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ORIGINAL PAPER

# The use of a surgical helmet system with a high-efficiency particulate air filter as possible protection equipment during the coronavirus disease 2019 pandemic: a double-blinded randomized control study

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## Abstract

**Purpose** The rapid spread of coronavirus disease 2019 (COVID-19) has increased the use of personal protective equipment. The purpose of this study was to investigate whether a commercially available sterile surgical helmet system (SSHS) can be considered protective against COVID-19 and therefore safe for use.

**Methods** A double-blinded randomized controlled study was performed to investigate the efficacy of the *ViVi*® SSHS with a high-efficiency particulate air filter called *HFD Hood* (*THI*, Total Healthcare Innovation GmbH, Feistritz im Rosental, Austria) to protect against respiratory droplets. Forty recruited participants were divided into two different groups. The SSHS was tested using a validated qualitative test for respirator masks through saccharin or placebo solutions based on random allocation into two cohorts. Saccharin droplets are a validated surrogated marker for any elements of viral size, such as coronaviruses. A positive report of sweet taste after saccharin exposure was suggestive of *ViVi*® SSHS inefficacy in protection against droplets.

**Results** One participant out of 21 (4.8%) reported positive for taste within the placebo cohort, while five out of 19 (26.3%) reported positive for taste within the saccharin cohort upon testing. Two out of 21 (9.5%) participants reported positive for taste within the placebo cohort, and two out of 19 (10.5%) reported positive for taste within the saccharin cohort upon retesting. There were no statistically significant differences between the saccharin and placebo groups in either the test or retest measurements ($p = 0.085$ and $p = 1.000$, respectively).

**Conclusions** This study demonstrates that the *ViVi*® SSHS equipped with *HFD Hood* protects against respiratory droplets, increasing protection against several microorganisms, including the virus that causes COVID-19, allowing surgeons to carry out procedures on COVID-positive patients in a more comfortable and safer way.

**Keywords** SARS-CoV-2 · Personal protective equipment · Surgical mask · Filter · Droplets · Aerosol generating procedures

## Introduction

Since its first presentation in 2020, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-caused pandemic continues to cause unprecedented impact worldwide [1–6]. The rapid spread of SARS-CoV-2, the aggressive infectious nature and airborne transmissibility of the virus, and the rise of viral variants have increased the use of personal protective equipment (PPE) [4, 7], leading to the development of international guidelines, which are still developing [8–10]. Thus, as the global population radically changed its lifestyle, all healthcare workers began implementing solutions to safely deal with this virus. Surgeons tried to improve the protections used in their daily working conditions, such as using a sterile surgical helmet system (SSHS), commonly used in orthopedic surgery to protect both the surgeon and the patient, to reduce microorganism spread to the surgical site, and to protect the surgeon from contamination resulting from blood splashes [11, 12]. However, these systems have not been validated for use with aerosol contact and have not been recommended for this purpose by manufacturers [13, 14]. It was recently demonstrated that many SSHSs and their filters were not protective

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against COVID-19 [15], so SSHSs need to be used alongside respirator masks. Thus, custom SSHSs have been developed, adopting modified devices with high-efficiency particulate air filtration equal to or better than that of the recommended N-95 masks [16–18].

The purpose of this study was to investigate whether a SSHS equipped with a new type of hood made with a special four-layer filter can be considered protective against coronavirus disease 2019 (COVID-19).

## Materials and methods

### Study design and sample size

A double-blinded randomized controlled study was performed to investigate the efficacy of the *ViVi*® SSHS equipped with an *HFD Hood* (*THI*, Total Healthcare Innovation GmbH, Feistritz im Rosental, Austria [19]) in providing protection against respiratory droplets and thus COVID-19.

