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ORIGINAL

An innovative, reusable and sustainable face-seal device to improve protection efficacy of surgical masks against COVID-19

Un dispositivo de sellado facial innovador, reutilizable y sostenible para mejorar la eficacia de protección de las mascarillas quirúrgicas contra COVID-19

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Abstract

The outbreak of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS- CoV-2) pandemic has had a direct impact on the global health system, causing an alarming shortage of Personal Protective Equipment (PPE). Recent studies have shown that a significant number of healthcare professionals have been contaminated by the COVID-19 at their workplace due to the lack of appropriate PPE. Consequently, the PEE requirements have changed, making the use of filtering face-piece respirators (FFR) N95 and NK95 (FFP2 or FFP3, respectively) mandatory in place of the surgical masks previously used by healthcare professionals. Applying individualized face-seal devices in surgical masks, such as a thermoplastic resin ring, may significantly avoid inhalation of unfiltered air. Besides reducing leakage around the mask, which could convert surgical masks into PPE dual masks due to the high percentage of face-seal, it would allow a bidirectional protection for both healthcare professionals and patients, thus becoming a medical device. The polylactic acid (corn starch) thermoplastic resin ring is the device proposed here to be used in order to decrease leakage of potentially contaminated air. The use of poly lactic acid is of particular interest due to the fact that is a material appropriate for sanitary use, reusable and biodegradable. Therefore, healthcare professionals and organizations can maintain clinical activity in a cost-efficient manner whilst improving clinical safety.

Keywords: COVID-19, Personal Protective Equipment, surgical masks.

Resumen

El brote de la pandemia del síndrome respiratorio agudo severo coronavirus 2 (SARS CoV-2) ha tenido un impacto directo en el sistema de salud mundial, provocando una alarmante escasez de Equipos de Protección Personal (EPP). Estudios recientes han demostrado que un número significativo de profesionales de la salud han sido contaminados por la COVID-19 en su lugar de trabajo debido a la falta de EPP apropiado. En consecuencia, los requisitos de PEE han cambiado, haciendo obligatorio el uso de respiradores con máscara filtrante (FFR) N95 o NK95 (FFP2 o FFP3, respectivamente) en lugar de las mascarillas quirúrgicas previamente utilizadas por los profesionales sanitarios. La aplicación de dispositivos de sellado facial individualizados en máscaras quirúrgicas, como un anillo de resina termoplástica, puede evitar significativamente la inhalación de aire sin filtrar, además de reducir las fugas alrededor de la máscara, lo que podría convertir las máscaras quirúrgicas en máscaras duales de EPP debido al alto porcentaje de sellado facial, lo que permitiría una protección bidireccional tanto para los profesionales sanitarios como para los pacientes, convirtiéndose así en un dispositivo médico. El anillo de resina termoplástica de ácido poliláctico (almidón de maíz) es el dispositivo propuesto aquí para ser utilizado, con el fin de disminuir la fuga de aire potencialmente contaminado. El uso de ácido poliláctico es de especial interés debido a que es un material apropiado para uso sanitario, reutilizable y biodegradable. Por tanto, los profesionales sanitarios y las organizaciones pueden mantener una actividad de forma rentable, al tiempo que mejora la seguridad clínica.

Palabras clave: COVID-19, equipos de protección personal, mascarilla quirúrgica.

Introduction

The outbreak of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS- CoV-2) pandemic has had a direct impact on the global health system, causing an alarming shortage of Personal Protective Equipment (PPE)[1,2]. This shortage, together with an increasing demand, has resulted in exaggerated costs and a global depletion of mask reserves[3]. Health care professionals belong to a highly exposed group who are particularly vulnerable to COVID-19[4], being classified by the Occupational Safe and Health Administration (OSHA) as "very high risk" of infection based on exposure[5]. Consequently, the PEE requirements have changed, making the use of filtering face-piece respirators (FFR) N95 and NK95 (FFP2 or FFP3, respectively) mandatory in place of the surgical masks[6] previously used by health care professionals.

