Received: 14 April 2022 | Revised: 31 May 2022 | Accepted: 4 June 2022

DOI: 10.1111/iwj.13871

ORIGINAL ARTICLE

IWJ WILEY

Feasibility of nasal bridge pressure injury prevention using a protective dressing and the Halyard Fluidshield® N95 mask in a COVID-positive environment

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Abstract

The purpose of this study was to prevent nasal bridge pressure injury among fit-tested employees, secondary to long-term wear of the N95 mask during working hours. A prospective, single-blinded, experimental cohort design. Participants were enrolled using the convenience sampling methods and randomisation was utilised for group assignment. Eligibility was determined by a COVID Anxiety Scale score and non-COVID clinical assignment. Participants with a history of previous skin injury or related condition were excluded. The experimental group was assigned Mepilex Lite® and the control group used Band- Aid®. Formal skin evaluations were done by Nurse Specialists who are certified in wound and ostomy care by the Wound, Ostomy, Continence, Nursing Certification Board (WOCNCB®). Fit test logs were provided to participants to measure subjective user feedback regarding mask fit and level of comfort. The results of this feasibility trial are promising in supporting the use of a thin polyurethane foam dressing as a safe and effective dressing to apply beneath the N95 mask. Additional research is needed to validate results due to limited data on efficacy and safety of the various barrier dressings as a potential intervention to prevent skin breakdown to the nasal bridge.

KEYWORDS

N95, nasal bridge, polyurethane foam dressing, PPE, pressure injury

Key Message

The use of a thin-profile polyurethane foam dressing has potential for nasal bridge pressure injury prevention, while maintaining the mask seal, with long-term wear of the Halyard Fluidshield® N95 respirator.

1 | INTRODUCTION

According to the World Health Organization (WHO), Coronavirus Disease (COVID-19), caused by the SARS CoV 2 virus, raised global alarm in December 2019.[1] In less than 100 days, the WHO declared it a pandemic.[2] To date, COVID-19 continues to challenge healthcare systems across the globe, necessitating healthcare personnel and organisations to constantly adapt and evolve to remain one step ahead of COVID-19. Long-term wear of personal protective equipment (PPE), including the N95 Particulate Filtering Facepiece Respirator mask, is one such adaptation that is specific to this pandemic.

In the clinical setting, healthcare personnel utilise PPE (i.e., gowns, goggles, face shields, gloves and facial masks) to provide care for potentially infectious patients. Prior to COVID-19, PPE use was relegated only to the point of possible exposure. COVID-19 can be transmitted via droplets from the secretions of infected individuals or inhaled smaller airborne particles.[3,4] The nature of the pathogen's virulence, coupled with its potential for rapid transference translated to healthcare personnel wearing the PPE for an extended period.[5]

Currently, the N95 respirator facial mask is a standard part of healthcare personnel's PPE, protecting staff from inhalation exposure of both aerosol and droplet pathogens, including COVID-19. The Center for Disease Control and Prevention (CDC) recommends using the N95 mask as part of isolation precautions for pathogens transmitted via the airborne and droplet route.[6,7] The N95 mask is secured to the face by elasticised straps which are placed posteriorly to the back of the head and moulding a padded-metal ridge over the wearers' nasal bridge, to achieve a seal.[8] Proper use of the N95 mask includes a complete seal over the nose and mouth, to prevent inhalation exposure. Rigorous testing by National Institute for Occupational Safety & Health (NIOSH) certifies the N95 mask as capable of filtering 95% of pathogens to a 0.3 μm filter.[9]

