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REVIEW ARTICLE

The effectiveness and efficacy of respiratory protective equipment (RPE) in dentistry and other health care settings: a systematic review

Lakshman Perera Samaranayake[a], Kausar Sadia Fakhruddin[b], Hien Chi Ngo[c], Jeffrey Wen Wei Chang[a] and Chamila Panduwawala[b,d]

[a]Faculty of Dentistry, The University of Hong Kong, Hong Kong Special Administrative Region, China; [b]Department of Preventive and Restorative Dentistry, University of Sharjah, Sharjah, UAE; [c]School of Dentistry, University of Western Australia, Perth, Australia; [d]Department Oral and Craniofacial Health Sciences, University of Sharjah, Sharjah, UAE

ABSTRACT

Objective: The global pandemic of coronavirus disease-19, caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), is the latest hazard facing healthcare workers (HCW) including dental care workers (DCW). It is clear that the major mode of SARS-CoV-2 transmission is the airborne route, through inhalation of virus-infested aerosols and droplets. Several respiratory protection equipment (RPE), including masks, face shields/visors, and respirators, are available to obviate facial and conjunctival contamination by microbes. However, as their barrier value against microbial inhalation has not been evaluated, we systematically reviewed the data on the effectiveness and efficacy of face-masks and respirators, including protective eyewear, with particular emphasis on dental healthcare.

Material and methods: PubMed, MEDLINE, the Cochrane Library, and Embase databases were searched between 01January 1990 and 15 May 2020.

Results: Of 310 identified English language records, 21 were included as per eligibility criteria. In clinical terms, wearing layered, face-fitting masks/respirators and protective-eyewear can limit the spread of infection among HCWs. Specifically, combined interventions such as a face mask and a face shield, better resist bioaerosol inhalation than either alone. The prolonged and over-extended use of surgical masks compromise their effectiveness.

Conclusions: In general, RPE is effective as a barrier protection against aerosolized microbes in healthcare settings. But their filtration efficacy is compromised by the (i) inhalant particle size, (ii) airflow dynamics, (iii) mask-fit factor, (iv) period of wear, (v) 'wetness' of the masks, and (vi) their fabrication quality. The macro-data presented here should inform policy formulation on RPE wear amongst HCWs.

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Facial protection; aerosols; dentistry; efficacy

Introduction

The critical importance of personal protective equipment (PPE) that safeguards both patients and healthcare workers (HCW) against infectious hazards is universally accepted. These have come rescued HCW and saved thousands of lives during the various epidemics such as the Ebola and Zika virus crises, and the pandemic of influenza that occurred in the last century. Currently, the world is experiencing a pandemic of coronavirus disease-19 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Due to the lack of efficacious and effective therapeutic medications and a reliable vaccine, as yet, the current pandemic control solely relies on public health interventions such as social distancing, quarantine and contact tracing facilitated by wearing of PPE. Personal protective equipment includes respiratory protective equipment (RPE), such as face masks and face shields [1]. PPE plays a pivotal role in limiting COVID-19 spread as the primary mode of SARS-CoV-2 transmission is the airborne route, through inhalation of virus-infested aerosols and droplets from infected individuals both in the community and clinical settings. In hospital settings, for instance, Wang et al. [2] reported the heavy viral load in the sputum and bronchoalveolar specimens of COVID-19 patients, and others [3] have noted that critical care nursing staff are more prone to contracting the infection during patient intubation procedures, particularly in the absence of RPE.

Several interventional procedures are well-known to aerosolize respiratory secretions in healthcare settings [4–6]. In dentistry, viral particles may possibly be aerosolized by the high-speed handpiece and the add-on air jet, air/water syringes, ultrasonic scaling, and air polishing procedures [4]. Interestingly, in an early laboratory study, Miller et al. [7] noted that aerosolized microbes produced by powered dental drills and periodontal scalers may well spread to up to 200 cm distance from the operative focus. More recently, van Doremalen and colleagues [8] observed that the SARS-CoV-2 once aerosolized could be entrained in ambient air for up to 3 h particularly in the absence of good ventilation [8].

CONTACT Lakshman Perera Samaranayake lakshman@hku.hk Faculty of Dentistry, The University of Hong Kong, Hong Kong Special Administrative Region, China; Kausar Fakhruddin kfakhruddin@sharjah.ac.ae Department of Preventive and Restorative Dentistry, University of Sharjah, Sharjah, UAE

They stated that due to the relatively high viability and robustness of SARS-CoV-2, the infectious virions might either be suspended in bio-aerosols, or sequestrated within shed inocula for several days, on solid surfaces such as steel and cardboard [8].

The foregoing clearly indicates that DHCWs are continuously exposed to the airborne threat of viral particles in clinic settings and the need to protect themselves and minimise exposure not only by curtailing aerosol-generating procedures, but also by averting inhalation of viral-infested aerosols. There are several types of PPE for the latter purpose, as well as for eye protection and these include surgical face masks, face shields, filtering facepiece respirators (FFRs-non powered), and powered air-purifying respirators.

The significant advantages and the disadvantages of these equipments have been outlined in several reports in the literature but not in a systematic manner. Here, we systematically review, the protective efficacy of RPE, such as surgical facemasks, N95 respirators, FFRs and face shields. We also evaluate the effectiveness of protective eyewear (face shields, visors, goggles) in shielding trans-ocular entry of bioaerosols in healthcare settings. In terms of protective barrier efficacy, available data on the fit factor of masks and eyewear, and the mask-wearing period were also reviewed.

Methods

Data sources

We (LPS, KSF, and JWWC) performed an electronic data search of English language manuscripts using PubMed, MEDLINE, the Cochrane Library, and Embase databases. Published clinical reports between 01 January 1990 and 15 May 2020, were accessed. We identified a total of 21 studies comprising, surgical facemask versus N95 respirators (6 studies), protective eyewear [5], mask-fit factor [7], and the wearing period of surgical facemasks versus N95 respirators [3].

