Comparison of PAP Interface Pressure on the Nasal Bridge: Soft Cloth vs. Traditional Masks

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BACKGROUND

Skin-breakdown caused by medical devices, particularly NIV (non-invasive ventilation) and CPAP (constant positive airway pressure) masks, is a significant cause of poor patient outcomes and healthcare costs. Pressure ulcers are the third most expensive disorder after cancer and cardiovascular diseases.[1] It is estimated that up to 44% of hospital-acquired pressure ulcers are derived from medical devices. NIV and CPAP mask interfaces are the root cause of 17% of the pressure ulcers attributed to medical devices in the inpatient setting.[2]

According to the Minnesota Pressure Ulcer Initiative,[3] pressure between a CPAP mask and the skin is a significant contributor to irritation. Several studies have investigated the pressure exerted on the bridge of the nose and have postulated that CPAP interfaces with greater pressure levels in this location may lead to an increase in patient discomfort and a decrease in compliance, and have shown that different mask designs/materials can significantly change the pressure exerted on the skin by the CPAP mask.[4] A 90 day adherence study showed a 107 minute nightly increased use of CPAP when fitted with a cloth mask (CM) compared to a traditional mask (TM). Patients in this study used the CM more and were more likely to continue with therapy than the TM group.[5]

OBJECTIVES

To objectively quantify the pressure exerted by nasal CPAP masks on the skin over the nasal bridge in vivo, and compare the results of cloth-based interfaces and non-cloth interfaces. We hypothesized that cloth-based masks would exert a lower nasal bridge pressure than non-cloth products.

MATERIALS & METHODS

We evaluated the pressure exerted by seven types of nasal masks in three trials onto the nasal bridge of 2 healthy adult volunteers, one male and one female, while they received 10cmH2O of continuous positive airway pressure ventilation. 10cmH2O was chosen because it is considered the average pressure in patients treated with CPAP therapy.

Five different commercially available vented CPAP masks constructed primarily of polyester cloth (SleepWeaver® 3D, SleepWeaver® Advance Pediatric, SleepWeaver® Élan, and SleepWeaver® Prevent, Circadiance®, LLC, Turtle Creek, PA) were tested as were three different traditional masks constructed primarily of silicone and plastic (DreamWisp™, Philips Respironics, Inc., Murrysville, PA; Mirage™, ResMed, San Diego, CA; Zest™, Fisher & Paykel Healthcare, Auckland, NZ).

Pressure was detected using a texsens®-g, a validated[6] low pressure sensor force measuring device (novel electronics inc., Saint Paul, MN, USA.) Device specifications: sensor size 1 cm diameter; pressure range 1-10 kPa (8-80g); 50 Hz measurement rate.

The thin and flexible sensor was placed in the same position over the nasal bridge between the facial skin and CPAP mask for all measurements. The mask was gently placed over the pressure sensor on the participant's face and connected to the CPAP machine. The mask fit was then adjusted until there was no or minimal air-leak from the interface defined as no subjective irritating air-leak alongside the mask disturbing the participant. After completion of the mask fitting we allowed for a 1 min equilibrium period of stable breathing on CPAP. Leaks that occurred during the equilibrium interval were corrected. Then, the contact pressure exerted by the CPAP mask was recorded. To account for pressure changes during the respiratory cycle, pressure over the nasal bridge was recorded for a period of 30 s. After each measurement, CPAP was stopped, the mask removed and refitted for the next measurement.

Pressure data from each 30 second trial were summarized as the median value after confirming that pressure did not vary by time (one-way ANOVA, p = 0.7393). Median values were then compared across trials, subjects, and masks using one-way ANOVAs and student's t-tests.