The N95 mask demonstrated effective protection from the transmission of aerosolised and droplet pathogens. Prolonged use of the N95 mask became common in response to the COVID-19 pandemic.[5] However, due to this unprecedented, longer wear time of the N95 masks, healthcare personnel are at increased risk for skin injury to the nasal bridge with an unknown effect on the integrity of the mask seal. Prior studies investigating long-term use of facial masks have noted 'reduced tissue perfusion over the bony prominence of the nose.'[10] This increases the potential for skin injury to the nasal bridge, specifically with bi-level positive airway pressure or continuous positive airway pressure masks, in the patient population. A recent study by Jiang et al.[5] demonstrated that 80% of healthcare personnel that wore masks as part of their PPE requirements developed skin damage and were at an increased risk of infection. Similarly, Gefen found that skin injury can occur in as little as 4-6 hours of N95 mask use.[13]

There is existing evidence to support the use of a thin polyurethane foam dressing for prevention of skin injury. A prospective randomised controlled trial conducted by Kalowes et al.[11] stated that the use of a thin polyurethane foam dressing, on the coccyx and sacral area, combined with preventative care yielded a statistically and clinically significant benefit in reducing the incidence and severity of pressure injuries. Mepilex Lite® is a proprietary branded range of thin, absorbent, conformable, atraumatic self-adhesive foam dressings with a soft silicone wound contact layer from the company Mölnlycke®. Prior to this study, this dressing was used as an evidence-based intervention for pressure injury prevention and wound healing.[12]

The overall goal of this study was to prevent nasal bridge pressure injury among fit-tested employees, secondary to long-term (>8+ hours) wear time of the N95 mask during working hours. Specific aims included the following: 1) To explore the feasibility of applying the Mepilex Lite® dressing on the nasal bridge of fit-tested employees—directly between the skin and the N95 mask as a pressure injury prevention modality, secondary to long-term (>8+ hours) wear time of the N95 mask during working hours; and 2) To test the integrity of the N95 mask, seal/fit before and after application of the allocated dressing (Band-Aid® or Mepilex Lite®), according to facility approved fit testing guidelines. This study uses the Halyard Fluidshield® N95 Particulate Filter Respirator mask, commonly known as the 'duckbill mask', among healthcare personnel.

2 | METHODS

The initial design of this feasibility study included a prospective, single-blinded, experimental cohort design, with an initial target sample N = 90. Due to the rapidly changing nature of COVID-19 with increased hospitalisations and infiltration into all areas of clinical care, the study was adapted to a feasibility study and approved by the IRB accordingly. This was done in order to maintain the safety of all potential participants.

This study was conducted at a 280-bed community hospital in metropolitan New York. Participants were enrolled using convenience sampling methods, due to the nature of the pandemic. Randomisation was utilised for group assignment, whereby participants were randomly assigned to the study group or the control group via

Qualtrics in the order that they volunteered. This single-blinded design, where participants were not aware of their assigned study group placement, was used to evaluate the effectiveness of each dressing and to reduce the risk of selection bias.[14]

The target population included hospital-employed clinicians working with non-COVID patients and their families. This population was selected because of unprecedented long-term wear of the N95 mask when providing care for COVID-19 patients and reports of prior episodes of pressure injury development or skin injury on the nasal bridge.

Inclusion criteria for potential participants were as follows: 1) Hospital employees who worked on a non-COVID unit and 2) Received a score of less than or equal to five on the COVID-19 Anxiety Scale.[15] This scale was used as a precursor to our consent form—a tool to protect the safety of our study participants. This study was not intended to diagnose or treat anxiety. Participants were excluded if they had a score greater than five on the COVID Anxiety Scale. Excluding participants with a score of greater than five on the COVID Anxiety scale was implemented to prevent unnecessary harm to study participants or exacerbate symptoms of COVID-related anxiety.

Additional exclusion criteria included the following: 1) Fit-tested hospital employees working in the Emergency Department, Intensive Care Unit or a unit with a focus on the exposed COVID-19 population; 2) Fit-tested facility employees who have been temporarily assigned to care for COVID-19 patients or are a part of the float pool, volunteer or agency; 3) Fit-tested hospital employees and support staff, with a known history of skin breakdown or damage to the nasal bridge, history of skin-related conditions (e.g. Psoriasis or active herpetic lesions to the mouth or nasal areas); 4) History of surgery to nasal bridge; 5) Pregnant fit-tested hospital employees in their third trimester; and 6) History of respiratory extended respirator use in addition to the hours collected in this study.

