

Modified full-face snorkeling mask for thoracic surgery and otolaryngology surgical use: comfort and usability assessment during the COVID-19 pandemic

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ABSTRACT

Background: *A worldwide personal protection equipment (PPE) shortage has emerged during COVID-19 pandemic, contributing to the high incidence of SARS-CoV-2 infection among health care providers. To address this lack of PPE, new solutions have been researched. Among those, full-face snorkeling masks demonstrated to be an interesting option. Among surgical specialties otolaryngologists and thoracic surgeons are at high risk of infection, due to the close contact with airway secretions. Objectives:* *We tested the comfort and usability of a modified full-face snorkeling mask (Ocean ReefMask Aria QR+) as a protective device for otolaryngologic and thoracic surgeries. Methods:* *The mask was customized with a 3D-printed adaptor supporting many industrial filter types, including FFP3 and heat and moisture exchangers (HME). We evaluated surgical performances of the mask, both subjectively, with a questionnaire filled in by the surgeons, as well as objectively, monitoring transcutaneous PCO₂ and PO₂ values of surgeons during surgical procedures. Results:* *The modified full-face snorkeling mask was tested during 9 otolaryngologic and 15 thoracic surgery procedures. The device demonstrated very good overall vision quality with some limitations regarding lateral vision and almost no difficulties in usability. Water condensation into the mask was absent in almost every case. Both PO₂ and PCO₂ parameters remained within normal ranges during every procedure. Discussion:* *The modified full-face snorkeling mask can be an innovative PPE. In the current COVID-19 pandemic scenario, the worldwide shortage of protective masks and goggles may exploit this ready-to-use and low-cost solution, especially for high-risk surgical procedures.*

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INTRODUCTION

On the 11th of February 2020 the Director-General of the WHO announced the emergence of a new disease named COVID-19, caused by a novel coronavirus, SARS-CoV-2 (21). Although the initial phase of the outbreak, since December 2019, was limited to China and East-Asia, it soon spread to other countries and continents, being characterized a month later, on the 11th of March, as a pandemic (20). On the 20th of February the first local case of COVID-19, without any connection to China was identified in Codogno, and in the following weeks Italy became the first epicenter of the infection in Europe. Immediately, the healthcare system and personnel were overloaded with rising numbers of critical patients, massively increasing the demand for personal protective equipment (PPE), however, without the required supply. Similar situations followed in other highly developed countries (15). Indeed, a worldwide shortage of PPEs, especially in the hospital setting, is contributing to the spread of the SARS-CoV-2 disease and thinning out the health-care providers (HCPs) population available to face the pandemic. The safety of HCPs who keep critical infrastructures operating is paramount. According to the official online data survey, on the 6th of May 2020, of the 212,532 Italian people infected, more than 10%, 23,718, are healthcare providers (8). It is clear that this category, among others, presents higher risk, and more efforts are needed in order to reduce the risk of infection of this population.

Viral transmission occurs mainly through droplets spread among people in close contact. However, other residual transmission routes are being investigated, including the oro - fecal route and the airborne route. Of particular interest for the protection of HCPs, currently there is an intense debate in the scientific world concerning the possibility of transmission through aerosol, with accumulating evidence that in particular circumstances a close-range airborne transmission could be probable, like during aerosol generating procedures (AGP), or with assisting patients in congregate settings or non-ventilated (1, 4, 5, 11, 17, 19). These concerns come from the evidence that part of the droplets containing the virus decrease their dimension up to 5 mi-

croons or less with water evaporation: losing weight, these particles can be carried by air and enhance virus spread especially in indoor environments (18). Therefore, extreme caution should be taken when dealing with airways interventions, especially for aerosol-generating procedures. Accordingly, otolaryngologists and thoracic surgeons, among other health care providers, could be at a higher risk of exposure. Both otolaryngology and thoracic surgeries face different kinds of at-risk situations. During urgent procedures, surgeons often have to operate patients with unknown SARS-CoV-2 infection status. On the other hand, elective surgeries like tracheotomies and thoracic drainages have become increasingly requested for SARS-CoV-2 positive patients admitted in the intensive care units, to facilitate the restoration of spontaneous breathing after prolonged intubation. In this scenario, concerns have been expressed regarding the safety of airway surgery with high risk of aerosolization, in fact during these interventions HCPs may not be adequately protected by standard masks and eye protections (16). It is also important to underline that both otolaryngologists and thoracic surgeons face every day trans-nasal and trans-oral endoscopic examinations (i.e. pharyngo-laryngoscopy, bronchoscopy, etc.) which expose this category to higher risk as well. In light of this, adequate prevention of the risk should be adopted, starting from the assumption that every patient is potentially infected with SARS-CoV-2 until proven otherwise.