Among the most common transmission routes for COVID-19, the most critical one for healthcare professionals occurs when working in direct contact with secretions or oropharyngeal exudates of a patient. In such conditions, the quantitative presence of COVID-19 is proportional to the viral load of the infected person, who can transmit the virus to the environment through Flügge drops expelled via expiration, speech or cough. In turn, these exhaled particles represent a potential mode of infection when inhaled by another person present in such environment[7]. Since there is strong evidence showing that severe acute respiratory distress syndrome virus (SARS) spreads through aerosol transmission, it can be assumed that COVID-19 can also be spread by the aerosols generated by high-speed engines with water cooling systems used during dental and medical procedures[9,10].

Recent studies have shown that a significant number of healthcare professionals have been contaminated by the COVID-19 at their workplace due to a lack of appropriate PPE[11]. More specifically, the surgical masks commonly used by these professionals do not ensure the required protection, mainly because of an inadequate face-seal. In turn, FFR are now being recommended by the governing health administrations because of the suitable face-seal they provide[12]. However, a study showed that only 13.6% of individuals achieve an optimal face-seal when using FFR[13], due to the non-individualized, standardized character of manufacturing.

To date, there are no studies published comparing the efficacy of surgical masks versus FFR regarding infection by COVID-19. Besides, a recent systematic review and meta-analysis failed in demonstrating the superiority of FFR in comparison with surgical masks during the influenza virus pandemic[14].

Respiratory Protection Equipment

In reference to the Respiratory Protection Equipment (RPE) that must be used by health care professionals, and which are considered half masks based on UNE Standards and European Regulations, there are three categories of masks:

1. Surgical masks: Half respiratory masks which are considered a medical device and can be classified as Type II and Type IIR, regulated by the UNE-EN14683: 2019 + AC: 2019[13] standard or its equivalent in the USA. NIOSH-21CFR878.4040 standard. Bacterial Filtration Efficiency (BFE) % tests (TYPE II> 98, TYPE IIR> 98) are performed.
2. Filtering face-piece respirators (FFR): Half respiratory masks which are considered PPE and not medical devices, classified as FFP2 and FFP3, and regulated by the UNE-EN149:2001+A1: 2010[14] standard or its equivalent in the USA. NIOSH-42CFR84 standard N95 OR NK95. These masks are not submitted to biological tests.
3. Dual Masks: Half respiratory masks that possess the technical and functional properties of both surgical masks and FFR, complying with both standards. The aim of theses masks is to provide a bidirectional protection for both the healthcare professional and the patient, taking into account what is stated in the Decrees Regulation 1591/2009[15] and 1407/1992[16].

Hypothesis

Applying individualized face-seal devices in surgical masks, such as a thermoplastic resin ring, may significantly avoid inhalation of unfiltered air. Besides reducing leakage around the mask, which could convert surgical masks into PPE dual masks due to a high percentage of face-seal, it would allow a bidirectional protection for both healthcare professionals and patients, and thus becoming a medical device. The face-seal device would be an improvement compared to the FFR, which are manufactured using standardized sizes and designed with cephalometric patterns that in many cases differ from the morphogenetic typology of the individual.

Hypothesis Evaluation

The polylactic acid (corn starch) thermoplastic resin ring is the device proposed to be used in order to decrease the leakage of potentially contaminated air. Polylactic acid is appropriate for sanitary use, reusable, biodegradable and allows for disinfection with 0.1% sodium hypochlorite[21]. The thermoplastic ring can be adapted by digital pressure on the facial surface of each individual using a surgical

mask, after pre-heating it by immersing the device in warm water at 60ºC for 1-2 min. When it cools down to room temperature, it hardens after 15-20 seconds and maintains the exact anatomical shape of the individual's facial surface, and thus it is personalized to the user. Since it is reusable, if it is heated again it loses its shape and can be readapted to the facial surface of the same or another individual after disinfection. Thus, the device can guarantee a face-seal in a surgical mask, since it is well-adapted to the peripheral area by means of a controlled elastic traction on the individual's facial surface.

In order to control the pressure used in the thermoplastic device, an adjustable safety dynamometer (Medicaline Orthodontics, 2779ML1, Castellón, Spain) will be used, with a bilateral traction control and measuring the tension exerted on the peripheral hooks of the face-seal device. Then, this same tension can be used in all individuals, determined by comfort and safety of the elastic system at 4.5 N.