Search terms

A single search string was structured for each of the databases which included the following (PICO) search terms.

Population

healthcare worker, HCW, healthcare workers, HCWs, healthcare worker, health- care workers, healthcare professional, healthcare professionals, healthcare staff, healthcare practitioners, healthcare professionals, dentist, nurse, doctor, staff, dental assistant, healthcare personnel, healthcare personnel, healthcare personnel.

Comparison/intervention: face masks versus respirators

facemask, face mask, surgical facemasks, medical mask, medical-grade masks, medical facemask, medical face masks, surgical masks, surgical facemask, surgical face mask, N95, respirator, respiratory protection, respiratory protective device, respiratory protective devices, personal protective equipment, PPE, aerosol face protection, airborne precaution, aerosol protection

Intervention – protective eyewear

face shields, face shield, eye protection, goggles, prescription glasses, eye shield, surgical telescopic loupes, surgical loupes, visors, droplets, personal protective equipment, PPE, aerosol face protection, airborne precaution, aerosol protection

Outcome

influenza, parainfluenza, flu, pandemic influenza, SARS, influenza-like illness, ILI, respiratory syncytial viruses, infection control, communicable disease transmission, infectious disease transmission, cross-infection, cross-infection, infection, respiratory infection, respiratory tract infection, acute respiratory infection, upper respiratory tract infection, epidemic, pandemic, common cold, flu, healthcare-associated infection, healthcare-associated infection, health-care-associated infection, health care-associated infections.

Study selection

Inclusion criteria

a. *Study design*: randomised control trials (RCTs), laboratory-controlled -simulated model design, case-control, cross-sectional studies
b. *Population:* Healthcare workers (medical doctors, surgeons, nurses, dentist, allied medical personnel)
c. *Intervention*: RPE (surgical facemasks versus N95 respirators) and protective eyewear (goggles, face shield, visor)
d. *Setting*: any healthcare setting (hospitals, dental clinics) and simulation laboratory setups.
e. Country or date enforced no limitations

Exclusion criteria

a. Review articles
b. Editorials, comments, poster/conference presentation/ abstracts, grey literature, and unpublished research information were neither considered nor used.
c. Reports presenting incomplete outcome details
d. Studies evaluating mask or respirators effectiveness in protection against non-respiratory infections, e.g. surgical-site infection
e. Studies where RPE was worn by patients and not the healthcare workers
f. Studies that do not allow data extraction required to meet the set study objectives

Outcome

The key findings of the present review was the systematic assessment of protective barrier efficacy of RPE (surgical facemasks and N95 respirators) and protective eyewear against airborne transmission of respiratory pathogens. Influencing factors (mask-fit and wearing time) on the protective barrier efficiency of RPE.

Electronic data search and analysis

For a systematic and comprehensive approach, we followed PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [9,10]. The employed search approach and the generated results are presented in (Figure 1).

During stage-one of the three-staged electronic data-search and analysis, we screened the titles and abstracts of all relevant studies that met our set inclusion criteria. In stage-two: to get a comprehensive view of the data, a full-text review of all the related articles was performed. A thorough analysis of the full text of the retrieved literature ensured that the eligibility criteria were met, and the reported outcomes were according to the set systematic review objectives. References of the included studies were examined as a backward search. During stage-three: the reviewers (LPS, KSF, and CP) extracted and evaluated the data.

After the full-text review, specific points related to the characteristics of each included study were charted utilising the Cochrane model. This facilitated in classifying the setting, study design, intervention, and the country. Besides, sample size, evaluation time, assessment methods, and study conclusions were systematically examined. The identified manuscripts were compiled using a bibliographic software tool, Endnote version 9 (Clarivate Analytics, USA). Summary of the characteristics of included clinical trials and the reported results on the protective barrier efficacy of RPE are provided in (Tables 1–4).

Quality assessment and overall risk of bias

Two investigators (LPS and KSF) independently performed the quality assessment of the eligible studies. Third and fourth reviewers (CP and HCN) were referred, in case of any

