Noninvasive ventilation (NIV) is a mechanical ventilation modality where a patient’s respiration is supported externally by delivering air through noninvasive interface devices such as a mouthpiece, nasal pillows, nasal-, oronasal-, full-face-, or total face masks, or a helmet.¹ Common complications of NIV therapy include patient discomfort and intolerance, pressure-related facial/nasal lesions, and air leaks.²

Medline Flex™ NIV full face mask with FlexiPlane™ Technology (henceforth referred to as “Medline Flex”), was evaluated and compared with a “hard shell NIV mask” and/or a “silicone NIV mask”, in terms of pressure on the headform model, air leak around the mask, the force required to pull the silicone insert from the NIV mask, and the total weight of the NIV mask.³

**Materials**

- 3-dimensional headform simulating a patient’s face/head (NIOSH specifications used)
- Pressure SensorMat (XSENSOR # PX100:36.36.02)
- NIV full face masks
- Calibrated weighing scale (Sartorius # SECURA613-1S)
Test methods

General setup
- A custom-built setup was used to perform pressure and air leak measurements.
- Pressure of 15 cmH2O was maintained in the system.
- Baseline air leak between mask and headform was set at approximately 15 liters per minute (LPM).

Pressure testing (Medline Flex™ versus hard shell NIV mask)
Straps of the NIV mask headgear were used to tighten the NIV mask on to the headform until the air leak was 15 LPM. The mask was removed and re-attached with a pressure sensor mat placed between the mask and the headform. The pressure exerted by the mask was measured in “mmHg”. The headform was rotated from 0 to 5, 10, and 15 degrees to simulate a patient moving their head/body.

Air leak testing (Medline Flex™ versus hard shell NIV mask)
Straps of the NIV mask headgear were used to tighten the NIV mask on to the headform until the air leak was 15 LPM. This was considered an acceptable air leak at zero degrees rotation of the mask (referred to as “baseline air leak”) and also indicated that a proper seal was met. The headform was rotated from 1 through 20 degrees to simulate clinical use of a patient turning their head/body. Testing was stopped after the air leak reached 50 LPM.

Pull force testing (Medline Flex™ versus silicone NIV mask)
The silicone insert of the mask was pulled out by applying force first from the left side of the insert, followed by the right side. The force (measured in ‘pound-force [lbf]”) required to remove the silicone insert was measured by fixing the mask in position, using one strap of the headgear attached to the mask.

Mask weight measurement (Medline Flex™ versus hard shell and silicone NIV masks)
The mask and the headgear were weighed separately in “grams (g)”.

Note:
1. For all outcomes, n=3 per NIV mask; except weight for which n=6 per NIV mask.
2. The term “NIV mask” refers to the entire device, that is, the headgear and the mask.
3. The error bars in the graphs represent mean +/- SD.

Statistical methods
Peak pressure and overall pressure under the mask was compared between the NIV masks separately for each degree of rotation. Air leak at each degree of rotation for which three samples were collected, was compared to the baseline air leak, separately for each NIV mask. Pull force was compared between the NIV masks separately for each mask side. The aforementioned outcomes were log-transformed before analysis with t-tests with Satterthwaite degrees of freedom. Log-transformed mask weight was compared across the NIV masks with an ANOVA adjusted for unequal variance followed by Bonferroni adjusted t-tests.
Results

Peak pressure under the mask
Medline Flex™ exerted significantly lower “peak pressure under the mask” than the hard shell NIV mask at all degrees of rotation tested (39%, 37%, 51%, and 43% lower than the hard shell mask, at zero, 5, 10, and 15 degrees of rotation, respectively [P < .05]).

Overall pressure exerted under the mask
The Medline Flex™ NIV mask exerted significantly lower overall pressure under the mask at both 10 and 15 degrees of rotation (20% lower, and 21% lower, respectively [P < .05]).

Air leak around the NIV masks
Medline Flex™ showed no statistically significant differences in air leak between the baseline and each degree of rotation assessed.

The hard shell mask demonstrated a significantly lower air leak at 1, 2, and 5 through 8 degrees, and significantly greater air leak at 15 through 17 degrees of rotation in comparison to the baseline air leak.
Pull force testing

A significantly higher pull force was required to remove the silicone insert from the Medline Flex™ compared to the silicone NIV mask (left side = 9.8 times and right side = 4.8 times higher, respectively [P < .05]).

Mask weight measurement

The total weight (headgear and mask) of Medline Flex™ was significantly less than both the hard shell (21% less, [P < .05]) and the silicone (13% less, [P < .05]) NIV masks.

Conclusion

Medline Flex™ was shown to be better compared to the other two NIV masks in terms of peak pressure exerted on the face, overall pressure exerted under the mask at higher degrees of rotation, pull force required to remove the silicone insert from the NIV mask, and the total weight of the NIV mask.

Discussion

Appropriate use of NIV can decrease the incidence of associated complications, enhance patient comfort, and improve patient outcomes. Avoiding complications occurring during NIV is important for the wider application of this therapy.

Nasal skin lesions account for a large proportion of NIV complications.

Pressure exerted by the mask on the patient’s face may be one of the critical factors affecting formation of such lesions.

- Medline Flex™ exerted significantly lower peak pressure under the mask than the hard shell NIV mask, both at baseline as well as during conditions simulating clinical use.
- At higher degrees of rotation, Medline Flex™ exerted significantly lower overall pressure directly under the mask compared to the hard shell NIV mask.
- Medline Flex™ was found to be significantly lighter in total weight than both the hard shell and silicone NIV masks.

In a clinical context:

- Medline Flex™ may be more comfortable for the patient compared to other NIV masks.
- Use of Medline Flex™ may reduce the possibility of developing pressure-related facial skin lesions compared to hard shell NIV masks.

Air leak is a major contributing factor for patient-ventilator dyssynchrony and NIV failure.

- Medline Flex™ showed no statistically significant differences between its baseline air leak and air leak at any subsequent degrees of rotation.
- Conversely, the hard shell mask demonstrated significantly less air leak at lower degrees of rotation compared to its baseline air leak and significantly greater air leak at higher degrees of rotation.

In a clinical context:

- Any change in air leak from baseline may lead to intolerance and NIV failure.
- Increased air leak may also prompt the clinician to tighten the mask, which in turn may increase patient discomfort, reduce tolerance to NIV therapy, and may lead to pressure-related skin injuries.
- Significant decrease in air leak at lower degrees of rotation observed for the hard shell NIV mask may suggest that the mask is being pushed against the face with a greater force, which may lead to pressure-related injuries long-term.

In a clinical setting, a patient or caregiver may accidentally tug at and remove the silicone insert of the NIV mask.

Significantly higher force required to remove the silicone insert from Medline Flex™ suggests that there is a lesser likelihood of accidental insert removal or displacement leading to air leak and/or patient discomfort for Medline Flex™.

References: