,5</sup> Within these groups, PEEP has been shown to reduce pulmonary shunting,<sup>5</sup> improve arterial oxygenation (PaO<sub>2</sub>) concomitant with increased functional residual capacity,<sup>6,7</sup> and reduce the work of breathing.<sup>8</sup> Increasing PEEP, combined with increasing the fraction of O<sub>2</sub> inspired, is a primary method applied in mechanically-ventilated patients to increase oxygen saturation and PaO<sub>2</sub> levels.

While the use of PEEP in pulmonary medicine is well-accepted, the possibility of an exercise benefit for healthy and athletic men and women has not been explored until now. The light-weight, wearable PMP tested in this present study employs the user's own expiratory force to generate mild (4.2 cmH<sub>2</sub>O) PEEP with almost no restriction on inspiration. Thus, the PMP can be comfortably used during exercise training and during competition, and could in theory improve PaO<sub>2</sub>. An increase in PaO<sub>2</sub> in athletes has long been known to improve exercise capacity.<sup>9,10</sup> On this basis we hypothesized that wearing the PMP would enhance endurance performance. Therefore, we designed two similar experiments to answer a singular question: Does wearing a PMP confer an exercise performance advantage to healthy, physically active men and women performing high-intensity cycling endurance exercise?

\* Corresponding author. Department of Health and Kinesiology Texas A&M University, 4245 TAMU, College Station, TX, 77843, USA.

E-mail address: [s-crouse@tamu.edu](mailto:s-crouse@tamu.edu) (S.F. Crouse).

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**Abbreviations:**

BP	blood pressure (mmHg)
BMI	Body Mass Index
CON	Control Mouthpiece (Battle Sports Science®)
ES	Effect Size <0.1 (N), 0.1–0.3(S), 0.3–0.5(M), 0.5–0.7(L), >0.7(VL)
EXP	Experiment
GXT	Graded Exercise Test performed on Corival Lode® Cycle Ergometer
HR	Heart Rate (bpm)
MAP	Mean Arterial Pressure (mmHg)
NMP	No Mouth Piece
O <sub>2</sub> pulse	Oxygen pulse (mlO <sub>2</sub> *bt <sup>-1</sup> )
PEEP	Positive End-Expiratory Pressure (cmH <sub>2</sub> O)
PMP	PEEP Mouthpiece
RER	Respiratory Exchange Ratio calculated as $\dot{V}CO_2 \div \dot{V}O_2$ (ml*min <sup>-1</sup> )
RPE	Ratings of Perceived Exertion
RPM	Revolutions per minute
TTE	Time to Exhaustion (sec)
$\dot{V}$	O <sub>2</sub> peak $\dot{V}O_2$ at Voluntary Exhaustion (mlO <sub>2</sub> *kg <sup>-1</sup> *min <sup>-1</sup> )
VT	Ventilatory Threshold
VTER	Ventilatory Threshold Endurance Ride (sec)

**Material and methods***Subjects*

Thirty-two adult men and women responded to word-of-mouth and email advertisements to participate. Nineteen met our inclusionary criteria of: 1) self-reported to be physically healthy with no known contraindications for high-intensity exercise; 2) physically active as defined by regular aerobic exercise training  $\geq 3$  days per week for at least 6 months; and 3) were able to commit to the schedule required to complete all phases of testing (Table 1 Demographics). The procedures were approved by the institutional review board for research involving human subjects (IRB PR000020755), and all volunteers signed a written informed consent prior to participating in the experimental procedures.

*Description of the PMP*

The PMP used in this study was a self-contained breathing device (Fig. 1) (Patent #10,252,021 and #9,555,201 B2). Not dissimilar to a traditional central-opening mouth guard often used in sports, the device has a breathing port 1<sup>3</sup>/<sub>16</sub>" wide x 5/8" high to allow seamless inhalation without resistance or assistance. Upon exhalation, a thin, light-weight silicone valve deploys to obstruct the central breathing opening. Expired air is then forced through smaller openings around the outer

**Table 1**  
Subject demographics for Experiment 1 and 2.

EXP-1	Variable	Men (n = 5)	Women (n = 4)	Combined (n = 9)
	Age (yr)	32 ± 8	28 ± 5	31 ± 5
	Height (cm)	178.3 ± 6.2	164.3 ± 11.2	172.2 ± 7.4
	Weight (kg)	79.6 ± 3.6	62.8 ± 10.1	72.2 ± 7.3
	BMI (kg*m <sup>2</sup> )	25.1 ± 1.7	23.5 ± 5.3	24.4 ± 2.4
EXP-2	Variable	Men (n = 7)	Women (n = 3)	Combined (n = 10)
	Age (yr)	27 ± 2	28 ± 3	27 ± 2
	Height (cm)	181.3 ± 4.3	172.7 ± 11.5	178.8 ± 4.9
	Weight (kg)	80.6 ± 7.4	67.8 ± 10.9	76.7 ± 7.0
	BMI (kg*m <sup>2</sup> )	24.5 ± 2.1	22.6 ± 1.5	23.9 ± 1.6

Values mean ± 95%CI.

edge of the breathing port controlled by elastic springs to open when expired pressure is greater than 4.2 cmH<sub>2</sub>O, thereby producing mild PEEP to the wearer. The mouthpiece also has an interdental portion and buccal flange which serves to protect the teeth in a contact environment, and provides a bite surface to ensure the mouthpiece can be retained inside the mouth. Lastly, the version of the PMP device designed for use in contact sports includes a larger lip guard to further protect the user's lips and mouth against contact.