Especially for low- and middle-income countries, which presumably are more exposed to the risk of lack of adequate supply of PPEs, including FFP2/FFP3/N95/N99 masks, new solutions are required, such as regenerated and cost-affordable reusable gear (6, 12). Many governments adopted extraordinary measures to address this critical shortage of PPEs, encouraging industrial reconversion to produce medical equipment (9).

As respirators are growing in use while supplies are limited, strategies have been proposed to extend their use. To suit limited supplies, techniques for extended use, reuse and sterilization of PPE are considered relevant, as well as the design of new pioneering PPEs, especially in a emergency period. The masks commonly employed nowadays (includ-

ing N95 respirator) are filtered by static electricity, nevertheless, they can be damaged, especially after being cleaned or worn for a long time; therefore, this type of mask is intended to be single-use (10). In this regard, properly engineered and validated reusable masks may protect workers during such epidemics, particularly to prevent outbreaks in health-care settings.

In this respect, an appealing option may be to use already widely available gear readapted to fulfill current standards of safety: this solution would immediately provide ready-to-use PPE even for low- and middle-income countries. With this aim, several industrial manufactures have already started to modify their products. Recently, there was an increasing interest in adapting snorkeling masks for medical use. This enthusiasm is due to the unique structure of these masks that allows a complete seal of the operator's face, combining at the same time face shield with a nose/mouth protection. Furthermore, the native assembly of these masks establishes a one-way air inlet through the top of the mask, where the mouthpiece is usually located. The mouthpiece can be replaced with a 3D printed specific adaptors on which industrial FFP3 filters can be tightened. The mask is, by design, completely waterproof and can go through sterilization processes. All these characteristics, together with the low price and wide availability, make these masks an attractive and ready-

to-use option during the COVID-19 outbreak. However, in many countries, safety certifications of snorkeling masks as PPEs are still undergoing the required evaluations.

Our study is focused on the proposal of a modified full-face snorkeling mask as a protective equipment against SARS-CoV-2 virus infection: we tested the surgical feasibility of these customized devices during operative procedures for otolaryngologic and thoracic surgery.

METHODS

From March to April 2020, a modified full-face snorkeling mask (Ocean Reef mod. Aria QR+) was tested during surgical procedures, as an alternative to standard PPE previously employed (FFP3 mask, goggles/ face shields), at the Otolaryngology – Head and Neck Surgery and Thoracic Surgery Departments of IRCCS Ospedale Policlinico San Martino, Genoa, Italy. The mask (Figure 1 A – 1 B) was modified with a patent-pending adapter (APA-Aria protection ORO30100 40 mm 1/7") (Figure 2): this device exploits the standard connection EN148-1 to attach the mask to air-filters and provides a built-in unidirectional valve. The adapter supports many industrial filter types, including FFP3 filters, and even heat and moisture exchangers (HME) filters, which are commonly used in the respirators connec-



Figure 1 - A) OceanReef Aria QR+ mask with adapter and industrial FFP3 filter. **B)** Surgeon Wearing OceanReef Aria QR+ mask

tors in the intensive care units (RD40-22 adaptor is required for the latter, Figure 3). All the procedures were carried out with a FFP3 filter. The modified full-face snorkeling mask is still under evaluation for definitive National Institute for Insurance against Accidents at Work (INAIL) certification as PPE. The mask has a flat frontal polycarbonate



