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Lubrication to reduce tissue shear loading - effects on comfort perception and tissue damage when wearing a facemask

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ABSTRACT

Patients with respiratory disease often require breathing support delivered via a nasal or facemask. The use of such a mask causes continued loading of the skin which can result in discomfort or skin injury, which may lead to low adherence to treatment. It is hypothesised that lubricating the mask-skin interface will reduce shear stress, thus reducing the load on the skin. The aim of this study was to determine whether the application of a novel lubricant to the mask improved discomfort and/or skin injury measured using three outcomes: subjective comfort, erythema, and the presence of epidermal interleukins.

Ten healthy participants were randomised to wear a lubricated or unlubricated facemask for one hour. Each participant switched over after a one-hour washout period. Subjective comfort was measured using visual analogue scales. Erythema was quantified from facial photographs and interleukins were obtained using tape stripping and ELISA assay analysis. Results show that the subjective comfort significantly improved after one hour with the application of a novel lubricant, compared to no lubrication ($p=0.015$), however erythema and interleukins were not significantly different. As comfort perception may affect adherence, this novel lubricant may be beneficial in the clinical care of those needing to wear facemasks.

1. Introduction

Patients with acute and chronic respiratory failure require respiratory support to aid breathing, e.g., mechanical ventilation and continuous positive airway pressure (CPAP) [1]. The delivery of these therapies occurs using a nasal or facemask that covers the nose and/or mouth and is connected to an air supply, such as a ventilator. Patients needing respiratory support can find wearing facemasks uncomfortable, especially if they are wearing the facemask for long periods of time, e.g. overnight [2,3].

Obstructive sleep apnoea (OSA) is a common respiratory disorder that affects an estimated 936 million adults globally [4]. This prevalence is likely to increase due to its association with obesity and increasing age [5,6]. CPAP is mandated as the first-line treatment for patients with OSA, where it acts to splint the upper airway during sleep [1]. The recommended usage for symptom relief is more than 4 h per night for 70 % of the monitored nights [7]. Effective CPAP is associated with reductions in sleepiness, the main symptom of OSA, and improvements in quality of life [8–10]. CPAP withdrawal is associated with increased sleepiness, impaired endothelial dysfunction, increased blood pressure and increased heart rate [11]. Despite the clinical effectiveness of CPAP [8–10], adherence is limited in some patients [12] and an overall compliance rate of 65.9 % has been reported [13].

Medical facemask design has progressed greatly in the last decade, and current commercially available facemasks have soft, elastomer materials that interface with the face and have improved strap designs [13]. However, patient adherence to CPAP is still a problem [12] and there are a multitude of factors influencing adherence, including psychological factors, social variables and facemask-related side effects [12, 14–18]. Skin discomfort and injury have been linked to the continued over-loading of the skin when wearing a facemask, which may occur due to a variety of reasons; the airflow from a leaking facemask may cause dry eyes, and a typical response to such a leak would be to tighten the facemask straps, which increases the pressure exerted on the skin [19, 20] which can cause further discomfort and pressure-related skin injury [20]. Overall, this leads to dissatisfaction with the CPAP treatment and

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low adherence, therefore, ensuring patients are comfortable is essential [15,21]. Secondly, in acute respiratory disease, mechanical ventilation is critical to maintaining blood gas homeostasis [22], meaning the facemask cannot easily be removed. The prolonged treatment and resulting load acting on the skin may result in skin injury such as rashes and pressure injuries [23–25]. These device-related pressure injuries are more prominent around the nasal bridge compared to anywhere else on the face [20,26], can occur after just two hours of loading [24,27] and treatment ranges from the application of topical steroids to skin grafts [23].

The development of skin injury has been linked to the shear stresses in the tissue [28,29]. Approaches that have been used to reduce the shear loading on the skin when wearing a facemask include the application of protective coverings over the nasal bridge, which have been reported effective in the prevention of pressure injuries during non-invasive ventilation use in critical care [30–32]. However, the risk of facemask leakage is a concern in patients using additional coverings between the mask-skin interface.

The topical application of a non-absorbent lubricant has been proposed to prevent device-related pressure injury, as the lubricant reduces the frictional shear stresses in the mask-skin interface. Yap et al developed a novel wax/oil mixture and reported a reduction in friction in a laboratory setting, measured against skin on the volar forearm, both immediately after application (CoF = 0.14) as well as up to 4 h after application of the lubricant (COF = 0.46) compared to the unlubricated control (CoF= 1.14) [33]. This lubricant has not yet been tested on facial skin, or whilst wearing a commercially available facemask. If the lubricant improves subjective comfort and/or reduces erythema, it may be of value to patients who need CPAP treatment and/ or ventilatory support.