*Testing procedures*

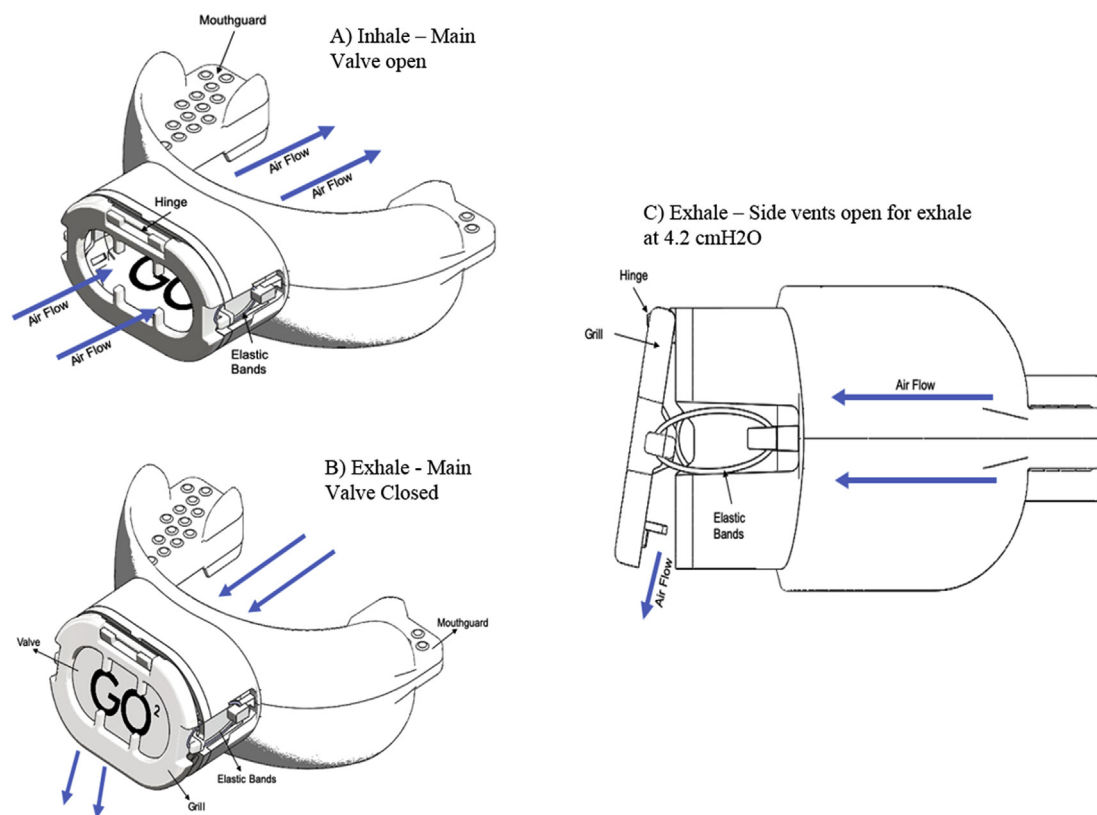
All procedures for this investigation were performed at an independently contracted laboratory (Orthopedic Biomechanics Research Laboratory, Houston Methodist Hospital, Houston TX). The laboratory altitude was 15 m above sea level (101325 Pa), and environmental conditions were controlled for all test sessions at a room temperature of 23 °C and 23% relative humidity. Two separate experiments were carried out using the same exercise protocol for each, but with different subject cohorts. EXP-1 was designed to compare maximal cycling performance using the PMP with a commercially-available mouthpiece (Battle Sports Science®) as a control. EXP-2 procedures were identical to those for EXP-1, except that cycling performance with the PMP was compared to breathing with NMP. All exercise was performed under standardized laboratory conditions, supervised by the same investigator giving verbal encouragement to the subject during exercise, and on the same electronically-braked cycle ergometer (Corival, Lode®). Continuous measures of gas exchange and HR were made using a calibrated metabolic cart with an integrated electrocardiograph (Ultima, MGC Diagnostics®). Subjects enrolled in EXP-1 and EXP-2 performed a maximal GXT at timepoint 1, and returned to the laboratory 72 h later for timepoint 2 testing to complete their VTER at an intensity equivalent to their VT (methods to follow). The following week subjects returned to complete the same order of the performance tests (testing timepoints 3 and 4), matched for time of day and day of the week, under the alternate mouthpiece condition. The mouthpiece order was assigned at random. The warm-up for all testing sessions was as follows<sup>1</sup>: pedaling for 3-min at 100 W at a self-selected RPM,<sup>2</sup> 1-min seated rest,<sup>3</sup> pedaling for 1-min with no resistance after which the test protocol was initiated. Each subject's self-selected RPM chosen during the initial testing session was matched during each exercise trial thereafter.

