Mask pressure effects on the nasal bridge during short-term noninvasive ventilation

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ABSTRACT The aim of this study was to assess the influence of different masks, ventilator settings and body positions on the pressure exerted on the nasal bridge by the mask and subjective comfort during noninvasive ventilation (NIV).

We measured the pressure over the nasal bridge in 20 healthy participants receiving NIV via four different NIV masks (three oronasal masks, one nasal mask) at three different ventilator settings and in the seated or supine position. Objective pressure measurements were obtained with an I-Scan pressure-mapping system. Subjective comfort of the mask fit was assessed with a visual analogue scale.

The masks exerted mean pressures between 47.6±29 mmHg and 91.9±42.4 mmHg on the nasal bridge. In the supine position, the pressure was lower in all masks (57.1±31.9 mmHg supine, 63.9±37.3 mmHg seated; p<0.001). With oronasal masks, a change of inspiratory positive airway pressure (IPAP) did not influence the objective pressure over the nasal bridge. Subjective discomfort was associated with higher IPAP and positively correlated with the pressure on the skin.

Objective measurement of pressure on the skin during mask fitting might be helpful for mask selection. Mask fitting in the supine position should be considered in the clinical routine.

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Introduction
Noninvasive ventilation (NIV) is an established treatment for acute and chronic respiratory failure [1], but the adherence to NIV and its effectiveness may be reduced by mask-related side effects. Discomfort from the mask and skin breakdown, which can occur even after only a few hours of treatment, are common problems during mask ventilation and NIV masks have been identified as a relevant source of medical device-related pressure ulcers [2–5]. Despite the awareness of the problem and the increasing number of available interface types and designs, pressure sores are still a frequent complication in the acute NIV setting, affecting 10–31% of patients [3, 6–13]. This can partially be attributed to the extension of NIV treatment to more severely ill or frail patients and those at the extremes of age, the establishment of high-intensity ventilator settings and the increasing use of NIV outside experienced intensive care or respiratory units [14–16].

The area of the face that is predominantly affected by pressure effects from NIV is the nasal bridge [1, 2]. This can be explained by anatomical factors including reduced tissue perfusion over the bony prominence of the nose and the usually higher pressures exerted by oronasal and nasal NIV masks on this facial region [17–21].

An appropriate choice of the interface and a good mask fit can influence the pressure exerted by NIV masks over the nasal bridge [22], but overall there is little information on the pathophysiology of facial pressure necrosis induced by facemasks and factors that might influence the created pressure.

This study aimed to objectively quantify the pressure exerted by NIV masks on the skin over the nasal bridge in vivo. We hypothesised that different body positions, ventilator settings and mask designs can significantly change the pressure exerted on the skin by the NIV mask and also affect the users’ comfort level.

Material and methods
The study was conducted in the National Institute for Health Research (NIHR) Respiratory Biomedical Research Unit of the Royal Brompton and Harefield NHS Foundation Trust (London, UK) from June 2014 until January 2015. The study was approved by the London-Riverside Research Ethics Committee (REC number: 14/LO/0809), and was conducted according to the ethical principles of the Declaration of Helsinki. All participants gave written informed consent prior to inclusion in the study.

Study participants
Eligible healthy volunteers naïve to NIV were recruited by word of mouth. Inclusion criteria were an age of 18 years or older and the ability to consent. Exclusion criteria were pre-existing lesions or a rash on the face in the area of mask application, pregnancy, current or chronic respiratory disease or nasal symptoms, and a history of claustrophobia or pneumothorax.

Experimental protocol, masks, ventilator settings and postures
We investigated four different commercially available vented NIV masks: a disposable oronasal mask with a dual wall cushion (Hospital Fullface; ResMed Ltd, Bella Vista, Australia), a reusable oronasal mask with a dual wall cushion (Quattro Air; ResMed Ltd), a reusable oronasal mask with a gel cushion and additional silicon flap (Comfort Gel Full; Philips Respironics Inc., Murrysville, PA, USA), and a reusable nasal mask with a dual silicone cushion construction (Easylife; Philips Respironics Inc., Murrysville, PA, USA). For all measurements a Stellar 150 ventilator (ResMed Ltd) was used in a flow-triggered spontaneous breathing mode (S-mode) with a single limb circuit and without a humidifier.