The primary aim of this randomised, crossover study was to determine if a novel lubricant applied to a facemask improved subjective comfort, compared to no lubrication, when wearing a facemask for a relatively short time. The secondary aims were to determine if lubrication decreased erythema formation and decreased the presence of interleukins (IL-8, IL-1α) in the epidermis, compared to no lubrication, when wearing a facemask.

2. Methods

This randomised, crossover study tested the hypothesis that subjective comfort, measured after wearing a lubricated facemask for one hour, would be significantly improved, compared to the subjective comfort measured after wearing a non-lubricated facemask.

The study was approved by the Imperial College Research Ethics Committee (ICREC Reference Number: 22IC7438). All participants gave written informed consent prior to the study, which was carried out according to the protocol shown in Fig. 1.

2.1. Study participants

Eligible healthy volunteers from Imperial College London were included in the study by convenience sampling. Inclusion criteria were healthy people > 18 years with the ability to consent. Exclusion criteria were severe claustrophobia precluding wearing a facemask, pre-existing skin damage and known allergies to the contents of any of the lubricant ingredients.

2.2. Experimental protocol

2.2.1. Facemask and fit

A commercially available reusable full facemask with a dual wall cushion was used in this study (ResMed Airfit F10, Resmed Ltd, Didcot, UK). Facemask sizes for each participant (small, medium, large) were selected based on manufacturer's instructions. Facemask fittings were performed in a standardised way before wearing the mask with or without lubrication for one hour as follows: a CPAP machine was set to an airflow of 8 kPa and the setting 'Check Fit' was selected. Any leaks were identified and the facemask was subsequently adjusted. This was repeated until both the participant and researcher were satisfied with the fit and when the fit was reported as 'Good' by the CPAP machine. The room temperature was maintained at 21.3 ± 1.9 °C.

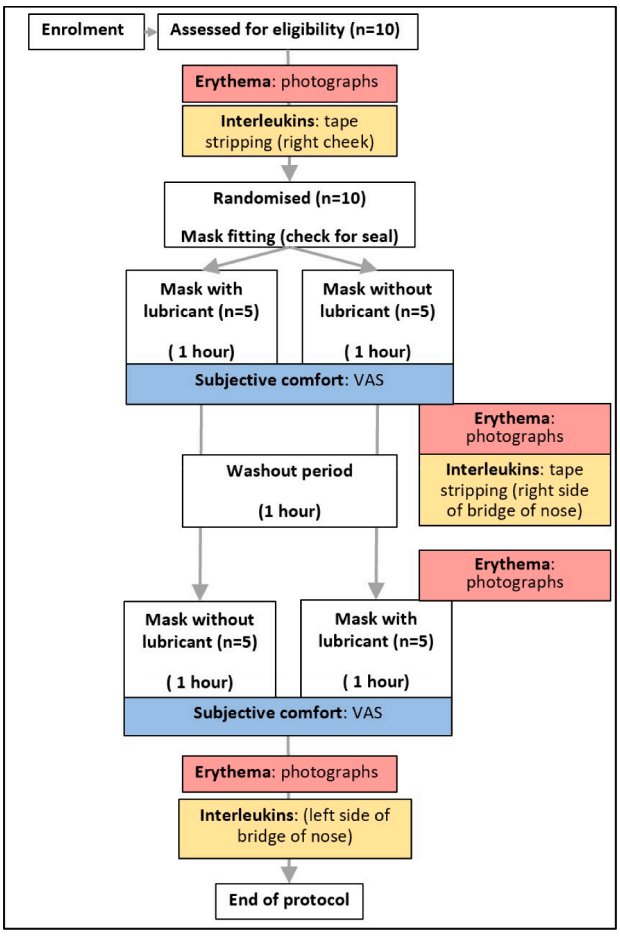


Fig. 1. Flowchart illustrating the experiment protocol.

2.2.2. Lubricant

A novel lubricant composed of beeswax (20 wt %), olive oil (40 wt %) mineral oil (40 wt %) and one drop of vitamin E for every 20 ml lubricant was applied to the facemask [33]. This lubricant was previously assessed for its shear reducing capability. Approximately 0.9 ml of lubricant was applied on the outer surface of the cushion of the facemask with a cotton-bud applicator to create a very thin layer of lubricant on the facemask contact surface (calculated to be 92.5 cm^2). The same operator prepared all facemasks, thus limiting variability. Each participant wore the facemask with and without lubricant for a one-hour period, with a one-hour washout period. The order of lubricant application was randomised between participants. This was done using the sealed envelope technique. Neither the participant, nor the researchers were blinded to the intervention arm.

2.3. Outcome measurements

Time was measured with a stopwatch throughout the experiment.

