



## Original research

# Effectiveness of an anti-fog polymer coating in protective eyewear: a blinded, randomised controlled cross-over trial with healthcare providers in an emergency department setting

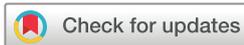
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## ABSTRACT

**Background** Eye protection is a mandatory component of the personal protective equipment in healthcare settings, especially for suspected or confirmed cases of COVID-19 and during aerosolising procedures. Fogging of protective eyewear is a frequent problem experienced by providers. The hydrophilic property of a sulfonated polymer, BiaXam, may be able to decrease fogging through wicking moisture from the lens. In this study, we tested the anti-fogging properties of this polymer when applied to protective eyewear.

**Methods** An investigator-initiated prospective, randomised, single-blinded cross-over study was conducted in an emergency department in a large, tertiary care hospital. Participants were blinded and randomised first to either a pair of anti-fog coated or uncoated eyewear, and then to the alternative pair after 2 hours. Study participants completed an identical survey at the end of each 2-hour period.

**Results** 50 emergency medicine healthcare providers were enrolled and 48 completed the study. Results demonstrated a significant difference in fogging between the coated and uncoated eyewear, as 81% of the participants reported fogging of the uncoated lenses and only 55% of the participants reported fogging in the coated pair ( $p=0.0029$ ). Participants reported that the uncoated lenses fogged two times as frequently on a 10-point Likert scale ( $4.5\pm 3.3$  vs  $2.1\pm 2.5$ ;  $p<0.0001$ ). Subgroup analysis of participants who wore only a surgical mask demonstrated even more efficacious results with coated eyewear.

**Conclusion** Overall, sulfonated polymer-coated eyewear improved provider visualisation, user

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Several studies in the literature describe fogging of protective eyewear as a widespread problem, but few offer solutions. Although other anti-fog coated lenses do exist, we are not aware of any that have been effectively validated in clinical environments.

## WHAT THIS STUDY ADDS

⇒ Given the paucity of the literature validating effective anti-fog coating of polyethylene terephthalate or alternative measures, as well as the dearth of studies looking at the impact of fogging of eyewear in the clinical setting, this study demonstrates value through assessing the effectiveness of a novel anti-fog coating.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Since there is currently no other gold-standard, anti-fog coating for personal protective equipment eyewear, future studies may compare this polymer to other coatings on the market. Further studies are required to determine durability, longevity and effectiveness of this novel anti-fog coating after prolonged periods of wear in non-disposable eyewear.

experience and perceived mitigation of potential medical errors.

## BACKGROUND

Donning personal protective equipment (PPE) is mandatory while caring for patients during the COVID-19 pandemic

to prevent the spread of infection. In emergency departments (EDs) and other healthcare settings, PPE typically consists of protective masks, gloves, gowns and protective eyewear. Eye protection is essential to prevent the spread of viral particles through mucosal membranes and is now a mandatory component of the PPE used during patient encounters, notably for suspected or confirmed cases of COVID-19 and during aerosolising procedures.<sup>1</sup> This is recommended by leading health agencies such as the Centers for Disease Control and Prevention and the Occupational Safety and Health Administration.<sup>2,3</sup> In our experience working at a large tertiary-care hospital, fogging of protective eyewear is a frequent problem experienced by many front-line providers and may impact patient care, provider safety and experience, and adherence to proper wear and usage. Several studies in the literature describe this widespread problem too, but few offer solutions.<sup>4-7</sup> Fogging of protective eyewear is frequently produced through moisturised, expired air leaking around the contours of masks. Unfortunately, fog-resistant protective eyewear currently on the market make claims that are often unfounded and have not been properly tested in clinical environments.<sup>8,9</sup>

Although PPE eyewear is considered essential in preventing occupational risk to healthcare workers, practical considerations must be addressed to ensure there are not issues related to fogging that may impact patient and provider safety as well as user experience. A study by Jordan and Pritchard-Jones<sup>10</sup> found that a tightly sealed face mask, such as the N-95 mask, is effective in reducing fogging. Although this is a simple and effective method, N-95 masks are more expensive and relatively scarce compared with surgical masks. Also, these masks are less comfortable due to their tight-fitting design and have been associated with other side effects after prolonged use. A cross-sectional study by Ong *et al*<sup>11</sup> found that the combined usage of the N-95 mask with protective eyewear was independently associated with developing de novo PPE-associated headaches. Another reported method to prevent fogging is the application of an adhesive strip on the nasal bridge-mask junction to block some of the air leakage around the nasal ridge.<sup>12</sup> Application of a detergent-based surfactant (eg, soapy water) that is then dried with a cloth has also been shown to temporarily reduce fogging by creating lower surface tension on the lens, which causes the water molecules to spread out more thinly thereby decrease the scattering of light.<sup>7,8,13,14</sup> Anti-fogging sprays and gels, used widely by scuba divers,<sup>15</sup> have a similar mechanism of action to the application of a detergent based surfactant. However, these require frequent reapplication, can be cumulatively expensive and require more user diligence as compared with a durable anti-fog coating.<sup>7</sup> Hence, these alternative solutions offer only temporary, postmanufacturing fogging reductions. Although other anti-fog coated lenses do exist, we are not aware

of any that have been effectively validated in a clinical environment. Furthermore, the lack of standardisation in PPE eyewear may prevent clinicians from developing proficiency and adherence in its use. To enhance safety and usage of PPE eyewear, increased attention needs to be directed towards anti-fogging performance in clinical settings.