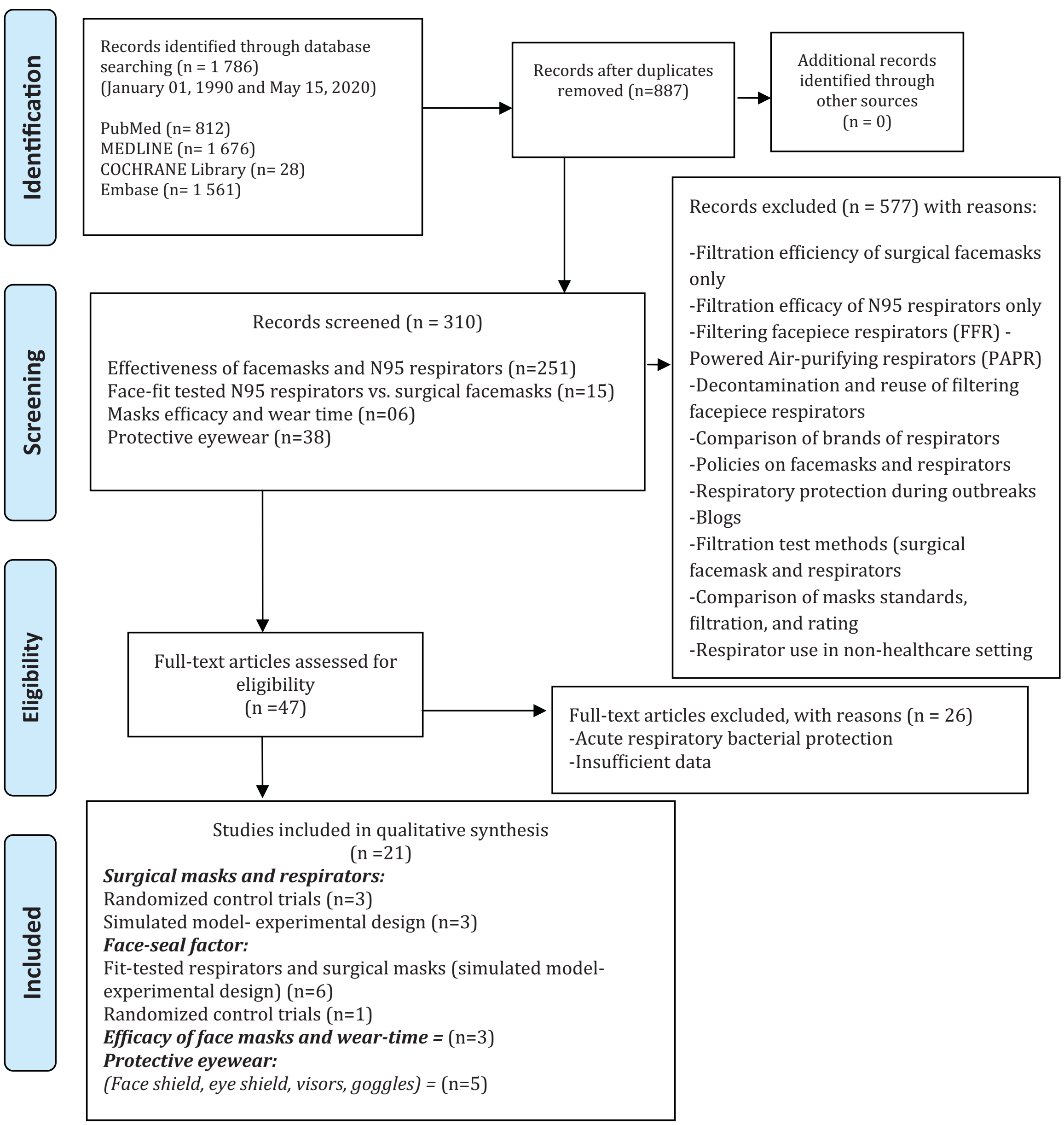

Figure 1. PRISMA flow chart of the literature search and study selection.

Table 1. Facemasks versus N95 respirators -airborne filtration efficiency.

Study	Population No. of patients (No.)	Country	Procedure	Aerosol-method of assessment	PPE (face masks, respirators)	Outcome
PPE – Surgical face masks/respirators – air borne particulates filtering efficacy						
Checchi et al. [17]	Simulated model	Italy	818Tie-On surgical mask 1942 FB fluid resistant moulded surgical mask Personal respirator (1862 healthcare particulate respirator)	Spray bicarbonate particulate on mannequin wearing three types of masks placed 40 cm away Airflow rates (0.5 and 9 m3/hr.)	Filtering efficiency: Tie-on surgical mask 90 to 92 % Moulded surgical mask 85 to 86% Respirator 94–96	All three masks provide significant filtering abilities Respirator performed the best
Balazy et al. [18]	Simulated model	USA–Poland	Two types of N95 half-mask filtering face piece respirators 2 types of surgical masks	Aerosolized MS2 virus of particle size (range of 10–80 nm), at an inhalation flow rate of 85 L/min	Surgical masks showed a much higher particle penetration than the N95 respirators Surgical mask 1: 20.5 % Surgical mask 2: 84.5 %	The protection by N95 respirators was below 95% at higher inhalation flow rates
Liu et al. [19]	Simulated model	Taiwan	High speed rotary instrument for drilling and grinding of extracted teeth Tie on -medical surgical masks N95 masks	Removal efficiency of suspended particulate matter after 2 minutes by Surgical/N95 masks The particle size and their concentration were assessed at the distance of 15 cm from the treated teeth	No significant filtration efficiency difference were observed between the two tested masks	The N95 and medical surgical masks do not offer a sufficient protection efficiency in preventing nanoparticle
PPE – surgical face masks/respirators – air borne particulates filtering efficacy (RCTs)						
Loeb et al. [14]	Hospital settings (446 nurses) In in 8 tertiary care units of Ontario hospitals	Canada	Surgical mask (225 nurses) N95 respirator (221 nurses)	Nasopharyngeal and nasal specimens (RT PCR) 4-fold rise in serum antibodies influenza strain antigens	Laboratory confirmed influenza infection: Fifty nurses (23.6%) in the surgical mask group Forty eight nurses (22.9%) in the N95 respirator group	The laboratory-confirmed influenza was similar in both groups Surgical masks appear to be noninferior to N95 respirators
MacIntyre et al. [15]	Hospital Healthcare workers (1669) in 19 hospitals	China	Medical masks N95 respirators Targeted (intermittent) use of N95 respirators during high-risk procedures or barrier nursing	Pharyngeal swabs were collected from symptomatic HWC to confirm for clinical respiratory illness (CRI) Or laboratory-confirmed respiratory pathogens	Clinical respiratory illness (CRI) Medical mask arm (98 of 572; 17%) Targeted N95 group (61 of 516; 11.8%), N95 arm (42 of 581; 7.2%) Bacterial respiratory tract colonisation with CRI: Medical mask group (14.7%; 84 of 572) Targeted N95 group (10.1%; 52 of 516) N95 arm (6.2%; 36 of 581)	Continuous use of N95 respirators was more efficacious against CRI than intermittent use of N95 or medical masks Targeted N95 use was not superior to medical masks
Radonovich et al. [16]	Healthcare workers (2862) at 137 outpatient study sites in 7 US medical centres	USA	Surgical mask N95 respirator	Swabs of the anterior nares and oropharynx with self-reported symptoms of respiratory illness. Detection of influenza A or B virus by RT-PCR or serological evidence of infection	N95 respirator group: 207 (8.2% of HCP-seasons) Medical mask group: 193 (7.2% of HCP-seasons)	No significant difference N95 respirators vs. medical masks groups

Table 2. Surgical face masks/respirators – face-seal factor.