2.3.1. Comfort

The subjective comfort of wearing the facemask was assessed using a Visual Analogue Scale (VAS) with a length of 10 cm, with 0 indicating

'Uncomfortable', which was additionally clarified with the statement "I want to take this mask off immediately", and 10 being 'Comfortable', i.e. "I could wear this mask for another hour", as shown in Fig. 2. The VAS rating was performed during the last minute of lubricated and non-lubricated facemask wearing. VAS comfort scores were calculated by manually measuring the 'X' on the VAS with a ruler accurate to one millimetre [34]. Participants were also given the opportunity to provide additional information about their facemask wearing experience in the form of freeform text.

2.3.2. Erythema

A common method used for the early detection of pressure injuries is the occurrence of non-blanchable erythema [35,36], a localised area of intractable redness on intact skin that may appear differently in darkly pigmented skin [37]. Non-blanchable erythema indicates post-ischaemia and can be the consequence of external stimuli, immunological reactions and viral infection [38,39]. Photographs were taken of participants before the facemask was placed, and after the facemask was worn (pre and post) in a standardised method (see Fig. 3).

Photography and lighting conditions were standardised for all participants by using the same lights and location in the participant room, which had blackout blinds in the window. All photographs were taken using an iPhone 13 Pro camera and stored locally. Photographs were taken with minimal ISO variation and the same aperture, shutter speed, exposure and focal length. Photographs were subsequently uploaded to a secure Microsoft Teams Channel and deleted from the camera phone.

Erythema analysis was completed using the protocol adapted from the validated and reproducible study of Logger et. al [40]. In summary, each photograph was split into the LA*b colour space using ImageJ (U.S. National Institutes of Health, Bethesda, Maryland, USA). The a* channel displays the spectrum of green to red, with true green as black, and true red as white. The a* channel images were isolated, and the region of interest (ROI) was selected (see Fig. 3). The ROI encompassed the superior half of the dorsum nasi and avoided any reflective surface of the skin. For all photographs, the same ROI was used after adjusting for minor changes in positioning of the participant in each photograph. A greater a* value equalled a greater amount of true red that was detected by the software in the ROI.

2.3.3. Inflammatory cytokines

Assessment of the inflammatory response of the skin was performed by tape stripping of the skin surface [41]. D-Squame adhesive discs (Clinical & Derm, Dallas, TX, USA) with a 14 mm diameter were used. Tape stripping was performed on the right cheek, on the right side of the bridge of the nose (after the first hour of facemask use) and on the left side of the bridge of the nose (after the second hour of facemask use). The applied pressure during application of the discs was standardised using a tongue depressor applied over each disc for ten seconds. In each location, ten discs were collected and individually placed into coded Eppendorf tubes that were immediately stored on dry ice.

At the end of the protocol, the tubes were transported and stored in a -80 °C freezer. The methodology of extraction and analysis of collected samples was based on Soetens [42]. After discarding the first two tapes of each location, the next 8 tapes were pooled to be placed in 2 ml of phosphate-buffered saline. This was repeated for each location on each participant, which totalled to 30 samples. These samples were placed on a roller mixer for one hour and then sonicated for ten minutes at room temperature. The concentration of IL-8 and IL-1α were determined using ELISA testing using the Invitrogen™ Human IL-8 ELISA Kit (Catalog No. KAC1301) and Human IL-1 alpha ELISA Kit (Catalog No. BMS243–2) respectively. Additionally, total protein concentration in the samples was determined using a Thermo Scientific™ Micro BCA™ Protein Assay Kit (product no. 23,225), which enabled correction for protein uptake during each measurement period.

2.3.4. Statistical analysis

Statistical analysis was performed using Graphpad Prism 9. Data was assessed for normality using four normality tests (Anderson-Darling Test, D'Agostino & Pearson Test, Shapiro-Wilk test, Kolgomorov-Smirnov test). For each parameter (VAS comfort scores and a* values), normal distribution was only assumed if all four normality tests were successful in each sub-dataset. Data are presented as mean ± standard deviation (SD) or median ± inter-quartile range (IQR) (depending on normal distribution). To compare the change in a* values after lubricated and non-lubricated facemask use, Δa* values were calculated by subtracting pre a* values from corresponding post a* values. Δa* values, IL-8, IL-1α and VAS comfort scores were analysed with paired *t*-tests or