Researchers at North Carolina State University initially discovered that a sulfonated polymer, BiaXam, produced by Kraton Polymers LLC, has inherently self-sterilising properties.<sup>16</sup> It was subsequently determined that the polymer also has anti-fog properties.<sup>17</sup> The hydrophilic property of this BiaXam sulfonated polymer may be able to decrease fogging through wicking moisture from the lens. To ensure widespread and safe usage of protective eyewear, eye protection must permit sufficient vision without disruptive fogging. Furthermore, fogging may not only impact the user-experience, but also impede providers' ability to safely perform critical tasks. In addition, removal of protective eyewear, even temporarily, to wipe down and defog the lens may also put the user at risk of infection, either through direct touching of one's face or through respiratory aerosols or droplets. In this first of its kind clinical trial, we sought to test the anti-fogging properties of this polymer when applied to protective eyewear in a real-world clinical setting in a high-throughput ED. In addition to anti-fog properties, we wished to assess the relative user-experience and safety factors as compared with current-use protective eyewear.

## METHODS

We conducted an investigator-initiated prospective, randomised, single-blinded cross-over study to assess the experience and effectiveness of an anti-fog sulfonated polymer coating in protective eyewear in April and May 2021. The study was performed in a high-volume ED in a large, tertiary hospital in Boston, Massachusetts, USA. Study participants included healthcare providers (physicians, advanced practice providers including physician assistants and nurse practitioners, and registered nurses) who were working on shift and caring for patients in the ED. Healthcare providers who also wore corrective eyeglasses were excluded from the study as it was assumed it would interfere with their ability to properly assess and distinguish fogging on their corrective lenses from the protective eyewear provided. Study participants were verbally consented prior to enrolment by trained, ED research associates. The research associates were additionally responsible for the randomisation of participants on REDCap, a secure electronic platform. The ambient condition of the ED is maintained in a relative humidity and temperature range of 30%–60% and 21°C–24°C, respectively.

Study participants were blinded and randomised to wear either a pair of disposable anti-fog coated

polyethylene terephthalate (PET) eyewear (intervention) or disposable uncoated PET eyewear (control). Both types of disposable eyewear appeared the same and were otherwise indistinguishable to the user. After the participant wore the first pair of eyewear for 2 hours, they were then provided with the alternative pair to wear for an additional 2 hours. Participants wore the goggles during the course of their clinical duties with typical tasks including, for example, patient assessment, intravenous line placement, blood draws, reading of vitals signs and electronic medical record (EMR) data, administration of medications, and endotracheal intubation. Each study participant acted as their own control according to the crossover design of the study. The study participants completed an identical electronic survey on REDCap at the end of each 2-hour period. Statistical analysis was performed to evaluate for user-experience differences between uncoated and coated eyewear. A subgroup analysis was also performed to determine differences based on the type of mask worn by the user during the study. McNemar's test was performed to test for significance on paired survey questions with nominal responses and the Student's t-test was performed to test for significance on ordinal scale, interval data (Likert scale responses). A  $p$  value  $<0.05$  was considered statistically significant. SAS V.9.4 was used for statistical analysis.

## RESULTS

### Demographics

Overall, 50 emergency medicine healthcare providers were enrolled in the study. Two participants (0.04%) were eliminated from the study after not completing both surveys. Overall, 48 emergency medicine healthcare providers completed the study. Of the 48 participants who completed the study, there were 15 physicians, 18 advanced practice providers and 15 registered nurses. Overall, 30 (62.5%) of the participants were female and 18 (37.5%) were men with a reported mean age of 30–34 years with participants

ranging from 25 to 64. 29 (60%) of participants were first randomised to the anti-fog coated eyewear.

