# **Journal of Visualized Experiments**

# Effects of Surgical Masks on Cardiopulmonary Function in Healthy Subjects --Manuscript Draft--

Article Type:	Invited Methods Article - JoVE Produced Video
Manuscript Number:	JoVE62121R2
Full Title:	Effects of Surgical Masks on Cardiopulmonary Function in Healthy Subjects
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1 TITLE: 2 Effects of Surgical Masks on Cardiopulmonary Function in Healthy Subjects 3 4 **AUTHORS AND AFFILIATIONS:** Qiang Lin<sup>1,2,3,4#</sup>, Mei Li<sup>1,2,4#</sup>, Qinyi Li<sup>1,2,4</sup>, Junjie Liang<sup>1,2,4</sup>, Weihao Liao<sup>1,2,4</sup>, Shijuan Lang<sup>1,2,4</sup>, Hongxin 5 Chen<sup>1,2,4</sup>, Yafei Wang<sup>5</sup>, Kun Tang<sup>1,2,4</sup>, Haining Ou<sup>1,2,3,4\*</sup>, Yuxin Zheng<sup>1,2,4\*</sup> 6 7 8 <sup>1</sup>Department of Rehabilitation Medicine, The Fifth Affiliated Hospital of Guangzhou Medical 9 University, Guangzhou, China 10 <sup>2</sup>The Rehabilitation Medicine Lab of Guangzhou Medical University, Guangzhou, China <sup>3</sup>Guangzhou Key Laboratory of Enhanced Recovery after Abdominal Surgery, The Fifth Affiliated 11 12 Hospital of Guangzhou Medical University, Guangzhou, China 13 <sup>4</sup>Department of Rehabilitation Therapy, Guangzhou Medical University, Guangzhou, China 14 <sup>5</sup>Department of Rehabilitation Medicine, The Sixth Affiliated Hospital of Sun Yat-sun University, 15 Guangzhou, China 16 17 \*These authors contributed equally. 18 \*These authors contributed equally. 19 20 **Corresponding authors:** 21 Yuxin Zheng (zhengyx@gzhmu.edu.cn) 22 Haining Ou (ouhaining@gzhmu.edu.cn) 23 24 **Email addresses of co-authors:** 25 Qiang Lin (gianglin0925@gzhmu.edu.cn) 26 (2016687004@gzhmu.edu.cn) Mei Li 27 (liginyi@stu.gzhmu.edu.cn) Qinyi Li (ljj88961@gzhmu.edu.cn) 28 Junjie Liang (liaoweihao@stu.gzhmu.edu.cn) 29 Weihao Liao 30 (langshijuan@stu.gzhmu.edu.cn) Shijuan Lang (chenhongxin@gzhmu.edu.cn) 31 Hongxin Chen (wangyf89@mail.sysu.edu.cn) 32 Yafei Wang (2432064404@gg.com) 33 **Kun Tang** 34 (zhengyx@gzhmu.edu.cn) Yuxin Zheng 35 Haining Ou (ouhaining@gzhmu.edu.cn) 36 37 **KEYWORDS:** 38 surgical mask, cardiopulmonary function, CPET, cardiopulmonary exercise test, aerobic exercise 39

#### **ABSTRACT:**

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We study the effect of surgical masks on cardiopulmonary function based on a cardiopulmonary exercise test (CPET). This study shows that surgical masks reduce cardiopulmonary exercise capacity and ventilation in healthy young subjects and wearing masks might affect aerobic exercise capacity more in female subjects than in male subjects.

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#### **INTRODUCTION:**

Wearing a face mask in public areas might impede the spread of an infectious disease by preventing both the inhalation of infectious droplets and their subsequent exhalation and dissemination<sup>1</sup>. Although the effect of reducing the risk of transmission of respiratory viruses remains controversial, wearing masks remains one of the major ways people in the community have chosen to prevent the spread of droplets among individuals in daily life<sup>2-4</sup>.