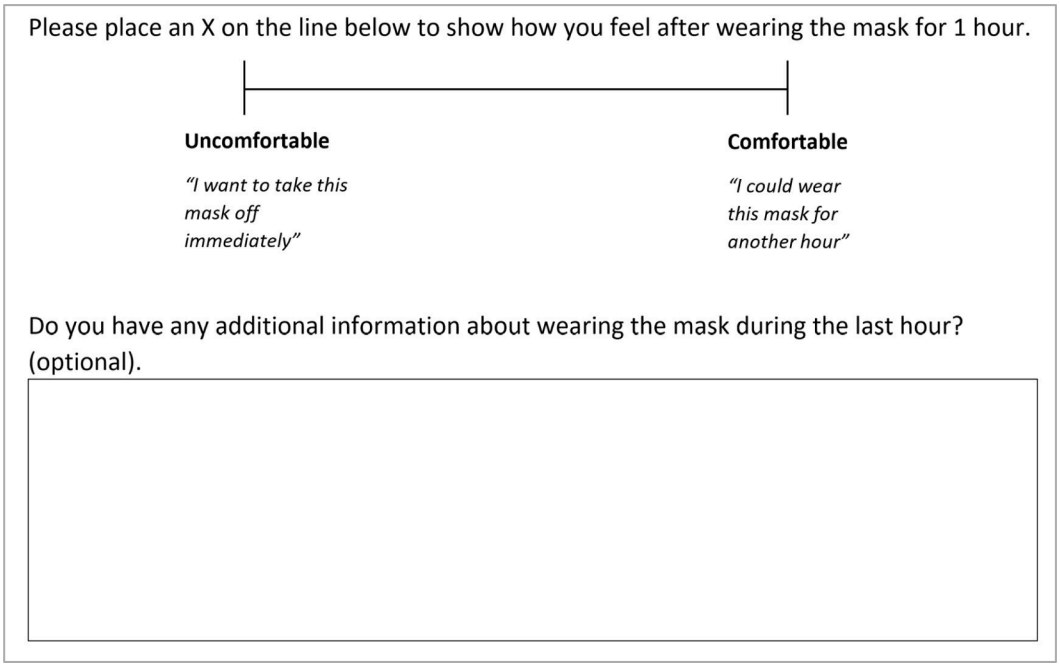


Fig. 2. The participant comfort questionnaire. Participants were asked to place an 'X' on the Visual Analogue Scale during the last minute of facemask use and to write in the textbox if they wished.

