Non-Invasive Ventilation Sensor Mask (NIVSM): Preliminary Design and Testing

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***Abstract*— Previous research has emphasized the significance of mask and interface design in non-invasive ventilation (NIV) and the prevention of pressure ulcers (PUs). Multiple variables are involved in the necrosis process, but the skin-mask interface has the significant impact. A preliminary design of a custom-fit Mask (CFM) embedded with microclimate sensor has been introduced previously. This study aims to improve the comfort and safety of patients that use NIV masks for long periods. The personalized cushion fit (PCF) is designed using 3D scanning and printing technology and integrated into a pre-existing mask. Integration with a pre-existing mask has been achieved by fabricating a modular design that acts as a disposable PCF. Embedded sensors are added to the mask to measure the skin-mask microclimate. Real-time data is plotted and monitored for critical conditions and to identify other key features. A preliminary temperature-humidity (T-H) monitoring of the skin-mask interface for both PCF and pre-existing mask shows fluctuation trends that could potentially induce PUs. However, there is a more sensitive reaction in the PCF test.**

Keywords—ventilation mask, microclimate sensor, skin-mask interface, pressure ulcers.

I. INTRODUCTION

Non-invasive ventilation (NIV) is the administration of oxygen through a face mask, obviating the need for an endotracheal airway [1]. By reducing the work of breathing and improving gas exchange, NIV achieves comparable physiological benefits to conventional mechanical ventilation [2]. According to research [3], NIV after early extubation appears to be beneficial in reducing the total number of days spent on invasive mechanical ventilation.

Because of the expanding popularity of NIV, pressure ulcers (PUs) connected with its use are becoming a growing clinical concern. The prevalence of grade I pressure ulcers is estimated to be 5-50% within a few hours and 100% after 48 hours [4]. PUs are related with poor clinical outcomes, increased comorbidities, and length of hospital stay, all of which aggravate the effects of acute illness. Medical equipment, such as NIV masks, have distinct risk factors, such as the presence of a microclimate specific to the device, the way by which the device is attached, the fact that devices may obscure the skin, and the fact that the areas at risk are not frequently checked [5].

Achieving a mask seal has been the main goal for clinicians because air leaks are linked to decreased tolerance for the intervention [6]. Bi-level positive pressure's alternating airflow necessitates a seal in order to prevent ventilator asynchrony. As a result, the risk of pressure damage is reduced, and strap tension is increased [7]. Due to drowsiness, medicine, neurological disease or injury, or an uncomfortable mask fit, the patient may not be able to respond to an excessive load given to delicate skin areas. Additionally, the patient might be too frail to move the device. Although different interfaces have been suggested as being superior, oronasal masks have historically been chosen for their comfort and usability [8].

PUs occur when fragile tissues are forced between the bone and the external surface, which causes skin ischemia and necrosis [9]. The damage may appear as intact skin or as an open ulcer. It is carried on by extreme pressure, sustained pressure, or pressure combined with shear. PUs can develop over any bony part of the body. However, PUs due to the usage of NIV masks has developed recently, especially during the pandemic of Covid 19 where patients were exposed more to using NIV masks for treatment. According to [5], 34.5% of all PUs obtained in hospitals are due to medical devices. For instance, people who are critically ill and on life support are frequently unaware of the pressure the machine is applying. Regardless of the environment, there is a strong correlation between device-related pressure ulcers and breathing equipment, which accounts for 68% of all device-related pressure ulcers, [10].

The mean cause for PUs when using an NIV mask for prolonged periods is the pressure exerted by the device on the skin which results in the reduction of blood flowing to the skin and underlying tissues, leading to tissue damage and ultimately, the development of PUs. Other factors enhance the development of PUs in parallel with the pressure of the device, such as the friction between the NIV mask on the skin can cause shearing forces that damage the skin, especially if the mask fits poorly (too tight or too small) or moves around during use. The buildup of moisture under the mask is another reason to consider that encourages the risk of PUs which can increase the susceptibility of the skin to damage from pressure and friction. It creates a warm and damp environment, which can cause the skin to become macerated or soft and more susceptible to damage [11].

Along with the causes of PU mentioned above, increased humidity and temperature can affect both the structural and physiological capability of the skin to withstand the pressure by altering the skin's properties and making it more susceptible to damage [12]. An increase in humidity can cause the skin to absorb more moisture, making it softer and more pliable. This causes the skin to be more sensitive to deformation and damage when subjected to pressure. On the other hand, the higher temperature on the skin reduces its elasticity resulting in the inability to stretch and accommodate pressure without damage.