*GXT*

The GXT in both EXP-1 and EXP-2 was completed by each subject at timepoint 1 and 3 of their laboratory visits. Following the warm-up described above, the protocol was initiated at the subject's self-selected RPM and an initial workload of 150 W, then increased 30 W every 2 min until exhaustion. The elapsed time from the initiation of the GXT protocol to the point at which the subject's pedal RPM fell 10 below their initial self-selected RPM was recorded as the GXT TTE. Variables recorded at the end of each 2-min stage and at TTE included: HR,  $\dot{V}O_2$  (ml\*min<sup>-1</sup> and ml\*kg<sup>-1</sup>\*min<sup>-1</sup>),  $\dot{V}CO_2$  (ml\*min<sup>-1</sup>), minute ventilation RER, systolic BP and diastolic BP from manual sphygmomanometry by the same trained technician, MAP,<sup>11</sup> and RPE.<sup>12</sup>  $\dot{V}O_{2peak}$  was considered valid if at least two of the following criteria were achieved; a  $\dot{V}O_2$  plateau in spite of an increased workload, RER  $\geq 1.2$ , RPE  $\geq 17$ , and HR > 85% age-predicted maximal HR.<sup>13</sup> At the point of exhaustion, the resistance on the ergometer was removed and subjects pedaled at their self-selected RPM for a recovery period of 5 min. All measures detailed above except RPE were recorded at 1, 3, and 5 min of recovery.

*Cycle VTER*

Using data from the GXT test,  $\dot{V}O_2$  at VT was calculated for each subject using the V-Slope method.<sup>14</sup> Each subject's VT-equivalent power



**Fig. 1.** Illustrations of the PEEP breathing valve as part of the PMP (Patent #10,252,021 and #9,555,201 B2). A) Airflow in during inspiration though the open, hinged central valve. B) Central hinged valve closes during exhalation. C) When exhaled pressure reaches about 4 cmH<sub>2</sub>O, the bottom of the grill face is forced open, and exhaled air flows out.

(W) was estimated by linear regression of stage-by-stage  $\dot{V}O_2$  and power output (W), then subsequently used for the VTER (sessions 2 and 4) performed 72 h after their GXT. Following their prescribed warm-up, participants were asked to maintain their self-selected RPM and VT power output until exhaustion (defined above). During the VTER and 5 min of recovery, each subject's HR, RPE, BP, and metabolic gas exchange measures were assessed every 2 min in the same manner as during the GXT.

#### Statistical analysis

For EXP-1 and EXP-2, a paired sample T-test was used for comparison of all primary variables of interest, Type I Error set at  $\alpha = 0.05$ . Effect size was calculated using a Cohen's D statistic for all significant pairwise comparisons and interpreted as follows: <0.1, negligible (N); 0.1–0.3, small (S); 0.3–0.5, moderate (M); 0.5–0.7, large (L); >0.7, very large (VL).<sup>15</sup>

#### Results

Average  $\dot{V}O_{2peak}$  values were as follows (mean  $\pm$  95%CI): EXP-1 women =  $42.9 \pm 7$ , men =  $42.2 \pm 6$ ; EXP-2 women =  $40.0 \pm 7$ , men =  $42.8 \pm 3.2$ . Findings for the primary outcome variables are shown in Tables 2 and 3, and in Figs. 2 and 3. The GXT  $\dot{V}O_2$  and  $O_{2pulse}$  at peak exercise were significantly greater (3.1%–6.7%, ES range 0.32[S] to 0.49 [M]) with the PMP compared with CON and NMP (Fig. 2A–D). There were no differences in measured  $\dot{V}O_2$  at submaximal stages by mouthpiece condition. Moreover,  $\dot{V}O_2$  at VT was 7% higher (ES 0.49[M]) with the PMP compared with NMP (Fig. 2F). Although not significant, VT was over 4% higher with the PMP compared to CON (Fig. 2E). These findings

were observed with correspondingly greater GXT-TTE with the PMP (PMP vs CON =  $+26 \pm 5$  s,  $+5.8 \pm 1.4\%$ , ES 0.12[S]); PMP vs NMP =  $+25 \pm 8$  s,  $+5.9 \pm 1.74\%$ , ES 0.16[S]) (Fig. 3A and B). The TTE during the VTER was over 13% higher with the PMP compared with CON and NMP, but neither of these differences were statistically significant (Fig. 3C and D). During VTER, systolic BP was measured to be about 4% higher with the PMP compared with CON (Table 3).

#### Discussion

Medical practice has established the fact in clinical populations that the application of PEEP provides measurable benefits to pulmonary function, arterial oxygenation, and reduced postexercise dyspnea.<sup>1,3,4,6</sup> Also, COPD patients exhibit increased exercise tolerance and lower dyspnea scores when PEEP is combined with inspiratory pressure support during cycling exercise.<sup>2</sup> We are aware of only one published study prior to our own in which PEEP was applied to healthy adults performing exercise. Nespoulet et al.<sup>16</sup> reported that PEEP administered to healthy men significantly increased arterial and quadriceps oxygenation under normobaric and hypobaric conditions, and at 4350 m of altitude.

Our current study is the first to show that the application of mild PEEP by wearing a novel PMP during maximal exercise enhances cycling endurance performance in healthy, moderately trained men and women. Notably: 1) the exercise benefit of the PMP did not require training with the mouthpiece; 2) the gain in performance was immediate upon commencing use; and 3) the >4% improvement in  $\dot{V}O_{2peak}$ , along with a nearly 6% increase in GXT-TTE, was similar to the 3–5% improvement realized by competitive runners after 21–27 days of “live high, train low” protocols.<sup>17,18</sup> Furthermore, the minimal expiratory resistance provided

**Table 2**  
Results GXT at Peak Exercise: PMP vs. CON & PMP vs. NMP.

Variable		Peak Exercise		Peak Exercise
RER ( $\dot{V}CO_2/\dot{V}O_2$ )	<b>PMP</b>	1.2 ± 0.06	<b>PMP</b>	1.3 ± 0.06
	<b>CON</b>	1.2 ± 0.04	<b>NMP</b>	1.2 ± 0.06
	<i>Diff.</i>	0.02 ± 0.06	<i>Diff.</i>	0.02 ± 0.03
	<i>Sig.   Effect Size</i>	NS	<i>Sig.   Effect Size</i>	NS
Watts	<b>PMP</b>	268.7 ± 35.9	<b>PMP</b>	261.0 ± 26.4
	<b>CON</b>	260.0 ± 35.3	<b>NMP</b>	258.0 ± 25.1
	<i>Diff.</i>	6.6 ± 8.6	<i>Diff.</i>	3.0 ± 5.3
	<i>Sig.   Effect Size</i>	NS	<i>Sig.   Effect Size</i>	NS
Systolic BP (mmHg)	<b>PMP</b>	186.0 ± 9.6	<b>PMP</b>	171.8 ± 16.4
	<b>CON</b>	193.3 ± 10.9	<b>NMP</b>	177.2 ± 15.4
	<i>Diff.</i>	-7.3 ± 5.9	<i>Diff.</i>	-5.4 ± 7.0
	<i>Sig.   Effect Size</i>	*   0.47(M)	<i>Sig.   Effect Size</i>	NS
Diastolic BP (mmHg)	<b>PMP</b>	73.8 ± 4.5	<b>PMP</b>	68.6 ± 7.1
	<b>CON</b>	74.4 ± 5.0	<b>NMP</b>	67.6 ± 5.7
	<i>Diff.</i>	-0.7 ± 3.8	<i>Diff.</i>	1.0 ± 2.9
	<i>Sig.   Effect Size</i>	NS	<i>Sig.   Effect Size</i>	NS
Mean Arterial BP (mmHg)	<b>PMP</b>	111.2 ± 5.5	<b>PMP</b>	103.0 ± 9.5
	<b>CON</b>	114.1 ± 5.6	<b>NMP</b>	104.1 ± 8.5
	<i>Diff.</i>	-2.9 ± 3.5	<i>Diff.</i>	-1.1 ± 3.5
	<i>Sig.   Effect Size</i>	NS	<i>Sig.   Effect Size</i>	NS
Heart Rate (bpm)	<b>PMP</b>	185.1 ± 4.9	<b>PMP</b>	180.2 ± 5.0
	<b>CON</b>	184.4 ± 5.5	<b>NMP</b>	178.6 ± 5.4
	<i>Diff.</i>	0.6 ± 1.7	<i>Diff.</i>	1.6 ± 1.6
	<i>Sig.   Effect Size</i>	NS	<i>Sig.   Effect Size</i>	NS
Minute Ventilation (L/min)	<b>PMP</b>	128.7 ± 22.7	<b>PMP</b>	129.0 ± 13.8
	<b>CON</b>	119.6 ± 19.6	<b>NMP</b>	123.1 ± 12.9
	<i>Diff.</i>	9.1 ± 9.7	<i>Diff.</i>	5.9 ± 10.1
	<i>Sig.   Effect Size</i>	NS	<i>Sig.   Effect Size</i>	NS

by the PMP did not alter breathing patterns during strenuous exercise. This was demonstrated in our study by the fact that there were no significant differences in average and peak ventilatory rates between PMP, NMP, and CON conditions during the VTER and GXT sessions (Tables 2 and 3).

The VT was improved 4.1%–7.4% with the use of the PMP (Fig. 2E and F). In this regard, an increase in VT relative to  $\dot{V}O_{2max}$  has been shown to be related to an improved endurance performance, and raising the VT is often a goal of endurance training.<sup>19,20</sup> Others have shown that a significant improvement in VT generally requires at least 8–12 weeks of repeated high-intensity training bouts at or above the baseline VT.<sup>21</sup> By contrast in our study, the PMP increased VT during a single, intense exercise session without prior training. Though training studies with the PMP have yet to be completed, we suggest that the higher VT with PMP would enable competitive athletes to train at relatively higher intensities with less fatiguing lactate accumulation and related pH changes.

The PMP also resulted in a 13%–14% increase in TTE during the VTER (Fig. 3C and D). Although this would be considered a meaningful benefit by competitive athletes, in our study the improvement did not reach statistical significance. Indeed, we recommend caution in interpreting both the GXT-TTE and VTER TTE findings. Others have shown TTE to be subject to a number of confounding factors which are difficult to control, and which likely contributed to the wide variation of the individual responses noted in our study (Fig. 3).<sup>22</sup> Furthermore, TTE has been shown to be an unreliable predictor of actual cycling time trial performance.<sup>23</sup> In spite of this time-trial reliability question, other researchers have shown TTE to be sensitive to changes in endurance

**Table 3**  
Results ventilatory threshold endurance ride (VTER).

Variable		Average		Average
RER ( $\dot{V}CO_2/\dot{V}O_2$ )	<b>PMP</b>	1.1 ± 0.04	<b>PMP</b>	1.1 ± 0.04
	<b>CON</b>	1.1 ± 0.07	<b>NMP</b>	1.1 ± 0.05
	<i>Diff.</i>	0.0 ± 0.05	<i>Diff.</i>	0.0 ± 0.03
	<i>Sig.   Effect Size</i>	NS	<i>Sig.   Effect Size</i>	NS
Watts	<b>PMP</b>	197.8 ± 22.9	<b>PMP</b>	196.6 ± 6.3
	<b>CON</b>	197.8 ± 22.9	<b>NMP</b>	196.6 ± 6.3
	<i>Diff.</i>	-	<i>Diff.</i>	-
	<i>Sig.   Effect Size</i>	NS	<i>Sig.   Effect Size</i>	NS
Systolic BP (mmHg)	<b>PMP</b>	178.0 ± 10.0	<b>PMP</b>	162.1 ± 13.3
	<b>CON</b>	171.2 ± 10.0	<b>NMP</b>	166.6 ± 13.5
	<i>Diff.</i>	6.8 ± 5.7	<i>Diff.</i>	-4.5 ± 4.7
	<i>Sig.   Effect Size</i>	*   0.44 (M)	<i>Sig.   Effect Size</i>	NS
Diastolic BP (mmHg)	<b>PMP</b>	73.5 ± 5.7	<b>PMP</b>	66.5 ± 4.4
	<b>CON</b>	70.5 ± 3.6	<b>NMP</b>	65.1 ± 4.4
	<i>Diff.</i>	2.2 ± 5.3	<i>Diff.</i>	1.4 ± 2.0
	<i>Sig.   Effect Size</i>	NS	<i>Sig.   Effect Size</i>	NS
Mean Arterial BP (mmHg)	<b>PMP</b>	108.3 ± 6.3	<b>PMP</b>	98.4 ± 6.9
	<b>CON</b>	104.0 ± 6.1	<b>NMP</b>	98.9 ± 7.1
	<i>Diff.</i>	3.5 ± 4.5	<i>Diff.</i>	-0.6 ± 2.3
	<i>Sig.   Effect Size</i>	NS	<i>Sig.   Effect Size</i>	NS
$\dot{V}O_2$ (L*min <sup>-1</sup> )	<b>PMP</b>	2.5 ± 0.4	<b>PMP</b>	2.6 ± 0.3
	<b>CON</b>	2.5 ± 0.4	<b>NMP</b>	2.5 ± 0.4
	<i>Diff.</i>	0.0 ± 0.1	<i>Diff.</i>	0.1 ± 0.1
	<i>Sig.   Effect Size</i>	NS	<i>Sig.   Effect Size</i>	NS
Heart Rate (bpm)	<b>PMP</b>	170.9 ± 5.1	<b>PMP</b>	162.7 ± 6.3
	<b>CON</b>	170.2 ± 4.5	<b>NMP</b>	162.1 ± 5.2
	<i>Diff.</i>	-0.4 ± 0.6	<i>Diff.</i>	0.6 ± 2.8
	<i>Sig.   Effect Size</i>	NS	<i>Sig.   Effect Size</i>	NS
Minute Ventilation (L/min)	<b>PMP</b>	78.5 ± 17.4	<b>PMP</b>	81.9 ± 9.6
	<b>CON</b>	78.2 ± 13.9	<b>NMP</b>	81.6 ± 9.7
	<i>Diff.</i>	3.8 ± 8.5	<i>Diff.</i>	0.3 ± 3.1
	<i>Sig.   Effect Size</i>	NS	<i>Sig.   Effect Size</i>	NS

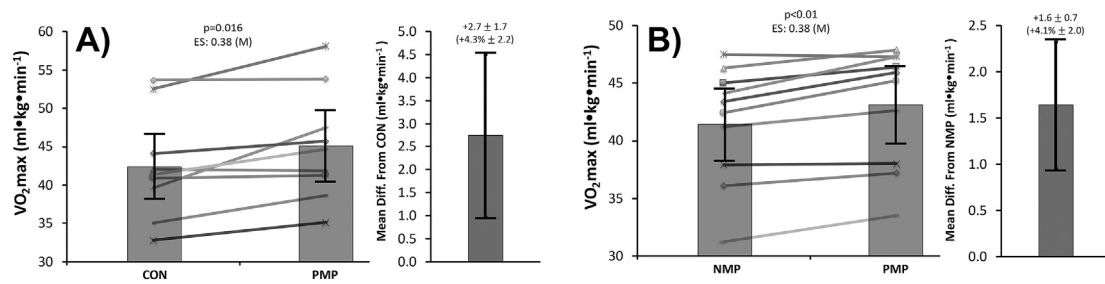
Values mean ± 95%CI, \* =  $p < 0.05$ . ES = <0.1 (N), 0.1–0.3(S), 0.3–0.5(M), 0.5–0.7(L), >0.7(VL).

performance.<sup>24</sup> On this basis, we suggest that at least the significant increase in the GXT-TTE represents a real change in subject endurance performance with the PMP. However, since we did not perform a cycling time trial test, we make no inference to an increase in time trial performance with the PMP.

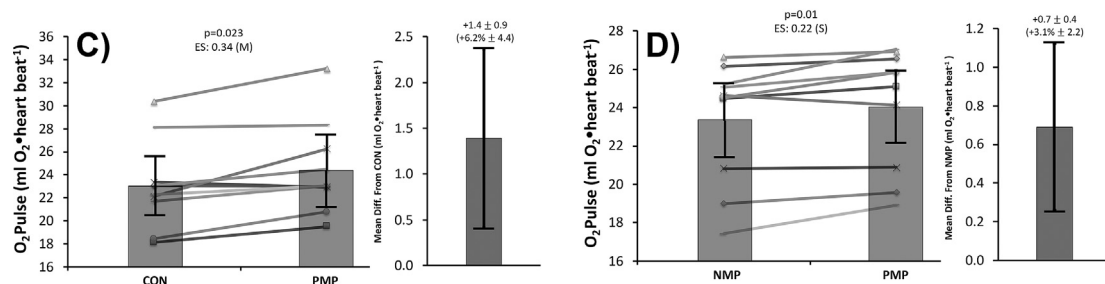
The comparatively higher  $O_{2pulse}$  with the PMP during maximal exertion on the GXT is consistent with the elevated  $\dot{V}O_{2peak}$  measured in this study. Since  $O_{2pulse}$  is a function of heart stroke volume, we speculate that the PMP induced an increase in this cardiac variable at max exercise compared with CON or NMP conditions. Though we have no direct measure of stroke volume in our study, Bhambhani<sup>25</sup> has shown that this cardiovascular performance variable can be reasonably predicted in healthy men and women from  $O_{2pulse}$ . Applying Bhambhani's<sup>25</sup> regressions to our data suggest an estimated increase in stroke volume of approximately 3–4% in our subjects averaged across both experiments. Such an increase with the PMP would at least partially explain the improvement in  $\dot{V}O_{2peak}$ .

Although we did not design our study to investigate the mechanism by which the PMP improved performance (e.g.,  $\dot{V}O_{2peak}$ ), clinical literature suggests the mild PEEP could improve alveoli recruitment and reduce pulmonary shunting.<sup>5,7</sup> We also point out that the PMP is different in design and function from elevation training masks, which

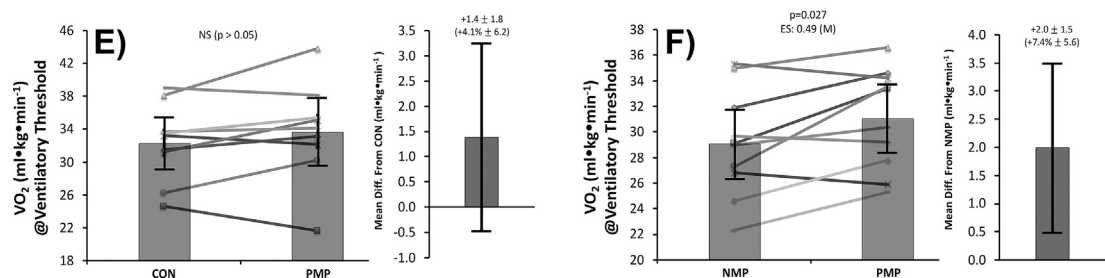
# AEROBIC CAPACITY



# OXYGEN PULSE



# VENTILATORY THRESHOLD



**Fig. 2.**  $\dot{V}O_{2peak}$  (A & B), peak oxygen pulse (C & D), and  $\dot{V}O_2$  at ventilatory threshold (E & F) resulting from PMP breathing during the cycle ergometer graded exercise test (GXT). For each figure, data are presented as mean  $\pm$  95%CI for each trial as well as for the difference between trials. Type I error set at  $\alpha = 0.05$  for all comparisons. For all significant comparisons, effect size (ES) is shown as Cohen's d statistic and interpreted as follows: <0.1, Negligible (N); 0.1–0.3, Small (SL); 0.3–0.5, Moderate (M); 0.5–0.7, Large (L); >0.7, Very Large (VL). PMP=PEEP mouthpiece, CON = control mouthpiece, NMP = no mouthpiece.

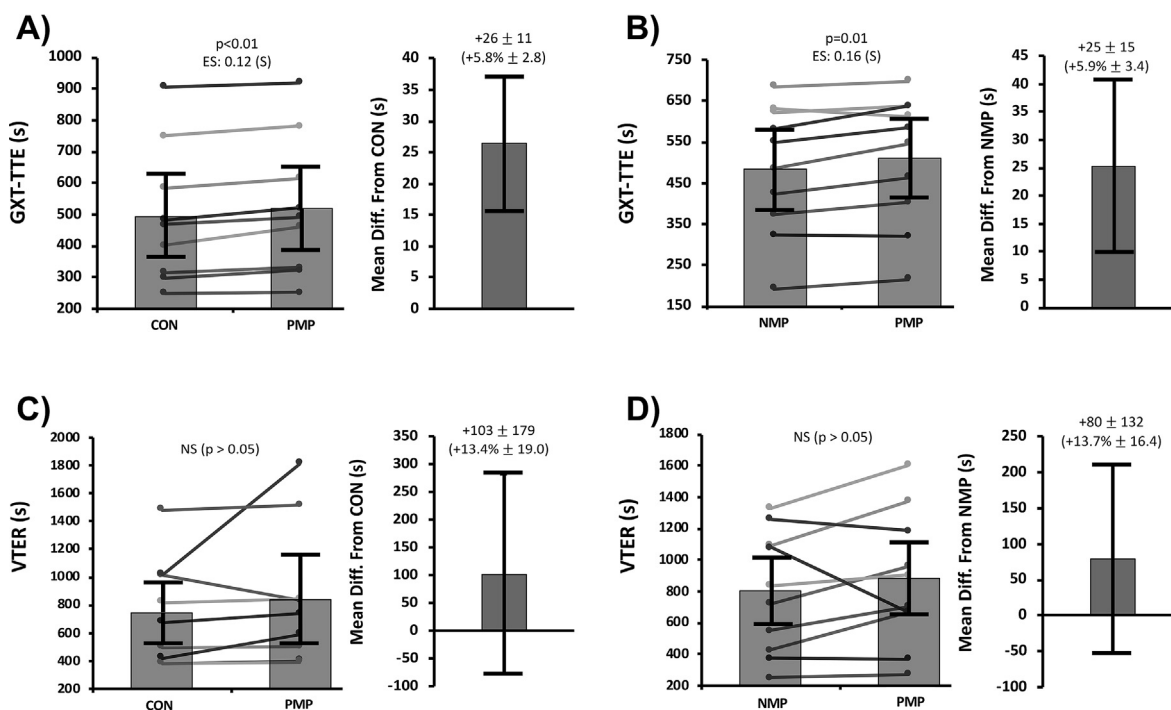
have been applied to exercise training. (e.g., Welnetz' patented design<sup>26</sup>). By comparison, the elevation training masks generally simulate altitude by employing filters to decrease oxygen density of inhaled air, and provide inspiratory and expiratory breathing resistance. Porcari et al.<sup>27</sup> reported no significant advantage of mask training for improvements in  $\dot{V}O_{2max}$  in moderately trained adults, and concluded that the mask did not simulate altitude. The majority of other published research supports these findings.<sup>27–30</sup> There are no published studies showing a performance advantage of using elevation training masks during competition or while actually performing a single session of heavy exercise (e.g., during an exercise test). This is in contrast to the performance improvement realized during a single session of exercise

with the PMP.

## Conclusions

Our results demonstrated that mild PEEP produced by a lightweight, wearable PMP was an effective and safe means to acutely improve performance in high-intensity, maximal effort cycling exercise. These benefits were without negative consequences on any of the performance or cardio-pulmonary variables measured. Whether or not the PMP augments long-term physical training of various training durations, intensities, and modalities remains to be determined, though such a training benefit is a reasonable hypothesis. It is also possible that this technology could be of advantage when oxygen supply is limiting

## Maximal Exercise Time To Exhaustion



**Fig. 3.** The time (s) to exhaustion during the maximal cycle graded exercise test (GXT-TTE: A & B) and during the ventilatory-threshold endurance ride (VTER: C & D). Data are presented as mean  $\pm$  95%CI for each trial as well as the difference between trials. Type I error set at  $\alpha = 0.05$  for all comparisons. For all significant comparisons, effect size (ES) is shown as Cohen's  $d$  statistic and interpreted as follows:  $<0.1$ , Negligible (N);  $0.1-0.3$ , Small (SL);  $0.3-0.5$ , Moderate (M);  $0.5-0.7$ , Large (L);  $>0.7$ , Very Large (VL). PMP=PEEP mouthpiece, CON = control mouthpiece, NMP = no mouthpiece.

exercise, such as at altitude, in certain cardiopulmonary disease conditions, or when personal protective masks must be worn by first responders. Future research is needed to determine the mechanisms responsible for PMP effectiveness, and to verify our findings in other trained and untrained men and women engaged in other modes of exercise.

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### Submission statement

The results of the study are presented clearly, honestly, and without fabrication, falsification, or inappropriate data manipulation. The manuscript has not been published and is not under consideration for publication elsewhere.

### Ethical approval

The procedures were approved by the institutional review board for research involving human subjects (IRB PR000020755), and all volunteers signed a written informed consent prior to participating in the experimental procedures.

### Authors' contributions

SFC; study research design, data collection & analyses, manuscript development.

JRL; data analysis, assistance on manuscript development.

SB; design of PMP, study research design, contribution to manuscript. WB; study design and subject recruitment.

MM; consulted on research design.

PMM; provided laboratory resources for carrying out data collection.

BSL; study research design, subject recruitment, data collection and analyses, manuscript development.

### Conflict of interest

The authors declare no competing interests. We wish to draw the attention of the Editor to the following facts which may be considered as potential conflicts of interest and to significant financial contributions to this work.

### References

- Acosta P, Santisbon E, Varon J. The use of positive end-expiratory pressure in mechanical ventilation. *Crit Care Clin.* 2007;23(2):251–261.
- Oliveira CC, Carrascosa CR, Borghi-Silva A, et al. Influence of respiratory pressure support on hemodynamics and exercise tolerance in patients with COPD. *Eur J Appl Physiol.* 2010;109(4):681–689. <https://doi.org/10.1007/s00421-010-1408-8>.
- Ubolsakka-Jones C, Pongpanit K, Boonsawat W, et al. Positive expiratory pressure breathing speeds recovery of postexercise dyspnea in chronic obstructive pulmonary disease. *Physiother Res Int.* 2019;24(1). <https://doi.org/10.1002/pri.1750>.
- Kim DH, Park JY, Yu J, et al. Positive end-expiratory pressure increases arterial oxygenation in elderly patients undergoing urological surgery using laryngeal mask airway in lithotomy position. *J Clin Monit Comput.* 2019. <https://doi.org/10.1007/s10877-019-00281-4>. Epub 2019/02/23, PubMed PMID: 30788809.
- Smith TC, Marini JJ. Impact of PEEP on lung mechanics and work of breathing in severe airflow obstruction. *J Appl Physiol.* 1988;65(4):1488–1499.
- Falke KJ, Pontoppidan H, Kumar A, et al. Ventilation with end-expiratory pressure in acute lung disease. *J Clin Invest.* 1972;51(9):2315–2323.
- Diaz O, Iglesia R, Ferrer M, et al. Effects of noninvasive ventilation on pulmonary gas exchange and hemodynamics during acute hypercapnic exacerbations of chronic obstructive pulmonary disease. *Am J Respir Crit Care Med.* 1997;156(6):1840–1845.