Recruitment methods included the following: dissemination of printed posters in hospital-approved areas, and notification of study availability sent via email and posted to facility approved digital communication platform (Epic® Secure Chat and email). Access to the general listserv was temporarily provided to the study investigators by facility leadership. The recruitment email was sent by study investigators once per week during all phases of enrollment. To avoid coercion or undue influence of participation, the email was sent to the general listserv that included all clinical employees. Study investigators did not hold a supervisory or clinical/instructor role over the population of interest. Recruitment was initially slated to continue until the target sample of 90 participants were obtained. Due to the evolving pandemic, the hospital needed to adapt accordingly; therefore, our sample pool decreased. The Participant Recruitment Flow Diagram demonstrates how the study was modified to enhance recruitment (see Appendix A).

All data, assessments and protocol procedures occurred onsite at the hospital facility as directed by the governing IRB. Participants were consented in-person by a trained member of the study team, in the hospital-approved area located away from any patient-care areas. Privacy screens were set-up to protect confidentiality of study participants as well as maintaining social distancing of six-feet in between any participants and study staff.

3 | PROCEDURES

All potential participants first completed a digital version of the COVID-19 Anxiety Scale (Appendix B). Participants scoring less than or equal to five, completed the face-to-face, HIPAA-compliant consent process by study investigators or trained research assistants at the designated, on-site study area. Participant's privacy and confidentiality were supported with privacy screens throughout the process of enrolment, consent, pre/post-skin assessment, and fit testing. Participants were blinded to the assignment of either the thin polyurethane foam dressing or the flexible fabric bandage as a nasal bridge pressure injury prevention modality. The detailed study process is outlined in Appendix C.

Block randomisation was completed via Qualtrics®, two blocks assigned 50 alpha numeric variables to the eligible participants. Eligible participants were blinded and randomly assigned an alpha numeric code at the start of the socio-demographic survey. N95Z was the experimental group—wearing the N95 mask in the care of the non-COVID-19 patient, using a pre-cut, (1 inch in length and 2 inches in width) Mepilex Lite® dressing over the nasal bridge. N95X was the control group—wearing the N95 mask in the care of the non-COVID-19 patient, using the Band-Aid® flexible fabric (1 inch in length and 3 inches in width) over the nasal bridge. The automatically generated alphanumeric code was used as an identifier on the HIPAA-compliant consent form as well as the fit test log.

Formal skin evaluation was done by the Certified Wound and Ostomy Nurse (CWON) study investigators before and after the dressing was applied. The CWON reviewed the skin over the nasal bridge using current, National Pressure Injury Advisory Panel (NPIAP), clinical practice guidelines in their assessment for current or potential skin injury (see Appendix E). Fit test logs were provided to participants to measure subjective user feedback regarding mask fit and level of comfort. The fit test