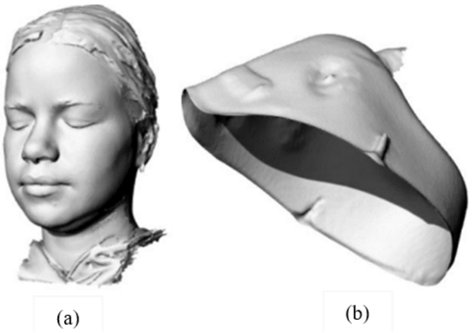
(a) (b)

Fig. 1. 3D scan of subject's face (a), 3D scan of the pre-existing mask (b)

This study aims to develop a novel NIV mask with a personalized cushion fit (PCF) and microclimate sensors to enhance patient comfort and reduce skin injury.

II. METHODOLOGY

A. Cushion Design

The modelling of a cushion fit that exactly complements the patient's face is made possible by the use of 3D scanning technology to collect precise measurements of the patient's face and the mask. A specialised camera was used to scan the patient's face to capture its dimensions and contours. A detailed model of the patient's face and mask is created by combining the two images after scanning the existing mask with the same technique (Fig.1). The cushion part of the mask was designed using Mesh Mixer software, where the 3D scans of the face and the mask were imported. The size of the mask is then adjusted on the top of the face mesh to have an observation of how the cushion would be sized. The surrounding border was drawn on the face mesh while considering taking the same size as the bottom part of the mask to fit. The cushion part is edited to be the same size, thickness, and consistency as the mask (Fig. 2).

B. Design of the Microclimate Sensing System

The DHT22 sensor was used to collect temperature and humidity data, which was then output to the LCD for real-time data display and, eventually, the PC by the electronic circuit. The data is processed in MATLAB where a serial communication was created between the Arduino and MATLAB to receive temperature and humidity reading in the form of a real-time graph. This helped in identifying patterns in temperature functionality and humidity levels, allowing more informed decisions to be made based on the insights derived from the data.

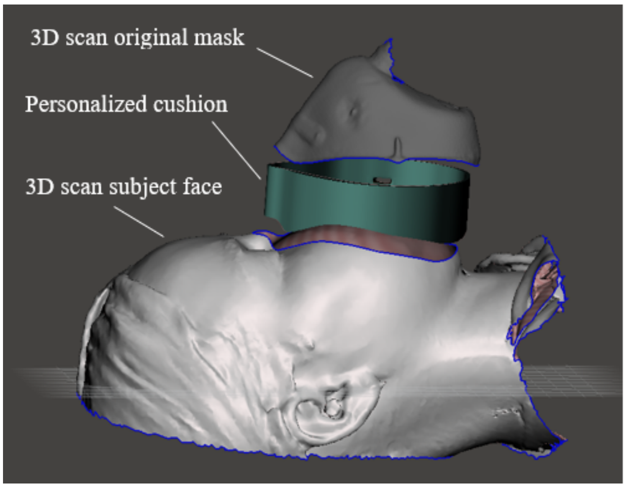

Fig. 2. Modeling the cushion part with the mask and face's consistency.

C. Threshold Microclimate Values

Though the ideal microclimate range is unknown, plausible hypotheses have been put forth [13]. The monitor's ensuing threshold limits and unsafe levels were calculated based on earlier investigations.

While establishing temperature limitations, it has been demonstrated that temperatures above 35°C cause the stratum corneum's mechanical rigidity and strength to decrease [14]. After that, the metabolic load increases by 13% for every 1°C rise, further depleting the PU area's energy reserves and wearing down the related tissue [15]. On the other hand, skin temperature in the NIV shouldn't drop below 22°C since alveolar gas exchange requires a certain amount of warm air [16].

To ascertain the dangers of an unstable microclimate, Engebretsen et al. [17] reviewed numerous studies. The lower RH threshold has been set at 40% because the report states that a normal RH value ranges from 40% to 70%. The strength of the stratum corneum is claimed to be 25 times weaker at 100% RH than at 50% RH [12], indicating an upper RH threshold of 100%. However, a high amount of humidification is necessary for NIV.

III. TESTING AND RESULTS

The personalized cushion is completely integrated into the mask and well attached to the contours of the face. To avoid displacements, the DHT22 sensor is inserted inside the mask and secured in place (Fig. 3). A comprehensive evaluation of both the pre-existing NIV mask with the DHT22 sensor and the novel design of the NIVSM were conducted. The primary objective of testing was to assess the performance and functionality of these masks over a period of 3 hours use. Through this testing, the efficacy, comfort, and usability of the two mask designs were compared. Various parameters were carefully monitored, such as temperature, humidity, and comfort ratings, to collect quantitative and qualitative data for analysis. The comparison between the pre-existing NIV mask and the NIVSM would provide valuable insights into the potential improvements of the overall effectiveness of NIV ventilation methods.