Study	Study design /Population No. of patients (No.)	Country	Procedure	Aerosol-method of assessment	PPE (face masks/respirators)	Outcome
Noti et al. [20]	Simulated model	USA	Surgical mask N95 respirator	The aerosol samplers collected size-fractionated aerosols for one hour at the mouth and beside the mouth of the breathing manikin and at 3 other locations in the room Total recovered virus was quantitated by quantitative PCR Viral infectivity was determined by the viral plaque assay and an enhanced infectivity assay	Tightly sealed mask to the face blocked 94.5% of total virus and 94.8% of infectious virus Tightly sealed respirator blocked 99.8% of total virus and 99.6% of infectious virus A poorly fitted respirator blocked 64.5% of total virus and 66.5% of infectious virus A loosely fitting mask blocked 68.5% of total virus and 56.6% of infectious virus	Poorly fitted respirators performance was not better than loose fitting surgical masks
Lindsley et al. [21]	Simulated model	USA	Coughing patient simulator Breathing worker simulator N95 FFRs masks Surgical masks	The aerosol particles with optical diameters range 0.3 to 7.5 μm Penetration of cough aerosol particles through 9- models of tested surgical masks on the breathing simulator at 32 L/min and 85 L/min flow rates	With no personel protective equipment the aerosol exposure was highest, followed by surgical masks The least exposure with N95 respirators	N95 (FFRs) without face seal leakage consistently protected from cough aerosol particles of all sizes Surgical masks could not provide adequate protection from small particles even when sealed to the head
Wen et al. [22]	Simulated model	China	Five models of surgical masks Two models N95 masks One model N99 mask	Percentage efficiency value calculated against test phage SM702 aerosols which surrogates of viral – pathogen aerosol (dsDNA virus of about 100 nm size)	Lower face-fit factor of surgical facemasks unable to provide adequate protection against viral aerosol The protection performances of N95 or N99 masks were many times higher considering the face-fit factor	The protection performances of N95 or N99 masks were many times higher when considering the face fit factor Surgical masks cannot offer sufficient due to inadequately close face seal
Derrick et al. [23]	A total of 6 volunteers in laboratory setting	Hong Kong, China	Multiple layers of surgical masks (one vs. five masks) have been tried to prevent transmission of SARS	Comparisons of particle counts outside and inside the masks during a series of activities: *Normal breathing* *Deep breathing* *Turning the head from side to side* *Flexing and extending the head* *Talking loudly* *Bending over followed by normal breathing*	The median reduction in particle count for a single surgical mask was 2.7 This increased to 5.5 with five surgical masks	Use of multiple masks are not a suitable alternative to N95 masks
Suen et al. [49]	HCWs -nursing students (120)	Hong Kong, China	3 models of N95 respirators	HCWs adopted different postures during nursing procedures: *Normal breathing* *Deep breathing* *Head side to side* *Head up and down* *Talking, and* *Bending over*	The average fit factor of the best fitting respirator dropped significantly after nursing procedures (184.85 vs 134.71) as detected by the quantitative fit test (QNFT)	Body movements during patient care procedures may increase the risk of face seal leakage of N95 respirators

(*continued*)

Table 2. Continued.

Study	Study design /Population No. of patients (No.)	Country	Procedure	Aerosol-method of assessment	PPE (face masks/respirators)	Outcome
Harnish et al. [24]	Simulated model	USA	N95 filtering facepiece respirators (FFRs) (5 in quantity)	Viable H1N1 influenza virus were aerosolized at continuous flow rates of 85 and 170 litres per minute Filtration efficiency determined through viable sampling assayed using Madin-Darby canine kidney cells	N95 FFRs filtered 0.8-µm particles of both H1N1 influenza and inert origins with more than 95% efficiency	Properly fitted FFR reduces inhalation exposure to airborne influenza virus
PPE – surgical face masks/respirators – face-fit factor (RCTs)						
MacIntyre et al. [25]	Hospital healthcare workers (1441 nurses and doctors) in 15 hospitals	China	Medical masks vs. N95 respirators (fit tested and non-fit tested) Subjects wore the mask/respirator on every shift (8–12 hours) for four consecutive weeks Controls	Pharyngeal swabs were collected from symptomatic HCWs	Bacterial colonisation: 2.8% in the N95 group 5.3% in the medical mask 7.5% in the control group	Medical mask arm had a higher rate of dual virus infection N95 demonstrated efficacy against multiple bacterial and against co-infection with a virus and bacteria or against dual virus infection

Table 3. Surgical facemasks – efficacy versus wear time.

Study	Population No. of patients (No.)	Country	Procedure	Aerosol-method of assessment	PPE (face masks, respirators)	Outcome	Risk of bias
PPE – surgical face masks/respirators – efficacy versus time							
Barbosa et al. [26]	Hospital setting (64 experiments; 32 in each group)	Brazil	Surgical masks with (95% Bacterial Filtration Efficiency) Data were collected in the operating theatre (OT) unit	Filtration efficiencies of disposable surgical masks after 1, 2, 4 and 6 hours of wearing time Temperature in the OT (19 and 24°C. Relative air humidity between 45 and 60%. The OTu had controlled positive pressure	Between 4 and 6 hours, both groups (experimental and control) presented an increase in the microbial counts	The tested masks showed a decrease in efficacy after a wearing time of 4-hour	******
Chughtai et al. [27]	Pilot study (clinical setting) (12) Hospital setting (148 HCWs) in three hospitals from the infectious disease, respiratory/chest-wards and intensive care unit (ICU)	Australia China	Disposable surgical face masks Disposable surgical face masks	Wore medical facemasks for a shift (minimum 30 min) Samples used by participants who examined more than 25 patients per day for 6 hours or more	Three samples were positive for human enterovirus Adenovirus was the most commonly isolated from the masks ($n = 7$), Followed by bocavirus ($n = 2$), Respiratory syncytial virus ($n = 2$) and influenza virus ($n = 2$)	Overall virus positivity rate was 10.1% Significantly higher virus positivity in masks samples worn for > 6 h	*****
Sachdev et al. [28]	Cross sectional (130)	India	240 used surgical masks collected from 130 dental personnel working in department of Oral and maxillofacial surgery, Oral Medicine, Radiology, Pedodontics, Endodontics, Periodontics, and Dental emergency room	Used surgical masks (30 minutes duration)	Bacterial contamination on the outer surface of the used masks 180 ± 110 CFU/ml/mask Fungal contamination on the outer surface of the used masks 32 ± 13 CFU/ml/mask	Outer surface of the used mask carries significantly higher bacterial and fungal load	***