Consequences of the hypothesis and discussion

Contrary to FFR (FPP2 and FFP3), the surgical masks' fabric is the only one that is submitted to controls against biological risks, as stated in the Standards UNE-EN14683: 2019 + AC: 2019 (13), UNE-EN149: 2001 + A1: 2010[14] and Regulation (EU) 2020/403[17]. Therefore, in order to provide a safe use, FFR should be covered by a surgical mask when using it, although this would not comply with the provisions of the breathability tests. However, this aspect would not be compromised when using the surgical masks with the face-seal device proposed here, since these tests are inherent to the characteristics of the filtering fabric that were submitted to bidirectional tests against biological agents.

Thus, this innovative device offers an improvement in clinical safety for both patients and health care professionals, by providing a new and optimal option of respiratory protection against COVID-19 infection. Moreover, it means that surgical masks, which have a reduced cost and great availability, can still be used together with the face-seal device proposed. Therefore, health care professionals and organizations can maintain their clinical activity in a cost-efficient manner whilst improving clinical safety.

Figure 1: Representative image of the surgical mask sealed with the thermoplastic resin Ring Face-Seal device, where 1: thermoplastic resin ring; 2: area of peripheral sealed; 3: thermoplastic resin ring traction hook; 4: elastic; 5: surgical mask.

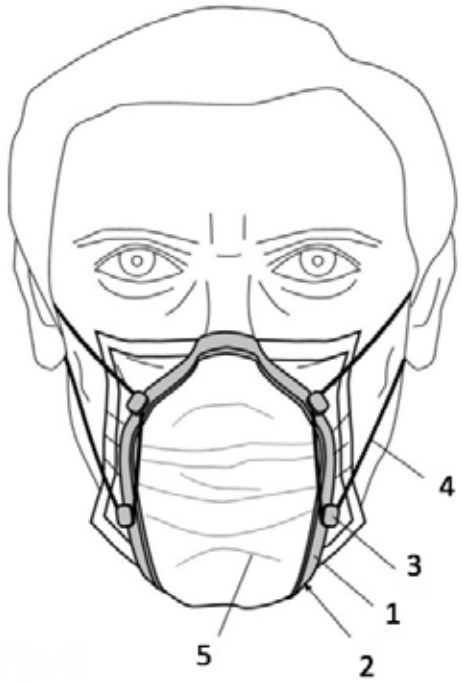


Figure 2: Representative image of the frontal view of the Thermoplastic resin ring, where 1: Thermoplastic resin ring; 2: area of peripheral seal; 3: thermoplastic resine ring traction hook.

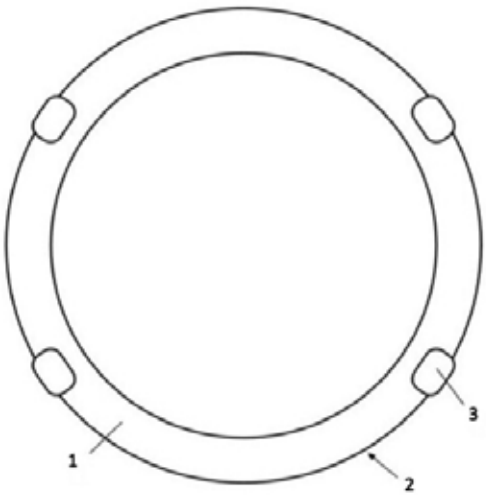
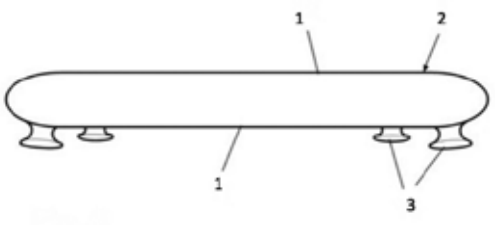


Figure 3: Representative image of the lateral view of the thermoplastic resin ring, where 1: thermoplastic resin ring 2: area of peripheral seal; 3: thermoplastic resine ring traction hook.



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