## SURVEY RESULTS

### Entire cohort

Survey results (table 1) demonstrate a significant difference in fogging between the coated and uncoated eyewear, as 39 (81%) of the participants reported any fogging of the uncoated eyewear and only 26 (55%) of the participants reported fogging in the coated pair ( $p=0.0029$ ). Participants reported that the uncoated eyewear fogged two times as frequently on a 10-point Likert scale ( $4.5\pm 3.3$  vs  $2.1\pm 2.5$ ;  $p<0.0001$ ). Two times as many participants also reported that the uncoated eyewear had fogging that may have impacted the care of their patients and possibly led to safety concern(s) (35% vs 17%;  $p=0.0067$ ). Similarly, participants reported that fogging of the uncoated eyewear limited their ability to perform patient-centric tasks more frequently than the coated eyewear ( $2.5\pm 3.0$  vs  $1.4\pm 2.5$ ;  $p=0.0425$ ). Fogging of the uncoated eyewear caused participants to touch their face nearly two times as frequently compared with the coated eyewear ( $3.4\pm 3.3$  vs  $1.8\pm 2.8$ ;  $p=0.0181$ ). Aside from fogging, there was no significant difference in distortion or limitation of one's vision between the two pairs of protective eyewear ( $p=0.2274$ ).

### Subgroup analysis: surgical mask only

A subgroup analysis of the participants who wore only a surgical mask ( $n=15$ ) during the entire duration of the study was performed (table 2). Overall, results demonstrate a significance in reduction of 'ever' fogging and 'frequency' of fogging, as well as improved safety while performing clinical duties while wearing the coated eyewear. The participants who wore only a surgical mask reported higher efficacy and improved experience relative to that of the entire cohort.

**Table 1** Entire cohort analysis ( $n=48$ )

Survey questions	Percentage of respondents who answered 'yes'		
	Uncoated (control)	Coated (intervention)	P value
Did the goggles you just wore ever fog while wearing them on today's shift?	39/48 (81%)	26/48 (55%)	0.0029
Were there any instances today that fogging of the goggles you have just worn may have impacted the care of your patient and possibly have led to a safety concern (eg, fogging while performing a procedure, difficulty with reading the patient monitor or labels, etc)?	17/48 (35%)	8/48 (17%)	0.0067
	<b>Mean (0 (not at all) to 10 (very frequently))</b>		
How often did the goggles fog?	$4.5\pm 3.3$	$2.1\pm 2.5$	$<0.0001$
How often did fogging of your goggles limit your ability to perform your tasks (eg, reading, communicating, performing procedures, etc)?	$2.5\pm 3.0$	$1.4\pm 2.5$	0.0425
Aside from fogging, did the goggles you wore limit or distort your vision?	$1.5\pm 2.4$	$2.0\pm 2.6$	0.2274
Approximately how often did fogging of the goggles you have just worn cause you to touch your face or head to either remove your goggles and/or face mask?	$3.4\pm 3.3$	$1.8\pm 2.8$	0.0181
Survey responses for nominal and Likert scaled questions.			

**Table 2** Subgroup analysis: surgical mask only (n=15)

Survey questions	Percentage of respondents who answered 'yes'		
	Uncoated (control)	Coated (intervention)	P value
Did the goggles you just wore ever fog while wearing them on today's shift?	13/15 (87%)	7/15 (47%)	0.0143
Were there any instances today that fogging of the goggles you have just worn may have impacted the care of your patient and possibly have led to a safety concern (eg, fogging while performing a procedure, difficulty with reading the patient monitor or labels, etc)?	6/15 (40%)	1/15 (7%)	0.0253
	Mean (0 (not at all) to 10 (very frequently))		
How often did the goggles fog?	5.5±3.7	2.2±2.7	0.0151
How often did fogging of your goggles limit your ability to perform your tasks (eg, reading, communicating, performing procedures, etc)?	3.7±3.7	1.1±2.1	0.0439
Aside from fogging, did the goggles you wore limit or distort your vision?	1.8±2.9	2.2±2.2	0.791
Approximately how often did fogging of the goggles you have just worn cause you to touch your face or head to either remove your goggles and/or face mask?	4.9±3.8	2.1±3.2	0.0313
Survey responses for nominal and Likert scaled questions.			

**Subgroup analysis: N-95 mask only**

A subgroup analysis of the participants who wore only an N-95 mask (n=9) during the entire duration of the study was performed (table 3). In this subgroup analysis, there was no significant difference to any of the survey questions, including the frequency of fogging, how frequently fogging may have impacted patient care and provider safety and experience.

**DISCUSSION**

Our study demonstrates the effectiveness and improved provider experience while wearing anti-fog coated PPE eyewear in clinical settings particularly while also wearing a surgical mask. We believe the application of an anti-fog material, such as the BiaXam sulfonated polymer, to protective eyewear should be considered as one solution in remedying the widespread problem of fogging. The coated eyewear demonstrated a significant reduction in fogging both 'ever' and with respect to the frequency of fogging in what appears a clinically meaningful way. Importantly, healthcare providers perceived that the uncoated eyewear would significantly impact

clinical care negatively at approximately double the rate compared with coated pair (35% vs 17%). In subgroup analysis, this difference was even more dramatic in people wearing only surgical masks (40% vs 7%). However, the difference in fogging or perceived negative care impacts was not seen when wearing only N-95 masks. Hence, our findings corroborate the study by Jordan and Pritchard-Jones<sup>10</sup> that found tightly sealed face masks, such as N-95's, are effective in reducing fogging. This is not an unexpected finding given that the design and seal of N-95 masks permits less moisturised expired air leaks than the more commonly worn surgical masks.