The NIVSM and the pre-existing NIV mask with the DHT22 sensor were both worn by the subject over 3 hours testing period (Fig. 4 and 5). Temperature and humidity readings are captured in real-time by the DHT22 sensor, which is built into the pre-existing NIV mask. A similar sensor is also present in the NIVSM. Continuous sensor data collection during the testing time allowed for the continuous recording of the subject's changing environmental circumstances. The gathered data was plotted using MATLAB in order to provide this information in a way that is easy to understand visually. The resulting graph provides a clear representation of the patient's temperature and humidity levels over the 3 hours testing period, enabling healthcare professionals to analyze the data and gain valuable insights into the patient's respiratory condition and the mask's performance.

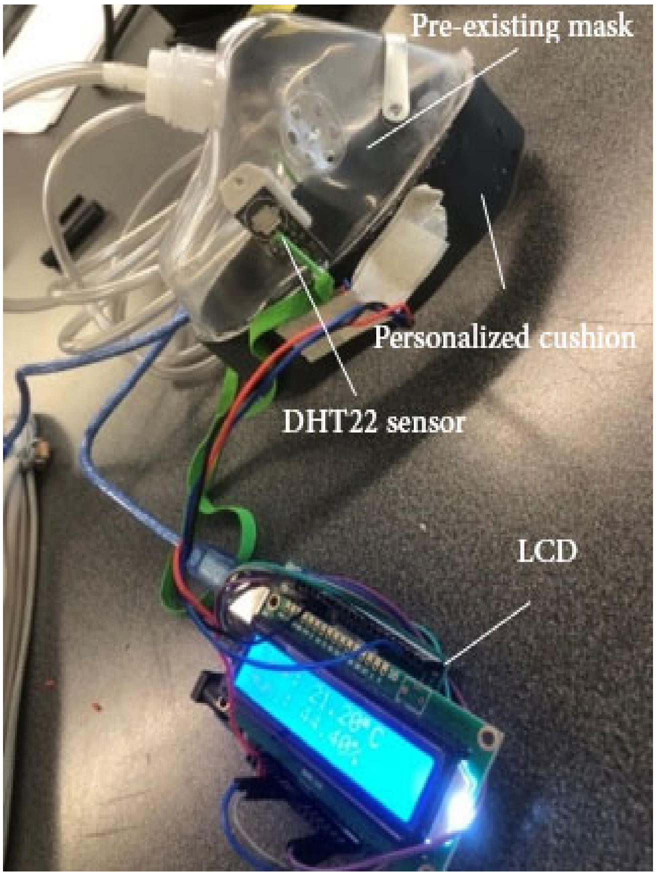

Fig. 3. The integration of the NIVSM system.

It was crucial to evaluate the mask's efficiency in various environmental settings in addition to evaluating it on a real patient's face. One such scenario that can affect mask performance is exposure to high humidity and temperature, which is frequent for patients utilising NIV masks. In order to assess the mask's reactivity in a steam environment utilising a steam source, testing is done (Fig. 6).

Several aspects were taken into account when evaluating the mask's behaviour in response to steam, including any variations in humidity or temperature levels detected by the sensor. The mask's ability to keep a seal and provide enough ventilation support while steam is present is also evaluated.

Understanding how the mask will perform in actual use can be learned via testing it in a steam setting. Possible issues can be found by analysing how the mask reacts to the steam source, and any changes that are required to enhance the mask's performance can be made. Overall, the results of this testing show that the customised cushion fit and sensor-equipped NIV mask design are durable and can provide patients with reliable support in a range of environmental conditions.

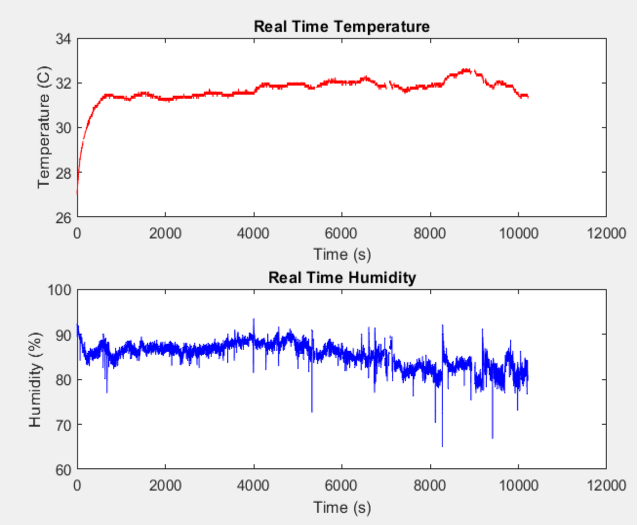

Fig. 4. Real-time graph of temperature and humidity using the pre-existing NIV mask on the subject for 3 hours.