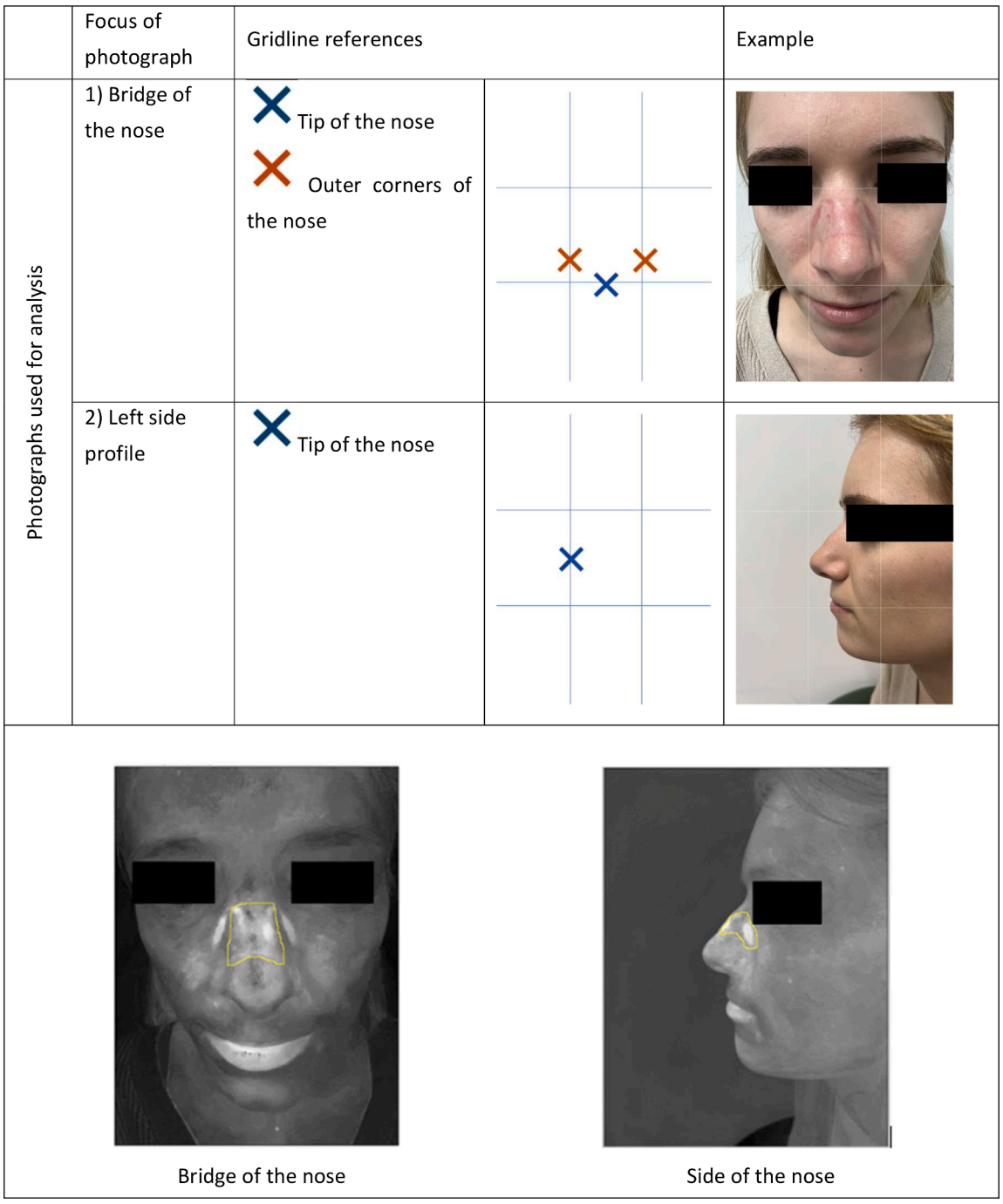


Fig. 3. Erythema assessment – standardisation, and selection of Region of Interest (ROI). Photographs were taken before and after each facemask use.

Wilcoxon signed-rank tests depending on normality distribution. The significance level of all analyses was set to 0.05.

3. Results

3.1. Study participants

Ten healthy participants (three males, seven females; mean ±SD age: 23.7 ± 3.33 years; height: 173 ± 10.1 cm and weight: 65.6 ± 13.9 kg) were recruited. Self-recorded ethnicities were: White British (n=8), White Greek (n=1) and Indian (n=1). All participants completed the protocol, and contributed to a full data set.

3.2. Subjective comfort

The subjective comfort (see Fig. 4) was significantly improved after one hour of wearing the facemask with lubrication, compared to no lubrication (median ±SD, VAS comfort score: no lubrication 6.53 ± 1.97; lubrication 8.04 ± 1.84; p=0.0153, paired *t*-test). Note that Cohen's paired d = 0.944, and the statistical power of the paired test is 75.7 %.

3.3. Erythema

On the bridge of the nose (see Fig. 5**: Left panel**), erythema did not significantly change after one hour of wearing the facemask with

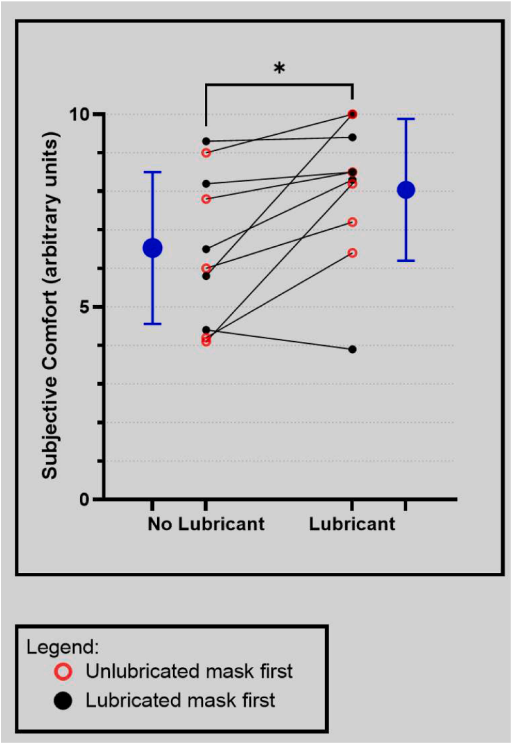


Fig. 4. The change in subjective comfort levels after one hour of wearing the facemask, with 0 being most uncomfortable and 10 being most comfortable. The open/ closed circles identify participants who were randomised to wearing unlubricated/ lubricated masks first respectively. The blue data points and lines represent the group mean and standard deviation. * The black horizontal bar and asterisk indicate the statistical significance between the two data sets. p-value = 0.0153, paired *t*-test.

lubrication, compared to no lubrication (median ±IQR Δa* value: no lubrication 2.50 ± 5.32 a.u; lubrication 2.33 ± 3.30 a.u; p=0.084, Wilcoxon signed-rank test). On the side of the nose (see Fig. 5**: Right panel**), erythema did not significantly change after one hour of wearing the facemask with lubrication, compared to no lubrication (median ±IQR Δa* value: no lubrication 3.97 ± 1.70 a.u; lubrication 2.02 ± 2.26 a.u; p=0.322, Wilcoxon signed-rank test)**.**