Different types of masks have different effects on increasing expiratory resistance and inspiratory resistance<sup>5</sup>. Meanwhile, during a respiratory disease pandemic, people (including healthy people and patients with cardiopulmonary diseases) might need to wear masks for a long time to perform daily activities. However, there are few studies on the effect of wearing a mask on cardiopulmonary function.

Cardiopulmonary exercise testing (CPET) is an important means of cardiovascular rehabilitation risk assessment by reflecting various parameters of the body's cardiopulmonary function during exercise with increasing load and is considered to be the gold standard for cardiopulmonary reserve testing<sup>2</sup>. We use CPET under different conditions (mask-on and mask-off) to study the changes in cardiopulmonary function parameters of healthy young subjects, to evaluate the interference of masks objectively and quantitatively on cardiorespiratory reserve and exercise endurance from a novel methodological perspective to guide the application of masks in particular respiratory infectious disease pandemic. Although FFP2/N95 has been suggested to be more efficacious than surgical masks at reducing exposure to viral infections, medical-surgical masks are more convenient and common to obtain and use than FFP2/N95 face masks. Thus, this study focuses only on the effects of medical surgical masks on cardiopulmonary function.

#### PROTOCOL:

The clinical project was approved by the Medical Ethics Association of the Fifth Affiliated Hospital of Guangzhou Medical University (No. KY01-2020-06-06) and has been registered at the China Clinical Trial Registration Center (No. ChiCTR2000033449) and entitled "The effects of masks on cardiopulmonary and lower limb function".

#### 1. Participant recruitment

1.1. Include subjects between 18 and 26 years old: who can pass the PAR-Q test<sup>6</sup>; are physically healthy; without professional sports training experience; and able to understand the experiment and voluntarily cooperate with the whole test process.

1.2. Exclude subjects: with cardiovascular diseases and respiratory diseases; with lower limb motor dysfunction caused by other diseases; who cannot cooperate with the experiment; and smokers<sup>7</sup>.

1.3. Obtain written informed consent from each subject before their participation.

- 1.4. Inform the subject that strenuous activities are prohibited 48 h before the test and during the test, and that food and beverages (except water) are not allowed 2 h before the test.
- 92 1.5. Collect the subjects' basic information (name, gender, date of birth, height, weight).
  - 1.6. Randomly allocate the subjects into two groups by SPSS generated digit table. Group 1 first received CPET in the mask-on condition followed by 48 h of washout, and then received CPET in the mask-off condition. Group 2 first received CPET in the mask-off condition followed by 48 h of washout, then received CPET in the mask-on condition.

# 2. Laboratory settings and equipment preparation

- 2.1. Set the laboratory temperature to 25 °C and equip with first aid equipment.
- 2.2. Calibrate the cardiopulmonary function analyzer to ensure the accuracy of the CPET test,
   including flow sensor calibration, indoor air calibration, gas analysis calibration, and respiratory
   rate calibration.
- NOTE: For gas analysis calibration, use 5% CO<sub>2</sub> and 16% O<sub>2</sub> concentrations and N<sub>2</sub> for balance.

# 3. Spirometry

- 3.1. Ask the subject to sit upright without leaning on the back of the chair, with their feet on the ground, but without tilting their feet. Ask them to keep their head at a natural level or slightly tilted upwards, but not to bend their head down or bend over.
- 3.2. Forced Vital Capacity (FVC) test: Ask the subject to breathe calmly for 5 s, inhale strongly, and then exhale strongly for 6 s. Finally, inhale back and keep breathing calmly. Perform the whole procedure under the guidance of a doctor or a formally trained exercise physiologist.
- 3.3. Maximum Voluntary Ventilation (MVV) test: Ask the subject to breathe calmly four or five times. Then repeat the breath continuously for 12 s or 15 s at the maximum breathing amplitude and the fastest breathing speed after the baseline with expiratory volume is stable (**Figure 1**).
- NOTE: If the subject does not perform well during static lung function test, the subject will be asked to perform the tests one more time after a 3-min rest. If the subject fails the test twice, exclude the subject.
  - 4. Cardiopulmonary exercise test (CPET)
- 129 4.1. Subject preparation for CPET130
- 4.1.1. Briefly introduce the process to the subject.