The four NIV masks were applied randomly at the following different ventilator settings and body positions in each participant: inspiratory positive airway pressures (IPAP) of 15, 20 or 25 cm H2O with the volunteer being seated, and in the supine position with an IPAP of 20 cm H2O. The expiratory positive airway pressure was maintained at 5 cm H2O for all measurements. The mask types, pressure settings and postures were studied in a random order on each participant.

Mask fitting and pressure measurement
Mask fittings and pressure measurements were performed in a standardised way by two investigators who were experienced in NIV (A-K. Brill; R. Pickersgill). The mask sizes were chosen individually for each participant according to the manufacturers’ instructions with the provided sizing gauges. Pressure measurements were taken over the nasal bridge as the most vulnerable part of the face with an I-Scan® pressure mapping system (Tekscan Inc., South Boston, MA, USA) and a 4201-pressure sensor as described previously [22]. In brief, the sensor was calibrated with a four-point calibration with a PB5A calibration device (Tekscan Inc.). The thin and flexible sensor was placed in the same position over the nasal bridge between the facial skin and NIV mask for all measurements. The mask was gently placed over the pressure...
sensor on the participants’ face and connected to the ventilator. The mask fit was then adjusted until there was no or minimal air-leak from the interface defined as an unintentional air-leak of <10 L·min⁻¹ detected by the ventilators inbuilt leak-detection programme and no irritating air-leak alongside the mask disturbing the participant. After completion of the mask fitting we allowed for a 5–8 min equilibrium period of stable breathing on NIV. Leaks that occurred during the equilibrium interval and exceeded 10 L·min⁻¹ were corrected. Then, the contact pressure exerted by the NIV mask was recorded. To account for pressure changes during the respiratory cycle, the outcome parameter for the pressure measurements was defined as the mean contact pressure over the 2.5 cm² measurement area over the nasal bridge during a measurement period of 25 s. After each measurement, NIV was stopped, the mask removed and refitted for the next measurement. The average duration of assessment time for all pressure settings and postures was about 1 h per mask. The facial skin in the area of the mask and pressure sensor placement was assessed before and after the completion of the session.

Subjective comfort
Subjectively perceived comfort of the mask fit was assessed using a handhold 100 mm long visual analogue scale (VAS) for mask discomfort ranging from 0–100, with 0 being most comfortable and 100 being least comfortable [9, 22, 23]. Subjective comfort was rated immediately after each pressure measurement. The participants were blinded to the results of the pressure measurement over the nasal bridge.

Statistical analysis
Data are presented as mean±SD. Differences between ventilator settings and masks were assessed with repeated measurements ANOVA and post hoc t-tests with a Bonferroni correction for pairwise comparisons. The two postures were compared for each mask with paired t-tests or Wilcoxon signed rank tests depending on normality distribution. Pearson’s correlation coefficient was used to assess the relationship between variables. The significance level of all analyses was set to 0.05. Statistical analysis was performed using SPSS version 22 (IBM, Chicago, IL, USA) and Graphpad Prism 6 (Graphpad software, La Jolla, CA, USA).

Results
Study participants
All 20 participants (12 male, eight female) completed the measurements with valid data. Participants were healthy with a mean age of 36±11 years and BMI of 25.1±3.3 kg·m⁻². The self-reported ethnicity of the participants was predominantly Caucasian (14 Caucasian, one Chinese, one African, and four Asian other). No-one used analgesic medication.

IPAP levels
Repeated measures ANOVA showed that the mean contact pressure over the nasal bridge did not differ between the different IPAP levels with the three oronasal masks while with the nasal mask there was a higher nasal bridge contact pressure of 5.6±5.8 mmHg, p<0.001 at an IPAP of 25 cm H₂O compared with an IPAP of 15 cm H₂O (table 1 and figure 1). There were no statistically significant differences in air-leak between the different IPAP levels for all masks, which can be attributed to the study design in which mask leak was assessed systematically and a fine-tuning of mask fit carried out until the leak was minimised <10 L·min⁻¹.

Subjective comfort levels showed an increase towards more discomfort on the VAS with higher IPAP levels with the three oronasal masks and no significant change with the nasal mask. Overall, there was a weak positive correlation between higher nasal bridge contact pressure and mask discomfort with all masks (correlation coefficient r=0.247, n=320; p<0.001).