The *ViVi*® SSHS is a medical device and a PPE certificate class II infection protection system [19], consisting of a helmet equipped with a breathable self-donning patented visor shape, namely, the *ViVi*® *High Filtration Hood* (Fig. 1A–B), which consists of three parts. The first part is a lens of clear polycarbonate; the second part is light blue-colored trilaminate material made from a polypropylene outer layer and breathable film, which is a viral barrier in compliance with ASTM F1670, 1671, and EN 13795 requirements and with Association for the Advancement of Medical Instrumentation (AAMI) class 4; and the third part is white-colored (on the top), *spunbond-meltblown-spunbond* (SMS) point-bond material that acts as a filter, giving high protection against bacteria and viruses. The *ViVi*® *Helmet* is equipped with two inflow- and outflow-powered fans to provide an equal pressure suit and avoid airflow interference, which might spread particles before surgical gowning.

A touchless system, avoiding possible contamination of the sterile hood, and an exhausted air expulsion mechanism, filtering air before release in the operating room, are integrated in the *ViVi*® SSHS.

The SSHS was tested using a validated qualitative test for respirator masks: participants were exposed to an aerosolized saccharin solution while they wore the helmet, and they were asked if they perceived a sweet taste in their mouth. A negative taste result indicated the success of the equipment in protecting against COVID-19 [20, 21]. This aerosolized protocol followed standards set by international guidelines [22, 23]. Participants satisfying the inclusion criteria were (1) aged greater than 18 years old, (2) healthy individuals, and (3) without a history of tasting and smelling comorbidities. A one-degree-of-freedom a priori power analysis was performed for two-per-two contingency tables, which equated to a sample size giving a calculated power value greater than 0.8, and forty candidates were finally enrolled.

### Sensitivity evaluation

In the USA, fit testing is a required component of any Occupational Safety and Health Administration (OSHA) written respiratory protection program in which workers are required to wear tight-fitting respirators. The 3M™'s qualitative fit test kit (3M, St. Paul, MN, USA) used in the present study

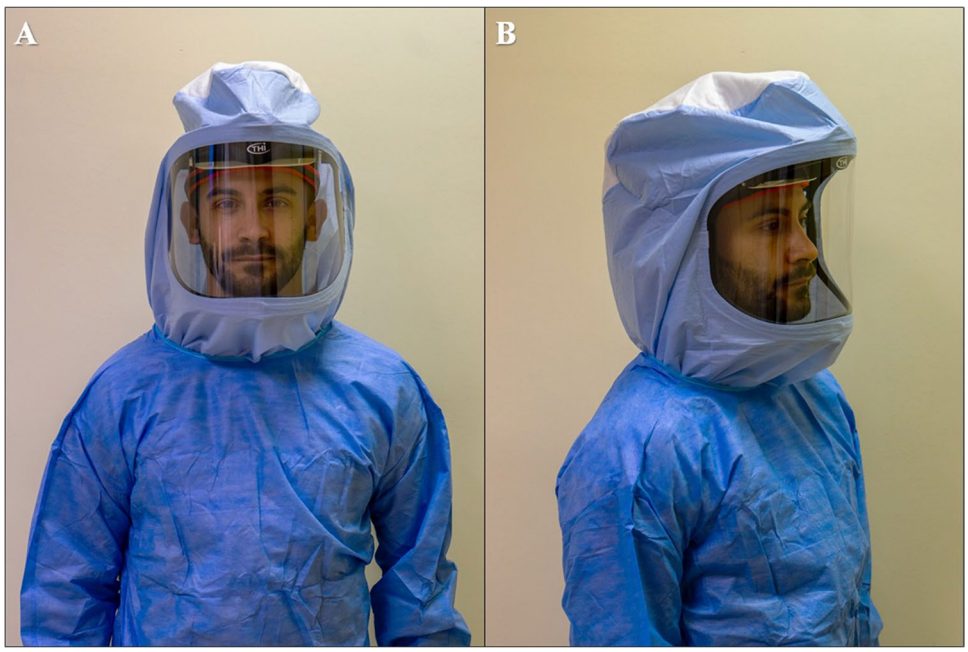


**Fig. 1** The *ViVi*® *High Filtration Hood* (*THI*, Total Healthcare Innovation GmbH, Feistritz im Rosental, Austria) in frontal (**A**) and right oblique (**B**) views

meets the OSHA's performance criteria for fit testing for respirators, and the FT-10 kit contains the solutions specified by the Saccharin Solution Aerosol Protocol [24]. Following these guidelines and instructions [24, 25], enrolled participants were given 15 minutes to clear the taste from smoke, chewing gum, food, and beverages; thereafter, they drank a cup of mineral water and wore the 3M™ Qualitative Hood Test Apparatus (Fig. 2A–B). A saccharin taste sensitivity test was performed using the 3M™ FT-10 Sensitivity Test Kit on all candidates: a maximum of 30 puffs of a sodium saccharin solution were administered through a hole made in the anterior part of the visor (Fig. 3), and the test ended as soon as the subject detected a sweet taste. The corresponding number of puffs was registered. This screening pretest evaluates the saccharin taste threshold, allowing investigators to stratify candidates into three groups: individuals sensitive to saccharin (1) between one and ten puffs, (2) between 11 and 20, and (3) between 21 and 30. Candidates who required 30 puffs to report positive taste at the sensitivity pretest were excluded from the study [25].

## Test procedure

Participants were subsequently randomized using a computer-generated random allocation: 21 were assigned to the placebo group and were exposed to a nebulized normal saline solution, and 19 were exposed to a sodium saccharin solution. Both solutions were blinded to the examiner and participants. Each test was undertaken over a maximum of 17 minutes according to guidelines and instructions [26]. In detail, after another 15 minutes of taste clearing, participants underwent the 3M™ FT-10 Fit Test using the *ViVi*®

**Fig. 3** A right profile view of the sensitivity test performed using the 3M™ FT-10 Sensitivity Test Kit (3M, St. Paul, MN, USA) and throughout any puffs of a sodium saccharin solution administered through a hole made in the anterior part of the visor of the 3M™ Qualitative Hood Test Apparatus (3M, St. Paul, MN, USA)

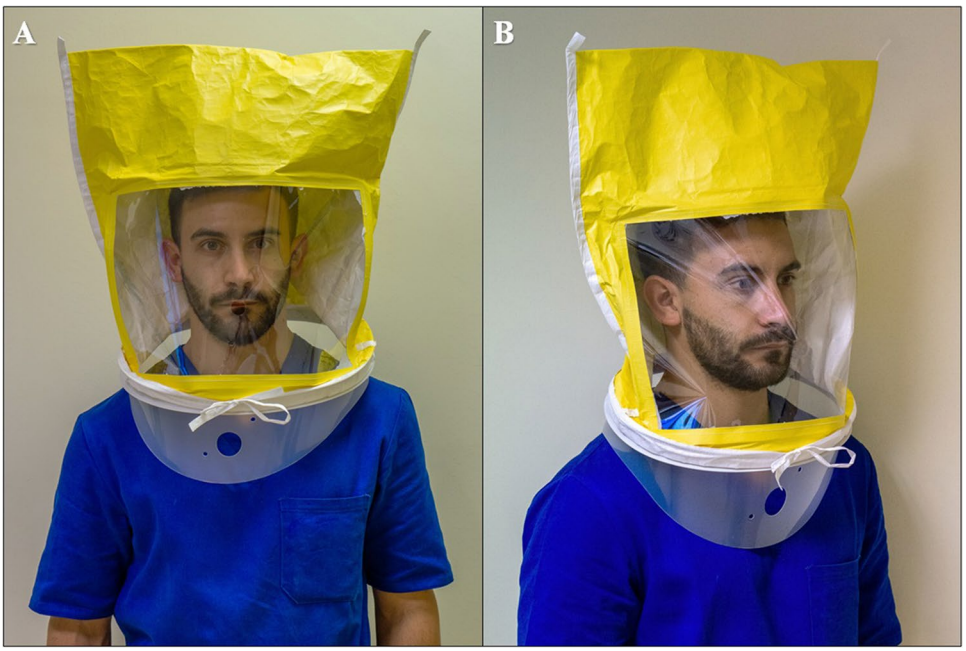


**Fig. 2** The 3M™ Qualitative Hood Test Apparatus (3M, St. Paul, MN, USA) in frontal (**A**) and right oblique (**B**) views