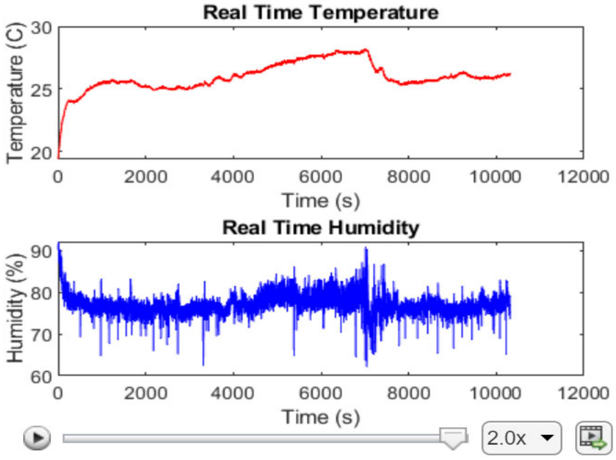

Fig. 5. Real-time graph of temperature and humidity using the NIVSM mask on the subject for 3 hours.

IV. DISCUSSION

Over the course of 3 hours, significant differences between the traditional NIV mask and the NIVSM become obvious. The pre-existing NIV mask had a higher propensity to leak, especially around the nose, which reduced its efficacy. The NIVSM, in comparison, proved to be leak-free because to its specialised cushion that closely conforms to the contours of the face to ensure a solid seal. Additionally, because of its propensity to wander around, the NIV mask frequently needed to be readjusted, which presented a problem for patients to utilise. In contrast, the NIVSM stayed put on the face without moving much at all, not even when the wearer slept. This steadiness improved the patient's comfort while also making it easier to offer non-invasive breathing continuously and without interruption.

Both the pre-existing NIV mask and the NIVSM contain DHT22 sensors, which have shown to be quite helpful in accumulating real-time temperature and humidity data over an extended period of time. By enabling the monitoring of microclimate changes and the gathering of useful data for subsequent analysis, this feature shows the potential for these sensors to be included into any mask design. The sensors provide information about the local environment surrounding the patient's face during NIV therapy by continuously measuring the levels of humidity and temperature. This information can be essential for determining the mask's efficiency, pinpointing any discomfort or negative consequences that could emerge from insufficient temperature or humidity regulation, and optimising the ventilation plan as a whole.

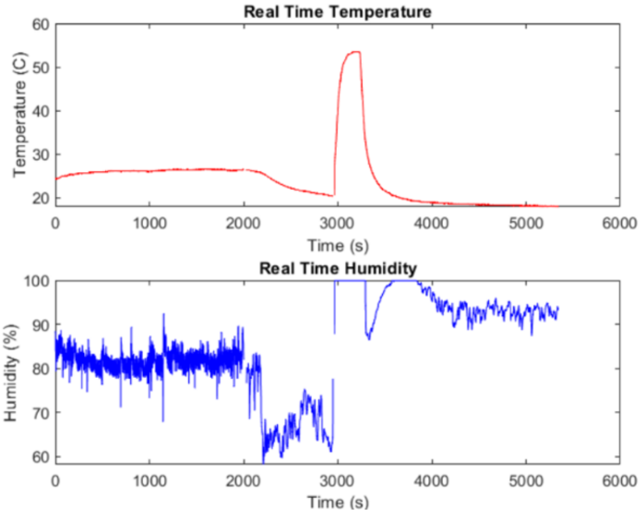

Fig. 6. Real-time graph of temperature and of steam experiment.

Healthcare practitioners can also study trends and patterns over time by having the data saved for subsequent analysis. This gives them a thorough picture of the patient's respiratory problems and the effects of various environmental factors. The use of DHT22 sensors into NIV masks ultimately creates new opportunities for improved monitoring, customization, and improvement of respiratory therapy, which is advantageous for both patients and medical professionals.

Despite the positive findings of the NIVSM sysstem, there is still room for improvement to increase the results' accuracy. The cushion material used in the project as an example was just used for prototype purposes; more precise results in terms of the comfortability and weight of the mask might be obtained by using higher medical-grade materials. Additionally, using more accurate sensors to track the microclimate inside the mask will deliver more accurate input and allow for quick readings of the microclimate.