Body position
The contact pressure over the nasal bridge was significantly lower in the supine position compared with the seated position in all masks with an IPAP of 20 cm H₂O and EPAP 5 cm H₂O. Overall the pressure was 57.1±31.9 mmHg supine and 63.9±37.3 mmHg seated (p<0.0001). Values for the individual masks with significant reductions of the pressure on the skin in the supine position ranging between 4.1±6.9 mmHg (nasal mask Easy life) to 12.8±11.9 mmHg (oronasal mask Comfort Gel) are shown in table 2. Subjectively perceived comfort of the mask fit was not influenced by the posture (table 2).

Mask designs
The repeated measures ANOVA showed significant differences in nasal bridge contact pressure (F (1.942; 228)=93.698; p<0.001) across the tested masks, irrespective of the ventilator setting or body position of the participant. The oronasal mask Hospital Fullface created the lowest pressures followed by the Easy life
nasal mask, the Quattro Air and the Comfort Gel mask. The unintentional air-leak did not differ significantly between masks, ventilator settings and postures (F (9; 228)=0.72; p=0.690). Subjective comfort on the VAS varied between the masks (F (7.748; 196.288)=0.338; p<0.001) with the masks Quattro Air and Easy life being rated as most comfortable. Their ratings did not differ in the post hoc test using a Bonferroni correction, while the other two masks had significantly higher values on the VAS scale reflecting a subjectively less comfortable mask fit (tables 1 and 2).

### Table 1: Comparison of different inspiratory positive airway pressure (IPAP) levels in a seated position in 20 participants

| Mask Type                  | Pressure mmHg | Air-leak L·min⁻¹ | VAS mm | F (df; df error) | p-value |
|----------------------------|---------------|------------------|--------|------------------|---------|
| Oronasal mask: Hospital Fullface | 49±9.3±22.9   | 1.9±2.6          | 31.9±18.5 | 0.410 (1; 25.6) | 0.588   |
| Oronasal mask: Quattro Air | 62.3±28.9     | 1.4±1.9          | 18.8±10.4 | 0.380 (2; 38)   | 0.963   |
| Oronasal mask: Comfort Gel | 90.4±44.9     | 1.4±2.1          | 41.5±21.9 | 0.180 (2; 38)   | 0.836   |
| Nasal mask: Easy life      | 50.9±29.0     | 0.7±1.6          | 22.9±20.0 | 0.050 (2; 38)   | 0.001   |

Data are presented as mean±sd, unless otherwise stated. F (df; df error): F-ratio (degrees of freedom; degrees of freedom error); EPAP: expiratory positive airway pressure; VAS: visual analogue scale for comfort with 0 being most comfortable and 100 being least comfortable. 1 mmHg equals 1.36 cmH₂O. #: p<0.05 compared with IPAP 15 cm H₂O; ¶: p<0.05 compared with IPAP 20 cm H₂O.

Adverse events

No adverse events (reddening of the skin, skin lesions, pain and respiratory symptoms) occurred during the study, although exposure time was limited to the duration of the assessments.

Discussion

The main findings of this study were that an increase in IPAP does not influence the mask pressure exerted on the nasal bridge in oronasal masks, while the pressure exerted by the mask over this area is lower in the supine position than seated. We also showed that the amount of pressure exerted on the skin of the same participant can vary substantially with different mask models.

Bench studies using face masks with simple cushions and different measurement approaches provide information on the minimally necessary mask pressure to prevent air-leak, which is 1–2 cm H₂O above the set inspiratory ventilator pressure [24, 25]. However, these previous bench studies do not give information on the pressure exerted to the maximal points of pressure on the face in vivo which are often higher. MUNCKTON et al. [17] measured the pressure exerted on the face during NIV by simple NIV mask cushions in 2007 and identified the nasal bridge as the area of the face where the highest pressure was exerted. Since then, NIV mask design has improved and better measurement systems are now available, allowing us to carry out this assessment of the pressure applied to the nasal bridge during ventilation in different situations.

Masks are often fitted when patients are seated but, with the exceptions of daytime use in the acute setting or in home mechanical ventilation, they are normally used when the patient is recumbent. In our study, the pressure over the nasal bridge was lower in the supine position with the same level of comfort. In the absence of measurements around the total skin-mask interface this leaves us to assume that the mask fit might be improved with the help of gravitational forces that allow for less tightening of the straps or, more likely, that there is a shift of the pressure towards other areas of the face. Therefore, we think that, when possible, mask fitting in the supine position should be preferred in the clinical routine.
It might be expected that ventilator modes that impose higher levels of respiratory pressures are associated with greater pressures from more tightly fitted masks to prevent air-leaks and therefore also have a higher risk of developing skin lesions. In this study, we demonstrated, using objective measurements that the pressure exerted on the skin over the nasal bridge does not change in appropriately fitted oronasal masks with an increase in IPAP. In addition to the already available data we showed that this is still true for