133 4.1.2. Scrape the body hair at the position of the electrocardiograph (ECG) electrodes (V1 to V6), and then use 75% alcohol to remove extra dander and grease.

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NOTE: V1 is the 4th intercostal space to the right of the sternum. V2 is the 4th intercostal space, to the left of the sternum, V3 is between V2 and V4 electrodes, V4 is the 5th intercostal space on the midclavicular line, V5 is the 5th intercostal space, on the anterior axillary line, and V6 is the 5th intercostal space on the left midaxillary line. Place limb electrodes for the arms in the subclavicular areas, and place limb electrodes for the legs placed on the trunk at the level of the bottom rib. The electrode placement should be lateral to avoid excessive movement artifact during cycling.

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4.1.3. Place the ECG electrodes and attach them to the 12-lead ECG wires.

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4.1.4. Fix the ECG machine to the chest using a strap (Figure 2).

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4.1.5. Choose a mask that fits the size of the subject's face and attach it firmly to the face to ensure that there is no gap between the mask and the face (**Figure 3**).

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NOTE: The tester could use their hand to press gently on the vest and lightly exhale to ensure that there is no gap.

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4.1.6. Fix the flow meter on the vent and then fix the K4 device onto the vest (**Figure 4**).

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156 4.1.7. Sit on the seat and adjust the height of the handlebars to a comfortable position for the subject.

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4.1.8. Grab the handlebar with both hands and step on the pedals with bilateral feet to ensure
 that the right knee joint bends with flexion at 30°.

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4.1.9. Place a blood pressure cuff on the upper-right arm for dynamic blood pressure recording. Place a finger pulse oxygen on the left index finger for dynamic recording of blood oxygen.

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4.1.10. Calculate the subject's exercise resistance/increased incremental per min (W) parameters and set the progressive resistance plan for the exercise phase<sup>8</sup>.

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NOTE: Exercise resistance (male) = [(height - age) \* 20 - (150 + 6 \* weight)] / 100 Exercise resistance (female) = [(height - age) \* 14 - (150 + 6 \* weight)] / 100

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4.2. CPET executing phase

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NOTE: Ask the subject not to speak during the whole procedure to prevent extra exhalation and inhalation during speaking, which might affect the accuracy of the cardiopulmonary data. Ask the subject to please raise their hand to indicate if there is any questions or discomfort that results in the test interruption.

4.2.1. Click on the **Start** button to activate cycle ergometer by tester.

4.2.2. Keep a static sitting posture for 2 min (Rest stage).

182 4.2.3. Start cycling for 2 min (Warm-up stage: resistance to 0 W, speed to 60 rpm).

4.2.4. Continue cycling until the time point when the subject could not maintain or show the ending signs (Ramp exercise stage: Incremental resistance, X watt resistance per min, 60 rpm).

NOTE: X watt resistance per min is based on the formulas in step 4.1.10.

4.2.5. Ask the subject to cycle for 3 min (cool-down stage: resistance to 0 W, speed to 40 rpm).

191 4.2.6. Keep the static sitting posture for 3 min for observation of vital signs (observation stage).

NOTE: Criteria for discontinuing are as follows: Subjects are encouraged to exercise to their maximum endurance or until the practitioners end the exercise due to symptoms such as ischemic ECG changes, complex ectopy, second or third degree heart block, fall in systolic pressure >20 mm Hg from the highest value during the test, hypertension (>250 mm Hg systolic; >120 mm Hg diastolic), severe desaturation (oxyhemoglobin saturation (SpO<sub>2</sub>)  $\leq$  80%), symptoms and signs of severe hypoxemia (sudden pallor, loss of coordination, mental confusion, dizziness, faintness), signs of respiratory failure, or exhaustion (Borg  $\geq$  17–18 points) failed maintaining the cycling speed (lower than 40 rpm). The test will be terminated immediately if the subjects show extreme verbal or physical fatigue<sup>7</sup>, which is lower than 40 rpm.

4.2.7. Remove data acquisition equipment, face mask, vest, and ECG electrodes.

5. CPET post testing

5.1. Use the Rating of Perceived Exertion (RPE) scale to measure physical activity intensity levels that are apparently related to the heart rate (HR) during exercise<sup>9,10</sup>.

5.2. Use the Borg's scale (6–20 scale) to evaluate exertion of resistance training <sup>11</sup>. A score of 6 represents resting activity with no effort and a score of 20 represents exhaustive exercise.

6. Statistical analysis

215 6.1. Analyze the data using SPSS software (version 25) and the methodology referenced in the previous study<sup>12</sup>.

218 6.2. Present the parametric data as mean and standard deviation (SD) if normally distributed 219 or median if not.

221 6.3. Allocate the subjects into male or female groups for statistical analysis, respectively.

6.4. Use the paired t-test to compare the differences of CPET parameters between subjects in the mask-on condition and mask-off condition. Statistical significance is P < 0.05.

#### **REPRESENTATIVE RESULTS:**

Ten subjects (five males and five females) from the Department of Rehabilitation Medicine at Guangzhou Medical University were recruited in this pilot study. The participants had similar baseline characteristics, such as age (mean age: male  $21.00 \pm 1.58$  years; female  $21.20 \pm 0.45$  years) and physical fitness [sports activity and body mass index (BMI)]. There were no significant differences in age, height, or BMI between the male and female groups. Moreover, for the spirometry, the female group showed lower FVC, lowered forced expiratory volume in 1 s (FEV1), lower MVV, and lowered peak expiratory flow (PEF) compared with the male group (**Table 1**).

The results of CPET under different conditions (mask-on and mask-off) are depicted in **Table 2**. For exercise tolerance and cardiac function, compared to the mask-off condition, both male and female groups during the mask-on condition showed a significant decrease in anaerobic threshold per kilogram, i.e.,  $VO_2/kg$  (LT), and oxygen pulse, i.e.,  $O_2/HR$  (peak), whereas no significant differences in oxygen uptake related to work rate, i.e.,  $\Delta VO_2/\Delta WR$  and HR (rest). Moreover, the male group also showed a significant decrease in HR (rest), and the female group showed a significant decrease in peak oxygen uptake per kilogram, i.e.,  $VO_2/kg$  (peak) during the mask-on condition. For ventilatory function, compared to mask-off condition, both male and female groups during mask-on condition showed a significant decrease in tidal volume, i.e., VT (peak), but no differences were found in the breathing reserve in percentage, i.e., BR%. For gas exchange, compared with the mask-off condition, both male and female groups during the mask-on condition showed a significant decrease in the ventilation, i.e.,  $V_E$  (peak), but no differences were found in  $V_E/VCO_2$ . For the total CPET performance, both male and female groups showed no difference in Load<sub>max</sub>, RPE scale, and Borg's scale.

# FIGURE AND TABLE LEGENDS:

Figure 1: Diagram for spirometry.

Figure 2: The ECG electrode settings.

Figure 3: Fitting of mask. (A) shows the mask-off condition. (B) shows the mask-on condition.

Figure 4: Diagram for CPET settings.

260 Table 1: Baseline characteristics and spirometry results.

Table 2: Results of the CPET in healthy young subjects wearing a surgical mask (mask-on) and not wearing a surgical mask (mask-off) depicted as mean ± standard deviation.

#### **DISCUSSION:**

CPET provides valuable insights into the comprehensive functions of cardiovascular, ventilation, and skeletal muscle systems<sup>13</sup>. We proposed a CPET protocol on mask-on and mask-off conditions to explore the effect of the surgical mask on the cardiopulmonary function in healthy young subjects.

The design of this protocol was based on three main points. First, we recruited young healthy college students as the subjects for the study due to relatively high intensity of CPET in mask-on condition and similar physical fitness. Second, the subjects should be allocated into a male group and a female group considering the gender as the major factor in pulmonary function based on the spirometry results and previous research<sup>14</sup>. Third, we randomized the order of conditions (mask-on and mask-off) during CPET to eliminate the potential bias brought by sequencing.

Although the recruited subjects showed no significant difference on subjective sensation between two condition CPETs (mask- on and mask-off condition) based on the RPE scale and Borg's scale, there were some objective cardiopulmonary parameters that were significantly decreased by wearing a mask, such as in  $VO_2/kg$  (LT),  $O_2/HR$  (peak), VT (peak), and VE (peak). The decrease in  $VO_2/kg$  (LT) suggests that wearing a mask might reduce the ability of muscle mitochondria to use oxygen, thereby affecting exercise capacity. The decrease in  $O_2/HR$  (peak) indicated decreased cardiac output. The increased  $V_E$  (peak) suggested wearing a mask might affect carbon dioxide emissions. All these affected parameters indicate that the subjects with cardiopulmonary diseases might have a higher risk when they do the aerobic exercise wearing a surgical mask. Moreover, gender differences might also be a factor in the effects of masks on cardiopulmonary function. For example, just the female group showed a significant decrease in  $VO_2/kg$  (peak) after wearing a mask. Due to  $VO_2/kg$  (peak) as the major parameter of aerobic exercise capacity evaluation, the result indicated that the influence of wearing a mask might be more obvious for females, especially during vigorous exercise.

This study has two main limitations. First, the sample size was small, although we recruited subjects with similar physical baseline characteristics and the representative results already showed some significant differences. Second, this study only recruited healthy young subjects, although we ensured maximum consistency in this pilot study. In future research, we could recruit more subjects in different age stratification and combined with cardiopulmonary diseases to extend our protocol to the wide population. Such work would help guide mask-wearing during daily life, especially during the epidemic stage of respiratory infectious diseases.

#### **ACKNOWLEDGMENTS:**

This study was supported by National Natural Science Foundation for Young Scientists of China (No.81902281); General Guidance Project of Guangzhou Health and Family Planning Commission (No.20191A0011091 and 20201A011108), Guangdong Provincial Department of Education (No. 2019KQNCX119) and Guangzhou Key Laboratory Fund (No.201905010004). This study also thanks Lixin Zhang, Peilin Ruan, Kaihang Ji, and Gulifeiya Tuerxun from Guangzhou Medical University for data collection.

#### DISCLOSURES:

310 The authors have nothing to disclose.

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Table 1. Baseline characteristics and spirometry results.

Parameters	Unit	Male group (n=5)	Female group (n=5)	P value
Age	years	21.00±1.58	21.20±0.45	0.792
Height	cm	$172.60\pm4.45$	$157.00\pm3.80$	< 0.001
Weight	kg	59.40±3.50	49.10±2.49	0.001
BMI	$kg/m^2$	$19.94 \pm 0.80$	19.91±0.41	0.955
Spirometry				
FVC	L	$4.43\pm0.26$	$3.13\pm0.31$	< 0.001
FEV1	L	$3.70\pm0.24$	$2.78\pm0.23$	< 0.001
MVV	L/min	131.78±12.42	76.38±13.57	< 0.001
PEF	L/s	8.96±1.11	5.95±1.41	0.060

Notes: Significant results are indicated in bold. FVC, forced vital capacity; FEV1, forced expiratory volume in 1 s; MVV, maximum voluntary ventilation. PEF, peak expiratory flow; L, liter; s, second.

Table 2 Results of the CEPT in health young subjects wearing surgical  $\max$  (Mask 1) and not wearing surgical  $\max$  (Mask 0) depicted as mean  $\pm$ standard deviation.