SSHS, which was placed over the top, allowing the atmosphere around the helmet to be controlled. The fan power was always set at the highest level provided by the device. Solutions were nebulized 10 to 15 cm from the inflow filter system (Fig. 4). At the beginning of the test, ten puffs were administered to those who were sensitive between one and ten puffs at the pretest, 20 puffs to those between 11 and 20, and 30 puffs to those between 21 and 30. Every 30 s until the end of the test, half the number of squeezes used at the start of the test was administered to maintain the concentration of solution during the test. While wearing the *ViVi*® SSHS, candidates were asked to perform the following exercises, changing them each minute: (1) normal breathing, (2) deep breathing, regularly, (3) turning head side to side, (4) nodding head, (5) talking, (6) bending at waist, and (7) normal breathing again. As per guidelines, a positive sweet taste after saccharin exposure was considered a failure of the helmet system to protect against the droplets generated by nebulizers. When a participant experienced a sweet taste during any phase, the test ended. After another 15 minutes of taste clearing, candidates underwent a retest, with the same methodology previously described and with the same solution to which they were subjected during the test.

**Fig. 4** A right profile view of the 3M™ FT-10 Fit Test (3M, St. Paul, MN, USA) using the *ViVi*® (*THI*, Total Healthcare Innovation GmbH, Feistritz im Rosental, Austria) SSHS: solutions were nebulized 10 to 15 cm from the inflow filter system

## Statistical analysis

All data were reported to one-decimal accuracy. The mean, standard deviation, and range were noted for continuous variables; counts were recorded for the categorical variables. McNemar's test was performed to test homogeneity in the two consecutive examinations. Two-tailed chi-squared Fisher's exact test was performed to evaluate significant differences between values, and Phi ($r_{\varphi}$) correlation values, assessing the strength of any association, were reported. IBM SPSS Statistics software (version 26, IBM Corp., Armonk, NY, USA) and G*Power (version 3.1.9.2, Institut für Experimentelle Psychologie, Heinrich Heine Universität, Düsseldorf, Germany) were used for database construction and statistical analysis. A $p$ value less than 0.05 was considered significant.

## Results

The demographics of the included participants are reported in Table 1. No participant exceeded the sensitivity test limit of 30 puffs, and thus, all enrolled individuals completed the study. As shown in Tables 2 and 3, one out of 21 (4.8%) and 5 out of 19 (26.3%) reported positive for taste within the placebo and saccharin cohorts, respectively, in the fit test. Two out of 21 (9.5%) reported positive for taste within the placebo cohort, and two out of 19 (10.5%) reported positive for taste within the saccharin cohort at the retest.

An exact McNemar's test was used to determine that there were no statistically significant differences in the proportion of positive tasting patients at the test and retest measurements within either the placebo or the saccharin cohorts ($p = 1.000$ and $p = 0.250$, respectively). Therefore, there were no influencing factors that could affect the two consecutive tests in the same population, making them comparable. Chi-square Fisher's exact test demonstrated no statistically

**Table 1** Baseline characteristics of included participants

| | Placebo group (No. = 21) | Saccharin group (No. = 19) |
|---|---|---|
| Gender | | |
| Male | 14 (66.7%) | 5 (26.3%) |
| Female | 7 (33.3%) | 14 (73.7%) |
| Age (years) | 41.1 ± 9.7 (28–62) | 35.9 ± 13.3 (25–65) |
| Smoke habits | 8 (38.1%) | 3 (15.8%) |

*No* number

Dichotomous variables are reported as number (percentage) and nominal variables as mean ± standard deviation