Figure 2 - 3D Printed Adapters to connect industrial FFP3 filters



Figure 3 - 3D Printed Adapters to connect heat and moisture exchangers (HME) filters

glass with enhanced optical characteristics that allows a wide vision. Face sealing is promoted by the intrinsic waterproof design and by silicone frame that adheres to the operator's face. Both the mask and the adaptor are fully sterilizable with a standard procedure at 105 °C. Air filtration and purification are guaranteed by the FFP3 filter: during the inspiratory phase, the air enters only through the filter on the top of the mask, while during the expiratory phase the air exits through the inferior part of the mask, by the chin valve. At this site, an additional filter can be plugged to clean the outgoing air, and this would be strongly recommended in surgical operations in order not to contaminate the sterile field through exhaled air. Objective evaluation of breathing efficacy was carried out by monitoring transcutaneous oximetry $tcPO_2$ and transcutaneous carbon dioxide tension ($tcPCO_2$) during surgical procedures. A probe (SenTec V - Sign System, SenTec AG - Therwil, Basel, Switzerland) was placed on the pinna of the operator, and measures were recorded continuously. At the end of every surgery, each operator was asked to fill a questionnaire to subjectively assess the surgical feasibility of the device (Table 1). Information was collected using a Visual Analogue Scale (VAS). Difficulty in breathing, difficulty of use, lateral and central vision alterations, optical distortion, glasses and mask fogging were rated from 1 (no impact on surgery) to 10 (impossibility to proceed with surgery). Additionally, mask-wearing time was recorded as lesser than 1 hour, 1-2 hours, 3-4 hours, and more than 4 hours. Responses were anonymously collected.

As the device has not yet obtained standard safe authorizations in our country, it was used only for procedures on SARS-CoV-2 negative patients, preoperatively confirmed by two consecutive nasopharyngeal swabs.

Institutional review board approval was not requested as no patients were involved in the study.

RESULTS

The modified full-face snorkeling mask was tested during 24 procedures, 9 otolaryngologic procedures, and 15 thoracic surgery procedures (Table 2). In the Thoracic Surgery Departments, the following

procedures were performed: 4 video-assisted thoracic surgery lobectomies, 3 open surgery lobectomies with bronchial sleeve resections, and 8 pleural drainages were surgically placed. In the Otolaryn-

Table 1 - Evaluation questionnaire

Question	Format
Email	text
Operator's Name	text
Date of surgery	data
Type of filter	FFP3/HME
Type of procedure	text
Type of anaesthesia	text
Time of surgery	text
Use eyeglasses	yes/no
Difficulty of use	1-10
Comfort	1-10
Central vision alteration	1-10
Lateral vision alteration	1-10
Optical distortion	1-10
Mask Fogging	Text
tcPCO ₂ min	Text
tcPCO ₂ max	Text
tcPO ₂ , % during surgery	Text
Difficulty in breath	Text

Table 2 - Number and type of surgical procedures

Number of surgical procedures	No.=24
ENT surgery procedures	9
Thoracic surgery procedures	15
Type of anaesthesia	
General anaesthesia	16
Local anaesthesia	6
Mild sedation	2
Type of procedures	
Video-assisted thoracic surgery lobectomies	4
Lobectomies with bronchial sleeve resections	3
Pleural drainage	8
Tracheotomy	9

gology – Head and Neck Surgery Department, 9 surgical tracheotomies were carried out in the operating room. Sixty-seven % of procedures were performed under general anaesthesia, 25% under local anaesthesia, and 8% under mild sedation. Mask-wearing time was less than 1 hour in 50% of procedures, between 1 and 2 hours in 21%, between 2 and 3 hours in 8%, between 3 and 4 hours in 8% and more than 4 hours in 13%. The use of glasses was reported in 29% of the procedures: glasses fogging parameter showed a mean value of 1.1 out of 10, resulting in no impact on surgery. However, wearing glasses under the mask is not always possible due to glasses encumbrance.

All interventions were carried out wearing the mask without interruptions. None of the operators reported any problem with mask suitability or any adverse event. Table 3 shows the results of operators' subjective feedback. The modified full-face snorkeling mask demonstrated very good overall vision quality with some limitations regarding lateral vision with an acceptable optical distortion and almost no difficulties in usability. Water condensation into the mask was absent in all surgeries. Objective measures of respiratory parameters are listed in Table 4. Both PO₂ and PCO₂ parameters remained within normal ranges during every procedure.