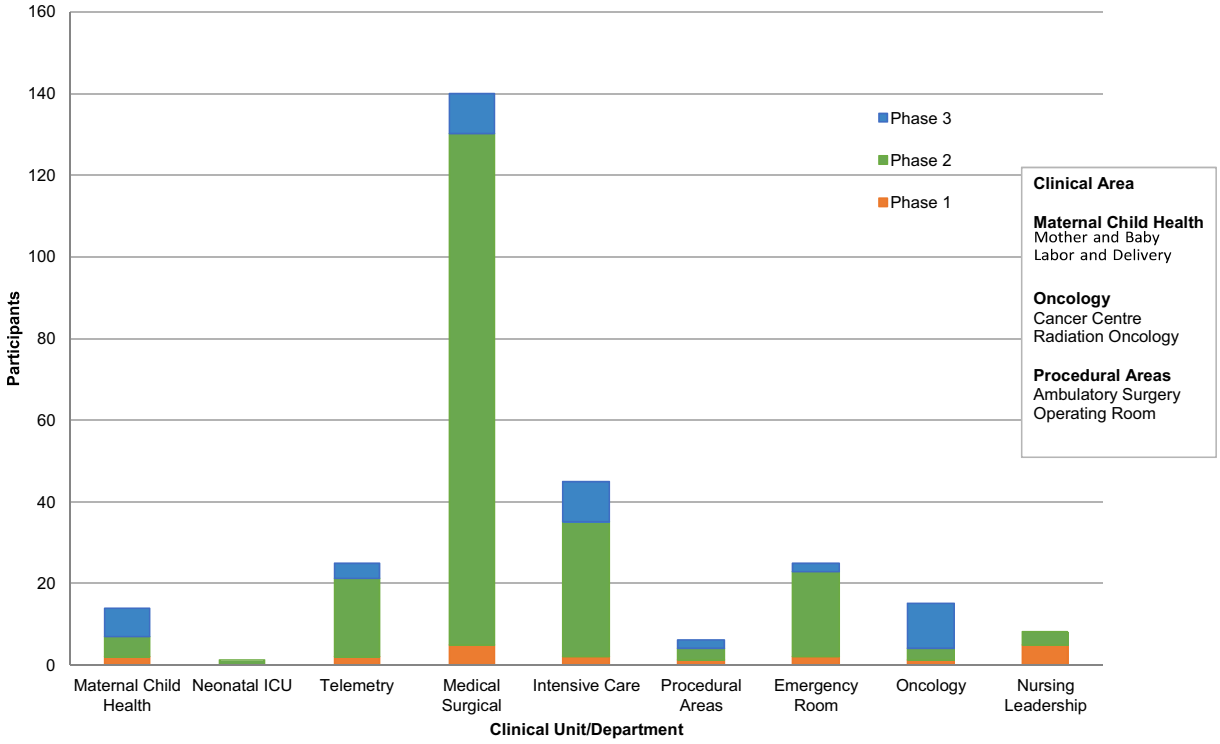

CHART 1 Distribution of participants by clinical unit

was completed before and after dressing application (see Appendix D).

4 | RESULTS

Descriptive statistics were analysed using Qualtrics®. Thirteen individuals participated in this study, with seven in the experimental group and six in the control group. Their ages ranged from 25 to 65 years with a mean age of 44.1. Six clinicians reported in the 25-to-40 age group and seven in the 40-to-65 age group. Of N = 13 enrolled, 12 participants identified as female and one as male. The self-identified racial/ethnic breakdown included 1.4% Asian, 15.4% Black, 23.0% Hispanic and 40.2% White. Clinician data, specific to their respective units, was also represented using descriptive statistics; see Chart 1.

Subjective data, including written participant responses in the fit test logs, were reviewed by three study team members. Overall, participant's subjective experience of wearing the flexible fabric bandage differed from that of the thin polyurethane foam dressing. One participant outlined the need for 'constant readjustment' and mask slipping with the Band-Aid®. Though no documented injury occurred according to current clinical practice guidelines, one participant demonstrated blanchable erythema at the nasal bridge with use of the Band-Aid. Blanchable erythema is not stageable as a pressure injury as per NPIAP pressure injury staging guideline.[16] Regarding mask fit, one participant in the Band-Aid® group failed the fit test when they experienced a strong taste of the fit test solution. The study design, with a focus on the non COVID-19 environment, allowed the participant to remain engaged in the study process. Comparatively, there was no observable evidence of blanchable or unblanchable erythema or skin breakdown noted by our WOCN team in the intervention group. Further, all seven participants passed the fit test after the dressing was applied.

No additional ancillary analyses were performed. Moreover, no actual harm or unintended events were reported or observed across the three enrollment phases of this study. One participant, in Phase two, reported to have provided care for a patient affected by COVID-19 prior to enrolment. The participant reported this after participation in this study and did not provide care for COVID-19 patients during the intervention and experienced no harm (Table 1).