The barriers to increased or uniform usage of N-95 masks, the short-term nature and increased user diligence required for many alternative anti-fog measures, as well as the dearth of other studies looking at the impact of fogging of eyewear in the clinical setting have resulted in inadequate anti-fog eyewear solutions in healthcare. We believe this study demonstrates the effectiveness of this anti-fog eyewear coating while wearing a mask in a clinical setting.

**Table 3** Subgroup analysis: N-95 mask only (n=9)

Survey questions	Percentage of respondents who answered 'yes'		
	Uncoated (control)	Coated (intervention)	P value
Did the goggles you just wore ever fog while wearing them on today's shift?	5/9 (56%)	6/8 (75%)	0.3173
Were there any instances today that fogging of the goggles you have just worn may have impacted the care of your patient and possibly have led to a safety concern (eg, fogging while performing a procedure, difficulty with reading the patient monitor or labels, etc)?	0/9 (0%)	1/8 (13%)	p=N/A
	Mean (0 (not at all) to 10 (very frequently))		
How often did the goggles fog?	1.4±1.7	2.0±2.1	0.6875
How often did fogging of your goggles limit your ability to perform your tasks (eg, reading, communicating, performing procedures, etc)?	0.4±0.7	1.1±2.3	0.5
Aside from fogging, did the goggles you wore limit or distort your vision?	0.9±1.2	1.4±1.6	0.5
Approximately how often did fogging of the goggles you have just worn cause you to touch your face or head to either remove your goggles and/or face mask?	0.9±1.2	1.7±2.3	0.5
Survey responses for nominal and Likert scaled questions.			

A recent study by Herkert *et al*<sup>18</sup> at Duke's Nicholas School of the Environment found that anti-fogging sprays and cloths commonly used to prevent fogging on protective eyewear may contain high levels of polyfluorinated alkyl substances. Exposure to these substances has been associated with toxicological effects such as impaired immune function, cancer and thyroid disease. With this concern, the authors of this study requested safety information of BiaXam from the manufacturer and received a statement from the Kraton Polymers LLC Product Safety and Regulatory Team. 'BiaXam is considered a polymer of low concern to human and environmental health and meets the US EPA Polymer Exemption criteria (40 CFR 723.250). The BiaXam polymer is over 99% pure, with no known persistent, bioaccumulative or toxic substances intentionally added to the pure polymer. In addition, no known carcinogenic, mutagenic or reproductive substances are intentionally blended into the pure polymer. Results from independent laboratory studies performed to date report no detected adverse aquatic toxicity, dermal irritation, dermal toxicity or sensitisation effects, and continue to support the conclusion that BiaXam is a low risk to human health and the environment.'

Our study evaluated the effectiveness and experience after clinicians wore each type of PPE eyewear (coated and uncoated) for 2 hours. This is a reasonable duration given the short-term use, and disposable design of the eyewear used for this study. However, future studies are needed to evaluate the durability and longevity of this polymer in non-disposable eyewear. Also, given the hydrophilic nature of this polymer (and other, anti-fog polymers), further evaluation of anti-fog properties should be evaluated with longer uses as the anti-fog properties may have a saturation threshold and, hence, may become less effective over time. Lastly, our study compared the anti-fog properties of a sulfonated polymer against an uncoated pair in order to understand its effectiveness, as well as the importance of anti-fog lenses in the clinical setting. Since there is currently no other gold-standard, anti-fog coating for PPE eyewear, future studies may compare this polymer to other commonly used coatings on the market.

## CONCLUSION

Overall, BiaXam-coated protective eyewear greatly improved provider's visualisation due to its anti-fogging properties and was perceived to have significantly reduced potential negative care impacts and improved user's experiences for providers wearing a protective face mask. Due to the improved experience of wearing the coated eyewear, it is anticipated that the BiaXam coating would aid with improved eyewear-mandate compliance. Further study is required to determine durability and effectiveness of this novel anti-fog coating after prolonged periods of wear.

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**Contributors** YGK and KRO were responsible for the study's conceptualisation, design, implementation and are the guarantors of this study. JDM assisted in data collection. YGK, KRO and HZ performed the data analysis. YGK and KRO interpreted the results. YGK and KRO wrote the original draft of the manuscript. ASR and JDM provided edits and revisions to the manuscript.

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**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and was approved by Mass General Brigham IRB, approved on 8 January 2021, protocol number 2020P003998. Participants gave informed consent to participate in the study before taking part.

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