**Table 2** Characteristics of placebo solution cohort's tested participants

| | Gender | Age | Smoke habits | Sensitivity test | Test tasting | Re-test tasting |
|---|---|---|---|---|---|---|
| | | Years | | Puffs to positivity | | |
| 1 | F | 37 | − | 6 | − | − |
| 2 | M | 29 | − | 5 | − | − |
| 3 | M | 31 | − | 4 | − | − |
| 4 | M | 32 | − | 6 | − | − |
| 5 | F | 28 | − | 5 | − | − |
| 6 | M | 49 | + | 7 | − | − |
| 7 | M | 44 | − | 12 | − | − |
| 8 | F | 50 | + | 11 | − | + |
| 9 | M | 41 | + | 7 | − | − |
| 10 | M | 47 | + | 2 | − | − |
| 11 | M | 57 | − | 9 | − | − |
| 12 | M | 62 | − | 3 | − | − |
| 13 | F | 46 | − | 6 | − | − |
| 14 | M | 28 | − | 5 | − | − |
| 15 | M | 33 | − | 4 | − | − |
| 16 | F | 52 | − | 5 | − | − |
| 17 | M | 35 | + | 17 | − | − |
| 18 | M | 34 | − | 1 | − | − |
| 19 | F | 46 | + | 4 | − | − |
| 20 | F | 42 | + | 8 | − | − |
| 21 | M | 40 | + | 7 | + | + |

*F* female, *M* male

**Table 3** Characteristics of saccharin solution cohort's tested participants

| | Gender | Age | Smoke habits | Sensitivity test | Test tasting | Re-test tasting |
|---|---|---|---|---|---|---|
| | | Years | | Puffs to positivity | | |
| 1 | F | 28 | − | 6 | − | − |
| 2 | M | 28 | + | 6 | − | − |
| 3 | F | 28 | − | 4 | − | − |
| 4 | F | 27 | − | 5 | − | − |
| 5 | M | 29 | − | 6 | − | − |
| 6 | M | 65 | − | 5 | − | − |
| 7 | F | 34 | − | 2 | + | + |
| 8 | F | 56 | − | 6 | + | − |
| 9 | F | 60 | − | 19 | − | − |
| 10 | F | 37 | + | 5 | − | − |
| 11 | F | 34 | − | 5 | − | − |
| 12 | M | 28 | + | 5 | − | − |
| 13 | F | 60 | − | 3 | − | − |
| 14 | M | 32 | − | 6 | − | − |
| 15 | F | 27 | − | 3 | − | − |
| 16 | F | 26 | − | 4 | + | + |
| 17 | F | 31 | − | 2 | + | − |
| 18 | F | 25 | − | 5 | + | − |
| 19 | F | 28 | − | 4 | − | − |

*F* female, *M* male

significant differences between the saccharin and placebo groups in either the test or retest measurements ($p = 0.085$, $r_{\varphi} = -0.301$ and $p = 1.000$, $r_{\varphi} = -0.017$, respectively).

## Discussion

The purpose of this study was to verify whether the saccharin in the 3M™ FT-10 Fit Test as a validated surrogated marker for any element of viral size, such as SARS-CoV-2 [15, 26, 27], passes into the *ViVi*® SSHS. We demonstrated that the *ViVi*® SSHS equipped with a *HFD Hood* should actually protect against nebulized droplets resembling microorganisms such as respiratory viruses, including the SARS-CoV-2, allowing physicians to deal with surgery on COVID-positive patients in a more comfortable and safer way.

In the current study, no statistically significant differences between the saccharin and placebo groups were found in either the test or retest measurements. This, the *ViVi*® SSHS was effective in preventing the spread of respiratory droplets, such as the nebulized saccharin solution, into the helmet.