3.4. *Inflammatory cytokines*

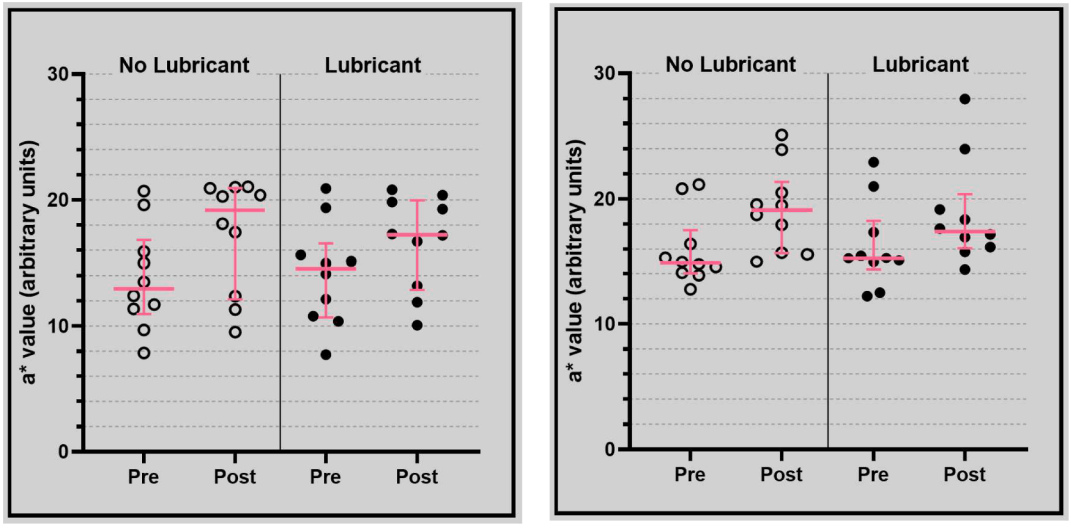
The concentration of IL-8 (see Fig. 6**: Left panel**) did not significantly change after wearing the facemask with lubrication, compared to no lubrication, both compared to baseline (median ±IQR ΔIL-8 concentration: no lubrication 5.49 ± 28.2 pg/mL; lubrication 5.55 ±11.4 pg/mL; p=0.770). The concentration of IL-1α (see Fig. 6**: Right panel**) did not significantly change after wearing the facemask with lubrication, compared to no lubrication, both compared to baseline (median ±IQR ΔIL-α concentration: no lubrication 5.49 ± 28.2 pg/mL; lubrication 5.55 ±11.4 pg/mL; p=0.770).

4. Discussion

The main finding of this study was that novel lubrication improves subjective comfort when wearing a facemask with, compared to no lubrication. Application of the lubricant did not reduce erythema, nor reduce the upregulation of inflammatory cytokines in the skin.