*The Newcastle–Ottawa Scale for the risk of bias assessment (more stars mean lower risk).

Table 4. Protective eyewear against respiratory droplets and bioaerosols.

Study	Study design/ Population No. of patients (No.)	Country	Procedure	Aerosol-method of assessment	PPE – protective eyewear (face shields/ eye shield, goggles, visors)	Outcome
PPE – face masks, protective eye wear, face shield/visors – aerosols shielding efficacy						
Mansour III et al. [29]	Simulated model	USA	Prescription glasses Standard surgical telescopic loupes Hard plastic contoured glasses Disposable plastic glasses A combination facemask and eye shield, and No protection (control)	The manikin head was placed at an appropriate distance from the surgical field during femoral osteotomy on a cadaver thigh	Conjunctival contamination rates of 83% with prescription glasses Standard surgical telescopic loupes conjunctival contamination rate was 50% Facemask and eye shield (30%) Hard-plastic glasses (17%) Disposable plastic glasses (3%)	Facemask together with eye-shield offered better protection
Bischoff et al. [30]	28 participants in the laboratory setting	USA	N95 respirators (fit tested) Surgical masks Eye protection	Exposure to monodispersed live attenuated influenza vaccine (LAIV) particles (4.9 μm) Influenza was detected by (RT-PCR) and culture in nasal washes of the participants	Surgical mask was inferior to a fit-tested N95 respirator in obviating aerosols	Fit tested N95 respirator with eye protection provided the best guard
Lindsley et al. [31]	Simulated model	USA	Coughing patient simulator Breathing worker simulator Face shields	Influenza virus laden cough aerosol with a volume median diameter (VMD) of 8.5 μm and 3.4 μm	Face shield reduced the inhalational exposure of aerosol (VMD 8.5 μm) by 96% in the period immediately after a cough Increased distance between the patient and worker to 183 cm (72 inches) reduced the exposure to influenza by 92%	Face shields is a useful adjunct to respiratory protection Face shield cannot be used as a substitute for respiratory protection
PPE – face masks, protective eye wear, face shield/visors – face fit factor						
Loveridge et al. [32]	Simulated model	UK	A visor worn in a conventional position compared with a visor worn in an inverted position Vs. wearing a standard face mask over the face without a visor	Droplets on the face or inside the visor shield. Contamination of the face was confirmed by visual inspection, felt by the surgeon, and confirmed by blotting	Four facial splashes in the conventional position (6.5%) versus zero in the inverted position (0%) Twenty-five splashes on the inside of the visor in the conventional position (40.3%), versus 11 in the inverted position (17.7%) In total, 29 incidences of contamination in the conventional position (46.8%), versus 11 in the inverted position (17.7%)	Conventional visor worn in the inverted position provides superior protection
Bentley et al. [33]	Adult patient (2)	USA	Restorative procedure using high-speed handpiece and high-volume evacuator for 30 minutes Ultrasonic scaling with conventional salivary ejector for 30 minutes	Blood agar plates were placed on the 6- spokes of the head-rest extension device at 12 and 24 inches from patients' mouth And also, on operators face mask, disposable gowns, head caps.	Colonies of alpha-hemolytic streptococci Fluorescent dye in the aerosols deposited on face masks behind the face shields	Face shields were substantially inferior to masks in obviating penetration of airborne debris because of lack of peripheral fit

disagreement. For assessing the methodological quality of the randomised control trials, we used the Cochrane Collaboration risk of the bias assessment tool [11]. Any discrepancies were discussed until a mutual agreement was reached among the reviewers. The evaluated studies were documented as low-risk, unclear, or high-risk (Tables 5 and 6). Studies with a high-risk of bias were excluded from the present systematic review. Newcastle-Ottawa scale was used to measure the risk of bias for comparative non-randomised studies to cohort or case-control study design [12].

According to the evidence pyramid, *in vitro* laboratory, trials/studies yield the lowest levels of evidence. This is due to the possible preponderance of 'false-positive' results, lack of external validity, and poor generalizability to clinical scenarios [13]. Hence, we evaluated the transparency and quality of included laboratory trials with respect to consolidated standards of reporting trials (CONSORT). Accordingly, Items such as sample size, specimen preparation and handling, allocation sequence, randomisation, and blinding were thoroughly assessed for inclusion in the systematic review.

Results and discussion

In total, we analysed in detail 20-articles retrieved from four databases, that fitted our selection criteria. Of these, six studies appertained to filtering efficacy of facemasks and respirators *vis a vis,* airborne particulates, of which three were randomised control trials (RCTs) [14–16], and the remainder were simulated laboratory or clinical settings [17–19]. The review also included five face-seal/fit model studies [20–24], and a single RCT [25] on issues related to surgical facemasks and N95 respirator wear. Further, three more investigations [26–28] on wearing time factor versus filtering efficiencies of RPE (masks and respirators) were also reviewed.

To assess the shielding efficacy of protective eyewear (face shield, visor, and goggles), a total of five available studies [29–33] that met our set inclusion criteria were finally included in the review.