V. CONCLUSION

In addition to monitoring the variables that can cause PUs during therapy, this study suggested a way to lessen PU formation. In order to lessen the effect of mask loading and monitor crucial factors during non-invasive ventilation (NIV), a non-invasive ventilation sensor mask (NIVSM) was developed by combining an pre-existing mask with a personalized cushion integrated with sensors. In terms of minimizing and tracking the effects of ventilation masks on the skin, preliminary testing and validation point to a good result.

The NIVSM will be utilized in the future to establish ideal levels of humidity and temperature at the skin to prevent the formation of PUs. Additionally, the advantages are greatest when used on patients who require long-term ventilation.

REFERENCES

[1] S. Nava, N. Hill. "Non-invasive ventilation in acute respiratory failure". Lancet, vol. 374(9685), pp. 250-9, July 2009.

[2] M. Vitacca, et al. "Physiological response to pressure support ventilation delivered before and after extubation in patients not capable of totally spontaneous autonomous breathing", Am. J. Respir. Crit. Care, vol. 164(4), pp. 638-41, August 2001.

[3] R. Vaschetto, et al. "Effects of early extubation followed by noninvasive ventilation versus standard extubation on the duration of invasive mechanical ventilation in hypoxemic non-hypercapnic patients: a systematic review and individual patient data meta-analysis of randomized controlled trials", Crit. Care, vol. 25(1), pp. 1-13, June 2021.

[4] M. Carron, et al. "Complications of non-invasive ventilation techniques: a comprehensive qualitative review of randomized trials", Br J Anaesth, vol. 110(6), pp. 896-914, June 2013.

[5] JM. Black, JE. Cuddigan, MA. Walko, LA. Didier, MJ. Lander, MR. Kelpe. " Medical device related pressure ulcers in hospitalized patients", Int Wound J, vol. 7(5), pp. 358-65, October 2010.

[6] D. Dellweg, D. Hochrainer, M. Klauke, J. Kerl, G. Eiger, D. Kohler. "Determinants of skin contact pressure formation during non-invasive ventilation", J Biomech, vol. 43(4), pp. 652-7, March 2010.

[7] WP. Yamaguti, et al. "Treatment-related risk factors for development of skin breakdown in subjects with acute respiratory failure undergoing noninvasive ventilation or CPAP", Respir Care, vol. 59(10), pp. 1530-6, October 2014.

[8] R. Vaschetto, et al. "Comparative evaluation of three interfaces for non-invasive ventilation: a randomized cross-over design physiologic study on healthy volunteers", Crit Care, vol. 18(1), R2, January 2014.

[9] J. Apold and D. Rydrych, "Preventing Device-Related Pressure Ulcers", Journal of Nursing Care Quality, vol. 27(1), pp. 28–34, March 2012.

[10] A. Gefen, K. Ousey. "Safe and effective wound care during the COVID-19 pandemic". J Wound Care, vol. 29, pp. 622-623, November 2020.

[11] M. Visscher, C. White, J. Jones, T. Cahill, D. Jones, B. Pan, "Face Masks for Noninvasive Ventilation: Fit, Excess Skin Hydration, and Pressure Ulcers", Respiratory Care, vol. 60(11), pp. 1536-47, 2015.

[12] J. Alqahtani, P. Worsley, D. Voegeli. "Effect of humidified noninvasive ventilation on the development of facial skin breakdown". Respiratory Care, vol. 63(9), pp. 1102-1110, 2018.

[13] J. Kottner, J. Black, E. Call, A. Gefen, N. Santamaria, "Microclimate: A critical review in the context of pressure ulcer prevention". Clin Biomech, vol. 59, pp. 62-70, November. 2018.

[14] H. Orsted, K. Harding, "Pressure ulcer prevention: pressure, shear, friction and microclimate in context". International Review, pp. 1-25, Sep. 2010.

[15] E. Du Bois, "The basal metabolism in fever". J Am Med Assoc, vol. 77, no. 5, pp. 352-357, July. 1921.

[16] D. Chiumello, "Is Humidification Always Necessary During Noninvasive Ventilation in the Hospital?". Respir Care, vol. 55, no. 7, pp. 950, July. 2010.

[17] K. A. Engebretsen, J. D. Johansen, S. Kezic, A. Linneberg, J. P. Thyssen, "The effect of environmental humidity and temperature on skin barrier function and dermatitis". J Eur Acad Dermatol Venereol, vol. 30, no. 2, pp. 223-249, February. 2016.