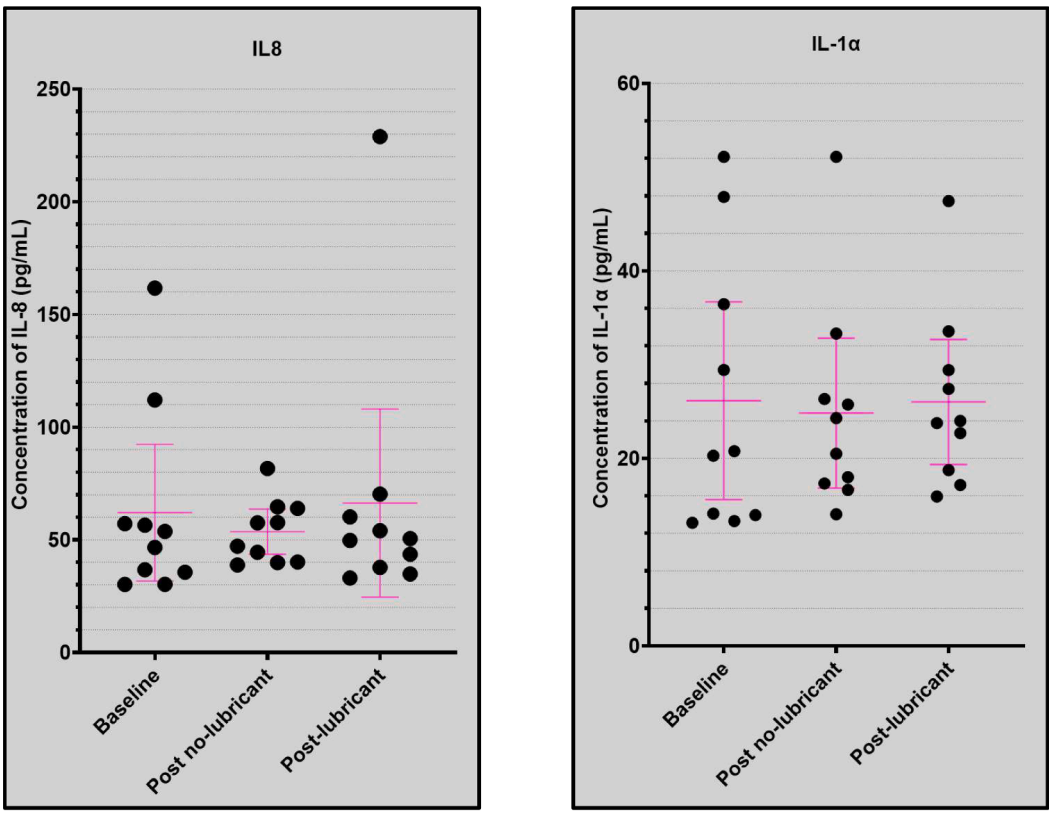
Shear forces are the result of friction in the mask-skin interface [28,29]. Application of a lubricant could reduce the frictional force or traction between the facemask and skin, thereby reducing the overall shear force exerted on this area of the skin. Yap et. al previously reported an 88 % reduction in shear forces acting on the skin of the volar forearm using the same novel lubricant employed in the present study, compared to no lubricant [33]. Whilst the objective measurement of shear force [28,29] and the subjective comfort in the present study cannot be directly compared, shear forces are known to increase the risk of pressure injury formation in healthcare [43]. Nevertheless, future studies should quantify shear forces at the mask-skin interface to confirm the proposed mechanism. The load acting on the skin as a result of using a facemask occludes the vascular supply to the overlying epithelium [43]. This potential reduction in shear may have been sensed by the participants, thereby increasing subjective comfort levels of facemask use.

Comfort is a subjective feeling that is difficult to objectively quantify and is influenced by a wide range of factors [44]. A visual analogue scale (VAS) is one of multiple possible methods of assessing and measuring subjective feelings [34] including pain intensity [45,46], depression [47,48] sleepiness [49] and pre-operative anxiety [50]. A VAS typically consists of a horizontal line with verbal descriptors at either end, describing two extremes of a single feeling. To complete a VAS, an 'X' is



(a) bridge of the nose *(b) side of the nose*

Fig. 5. Scatter plots showing the calculated a* values for each region of interest for the bridge and side of the nose. Each dot represents the a* value pre and post facemask use (n=10). The pink horizontal lines indicate the median values for each dataset, and the vertical lines indicate the inter-quartile range for each dataset.



(a): IL-8 *(b): IL-1α*

Fig. 6. A scatter plot showing the derived concentrations of IL-8 (left) and IL-1α (right) for baseline, post-lubrication and post-no lubrication. Each dot represents the concentration pre and post facemask use (n=10). The pink horizontal lines indicate the median values for each dataset, and the vertical lines indicate the inter-quartile range for each dataset.

marked on the horizontal line at the point that accurately expresses how the person is feeling, in relation to the verbal descriptors [34]. The benefit of using a continuous line is that users are not limited to a small number of answers, but can use a continuous gradient ranging from one extreme to the other [51]. It is important for there to be a tangible point of relatability on either end of the line, to ensure the user's answer is placed in the context of all possibilities of the feeling. Current uses of the VAS, to evaluate patient comfort, have been achieved in similar areas of research, but the reproducibility and validity of these in the context of facemask usage is unclear [52–55]. It should be noted that a marked difference was observed for the order of application. Participants who first wore the unlubricated facemask followed by the lubricated facemask all reported improved comfort. However, the responses from participants who first wore a lubricated facemask included the one response reporting decreased comfort, and two responses that were almost level. Therefore, there may be an order-effect; additionally, the fact that this investigation does not allow for blinding may have led to a placebo effect as well.

Two noteworthy limitations to the current study include the relatively small sample of healthy, younger participants that wore the facemask for one hour only. The healthy volunteers had a mean ±SD age of 23.7 ± 3.33 years. In contrast, patient populations that are susceptible to pressure injuries include elderly [56], malnourished [57] and patients with pre-existing skin damage [58], or younger patients wearing a mask for longer [59]. This therefore limits the applicability of the results to the target patient population and may also explain the lack of significance in the erythema and tape stripping data. It is hypothesised that a follow-up study in the target patient population, who are more susceptible to pressure injuries, potentially with a duration of four hours, may yield significant results in erythema and tape stripping. In addition, the duration that the facemask was worn may not have been sufficient to see a significant interleukin response. Cornelissen et al found significant quantities of IL-1α and IL-8 after one hour of 150 mmHg pressure on an epidermal equivalent medium *in vitro*, but these authors also suggested that the first signs of visible tissue damage only occur after four hours of epidermal loading. In addition, the load of 150 mmHg is significantly higher than that which would be expected at the facemask-skin interface [26,60].