Surgical facemasks versus filtering facepiece respirators- airborne particulate filtering efficacy

Inhalation is one of the principal routes of respiratory pathogen entry into the human body [34]. To prevent such pathogen inhalation in patient care settings, there are two key types of disposable respiratory-protection tools available: the medical grade-facemasks, and the filtering- facepiece respirators [35]. Face masks have been endorsed as an integral part of universal precautions in clinical settings, despite the fact that they have limitations in the provision of adequate

Table 5. Risk of Bias of the included RCTs.

Study	Selection bias Baseline characteristics similarity/ appropriate control selection	Selection bias Allocation concealment	Selection bias Randomisation	Performance bias Blinding of researchers	Detection bias Blinding of outcome assessors	Reporting bias Selective outcome reporting	Incomplete outcome data (attrition bias)
PPE – surgical face masks/respirators – air borne particulates filtering efficacy							
Loeb et al. [14]	+	–	+	?	+	+	–
MacIntyre et al. [25]	+	+	+	?	+	?	+
MacIntyre et al. [15]	+	–	+	–	?	?	–
Radonovich et al. [16]	+	+	+	?	+	+	+
PPE – protective eye wear and aerosols protection efficacy							
Bentley et al. [33]	+	+	–	+	?	+	+
Lindsley et al. [31]	+	+	+	?	+	+	?

Risk of bias legends: + (Low risk); - (High risk); ? (Un-clear risk).

Table 6. Risk of Bias of the included laboratory – controlled experiments.

Study	Selection bias Baseline characteristics similarity/ appropriate control selection	Sample size	Specimen handling and allocation sequence	Performance bias Blinding of Researchers	Detection bias Blinding of outcome assessors	Reporting bias Selective outcome reporting
PPE – Surgical face masks/respirators – air borne particulates filtering efficacy						
Checchi et al. [17]	+	?	+	?	?	+
Balazy et al. [18]	+	?	+	?	?	+
Harnish et al. [24]	+	?	?	?	?	+
Noti et al. [20]	+	?	+	?	?	+
Liu et al. [19]	+	?	+	?	?	+
PPE – surgical face masks/respirators – face fit factor						
Derrick et al. [23]	+	?	+	?	?	+
Lindsley et al. [21]	+	?	+	?	?	+
Wen et al. [22]	+	?	?	?	?	+
Suen et al. [49]	+	?	+	?	?	+
PPE – protective eye wear and aerosols protection efficacy						
Bischoff et al. [30]	+	?	+	?	?	+
Mansour III [29]	+	+	+	+	+	+
Loveridge et al. [32]	+	?	+	?	+	+
Lindsley et al. [31]	+	+	+	?	+	+

Risk of bias legends: + (Low risk); - (High risk); ? (Un-clear risk).

protection for HCWs under some circumstances [36,37]. The premier version of the face mask is the more sought after, and costly, NIOSH (National Institute for Occupational Safety and Health) recommended filtering – facepiece N95 respirators approved for the healthcare workers [38]. The N95 respirators can trap 95% of particles of size $\geq$300 nm (0.3 μm) under the airflow rate of 85 L/min, equivalent to strenuous breathing [39].

We included three laboratory-controlled studies [17–19] comparing the relative filtering efficacy of surgical masks and facepiece respirators (Table 1). Collaborative US–Polish research by Balazy et al. [18] has confirmed, through scanning electron microscopic observations, that surgical masks permitted the penetration of a significant fraction of aerosolized virions of 10-80 nm at an inhalation rate of 85 L/min. On the contrary, in a manikin-based laboratory study, the latter workers demonstrated the much higher filtering efficacy of N95 respirators than the surgical mask. However, the tested respirators were ineffective against nano-sized virions, especially at higher flow rates (85 L/min).

An analogous study by Liu et al. [19] compared the filtration efficacy of surgical masks versus N95 respirators during drilling and grinding of teeth using high-speed rotary instruments. They noted some limitations of N95 respirators against aerosolized biological particulates of size $<$1 μm (nanoparticles) created during dental procedures. The high-flow rate of bioaerosols engendered during dental drilling may have influenced the filtration efficiency of N95 respirators tested. Under laboratory conditions, mimicking human breathing at rest (0.5 m^3/hour) and at full exertion (9 m^3/hour), Checchi et al. [17] challenged RPE (masks and respirators) with aerosolized bicarbonate dust that simulated artificial aerosols. They noted that at both airflow rates, the respirators were better than the tie-on and moulded surgical masks in preventing exposure to respirable particulates.

Also, three RCTs [14–16] with a total of 4977 healthcare workers (HCW) from hospital settings were included in the review. These RCTs compared protection from medical masks and N95 respirators against laboratory-confirmed viral [14,16] and bacterial [15] airborne pathogens (Table 1).

Transmission of respiratory virus infections occurs from inhaling aerosolized virions of sizes ranging from 0.1 to 100 μm range [40]. Loeb et al. [14] in tertiary care hospital-settings evaluated the effectiveness of RPE (fit-tested N95 respirator vs. surgical masks) among nurses, caring for patients with febrile respiratory illnesses. They observed no difference in the influenza infection rates between the surgical mask and N95 groups. Recently, Radonovich's team [16] has also examined the incidence of laboratory-confirmed influenza among HCWs who were providing outpatient care in seven US medical centres, and they too could not elicit any difference in acquiring infection between N95 respirator and the surgical masks wearing cohorts. In contrast, McIntyre and team [15] assessed the filtering efficacy of medical masks and N95 respirators against respiratory bacterial infections and noted that continuous use of N95 respirators during high-risk procedures, showed significantly lower rates of bacterial infections compared to surgical masks.