5 | DISCUSSION

The feasibility of studying the use of the Mepilex Lite® dressing beneath the N95, Halyard Fluidshield® mask in a randomised trial was established. Our preliminary results suggest that the use of the thin polyurethane foam dressing, Mepilex Lite®, is a safe, prophylactic intervention to

TABLE 1 Nasal bridge pressure injury prevention feasibility study results

Randomised Group	Fit Test	Skin Assessment	Subjective data
Control Group Band-Aid®			
42N95X	Fail	No injury	Dizziness and lightheadedness. Constant readjustment of mask.
17N95X	Passed	Blanchable erythema	··
37N95X	Passed	No injury	··
49N95X	Passed	No injury	··
95N95X	Passed	No injury	··
22N95X	Passed	No injury	··
Experimental – Mepilex Lite®			
15N95Z	Passed	No injury	··
32N95Z	Passed	No injury	··
43N95Z	Passed	No injury	··
30N95Z	Passed	No injury	··
50N95Z	Passed	No injury	··
29N95Z	Passed	No injury	··
1N95Z	Passed	No injury	··

prevent skin breakdown that commonly occurs to the nasal bridge secondary to long-term PPE wear. The mask seal/fit of the N95 with the dressing was maintained, limiting clinician exposure to potential airborne/droplet pathogens. Based on these initial results, the Band-Aid® dressing also preserved skin integrity but compromised mask seal/fit suspected secondary to qualities of the flexible fabric. Based on our study results, we would not recommend the use of Band-Aid® as a pressure injury prevention modality due to risk of a compromised mask seal/fit. Although limited, recommendations of comparable, current research support use of a foam dressing, like Mepilex Lite®, as a nasal bridge pressure injury prevention modality for both the inpatient and the healthcare worker.[17–19]

As the pandemic evolved and higher incidence of facial skin injury was noted with long-term PPE wear. The NPIAP acknowledged the need for prophylactic measures to mitigate pressure injuries secondary to PPE use.[20] However, they also reported the uncertainty of utilising dressings under PPE due to the risk of seal integrity.[21] Therefore, our study protocol included standardised fit testing, before and after, application of the tested dressings, as a secondary aim and additional safety element.

The results of this feasibility study are further bolstered by Gasparino et al.[22] who also examined the prophylactic use of foam or hydrocolloid dressings with clinician PPE-related pressure injuries. Similar to our evaluation with a thin polyurethane foam dressing on the nasal bridge, Gasparino et al.[22] tested use of a foam or hydrocolloid dressing on 88 clinicians who provided direct or indirect COVID care. Clinical significance was determined to the forehead and cheeks ($P < 0.02$), bilateral ears and nasal bridge ($P < 0.01$), while testing three types of PPE, namely N95 masks, hats and goggles/visors (Gasparino et al[22]). Notably, clinical practice guidelines for skin assessment were not mentioned in this study or the clinical expertise of the skin appraisers' post-intervention.[22] Further, the study did not include procedural standardised fit testing procedures prior to or after the application of prophylactic dressings to the study regions.[22,23] In consideration of potential risk of exposure to the virus, we do not recommend testing of mask use with various dressings without a formal skin assessment and standardised fit test, with direct exposure to COVID-19 patient-care areas.

Moreover, a quality improvement project by Pacis et al.[23] evaluated three different masks with six skin-protection treatments, including the following: 1) liquid polymer acrylate, 2) an alcohol-free liquid acrylate dressing, 3) a thin film dressing, 4) a thin hydrocolloid dressing, 5) a hydrocolloid blister care cushion a silicone-based thin foam transfer dressing and 6) a hydrophilic polyurethane membrane matrix with a semipermeable polyurethane. Subjective discomfort was reported with 1) liquid polymer acrylate and 2) alcohol-free dressings. Differently, Pacis et al.[23] utilised a user-performed seal check, which included a subjective evaluation of mask seal around the face and nasal bridge. In consideration of

safety and efficacy of application of a skin protectant dressing beneath the N95 masks, we recommend formal assessment to the integrity of the mask seal prior to and after the dressing is applied, as current research or practice guidelines do not exist.