In this study, three different measures were employed to assess the effects of the lubricant. The primary outcome was the subjective comfort, measured using a Visual Analogue Scale. This outcome measure has been used in previous studies, with the benefit that instead of categorial scales, the VAS responses between participants can be directly compared and quantified [51]. A disadvantage in this methodology that must be recognised is the unblinded study design for this outcome, leading to the placebo effect, which can be very influential in clinical practise [61]. However, the crossover design and randomisation of the order of mask wearing (lubricated or unlubricated) strengthens the study and mitigates a potential order effect. In addition, to the VAS, free text comments were made by the participants after facemask usage. The comments have been transcribed and separated by intervention in Supplemental Table 1. Most participants found that lubrication improved subjective comfort when wearing the facemask. Examples of comments were that they felt 'much less pressure on the skin' and wearing a non-lubricated facemask felt like 'it pulls when I talk'.

Erythema is an important clinical sign that is usually quantified by visual inspection. However, visual examination of subtle differences in erythema is not reliable because of varying (subjective) perceptions of colour [62]. Logger developed a procedure to assess inflammatory dermatoses in clinical practice using facial imaging [40] and correlated clinical erythema grading scores with a* values obtained from images of the face of patients with rosacea. The benefits of using the a* value is

that the analysis is non-invasive, fast and retrospective in nature. However, a* values are known to be influenced by haemoglobin levels, vascularisation to the tissue, and lighting [40]. In the present study no decrease in erythema was seen when the facemask was used with a novel lubrication, when compared to no lubricant. However, the use of these carefully defined imaging techniques to detect skin irritation and injury is promising, and further work is required to validate its use in the measurement of erythema.

Tape stripping is a well-known technique for measuring a variety of epidermal biomarkers, including interleukins [41]. Cytokines such as IL-1α and IL-8 have been detected in the epidermis after sustained mechanical loading *in vitro* and on the volar forearm [63,64] and a recent study observed increased IL-1α levels on facial skin in response to increased strap tensions of ventilation facemasks [65]. Interleukins may therefore be of use to objectively assess the impact of facemask pressure on the skin. However, in the present study, no significant results were found. Soetens et al compared cytokine release over time during continuous and intermittent loading relative to a baseline measured at the same anatomical location (n=9). They found a high individual variability and two distinct sub-populations to the interleukin response and attributed their statistically insignificant results to this, which may also explain our results [42]. Worsley's investigation focused on facemasks, investigating varying mask strap tensions and only found significant amounts of IL-1α on the bridge of the nose at the highest tension [65], whilst in the present study the mask strap tension was not set to be high, but rather to achieve a 'good fit' from the CPAP machine feedback, which is typically achieved at lower strap tension levels. Additionally, Worsley's tape stripping methodology varied (only one strip was used and in the same location both before and after the intervention) and their mask wearing length was also less (10-minute periods) [65]. Although interleukin analysis using tape stripping is a well-known technique, there is a wide variety of methodologies, which makes it difficult to compare studies investigating similar outcomes [41].

5. Conclusion

The novel lubricant tested in this study improved perceived comfort when wearing a facemask. It is proposed that this is the result of the reduced shear stresses in the skin-mask interface. Additional measurements, such as erythema and biomarker upregulation, were performed using objective measurements, but these results showed no significant effect of application of a lubricant on erythema or the release of inflammatory biomarkers. Further research is needed to establish the reliability of the subjective measurements obtained in the study and, additionally, to evaluate the relationship between subjective scores and the inflammation in the skin. As comfort perception may affect adherence to treatment, it can be concluded that the tested novel lubricant may be of benefit to those needing to wear a facemask to support breathing.

Ethics

The study was approved by the Imperial College Research Ethics Committee (ICREC Reference Number: 22IC7438). All participants gave written informed consent prior to inclusion in the study.

Use of artificial intelligence (AI) and AI-assisted technologies

The authors did not use any AI-assisted technology in preparing this manuscript.

CRediT authorship contribution statement

Urvi Sonawane: Writing – original draft, Visualization, Project administration, Methodology, Investigation, Formal analysis, Data curation. **Jack Hayes:** Visualization. **Mary J. Morrell:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Marc A. Masen:** Writing – review & editing, Supervision, Methodology, Conceptualization.

Declaration of competing interest

The authors of this manuscript have no competing interests in regard to this study.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.bea.2026.100208.

Data availability

Data supporting this study are openly available at.

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