Aerosolized pathogens are highly variable in their size ranging from bacteria ranging from 0.3 to 1.0 μm in size compared to nanosized viruses [41–43]. Hence, as noted in the foregoing section from RCTs and simulated *in vitro* laboratory trials, the protective efficacy of RPE depends upon the size of the airborne pathogens. For instance, N95 respirators offered better protection compared with the surgical masks, for (bacterial) particles $\leq$20 μm in diameter where efficiency estimates ranged from 2% to 92% [44,45]. These data indicate the limitation of the N95 respirator depending on the particle size [43], as well as the airflow dynamics.

The preceding reports do not take into consideration the N95 mask fit factor into account. As the latter is critical in preventing inhalation of viral particles, several workers have addressed this all-important issue, as discussed below.

Mask-fit factor and functional efficacy of surgical masks and respirators

There are reports which indicate that HCW contract viral infections through exposure to aerosolized microbes due to leakage of protective face masks or respirators [46,47]. The reliability of the RPE depends on the precise, tailored fit of the device that is worn [48]. For instance, the face-fit competence of N95 masks appears to be a significant factor contributing to their functional efficacy [46]. We reviewed data related to the face-fit element of masks, retrieved from five laboratory-controlled settings [20–23,49], and a single clinical trial [50] (Table 2).

Wen et al. [22] in a simulated model setting tested filtering efficiency and mask-fit factor of varying models of N95, N99, and surgical masks against viral pathogens. They noted that surgical masks could filter virions if appropriately fitted, but their inadequate face-fit potentially limits the efficacy. Noti et al. [20] also surmised that a poorly fitted respirator's performance is no better than a loosely fitting surgical mask. Their inferences were based on the fact that the quantified viral pathogens in aerosol samples, collected from tightly- and loosely fitted surgical masks and N95 respirators, tied on to breathing simulators. However, a contrasting observation was reported by Lindsley et al. [21], where they found inadequate protection against bacterial and viral microbes by surgical masks irrespective of their fit. Nevertheless, they noted that an adequately fitted N95 respirator to a breathing simulator offered adequate protection from cough aerosols. These reports are somewhat confusing, although the weight of evidence seems to indicate that a fitted and tailored mask is more efficient than a loosely fitting mask.

Others have observed mask efficacy while simulating head movements in clinical settings. Thus, after observing the barrier efficiency of single and multiple-layered masks and N95 respirator while simulating different head movements and face-seal leakage, Derrick et al. [23]concluded that neither the single or layered surgical masks were a good substitute for properly face-sealed N95 masks. Conversely, Seun's team [49] noted that body movements during patient-care procedures might increase the risk of face-seal breach of N95 respirators. Their nursing recruits performed the routine patient procedures for 10-minutes in a hospital setting while wearing a portable aerosol-spectrometer on their backs to detect air particles inside the respirator.

We only found only a single, substantive paper by MacIntyre et al. [50] on mask-fit in an inpatient hospital ward setting. In their RCT [50], they enrolled a total of 1441 HCWs, in 15 different hospitals to compare the efficacy of surgical masks and N95 respirators. They observed lower rates of respiratory infections in HCW who used fit-tested N95 respirators as opposed to surgical masks. Intriguingly, when either fit- or non-fit- tested N95 respirators were compared, no significant difference in shielding against respiratory infections between the two groups could be elicited. They surmised that fit-tested N95 masks offered better protection against bacterial and viral respiratory pathogens than surgical masks. The latter MacIntyre et al. [50] findings contrast with a reasonable body of *in vitro* evidence of a significant reduction in exposure to airborne viral particles with efficient peripheral seal. Hence, fit testing of N95 masks is now universally recommended for healthcare professionals, as a defective seal could lead to breach of the infection control chain, thus nullifying the protective benefit of a mask [48].

All of the foregoing data reviewed appertains to medical settings, and we could not identify any clinical reports comparing the efficacy of face fitted N95 masks or surgical masks in dentistry. Nevertheless, the available data, when extrapolated to dental settings, where aerosol-generating procedures are the norm, clearly indicate that wearing tailored-fit N95 masks with a peripheral patent seal assures a great protective shield from infectious bioaerosols.

Finally, in this regard, our review has brought into focus the dire necessity for further comprehensive studies on the face mask fit and their filtration efficacy in both medical and dental settings. It is critical to do so mainly given the current pandemic and the eventual possible endemicity of COVID-19, coupled with the asymptomatic disease carriers who are highly likely to attend for dental or medical treatment.

Wearing time and functional efficacy of medical masks and respirators

In any healthcare setting, the use of medical masks is integral [51]. At these locations, microbial pathogens may be generated due to coughing, sneezing, and even talking with patients, as well as during aerosol-generating dental and medical procedures [51,52]. Moreover, in the absence of adequate air-conditioning and air changing protocols, the expelled pathogens can be entrained and airborne for over 3 h [53] and inhaled by unsuspecting victims. Predicated upon the mask use/re-use and the period of mask wear, respiratory pathogens trapped on the superficial layers of the used masks may pose another infectious hazard for other co-workers [54–57]. Considering the current worldwide scarcity of RPE, the optimal wear period of a single mask, their re-use after sterilisation, and the factors affecting the deterioration of the filtration efficacy has come under intense scrutiny [58,59].

We reviewed two medical [26,27], and a single dental RCT [28] evaluating medical masks and their functional efficacy over time. In total, 354 healthcare workers (224 medical and 130 dental) were enrolled in these three studies (Table 3).

In one of the more extensive studies, Chughtai et al. [27] tested mask-wear time and their efficacy, in three high-risk wards of two hospitals, using a cohort of 148 healthcare staff. They studied the association between risk of mask contamination with the duration of mask-use and the number of patients seen by each healthcare provider. They concluded that the virus positivity was significantly higher in masks worn for over 6 h. In another experimental setting, Barbosa et al. [26] evaluated 95% of bacterial filtration efficacy of surgical masks at 1, 2, 4, and 6 h of mask-wearing. Their results, evaluated by quantifying the microbial load on the worn masks, in terms of colony-forming unit (CFU) counts of bacteria, indicated the proportionate decreasing efficacy after a 4-hour of mask wear.