The International Consensus Group advocated the use of SSHSs in joint arthroplasty surgery [13]. During the COVID-19 pandemic, new growing interest has been directed toward protection against virus transmission [28, 29] and the possibility of using common orthopaedic surgical devices against respiratory viruses. In 2004, Derrick and Gomersall found that the *Stryker T4* (Stryker Instruments, Kalamazoo, MI, USA) and *Stackhouse Freedomaire* (Stackhouse Incorporated, Palm Springs, CA, USA) helmet-hood filters alone were not sufficient to protect against SARS transmission [30]. A recent study using the 3 M™ Fit Test demonstrated that the *Stryker Flyte* surgical helmet filtering system (Stryker Corporation, Kalamazoo, MI, USA) did not protect against aerosol-borne particulates [15]. The need for safer equipment for the operating room to prevent surgical infections for both surgeons and patients, especially in the first period of the COVID-19 pandemic era, resulted in custom-made SSHSs and then the development of new filter systems. Other medical disciplines used modified SSHSs to fight infection risks, with satisfying results [31]. The modified breathing system filters could provide filtration protection against aerosol and airborne pathogens in mechanical ventilator systems [16–18]. The helmet filter systems usually consist of an AAMI (The Association for the Advancement of Medical Instrumentation) level 3 or 4 hood [14, 18]. Class 4 devices provide the highest level of protection against pathogens, but this classification is based on direct contact with a liquid [12]. The SSHS used in the present study is equipped with a hood made of AAMI level 4 front material, which is a viral barrier, and a special four-layer filter both outside and inside the hood, giving protection against body fluids and providing a high respiratory viral barrier. In addition, the *ViVi*® *Helmet* is equipped with filtered inflow and outflow powered fans, which avoid airflow interference, especially at the highest level of power and indrawing, as set in our study. This system avoids over-pressurization in the suits, which may spread particles before surgical gowning, and the exhausted air expulsion mechanism filters the air before release into the operating room, with advantages for the protection of both surgeons and patients [19].

The findings of the current study could raise questions about recent guidelines developed by the International Consensus Group on elective orthopedic surgery following the COVID-19 pandemic that suggest not using surgical helmets as primary protection against airborne diseases [13].

This study has some strengths: first, the randomized double-blinded nature of this study with saccharin and control groups; second, the appropriate study set up, with a priori power analysis certifying an appropriate effect size and $\beta$ value, and an accurate data analysis to ensure statistical significance; and third, saccharin nebulized molecules and subsequent taste as a marker for aerosol-borne viruses is a validated and safe method of testing.

Some limitations should be considered: (1) the length of surgical procedures is variable, and the filters could undergo saturation over time; (2) it is not certain that any splashes of body fluids or inert substances can reduce or overcome the filtering power of these systems (e.g., the white-colored part of the hood), exposing the surgeon to an infectious risk; and (3) despite validated methods of evaluating the tested SSHS in the setting of a respiratory droplet-spread viral pandemic, it is not possible to completely guarantee total protection against COVID-19. In this light, further laboratory and clinical studies are required to delineate whether surgical helmets with filtering systems could protect for longer times and during higher exposure to particulate flow aerosol substances and surgical gases. The COVID-19 pandemic era has shined harsh light on the vulnerabilities of personal protective equipment, and an expansion of the indication for SSHS use either for emergency or elective surgery could be considered at present.

## Conclusions

This double-blinded randomized controlled study demonstrates that the *ViVi*® SSHS equipped with a *HFD Hood* could increase protection against several microorganisms, including SARS-CoV-2 causing COVID-19, allowing surgeons to carry out procedures on COVID-positive patients in a more comfortable and safer way.

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**Author contribution** Each author fulfills each of the authorship requirements.

G. Gasparini: conceived and coordinated the study, participated in the design of the research and in the acquisition and interpretation of data, and drafted the final version of the manuscript, as submitted.

D. Castioni: participated in the design of the study and in the acquisition and interpretation of data, performed the statistical analysis, and drafted the final version of the manuscript.

G. Spina: participated in the acquisition and interpretation of data.

F. Familiari: participated in the interpretation of data and drafted the manuscript.

O Galasso: participated in the interpretation of data and critically revised the manuscript.

M. Mercurio: conceived the study and critically revised the final version of the manuscript, as submitted.

All authors read and approved the final manuscript.

**Data availability** This study did not undertake a health-related clinical or surgical intervention on people, as defined by the ICMJE, since the use of a surrogate marker instead: registration in a public trial registry does not apply.

## Declarations

**Ethics approval** The study protocol was approved by the local ethics committee, and the research was conducted in compliance with the Declaration of Helsinki.

**Consent to participate** Informed consent was obtained from all individual participants included in the study.

**Consent for publication** All participants gave informed consent for publication of the study.

**Conflict of interest** The authors declare no competing interests.

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