Table 3 - Operators' feedback

Subjective Parameters	Mean	Standard Deviation
Mask Fogging	1.04	0.20
Difficulty of use	1.54	0.59
Central vision alteration	1.67	0.76
Lateral vision alteration	3.71	0.95
Optical distortion	2.04	0.90
Difficulty in breathing	1.21	0.41

Table 4 - Objective measures of respiratory parameters (%)

Objective parameters	Mean	Standard Deviation
tcPCO ₂ min	34.86	0.72
tcPCO ₂ max	37.00	0.63
tcPO ₂ min	96.33	1.17

DISCUSSION

In the COVID-19 era, the protection of health-care workers, as well as other frontline workers, is of critical importance: HCPs assisting suspected or confirmed COVID-19 patients, particularly in areas where AGPs are performed, must be supplied with full respiratory protection, including filtering face-piece respirators, as well as eye protection. However, soon after the beginning of the pandemic, supply chains of PPEs were overwhelmed, creating a shortage in available disposable devices. Strategies to optimize resources in order to prioritize the use of respirators reserving them for the most exposed workers, as well as recommendations to limited re-use and extended use of PPEs were implemented. Safe decontamination methods are being evaluated in order to reprocess used PPEs, however questions remain on the number of cycle that can be sustained and impacts on filter effectiveness must also be taken into account (3). Several institutions and experts in the fields of industrial hygiene and occupational health have suggested that reusable respirators, such as elastomeric respirators or powered air purifying respirators (PAPRs), designed for other applications such as construction and industrial settings, might offer a more beneficial approach to protect workers against biological hazards (2, 13). In this perspective, the development of new reusable PPE is mandatory. New solutions that combine adequate protection levels and comfortable usability are required for HCPs, especially in the surgical field. In this respect, the waterproof structure of full-face snorkeling masks allows a long-lasting complete sealing of the operator's face without losing filtering power. Compared to surgical goggles or face shields, these devices offer the important advantage of avoiding condensation, as reported by almost every participant to our survey, which is crucial during surgery.

One of the most critical aspects concerning the protection of the respiratory tract in HCPs, relating the use of N95 or N99 respirators, regards the gaps in the fit-test.

Indeed, HCPs often do not undergo regular fit tests, although this measure is strongly enforced in IPC programs (14). This aspect become critical in a pandemic period like the current one, both in terms

of occupational health and safety and in terms of time constraints to perform large scale tests in a short time-scale. In particular, proper use of respiratory protection by HCPs requires a comprehensive program that includes the training of HCPs on the appropriate use of respirators, including donning (putting on) and doffing (removing) them, limitations on their use, and maintenance. These issues, if not adequately addressed, might represent critical aspects and pitfalls in protection programs. The development of innovative PPE, could tackle some shortcomings and could be of great importance, particularly in a crisis context. For the intended purpose, leakage tests of snorkeling masks are carried out by manufacturers underwater. Although this aspect still requires studies in the medical sector, the seal testing of snorkeling masks could perform better than using PPE when not performing a fit test. Moreover, the availability of a unique protective device for eyes, nose and mouth could reduce the risk of self-contamination when donning and doffing PPE. In addition, many HCPs see the availability of having a single piece, reusable, eye, nose and mouth covering protection device as a useful asset (7). Properly designed and validated reusable masks should tailored to the specific procedure (i.e AGPs) and task in order to provide the most appropriate level of protection.

Our tests demonstrated that full-face snorkeling masks allow normal breathing even during long-duration surgeries. Notably, gas exchange values remained within normal ranges during all the procedures. On these bases, other surgical disciplines may particularly benefit from these devices, especially those with a high risk of viral particle aerosolization such as Maxillo-facial surgery, anesthesiology and dentistry.

However, these masks have some drawbacks. Firstly, their design should be adapted to facilitate surgeons wearing glasses, especially surgical magnifying goggles, which are widely used in otolaryngology surgery. Another issue that should be addressed is the improvement of the inferior visual field. To date, the surgical microscope cannot be used with the currently available models of full-face snorkeling masks due to an increased optical distance between the eye and the ocular. Moreover, the maximum

number of sterilization cycles in which a mask can be submitted to, without losing its sealing characteristics, is under investigation. Another limitation of the present study is the lack of an actual filter efficacy and pressure drop measurement. Full validation of this category of devices as a PPE would require further analysis in this regard.

In conclusion, our study demonstrates that the modified full-face snorkeling mask may be a personal protective device particularly suitable for surgical use. In the current COVID-19 pandemic scenario, the worldwide shortage of protective masks and goggles may favour this ready-to-use and low-cost solution, especially for high-risk surgical procedures.

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