In the only study related to dental care, Sachdev et al. [28] tested used surgical masks worn by dental personnel for 30-minutes during various patient care procedures. They observed that the used masks from staff working in the outpatient dental clinics had a high bacterial and fungal load. However, their report had data lapses, particularly in the precise quantification of CFU of surgical masks relative to the different dental treatment procedures. Such information is essential to evaluate the quality of the study as the volume of bioaerosol generated varies according to the nature of the dental procedure. For instance, ultrasonic scaling, subgingival restorations, and oral surgical procedures with tools such as micro-motor handpieces, air-water syringe, etc., generate copious bioaerosols in comparison to hand scaling, and atraumatic restorative procedures [5]. It is also known that exposure to aerosol-generating procedures, the number of patients seen, the nature and severity of infection as well as humidity, air quality, and temperature determines microbial concentration on the surgical masks [5,54,60].

The preceding clearly exposes the appalling dearth of data in the literature on the factors determining mask efficacy. Hence further studies are urgently needed on these elements, and the data generated could contribute immensely to rationalise the routine mask-wearing practices both in dentistry and medicine that appear to be more ritualistic rather than fact-driven.

Shielding efficacy of face shields and protective eyewear

We identified four studies [29,30,32,33] that examined bundled interventions against aerosol- mediated infection, using various PPE components, including face shields/visors and face masks (Table 4). Lindsley et al. [31] employed a laboratory model simulating artificial coughing and breathing, and demonstrated that face shields could effectively reduce the risk of inhalation of over 90% expelled particulate matter following aerosol generation. This observation has also been made by Bentley and colleagues [33]. They noted that the use of a face shield by dental personnel during simulated dental procedures on a mannequin head did not prevent aerosol contamination of a concurrently worn, cup-shaped surgical face mask.

However, in practice, the absence of a peripheral seal in face shields makes its use as a sole protective measure against respiratory pathogens rather impractical. In a study with volunteers using sprayed water during simulated surgery, Loveridge et al. [32] observed a 40.5% incidence of contamination of the inner surface of a combination surgical mask with integral visor and 6.5% contamination of the wearers' face. In an experimental setting, using a simulated 'head' compared face fit factor of visors both in conventional and inverted positions (i.e. securing the face mask around the brow with the visor attached). They noticed that the inverted position of the visor offered better safety against splash exposures. Hence, in a conventional position, contamination inside the visor can trickle down towards the operator's mouth, and perversely, an inverted position appears to be more effective in such situations.

In terms of trans ocular viral infection *via* conjunctivae, Lu et al. [61] alluded to the transmission of SARS-CoV-2 through the conjunctive in an HCW who was wearing only a protective N95 respirator. It is known that the Angiotensin converting-enzyme2 (ACE_2) receptors for the virus are present in the aqueous humour of the human eye [62], and the latter report appears to be the first in the literature confirming conjunctival route of SARS-CoV-2 transmission.

Previous such reports have been mainly in relation with influenza viruses and confirm the likelihood of trans-ocular transmission of viruses suggesting the importance of the use of protective eyewear in addition to masks/respirators [63,64]. Bischoff et al. [30] challenged the fit-tested N95 respirators, with and without eyewear, using live attenuated influenza viruses of defined concentrations and sizes. Additionally, Mansour et al. [29] in laboratory experiments, have shown that surgical face masks with eye shield offer better barrier protection against bioaerosols produced during surgical procedures. The wearing of masks alone, therefore, does not guarantee protection against COVID-19 infection, and additional protective measures such as goggles or face shields are essential for the purpose.

To conclude, then, to offer desired optimal protection against respiratory pathogens and bioaerosols in healthcare settings, a combination of interventions, incorporating face shields, and eyewear/visors should be worn as an adjunct to fit-tested masks or respirators.

Limitations of the reviwed studies

Though the included trials in the review give a rational body of evidence, there are some critical limitations. The range of respiratory viral infections studied, mostly focus on influenza. None of the available studies gauge the filtration efficiency of N95 respirators versus medical-grade masks during medical or dental bioaerosol generating procedures, especially in a clinical setting. Additionally, we found no data on the wear-time efficiency or extended use of N95 masks in the clinical setting and notably during bioaerosol producing processes.

The included RCT in the hospital settings has several inherent limitations. Personal exposure risks of HCW are not just limited to their patient contacts inside the hospital but may be influenced by exposure to infective hazards outside the work-setting, for instance in the community. These potential risks may be highly variable and difficult to account for, particularly in field studies. Furthermore, stringent compliance with other infection control measures such as precautions related to donning and doffing of PPE, hand hygiene, etc., considerably influences individual exposure risks.

Conclusions

Defining the ideal means to ensure facial protection against respiratory pathogens is a complex task and fraught with many issues and variables. These entail not only the efficiency of RPE, facepiece peripheral seal, mask-wearing period, and the fabrication quality of the masks, but also extraneous factors such as airflow dynamics of the patient care area, the aerosol-generating procedure, and aerosolized pathogen size and load, and the airflow rate. Most of the reviewed studies employed highly controlled-laboratory settings, lacking the contextuality of actual clinical settings.

In general, RPE is effective as a barrier protection against aerosolized microbes in healthcare settings. The poor fitness, prolonged period of wear, and the wetness of the masks compromise their microbe filtration efficacy. Most importantly, none of the mentioned interventions (surgical masks, N95 respirators, face shields/visors, goggles) afforded complete protection from infection, if used individually. The proper and consistent wearing of masks/respirators may improve the effectiveness of such equipment but remains a significant challenge.

Hence, due to the marked methodological variability across the included studies as well as the high-risk of bias in few of the included studies, further well-designed and controlled clinical trials using standardised methodologies are highly recommended to discern the clinical efficacy and effectiveness of RPE used in both dental and medical care.

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Disclosure statement

No potential conflict of interest was reported by the author(s).

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