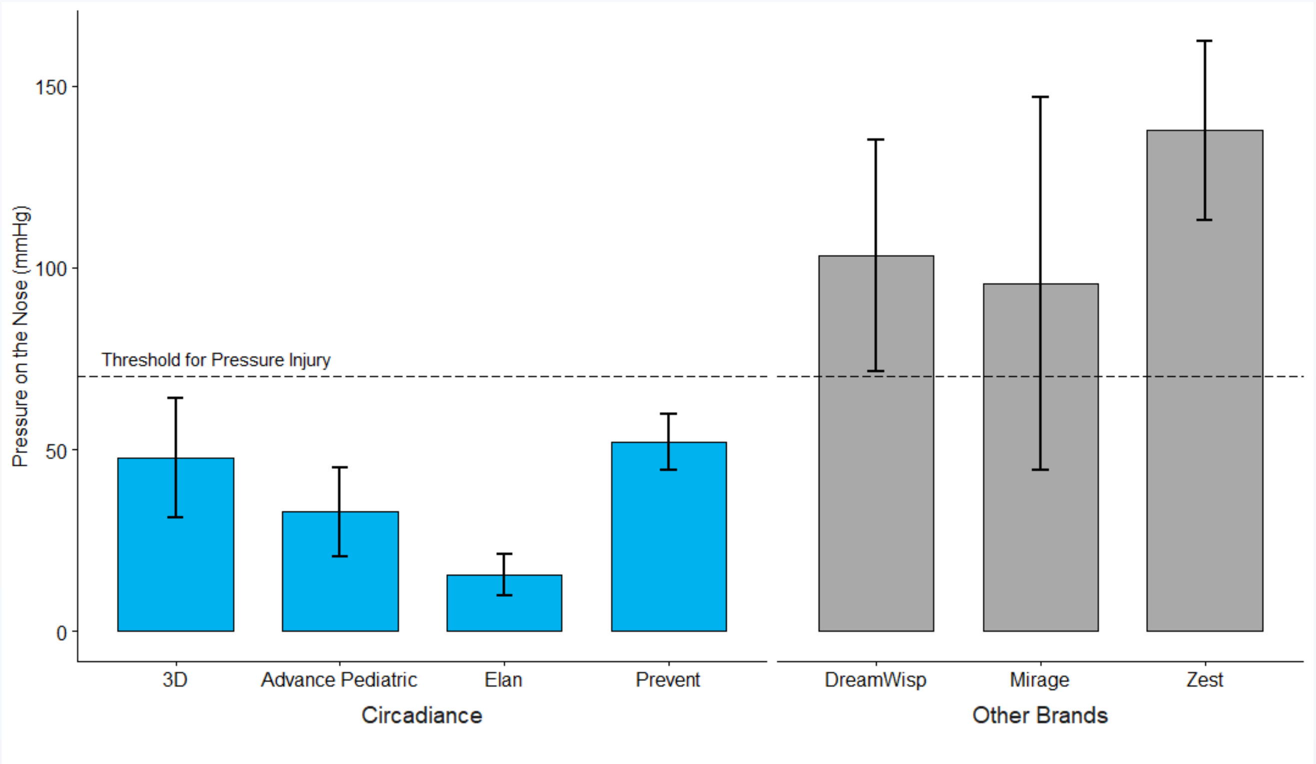
RESULTS

Table 1: Nasal bridge pressure by mask type.

Cloth Masks (CM)	Pressure (mmHg)*	P
3D (Circadiance, LLC)	47.59 (15.65)	< 0.0001
Advance Pediatric (Circadiance, LLC)	32.84 (11.69)	
Elan (Circadiance, LLC)	15.5 (5.36)	
Prevent (Circadiance, LLC)	51.97 (7.31)	
Traditional Masks (TM)	**Pressure (mmHg)***	**P**
DreamWisp (Philips Respironics)	103.35 (30.26)	0.1291
Mirage (ResMed, Inc.)	95.63 (48.71)	
Zest (Fisher & Paykel, Inc.)	137.72 (23.46)	

After confirming that pressure did not vary by trial (one-way ANOVA, p=0.4585) or subject (t-test, p=0.0938), pressure data were summarized by mask. These data are presented in Table 1 and in Figure 1. On average, cloth masks exerted 37.0 (17.7) mmHg of nasal bridge pressure, although there was significant variation across masks (one-way ANOVA, p < 0.0001). Conversely, traditional masks averaged 112 (38.5) mmHg of nasal bridge pressure without significant variation across masks (one-way ANOVA, p=0.1291). **Cloth masks averaged 75.26 mmHg less pressure than traditional masks (p < 0.0001), a difference of 67 percent.**

DISCUSSION



Noninvasive ventilation (NIV) applied via different interfaces is increasingly used in the treatment of acute respiratory failure,[7] and constant positive airway pressure (CPAP) is the gold standard treatment for obstructive sleep apnea (OSA). The choice of interface is a key factor in determining success of NIV and CPAP due to adverse effects such as skin irritation. The aim of this article is to provide practical information on interface choice. The nasal bridge has been identified in previous research as the area of the face where the highest pressure is exerted, and is the reason for the location chosen for all of the measurements taken in this study.[8]

We showed that the amount of pressure exerted on the skin can vary substantially with different mask models. Furthermore, the null hypothesis was rejected. The data supports the hypothesis that cloth mask pressures on the bridge of the nose are significantly lower than a sample of traditional masks with similar shape and style.

Pressure Ulcer has been defined in the literature as, *an area of localized soft tissue ischemic necrosis caused by prolonged pressure higher than the capillary pressure with or without shear, related to posture which usually occurs over a bony prominence*.[1] The mechanism for developing a pressure ulcer is prolonged pressure over bony prominences that exceeds supra capillary pressure (70mm Hg).[9]

Figure 1 shows the mean pressure of cloth compared to traditional masks in relation to capillary closing pressures cited in the literature.

This study was limited by a small sample size which is not representative of the population at large. However, the relative differences between masks does have clinical importance for adverse outcomes related to skin irritation in the selection of NIV and CPAP masks.

CONCLUSIONS

These study results suggest that the use of cloth masks have the potential to carry a lower pressure profile than comparable nasal interfaces constructed of traditional materials, and should be considered for patients with skin sensitivity, comfort and compliance concerns.

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DISCLOSURE STATEMENT

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