8. Kyroussis D, Polkey M, Hamnegard C, et al. Respiratory muscle activity in patients with COPD walking to exhaustion with and without pressure support. *Eur Respir J*. 2000;15(4):649–655.
9. Bannister RG, Cunningham DJC. The effects on the respiration and performance during exercise of adding oxygen to the inspired air. *J Physiol-London*. 1954;125(1):118–137. PubMed PMID: WOS:A1954UH83800008.
10. Welch HG. Effects of hypoxia and hyperoxia on human-performance. *Exerc Sport Sci Rev*. 1987;15:191–221. PubMed PMID: WOS:A1987H560900007.
11. Whipp BJ, Higgenbotham MB, Cobb FC. Estimating exercise stroke volume from asymptotic oxygen pulse in humans. *J Appl Physiol*. 1996;81(6):2674–2679. <https://doi.org/10.1152/jappl.1996.81.6.2674>. PubMed PMID: 9018521.
12. Borg GAV. Perceived exertion - note on history and methods. *Med Sci Sports Exerc*. 1973;5(2):90–93. PubMed PMID: WOS:A1973Q260100005.
13. Howley ET, Bassett DR, Welch HG. Criteria for maximal oxygen-uptake - review and commentary. *Med Sci Sports Exerc*. 1995;27(9):1292–1301. PubMed PMID: WOS:A1995RU23500009.
14. Beaver WL, Wasserman K, Whipp BJ. A new method for detecting anaerobic threshold by gas-exchange. *J Appl Physiol*. 1986;60(6):2020–2027. PubMed PMID: WOS:A1986C850400031.
15. Lakens D. Calculating and reporting effect sizes to facilitate cumulative science: a practical primer for t-tests and ANOVAs. *Front Psychol*. 2013;4:863. <https://doi.org/10.3389/fpsyg.2013.00863>. PubMed PMID: 24324449.
16. Nespoulet H, Rupp T, Bachasson D, et al. Positive expiratory pressure improves oxygenation in healthy subjects exposed to hypoxia. *PLoS One*. 2013;8(12). <https://doi.org/10.1371/journal.pone.0085219>.
17. Park HY, Park W, Lim K. Living high-training low for 21 days enhances exercise economy, hemodynamic function, and exercise performance of competitive runners. *J Sports Sci Med*. 2019;18(3):427–437. Epub 2019/08/21. PubMed PMID: 31427864; PubMed Central PMCID: PMC6683611.
18. Stray-Gundersen J, Chapman RF, Levine BD. "Living high-training low" altitude training improves sea level performance in male and female elite runners. *J Appl Physiol*. 2001;91(3):1113–1120. PubMed PMID: WOS:000170552800014.
19. Davis JA. Anaerobic threshold: review of the concept and directions for future research. *Med Sci Sports Exerc*. 1985;17(1):6–21. Epub 1985/02/01. PubMed PMID: 3884961.
20. Davis JA, Frank MH, Whipp BJ, et al. Anaerobic threshold alterations caused by endurance training in middle-aged men. *J Appl Physiol*. 1979;46(6):1039–1046.
21. Londeree BR. Effect of training on lactate/ventilatory thresholds: a meta-analysis. *Med Sci Sports Exerc*. 1997;29(6):837–843. <https://doi.org/10.1097/00005768-199706000-00016>. PubMed PMID: WOS:A1997XH57000016.
22. Nicolò A, Sacchetti M, Girardi M, et al. A comparison of different methods to analyse data collected during time-to-exhaustion tests. *Sport Sci Health*. 2019;15(3):667–679. <https://doi.org/10.1007/s11332-019-00585-7>.
23. Jeukendrup A, Saris WHM, Brouns F, et al. A new validated endurance performance test. *Med Sci Sports Exerc*. 1996;28(2):266–270. PubMed PMID: WOS:A1996TV61200017.
24. Amann M, Hopkins WG, Marcora SM. Similar sensitivity of time to exhaustion and time-trial time to changes in endurance. *Med Sci Sports Exerc*. 2008;40(3):574–578. PubMed PMID: WOS:000253289700025.
25. Bhambhani YN. Prediction of stroke volume during upper and lower-body exercise in men and women. *Arch Phys Med Rehabil*. 1995;76(8):713–718. [https://doi.org/10.1016/s0003-9993\(95\)80524-9](https://doi.org/10.1016/s0003-9993(95)80524-9).
26. Welnetz RJ. Altitude Mask Simulator. Google Patents; 1998.
27. Porcari JP, Probst L, Forrester K, et al. Effect of wearing the elevation training mask on aerobic capacity, lung function, and hematological variables. *J Sports Sci Med*. 2016;15(2):379.
28. Biggs NC, England BS, Turcotte NJ, et al. Effects of Simulated altitude on maximal oxygen uptake and inspiratory fitness. *IJES*. 2017;10(1):127.
29. Heimdal T, Rajan L, Vickery J, et al, eds. *Chronic Effects of an Elevation Training Mask on Aerobic Capacity, Anaerobic Endurance, and Pulmonary Function*. IJES; 2018.
30. Warren BG, Spaniol F, Bonnette R. The effects of an elevation training mask on vo2max of male reserve officers training corps cadets. *IJES*. 2017;10(1):37–43.