Parameters	Unit	Male group		Female group			
rarameters	Oint	Mask-off	Mask-on	P value	Mask-off	Mask-on	P value
Exercise toleran	ce and cardiac fu	ınction					
VO <sub>2</sub> /kg (peak)	(mL/min)/kg	36.21±3.8	$28.46\pm4.96$	0.063	$26.86 \pm 4.86$	22.96±5.45	0.002
VO <sub>2</sub> /kg (LT)	(mL/min)/kg	22.66±2.26	19.74±2.23	< 0.001	$18.48\pm2.89$	$14.28\pm2.6$	0.026
O <sub>2</sub> /HR (peak)	ratio	12.14±0.63	10.02±1.7	0.028	$7.96\pm0.87$	6.9±1.15	0.004
$\triangle VO_2/\triangle WR$	mL/(min*W)	8.96±0.3	7.52±1.4	0.083	8.66±0.51	7.86±1.17	0.217
HR (rest)	bpm	85.2±16.08	77.6±7.09	0.244	84±10.56	83.4±5.94	1.000
HR (peak)	bpm	177.6±10.5	170.6±11.33	0.007	162.6±17.67	162.6±21.72	1.000
Ventilatory fund	ction						
VT (peak)	L/min	2.23±0.31	1.9±0.4	0.004	1.33±0.28	1.21±0.28	0.018
BR%	%	50.2±8.14	56.6±10.53	0.086	53.6±8.91	57.8±10.94	0.086
Gas exchange							
V <sub>E</sub> /VCO <sub>2</sub>	ratio	28.64±3.42	30.44±5.26	0.379	32.34±3.63	31.54±4.3	0.616
V <sub>E</sub> (peak)	L	74±13.36	62.6±15.35	0.022	51.8±13.35	43.22±11.72	0.042
CPET performa	nce						
Load <sub>max</sub>							
$Load_{max}(LT)$	watts	98.2±18.38	102±11.81	0.438	56.8±11.48	50.8±9.96	0.104
Load <sub>max</sub> (RC)	watts	155.6±22.47	159±24.37	0.223	87.8±18.47	86.2±19.6	0.816
Load <sub>max</sub> (Peak)	) watts	187±28.15	184.8±26.81	0.604	107.6±29.25	105.6±30	0.116
RPE scale	scores	17.8±0.84	17±1.73	0.371	17.4±0.89	17.2±1.3	1.000
Borg's scale	scores	4.2±0.84	4.8±1.64	0.468	4.8±0.45	$4.8 \pm 0.84$	1.000

Notes: Significant results are indicated in bold.  $VO_2/kg$  (peak), peak oxygen uptake per kilogram;  $VO_2/kg$  (LT), anaerobic threshold per kilogram;  $O_2/HR$ , oxygen pulse;  $\triangle VO_2/\triangle WR$ , oxygen uptake related to work rate; BR%, breathing reserve in percentage;  $V_E$ , ventilation; VT, tidal volume; bpm, beat per minute. RPE scalse, Rating of Perceived Exertion scale; L, liter; min, minute.

Click here to access/download; Table; Table 2-R1.xlsx ±

Name of Material/ Equipment	Company	<b>Catalog Number</b>	Comments/Description
Cardiopulmonary test system Cycle for CPET	COSMED Srl - Italy COSMED Srl - Italy		Pulmonary Function Equipment cycle ergometer 100 P w/BP
Eectrocardiograph Mask	COSMED Srl - Italy COSMED Srl - Italy	~	12-Channel ECG Street Test Unit V2 Mask
Software Surgical masks	COSMED Srl - Italy	PFT SUITE	PC Software

RE JoVE62121-R1: Manuscript Revision Required

Dear Editor,

Greetings!

Thanks for the review of this manuscript (ID: JoVE62121) and gave us the second opportunity to address editor's comments. All points in the editor's comments have been addressed in the manuscript. Please also see the response to editor's comments.

We would like to submit the revised version for your consideration to be published soon.

Thank you so much!

Yours sincerely,

# **Editorial comments:**

1. Figure 3B: Is this supposed to be a mask-on condition as in the Figure?

Response to the comments: Thank you for the comment. We corrected the "mask-on" notes for Figure 3.

2. References: Reference 7 and 9 are the same. Please revise.

Response to the comments: Thank you for the comment. We deleted the duplicated reference.



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