The major limitations of this study include the following: 1) limited generalisability due to sample size, 2) study enrolment challenges due to COVID-19 resurgence and 3) subjective bias. Although our study findings are limited due to sample size, feasibility of use of the Mepilex Lite® dressing beneath the Halyard Fluidshield® mask was established for further evaluation in a trial. Recruitment challenges were encountered with the evolving needs of the hospital with COVID-19 increase, thus the study was modified several times to include a broader sample of participants.[24] This process may have added some measure of uncertainty in eligibility among prospective participants—nurses only, then all clinicians, then fit-tested employees. Subjective bias may have altered results as nursing personnel were previously familiar with using Mepilex Lite® on patients prior to the beginning of the study and to other verified and tested regions of the body.

Although our study provides initial evidence to support the use of a thin-profile polyurethane foam dressing applied to the nasal bridge beneath the N95, Halyard Fluidshield® mask as a safe and feasible option, further research is needed to further generalise and verify study results. Additional randomised clinical trials are recommended to compare evidence and to further evaluate the safety and efficacy of various, commercially available barrier methods to be applied beneath various N95 respirator masks. Recommended study safety modifications include the following: 1) scientific verification of the industry standard for fit-testing with the thin polyurethane foam dressing in situ, 2) a second verification process to provide additional scrutiny for any variability in potential participant exposure and 3) study replication in a laboratory setting free of any transmissible, pathogenic agents. The financial impact of this study can be evaluated through a cost/benefit analysis for use of the Mepilex Lite® with the Halyard Fluidshield® as compared to other commercially available masks.

In conclusion, results of this feasibility study are promising in supporting the use of a thin polyurethane foam dressing (Mepilex Lite®) as a safe and effective dressing to apply beneath the Halyard Fluidshield® N95 mask. Additional research is needed to validate results due to limited data on efficacy and safety of the various barrier dressings as a potential intervention to prevent skin breakdown to the nasal bridge. With an ongoing pandemic and need for use of N95 respirator masks, research on skin protectant barriers are necessary for healthcare personnel who are exposed to prolonged wear time of the masks.

The original protocol is available at ClinicalTrials.gov, with Identifier: NCT04761679. All study materials were supplied by the study facility. No external sources of funding was received for this study. This study was approved by the Columbia University Institutional Review Board: Reference number AAAT-2889.

ACKNOWLEDGEMENTS

We would like to acknowledge the gracious support of New York Presbyterian Lawrence Hospital in this research effort: Dr. Laurie Walsh DNP, RN (Chief Nursing Officer, Vice President Patient Care Services), Dr. Rey Rivera DNP, RN (Director of Nursing Research and Innovation), Danielle Le Strange (Director of Critical Care Services), Dr. Anthony Pucillo MD (Chief Medical Officer), Amanda Hess (Research Assistant), Neil Nuguid (Research Assistant), Study Participants, Damion Crawford, Dariusz Dzwonczyk, Eric Shore

Ian Saludares, James Keogh, James Saintfleur, Janice Leone, Jennifer Bailey, Melinda Warnken, Pratik Thacker, Randy Subramany, Robert Glaser, Sandra Lang, Susan Cho, Thomas Owens, Virginia Crimarco.

CONFLICT OF INTEREST

No conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Holder H, Aningalan AM, Walker S, Cato K, Gannon B". Feasibility of nasal bridge pressure injury prevention using a protective dressing and the Halyard Fluidshield® N95 mask in a COVID-positive environment. *Int Wound J*. 2022; 1-7. doi:10.1111/iwj.13871