![Contact pressure over the nasal bridge for the four masks and different situations. Data are presented as mean and 95% confidence interval.](https://doi.org/10.1183/23120541.00168-2017)

### TABLE 2 Comparison of two different postures in 20 participants

| Mask                           | IPAP: 20 cmH₂O; EPAP 5 cmH₂O; position: seated | IPAP: 20 cmH₂O; EPAP 5 cmH₂O; position: supine | p-value |
|--------------------------------|-----------------------------------------------|-----------------------------------------------|---------|
| Oronasal mask: Hospital Fullface | 47.6±29.0                                     | 42.4±24.6                                     | 0.017   |
| Pressure mmHg                  | 1.6±2.8                                        | 0.9±1.8                                       | 0.046   |
| VAS mm                         | 36.2±21.1                                      | 36.4±20.2                                     | 0.795   |
| Oronasal mask: Quattro Air      | 61.7±30.2                                      | 56.6±27.2                                     | 0.004   |
| Pressure mmHg                  | 2.0±2.6                                        | 1.4±2.0                                       | 0.389   |
| VAS mm                         | 22.9±13.6                                      | 23.4±12.7                                     | 0.683   |
| Oronasal mask: Comfort Gel      | 91.9±42.4                                      | 79.1±36.2                                     | <0.001  |
| Pressure mmHg                  | 0.8±1.2                                        | 1.2±2.3                                       | 0.673   |
| VAS mm                         | 44.8±22.0                                      | 47.5±22.5                                     | 0.132   |
| Nasal mask: Easy life          | 54.5±31.8                                      | 50.4±27.8                                     | 0.001   |
| Pressure mmHg                  | 0.6±1.4                                        | 1.1±2.5                                       | 0.462   |
| VAS mm                         | 25.7±21.8                                      | 21.5±16.7                                     | 0.123   |

Data are presented as mean±SD, unless otherwise stated. IPAP: inspiratory positive airway pressure; EPAP: expiratory positive airway pressure; VAS: visual analogue scale for comfort with 0 being most comfortable and 100 being least comfortable. 1 mmHg equals 1.36 cmH₂O.
oronasal masks used with an IPAP of up to 25 cm H₂O, with an unchanged unintentional air-leak. This is important for high-intensity NIV in which oronasal masks are predominantly applied [21, 26].

Subjectively perceived comfort can help to determine a good mask fit, but it has been shown to be too inaccurate to determine the applied pressure over the nasal bridge [22]. The correlation of higher IPAP with more discomfort in the same mask despite unchanged objective pressures over the nasal bridge in the oronasal masks and unchanged discomfort despite higher pressures on the skin in the nasal mask prompts speculations that our NIV-naïve participants might have also focussed on other factors that influence comfort than the mask pressures only. Thus, for NIV masks, an objective measurement option to monitor and reduce pressures exerted on the face by NIV masks could be helpful to reduce pressure effects and optimise the mask fit. As a clinical comparison the estimation of endotracheal tube cuff inflation pressure by palpation is inadequate to determine an estimate of the pressure existing inside the cuff [27] and the objective monitoring of endotracheal tube cuff pressures has become a standard procedure during endotracheal intubation.

However, with the Comfort Gel mask, which applied much higher pressures than the other three models, the discomfort ratings were overall also higher than for the other masks implying that at least very high pressures are perceptible. The reason why the Comfort Gel mask created much higher pressures in our participants than the other mask models is not entirely clear. This might be due to a slightly more rigid material of the gel cushion, but we cannot exclude that the pressures would have been lower in another group of participants.

More recent mask designs and different participant characteristics may explain why the pressures created by the masks in our study were partially lower than those measured by MUNCKTON group of participants.

In conclusion, objective pressures created by masks on the vulnerable skin over nasal bridge can vary substantially with different mask models, the body position influences the pressure while an increase of IPAP does not alter the pressure to a greater extent if the mask is fitted appropriately. The implementation of objective monitoring devices into clinical routine could help to overcome the limitations of a subjective estimation of the mask pressure, help to identify safe pressure thresholds for NIV masks and thus result in more effective preventive strategies to reduce the adverse effects of interface pressure during non-invasive ventilation.
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